Background: Most patients that undergo cardiac surgery develop post-operative pulmonary complications. The use of an incentive spirometer associated with positive end-expiratory pressure (PEEP) and non-invasive ventilation (NIV) may contribute to the reduction of such complications. **Objective:** To compare the efficacy of an incentive spirometer associated with positive end-expiratory pressure to NIV in pulmonary complications in the PO of heart surgery during hospitalization in the intensive care unit (ICU). **Methods:** A randomized clinical trial conducted from July 2012 to July 2015 at the ULBRA Mãe de Deus University Hospital -Canos/RS. Patients were randomized into three groups: Group I – NIV; group II - volumetric incentive spirometer (IS) associated with positive end-expiratory pressure (PEEP) (IS+EPAP); and group III - conventional (CG). The three groups received motor physiotherapy. Post-operative monitoring of pulmonary complications was performed through radiology service reports until the time of discharge from the ICU. **Results:** 49 patients were included in the study, 13 patients in Group I, 16 patients in Group II and 20 patients in Group III. The average age of Group I was 61.7 ± 10.4 years, 61.4 ± 10.2 years in Group II, and 62.9 ± 11.5 years in Group III. Atelectasis was the pulmonary complication that had the highest statistical significance when comparing the three groups in the immediate PO (p=0.035). **Conclusion:** When comparing non-invasive ventilation (NIV) to incentive spirometry (IS) associated with positive end-expiratory pressure (PEEP) or respiratory exercises, we could not conclude that this particular technique is superior in relation to the decrease of pulmonary complications.
INTRODUCTION

Coronary artery disease (CAD) is characterized by insufficient blood supply to the heart through the coronary arteries. It is directly associated with the degree of obstruction of blood flow by atherosclerotic plaques, resulting in narrowing of the coronary arteries, decreasing the oxygen supply to the heart. In developed countries, cardiovascular diseases (CVD) are among the leading causes of death and their incidence has increased epidemically in developing countries, persisting as the leading cause of death worldwide. Among the options for the treatment for CAD, cardiac surgery has shown good results and has contributed to an increase in expectation and quality of life of patients with CVD. However, the occurrence of post-cardiac surgery pulmonary complications are very common, constituting a major cause of morbidity and mortality, even with the numerous advances achieved in these interventions. The increased morbidity is the result of a multifactorial relationship between anesthesia, surgical trauma, extracorporeal circulation (ECC), duration of surgery, duration of mechanical ventilation and pain, which may lead to decreased functional residual capacity (FRC) and increased intrapulmonary shunt.

Respiratory therapy is an integral part in cardiac patient care, and the main goals in the post-operative phase aim to promote the re-expansion of collapsed lung tissue, proper maintenance of ventilation, elimination of bronchial secretions and assistance in bed positioning. Conventional physical therapy corresponds to breathing exercises aimed at bronchial hygiene, lung re-expansion and mobility. Techniques such as deep breathing through incentive spirometry (IS) aim to increase and sustain transpulmonary pressure, with consequent expansion of collapsed alveoli, in order to prevent and/or treat pulmonary complications. Among other physical therapy resources, the application of positive pressure to the airways promote better distribution of pulmonary ventilation, thus preventing the collapse of smaller caliber routes which can minimize post-operative complications such as atelectasis and help to eliminate secretions.

According to Ferreira et al., the use of a volumetric incentive spirometer associated with expiratory positive airway pressure (EPAP) in patients subjected to coronary artery bypass graft (CABG) surgery is able to reduce the loss of lung function, respiratory muscle strength and functional capacity within 30 days after the surgical intervention. In a randomized clinical trial, NIV through BiPAP (Bi-level Positive Airway Pressure) was effective in treating hypoxemia in patients in the immediate post-operative period after cardiovascular surgery, and these benefits were maintained even one hour after interrupting the protocol in the intervention group. However, a study comparing the success and failure of NIV observed that the failure group had a greater length of stay in the ICU.

The objective of this study was to evaluate the effectiveness of incentive spirometry associated to positive end-expiratory pressure technique (PEEP) when compared to non-invasive ventilation with two pressure levels on the incidence of potential pulmonary complications in the post-operative cardiac surgery period.

