Crit Care Nurs J. 2018 February; 11(1):e65300. doi: 10.5812/ccn.65300.

Published online 2018 February 26. **Research Article**

Patient Compliance to Non-Invasive Ventilation in Sub-Intensive Care Unit: An Observational Study

Alessia D'Orazio,[1,*] Antonella Dragonetti,[1] Giorgio Campagnola,[2] Cristina Garza,[3] Fabrizio Bert,[4] and Simona Frigerio[5]

[1]High Dependency Unit, San Giovanni Bosco Hospital, Torino, Italy
[2]A and E Department, High Dependency Unit, Humanitas - Gradenigo Hospital, Torino, Italy
[3]Department of Pneumology, Subintensive Care Unit, Umberto I Hospital, Torino, Italy
[4]Hygiene and Public Health, Department of Public Health Sciences and Pediatrics, University of Torino, Torino, Italy
[5]Health Professions Direction, AOU Citta Della Salute e Della Scienze, CTO Hospital, Turin, Italy

[*]*Corresponding author*: Alessia D'Orazio, Via Azuni 5, 10151 Turin, Italy. Tel: +39-3899673494, E-mail: alessia-dorazio@libero.it

Received 2017 December 18; **Revised** 2018 February 22; **Accepted** 2018 February 24.

Abstract

Background: The success of non invasive ventilation depends on many factors and effective delivery requires team work. Information on the therapeutic program must be sustained by healthcare staff and family.
Objectives: Investigate the clinical and care factors that affect the level of patient compliance to non invasive ventilation.
Methods: A prospective, observational and multicentre study was conducted between November 1, 2015 and February 15, 2016 in three sub-intensive wards. A data collection tool was created with the working definition of "Patient intolerant to non invasive ventilation" and a structured interview was conducted to investigate patient experience of NIV. Statistical analysis was conducted with the STATA MP13 software.
Results: Coordination of patient-ventilator interaction prevents intolerance (OR = 0.68, 95% IC 0.46 - 0.98; P = 0.04). Overweight and obese patients showed a higher probability of intolerance to non invasive ventilation with respect to underweight and normal weight patients (OR = 0.53, 95% IC 0.34 - 0.82; P = 0.005). Patients with a higher probability of intolerance experienced a NRS level of 4/5 (OR = 1.76, 95% IC 1.30 - 2.41; P $\leq$ 0.001) while receiving continuous treatment (OR = 1.26, 95% IC 1.04 - 1.53; P = 0.019). Patients in open-space settings experienced less intolerance (4.7 SD $\pm$ 1.2) with respect to patients in single rooms (2.5 SD $\pm$ 0.9). Anxious patients developed more intolerance than calm and informed patients (OR = 7.39, 95% IC 3.19 - 17.13; P $\leq$ 0.001)
Conclusions: Compliance to non invasive ventilation depends on multiple factors, including relational aspects that affect treatment success. Attention to patient comfort, pain control, and collaboration with the caregiver appear to have the most influence on patient compliance.

Keywords: Nurses, Patients, Noninvasive Ventilation, Intensive Care Units, Compliance, Masks

1. Background

The utilization of noninvasive mechanical ventilation (NIV) has become one of the most important developments in the field of mechanical ventilation over the past 2 decades. The use of NIV during acute respiratory failure has increased since the late 1990s for all diagnoses (1, 2).

The use of NIV, as an alternative method of ventilatory support, reduces the need for intubation, a procedure that can lead to multiple complications, and can reduce the incidence of infectious complications (1-3). This method is now increasing and being used in Emergency departments and hospital wards and reducing mortality and hospital stays (4-7).

However, NIV is associated with frequent uncomfortable or even life-threatening adverse effects, and patients should be thoroughly screened beforehand to reduce potential severe complications.

All major NIV complications are: pressure ulcers/necrosis (nasal bridge), facial or ocular abrasions, claustrophobia, anxiety, agitation, air swallowing with gastric/ abdominal distension potentially leading to vomiting and aspiration, barotrauma, hypotension related to positive intrathoracic pressure, oronasal mucosal dryness, increased intraocular pressure, impaired communication, and impaired nutrition (2, 3).

Importantly, recognize that certain parameters may predict successful noninvasive ventilation or failure of noninvasive ventilation (1, 5, 8).

The success of NIV depends on many factors: competence of the healthcare staff, correct patient selection, choice of appropriate interface, patient care setting and presence of care-giver (1, 5, 8). Effective delivery of NIV requires the work of a multidisciplinary team, information on the therapeutic program must be shared and sustained by healthcare staff and family relatives (9, 10).

A correct interface decreases the work of breathing, ensures patient-ventilator synchronism, avoids facial pressure sores, and increases patient comfort (11-14). An excessive level of anxiety or scarce pain control will hinder patient-ventilation interaction (3-5). Nursing staff plays a key autonomous role in these cases helping patients feel more comfortable (5, 6, 15-19).

Predictors of success, with a response to a trial of NIV, are: decrease in $PaCO_2$ greater, correction of respiratory acidosis, decrease of dispnoea, and respiratory rate (15).

