Evaluation of the Total Face Mask for Noninvasive Ventilation to Treat Acute Respiratory Failure

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Background

We hypothesized that the total face mask (TFM) would be perceived as more comfortable than a standard oronasal mask (ONM) by patients receiving noninvasive mechanical ventilation (NIV) therapy for acute respiratory failure (ARF) and would be quicker to apply by respiratory therapists.

Methods

Sixty patients presenting with ARF were randomized to receive NIV via either an ONM or a TFM. Mask comfort and dyspnea were assessed using visual analog scores. Other outcomes included time required to apply, vital signs and gas exchange at set time points, and early NIV discontinuation rates (ie, stoppage while still requiring ventilatory assistance).

Results

Mask comfort and dyspnea scores were similar for both groups through 3 h of use. The time required to apply the mask (5 min [interquartile range (IQR), 2-8] vs 3.5 min [IQR, 1.9-5]), and duration of use (15.7 h [IQR, 4.0-49.8]) vs 6.05 h [IQR, 0.9-56.7]) were not significantly different between the ONM and the TFM group, respectively. Except for heart rate, which was higher at baseline in the TFM group, no differences in vital signs or gas exchange were detected between the groups during the first 3 h (P > .05). Early NIV discontinuation rates were similar for both the ONM group and TFM group (40% vs
57.1%); however, eight patients in the TFM group were switched to an ONM within 3 h, and none from the ONM group was switched to a TFM (P < .05).

Conclusions

Among patients with ARF requiring NIV, the ONM and TFM were perceived to be equally comfortable and had similar application times. Early NIV discontinuation rates, improvements in vital signs and gas exchange, and intubation and mortality rates were also similar.

Trial Registry

ClinicalTrials.gov; No.: NCT00686257; URL: www.clinicaltrials.gov

Abbreviations

ARF
acute respiratory failure

BPAP
bilevel positive airway pressure

CPAP
continuous positive airway pressure

EPAP
expiratory positive airway pressure

ETI
endotracheal intubation

IPAP
inspiratory positive airway pressure

IQR
interquartile range

NIV
noninvasive ventilation

NM
nasal mask

ONM
oronasal mask

TFM
total face mask

Mask (or interface) intolerance, attributed to mask discomfort or poor fit, excessively tightened straps, excessive air leaks, patient-ventilator asynchrony, or claustrophobia, is considered a common cause of NIV failure. Although certain masks are better tolerated than others, mask intolerance remains an impediment to higher NIV success rates.

Oronasal masks (ONMs) cover the nose and mouth and are the most commonly used masks for NIV in the acute care setting, followed by nasal masks (NMs), which cover the nose alone. Although NIV via an ONM or NM is usually successful, these masks may cause patient discomfort, skin breakdown, or air leaks because of poor fit over the bridge of the nose or mandible.

The total face mask (TFM) (Respironics, Inc; Pittsburgh, Pennsylvania) is considerably larger than the ONM or NM and covers the entire face, thus avoiding some of their limitations. It creates an air seal using a silicon gasket around the perimeter of the face, thus eliminating discomfort over the nasal bridge. Also, the TFM is designed as one size to fit most patients and has only two straps in an effort to facilitate mask fitting and rapid initiation of ventilatory assistance. Limited clinical experience to date suggests that the TFM is well tolerated, and although the larger volume compared with the ONM has raised concerns about increased dead space, two recent studies showed no increase in effective dead space compared with the ONM, which was probably related to air streaming within the TFM.

In the present study, we hypothesized that when used to treat ARF, the TFM would improve mask comfort scores and reduce the amount of time required for initiation of NIV compared with a standard ONM, possibly reducing early NIV discontinuation rates. We also anticipated that the TFM would be as effective as the ONM in improving respiratory distress, vital signs, and gas exchange.

Materials and Methods

Performance Sites

The study was performed at Tufts Medical Center, Boston, Massachusetts, and Rhode Island Hospital, Providence, Rhode Island, and was approved by the institutional review boards at each institution (approval numbers 6060 and 0198-01, respectively). At Tufts Medical Center, the study was deemed to add minimal risk, and a consent waiver was granted. Informed consent was obtained from patients or their proxies at Rhode Island Hospital.

Patients

Patients ≥ 18 years old with acute respiratory distress presenting to the ED or an inpatient ward were recruited. They were enrolled if they met the standard clinical and/or blood gas criteria for use of NIV to treat ARF, as described previously.

