

Use of Non-Invasive Ventilation VS Simple Face Mask After Extubation After Cardiac Surgery

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Abstract

Background: The application of noninvasive positive pressure ventilation (NPPV) is effective after extubation as a weaning in patients after cardiac surgery to be clarified.

Methods: With institutional ethic committee approval, the patients ventilated invasively post operatively after cardiac surgery were enrolled in this study. After extubation, patients were assigned randomly to two groups:

Group 1: (control group) Patients randomized to put on the oxygen-mask immediately after extubation through a facial mask with a flow of 5 L/min.

Group 2: (NPPV group) Patients randomized to Noninvasive ventilation received ventilator through an oro-nasal mask. The rate of re-intubation, the frequency of respiratory failure, the duration of NPPV, and the length of intensive care unit (ICU) stay were also recorded.

Results: 54 patients completed this study, 27 in group. The mean age was years 46.8 ± 10.0 for NPPV group, 52.5 ± 13.2 for the control none of the patients for the two group was reintubated. Patients undergoing early ventilatory support showed better results in the assessments throughout the hospitalization time. The length of ICU stay was 3.44 ± 1.12 , 4.85 ± 2.33 days, respectively as it was high in the control group.

Conclusions: NPPV could be applied effectively and safely after extubation in patient after cardiovascular surgery as a weaning from mechanical ventilation.

Keywords: Weaning; Invasive Mechanical Ventilation; Noninvasive Positive Pressure Ventilation; Cardiac Surgery

Introduction

Heart surgery intraoperative issues lead to pulmonary volumes reduction, reducing the respiratory system complacency, and may progress to ARF although using oxygen supplementation [1].

Common postoperative pulmonary complications include atelectasis; pleural effusion, diaphragmatic dysfunction, and pneumonia are associated with a marked worsening in hospital survival and length of stay [2].

Noninvasive mechanical ventilation (NIMV) is routine in patients with acute respiratory failure (ARF) following tracheal extubation. NIMV benefits are well established for ARF secondary to other causes, including in the post-operative period of thoracic surgeries and also as a supportive tool for conventional mechanical ventilation weaning [3].

The British Thoracic Society guidelines state that the use of noninvasive ventilation in thoracic post-operative chest complications reduces the reintubation risk, time of intensive care unit (ICU) stay, and consequently, mortality, with evidence level B [4].

NIMV has been shown a feasible alternative, as it improves alveolar ventilation and gas exchange, reduces the ventilatory load, increases the pulmonary volumes, reduces the mechanical ventilation time, therefore preventing reintubation and consequently shortening the ICU stay time [5].

This study was aimed to measure the effectiveness of preventive NIMV use during the immediate postoperative period in cardiac surgery patients, evaluating its impact up to the sixth hospitalization day.

