

Comparison of noninvasive respiratory support methods in the postoperative period in cardiac surgery patients: a prospective randomized trial

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Abstract

INTRODUCTION: The frequency of respiratory failure in the postoperative period is 17–22 % [1–3]. The most commonly used methods: noninvasive positive pressure mask ventilation (NIPPMV), high-flow nasal cannula (HFNC), noninvasive positive pressure helmet ventilation (NIPPHV). **OBJECTIVE:** Comparison of the effectiveness of respiratory support methods depending on their effect on gas exchange in patients with mild to moderate respiratory failure in the early period after cardiac surgery. **MATERIALS AND METHODS:** The study included 42 cardiac surgery patients with $200 < P/F < 300$ who were divided into 3 groups depending on the methods of respiratory support used (NIPPMV, HFNC, NIPPHV). The main point of the study is to assess the dynamics of the gas exchange indicators before, during and after their use. **RESULTS:** All three methods of NIVL contribute to a statistically significant improvement in gas exchange during NIVL, which persisted after the end of therapy (SpO_2 , PaO_2 , P/F , Qsp/Qt). In the group with the use of NIPPMV and HFNC an increase in the oxyhemoglobin fraction. In the course of this study, no data were revealed on changes in $PaCO_2$. The largest increase in SpO_2 was revealed in groups using a mask and helmet, but at the end of the NIVL session there were no statistically significant differences between the groups. A decrease in the proportion of patients with $P/F < 300$ after a single session in the NIPPMV group by 2 times, in the HFNC group — by 1.6 times, in the NIPPHV group — by 3.5 times. **CONCLUSIONS:** Conducting noninvasive respiratory support significantly improves the indicators of oxygenating lung function in the early postoperative period in cardiac surgery patients. NIPPHV and NIPPMV are more effective compared to HFNC. When using a helmet, a higher level of support is required.

Сравнение эффективности методов неинвазивной респираторной поддержки в послеоперационном периоде у кардиохирургических больных: пилотное исследование

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Реферат

АКТУАЛЬНОСТЬ: Частота развития дыхательной недостаточности после кардиохирургических вмешательств составляет 17–22 % [1–3]. Методы неинвазивной респираторной поддержки: неинвазивная масочная вентиляция легких (НИМВЛ), высокопоточная назальная оксигенотерапия (ВНО) и неинвазивная вентиляция с помощью шлема (НИВЛШ) находят все более широкое применение в терапии дыхательной недостаточности у этих пациентов. **ЦЕЛЬ ИССЛЕДОВАНИЯ:** Сравнение эффективности методов респираторной поддержки в зависимости от их влияния на газообмен у пациентов с легкой степенью тяжести дыхательной недостаточности в раннем периоде после кардиохирургических вмешательств. **МАТЕРИАЛЫ И МЕТОДЫ:** В работу включены 42 кардиохирургических пациента с $200 < P/F < 300$, которые были разделены на 3 группы в зависимости от применяемого метода респираторной поддержки (НИМВЛ, ВНО или НИВЛШ). Основная точка исследования — оценка динамики показателей газообмена до, во время и после их применения. **РЕЗУЛЬТАТЫ:** Все три метода НИВЛ способствуют статистически достоверному улучшению показателей газообмена во время проведения НИВЛ, которое сохранялось и после завершения терапии (SpO_2 , PaO_2 , P/F , Qsp/Qt). В группе с применением НИМВЛ и ВНО отмечен прирост фракции оксигемоглобина. Значения $PaCO_2$ в группах сравнения не различались. Наибольший прирост SpO_2 наблюдаем в группах с использованием маски и шлема, но по завершении сеанса НИВЛ статистически значимых различий между группами не было. Доля пациентов с $P/F < 300$ после однократного сеанса в группе НИМВЛ снизилась в 2 раза, в группе ВНО — в 1,6 раза, в группе

KEYWORDS: noninvasive ventilation, helmets, oxygen inhalation therapy, respiratory insufficiency, hypoxia

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НИВЛШ — в 3,5 раза. **Выводы:** Проведение неинвазивной респираторной поддержки значительно улучшает показатели оксигенирующей функции легких в раннем послеоперационном периоде у кардиохирургических больных. НИВЛШ и НИМВЛ более эффективны по сравнению с ВНО. При использовании шлема требуется более высокий уровень респираторной поддержки.

