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ORIGINAL ARTICLE

# Inspiratory muscle training and functional capacity following coronary artery bypass grafting in high-risk patients: A pilot randomized and controlled trial

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Abstract

**Background:** Coronary artery bypass graft (CABG) surgery is associated with worsened functional capacity, pulmonary complications, and increased length of hospital stay. These negative effects are exacerbated in patients who are at high risk of post-operative (PO) pulmonary complications before CABG. Inspiratory muscle training (IMT) has been shown to benefit CABG patients in their recovery process. However, in high-risk patients, there is little evidence to support the post-operative implementation of IMT for purposes of faster recovery.
**Aim:** The aim of the study was to test the hypothesis that IMT improves the functional capacity, pulmonary complications, and length of hospital stay in patients prone to pulmonary complications who had undergone CABG.
**Methods:** This is a pilot clinical trial carried out with patients at high risk for pulmonary complications in the PO phase. In the pre-operative period, maximal inspiratory pressure (MIP), maximal expiratory pressure (MEP), and 6-min walk test (6MWT) were determined and administered. On the first PO day, patients were divided into two groups: A control group (CG) that received routine intervention and an IMT group that, in addition to routine care, was subjected to an IMT protocol until hospital discharge. On the day of discharge, the patients were reassessed with respect to ventilatory muscle strength, functional capacity, PO complications, and length of stay.
**Results:** Twenty-nine patients were evaluated, 15 in the CG and 14 in the IMT group. No significant differences were observed in relation to MIP (difference between the mean of −7 $cmH_2O$; 95% CI = −16.52–2.52), MEP (difference between the mean of −7cm $H_2O$; 95% CI = −15.39–1.39), and in the 6MWT (difference between the mean of −9 m; 95% CI = −43.71−25.71). There was a decrease in the length of stay in the IMT group compared to the CG (9 ± 3 vs. 12 ± 4 days; $P = 0.04$). The IMT group had a lower rate of atelectasis and pneumonia.
**Conclusion:** IMT does not minimize the loss of functional capacity, but it reduces pulmonary complications and the length of stay of patients undergoing CABG who are preoperatively at a high risk of pulmonary complications.
**Relevance for Patients:** The increase in ventilatory muscle strength, associated with IMT, can reduce PO pulmonary complications, resulting in shorter hospital stays, and improved quality of life.

## 1. Introduction

Decreased functional capacity and muscle strength are expected outcomes in patients following coronary artery bypass graft (CABG) [1,2]. Pulmonary complications such as atelectasis, pleural effusion, and pneumonia are also expected post-operative complications outcomes for these individuals [3,4]. It is known that anesthesia, surgical incision, duration

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of cardiopulmonary bypass, and mechanical ventilation are contributing factors to muscle strength reduction and increased incidence of pulmonary complications after surgery [5,6], leading to extended length of stay and considerable mortality rates.

Growing evidence suggests that inspiratory muscle training (IMT) seems to be a key component within the rehabilitation process following heart surgery since it has been linked to enhanced respiratory muscle force, shorter length of hospital stay, and lower rates of respiratory complications [7]. However, we have noticed that most of the currently published studies did not include patients with lung disease, smokers, and patients susceptible to other risk factors for complications. The potentially beneficial effects of IMT in high-risk patients have yet to be investigated.

Therefore, the aim of this study is twofold: To determine the effects of IMT on functional capacity and respiratory muscle force and to evaluate the IMT impact on pulmonary complications rates and length of hospital stay.

## 2. Methods

### *2.1. Study design*

This was a pilot randomized and controlled clinical trial conducted between January and October 2018 at Instituto Nobre de Cardiologia (INCARDIO), Feira de Santana, Bahia, Brazil. The study was approved by the Ethics and Research Committee of Faculdade Nobre de Feira de Santana, under the protocol no. 2,366,995 and registered in the Brazilian Registry of Clinical Trials (ReBEC) under the protocol no. RBR-8dqrdq. All participants signed an informed consent form.

### *2.2. Screening and eligibility*

Individuals of both genders, over 60 years old, smokers, with moderate and severe chronic obstructive pulmonary disease (COPD) confirmed by clinical and spirometric examination, and body mass index (BMI) of over 27 kg/m$^2$ were included in the study.

