

Structured practices increasing patient compliance to noninvasive mechanical ventilation therapy: example of best practice

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ABSTRACT

Aim: The initiation of non-invasive mechanical ventilation (NIV) therapy, mask choice, device settings, and patient followup are carried out jointly by physicians and nurses. The physician and the nurses should have knowledge and experience. A checklist for the patient follow-up may increase identifying and preventing problems that may occur. Our study aims to share our data and experiences by documenting the NIV implementation success of our pulmonary intensive care unit (PICU) as an example of best practice.

Material and Method: Patients with respiratory failure who had an indication for NIV therapy between 01.01.2021 and 15.09.2021 were included in the study. Patient data were obtained retrospectively. With the NIV therapy application checklist, what should be done in the preparations, initiation, and follow-up steps of the therapy are standardized. All checkpoints and the outcome of the checklist were recorded routinely.

Results: One hundred one patients with the diagnosis of hypercapnic respiratory failure treated by NIV therapy in PICU were included in the study. There was a significant difference between NIV compliant and NIV noncompliant patients in terms of $PaCO_2$ in arterial blood gas analysis (p=0.009). $PaCO_2$ was significantly lower in patients who were noncompliant to treatment than those who were compliant with treatment (p<0.05). In all of the patients who were noncompliant with NIV treatment, the problem was detected, the training and the motivation were repeated, and the noncompliance was resolved in 52.6%. For the non-compliant patients who were not resolved, the need for restriction (21.1%) and/or the need for sedation (21.1%) were observed.

Conclusion: Structured checklist is useful in common problems in the implementation and follow-up of the NIV therapy. Increased compliance with NIV therapy reduces the length of stay in the hospital and intensive care unit and decreases the rates of mortality and morbidity.

Keywords: Noninvasive mechanical ventilation, pulmonary intensive care, respiratory failure

INTRODUCTION

Noninvasive mechanical ventilation (NIV) is a therapy that provides positive pressure support through a mask without the use of an endotracheal tube (1). The NIV has been accepted as the first-line therapy in patients with acute respiratory failure and acute exacerbation of chronic obstructive respiratory disease (COPD) (2). Compared with invasive mechanical ventilation (IMV), NIV reduces the length of stay in hospital and intensive care units, mortality, and morbidity of patients with acute and chronic respiratory failure (3). The most appropriate management of NIV can be achieved if all team members are experienced and trained. NIV practices are successfully implemented by trained intensive care nurses under the management and control of physicians. In many countries, respiratory therapists are responsible for selecting the appropriate mask, optimal mask placement on the face, adjusting ventilator settings, and initiating NIV (4). In our country, nurses in intensive care units often replace the mask, start or pause the ventilator for

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inhalation treatments, nutritional support, removal of secretions, and monitoring the vital values of the patient. Also, nurses are responsible for the compliance, and management of mask complications together with physicians. For this reason, nurses and physicians should be knowledgeable and experienced in the follow-up of the patient, identifying and preventing problems that may occur while NIV therapy.

Many factors affect the success of NIV such as choosing the right mask and connecting it correctly to the patient, ensuring the compatibility of the patient and the ventilator, and the training status and experience levels of the practitioners.

In the studies about the success of NIV in COPD acute exacerbation and acute respiratory failure, the results were shifting between 5% and 60% (5). In an NIV knowledge level survey study conducted by Raurell-Torredà et al. on 407 physicians and nurses in 3 university hospitals, they showed that the rate of correct answers to the questions measuring the level of knowledge was 50%, with no difference between units and hospitals. The level of knowledge of the physicians was significantly higher than the nurses (6).

Our hospital's pulmonary intensive care unit (PICU) has a team of experienced physicians and nurses who specializes in the implementation of NIV. In our PICU, the rate of the NIV failure (due to all causes) was 11.2% in 2019 (n=720) and 9.26% in 2020 (n=745). This study aims to share the experience and the data about the NIV implementation success as an example of best practice.

