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Original Article

Non-Invasive Ventilation: a Safe and Effective Respiratory Support Method in Hypoxemic Acute Respiratory Failure Due to Pneumonia with or without Acute Respiratory Distress Syndrome

Viktoria Ilieva, Yordanka Yamakova

Department of Anesthesiology and Intensive Care, Medical University of Sofia, Sofia, Bulgaria

Corresponding author: Viktoria Ilieva, Department of Anesthesiology and Intensive Care, Medical University of Sofia, 92 Banishora St., 1233 Sofia, Bulgaria; E-mail: dr_viktoria_ilieva@abv.bg; Tel.: +359 889 907 202

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Abstract

Introduction: The benefit of non-invasive ventilation (NIV) in cases of hypercapnic acute respiratory failure (ARF) has already been proven. Still, its safety and efficacy as a respiratory support method for patients with hypoxemic ARF hasn't been studied so well.

Aim: The aim of our study was to examine the safety and efficacy of NIV in hypoxemic ARF of primary lung origin.

Materials and methods: This was a prospective observational cohort study of patients with hypoxemic ARF due to community acquired pneumonia with or without acute respiratory distress syndrome (ARDS) treated using NIV. They were divided into four groups: pneumonia without ARDS, mild, moderate, or severe ARDS. Their clinical and ABG parameters were recorded before initiation of NIV, at 1 hour and 24 hours after ventilation onset and at transition to non-intensive NIV or before endotracheal intubation in NIV failure cases.

Results: A total of 63 patients were included. NIV trial was successful in 85.71% of them, while 14.29% experienced NIV failure. In the general population, we observed a significant difference in PaO_2/FiO_2 only before transition to non-intensive NIV in comparison to the value at admission. This trend was seen in the patients with pneumonia without ARDS and moderate ARDS, but not in those with mild and severe ARDS. The clinical parameters showed improvement early in the course of treatment both in the entire study population and all subgroups.

Conclusions: NIV is an effective and safe option for respiratory support in patients with severe CAP only when an adequate etiological treatment has been applied.

Keywords

ARDS, non-invasive ventilation, pulmonary inflammation

INTRODUCTION

The benefit of NIV for the survival of patients with certain conditions (COPD, cardiogenic pulmonary edema and difficult weaning from invasive mechanical ventilation) has already been proven.[1] However, the safety and efficacy of NIV as a respiratory support method for patients with de novo hypoxemic ARF hasn't been studied very well. To date, only ten randomized controlled trials have been published on this topic.[2-11] Only two of them include only non-hypercapnic immunocompetent patients and can serve as strong evidence for giving recommendations for the use of NIV in this type of patients. That is why the European Respiratory Society and the American Thoracic Society don't give any recommendations for the use of NIV for de novo hypoxemic ARF in their new 2017 guidelines[12], making the topic highly controversial.

AIM

To determine the degree of clinical and arterial blood gas (ABG) values improvement during the course of NIV treatment in patients with hypoxemic ARF due to severe community acquired pneumonia CAP with or without ARDS.

MATERIALS AND METHODS

This was a prospective observational cohort study of patients with hypoxemic ARF due to CAP with or without ARDS. It was conducted between 2015 and 2018 in the ICU of a specialized hospital for pulmonary diseases. The trial was approved by the local Ethics Committee of the same hospital and conducted in accordance with the Good Clinical Practice guidelines and the principles of the Declaration of Helsinki.

Consecutive patients over 18 years of age with severe CAP and PaO_2 < 60 mmHg that could not be corrected with oxygen therapy were included in the study. The patients were split into four groups: patients with pneumonia without ARDS, and with pneumonia with mild, moderate, or severe ARDS. ARDS severity was assessed using the criteria of the Berlin definition[13]: acute onset of the disease; bilateral opacities on the chest X-ray not fully explained by effusions, lobar/lung collapse or nodules; respiratory failure of non-cardiac origin; and PaO_2/FiO_2 on at least 5 cm H_2O of CPAP between 300 and 200 mmHg for mild ARDS, between 200 and 100 mmHg for moderate ARDS, and under 100 mmHg for severe ARDS. Patients with any of the following conditions were excluded: pregnancy, cardiogenic pulmonary edema, lung carcinoma, active tuberculosis, severe encephalopathy, cardiac or respiratory arrest, hemodynamic instability, unstable arrhythmia, acute myocardial infarction, excessive sputum production, hematemesis or hemoptysis, facial trauma, uncontrolled vomiting, pneumothorax without a chest tube in place, and pleural effusion.