The predictive risk factors of NIV failure are differents, they should be kept under observation and prevent (15). The possible causes of immediate failure (within minutes to < 1 hour) are a weak cough reflex, excessive secretions, hypercapnic encephalopathy, intolerance, agitation, and patient-ventilator asynchrony (15).

Every clinician dealing with NIV should be aware of these risk factors and the predicted parameters of NIV failure that may change during the application of NIV. Close monitoring is required to detect early and late signs of deterioration (3, 11, 12, 15).

The litterature shows that the patients with an acute episode of respiratory distress have a higher adherence level compared to patients with chronic pathologies (2, 13).

Patient's compliance is one of the major problems in clinical practice (20, 21). Low compliance leads to negative outcomes and increase healthcare costs (21).

Identifying at an early stage, which are the pricipal factors correlated to the development of NIV intollerance, lets the health professional to implement preventive measures in order to improve compliance to the treatment.

The purpose of the study is to investigate the clinical and care factors that affect the level of patient compliance to NIV.

2. Objectives

Investigate the clinical and care factors that affect the level of patient compliance to NIV.

3. Methods

3.1. Study Design

A prospective, observational, and multicentre study. A mixed method design was used.

3.2. Setting

This case study was conducted in 3 multidisciplinary Italian sub-intensive care units, each having consistent structural, organizational, and professional staff characteristics.

These sub-intensive therapies are located in tertiary teaching hospitals, which include highly specialized departments. Each of them counts on 7 - 9 beds, each of which is equipped with instruments for both invasive and non-invasive patient monitoring. They are multidisciplinary sub-intensive therapies, which admit patients from both the emergency room and other hospital departments. The structures include patients with different kinds of organ failures who need a higher standard of medical and nursing care compared to that offered by ordinary hospital wards. All centers ensure a high level of healthcare protection, with a minimum 1-to-4 nurse / patient ratio and a 24 hours dedicated doctor. These structures are characterized by a very low turnover rate of about 3 days.

The basic minimum enrolment requirement for the center was the presence of nursing staff who would already be adequately trained in the management of critical patients subjected to non-invasive ventilation, together with at least 3 years of specific work experience, certified by a professional curriculum. The staff involved presented a training and professional curriculum that could potentially be overlapped in various centers.

The research protocol was shared with the nursing staff of the study centers and was preceded by a training meeting for its correct use.

3.3. Partecipants

Patients that had received NIV treatment between November 1, 2015 and February 15, 2016 were enrolled. Minors were excluded as were patients with a < -3 score on the richmond agitation sedation scale (RASS) (22) or resulting positive to the confusion method assessment intensive care unit (CAM-ICU) (23). It was decided to establish the latter exclusion criterion due to the fact that patients with pre-existing cognitive impairment could have potentially led to an evaluation bias.

3.4. Data Sources

The data collection tool consisted of 3 cards. The "Medical history card" compiled when the patient was enrolled, in this sheet the main anamnesis and some specific variables present at the time of admission are collected. The "daily assessment card" containing the clinical and relational variables of the patient during NIV; compiled 1 hour from the start of NIV for the entire duration of the treatment, differentiated in parameters related to the patient

and parameters related to the ventilator; and of a relational nature such as the location of the patient within the ward and the presence of the caregiver.

Some validated scales are included within the daily card:

- NRS (numerical rating scale) scale for pain monitoring (24)

- GCS (glasgow coma scale) for monitoring the state of consciousness (25)

- BORG (RPE rate of perceived exertion scale) for the monitoring of dyspnea (26)

- RASS (richmond agitation sedation scale) for monitoring the level of sedation and agitation (22).

This card was compiled for 8 hours and for each episode of intolerance.

The "patient interview card", a structured interview consisting of 7 closed questions: the 1st 5 investigate the "Patient Information" area and the last 2, the "patient experiential past" area with respect to ventilatory treatment.

It was compiled 24 hours after the start of the treatment, according with clinical condition. This interview was designed to investigate the experiences and perceptions of participants using NIV.

It created a working definition of "Patient intolerant to NIV" (patients who expressed their unwillingness, either verbally or with gestures, to continue the NIV despite medical advice).

The staff involved in the study were trained to use the data collection tool and a pilot feasibility study was conducted from September 1 to October 31, 2015.

3.5. Statistical Methods

The statistical analysis was conducted with STATA MP13 software (Stata Corp., College Station, TX, 2013). The statistical significance was determined using the chi-square test for categorical variables (or Fisher Test where appropriate) and t-student test for continuous variables. Then, in order to assess the potential predictors of intolerance, a multivariate analysis throughout a logistic regression model was performed. All the results of each statistical analysis were considered statistically significant when the P value was below 0.05.

3.6. Ethical Approval

The study was authorized and approved by the directorate-general of the local health authority TO2 (protocol no. 39447 dated 22.06.2015) and by the competent ethical committee (protocol no. 40594 dated 29.06.2015).

All patients were assured that the safety and suitability standards were observed and given an informed consent form for enrolment.

4. Results

4.1. Partecipants

A total of 323 patients were enrolled, of which 171 were men (52.9%) with a mean age of 71.23 (SD $\pm$ 13.71), and a mean BMI of 26.17 (SD $\pm$ 6). Mean SAPSII was 33.6 (SD $\pm$ 15.1) and SOFA 4.0 (SD $\pm$ 3.1)

The average length of hospitalization with NIV is 2.5 (SD $\pm$ 1.96) days. The general characteristics of the population are shown in Table 1.

