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ORIGINAL ARTICLE

Two types of inspiratory muscle training on muscle strength in patients submitted to coronary artery bypass grafting: clinical trial

Dois tipos de treinamento muscular inspiratório sobre a força muscular de pacientes após revascularização do miocárdio: ensaio clínico

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Abstract

Introduction: Coronary artery bypass grafting (CABG) causes changes in the respiratory musculature that affects functional capacity and postoperative complications (POC). Inspiratory muscle training (IMT) is a tool used for these patients, but it is not known what the best form is to increase strength. *Objective:* To investigate whether IMT with a linear pressure load device is superior to the inspiratory incentive on functional capacity and muscle strength of patients undergoing CABG. *Methods:* This is a clinical trial. Patients were assessed preoperatively for inspiratory muscle pressure (MIP), expiratory pressure (MEP), peak expiratory flow (PEF), six-minute walk test (6MWT) and functional independence measure (FIM). After surgery, they were divided into three groups: control group (CG), training group with linear pressure load (IMT) and inspiratory incentive group (IG). On the day of discharge, all patients had their previous variables reassessed. *Results:* The study included 56 patients, 31 (55.4%) were male and an average age of 55 ± 12 years. There was a significant reduction in all variables, in relation to MIP, the IMT showed a higher value in the postoperative period 83 ± 19 cmH₂O, against 70 ± 15 cmH₂O in the CG and 80 ± 15 cmH₂O in the IG ($p < 0.001$). The same behavior was observed in MEP, 77 ± 12 cm H₂O in IMT, 67 ± 14 cmH₂O in CG and 75 ± 10 cmH₂O in IG ($p < 0.001$). Regarding the 6 MWT, there was a lesser loss in the IMT from 434 ± 15 m to 398 ± 20 m in IG ($p < 0.001$). *Conclusion:* It is concluded that muscle training with a linear pressure load device is superior to training with incentive on functional capacity and muscle strength in patients undergoing CABG.

Keywords: physical therapy; myocardial revascularization; muscle strength.

Resumo

Introdução: A cirurgia de revascularização do miocárdio (CRM) causa alterações na musculatura respiratória que afetam a capacidade funcional e complicações pós-operatórias (DCP). O treinamento muscular inspiratório (TMI) é uma ferramenta utilizada por esses pacientes, mas não se sabe qual é a melhor forma de aumentar a força. *Objetivo:* Investigar se o TMI com dispositivo de carga de pressão linear é superior ao incentivo inspiratório na capacidade funcional e força muscular de pacientes submetidos à CRM. *Métodos:* Este é um ensaio clínico. Os pacientes foram avaliados no pré-operatório para pressão muscular

inspiratória ($PI_{m\acute{a}x}$), pressão expiratória (PEF), pico de fluxo expiratório (PFE), teste de caminhada de seis minutos (TC6) e medida de independência funcional (MIF). Após a cirurgia, eles foram divididos em três grupos: grupo controle (GC), grupo treinamento com carga linear de pressão (IMT) e grupo incentivo inspiratório (GI). No dia da alta, todos os pacientes tiveram suas variáveis anteriores reavaliadas. *Resultados:* O estudo incluiu 56 pacientes, 31 (55,4%) eram do sexo masculino e idade média de 55 ± 12 anos. Houve redução significativa em todas as variáveis, em relação à $PI_{m\acute{a}x}$, o IMT apresentou valor maior no pós-operatório 83 ± 19 cmH₂O, contra 70 ± 15 cmH₂O no GC e 80 ± 15 cmH₂O no GI ($p < 0,001$). O mesmo comportamento foi observado na $PE_{m\acute{a}x}$, 77 ± 12 cmH₂O no IMT, 67 ± 14 cmH₂O no GC e 75 ± 10 cmH₂O no GI ($p < 0,001$). Em relação ao TC6, houve menor perda no TMI de 434 ± 15 metros para 398 ± 20 metros no GI ($p < 0,001$). *Conclusão:* Conclui-se que o treinamento muscular com dispositivo de carga pressórica linear é superior ao treinamento com incentivo inspiratório na capacidade funcional e da força muscular em pacientes submetidos à CRM.

