Bilevel positive airway pressure improves the autonomic balance in the postoperative period following cardiac surgery: a randomized trial

Pressão positiva de duplo nível em via aérea melhora o balanço autonômico no pós-operatório de cirurgia cardíaca: ensaio randomizado

La presión positiva de doble nivel en las vías respiratorias mejora el equilibrio autonómico posoperatorio de cirugía cardíaca: un ensayo aleatorizado

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ABSTRACT | The use of bilevel positive airway pressure (BiPAP) has repercussions on cardiorespiratory outcomes. However, the literature still lacks analyses of the postoperative influence of BiPAP on the modulation of the autonomic nervous system after cardiac surgery. This study aimed to evaluate the effects of BiPAP on peripheral oxygen saturation, vital signs, and autonomic balance during hospitalization after cardiac surgery. This randomized controlled trial evaluated 36 patients before and after surgery. The BiPAP group was treated in two 20-minute daily sessions of routine physical therapy since 18 hours after surgery until discharge. The control group received routine physical therapy during the same period. Our primary outcome was peripheral oxygen saturation. Secondary outcomes were vital signs and autonomic balance evaluated by heart rate variability. We observed that peripheral oxygen saturation and blood pressure were unaffected at hospital discharge. Both groups showed a similar increase in heart and respiratory rates. The BiPAP group showed a reduction of the low sympathetic frequency component in -27.1 n.u. (95% CI: -39 to -15.2), increase of high parasympathetic frequency in 27.1 n.u. (95% CI: 15.2 to 39), and an improvement to the LF/HF ratio in -2.5 (95% CI: -3.8 to -1.2), when compared to the control group. BiPAP attenuated sympathetic activity and improved vagal modulation and autonomic balance at hospital discharge. These findings

evidence that BiPAP enables more efficient autonomic mechanisms during hospitalization after cardiac surgery. **Keywords** | Cardiac Surgery; Postoperative Period; Noninvasive Ventilation; Autonomic Nervous System; Randomized Controlled.

RESUMO | O uso da pressão positiva de duplo nível nas vias aéreas (BiPAP) tem repercussões sobre desfechos cardiorrespiratórios. No entanto a influência da BiPAP na modulação do sistema nervoso autônomo no pós-operatório de cirurgia cardíaca ainda não foi explorada. O objetivo do estudo foi avaliar os efeitos da BiPAP na saturação periférica de oxigênio, sinais vitais e balanço autonômico no período de hospitalização após cirurgia cardíaca. Este ensaio controlado e randomizado avaliou 36 pacientes no pré-operatório e na alta hospitalar. O grupo BiPAP recebeu tratamento 18 horas após a cirurgia até a alta hospitalar, em duas sessões diárias de 20 minutos associado à fisioterapia de rotina. O grupo controle recebeu apenas a fisioterapia de rotina durante o mesmo período. O desfecho primário foi a saturação periférica de oxigênio, enquanto os desfechos secundários foram sinais vitais e equilíbrio autonômico avaliado pela variabilidade da frequência cardíaca (alta frequência - HF, baixa frequência -LF, relação LF/HF). Observou-se que a saturação periférica

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de oxigênio e a pressão arterial não se alteraram na alta hospitalar. Houve um aumento similar na frequência cardíaca e na frequência respiratória em ambos os grupos. O grupo BiPAP teve uma redução do componente LF (simpático) em -27,1 n.u. (IC 95% -39 a -15,2), aumento de HF (parassimpático) em 27,1 n.u. (IC 95% 15,2 a 39) e melhora na relação LF/HF em -2,5 (IC 95% -3,8 a -1,2) em comparação ao grupo controle. A BiPAP atenuou a atividade simpática, melhorou a modulação vagal e o equilíbrio autonômico na alta hospitalar. Esses achados evidenciam que a BiPAP possibilita mecanismos autonômicos mais eficientes durante a hospitalização após a cirurgia cardíaca.

Descritores | Cirurgia Cardíaca; Pós-operatório; Ventilação Não Invasiva; Sistema Nervoso Autônomo; Ensaio Clínico Controlado Aleatório.

