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A M E R I C A N C O L L E G E O F
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Prophylactic Nasal Continuous Positive Airway Pressure Following Cardiac Surgery Protects From Postoperative Pulmonary Complications*

A Prospective, Randomized, Controlled Trial in 500 Patients

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Background: Continuous positive airway pressure is a noninvasive respiratory support technique that may prevent pulmonary complications following cardiac surgery. This study was conducted to determine the efficacy of prophylactic nasal continuous positive airway pressure (nCPAP) compared with standard treatment. The primary end points were pulmonary adverse effects defined as hypoxemia ($\text{PaO}_2/\text{fraction of inspired oxygen} [\text{FIO}_2] < 100$), pneumonia, and reintubation. The secondary end point was the readmission rate to the ICU or intermediate care unit (IMCU).

Methods: We prospectively randomized 500 patients scheduled for elective cardiac surgery. Following extubation either in the operating room (early) or in the ICU (late), patients were allocated to standard treatment (control) including 10 min of intermittent nCPAP at 10 cm H_2O every 4 h or prophylactic nCPAP (study) at an airway pressure of 10 cm H_2O for at least 6 h.

Results: Prophylactic nCPAP significantly improved arterial oxygenation ($\text{PaO}_2/\text{FIO}_2$) without altering heart rate and mean arterial BP. Pulmonary complications including hypoxemia (defined as $\text{PaO}_2/\text{FIO}_2 < 100$), pneumonia, and reintubation rate were reduced in study patients compared to controls (12 of 232 patients vs 25 of 236 patients, respectively; $p = 0.03$). The readmission rate to the ICU or IMCU was significantly lower in nCPAP-treated patients (7 of 232 patients vs 14 of 236 patients, respectively; $p = 0.03$).

Conclusions: The long-term administration of prophylactic nCPAP following cardiac surgery improved arterial oxygenation, reduced the incidence of pulmonary complications including pneumonia and reintubation rate, and reduced readmission rate to the ICU or IMCU. Thus noninvasive respiratory support with nCPAP is a useful tool to reduce pulmonary morbidity following elective cardiac surgery. (CHEST 2009; 135:1252-1259)

Key words: cardiac surgery; nasal continuous positive airway pressure; pulmonary complications

Abbreviations: CPAP = continuous positive airway pressure; FIO_2 = fraction of inspired oxygen; FRC = functional residual capacity; IMCU = intermediate care unit; nCPAP = nasal continuous positive airway pressure; PEEP = positive end-expiratory pressure

Recovery from elective cardiac surgery is usually fast and uncomplicated, but postoperative pulmonary complications occur in the course of many patients, leading to increased morbidity, mortality, and costs as a result of prolonged length of stay in the hospital or in the ICU.¹ Postoperative pulmonary complications manifest early as arterial hypoxemia,²

during the later course as pneumonia, and in rare cases also as acute lung injury.³

One major cause of postoperative respiratory complications is pulmonary atelectasis. Atelectasis and the associated loss of functional alveolar units has been recognized as a major pathophysiological mechanism responsible for postoperative hypox-

emia.^{4,5} During invasive mechanical ventilation the formation of atelectasis may be prevented by the application of positive end-expiratory pressure (PEEP). After extubation, however, positive airway pressure is lost and derecruitment of lung areas starts immediately.⁶ In conjunction with poor post-operative coughing, lack of deep inspirations, pleural effusions, and increased interstitial lung water, the formation of atelectasis proceeds, thereby reducing pulmonary oxygen transfer.⁵ Therefore, the main goal is to prevent atelectasis, hypoxemia, and subsequent development of pulmonary complications following extubation.