MATERIAL AND METHOD

This study was approved by the Health Sciences University Keçiören Education and Training Hospital Clinical Studies Ethics Board (Date: 12/10/2021, Decision No: 2012-KAEK-15/2394). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

The study was carried out in a tertiary pulmonary diseases training and research hospital. Our study included 101 patients with respiratory failure who were needed NIV therapy and hospitalized in the PICU between 01.01.2021 and 15.09.2021, and their data were obtained retrospectively. The NIV implementation checklist, which was created by the education officer and physicians of PICU and approved by the hospital's internal quality control unit and the administration of the hospital, was used (**Appendix 1**). This checklist standardized what should be done to the patient before, during, and immediately after NIV therapy.

(G) SEÚ ANKA	RA ATATÜRK	T.C. SAĞLIK BAKAN GÖĞÜS HASTAL VE ARASTIRMA	ILIĞI IKLARI VE OĞĞÜS CERRAHİSİ HASTANESİ	Doküman Kodu :HBJR.3 Yayın Tarihi :18.03.20 Revizyon No :00 Revizyon Tarihi :
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3. Maske seçimi: Oronazal maske	Evet 🗌	Hayır	Süre: Aralıklı 🗌 Sıkı 🔲	Sadece gece
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5. NIMV Başlanması:			İdame Tedavi Planı:JJ	Tarih: <i>IJ</i>
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Appendix 1.

Statistical Analysis

Data analyzes were performed using SPSS for Windows, version 22.0 (SPSS Inc., Chicago, IL, United States). Whether the distribution of continuous variables was normal or not was determined by the Kolmogorov Smirnov test. Levene's test was used to evaluate the homogeneity of variances. Unless otherwise stated, continuous data were defined as mean±SD for normal distributions and median (interquartile range: third quartile - first quartile) for skewed distributions. Categorical data were defined as the number of cases (n, %). Statistical analysis differences in normally distributed variables between two independent groups were compared with Student's t-test. The Mann-Whitney U test was used to compare data that did not show normal distribution. Categorical variables were compared using the Pearson Chi-square test or the Fisher exact test. A p-value of <0.05 was considered significant in all statistical analyses.

RESULTS

The study comprised 101 patients with the diagnosis of hypercapnic respiratory failure who were needed NIV therapy in PICU between 01.01.2021 and 15.09.2021. Patients were classified into two groups as compliant with NIV therapy or not. The NIV mode selection and adjusting parameters were personalized for each patient by the chest physician. S/T mode was the most common choice (93.1%) and the second was intelligent volume assured pressure support (iVAPS (6.9%). The initiation inspiratory positive airway pressure (IPAP) varied between 16-26 cmH2O and, the expiratory positive airway pressure (EPAP) varied between 6-8 cmH2O, and backup respiratory rates (RR) were adjusted to be 14 or 16 or 18. The NIV therapy periods were analyzed and 88.1% of the patients were given NIV therapy 10-12 hours/day, 7.9% were given 18-20 hours/day, and 4% were given only for nighttime (Table 1). There was no significant difference in terms of any variable affecting compliance with the NIV therapy (p>0.05).

The analyzes of arterial blood gas (ABG) parameters between the compliant and non-compliant groups are shown in **Table 2.** These results were based on the results of baseline ABGs. There was no significant difference between the two groups in the ABG parameters other than $PaCO_2$ (p>0.05). The $PaCO_2$ levels were significantly lower in patients who were in the non-compliant group (p<0.009). In addition, if the patients' consciousness was acceptable, NIV training was given to all. The adherence to NIV therapy was not significantly affected by the patients' state of consciousness, the status of training, and the status