RESUMEN | El uso de la presión positiva de doble nivel en las vías respiratorias (BiPAP) tiene impacto en los resultados cardiorrespiratorios. Pero todavía no se sabe la influencia de la BiPAP en la modulación del sistema nervioso autónomo en el posoperatorio de cirugía cardíaca. El objetivo de este estudio fue evaluar los efectos de la BiPAP sobre la saturación periférica de oxígeno, los signos vitales y el equilibrio autonómico en el periodo de hospitalización después de la cirugía cardíaca. Este ensayo controlado aleatorizado

evaluó a 36 pacientes antes de la operación y al alta hospitalaria. El grupo BiPAP recibió tratamiento 18 horas después de la cirugía hasta el alta hospitalaria, en dos sesiones diarias de 20 minutos cada, asociado a la fisioterapia habitual. El grupo de control recibió solo fisioterapia habitual durante el mismo periodo. El resultado primario fue la saturación periférica de oxígeno, mientras que los resultados secundarios fueron los signos vitales y el equilibrio autonómico evaluados por la variabilidad de la frecuencia cardíaca (frecuencia alta – HF, frecuencia baia – LF, relación LF/HF). Se observó que la saturación periférica de oxígeno y la presión arterial no presentaron cambios al alta hospitalaria. Hubo un aumento similar en la frecuencia cardíaca y la frecuencia respiratoria en ambos grupos. El grupo BiPAP tuvo una reducción del componente LF (simpático) en -27,1 n.u. (IC 95% -39 a -15,2), incremento de HF (parasimpático) en 27,1 n.u. (IC 95% 15,2 a 39) y mejora en la relación LF/HF en -2,5 (IC 95% -3,8 a -1,2) en comparación con el grupo de control. La BiPAP redujo la actividad simpática y mejoró la modulación vagal y el equilibrio autonómico al alta hospitalaria. Estos hallazgos muestran que la BiPAP permite mecanismos autonómicos más eficientes durante la hospitalización después de una cirugía cardíaca. Palabras clave | Cirugía Cardíaca; Postoperatorio; Ventilación no Invasiva; Sistema Nervioso Autónomo; Ensayo Clínico Controlado Aleatorio.

INTRODUCTION

The rates of postoperative complications (PC) of coronary artery bypass grafts (CABG) or valve replacements remain high, with expressive morbidity and mortality^{1,2}. Pulmonary complications are the most common of these, a result of the interaction between risk factors associated with surgical procedure, effects of anesthesia, cardiopulmonary bypasses, and pre-existing comorbidities^{1,3}. To prevent and to minimize these complications and improve cardiorespiratory outcomes, the use of noninvasive ventilation, specifically bi-level positive airway pressure (BiPAP), can be beneficial to restore lung function and to improve oxygenation in patients undergoing cardiac surgery⁴⁻⁶.

The use of positive airway pressure has repercussions on the cardiovascular system because its effects change hemodynamics and cardiac autonomic regulation⁷. The autonomic modulation of the cardiovascular system can be investigated by heart rate variability (HRV), which expresses autonomic balance and consists of the variation between consecutive heartbeats, recorded from R-R intervals^{8,9}. The increase in HRV, mediated by parasympathetic action, refers to good adaptation of the autonomous system, whereas the reduction of HRV, by greater sympathetic activation, indicates abnormal and insufficient adaptation^{8,10,11}.

Changes in the autonomic cardiovascular are well evidenced in patients with cardiovascular disease¹², as is the wide use of the HRV measurement in the diagnosis of autonomic dysfunction as a predictor of cardiovascular risk¹³. CABG¹⁴⁻¹⁶ and cardiac valve surgery¹⁷ significantly change autonomic function, observed in HRV reduction. However, the postoperative influence of BiPAP on the modulation of the autonomic nervous system is yet to be explored and, to our knowledge, the literature lacks such reports. Its effects can play a decisive role in improving autonomic responses at hospital discharge and, thus, positively affect patients in more advanced phases of cardiac rehabilitation programs.

Therefore, this randomized trial aimed to evaluate the effects of BiPAP on peripheral oxygen saturation, vital signs, and autonomic balance during hospitalization after cardiac surgery. We hypothesize that BiPAP could improve peripheral oxygen saturation, vital signs, and autonomic balance in comparison to the control group.

