Effects of a muscular training program on chronic obstructive pulmonary disease patients with moderate or severe exacerbation antecedents

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Abstract

Background: Muscular training is the corner stone of pulmonary rehabilitation programs.

Aim: To evaluate the effects of a muscular training program - carried out on chronic obstructive pulmonary disease (COPD) subjects with antecedents of moderate or severe exacerbation - on exercise tolerance, Health Related Quality of Life (HRQoL) and illness prognosis.

Design: A quasi-experimental study.

Setting: University Hospital.

Population: Twenty-five subjects with COPD (Global Initiative for Chronic Obstructive Lung Disease (GOLD) degrees II, III and IV); with moderate or severe exacerbations and functional deterioration due to respiratory disability; with commitment and capacity to participate in the program. Subjects were selected by consecutive sampling.

Methods: Subjects underwent 20 muscular training sessions consisting of 30 minutes of inspiratory muscle training, 15 minutes of warm-up protocol of upper limb exercises, 30 minutes of muscle training in ergometric cycle, 5 minutes of stretching protocol of lower limbs plus illness awareness. The main outcome measures were six minute walking test (6MWT), specific HRQoL questionnaires (St. Georges Respiratory Questionnaire (SGRQ), Chronic Respiratory Disease Questionnaire (CRDQ) and Airways Questionnaire 20 (AQ20)) and the BODE Index.

Results: All subjects improved significantly (P<0.001) their HRQoL in the SGRQ, the CRDQ and the AQ20, and this was demonstrated in each one of the evaluated dimensions. A positive response in relation to exercise tolerance and illness prognosis was observed. Following the program subjects walked an average of 56 meters more (P<0.001) and the BODE index was a mean of 1.5 less regarding the initial value (P<0.001).

Conclusions: A 20-session muscular training program contributes to an improvement in HRQoL, exercise tolerance and illness prognosis in COPD subjects with moderate or severe exacerbations.

Clinical rehabilitation impact: The intervention program could be easily implemented since it needs a minimum of human and technological resources.

Key words: Pulmonary disease, chronic obstructive, Exercise tolerance, Quality of life, Prognosis.

Chronic obstructive pulmonary disease (COPD) affects more than 52 million people worldwide and caused more than 2.74 million deaths in the year 2000. In developed countries it is the fourth cause of death after cancer, cardiovascular and cerebrovascular illnesses. In fact, it is the only cause of death that is currently increasing. It is estimated that it will become the third cause of death in the near future. COPD is responsible for 10% of pulmonology consultations, 7% of all hospital admissions and 35% of permanent invalidities. Consequently, it has a high sanitary and socio-economic impact.

The epidemiological study EPI-SCAN, developed between May 2006 and July 2007, established COPD prevalence in Spain, accordingly to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria, as 10,2% (CI 95% 9.2-11.1) of individuals between 40 and 80 years of age^{.1}

Although COPD primarily affects the pulmonary system, it also has important systemic consequences,² such as muscular dysfunction and muscular fatigue ³ that lead to patients having to adopt a sedentary lifestyle with significant inactivity and deterioration in their physical state.⁴ As a consequence, effort intolerance appears and undermines patient's health related quality of life (HRQoL) and has a negative impact on health resources and the survival of patients.³ This situation is even more acute in COPD patients with frequent exacerbations who need repeated hospital admissions and has a substantial negative impact on the wellbeing, prognosis and exercise capacity of patients.⁵⁻⁷

Recent studies have shown that pulmonary rehabilitation programs carried out on COPD patients after hospital admission diminish dyspnea perception, improve effort tolerance and ameliorate peripheral muscle dysfunctions. In addition, these programs improve patient recovery from an exacerbation decreasing the negative impact on their functional capacity, reducing hospital readmissions and shortening the length of the hospital stay.^{3,6-10}

The effectiveness of pulmonary rehabilitation programs on COPD patients with exacerbation is demonstrated to have a level 2++ of evidence and a B degree of recommendation.¹¹ Muscular training is the corner stone of pulmonary rehabilitation programs.¹² Some authors ^{6,7} agree in the need to deepen our understanding of the effects that the principles of muscular training produce in the outpatient after a COPD exacerbation and to accurately determine the measures to be followed in the training protocols.

The aim of our study was to evaluate the effects of a muscular training program - carried out on COPD patients with antecedents of moderate or severe exacerbation- on exercise tolerance, HRQoL and illness prognosis.

