Interruption positive pressure ventilation via the mouth as an alternative to tracheostomy for 257 ventilator users.

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Intermittent Positive Pressure Ventilation via the Mouth as an Alternative to Tracheostomy for 257 Ventilator Users*


Despite wider application of the use of nocturnal intermittent positive pressure ventilation (IPPV) via nasal access for the management of nocturnal hypoventilation, there continues to be a lack of familiarity with the use of IPPV via the mouth for ventilatory support. Unlike nasal IPPV, which is generally practical only for nocturnal use, up to 24-h mouth IPPV was the key method of noninvasive ventilatory support that permitted the avoidance or elimination of tracheostomy for 257 individuals with acute or chronic ventilatory failure. Mouth IPPV was delivered via commercially available mouthpieces for daytime aid and mouthpiece with lip seal or custom orthodontic interfaces for nocturnal support. The use of mouth IPPV alone or in a regimen with other noninvasive ventilatory aids was reviewed for these 257 individuals. Mouth IPPV was used for nocturnal aid by 163 individuals, 61 of whom had little or no measurable vital capacity or significant ventilator-free breathing time, for more than 1,560 patient-years with few complications. It was also the predominant method of daytime ventilatory support for 228 individuals for more than 2,350 patient-years. We conclude that for individuals with adequate bulbar muscle function but chronic respiratory muscle insufficiency, mouth IPPV can be an effective alternative to tracheostomy. It can significantly prolong survival while optimizing convenience, safety, and communication.

Respiratory support can be provided by invasive means, including intermittent positive pressure ventilation (IPPV) via endotracheal or tracheostomy tube and electrophrenic pacing for some individuals. It can also be provided up to 24 h/d by strictly noninvasive means.† Although since 1987 nasal IPPV has become a popular noninvasive technique for the nocturnal ventilatory assistance of patients with chronic alveolar hypoventilation,4,8,9,14 when more than nocturnal ventilatory aid becomes necessary, tracheostomy is almost invariably recommended. Elective tracheostomy is usually refused by the patient, however, until acute life-threatening pulmonary complications lead to intubation. If the patient survives and ventilator weaning is unsafe or impossible, the patient then most often acquiesces to undergoing a tracheostomy.

There are numerous potential acute and long-term life-threatening complications that can result from the presence of an indwelling tracheostomy.15-27 Indeed, the majority of deaths in tracheostomized ventilator users appear to result from pulmonary complications or other complications that are directly or indirectly associated with the presence of an indwelling tracheostomy.15,28 Natural airway defense mechanisms are incapacitated. Bronchial mucous plugging, infection, and granuloma formation result from chronic bacterial colonization. Swallowing mechanisms are impaired,17 and tracheal suctioning is often ineffective, particularly for clearing the left main-stem bronchus.29 The inability to create sufficient abdominal pressure or use manual assistance techniques to generate an adequate cough during tracheostomy IPPV can increase the risk of pulmonary complications. Further, patients receiving long-term tracheostomy IPPV, particularly with inflated cuffs, often demand high ventilator volumes. This results in chronic hypocapnia that may lead to increased bone resorption.30

Electrophrenic respiration is occasionally indicated for treating ventilatory failure due to central nervous system lesions above the level of the anterior horn cell. It has an initial cost of approximately $300,000 in the United States. It is most often not fully successful and is associated with a variety of difficulties.28 Since the tracheostomy site can rarely be closed in these individuals because of pacer-induced airway collapse during sleep, the patient is subject to the hazards and complications of both the electrophrenic pacemaker and the tracheostomy.

Noninvasive means of ventilatory support include the use of body ventilators such as the iron lung, Porta-lung (Lifecare, Lafayette, Colo), cuirass, "wrap" ventilators, rocking bed, and intermittent abdominal pressure ventilator (IAPV). These methods have been well described in the literature.31-34 Among the negative...
pressure body ventilators, only the cuirass can occasionally be used for ventilatory assistance in the sitting position. For the seated individual, however, mouth IPPV is more practical and effective, and the IAPV is often the patient-preferred method for those with less than 1 h of ventilator-free time. When used during sleep, the rocking bed and negative pressure body ventilators subject some patients to potentially significant oxyhemoglobin desaturation due to airway collapse. The nocturnal blood gas alterations and disturbed sleep can cause chronic fatigue, impaired concentration, and general psychosocial dysfunction. Although body ventilators have been used as alternatives to tracheostomy for up to 24-h support in many centers since the 1930s, they are bulky, impractical for travel and for sleeping with a significant other and tend, therefore, to restrict ventilator user lifestyles.

