Background  Device-related pressure ulcers from non-invasive ventilation masks alter skin integrity and cause patients discomfort.

Objective  To examine the incidence, location, and stage of pressure ulcers and patients’ comfort with a nasal-oral mask compared with a full-face mask.

Methods  A before-after study of a convenience sample of patients with noninvasive ventilation orders in 5 intensive care units was conducted. Two groups of 100 patients each received either the nasal-oral mask or the full-face mask. Skin was assessed before the mask was applied and every 12 hours after that or upon mask removal. Comfort levels were assessed every 12 hours on a Likert scale of 1 to 5 (1, most comfortable).

Results  A pressure ulcer developed in 20% of patients in the nasal-oral mask group and 2% of patients in the full-face mask group \((P < .001)\). Comfort scores were significantly lower (more comfortable) with the full-face mask (mean \([SD]\), 1.9 [1.1]) than with the nasal-oral mask (mean \([SD]\), 2.7 [1.2], \(P < .001\)). Neither mean hours worn nor percentage adherence differed significantly: 28.9 (SD, 27.2) hours and 92% for full-face mask and 25 (SD, 20.7) and 92% for nasal-oral mask. No patients who had a pressure ulcer develop with the nasal-oral mask had a pressure ulcer develop with the full-face mask.

Conclusion  The full-face mask resulted in significantly fewer pressure ulcers and was more comfortable for patients. The full-face mask is a reasonable alternative to traditional nasal-oral masks for patients receiving noninvasive ventilation. (American Journal of Critical Care. 2015;24:349-357)
Noninvasive ventilation is the application of positive pressure via the upper respiratory tract for the purpose of augmenting alveolar ventilation and respiratory support.¹ The goal of noninvasive ventilation is to relieve symptoms associated with hypoventilation, exacerbation of chronic obstructive pulmonary disease, or impending respiratory failure; enhance gas exchange; maximize patients’ comfort; and avoid intubation and invasive ventilation.¹,² Use of noninvasive ventilation is associated with device-related development of pressure ulcers under the mask. Published rates for the incidence of facial pressure ulcers associated with noninvasive ventilation masks range from 10% to 31%.³⁻⁵ Identification of device-related pressure ulcers, such as those associated with noninvasive ventilation masks, is becoming more common.⁶⁻⁸

No research related to interventions to reduce the incidence or severity of pressure ulcers associated with noninvasive ventilation was found. However, several non–research-based recommendations were found in the literature. The Minnesota Hospital Association and recently the National Pressure Ulcer Advisory Panel (NPUAP) recommended consideration of a wound dressing such as a transparent film, silicones, thin foams, or hydrocolloids to reduce friction and shear to prevent pressure ulcers.⁹,¹₀ Periodic repositioning of the mask, alternating 2 different types of masks, or interruptions of 10 minutes as tolerated are also recommended to promote blood flow to the tissues.⁹,¹¹ Many patients in intensive care units (ICUs) cannot tolerate even brief interruptions in noninvasive ventilation therapy. Continuous positive airway pressure delivered via helmets and nasal prongs may also be used because of skin issues.¹²⁻¹⁵ However, the use of a helmet in adult volunteers resulted in rebreathing of carbon dioxide.¹²

A full facial mask has the potential for greater redistribution of pressure because it covers the forehead and a larger area of the cheek/side of face than other masks. Lemyze et al² switched patients to the full-face mask when patients had painful skin breakdown or mask intolerance. Patients switched to use of the full-face mask had significantly fewer pressure ulcers develop without a protective dressing.⁷ In our ICUs, we observed stage III and IV pressure ulcers as well as deep tissue injury with a nasal-oral mask. The objective of this study was to examine the incidence, location, and stage of pressure ulcers and patients’ comfort with a nasal-oral mask (Performatrak, Respironics, Philips Healthcare) compared with a full-face mask (Performax, Respironics, Philips Healthcare). Secondary outcomes included length of time on noninvasive ventilation, need for invasive ventilation, and ICU and hospital lengths of stay.

Methods

A before-after comparison study was conducted in 5 ICUs (111 ICU beds) at a university-affiliated medical center. The institutional review board granted approval for delayed consent because of the emergent nature of noninvasive ventilation. Enrollment of patients and data collection began immediately after screening of inclusion/exclusion criteria. Once the patient’s condition was stabilized, during family visitation or during a family telephone discussion, the patient, the patient’s legally authorized representative, or both were provided with study information. If consent was obtained, data collection continued. If consent was not obtained, all data that had been collected were destroyed.