Individuals were excluded if they had (a) surgical reintervention, (b) use of intra-aortic balloon, (c) valve disease, patients (d) cognitive impairment that led them to be unable to understand physiotherapist's instructions, (e) hemodynamic instability during physical assessment as well as the IMT, and (f) physical impairments precluding functional capacity assessment.

### *2.3. Surgical and postoperative (PO) treatment*

The surgery was performed through median sternotomy. For CABG, saphenous vein grafts and/or left or right internal mammary artery grafts were used. During anesthesia and after surgery, all patients inspired 40–80% oxygen concentration. Postoperatively, patients were artificially ventilated with a positive end-expiratory pressure of 5 cm $H_2O$. After extubation, all patients received pain relief with 1 g paracetamol 4 times daily for as long as necessary after discharge. Demographic and descriptive data were collected from the medical records.

### *2.4. Study protocol*

Patients had their respiratory muscle performance lung function and functional capacity evaluated preoperatively. Muscle performance was assessed by obtaining a maximal inspiratory pressure (MIP) and expiratory pressure (MEP) and functional capacity was determined by the 6-min walk test (6MWT).

On the first PO day, study participants were assigned randomly to groups by using a simple draw.

Control group patients were treated based on the hospital protocol of the institution, which was based on the pre-operative period. The patients were instructed about the surgical procedure, about the activities they could perform, all functional assessment, kinesiotherapy for upper and lower limbs, and ambulation. In the PO period, they performed non-invasive ventilation, transfer from lying down to sitting position, kinesiotherapy, and sitting chair procedures on the 1$^{st}$ day. From the 2$^{nd}$ day on, they were already walking around the unit. All these behaviors were maintained until hospital discharge, increasing the time and distance.

In the training group (IMT), patients performed the same activities of the control plus IMT. Patients were instructed to perform the MIP assessment and started MIP using a linear pressure loading device (PowerBreathe Knectic Series, HaB International, UK), with 40% of the MIP, developing three sets with 15 repetitions. Every 5 days, muscle strength was reassessed, and a 40% load was applied based on the new value. This training was performed twice a day until the patient was discharged. The intervention was performed by a physical therapist with 3 years of work experience and practice in IMT.

Lung function and functional capacity were reassessed by the same pre-operative examiner who was blinded to the groups at discharge.

### *2.5. Primary and secondary outcome*

The primary outcome was functional capacity and secondary outcomes were inspiratory muscle force and the incidence of pulmonary complications.

### *2.6. Inspiratory muscle force assessment*

Pre-operative inspiratory muscle force assessment was performed using an Indumed analog manovacuometer. Patients were required to perform a maximal expiration up to residual pulmonary volume followed by a maximal and prolonged inspiration up to total lung capacity. Inspiratory maneuvers were executed 3 times and the highest value was included in the final analysis as long as it was not the last [8].

The MEP was also measured with the same device but in a different manner. Initially, the patient was instructed to perform a maximum inspiration until he/she reached his/her total lung capacity. Then, after positioning the mask, a maximum expiration was requested until reaching the residual capacity, following the same rule of MIP (using the highest value, except when this is the last [9]).

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### 2.7. Functional capacity assessment

The 6MWT is considered to be a simple and low-cost assessment of functional capacity. The 6MWT is performed on a flat, obstacle-free, and 30-m surface. Before performing the test, the patient rests for 10 min. During this period, data such as blood pressure (using Premium Aneroid sphygmomanometer and 3M Littmann stethoscope), pulse oximetry (pulse oximeter - Rossmax), level dyspnea (Borg's perceived exertion scale), heart rate (evaluated by palpating the radial artery and counting over a period of 1 min), and respiratory rate (evaluated by checking the respiratory incursion over a period of 1 min) were obtained.

After the 10-min rest period, the patient was asked to walk as fast as possible for 6 min, the therapist should observe the patient's physiological responses and finally the distance walked according to each individual's variables. This test is currently considered the best indicator to measure functional capacity. Besides considering the risk of returning to the hospital, it also observes the patient's performance when related to activities of daily living [9].

Throughout the 6MWT, the patient was monitored so the test could be stopped at any time when a heart rate of <20% of baseline, increase in systolic and/or diastolic blood pressure >30% of baseline, increase in respiratory rate >25 breaths/min, and peripheral oxygen saturation <90% were observed.