Twenty-four-hour body ventilator support can be adequate for many individuals, particularly those who have mastered the use of glissopharyngeal breathing. However, the lack of familiarity that most clinicians have with mouth IPPV and noninvasive manual and mechanical methods of airway secretion clearance render the sole use of body ventilators unnecessarily hazardous, particularly during respiratory tract infections (RTIs). This can result in patients being hospitalized and reluctantly and unnecessarily intubated and tracheostomized.

IPPV can be delivered noninvasively via oral or oral-nasal patient-ventilator hose interfaces. Although the latter two methods are desirable only for nocturnal aid, there are occasional patients whose neck or oral muscles are too weak to grab or hold a mouthpiece between the lips and teeth without air leakage out of the mouth during IPPV, and who use nasal IPPV up to 24 h/d. In one center,

### Table 1—Ventilator-Assisted Individuals Using Daytime Mouth IPPV

<table>
<thead>
<tr>
<th>Patients</th>
<th>Diagnosis*</th>
<th>Age, yr†</th>
</tr>
</thead>
<tbody>
<tr>
<td>101 Polio</td>
<td>20.7 ± 16.2</td>
<td></td>
</tr>
<tr>
<td>43 DMD</td>
<td>18.4 ± 4.1</td>
<td></td>
</tr>
<tr>
<td>31 SCI</td>
<td>30.9 ± 17.8</td>
<td></td>
</tr>
<tr>
<td>27 Myopa</td>
<td>32.7 ± 11.1</td>
<td></td>
</tr>
<tr>
<td>5 ALS</td>
<td>61.2 ± 8.1</td>
<td></td>
</tr>
<tr>
<td>4 SMA</td>
<td>29.7 ± 9.1</td>
<td></td>
</tr>
<tr>
<td>4 MS</td>
<td>41.7 ± 20.1</td>
<td></td>
</tr>
<tr>
<td>3 Polymyos</td>
<td>39.3 ± 2.9</td>
<td></td>
</tr>
<tr>
<td>3 OHS</td>
<td>40.0 ± 27.9</td>
<td></td>
</tr>
<tr>
<td>3 Myelo</td>
<td>31.0 ± 14.1</td>
<td></td>
</tr>
<tr>
<td>2 Resect</td>
<td>41.3 ± 7.8</td>
<td></td>
</tr>
<tr>
<td>1 Scol</td>
<td>56.6</td>
<td></td>
</tr>
<tr>
<td>1 COPD</td>
<td>56.1</td>
<td></td>
</tr>
</tbody>
</table>

*Male subjects with Duchenne muscular dystrophy who were wheelchair-dependent before 13 years of age, ventilator-assisted on or before 25 years of age, and who satisfied other diagnostic criteria; SCI = traumatic high-level quadriplegic individuals; myopa = patients with non-Duchenne myopathies or muscular dystrophies who were wheelchair-dependent after 12 years of age, ventilator-dependent after age 25 years, or female; ALS = amyotrophic lateral sclerosis; SMA = spinal muscular atrophy; MS = multiple sclerosis; polymyos = polymyositis; OHS = obesity-hypoventilation syndrome; myelo = myelopathy, including one individual with syringomyelia; resect patients with predominantly restrictive conditions with a combination of intrinsic lung disease and lung resections associated with tuberculosis and Milroy's disease, respectively; scol = kyphoscoliosis; and COPD = chronic obstructive pulmonary disease and ventilatory insufficiency.

†Age in years at onset of permanent ventilatory support.

