ORIGINAL ARTICLE

Inspiratory and Peripheral Muscle Training in Patients with Heart Failure: Randomized Controlled Trial

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Abstract

Background: Current guidelines recommend incorporating exercise and physical activity, such as inspiratory muscle training (IMT) and neuromuscular training, as adjunctive therapies alongside pharmacological treatments for patients with heart failure (HF).

Objective: To evaluate the effects of IMT and peripheral muscle training (PMT) on respiratory and peripheral muscle strength, lung function, and functional capacity in patients with HF.

Methods: This is a randomized controlled trial. Prior to randomization, all patients were assessed with the 6-minute walk test, inspiratory muscle strength (maximum inspiratory pressure [MIP]), expiratory muscle strength (maximum expiratory pressure [MEP]), vital capacity (VC), peak expiratory flow (PEF), and peripheral muscle strength (using the Medical Research Council [MRC] scale). Participants were then randomly assigned to one of four groups: group 1 (control), group 2 (IMT), group 3 (PMT), or group 4 (IMT + PMT). This study was registered in the Brazilian Registry of Clinical Trials (ReBEC) under number 2.382.698. One-way ANOVA with Bonferroni post-test was used to evaluate the four groups. The paired Student's t test was used to compare the groups at different times. A p value < 0.05 was considered significant.

Results: A total of 52 patients were assessed. Regarding muscle strength, the group that underwent IMT combined with PMT showed a significant increase in both MIP (74 \pm 15 at baseline versus 91 \pm 16 at hospital discharge, p < 0.01) and MEP (92 \pm 19 at baseline versus 102 \pm 18 at hospital discharge, p < 0.01).

Conclusion: Based on these findings, it can be concluded that IMT combined with PMT has a positive impact in patients with HF, including improvements in both peripheral and respiratory muscle strength, reduction in dyspnea and fatigue, and enhanced tolerance to physical exercise.

Keywords: Heart Failure; Breathing Exercises; Muscle Strength.

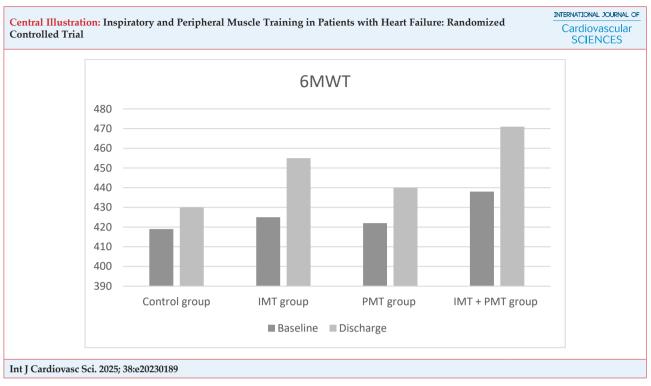
Introduction

Patients with heart failure (HF) report a subjective feeling of tiredness and dyspnea associated with a lack of conditioning of the respiratory and peripheral muscles.¹ Current guidelines suggest incorporating exercise and physical activity as supplementary therapies alongside pharmacological treatment, including inspiratory muscle training (IMT) and neuromuscular approaches.²

For individuals affected by HF, there are several factors that contribute to the impairment of skeletal muscles, such as vascular and metabolic factors and tissue alterations,³ which, in combination, can lead to patient limitations when exercising.⁴ In view of these aspects, it is recommended to limit the intensity of exercise when it is not carried out in hospital environments, thus avoiding possible adverse events.⁵

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IMT: inspiratory muscle therapy; PMT: peripheral muscle training; 6MWT: six-minute walk test.