Material and Methods

Design and study population

This was a prospective randomized controlled study carried out in cardiothoracic Critical Care Unit at Menoufia University Hospitals. Fifty Four patients enrolled in the study. A written informed consent taken from all patients or their guardians. All adult Patients (18 - 60 years old) who undergone electively on pump cardiac surgery included in this study. Patients with any of the following excluded from the study; Disturbed consciousness level, Severe uncontrolled agitation or uncooperative behavior, Hemodynamic instability, Respiratory arrest, High risk of aspiration, Excessive respiratory secretion, Recent gastric or esophageal surgery, Tracheostomized patients, Lack of informed consent. At the beginning of the study, the patients randomized using a computer generated sequence preoperatively. Preoperative patient data recorded as {age, sex (M/F), height (cm), weight (kg), vital capacity (ml), FEV₁ (ml), PH, PaCO₂, and PaO₂}. All patients post operatively at cardiac critical care intubated and mechanically ventilated. The patients weaned according to these criteria: a) Clinical assessment as, Adequate cough and Absence of excessive tracheobronchial secretion. b) Objective criteria as, Adequate oxygenation: PaO₂ > 60 mmHg with PEEP ≤ 8 cm H₂O, SaO₂ ≥ 90%, FIO₂ ≤ 0.5, PaO₂/FIO₂ > 200, Respiratory rate < 30/min, PH and PaCO₂ appropriate for patients' baseline respiratory status, Hemodynamically stable: minimal or no vasopressor/inotropes, no evidence of myocardial ischemia, HR < 140 beats/min and Patient was arousable. Respiratory mechanics parameters measured including maximal inspiratory pressure (PI_{max}), minute ventilation (V'E), tidal volume (VT), respiratory rate, rapid shallow breathing index (RSBI) (respiratory rate/VT) with a spirometer by disconnecting the patient from the ventilator for 2 min to determine if the patient can proceed to SBT. If Pi_{max} ≤ 25 cm H₂O, V'E ≤ 10 L/ min, VT ≥ 5 mL/kg, respiratory rate ≤ 25 breaths/min, RSBI ≤ 105 cycles/min/L, oxygen saturation (SaO₂) ≥ 90% at an FIO₂ of 40% or less and a PEEP of 5 cm H₂O, then an SBT was performed. The SBT conducted through the ventilator using pressure support (PS) ventilation of 5 - 7 cm H₂O. SBT was done as follows:

Allow 30 to 120 minutes of initial trial of spontaneous breathing

- Increase the FIO₂ by 10% for the period of spontaneous breathing
- SBT was considered failure when patients develop respiratory, cardiovascular, or neurological disability.

Extubation done after assessment of patient's ability to protect and maintain airway, Level of consciousness, Cough strength, Quantity of secretion and frequency of suction.

Study protocol and measurements

After extubation, patients randomly assigned to two groups:

Group 1: (control group) Patients randomized to the oxygen-mask group received oxygen immediately after extubation through a facial mask with a flow of 5 L/min.

Group 2: (NPPV group) Patients randomized to NIV received ventilator through an oro-nasal mask. The NIV support initiated at a level of 5 cm H₂O expiratory positive airway pressure (EPAP) and 10 - 12 cm H₂O inspiratory positive airway pressure (IPAP) in a spontaneous mode. EPAP titrated in increments of 2 cm H₂O to achieve a SaO₂ of 92% while IPAP titrated in increments of 2 cm H₂O to achieve a pH of > 7.35 and patient respiratory rate of < 25 breaths/min. IPAP and EPAP optimized according to the patient's tolerance and to keep tidal volume as 8 - 10 ml/kg.

Before NIV begin, the head of the patient's bed elevated to a > 45° angle. BIPAP applied after extubation for three episodes of 20 minute duration and 2 hours apart without an acute respiratory failure episode. The pressures gradually adjusted as tolerated based on continuous pulse oximetry to achieve an oxygen saturation of greater than 92%, a normal pH on arterial blood gases. The facial skin assessed for any signs of pressure damage. In both study groups, patients reintubated if they met at least one of the following criteria: - systolic arterial pressure ≥ 180 mm Hg or ≤ 90 mm Hg, heart rate ≥ 140 beats/min, life-threatening arrhythmia, decreased level of consciousness or intense agitation requiring sedation, respiratory rate ≥ 30/min, PaO₂ ≤ 60 mm Hg or SaO₂ ≤ 90%, PaCO₂ ≥ 50 mm Hg, pH < 7.2, or significant difficulty in eliminating respiratory secretions.

Data Collection

At baseline, the following data registered for every patient: General demographic information (age, sex, weight, height), Surgical variables (type of surgery, duration of cardiopulmonary bypass), Acute Physiology and Chronic Health Evaluation II (APACHE II) score, and diagnosis recorded for all patients, Duration of mechanical ventilation before initial extubation recorded, as will the following weaning parameters when available: vital capacity, minute ventilation, respiratory rate, and maximal negative inspiratory pressure, Clinical data after the extubation for all patients: Heart rate, arterial blood pressure, respiratory rate, oxygen saturation, Blood gas analysis after extubation for all patients, For those patients randomized to receive NPPV, the time to application of NPPV, the initial settings used for IPAP and EPAP, and whether the patient tolerated NPPV recorded, Patients followed up throughout their ICU and hospital stay. The need for reintubation recorded, as well as the length of ICU stay and hospital mortality, Vital status on discharge from ICU and hospital.