Of all the patients examined, 286 (88.5%) arrived from the emergency department. In total, 134 (41.49%) had been given NIV in previous hospital stays, while only 27 (8.3%) of the patients had used NIV at home. A total of 975 episodes of intolerance were recorded during NIV over a total of 2153 observations, a mean of 3.02 (SD $\pm$ 1.4) episodes/patients. The 1st episode of intolerance arose at around 2.47 (SD $\pm$ 1.89) hours from the start of the treatment. The general characteristics of the population during episodes of intolerance are listed in Table 2 and the specific characteristics of the population during episodes of intolerance are listed in Table 3.

4.2. Main Results

A multivariate regression model was adopted and the principal outcomes associated for "Intolerance" variable are shown in Table 4.

There is a lower probability of developing episodes of intolerance for patients with BMI $<$ 18 (OR = 0.53, 95% IC 0.34 - 0.82; P = 0.005), while patients with BMI $>$ 31 $<$ 35 present a higher risk (OR = 1.54, 95% IC 1.17 - 2.04; P = 0.002). Higher RASS scores are associated with a higher risk of intolerance to NIMV.

The use of accessory muscles appears to be an underlying factor of developing intolerance (OR = 1.45, 95% IC 1.09 - 1.92; P = 0.01). A total of 87.18% of the patients recorded synchronous chest-ventilator movement during episodes of intolerance, which appears to be a protective factor against developing intolerance (OR = 0.68, 95% IC 0.46 - 0.98; P = 0.04). Patients able to suspend the treatment showed a lower probability of developing intolerance with respect to those that received continuous treatment (OR = 1.26, 95% IC 1.04 - 1.53; P = 0.01).

A total of 223 interviews were conducted, and the details interviews with patients undergoing NIV are indicated in Table 5.

5. Discussion

The subjects enrolled in the study are elderly (mean age of 71.23 SD $\pm$ 13.71) and suffering from chronic respiratory diseases, which makes it more difficult for the patients

Table 1. General Characteristics of the Population[a]

Description of the Sample	Total (No. = 323)	Males (No. = 171)	Females (No. = 152)	P value
Age, y				0.005
17 - 45	27 (8.36)	23 (13.45)	4 (2.63)	
46 - 65	41 (12.69)	22 (12.87)	19 (12.5)	
66 - 75	114 (35.29)	59 (34.5)	55 (36.18)	
> 75	141 (43.65)	67 (39.18)	74 (48.68)	
Mean age (y) ± SD	71.23 ± 13.71	68.48 ± 15.18	74.32 ± 11.1	< 0.001
Body mass index				0.373
< 18.5	18 (5.57)	7 (4.09)	11 (7.24)	
18.6 - 25	141 (43.65)	75 (43.86)	66 (43.42)	
26 - 30	83 (25.7)	49 (28.65)	34 (22.37)	
31 - 35	60 (18.58)	27 (15.79)	33 (21.71)	
36 - 40	10 (3.1)	7 (4.09)	3 (1.97)	
> 40	11 (3.41)	6 (3.51)	5 (3.29)	
Mean body mass index ± SD	26.17 ± 6	26.25 ± 6	26.08 ± 6	0.799
Reason for starting NIV[b]				0.002
IR Type 1	68 (21.05)	48 (28.07)	20 (13.16)	
IR Type 2	102 (31.58)	44 (25.73)	58 (38.16)	
BPCO	91 (28.17)	47 (27.49)	44 (28.95)	
Acute pulmonary embolism	8 (2.48)	3 (1.75)	5 (3.29)	
Pneumonia	48 (14.86)	28 (16.37)	20 (13.16)	
Atelectasis	5 (1.55)	0 (0)	5 (3.29)	
Acute respiratory distress syndrome (ARDS)	1 (0.31)	1 (0.58)	0 (0)	
Comorbidity[b]				0.069
Traumatic	13 (4.02)	4 (2.34)	9 (5.92)	
Respiratory	154 (47.68)	78 (45.61)	76 (50)	
Cardiological	91 (28.17)	49 (28.65)	42 (27.63)	
Neurological	7 (2.17)	4 (2.34)	3 (1.97)	
Psychiatric	6 (1.86)	4 (2.34)	2 (1.32)	
Neoplastic	11 (3.41)	8 (4.68)	3 (1.97)	
Metabolical	8 (2.48)	6 (3.51)	2 (1.32)	
Post-surgical	13 (4.02)	11 (6.43)	2 (1.32)	
Other	20 (6.19)	7 (4.09)	13 (8.55)	
Procedure initiated in				0.274
Emergency Medicine	158 (48.92)	83 (48.54)	75 (49.34)	
Emergency department	153 (47.37)	84 (49.12)	69 (45.39)	
Intensive care ward	12 (3.71)	4 (2.34)	8 (5.27)	
Patient already undergoing NIV				0.026
No	189 (58.51)	106 (61.99)	83 (54.61)	
Yes, emergency medicine	32 (9.91)	21 (12.28)	11 (7.24)	
Yes, emergency department	22 (6.81)	12 (7.02)	10 (6.58)	
Yes, at home	27 (8.36)	9 (5.26)	18 (11.84)	
Yes, intensive care ward	16 (4.95)	5 (2.92)	11 (7.24)	
Yes, recovery ward	7 (2.17)	1 (0.58)	6 (3.95)	
Yes, different contexts	30 (9.28)	17 (9.94)	13 (8.55)	
Mean hospital stay (days) ± SD	2.58 ± 2.95	2.79 ± 2.21	2.33 ± 1.58	< 0.001
Mean NIV treatment (days) ± SD	2.50 ± 1.96	2.74 ± 2.26	2.22 ± 1.54	< 0.001
Transferred from				0.19
Emergency medicine	286 (88.5)	152 (53.14)	134 (46.86)	
Recovery ward	26 (8.04)	15 (57.69)	9 (42.31)	
Intensive care	11 (3.4)	8 (72.72)	3 (27.28)	