Inadequate blood perfusion of the cardiovascular system in patients with HF leads to early fatigue of the peripheral and respiratory systems.⁶ These patients fatigue early, since they have metabolic changes and changes in the types of muscle fibers, with type II predominating in their composition, which are more fatigable.7 These factors cause a decrease in strength, contraction speed, and power.8

Based on the above, IMT is an effective cardiac rehabilitation intervention for patients with HF. In the hospital environment, IMT helps patients with HF improve their inspiratory muscle strength. This improvement can help increase walking distance and reduce dyspnea.9

IMT can reduce symptoms such as dyspnea and inspiratory muscle fatigue through its effects on the cardiovascular and respiratory systems. Thus, IMT reduces inspiratory muscle work and attenuates the inspiratory metaboreflex, improving exercise tolerance.¹⁰ It also shows a significant improvement in systemic vasodilation and peripheral muscle perfusion, generating beneficial effects for patients by enhancing ventilatory function and functional capacity.11

There are studies that have shown the effects of IMT in patients with HF, but we did not find any studies in which peripheral muscle training (PMT) was applied alongside IMT; therefore, the aim of this study was to evaluate the effects of IMT and PMT on respiratory and peripheral muscle strength, lung function, and functional capacity in patients with HF.

Methods

Study Design

A randomized clinical trial was conducted with patients with HF at the Instituto Nobre de Cardiologia in Feira de Santana, Bahia, from August to December 2022. This study was registered in the Brazilian Registry of Clinical Trials (ReBEC) under number 2.382.698.

Inclusion and Exclusion Criteria

The following inclusion criteria were used: individuals of both sexes with HF (functional class III and IV according to the New York Heart Association classification) over 18 years of age. Patients were excluded if they had unstable ventricular arrhythmia, peripheral vascular disease, acute respiratory disease, unstable angina, aortic stenosis, current smoking, chronic kidney disease or undergoing hemodialysis, fever and/or infectious disease, malignant neoplasms, or cognitive difficulties; were unable to perform the proposed techniques; or did not agree to sign the consent form.

Ethical Aspects

Our study was submitted to and approved by the Ethics and Research Committee of the Faculdade Nobre de Feira de Santana under protocol number 2.382.698. All participants signed an informed consent form.

Study Protocol

The patients underwent clinical assessment; anthropometric data and clinical history were collected. After assessment and before randomization, all patients underwent the following tests: the six-minute walk test (6MWT),¹² measurement of inspiratory muscle strength (maximum inspiratory pressure [MIP]), measurement of expiratory muscle strength (maximum expiratory pressure [MEP]), vital capacity (VC), peak expiratory flow (PEF), and peripheral muscle strength analysis using the Medical Research Council (MRC) scale. Patients were recruited from August to December 2022, through verbal invitations during their hospital stay.

In addition, before and after the procedures, all patients had the following vital signs assessed: blood pressure, heart rate, respiratory rate, peripheral oxygen saturation, double product, and Borg scale.

Participants were randomly assigned to one of four groups: group 1 (control), group 2 (IMT), group 3 (PMT), or group 4 (IMT + PMT), using a lottery system. In this draw, there were four balls with a piece of paper on each referring to the groups, and a member of the on-call team was asked to choose one of the balls, the result being the patient's allocation group.

Patients in group 1 (control) were managed according to the institution's protocol, which consists of non-invasive ventilation, breathing exercises, kinesiotherapy, and walking. Care was provided three times a day while in the intensive care unit and twice a day while in the open unit. The total duration of the service was 20 to 30 minutes.

Group 2 (IMT) carried out the same activities as the control group with the addition of the IMT protocol, which consisted of undergoing MIP assessment and starting IMT with a linear pressure loading device (PowerBreathe®), at 40% of MIP, performing 3 sets of 10 repetitions.

Group 3 (PMT) performed the same activities as the control group plus dorsiflexion, plantarflexion, inversion, and eversion with a theraband, hip flexion/extension/abduction/adduction with an outstretched leg, and knee flexion/extension using a shin guard. These exercises were performed in 3 sets of 12 repetitions, twice a day. To measure the load, the maximum repetition test (1-repetition maximum) was applied, assessing the patient's physical strength capacity.

Group 4 (IMT + PMT) performed the same activities as the control group and together underwent the IMT tests with the Powerbreathe device (IMT), as well as the PMT, as follows: dorsiflexion, plantarflexion, inversion and eversion with theraband, hip flexion/extension/abduction/adduction with the leg extended, and knee flexion/extension using a shin guard. These exercises were performed in 3 sets of 12 repetitions, twice a day.

