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Effects of two different inspiratory muscle training devices on respiratory muscle strength, cardiopulmonary functional capacity, and quality of life of COPD patients

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ABSTRACT

Background: Inspiratory muscle weakness is one of the complications of chronic obstructive pulmonary disease (COPD). This condition has been minimized by inspiratory muscle training (IMT). Still, different IMT devices need to be compared to identify the best option. **Objective:** To evaluate the effects of two IMT devices on respiratory muscle strength, cardiorespiratory functional capacity, and life quality of COPD patients. **Method:** Before and after the IMT protocol, 17 patients were submitted to manovacuometry, six-minute walk test (6MWT), and questionnaire from the Saint George Hospital in Respiratory Disease (SGRQ) for inspiratory muscle strength, cardiorespiratory functional capacity, and life quality assessments, respectively. Afterwards, they were divided into two groups to perform IMT for four weeks, one by Threshold® IMT (IMTG) and the other by POWERbreathe® Classic (PG). **Results:** Maximal inspiratory pressure increased significantly from -62.00±16.03 to -75.55±22.84 cmH_2O in IMTG, and from -56.00±22.01 to -71.25±27.67 cmH_2O in PG. The distance covered in the 6MWT clinically increased with both IMTG and PG. The SGRQ answers showed improvements in all domains evaluated for both groups. However, the intergroup results showed no statistically significant differences. **Conclusion:** Both IMT devices increased inspiratory muscle strength, improved life quality, and optimized cardiorespiratory functionality in COPD patients. None was superior to the other for the analyzed parameters.

Keywords: COPD; muscle strength; respiratory muscles; training; cardiopulmonary functional capacity; quality of life.

BACKGROUND

Chronic obstructive pulmonary disease (COPD) is a preventable and treatable respiratory disease, known for its progressive and not fully reversible airflow limitation, usually caused by inhalation of harmful particles or gases[(1)]. COPD patients have changes in lung function which can lead to skeletal muscle dysfunction that is characterized mainly by weakness of both the peripheral and respiratory muscles[(2)]. This phenomenon leads to increases in dyspnea, less tolerance to exercise, limitations in activities of daily living and, thus, decreasing quality of life (QOL)[(2,3)].

In order to minimize such losses, inspiratory muscle training (IMT) can be performed[(4)]. IMT has shown benefits when used both in isolation and associated with peripheral muscle training (PMT)[(5)].

There are different types of equipment which may be used for IMT. Among them, there are two that stand out and use similar spring systems, the Threshold® IMT and the POWERbreathe Classic®. For both devices, the patient has a mouthpiece adjusted and is instructed to inhale by overcoming the resistance of a linear pressure load, which has been previously adjusted[(6,7)].

There seems to be a consensus on the need to assess respiratory muscle strength and its training in COPD patients and to verify the effects of this training on cardiopulmonary functional capacity and QOL[(8)]. Nonetheless, considering that there is more than one device used to perform the IMT, the assessment of their outcome in COPD patients is yet to be found in the literature. Therefore, this study aimed to evaluate the effects of two different inspiratory muscle training devices on respiratory muscle strength, cardiopulmonary functional capacity, and quality of life of COPD patients.

The hypothesis is that the Threshold® IMT and POWERbreathe Classic® have similar outcomes in COPD patients. As these devices have the same operating mechanism for training respiratory muscles, both may increase respiratory muscle strength, improving the cardiopulmonary functional capacity and, consequently, the quality of life of subjects with COPD.

METHODS

Study design

This is a prospective, quantitative, exploratory, field, non-randomized clinical trial. This study was approved by the Biosciences Institute Research Ethics Committee at Unesp Rio Claro under protocol number nº 2,894,657 and by ReBEC under number RBR-8d755f.

All participants were duly informed about the nature of the research and signed an Informed Consent Form.

Participants

The sample consisted of 17 individuals of both sexes from the city of Rio Claro (São Paulo, Brazil). All were referred from a pulmonology outpatient clinic and had a previous clinical and functional diagnosis of COPD.

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The inclusion criteria for this trial were patients who had been diagnosed with COPD according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD); were over 50 years of age; had been clinically stable for the previous four weeks; had no exacerbation of the disease; and were non-smokers for at least six months. Users of controlled substances did not stop it or change the dosage during the training program.