Education

Before the start of the study, the coprimary investigators (M.S., L.C.) spent 6 weeks training all
respiratory therapists and ICU-registered nurses. Education tools included a PowerPoint presentation and demonstration. Education focused on proper mask size and fit with acceptable leak parameters, study criteria, identification of pressure ulcers, comfort scale, and data collection. Education on the proper application of both noninvasive ventilation masks included selection of proper mask size and fit. Therapists and nurses practiced application and proper adjustments of the masks on a mannequin. Nurses and therapists were also educated on visual skin assessment for redness or discoloration and application of light touch for the identification of blanchable versus nonblanchable redness or discoloration. Staging of pressure ulcers by using NPUAP staging guidelines was reviewed. Additionally, the hospital uses descriptive wording based on NPUAP staging in the electronic medical record. Therefore, all nurses were familiar with assessment and documentation of changes in skin integrity. During the first month of data collection, the coprimary investigators worked together with team members to ensure that all team members were collecting data correctly and assessing skin correctly. During this time period, the team members had 100% agreement on skin assessment. The team members remained constant throughout both phases of the study: 2 respiratory therapists and 5 registered nurses. If questions arose regarding skin integrity or pressure ulcer stage, a primary investigator was contacted for consultation and agreement was reached for final documentation.

Sample

A convenience sample of 200 patients with noninvasive ventilation orders was recruited. No previous studies with the primary outcome measure of pressure ulcers were available for a power analysis to determine sample size. The first group of 100 patients received noninvasive ventilation initiated with the nasal-oral mask. The second group had noninvasive ventilation initiated with a full-face mask. Both the full-face mask and the nasal-oral mask are made of the same material, and securing straps for each are made of the same material.

Before a noninvasive ventilation mask was applied, the patient’s skin was assessed to ensure that no pressure ulcers were present on the bridge of the nose, cheeks, or forehead. The mask was then applied and noninvasive ventilation was initiated by the respiratory therapist. Within 1 hour of initiation of noninvasive ventilation, patients were assessed for inclusion in and exclusion from the study. Inclusion criteria were noninvasive ventilation order and age at least 18 years and less than 90 years. Exclusion criteria included existing redness or pressure ulcer, stage I or higher, on facial areas that would be under the mask, history of glaucoma or eye surgery within the past 6 weeks, use of home equipment for noninvasive ventilation in the hospital, and women who were pregnant.

Data Collection and Procedures

Skin integrity was assessed when noninvasive ventilation was started and documented by the research team member or ICU nurse. Patients' skin was assessed and documented every morning by a member of the study team and every evening by the bedside nurse. Skin was assessed by briefly removing the noninvasive ventilation mask for inspection of the face, forehead, and bridge of the nose for any redness or pressure ulcer. In addition, with any repositioning, removal, and or reapplication of the mask, skin assessment was completed by the bedside nurse and respiratory therapist. Patients who had a nonblanchable redness or discoloration, a stage I pressure ulcer, or any higher stage pressure ulcer develop were immediately transitioned to the alternative noninvasive ventilation mask. Patients switched to the alternative mask were followed up for pressure ulcers but were not included in any further data collection or data analysis. Skin assessment continued with the new mask to ensure no further development of any pressure ulcers and for monitoring of all pressure ulcers until they healed or the patient died. Other reasons for switching to the alternative mask included patients’ refusal or intolerance of the initial mask. Patients were removed from the study at this point.

Within the first hour of wear, the comfort level was obtained and documented by the respiratory therapist. Patients were asked to assess the level of comfort with the mask. The comfort scale consisted of a 5-point Likert visual analogue scale: 1 = comfortable with noninvasive ventilation mask, 2 = mild discomfort but will continue with the mask, 3 = moderate discomfort but will continue with the mask, 4 = severe discomfort with the mask, and

The first 100 patients received noninvasive ventilation initiated with the nasal-oral mask, the second with the full-face mask.
Mean time to pressure ulcer development was 28.4 hours for the nasal-oral mask phase versus 61.37 hours for the full-face mask phase.

