Conference Proceedings

History and Epidemiology of Noninvasive Ventilation in the Acute-Care Setting

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Introduction
Evolution of Ventilatory Support in Acute Respiratory Failure
History of Noninvasive Ventilation in the Acute-Care Setting
Epidemiology of Noninvasive Ventilation in the Acute-Care Setting
  Noninvasive Ventilation Outside the Setting of Clinical Trials:
    Efficacy Versus Effectiveness
  Data From Surveys: What Clinicians Say They Do
  Data From Observational Studies of Actual NIV Use
Problems With the Accurate Assessment of Current NIV Use
Summary

Although noninvasive ventilation (NIV) was first used to treat patients with acute respiratory failure in the 1940s, the history of this mainstay of today’s respiratory care armamentarium has mainly been written in the last 20 years. There is now a robust evidence base documenting the efficacy of NIV in exacerbations of chronic obstructive pulmonary disease, cardiogenic pulmonary edema, and acute respiratory failure in immunocompromised patients, and evidence in support of NIV in other settings, such as hypoxic acute respiratory failure and the management of patients who decline endotracheal intubation, is accumulating rapidly. Efficacy as demonstrated in clinical trials does not necessarily translate to clinical effectiveness in practice, however, and important barriers need to be overcome if NIV is to realize for the average patient the potential it has shown in research studies. However, although the expansion of its use in everyday patient care has lagged behind the growth of its evidence base, an increasing number of studies document the steadily expanding use of NIV in the acute-care setting. This article reviews the history of NIV as applied in acutely ill patients and summarizes the studies of NIV outside the research setting during the last decade. Key words: noninvasive ventilation, NIV, epidemiology, history, clinical practice, acute respiratory failure, chronic obstructive pulmonary disease, COPD, acute care. [Respir Care 2009;54(1):40–50. © 2009 Daedalus Enterprises]
Table 1. Noninvasive Ventilation in the Acute Care Setting: Clinical Conditions and Strength of Supporting Evidence

| Evidence from multiple randomized controlled trials and meta-analyses |
| Exacerbation of chronic obstructive pulmonary disease |
| Cardiogenic pulmonary edema |
| Acute respiratory failure in immunocompromised patients |
| Prevention of weaning failure in high-risk patients |
| Not effective in established extubation failure |
| Consistent findings in more than one published clinical trial, case-control series, or cohort study |
| Postoperative respiratory failure |
| Oxygenation prior to endotracheal intubation |
| Support during endoscopy |
| Case series or conflicting findings in other types of studies |
| Acute lung injury and acute respiratory distress syndrome |
| Extubation failure |
| Acute severe asthma |
| Pneumonia |
| Acute respiratory failure in patients who do not wish to be intubated |

(Adapted in part from Reference 10.)

Noninvasive ventilation has been used in numerous other clinical settings.8-11 Table 1 lists the most prominent of these settings for NIV, in relation to the strength of the supporting evidence in each.10 The table refers mainly to the use of NIV in adult patients, although this therapy is also being used with increasing frequency in infants and children.12-14 To the clinical settings listed under the table’s third category (that is, those supported by the least firm evidence at this point) can be added acute neuromuscular disease,15-17 pre-hospital and emergency-department use for patients with acute respiratory distress,18-20 use during the performance of tracheotomy,21 and acute application in palliative care.22-24

The literature on NIV consists primarily of the results of technical assessments and reports of clinical investigations. Much less has been written about the extent and nature of NIV use in everyday patient care. As the first of the series of reviews developed from the conference, “Noninvasive Ventilation in Acute Care: Controversies and Emerging Concepts,” this article first traces the historical development of NIV as an intervention in managing acutely ill patients, and then reviews what is known about the clinical use of this therapy outside the research setting.

Evolution of Ventilatory Support in Acute Respiratory Failure

Noninvasive methods for supporting ventilation have featured prominently throughout the history of respiratory care, which in turn has been determined in large measure by the need to support the failing respiratory system (Table 2). Although supplemental oxygen was used clinically in a few hospitals in the 1920s, the first feasible means for sustaining life in patients who were unable to breathe for themselves came with the introduction of the tank ventilator (iron lung) at the end of that decade.25-28 The emergence of mechanical ventilation in its modern sense was spurred by the devastating polio epidemics of the 1950s, when experience in Denmark,29 and subsequently in the United States and elsewhere, demonstrated that lives could be saved acutely, and apneic patients supported virtually indefinitely with tracheostomy and positive-pressure ventilation.30-32 Thereafter, once mid-20th century medicine evolved from a home-based activity to an institution-focused enterprise taking place primarily in hospitals,33 advances in the understanding of normal and abnormal respiratory physiology combined with new devices and other technology to create the first intensive care units (ICUs), whose emergence was driven in large part by the need to support and monitor ventilation, oxygenation, and airway care.

