

Noninvasive Ventilation in Acute Care: Controversies and Emerging Concepts

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This conference brought together experts on noninvasive ventilation (NIV) to discuss and debate the advances in evidence and technology over the past decade. A major impetus for the conference was that many institutions have not systematically integrated NIV into their clinical practice, despite mounting, high-level evidence supporting its effectiveness. NIV clearly improves outcomes for patients with chronic obstructive pulmonary disease and acute cardiogenic pulmonary edema when instituted as a first-line therapy. Although the evidence is less persuasive, initial intervention with NIV also might benefit a carefully selected subset of patients with acute lung injury, as well as those with acute respiratory failure who are immunocompromised. The papers in this and last month's special issue of the Journal provide an informative guide for clinicians attempting to implement NIV in their institutions. This paper summarizes the major findings from each presentation and the discussions that followed. Key words: noninvasive ventilation, NIV, noninvasive positive-pressure ventilation. [Respir Care 2009;54(2):259–263. © 2009 Daedalus Enterprises]

Introduction

It has been approximately 10 years since the Journal convened a state-of-the-art conference on noninvasive ven-

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Mr Kallet presented a version of this paper at the 42nd RESPIRATORY CARE Journal Conference, "Noninvasive Ventilation in Acute Care: Controversies and Emerging Concepts," held March 7-9, 2008, in Cancún, México.

The author reports no conflicts of interest related to the content of this paper.

tilation (NIV).¹ In the intervening years, numerous clinical trials have added to the body of evidence informing our practice. When instituted as a first-line therapy, NIV clearly improves outcomes for patients with chronic obstructive pulmonary disease (COPD) and acute cardiogenic pulmonary edema, as these conference proceedings reveal. Although the evidence less persuasive, initial therapeutic intervention with NIV also might benefit a carefully selected subset of patients with acute lung injury (ALI) and immunocompromised patients with acute respiratory failure.

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Unfortunately, despite mounting positive evidence, many institutions have not systematically integrated NIV into their clinical practice. In the era of evidenced-base medicine, such a discrepancy between evidence and practice represents a serious concern for the entire acute-care community and for the respiratory care profession in particular. To address this problem, many of the top authorities came together for 2 days in March 2008, with the objective of discussing the role of NIV in the management of patients with various causes of acute respiratory failure, and to outline practical aspects of how and where NIV should be implemented. The papers in this and last month's special issues of the Journal provide an informative guide for clinicians to implement NIV in their institutions. I will summarize the major findings from each of the presentations and the discussions that followed.

In his lecture on the epidemiology of NIV, David Pierson pointed out that both skills-related impediments and clinical practice differences may partially explain the lack of congruence between positive clinical trials and the apparent lack of clinical efficacy.² In the ensuing discussion, the participants attempted to formulate ways to bridge that divide. One point raised was that the issue is not necessarily to increase the use of NIV, but rather to increase its *effective* use, specifically, to focus clinicians on the timing and location of NIV and to ensure that the appropriate patient populations are targeted. This necessarily raised the question of whether the problem was under-utilization or insufficient training.

Training, Organization, and Execution

David Pierson's presentation provided a seamless transition to the topic of how best to organize a successful NIV program. John Davies outlined the 5 essential elements of such a program, namely: training, equipment, monitoring, quality assurance, and organizational "buy-in."³ The post-presentation discussion was dominated by the interrelated issues of severity of illness versus assessment. In what probably mirrors common discussions at the bedside, there was a vigorous argument as to how long a patient receiving NIV should be kept in the intensive care unit (ICU), and whether NIV ever should be allowed on the general wards. Some discussants argued that allowing NIV on the general wards would probably cause over-utilization and tax limited resources. Paradoxically, this could adversely affect the care of those most likely to benefit from NIV. On the other hand, strictly limiting NIV to the critical care setting may potentiate under-utilization and undercut NIV's primary economic advantages: shorter ICU stay or obviating ICU admission.

What was most interesting about this debate was that proponents of NIV on the general wards tended to be those who had central cardiac and ventilator monitoring avail-

able in those patient care areas and an established, rigorous assessment program, whereby both respiratory care and nursing supervisors frequently assess whether the care environment is appropriate for the individual patient's condition.