[a]Values are expressed as mean ± SD or No. (%).
[b]The variables may coexist for the same patient.

Table 2. General Characteristics of the Population During Episodes of Intolerance to NIV

General Characteristics of Episodes of Intolerance	No. (%)	Mean Episodes/Patients (± SD)
Episodes of intolerance	975 (45.29)	3.02 (± 1.4)
Placement of patient during intolerance		
Open space ward	908 (93.13)	4.7 (± 1.2)
Hospital room	67 (6.87)	2.5 (± 0.9)
Caregiver		
Absent	800 (82.05)	4.8 (± 1.5)
GCS score		
> 14	822 (84.31)	
13 - 9	149 (15.28)	
< 9	4 (0.41)	
RASS score		
-3 - (-1)	29 (2.97)	
0	428 (43.9)	
1 - 2	475 (48.72)	
> 2	43 (4.41)	
BORG-RPE score		
0 - 3	706 (72.41)	
4 - 5	177 (18.15)	
6 - 7	85 (8.72)	
> 7	7 (0.72)	

Abbreviations: BORG (RPE), Rate of Perceived Exertion (25); GCS, Glasgow Coma Scale (24); NRS,Numerical Rating Scale (26); RASS, Richmond Agitation Sedation Scale (22).

Table 3. Specific Characteristics of the Population During Episodes of Intolerance to NIV

Specific characteristics of intolerance episodes	No. (%)	Mean episodes/patients (± SD)
Synchronous chest motion with ventilator		
Yes	850 (87.18)	2.6 (± 1.2)
Use of accessory muscles		
Yes	260 (26.67)	3.1 (± 1.4)
Suspension of NIV (min 10 minutes every 2 h)		
Yes	540 (55.38)	2.6 (± 0.5)
Interface used		
Oronasal mask	336 (34.46)	4.3 (± 1.4)
Full face mask	538 (55.18)	2.9 (± 2.1)
Hood/Zip helmet	98 (10.04)	3.7 (± 1.3)
Nasal mask	3 (0.31)	0.7 (± 1.3)
Possibility to alternate interface		
Yes	140 (14.36)	2.7 (± 0.9)
Method of ventilation		
SIMV	29 (2.97)	
NPPV	705 (72.31)	
CPAP	165 (16.92)	
BIPAP	76 (7.79)	
Risk factors[a]		
Pressure ulcers on face	597 (61.33)	4.4 (± 1.2)
Central venous catheter (neck blood vessels)	126 (12.92)	6.3 (± 2.6)
Nasogastric tube	252 (25.85)	4.2 (± 1.4)

Abbreviations: B-PAP, Bilevel Positive Airway Pressure; C-PAP, Continuous Positive Airway Pressure; NPPV-PSV, Non Invasive Positive Pressure Ventilation; SIMV, Synchronized Intermittent Mandatory Ventilation.
[a]Variables can coexist in same patient.

to understand the need to initiate NIV and consequently may affect their acceptance of the treatment (2, 13).

The nursing staff must carefully monitor the patient's breathing (2, 3, 19). Lack of patient-ventilator synchrony can increase the patient's effort to breathe and cause discomfort (12, 13). This synchrony is difficult to achieve in dyspnoeic patients where the greater the dyspnoea and the harder it will be to achieve interaction (19). During episodes of intolerance 125 (12.8%) of the cases were due to patient-ventilator asynchrony. The ability to coordinate chest and ventilator motion helps to prevent the onset of intolerance.

Monitoring the patient's respiratory mechanics is important because the patients that used accessory muscles during the episodes of intolerance, a further sign of respiratory distress (13) as the use of these muscles, leads to a higher probability of developing intolerance to NIV.