Continuous positive airway pressure (CPAP) is a method to apply noninvasively a positive airway pressure during both inspiration and expiration in spontaneously breathing patients. The application of CPAP prevents collapse of alveolar units, may increase functional residual capacity (FRC)⁷ and arterial oxygenation,⁸ and reduce respiratory workload and cardiac preload.⁹ Prophylactic application of CPAP can reduce the incidence of endotracheal intubation^{10,11} and pneumonia,¹⁰ and the length of stay in the ICU¹⁰ and hospital after major surgery.¹² In this context, prophylactic CPAP has also been studied following cardiac surgery. Improvements in physiologic parameters were documented but, surprisingly, no clinical trial has confirmed that improved gas exchange results in reduced morbidity, mortality, or hospitalization.¹³ A major shortcoming of these studies was that the CPAP pressures used were too low to exceed ongoing positive effects. CPAP pressures of 9 to 10 cm H₂O are required to keep tracheal pressure positive during the entire respiratory cycle and to improve gas exchange consistently, especially in patients following thoracotomy.⁸

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These CPAP pressures are safe, and no adverse hemodynamic effects were observed.⁸

Therefore, we conducted a prospective, randomized clinical trial using CPAP pressures of 10 cm H₂O to test the hypothesis whether prophylactic application of nasal CPAP (nCPAP) following cardiac surgery can reduce pulmonary complications defined as hypoxemia (PaO₂/fraction of inspired oxygen [FIO₂] ratio < 100), pneumonia, and reintubation. Furthermore, we investigated as secondary end point whether the prophylactic application of nCPAP can reduce the hospital readmission rate to the ICU or intermediate care unit (IMCU).

MATERIALS AND METHODS

Patients

The ethics committee of Heinrich Heine University of Düsseldorf approved the protocol, and written informed consent was obtained from the patients before surgery. The study was conducted in accordance with the principles outlined in the Declaration of Helsinki.

All patients electively scheduled for coronary bypass surgery or heart valve replacement were eligible to participate in the study. Patients were excluded for one of the following reasons: no consent was obtained, age < 18 years, pulmonary emphysema with bullae, glucocorticoid treatment, left ventricular ejection fraction < 40%, perioperative myocardial ischemia, postoperative therapy with catecholamines, rethoracotomy, and postoperative ventilation for > 18 h.

Depending on the clinical condition, patients were extubated after surgery already in the operating room (early) or ventilated in the ICU (late) until they met extubation criteria.¹² Mechanical ventilation was carried out as previously described.¹²

Study Design

All patients were transferred to the ICU after the operation. Following arrival on the ICU, concealed randomization was conducted using a randomization list (Fig 1). We compared differences between control and study group separately for those patients who were extubated immediately following skin closure (*ie*, in the operating room) and those who were mechanically ventilated in the ICU. Thus, there were four groups (early extubation control, early extubation nCPAP, late extubation control, and late extubation nCPAP).

Without regard to the time of extubation, patients in both study groups (early and late extubation) obtained nCPAP at an airway pressure of 10 cm H₂O. nCPAP was applied following extubation as previously described.¹² Prophylactic nCPAP was applied for at least 6 h. Criteria to terminate nCPAP before the end of the study period were withdrawal of consent.

Patients in the control group received standard treatment as previously described,¹² consisting of oxygen, physiotherapy, intermittent nCPAP for 10 min at 10 cm H₂O every 4 h, and drug treatment.

In the ICU, hemodynamics (*ie*, heart rate, arterial BP, and central venous pressure) were measured continuously in all patients. To calculate the PaO₂/FIO₂ ratio, the oxygen concentration at the oxygen blender was chosen as FIO₂. For oxygen flows of at least 25 L/min, the chosen concentration is similar to the

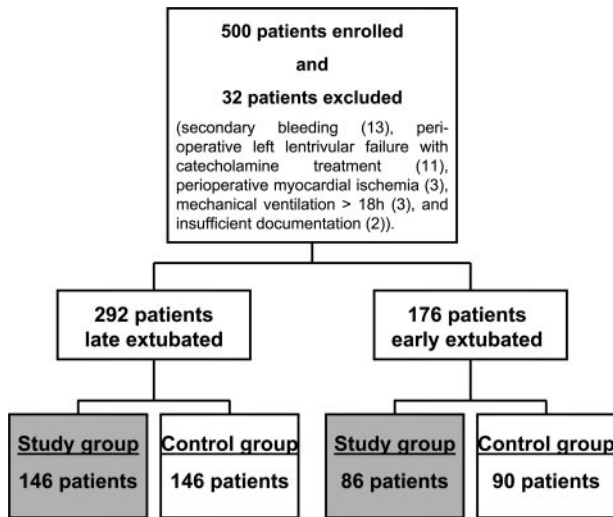


FIGURE 1. Patient flow chart.