We provided NIV only via dedicated critical care respirators. The initial expiratory positive airway pressure (EPAP) was set at 5 cm H_2O and increased until alveolar recruitment with oxygenation improvement was achieved. Inspiratory positive airway pressure (IPAP) was started 2-4 cm H_2O above the EPAP and increased gradually until a tidal volume of 6 ml/kg was achieved. Respiratory rate was 20-25/min and the fraction of inspired oxygen – 0.6–1. In the first few days after treatment initiation, the patients were on NIV for more than 16 hours a day. When their oxygenation started to improve, the ventilator-free time was extended until we were able to correct their hypoxemia with oxygen therapy alone.

Deterioration of oxygenation, unresponsive to changes in the ventilator settings, impaired consciousness, hemodynamic instability, and inability to protect the airway were defined as criteria for NIV failure with the need for endotracheal intubation.

We monitored the patients' respiratory rate (RR), heart rate (HR) and ABG parameters before initiation of NIV, at 1 hour and 24 hours after ventilation onset and at transition to non-intensive NIV (less than 16 hours a day) or before endotracheal intubation.

Because of the non-parametric fashion of the data, results were presented as median and interquartile range (IQR). The differences between medians of paired variables were analyzed with the Wilcoxon signed-rank test. A p-value < 0.05 was considered statistically significant. The statistical analysis was done using the IBM SPSS v.25 package.

RESULTS

During the three-year study period, 63 patients with severe CAP met the inclusion criteria of the study and were put on NIV. The median age of the subjects was 58 (IQR: 19) years. Thirty-five of them were male and 28 – female. Eleven of them had COPD (without hypercapnia), 9 had obesity hypoventilation syndrome, 5 – obstructive sleep apnea, 29 – hypertension, 12 – heart failure, 11 – ischemic heart disease, 17 – diabetes, 21 – other conditions, 13 patients were without any comorbidities. Their median CURB-65 score was 2 (IQR: 2) and SAPS II score – 33 (IQR: 20). Their treatment duration was median 92 hours (max 216 hours, min 12 hours). 27% (n=17) had pneumonia without ARDS, 19% (n=19) – mild ARDS, 41% (n=26) – moderate ARDS and 13% (n=8) – severe ARDS.

The NIV trial was successful in 85.71% (n=54) of the patients, while 14.29% (n=9) experienced NIV failure and were intubated. Five (7.94% from the whole study population and 55.56% from the NIV failure group) died and the other three were extubated successfully. The indications for endotracheal intubation were: deterioration of oxygenation (n=7), high leak (n=1) and impaired consciousness (n=2). Amongst the deceased, three were with mild, three with moderate, and two with severe ARDS. None of the NIV success patients died.

First we conducted a statistical analysis to determine the dynamics of the clinical and ABG parameters in the whole study population **(Table 1)**. In the general study population, we observed a statistically significant difference in oxygenation (defined by the PaO_2/FiO_2) only between the initial and the last value, while PaO_2 improves on the first hour after ventilation onset. The clinical parameters showed rapid improvement early in the course of treatment.

To assess the dynamics of the monitored parameters according to disease severity, we allocated the patients into four groups. For every group, a separate statistical analysis was conducted **(Tables 2-5)**. The results show that in the "pneumonia without ARDS" and "moderate ARDS" groups, the dynamics of ABG parameters follows the trend observed in the entire population. In the severe ARDS group, PaO_2/FiO_2 was significantly higher at 1 hour, then deteriorated and improved again later. In the mild ARDS group, we could not observe any significant improvement of PaO_2/FiO_2 in comparison to the initial values.

The clinical parameters improved significantly at 1 hour after ventilation onset in all groups, except for the mild ARDS, where the RR and HR decrease at 24 hours.