Underweight patients (BMI < 18) had a lower probability of developing intolerance to NIV with respect to normal weight patients. On the contrary, overweight (BMI > 26 < 30) and obese (BMI > 36 < 40) patients showed a higher probability. This may be correlated to the fact that, while thin hydrocolloid films are available for underweight patients, which facilitate adherence of the mask making it more comfortable to wear, the interfaces are not easily adaptable to the face anatomy of patients with a higher BMI. The mask may have to be fastened too tightly to ensure no leakage of air during NIV, as well as become very uncomfortable over time. Thus, a particular fleshy face conformation could nullify success of NIV and lead to intolerance (12, 13). In order to ensure adequate ventilation for an obese patient, higher PSV settings are required implying a greater

Table 5. Details of Interviews with Patients Undergoing NIV (No = 223)

Questions	No. (%)
1- When you started NIV, did someone explain the treatment and what it involved?	
Yes	149 (66)
2- Who explained the treatment?	
Doctor and nurse	71 (32)
Doctor	62 (27)
Nurse	61 (27)
Other (relatives, caregiver)	29 (13)
3- Did you understand what you were told?	
Yes	124 (55)
4- Did you understand why it was necessary to maintain NIV constantly?	
Yes	141 (63)
5- Would you have liked to receive more information?	
Yes	99 (44)
6- What was the most distressing sensation you felt?	
Thirst	128 (57)
Insomnia	33 (14)
Pain	27 (12)
Noise	20 (8)
Difficulty in talking to your relatives	6 (2)
Claustrophobia	4 (1)
Difficulty in talking to the staff	4 (1)
Other	33 (14)
7- What did you feel the most?[a]	
Fear	96 (43)
Anxiety	54 (24)
Isolated	42 (18)
Relief	36 (16)
Sadness	19 (8)
Loneliness	17 (7)
Anger	17 (7)
Safety	15 (6)
Boredom	12 (5)
Protection	10 (4)

[a]These variables may coexist.

pressure of air on the patient's face. Nasal masks and hoods are better tolerated in these cases (2, 9, 14).

The helmet reduces the possibility of developing facial pressure injuries, eye irritation, and gastric distension, while facilitating patient interaction with the surrounding environment; this is at the expense of a rubbing in the axillary cable and greater noise (12, 13). The helmet can be used only in certain ventilation modes due to the large "gap" that is created (14).

In this study the interface best tolerated by patients was the full face mask, which presented fewer episodes of intolerance with respect to the mean. The choice of an appropriate interface is crucial to ensure compliance with NIV (12). Moreover, air leaks, due to an inappropriate interface, can hinder improvement of the patient's health and increased breathing efforts (12, 13).

Alternating the interfaces at set intervals appeared to be an excellent strategy for encouraging patients to comply with the treatment (12, 13). The patients that experienced at least 1 episode of intolerance, only in 140 (14.36%) of cases, was the interface alternated during the treatment, whereas when the interface was changed at intervals, a lower rate of intolerance was recorded.

Any pain felt by the patients due to the interface used can result in intolerance of NIV (2, 5, 18). A level of slight pain was recorded during episodes of intolerance (NRS 1 - 3), which highlighted just how much attention was paid by the nursing staff to prevent and control the pain experienced by the ventilated patient. Patients with a higher pain level (NRS 4 - 5), indicated that they had a higher probability of developing intolerance to NIV than patients reporting no pain.

After analyzing the obtained results, it is highlighted how the treatment setting plays a crucial role in the patient's adherence to the NIV.

Patients in an open space with other patients experienced more episodes of intolerance with respect to patients in single rooms. This finding is backed by the specialist literature, which highlights how disorienting and distressing a critical care ward can be for an elderly patient, and therefore counter-productive in treatments where patient collaboration is vital (27).

Distressed patient (RASS > 2) is more likely to develop intolerance to NIV, than a calm and informed patient (RASS 0).

The studies increase the awareness of nursing staff caring for patients undergoing NIV with regard to the fact that, provided their respective clinical conditions allow, short breaks during the treatment enable the patient to rest and consequently encourage their compliance (5, 18). The data confirms the literature: 55.38% of the patients enrolled in the study were possible to suspend NIV for 10 minutes every 2 hours, while patients receiving continuous treatment had a higher probability of developing intolerance. These pauses from the NIV are fundamental for the patient because they allow him/ her to relate to the surrounding environment and to the nurse. This is due to the fact that he/she can monitor the skin, mucous membranes and conjunctivae, thus, to ensure an early identification of development of possible complications caused by the treatment.

Understanding the experiences of patients treated with NIV is critical to person-centred care (28).

Patients undergoing NIV often complained of intense thirst as the high flow of air dries the mouth tissues and

therefore, short breaks in the treatment would allow patients to drink and feel more comfortable, and better accept the treatment (5, 18). From the interviews conducted, it emerged that the sensation of thirst was the main cause of discomfort during the administration of NIV (128 (57%)), followed by insomnia (33 (14%)) and pain caused by the interfaces (27 (12%). Controlling pain caused by the interfaces used is a fundamental aspect of caring for the ventilated patient and is correlated with the development of intolerance to the treatment. Pain can be prevented by swapping the masks, which have different pressure points on the face, by applying thin hydrocolloid protective films under the masks and by suspending the treatment for brief intervals.

The successful administration of NIV, as for other therapies that require a good interaction with the patient, needs the multidisciplinary team work of diverse professionals (10). This study has attempted to favor an integrated doctor-nurse approach in order to reach the highest possible level of understanding for the specific case. According to literature, patients usually described a high level of trust in healthcare professionals and delegated decision-making to them regarding ongoing care (28).

The interviews indicated how the compliance with NIV requires not only providing adequate information on the treatment, but above all joint participation in the therapeutic process to obtain the collaboration of the patient (21).

