SPECIAL ARTICLE

Setting Up and Organizing a Noninvasive Ventilation Unit for Hospital and Home Therapy

S. Díaz-Lobato[a] and S. Mayorales-Alises[b]

[a]Servicio de Neumología, Hospital Ramón y Cajal, Madrid, Spain.
[b]Hospital de Móstoles, Móstoles, Madrid, Spain.

Introduction

Few specialties have increased their scientific and clinical foundations as quickly as respiratory medicine. The assimilation of new diagnostic and therapeutic techniques has extended horizons beyond what could have been imagined only a few years ago.[1] Sleep disorders,[2] home care and home hospitalization,[3-5] chronic obstructive pulmonary disease (COPD),[6-9] or the recovery of patients with lung cancer[10,11] are good examples of clinical settings that have seen progress. More and more patients are candidates for care by a pneumologist and the list of diseases that clearly fall to our responsibility has grown steadily.[12-17] Respiratory disease patients now live longer and our approach to chronically and terminally ill patients has changed, adding to case loads.[18,19] We are currently able to offer patients not only a longer life but, more importantly, a better quality of life.[20,21]

Among the new therapeutic modalities adopted by pneumology, noninvasive ventilation (NIV) deserves special mention for its importance and impact on how we organize our work.[22-24] A pneumology department that considers itself modern must adapt to scientific and clinical progress and that means having a specialist unit to support hospital and home NIV therapy. We will briefly present reflections on current indications for NIV and on the way it is provided. We will then focus on the basic requirements for creating a NIV program.

Indications for NIV

Chronic Respiratory Failure

NIV modalities have meant enormous progress in our ability to treat restrictive chronic respiratory failure.[25-27] Results indicate that for patients who use it, NIV improves quality of life, prolongs survival, enhances gas exchange, and provides better sleep quality.[28] Currently, indications are well defined for patients with neuromuscular and chest wall diseases, complications of tuberculosis, and hypoventilation–obesity syndrome, and other syndromes involving alveolar hypoventilation.[29-31]

Clear criteria for prescribing NIV for patients with COPD or chronic respiratory failure have not been established, however. The British Thoracic Society (BTS) recommends considering home NIV for patients requiring more than 7 days of therapy during an exacerbation, for those with severe hypercapnia when correctly oxygenated, or those admitted to hospital with hypercapnic respiratory failure 3 or more times within a year.[32] After the 1999 consensus conference, on the other hand, it was suggested that nighttime ventilatory support be prescribed when patients with hypoventilation symptoms also have a $PaCO_2$ above 55 mm Hg.[26] If $PaCO_2$ ranges from 50 to 55 mm Hg, there is general agreement that ventilation should be started for a patient with nocturnal desaturation defined as a pulse oximeter reading that indicates less than 88% saturation for more than 5 consecutive minutes in spite of receiving oxygen at a flow rate of 2 L/min. Finally, nighttime ventilatory support is considered, as in the BTS guidelines, for COPD patients with $PaCO_2$ between 50 and 55 mm Hg who have been hospitalized with hypercapnic respiratory failure at least twice in a year. From the clinical perspective, the lack of clearly defined criteria leads to considerable variability in the application of NIV in hypercapnic patients with stable COPD. Information about the prevalence of NIV in COPD patients, therefore, is unavailable.

Acute Respiratory Failure

Alongside the growing use of NIV in patients with chronic respiratory failure, its application has also gradually increased in the context of acute respiratory failure of a variety of etiologies and in patients with exacerbated COPD, a setting for which the highest level of evidence of efficacy is available.[33-36] Elliot[37] proposed NIV as a new gold standard for the treatment of acute

Correspondence: Dr. S. Díaz-Lobato.
Federico García Lorca, 2, portal 7, 2.º A.
28770 Colmenar Viejo. Madrid. España.
E-mail: sdl01m@nacom.es

Manuscript received March 15, 2005. Accepted for publication April 5, 2005.

exacerbation of COPD, and its importance is recognized in the statement issued by the Global Initiative for Chronic Obstructive Lung Disease as supported by the highest level of scientific evidence.[38] At present, hospitals who treat patients with exacerbated COPD must be equipped to provide NIV.

