Noninvasive Ventilation Outside the Intensive Care Unit From the Patient Point of View: A Pilot Study

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BACKGROUND: Noninvasive ventilation (NIV) is increasingly utilized outside the ICU for patients with acute respiratory failure. However, success and failure risk factors and patient safety aspects have been poorly explored in this setting. So far, no study has evaluated the perspective of the patient, despite the known high relevance of patient participation for NIV success. METHODS: We prospectively interviewed (following a standard questionnaire) the patients successfully treated with NIV for acute respiratory failure outside the ICU. Subjects were interviewed 24–48 hours after NIV suspension. Exclusion criteria: NIV failure, patient not competent, patient unwilling to participate in the study, patient transferred to the ICU. RESULTS: Forty-five consecutive patients were included in the study. Only 20% participated in the initial setting of NIV parameters. More than 40% reported they never had the possibility to discuss the NIV treatment. Eighty percent reported they were never asked to try another interface. All subjects knew how to call for help, but only one fourth had been trained to remove the mask, and 22% reported not being able at all to remove the mask if needed. One half of the subjects reported having received help immediately when needed, but 15% waited more than 3 min. All subjects reported complications, and 18% reported respiratory worsening while on NIV. CONCLUSIONS: Subjects reported a low level of involvement in the initial setting of NIV treatment, low satisfaction about communication with the caring staff, and a suboptimal safety level in case of emergency. *Key words: noninvasive ventilation; acute respiratory failure; patient safety; patient satisfaction.* [Respir Care 2012;57(5):704–709. © 2012 Daedalus Enterprises]

Introduction

Noninvasive ventilation (NIV)[1-3] is increasingly used for patients with acute respiratory failure (ARF). Even if ICUs are considered the safest place in which to treat patients with NIV, the shortage of intensive care beds is very common worldwide and has forced NIV application outside the ICU.[4-7] An increasing confidence in the technique,[8] the opportunity to treat ARF in a more responsive phase,[9] and psychological and economic considerations[8,10] contribute to NIV application outside the ICU; the positive results from the first pilot studies reinforced this trend.[7,11,12] Several surveys from many countries[13-17] reported NIV utilization in ordinary wards.

However, NIV use outside the ICU remains controversial.[18-20] Safety aspects have been poorly explored. Furthermore, NIV can have a very high failure rate (up to 80% in ARDS),[2] and delay in ICU admission or tracheal intubation should be carefully avoided.[20,21] A recent survey showed that the ordinary ward nurses applying NIV perceived a high incidence of technical problems or complications[22]; on the other hand, 2 surveys[13,17] reported a perceived modest mean success rate. Given the limited available data (in particular high quality data from pro-

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The authors have disclosed no conflicts of interest.

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DOI: 10.4187/respcare.01474

spective systematic data collections) on NIV safety and efficacy when applied outside the ICU, a prudential approach is required and further research warranted.

To our knowledge, to date no study has evaluated the perspective of the patient, despite the known high relevance of patient adherence for NIV success. For this reason we prospectively interviewed patients treated with NIV for ARF in this setting.

QUICK LOOK

Current knowledge

Noninvasive ventilation (NIV) is more frequently being used outside the ICU, for a variety of pulmonary conditions. The success and failure risk factors in this group are poorly defined.

What this paper contributes to our knowledge

Patients receiving NIV outside the ICU were rarely offered a second interface, and only 40% were asked about their options for NIV treatment. All patients were trained to call for help, but only a small percentage (25%) had been instructed to remove the mask when in distress. Most patients reported receiving assistance immediately after calling for help.

Methods

The study took place from August to December 2010, at the San Raffaele Hospital, a teaching institute with 1,100 beds, after ethical committee approval and patients' written informed consent. In our institute, NIV treatments outside the ICU started more than 15 years ago. The organizational aspects of the local NIV service have been described in detail elsewhere.[7] Briefly, the decision to prescribe NIV is reserved to the anesthesiologist on duty, who serves on the medical emergency team (MET)[23] and is always present in the hospital. The MET is dedicated to critical or pre-critical patients in the emergency department or in the wards, and to their follow-up. When called for patients with ARF, the MET evaluates if NIV is indicated. Patient monitoring is performed by the MET in conjunction with ward staff. At the end of the first visit, the MET plans the timing of his/her further visits (during which he/she can change the ventilatory parameters, or decide to intubate the patient, or stop NIV after improvement), and the intensity and frequency of monitoring (which is mainly performed by the ward staff). The MET also decides if the patient can be treated safely in the ward or if admission to the ICU for better monitoring is needed.