A total of 149 (66%) of the patients declared that before starting NIV, a caregiver took time to explain what it involved, and after the explanation, 124 (55%) of the subjects interviewed stated to have understood, proving that the information was provided in an effective manner. Nevertheless, 99 (44%) would have liked more information and for 82 (37%) of them, it was still not clear why they had to persist with NIV.

This factor reveals how communication should be enhanced in the healthcare field and could improve compliance with NIV.

In 62 (27%) of the cases, the information was provided exclusively by the doctor, in 61 (27%) by the nursing staff, while in 71 (32%) an integrated doctor-nurse approach was adopted, as recommended in the literature (10, 20).

The involvement of relatives in the care process appears to influence a greater compliance with NIV and should be encouraged as soon as possible, without forgetting that each person reacts in a unique and distinct manner to illness and distressing situations (5, 6). A total of 800 (82%) of the episodes of intolerance occurred while the caregiver was absent and, on average, patients lacking the support of a caregiver experienced more episodes than the general average.

Communication with patients during treatment is inhibited because of the mask, the noise from the machine, and patient distress; for this reason, the presence of relatives could be reassuring (28).

Of the patients interviewed, 96 (43%) declared to have felt afraid during NIV, while 18% had felt isolated. The caregiver can establish a therapeutic alliance with the patient so as to counter any negative feelings that could affect the success of NIV (5, 6).

The dyspnoeic patient may experience a growing level of anxiety, becoming a vicious circle of "dyspnoea-anxiety-dyspnoea", which has a negative effect on the NIV (4). Most patients in this study, according with literature, talked about anxiety: anxiety of being choked, being alone with new technology, lack of predictability (28).

The presence of a nurse during the initial phases of the treatment is fundamental for helping the patient feel less afraid, isolated, and anxious as well as giving them time to adapt. This factor is confirmed in the interviews where 54 (24%) declared they felt anxiety during NIV. Conversely, positive emotions emerged from the interviews where 36 (16%) felt relief and 10 (6%) felt safe, confirming the fact that by supporting patient breathing, this therapeutic treatment alleviates the exerted respiratory muscles, giving a sense of security that could stem from the sensation of being cared for and assisted (14).

The success of NIV depends on multiple factors. Numerous clinical and relational aspects are involved in patient-ventilator interaction.

The objective of this study was to identify the factors that affect patient compliance to NIV in order to organise preventive actions to improve it.

There is a need to look at NIV from a prospective still only seldom explored by specialist literature. The attention to patient comfort ensuring breaks in the ventilation treatment, pain control and management of anxiety and fear in collaboration with the caregiver, and fundamental nursing care activities are among the factors that appear to have the main influence on patient compliance with NIV.

5.1. Conclusions

The success of non-invasive ventilation is related to multiple factors. There are numerous clinical and relational aspects involved in the patient-ventilator interaction and that affects the patient following the treatment. The objective of this study is to identify these factors so that we can plan corrective actions and improve compliance. The importance of analyzing NIV from a perspective that is still poorly explored in the literature emerges from this study. We have highlighted some areas that need further study for patient assistance. The patient's emotional sphere, a topic that was not dealt with in the literature

and that was analyzed here superficially, deserves a specific qualitative analysis. So do attention to patient comfort, care setting, and caregiver involvement are all basic nursing activities.

5.2. Study Limitations

The study has some limitations related to the used method and instrument: it was necessary to create an ad hoc tool, both for the quantitative and qualitative parts, since no already validated tool related to this topic was found in the literature; moreover, data collection was carried out in 3 hospitals of the same city and therefore, the result could not be generalized to all patients subjected to NIV.

5.3. Relevance to Clinical Practive and Suggestions for Future Studies

Focus on patients' perspectives in treatment with noninvasive ventilation resulted in the development of new management strategies regarding patient care.

In the future we would like to have the data collection tool validated, while expanding the qualitative research part so that we can repeat the study on a larger and more representative sample.

Acknowledgments

We would like to extend our thanks to high dependency unit, San Giovanni Bosco hospital, and Umberto I hospital staff for their assistance in this project

Footnote

Authors' Contribution: Alessia D'Orazio, Antonella Dragonetti, and Giorgio Campagnola, searching, data gathering, and writing the manuscript; Simona Frigerio, research methodology and searching; Cristina Garza, data gathering; Fabrizio Bert, data analysis.