MATERIALS AND METHODS

This study was an unregistered randomized clinical trial (RCT), approved by the Research Ethics Committee of the ULBRA (Decree number 52666) carried out from July 2012 to July 2015 at the ULBRA/Mãe de Deus Canoas University Hospital.

Adults over 18 years of both genders with heart disease (ischemic heart disease and heart failure) who had undergone cardiac surgery were included in the research. To be included, patients were invited to participate in the study, then received information about the study and signed the Clear and Informed Consent Form (IC), drafted in accordance with the Guidelines and Standards of research involving human subjects contained in the Resolution of the National Health Council number 466/12. Patients requiring mechanical ventilation for more than 24 hours, a need for reintubation, or having hemodynamic instability, or respiratory infection requiring antibiotic therapy were excluded.

All patients received physiotherapy twice a day, for 45 minutes during the ICU hospitalization period. When starting the protocol, the items in the data collection form regarding patient identification data, medical records, factors preceding surgery (pre-existing conditions), items that were analyzed during surgery (type of surgery and cardiopulmonary bypass time) and items during the post-
operative period (length of stay in ICU and pulmonary complications) were filled in. Post-operative follow-up of pulmonary complications was performed through a radiology service report, always conducted by the same radiologist blinded to the group to which the patient belonged, by observing the chest radiographs obtained in the immediate post-operative period and on the day of ICU discharge if/when occurred. The examination was performed in the supine position, identifying pulmonary complications such as atelectasis, pneumonia and pleural effusion.

On the first day after surgery, patients were randomized through Random Allocation Software (Windows software) into three groups: group I (NIV), group II (IS + EPAP) and group III (CG):

• Group I (NIV): Non-invasive intermittent ventilation by pressure ventilation support (PVS) was applied through a Puritan Bennett® mechanical ventilator, using a Respironics® face mask for 20 minutes twice a day. The pressure level was adjusted during inhalation (pressure support), being sufficient to maintain tidal volume ≥ 5 ml/kg and a pressure level during expiration (PEEP) ranging from 5 cmH2O to 7 cmH2O, according to peripheral oxygen saturation. The sensitivity was set at -2 cmH2O and the fraction of inspired oxygen (FiO2) was set at 40%.

• Group II (IS + EPAP): patients submitted to this method used a mask completely covering the oral-nasal region. An opening was connected to a Vital Signs® expiratory valve spring to graduate the level of positive expiratory pressure in the airway (PEEP). A 4000 ml volumetric incentive spirometer from DHD Healthcare Coach 2® was connected to a corrugated tube, where patients were instructed to perform one maximum and sustained inspiration. PEEP was progressively increased according to the study by Ferreira et al. as follows: 1st and 2nd day post-operation (PO) (5 cmH2O), 3rd day PO (6 cmH2O), 4th and 5th day PO (8 cmH2O); 6th day PO until discharge from the ICU (10 cmH2O). If the patient was unable to perform the exercise properly, the load was maintained and only increased on the following day. The protocol was performed twice daily in 3 sets of 10 repetitions, according to the guidelines of cardiac rehabilitation.

• Group III (CG): conventional group received conventional physical therapy, according to the routine care protocol of the ULBRA/Mãe de Deus Canoas University Hospital ICU. Ventilatory patterns were conducted such as DEEP Inspiration I (deep inspiration up to the average inspiratory reserve volume level) and DEEP Inspiration II (deep inspiration up to the maximum level of inspiratory capacity), inspiratory hiccups, fractional inspiration of 2 or 3 times and pursed lips according to patient tolerance. 1 set of 10 repetitions were performed for all ventilation standards.

All three groups received motor physical therapy which consisted of:

1st PO: Patient in dorsal decubitus (DD), passive hip adduction, abduction, and flexion exercises, knee flexion and extension exercises and metabolic lower extremity exercises, performing 3 sets of 8 repetitions for each movement and passive elevation of the upper limbs to 90°.