All healthcare personnel know the beeper number and are authorized to call the MET. Ward staff physicians are responsible for summoning the MET, and they are commonly involved by the MET in the decision to start NIV; in the following days they cooperate with the MET in the clinical monitoring of the patient; they participate in the evaluation of the trend of the patient and in the choice of what to do in case of NIV failure. The timing of NIV suspension in case of success is usually a shared decision. A local protocol for NIV application is in use. Both CPAP (Vital Flow 100, Vital Signs, Totowa, New Jersey) and ventilators for bi-level positive airway pressure (BPAP) (Vivo 40, Breas Medical, Mölnlycke, Sweden) are available. As the interface, a face mask is always applied; different models and sizes are available.

A questionnaire was developed by a group of anesthesiologists experienced in NIV. The questionnaire largely mirrored the instructions included in the local protocol, to explore if they were followed. Also, a checklist describing the steps to be followed when starting NIV was present on every NIV device well before the study. As comprehension by patients was expected to be potentially difficult or ambiguous, we decided not to simply administer the questionnaire, preferring to interview the subjects while reading and explaining the questionnaire. Subjects were interviewed after 24–48 hours of NIV suspension. Inclusion criteria were: adult patients on ordinary wards successfully treated with NIV for ARF. NIV success was defined as suspension of NIV after resolution of the ARF (hence, without considering following outcomes like hospital mortality). Exclusion criteria were: NIV failure (with subsequent tracheal intubation or death), patient not competent, patient unwilling to participate in the study, patient transferred to the ICU, starting of chronic NIV treatment. To assure a homogenous approach, the interviews were conducted by only 3 physicians (EM, EN, and GL), all of whom were initially supervised by the main investigator (LC). After the study was explained to the patient and the written informed consent was obtained, the interview took place in the subject's room and lasted about 30 minutes on average; if the patient agreed, his/her family members were allowed to participate.

Results

During the study period, 45 consecutive patients (26 males, 19 females, mean age 67.5 years) were interviewed. No eligible patient refused to participate in the study. The mean duration of the NIV treatment was 5.6 $\pm$ 4.4 days. The CPAP device was used in 18 cases, the portable ventilators for BPAP in 26; one subject was initially treated with the CPAP and then with BPAP. The medicine ward was the most common setting (22 subjects), followed by the abdominal surgery ward (7 subjects) and the vascular surgery ward (4 subjects). The most frequent causes of ARF were pneumonia (14 cases), cardiogenic pulmonary edema (11 cases), and COPD exacerbation (5 cases).

Table 1. Patient Involvement in the Starting Phase (n = 45)

Question	Percentage
Did you have the opportunity to express your opinion about starting NIV?	
Yes	24
No	69
I can't remember	7
Was a nurse present when NIV was initially applied?	
Yes	53
No	13
I can't remember	34
Have you been informed about the NIV treatment from:	
The ward doctor	10
The anaesthesiologist	52
A ward nurse	5
A next of kin	0
I can't remember	33
The explanation about the treatment was:	
Clear, and it allowed me to accept the treatment with confidence	45
It was not complete	22
It was unclear and too difficult for me	15
I can't remember	18
Did you contribute to the initial setting of the ventilatory parameters?	
Yes	20
No	67
I can't remember	13

NIV = noninvasive ventilation

In Table 1 the questions regarding the initial phase of the treatment are summarized; in particular, the patient involvement was evaluated. In Table 2 we report the questions exploring the following phases: the ward staff preparation for the planned treatment and the device's functioning, the communication opportunities, the possibility to change interface, the observation of the planned treatment, the subject's opinions on the number and length of the NIV cycles, and the subject's perception on the time of NIV suspension. Finally, in Table 3, questions on patient safety issues are reported: the ability to remove the mask and to call for help if needed, the timeliness of ward staff response in case of emergency, and complications.

Discussion

This is the first study evaluating NIV treatments outside the ICU from a patient perspective, offering original data on "real life" treatments. A low grade of patient involvement and relevant safety issues are the main findings, suggesting the need to improve patient training and communication; a better patient adherence to the treatment, and hence a better efficacy, could be expected.