### 2.8. Statistical analysis

The analysis was performed using the SPSS 20.0 program. Normality was assessed using the Shapiro–Wilks test. The variables were expressed as means and standard deviations. Chi-square was used to compare categorical variables. To compare values between groups, the independent Student's *t*-test was used and the intragroup comparison was the paired Student's *t*-test. It was considered as significant when $P < 0.05$. The delta value (Δ) was found by subtracting the pre-operative value from the value found on the day of discharge.

### 2.9. Calculation of statistical power

In our study, 29 patients were evaluated with standard deviation in the average distance walked in the control group ($n = 14$) of 110 m and in the training group ($n = 15$) of 101 m and, difference between the averages of the distances walked by the 9 m groups, this sample of convenience allowed a statistical power of 74% (alpha of 5%).

## 3. Results

During the study period, 38 patients were hospitalized, of which nine were excluded from the study, two due to combined surgery, six due to pulmonary disease, and one due to physical limitations, leaving 29 subjects (Figure 1).

Patients were mainly male (62%), with mean ± SD age of 67 ± 4 years and a BMI of 31.5 ± 2.5 kg/m$^2$. The most prevalent comorbidity observed was sedentarism (72.4%). Surgical and clinical variables are presented in Table 1.

Table 2 shows the values of respiratory muscle force and functional capacity between groups. No significant differences were observed for MIP (mean difference of −7 cm$H_2O$; 95% CI = −16.52–2.52), MEP (mean difference of −7 cm$H_2O$; 95% CI = −15.39–1.39), and in the 6MWT (mean difference of −9 m; 95% CI = −43.71–25.71).

Patients who underwent muscle training had a lower rate of atelectasis and pneumonia. The values and other variables are expressed in Table 3.

## 4. Discussion

We found that the IMT protocol applied to patients at high risk of pulmonary complications was not associated with a decrease in loss of functional capacity. In addition, we found that IMT shortens the length of hospital stay and reduces pulmonary complications, such as atelectasis and pneumonia.

The decline in functional capacity is a common finding in patients in the PO period of CABG, and in this study, we did not verify the impact of IMT in preventing this loss. Although the previous studies have demonstrated the protective effect of training on functional capacity [1,4], the exclusion of patients at higher risk of pulmonary complications, usually found in the literature, reduces the power of comparison with our results.

In the study by Cordeiro *et al*. [1] and Zanini *et al*. [10] showed less loss of functional capacity in patients undergoing CABG but excluded patients with known or suspected lung disease. Therefore, predictor variables such as COPD, advanced age, and high body mass are associated with worse outcomes and protective training is not for this population. Both studies [1,10] applied IMT, however, in the study by Zanini *et al*. [10], three more groups were created involving peripheral muscle training as well. The main difference between these two studies and the current one is the performance of IMT in patients at high risk of pulmonary complications, which was used as an exclusion criterion in the previous studies [1,10].

Patients with COPD have decreased aerobic capacity due to lung hyperinflation, intense inflammatory process, and loss of Type 1 [11-13] muscle fibers. The sum of these factors with the functional changes resulting from the surgical procedure can increase the worsening of functional capacity and IMT is not preventive for this outcome. In addition, the short period that this patient remains hospitalized makes it difficult to obtain better results; therefore, pre-operative training should be encouraged in other studies.

The inflammatory process is also observed in obese and diabetic patients and these factors have a harmful potential like COPD [14,15]. It is necessary to stratify the degree of obstruction and correlate it with the decline in functional capacity in these patients. Inflammation by cardiopulmonary bypass worsens pulmonary function by interfering with hematosis and, consequently, decreasing aerobic capacity [16].

In addition to these factors, there is an increase in metaboreflexus, another factor associated with decreased functional capacity [17]. Although studies show that IMT can attenuate metaboreflex, in an at-risk population such as ours, this condition has not been verified [1,18,19]. This may occur secondary to lung hyperinflation in COPD patients, where diaphragmatic dysfunction is well established and short-term training is not sufficient [20,21].