actual inspiratory oxygen concentration.⁷ Severe pulmonary oxygenation dysfunction was defined as a $\text{PaO}_2/\text{FIO}_2$ ratio of < 100 . Pneumonia was defined according to the Centers for Disease Control and Prevention criteria.¹⁴

ICU dismissal criteria were hemodynamic stability without IV medication, oxygen saturation $> 90\%$ on $< 40\%$ oxygen, respiratory rate between 8 and 20/min, no clinical features of respiratory distress, inconspicuous neurology, sufficient diuresis (> 1 mL/kg/hour). In order not to bias the decision of transferring patients to a general ward, which was conducted by blinded intensive care physicians and attending surgeons, all nCPAP devices were removed from the patient's room at the end of the night shift before the daily ward round.

The criteria for readmission to the ICU or IMCU included general criteria (disturbance of consciousness, diuresis < 200 mL/8 h), pulmonary criteria (respiratory arrest, respiratory rate > 40 or < 8 breaths/min, oxygen saturation $< 90\%$ on $> 50\%$ oxygen, rising PaCO_2 with respiratory acidosis [$\text{pH} < 7.2$], inability to clear secretions, frequent nasotracheal suction, noninvasive ventilation, or mechanical ventilation), and hemodynamic criteria (systolic BP < 90 mm Hg, pulse rate < 40 or > 140 beats/min, inadequate tissue perfusion, significant hemodynamic instability, requirement of invasive monitoring, use of inotropes, and life-threatening arrhythmias). Reintubation was carried out if one of the following intubation criteria was fulfilled: $\text{PaO}_2 < 60$ mm Hg with $\text{FIO}_2 > 60\%$ by ventilation mask; $\text{PaCO}_2 > 50$ mm Hg and $\text{pH} < 7.30$; respiratory rate > 40 breaths/min with physical signs of distress, acute deterioration of level of consciousness, or new onset of global neurologic deficit, with an inability to protect the airway from aspiration of oropharyngeal secretions and gastric contents, severe hemodynamic instability, or cardiogenic shock. Adverse cardiac effects include myocardial ischemia, left ventricular failure resulting in pulmonary edema, tachycardia, serious arrhythmia (eg, ventricular fibrillation, ventricular tachycardia, loss of sinus rhythm), and hypotension with the need of IV inotropic support (ie, decision of physician in charge based on hemodynamic parameters and blood results).

Outcome Variables

We recorded data of the surgical procedure and demographic data. Primary outcome variables were the rates of pulmonary

complications: decreased pulmonary oxygen transfer ($\text{PaO}_2/\text{FIO}_2$ ratio < 100), nosocomial pneumonia, reintubation rate, and readmission to the ICU or IMCU after elective discharge to the general ward. Secondary outcome variables were length of stay in the ICU and in the hospital.

Statistical Analysis

All analyses were conducted on an intention-to-treat basis. Data are shown as the mean \pm SD. For normally distributed data, an analysis of variance for repeated measurements was performed followed by *post hoc* testing with the Scheffé test in case of significant differences between the study group and the control group. To compare nominal variables, the χ^2 test was used. The Bonferroni correction for multiple comparisons was applied. A p value of < 0.05 was considered to be significant.

A *post hoc* power analysis (*t* test) for pulmonary complications was performed on the basis of the data available of the 468 patients who were enrolled in this study. This revealed the study to have a power of 99% to detect a 35% decrease of pulmonary complications with $\alpha = 0.05$; $p < 0.05$ was needed for significance.