КЛЮЧЕВЫЕ СЛОВА: неинвазивная вентиляция легких, шлемы, назальная оксигенотерапия, дыхательная недостаточность, гипоксемия

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Introduction

The incidence of postoperative respiratory failure (ARF) in cardiac surgery patients reaches 17–22 % [1–3]. This fact increases the terms of patients' stay in intensive care unit, duration of hospitalization, as well as the number of complications and fatal cases, and requires a lot of medical and economic resources [4, 5]. During recent years correction of decreased oxygenating function of the lungs with the help of different methods of non-invasive lung ventilation is taking an increasingly strong position.

Methods of noninvasive respiratory support used in early postoperative period have proven themselves in clinical practice [6, 7]. They are used to improve gas exchange, decrease work of breathing, and straighten collapsed alveoli in hypoventilation and microatelectatic areas.

In modern practice the most frequently used are non-invasive positive pressure mask ventilation, high-flow nasal

cannula and noninvasive positive pressure helmet ventilation [8–14].

These methods permit to avoid tracheal intubation and achieve significant improvement of blood gases, but there is no consensus about their efficiency in different patient populations, and in cardiac surgery this problem has been studied insufficiently [15].

Objective. To compare the efficiency of respiratory support methods depending on their influence on gas exchange in patients with mild respiratory failure in the early period after cardiac surgery.

Materials and methods

Design — a pilot prospective randomized trial. Registration number on the website: <https://clinicaltrials.gov> — NCT 04787666.

Table 1. Clinical characteristics of patients

Parameter	NIPPMV	HFNC	NIPPHV	p
Body mass index, kg/m ²	26.6 ± 4	28.7 ± 3	27.5 ± 3.7	0.89
Age (years)	54 ± 11	58 ± 13	54 ± 9	0.53
Smoking history	5	6	5	0.91
Associated pathology of the bronchopulmonary system	3	2	2	0.85
The length of a surgery				
Cardiopulmonary bypass, min	111 ± 57	108 ± 65	121 ± 44	0.27
Aortic cross-clamp, min	61 ± 28	76 ± 34	70 ± 38	0.15
Surgical approach				
Mini-thoracotomy	2	3	3	0.87
Sternotomy	12	11	11	0.87
Heart valve replacement/repair	3	5	6	0.49
Septal myectomy	2	1	1	0.77
Septal myectomy + heart valve replacement	2	2	0	0.35
Coronary revascularization				
Of pump	1	2	1	0.77
On pump	1	1	2	0.77
Coronary revascularization + Prothesis or plastic of thoracoabdominal aorta	1	3	1	0.42
Coronary revascularization + Heart valve replacement or repair	0	0	2	0.38
Prothesis of thoracoabdominal aorta + Coronary revascularization + heart valve replacement	1	2	2	0.42

HFNC — high-flow nasal cannula; NIPPHV — noninvasive positive pressure helmet ventilation; NIPPMV — noninvasive positive pressure mask ventilation.

42 patients after cardiac surgeries performed in Petrovsky National Research Centre of Surgery in 2021–2022 were included in the study (Table 1).

Criteria for inclusion in the study: decreased oxygenating lung function ($\text{PaO}_2/\text{FiO}_2$ ratio) — $200 < \text{PaO}_2/\text{FiO}_2$ ratio < 300 after extubation [16], availability of informed consent of patient for participation in this study.

Exclusion criteria: tracheal intubation, apnea, unstable hemodynamics or hemodynamically significant disorders of rhythm, stroke, shock of various etiologies, inability to provide airway protection, inability of productive contact with patient, refusal of the patient to participate in this study.

Patients were divided into three groups based on the random number method according to the respiratory support: Group 1 — NIPPMV; Group 2 — HFNC; and Group 3 — NIPPHV.

The primary endpoint of the study was the assessment of the dynamics of P/F ratio and blood gases.

In 42 patients operations were performed with cardiopulmonary bypass under normothermic or moderate hypothermic conditions. Analgesia — Fentanyl (0.2–0.3 mg on induction with continuous infusion of 3.0–3.5 mcg/kg/h), myoplegia — Pipecuronium bromide (10–12 mg) or Cisatracurium bromide (10–15 mg at the induction anesthesia followed by infusion at a calculated dose), hypnotic — Propofol (1–2 mg/kg at the induction with following infusion) in combination with the inhalation anesthetic Sevoflurane (1.0 vol% MAC). As cardioplegia “del Nido” solution was used or blood cardioplegia under normothermic or moderate hypothermic conditions.