DISCUSSION

The results of this study suggest that the use of NIV helped avoiding invasive ventilation in 85.71% of the patients with severe CAP in the present cohort. The NIV failure rate in our study was lower than that reported in other studies (between 20% and 70.3%).[14-17] The great difference between the NIV success rates in the different studies is mainly due to the variable patient selection criteria. In time, the criteria become stricter and this leads to reduction of failed NIV attempts. This thesis is confirmed by Demoule et al., who report an increase of NIV success in de novo hypoxemic ARF patients in the last 15 years.[18]

The use of NIV in all groups was associated with a significant improvement of RR and HR shortly after ventilation onset with a tendency of normalization at the end of intensive NIV treatment. This means that there is a reduction in the work of breathing, the O_2 consumption, heart muscle strain, and improvement in the psychological state of patients. Similar effects of NIV have been reported by other authors.[14-16]

Improvement in PaO_2/FiO_2 ratio in the whole study population was observed only after a few days of complex antibiotic and supportive treatment. A possible explanation for this phenomenon is the fact that PaO_2/FiO_2 is the main indicator for ventilation/perfusion mismatching and mirrors the degree of lung tissue damage. This means that it can improve significantly only after reduction of the inflammatory process itself. The late improvement of PaO_2/FiO_2 we observed correlates with the results reported in other studies.[19,21,22]

In the patients with pneumonia without ARDS and moderate ARDS, the central tendency mirrors that of the

Table 1. Dynamics of the monitored parameters in the whole study population (n=63)

	Before initiation of NIV		At 1 hour		p_1	At 24 hours		p_2	At transition to non-intensive NIV/ before endotracheal intubation		p_3
RR	Median: 34	→ IQR: 6	Median: 28	→ IQR: 6	**<0.001**	Median: 24	→ IQR: 5	**<0.001**	Median: 20.5	→ IQR: 5	**<0.001**
HR	Median: 100	→ IQR: 27.5	Median: 90	→ IQR: 17.5	**<0.001**	Median: 86	→ IQR: 20	**<0.001**	Median: 82	→ IQR: 14	**<0.001**
pH	Median: 7.48	→ IQR: 0.08	Median: 7.44	→ IQR: 0.12	**0.001**	Median: 7.45	→ IQR: 0.07	**0.002**	Median: 7.45	→ IQR: 0.07	0.114
$PaCO_2$	Median: 31.2	→ IQR: 9.1	Median: 34	→ IQR: 8.6	**<0.001**	Median: 36.2	→ IQR: 8.4	**<0.001**	Median: 36.45	→ IQR: 9.3	**<0.001**
PaO_2	Median: 47.6	→ IQR: 14.9	Median: 83.3	→ IQR: 30.1	**<0.001**	Median: 80.8	→ IQR: 23.85	**<0.001**	Median: 80.05	→ IQR: 37	**<0.001**
PaO_2/FiO_2	Median: 157.92	→ IQR: 87.73	Median: 156.4	→ IQR: 87.82	0.837	Median: 181.25	→ IQR: 82.42	0.129	Median: 225.28	→ IQR: 106.47	**<0.001**
HCO_3	Median: 23.3	→ IQR: 5.5	Median: 23.9	→ IQR: 5.3	**0.003**	Median: 24.9	→ IQR: 6.9	**0.002**	Median: 24.95	→ IQR: 5.93	**<0.001**
Sat %	Median: 86.5	→ IQR: 11.8	Median: 96.8	→ IQR: 3	**<0.001**	Median: 96.5	→ IQR: 2.9	**<0.001**	Median: 95.9	→ IQR: 5.18	**<0.001**

p_1: comparison between the parameters before NIV initiation and at 1 hour after ventilation onset; p_2: comparison between the parameters before NIV initiation and at 24 hours after ventilation onset; p_3: comparison between the parameters before NIV initiation and at transition to non-intensive NIV/ before endotracheal intubation

Table 2. Dynamics of the monitored parameters in the group of pneumonia without ARDS (n=17)