The primary outcome; NIV success rate as a weaning from mechanical ventilation after cardiac surgery without need for reintubation and The secondary outcomes; The effect of NIV as a preventive procedure to decrease incidence of on ventilator associated pneumonia and length of ICU and hospital stay and mortality.

Statistical analysis

Data were collected, tabulated, statistically analyzed using an IBM personal computer with Statistical Package of Social Science (SPSS) version 20 where the following statistics were applied.

Descriptive statistics: In which quantitative data were presented in the form of mean (\bar{X}), standard deviation (SD), range, and qualitative data were presented in the form numbers and percentages.

Analytical statistics: Used to find out the possible association between studied factors and the targeted disease. The used tests of significance included:

- *Chi-square test (χ^2): was used to study association between two qualitative variables.
- *Student t-test: is a test of significance used for comparison between two groups having quantitative variables.
- *Mann-Whitney test (nonparametric test): is a test of significance used for comparison between two groups not normally distributed having quantitative variables
- *Paired t-test: is a test of significance used for comparison between two related groups having quantitative variables.
 - P value of > 0.05 was considered statistically non-significant
 - P value of < 0.05 was considered statistically significant
 - P value of < 0.001 was considered statistically highly significant.

Results

This is a prospective randomized controlled study included 57 cases who undergo on pump cardiac surgery. After extubation, patients will be randomly assigned to two groups:

Group 1: (control group) Patients randomized to the oxygen-mask group received oxygen immediately after extubation through a facial mask with a flow of 5 L/min.

Group 2: (NPPV group) Patients randomized to NIV will receive ventilator through an oro-nasal mask.

Studied variable	NPPV group (N=27)		Control group (N=27)		Test of sig.	P value
	Mean ± SD		Mean ± SD			
Age/years	46.8 ± 10.0		52.5 ± 13.2		t-test 1.90	0.063 (NS)
Height (cm)	165.7 ± 8.17		166.9 ± 7.31		t-test 0.614	0.542 (NS)
Weight (kg)	72.7 ± 15.7		80.7 ± 13.8		t-test 2.02	0.051 (NS)
Gender	No.	%	No.	%	χ ² 2.70	0.100 (NS)
• Male	12	40.4	18	66.7		
• Female	15	55.6	9	33.3		

Table 1: Personal data of studied groups (N = 54).

(NS): non –significant

There was anon significant difference between studied groups regarding their age, sex, weight and height P value > 0.05.

Studied vari-ables	NPPV group (N=27)			Paired t-test	P value
	1	2	3		
	Mean ± SD	Mean ± SD	Mean ± SD		
PH	7.36 ± 0.05	7.37 ± 0.03	7.37 ± 0.05	1.44 1.39	P1:0.160(NS) P2:0.175(NS)
PaCO ₂	36.5 ± 6.27	37.4 ± 4.92	38.8 ± 2.78	0.506 1.75	P1:0.617(NS) P2:0.091(NS)
Pao ₂	130.4 ± 46.7	137.9 ± 41.8	157.6 ± 43.9	1.39 4.12	P1:0.174(NS) P2:0.001(HS)
HCO ₃	22.4 ± 1.04	22.6 ± 0.85	22.9 ± 1.51	0.905 1.73	P1:0.374(NS) P2:0.095(NS)
SPO ₂ %	97.2 ± 1.66	97.2 ± 1.64	98.4 ± 0.99	0.590 4.31	P1:0.560(NS) P2:0.001(HS)
HR	88.9 ± 17.4	75.7 ± 32.8	85.6 ± 15.5	2.09 3.60	P1:0.046(S) P2:0.001(HS)
SBP	113.4 ± 12.9	117.5 ± 12.7	115.6 ± 10.8	2.42 1.06	P1:0.022(S) P2:0.298(NS)