By the early 1970s virtually every American acute-care hospital had an ICU, and a respiratory therapy department whose members were becoming specialists in invasive mechanical ventilation. Ventilators rapidly became more capable and more sophisticated, with a plethora of new modes and other features, whose use was guided by blood gas analysis and other new ways of physiologic monitoring. Soon, however, awareness of the complications of invasive mechanical ventilation34,35 and artificial airways,36 and subsequently of ventilator-induced lung injury,37,38 led to renewed interest in less aggressive, potentially less injurious ventilatory support.

History of Noninvasive Ventilation in the Acute-Care Setting

The application of intermittent positive inspiratory pressure via an anesthesia mask in the treatment of acute respiratory illness was studied by Motley and colleagues at Bellevue Hospital in the 1940s.39 These clinician-investigators used the apparatus shown in Figure 1 to deliver intermittent positive-pressure ventilation to patients with pneumonia, pulmonary edema, near-drowning, Guillain-Barré syndrome, and acute severe asthma.39 However, this approach to life support in the acute-care setting took a back seat to invasive mechanical ventilation as the latter emerged and was refined during the next 2 decades.

Noninvasive positive-pressure ventilation did not disappear from the scene, however; it found wide use both in acute-care hospitals and for outpatient treatments in the form of intermittent positive-pressure breathing (IPPB).40 So widespread did the use of IPPB become by the early 1970s—administered to 10% or more of all hospitalized patients, with each respiratory therapist typ-
Table 2. Evolution of Ventilatory Support in the Acute-Care Setting, Particularly With Respect to Noninvasive Ventilation

<table>
<thead>
<tr>
<th>Pre-1930s</th>
<th>1930s-1940s</th>
<th>1950s</th>
<th>1960s</th>
<th>1970s</th>
<th>1980s</th>
<th>1990s</th>
<th>2000s</th>
</tr>
</thead>
<tbody>
<tr>
<td>First clinical use of supplemental oxygen in hospitals</td>
<td>Introduction of tank ventilators</td>
<td>Polio epidemics in Europe and United States</td>
<td>Major progress in understanding pulmonary gas exchange</td>
<td>Major progress in understanding lung physiology and pathology</td>
<td>Increasing focus on respiratory muscle function in acute care settings</td>
<td>Increasing reported experience with NPPV in acute-care settings other than COPD</td>
<td>Rich database on efficacy of NPPV: multiple RCTs; meta-analyses; evidence-based clinical practice guidelines</td>
</tr>
<tr>
<td>No practical means for supporting ventilation</td>
<td>Support of apneic patient possible for first time</td>
<td>Introduction of positive-pressure ventilation via tracheostomy</td>
<td>Widespread use of IPPB in United States hospitals for “breathing treatments”</td>
<td>Use of CPAP in neonates</td>
<td>Invasive mechanical ventilation as initial approach in virtually all settings of acute respiratory failure</td>
<td>First randomized controlled trials of NPPV in acute respiratory failure</td>
<td>NPPV as standard of care for COPD exacerbation</td>
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<tr>
<td></td>
<td></td>
<td>Development of special cadre of hospital workers for caring for patients with respiratory problems (inhalation therapists)</td>
<td>Experience with IPPB in acute respiratory insufficiency</td>
<td>Presence of ICUs in virtually all acute-care hospitals</td>
<td>Increasing use of pulse oximetry and other noninvasive respiratory monitoring</td>
<td>Incorporation of $F_{\text{O}_2}$ control and better monitoring into bi-level ventilators for NPPV</td>
<td>Increasing use of NPPV in other settings</td>
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<tr>
<td></td>
<td></td>
<td>Use of supplemental oxygen and IPPB in aviation</td>
<td>Widespread introduction of volume ventilators</td>
<td>More sophisticated and capable ICU ventilators</td>
<td>Increasing computerization of ventilators and other respiratory care equipment</td>
<td>Increasing variety of patient interfaces for NPPV</td>
<td>Increased focus on NPPV and palliative care in the acute-care setting</td>
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<td></td>
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<td></td>
<td>Availability of improved endotracheal tubes</td>
<td>Introduction of intermittent mandatory ventilation and other new ventilation modes</td>
<td>Introduction of nasal CPAP for treating obstructive sleep apnea</td>
<td>RESPIRATORY CARE consensus conference on NPPV in the acute care setting</td>
<td>Increasing focus on knowledge-transfer and addressing the gap between efficacy and effectiveness</td>
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<td></td>
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<td>Use of arterial blood gases in patient assessment</td>
<td>Increasing awareness of complications of invasive mechanical ventilation</td>
<td>Increasing experience with long-term NPPV in settings other than polio</td>
<td>Rapid worldwide dissemination of research findings</td>
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<td></td>
<td>First dedicated ICUs</td>
<td>First use of PEEP to treat hypoxemia in ARDS</td>
<td>First reports of use of NPPV in acute hypercapnic respiratory failure in COPD</td>
<td>Concept of NPPV as bridge to weaning</td>
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<td></td>
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<td></td>
<td>Recognition of ARDS</td>
<td>Use of arterial blood gases in patient assessment</td>
<td>Introduction of pressure support</td>
<td>Ventilator-associated pneumonia and its relationship to intubation</td>
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<td></td>
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<td></td>
<td>First use of PEEP to treat hypoxemia in ARDS</td>
<td>First dedicated ICUs</td>
<td>Introduction of bi-level pressure-targeted ventilators for NPPV</td>
<td>Increased focus on DNAR/DNI and withdrawal of life support</td>
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<tr>
<td></td>
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<td></td>
<td>Major progress in understanding lung physiology and pathology</td>
<td>Invasive mechanical ventilation as initial approach in virtually all settings of acute respiratory failure</td>
<td>Increasing focus on ventilator-induced lung injury and concept of lung-protective ventilation</td>
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<td></td>
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<td></td>
<td>Use of CPAP in neonates</td>
<td>Widespread use of pulse oximetry and other noninvasive respiratory monitoring</td>
<td>Increasing focus on ventilator-induced lung injury and concept of lung-protective ventilation</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Presence of ICUs in virtually all acute-care hospitals</td>
<td>Increasing computerization of ventilators and other respiratory care equipment</td>
<td>Concept of NPPV as bridge to weaning</td>
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<td></td>
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<td></td>
<td></td>
<td>More sophisticated and capable ICU ventilators</td>
<td>Introduction of nasal CPAP for treating obstructive sleep apnea</td>
<td>Ventilator-associated pneumonia and its relationship to intubation</td>
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<tr>
<td></td>
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<td></td>
<td>Introduction of intermittent mandatory ventilation and other new ventilation modes</td>
<td>Availability of improved endotracheal tubes</td>
<td>Increased focus on DNAR/DNI and withdrawal of life support</td>
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<td></td>
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<td></td>
<td>Use of arterial blood gases in patient assessment</td>
<td>Use of arterial blood gases in patient assessment</td>
<td>Increasing focus on knowledge-transfer and addressing the gap between efficacy and effectiveness</td>
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</tbody>
</table>