METHODOLOGY

This is a clinical and controlled trial with blinding of outcome assessors and concealed allocation. This study was approved by the Ethics Committee in Local Research, according to the Resolution 466/2012 from the National Health Council, and was registered on ClinicalTrials.gov. Informed consent was obtained from all patients in the preoperative period, in accordance with the principles of the Declaration of Helsinki. Moreover, semi-structured interviews were conducted and data, collected from medical records.

Participants were randomly allocated to either the BiPAP (BiPAPG) or control group (CG). A researcher, absent from patient recruitment, assessment or treatment used a web-based system to generate a blocked random allocation schedule for the 36 participants. Blocking ensured an equal numbers of participants in both groups. Allocations were sealed in sequentially numbered, opaque envelopes which were kept off-site. After participants underwent baseline assessment, trial staff contacted them. Envelopes were then opened, revealing group allocation. Patients only knew to which group they had been allocated after cardiac surgery, i.e., immediately at the beginning of therapy.

Adult patients hospitalized for CABG or valve replacement surgery at a university hospital were recruited. Patients with some cognitive dysfunction that made the evaluations difficult, who had undergone CABG associated with valve replacement; or showed chronic obstructive pulmonary, cerebrovascular, chronic degenerative musculoskeletal or chronic infectious diseases; and unstable angina or hemodynamic instability; to whom invasive ventilation was contraindicated were excluded.

Intervention

Before surgery, BiPAPG patients received adaptation to equipment and explanations regarding possible discomfort. BiPAP therapy began in the first 18 hours of PC, lasting until discharge from the hospital, taking place in two daily sessions of 20min, with a positive expiratory pressure of 10cmH₂O and a positive inspiratory airway pressure of 15cmH₂O¹⁸. An oronasal mask (Mirage Four, Resmed, San Diego, United States) and a bi-level positive pressure generator (model Sullivan VPAP II ST-; ResMed; Sydney, Australia) were used. Peripheral oxygen saturation (SpO₂), heart rate (HR), and respiratory rate (RR) were monitored. Both BiPAPG and CG received usual care based on medical routine, nursing, and physiotherapy (pulmonary expansion maneuvers, bronchial hygiene, active motor physiotherapy of limbs, walking, and seating).

Outcome measures

Our primary outcome was peripheral oxygen saturation (SpO_2) . Secondary outcomes were HR, RR, systolic and diastolic blood pressure, and HRV variables. All measures were taken in the pre-operative period (before surgery) and at hospital discharge (after surgery).

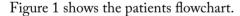
 SpO_2 was assessed with a portable pulse oximeter (Choice Electronic, MD300C1, Beijing, China). HRV assessment occurred with patients in the dorsal decubitus position, using a frequency meter Polar S810i (Polar®, Kempele, Finland) that captures and stores heart rate (HR) by each beat^{19,20}. The R-R interval sender (iR-R) was placed at the level of the fifth intercostal space and the receiver on the wrist. The acquisition of ECG signal (sample rate - 1kHz) of the RR time series was acquired in continuous intervals (10min). Data on HR and iR-R, beat by beat, were recorded by the software Kubios HRV 2.2 (Kuopio, Finland) and stored in a microcomputer. HRV was analyzed for time and frequency, using the area of greatest stability in RR intervals corresponding to 5 min of recordings (containing at least 256 consecutive beats) during controlled breathing, as previously described by Gamelin et al.¹⁹.

Analysis was performed using spectral power density. This analysis decomposes HRV in fundamental oscillatory components: the high frequency component (HF), from 0.15 to 0.4Hz, corresponds to respiratory modulation and indicates the vagus nerve action on the heart; the low frequency component (LF), from 0.04 to 0.15Hz, is due to the joint action of the vagal and sympathetic components of the heart, with sympathetic predominance. LFnu and HFnu are the normalized spectral HRV measurements. The LF/HF index reflects the absolute and relative changes between the sympathetic and parasympathetic components, characterizing the sympatho-vagal balance of the heart. Total power reflects total variance in heart rate patterns over the length of recording. Both sympathetic and parasympathetic nervous system activity contribute to SDNN. RMSSD and PNN50 are used for a snapshot measurement of the parasympathetic branch. The triangular index is an estimate of overall HRV¹⁹. Ectopy-containing segments or other artefacts such as missed, extra or misaligned beat detections were excluded from data analysis.