The non-inclusion criteria were patients who had a history of hospitalization in the four weeks before the start of training; were clinically unstable; had been diagnosed with neuropathies or orthopedic, rheumatological, or cardiac diseases that prevented the performance of any of the proposed activities; were mentally ill; were deaf; had total loss of vision; had participated in any pulmonary rehabilitation program; or did not accept to participate in the trial for any reason.

Individuals who were unable to perform all the proposed tests; did not attend at least 85% of the training sessions; had an exacerbation of the disease during the training program; and needed hospitalization for any reason were excluded from the sample.

Evaluations

First, individuals completed an evaluation form to characterize the sample. It included information regarding personal data, personal and family history, associated diseases, physical activity, and use of medications. Subsequently, they responded to the Saint George's Respiratory Questionnaire (SGRQ), validated for the Brazilian population, to assess their quality of life.

This questionnaire comprises three domains that assess how the disease interferes with the individual's life, namely symptoms, activity, and psychosocial impact. Each domain has a maximum score. The sum of the points is then referred to as a percentage. Values above 10% reflect an altered QOL in that domain. Changes equal to or greater than 4% after an intervention indicate a significant change in QOL[9].

The subjects' weight (kg) and height (cm) were measured using an anthropometric scale (Welmy®) and a stadiometer, respectively. Their body mass index (BMI) was then calculated using the formula mass (kg)/height (cm^2)[10].

Participants underwent spirometry to confirm the presence and degree of airway obstruction. Spirometry was performed using a Spirobank G MIR® portable digital spirometer, following the standards of the American Thoracic Society[11] and the Guidelines for Pulmonary Function Testing[12]. At least three tests of forced vital capacity (FVC), reproducible and acceptable, were performed. From these results (in liters and percentage of predicted), the forced expiratory volume in one second (FEV_1), the forced vital capacity, and the FEV_1/FVC[13] ratio were assessed.

On the second day of evaluation, respiratory muscle strength was measured using an analog manovacuometer (GLOBALMED® M120), graduated in cmH_2O, connected to a mouthpiece adapted with a 4-mm orifice. For the maneuver, the individual remained seated with an adapted nasal clip. The measurement of the maximum inspiratory pressure (MIP) was performed after a maximum inspiratory effort from the residual volume (RV). To determine the maximum expiratory pressure (MEP), the individuals produced a maximum expiratory effort from the total lung capacity (TLC)[14]. The normal values for manovacuometry were determined by the equations proposed by Neder et al.[15] and compared with real values. At least three maneuvers were performed, and the highest value was recorded, as long as it did not exceed 10% of the second-highest value. If it did, a new maneuver was performed, with a maximum of four maneuvers. Respiratory muscle strength was the main variable analyzed in the participants.

After at least 30 minutes, or once the individual felt comfortable, the six-minute walk test (6MWT) was performed to assess cardiopulmonary functional capacity. The test was carried out in a 30-meter unimpeded walkway, marked at every three meters and with cones placed at either end of the 30-meter stretch. Patients were instructed to walk the longest distance for six minutes, as quickly as possible, being allowed to stop or slow down if they thought necessary. A standardized verbal command was given every minute by the evaluator[16]. At the end of the test, the total distance was recorded and compared with the values predicted for the Brazilian population[17]. The test could be interrupted if the individual reported chest pain, severe dyspnea, fatigue, and exhaustion, or if requested[16]. If the individual increased the distance by 25 meters after the intervention, it was considered a significant clinical difference[18].

Before and after the 6MWT, individuals' vital signs were evaluated. Heart rate (HR) and peripheral oxygen saturation (SpO2) were assessed using a pulse oximeter (RISINGMED®). Systolic blood pressure (SBP) and diastolic blood pressure (DBP) were measured using an aneroid sphygmomanometer (PREMIUM®) and a stethoscope (LITTMANN® Classic III). The perception of dyspnea was assessed using a modified Borg scale[19].

Individuals were assigned to training groups, as they completed the tests. Odd-numbered individuals were part of the group that trained inspiratory muscles

using the Threshold® IMT, called IMTG. Even-numbered individuals were placed in the group that performed IMT using the POWERbreathe Classic®, called PG.

Inspiratory Muscle Training

The inspiratory muscle training was done using the Threshold® IMT and POWERbreathe Classic® devices.