Randomization

Upon study entry, patients were randomized to receive NIV via the TFM or the ONM. A computerized randomization scheme was used, secured in a sealed envelope, assuring equal distribution of patients in each group.

Masks

Masks were the reusable TFM and the standard disposable ONM used at the respective hospitals (Comfort Full [Phillips Respironics Inc; Murrysville, Pennsylvania] used at Rhode Island Hospital and RT040 [Fisher & Paykel Inc; Wellington, New Zealand] used at Tufts Medical Center). The ONMs were similar except for the “under-chin design” (RT040) that helps to stabilize the mandible. The TFM comes in only one size, whereas the ONM comes in three different sizes: small, medium, and large.
Figure 1  A comfort full oronasal mask (ONM).

Figure 2  A Fisher & Paykel RT040 ONM as shown on one of the coauthors. See Figure 1 legend for expansion of the abbreviation.
Initiation of Ventilation

A respiratory therapist gently fitted and strapped the assigned mask on the patient's face at the minimum tension necessary to maintain an adequate air seal. Ventilation was via a bilevel device using either the bilevel positive airway pressure (BPAP) mode with inspiratory positive airway pressure (IPAP) of 8 to 10 cm H₂O and expiratory positive airway pressure (EPAP) of 4 cm H₂O, or continuous positive airway pressure (CPAP) mode of 5 to 10 cm H₂O as ordered by the treating physician. IPAP was then increased as tolerated to reduce respiratory distress. Subsequent adjustments in IPAP, EPAP, or CPAP were made according to the patient's clinical course and blood gas results. Oxygen supplementation was provided to maintain oxygen saturation > 90%. All patients received standard medical and respiratory care for the underlying cause of their respiratory failure. Patients were encouraged to leave the mask in place and to relax as much as possible. In both groups, patients intolerant of the initial assigned mask could try the other mask before discontinuation of NIV.

Outcome Variables

Primary outcomes were mask discomfort (using a visual analog scale with -1 being least discomfort and 10 being most discomfort[26]) during the first 3 h of NIV use and time required for mask placement (measured by the respiratory therapist as the time mask placement first began to the time ventilation was initiated). Secondary outcomes (obtained at baseline and after 30 min and 1, 3, and 24 h of NIV) were changes in dyspnea (assessed using the same visual analog scale), gas exchange, and vital signs, and early NIV discontinuations. Early NIV discontinuation was defined as the inability of the patient to continue NIV while there was still an indication for ventilatory support. Tertiary outcomes included the total duration of NIV use, length of hospital stay, and in-hospital mortality. Complications, including skin irritation or ulcers, gastric distension, pneumothorax, hypotension, conjunctivitis, claustrophobia, and aspiration, were also monitored. Mask fit was rated as “good” or “poor” by the therapist according to the ease of creating an air seal. Air leaks, determined by averaging the estimated leak provided by the NIV device (mild, < 40 L/min; moderate, 50-80 L/min; and large, > 80 L/min) and ventilator synchrony (“good” or “poor” based on clinical findings, such as wasted effort or autotriggering) were rated by the therapists who made adjustments to optimize these throughout the trial.

Criteria for Endotracheal Intubation

Endotracheal intubation (ETI) was performed at the discretion of the ED or critical care physicians, without input from study personnel, based on clinical and/or arterial blood gas criteria as described previously.[26] Criteria used for ETI were noted in each case for subsequent comparison between groups.

Criteria for Discontinuation of NIV
Mask ventilation could be interrupted for brief intervals every few hours as deemed necessary by the staff or desired by the patient.\textsuperscript{20} NIV was discontinued if an oxygen saturation of > 90\% could be maintained on \leq 40\% FIO$_2$ and the patient’s breathing frequency was < 24 breaths/min. Vital signs and pulse oximetry were closely followed, and NIV was resumed if enrollment criteria were once again met. If the patient did not deteriorate and remained off ventilation for > 12 h, NIV was considered discontinued.

**Statistical Analysis**

Statistical analysis was performed using SPSS 12.0.0 statistical analysis software (SPSS Inc; Chicago, Illinois). A required sample size of 60 was calculated using a power analysis for repeated measures within factors for analysis of variance comparison, power (1-\(\beta\)) = 0.95, and \(\alpha\) = 0.05 to detect a 20\% difference in mask discomfort between the two groups.