All patients in postoperative period had multimodal analgesia according to the following scheme: Paracetamol 1 g intravenous infusion 30 min before extubation, then every 8 hours or nonsteroidal anti-inflammatory drugs (Ketoprofen 100 mg or Lornoxicam 8–16 mg) twice a day intravenously. As additional opioid analgesia in case of VAS > 40 mm,

Table 2. Causes of respiratory failure in the early postoperative period in cardiac surgery patients

Cause	NIPPMV	HFNC	NIPPHV	<i>p</i>
Operation				
Lung injury during the operation	2	3	3	0.87
Anaesthesia				
Mild acute respiratory distress syndrome	14	14	14	1.00
Intraoperative single-lung ventilation	1	2	1	0.77
Microatelectasis	2	2	2	1.00
Cardiopulmonary bypass	11	12	14	0.22
Massive blood transfusion	9	10	8	0.75
Associated pathology				
COPD	1	3	2	0.58
Bronchial asthma	1	1	1	1.00
Chronic bronchitis	2	3	2	0.85
Combination of factors	4	3	5	0.72

COPD — chronic obstructive pulmonary disease; HFNC — high-flow nasal cannula; NIPPHV — noninvasive positive pressure helmet ventilation; NIPPMV — noninvasive positive pressure mask ventilation.

Trimeperidine 20 mg, or Morphine in a dose of 10 mg, or Tramadol 100 mg intravenously were used.

Noninvasive respiratory support sessions were performed 8–10 h after tracheal extubation. Arterial blood gases and pulse oximetry oxygen saturation (SpO₂) 10 min before the session, 30 min on respiratory support, and 20 min after it were registered. The exposition of the sessions was 1 hour. Subsequently, after a single session we continued humidified oxygen inhalation with low flow or continued noninvasive respiratory support therapy if gas exchange indices were unsatisfactory.

Noninvasive ventilation was performed using Philips Respironics naso-oral mask and Intersurgical's helmet in BiPAP mode (two-level regulation of inspiratory and expiratory pressure). HFNC was performed through Fisher Paykel nasal cannulas. We used Hamilton-G5 respirators with special options for these NIVL methods.

The ventilation parameters: for NIPPMV and NIPPHV — pressure support mode with positive end-expiratory pressure (PEEP) 5 cmH₂O, inspiratory pressure — (PS) 7 cmH₂O, FiO₂ 40%; the inspiratory pressure was set to achieve tidal volume 6–8 ml/kg of ideal body weight; for HFNC — respiratory flow rate of 40 l/min at FiO₂ 40%.

Ventilation parameters to achieve optimal gas exchange were changed towards increased support in NIPPMV and NIPPHV (Table 3). The group used of helmet required higher PS and PEEP to achieve optimal gas exchange than

the NIPPMV group. This was due to the need to ventilate additional space inside the helmet.

The trigger modes were used for NIPPMV and NIPPHV: 40–50 % expiratory trigger, –1.5–2.0 cmH₂O pressure trigger, 2–3 l/min flow trigger.

Statistical analysis

Statistical analysis was performed using Statistica 10.0 and Jamovi 1.2.27 software. The results obtained during the study were evaluated according to the law of normal distribution according to the Shapiro-Wilk criterion. Methods of parametric and nonparametric analysis were used. In the case of quantitative indicators with normal distribution we calculated arithmetic mean (M) and standard deviations (SD); in the case of non-normal distribution we presented data as median and lower and upper quartiles — Me [10 : 90]. Statistical significance of intergroup differences in quantitative indices with normal distribution was assessed by single-factor analysis of variance using Bonferroni's multiple comparison-adjusted F test (ANOVA). When comparing several samples of quantitative data having a distribution other than normal, the Kruskal-Wallis test was used. Frequency of events in the group was determined by Fisher's exact test. Indicators at *p* < 0.05 were considered statistically significant.