Subjects reported a very low level of involvement. Even if all enrolled subjects suffered from ARF and required NIV urgently, leaving only a short time for communication, it is well known that the patient acceptance of and cooperation with initial setting are very important to the success of the treatment.[24] A too rushed initial phase, or a paternalistic approach, seem to negatively characterize the first contact between the patient and the MET. However, a large percentage of subjects remembered almost nothing about the start of the treatment, perhaps confirming severe initial conditions not allowing long discussion and posing some doubts on patient competency in that phase, which is a relevant issue for researchers needing a written consent. The reliability of subjects' memories about the very initial period of treatment with NIV deserves further investigation.

Also, subjects seemed too often not satisfied about communication. In particular, it is alarming that the majority reported they were never asked to try another interface: interface choice is crucial to patient comfort and NIV success,[25] and different sizes and models were always available. We can speculate that the MET suffered a lack of time to dedicate to NIV patients, or lacked the training to deeply understand the role of interface choice or rotation among different interfaces. The issue is of particular relevance, as analgosedation to improve patient tolerance to NIV[26-28] is unsafe in the setting of an ordinary ward. Should the patient become intolerant of the mask, NIV failure is very likely.

The main finding of our study is most likely related to patient safety. Most subjects said that they were not trained on mask removal or they were not able at all to remove it. Patient clinical and instrumental monitoring on an ordinary ward is limited,[18,29] and the ability to remove the mask in case of vomit or ventilator malfunctioning should be assured and verified. The timeliness of assistance in case of emergency seems suboptimal if compared to an ICU: patients with severe ARF (in particular if hypoxemic) should be admitted to better monitored and staffed units. Interestingly, all subjects reported at least one complication, and 18% reported a respiratory worsening while on NIV, indirectly confirming the need to improve clinical monitoring.

NIV application for ARF outside the ICU has been reported from many countries. Even if the main cause of NIV use in ordinary wards is the shortage of ICU beds, psychological and economic reasons play a relevant role. Furthermore, NIV can be applied with a high success rate in patients who are commonly not admitted to ICU.[2] Very few studies have reported data on NIV efficacy and safety when applied outside the ICU[7,12,30,31]: however, it seems a promising field of application, and a growing use in this setting can be expected. Every effort should be made to identify the best organizational modality and the required staff training.[32] When this study took place, no training on NIV was offered to wards staff and the MET. The findings of this study clearly show that the local protocol was not adequately applied, so a formal 5-hour course was intro-

Table 2. Patients' Opinions on NIV Treatment After the Initial Phase (n = 45)

Question	Percentage
In your opinion, were the ward physicians prepared about NIV ventilator functioning, duration, and daily number of treatment cycles?	
Yes, always	41
Yes, often	13
Only sometimes	20
No	13
I can't remember	13
In your opinion, were the ward nurses prepared about NIV ventilator functioning, duration, and daily number of treatment cycles?	
Yes, always	59
Yes, often	12
Only sometimes	23
No	6
In the following days, did you have the opportunity to discuss NIV treatment with the ward physician?	
Yes, and his/her answers were clear and complete	56
Yes, but his/her answers were insufficient	2
No	42
In the following days, did you have the opportunity to discuss NIV treatment with the anaesthesiologist?	
Yes, and his/her answers were clear and complete	55
Yes, but his/her answers were insufficient	0
No	45
Did you have the opportunity to express your opinion on the NIV treatment?	
Yes, always	59
Only sometimes	11
No	30
Were you given the possibility to try a different interface?	
Yes	20
No	80
Were the prescribed schedule and duration of NIV cycles observed?	
Yes, always	80
Yes, often	13
Only rarely	7
When the plan was not observed, which explanation did you receive?	
None	12
Lack of personnel, other duties	4
Ward personnel reported not to be informed of the ventilatory plan	0
Other adequate explanations	1
I can't remember	83
Would you have preferred:	
More daily cycles but shorter	51
Less daily cycles but longer	13
Daily frequency and cycle duration were correct	36
In your opinion, the NIV treatment was stopped	
At the correct time	89
Too late	4
Too early	7

NIV = noninvasive ventilation

duced. The course addresses the principle of NIV first in lectures, and then trains the participant on the pertinent skills through workshops using the actual NIV devices and full-scale manikins. Perhaps technical aspects (ventilators, interfaces) need to be adapted to this less monitored and less staffed environment. To optimize NIV treatments in ordinary wards, good communication with the patient, sufficient time spent to obtain his/her cooperation, a constant attention to his/her needs, and the choice of the most comfortable interface are as (or even more) important than setting the best ventilatory parameters[24] to improve the success rate. Continuously or at least periodically collecting patient perspectives on NIV treatment could be highly useful and complementary, not redundant, to commonly