### Table 2—Mouth IPPV for at Least Nocturnal Ventilatory Support

<table>
<thead>
<tr>
<th>Diagnosis*</th>
<th>Patients</th>
<th>Onset†</th>
<th>VC, ml (%pred)</th>
<th>Duration, yr (Range)</th>
<th>Use‡ &gt;10 yr</th>
<th>&lt;1 hr</th>
<th>&lt;10 min</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polio</td>
<td>69</td>
<td>37.1 ± 14.8</td>
<td>568 (14.6)</td>
<td>13.4 (1 wk-33 yr)</td>
<td>40</td>
<td>47</td>
<td>37</td>
</tr>
<tr>
<td>DMD</td>
<td>38</td>
<td>19.3 ± 5.4</td>
<td>305 (7.5)</td>
<td>6.0 (1 mo-23 yr)</td>
<td>6</td>
<td>29</td>
<td>24</td>
</tr>
<tr>
<td>Myopa</td>
<td>23</td>
<td>31.7 ± 11.4</td>
<td>369 (8.1)</td>
<td>9.1 (6 mo-19 yr)</td>
<td>8</td>
<td>16</td>
<td>12</td>
</tr>
<tr>
<td>SCI</td>
<td>19</td>
<td>34.5 ± 17.4</td>
<td>779 (17.9)</td>
<td>4.8 (1 wk-19 yr)</td>
<td>4</td>
<td>13</td>
<td>9</td>
</tr>
<tr>
<td>Polymyos</td>
<td>3</td>
<td>40.0 ± 4.0</td>
<td>318 (8.0)</td>
<td>4.0 (2-8 yr)</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>OHS</td>
<td>3</td>
<td>53.3 ± 9.9</td>
<td>876 (20.3)</td>
<td>0.7 (1 wk-1.9 yr)</td>
<td>0</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Myelo</td>
<td>2</td>
<td>31.0 ± 14.1</td>
<td>675 (22.0)</td>
<td>11.0 (7-15 yr)</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>SMA</td>
<td>2</td>
<td>14.0 ± 5.5</td>
<td>260 (9.0)</td>
<td>13.5 (10.5-17 yr)</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>ALS</td>
<td>1</td>
<td>67.0</td>
<td>0 (0)</td>
<td>3.0 (3)</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Scol</td>
<td>1</td>
<td>56.0</td>
<td>848 (27.0)</td>
<td>8 (8)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>TB</td>
<td>1</td>
<td>31.0</td>
<td>960 (30.0)</td>
<td>20 (20)</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>MS</td>
<td>1</td>
<td>51.0</td>
<td>330 (8.0)</td>
<td>0.5 (0.5)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Tot</td>
<td>163</td>
<td>32.1 ± 14.8</td>
<td>519 (13.5)</td>
<td>9.6 (1 wk-33 yr)</td>
<td>61</td>
<td>108</td>
<td>86</td>
</tr>
</tbody>
</table>

*See Table 1 for abbreviations. TB = tuberculosis with resection.
†Age in years at onset of nocturnal mouth IPPV.
‡Recent vital capacity, the maximum in four or more attempts, in milliliters and in percentage of predicted normal measured with the patient in a supine position.
§Duration of nocturnal use of mouth IPPV.
||Number of patients who used mouth IPPV overnight for 10 years or more.
||Ventilator-free time measured with the patient in a supine position.

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Mouth IPPV has been used as a principal noninvasive method of daytime ventilatory support since 1957 and for nocturnal support since 1964. Mouth IPPV has also been used as a technique for the ventilator weaning of tracheostomized patients and for their conversion to noninvasive ventilatory support alternatives. This is a study of 257 individuals who have been maintained by us on mouth IPPV alone or in combination with other noninvasive methods for up to 24-h ventilatory support.