Table 3. Starting and optimal ventilation parameters during noninvasive respiratory support

Parameter	NIPPMV		HFNC		NIPPHV	
	Start	After 30 min	Start	After 30 min	Start	After 30 min
PEEP, cmH ₂ O	5	6	—	—	5	10
PS, cmH ₂ O	7	8	—	—	7	12
FiO ₂ , %	40	40	40	40	40	40
Flow, l/min	—	—	40	40	—	—

FiO₂ — fraction of inspired oxygen; HFNC — high-flow nasal cannula; NIPPHV — noninvasive positive pressure helmet ventilation; NIPPMV — noninvasive positive pressure mask ventilation; PEEP — positive end-expiratory pressure; PS — inspiratory pressure.

Results

The study was conducted in the early period after cardiac surgical operation. Respiratory disorders are typical for this category of patients, which in addition to concomitant pathology can be associated with the specificity of these operations: cardiopulmonary bypass during which there is no blood flow and ventilation in the lungs, the formation of microatelectasis and areas of hypoventilation in the lungs due to prolonged position on the back, lung injury due to prolonged invasive ventilation of the lungs, blood transfusion and its components, ARDS and other factors. These factors and causes of ARF are presented in Tables 1

and 2, which show no significant differences between the groups.

All methods of respiratory support lead to statistically significant improvement of gas exchange indices during NIV, which persisted even after its completion (Table 4). It concerned oxygen saturation (SpO₂), arterial partial pressure of oxygen (PaO₂), PaO₂/FiO₂ ratio coefficient and shunt fraction (Qsp/Qt).

Significant increase of oxyhemoglobin (HbO₂) saturation at the used of noninvasive support sessions was registered in all groups, however after its completion statistically significant differences were revealed in two NIPPMV and HFNC groups. PaCO₂ had no significant changes in all groups.

Table 4. Dynamics of indicators of blood gas composition and pulse oximetry at the stages of noninvasive respiratory support in three groups (n = 42)

Parameter	Group 1 (n = 14) NIPPMV	Group 2 (n = 14) HFNC	Group 3 (n = 14) NIPPHV
SpO₂, %			
before the session (p1)	87 ± 3	90 [87; 98]	89 ± 2
during the session (p2)	97 ± 2	97 [93; 98]	98 ± 2
after the session (p3)	92 ± 3	92 ± 3	94 ± 3
p1–p2	< 0.001	< 0.001	< 0.001
p2–p3	< 0.001	< 0.001	< 0.001
p1–p3	< 0.001	0.02	< 0.001
PaO₂, mmHg			
before the session (p1)	57 [50; 60]	57 [50; 62]	56 ± 10
during the session (p2)	107 ± 22	85 ± 20	100 ± 26
after the session (p3)	62 ± 7	60 ± 9	63 [59; 77]

Parameter	Group 1 (n = 14) NIPPMV	Group 2 (n = 14) HFNC	Group 3 (n = 14) NIPPHV
p1–p2	< 0.001	< 0.001	< 0.001
p2–p3	< 0.001	< 0.001	< 0.001
p1–p3	< 0.001	0.04	0.01
PaO₂/FiO₂ ratio			
before the session (p1)	273 [238; 285]	270 [238; 295]	281 ± 11
during the session (p2)	318 ± 110	232 ± 55	287 ± 64
after the session (p3)	291 ± 31	287 ± 45	300 [281; 366]
p1–p2	< 0.001	0.03	0.92
p2–p3	0.01	0.01	0.07
p1–p3	0.01	0.03	0.02
PaCO₂, mmHg			
before the session (p1)	40 ± 5	40 [35; 46]	39 ± 5
during the session (p2)	39 ± 4	40 ± 5	39 ± 4
after the session (p3)	40 ± 4	39 ± 4	38 ± 3
p1–p2	0.21	0.78	0.47
p2–p3	0.08	0.31	0.37
p1–p3	0.56	0.27	0.11
HbO₂, %			
before the session (p1)	88.1 ± 3.8	88.58 ± 3.36	91.31 ± 3.3
during the session (p2)	96.4 [94; 97.3]	95.72 ± 0.92	97.1 ± 1.2
after the session (p3)	90.4 ± 3.6	90.53 ± 3.36	92.7 ± 2.8
p1–p2	< 0.001	< 0.001	< 0.001
p2–p3	< 0.001	0.002	< 0.001
p1–p3	0.02	0.02	0.14
Qsp/Qt (est), %			
before the session (p1)	29.28 ± 7.93	28.6 [7.9; 35.5]	23.63 ± 7.46
during the session (p2)	17.9 [7.9; 20]	19.8 ± 6.1	15.76 ± 5.54
after the session (p3)	18.49 ± 10.86	20.7 ± 7.83	16.46 ± 8.52
p1–p2	< 0.001	< 0.001	0.03
p2–p3	0.37	0.87	0.87
p1–p3	< 0.001	0.03	0.01