RESULTS

Five hundred patients were enrolled in the study during 1 year, of whom 32 were excluded for the following reasons: rethoracotomy due to bleeding (13), perioperative left ventricular failure with catecholamine treatment (11); perioperative myocardial ischemia (3); mechanical ventilation > 18 h (3); and insufficient documentation (2).

Accordingly, 468 patients were left for analysis (Fig 1). There were no statistical differences regarding demographic and surgical procedure data between the control and study groups (Table 1).

After admission to the ICU, late extubated patients of the control and study group were ventilated for the same time (study group, 6.2 ± 0.5 h; control group, 6.0 ± 0.7 h; $p > 0.05$). Following extubation, patients of the study group received prophylactic nCPAP for 9.1 ± 1.2 h.

The duration of the prophylactic nCPAP treatment in the early extubated study group (14.6 ± 1.9 h) was significantly longer compared with the late extubated study group ($p = 0.004$). However, patients of the late extubated study group received a PEEP of 5 to 7 cm H_2O during mechanical ventilation.

The $\text{PaO}_2/\text{FIO}_2$ ratio following extubation was lower in early extubated patients compared with late extubated patients (Fig 2). Following the application of prophylactic nCPAP, the $\text{PaO}_2/\text{FIO}_2$ ratio increased significantly in both study groups. This effect persisted for the time of the CPAP application. The pulmonary oxygen transfer returned to baseline values in patients of the late extubated study group after termination of nCPAP therapy (Fig 2). However, $\text{PaO}_2/\text{FIO}_2$ remained significantly elevated in patients of the early extubated study group (Fig 2).

Table 1—Demographic Data and Data on the Surgical Procedures of the Study and Control Groups*

Variables	Late Extubated		Extubated		p Value
	Study Group (n = 146)	Control Group (n = 146)	Study Group Early (n = 86)	Control Group Early (n = 90)	
Gender, %					NS
Male	71	70	72	73	
Female	29	30	28	27	
Age, yr	66 ± 1	64 ± 1	62 ± 2	63 ± 1	NS
Height, cm	175 ± 3	176 ± 2	176 ± 2	177 ± 3	NS
Weight, kg	82 ± 3	82 ± 2	81 ± 1	80 ± 2	NS
Coronary artery bypass graft	105	108	60	63	NS
Valve replacement	41	38	26	27	NS
Duration of operation, min	219 ± 7	214 ± 6	204 ± 4	205 ± 4	NS
Duration of extracorporeal circulation, min	109 ± 4	105 ± 5	101 ± 3	103 ± 3	NS
Aortic occlusion time, min	51 ± 5	51 ± 4	45 ± 3	50 ± 3	NS

*NS = not significant.

The hemodynamic parameters, heart rate, and mean arterial BP were not different between the four groups before, during, and after the nCPAP therapy (data not shown). Patients of the late extubated study group had a significantly elevated central venous pressure compared with the corresponding control group. However, this small difference of < 2 mm Hg is clinically irrelevant.

The incidence of pulmonary complications ($\text{PaO}_2/\text{FIO}_2 < 100$, pneumonia, reintubation rate) was significantly lower in study group patients (12 of 132) compared to the control group patients (25 of 236 patients; $p = 0.03$). The rate of cardiac adverse effects was not different between control and study groups (Table 2).

The rate of readmission to the ICU or IMCU was lower in patients treated with prophylactic nCPAP

