Mechanically assisted intermittent positive-pressure ventilation effectively provides ventilatory support in patients with respiratory failure but requires placing an artificial airway. We have previously reported our successful experience delivering mechanical ventilation via a face mask (FMMV) rather than with an endotracheal tube in a pilot study of patients with acute respiratory failure. The present investigation evaluated an additional 18 patients with hypercapnic respiratory failure to determine the efficacy of FMMV in a more homogeneous group and to determine factors predicting its success. FMMV was successful in avoiding intubation in 13 of the 18 patients. A significant initial improvement in Pco2 (>16 percent decrease) and in pH (from <7.30 to >7.30) predicted success. The five patients who failed on FMMV required endotracheal intubation because of inability to improve gas exchange (three patients), apnea due to sedatives (one patient), and management of secretions (one patient). FMMV was generally well accepted with only two patients withdrawn because of intolerance of the mask. The mean duration of FMMV was 25 h. Complications were seen in only two patients (11 percent): aspiration (one patient) and mild skin necrosis (one patient). Seven patients entered the study by meeting entrance criteria after an unsuccessful extubation attempt and therefore received both forms of mechanical ventilation. All but one patient avoided reintubation, and the face mask proved to be as effective as the endotracheal tube as a conduit for delivering the mechanical tidal volume and improving gas exchange. Our findings indicate that FMMV is a viable option for short-term (one to four days) ventilatory support of patients with hypercapnic respiratory failure and insufficiency.

(Chest 1991; 100:445-54)

AMR = accessory muscles of respiration; CIPP = constant inspiratory positive pressure; CFPB = continuous positive pressure breathing; Edi = transdiaphragmatic EMG; EMG = electromyogram; ET = endotracheal; ETI = endotracheal intubation; FMMV = mechanical ventilation via a face mask; IMV = intermittent mandatory ventilation; IPAP = inspiratory positive airway pressure; MV = mechanical ventilation; NIPPV = positive pressure ventilation via a nasal mask; PAM = paradoxical abdominal motion; Pdi = transdiaphragmatic pressure; PSV = pressure support ventilation; SBP = systolic blood pressure

Mechanically assisted intermittent positive-pressure ventilation effectively provides ventilatory support in patients with respiratory failure but requires placing an artificial airway, the endotracheal (ET) tube. Complications can result from the intubation procedure, during the course of ventilation, or after removal of the tube.1,2 Injury to the pharynx, larynx, and trachea can occur at the points of contact between the mucosa and the tube or cuff resulting in ulceration, edema, and hemorrhage with potential long-term complications, ie, stenosis. In addition to local damage, the ET tube places the patient at significant risk for developing nosocomial infections, mainly sinusitis and ventilator-associated pneumonia. Sinusitis occurs from occlusion of the sinus ostia and is increasingly recognized as a cause of unexplained fever and sepsis in ventilated patients.3 Endotracheal intubation (ETI) is the single most important predisposing factor for nosocomial pneumonia.4 ETI bypasses the mechanical defenses of the upper airways and causes local injury, both of which predispose patients to colonization of the trachea by pathogenic bacteria. In addition, the portion of the upper trachea between the inflated cuff and the vocal cords behaves as a reservoir for secretions originating from the sinuses, the nasal and oral cavity, the pharynx, and the stomach. Such secretions can be introduced as a bolus (with high concentration of bacteria) into the lung by even minor ET tube manipulation.

Respiratory muscle fatigue is a primary determinant of ventilatory failure and usually occurs in the face of increased demand on the respiratory system.5 Mechanical ventilation (MV), instituted when conservative treatment fails, aims to correct gas exchange and rest the respiratory muscles, while pharmacologic intervention is directed at the exacerbating factors. It is often difficult to discriminate a priori which patient with respiratory failure will require prolonged mechanical ventilation. While the need for intubation is undisputed for long-term support of patients with respiratory failure, we have previously reported our
successful experience delivering MV with a face mask (FMMV) as an alternative to ETI for up to four days in a heterogeneous group of patients with respiratory failure. This prospective clinical observational study was conducted (1) to assess the subjective, objective, and physiologic responses to noninvasive FMMV in patients with acute hypercapnic respiratory failure/insufficiency resulting from intrinsic lung disease, and (2) to identify parameters that can predict successful response to FMMV early in treatment.