IPPB = intermittent positive-pressure breathing; ICU = intensive care unit; ARDS = acute respiratory distress syndrome; PEEP = positive end-expiratory pressure; CPAP = continuous positive airway pressure; NPPV = noninvasive positive-pressure ventilation; COPD = chronic obstructive pulmonary disease; $F_{\text{O}_2}$ = fraction of inspired oxygen; DNAR = do not attempt resuscitation; DNI = do not intubate; RCT = randomized controlled trial
ically giving 150–200 “treatments” per month, at an annual cost to the United States health-care system of more than $400 million—that the National Institutes of Health and the American Thoracic Society convened a special conference (the “Sugarloaf Conference”) to review the issue. In large part because of the dearth of scientific evidence to support IPPB at that conference, its use subsequently decreased.

Although it was first tried as early as the 1950s, and was subsequently used in a few centers of special expertise, long-term support of ventilation via NIV only became widespread starting in the 1980s. Continuous positive airway pressure (CPAP), delivered via nasal mask to patients with obstructive sleep apnea, had been introduced by Sullivan et al in 1981. In 1987 Sullivan’s group reported the successful use of NIV via nasal mask in 3 patients with post-infection muscle weakness and 2 with muscular dystrophy. Several other reports quickly followed and demonstrated that NIV could be effective in various long-term settings and diagnoses.

Stimulated by the successful application of nasal CPAP in sleep apnea, the availability of improved patient interfaces, an increasing desire to avoid the complications of invasive mechanical ventilation, and the refusal of some patients to be intubated, there followed a renewed interest in NIV for managing ARF. In 1989, Meduri and colleagues reported the successful application of NIV via full-face mask in 10 patients, and the avoidance of intubation in 8 of them (4 of 6 with COPD, 2 of 2 with congestive heart failure, and 2 of 2 with pneumonia). A number of other studies confirmed the efficacy of NIV in COPD exacerbations, using both nasal and full-face masks.