Palavras-chave: fisioterapia; revascularização miocárdica; força muscular.

Introduction

Coronary artery bypass grafting (CABG) despite all advances is associated with complications in the postoperative period (PO) that change pulmonary function causing pneumothorax, pleural effusion, atelectasis, and pneumonia. These complications can lead to an increase in hospital stay, risk of functional decline and increased mortality rate. In this sense, inspiratory muscle training (IMT) appears as a tool for hospital rehabilitation of this population [1-5].

Some intra and postoperative procedures are directly linked to these complications: the median sternotomy, the effects of anesthesia, cardiopulmonary bypass (CPB), use of chest tubes and invasive mechanical ventilation can alter respiratory mechanics [6,7].

To detect all these complications, it is important to monitoring of pulmonary function by measuring the maximum respiratory pressures, which are the maximum inspiratory pressure (MIP) and expiratory pressure (MEP), both of which assess muscle strength using a manovacuometer [8]. The measure of the

patient's functional limitation can be assessed using the 6-Minute Walk Test (6MWT) simple and low-cost procedure, which aims to measure the patient's functional capacity [10]. The level of dependence during motor and cognitive activities is determined using the Functional Independence Measure (FIM) scale [11].

From the detection of changes in muscle strength, inspiratory muscle training (IMT) is performed, which is aimed at strengthening the respiratory musculature, benefiting the efficiency in airway clearance, maximum inspiratory and expiratory pressure and prevention of muscle fatigue [12]. Among these trainings are the pressure load device and the flow incentive.

The pressure device, also known as Threshold®, works by a spring system, with a pre-determined pressure based on MIP [13]. The flow incentive, has a turbulent and variable initial flow increasing the respiratory work, also promotes visual feedback, stimulating the patient to take maximum and sustained inspirations, leading to an increase in transpulmonary pressure [14].

There are still few studies that talk about the comparison of the respiratory stimulator with the Threshold® in postoperative patients of CABG. Therefore, the objective of this research was to investigate whether inspiratory muscle training with a linear pressure load device is superior to the inspiratory stimulator on functional capacity, pulmonary complications, functionality, pulmonary function and length of hospital stay of patients undergoing to CABG.

Methods

The study is a randomized and controlled clinical trial, approved by the Research Ethics Committee of Faculdade Nobre under the number 2,088,636. All patients were informed of the research objectives and signed a Free and Informed Consent Form (ICF). Data collection was carried out from October 2019 to July 2020 at the Instituto Nobre de Cardiologia (INCARDIO), Feira de Santana-Bahia, a regional reference center for cardiological treatments. The work was registered in the Brazilian Registry of Clinical Trials (ReBec) under the number RBR-36fvws.

Patients

Inclusion criteria were individuals of both genders, older than 18 years and submitted to coronary artery bypass grafting via median sternotomy and extracorporeal circulation. Exclusion criteria: patients who did not understand how to perform the techniques, who presented hemodynamic instability (20% more or less of heart rate, systolic blood pressure or diastolic blood pressure) during the assessment of inspiratory pressure maximum or muscle training, diagnosis of pneumopathy, uncontrolled arrhythmias and cognitive alterations, length of stay in the Intensive Care Unit (ICU) longer than 4 days and those who required Invasive Mechanical Ventilation for more than 24 hours.

Patients were assessed preoperatively for maximum inspiratory pressure (MIP), maximum expiratory pressure (MEP), peak expiratory flow (PEF), six-minute walk test (6MWT) and functional independence measure (FIM). On the first postoperative day, they were randomized by simple drawing into three groups. The groups were as follows: control group (CG), inspiratory muscle training group (IMT) and inspiratory incentive group (IG).