**Methods and Materials**

The study was conducted at the University of Tennessee Health Science Center in Memphis from February 1989 to March 1990. The protocol was approved by the institutional review boards of both the University of Tennessee and the VA Medical Center, Memphis.

Diagnostic criteria for hypercapnic respiratory failure included all of the following: (1) severe dyspnea at rest; (2) respiratory rate (RR) >25 breaths per minute; (3) use of accessory muscles of respiration (AMR) or paradoxical abdominal motion (PAM); (4) acute respiratory acidosis defined as pH <7.30 and PaCO₂ >60 mm Hg; and (5) the clinical decision that the patient requires immediate support with MV. Patients with status asthmaticus and acute respiratory acidosis (stage 5) were also candidates for this investigation.

Diagnostic criteria for hypercapnic respiratory insufficiency in-cluded all of the following: (1) dyspnea at rest; (2) RR >25 breaths per minute; (3) acute hypercapnia (PaCO₂ >45 mm Hg) and respiratory acidosis (pH ≤7.35); and (4) the clinical decision that the patient does not require immediate support with MV.

Criteria for excluding patients from the study included the following: (1) systolic blood pressure (SBP) <90 mm Hg or the use of vasopressors; (2) electrocardiographic (ECG) instability; (3) history of unstable angina or recent (three months) myocardial infarction; (4) need for ETI to protect the airways (coma or seizure

![Figure 1](image-url). Patient with face mask connected to a mechanical ventilator.

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Diagnosis</th>
<th>Age, yr/sex</th>
<th>Duration of MV, FMMV</th>
<th>Physiologic</th>
<th>Objective</th>
<th>Subjective</th>
<th>Complications</th>
<th>Outcome</th>
<th>Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>COPD exac</td>
<td>61/F</td>
<td>89</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
<td>None</td>
<td>S</td>
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<td>59/M</td>
<td>2</td>
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<td>Positive</td>
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<td>3</td>
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<td>Positive</td>
<td>Positive</td>
<td>Mild FPN</td>
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<td>19/1008</td>
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<td>5/25</td>
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<td>F</td>
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<tr>
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<td>E/S</td>
<td>Yes</td>
</tr>
<tr>
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<td>COPD exac, s/p extub</td>
<td>64/M</td>
<td>7</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
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<td>S</td>
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</tr>
<tr>
<td>Mean</td>
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<td>62</td>
<td>27/260</td>
<td>67% Pos</td>
<td>83% Pos</td>
<td>78% Pos</td>
<td>11% S = 72%</td>
<td>94%</td>
<td></td>
</tr>
</tbody>
</table>

* COPD = chronic obstructive pulmonary disease; exac = exacerbated; extub = extubated; ESRD = end-stage renal disease; CHF = congestive heart failure; E = exited; S = success; F = failure; status = status asthmaticus; F edema = cardiogenic pulmonary edema; s/p ext = postextubation distress; FMMV = face mask mechanical ventilation; MV = mechanical ventilation with intubation; Pos = improvement; Neg = lack of improvement; FPN = face mask mechanical ventilation.
disorders) or to manage secretions; and (5) inability to properly fit the face mask.

Criteria for exit from the study included the following: (1) patient's request; (2) inability to tolerate the mask (discomfort or pain); (3) need for ETT (inability to improve alveolar ventilation or oxygen exchange or management of secretions); (4) hemodynamic instability with SBP < 90 mm Hg; (5) ECG instability with evidence of ischemia or significant ventricular arrhythmias; or (6) failure to improve mental status of patients who are lethargic from CO2 retention or agitated from hypoxemia before initiating FMMV.

Each patient was assessed by one of the investigators on admission to the emergency department or the medical intensive care unit (ICU). If the patient met entrance criteria and consented to the study, a clear, air-sealed, full face mask (Hospitak Inc) was tightly fitted using rubber head straps (Fig 1). A soft nasogastric tube was inserted before initiating face-mask ventilation and placed on low, intermittent suction to prevent gastric insufflation; the head of the bed was kept elevated at ≥45° at all times.