Analysis
One of the principal investigators (M.S.) coded all the admitting diagnoses into 1 of 8 categories and entered all data. Data were entered for analysis into SPSS 18 (IBM Corporation). A Pearson $\chi^2$ test was used for analysis of differences in pressure ulcer incidence and other categorical data. A Student t test was conducted for continuous data comparisons between groups, and a Mann-Whitney U test was used to analyze comfort scores.

Results
Patients were enrolled from May 2012 to May 2013. A total of 1204 patients with orders for noninvasive ventilation were screened; 357 were excluded in the nasal-oral mask phase and 647 were excluded in the full-face mask phase (Figure 1). One hundred patients were enrolled and provided consent in each phase. Mean age, sex, race, admitting diagnosis category, APACHE II score, and indication for noninvasive ventilation were not significantly different between phases (Table 1). Skin observations and comfort assessments were not significantly different between groups with a mean (SD) number of 2.95 (2.03) skin observations and comfort assessments in the nasal-oral mask phase and a mean (SD) of 2.87 (2.08) in the full-face mask phase ($P = .78$).

Primary Outcome: Pressure Ulcer Incidence, Stage, and Location
Pressure ulcer development differed significantly ($P < .001$) between the 2 masks. Twenty percent of patients in the nasal-oral mask phase had a pressure ulcer develop on the nose or the face area under the mask. Sixteen pressure ulcers were stage I, and 4 were stage II. Two percent of patients in the full-face mask phase had a pressure ulcer develop: 1 stage II pressure ulcer on the face area under the mask and 1 deep tissue injury of the scalp under the strap. The distribution of pressure ulcer locations is shown in Figure 2. Because of the skin being assessed each time the mask was removed, time to detection of pressure ulcers varied. Time for pressure ulcer development ranged from 1.25 hours to 74 hours with a mean (SD) of 28.4 (19.46) hours for the nasal-oral phase and 24.75 to 98 hours with a mean (SD) of 61.37 (51.79) hours for the 2 pressure ulcers in the full-face phase. Identification of pressure ulcers during the nasal-oral mask phase occurred throughout the data collection period, with 3 to 6 pressure ulcers identified each month.

Secondary Outcome: Comfort Score
Patients in the full-face mask phase reported a significantly lower ($P < .001$) comfort score (mean [SD], 1.9 [1.1]), representing mild discomfort, compared with the nasal-oral mask phase (2.7 [1.2]).

Wear Time and Other Outcomes
Wear time and adherence were not significantly different between phases. Mean wear time was greater than 24 hours and adherence was greater than 90% with both masks (Table 2). Total days of noninvasive ventilation and subsequent use of noninvasive ventilation were significantly higher for the nasal-oral mask phase because patients were switched to the full-face mask when a pressure ulcer was identified. Days of mechanical ventilation and ICU and hospital length of stay did not differ significantly between phases (Table 2). The reason for...
Figure 1  Participant flow.

Nasal-Oral (NO) Mask Phase  
May 2012-September 2012  
Assessed for eligibility (n = 457)

Excluded (n = 357)  
- Glaucoma, recent eye surgery (4)  
- Nose abrasion, pressure ulcer (9)  
- Started in emergency department or other area (15)  
- Refusal to wear (12)  
- Home unit (79)  
- Nights only (55)  
- Missed on night shift (53)  
- Standby (33)  
- Wore for 4 hours or less (25)  
- Declined participation (11)  
- Use only as needed (11)  
- Nasal pillow continuous positive airway pressure (15)  
- High-flow nasal cannula (2)  
- Comfort care (6)  
- Intubated (4)  
- Foam dressing applied (8)  
- Not English speaking (1)  
- Prisoner or ward of state (1)  
- Mask did not fit (1)  
- > 90 years old (1)  
- Physician refused NO mask (0)

Received NO mask intervention (n = 100)

Lost to follow-up (0)  
Discontinued intervention (11)  
- Refusal of noninvasive ventilation (6)  
- Request to change mask (1)  
- Poor fit, changed to FF (1)  
- Foam dressing applied for patient’s complaint of discomfort (3)

Analysis  
Analyzed (n = 100)

Full-Face (FF) Mask Phase  
November 2012-May 2013  
Assessed for eligibility (n = 747)