The training was always carried out at the same location and period of the day, in a ventilated room. Before starting each session, the individual was comfortably seated in a chair, and the following parameters were evaluated: HR, SpO2, SBP, DBP, and Borg. After clinical stability was assessed, subjects rested for at least five minutes and, as soon as they reported feeling comfortable, the session started. Individuals remained seated at all times, wearing an adjusted nose clip and mouthpiece. They were instructed to breathe deeply and slowly against an inspiratory load which had been adjusted by the evaluator. Participants were also told to keep their shoulders and legs relaxed during the exercises. These procedures were adopted for both groups.

The training was developed based on the recommendations of the meta-analysis done by Gosselink et al.[20]. They demonstrated that COPD patients adapt well to a respiratory muscle training with a 30% MIP initial load. Both groups attended 12 sessions, 3 per week, with a 10% increase in the load each week. Exercises were performed in seven one-minute training sessions interspersed with one-minute recovery intervals.

After the end of the training, subjects were evaluated again using a manovacuometer, the 6MWT, and the SGRQ.

Statistical analysis

The general characteristics of the categorical variables are presented in absolute frequency and percentage, while the continuous variables, in mean ± standard deviation and median (interquartile range). The normality of the data was verified with the Kolmogorov-Smirnov test.

In order to compare the characteristics of the groups, the t test was used for independent samples of continuous variables and the χ^2 test was used to compare categorical variables.

For comparing the predicted, pre-and post-training intragroup data of the variables with normal distribution, the ANOVA test was used. Regarding the non-normal distribution variables, the data was analyzed using the Friedman test along with the Tukey post-test.

To compare the pre-and post-training between-groups data of variables with normal distribution, the ANOVA test was used and, of variables with non-normal distribution, the Kruskal Wallis test was used with the Tukey post-test.

A significance level of 5% was adopted. The analyses were performed using statistical software SigmaSTAT®. The G-Power software was used to determine the sample power, considering the difference between the means, p-value, and sample size.

RESULTS

Thirty-five patients were referred for the trial, of which 12 were not included (eight for not accepting to participate, three for reporting mobility difficulties, and one for undergoing pulmonary rehabilitation). Twenty-three subjects underwent spirometric evaluation, of which three were excluded (one for not presenting compatible spirometry with obstructive disease and two for being unable to complete the test). Each experimental group was initially composed of ten participants. Nine and eight individuals completed the program in the IMTG and the PG groups, respectively.

All individuals who participated in the trial did not present any complications during the program. In both groups, patients showed tolerance to the loads increased weekly. Of the 17 individuals who participated in the trial, all had a previous clinical and functional diagnosis of COPD. The characteristics of the sample according to the groups are shown in Table 1. There was no significant difference when comparing the characteristics of the IMTG and PG.

Maximal inspiratory pressure (MIP) increased significantly after the training program in both groups, IMTG and PG. Before training, MIP values were lower than those predicted for both groups (Figure 1). The sample power for MIP, the main variable in this study, was 85% for the IMTG and 74% for the PG. When comparing the values between groups, no significant difference was found. The maximum expiratory pressure (MEP) values were below predicted for both groups; however, a significant difference was seen only in the PG. After the IMT, there was no significant increase in the MEP of either group.

As for the distance walked in the six-minute walk test (D6MWT), the patients had significantly lower values pre-training than those predicted. After the IMT, a clinical increase was seen in the D6MWT values in both groups (Table 2). When comparing between-groups values, no significant difference was found.

Table 1. Characteristics of the sample.

Variables	IMTG n= 9	PG n= 8	p-value
Age (years)#	67.11±9.5	65.62±9.11	0.748
Sex n (%)&			
Female	2 (22.2)	2 (25)	0.89
Male	7 (77.7)	6 (75)	
BMI n (%)&	26.8±3.53	28.5±6.91	0.73
Associated diseases n (%)&			
SAH	5 (55.5)	5 (62.5)	0.77
DM	2 (22.2)	1 (12.5)	0.60
Physical activity n (%)&			
Yes	2 (22.2)	0	0.16
No	7 (77.7)	8 (100)	
Tobacco use n (%)&			
Former smoker	7 (77.7)	7 (87.5)	0.60
No	2 (22.2)	1(12.5)	
Spirometry#			
FVC (L)	2.85±1.22	3.01±0.99	0.767
FVC (%)	85.42±31.67	102.02±22.85	0.238
FEV_1 (L)	1.39±0.57	1.73±0.47	0.207
FEV_1 (%)	47.6±13.03	58.86±13.51	0.065
FEV_1/FVC (%)	58±10.55	60±7.81	0.667
Severity of the disease n (%)&			
Moderate (Grade II)	4 (44.4)	6 (75)	
Severe (Grade III)	4 (44.4)	2 (25)	0.365
Very severe (Grade IV)	1 (11.1)	0	
Time since diagnosis (years)#	10.55±5.27	8.50±6.39	0.479

***Note:** BMI (body mass index); SAH (systemic arterial hypertension); DM (diabetes mellitus); FVC (forced vital capacity); FEV_1 (forced expiratory volume in one second); FEV_1/FVC (ratio between forced expiratory volume in one second and forced vital capacity); L (liters); n (sample number); # (t test); & (Chi-square test).