All patients received mechanical ventilation using a ventilator (Puritan Bennett 7200; Puritan Bennett Co, Overland Park, Kan). Initial ventilatory settings were continuous positive airway pressure (CPAP) mode with pressure support ventilation (PSV) of 10 to 20 cm H2O titrated to achieve an RR < 25 breaths per minute and a tidal volume (TV) ≥ 7 ml/kg. If a significant leak was present to the mask prevented the use of PSV, the patient was placed on an intermittent mandatory ventilation (IMV) mode. Ventilator settings were adjusted based on results of arterial blood gases (ABG) obtained at 1, 2 to 6, and 6 to 12 h following initiation of MV. Patients received continuous ECG and arterial oxygen saturation monitoring (Novametric Co, Wallingford, Conn).

Patients were weaned from mechanical ventilation by removing the ventilator; patients received supplemental oxygen by nasal cannula or a face mask. The periods off MV were titrated to patient tolerance and objective findings, similar to a T-piece weaning trial.

The following data were collected: (1) patient's subjective response: dyspnea quantification (7 to 10 = severe; 4 to 7 = moderate; 1 to 4 = mild; 0 = none), comfort, and mental status; (2) patient's objective response: blood pressure (BP), heart rate (HR), PAM, and use of AMB; (3) physiologic response: PaO2/FIO2, PaCO2, minute ventilation (Ve), and exhaled TV; (4) complications: abdominal distention, aspiration, pneumonia by clinical criteria, and local tissue damage (facial pressure necrosis); (5) duration of ventilation in hours; and (6) Outcome.

A successful outcome was defined as improvement in gas exchange (positive physiologic response) and avoidance of the need for intubation. Failure meant that patient required intubation because of (1) negative physiologic response, (2) development of complications (abdominal distention, aspiration, local tissue damage), or (3) withdrawal from FMMV at patient's request.

Statistical Analysis

We evaluated patients repeatedly at 1 h (baseline), 2 to 6 h, and 6 to 12 h. Response variables were PO2, PaO2/FIO2, ratio, pH, and RR. In addition, we calculated change from the baseline for each response at 2 to 6 h and 6 to 12 h. After adjusting for patient differences, we compared average responses for all variables at the evaluation times using analysis of variance (ANOVA) and standard t tests. At the conclusion of the study, we evaluated whether those patients who improved while using FMMV differed from patients who failed to improve. We compared the two designated groups overall and at each evaluation time using ANOVA for the typical split-plot experimental design. Because all comparisons were pre-planned, we used Fisher's least significant difference test and considered a two-sided test significant at α = 0.05.

RESULTS

Hypercapnic Respiratory Failure Group

Eleven patients (patients 1 to 11), eight men and three women, met all criteria for hypercapnic respi...
The objective and After chodilators group, per breaths noted h, to iologic to patient but properly excluded FMMV required mean status respiratory PaCO₂ to 3.6 7.35 (range, 7.29 to 7.35) and a mean PaCO₂ of 60 mm Hg (range, 47 to 73 mm Hg). Based on their clinical and physiologic status, all would have required intubation and MV. Two patients with status asthmaticus (stage 5) had failed aggressive inpatient treatment for more than 24 h and had developed signs of respiratory muscle fatigue in addition to hypercarbia.

Acceptance of FMMV was excellent with only one patient developing intolerance to the mask. This patient (patient 2) was initially lethargic and difficult to arouse but became alert soon after initiating FMMV. After 2 h of treatment, he complained of discomfort and refused to continue FMMV but did not require additional ventilatory support.

Eight patients (73 percent) had a positive physiologic response, and nine (82 percent) had positive objective and subjective responses. Clinical and physiologic improvement was seen shortly after beginning FMMV (Fig 2).

Patients 4 and 5 required ETI because of an inability to improve gas exchange. Patient 5 had end-stage renal disease and pulmonary fibrosis and died after 42 days of MV with ETI. Patient 4 had COPD and required six days of MV with ETI.

The mean dyspnea value was 8 at entrance, 4 at 1 h, and 2 at the 2- to 6-h interval; no difference was noted between the failure and success groups. The mean RR in the successful group dropped from 34 breaths per minute at baseline to 23 breaths per minute at 1 h and to 18 within 2 to 6 h. In the failure group, RR decreased from 31 breaths per minute to 25 breaths per minute at 1 h but rose to 38 breaths per minute in the next 2 to 6 h. The PCO₂ mean value at baseline, at 1 h, and at the 2- to 6-h intervals were 79, 64, and 62 mm Hg, respectively, in the successful group, and 92, 88, and 89 mm Hg in the failure group. The mean pH values at the same time intervals were 7.27, 7.32, and 7.36 in the successful group and 7.17, 7.18, and 7.20 in the failure group.