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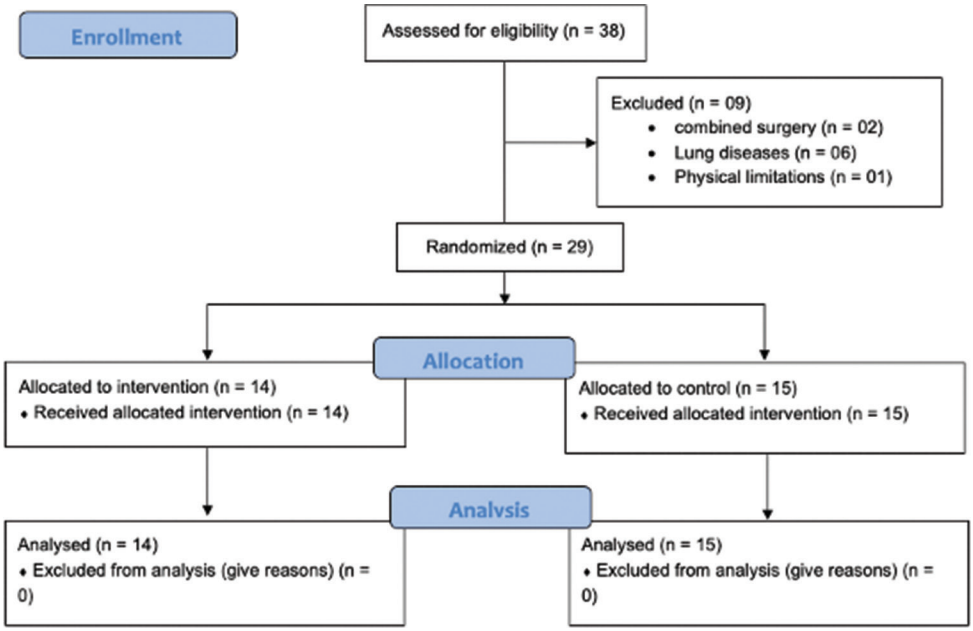


**Figure 1.** Flowchart of patient selection process.

**Table 1.** Clinical and surgical data of patients undergoing coronary artery bypass grafting.

| Variables | IMT (*n*-14) (%) | CG (*n*-15) (%) | *P* |
|---|---|---|---|
| Gender | | | |
| Male | 9 (64) | 9 (60) | 0.31[a] |
| Female | 5 (36) | 6 (40) | |
| Age (years) | 66±3 | 68±4 | 0.65[b] |
| BMI (kg/m$^2$) | 32±2 | 31±3 | 0.42[b] |
| Comorbidities | | | |
| DM | 9 (64) | 9 (60) | 0.32[a] |
| SAH | 10 (71) | 9 (60) | 0.64[a] |
| DLP | 9 (64) | 10 (67) | 0.57[a] |
| Sedentary lifestyle | 11 (79) | 10 (67) | 0.34[a] |
| AMI | 7 (50) | 5 (33) | 0.24[a] |
| MV time (hours) | 6±2 | 7±3 | 0.23[b] |
| CPB time (min) | 96±12 | 92±15 | 0.23[b] |
| Number of grafts | 2.6±0,8 | 2.5±0,6 | 0.65[b] |
| ICU stay (days) | 2±1 | 3±1 | 0.35 |
| Hospital stay (days) | 9±3 | 12±4 | 0.04 |

[a]Chi-square, [b]Independent student's t-test, CPB: Cardiopulmonary bypass, DLP: Dyslipidemia, DM: Diabetes mellitus, SAH: Systemic arterial hypertension, AMI: Acute myocardial infarction, BMI: Body mass index, MV: Mechanical ventilation

**Table 2.** Average of the differences between the groups studied with 95% CI.

| Variables | IMT (*n*-14) | CG (*n*-15) | Difference between groups 95% CI |
|---|---|---|---|
| MIP (cm$H_2O$) | | | |
| Pre-operative | 103±15 | 105±17 | −2 (−14.25–10.25) |
| Discharge | 80±14 | 75±15 | 5 (−6.08–16.08) |
| Δ | 2313 | 30±12 | −7 (−16.52–2.52) |
| MEP (cm$H_2O$) | | | |
| Pre-operative | 82±12 | 85±13 | −1 (−11.40–9.40) |
| Discharge | 60±11 | 56±12 | 4 (−4.79–12.79) |
| Δ | 2211 | 29±11 | −7 (−15.39–1.39) |
| 6MWT | | | |
| Pre-operative | 386±43 | 398±56 | −12 (−50.25–26.25) |
| Discharge | 285±51 | 288±45 | −3 (−39.59–33.59) |
| Δ | 10145 | 110±46 | −9 (−43.71–25.71) |