**Patients and Methods**

Patients were referred to an acute hospital trauma center, Muscular Dystrophy Association clinic, or a rehabilitation center with a ventilator unit in the New York metropolitan area. Over the last 39 years, of the hundreds of patients who used mouth IPPV during ventilator weaning, 257 unweanable individuals and patients with acute or chronic ventilatory insufficiency with the diagnoses noted in Tables 1 and 2 were successfully placed on and supported by noninvasive means of ventilatory support that included at least nocturnal or daytime mouth IPPV. Both portable volume preset ventilators (from Lifecare Inc., Lafayette, Colo; Puritan-Bennett Inc., Boulder, Colo; and Aequitron Medical Inc., Minneapolis, Minn) used in assist control or control modes, and pressure preset ventilators (including the Thompson Bantam, recently available through Lifecare; and the BiPAP, Respironics Inc., Monroeville, Pa) that better compensate oral or nasal air delivery leakage were used.

The study population does not include the approximately 100 individuals from the same centers who were largely supported by body ventilators and glossopharyngeal breathing and who used mouth IPPV only briefly each day during transfer between body ventilators, for assisted coughing, increasing voice volume, etc. There were also numerous individuals who alternated daytime mouth IPPV with IAPV use and glossopharyngeal breathing depending on the circumstances of their day-to-day living, and many others who resorted to daytime or nocturnal mouth IPPV only during RTIs or periods of excessive fatigue.

The manner in which patients were placed directly onto noninvasive ventilatory assistance or converted from endotracheal or tracheostomy tubes to noninvasive aids, including mouth IPPV, has been described. Spirometry was performed at least yearly and nocturnal end-tidal Pco₂ and/or oxyhemoglobin saturation monitoring were performed to monitor the effectiveness of the noninvasive support. A survey was undertaken of 24-h ventilator users who were converted to tracheostomy IPPV and of patients with access to mechanical exsuffiation to explore the conditions leading to the need for tracheostomy placement.

**Results**

All motivated patients with oropharyngeal muscle strength adequate for swallowing and intelligible speech were successful in using mouth IPPV for ventilatory support. Some individuals, particularly those with lower vital capacity in a supine position than when sitting, initially required only part-time ventilatory assistance, usually during sleep. Of these, 29 continued to require only nocturnal assistance, 11 only daytime assistance, 73 went on to use noninvasive methods of ventilatory support up to 20 h/d, and 144 became ventilator supported around the clock. Of the latter two groups, 178 were either switched from less effective body ventilators to mouth IPPV or used mouth IPPV exclusively up to 24 h/d from onset of ventilatory failure.

Although many patients began using nocturnal mouth IPPV without lip seal fixation of the mouthpiece in the mouth, most patients eventually converted to the more effective lip seal retention systems (Fig 1). These retain the mouthpiece firmly in the mouth during sleep and diminish insufflation leakage out of the mouth. Four patients used custom molded orthodontic acrylic mouth pieces without lip seals (Fig 2) for more comfortable and firm retention without the use of straps. Custom acrylic mouthpiece-lip seals (Fig 3) firmly retain the mouthpiece, seal the lips, and can seal the nose during sleep. These were used by eight individuals. Five of the 163 individuals who used mouth IPPV during sleep plugged their noses with cotton pledgets kept in place with tape or used nose...
clips during sleep. Three of these five eventually converted to the custom acrylic mouthpiece-lip seals. One individual manually pinched her nose to prevent excessive nasal leakage during sleep.

The number of patients who had tracheostomy tubes removed in favor of noninvasive ventilatory support, including mouth IPPV, and those who underwent tracheostomies after using noninvasive ventilatory support are listed in Table 3. The most recent vital capacities, most recent maximum tolerated ventilator-free time, and the duration of use of mouth IPPV are reported in Tables 2, 4, and 5. Thus, 257 ventilator users used noninvasive methods, including mouth IPPV, for a mean of 13.2 ± 12.2 years. Of the 163 who used at least nocturnal mouth IPPV, 111 have