The mean duration of FMMV was 28 h with a range of 2 to 89 h. The only complication observed in this group was patient 3 who developed mild facial skin pressure necrosis at the site of mask contact; necrosis healed spontaneously in two days.

Hypercapnic Respiratory Insufficiency Group

Seven patients (patients 12 to 18), five men and two women, met all our criteria for respiratory insufficiency. Their mean age was 64 years (range, 41 to 82 years). All but two patients were on MV with ETI for respiratory failure and developed respiratory distress shortly after extubation (mean, 2.5 h). They had not yet reached clinical and objective criteria for reintubation at the time of entering the study. The causes of respiratory failure for which they originally required MV were COPD with acute bronchospastic exacerbation (four patients) and pneumonia (one patient).

All patients had moderate to severe respiratory distress, mean RR was 32 breaths per minute (range, 25 to 40 breaths per minute), and all but one was using AMR.

The ABC samples drawn before initiating FMMV showed a mean pH of 7.33 (range, 7.29 to 7.35) and a mean PaCO₂ of 60 mm Hg (range, 47 to 73 mm Hg).

Patient 6 exited the study because of intolerance of the mask after 14 h of FMMV; however, he required no further ventilatory support.

A positive physiologic response was seen in four patients, objective response in six, and subjective response in five.

Endotracheal intubation was required in three patients (patients 13, 14, and 16). Patient 13, who had a positive response to FMMV, developed apparent aspiration pneumonia and required ETI to manage secretions. Patient 14 was intubated because of inability to improve gas exchange, and patient 16 became apneic after receiving an inappropriate dosage of sedatives, necessitating immediate ETI.

The mean dyspnea value was 6 at entrance, 3 at the first hour, and 2 at 2 to 6 h; in the success group, it changed from 6 to 2.5 and 2, in the failure group from 5 to 3.6 and 1.7. The mean RR in the successful group decreased from 35 breaths per minute at baseline to 21 breaths per minute at 1 h and 20 breaths per minute in 2 to 6 h. In the failure group, RR decreased from 31 breaths per minute to 17 breaths per minute by 1 h but later returned to 31 breaths per minute (2 to 6 h later). The mean Pco₂ value at baseline, 1 h, and at 2- to 6-h intervals were 72, 59, and 59 mm Hg, respectively, in the successful group, and 82, 79, and 81 mm Hg in the failure group. The mean pH values, at the same time intervals, were 7.29, 7.34, and 7.36.
in the successful group, and 7.24, 7.23, and 7.26 in the failure group (Fig 2).

The mean duration of FMMV was 21 h (range, 5 to 48 h). The only complication observed was presumed aspiration pneumonia in patient 13, who required ETI to manage secretions.

Comparison of Physiologic Responses to FMMV and MV with ETI

Seven patients developed respiratory failure (patients 3 and 6) or insufficiency (patients 12, 13, 15, 17, and 18) shortly after extubation (self-extubation in two). This provided the opportunity to compare the physiologic response of each individual patient with MV delivered by two different routes within a time interval of a few hours and without a significant change in respiratory status. Ventilatory settings and ABC samples prior to extubation (values during weaning trial by CPAP or T-piece excluded) were compared with the findings in the 2- to 6-hour interval with FMMV and are shown in Figure 3. The mean values obtained during FMMV compared with MV with ETI and the differences (FMMV-MV) were as follows: 

- $V_e$, 11 L/min and 9.5 L/min ($\Delta = +1.5$); measured exhaled (as determined by the exhalation flow sensor) 
- $TV$, 606 ml and 767 ml ($\Delta = -154$); 
- $P_{CO_2}$, 45.3 mm Hg and 44 mm Hg ($\Delta = +1.3$); and 
- $PaO_2/ FiO_2$ ratio, 310 and 290 ($\Delta = +20$). Only patient 13 required reintubation, not for failure to improve gas exchange with FMMV but for management of secretions due to presumptive aspiration.