DBP	65.1 ± 4.98	68.5 ± 4.15	66.4 ± 5.47	3.86 1.09	P1:0.001(HS) P2:0.282(NS)
RR	15.1 ± 2.31	14.7 ± 1.96	13.4 ± 1.57	1.22 3.65	P1:0.233(NS) P2:0.001(HS)
O ₂ saturation %	97.1 ± 1.05	97.8 ± 0.83	98.4 ± 0.89	3.03 5.09	P1:0.005(HS) P2:0.001(HS)

Table 2: Comparison between different episodes among NPPV group (N = 27).

(NS): non-significant; (S): significant; HS: highly significant

P1: between episode 1 and 2 p2: between episode 1 and 3 PH, paco₂ not significantly different among the three episodes of NPPV, But there is highly significant difference in the po₂, spo₂%, HR, RR and O₂% saturation between episode 2 and 3 ...significant difference between episode1 and 2 in the HR and SBP and highly significant in DBP and O₂%.

Studied variable	NPPV group (N = 27)		Control group (N = 27)	
	No.	%	No.	%
Need of intubation				
Yes	0	0.00	0	0.00
No	27	100	27	100
Criteria for re intubation				
• Yes	0	0.00	0	0.00
• No	27	100	27	100
Pneumonia				
• Yes	0	0.00	0	0.00
• No	27	100	27	100
Mortality				
• Yes	0	0.00	0	0.00
• No	27	100	27	100

Table 3: Complication among studied groups (N = 54).

There was non significant difference between studied groups regarding Need of intubation, Criteria for re intubation, Pneumonia, Mortality P value > 0.05.

Studied variables	NPPV group (N = 27)	Control group (N = 27)	Mann Whitney test	P value
	Mean ± SD	Mean ± SD		
ICU stay	3.44 ± 1.12	4.85 ± 2.33	2.07	0.038 (S)
Hospital stay	7.29 ± 2.23	10.4 ± 4.17	2.75	0.006 (HS)

Table 4: Mean ICU and hospital stay among studied groups (N = 54).

HS: Highly significant

There was significant differences and highly significant difference as regard hospital stay being high in the control group.

Discussion

We observed that along the first 6 hours of the protocol, the variables SaO₂ and PaO₂ showed significant increases in the NPPV group, when compared with the control group there was high significant difference. These results are similar to those found by Celebi., et al. [6],

which was done on One-hundred patients undergoing coronary artery bypass surgery and were randomized into four groups 25 each after the operation, RM with sustained inflation during mechanical ventilation postoperatively, RM combined with NIV applied for 1/2-h periods every 6h in the first postoperative day after tracheal extubation, NIV after tracheal extubation and a control group consisting of patients receiving neither RM nor NIV, they found that Oxygenation was better in the RM-NIV and NIV groups than in the control group at the end of the study.

Our results also matched the study done by Olper, *et al.* [7], which was done on Sixty-four patients with hypoxemia ($\text{PaO}_2/\text{FIO}_2$ ratio between 100 and 250) admitted to the main ward after cardiac surgery. They were randomized to receive standard treatment or non-invasive continuous positive airway pressure in addition to standard treatment. Continuous positive airway pressure was administered 3times a day for 2 consecutive days. Every cycle lasted 1 to 3 hours. They found that there was significant improvement in oxygenation in CPAP group compared with the standard group.

Another study which was done by Suzuki, *et al.* [8], which enrolled Patients who underwent cardiovascular surgery from April 2011 to December 2011 in their hospital, they aimed to examine the effect and the safety of NPPV application following extubation in patients requiring moderate PEEP level for sufficient oxygenation after cardiovascular surgery. Patients ventilated invasively for over 48h after cardiovascular surgery were enrolled in this study. Respiratory parameters (partial pressure of arterial oxygen tension to inspiratory oxygen fraction ratio: P/F ratio, respiratory ratio, and partial pressure of arterial carbon dioxide: PaCO_2) 2h after extubation were evaluated with those just before extubation as the primary outcome, 51 post cardiovascular surgery patients were screened, 6 patients received NPPV after extubation. P/F ratio was increased significantly after extubation compared with that before extubation. The other respiratory parameters did not change significantly. Re-intubation, respiratory failure, and intolerance of NPPV never occurred.