### Table 3—Ventilator Users Switched From and to Tracheostomy Ventilation

<table>
<thead>
<tr>
<th>Diagnosis*</th>
<th>Patients Whose Tracheostomy Tubes Were Removed</th>
<th>Patients Whose Tracheostomy Tubes Were Placed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>No.</td>
</tr>
<tr>
<td>Polio</td>
<td>32†</td>
<td>11</td>
</tr>
<tr>
<td>SCI</td>
<td>24†</td>
<td>7</td>
</tr>
<tr>
<td>Myopa</td>
<td>6§</td>
<td>11</td>
</tr>
<tr>
<td>Intrinsic</td>
<td>2‡</td>
<td>0</td>
</tr>
<tr>
<td>DMD</td>
<td>1‡†</td>
<td>12</td>
</tr>
<tr>
<td>Polym</td>
<td>1**‡†</td>
<td>2</td>
</tr>
<tr>
<td>Scol</td>
<td>1‡†</td>
<td>0</td>
</tr>
<tr>
<td>ALS</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>MS</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Myelo</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>SMA</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>67</td>
<td>52</td>
</tr>
</tbody>
</table>

*See Tables 1 and 2 for abbreviations.
†Poliomyelitis, including two patients who had tracheostomies three and four times, respectively, and decannulation each time to return to noninvasive ventilatory support.
‡Traumatic spinal cord injury, including one patient who had tracheostomy three times and decannulation each time to return to noninvasive ventilatory support.
§Non-Duchenne myopathies.
‖Intrinsic lung disease, including one patient each with chronic obstructive pulmonary disease, and Milroy’s disease, the latter having undergone a pneumonectomy.
*Duchenne muscular dystrophy, including one patient who had decannulated twice to return to noninvasive ventilatory support.
**Polymyositis.
††Kyphoscoliosis; this patient had decannulation three times to return to noninvasive ventilatory support.

### Table 4—Patients Requiring 10 to 20 h/d of Ventilatory Support and Using Mouth IPPV for at Least Daytime Support

<table>
<thead>
<tr>
<th>Diagnosis*</th>
<th>Patients</th>
<th>VC,† ml (%pred)</th>
<th>Duration,‡ yr (Range)</th>
<th>Use,§ &gt;10 yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polio</td>
<td>38</td>
<td>940 (23.8)</td>
<td>9.0 (0.5-32 yr)</td>
<td>15</td>
</tr>
<tr>
<td>DMD</td>
<td>11</td>
<td>433 (10.5)</td>
<td>4.5 (2-12 yr)</td>
<td>1</td>
</tr>
<tr>
<td>Myopa</td>
<td>7</td>
<td>882 (26.7)</td>
<td>6.0 (3.0-11 yr)</td>
<td>1</td>
</tr>
<tr>
<td>SCI</td>
<td>7</td>
<td>671 (15.7)</td>
<td>8.8 (3 wk-32 yr)</td>
<td>2</td>
</tr>
<tr>
<td>OHS</td>
<td>1</td>
<td>1,210 (37.0)</td>
<td>1 wk (1 wk)</td>
<td>0</td>
</tr>
<tr>
<td>Myelo</td>
<td>2</td>
<td>850 (27.0)</td>
<td>3.8 (0.5-7 yr)</td>
<td>0</td>
</tr>
<tr>
<td>SMA</td>
<td>1</td>
<td>960 (56.0)</td>
<td>5.0 (5)</td>
<td>0</td>
</tr>
<tr>
<td>ALS</td>
<td>4</td>
<td>758 (18.0)</td>
<td>1.9 (0.2-3.8 yr)</td>
<td>0</td>
</tr>
<tr>
<td>TB</td>
<td>1</td>
<td>1,020 (30.0)</td>
<td>22.0 (22)</td>
<td>1</td>
</tr>
<tr>
<td>MS</td>
<td>1</td>
<td>880 (20.0)</td>
<td>2.4 (2.4)</td>
<td>0</td>
</tr>
<tr>
<td>Tot</td>
<td>73</td>
<td>870 (22.9)</td>
<td>7.1 (1 wk-32 yr)</td>
<td>20</td>
</tr>
</tbody>
</table>