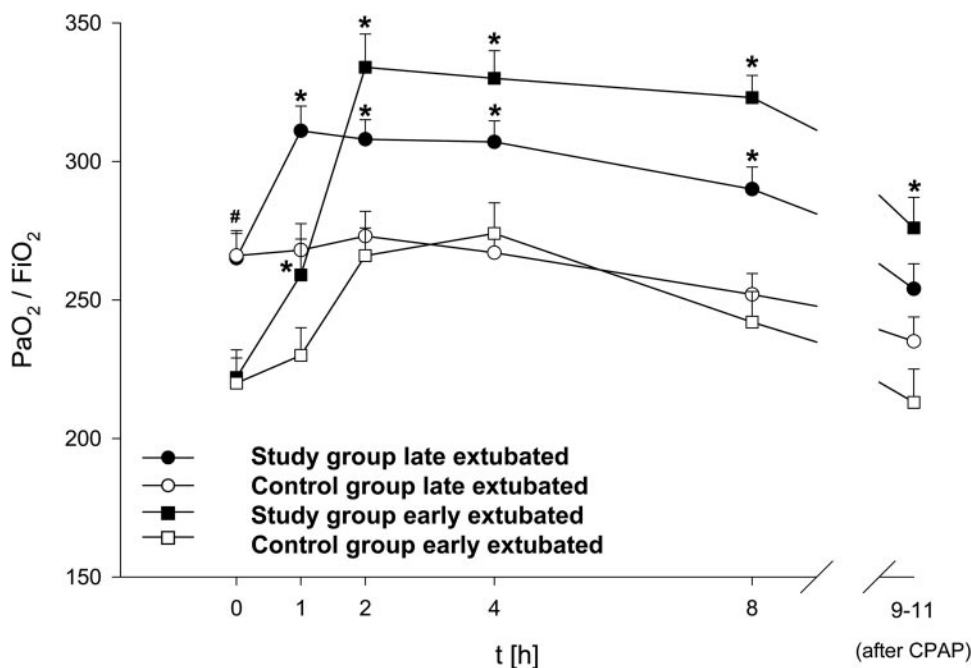


FIGURE 2. Pulmonary oxygen exchange. Arterial oxygenation, depicted as $\text{PaO}_2/\text{FIO}_2$ ratio, in the two study groups and control groups during the first 11 h following extubation (before, during, and after nCPAP or standard therapy) is shown. The application of nCPAP significantly improved $\text{PaO}_2/\text{FIO}_2$ ratios in the study groups compared with the corresponding control groups. Following termination of nCPAP therapy, pulmonary gas exchange in the early extubated study group remained significantly elevated compared with the early extubated control group. * = $p < 0.05$ for comparison of the study group vs the corresponding control group.

Table 2—Pulmonary and Cardiac Complication and Resumption on the ICU or IMCU in the Study and Control Groups*

Variables	Study Group		Σ	Control Group		Σ	p Value
	Late Extubation (n = 146)	Early Extubation (n = 86)		Late Extubation (n = 146)	Early Extubation (n = 90)		
Pulmonary complications			12			25	0.03
PaO ₂ /FIO ₂ < 100	0	8	8	4	10	14	
Pneumonia	1	0	1	3	2	5	
Reintubation	3	0	3	2	4	6	
Cardiac complications			81			92	NS
Myocardial infarction	6	3	9	7	2	9	
Cardiac arrhythmia	30	36	66	39	37	76	
Left ventricular failure	4	2	6	5	2	7	
Readmission to ICU or IMCU	2	5	7	6	8	14	0.03

*See Table 1 for abbreviation not used in the text.

($p = 0.03$) [Table 2]. Fourteen patients of the control group and 7 patients of the study group were readmitted to the ICU or IMCU. There was no difference between the study group and control group regarding the length of stay in the ICU (study group, 27 ± 1.6 h; control group, 28 ± 1.7 h; $p > 0.05$) and the hospital (study group, 13 ± 0.5 days; control group, 14 ± 0.6 days; $p > 0.05$).