NIV		NIV npliant	NIV noncompliant Total		otal	р	
parameters	n	(%)	n	(%)	n	(%)	valu
Equipment		(70)		(/0)		(/0)	0.569
Vision™	7	8.5%	1	5.3%	8	7.9%	01001
Resmed™	68	82.9%	18	94.7%	86	85.1%	
Weinmann™	7	8.5%	0	0%	7	6.9%	
Mode							0.342
ST	75	91.5%	19	100%	94	93.1%	
iVAPS	7	8.5%	0	0%	7	6.9%	
Period (hours/	dav)						0.194
10-12 h	73	89%	16	84.2%	89	88.1%	
18-20 h	7	8.5%	1	5.3%	8	7.9%	
Full night	2	2.4%	2	10.5%	4	4.0%	
IPAP (cmH2C	-	211/0	-	1010 /0	-	110 / 0	0.634
16	1	1.2%	0	0%	1	1.0%	0100
18	3	3.7%	2	10.5%	5	5.0%	
20	3	3.7%	1	5.3%	4	4.0%	
2.2	23	28%	6	31.6%	29	28.7%	
24	48	58.5%	9	47.4%	57	56.4%	
26	4	4.9%	1	5.3%	5	5.0%	
EPAP (cmH2C	-	1.)/0	1	5.570	5	5.070	0.315
6	4	4.9%	2	10.5%	6	5.9%	0.51.
8	78	95.1%	17	89.5%	95	94.1%	
Delta for Wein	, 0		17	07.570))	J-1.1 /0	0.999
4	2	28.6%	0	0%	2	25.0%	0.77.
6	4	57.1%	1	100%	5	62.5%	
8	4	14.3%	0	0%	1	12.5%	
RR (per min.)	1	14.370	0	070	1	12.370	0.282
14	29	35.8%	5	26.3%	34	34%	0.20
14	29 51	63%	13	68.4%	54 64	54% 64%	
18	1	1.2%	15	5.3%	2	2%	
Tidal Volume (-	1.270	1	5.5%	2	270	
400	111L) 1	14.3%	0	0%	1	14.3%	-
400 500	5	71.4%	0	0%	5	71.4%	
500 550	5	14.3%	0	0%	5	14.3%	
	-		0	0%	1	14.3%	0.72
Inspiration tim		,	0	00/	7	7%	0.724
1	7	8.6%	0	0%	7		
1.1	21	25.9%	6	31.6%	27	27%	
1.2	40	49.4%	10	52.6%	50	50%	
1.3 Diagotinas (acces	13	16%	3	15.8%	16	16%	
Rise time (seco		1000/	10	1000/	100	1000/	-
0.1 Categorical variable	81	100%	19	100%	100	100%	

of verbal consent given before NIV therapy (p>0.05). The blood pressure, pulse per minute, and respiratory rates before NIV therapy were compared between the two groups. There was no significant difference in terms of any variable that affected the compliance of NIV therapy (p>0.05). The median systolic blood pressure was lower in noncompliant patients but this difference was not statistically and clinically significant.

There was no significant difference in terms of any variable affecting the NIV compliance (p>0.05) (**Table 3**). However, it was observed that mask leakage was more common (10.5%) in those who were non-compliant but the difference was not statistically significant (p=0.236).

 Table 2. Baseline arterial blood gas parameters and baseline blood pressure, pulse per minute, and respiratory rates before the NIV therapy were compared between the two groups

Baseline parameters	NIV co	mpliant	NIV non	compliant	Т	otal	p-value
рН	7.38	±0.07	7.40	±0.09	7.39	±0.07	0.308
PaO ₂	59	23.4	70	26.6	61	26.8	0.050
PaCO ₂	68.9	16.6	56.8	20	65.5	18	0.009
HCO3	38.61	±7.76	36.92	±8.54	38.27	±7.90	0.421
BE	11.8	8.2	12.1	9	11.8	8.1	0.539
SaO ₂	90.45	12.7	94	6.6	91.2	11.5	0.119
Systolic Blood Pressure	126.5	15	124	27	125	15	0.375
Diastolic Blood Pressure	67	11	64	10	65	10	0.153
Pulse per minute	81.5	12	80	9	81	9	0.698
Respiration Rate	20	2	20	2	20	2	0.856
SpO ₂	93	4	93	3	93	4	0.662

Continuous variables were expressed as either the mean ± standard deviation (SD) or median (IQR). Continuous variables were compared with the Student t-test or Mann-Whitney u test. Statistically significant p-values were in bold.