Statistical analysis

Sample calculation was estimated to obtain a significance level (alpha) of 5% (p<0.05) and a power (beta) of 80%. It has been suggested that 36 patients are needed to compose this type of study, 18 patients in each group, with a 2% effect magnitude in SpO_2^{14} . Data analysis was performed using a standard software. Data distribution was assessed by the Kolmogorov-Smirnov normality test. Data are shown as mean and standard deviation (SD), percentages, and 95% confidence intervals (95% CI). Comparisons within and between groups were performed by two-way ANOVA with repeated measures, followed by the Bonferroni post-hoc test. A significance level of 5% (p<0.05) was considered.

RESULTS



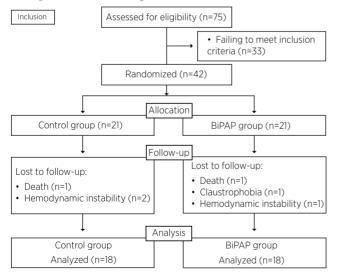


Figure 1. Patient flowchart

The groups showed similar baseline characteristics, such as length of stay in intensive care unit and hospital, extracorporeal circulation time, and duration of mechanical ventilation (Table 1). The main complications recorded in PC were atelectasis and pleural effusion, which were similar between the groups. We found no difference in postoperative length of stay, extended length of stay in intensive care unit, extended mechanical ventilation, and reintubation rates between the groups.

Table 1. Baseline characteristics of patients

Characteristic	Control (n=18)	BiPAP (n=18)
Age (years)	62±7.8	63±8.2
Men	11 (61)	11 (61)
BMI (kg/m²)	27±3.8	29±3.6
LVEF (%)	54.4±7.2	56.6±8.0
Smoking	7 (39)	8 (44)
CABG	16 (89)	17 (94)
Medications		
ACE inhibitor	16 (89)	14 (78)
Analgesic	18 (100)	18 (100)
Anticoagulant	12 (67)	12 (67)
Anti-inflammatory	14 (78)	18 (100)
Beta-blocker	16 (89)	18 (100)
Diuretic	14 (78)	18 (100)
Baseline disease		
Hypertension	16 (89)	14 (78)
Type 2 Diabetes	8 (44)	9 (50)
LoS in ICU (days)	4.7 (0.6)	4.9 (1.4)
LoS in hospital (days)	7 (1.5)	7.8 (4)
Extracorporeal circulation time (min)	88.9 (14)	94 (13.2)
Duration of MV (hours)	14.3 (3)	13.9 (4.1)

Values expressed as mean±SD or n (%); ACE: angiotensin-converting enzyme; BMI: body mass index; CABG: coronary artery bypass graft; LVEF: left ventricular ejection fraction; LoS: length of stay; ICU: intensive care unit; MV: mechanical ventilation.

We found no difference in SpO₂ and blood pressure between the pre-operative period and hospital discharge or between groups. Resting HR and RR increased in CG and BiPAPG, but were similar between groups (Table 2). Table 2. Peripheral oxygen saturation and vital signs before and after the intervention and comparison between groups

Outcome	Group			Difference within groups		Mean (95%CI) difference between groups	
	Before		After		After minus before		After minus before
	BiPAP	Control	BiPAP	Control	BiPAP	Control	BiPAP minus control
SpO ₂ (%)	97.1±1.2	96.9±1.5	96.2±2.0	96.7±1.4	-0.9±1.8	-0.2±1.5	-0.7 (-1.8 to 0.4)
Heart rate (bpm)	70.7±11.3	72.3±12.4	82.6±12.6*	89.4±12.1*	11.9±13.0	17.2±16.3	-5.3 (-14.9 to 4.3)
Respiratory rate (rpm)	18.2±4.6	18.7±3.4	21.7±4.2*	22.5±6.4*	3.5±6.2	3.8±4.9	-0.3 (-4.0 to 3.4)
Systolic BP (mmHg)	118.9±14.5	116.1±11.4	119.4±11.1	118.3±10.4	0.6±13.5	2.2±10.6	-1.6 (-9.5 to 6.3)
Diastolic BP (mmHg)	73.3±5.9	73.9±9.2	75.3±8.5	75.0±8.6	1.9±10.5	1.1±10.2	0.8 (-6.0 to 7.6)

Values expressed as mean±SD or mean difference (95%CI); BP: blood pressure; SpO2: peripheral oxygen saturation; *: Significant differences (p<0.05) vs before.