Other study done by Zhang, *et al.* [9], on Twenty-five patients (3 months to 11 years, mean 2.3 years) who underwent corrective cardiac surgery and develop respiratory insufficiency after extubation were enrolled in the study. All patients required airway support or oxygenation/ventilatory support and were firstly treated with noninvasive BiPAP ventilation before re-intubation. The changes of clinical symptoms and arterial blood gas were measured. They found that noninvasive nasal mask BiPAP can be safely and effectively used in children after cardiac surgery to improve oxygenation/ventilation, decrease the work of breathing. It may be particularly useful in patients whose underlying condition warrants avoidance of re-intubation. However these results not matched our study as regard the age group and type of operations.

Another study done by Coimbra, *et al.* [10], which enrolled seventy patients with hypoxemic ARF randomized to one of three modalities of NIV - continuous positive airway pressure (CPAP) and ventilation with two pressure levels). Ventilation oxygenation-related, and hemodynamics variables were analyzed at pre-application, and 3, 6, and 12 hours after the protocol began. Patients with hypoxemic ARF in the postoperative stage after cardiovascular surgery showed better oxygenation, RR, and HR during NIV application. In older patients and those with higher baseline RR and HR values, NIV was not sufficient to reverse ARF. The two-pressure level modes showed better results.

Filho, *et al.* [11], made a controlled study, where patients in immediate postoperative period of cardiac surgery were randomized into two groups: control (G1) and investigational (G2) which received noninvasive ventilation set on pressure support mode and positive end expiratory pressure, for 2 hours following extubation. Were evaluated ventilatory, hemodynamical and oxygenation variables both immediately after extubation and after noninvasive ventilation in G2. The study done on Thirty-two patients. They found that Noninvasive postcardiac surgery ventilation was proven effective, as demonstrated by increased vital capacity, decreased respiratory rate, prevention of post-extubation acute respiratory failure and reduced reintubation rates.

However another study which was done by Stéphan, *et al.* [12], A total of 830 patients were randomly assigned to receive high-flow nasal oxygen therapy delivered continuously through a nasal cannula or BiPAP delivered with a full-face mask for at least 4 hours per day. They found that High-flow nasal oxygen therapy was not inferior to BiPAP. This difference from our results was mainly due to the usage of high nasal flow cannula.

Our work showed high significant improvement in hemodynamics (the SBP, DBP, HR and the respiratory rate) after the second and third episode comparing to post-operative baseline, the overall results of hemodynamics showed also highly significant improve in NPPV compared to the control group. These results matched the study done by Pantoni, *et al.* [9], the study involved 80 patients undergoing CABG who were evaluated postoperatively during spontaneous breathing (SB) and application of four levels of CPAP applied in random order: (3 cm H₂O), 5 cm H₂O, 8 cm H₂O, and 12 cm H₂O. HR and blood pressure were analyzed. They found that higher levels of positive pressure (8 and 12 cm H₂O) applied by CPAP were able to positively modify the cardiac autonomic function and BP of these patients.

The application of positive airway pressure produces mechanical effects on the cardiovascular system with changes in hemodynamics and in the cardiac autonomic nervous system. We hadn't identified studies about the influence of short-term application of CPAP on the breathing pattern (BP) and HRV of patients undergoing CABG surgery [13].

In the current study there was no significant difference as regard the rate of reintubation, rate of mortality or occurrence of ventilator associated pneumonia between patients of NPPV group and the control group.