Data represented as Mean ± Standart deviation (M ± SD) or as Median ± 10th and 90th percentiles.
HbO₂ — oxyhemoglobin saturation; PaCO₂ — partial pressure of arterial carbon dioxide; PaO₂ — partial pressure of arterial oxygen; PaO₂/FiO₂ ratio — partial pressure of arterial oxygen to the fraction of inspired oxygen; Qsp/Qt (est) — shunt fraction; SpO₂ — oxygen saturation.

In all three groups the initial values of SpO₂ were less than 90 %, during the session they increased in average to 97–98 %, and after the session remained above the initial level in the range of 92–94 %. This is confirmed by reliable differences in SpO₂ values.

Assessment of the “residual” effect of noninvasive respiratory support is no less important. For this purpose, we assessed the increase in gas exchange parameters after discontinuation of NIV session compared to the initial values. It turned out that reliable differences were found in SpO₂ increase between HFNC groups and when using mask or helmet (Table 5).

Table 5. The increase in indicators of oxygenating lung function (Δ) of three methods of ventilation before and after the end of a 1-hour session of respiratory support

Parameter	NIPPMV	HFNC	NIPPHV	<i>p</i>
ΔSpO_2, %				
1–2				0.02
2–3	4 \pm 2	1.5 \pm 1	5 \pm 2	0.004
1–3				0.35
ΔPaO_2, mmHg				
1–2				0.50
2–3	5 \pm 4	3 \pm 2	7 \pm 5	0.54
1–3				0.27
$\Delta\text{PaO}_2/\text{FiO}_2$, ratio mmHg				
1–2				0.50
2–3	24 \pm 20	16 \pm 7	33 \pm 21	0.21
1–3				0.42
HFNC — high-flow nasal cannula; increase ΔPaO_2 — partial pressure of arterial oxygen; increase $\Delta\text{PaO}_2/\text{FiO}_2$ ratio — partial pressure of arterial oxygen to the fraction of inspired oxygen; increase ΔSpO_2 — oxygen saturation; NIPPHV — noninvasive positive pressure helmet ventilation; NIPPMV — noninvasive positive pressure mask ventilation.				

A single session within an resulted in a significant improvement of gas exchange indices hour in all three groups, as evidenced by the reduction of the percentage of patients with $\text{PaO}_2/\text{FiO}_2$ ratio < 300 in NIPPMV group by 2 times, in HFNC group — by 1.6 times, and

the most significant decrease of patients with respiratory failure was registered in NIPPHV group — by 3.5 times (Table 6).

There were no complications and refusals to perform the procedures on the part of the patients.

Table 6. The number of patients with P/F less than 300 mmHg before and after application of noninvasive respiratory support ($n = 42$)

Research stage	NIPPMV <i>p</i> = 0.01	HFNC <i>p</i> = 0.04	NIPPHV <i>p</i> = 0.0002
Before the session, <i>n</i> (%)	14 (100)	14 (100)	14 (100)
After the session, <i>n</i> (%)	7 (50)	9 (64)	4 (29)
HFNC — high-flow nasal cannula; NIPPHV — noninvasive positive pressure helmet ventilation; NIPPMV — noninvasive positive pressure mask ventilation.			

Discussion

Our results showed that the applied methods of noninvasive respiratory support (NIPPMV, HFNC, and NIPPHV) provide significant improvement of gas exchange parameters. Significantly increased oxygen saturation, partial pressure of arterial oxygen, and P/F index, and decreased shunt.

