The use of non-invasive ventilation for acute respiratory failure in general medical wards: a regional Italian survey

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ABSTRACT

Non-invasive ventilation (NIV) is a rapidly spreading method in the last years even outside of intensive care units for the treatment of patients with acute respiratory failure. Its use in general medical wards in Italy and Europe is still largely incomplete and there are clear gaps in terms of organization, training, selection, and patient monitoring. If these gaps are filled, NIV has also proven to be effective in general medical wards, especially if they have a critical care area. This publication reports the data collected by an Italian regional survey on the use of NIV in internal medicine, highlighting positive and negative aspects.

Introduction

Non-invasive mechanical ventilation (NIV) is a rapidly spreading method in the last years for the treatment of various forms of acute respiratory failure (ARF). Under certain clinical conditions, it has proven to be effective in reducing the need for intubation, acute mortality, intensive care stay time, costs related to patient hospitalization, as well as in improving clinical and gas-analytic parameters.[1-3] Developed first within intensive care units in the hands of physicians to try to reduce complications related to tracheal intubation and invasive mechanical ventilation, its use has subsequently expanded into other areas, with documented effectiveness, between the emergency departments and general medical wards due to various factors:[4-7] i) the need to treat patients with ARF early to avoid deterioration of respiratory function; ii) the shortage of beds in intensive care; iii) the increasing number of elderly, fragile, immunocompromised patients, with comorbidities that are not eligible for intubation and therefore manageable outside intensive care units; iv) the growing evidence of the effectiveness of the method also in general medical wards if organization and logistics, training of dedicated staff, accurate patient selection, and adequate monitoring are present; v) evidence of the effectiveness of NIV also for palliative care, for symptom control.

The problem of setting where to make NIV has been debated for years in literature. The etiology and severity of ARF certainly play an important role in the choice but today also the changed epidemiology of patients, age and comorbidity, are decisive.[7-10] Lately, there were no documents of international consensus that defined the minimum criteria necessary to activate a NIV service within a hospital; today, however, the UK guidelines[2,4] define this area as level 2 of intensive care, a facility in which there is at least one dedicated nurse every 2 patients in NIV (during daylight hours), and where are managed patients with organ failure with appropriate methods to support it, according to the philosophy of *non-invasiveness*, with a valid local organization. These characteristics are well suited to the critical/semi-intensive areas born in recent years within some Units of Internal Medicine in Italy according to organizational models for intensity of care and care complexity, but also where these areas are not well structured the literature allows the use of NIV in internal medicine departments if organizational, logistical and training standards are respected.[5]

Despite this, the current use of NIV during ARF in medical units in Italy is still very heterogeneous.[11]

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Key words: Acute respiratory failure; general medical ward; non-invasive ventilation.

Conflict of interests: the authors declare no potential conflict of interests.

Received for publication: 18 January 2020.
Accepted for publication: 27 February 2020.

Licensee PAGEPress, Italy
Italian Journal of Medicine 2020; 14:62-68
doi:10.4081/itjm.2020.1260

There are places where the method is well known and used with a good organization, while there are other realities where the ventilator is not present and the management of these patients is always and in any case referred to other specialists; between these 2 extremes there are intermediate situations very different from each other although geographically close, sometimes also belonging to the same region. Surveys prior to this[12-16] showed that the main limitations related to the use of NIV in internal medicine relate to gaps in organization, training and resources.[17-23]

Materials and Methods

FADOI (Federation of Associations of Hospital Doctors on Internal Medicine) is a scientific society of Italian hospital internist physicians very active in the field of training and research, organized in autonomous regional directors and a central national organization. In 2018, the Emilia Romagna section decided to draw up a questionnaire on the use of NIV in ARF to be submitted to the units of internal medicine of the region to collect information on how and if they managed NIV. The questionnaire included 23 multiple-choice questions (see online Appendix 1 - in Italian), it was easy to understand and quickly filled in (a text file with pre-filled form fields was used), it was sent by e-mail to the directors of the internal medicine units of the Emilia Romagna region. 81 units were contacted, 33 responded by resubmitting the completed questionnaire. Collected data were transferred to an electronic spreadsheet in which statistical processing was carried out. The surveyed units did not present a specific pneumological *vocation*, only in 2 out of 33 cases there was a pulmonologist in the staff.