Severity of Underlying Lung Disease

Prior pulmonary function testing was available in 14 patients; in ten of the 13 with COPD, nine of the 11 patients with successful FMMV, and three of the five who failed (Table 2). In patients with COPD, the mean FEV1 value was 852 ml (31 percent of predicted). Patients who succeeded with FMMV had the same degree of physiologic impairment as the group that failed. The mean FEV1 values in the successful and failure groups were 862 and 856 ml, respectively (29 percent of predicted vs 26 percent).

Outcome

In analyzing the data, the two groups were considered together and patients were divided into those who succeeded, failed, or exited the study (Table 3). The two patients who exited were not considered for statistical analysis and did not require intubation.

In the successful group, the mean $P_{CO_2}$ dropped from a baseline value of 72 mm Hg to 59 mm Hg (16 percent decrease) at 1 h ($p = 0.0005$) and 55 mm Hg (19 percent decrease) at 2 to 6 h ($p = 0.0001$). In the failure group, the mean $P_{CO_2}$ dropped from 82 mm Hg at baseline to 77 mm Hg (5 percent decrease) at 1 h but increased to 81 mm Hg at 2 to 6 h. Comparing the changes in $P_{CO_2}$ between the two groups, there was no significant difference at baseline ($p = 0.06$) which we did not consider to be a type 2 error because the range of $P_{CO_2}$ in the successful group was 47 to 110 mm Hg compared with 70 to 107 mm Hg in the failure group. There was a significant drop in $P_{CO_2}$ in the successful group at 1 h ($p = 0.01$) and at 2 to 6 h ($p = 0.001$) compared with the failure group.

In the successful group, the mean pH rose from a baseline value of 7.29 to 7.34 at 1 h ($p = 0.007$) and
Table 2—Pulmonary Function Testing

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>FVC, ml (%)</th>
<th>FEV₁, ml (%)</th>
<th>FEV₁/FVC, %</th>
<th>RV/TLC, %</th>
<th>DSB, mCO₂/min/mm Hg (%)</th>
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<tbody>
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<td>440 (21)</td>
<td>38</td>
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<tr>
<td>2</td>
<td>2,050 (49)</td>
<td>1,410 (69)</td>
<td>69</td>
<td>57</td>
<td>20.1 (66)</td>
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<tr>
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<td>823 (32)</td>
<td>50</td>
<td>56</td>
<td>9.5 (38)</td>
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</table>

*Patients with asthma.

7.37 at 2 to 6 h (p = 0.0001). In the failure group, the mean pH increased from 7.24 at baseline to only 7.26 at 1 h and did not change at 2 to 6 h. Achieving a pH value of >7.30 at the 2- to 6-h interval predicted success of FMMV with a positive predictive value of 92 percent.

In the successful group, the mean RR decreased from 34 at baseline to 23 (33 percent decrease) at 1 h (p = 0.03) and 19 (42 percent decrease) at 2 to 6 h (p = 0.003). In the failure group, the mean RR dropped from a baseline value of 31 to 22 (17 percent decrease) at 1 h (p = 0.07) but returned to 31 at 2 to 6 h.

The changes in PaO₂/FIO₂ at the first two intervals were not significantly different between the two groups.

**DISCUSSION**

Inspiratory muscle fatigue is thought to be the final common pathway that causes ventilatory failure in patients with COPD. Fatigue occurs when the balance between mechanical impedance and muscle power is tipped in favor of impedance against which the respiratory muscles must work. The additional workload is caused most frequently by an increase in airway resistance (bronchospasm, secretions) and less commonly by a reduction in compliance (congestive heart failure, pneumonia). Patients demonstrate dyspnea and a high respiratory frequency. However, most of these breaths are shallow, and much of the TV is wasted as dead space ventilation, a situation resulting in retention of CO₂ and respiratory acidosis. For these patients, mechanical ventilation is a life-supportive measure the primary purposes of which are to (1) relieve respiratory distress, (2) improve pulmonary gas exchange, and (3) rest the fatigued respiratory muscles.