	Before initiation of NIV	At 1 hour	p_1	At 24 hours	p_2	At transition to non-intensive NIV/ before endotracheal intubation	p_3
RR	Median: 34; → IQR: 5	Median: 28; → IQR: 6	**0.002**	Median: 22; → IQR: 5	**0.001**	Median: 20 → IQR: 2	**0.002**
HR	Median: 100; → IQR: 35	Median: 95; → IQR: 10	**0.023**	Median: 90; → IQR: 19	**0.003**	Median: 84.5 → IQR: 12.5	**0.003**
pH	Median: 7.49; → IQR: 0.1	Median: 7.45; → IQR: 0.13	**0.032**	Median: 7.45; → IQR: 0.08	**0.014**	Median: 7.46 → IQR: 0.07	0.581
$PaCO_2$	Median: 32; → IQR: 9.2	Median: 36.3; → IQR: 14.3	0.2	Median: 36.7; → IQR: 10.7	**0.006**	Median: 35.8 → IQR: 8.8	0.19
PaO_2	Median: 49.2; → IQR: 19.6	Median: 78.2; → IQR: 28.9	**0.001**	Median: 85.2; → IQR: 35.4	**0.001**	Median: 76.8 → IQR: 47.7	**0.004**
PaO_2/FiO_2	Median: 180; → IQR: 76.37	Median: 180.6; → IQR: 118.55	0.733	Median: 208.8; → IQR: 82.46	0.256	Median: 253.17 → IQR: 56.3	**0.005**
HCO_3	Median: 23.6; → IQR: 5.6	Median: 24.4; → IQR: 7.1	0.41	Median: 25.6; → IQR: 7.9	0.334	Median: 25.3 → IQR: 6.23	**0.002**
Sat %	Median: 87.7; → IQR: 13.4	Median: 96.4; → IQR: 4.3	**0.001**	Median: 97.1; → IQR: 3.9	**0.001**	Median: 95 → IQR: 5.85	**0.05**

p_1: comparison between the parameters before NIV initiation and at 1 hour after ventilation onset; p_2: comparison between the parameters before NIV initiation and at 24 hours after ventilation onset; p_3: comparison between the parameters before NIV initiation and at transition to non-intensive NIV/ before endotracheal intubation

Table 3. Dynamics of the monitored parameters in the group of mild ARDS (n=12)

	Before initiation of NIV	At 1 hour	p_1	At 24 hours	p_2	At transition to non-intensive NIV/ before endotracheal intubation	p_3
RR	Median: 34.5 → IQR: 7.5	Median: 33.5 → IQR: 10.75	0.163	Median: 25 → IQR: 9	0.033	Median: 24.5 → IQR: 10	0.003
HR	Median: 105 → IQR: 43.75	Median: 97.5 → IQR: 33.75	0.124	Median: 86 → IQR: 18	0.017	Median: 82 → IQR: 17.5	0.012
pH	Median: 7.47 → IQR: 0.05	Median: 7.43 → IQR: 0.08	0.01	Median: 7.43 → IQR: 0.05	0.377	Median: 7.45 → IQR: 0.05	0.244
$PaCO_2$	Median: 30.15 → IQR: 9.3	Median: 34.9 → IQR: 6.28	0.02	Median: 35.35 → IQR: 9.7	0.079	Median: 34.85 → IQR: 10.1	0.022
PaO_2	Median: 49.15 → IQR: 14.05	Median: 86.55 → IQR: 21.8	<0.001	Median: 81.7 → IQR: 16.39	0.002	Median: 74.7 → IQR: 32.43	0.006
PaO_2/FiO_2	Median: 218.33 → IQR: 60.76	Median: 197.68 → IQR: 135.68	0.301	Median: 204.5 → IQR: 73.85	0.221	Median: 258.94 → IQR: 85.51	0.124
HCO_3	Median: 21.75 → IQR: 8.1	Median: 22.05 → IQR: 5.7	0.348	Median: 23 → IQR: 4.5	0.286	Median: 22.9 → IQR: 5.98	0.041
Sat %	Median: 86.15 → IQR: 9.05	Median: 97.2 → IQR: 2.28	<0.001	Median: 96.75 → IQR: 1.9	0.002	Median: 94.9 → IQR: 5.55	0.009

p_1: comparison between the parameters before NIV initiation and at 1 hour after ventilation onset; p_2: comparison between the parameters before NIV initiation and at 24 hours after ventilation onset; p_3: comparison between the parameters before NIV initiation and at transition to non-intensive NIV/ before endotracheal intubation

Table 4. Dynamics of the monitored parameters in the group of moderate ARDS (n=26)