2nd PO: Patient in DD, active-assisted hip adduction, abduction and flexion exercises, knee flexion and extension exercises, and metabolic lower extremity exercises, performing 3 sets of 8 repetitions for each movement and passive elevation of the upper limbs to 90°.

3rd PO: Patient sitting in the armchair, active-assisted hip adduction, abduction and flexion exercises, knee flexion and extension exercises and metabolic lower extremity exercises, performing 3 sets of 8 repetitions for each movement and passive elevation of the upper limbs to 90°.

4th PO until ICU discharge: Addition of upper and lower limb stretches and moving around the room according to patient tolerance.

At any sign of discomfort such as dyspnea and pain, therapy was interrupted in all groups and vital signs (BP, SpO2, HR, RR) were reassessed, and if needed, a medical evaluation was requested.

All patients were advised to cough with restraint due to the surgical wound and not to force or lean against the upper body. The protocol was performed after training by physiotherapists in the multi-residency program in adult and elderly health along with the physiotherapy team of the ULBRA/Mãe de Deus Canoas University Hospital. The materials used were sterilized at the center of materials and sterilization of the hospital.

Calculation of the sample size was performed using the WinPEPI (Programs for Epidemiologists for Windows) program version 11.43. A 5% significance level, 80% power.
and 1.2 standard deviations effect size between groups required 12 patients per group, totaling 36 patients. Quantitative variables were expressed as mean and standard deviation or median and interquartile range. The qualitative variables were described by absolute and relative frequencies. To compare means between groups, one way analysis of variance (ANOVA) was applied; in the event of asymmetry, the Kruskal-Wallis test was used. Pearson’s chi-square test was used for comparison of proportions between groups; the McNemar test was used to compare the complications of the immediate post-operative discharge from the ICU, the adopted significance level was 5% (p ≤ 0.05) and analyzes were performed using SPSS version 21.0.

RESULTS

Fifty-eight patients were initially included in the protocol between July 2012 and July 2015. Of these, 49 completed the study, and the others were excluded due to the following criteria: the need for prolonged mechanical ventilation (1 patient), reintubation (2 patients), discontinuity of care protocol according to the proposed methodology (3 patients) and death (3 patients). The mean age was 62 ± 10.7 years, with a higher incidence of males (61.2%). Table 1 shows the characterization of the sample, in which homogeneity is observed between the groups. As shown in figure 1, 78.3% of patients underwent the procedure of coronary artery bypass surgery and 21.7% underwent valvuloplasty.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group NIV (n=13)</th>
<th>Group IS+EPAP (n=16)</th>
<th>Group CG (n=20)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) – mean ± SD</td>
<td>61.7 ± 10.4</td>
<td>61.4 ± 10.2</td>
<td>62.9 ± 11.5</td>
<td>0.912</td>
</tr>
<tr>
<td>Males – n(%)</td>
<td>7 (53.8)</td>
<td>12 (75.0)</td>
<td>11 (55.0)</td>
<td>0.386</td>
</tr>
<tr>
<td>Associated comorbidities – n(%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DM</td>
<td>5 (38.5)</td>
<td>8 (50.0)</td>
<td>10 (50.0)</td>
<td>0.775</td>
</tr>
<tr>
<td>CHF</td>
<td>3 (23.1)</td>
<td>3 (18.8)</td>
<td>6 (30.0)</td>
<td>0.731</td>
</tr>
<tr>
<td>COPD</td>
<td>3 (23.1)</td>
<td>3 (18.8)</td>
<td>4 (20.0)</td>
<td>0.958</td>
</tr>
<tr>
<td>Ejection Fraction (%) - mean ± SD</td>
<td>54.2 ± 7.3</td>
<td>53.6 ± 17.0</td>
<td>54.4 ± 12.0</td>
<td>0.986</td>
</tr>
<tr>
<td>Hospital stay (in days) – md</td>
<td>5 (3 – 7)</td>
<td>4.5 (3 – 7)</td>
<td>4.5 (4 – 7)</td>
<td>0.807</td>
</tr>
<tr>
<td>Number of consultations – md (P25-P75)</td>
<td>10 (6 – 14)</td>
<td>9 (6 – 13.5)</td>
<td>9 (8 – 14)</td>
<td>0.807</td>
</tr>
<tr>
<td>ECC duration (min) – mean ± SD</td>
<td>51.9 ± 13.1</td>
<td>62.2 ± 17.3</td>
<td>60.2 ± 6.7</td>
<td>0.085</td>
</tr>
<tr>
<td>Ischemia duration (min) – mean ± SD</td>
<td>33.7 ± 10.8</td>
<td>39.8 ± 15.4</td>
<td>38.1 ± 6.9</td>
<td>0.370</td>
</tr>
</tbody>
</table>