The Control Group (CG) received routine care from the hospital without any interference from the researchers; the conducts applied were sedation, ambulation, breathing exercises, cycle ergometry and kinesiotherapy. The IMT group performed inspiratory muscle training using the linear pressure load device (Threshold IMT®) with a load corresponding to 40% of MIP, performing three sets of 10 repetitions, twice a day until the moment of hospital discharge. The third group (IG) carried out training with the inspiratory flow motivator, performing maneuvers with deep inspirations and with the highest possible inspiratory flow peak, aiming to reach a load equivalent to 50% of MIP, with 30 inspirations and twice per day until hospital discharge. These last two groups underwent conventional physical therapy with the addition of the muscle training protocol prescribed for their group.

Pulmonary function and muscle strength

Preoperative assessment of inspiratory muscle strength (MIP) was performed using an Indumed® (São Paulo, Brazil) analogue manovacuometer.

During the evaluation, a maximal expiration until the residual volume was requested, and then a maximal and slow inspiration to the total lung capacity was required. This test was done using the unidirectional valve method, being possible a flow through a hole of one millimeter, aiming to exclude the action of the buccinator, and repeated for three times, being used the highest value reached, if this value was not the last. MEP was evaluated using the same apparatus and the patient was instructed to perform a maximal inspiration until he reached his total pulmonary capacity, the mask was placed, and after that a maximum expiration was requested until the residual capacity was reached. The test was repeated three times and it was considered the highest value result, if this value was not the last [8]. Both tests were performed with the patient seated, lower limbs resting on the ground.

To assess VC, we used the analogue ventilometer Ferraris Mark 8 Wright Spirometer (Louisville, Colorado, United States of America). The ventilometer was unlocked, cleared, and soon after the facial mask was placed on the face of the individual. The patient underwent deep inspiration until he/she reached his/her total pulmonary capacity, and soon after a slow and gradual expiration until reaching the residual volume. After this, the ventilometer was locked and the result observed and noted. The test was repeated three times, being considered the highest value result [10].

Peak expiratory flow was evaluated using the peak flow of the Mini Wright® brand. During the evaluation, the patient was seated, with his head in a neutral position and a nasal clip to prevent air from escaping through the nostrils. The patient took a deep breath, until total pulmonary capacity, followed by forced expiration with the mouth in the device. After three measurements, the highest value was chosen and there could be no difference > 40 liters between measurements [9].

Measurement of functional capacity

The 6MWT was used following the recommendations of the American Thoracic Society, or ATS, being conducted in a 30-meter, flat, and totally obstacle-free corridor. Prior to the test, patients had a rest period of at least 10 minutes. During this period, they were evaluated for contraindications, blood

pressure data (through Premium aneroid sphygmomanometer and 3M Littmann stethoscope), pulse oximetry (Rossmax), dyspnea level (Borg scale), heart rate (assessed by palpation of the radial artery and counting over a period of one minute), and respiratory rate (evaluated by verifying the respiratory incursion during one minute). The patient was advised to walk as fast as possible, without running, in this corridor for six minutes. During the test, encouragement phrases were used each minute. At the end of the test, the examiner quantified the distance covered within those six minutes [10].

During the protocol, patients were monitored, and in the presence of an increase in systolic and/or diastolic blood pressure $> 30\%$ of baseline, heart rate $< 20\%$ of baseline, peripheral oxygen saturation $< 90\%$, and increased respiratory rate > 25 breaths per minute, the test was discontinued.

Functionality assessment

These individuals were also assessed for the Functional Independence Measure (FIM), a questionnaire that uses a 7-point scale to assess 18 items in the areas of personal care, sphincter control, mobility, locomotion, communication, and social cognition. This assessment was designed to measure the patient's level of dependence. Each dimension is analyzed by the sum of its categories from 1 to 7, the lower the score, the greater the degree of dependence. Adding the points of the dimensions of the instrument, it reaches a minimum total score of 18 and a maximum of 126 points, which characterize the levels of dependence [11].