Traditionally, an ET tube is inserted to deliver mechanical tidal breath to the patient's lungs. Placing this artificial airway is an invasive procedure associated with potential complications and discomfort, but most important, MV is usually confined to life-threatening conditions and is used only in specialized hospital settings. Noninvasive ventilatory support, delivered without using an ET or tracheostomy tube, has been investigated in patients with both chronic and acute respiratory failure of varied etiologies.

When positive end-expiratory pressure (PEEP) was originally introduced in the management of acute pulmonary edema by Barach et al in 1938, it was delivered in a noninvasive mode via a tightly fitted face mask using a flow generator. Continuous positive pressure breathing (CPPB) was delivered throughout both phases of respiration.
Continuous positive airway pressure without assisted MV applied through a face mask has recently received widespread application in the treatment of patients with acute hypoxemic respiratory failure. In addition, mask CPAP has been shown to reduce the load of breathing and to improve inspiratory muscle efficiency in asthmatic subjects with acute exacerbation.

Noninvasive mechanically assisted ventilation has been investigated mainly in chronic respiratory failure from COPD and neuromuscular disease. Resting the chronically fatigued respiratory muscles of patients with severe COPD with intermittent negative pressure ventilation (tank, cuirass, and poncho) has improved ABG values, dyspnea, inspiratory muscle strength, exercise tolerance, and quality of life. A marked reduction in the number of hospital admissions and the length of hospitalizations per year (from 39 ± 30 days/year to 4 ± 10 days/year) were also observed. The physiologic effects of positive pressure ventilation via a nasal mask (NIPPV) in normal subjects and in patients with chronic respiratory failure of varied etiology have been studied by Carrey and coworkers. NIPPV decreased spontaneous inspiratory efforts, the phasic diaphragm electromyographic (EMG) amplitude, and the activity of the AMR. Intermittent positive pressure ventilation via a face or a nasal mask has been used successfully in patients with chronic paralytic respiratory failure. Nocturnal ventilation in these patients is frequently effective in avoiding or postponing for years the need for tracheostomy and results in improved gas exchange and quality of life.

Noninvasive MV via a face or nose mask has also been used to support patients with acute respiratory failure (ARF). Leger and coworkers have used a silicone customized nasal mask to ventilate 13 patients with COPD and ARF. Intermittent MV, using assist control mode, was delivered for an average of 11.4 h/day with a mean duration of ventilation of 10 ± 3.4 days. Ventilation was stopped after the Pco2 remained stable during a 3-h period off the ventilator. Two patients required ETI on the second day of the study, while the rest (85 percent) had a significant improvement in ABG values and were discharged from the ICU and later from the hospital.

Muir and coworkers used a volumetric respirator and a customized nasal mask to deliver NIPPV to 12 elderly patients with ARF who were not candidates for ETI because of age and poor physiologic condition. Ten patients clinically improved within a few hours, oxygenation improved rapidly, and correction of alveolar ventilation occurred over several hours. Three patients failed to continue to improve, two of whom later died. Two additional patients died of nonrespiratory reasons.

Brochard and coworkers have used a special respiratory assistance device to deliver an adjustable constant inspiratory positive pressure (CIPP) via a face mask. The physiologic effects of this modality were studied for 30 min in 11 patients with COPD and acute exacerbation of their lung disease, and results were compared with both before and after CIPP values. An increase in alveolar ventilation and a decrease in diaphragmatic activity, based on comparison of ABC values, RR, transdiaphragmatic pressure (Pdi), and diaphragmatic EMG (Edi) were reported. A clinical study compared the response of conventional treatment versus noninvasive ventilation in patients with acute exacerbation of COPD who were considered likely to require ETI with MV (recent worsening of dyspnea, RR >30/min, PO2 <55 mm Hg on room air, and pH <7.35). Thirteen patients were placed on inspiratory positive airway pressure (IPAP) and 13 were treated as controls with conventional therapy. In the control group, 11 patients required MV with ETI; two patients died during MV, and the mean duration of stay in the ICU was 19 days. In the IPAP group, one required conventional MV with ETI; only two patients died, and their mean duration of stay in the ICU was seven days. The authors concluded that the use of this noninvasive assistance device in patients with acute exacerbation of COPD can obviate ETI and shorten the time required for ICU stay.