Legend: NIV: non-invasive ventilation; IS + EPAP: incentive spirometer and expiratory positive airway pressure; CG: conventional group; DM: diabetes mellitus; CHF: congestive heart failure; COPD
COPD: chronic obstructive pulmonary disease; ECC: extracorporeal circulation; SD: Standard Deviation.

Regarding radiological changes by analyzing pulmonary complications in the immediate post-operative period, IS + EPAP group had higher prevalence of atelectasis (50%), and this difference was statistically significant between groups (p=0.035). A reduction of this complication in the IS + EPAP (25%) group was observed at the time of discharge from the ICU; however, there was an increase in the conventional group (CG) from 3 (15%) to 5 patients (25%).

Incidence of infiltrates, pleural effusion and consolidation were similar between groups. 60% of patients showed the presence of infiltrates in CG and around 40% of pleural effusion in the 3 groups at ICU discharge, however there was no significant difference between groups (p=0.63). Table 2 shows the distribution of pulmonary complications per group.

### Table 2 – Pulmonary complications by group.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group NIV (n=13)</th>
<th>Group IS+EPAP (n=16)</th>
<th>Group CG (n=20)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate PO Complications - n(%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atelectasis</td>
<td>2 (15.4)</td>
<td>8 (50.0)</td>
<td>3 (15.0)</td>
<td>0.035</td>
</tr>
<tr>
<td>Infiltrate</td>
<td>5 (38.5)</td>
<td>4 (25.0)</td>
<td>7 (35.0)</td>
<td>0.713</td>
</tr>
<tr>
<td>Pleural effusion</td>
<td>5 (38.5)</td>
<td>4 (25.0)</td>
<td>4 (20.0)</td>
<td>0.495</td>
</tr>
<tr>
<td>Consolidation</td>
<td>1 (7.7)</td>
<td>2 (12.5)</td>
<td>2 (10.0)</td>
<td>0.913</td>
</tr>
<tr>
<td>Complication at ICU discharge - n(%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atelectasis</td>
<td>2 (15.4)</td>
<td>4 (25.0)</td>
<td>5 (25.0)</td>
<td>0.776</td>
</tr>
<tr>
<td>Infiltrate</td>
<td>6 (46.2)</td>
<td>5 (31.3)</td>
<td>12 (60.0)</td>
<td>0.228</td>
</tr>
<tr>
<td>Pleural effusion</td>
<td>6 (46.2)</td>
<td>8 (50.0)</td>
<td>7 (35.0)</td>
<td>0.639</td>
</tr>
<tr>
<td>Consolidation</td>
<td>1 (7.7)</td>
<td>0 (0.0)</td>
<td>1 (5.0)</td>
<td>0.561</td>
</tr>
</tbody>
</table>

Legend: NIV: non-invasive ventilation; IS + EPAP: incentive spirometer and expiratory positive airway pressure; GC: conventional group; ICU: intensive care unit.
DISCUSSION

The frequent incidence of pulmonary complications and their consequences in patients after cardiac surgery have been increasingly elucidated in the literature. According to some studies, the presence of such respiratory disorders is considered a major cause of mortality and morbidity during this period. This study aimed to analyze the efficacy results of volumetric incentive spirometry combined with positive end-expiratory pressure (PEEP) in comparison to non-invasive ventilation, or even conventional respiratory physiotherapy techniques (ventilatory patterns) in the incidence of pulmonary complications in the post-operative period.