The increased use of NIV in the ICU and in other acute-care settings was facilitated by the introduction of improved bi-level ventilators that have effective compensation for air leaks, such as the Respironics BIPAP ST/D, which replaced an earlier home-care model in the early 1990s (personal communication, Derek Glinsman RRT FAARC, Respironics, June 10, 2008). In a 1995 review, Sassoon summarized the subsequent rapid increase in reported experience with NIV in various forms of ARF (Fig. 2). The years since 1995 have brought an avalanche of clinical investigations and other publications on the use of NIV in ARF.

As noted in a previous review of the history of NIV, this form of ventilatory support has been called different things by different researchers, clinicians, and manufacturers, which led to confusion on the part of clinicians and investigators alike. To some extent this diversity of terminology persists. However, as familiarity with NIV has increased, the resulting confusion may now be less. The term noninvasive positive-pressure ventilation (abbreviated NPPV or NIPPV) was formerly used to distinguish it from noninvasive negative-pressure ventilation, although considering the rarity of the latter today, the simpler term NIV is more convenient. Because a number of bi-level ventilators are now available for NIV (and also because of its use by one European manufacturer of ICU ventilators for one of its modes), colloquial use of the term BIPAP (a proprietary product name) as a generic term for NIV should be discouraged.
Epidemiology of Noninvasive Ventilation in the Acute-Care Setting

Noninvasive Ventilation Outside the Setting of Clinical Trials: Efficacy Versus Effectiveness

As indicated in Table 1, evidence supporting the use of NIV, particularly in some settings, is now plentiful and compelling. However, such evidence has been gained primarily in the context of clinical research rather than from everyday clinical practice. Both anecdotal observation of NIV use and a large body of literature on other health-care interventions suggest that both utilization and outcomes may be very different in these 2 settings. A main reason is the distinction between efficacy, which is what is demonstrated under the structured conditions of a clinical study, and clinical effectiveness, which is what happens in ordinary, everyday practice (Table 3).

Regardless of the evidence supporting it in the research setting, for any new procedure or treatment approach to be successfully implemented in an institution, a number of conditions must be met and important barriers overcome. This has been amply demonstrated with weaning protocols,61,62 other aspects of ventilator management,63 and other respiratory care64 and acute-care interventions.65,66

As emphasized by several of the other presentations at this Journal Conference, NIV is as much an art as a science, with a substantial learning curve and important prerequisites for successful implementation at a particular hospital.

Evidence for the current use of NIV outside the setting of clinical research comes from 2 kinds of studies: surveys, in which institutions or individual practitioners who care for patients who are potential candidates for NIV are queried about their use of it; and observational studies that document actual utilization in specific clinical settings. Published evidence available at the time of writing for each of these contexts is summarized below.

Data From Surveys: What Clinicians Say They Do

Seven studies have characterized the use of NIV in the acute-care setting, as determined by survey data.23,67-72 Table 4 summarizes those studies’ participants, clinical contexts, patient populations, and main findings, in the order in which they were carried out, in the decade between 1997 and 2006. Three of these surveys69,70,72 sought information on all NIV use in acute-care settings, whereas 3 others67,68,71 dealt only with the management of COPD exacerbations, and one23 was restricted to do-not-intubate patients. Five67-71 sought information on institutional availability and use of NIV, two70,72 queried individual physicians about their personal practices and attitudes, and one23 included both physicians and respiratory therapists. One of the studies72 surveyed individual physician attitudes and experience rather than the practice of the institutions with which they were affiliated, whereas another study68 dealt only with the use of NIV in the emergency department.

Figure 4, from the study by Devlin et al,72 shows the frequency of NIV use in different types of ARF, as reported by 623 North American and European critical-care physicians. The respondents indicated that they used NIV most frequently in patients with obesity hypoventilation syndrome, COPD exacerbations, and cardiogenic pulmo-

Table 3. Important Distinctions Between Efficacy (as Demonstrated in Clinical Trials) and Clinical Effectiveness (as Experienced in Everyday Practice)

<table>
<thead>
<tr>
<th>Efficacy</th>
<th>Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results under research conditions</td>
<td>Results obtained in real-world, everyday clinical practice</td>
</tr>
<tr>
<td>Patients carefully selected</td>
<td>Unselected patients</td>
</tr>
<tr>
<td>No comorbidities or other interfering problems</td>
<td>Many patients have other medical conditions and other problems that complicate management</td>
</tr>
<tr>
<td>Rigidly controlled protocol for management and monitoring</td>
<td>Techniques and protocol may or may not match what was done in the clinical trial</td>
</tr>
<tr>
<td>Overseen by investigators and dedicated research staff</td>
<td>No special oversight of the intervention</td>
</tr>
<tr>
<td>Study</td>
<td>When Performed</td>
</tr>
<tr>
<td>---------------</td>
<td>----------------</td>
</tr>
<tr>
<td>Doherty</td>
<td>1997</td>
</tr>
<tr>
<td>Vanpee</td>
<td>2001</td>
</tr>
<tr>
<td>Maheshwari</td>
<td>2002-2003</td>
</tr>
<tr>
<td>Burns</td>
<td>2003</td>
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<tr>
<td>Sinuff</td>
<td>2003-2005</td>
</tr>
<tr>
<td>Drummond</td>
<td>2004</td>
</tr>
<tr>
<td>Devlin</td>
<td>2006</td>
</tr>
</tbody>
</table>