All assessments and interventions were carried out by a blind examiner. At the time of hospital discharge, all patients were re-evaluated, and MIP, MEP, VC, PEF, MRC, and 6MWT were assessed.

Measurement

Preoperative assessment of inspiratory muscle strength (MIP) was carried out using an Indumed® (São Paulo, Brazil) analogue manovacuometer. During the evaluation, a maximum exhalation up to the residual volume was requested, followed by a maximum and slow inhalation up to the total lung capacity. This test was carried out using the unidirectional valve method, allowing a flow rate through a 1-millimeter orifice in order to exclude the action of the mouthpiece, and repeated 3 times, using the highest value achieved as long as this value was not the last one.13 Expiratory muscle strength MEP) was assessed using the same device, and the patient was instructed to perform a maximum inspiration until they reached their total lung capacity. The mask was subsequently put on, and a maximum expiration was requested until residual capacity was reached. The test was repeated 3 times, and the result with the highest value was taken into account.13

To assess VC, a face mask was connected to the expiratory branch of the analog respirometer (Ferraris, Mark 8 Wright Respirometer, Louisville, CO, USA), and the patient was instructed on all the phases of the test. The respirometer was unlocked, set to zero, and the face mask was subsequently placed on the subject's face. Participants inhaled deeply until reaching their

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total lung capacity, then exhaled slowly and gradually until reaching their residual volume. After this, the respirometer was stopped, and the result observed and recorded. The test was repeated 3 times, considering the result with the highest value.¹⁴

PEF was assessed using a Mini Wright® peak flow meter (England, UK). During the assessment, patients were seated, with their head in a neutral position and a nose clip to prevent air from escaping through the nostrils. The patient took a deep inhalation, up to full lung capacity, followed by a forced exhalation with the mouth on the device. After 3 measurements, the highest value was chosen, with no difference greater than 40 liters between the measurements.¹⁴

Before the procedures, all the patients were assessed and underwent the 6MWT. To carry out this test, the location should be a 30-meter-long corridor, indoors or outdoors, where there are no people passing by, with markings every 3 meters, with a comfortable temperature, an even and resistant surface, without obstacles, and a cone marking the return point at the end of the route. Patients are instructed to walk at their own pace as far as possible during the 6 minutes. They should receive instruction and clarification regarding any possible cardiorespiratory changes that may arise. They are allowed to walk slowly, stop and rest when necessary, and resume walking when they feel fit. Without talking to the people around them, patients should walk to the cones and turn around them quickly, continuing the walk without hesitation.14

Peripheral muscle strength was assessed using the MRC scale, which is commonly used to measure muscle strength capable of moving the joint; it is low cost and easy to apply.¹⁵ With the patient seated, hip joints in 90° flexion, knees in 60° flexion and the trunk erect, the following joint movements were requested: shoulder abduction, elbow flexion, wrist extension, hip flexion, knee extension, and ankle dorsiflexion. Manual resistance was applied by the examiner during the movements. Each joint movement was scored from 0 to 5, and the scores were added up. The final MRC can vary from 0 (tetraplegia) to 60 (normal muscle strength); patients with scores below 48 are considered to have muscle weakness.

Statistical Analysis

The Statistical Package for Social Sciences (SPSS) version 20.0 was used to analyze the data. Normality

was assessed using the Shapiro-Wilk test. Data were expressed as mean and standard deviation. Categorical variables were presented as absolute and relative frequencies and assessed using the chi-square test. One-way ANOVA with Bonferroni post-test was used to evaluate the four groups. The paired Student's t test was used to compare the groups at different times. A p value < 0.05 was considered significant.

Results

Over the course of the study, 52 patients were assessed, with an average age of 56 ± 5 years and a prevalence of males with 35 participants (67%). In terms of New York Heart Association classification, 37 (71%) of the patients had class III HF. The most common comorbidity was systemic arterial hypertension, which affected 44 (85%) of the patients, and hypertension was the most dominant etiology of HF. The other characteristics are shown in Table 1.