This underscored the issue of where NIV should be delivered. In the presentation by Nicholas Hill this problem was honed down to patient-related and resource-related issues.⁴ In brief, the intensity of a patient's monitoring needs must be matched to the availability of suitable monitoring and adequate staffing of appropriately trained clinicians to manage patients on NIV. Insufficient attention to these requirements could lead to inappropriate placement of a patient receiving NIV, and may have catastrophic consequences.

Solutions to these logistical problems were offered by conference participants with established NIV programs. In their institutions, supervisory personnel assess all patients receiving NIV outside the ICU at least every 12 hours. In addition, NIV ventilator alarms can be linked, via commercially available communication systems, to both the nursing call system and wireless communication devices, to immediately alert both nursing and respiratory care personnel to a ventilator disconnect.

Dean Hess addressed how to initiate an NIV program.⁵ One of the key elements to successfully disseminating new practices in health care is the identification of the "agents of change" within an institution. These are clinicians who are most receptive to change and become the clinical "champions" who move health care practice forward. An equally important element cited by Hess was recognizing barriers to change. Among the most salient of these barriers are a lack of awareness of and lack of agreement regarding the evidence that supports a therapy, and clinician "inertia" associated with habituation to previous practice. Awareness of these impediments is essential to developing an effective NIV program. Those tasked with developing an NIV program would be wise to assess potential problems in their own institution prior to implementation, and then devise a proactive strategy to circumvent or minimize them.

As will be seen, the discussion following Hess's paper raised several interesting points. One of these was the importance of respiratory-therapist-driven protocols in the adoption of NIV and creating a well-structured in-service training program for therapists. For example, at Massachusetts General Hospital, all respiratory therapists undergo a half-day NIV training program.

Interfaces and Ventilators

Without question, the most important element of successful implementation of NIV is patient tolerance, and the most fundamental determinant of a patient's acceptance of NIV is the suitability of the interface. Tight-fitting masks,

while essential to NIV, commonly lead to pressure sores, but also to eye irritation and claustrophobia. Stefano Nava described the 6 types of interface available for delivering NIV.⁶ In selecting an interface the clinician first must take into consideration the severity of respiratory failure, because this determines the peak pressure and positive end-expiratory pressure, which in turn determine the likelihood of leaks and mask tightness. Mask dead space, particularly in patients with hypercapnic respiratory failure, must be considered. Other considerations include facial contour, patient adaptation, and skin breakdown.

An important theme that arose during the ensuing discussion was that mask-fitting is an *art form* that clinicians acquire through patience and practice. Evidence from clinical trials offers little guidance, because differences between masks were small and the studies were limited by numerous confounders. During the discussion some participants voiced the opinion that issues such as the risk of gastric distention and the ostensible effects of mask dead space are somewhat exaggerated.

The issue of choosing a ventilator and mode to deliver NIV was tackled by Rob Chatburn, who developed a preliminary decision map structured primarily for clinicians who lack experience with NIV.⁷ In this model, clinicians are focused on weighing the sometimes competing needs of safety (ie, preventing apnea, gas exchange deterioration, and lung injury) and comfort (ie, control of leaks, promoting synchrony, and reducing work of breathing). This proposal generated a very interesting discussion regarding the lack of evidence on the relative effectiveness of different NIV modes. Moreover, the additional difficulty of assessing the impact of ventilation modes adds difficulty to the issue because of substantial performance differences between various manufacturers' versions of the same mode, and differences between ventilators designed for NIV versus for invasive mechanical ventilation.

Physiologic Effects

My own presentation on the physiologic effects of NIV was based on the substantial number of physiologic studies done primarily with pressure-support ventilation (PSV) and proportional-assist ventilation.⁸ These studies were carried out predominantly in patients with COPD. Essentially, application of 15 cm H₂O inspiratory pressure-assist markedly reduces work of breathing, whereas only 4–5 cm H₂O end-expiratory pressure very effectively counterbalances the effects of intrinsic positive end-expiratory pressure. Several conference participants raised an important but largely neglected issue: NIV settings that optimize work of breathing during the awake state do not necessarily translate to what occurs during sleep. High NIV pressure may disrupt sleep and cause an unstable breathing

pattern. Little is known about the effect of NIV on sleep, and much physiologic research is needed.