*See Tables 1 and 2 for abbreviations.
†Recent vital capacity (the maximum in four or more attempts) measured with the patient in a sitting position.
‡Duration of mouth IPPV use for 2 to 20 h/d for patients requiring up to 20 h/d of total ventilatory support (all patients who used less than 10 h/d of mouth IPPV used nocturnal body ventilator support).
§Number of patients who used daytime mouth IPPV for total support less than 20 h/d for 10 years or more.
continued to do so for a mean of 15.8 ± 13.5 years. Fifty-two mouth IPPV users were converted to tracheostomy IPPV after a mean of 6.5 ± 9.0 years of using mouth IPPV and 16 patients were unavailable for follow-up after 10.6 ± 6.9 years of mouth IPPV. Fifty-eight of the 163 patients died after noninvasive aid for 14.8 ± 10.8 years. Of the 52 patients who ultimately underwent definitive tracheostomy, 27 died after a mean of 3.7 ± 3.4 years using tracheostomy IPPV, 10 were unavailable for follow-up after 3.1 ± 2.6 years, and 15 have continued to use tracheostomy IPPV for 4.9 ± 4.4 years.

The reason for hospitalization, intubation, and tracheostomy for the 52 patients who were converted to tracheostomy IPPV was most frequently acute respiratory encumberment from an intercurrent RTI and difficulty managing airway secretions, although in several cases a tracheostomy was placed to facilitate an elective surgical procedure. None of the patients who underwent tracheostomy had had access to mechanical exsufflators in their homes since the 1950s and 60s.

In a survey of 24-h/d ventilator users with access to mechanical exsufflation, of the six who have had exsufflators in their homes since the 1950s and 60s others with quick access to these devices as needed over the last 1 to 40 years, none have undergone permanent tracheostomy, and several have successfully returned to noninvasive aids following intubation for surgical procedures.

The reasons for the 58 deaths of individuals using noninvasive ventilatory aid and the 27 deaths of individuals supported by tracheostomy IPPV are listed in Table 6. Fourteen of 27 tracheostomized ventilator users died of complications associated with the use of tracheostomy IPPV, and an association with tracheostomy IPPV was possible for 24 of the 27 patient deaths. For individuals using mouth IPPV, 11 of 58 died of respiratory complications or complications associated with mechanical ventilation, and such complications may have played a role in 38 of the 58 deaths. Accidental tracheostomy tube disconnection and complications incurred during surgical placement of the tracheostomy caused two deaths. Six individuals who used mouth IPPV only during daytime hours and who used less effective body ventilators during sleep (the rocking bed or chest shell ventilator) were warned to switch to 24-h mouth IPPV but refused and died overnight. For three other deceased patients, the lip seals and mouthpieces were found on the floor in the morning. Four other individuals who used mouth IPPV without a lip seal despite being urged to do so also died during sleep. These latter seven deaths were considered to be possibly related to the use of mechanical ventilation, although these patients appeared to not be using mouth IPPV in the prescribed manner. Four individuals using mouth IPPV died as a result of motor vehicle accidents and two others died following emergency surgery and general anesthesia for unrelated conditions. Deaths following general anesthesia in noninvasive aid users have also been reported elsewhere.

Nocturnal oximetry studies were obtained and reviewed for 75 nocturnal mouth IPPV users who required 24-h noninvasive ventilatory support with insignificant ventilator-free time. Seventy-six percent of the nocturnal oximetry studies yielded mean oxyhemoglobin saturations of 95 percent or greater. The lowest mean nocturnal oxyhemoglobin saturation for anyone using mouth IPPV was 92 percent. Interestingly, ventilator-assisted individuals who ex-
Deaths from clearly nonrespiratory-related causes.

Sudden, unexplained deaths, deaths attributed to cardiac disease without autopsy confirmation, and any deaths from unknown cause without evidence of fatal lung disease or mucous plugs at autopsy are considered possibly associated deaths.

*See Tables 1 and 2 for abbreviations.

Deaths associated with lung disease, an indwelling tracheostomy tube, and ventilator or equipment failure are considered deaths associated with mechanical ventilation.