These results matched the study done by Esteban, *et al.* [14], on Patients in 37 centers in eight countries who were electively extubated after at least 48 hours of mechanical ventilation and who had respiratory failure within the subsequent 48 hours were randomly assigned to either noninvasive positive-pressure ventilation by face mask or standard medical therapy. A total of 221 patients with similar baseline characteristics had been randomly assigned to either noninvasive ventilation or standard medical therapy. There was no difference between the noninvasive-ventilation group and the standard-therapy group in the need for reintubation. Noninvasive positive-pressure ventilation does not prevent the need for reintubation or reduce mortality in unselected patients who have respiratory failure after extubation.

Another study done by Delgado, *et al.* [15], it was retrospective observational study on 63 Patients with respiratory failure after extubation after cardiac surgery over a 3-year period in Intensive care unit in a university hospital. They found that reintubation was required in half of the NIV treated patients and was associated with an increased hospital mortality rate. Early respiratory failure after extubation (< 24 hours) is a predictive factor for NIV failure. This different from our results can be explained by the limitation they faced as their study was of retrospective nature.

A study done by Boeken, *et al.* over a period of 3 years they analyzed all patients who were extubated within 12 hours after cardiac surgery, and in whom pulmonary oxygen transfer (PaO₂/FIO₂) deteriorated without hypercapnia so that all these patients met predefined criteria for reintubation. There were three groups of patients: A = patients required immediate reintubation); B = patients had nCPAP with intermittent mask CPAP and C = patients had NPPV. They concluded that reintubation after cardiac operations should be avoided since nCPAP and NPPV are safe and effectively improve arterial oxygenation in the majority of patients with non- hypercapnic oxygenation failure. However, it was of great importance to pay special care to sternal wound complications in these patients.

In our work there were a significant decrease in ICU stay and a high significant decrease in hospital stay in NPPV group in comparison with the control group. In this instance, the study done by Al Jaaly, *et al.* [16], they performed a 2-group, parallel, randomized controlled trial. A total of 129 patients were randomly allocated to bilevel positive airway pressure or usual care. They found among patients undergoing elective coronary artery bypass grafting, the use of bilevel positive airway pressure at extubation reduced the recovery time.

Glossop, *et al.* [17], investigated in their meta-analysis three separate groups of patients who have all undergone a period of invasive ventilation and then been extubated who are all at risk of developing RE, requiring reintubation, and suffering increased morbidity and mortality as a result. The value of this analysis was that it includes patients from diverse backgrounds with differing pathologies representing the wider general critical care population, rather than a specific group such as COPD (where we already know NIV is frequently effective). They only included studies in this analysis that compare standard treatment of these groups against an additional intervention in the form of NIV-in an attempt to determine the potential impact that this intervention alone may have on patient outcomes in several similar and related clinical situations.

This meta-analysis demonstrated a reduction in rates of reintubation when used in post-surgery patients, and pneumonia in post-surgery, and weaning patients when compared with standard medical therapy. It was highly likely that the reduction in reintubation would impact on rates of pneumonia by removing the attendant risks of VAP in the groups studied. Again this was an important finding from a patient safety, morbidity, and economic perspective. The reduction in rates of reintubation and pneumonia were not evident in the post-ICU extubation subgroup. However, it is important to note that this group included studies where NIV was used for both prevention and treatment of post-extubation RF. The individual studies consistently demonstrate that the use of NIV to treat rather than prevent post-extubation RF is at best ineffective, and indeed may increase the rates of reintubation, which may have influenced the outcomes in this subgroup.

They found that the use of NIV had no effect on ICU survival when compared with standard therapy in either weaning patients or post-ICU extubation patients. As only one trial in the post-surgery subgroup reported ICU survival, insufficient data were available to provide meaningful analysis in this group. Hospital survival was increased in weaning and post-surgical patients who received NIV, but not in post-ICU extubation patients.

Conclusion

This study concluded that non-invasive ventilation can be used as a weaning step after extubation after mechanical ventilation post-operatively after cardiac surgery. It improves oxygenation and hemodynamics and decrease ICU and total hospital stay.

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