MEP: Maximum expiratory pressure, MIP: Maximum inspiratory pressure, 6MWT: 6-min walk test; Δ: pre-operative value less hospital discharge

**Table 3.** Comparison between groups related to pulmonary complications.

| Variables | IMT (*n*-14) (%) | CG (*n*-15) (%) | *P*-value[a] |
|---|---|---|---|
| Atelectasis | 2 (14) | 8 (53) | 0.01 |
| Pleural effusion | 7 (50) | 8 (53) | 0.87 |
| Pneumothorax | 1 (7) | 1 (7) | 0.92 |
| Pneumonia | 3 (21) | 6 (43) | 0.02 |
| Reintubation | 0 | 3 (20) | 0.06 |

[a]Chi-square

There was no impact of IMT on ventilatory muscle strength. The previous studies show that this protocol reduces losses, mainly of MIP [1,7]. The lack of significance in the present study may be related to the small sample size, increasing the risk of Type II statistical error. Another factor may be related to the higher metabolic consumption in inflamed patients, with the use of metabolic pathways for energy acquisition and the decreased capacity for muscle hypertrophy [22,23].

Hegazy *et al*. [24], when applying IMT to patients undergoing valve replacement, also showed an increase in pulmonary function, inspiratory muscle strength, and functional capacity. Despite being a different population from that studied in the present study; these results reinforce the benefit of IMT in patients undergoing cardiac procedures.

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A recent meta-analysis showed results like ours. It showed an improvement of 4.8 $cmH_2O$ in the group that performed IMT, in addition to an increase of 78 m in the distance walked in the 6MWT [25]. These data corroborate our study, although we did not perform the analysis involving the subgroup of high-risk patients.

Despite the lack of impact on functional capacity and respiratory muscle force, the IMT group presented reduced length of hospital stay. This result may be related to the decrease in PO pulmonary complications. Gomes-Neto *et al*. [7] and Kendall *et al*. [26] have shown that IMT is effective in reducing pulmonary complications and hospital length of stay.

Reduced hospital stay has been verified in other studies [25,26]. Increased respiratory muscle force is associated with improved coughing ability, reduced accumulation of bronchial secretions, and other pulmonary complications.

Kendall *et al*. [24] state that these positive results are more important in high-risk patients, such as those studied included in this study. Chen *et al*. [27] indicate that IMT performed in the pre-operative period may also contribute to reductions in pulmonary complications and length of hospital stay.

Regarding pulmonary complications, IMT was able to reduce the incidence of atelectasis and pneumonia. With increased muscle strength, patients can take deeper breaths, increasing transpulmonary pressure and, consequently, pulmonary volume [28]. This increase optimizes the ventilation/perfusion ratio and gas exchange, reducing the need for other resources such as non-invasive ventilation.

Pneumonia is a common complication in the PO period of cardiac surgery due to decreased lung capacity, pain, and weakness of the ventilatory muscles. The trained patients had a lower rate of pneumonia, which was associated with an increase in pulmonary volume and, consequently, an improvement in coughing efficiency.

A recent meta-analysis showed that ventilator-associated pneumonia was associated with a worse prognosis in patients undergoing cardiac surgery [29]. Despite the lack of statistical significance, the incidence of reintubation was higher in the control group. With the decreased rate of pneumonia and atelectasis, patients evolved with less respiratory failure and IMT may be protective for this patient profile.

The contribution contained in this study is toward consolidating IMT as a tool to prevent functional capacity, length of stay, and complications in a population that is usually excluded in most studies, patients at high risk of PO complications.

The limitations of the present study are the small cohort size, the failure to stratify lung function into mild, moderate, and severe limitation, and the lack of application of a scale to assess the level of pain.

## 5. Conclusion

Based on the results obtained, IMT was not effective in reducing the loss of functional capacity. There was no impact on respiratory muscle force but the incidence of pulmonary complications and the length of hospital stay decreased.

## Conflict of Interest

The authors declare that there is no conflict of interest.

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