Table 3. Safety Issues About NIV Treatment (n = 45)

Question	Percentage
If needed, were you able to quickly remove the NIV interface?	
Yes, and I was tested by the physician	18
Yes, I was tested by a nurse	7
I probably was, but nobody tested me	53
No	22
If needed, were you able to call for help?	
Yes	100
No	0
If a real emergency happened during an NIV cycle, did you receive help quickly from the ward staff?	
Yes, it was immediate	47
Yes, but I waited more than 3 min	11
No, I had to wait for a long time	4
I can't remember if a real emergency happened	38
If a real emergency happened during an NIV cycle, did you receive help with more latency:	
In the morning	0
In the afternoon	2
During the night	0
Without differences among day periods	53
I can't remember if a real emergency happened	45
If you suffered from complications, which was the worst one?	
Claustrophobia	35
Skin injuries due to the mask	18
Dyspnea, worsening of respiration during NIV	18
Other	29*

* Mouth dryness, 5 cases; eyes dryness, 4 cases; nausea, 2 cases; vomit, 1 case; excessive noise, 1 case.
NIV = noninvasive ventilation

performed data collection on NIV, and even to surveys performed among the ordinary ward personnel.[7,22]

We are not aware of studies similar to the present but performed in the ICU, even if hundreds of researchers have evaluated NIV in this setting. Considering that NIV is applied mainly in the ICU worldwide, such a study would be highly useful. In our opinion, the results would be quite different from ours, and different problems could be reported. Our findings may also be in part common to other intensive treatments performed in ordinary wards. There is an international trend to bring critical care ("without walls") outside the ICU, but we have not yet adequately studied the limitation of communication with critically ill patients outside the ICU: surely we should observe this phenomenon from the patient perspective, to improve communication and safety. A randomized controlled trial comparing patients whose perspective is actively investigated during their treatment with NIV to a control group not actively interviewed could verify if a better communication really impacts outcomes. Another still unexplored field of investigation is the impact of NIV on medium- and long-term patient perception of his/her level of health, applying validated questionnaires like the 36-item Medical Outcomes Study Short-Form questionnaire (SF-36).

The present study has some limitations. It is monocentric, and strictly reflects the characteristics of the local NIV service organization, in particular the role of the MET (who take care of a large number of patients outside the ICU, and are not dedicated to NIV) and the suboptimal training level of the ward staff: nevertheless, it clearly demonstrates how useful the patient perspective is as part of a continuous quality improvement program. Also, our organizational modality (an NIV service managed by the MET) may be not so unusual, and our findings could be of help to other institutions; recently a very similar organization was reported in 2 clinical studies.[12,31]

The questionnaire we used was not validated; however, it was developed by experts in the field of NIV outside the ICU and it underwent a brief test phase before the final version. The fact that subjects were interviewed allowed them to ask for explanation when needed, and at the same time the investigators were taught to do their best to ascertain that the subject had understood the question, and that they in turn understood the response. Competency and short-term memory were evaluated by the investigators in accordance with the caring physicians, but without applying a validated tool. However, a prudential approach was followed, asking the subject to make an affirmation only if he/she clearly remembered what happened.

The present study enrolled a selected subgroup of patients, in which NIV was successful and interrupted due to respiratory improvement. We are aware that much useful additional information could come from patients who experienced NIV failure, in particular when caused by interface intolerance or inadequate planning of treatments. However, we considered it unreliable to interview patients while intubated or after days in the ICU and tracheal extubation. We are aware that by interviewing all treated subjects the results could possibly have been worse. Some of our data could be considered as very informative "near misses" in which NIV failure did not happen but could have.

Finally, we did not collect full data about all NIV treatments, so we cannot know if the urgency of the problems reported by patients resulted in a high rate of NIV complications or failure rate. From a previous study[7] we know that the real failure rate is quite low and major complications rare: nevertheless, we believe that a better comprehension of patient point of view will help to further improve the quality and efficacy of our service and patient satisfaction.

Conclusions

In the present pilot study, subjects reported a low level of involvement in the initial setting of ventilatory param-

eters and in searching for the best comfort, a low satisfaction about communication with the caring staff, and a suboptimal safety level in case of emergency.

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