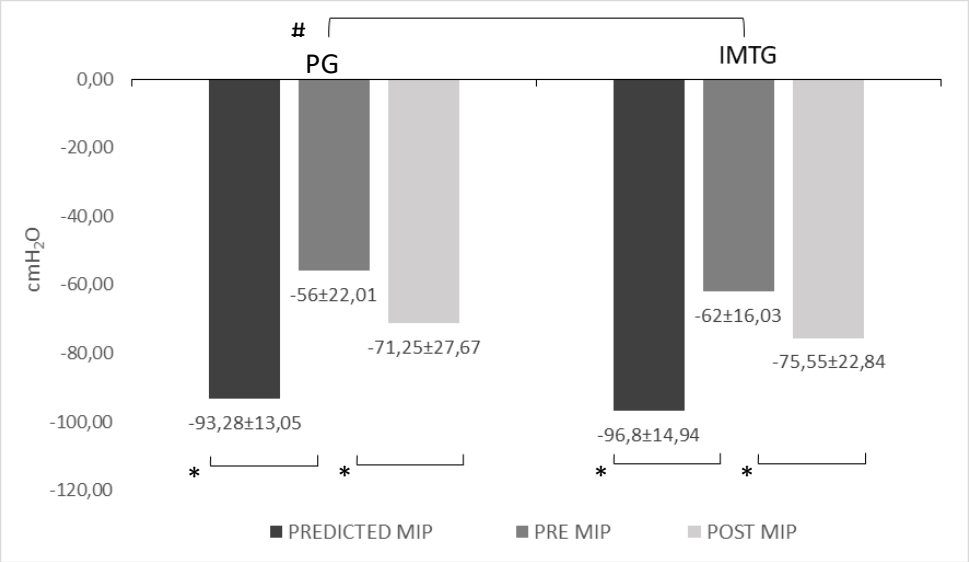

Figure 1. Values of the maximum inspiratory pressure (MIP) predicted, pre-and post-inspiratory muscle training for the PG (IMT using the POWERbreathe Classic®) and IMTG (IMT using the Threshold® IMT) groups. *p < 0.05; #p > 0.05.

As for the distance walked in the six-minute walk test (D6MWT), the patients had significantly lower values pre-training than those predicted. After the IMT, a clinical increase was seen in the D6MWT values in both groups (Table 2). When comparing between-groups values, no significant difference was found.

Table 2. Results of the distance walked in the 6MWT regarding the predicted, pre-and post-inspiratory muscle training values.

Variable (m)	IMTG	PG
Predicted D6MWT	546.40±40.05	543.29 (513.54-567.66)
Pre D6MWT	404.22±139.58 *	408.75 (360.75-514.00) *
Post D6MWT	437.77±137.30	439.50 (406.50-540.00)

***Note:** D6MWT (distance walked in the six-minute walk test); m (meters); IMTG (inspiratory muscle training group using the Threshold® IMT); PG (inspiratory muscle training group using the POWERbreathe Classic®). *p < 0.05 (significant difference between the pre-training and predicted values).

Concerning the data obtained from the hemodynamic evaluation of patients in the IMTG for the 6MWT before and after the IMT, there was a significant difference only for the Borg variable. This had a lower final value after the IMT program when compared to the value found pre-training (Borg value decreased from 4.27 ± 2.94 to 2.05 ± 2.24). Regarding the hemodynamic data of the patients in the PG for the 6MWT before and after the IMT, there was no significant difference found for any of the hemodynamic variables. When comparing both groups, no significant difference was seen.

Considering the result of the SGRQ, which demonstrates the patients' QOL, there was a significant difference in the domains activity, psychosocial impact, and total in both groups, showing significant improvement after IMT. Nonetheless, when comparing the between-groups results, there was no significant difference.