Regarding muscle strength, we observed that the group receiving IMT along with PMT experienced a significant increase in both MIP (74 \pm 15 at baseline versus 91 \pm 16 at hospital discharge, p < 0.01) and MEP (92 \pm 19 at baseline versus 102 \pm 18 at hospital discharge, p < 0.01). With regard to lung function, the groups that underwent IMT, IMT, or IMT with PMT showed an improvement in VC when comparing baseline with discharge (p < 0.01). With regard to peripheral muscle strength, there was no statistically significant difference between any group and the first assessment. However, in terms of distance traveled, we observed that the group undergoing IMT combined with PMT experienced a significant improvement in the 6MWT (Central Illustration).

Discussion

The aim of this study was to analyze the effects of IMT associated with PMT in patients with HF. There was an improvement in respiratory strength, pulmonary function, and peripheral strength, as well as an increase in the distance covered in the 6MWT. However, the group that performed IMT combined with PMT showed a statistically significant improvement.

Currently, the 6MWT can assess the progression of functional loss or the positive effect of therapeutic interventions. ¹⁶ Studies have shown that IMT

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	Control group (n = 13)	IMT group (n = 13)	PMT group (n = 13)	IMT + PMT group (n = 13)	p
Sex					0.8
Male	9 (69%)	8 (62%)	9 (69%)	9 (69%)	
Female	4 (31%)	5 (38%)	4 (31%)	4 (31%)	
Age (years)	56 ± 4	57 ± 5	55 ± 5	56 ± 3	0.7
BMI (kg/m²)	27 ± 2	26 ± 2	26 ± 3	25 ± 2	0.6
NYHA					0.8
Class III	9 (69%)	10 (77%)	8 (62%)	10 (77%)	
Class IV	4 (31%)	3 (23%)	5 (38%)	3 (23%)	
LVEF (%)	25 ± 1	26 ± 2	25 ± 2	24 ± 3	0.6
Comorbidities					
Atrial fibrillation	3 (23%)	4 (31%)	3 (23%)	3 (23%)	0.7
SAH	11 (85%)	12 (92%)	10 (77%)	11 (85%)	0.8
CAD	4 (31%)	4 (31%)	5 (38%)	4 (31%)	0.7
DM	3 (23%)	4 (31%)	4 (31%)	5 (38%)	0.8
Previous smoking	2 (15%)	3 (23%)	2 (15%)	2 (15%)	0.8
Previous AMI	3 (23%)	3 (23%)	4 (31%)	4 (31%)	0.7
Etiology Ischemic	3 (23%)	3 (23%)	4 (31%)	4 (31%)	0.8
Hypertensive	7 (54%)	7 (54%)	6 (46%)	7 (54%)	0.8
Idiopathic	2 (15%)	2 (15%)	3 (23%)	1 (8%)	0.6
Chagas disease	1 (8%)	1 (8%)	0	1 (8%)	0.9
Drugs					
Furosemide	11 (85%)	12 (92%)	10 (77%)	11 (85%)	0.7
Spironolactone	10 (77%)	11 (85%)	9 (69%)	10 (77%)	0.7

ACE inhibitor/	9	9	7	8	0.81
ARB	(69%)	(69%)	(54%)	(62%)	
β-blocker	10 (77%)	10 (77%)	7 (54%)	9 (69%)	0.73

ACE: angiotensin converting enzyme; AMI: acute myocardial infarction; ARB: angiotensin receptor blocker; BMI: body mass index; CAD: coronary artery disease; DM: diabetes mellitus; IMT: inspiratory muscle therapy; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; PMT: peripheral muscle training; SAH: systemic arterial hypertension. Values are presented as mean ± standard deviation.

attenuates the metaboreflex,¹⁷ which can limit exercise performance, especially in patients with HF and inspiratory muscle weakness.¹⁸ We found that IMT and PMT improved inspiratory muscle strength. The increased load on these muscles generates this increase in strength, optimizing greater vascularization in the lower limbs and, consequently, functional capacity.