COPD = chronic obstructive pulmonary disease  
NIV = noninvasive ventilation  
ED = emergency department  
DNI = do not intubate  
CMO = comfort measures only  
RT = respiratory therapist  
ACCP = American College of Chest Physicians  
ERS = European Respiratory Society  
ARF = acute respiratory failure
nary edema, and least often in failed extubation and patients who do not wish to be intubated.

As valuable as surveys can be for indicating awareness, access, and attitudes about NIV in the different contexts in which it is carried out, a number of shortcomings of such studies should be mentioned.73 The reported results are taken only from the surveys that were returned (which in the studies summarized in Table 4 ranged from 100% down to 27% of those sought), and may not reflect what the non-responders know, think, or do. Because they report data from individual practitioners and institutions, such surveys may or may not be relevant to other clinicians, in different practice contexts, for different types or sizes of institutions, or in other geographic or cultural areas. And, importantly, these studies can only tell us what the institutions and individuals surveyed say they do, not what they actually do. Reported and actual policies and practices may be quite different, as has been documented for ventilator charting and other respiratory care practices.74

Data From Observational Studies of Actual NIV Use

Observational cohort studies of the use of NIV in the acute-care setting get around at least some of the problems inherent to surveys. They document actual practice in the institutions in which they are performed, at least at the time of the study, for the patients included in the cohort, and in the clinical setting evaluated. Seven such studies have been published as full peer-reviewed articles,75-81 and an eighth was recently reported in abstract form82 (Table 5).

The reported studies differ considerably in design and sample size. Three75,78,79 report single-center cohorts, whereas the rest are multicenter studies, including data from 42 ICUs76 to as many as 361 separate ICUs.77 Two of them80,81 are follow-up studies in which current (or at least more recent) NIV use is compared to the results of previous cohorts76,77 from the same groups of investigators. In 7 of the 8 studies summarized in Table 5 the authors included all acute-care use of NIV in adult patients, and reported usage rates and outcomes among patients with COPD, congestive heart failure, and hypoxemic ARF.

In a study aimed at detecting temporal trends in ICU-related pneumonia and other hospital-acquired infections, Girou and associates75 tracked NIV use in the management of COPD exacerbations and cardiac pulmonary edema in their 26-bed medical ICU from 1994 through 2001. As
Table 5. Reported Results of Observational Studies of the Use of Noninvasive Ventilation in Acute Care Outside the Setting of Clinical Trials