Table 3 shows HRV analyses. We found an increase in the mean HR in CG and BiPAPG, but without differences between them. There was a significant between-group difference for LF in favor of BiPAPG due to a reduction in BiPAPG and an increase in CG. We also found a significant between-group difference for HF in favor of BiPAPG, with an increase in BiPAPG and a reduction in CG at hospital discharge. There was a statistically significant between-group difference in the LF/HF ratio, with a worsening in the CG at hospital discharge. We found no change in the other variables until hospital discharge.

Table 3. Heart rate variability before and after the intervention and comparison between groups

Outcome	Group				Difference within groups		Mean (95%CI) difference between groups
	Before		After		After minus before		After minus before
	BiPAP	Control	BiPAP	Control	BiPAP	Control	BiPAP minus control
Time domain							
Heart rate (bpm)	73.6±11.2	79.2±22.2	87.0±10.0*	95.9±18.5*	13.4±14.0	16.7±24.6	-3.3 (-16.4 to 9.8)
SDNN (ms)	52.6±36.3	35.5±34.7	25.5±29.3	34.0±43.0	-27.1±45.3	-1.5±40.5	-25.6 (-53.7 to 2.5)
rMSSD (ms)	31.0±24.3	29.6±31.9	19.0±19.9	23.7±39.7	-11.9±32.5	-6.0±25.9	-5.9 (-25.1 to 13.3)
pNN50 (%)	7.3±1.6	7.4±13.1	1.7±2.9	7.2±17.0	-5.6±11.2	-0.2±12.7	-5.4 (-13.2 to 2.4)
Triangular Index	8641.6±4495.7	7215.7±4683.9	6347.6±4932.4	5497.2±6038.8	-2294.0±7711.5	-1718.5±5480.1	-575.5 (-4946.0 to 3795.0)
Frequency domain							
TP (ms ²)	7610.6±5390.7	7812.4±4669.7	7723.1±5048.2	7613.3±6488.2	112.5±5929.7	-199.1±8481.3	311.6 (-4469.2 to 5092.4)
LF (ms ²)	1629.0±1593.7	1994.9±1909.8	1351.0±1007.0	1912.5±1920.9	-277.9±1680.9	-82.3±2632.9	-195.6 (-1638.7 to 1247.5)
HF (ms²)	1641.3±2328.7	1774.5±1245.9	2462.0±3181.3	1425.1±2130.5	820.7±3490.2	-349.4±2178.5	1170.1 (-730.6 to 3070.8)
LF (n.u.)	56.8±15.1	53.2±18.6	42.8±15.7*†	66.3±17.6*	-14.0±16.6	13.1±19.7	-27.1 (-39.0 to -15.2)
HF (n.u.)	43.2±15.1	46.8±18.6	57.2±15.7*†	33.7±17.6*	14.0±16.6	-13.1±19.7	27.1 (15.2 to 39.0)
LF/HF ratio	1.6±1.1	1.5±1.2	0.9±0.6†	3.3±3.1*	-0.7±1.1	1.8±2.5	-2.5 (-3.8 to -1.2)

Values expressed as mean±SD or mean difference (95%CI); HF: high frequency; LF/lev frequency; LF/HF: relationship between LF and HF components; SDNN: standard deviation of all normal RR intervals recorded in a time interval; pNN50: percentage of adjacent RR intervals whose difference is greater than 50ms; rMSSD: root mean square of successive differences; TP: total power; *: Significant differences (p<0.05) vs before; †: Significant differences (p<0.05) vs Control.