IMT is known to contribute to better exercise tolerance and positive cardiorespiratory responses in patients with HF.⁷ Therefore, inspiratory muscle conditioning is beneficial for patients with HF, attenuating the inspiratory metaboreflex.¹⁷

The group that performed IMT combined with PMT showed significant results compared to the control group. IMT with an emphasis on MIP in patients with HF reduces the loss of respiratory muscle strength¹⁹ and reduces dyspnea when performing physical exercise.¹⁰

In patients with muscle weakness, the most frequent change in pulmonary volume is a reduction in VC.²⁰ At the end of the protocol, there was a more marked increase in VC in the IMT + PMT group. In this context, the use of IMT helps to gain resistance in the inspiratory muscles, since patients with HF are predisposed to respiratory muscle weakness.¹

In relation to peripheral muscle strength, PMT increases muscle strength and the metabolism of creatine phosphate, which is a considerable energy store in the muscle. It also improves cardiovascular conditioning, corroborating an improvement in exercise tolerance and a reduced sensation of dyspnea.²¹ In this study, it is clear that the patients who underwent PMT and IMT + PMT had greater benefits, showing an improvement in quality of life when compared to the control group.

Table 2 - Data related to respiratory muscle strength, pulmonary function, and peripheral muscle strength

		Control group (n = 13)		IMT group (n = 13)		PMT group (n = 13)		IMT + PMT group (n = 13)	
	Baseline	Discharge	Baseline	Discharge	Baseline	Discharge	Baseline	Discharge	
Respiratory strength									
MIP (cmH ₂ O)	75 ± 15	74 ± 16	73 ± 14	81 ± 15	75 ± 13	78 ± 15	74 ± 15	91 ± 16*§	
MEP (cmH ₂ O)	90 ± 19	86 ± 15	92 ± 17	97 ± 15	94 ± 20	99 ± 17	92 ± 19	$102 \pm 18^{\S}$	
Pulmonary function									
VC (ml/kg)	45 ± 9	45 ± 6	47 ± 8	58 ± 9*§	43 ± 5	52 ± 8*§	45 ± 7	59 ± 5*§	
PEF (l/min)	423 ± 69	420 ± 71	432 ± 77	450 ± 69	429 ± 57	443 ± 71	430 ± 71	456 ± 67	
Peripheral strength									
MRC scale	50 ± 3	51 ± 3	49 ± 4	52 ± 3	50 ± 3	55 ± 1	50 ± 4	55 ± 3	
Distance covered									
6MWT (meters)	419 ± 51	430 ± 42	425 ± 43	455 ± 39	422 ± 44	440 ± 39	438 ± 47	471 ± 51*§	

IMT: inspiratory muscle therapy; MEP: maximum expiratory pressure; MIP: maximum inspiratory pressure; MRC: Medical Research Council; PEF: peak expiratory flow; PMT: peripheral muscle training; 6MWT: six-minute walk test; VC: vital capacity. *p < 0.05 versus baseline; § p < 0.05 versus control at the same time point.

In terms of PEF, the results showed that the protocols combining IMT and PMT were significant, perhaps due to IMT, which helps patients gain muscle strength and improve respiratory biomechanics.²² In the control group, PEF decreased, since the disuse of these muscles causes a decrease in quality of life and respiratory muscle strength.

In this study, an important limitation was the absence of a scale to assess patients' pain levels when carrying out the protocols. The scale is used to measure a patient's pain threshold during treatment and therapeutic interventions, helping to manage this individual for better adherence and treatment comfort.

Conclusion

Based on the above, it can be concluded that combining IMT with PMT positively impacts patients with HF. This includes improvements in peripheral and respiratory muscle strength, reductions in dyspnea and fatigue, and better physical exercise tolerance.

Author Contributions

Conception and design of the research and writing of the manuscript: Cordeiro ALL, Jesus FAS, Santos JC,

Nogueira VM; acquisition of data: Cordeiro ALL, Jesus FAS, Santos JC; analysis and interpretation of the data and statistical analysis: Cordeiro ALL.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

Sources of Funding

There were no external funding sources for this study.

Study Association

This study is not associated with any thesis or dissertation work.

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of the Centro Universitário Nobre under the protocol number 2.382.698. All the procedures in this study were in accordance with the 1975 Helsinki Declaration, updated in 2013. Informed consent was obtained from all participants included in the study.

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