Results

The 33 units that responded to the survey were located in 30 different hospitals. Table 1 shows the percentage of units within the hospital based on the number of beds. Most of the units that responded to the questionnaire were therefore placed in small hospitals.

Table 2 shows the units that have joined the survey according to the province they belong to.

The estimated percentage of patients treated with NIV for ARF in one year was 7.36% of admissions, the average value of patients treated with NIV was 7.36% of hospitalizations with a range from 1 to 20% in the various centers. Out of the 33 centers that responded to the survey, only 1 stated that they did not use any NIV methods: it is clear that this report, in favor of centers using NIV, could be overestimated by the fact that these centers, already confident about the method, were more motivated to respond.

With regard to ventilation techniques and technologies: i) CPAP was used by 87% of the centers, 92% owned a CPAP device in the unit, usually a simple Venturi flow generator or a disposable system; ii) double-pressure methods (bilevel or pressure support ventilation) were used in 83% of the centers. Fifty-one percent of operating units said they had at least one ventilator (range 1-4), and 32% said they would use it *on loan* from other units if necessary. In 88% of cases ventilators consisted in simple, home-derived machines or NIV-specific ventilators; no centers used complex intensive care ventilators.

Table 3 shows the interfaces used by the different centers.

The average experience of using NIV was overall 11 years for CPAP (range 4-20), and 9 years for bilevel-pressure methods (range 3-18).

The main forms of acute or acute on chronic respiratory failure treated with NIV in the different centers are shown in Table 4. COPD exacerbation with

Table 1. Percentage of internal medicine units that joined the study based on the size of the hospital in which they were placed.

<150 B.	40%
151-250 B.	16.6%
251-500 B.	20%
>501 B.	23.3%

B., beds.

Table 2. Number of internal medicine units who joined the study based on the province they belong to in Emilia Romagna.

Bologna	11 units
Modena	9 units
Reggio Emilia	3 units
Ravenna	1 unit
Rimini	5 units
Forlì Cesena	1 unit
Parma	2 units
Piacenza	1 unit

Table 3. Types of interfaces used and their prevalence.

Facial Mask	100%
Total Face	20%
Nasal Mask	10%
Helmet	3.3%

respiratory acidosis and acute cardiogenic pulmonary edema, were treated in all centers. These are the forms of ARF that are most prominent in terms of effectiveness of NIV even outside of intensive care.

In terms of local organization, only 35% of units had a well-defined and structured critical/semi-intensive area within the ward where they could manage patients on NIV. In 65% of cases, therefore, patients were ventilated in traditional general medical ward. Diagnostic and therapeutic path on management of ARF were present in only 35% of the centers, and in this case the internist was not involved in the design of the path that involved other specialists (emergency, resuscitators, pneumologists) instead.

Among the medical staff of the units that implemented NIV, there was an *expert* internal physician in only 62% of cases. The prescription of ventilator treatment and monitoring was carried out independently by the internists of the ward only in a minority of cases: more often the treatment consisted in a co-management with other specialists (Table 5).

The presence of protocols within the medical unit or hospital for the management of patients with ARF on NIV was present in only 46% of cases; these protocols were complete in their essential parts as defined by the guidelines only in 20% of cases. Table 6 shows the single components of the protocols in relation to the percentage of centers that covered them.

With regard to patient monitoring during ventilator treatment, this was completed, according to the guidelines, only in 13% of cases. 40% of medical units reported the use of less than 4 parameters. Table 7 shows the different monitoring parameters indicated as essential by the literature in relation to the percentages of the centers that used them.