A one-way analysis of variance was carried out to compare baseline characteristics between the TFM group and the ONM group. For ordered data such as mask discomfort and dyspnea score, Spearman rank coefficient was calculated. Nominal data, including sex, location of treatment, mask fit, and ventilator synchrony, were analyzed using \(\Phi\) coefficient. For other quantitative data, Pearson \(\chi^2\) analysis was used. \(P < .05\) was considered to be statistically significant and data are presented as mean \(\pm\) SD.

**Results**

**Baseline Characteristics**

Of 66 patients screened for enrollment, six patients were excluded (Fig 4). Baseline characteristics did not differ significantly between the two groups (Table 1), except for a higher heart rate in the TFM group. Patients in the TFM group tended to have more COPD exacerbations and those in the ONM group more pneumonia, but these differences were not statistically significant (Table 2). Three patients in the ONM group and four patients in the TFM group previously received home NIV therapy using NM.
Figure 4  Flowchart of patients and study outcomes according to mask assignment ventilatory. See text for details. ARF = acute respiratory failure; ETI = endotracheal intubation; NIV = noninvasive ventilation; TFM = total face mask. See Figure 1 legend for expansion of the other abbreviation.

<table>
<thead>
<tr>
<th>Table 1 -- Baseline Characteristics of the Groups</th>
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<tbody>
<tr>
<td><strong>Characteristic</strong></td>
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<tr>
<td>---------------------</td>
</tr>
<tr>
<td>Sex, male to female</td>
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<tr>
<td>Age, y</td>
</tr>
<tr>
<td>Hospital, [a] TMC to RIH</td>
</tr>
<tr>
<td>Heart rate, beats/min</td>
</tr>
<tr>
<td>Respiratory rate, breaths/min</td>
</tr>
<tr>
<td>Systolic BP, mmHg</td>
</tr>
<tr>
<td>Diastolic BP, mmHg</td>
</tr>
<tr>
<td>pH</td>
</tr>
<tr>
<td>Paco₂, mmHg</td>
</tr>
<tr>
<td>Paco₂, mmHg</td>
</tr>
<tr>
<td>Paco₂/Fio₂</td>
</tr>
<tr>
<td>HCO₃, mmol/L</td>
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</tbody>
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Table 2 -- Indications for NIV in the Groups

<table>
<thead>
<tr>
<th>Indication</th>
<th>ONM Group (n = 31)</th>
<th>TFM Group (n = 29)</th>
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<tbody>
<tr>
<td>COPD exacerbation</td>
<td>3 (9.7)</td>
<td>12 (41.4)</td>
</tr>
<tr>
<td>Asthma exacerbation</td>
<td>2 (6.5)</td>
<td>1 (3.4)</td>
</tr>
<tr>
<td>Pulmonary edema</td>
<td>6 (19.4)</td>
<td>3 (10.3)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>9 (29)</td>
<td>5 (17.2)</td>
</tr>
<tr>
<td>ALI/ARDS</td>
<td>3 (9.7)</td>
<td>2 (6.9)</td>
</tr>
<tr>
<td>ARF in immunocompromised</td>
<td>0</td>
<td>1 (3.4)</td>
</tr>
<tr>
<td>Postoperative respiratory failure</td>
<td>0</td>
<td>1 (3.4)</td>
</tr>
<tr>
<td>Weaning facilitation</td>
<td>5 (6.1)</td>
<td>1 (3.4)</td>
</tr>
<tr>
<td>Hypoventilation</td>
<td>3 (9.7)</td>
<td>3 (10.3)</td>
</tr>
</tbody>
</table>

Data are presented as No. (%). P > .05. ALI = acute lung injury; ARF = acute respiratory failure; NIV = noninvasive mechanical ventilation. See Table 1 legend for expansion of the other abbreviations.

Ventilators, Modes, and Settings

The BiPAP Vision (Respironics) was used for 27 patients in each group. The BiPAP ST/D (Respironics) and VPAP II ST (ResMed, Inc; San Diego, California) were used for one and two patients in the TFM group and the ONM group, respectively. Patients received BPAP, except for four who were given CPAP for pulmonary edema (one via ONM and three via TFM). After 3 h of NIV, mean pressure for CPAP was 6.7 (± 2.9) cm H2O, and BPAP patients had mean IPAP and EPAP of 12.4 (± 3.1) cm H2O and 5.8 (± 1.6) cm H2O, respectively. Pressures were similar between groups except at 3 h, when IPAP was 13.7 vs 11.5 cm H2O in the TFM group vs the ONM group (P = .024). After initiation, 81.7% (n = 49) of all patients had good synchrony with the ventilator, and 86.6% (n = 52), 10% (n = 6), and 1.7% (n = 1) had mild, moderate, and large mask leaks, respectively (all P > .05 between groups, data not shown).