	Before initiation of NIV	1-st hour	p_1	24-th hour	p_2	At transition to non-intensive NIV/ before endotracheal intubation	p_3
RR	Median: 32 → IQR: 6.5	Median: 25 → IQR: 6	**<0.001**	Median: 24 → IQR: 3.5	**<0.001**	Median: 21 → IQR: 4	**<0.001**
HR	Median: 100 → IQR: 30.5	Median: 85 → IQR: 17	**<0.001**	Median: 80 → IQR: 11.5	**<0.001**	Median: 80 → IQR: 9.75	**<0.001**
pH	Median: 7.49 → IQR: 0.26	Median: 7.47 → IQR: 0.14	0.494	Median: 7.45 → IQR: 0.1	0.028	Median: 7.45 → IQR: 0.07	0.807
$PaCO_2$	Median: 30.15 → IQR: 9.3	Median: 33.7 → IQR: 10.25	0.15	Median: 36.2 → IQR: 7.85	**0.015**	Median: 39.3 → IQR: 11.9	0.28
PaO_2	Median: 47.4 → IQR: 14.05	Median: 84.7 → IQR: 21	**<0.001**	Median: 81.5 → IQR: 25.45	**<0.001**	Median: 75.5 → IQR: 27.5	**<0.001**
PaO_2/FiO_2	Median: 140.31 → IQR: 29.48	Median: 137.75 → IQR: 56.8	0.527	Median: 150.62 → IQR: 68.17	0.143	Median: 182.4 → IQR: 97.28	**0.045**
HCO_3	Median: 24.3 → IQR: 5.35	Median: 25 → IQR: 4.15	0.022	Median: 25.6 → IQR: 6.2	**0.011**	Median: 25.6 → IQR: 5.6	**0.025**
Sat %	Median: 86.15 → IQR: 4.75	Median: 96 → IQR: 3.5	**<0.001**	Median: 96.5 → IQR: 3.5	**<0.001**	Median: 96.1 → IQR: 3.5	**<0.001**

p_1: comparison between the parameters before NIV initiation and at 1 hour after ventilation onset; p_2: comparison between the parameters before NIV initiation and at 24 hours after ventilation onset; p_3: comparison between the parameters before NIV initiation and at transition to non-intensive NIV/ before endotracheal intubation

Table 5. Dynamics of the monitored parameters in the group of severe ARDS (n=8)

	Before initiation of NIV	At 1 hour	p_1	At 24 hours	p_2	At transition to non-intensive NIV/ before endotracheal intubation	p_3
RR	Median: 36 → IQR: 4	Median: 26 → IQR: 6	**0.027**	Median: 24 → IQR: 2	**0.018**	Median: 22 → IQR: 8	**0.018**
HR	Median: 100 → IQR: 30	Median: 86 → IQR: 45	**0.043**	Median: 90 → IQR: 25	**0.018**	Median: 85 → IQR: 17	**0.018**
pH	Median: 7.48 → IQR: 0.1	Median: 7.46 → IQR: 0.06	**0.039**	Median: 7.45 → IQR: 0.03	0.672	Median: 7.45 → IQR: 0.2	0.176
$PaCO_2$	Median: 29.8 → IQR: 13.9	Median: 33.5 → IQR: 10.1	**0.043**	Median: 31.6 → IQR: 6.1	0.31	Median: 35 → IQR: 9.1	0.063
PaO_2	Median: 47.6 → IQR: 9.8	Median: 70.5 → IQR: 32.1	**0.018**	Median: 74.9 → IQR: 30.6	**0.018**	Median: 90.6 → IQR: 29.5	**0.028**
PaO_2/FiO_2	Median: 96.18 → IQR: 6	Median: 125 → IQR: 42.08	**0.043**	Median: 115.23 → IQR: 85.33	0.063	Median: 169.8 → IQR: 65.02	**0.028**
HCO_3	Median: 22 → IQR: 7.2	Median: 22.6 → IQR: 5.6	0.116	Median: 21.9 → IQR: 5.6	0.31	Median: 25.1 → IQR: 5.2	**0.018**
Sat %	Median: 86.5 → IQR: 11.1	Median: 96.4 → IQR: 4.3	**0.018**	Median: 95.5 → IQR: 4	**0.018**	Median: 97.2 → IQR: 1.4	0.128

p_1: comparison between the parameters before NIV initiation and at 1 hour after ventilation onset; p_2: comparison between the parameters before NIV initiation and at 24 hours after ventilation onset; p_3: comparison between the parameters before NIV initiation and at transition to non-intensive NIV/ before endotracheal intubation

entire population. Therefore, we can conclude that these groups shape the results observed in the cohort as a whole. Interestingly, we observed no improvement of PaO_2/FiO_2 in the mild ARDS group and a significant improvement of the same parameter early in the course of treatment in the severe ARDS group, which disagrees with the general perception that NIV is suited mainly for cases of mild to moderate ARDS.[23]