The *NIV Team* provides for the involvement of all specialists of a single hospital dedicated to the management of the patient with ARF on NIV, who must necessarily *speak the same language*, be trained in a homogeneous way, in order to give continuity to the treatment of the patient. Depending on the size of the hospital the following healthcare professionals may be involved: emergency physicians, resuscitators, pneumologists, internists, cardiologists, and others. Its function, essential for the effectiveness of treatment, has been defined by the guidelines for years. In our survey, the *NIV team* was present in only 21% of NIV practice centers, in no hospital there were defined network models such as *Hub & Spoke* for example for the rapid centralization of the most critical patients or on the contrary for the reliance on the hospital of territorial competence for stabilized patients. In most cases there was no therapeutic continuity even with regard to the technologies used (masks, circuits, different ventilators).

The most common complications related to NIV

Table 4. Types of acute respiratory failure and their prevalence in different medical units.

Acute exacerbation of chronic obstructive pulmonary disease	100%
Acute cardiogenic pulmonary edema	100%
Pneumonia	52%
Inhalation	46%
Immunodepressed	41%
DNI (patient not to be intubated)	39%
neuromuscular disease	33%
Acute respiratory distress syndrome	12%
Asthma	9%

Table 5. Prescriptive and non-invasive ventilation treatment monitoring responsibilities in the different centers involved in the survey in relation to the different specialists involved.

		Autonomy	Co-management
CPAP	**88.5% Internist**	**51.5%**	22% Anesthesiologist
	7.5% Pneumologist		11% Pneumologist
	4% Anesthesiologist		4% Emergency Physician
Bi-level	**65% Internist**	**19%**	24% Anesthesiologist
	15% Pneumologist		18% Pneumologist
	20% Anesthesiologist		4% Emergency Physician

treatment and their overall prevalence in our survey are shown in Table 8. 40% of medical units report more than 4 frequent complications. As you can see, it is a higher prevalence than the data reported in literature in other settings; this can be interpreted as a lack of local organization and staff training.

The involvement of nursing staff is essential, therefore, staff training has always been regarded by literature as one of the secrets of NIV success; it is fundamental to ensure a successful treatment, and also in terms of motivational aspects. In detail: i) training at the beginning of the center NIV experience: 15% of the centers did not complete initial training, 60% carried it out within the hospital, only 25% even with events outside the hospital; ii) periodical Retraining on a minimum annual basis: only 36% of units have been reported; iii) the involvement of nursing staff was considered optimal by 75% of the centers surveyed; iv) the feeling, the awareness of the effectiveness of NIV is still considered high, 100% of the physicians who answered the questionnaire have this opinion.

Table 6. Aspects covered in non-invasive ventilation management protocols and their prevalence in the different medical units.

Patient selection	100%
Indications/Contraindications	86%
Ventilation mode	86%
Prescription therapy card	46%
Definition of the non-invasive ventilation trial	40%
Definition of failure	73%
Monitoring	73%
Weaning	46%

Table 7. Monitoring parameters and their prevalence in the different medical units.

Continuous electrocardiogram (pt with arrhythmia)	40%
SpO_2 continuously	60%
Arterial blood pressure	68%
Heart rate	68%
Respiratory rate	64%
Neurological score	32%
EGA	100%
Nursing assessment	92%
Medical evaluation	92%

Table 8. Prevalence of non-invasive ventilation complications most frequently reported by the different medical units in the study.

Mask pressure injuries	68%
Excessive agitation	52%
Excessive air leaks	40%
ventilator malfunction	8%
Absolute rejection of treatment	36%
Poor collaboration of nursing staff	4%
Risk of inhalation/vomiting	12%
Risk of sinusitis/conjunctivitis	4%
Mucous dryness	36%
Claustrophobia	8%
Insomnia	12%
Risk of delaying intubation	12%
Gastric détente	4%

Discussion

The data collected in this Italian regional survey are essentially in line with what is reported in the literature in similar surveys conducted in recent years both in Italy and abroad,[11-23] with the particularity that this study, unlike others, is conducted exclusively in medical units that did not have a specific pneumological address: the NIV is rapidly spreading in internal medicine but still with non-homogeneous distribution even in limited geographical areas. This is often due to the lack of structured pathways for the patient with ARF by hospitals, and the management of these clinical conditions is thus left to the spontaneous initiative of the individual centers and to the local organization. In many internal medicine realities, despite the enthusiasm towards the method, there are still obvious gaps in terms of organization and logistics.