Major Outcome Variables

Mask discomfort scores were similar between groups (Fig 5). Median mask placement time was 3.5 min (interquartile range [IQR], 1.9-5) vs 5 min (IQR, 2-8) in the TFM group vs the ONM group (P > .05). Early NIV discontinuation rates were also similar in both groups (Fig 4, Table 3). Reasons for early discontinuation did not differ significantly between the groups (Table 3) and subsequent outcomes of these patients are depicted in Figure 4. Eight of the 16 patients using the TFM who discontinued NIV early were switched to the ONM; only one subsequently required intubation. None of the 12 ONM patients who discontinued NIV early was switched to a TFM (P = .008) (Fig 4).
Figure 5  Mean mask discomfort and dyspnea scores at baseline and during the first 3 h of NIV use as per designated mask type. Mean visual analog scale scores are shown, with 1 being the least effect and 10 the most. There were no statistically significant differences between groups at any time point. See Figure 4 legend for expansion of abbreviations.

<table>
<thead>
<tr>
<th>Table 3 -- Outcomes in Each Mask Group</th>
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<tr>
<td><strong>Outcome</strong></td>
</tr>
<tr>
<td>Early NIV discontinuations[^a],[^b]</td>
</tr>
<tr>
<td>Failure to improve</td>
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<tr>
<td>Mask intolerance</td>
</tr>
<tr>
<td>Agitation</td>
</tr>
<tr>
<td>Copious secretions</td>
</tr>
<tr>
<td>Claustrophobia</td>
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<tr>
<td>Intubation rate during hospitalization</td>
</tr>
<tr>
<td>Reasons for intubation[^a]</td>
</tr>
<tr>
<td>Severe respiratory distress</td>
</tr>
<tr>
<td>Deterioration in vital signs</td>
</tr>
<tr>
<td>Deterioration in gas exchange</td>
</tr>
<tr>
<td>Mask intolerance</td>
</tr>
<tr>
<td>Airway protection</td>
</tr>
<tr>
<td>Mean hospital length of stay (range)</td>
</tr>
<tr>
<td>Hospital mortality[^c]</td>
</tr>
</tbody>
</table>

Data are presented as No. (%). $P > .05$. See [Table 1] or [Table 2] legends for expansion of the abbreviations.
Some patients had multiple reasons.

One patient from each group was intubated for airway protection and was excluded from subsequent analysis.

Includes seven deaths (four ONM, three TFM) that occurred during the hospital stay after NIV discontinuation.

**Other Outcome Variables**

Respiratory rate and oxygen saturation improved similarly in both the ONM and the TFM group (Fig 6). Although the decrease in heart rate at 3 h was significantly greater in the TFM than in the ONM group ($P < .05$), the baseline heart rate was also higher in the TFM group ($P = .01$). $\text{Paco}_2$ improved similarly in both groups ($P > .05$).

![Heart Rate, Respiratory Rate, Oxygen Saturation](image)

**Figure 6** Mean vital signs (heart rate, respiratory rate, and oxygen saturation) at baseline and within the first 24 h of NIV initiation according to designated mask type. Except for heart rate, which was higher at baseline in the TFM group ($P = .01$), there were no significant differences between the groups. BPM = breaths per minute. See Figure 4 legend for expansion of other abbreviations.

The median duration of use of NIV with the ONM (15.7 h [IQR, 4.0-49.8]) tended to be longer than with the TFM (6.05 h [IQR, 0.9-56.7]), $P > .05$. The median total duration of NIV (including duration after switching masks) was similar in the ONM and the TFM group: 15.7 h (IQR 4.0-49.8) vs 18.8 h (IQR 5.3-75.5), respectively. ETI, reasons for intubation, hospital lengths of stay, and mortality were similar in both groups (Table 3). There were nine in-hospital mortalities, three in the TFM group and six in the ONM group ($P = .474$). Two deaths occurred during use of NIV (in the ONM group) (Fig 4) and the remainder after NIV discontinuation (Table 3).
Complications were similarly infrequent with both masks and included claustrophobia (four patients in the ONM group and six patients in the TFM group) and eye irritation in one TFM patient (both $P > .05$). Mask fit tended to be poor more often with the TFM than the ONM (17.2% vs 3.2%, $P = .07$) and there were no nasal bridge ulcerations.