Deaths due to pneumonia, chronic pulmonary disease, and patients with a history of chronic respiratory failure experiencing assisted ventilation for at least 1 month via an indwelling tracheostomy and via noninvasive methods of support, including mouth IPPV, almost invariably preferred the latter. For the group of postpolio-myelitis ventilator-assisted individuals, 32 had tracheostomies placed for management of acute medical or surgical conditions. Eleven retained the tracheostomy for continued ventilatory assistance. Five of these 11 died within 4 years of tracheostomy placement from pulmonary disease associated with mucous plugging and/or substance abuse in four cases and cor pulmonale in the other case. The other 24 individuals receiving mechanical ventilation had the tracheostomy sites closed and returned to 24-h noninvasive ventilatory support once the acute conditions had been resolved. Two patients underwent tracheostomy three times, but each time reverted back to noninvasive support. Of these 24 patients who have been receiving ventilator assistance for 25.5 ± 13.7 years, only one has died thus far. Her death was associated with substance abuse.

Besides losing the mouthpiece, other complications of mouth IPPV included aerophagia, orthodontic deformity for patients not using a custom orthodontic bite plate, and rarely, allergy to the plastic or strap materials of the mouthpiece or lip seal. Aerophagia tended to cause concern during the initial training period and occasionally be a persistent problem. We have not had to discontinue the use of mouth IPPV except for the uncommon individual who had symptomatic aerophagia even prior to using ventilatory support. Orthodontic deformity was a cosmetic but is not a functional problem. Allergy and mouthpiece or mask discomfort could be readily circumvented by substituting any of a variety of mouth or nose pieces and or using alternative fabrication materials such as rubber.

**Discussion**

The use of noninvasive IPPV methods, and in particular mouth IPPV, is not widely understood. Hill suggested that "timely intervention with body ventilators may stabilize" postpolio patients, but the stabilization is temporary, and when patients require more than nocturnal aid, the risk of acute pulmonary complications will continuously increase and intubation and tracheostomy will eventually become necessary. Our results suggest, however, that when bulbar musculature is adequate, alveolar ventilation can be maintained within normal limits by the use of up to 24-h noninvasive IPPV as necessary. When patients have access to effective noninvasive means of airway secretion clearance, tracheostomy is most often neither necessary nor desired by the patient. Hill also noted that "some patients discontinue using (mouth or nasal IPPV) because of intolerable facial or lip discomfort or difficulty swallowing secretions." This view continues to be expressed, despite the wide variety of comfortable and efficient custom molded mouth and nose pieces available today for the delivery of IPPV.

Following a nocturnal study of only three individuals using mouth IPPV and others using body ventilators and nasal IPPV, Ellis et al suggested that mouth IPPV may be more effective than cuirass ventilation but it is less effective than nasal IPPV. Hill also noted that noninvasive ventilatory assistance "is generally less effective than IPPV through a tracheostomy and should be reserved for patients with relatively stable chronic respiratory failure . . ." and patients "should be able to breathe spontaneously for at least several consecutive hours if body ventilators are to be considered." However, we and others have successfully used noninvasive IPPV methods, especially mouth IPPV, for the management of acute respiratory failure. We have also observed the maintenance of normal end-tidal PCO2 and generally normal oxyhemoglobin saturation for patients with no measurable vital capacity. Many of these patients have had no dips in saturation below 95 percent using nocturnal lip seal.
mouth IPPV with or without a nasal seal. The mean nocturnal oxyhemoglobin saturations we observed for 75 24-h ventilator users using nocturnal mouth IPPV were greater than those reported for comparable patient populations using nocturnal nasal IPPV and very significantly greater than those using body ventilators. We, and others, have found that these noninvasive positive pressure techniques, including mouth IPPV, are met "with a high degree of acceptance," particularly when the patient understands that the alternative is intubation or a tracheostomy.

Airway secretion management, particularly during RTIs, is the most frequent reason that patients with chronic alveolar hypoventilation are hospitalized and intubated. This is particularly true for patients receiving no or only part-time ventilatory aid. Individuals receiving ventilation either intubated or with indwelling tracheostomies, however, have increased risk of nosocomial morbidity and mortality. This study implies that individuals using noninvasive methods of ventilatory support may also experience increased risk of nosocomial morbidity and mortality, particularly when associated with general anesthesia and surgery. We have noted this to be true especially when such procedures are undertaken without the intimate participation of clinicians proficient in using noninvasive respiratory muscle aids. Lack of clinician familiarity with and confidence in using noninvasive techniques leads to patients remaining intubated for unnecessarily long postoperative periods.