DISCUSSION

The main findings of this research indicate the improvement in autonomic balance in patients treated with BiPAP during hospitalization after cardiac surgery. We found an attenuation of sympathetic activity in BiPAPG, whereas, in the CG, there was an increase in the sympathetic component. BiPAP promoted the increase of parasympathetic response in comparison with CG. SpO₂ failed to change at hospital discharge and was similar between the groups.

The LF component prevailed in CG, whereas, in BiPAPG, the HF component was higher. This shows the predominance of the parasympathetic action at hospital discharge in response to BiPAP, which expressed good cardiovascular autonomic adaptation^{8,10,11}. These findings show that BiPAP brought additional benefits to routine physiotherapy and usual care, which may be reinforced by improving autonomic balance, with a predominance of the parasympathetic nervous system. The LF/HF ratio showed similarities between the groups in the pre-operative period, but it was undermined in CG at hospital discharge. In BiPAPG, we found an attenuation of sympathetic activity, associated with the predominance of vagal stimulus inducing improvement of the LF/HF ratio and consequent benefit to the cardiovascular autonomic control system.

In heart failure, there is impairment of the autonomic balance resulting from sympathetic hyperactivation and reduction of the vagal cardiac tonus^{21,22}. Patients with heart failure who were hospitalized for acute decompensation benefited from therapy with BiPAP due to an improvement of autonomic responses via vagal activation²¹. HRV fall is considered an independent risk factor for cardiovascular mortality after acute myocardial infarction^{23,24}. Cardiac surgery also affects autonomic cardiovascular control by reducing HRV after CABG²⁵ and some studies have shown the effects of noninvasive ventilation after cardiac surgery^{5,14,26}. Different levels of continuous positive airway pressure (8 and 12cmH₂O) after CABG improved respiratory patterns and autonomic control¹⁴. Another report mentioned the effects of BiPAP which safely improved vital capacity and were well received by patients⁵. Still, BiPAP effects are similar to high-flow nasal oxygen therapy regarding complications and mortality after cardiothoracic surgery²⁶. Nevertheless, these studies using BiPAP ignored its effects on autonomic responses.

The use of noninvasive ventilation in patients with heart failure increases cardiac output and stroke volume, reduces post-load, and shows beneficial results to left ventricular function with a reduction in mitral regurgitation²⁷. This mechanism may explain our findings, suggesting functional adaptations of the cardiovascular system in response to the use of positive airway pressure.

Some factors may have contributed to SpO_2 stasis. All patients received routine physiotherapy with deep breathing exercises in PC, which might have been crucial to prevent SpO_2 fall since this intervention promotes oxygenation after cardiac surgery²⁸. With this, BiPAP was incapable of promoting additional effects, in addition to the respiratory therapy, on SpO_2 . Improved oxygenation could have been obtained if we had evaluated the acute effect of BiPAP or routine physiotherapy. However, SpO_2 measurement was performed at rest, both in the pre-operative period and at hospital discharge. Still, SpO_2 averages were in the normal range since the pre-operative period because the sample consisted only of stable patients.

Our results showed that the HR of both groups was greater in the postoperative period, following cardiac surgery, but with similar changes among the groups. These changes after the surgical procedure may be explained, at least in part, by the peculiarities and specific conditions of the surgery, such as incision by sternotomy, extracorporeal circulation, and thoracic manipulation²⁹. Among the limitations of this study, recording biochemical and inflammatory parameters could be useful for defining the stage of the disease and patients' clinical profile. It was impossible to perform the analysis by intention-to-treat since the patients lost in follow-up showed no clinical conditions or refused to be reassessed at hospital discharge.

CONCLUSIONS

Noninvasive ventilation with the use of BiPAP improved autonomic balance in patients after cardiac surgery, which is explained by the attenuation of sympathetic and increase of the parasympathetic activities, suggesting more efficient autonomic mechanisms. These adjustments to the autonomic nervous system show that BiPAP, widely used to alleviate respiratory and functional outcomes, can also benefit autonomic function in cardiovascular hospitalization after cardiac surgery. However, further studies are needed to identify the effects of BiPAP in the more advanced phases of cardiac rehabilitation, as well as to analyze the mechanisms related to our findings.

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