Interestingly, the autonomy of prescription and management of treatment with NIV, as well as the ownership of ventilators by the medical unit, the percentage of patients treated and a better organization were inversely related to the size of the hospital in which the medical ward was located. This makes, at least in Emilia Romagna, small and peripheral hospitals generally more *experienced* and *autonomous* in managing NIV; this is easily understood if we consider the role of internal medicine outside the large centers, which must often include the emergency medicine or at least supply the lack of skills not present in the hospital. On the other hand, in internal medicine wards located in large centers, NIV is less widespread and the team's skills are not adequately developed; this because, in large hospitals, there are *other* specialists involved in the management of the patient with ARF, often in intensive care setting (generalist or specialist intensive care units, emergency medicine, step down

units) and if the patient on NIV is managed in a medical ward, the internist is not the central figure but the other specialist as consultants (pulmonologist, resuscitator, emergency physician). Of the 7 internal medicine units located in hospitals with more than 500 beds participating in the study, 3 do not practice Bilevel ventilation but only CPAP occasionally, 3 practice Bilevel ventilation but do not have their own ventilators, therefore the ventilator is brought to the ward in case of need by the specialist involved in the prescription of the treatment (typically anesthesiologist or pneumologist). A medical unit finally stated that it did not practice any NIV methods. In most cases these medical units are located in University Hospitals where, in case of need of NIV, the patient is preferably transferred to other structures (usually intensive care). This particular situation highlights the problem of training on these issues of young internists who are often not so satisfied with the educational needs on topics of absolute relevance for modern internal medicine.

Another very important fact that emerges from this survey is that even the centers considered the most *expert* in NIV and that treat a large number of patients have obvious gaps in terms of organization and logistics. Doing NIV out of a protected environment such as intensive care or step-down unit and especially in general medicine wards where the personal/patient relationship is unfavorable imposes a high-level organization. Although guidelines[2] suggest we preferentially manage these patients within critical areas, this is still not possible in all internal medicine units: the literature also tells us that many of the studies conducted in wards without critical areas[10,24-28] showed NIV success rates similar to those reported in other studies conducted in intensive care units, if proper patient selection has been implemented and high organizational and safety standards are guaranteed. It is therefore necessary to implement aspects of the organization and management of treatment in the medical department such as: i) the presence of a physician more *expert* that acts as coordinator of the working group, granting his/her availability for the discussion of the most critical cases; ii) facilitating the development of therapeutic diagnostic pathways and clinical networks on the Hub & Spoke model within the hospitals for the rapid centralization and easy access to intensive care for critical patients; iii) to promote the establishment of multidisciplinary and multi-professional *teams* dedicated to patient management during ARF in NIV within the hospital. Not only the different medical specialists but also the nurses whose role, in the success of this method, is undisputed; iv) implement the development of internal protocols in the medical unit covering the different aspects related to treatment with NIV: correct patient selection, indications/contraindications, setting of ventilator parameters, prescription card of treatment, definition of *trial* and *failure*, elaboration of an individualized care plan for each patient, weaning techniques; v) improve and refine patient monitoring in NIV, which must not be particularly aggressive and complex, but respond to the philosophy of non-invasiveness and simplicity, and at the same time it must be precise and timely. Standalone bedside multi-parameter monitoring systems but with transmission of data and alarms to control unit and portable systems (tablets) are well suited to the structure of a general medical ward without necessarily forcing the design of a critical area. Limiting invasiveness as much as possible, in this perspective the assessment of blood gases can also be carried out on capillary sampling, CO_2 can also be monitored by transcutaneous way ($TcPCO_2$);[2] vi) to facilitate the adaptation of the patient to treatment and synchrony with the ventilator, through the choice of a correct interface, proper nursing, the adoption of protocols and sedation techniques, a correct setting of ventilation parameters, minimizing complications and side effects.