<table>
<thead>
<tr>
<th>Study</th>
<th>When Performed</th>
<th>Setting and Study Design</th>
<th>Diagnoses</th>
<th>Principal Findings</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gani15</td>
<td>1994–2001</td>
<td>Medical ICU of a French university hospital. Retrospective examination of prospectively collected data on mechanically ventilated patients.</td>
<td>COPD exacerbation and CHF</td>
<td>Among 479 patients ventilated during the 6-y period, 213 (45%) received NIV, of whom 35 (11%) subsequently required intubation. NIV use progressively increased as a proportion of all patients ventilated during the study period.</td>
<td>ICU mortality decreased from 21% in 1994 to 7% in 2001. The rate of ICU-acquired pneumonia decreased progressively from 20% to 8% over the same period. Patients treated with NIV had shorter ICU stay than those who received invasive ventilation (mean 10 vs 8 d. P = 0.2).</td>
</tr>
<tr>
<td>Cathcus16</td>
<td>1997</td>
<td>42 ICUs in France, Switzerland, Belgium, Spain, and Tunisia. Prospective study with 3-wk observation period NIV used as initial ventilation approach in 108 (16%) of 689 patients.</td>
<td>Hypoxemic ARF (48%), hypercapnic ARF (15%), coma (30%), CHF (7%)</td>
<td>NIV successful (no need for intubation) in 65 (60%) of 108 patients. NIV used in 35% of patients with hypercapnic ARF, 27% with CHF, 14% with hypoxic ARF, and 0% with coma.</td>
<td>Mean duration of NIV was 5.6 d in hypercapnic ARF, 2.4 d in CHF, and 6.3 d in hypoxic ARF. Mean hours of NIV per day was &lt; 9 h at all times in all groups.</td>
</tr>
<tr>
<td>Esteban17</td>
<td>1998</td>
<td>361 ICUs in 20 countries. Prospective cohort study of adult patients ventilated for &gt; 12 h during a 28-d period. NIV used as initial ventilation approach in 256 (4.9%) of 5,183 patients.</td>
<td>Hypoxemic ARF (69%, including CHF 10%), coma (17%), COPD exacerbation (10%)</td>
<td>85 COPD patients received NIV, of whom 22 (26%) were subsequently intubated. 54 (36%) of 148 patients with hypoxic ARF who received NIV were subsequently intubated.</td>
<td>Mortality in COPD patients was 14% when NIV was successful and 43% when intubation was subsequently required. In other patients treated initially with NIV, mortality was higher if intubation was required, compared to patients initially intubated (48% vs 31%).</td>
</tr>
<tr>
<td>Pass-Jenssen18</td>
<td>2001</td>
<td>Prospective cohort study of all NIV use in a Canadian teaching hospital over a 5-mo period. 75 patients were excluded: 64 NIV, 11 CPAP only.</td>
<td>Shortness of breath (24%), COPD exacerbation (17%), hypoxemic ARF (17%), CHF (13%), other (29%)</td>
<td>NIV initiated in ED (32%), ICU (27%), ward observation unit (23%), or general medical ward (18%). 13% of patients required intubation and 34% died (46% with DNAR status).</td>
<td>Study hospital had no NIV protocol or policy other than requiring a physician’s order. Study data were recorded by the RTs who provided the care.</td>
</tr>
<tr>
<td>Schettino19</td>
<td>2001</td>
<td>Prospective cohort study in teaching hospital of NIV use during 1-y period</td>
<td>All adult patients who received NIV or CPAP for an acute indication anywhere in the hospital. 458 episodes in 449 patients. NIV initiated in ICU in 47%, on general medical ward in 13%, in ED in 20%. Overall mortality 21% (47% when NIV was unsuccessful and intubation was carried out). 49% of NIV patients managed in an ICU were subsequently intubated, vs 27% on the general ward.</td>
<td>53% of patients were managed in an ICU after NIV initiation, 35% in general medical-surgical wards, and 12% exclusively in the ED. RT/patient ratio 1.6:1.8, and nurse/patient ratio 1.4:1.6 outside the ICU setting. Of the 97 patients with CHF, 40% were managed with CPAP alone, and only 18% of them required intubation, most of them were managed in the ED without admission to the ICU.</td>
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<tr>
<td>Demoule20</td>
<td>2002</td>
<td>Follow-up study 5 y after 1997 cohort.7 Follow-up study of all ventilated patients in 70 French ICUs (32 university, 38 non-university; 28 were also in 1997 study) over a 3-wk period</td>
<td>All adult patients ventilated in ICU. Hypoxemic ARF (42%), acute-on-chronic respiratory failure (16%), COPD 11%, restrictive disease 5%, coma (34%), CHF (8%).</td>
<td>Of 1,085 patients ventilated, 249 (23%) received NIV as initial support, compared to 86% in 1997 cohort. In patients not intubated prior to admission, NIV was used in 52%, vs 35% in 1997. 38% of NIV patients subsequently required intubation.</td>
<td>The proportion of all patients who received ventilation support who had NIV successfully applied without the need for intubation increased from 9% to 13%, compared to the 1997 cohort.</td>
</tr>
<tr>
<td>Esteban21</td>
<td>2004</td>
<td>Follow-up study of 1998 cohort.71 1-mo observational cohort study of all patients ventilated in 349 ICUs in 23 countries.</td>
<td>All adult patients ventilated in ICU for &gt; 12 h. Hypoxemic ARF (72%, including CHF 6%), coma (19%), COPD exacerbation (5%).</td>
<td>4,968 patients were included, of whom 1,675 were managed in 107 ICUs that also participated in the 1998 study. 11% of ventilated patients received NIV, vs 4% in 1998. NIV was used in 48% of 130 patients with COPD, and in 109 of 1,083 patients with primary ARF: each proportion significantly more than in the 1998 cohort.</td>
<td>Neither the requirement for intubation (35%) nor mortality (24%) was different in the 2004 cohort, compared to the patients studied in 1998.</td>
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<tr>
<td>Otraysal22</td>
<td>2007</td>
<td>Survey of NIV practice in 8 “low-utilization” hospitals in Massachusetts and Rhode Island, as identified in previous survey.65 Prospective 1-mo cohort study.</td>
<td>All acute applications of NIV in adults. Hypoxemic ARF (25%), CHF (26%), pneumonia (18%), other (31%).</td>
<td>244 (42%) of 581 patients began on mechanical ventilation received NIV. Excluding patients who were intubated for airway protection, NIV was initial approach in 81% of COPD patients, 71% with CHF, 49% with pneumonia, and 66% in other causes of ARF. Overall success rate with NIV was 71%, and mortality was 16%.</td>
<td>Reported only in abstract form as of the time of this writing.</td>
</tr>
</tbody>
</table>