Excluded (n = 647)  
- Glaucoma, recent eye surgery (7)  
- Nose abrasion, pressure ulcer (2)  
- Started in emergency department or other area (29)  
- Refusal to wear (25)  
- Home unit (113)  
- Nights only (71)  
- Missed on night shift (14)  
- Standby (63)  
- Wore for 4 hours or less (33)  
- Declined participation (6)  
- Unable to consent (19)  
- Started on NO (228)  
- Use only as needed (9)  
- Nasal pillow continuous positive airway pressure (5)  
- High-flow nasal cannula (0)  
- Comfort care (5)  
- Intubated (7)  
- Foam dressing applied (2)  
- Not English speaking (1)  
- Prisoner or ward of state (3)  
- Mask did not fit (1)  
- > 90 years old (1)  
- Physician refused FF mask (3)

Received FF mask intervention (n = 100)

Lost to follow-up (0)  
Discontinued intervention (2)  
- Refusal of noninvasive ventilation (1)  
- Changed to NO mask for epoprostone inhalation (1)

Analysis  
Analyzed (n = 100)
study exit was significantly different: discontinuation of noninvasive ventilation was higher in the full-face mask phase and pressure ulcer development was higher in the nasal-oral mask phase (Table 3). Intubation rates did not differ significantly between phases.

**Discussion**

With the comparison of the 2 noninvasive ventilation masks, patients in the full-face mask group had significantly fewer pressure ulcers develop and reported being more comfortable than the nasal-oral mask patients. Our findings are consistent with the results reported by Lemyze and colleagues, who used the full-face mask when patients had painful skin breakdown or nasal-oral mask intolerance. They reported that patients switched to the full-face mask had significantly fewer pressure ulcers develop. In this study, we identified pressure ulcer development as early as 1.25 hours after nasal-oral mask application. Because of the need for noninvasive ventilation for a mean of 25 to 28 hours with 90% adherence, patients are clearly at high risk for pressure ulcers related to masks used for noninvasive ventilation. The full-face mask is a reasonable alternative to traditional nasal-oral masks to decrease the incidence of pressure ulcers related to the noninvasive ventilation mask because of the full-face mask's larger surface area for pressure distribution. In addition, high-flow therapies such as administration of heated humidified air via a high-flow nasal cannula or noninvasive ventilation nasal pillows may provide an additional alternative to noninvasive ventilation masks with less risk for pressure ulcers. However, further research on these devices is needed, particularly comparison of the outcomes related to pressure ulcers, oxygenation, and ventilation, such as prevention of invasive ventilation.

During education of nurses and therapists, concerns were voiced regarding patients' discomfort and the potential for dry eyes. However, neither of these concerns were observed. The finding that the full-face mask was more comfortable, as indicated by patient-reported scores, was not expected by bedside clinicians. No patients complained of dry eyes.

This study had several limitations. First this was a nonrandomized before-after study. Although the participants' characteristics were not significantly different, there may have been an unknown factor that led to lower pressure ulcer rates and comfort scores during the full-face mask phase. Another major limitation is the large number of patients who were missed during the full-face mask phase. Because the institution's default was to initiate the nasal-oral mask on all patients, many ICU patients were not started in the study during the full-face mask phase. A total of 228 patients were not enrolled in the study because the noninvasive ventilation was started with the nasal-oral mask during the full-face mask phase. This led to a longer phase of data collection for the full-face mask. The large number of missed enrollment opportunities may have led to sample bias. Also, although members of the study team remained consistent throughout the study, a large number of bedside nurses and therapists conducted the evening assessments. To ensure

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**Table 1** Characteristics of participants in the study

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Nasal-oral mask</th>
<th>Full-face mask</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>61.9 (14.9)</td>
<td>61.1 (14.6)</td>
<td>.86</td>
</tr>
<tr>
<td>Score on Acute Physiology and Chronic Health Evaluation II, mean (SD)</td>
<td>19.8 (12.4)</td>
<td>17.7 (5.9)</td>
<td>.24</td>
</tr>
<tr>
<td>Sex, No. of patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>49</td>
<td>45</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>51</td>
<td>55</td>
<td></td>
</tr>
<tr>
<td>Race, No. of patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>75</td>
<td>76</td>
<td>.53</td>
</tr>
<tr>
<td>African American</td>
<td>25</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Admitting diagnosis category</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td>19</td>
<td>13</td>
<td>.08</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>33</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>Neuromuscular</td>
<td>6</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Cardiothoracic surgery</td>
<td>15</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>General surgery</td>
<td>11</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Trauma</td>
<td>1</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>4</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Medical</td>
<td>9</td>
<td>18</td>
<td></td>
</tr>
</tbody>
</table>