Where NIV Is Carried Out

Stable Patients

The period of adaptation to NIV of patients who are initiating treatment usually takes place on a scheduled in-patient basis, although it has been reported to have been undertaken successfully in day hospitals, outpatient clinics, and even in the patient's home.[39] Possibly more important than where the adaptation process takes place is the motivation, experience, and dedication of the caregivers assigned to carry it out.[22]

Patients With Acute or Exacerbated Chronic Respiratory Failure

The question asked until a few years ago about whether NIV should be applied on a conventional hospital ward or in an intensive care unit (ICU) has been answered by the conception of intermediate respiratory care units.[40-42] A recent task force of the European Respiratory Society established the characteristics a unit of this type should have.[43] Established admissions criteria stipulate that eligible patients are those with only respiratory system failure, those with acute respiratory failure who need monitoring but not necessarily mechanical ventilation, and tracheostomized patients who require artificial ventilation. Although NIV is the mainstay of therapy in these units, conventional mechanical ventilators must be on hand in case they are needed. An intermediate care unit must be able to monitor electrocardiography, pulse oximetry, noninvasive blood pressure, and respiratory rate. The recommended nurse-to-patient ratio is 1 to 4 and a senior staff physician should be on call 24 hours a day. A respiratory physiotherapist should also be on staff.

A fundamental aspect that is usually not taken into consideration is that NIV must be available 24 hours a day. The findings of the study by Plant et al[44] indicate that if NIV were used in all patients with COPD who have a pH less than 7.35 after receiving conventional emergency treatment for a short period of time, a referral hospital serving an area with 250 000 inhabitants would treat 70 patients annually, a figure that encompasses only COPD patients. The BTS guidelines for NIV in acute situations establish that all hospitals that receive this type of patient should have the appropriate infrastructure, which is to say, a dedicated space and staff expressly assigned.[32] A supervisor must decide where to treat a patient, assure that material is in optimal condition for use, update protocols, see to the training of team members, maintain patient records, and oversee quality checks. To this must be added time for teaching and research. Definitively, the task of providing NIV at this time requires specially trained personnel and a dedicated space, preferably following the model of an intermediate respiratory care unit.[44-46]

Principles for Organizing a Home NIV Unit

Basic Principles

Setting up a unit to support home NIV should involve following these guidelines as closely as possible:

– NIV requires an assigned space: an intermediate respiratory care unit or, if unavailable, beds specifically assigned for ventilation.
– NIV requires specific technology and equipment: respirators and interfaces. Such material can be acquired in a variety of ways, through loan, rental, or purchase depending on geographic area.
– NIV requires a specially assigned staff: a physician to be in charge of the NIV program, a dedicated team, motivated nurses and assistants.
– NIV must be dispensed 24 hours a day, so specialists must be on call or alternatives must be found. Care interruption, through which respirators are put in place on a Friday and the patient is left unsupervised until the following Monday, carries more risk than benefit and often represents genuine irresponsibility.

Clinical Settings in Which NIV Support Is Provided

NIV is an area of specialty care with clear indications and a well-established method. The task of providing NIV requires several types of coverage:

– Care on the ward of patients admitted for scheduled initiation of ventilation. Adaptation to a respirator usually requires at least 1 day and success depends on the amount of time invested in the early phases. A pulse oximeter must be available for use at night.
– Care of patients hospitalized with various types of acute or exacerbated chronic respiratory failure. Such patients are transfers from other wards (mainly internal medicine, pneumology, and cardiology), the ICU, or postoperative recovery unit, or are admitted from the emergency department.
– Monitoring of patients enrolled in home NIV programs. Patients using NIV at home need periodic examination, depending on their clinical situation and adherence to therapy. Examinations take place in outpatient clinics, although requests for attention outside scheduled appointments to resolve specific NIV-related problems are not uncommon.
– Specialist clinic for outpatients with respiratory failure. The clinic must operate once or twice per week and be able to resolve serious problems rapidly, performing such tests as arterial blood gas analysis and

pulse oximetry immediately. Such units must be able to deal with problems related to patient adaptation and respirators in need of resetting. Patients who bring their equipment in can have settings checked and corrected if there are problems. Five types of consultation account for the main part of a unit's activity. The protocol applied for each type is different:

– Assessment of indications for NIV in patients referred for that purpose.
– Routine check-up for patients with stable disease who are well adapted to nighttime ventilation, adhere to therapy, have optimal results, and report no NIV-related problems.
– Follow-up visits for patients with progressive neuromuscular diseases. The most dramatic situation is that of a patient with amyotrophic lateral sclerosis. Such patients require great dedication of resources and new decisions must be made often.
– Assessment of patients whose adherence to therapy is poor. In these cases, the main objective of a visit is to focus on improving health education.
– Re-assessment of cases in which NIV is ineffective in spite of good adaptation, tolerance, and adherence. The main aim in this situation is to detect the reason for ineffective therapy, so a protocol must be in place to monitor problems.
– Monitoring and management of severe chronic respiratory failure, usually in patients with COPD, grade IV.

Expected Case Load

To estimate the number of patients that would benefit from this type of unit, certain considerations must be taken into account:

– The prevalence of home NIV application per 100 000 inhabitants in 1999, according to a study by de Lucas et al,[47] was 10.11 in Madrid, 9.15 in Extremadura, and 7.11 in Catalonia. The overall prevalence in Spain was 4.59 per 100 000.
– Such differences from one community to another and in the rate of initiation of patients into a therapeutic program depend mainly on a group's experience. Departments with staff specially assigned to NIV have over 100 patients in home ventilation programs and initiate more than 10 patients per year. Such units become referral centers for other health care areas and patient groups.
– For a typical area of 500 000 inhabitants we can suppose that the prevalence of home mechanical ventilation would be 5 to 10 patients per 100 000, that between 25 and 50 patients would be using NIV, and that 10 new patients would begin therapy each year.
– Plant et al[48] estimated that in an area with 250 000 inhabitants, the referral hospital would probably be using NIV with some 70 patients with exacerbated COPD per year. Extrapolating from these findings, an area with 500 000 inhabitants could expect to treat around 140 patients annually in need of NIV during the acute phase of exacerbated COPD.
– The creation of an intermediate care unit will require establishing procedures to manage in-hospital respiratory failure that are different from the usual protocols. Admissions to ICUs should decrease and patients should be transferred out of such units earlier as they step down to a less complex level of care. This will increase the expected patient load.[49]

Resources Needed

– A space designated to be used specifically for NIV, to be considered an intermediate care unit. Experts in such care recommend that 4 to 8 beds on the respiratory medicine ward be assigned.[42,43] The designated beds should be managed independently from those of the conventional ward. They will be reserved for admitting patients who need NIV due to respiratory failure that is acute, chronic or chronic and exacerbated; tracheostomized patients receiving endotracheal ventilation; patients adapting to NIV; and patients with respiratory insufficiency transferred from an ICU.
– Specialized staff who are expert in NIV.
– Interdepartmental relationships. The NIV unit must agree on protocols to use with patients also treated by the emergency department, the ICU, the postoperative recovery unit, the neurology department (for neuromuscular patients), the pediatric department (for transfers of patients reaching adulthood), other medical and surgical services, and other hospitals.