References

1. Cabrini L, Landoni G, Oriani A, Plumari VP, Nobile L, Greco M, et al. Noninvasive ventilation and survival in acute care settings: a comprehensive systematic review and metaanalysis of randomized controlled trials. *Crit Care Med*. 2015;**43**(4):880–8. doi: 10.1097/CCM.0000000000000819. [PubMed: 25565461].
2. Ho RP, Boyle M. Non-invasive positive pressure ventilation in acute respiratory failure: providing competent care. *Aust Crit Care*. 2000;**13**(4):135–143. doi: 10.1016/S1036-7314(00)70641-2. [PubMed: 16948204].
3. Bello G, De Pascale G, Antonelli M. Noninvasive ventilation: practical advice. *Curr Opin Crit Care*. 2013;**19**(1):1–8. doi: 10.1097/MCC.0b013e32835c34a5. [PubMed: 23235541].
4. Bailey PH. The dyspnea-anxiety-dyspnea cycle-COPD patients' stories of breathlessness: "It's scary /when you can't breathe". *Qual Health Res*. 2004;**14**(6):760–78. doi: 10.1177/1049732304265973. [PubMed: 15200799].
5. Bambi S. Noninvasive positive pressure ventilation: an ABC approach for advanced nursing in emergency departments and acute care settings. *Dimens Crit Care Nurs*. 2009;**28**(6):253–63. doi: 10.1097/DCC.0b013e3181b3ffdc. [PubMed: 19855200].
6. Woodrow P. Using non-invasive ventilation in acute wards: Part 1. *Nurs Stand*. 2003;**18**(1):39–44. doi: 10.7748/ns2003.09.18.1.39.c3460. [PubMed: 14533250].
7. Sinuff T, Kahnamoui K, Cook DJ, Giacomini M. Practice guidelines as multipurpose tools: a qualitative study of noninvasive ventilation. *Crit Care Med*. 2007;**35**(3):776–82. doi: 10.1097/01.CCM.0000256848.47911.77. [PubMed: 17235258].
8. Kelly JL, Jaye J, Pickersgill RE, Chatwin M, Morrell MJ, Simonds AK. Randomized trial of 'intelligent' autotitrating ventilation versus standard pressure support non-invasive ventilation: impact on adherence and physiological outcomes. *Respirology*. 2014;**19**(4):596–603. doi: 10.1111/resp.12269. [PubMed: 24661390].
9. Hess DR. The evidence is in: noninvasive ventilation saves lives. *Crit Care Med*. 2015;**43**(4):927–8. doi: 10.1097/CCM.0000000000000845. [PubMed: 25768364].
10. Chevrolet JC, Jolliet P, Abajo B, Toussi A, Louis M. Nasal positive pressure ventilation in patients with acute respiratory failure. Difficult and time-consuming procedure for nurses. *Chest*. 1991;**100**(3):775–82. doi: 10.1378/chest.100.3.775. [PubMed: 1889272].
11. Antonelli M, Conti G, Pelosi P, Gregoretti C, Pennisi MA, Costa R, et al. New treatment of acute hypoxemic respiratory failure: noninvasive pressure support ventilation delivered by helmet–a pilot controlled trial. *Crit Care Med*. 2002;**30**(3):602–8. doi: 10.1097/00003246-200203000-00019. [PubMed: 11990923].
12. Scandroglio M, Piccolo U, Mazzone E, Agrati P, Aspesi M, Gamberoni C, et al. Use and nursing of the helmet in delivering non invasive ventilation. *Minerva Anestesiol*. 2002;**68**(5):475–80. [PubMed: 12029267].
13. Ozyilmaz E, Ugurlu AO, Nava S. Timing of noninvasive ventilation failure: causes, risk factors, and potential remedies. *BMC Pulm Med*. 2014;**14**(19). doi: 10.1186/1471-2466-14-19. [PubMed: 24520952].
14. Sorensen D, Frederiksen K, Groefte T, Lomborg K. Nurse-patient collaboration: a grounded theory study of patients with chronic obstructive pulmonary disease on non-invasive ventilation. *Int J Nurs Stud*. 2013;**50**(1):26–33. doi: 10.1016/j.ijnurstu.2012.08.013. [PubMed: 23017296].
15. Torheim H, Gjengedal E. How to cope with the mask? Experiences of mask treatment in patients with acute chronic obstructive pulmonary disease-exacerbations. *Scand J Caring Sci*. 2010;**24**(3):499–506. doi: 10.1111/j.1471-6712.2009.00740.x. [PubMed: 20030772].
16. Pisani L, Carlucci A, Nava S. Interfaces for noninvasive mechanical ventilation: technical aspects and efficiency. *Minerva Anestesiol*. 2012;**78**(10):1154–61. [PubMed: 23059520].
17. Schneider E, Duale C, Vaille JL, Ouchchane L, Gillart T, Guelon D, et al. Comparison of tolerance of facemask vs. mouthpiece for noninvasive ventilation. *Anaesthesia*. 2006;**61**(1):20–3. doi: 10.1111/j.1365-2044.2005.04400.x. [PubMed: 16409337].
18. Sorensen D, Frederiksen K, Grofte T, Lomborg K. Practical wisdom: a qualitative study of the care and management of non-invasive ventilation patients by experienced intensive care nurses. *Intensive Crit Care Nurs*. 2013;**29**(3):174–81. doi: 10.1016/j.iccn.2012.10.001. [PubMed: 23159242].
19. Goligher EC, Ferguson ND, Kenny LP. Core competency in mechanical ventilation: development of educational objectives using the Delphi technique. *Crit Care Med*. 2012;**40**(10):2828–32. doi: 10.1097/CCM.0b013e31825bc695. [PubMed: 22824937].
20. Bloom BS. Daily regimen and compliance with treatment. *BMJ*. 2001;**323**(647). doi: 10.1136/bmj.323.7314.647. [PubMed: 11566816].