Surgical procedure

Coronary artery bypass grafting was performed through median sternotomy and cardiopulmonary bypass. Left internal thoracic artery or saphenous vein graft was used. The surgical procedure has always been carried out by the same team, ending with the positioning of a subxiphoid drain, left intercostal drain and sternorrhaphy. Analgesia was optimized for all patients and was referred to the Intensive Care Unit.

Postoperative management

After the surgical procedure, all patients were referred to the Intensive Care Unit (ICU) to receive the immediate care necessary for their recovery. They underwent Invasive Mechanical Ventilation (IMV) in assisted mode controlled by volume or pressure, with tidal volume from 6 ml/kg to 8 ml/kg of the predicted weight, with respiratory rate (RF) of 12 to 18 ipm, inspired fraction of oxygen (FiO₂%) to maintain a peripheral oxygen saturation (SpO₂%) of 93 and 97%, an inspiration/exhalation ratio of 1: 2 and a positive pressure at the end of exhalation (PEEP) of 5 cmH₂O [21]. After interrupting ventilation or extubation, patients continued to receive medical and physiotherapeutic care until discharge from the ICU. Then they were taken to the ward where they continued to receive their usual care until discharge from the hospital where a new assessment of maximum inspiratory pressure (MIP), maximum expiratory pressure (MEP), peak expiratory flow (PEF) was performed, six-minute walk test (6MWT) and functional independence measure (FIM) to make a comparison with the data obtained in the preoperative moment.

Clinical results

During the hospitalization period, pulmonary complications in the postoperative period were analyzed: atelectasis, pleural effusion, pneumothorax, and pneumonia, which were diagnosed with the aid of chest radiography. CPB duration, mechanical ventilation, hospital stay, number of bridges and drains (mediastinum and hemothorax) were also recorded.

Statistical analysis

For data analysis, the program SPSS 20.0 was used. To evaluate the normality of the sample, the Kolmogorov-Smirnov test was used. Categorical variables were analyzed using the Chi-square. For pre and post training evaluation within the group, the paired Student's T-Test was used and for comparison in the three groups, the ANOVA Test was used. It was considered significant when $p < 0.05$.

Results

Between August 2017 and February 2018, 60 patients were admitted to the Instituto Nobre de Cardiologia (INCARDIO), in Feira de Santana/BA and 56 answered the inclusion criteria. The flowchart shows the progress of the study and how each group was divided (Figure 1).