What a Department Will Gain by Setting Up a Unit to Support Hospital and Home NIV

– Leadership in an emerging subspecialty of respiratory medicine. Intermediate care units are an area of pneumology with a future. Experts on the subject believe that this working model is a strategic opportunity for the specialty of respiratory medicine. We are looking at a unique chance to expand our field's scope in an area we have been barred from until now because of lack of knowledge or strategic foresight.[45]
– Improved scope of training for resident physicians. The medical resident training program in pneumology will include the management of NIV, probably designated as a 6-month rotation for these trainees.[50] Availability of the appropriate infrastructure will increase the demand for training in the discipline. Such availability will be a differential characteristic for a teaching hospital.
– The specialist on call is an ideal complement for supporting the work of the NIV unit. Experts generally concur that all members of a respiratory medicine department should be able to manage simple, easy-to-use NIV devices, whereas more complex equipment should be the province of staff specially assigned to manage ventilation.[46]

REFERENCES

1. Díaz Lobato S. En defensa de la neumología. Arch Bronconeumol. 1999;35:467-9.
2. Durán-Cantolla J, Mar J, de La Torre Muñecas G, Rubio Aramendi R, Guerra L. El síndrome de apneas-hipopneas durante el sueño en España. Disponibilidad de recursos para su diagnóstico y tratamiento en los hospitales del Estado español. Arch Bronconeumol. 2004;40:259-67.
3. Díaz Lobato S, González F, Gómez Mendieta MA, Mayoralas Alises S, Martín Arechabala I, Villasante C. Evaluación de un programa de hospitalización domiciliaria en pacientes con EPOC agudizada. Arch Bronconeumol. 2005;41:5-10.
4. Salcedo A, Girón R, Beltrán B, Martínez A, Máiz L, Suárez L. Conferencia de consenso. Tratamiento antibiótico intravenoso domiciliario en la fibrosis quística. Arch Bronconeumol. 2003;39: 469-75.
5. Giner J, Casan P. La espirometría en el domicilio del paciente: una tecnología al alcance de la mano. Arch Bronconeumol. 2004;40: 39-40.
6. Grupo de trabajo. Conferencia de consenso sobre EPOC. Arch Bronconeumol. 2003;39 Supl 3:1-47.
7. Clotet J, Gómez-Arbonés X, Ciria C, Albalad J. La espirometría es un buen método para la detección y el seguimiento de la EPOC en fumadores de alto riesgo en atención primaria. Arch Bronconeumol. 2004;40:155-9.
8. León Jiménez A. Año 2002 y EPOC. Arch Bronconeumol. 2003; 39:377.
9. Díaz Lobato S, Mayoralas Alises S. Análisis de las publicaciones sobre la EPOC en Archivos de Bronconeumología 2 años después de la designación del Año EPOC. Arch Bronconeumol. 2004;40:575-9.
10. Sampablo Lauro I, Izquierdo J. ¿Cuál debe ser el papel del neumólogo en el tratamiento quimioterapéutico del cáncer de pulmón? Arch Bronconeumol. 2003;39:483-4.
11. Muñoz A, Rubio Etxebarria I, López-Vivanco G. ¿Y qué es lo mejor para el paciente con cáncer de pulmón?. Arch Bronconeumol. 2004;40:385-6.
12. Egea Santaolalla C, Carmona Bernal C. Apneas del sueño e insuficiencia cardíaca, ¿está ya todo claro? Arch Bronconeumol. 2003; 39:141-2.
13. Parra Ordaz O. Trastornos respiratorios del sueño y enfermedad cerebrovascular. Arch Bronconeumol. 2004;40:34-8.
14. Martínez García M, Galiano Blancart R, Cabero Salt L, Soler Cataluña J, Escamilla T, Román Sánchez P. Prevalencia de trastornos respiratorios durante el sueño en pacientes con ictus isquémico agudo. Influencia del momento de aparición del ictus. Arch Bronconeumol. 2004;40:196-202.
15. Blanco Pérez J, Blanco-Ramos M, Zamarrón Sanz C, Souto Fernández A, Mato Mato A, Lamela López J. Acromegalia y apnea del sueño. Arch Bronconeumol. 2004;40:355-9.
16. Miguel E, Güell R, Antón A, Montiel J, Mayos M. Síndrome confusional agudo asociado a apnea-hipopnea obstructiva del sueño y agravado por acidosis metabólica secundaria a acetazolamida oral. Arch Bronconeumol. 2004;40:283-6.
17. Masa Jiménez J, Rubio González M, Findley L, Riesco Miranda J, Sojo González A, Disdier Vicente C. Los conductores somnolientos tienen alta frecuencia de accidentes de tráfico asociados a exceso de RERA. Arch Bronconeumol. 2003;39:153-8.
18. Pacheco Galván A. Expectativas en el paciente respiratorio terminal. Arch Bronconeumol. 2004;40:51-3.
19. Avendaño M, Güell R. Rehabilitación en pacientes con enfermedades neuromusculares y con deformidades de la caja torácica. Arch Bronconeumol. 2003;39:559-65.
20. de Miguel Díez J, Izquierdo Alonso J, Rodríguez González-Moro J, de Lucas Ramos P, Bellón Cano J, Molina París J. Calidad de vida en la enfermedad pulmonar obstructiva crónica. Influencia del nivel de asistencia de los pacientes. Arch Bronconeumol. 2004;40:431-7.