21. Burnier M, Brunner HR. *Compliance in healthcare and research. Monograph series*. Impact on clinical outcomes. Armonk, NY: Blackwell; 2001. p. 299–309.
22. Ely EW, Truman B, Shintani A, Thomason JW, Wheeler AP, Gordon S, et al. Monitoring sedation status over time in ICU patients: reliability and validity of the Richmond Agitation-Sedation Scale (RASS). *JAMA*. 2003;**289**(22):2983–91. doi: 10.1001/jama.289.22.2983. [PubMed: 12799407].
23. *Confusion assessment method for the ICU (CAM-ICU) the complete training manual [Internet]*. Vanderbilt University, Medical Center; 2014, [cited 2015 Dec 17]. Available from: http://www.mc.vanderbilt.edu/icudelirium/docs/CAM_ICU_training.pdf.
24. Teasdale G, Jennett B. Assessment of coma and impaired consciousness. A practical scale. *Lancet*. 1974;**304**(7872):81–4. doi: 10.1016/S0140-6736(74)91639-0. [PubMed: 4136544].
25. Borg GA. Psychophysical bases of perceived exertion. *Med Sci Sports Exerc*. 1982;**14**(5):377–81. [PubMed: 7154893].
26. Berthier F, Le Conte P, Garrec F, Potel G, Baron D. Assessment of acute pain management in an emergency department. *Réanimation Urgences*. 1998;**7**(3):281–5. doi: 10.1016/s1164-6756(98)80027-3.
27. Collinsworth AW, Priest EL, Campbell CR, Vasilevskis EE, Masica AL. A review of multifaceted care approaches for the prevention and mitigation of delirium in intensive care units. *J Intensive Care Med*. 2016;**31**(2):127–41. doi: 10.1177/0885066614553925. [PubMed: 25348864].
28. Smith TA, Agar M, Jenkins CR, Ingham JM, Davidson PM. Experience of acute noninvasive ventilation-insights from 'Behind the Mask': a qualitative study. *BMJ Support Palliat Care*. 2016. doi: 10.1136/bmjspcare-2015-000908. [PubMed: 27566721].

Table 4. Multivariate Regression Model Associated for "Intolerance" Variable[a]

Dependent variables	OR (IC 95%)	P Value
Sex		
Female	0.99 (0.81 - 1.21)	0.899
Age		
17 - 45	1	-
46 - 65	0.87 (0.59 - 1.32)	0.514
66 - 75	1.20 (0.83 - 1.72)	0.330
> 75	1.37 (0.95 - 1.96)	0.090
body mass index		
< 18.5	0.53 (0.34 - 0.82)	0.005
18.6 - 25	1	-
26 - 30	0.60 (0.47 - 0.77)	< 0.001
31 - 35	1.54 (1.17 - 2.04)	0.002
36 - 40	1.99 (1.15 - 3.46)	0.014
> 40	1.15 (0.69 - 1.94)	0.590
GCS index		
15	1	-
14 - 9	1.22 (0.9 - 1.66)	0.204
< 9	2.04 (0.47 - 8.95)	0.342
RASS index		
-3 - (-1)	2.30 (1.32 - 4.04)	0.004
0	1	-
1 - 2	2.30 (1.32 - 4.03)	0.003
> 2	7.39 (3.19 - 17.13)	< 0.001
BORG-RPE index		
0	1	-
1 - 3	1.53 (1.17 - 1.99)	0.002
4 - 5	1.59 (1.13 - 2.22)	0.007
6 - 7	3.26 (2 - 5.3)	< 0.001
NRS score		
1 - 3	1	-
4 - 5	1.76 (1.3 - 2.41)	< 0.001
≥ 6	0.90 (0.54 - 1.5)	0.686
Procedure initiated in		
Emergency Medicine	1	-
Emergency department	0.96 (0.78 - 1.17)	0.685
Intensive Care	1.62 (0.88 - 2.97)	0.118
Patient placement		
Hospital room	1	-
Open space ward	0.68 (0.45 - 1.01)	0.056

Risk factors[a]		
Pressure ulcers on face	1.12 (0.57 - 1.23)	0.945
Jugular CVC	1.03 (0.76 - 1.4)	0.853
Nasogastric tube	1.03 (0.81 - 1.31)	0.822
Synchronous chest motion with ventilator[a]	0.68 (0.46 - 0.98)	0.041
Use of accessory muscles[a]	1.45 (1.09 - 1.92)	0.010
Non suspension of NIV[a]	1.26 (1.04 - 1.53)	0.019
Interface used		
Oronasal mask	1	-
Full face mask	0.96 (0.79 - 1.18)	0.691
Hood/Zip helmet	0.77 (0.48 - 1.24)	0.280
Nasal mask	0.35 (0.08 - 1.44)	0.145
Alternation of interface[a]	1.16 (0.87 - 1.54)	0.322
Caregiver absent[a]	0.89 (0.7 - 1.14)	0.361
Duration NIV	1.02 (0.97 - 1.07)	0.486

Abbreviations: BORG (RPE), Rate of Perceived Exertion (25); GCS, Glasgow Coma Scale (24); NRS, Numerical Rating Scale (26); RASS, Richmond Agitation Sedation Scale (22).
[a]These were treated as dichotomous variables using NO/absent as a reference value.