Although interesting, the results might be biased by the unequal number of patients in the four study groups. If there were milder and more severe ARDS cases, the results could have been different and maybe more coherent with the observed central tendency. Therefore, further research is needed in order to draw any definite conclusions.

Limitations of the study

1. Small number of patients, particularly in the individual groups. The whole study population was not that small (a total of 63 patients), but none of the groups had more than 30 patients.

2. The patient groups do not have equal number of patients, which could have biased the results and shaped the central tendency in a wrong way.

3. The study was conducted at a specialized hospital for pulmonary diseases with great experience in NIV. Careful patient selection and the extensive training of the ICU personnel might have influenced the positive results, particularly in the severe ARDS group.

Strong points

1. Only a few studies assess the ABG dynamics in different ARDS patients treated with NIV.

2. The separation of results according to disease severity can help to distinguish which patient populations can benefit from a NIV trial.

3. The results in the mild and severe ARDS groups give rise to a discussion regarding the general perception that NIV is suitable only in cases of mild to moderate ARDS.

CONCLUSIONS

NIV is an effective, safe option for respiratory support in patients with severe CAP only when an adequate etiological treatment has been applied.

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Conflict of Interest

The authors have declared that no competing interests exist.

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Неинвазивная вентиляция: безопасный и эффективный метод респираторной поддержки при острой гипоксемической дыхательной недостаточности, вызванной пневмонией с острым респираторным дистресс-синдромом или без него

Виктория Илиева, Йорданка Ямакова

Отделение анестезиологии и интенсивного ухода, Медицинский университет – София, София, Болгария

Адрес для корреспонденции: Виктория Илиева, Отделение анестезиологии и интенсивного ухода, Медицинский университет – София, ул. „Банишора“ № 92, 1233 София, Болгария; E-mail: dr_viktoria_ilieva@abv.bg; Тел.: +359 889 907 202

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Резюме

Введение: Преимущества неинвазивной вентиляции (НИВ) в случаях острой дыхательной недостаточности (ОДН) уже доказаны. Однако его безопасность и эффективность как метода поддержания дыхания у пациентов с гипоксической ОДН до настоящего времени не изучались.

Цель: Целью нашего исследования было изучить безопасность и эффективность НИВ при гипоксической ОДН первичного лёгочного происхождения.

Материалы и методы: Это проспективное когортное исследование пациентов с гипоксической ОДН, вызванной внебольничной пневмонией (ВБП), с острым респираторным дистресс-синдромом (ОРДС) или без него, прошедших курс лечения НИВ. Они были разделены на четыре группы: пневмония без ОРДС, лёгкая, умеренная или тяжелая форма ОРДС. Их клинические параметры и параметры анализа газов крови регистрировались до начала НИВ, через час и через 24 часа после начала вентиляции и при переводе в неинтенсивный НИВ или перед эндотрахеальной интубацией в случаях неудачной НИВ.

Результаты: Всего было включено 63 пациента. Применение НИВ было успешным у 85.71% из них, а у 14.29% – применение НИВ не было успешным. Среди населения в целом мы наблюдали значительную разницу в PaO_2 / FiO_2 только в случаях перед переходом на неинтенсивный НИВ по сравнению с величиной при применении. Эта тенденция наблюдалась у пациентов с пневмонией без ОРДС и умеренным ОРДС, но не у пациентов с лёгким и тяжёлым ОРДС. Клинические параметры показали улучшение в начале курса лечения как в исследуемой популяции, так и во всех подгруппах.

Заключение: НИВ является эффективным и безопасным вариантом поддержания дыхания у пациентов с тяжёлыми сердечно-сосудистыми заболеваниями только при адекватном этиологическом лечении.

Ключевые слова

ОРДС, неинвазивная вентиляция лёгких, воспаление лёгких