Finally, another aspect to be refined within the operators who devote themselves to the NIV in internal medicine is the specific training, which, as evidenced by the data of this survey, is often lacking. Staff must be trained not only at the beginning of their experience with NIV but must also be trained periodically with moments of refresher courses that involve practical aspects. Healthcare facilities should be encouraged to organize internal training and clinical audits on these issues, but they should also make use of high-quality external training events (scientific societies or other companies with documented experience in the field). The recent and well-established turnover of medical and nursing staff in internal medicine requires further attention to continuous and periodic training.

In conclusion, we believe that some final considerations regarding the use of NIV in internal medicine are necessary, which emerge spontaneously from the data of this survey. The changing epidemiology of medical patients today, which includes elderly, complex, fragile and comorbidity patients, together with the lack of beds in intensive care units, has meant that, as needed, internal medicine approached the NIV: a large proportion of patients with ARF are managed in general medicine wards and in any case outside of intensive care because they would not be eligible for intubation and invasive ventilation (sometimes also by express will), and this trend is likely to increase in the next years especially for those patients with ARF potentially responsive to NIV (*e.g.* COPD exacerbated with respiratory acidosis, acute cardiogenic pulmonary edema).

While large randomized controlled trials on the effectiveness of NIV in the different causes of ARF[29,30] have always enrolled relatively young patients without

relevant comorbidities trying to demonstrate important endpoints (such as reduction in the need for intubation and mortality), today observational data from the use of NIV in the *real world*[4,31-33] tell us that we often treat completely different patients (who by characteristic and severity would have been excluded from large trials) and with different goals and results: in these patients NIV should aim to reduce symptoms (breathlessness), to correct gas exchanges, to overcome the acute event, well aware that the survival of the patient often depends on age and other chronic clinical conditions with unfavorable prognosis. Here too the role of internal medicine is inevitable, palliative treatment of patients with end-stage pathologies, not only cancer, is now an important part of the daily work of the internist, and the literature tells us that NIV can play an important role.[3]

Today, in patients with ARF, the choice of respiratory support, non-invasive *versus* invasive, represents a crucial factor, not only in terms of severity and etiology of the ARF (probability of favorable response to NIV) but also in terms of patient's characteristics (age, comorbidity, will) and of organization/local resources.

Conclusions

NIV in ARF is also effective in general medical wards if certain fundamental rules are respected, such as: i) the correct selection of patients; ii) the knowledge that it is not an alternative to invasive ventilation if this is indicated; iii) early application and proper monitoring; iv) high standards for organization, training and logistics.

The survey conducted by FADOI Emilia Romagna in the internal medicine units of the region showed that: i) bi-level pressumetric ventilation methods are less widely available globally but clearly prevalent in small peripheral hospitals; ii) CPAP is more widespread in general and for longer; iii) small centers are more *experienced*, *organized* and *autonomous*; iii) co-management with other specialists is frequent, especially in large centers; iv) treatment setting: only 35% ventilate in *critical area*, 65% in traditional ward; v) only half of the centers have their own ventilators, generally *simple* of home derivation; vi) the experience on NIV is not high, limited in time, but there is enthusiasm and desire to learn; vii) predominantly treated forms of ARF are: exacerbation of COPD, acute cardiogenic pulmonary edema; viii) there are important gaps in terms of staff organization and training: internal protocols, NIV team, *expert* internal physician, therapeutic diagnostic pathways, Hub & Spoke models, monitoring, involvement of nursing staff, basic training and periodic retraining.

For an effective NIV treatment it is important *how* you do it, not *where*. In order to further spread these methods in Italian internal medicine units, it is desirable to try to further homogenize different realities and filling the shortcomings currently present. In this direction, the role of scientific societies, which have always been involved in research and training, can be of great importance.

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