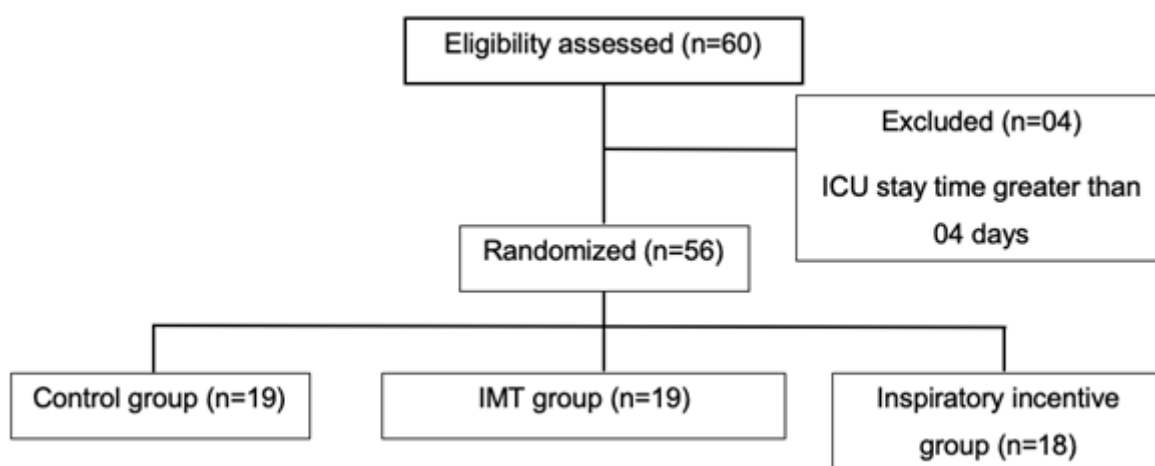


Figure 1 - Study progression and division of the studied groups

In the sample, we found 31 (55.4%) males with a mean age of 55 ± 12 years. The most common comorbidity was systemic arterial hypertension (SAH) in 44 (78.5%) of the patients (Table I).

Surgical data showed an average CPB time of 80 ± 14 minutes and an average MV time of 8 ± 4 hours. The other data are shown in Table II.

Regarding the functional variables, it was found that the TMI group in the 6MWT obtained a longer distance than the other groups (IMT 398 ± 20 m vs CG 305 ± 21 m vs IG 356 ± 19 m). As for the FIM, the Control Group was the one that lost the most points when compared to the two moments before 123 ± 2 and 112 ± 5 afterwards (< 0.001). The other variables are shown in Table III.

Pulmonary complications were less evident in the group that underwent conventional inspiratory muscle training when compared to the control group and the incentive group, with statistical significance in pneumothorax GTMI 0 vs GC 1 ($p < 0.32$), hypoxemia GTMI 3 vs GC 8 ($p < 0.02$), atelectasis GTMI 3 vs GC 8

($p < 0.02$) and pneumonia GTMI 0 vs GC 2 ($p < 0.45$). The complete data on complications in the postoperative period are described in the table below (Table IV).

The information related to pulmonary function and strength is shown in table V. A statistically significant reduction was observed in all groups, but a greater decline in variables was observed in the control group during hospitalization. We can observe the behavior of MIP in the CG before 110 ± 9 vs 70 ± 15 after ($p < 0.001$), GTMI before 107 ± 8 vs 83 ± 19 after ($p < 0.001$) and GI before 107 ± 10 vs 80 ± 15 after ($p < 0.001$).

Table I - Clinical characteristics of the patients included in the study

Variable	Control Group (n = 19)	IMT Group (n = 19)	Inspiratory incentive Group (n = 18)	p
Gender				0,22 ^a
Male	10 (53%)	11 (58%)	10 (56%)	
Female	9 (47%)	8 (42%)	8 (44%)	
Age (years)	57 ± 8	55 ± 10	54 ± 10	0,74 ^b
BMI (kg/m²)				
Eutrophic	5 (26%)	6 (32%)	5 (28%)	0,23 ^a
Overweight	11 (58%)	9 (47%)	9 (50%)	0,78 ^a
Obesity	3 (16%)	4 (21%)	4 (22%)	0,43 ^a
Comorbidities				
SAH	15 (79%)	14 (74%)	15 (83%)	0,35 ^a
DM	8 (42%)	9 (47%)	8 (44%)	0,53 ^a
DLP	9 (47%)	7 (37%)	8 (44%)	0,36 ^a
AMI	5 (26%)	5 (26%)	6 (33%)	0,74 ^a
Sedentary lifestyle	10 (52%)	12 (63%)	12 (67%)	0,27 ^a
Length of hospitalization (days)	9 ± 3	6 ± 2	7 ± 2	<0,001 ^b

^aChi-square test; ^bANOVA; IMT = Inspiratory Muscle Training; BMI = Body Mass Index; SAH = Systemic Arterial Hypertension; DM = Diabetes Mellitus; DLP = Dyslipidemia; AMI = Acute Myocardial Infarction