 Table 3. After initiation of the NIV therapy, the monitored parameters which may cause premature discontinuation, compared between the two groups

Interventions to provide sustainable		NIV c	NIV compliant		oncompliant	Total		
NIV therapy		n	(%)	n	(%)	n	(%)	– p value
Communication and motivation	Yes	82	100%	19	100%	101	100%	-
Patient position	Yes	82	100%	19	100%	101	100%	-
Mask leakage								0.236
	No	79	96.3%	17	89.5%	96	95%	
	Yes	3	3.7%	2	10.5%	5	5%	
Pressure adjustments								0.282
	Yes	45	54.9%	13	68.4%	58	57.4%	
	No	37	45.1%	6	31.6%	43	42.6%	
Oxygen level adjustments	Yes	82	100%	19	100%	101	100%	-
Alarm settings	Yes	82	100%	19	100%	101	100%	-

Categorical variables were expressed as either frequency (percentage). Variables were compared using Pearson's chi-square test or Fisher exact test. Statistically significant p-values were in bold.

The analyzes of vital parameters between the compliant and non-compliant groups are shown in **Table 4**. There was no significant difference in terms of any variable affecting the NIV compliance (p>0.05).

Patients who needed a break from the NIV therapy were classified for their reasons. These reasons were secretion cleaning, the need for drinking water, and the need for communication. These parameters were compared between the two groups (**Table 5**). The need for communication reasons was significantly frequent in the non-compliant group (p<0.001). There was no significant difference in terms of other parameters (p>0.05).

After the second hour of the NIV therapy, ABG analysis was performed and early complications of the NIV therapy were questioned. Due to the success of agile interventions, nurses and practitioners must be aware of the early complications. Earl complications were compared between the two groups in **Table 6**. There was no significant difference in terms of early complications between the groups (p>0.05). However, gastric distension was common (10.5%) in non-compliant patients but the difference was not significant.

The analyzes of arterial blood gas (ABG) parameters compared between the compliant and non-compliant groups are shown in **Table 7**. These results were based on the results of the ABGs at end of the second hour. There was no significant difference between the two groups in terms of the ABG parameters (p>0.05).

The interventions for the patients who were noncompliant with NIV were shown in **Table 8**. Allowing the patient to talk freely, identifying the underlying reason for non-compliance, repeating the training, and repeating the motivation resolved the non-compliance status in 52.6% of the patients. If non-compliance status was continued, restriction of the patient (21.1%) and/or sedation was performed (21.1%).

 Table 4. Monitored blood pressure, pulse per minute, respiratory rates, and pulse oximeter values while the recently started NIV therapy were compared between the two groups

Vital parameters	NIV co	mpliant	NIV non	compliant	To	otal	p-value
1st hour							
Systolic Blood Pressure (mmHg)	123.77	±14.83	121.05	±21.08	123.26	±16.10	0.510
Diastolic Blood Pressure (mmHg)	67	11	65	11	66	11	0.121
Pulse per minute	84	9	86	10	84	8	0.311
Respiratory rate (min.)	20	0	20	2	20	0	0.050
SpO2 (%)	93	3	93	1	93	2	0.197
2nd hour							
Systolic Blood Pressure (mmHg)	122.43	±14.49	120.63	± 14.81	122.09	± 14.50	0.629
Diastolic Blood Pressure (mmHg)	69.71	±8.89	67.11	±8.43	69.22	±8.82	0.249
Pulse per minute	84.5	8	85	9	85	8	0.708
Respiratory rate (min.)	20	2	22	2	20	2	0.096
SpO2 (%)	92	4	90	4	92	4	0.532

Continuous variables were expressed as either the mean ± standard deviation (SD) or median (IQR). Continuous variables were compared with the Student t-test or Mann-Whitney u test. Statistically significant p-values were in bold.

Table 5. Comparisons of the reasons for a break from the NIVtherapy were compared between the two groups

Monitoring		NIV npliant	non	NIV compliant	Total		р
parameters	n	(%)	n	(%)	n	(%)	value
Secretion clea	ning						0.342
Yes	1	1.2%	1	5.3%	2	2%	
No	81	98.8%	18	94.7%	99	98%	
Need for drin	king v	water					0.999
Yes	8	9.8%	1	5.3%	9	8.9%	
No	74	90.2%	18	94.7%	92	91.1%	
Need for com	muni	cation					< 0.001
Yes	13	15.9%	11	57.9%	24	23.8%	
No	69	84.1%	8	42.1%	77	76.2%	
Categorical varial	oles wer	e expressed	as eithe	r frequency (pe	ercenta	age). Variat	oles were

compared using Pearsons chi-square test or Fisher exact test. Statistically significant p-values were in bold.