DISCUSSION

The present study showed that IMT promotes an increase in the inspiratory muscle strength and cardiopulmonary functional capacity of COPD patients, as well as an improvement in their QOL with the use of both Threshold® IMT and POWERbreathe Classic®.

Although there are different loads prescribed in the literature, which makes it difficult to determine the best dose-response relationship, in this study, a 30% MIP initial load was used because it has already been shown that COPD patients adapt well to it[20].

The proposed IMT proved to be beneficial in improving inspiratory muscle strength in the patients from both sample groups. These results are similar to those found by Cutrim et al., who used a similar IMT program in COPD patients with an initial load of 30% MIP. The authors reported a significant increase in MIP when compared to a control group[21]. Another study[22] also demonstrated a significant increase in inspiratory muscle strength after implementing an IMT program with an initial load of 30% MIP. This research associated IMT with peripheral muscle training and, when comparing to the patients who underwent only PMT, they demonstrated that IMT must be considered in order to achieve increased inspiratory muscle strength.

Even though the PG had a greater variation in MIP before and after IMT, it was not significant when compared to the IMTG. However, part of this increase may be because the latter had greater muscle strength than the former. Patients with muscle strength less than 60cmH2O usually get a better response to a muscle training program, which happened in the PG group[20, 23].

The present study also found an increase in the distance walked in the 6MWT (D6MWT), which entails an improvement in cardiopulmonary functional capacity. It is known that IMT may help improve functional capacity, as this type of training leads to structural adaptations in the respiratory muscles and to physiological changes that make the COPD patient more resistant to intense physical activities[21,24]. However, a consensus cannot be found in the literature regarding the effect of IMT on cardiopulmonary functional capacity assessed by the 6MWT. Similar to the results found in this trial, some studies observed a non-statistically significant increase in functional capacity[25,26], but there is also a study that showed a significant increase after longer periods of IMT using the POWERbreathe Classic®[27]. This may be explained by differences in the protocols used.

Although there was not a statistical increase in the distance walked in both sample groups, there was a clinical increase, that is, greater than 25 meters[18]. For the IMTG, the increase was on average 33 meters, while for the PG it was 32 meters.

Regarding the hemodynamic values after the 6MWT, the present study found that the patients presented an increase in the D6MWT maintaining only the physiological responses to effort. Similar data were observed in another study, in which, after eight weeks of IMT, there was an increase in the 6MWT, but without significant hemodynamic changes[28].

As for the Borg scale, there was a significant difference only for the IMTG after the IMT. As for the PG, its value was already lower than that of the IMTG. According to some authors, the value of the Borg scale declines after IMT; however, oftentimes without statistically significant changes[29].

Considering the results of the SGRQ, improvement could be observed in all domains. It is known that changes equal to or greater than 4% in one of the domains or in their sum, which were seen in this study, represent a significant response to the intervention, demonstrating an improvement in the patients' QOL[9]. A study that used IMT alone and associated with PMT demonstrated that the total score of the SGRQ showed improvement in both groups, but greater improvement was seen in the one that did both trainings[21]. This may be because the patient's QOL depends not only on respiratory muscles but also on performing activities that require peripheral muscles.

The findings in this study showed that both devices have similar results in COPD patients. Still, it is worth mentioning that the Powerbreathe Classic® allows higher loads in comparison to the Threshold IMT®, in addition to having a stronger spring, having an anatomical mouthpiece, and being easier to sanitize.
This study also demonstrated that the proposed training program can be used safely and is viable for this population.

Despite the findings, this study was conducted with a small sample. This is because the participation of this population in trials is difficult, as these patients often have an exacerbated condition, are hospitalized, and have physical limitations that prevent the execution of the proposed training and tests, factors which also makes it difficult to carry out a randomized study. Therefore, further studies should be carried out in a randomized way and with increased time of follow-up and training to determine if the changes found in this study are the same in the long term for both devices.

CONCLUSION

In conclusion, IMT significantly increases inspiratory muscle strength and quality of life and clinically improves cardiopulmonary functional capacity. Furthermore, the devices were found to be similar, as their results were very much alike. Therefore, both seem to be viable resources to be used when designing an IMT program for COPD patients.

Authors' contribution: KCSO and ARPA contributed to the elaboration of the design of the study; KCSO, MNB, ARPA development of the study and data acquisition. KCSO, MNB, ARPA contributed to article design and data tabulation KCSO, MNB, ARPA contributed to the critical review, correction and approval of the final version.

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