**Discussion**

The key findings of this study are that the TFM and the ONM (1) are perceived as similarly comfortable by patients with ARF receiving NIV, (2) require similar amounts of time for placement, and (3) are associated with similar early NIV discontinuation rates, although the TFM tends to be associated with intolerance and poor fit more often than does the ONM.

Mask type can be a major factor affecting patient comfort and adherence to therapy during NIV. Using a randomized crossover design, Criner et al. compared the TFM to an ONM and an NM in four patients with chronic respiratory failure previously intolerant of either the ONM or NM. After 20 to 30 min, the TFM enhanced comfort and reduced air leakage and dyspnea, compared with the other masks. More recently, Cuvelier et al. found that the TFM and the ONM similarly improved gas exchange, encephalopathy, respiratory distress, and respiratory frequency during 48 h of NIV use in patients with acute hypercapnic respiratory failure. They also found that, although both masks were tolerated similarly for the first 24 h, the ONM was better tolerated between hours 24 and 48, perhaps because the patients were “more familiar” with the ONM, some having used it previously for NIV at home.

Similar to Cuvelier et al., but contrary to our own hypothesis, we found that comfort scores were similar between the TFM and the ONM after NIV initiation. Many of our patients completed NIV within the first 24 h so we did not have a sufficient sample to examine tolerance after 24 h of NIV. Our findings regarding mask comfort contrast with those of Criner et al., but their patients had already manifested intolerance to the other masks and did not have ARF.

Again contrary to our hypothesis, the TFM was not quicker to apply than was the ONM. The median mask placement time was actually 1.5 min shorter with the TFM but this was not statistically significant, nor is it likely to be clinically significant. Also, contrary to our expectations, the TFM was not easier to fit. In fact, there was a trend toward poorer fit with the TFM than with the ONM, related to facial anatomic idiosyncrasies, such as an excessively long nose or a small face.

In view of our negative findings regarding comfort and rapidity of placement, we were not surprised that the TFM failed to reduce early NIV discontinuation rates. However, the strong trend toward more early discontinuations due to mask intolerance in the TFM vs the ONM group (39.3% vs 16.7%) was unanticipated. Both rates were substantially higher than in the Cuvelier study (12% ONM vs 6% TFM), perhaps because of the higher rate of prior home NIV use in the Cuvelier study (41.2% vs 11.7% in the current study). In our study, both masks yielded similar improvements in dyspnea scores, vital signs (except for heart rate), and gas exchange over time, and similar intubation and mortality rates as well as hospital lengths of stay.

The limitations of this study include the variability introduced by different types of bilevel ventilators and NIV modes (BPAP and CPAP) and the enrollment of patients with a variety of diagnoses for ARF in different medical centers. However, this variability is representative of actual clinical practice and was, we believe, unlikely to affect our major outcomes of comfort and time for application. Although some secondary outcomes, such as early discontinuation, intubation, or mortality rates could depend on such factors, randomization should have helped control for them and no associations were apparent between these factors and outcomes. Also, blinding of investigators and patients was not possible. This is inevitable with interface trials, but every effort was made to encourage therapists to apply equal effort with both mask types. The significantly higher baseline heart rate in the TFM group compared with the ONM group raises concerns about the adequacy of matching, but other baseline measures were similar and this was unlikely to have affected mask comfort. Also, the question must be raised as to whether the sample size was sufficient. Comfort scores were quite similar, though, and the trend toward more early discontinuations in the TFM group suggests that we did not miss a subtle difference in comfort favoring the TFM.

**Conclusions**

In summary, our study demonstrates that the TFM does not offer significant advantages over the ONM. Despite the trend towards more early discontinuations because of mask intolerance with the TFM than with the ONM, the TFM performed as well as the ONM with regard to other major outcomes, such as avoiding intubation, and mortality, and should be considered a possible alternative when very rapid application is desired or when nasal ulcers or intolerance complicate the use of ONM.

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Dr Liesching: contributed to study design, data acquisition and analysis, and preparation of the manuscript.

Mr Howard: contributed to data acquisition and analysis and preparation of the manuscript.

Dr Hill: contributed to study design, data acquisition and analysis, and preparation of the manuscript.

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