**Figure 2** Location of pressure ulcers.
intervention fidelity, the study team had daily contact with nurses and therapists to answer questions and verify assessments. A final limitation is that the full-face mask cannot be worn by patients with a known history of glaucoma or who have had eye surgery in the past 6 weeks. Although the ventilator pressures are directed toward the mouth and nose, these patients were excluded because of the potential for increased ocular pressure as the mask covers the eyes.

Further research is needed to verify these results with a larger sample in a randomized study. In addition, research is needed on the use of various noninvasive ventilation masks with application of transparent film, silicone, thin foam, or hydrocolloid dressings to facial contact points to reduce friction and shear as recommended by the NPUAP.

**Implications for Practice**

For a variety of reasons, ICU patients may require noninvasive ventilation for greater than 24 hours of continuous wear. Development of pressure ulcers is a major concern with this extended wear and minimal removal time for pressure relief. We found that the use of a full-face mask that distributes the pressure to a larger surface area resulted in significantly fewer pressure ulcers and was more comfortable for patients. Frequent assessment of a patient’s skin is important to detect stage I pressure ulcers promptly and prevent the development of higher stages of pressure ulcers. Assessment of the skin beneath a noninvasive ventilation mask every 12 hours and whenever the mask is removed can lead to early identification of skin changes. The full-face mask is a reasonable alternative to traditional nasal-oral masks to decrease the incidence of pressure ulcers related to noninvasive ventilation masks.

**ACKNOWLEDGMENTS**

The authors thank all of the respiratory therapists and nurses who identified and initiated patients in the study and assessed and documented the data. We also thank respiratory therapy and nursing leadership for their support of this study. Without the assistance and support of therapists, nurses, and leaders, this study would not have been possible.

**FINANCIAL DISCLOSURES**

Marin Kollef’s efforts for the study were supported by the Barnes-Jewish Hospital Foundation.

**REFERENCES**

5. Schettino G, Altobelli N, Kacmarek RM. Noninvasive

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**Table 2** Results for wear time and length of stay

<table>
<thead>
<tr>
<th>Result</th>
<th>Nasal-oral mask</th>
<th>Full-face mask</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total hours worn</td>
<td>25.01 (20.78)</td>
<td>28.89 (27.18)</td>
<td>.26</td>
</tr>
<tr>
<td>Adherence, %</td>
<td>92.11 (12.5)</td>
<td>91.84 (12.13)</td>
<td>.88</td>
</tr>
<tr>
<td>Total days of noninvasive ventilation</td>
<td>4.45 (4.77)</td>
<td>2.15 (1.64)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Had subsequent days of noninvasive ventilation, %</td>
<td>39</td>
<td>24</td>
<td>.02</td>
</tr>
<tr>
<td>Total days of mechanical ventilation</td>
<td>7.21 (15.2)</td>
<td>5.04 (8.78)</td>
<td>.22</td>
</tr>
<tr>
<td>Days in intensive care unit</td>
<td>12.99 (15.1)</td>
<td>12.10 (22.3)</td>
<td>.74</td>
</tr>
<tr>
<td>Days in hospital</td>
<td>21.77 (19.97)</td>
<td>22.23 (26.41)</td>
<td>.89</td>
</tr>
</tbody>
</table>

*Values in second and third columns are mean (SD) unless otherwise indicated in this column.*

**Table 3** Reason for study exit

<table>
<thead>
<tr>
<th>Reason</th>
<th>% of patients</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharge from intensive care unit</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Discontinuance of noninvasive ventilation or wearing mask &lt; 60% of time</td>
<td>52 72</td>
<td>.005</td>
</tr>
<tr>
<td>Refusal of noninvasive ventilation</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Pressure ulcer</td>
<td>20</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Intubated</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Other (see Figure 1)</td>
<td>5</td>
<td>.44</td>
</tr>
</tbody>
</table>

*Reasons for patients who left the study are shown.*

**eLetters**

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