Table II - Surgical characteristics of the studied patients

Variable	Control group (n = 19)	IMT Group (n = 19)	Inspiratory incentive Group (n = 18)	p ^a
CPB time (minutes)	78 ± 12	80 ± 15	82 ± 14	0,43
MV time (hours)	9 ± 3	8 ± 4	9 ± 4	0,87
Grafts Number	2 ± 0,4	2 ± 0,7	2 ± 0,6	0,63
Drains number	2 ± 0,1	2 ± 0,5	2 ± 0,2	0,74

^aANOVA; IMT = Inspiratory Muscle Training; CPB = Cardiopulmonary bypass; MV = Mechanical Ventilation

Table III - Behavior of functional variables between groups

Variable	Control Group (n = 19)	IMT Group (n = 19)	Inspiratory incentive Group (n = 18)	p ^a
6MWT (meters)				
Preoperative	412 ± 23	434 ± 15	421 ± 16	0,53
Hospital discharge	305 ± 21	398 ± 20	356 ± 19	< 0,001
p	< 0,001	< 0,001	< 0,001	
FIM				
Preoperative	123 ± 2	125 ± 1	125 ± 0,8	0,56
Hospital discharge	112 ± 5	120 ± 3	117 ± 2	< 0,001
p	< 0,001	0,25	0,08	

^aANOVA; ^bPaired Student's t test; IMT = Inspiratory Muscle Training; 6MWT = Six-minute walk test; FIM = Functional Independence Measure

Table IV - Pulmonary complications of patients randomized according to the group

Variable	Control Group (n = 19)	IMT Group (n = 19)	Inspiratory incentive Group(n = 18)	p ^a
Pneumothorax	1 (5%)	0	0	0,32
Reintubation	2 (11%)	1 (5%)	1 (6%)	0,53
Pleural effusion	8 (42%)	5 (26%)	7 (39%)	0,43
Hypoxemia	8 (42%)	3 (16%)	8 (44%)	0,02
Atelectasis	8 (42%)	3 (16%)	8 (44%)	0,02
Acute lung edema	2 (11%)	0	1 (6%)	0,42
Pneumonia	2 (11%)	0	1 (6%)	0,45

^aANOVA; IMT = Inspiratory muscle training

Table V - Behavior of pulmonary variables between groups

Variable	Control Group (n = 19)	IMT Group (n = 19)	Inspiratory incentive Group(n = 18)	p ^a
MIP (cmH₂O)				
Preoperative	110 ± 9	107 ± 8	107 ± 10	0,68
Hospital discharge	70 ± 15	83 ± 19	80 ± 15	< 0,001
p ^b	< 0,001	< 0,001	< 0,001	
MEP (cmH₂O)				
Preoperative	108 ± 11	110 ± 12	105 ± 8	0,56
Hospital discharge	67 ± 14	77 ± 12	75 ± 10	< 0,001
p ^b	< 0,001	< 0,001	< 0,001	
PEF (l/min)				
Preoperative	433 ± 12	423 ± 9	412 ± 12	0,12
Hospital discharge	231 ± 21	311 ± 15	298 ± 19	< 0,001
p ^b	< 0,001	< 0,001	< 0,001	

^aANOVA; ^bPaired Student's t test; MIP = Maximum Inspiratory Pressure; MEP = Maximum Expiratory Pressure; PEF = Peak Expiratory Flow

Discussion

The present study aimed to verify which type of inspiratory muscle training is most effective to reduce the impact on functional capacity, pulmonary complications, functionality, lung function and length of hospital stay. It was shown that an IMT program with a linear pressure load device is efficient to minimize the loss of functional capacity, reduce postoperative complications and decline in functionality, decrease the worsening of pulmonary function, mainly of inspiratory muscle strength, and shorten the length of stay of this studied population.