ICU = intensive care unit
COPD = chronic obstructive pulmonary disease
DN1 = do not intubate
CHF = congestive heart failure
DNAR = do not attempt resuscitation
NIV = noninvasive ventilation
RT = respiratory therapist
ARF = acute respiratory failure
CPAP = continuous positive airway pressure

HISTORY AND EPIDEMIOLOGY OF NONINVASIVE VENTILATION IN THE ACUTE-CARE SETTING

RESPIRATORY CARE • JANUARY 2009 VOL 54 NO 1
shown in Figure 5, NIV use, as a proportion of all patients with these diagnoses who received mechanical ventilation in the unit, increased steadily throughout that period.

Schettino et al79 prospectively documented non-investigational NIV use during the year 2001 in a large teaching hospital with extensive experience with this therapy. They excluded do-not-intubate patients but included all other applications of NIV in patients ≥ 18 y old, in all areas of the hospital. Figure 6 shows the outcomes of the patients in 5 different diagnostic categories. The rates of NIV failure (that is, the need to intubate and invasively ventilate) and fatal outcome among patients who failed NIV differed considerably in the patient categories.

In a study not summarized in Table 5, Bruge et al18 recently reported the results of a 2-year prospective observational investigation of NIV in pre-hospital care, in emergency-response vehicles equipped with bi-level ventilators for NIV, operated by their institution in France. During the observation period, out-of-hospital NIV was attempted in 138 patients with congestive heart failure (56%), COPD exacerbation (28%), or primary ARF (16%). NIV was deemed successful (ie, intubation was not required either in the field or in the emergency department) in 102 patients (74%). Patients with congestive heart failure were more likely to be managed successfully with NIV, and major air leaks that signified inability to achieve a satisfactory mask seal predicted subsequent need for intubation. As of the time of this writing, no other reports of NIV use in pre-hospital emergency care have been published.

Problems With the Accurate Assessment of Current NIV Use

Although they are designated as evaluations of practice “outside the research setting,” the studies summarized here all involved the collection of data in “real time” in all instances of NIV use. Thus, the practices documented were, to a degree, observed in a research setting. However, except for investigations that involved large administrative databases, which are necessarily limited in what they can reveal about institutional practice and clinician behavior, this approach to studying current NIV use is probably the only practical way to address the issue.

The epidemiology of NIV use in the acute-care setting is, however, a moving target. Although, as in other areas of medicine, practice appears to have lagged behind the evidence base by several years, it is apparent that NIV is being used by more and more clinicians and is now available in most if not all acute-care institutions. Assessment of historical trends and current use has been complicated by different definitions of NIV (eg, the inclusion of CPAP in some studies), the variety of locations in which NIV has been used (eg, ICU vs general ward vs emergency department), the sometimes vague criteria for patient inclusion, the definitions of NIV success and failure, and the unclear denominators from which included patients were drawn in some series.

Summary

Since the 1940s, NIV has evolved in parallel with invasive mechanical ventilation in the care of patients with ARF. With the explosion of reported studies on NIV use in different patient populations and clinical contexts in the last 20 years has come a steady (if belated) increase in the use of this therapy in everyday practice. Although they probably do not reflect the dimensions of practice in 2009 very accurately, numerous studies of reported and actual NIV use in acute-care settings show that this modality is
now widely available and routinely used by increasing numbers of clinicians.

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Discussion

Hill: You alluded to the difficulty in getting accurate information on this topic, and I entirely concur, having done some of the work that you presented. One of the problems is that many of these studies, including our own, relied on questionnaires and lacked validation. Also, very few of the studies defined how the types of respiratory problems were diagnosed.

We’ve been doing follow-up work on-site—not relying on questionnaires, but documenting actual NIV utilization. And one of the challenges is defining the target population. There are patients who go on mechanical ventilation because of procedures, surgery, or general anesthesia, who are not relevant to what we’re talking about. And there are patients who get intubated for airway protection, who are comatose or have severe swallowing or secretion problems and should not be on NIV in any case.