Through radiological examinations we observed that the presence of pulmonary complications was significant, especially atelectasis. According to Matheus et al., atelectasis is the most frequent radiological alteration encountered in the CABG post-operative period, being related to a deterioration of gas exchanges, reduced lung volume and functional residual capacity. A similar result was found in a study by Jensen and Yang, who obtained a prevalence of 99.4% of pulmonary complications in CABG post-operative period, and with atelectasis and pleural effusion being the most frequent complications.

Despite pulmonary complications being frequent in the study period, there was no significant difference in the outcome between the groups analyzed; however, when comparing the immediate post-operative period with the time of discharge from the ICU, atelectasis in the IS + EPAP group reduced from eight to four patients, while it increased from three to five individuals in the CG. The increase in the number of patients developing atelectasis in CG may be associated to the non-use of positive pressure, as the NIV group maintained the result of the immediate PO when compared to the time of ICU discharge. A recent study by Cavalli and Nohama concluded that the implementation of PEEP was effective in reducing shunt areas and improving alveolar recruitment.

Beneficial effects of using volumetric incentive spirometry (IS) associated with expiratory positive airway pressure (EPAP) were cited in a study by Ferreira et al., where after CABG the patients in the intervention group showed improvement in dyspnea index, quality of life and decreased sensation of effort. On the other hand, a literature review by Freitas et al. found no benefits of using incentive spirometry in reducing pulmonary complications or decreasing the deleterious effects on pulmonary function after cardiac surgery. Similarly, Zangerolamo et al. concluded that the use of flow-oriented incentive spirometer associated with conventional respiratory therapy did not provide additional benefits compared to the control group.

A systematic review found no evidence of the effectiveness of using the incentive spirometer in surgical patients; the authors suggest new methodologically appropriate studies to clarify the purpose and justify the use of this technique. In this study, the NIV group showed no relevance in addressing pulmonary complications, however the incidence was lower compared to other groups studied at discharge from the ICU. These results corroborate the study of Franco et al., where the use of NIV in BiPAP was effective in reducing the respiratory work and increased compliance of the respiratory system by reverse microatelectasis. According to Jaaly et al., the use of positive pressure ventilation (BiPAP) was effective in the intervention group, where only 3% of patients presented atelectasis. Other authors also found benefits with the use of NIV, recommending its use in post-operative thoracic and cardiac surgery for prophylaxis. According to the Guidelines for mechanical ventilation, NIV in CPAP or BiPAP are able to prevent tracheal intubation/reintubation and its use should be prioritized immediately after extubation.

Regarding the presence of pleural effusion, there was an increase in incidence in all groups at the time of discharge from the ICU. According to a study by Morsch et al. which evaluated the ventilatory, radiological and clinical profile of patients undergoing CABG, the incidence of pulmonary complications was higher on the sixth post-operative day (78%) compared to the first day (40%), and pleural effusion was the most prevalent alteration (41%). In contrast, Labidi et al. studied the prevalence of pleural effusion after cardiac surgery and found a small percentage (6.6%) of patients had pleural effusion requiring thoracentesis.

In this study, we observed some factors that can influence the development of pulmonary complications after surgery, such as age ≥ 60 years, diabetes mellitus, congestive heart failure (CHF) and chronic obstructive pulmonary disease.
Branson et al.\(^3\) in accordance to the American Society of Anesthesiologists (ASA), identified COPD, age greater than 50 years and CHF as the major risk factors in the pre- and post-operative periods. The limiting factors during this study were patients’ intolerance to the interface used in group NIV, which impaired the patient’s initial adaptation to therapy. Thus, the protocol execution was according to patients’ tolerance.

**CONCLUSION**

In comparing NIV versus IS associated with PEEP or conventional breathing exercises, the present study could not conclude that this particular technique is better at reducing pulmonary complications in the PO of cardiac surgery.

**POTENTIAL CONFLICT OF INTERESTS**

No potential relevant conflict of interest.

**SOURCES OF FUNDING**

This study had no external funding sources.

**REFERENCES**