There was little history of smoking and, except for three patients, no significant obstructive or intrinsic pulmonary disease in the study population. By avoiding tracheostomy with the use of noninvasive aids, natural airway secretion clearance mechanisms remained intact. This made airway secretion management a problem only during intercurrent RTIs or following intubation for surgery. Along with the use of mechanical exsufflation, the effective use of manually assisted coughing techniques can be important for avoiding pulmonary complications. For individuals with less than 1 L of vital capacity, the use of manually assisted coughing should be preceded by a glosopharyngeal breathing-assisted deep breath or an assisted deep insufflation with the use of a manual resuscitator, positive pressure blower (Zephyr, Lifecare Inc, Lafayette, Colo), portable ventilator, or intermittently positive pressure breathing machine, to maximize peak cough expiratory flows. Since manually assisted coughing techniques cannot be used efficiently during tracheostomy IPPV and are difficult to employ effectively even in the presence of a plugged tracheostomy tube, the techniques have been largely forgotten and widely underutilized. The minimum of 5 to 6 L/s of peak cough expiratory flow necessary for airway secretion clearance, however, can usually readily be provided for patients with neuromuscular ventilatory failure by using these techniques. In the presence of severe scoliosis or during severe RTIs, manually assisted coughing is often inadequate and mechanical exsufflation becomes vital.

The manufacture of mechanical exsufflators ceased in the early 1960s, and exsufflators have only recently become available (J. H. Emerson Co, Cambridge, Mass). Access to these devices has been restricted, therefore, to the relatively few individuals who have owned and maintained them over the years and to patient care networks in which the devices are shared and made available to patients in time of need. During use, the success of mechanical exsufflation can be observed objectively by the appearance of mucus in the patient's mouth or the exsufflator mask, the increase in oxyhemoglobin saturation during and immediately following use by auscultation, and the increase in pulmonary volumes observed with the clearance of mucous plugs. In addition, 6 to 11 L/s of peak expiratory flow can be conveniently and reliably generated during mechanical exsufflation. Clinical and physiological studies demonstrated the safety and efficacy of this technique in the 1950s and we have come to rely on it to permit continuation of noninvasive ventilatory support during RTIs, for achieving earlier extubation of ventilator-assisted patients, and for preventing postoperative pulmonary complications particularly following abdominal surgery.

We are currently surveying the number of hospitalizations and serious pulmonary complications, including atelectasis and pneumonia, in 24-h noninvasive ventilatory support users, including some patients who use body ventilators as part of their daily regimen. Ninety-five such individuals from whom reliable data could be obtained reported 41 hospitalizations for pneumonia or atelectasis and 134 total pulmonary hospitalizations, mostly for management of intercurrent upper RTIs, in 1,376.8 patient-years of 24-h use. This amounted to 0.43 serious pulmonary complications and 1.41 hospitalizations over 14.5 years of 24-h use of noninvasive ventilatory support. These figures, which thus far are significantly better than for patients using nocturnal ventilatory aid only, indicate that irrespective of the extent of ventilatory insufficiency, patients for whom alveolar ventilation is maintained within normal limits 24 h/d and who have access to effective noninvasive airway secretion clearance methods, have very low incidence of serious pulmonary complications. Since none of these patients received supplemental oxygen therapy, these results call into question the all-too-common practice of treating patients with chronic alveolar hypoventilation with oxygen therapy rather than ventilatory assistance.

In conclusion, the use of noninvasive IPPV techniques, and in particular mouth IPPV that can be
effective and practical for both daytime and nocturnal ventilatory support, can indefinitely spare many individuals with ventilatory insufficiency from intubation or tracheostomy for ventilatory support. This can allow many to effectively use glosopharyngeal breathing for ventilator-free time, to provide perfect security in the event of sudden ventilator failure, and to give deep breaths for assisted coughing. Access to reliable and effective manually assisted coughing or mechanical exsufflation is also critical for the long-term success of an entirely noninvasive ventilatory support regimen.

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