We looked at the hospitals that were low NIV utilizers—less than 15% of the initial ventilator starts were with NIV in the Maheshwari et al study in 2003, but now NIV is being used in more than 50% of initial ventilator starts. I think we’re seeing more acceptance of NIV over the last half-a-dozen years. I don’t think the studies you showed are up-to-date enough to reflect that trend. Parenthetically, I think the Europeans are ahead of the North Americans on this, but the North Americans are catching up.

Pierson: Your point is a good one. The goal is not necessarily to increase NIV use in and of itself. There has been a disturbing tendency in some of the units in which I attend that any patient who develops an acute respiratory problem is immediately slapped on NIV, without as much consideration as perhaps there should be about the patient’s ability to protect the airway and clear secretions, the patient’s mental status, and so forth. Our goal shouldn’t just be to have the largest possible number of patients who have respiratory problems getting NIV.

Hill: I think I’m hearing less of that, Bob, than I did, say, half a dozen years ago.

Kacmarek: I agree.

Benditt: At our hospital one of the hardest things has been to convince the emergency-department physicians that NIV is effective. I would say that most of the appropriate NIV starts are in the emergency department, for COPD, where the effect seems to be greatest. We’ve started a liaison between our respiratory care department and our emergency department, with teaching sessions and so forth to try to increase early use of NIV. One of the major stumbling blocks is that maybe the pulmonologists and the intensivists are thinking about it, but maybe we are looking in the wrong place.

Pierson: Josh, you and I both practice in Seattle, which is world-renowned for its Medic One system. Not only do I agree that in the emergency department it’s very important to use the right decision-making, but also, increasingly, outside the hospital in pre-hospital conditions. I’ve heard it said that Seattle is an ideal place to have a catastrophic event out on the street, but it’s not a very good place to experience a simple faint, because if you do, you’re going to wind up in-
tubated and in the emergency department at Harborview! Many of our patients who are said to have had acute respiratory distress, when they first enter the emergency department, are already intubated.

Nava: Timing is important, especially when you take into consideration the epidemiology of NIV. Andrés Esteban found that COPD admission to the ICU dropped from 10% to 5% in the last 6 years. COPD exacerbations did not decrease, so that means that most of the patients were treated outside the ICU. And most of the surveys were performed in the ICUs, including those by Demoule, Esteban, and Hill. It’s important to understand where and how we treat those patients—not only in the ICU. In North America it’s a bit different, and Nick pointed out the difference between Europe and the States. In Europe we do a lot more NIV than they do in North America, including outside the ICU, in the emergency department and pulmonology ward, which is not an ICU. I think NIV is more popular in Europe because we have 2 big fields of application, depending on timing.


Hess: Addressing the international aspects of NIV, I’ll share an anecdote. Some time ago I was at a conference in Southeast Asia. I gave a lecture on NIV and how to initiate NIV in a hospital. A physician came up to me after that lecture and said that in his country he was certain there had never been a single use of NIV.

Mehta: We in this room, and others, are responsible for making the field of NIV overwhelming for many practitioners. There have been numerous trials in the last 10 years, and we can’t expect the average clinician to be aware of all those trials. So the goal of having all physicians, respiratory therapists, and institutions familiar and comfortable with NIV may be overly ambitious. And I’m not sure that we should be encouraging every single clinician to be comfortable with NIV, in that I think it might be dangerous.

We know that there are certain patients we can harm by using NIV too long, starting it too late, or delaying necessary intubation. Over the last year we’ve started outreach “access” teams throughout most of Canada—it’s become a government mandate—to have a dedicated team in the hospital who are extremely comfortable with NIV.

Also, the number of types of ventilators and masks and modes is overwhelming. And I don’t think we can expect the residents or average clinician to be comfortable with this. In my hospital the people who are most comfortable and have the expertise with NIV are the respiratory therapists, and they are present everywhere, including in the emergency department when patients arrive. Maybe they should be the group leading NIV use in many institutions?

Doyle: In the surveys on NIV and CPAP did they survey any neonatal groups? It seems to me that a lot of neonatal patients are not being intubated, but instead are placed on what I would call high-flow systems. Are those included in the surveys’ definitions of NIV? It also appears to me there’s a proliferation of use of high-flow (30-40 L/min) oxygen nasal-prongs systems in adult patients, which I suspect deliver some level of CPAP. Are such high-flow oxygen system included in the definitions of NIV?

Pierson: In my literature search, without any restriction on patient age, nothing popped up on any of the inquiries with respect to the neonatal and pediatric populations. The first NIV support of acute respiratory failure probably was in neonates—at least one of the early instances I heard about was—but I am not aware of any organized documentation of what the practice has been.

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