21. Díaz Lobato S, Mayoralas Alises S, Gómez Mendieta M, Sanz Baena S, Martín Sánchez R, Díaz-Agero P. Análisis de los aspectos logísticos y organizativos de un crucero para pacientes con insuficiencia respiratoria crónica. La Expedición RESpIRA y el Crucero de la EPOC. Arch Bronconeumol. 2003;39:266-73.
22. Díaz Lobato S, Mayoralas Alises S. Ventilación no invasiva. Arch Bronconeumol. 2003;39:566-79.
23. Raurich J, Pérez J, Ibáñez J, Roig S, Batle S. Supervivencia hospitalaria y a los 2 años de los pacientes con EPOC agudizada y tratados con ventilación mecánica. Arch Bronconeumol. 2004;40:295-300.
24. Servera E, Sancho J, Zafra M. Tos y enfermedades neuromusculares. Manejo no invasivo de las secreciones respiratorias. Arch Bronconeumol. 2003;39:418-27.
25. Leger P, Bedicam JM, Cornette A, Reybet-Degat O, Langevin B, Polu JM, et al. Nasal intermittent positive pressure. Long-term follow-up in patients with severe chronic respiratory insufficiency. Chest. 1994;105:100-5.
26. Consensus Conference. Clinical indications for noninvasive positive pressure ventilation in chronic respiratory failure due to restrictive lung disease, COPD, and nocturnal hypoventilation: a Consensus Conference Report. Chest. 1999;116:521-34.
27. Estopá R, Villasante C, de Lucas P, Ponce de León L, Mosteiro M, Masa JF, et al. Normativa sobre la ventilación mecánica a domicilio. Arch Bronconeumol. 2001;37:142-9.
28. Nauffal D, Doménech R, Martínez García MA, Compte L, Macian V, Perpiñá M. Noninvasive positive pressure home ventilation in restrictive disorders: outcome and impact on health-related quality of life. Respir Med. 2002;96:777-83.
29. Lisboa C, Díaz O, Fadic R. Ventilación mecánica no invasiva en pacientes con enfermedades neuromusculares y en pacientes con alteraciones de la caja torácica. Arch Bronconeumol. 2003;39:314-20.
30. Laserna E, Barrot E, Belaustegui A, Quintana E, Hernández A, Castillo J. Ventilación no invasiva en cifoescoliosis. Estudio comparativo entre respirador volumétrico y soporte de presión (BIPAP). Arch Bronconeumol. 2003;39:13-8.
31. Masa JF, Celli BR, Riesco JA, Hernández M, Sánchez de Cos J, Disdier C. The obesity hypoventilation syndrome can be treated with noninvasive mechanical ventilation. Chest. 2001;119:1102-7.
32. British Thoracic Society Standards of Care Committee. Non-invasive ventilation in acute respiratory failure. Thorax. 2002;57:192-211.
33. Fernández-Guerra J, López-Campos JL, Perea-Milla E, Pons J, Rivera R, Moreno LF. Metaanálisis de la eficacia de la ventilación no invasiva en la exacerbación aguda de la enfermedad pulmonar obstructiva crónica. Med Clin (Barc). 2003;120:281-6.
34. Peter JV, Moran JL, Phillips-Hughes J, Warn D. Noninvasive ventilation in acute respiratory failure: a meta-analysis update. Crit Care Med. 2002;30:555-62.
35. Keenan SP, Sinuff T, Cook DJ, Hill NS. Which patients with acute exacerbation of chronic obstructive pulmonary disease benefit from noninvasive positive-pressure ventilation? A systematic review of the literature. Ann Intern Med. 2003;138:861-70.
36. Lightowler JV, Wedzicha JA, Elliot MW, Ram FS. Non-invasive positive pressure ventilation to treat respiratory failure resulting from exacerbations of chronic obstructive pulmonary disease: Cochrane systematic review and meta-analysis. BMJ. 2003;326:185.
37. Elliot MW. Non-invasive ventilation in acute exacerbations of chronic obstructive pulmonary disease: a new gold standard? Intensive Care Med. 2002;28:1691-4.
38. Pauwels RA, Buist AS, Calverley PM, Jenkins CR, Hurd SS, GOLD Scientific Committee. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. NHLBI/WHO Global Initiative for Chronic Obstructive Lung Disease (GOLD) Workshop summary. Am J Respir Crit Care Med. 2001;163:1256-76.
39. Elliott MW, Confalonieri M, Nava S. Where to perform noninvasive ventilation? Eur Respir J. 2002;19:1159-66.
40. Confalonieri M, Kodric M, Garuti G. Respiratory intermediate (high dependency) unit care in Europe: models of service provision. Monaldi Arch Chest Dis. 2001;56:248-53.
41. Confalonieri M, Gorini M, Ambrosino N, Mollica C, Corrado A, Scientific Group on Respiratory Intensive Care of the Italian Association of Hospital Pneumonologists. Respiratory intensive care units in Italy: a national census and prospective cohort study. Thorax. 2001;56:373-8.
42. Calle M, Rodríguez JL, Álvarez-Sala JL. Unidades de cuidados respiratorios intermedios. Rev Patol Respir. 2003;6:113-8.
43. Corrado A, Roussos C, Ambrosino N, Confalonieri M, Cuvelier A, Elliot M, et al. ERS Task Force: respiratory intermediate care units: a European survey. Eur Respir J. 2002;20:1343-50.
44. Echave J. Ventilación mecánica no invasiva en la insuficiencia respiratoria aguda. ¿Estamos preparados? Rev Patol Respir. 2004;7:59-60.