NIPPMV and NIPPHV were more effective in comparison of HFNC due to the additional influence of positive inspiratory and expiratory airway pressures. Importantly, unlike HFNC, there is a “residual effect” after discontinuation of a one-hour NIV session with a mask or a helmet and improvement in gas exchange rates persists. It can be explained by microatelectasis straightening and reduction

of hypoventilation areas in the lungs under the influence of two-level pressure mode, which was used in these two groups of patients. We consider this fact as a basis for the recommendation to use short sessions of noninvasive ventilation with positive airway pressure as a method of respiratory rehabilitation in patients with post-extubation respiratory failure. The conclusion obtained also confirms a significant reduction in the proportion of patients with low $\text{PaO}_2/\text{FiO}_2$ ratio after completion of NIV. A single one-hour session contributes to a decrease in the number of patients with $\text{PaO}_2/\text{FiO}_2$ ratio < 300 : 1.6-fold in the HFNC group, and 2 and 3.5-fold in the mask and helmet groups, respectively.

In case of helmet and mask ventilation, we started from the initial parameters, which were then optimized according to individual demand of the patient. It is worth noting that the quality of NIV depends on the ventilation parameters chosen correctly, and it is important to keep in mind that when using a helmet, you should not forget the additional ventilated dead space inside it. PS and positive end expiratory pressure should be set at a higher level than when using a mask. It enables to achieve optimal values of pulmonary oxygenation function and avoid paCO_2 retention [17].

It is well known that cardiac surgery entails respiratory dysfunction in the most of the patients. Among the factors contributing to decreased respiratory function in early postoperative period are: intraoperative mechanical lung injury, acute respiratory distress syndrome, prolonged single-lung ventilation, microatelectasis, use of cardiopulmonary bypass, massive blood loss and transfusion, associated diseases (COPD, bronchial asthma, chronic bronchitis) and combination of several factors. This leads to a significant decrease in respiratory lung volume, impaired sputum evacuation and increased intrapulmonary blood shunt (venous admixture). The main outcome of these changes is the formation of atelectasis, work of breathing, impaired gas exchange, which increases the risk of repeated tracheal intubation [18, 19].

However, it is difficult to identify the primary factor leading to a reduction of oxygenating function of the lungs in the early postoperative period, and often it is worth considering this complication the result of multifactorial influence.

Noninvasive positive pressure mask ventilation, performed as two-level positive airway pressure (BiPAP), is often used in patients with hypoxemia after cardiothoracic surgery [20, 21].

High-flow nasal oxygen therapy is increasingly used to improve oxygenation due to its ease of implementation, better tolerability and clinical effectiveness [22]. The main effects of high-flow oxygen therapy are CO_2 elimination, reduction of atelectasized alveoli due to positive pressure, and improvement of mucociliary clearance [23, 24].

One of the directions in respiratory support is helmet-assisted ventilation, which has several advantages over NIPPMV.

Among the pronounced advantages are ensuring airway tightness of respiratory circuit and absence of damaging effect on facial skin and cornea [25, 26]. When using high-flow oxygen therapy, the patient should keep the mouth closed, otherwise this procedure will be ineffective due to high leakage. NIPPMV with prolonged use entails skin trauma, it is important to check tight contact sites for maceration or cracks, to rotate used devices for further NIPPMV (nasal, full-face masks or helmet). In short sessions, patients usually tolerate noninvasive respiratory support well, and the possibility of facial skin traumatization is practically eliminated, as shown by the results of our study.

Thus, our study demonstrated a positive effect of the studied NIV methods on pulmonary oxygenation function in patients with moderate or mild degree of respiratory postoperative insufficiency. We, as well as other researchers, have shown that clinical efficacy of noninvasive positive pressure mask ventilation and noninvasive positive pressure helmet ventilation -assisted ventilation contribute to training of respiratory muscles as well as to reduction of venous admixture fraction in lungs [27–30]. Continuous improvement of lung oxygenation function after using these methods allows to recommend them for postoperative respiratory rehabilitation of patients.

Limitations of the study

In this work we have evaluated oxygenating function of lungs after a single one-hour session of noninvasive respiratory therapy with the help of different methods. A more detailed study of clinical effectiveness of the presented methods is planned in the future: the frequency of reintubation, duration of stay in the ICU, overall clinical effect.

Conclusion

Noninvasive respiratory support significantly improves lung oxygenation function in mild to moderate respiratory failure occurring in early postoperative period in cardiac surgical patients.

Noninvasive lung ventilation through helmet or mask compared to high-flow oxygen therapy more effectively improves oxygenation indices, which may be due to the additional effect of positive inspiratory and expiratory pressures.

Ventilation with helmet requires a higher level of support due to the additional ventilated space inside the helmet.

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Author contribution. All authors according to the ICMJE criteria participated in the development of the concept

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