We first reported the use of continuous FMMV for the treatment of acute hypercapnic and/or hypoxemic respiratory failure in a pilot study of 10 patients. The mode and methods of ventilation were similar to those used in the present study. FMMV was well tolerated and resulted in improved gas exchange similar to what would have been achieved with conventional support. In the hypercapnic group, the mean Pco2 was reduced by 18 and 24 mm Hg at the first and sixth hour of ventilation, whereas the mean RR fell by 50 percent. Only 30 percent of patients required ETI, and the only complication of care was minimal facial skin pressure necrosis in two patients.

Noninvasive face mask MV has been shown, again, in this investigation to be effective in correcting gas exchange abnormalities and in avoiding intubation in the majority (72 percent) of patients with acute hypercapnic respiratory failure. This improvement occurred despite the severe underlying lung impairment with a mean FEV1 of 823 ml (Table 2). Subjective, objective, and physiologic improvement was seen after initiating FMMV. Several patients on FMMV in an IMV mode actually were ventilated without obvious respiratory muscle effort. Although the respiratory rate decreased in all patients with a mean reduction of 31 percent (from 32 to 22 breaths per minute), the Pco2 dropped significantly only in those who had successful FMMV. Achieving a pH of more than 7.30 at the 2- to 6-h
interval predicted success with a high degree of sensitivity (92 percent) and specificity (75 percent).

In our experience, FMMV offers significant potential advantages when compared with traditional ventilation with ETI.

Noninvasive Procedure

Placing an ET tube is an invasive procedure that requires local anesthesia, sedation, and occasionally paralysis and potentially causes vomiting with aspiration of gastric contents. This factor, and the concern that the patient may become “ventilator dependent,” has often delayed instituting MV until the late stages of ARF. Failure to rest fatiguing respiratory muscles may cause actual respiratory muscle cell necrosis and eventually prolong the duration of MV. The mortality rate of patients allowed to suffer a respiratory arrest before ETI is significantly higher than the mortality rate of patients receiving MV for acute exacerbation of COPD alone. Many of these patients also have underlying atherosclerotic coronary and cerebrovascular disease and may suffer ischemic damage from hypotension, hypoxia, and/or high catecholamine levels, both intrinsic and therapeutic, during the delay in instituting ETI and MV. FMMV, on the other hand, is simple and easy to institute, facilitating earlier intervention, and potentially eliminating life-threatening delays. In the present study, the delay in intubating patients who failed the FMMV trial was not associated with complications. Discontinuation of MV requires removal of the ET tube, a process often postponed by concern that the patient’s condition may deteriorate and the patient may require reintubation. In contrast, FMMV is easily discontinued and can be rapidly re instituted. Weaning from MV with ETI is commonly done by placing the patient on a T-piece. Keeping the ET tube in place results in increased work of breathing and may underestimate the patient’s potential for extubation. Weaning during FMMV occurs with the patient off the ventilator, on a face mask or a nasal cannula for O2 supplementation, a process that better reflects the patient’s true respiratory reserves.

Decreased Incidence of Pneumonia

Nosocomial pneumonia occurs in 9 to 27 percent of patients with different varieties of respiratory failure and is an important factor in determining outcome. The mortality rate in patients with respiratory failure who develop pneumonia compared with ventilated patients without lung infection is 48 percent vs 26 percent. Endotracheal intubation bypasses the anatomic defense barriers of the upper airways, behaving as a conduit for pathogenic organisms entering the endobronchial tree. In addition, it impairs mucociliary clearance, causes desquamation of ET epithelial cells leading to increased bacterial adherence and tracheal colonization, and alters cough. Most common nosocomial pathogens produce glycolysis, a molecular cement used to attach them to each other and to the polyvinyl chloride surface of ET tubes. An electron microscopy study of ET tubes, removed after an average of nine days of MV, found 84 percent to be coated with an amorphous material containing rod-shaped and coccoïd bacterial profiles. In this biofilm, large numbers of organisms are sequestered from both antibiotics and immunologic defenses and may gain access to the lower airway during suctioning. Most important, the upper part of the trachea (between the inflated cuff and the vocal cords) becomes a reservoir for organisms, sheltered from the patient’s own clearance ability and the reach of suction devices, that are easily aspirated into the lower airways. With FMMV, the trachea is not invaded by the ET tube or by suction catheters (patient can remove the mask and expectorate) and the vocal cords are not kept open, lowering the risk for aspiration, which is the leading cause of nosocomial pneumonia.