Monitoring	-	NIV ipliant	-	NIV noncompliant		otal	p value
parameters	n	(%)	n	(%)	n	(%)	value
Gastric dister	nsion						0.236
Yes	3	3.7%	2	10.5%	5	5%	
No	79	96.3%	17	89.5%	96	95%	
Nausea							0.188
Yes	0	0%	1	5.3%	1	1%	
No	82	100%	18	94.7%	100	99%	
Vomiting							0.188
Yes	0	0%	1	5.3%	1	1%	
No	82	100%	18	94.7%	100	99%	
ABG analyze at the end of the 2nd Hour -							
Yes	82	100%	19	100%	101	100%	

Table 7. The arterial blood gas parameters end of the second hourof the NIV therapy were compared between the two groups

ABG parameters		IV pliant	-	NIV mpliant	То	otal	p value
pН	7.42	±0.07	7.43	± 0.08	7.42	±0.07	0.496
PaO ₂	62.1	25.6	79	38.9	63	28.2	0.117
PaCO ₂	61	13.3	57	13	60.6	13.6	0.194
HCO3	38.41	±6.98	34.07	±10.81	37.61	±7.94	0.119
BE	11.5	8.7	9.9	10.6	11.4	9.1	0.683
SaO2	92.2	8.9	96	11	92.7	9.9	0.157

Continuous variables were expressed as either the mean \pm standard deviation (SD) or median (IQR). Continuous variables were compared with the Student t-test or Mann-Whitney U test. Statistically significant p-values were in bold.

Table 8. The interventions for the patients who were non-
compliant with NIV therapy

	for the patients who pliant with NIV	n	(%)				
Allowing the patient to talk freely							
	Succesful	19	100%				
Identifying the underlying reason of non-compliance							
	Succesful	19	100%				
Re-education							
	Succesful	19	100%				
Re-motivation							
	Succesful	19	100%				
Resolving the r	non-compliance status						
	Yes	10	2.6%				
	No	9	47.4%				
Need of restric	tion of the patient						
	Yes	4	1.1%				
	No	15	8.9%				
Need of sedation							
	Yes	4	1.1%				
	No	15	8.9%				
Categorical variable	es were expressed as either freq	uency (percentage	e).				

DISCUSSION

The NIV therapy is frequently initiated and followed by physicians and nurses in the hospitals of Turkey and there is a similar situation in Europe (7). Some of the studies emphasize that there is a lack of knowledge and education. This is a fact that especially for the skills which generally nurses are responsible for such as choosing the appropriate NIV mask size and fitting it correctly. This is probably due to the low level of participation in the training sessions led by training nurses and practices on low-quality simulators, insufficient observation of reallife practices (6,8). Montravers et al. (9) surveyed 32 intensive care units all over France and found that only 39% of the nurses received NIV training and this training was provided by physicians in 87% of them. The hospital was provided practical NIV training only for a few hours. The theoretical training will not substitute real practical experience in fitting on the NIV mask to the patients or monitoring the patient's response to therapy. Nurses must have trainers who are knowledgeable about choosing the appropriate mask size, fitting the mask to the patient, and trying to keep the mask in place throughout the therapy (10). This potential issue has gained prominence with the widespread use of NIV in general wards besides intensive care units and intermediate intensive care units. As a result, we've taken steps in our unit to ensure that NIV is implemented correctly and that NIV failure is minimized.