The Role of Noninvasive Ventilation in Managing Various Cardiopulmonary Diseases

The remainder of the conference primarily concerned the application of NIV in various patient populations. The largest body of clinical evidence supports NIV as the first-line treatment for patients with respiratory failure from acute cardiogenic pulmonary edema and from exacerbation of COPD.

Geeta Mehta's presentation on NIV for acute cardiogenic pulmonary edema highlighted the controversy over whether PSV offers any substantial benefit over continuous positive airway pressure.⁹ Some of this controversy emanated from her initial study¹⁰ that suggested that PSV may increase the risk of myocardial infarction. However, she presented more recent evidence that casts doubt on that link. Moreover, her talk reinforced the fact that, compared to conventional therapy with supplemental oxygen, continuous positive airway pressure rapidly improves oxygenation and vital signs while reducing both the need for invasive mechanical ventilation and mortality. The added benefit of noninvasive PSV may be a faster improvement in oxygenation and vital signs. The larger controversy of whether PSV offers any true advantage over continuous positive airway pressure was mirrored in the discussion among conference participants.

Probably the most daunting challenge for this conference was to summarize the evidence on NIV in other forms of acute respiratory failure. Sean Keenan did a masterful job describing the effectiveness of NIV in treating various etiologies of acute respiratory failure, including ALI, community-acquired pneumonia, chest trauma, COPD, and asthma.¹¹ Whereas there is a large body of high-level evidence that NIV reduces the need for endotracheal intubation and decreases mortality in patients with COPD, such is not the case when NIV is used to treat other forms of acute respiratory failure. Although some results are encouraging, to date the studies have been small and found only nonsignificant trends suggesting less need for invasive mechanical ventilation and lower mortality with NIV.

An important theme that dominated the discussion following Keenan's presentation was the need for careful evaluation of patients with ALI for NIV. This is particularly important because ALI can progress rapidly and its resolution often is prolonged. A unanimous opinion voiced by conference participants was that a patient with ALI should be intubated if the patient's condition does not markedly improve after a *brief* trial (limited to a few hours) of NIV.

Scott Epstein's lecture examined whether NIV should be used to facilitate early extubation and which patients are appropriate candidates.¹² The importance of this issue is underscored by evidence that delaying extubation increases the risk of pneumonia, duration of hospitalization, and mortality. However, early extubation also carries substantial risks, among which is a relatively high failure rate (particularly in medical and neurological ICU patients) and a higher mortality risk.¹³ Therefore, proper patient selection is essential. Epstein presented data from relatively small studies that suggested that NIV facilitates weaning and may reduce extubation failure, duration of mechanical ventilation, ventilator-associated pneumonia, and mortality. Another important aspect of Epstein's presentation was on patients who develop post-extubation respiratory distress. Recent evidence on this topic is contradictory; some studies found a clear benefit from NIV, whereas others found no benefit. When the details of these trials were discussed, it became apparent that appropriate patient selection is crucial. Patients suffering from COPD and heart failure appear to derive the most benefit from NIV.

In the ensuing discussion, several participants expressed reluctance to pursue early extubation in favor of NIV. Understandably, it can be difficult to trust that NIV might be effective in patients who very recently failed a trial of NIV, which precipitated invasive mechanical ventilation in the first place. Yet, other conference participants countered that 48 hours of invasive mechanical ventilation may provide sufficient time to recover from inspiratory muscle fatigue, particularly in those with COPD. Therefore, a second trial of NIV may produce markedly different results. Still others cautioned that these positive results from instituting NIV following early extubation come from institutions with decided expertise in the therapy, which may not necessarily transfer to less experienced institutions. My recommendation would be that institutions should first establish expertise in their practice of NIV. Only then should they use NIV in the more risky realm of early extubation.