DISCUSSION

Hypoxemia after cardiac surgery is a common complication^{15,16} and frequently caused by the impairment of the pulmonary ventilation perfusion ratio due to atelectasis.¹⁷ Atelectatic lung areas decrease FRC and increase right-left shunt⁶ even after uncomplicated cardiac surgery, and nonventilated lung areas may engage up to 20% of the total lung volume¹⁷ thus causing postoperative hypoxemia.¹⁵

A variety of factors have been identified that promote atelectasis, including operation-induced trauma to the lung, high oxygen concentration, and temporary diaphragmatic dysfunction.¹⁸ Furthermore, exposure of blood to the foreign surfaces of the cardiopulmonary bypass increases pulmonary permeability by activating the immune and coagulation-fibrinolytic system.¹⁹

Due to the high incidence of pulmonary complications following cardiac surgery, several studies have evaluated different methods to prevent such complications.^{20–22} However, although significant improvement of physiologic parameters was observed, these improvements did not reduce morbidity, and only in noncardiac surgery patients with thoracotomy was a reduced length of stay in the hospital following prophylactic application of nCPAP reported.¹²

In contrast to the prophylactic application of nCPAP, nCPAP therapy in surgical patients not only improved pulmonary oxygen transfer,⁸ but also reduced pulmonary complications and avoided reintubation of patients with severe postoperative respiratory failure.^{10,11} The underlying mechanism by which positive airway pressure exerts its effects is to increase intrathoracic pressure. This way, atelectasis formation is reduced, FRC increases, and respiratory workload decreases.^{9,23,24} Considering these proven effects of CPAP, at first glance, it is surprising that all clinical trials that evaluated the effect of prophylactic nCPAP following cardiac surgery failed to show improved clinical outcome.^{25–27}

Thomas et al²⁵ treated the patients only 1 hour with nCPAP and demonstrated a reduction of the right-left shunt. In two other studies,^{26,27} nCPAP was applied for 8 to 12 h after extubation and an improvement of the pulmonary oxygen transfer was recorded during nCPAP application. However, the clinical outcome in these studies was either unaffected by the treatment with nCPAP or was not investigated.

A common shortcoming of the studies just cited is that CPAP levels of only 5 to 7.5 cm H₂O were used. These airway pressures may be sufficient to have transitory effects on gas exchange but are too low to exert sustained effects that might reduce morbidity. If one assumes that prolonged effects of CPAP require pressures sufficiently high to keep lung areas open, positive airway pressure must be maintained over the complete respiratory cycle. In fact, with lower CPAP pressures this is not the case. In a previous study in patients following thoracic surgery, we demonstrated that pressures of at least 9 to 10 cm H₂O must be applied to keep the tracheal pressure positive during the entire respiratory cycle.⁸ Therefore, in the studies just described, the design was not

suited to answer the question whether nCPAP may reduce adverse pulmonary effects.

With sufficiently elevated airway pressures, we showed that prophylactic nCPAP can reduce the incidence of severe postoperative oxygenation dysfunction, defined as a $\text{PaO}_2/\text{FIO}_2$ ratio <100 , by 42% (14 of 236 patients in the control group vs 8 of 232 patients in the study group). This is most likely caused by a reduced formation of atelectasis via a sufficiently elevated airway pressure over the complete respiratory cycle. Thus our data show that pulmonary complications are significantly reduced by prophylactic application of nCPAP for at least 6 h following cardiac surgery. Most important, these significant differences between control and study group must be interpreted in the context that patients in the control group received 10 min of intermittent nCPAP every 4 h. Because this intervention was part of the standard operating procedure following cardiac surgery, we were not allowed to withhold it in control patients. The data demonstrate that the application of continuous nCPAP for longer periods has positive effects. Further studies have to address the question whether there exists a threshold effect for the application of nCPAP on pulmonary complications.

Pneumonia occurs in up to 6.5% of all patients following cardiac surgery,^{28,29} and the disease is associated with an increased mortality and medical costs due to a prolonged length of stay in the hospital.^{30,31} In our study, the incidence of pneumonia was 2.1% (5 of 236 patients) in the control group, which is lower than in the literature reported. This low incidence is explained by strict exclusion criteria. We excluded patients with significant concomitant pulmonary diseases (*ie*, severe COPD, those with corticosteroid therapy, but also those with impaired left ventricular function). The reason for doing so comes from experiences with older studies. First, positive effects of noninvasive ventilatory support in patients experiencing respiratory failure were found in many studies, but scrutiny of the patients frequently showed that many with severe COPD were included. This subgroup has a well-described benefit from CPAP or noninvasive ventilation but is not suited if one aims to investigate a prophylactic intervention in a general population. Second, increasing intrathoracic pressure by CPAP decreases afterload and transmural left ventricular pressure, thereby improving left ventricular function.^{32–34} Clinical improvements caused via an improved cardiac function are sometimes difficult to distinguish from the pulmonary effects, and thus we excluded those patients from the study. However, even in this low-risk group the application of prophylactic nCPAP further re-