Sorensen et al. (11) conducted a study in 2012 and they showed that experienced intensive care unit nurses are successful in ensuring patient adaptation to NIV, providing effective ventilation, and approaching carefully patients' perceptions of NIV. The healthcare professional who manages NIV therapy must be experienced, skilled, and high level of knowledge of the NIV therapy; this is the key component of success in practice (8). NIV training programs should include the sub-headings of the indications of NIV therapy, correct and effective mask choosing and fitting, correct use of ventilator equipment, adjusting ventilator settings, general maintenance of the ventilator, and solving problems in critical situations (12). Physicians should make decisions on how much oxygen to give and how to modify ventilator settings, and nurses should help set up the equipment. This setup includes installing a bacterial filter on the outlet port to reduce bacterial contamination, adjusting ventilator parameters, and adding oxygen to the circuit if needed. The nurses may consider using humidification as it can increase patient comfort and compliance. When installing the NIV therapy, the ventilator must be connected to the oxygen source and the amount of oxygen delivered (FiO2) must be monitored carefully. The nurses have to be aware of the equipment being used, because some NIV delivery systems have a built-in escape valve, and other systems may require these valves to be fitted.

NIV therapy is provided via a face mask; however, patients generally reported that they felt uncomfortable and claustrophobic (13). Alternative forms of application such as nasal mask, mouthpiece, and helmet mask can be used. However, it is a fact that mask selection is limited by the equipment available in the intensive care units or wards. Mask compliance should be considered regardless of the mask type chosen because mask compliance enhances patient comfort and reduces complications such as skin necrosis and pressure injuries (14). It was found that 9-22% of patients could not tolerate NIV due to pain, discomfort, claustrophobia, or agitation, and there was a lack of awareness of this situation in chest wards other than ICUs (15). This complication can also lead to disruption of NIV therapy because the agitated patient removes the mask or ties and increased leakage causes non-compliance. Sedation is not routinely administered during NIV because, as is well known, poor consciousness at the start of NIV therapy is a relative contraindication. Despite this, patients may not be able to tolerate the discomfort caused by the mask, claustrophobia, and anxiety, and sedation may be required (16).

In our PICU, the patient's agitation and discomfort are frequent due to advanced age and/or numerous comorbidities. With the checklist, from the preparation period until the end of the second hour, the implementation of proper practices guaranteed and possible pitfalls that may occur during NIV therapy detected earlier and timely interventions were ensured. The non-compliant patients, which constitute the largest group in NIV failure, were identified and the communication with patients was assured, the problem was determined and tried to solve, the NIV therapy training and the motivation were repeated. With these interventions, 53.3% of the non-compliant patients' (n=10) situations were resolved and NIV therapy was performed successfully. If non-compliance was still continued, restriction of the patient (n=4, 21.1%) and/or sedation was performed (n=4, 21.1%). Although it may be difficult for a patient with shortness of breath to voice their concerns before NIV therapy begins, the nurse and the physician should fully explain the therapy and address the patient's concerns.

Tully et al. (17) suggest that preparation of the NIV therapy should include addressing face masks and mask-related communication problems. In this study, the rate of the patients who needed a break from the NIV therapy was significantly higher in those who were non-compliant with NIV therapy (p<0.05). In addition, this checklist increased the efficiency and awareness of the nurse team, which has a critical role in the initiation, implementation, and followup of NIV therapy. Thus, the harmony of physicians and nurses who implements NIV therapy has increased and individual differences in practice have been minimized.

CONCLUSION

In suitable conditions, it is a fact that morbidity and mortality are significantly reduced by NIV therapy instead of invasive mechanical ventilation. Identifying frequent problems and taking measures will increase the success in NIV therapy and will minimize the need for an invasive mechanical ventilator. For this reason, we conclude that the NIV team should provide the best care to the patients by the selection of the right ventilators and mode, choosing and fitting the right mask, and also have to manage frequent complications, and monitoring patients. For all these interventions to increase patient compliance to NIV therapy, implementing a checklist will provide reliable support to the NIV team and increase NIV therapy success.

ETHICAL DECLARATIONS

Ethics Committee Approval: This study was approved by the Health Sciences University Keçiören Education and Training Hospital Clinical Studies Ethics Board (Date: 12/10/2021, Decision No: 2012-KAEK-15/2394).

Informed Consent: Since the study was designed retrospectively, informed consent was not obtained from the patients.

Conflict of Interest Status: The authors declared that there was no conflict of interest in this study.

Financial Disclosure: The authors declared that this study has received no financial support.

Author Contributions: All authors; declared that they participated in the design, execution, and analysis of the article and approved the final version.

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