The post-operative of myocardial revascularization is a large and very invasive procedure, which is why it requires some specific care, as patients can usually present pneumothorax, atelectasis, pleural effusion and pneumonia, reduced lung function and pain [16-23]. These complications lead to a decline in lung function, directly impacting functionality and functional capacity, leading this patient to stay in the hospital for more days. We noticed in our results that the

patients who had more pulmonary complications in the postoperative period were those in the control group, which also had a greater decline in lung function, observed by the reduction of MIP, MEP, PEF, walked less on the 6MWT, lost more point in the FIM when comparing pre and post intragroup and intergroup values.

We noticed in our study that the group that performed the IMT Threshold IMT® had fewer complications in the postoperative period, less three days of hospitalization when compared to the control group, lost less in the 6MWT compared to the pre- and postoperative moment and in relation to functionality was the group that lost the least points in the MIF. This result shows us that TMI with Threshold IMT® is beneficial for this audience and can have an influence on the patient's functional capacity and functionality. IMT becomes an essential tool in the rehabilitation of these patients, preventing these negative events from occurring.

Other authors have already shown that IMT is a safe and viable resource for the rehabilitation of patients in the Intensive Care Unit regardless of whether they are in invasive mechanical ventilation, helping to gain strength in the inspiratory muscles, especially in the activation of the diaphragm, improving the pulmonary function, functional capacity and, consequently, their quality of life [24-26].

Silva *et al.* [27] demonstrated that the IMT with the inspiratory flow motivator was able to increase the inspiratory muscle strength and the distance covered in the 6MWT in patients after cardiac surgery. A result like the study by Silva *et al.* [13] also found a significant increase in MIP in patients who used Threshold IMT®, and an inspiratory incentive to flow at volume in relation to the moment before training, and in the control group, no change was observed of MIP.

These results, like ours, the patients who underwent IMT with Threshold IMT® and with the inspiratory flow incentive lost less points in the FIM, walked more in the 6MWT and stayed less time hospitalized when compared with the patients in the control group, showing that the loss was minimized, showing a superior inspiratory muscle training.

It is worth highlighting the differences between the incentives that can influence the outcome of the training. Cordeiro *et al.* [4] show that patients

undergoing cardiac surgery have reduced pulmonary function, inspiratory muscle strength, peak expiratory flow up to one month after surgery, generating changes in ventilatory mechanics.

Of the variables evaluated, MIP, MEP and PEF showed a significant reduction in the immediate postoperative period of myocardial revascularization due to the changes suffered in the procedure, or because they already had predispositions related to cardiopulmonary problems. Data also observed by Santos *et al.* [28] in which changes in MIP and MEP were found after surgery when compared with the preoperative period. It was also reported the advantage that the IMT groups had in terms of restoring ventilatory function.

Ge [29] and Gomes Neto [30] corroborate the same results when they report that inspiratory muscle training in the postoperative period of cardiac surgery increases inspiratory muscle strength, improves tidal volume, peak expiratory flow, improving the effectiveness of coughing consequently. Better removal of secretion decreasing the risk of complications and the length of hospital stay.

The maximum respiratory pressures that had negative variations after surgery and recovered after the completion of physical therapy interventions. Among the three groups studied, two were used respiratory muscle training (IMT), which acts to recover ventilatory muscle strength.

The TMI presented significant indices with the use of the pressure device (Threshold IMT®) and the inspiratory incentive to flow. The control group that did not have any type of intervention related to the research relied only on the institution's physiotherapy protocol. This did not present significant results when compared with the Threshold IMT® and respiratory incentive to flow, maintaining disadvantage before the technique.

The present study has as limitations the lack of a sample calculation and the non-assessment of confounding factors, such as pain, through logistic regression.

Conclusion

Based on the findings of the present study, it is concluded that inspiratory muscle training with a linear pressure load device is superior to training with the

inspiratory flow motivator and has a positive impact on functional capacity, pulmonary complications, functionality, lung function, and it is also capable of reducing the length of hospital stay of patients undergoing coronary artery bypass grafting. It is noteworthy that the achievements of the two forms of inspiratory muscle training proved to be superior to conventional treatment.

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