duced the incidence of pneumonia in the study group to 0.43% (1 of 232 patients).

In our study, only 1.3% of patients (3 of 236 patients) from the study group, compared with 2.5% of patients (6 of 236 patients) from the control group were reintubated. In contrast to our data, previous studies reported a higher reintubation rate.^{16,35,36} This can be explained by the fact that we excluded patients from the study who had severe pulmonary diseases and were ventilated >18 h following surgery. A prolonged mechanical ventilation is associated with a higher reintubation rate.³⁵

Due to the low incidence of severe pulmonary complications in the study group, only 3% of this group (7 of 232 patients) were readmitted to the ICU or IMCU compared with 6% of patients from the control group (14 of 236 patients). The readmission to the ICU predicts an adverse postoperative course and is associated with a prolonged length of stay in the hospital and increased mortality.^{37–39} Therefore, the positive effect of the prophylactic nCPAP therapy on the readmission rate is of great importance for the clinical course of the patients. However, we failed to demonstrate a reduction in length of stay in the ICU or the hospital, which is explained by the low incidence of severe complications in our selected group of patients.

It is important to emphasize that nCPAP therapy is a well-tolerated, simple, and inexpensive technique. Because the elevated airway pressures is generated by a high-flow gas source and a PEEP valve, this technique does not require a ventilator.¹¹ A study conducted by Putensen et al⁴⁰ demonstrated that the acceptance of nCPAP is better compared to full face mask CPAP because normal oral uptake of fluids, effective clearance of respiratory secretions by cough, and communication is feasible. Therefore, this therapy allows continuous treatment for several hours, which is mandatory for successful therapy.¹¹ Due to the good acceptance of the nCPAP mask and the lack of complications like nasal bridge ulcers or claustrophobia, none of the patients withdrew the consent to the study.

Our study has some limitations. The first is that we excluded patients with concomitant pulmonary diseases (*ie*, severe COPD, those with corticosteroid therapy, but also those with impaired left ventricular function). Despite excluding high-risk patients, we were able to show in low-risk patients that prophylactic application of nCPAP significantly reduced pulmonary complications. Because high-risk patients profit more from the application of nCPAP,^{11,12} it can be assumed that the benefit of prophylactic nCPAP in high-risk patients following cardiac surgery is even more pronounced, which also leads to a reduction of the length of stay in the ICU and

hospital. Further studies have to address this question. Furthermore, this study was not designed to answer the question whether noninvasive ventilation is better in preventing postoperative atelectasis than nCPAP. However, one disadvantage of noninvasive ventilation is that it requires a ventilator and sophisticated knowledge of artificial ventilation. Therefore, it is limited to the ICU and may cause significant additional costs if applied in a generalized manner for prophylactic purposes.

Taken together, we show that compared with standard treatment, a continuous application of nCPAP for several hours at an airway pressure of 10 cm H₂O increased pulmonary oxygen transfer, reduced pulmonary complications including pneumonia and reintubation rate, and also reduced readmission rate to the ICUs and IMCU following elective cardiac surgery. nCPAP does not require sophisticated technical equipment, and it is easy to apply and quite inexpensive. Therefore, nCPAP can be recommended as a useful tool to prevent postoperative pulmonary complications in patients recovering from cardiac surgery.

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Prophylactic Nasal Continuous Positive Airway Pressure Following Cardiac Surgery Protects From Postoperative Pulmonary Complications

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