45. Torres A, Rodríguez Roisin R. Cuidados intensivos respiratorios. ¿Generales o especializados? Arch Bronconeumol. 1996;32: 263-4.
46. Servera E, Sancho J. Ventilación asistida ¿cuándo, dónde y por qué? In: Sánchez Agudo L, editor. Cuadernos de F.M.C. de la SEPAR. Avances en el manejo de la EPOC. Madrid: Medical & Marketing Comunications. 2002;4:9-21.
47. de Lucas P, Rodríguez González-Moro JM, Paz González L, Santa-Cruz Siminiani A, Cubillo Marcos JM. Estado actual de la ventilación mecánica domiciliaria en España: resultados de una encuesta de ámbito nacional. Arch Bronconeumol. 2000;36: 545-50.
48. Plant PK, Owen JL, Elliott MW. Early use of noninvasive ventilation for acute exacerbations of chronic obstructive pulmonary disease on general respiratory wards: a multicenter randomized controlled trial. Lancet. 2000;355:1931-5.
49. Echave-Sustaeta J, Pérez González V, Verdugo M, García Cosio FJ, Villena V, Álvarez C, et al. Ventilación mecánica en hospitalización neumológica. Evolución en el período 1994-2000. Arch Bronconeumol. 2002;38:160-5.
50. Álvarez-Sala J, Sánchez Gascón F, Agustí A, Díaz Cambriles M, Gómez de Terreros F, Lozano L, et al. Requisitos para la acreditación de unidades docentes en la especialidad de neumología. Arch Bronconeumol. 2003;39:42-4.