Novel Applications for Noninvasive Ventilation

Several novel uses of NIV have emerged over the past decade, including ventilatory support during bronchoscopy, postoperative respiratory care, management of obesity hypoventilation syndrome, and during a pandemic, when the limited supply of invasive ventilators will be taxed quickly. These issues were deftly addressed by Josh Benditt, who cited evidence that NIV promotes gas exchange and hemodynamic stability during bronchoscopy and decreases the need for invasive mechanical ventilation in the post-anesthetic recovery environment.¹⁴

Probably the most passionate discussion of the entire conference focused on whether NIV should be used during

a pandemic. The American Association for Respiratory Care's recent recommendation¹⁵ that NIV should *not* be used in the event of a pandemic was strongly criticized by one participant as "going too far." Others observed that in such an extraordinary situation it is impossible to predict what resources (both human and material) might be available and reasonably could be utilized effectively.

Complications

Peter Gay, who presented the complications associated with NIV, observed that numerous clinical trials of NIV did not report data on the occurrence of complications.¹⁶ Therefore, it is hard to accurately judge the true incidence and relative severity of adverse events associated with NIV. Although many of the known complications associated with NIV, such as skin breakdown, are relatively minor, other complications such as aspiration and severe hypoxemia warrant sober reflection. A concern voiced by many participants during the discussion was the perception that clinicians frequently "push the envelope" by instituting or maintaining NIV when invasive mechanical ventilation clearly would be the more prudent course of action.

Noninvasive Ventilation in Palliative Care

One of most engaging presentations was Bob Kacmarek's, on the role of NIV in palliative care.¹⁷ Personally, I was struck by the fact that a surprising number of terminally ill patients, in whom NIV is instituted to improve comfort, actually recover and are able to be discharged from the hospital. Notwithstanding this potential benefit, Kacmarek stressed the need to fully engage the patient and family on what NIV is likely to accomplish, and its limitations. NIV as a therapeutic option should be addressed openly and clearly delimited in the same manner as other interventions that are encompassed within do-not-resuscitate orders.

In the discussion following Kacmarek's presentation several important issues were raised. Among these was the fact that there is a dearth of prospective studies on NIV at the end of life. Participants differed on whether improved survival or improved comfort and quality of life should be the primary outcome variables studied.

How Should We Proceed With Noninvasive Ventilation as a Profession?

In summary, the second Journal conference on NIV raised many important issues that should be emphasized. First, NIV now has a wealth of high-level evidence that clearly demonstrates improved outcomes in certain patient populations, at the appropriate time in the disease process,

and in an environment conducive to executing the therapy. In my opinion it is beyond question that NIV should be the front-line therapy in patients with exacerbation of COPD and those with acute cardiogenic pulmonary edema. There are, very probably, equally effective applications of NIV in other conditions, such as ALI, but prospective research is needed to determine the appropriate patients and circumstances. As expressed at several junctures during the conference, NIV has distinct limitations and risks that should tamp down excessive enthusiasm.

It behooves the respiratory care profession to aggressively promote NIV and ensure appropriate training of NIV practitioners. After reviewing these conference papers it will become clear that NIV is an *art form* that must be approached in the same manner as any serious artist approaches his or her craft. The institutions that have had the most success with NIV emphasize that it is a skill that requires practice and is refined by constant exposure.

My own view is that there are 3 keys to successfully implementing NIV as a standard of care: political support from physicians and administration; intensive training in the art of NIV; and disciplined execution of a pragmatic, well-designed protocol. Protocol-driven care can be successful only when it is combined with a rigorous quality-assurance program, as would occur with any large randomized clinical trial. In the 12 years I have been coordinating both protocol-driven clinical trials and patient care, I have come to one inescapable conclusion: that adherence to protocols diminishes over time unless there is an appointed "protocol czar" who continuously monitors adherence and outcomes, and provides continuous education and feedback to clinicians.

In closing, I would like to acknowledge the conference organizers, Bob Kacmarek and Scott Epstein, for their hard work and putting together an exceptional conference, as well as our out-going and in-coming editors in chief, David Pierson and Dean Hess. In addition, this conference would not have been realized without the support of the American Association for Respiratory Care and the American Respiratory Care Foundation. Finally, over the past quarter century, our Journal conferences have been globally successful due in large measure to the untiring care and work of Ray Masferrer, Associate Executive Director of the American Association for Respiratory Care. I'm quite sure that over the years all conference organizers and

participants have felt a special sense of gratitude for his warmth and hospitality.

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