Decreased Incidence of Otitis and Sinusitis

Otitis and sinusitis frequently occur from the presence of the ET tube in the nasal or oral cavity. FMMV is not associated with tissue damage to the upper airways and may decrease infection of the paranasal sinuses, although a nasogastric tube, a known risk factor for sinusitis, may be required in patients requiring high ventilatory pressure. However, the main benefit in decreasing sinusitis and otitis may be the shorter duration of MV in patients who have achieved successful FMMV.

Comfort

Discomfort and pain derived from the presence of the ET tube in the oral cavity are a major source of distress in intubated patients. In the present study, the mask was well tolerated by all but two patients. Patients in a stable condition were able to remove the mask for rest periods of 10 to 15 min, during which time they could talk, drink small amounts of liquid, expectorate, or receive nebulized bronchodilator therapy. Successful FMMV did not interfere with sleep. Patients effectively ventilated with both modalities preferred FMMV because of the comfort, the ability to communicate, and the autonomy it provided instead of the “feeling of being controlled” (by the ventilator) experienced when the ET tube was in place.

Face mask mechanical ventilation has, however, potential risks: aspiration of gastric contents, transient hypoxemia, and facial pressure necrosis.
Aspiration

The most serious potential risk is aspiration of gastric contents into the lung, secondary to insufflation of the stomach. Based on previous studies that have measured normal upper esophageal opening pressure, a level of CPAP and PSV below 30 cm H₂O should not cause gastric insufflation.²⁶,³⁷ Brochard et al²¹ have not observed inflation of the stomach with peak airway pressure below 25 cm H₂O. However, because this complication was previously reported in patients with neuromuscular disease, every patient of ours had a nasogastric tube placed on low intermittent suction, and the head of the bed was kept elevated at a 45° angle. With these precautions, abdominal distention and vomiting were not observed. One patient had development of nosocomial bacterial pneumonia one day into FMMV, and an episode of unwatched aspiration could not be excluded.

Transient Hypoxemia

Transient hypoxemia can result from accidentally removing the mask, but this was rarely encountered. Continuous oximetry with proper ventilator alarm settings is crucial for rapid intervention.

Facial Skin Necrosis

Facial pressure necrosis of the skin at the site of mask contact was seen in one patient, but rapid healing occurred spontaneously.

Mechanical ventilation was delivered with a simple device: an air-sealed full face mask with straps that proved to be as effective a conduit system for the mechanical tidal breath as the ET tube. Leakage of air that frequently occurred at the site of contact between the mask and the nasogastric tube required adjustment of the mask or increased tidal volume to compensate. Ongoing development of face masks should easily overcome this problem.

Patient cooperation is critical for the use of FMMV. The patient must be able to voluntarily synchronize respiratory efforts with the ventilator or allow fully controlled ventilation in the IMV mode. Extremely anxious patients are better served by sedation and ETI, but moderate degrees of anxiety were frequently overcome once the necessary ventilatory support by FMMV was received. Relief of dyspnea, which occurred in most patients soon after institution of FMMV, was usually sufficient for ameliorating anxiety without the use of sedatives. Based on our experience, criteria for selection of patients appropriate for FMMV treatment are listed in Table 4.

Table 4 — Criteria for Selection of Patients for FMMV

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<tbody>
<tr>
<td>Hemodynamically stable</td>
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<tr>
<td>No history of recent myocardial infarction</td>
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<tr>
<td>Fully cooperative patient</td>
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<tr>
<td>Properly fitted mask</td>
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<tr>
<td>Body weight &lt;135 kg</td>
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<tr>
<td>No need for endotracheal intubation*</td>
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*For management of secretions or protection of the airways.

disease (FEV₁) or by the ABG values (P₂CO₂, pH) obtained before initiating ventilation. An improvement in P₂CO₂ and in pH after the first hour of FMMV accurately identified those patients who could be successfully ventilated by this means and who would require short-term ventilatory support (mean, 26 h of FMMV vs 323 h of MV with ETI). The face mask allowed easy access to ventilatory support and was effective as a delivery system for the mechanical tidal breath. FMMV was well tolerated, principally because it allowed the patient to be in control and to continue to communicate.

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