Materials and methods

A quasi-experimental study was undertaken Eligible participants were patients with a diagnostic of COPD degree II, III and IV defined by the GOLD; with moderate or severe exacerbations and functional deterioration due to respiratory disability; with motivation and commitment to participate in the program and the capacity to understand its purpose and content. The exclusion criteria described subjects with either a lack of motivation, significant cognitive deterioration, instability in their medical condition that could present risks for the subject (unstable angina, uncompensated cardiac insufficiency or other comorbidities), severe hypoxemia that does not correct with oxygen administration or the inability to participate in the exercise program by arthritis or another limiting condition. The COPD diagnosis was based on the existence of a smoking history (active or previous) of at least 20 packets a year, together with the presence of a not entirely reversible airway obstruction, defined as a quotient between FEV1 and the forced vital capacity (FVC) minor of 70% after bronchodilation.

The COPD exacerbation was defined as all sustained increase of the subject respiratory symptoms with regard to the basal situation that requires a modification in the usual medication and generates the need for medical care.¹³ An exacerbation was considered as moderate when the presence of episodes of aggravation leads to hospital emergency consultation. It was defined as severe in those cases that needed hospital admission in the year previous to the study.

Each participant gave their consent before the intervention commenced. The study was conducted in accordance with the Ethical Principles for Medical Research Involving Human Subjects and was approved by the Ethics Committee of the University of A Coruña.

Study setting

This study took place at the University Hospital of A Coruña, Spain, from October 2009 to May 2012.

Intervention

Patients performed 20 individual 1 – hour muscular training sessions, three times a week. Training sessions were divided, by order, into:

— an inspiratory muscle training protocol using a pressure threshold breathing device (Threshold IMT© Philips Respironic, Murrysville, p Murrysville, PAa, USA). The pressure load was established between 30-60% of the maximal inspiratory pressure (MIP). The training started with the minimum established load, increasing weekly according to patient tolerance until achieve the 60% of the initial MIP. Subjects trained for 30 minutes (15 minutes under professional supervision and 15 minutes at home without supervision). The diaphragmatic pattern with deep inhalations and a respiratory rate of 15 to 20 was used.

— A 15 minute warm-up protocol of upper limb exercises. Active exercises of shoulder and pelvic girdle were included.

— A 30-minute muscle training of lower limbs, through an ergometric cycle, in an interval modality.²¹ The work load was established at 75% of the maximum capacity of work (achieved in a submaximal incremental effort test) for one minute and at 40% during the four minutes recovery time. The control of dyspnea perception was established according to a Borg score of 4 to 6.^{8, 22, 23} A 5-minute stretching protocol of the lower limbs was applied.

There were a daily control of vital signs and dyspnea subjective perception and lower limbs fatigue through the Borg Scale ¹⁴ applied at the baseline, during and at the end of the training.

Subjects with oxygen saturation < 90% before or during the exercise were supplied with supplementary oxygen. The training was conducted with subjects following their routine pharmacological regimens, especially involving the use of bronchodilators. The session was suspended if signs of obstruction or bronchospam appear, although the subject could continue to follow the program.

In the week previous to the commencement of the program, health education sessions to describe the illness and recommendations to manage it were delivered. Subjects were instructed in breathing exercises and bronchial hygiene exercises to be done daily at home.

In each session, the importance of following the exercise protocol at home was emphasized. This involved inspiratory muscle training using the Threshold IMT© (15 or 30 minutes depending on whether the patient attended the program at hospital or not). In addition to the warmup exercises, a minimum of 30 minutes walk on level ground and bronchial hygiene exercises had to be done.

Outcomes

Participants were assessed before and after the training. Assessments were performed at the same time, under the same conditions by the same examiner. The main outcomes were exercise tolerance, HRQoL and Illness prognosis.

Exercise tolerance was measured through the standardised six-minute walk test (6MWT) complying with international recommendations.¹⁵

HRQoL was assessed using validated Spanish versions of three specific questionnaires for respiratory disorders: the St. Georges Respiratory Questionnaire (SGRQ), the Chronic Respiratory Disease Questionnaire (CRDQ) and the Airways Questionnaire (AQ20). The SGRQ¹⁶ has three components (subscales) that evaluate symptoms, activity and impact of the illness. Scores range from 0 to 100 with higher scores indicating more limitations and a poorer quality of life. A mean change score of 4 units¹⁷ is considered clinically significant. The CRDQ¹⁸ total score ranges from 20 to 140 points. This questionnaire evaluates 4 dimensions (dyspnea, fatigue, emotional function and illness control). Items are scored from 1 (most severe) to 7 (no impairment). A change in the score >0.5 on the 7 point scale is considered clinically significant. Finally, the AQ20¹⁹ consists of 20 questions with 3 answer options: "yes", "no" or "not applicable"; the maximum score is 20 (the poorest quality of life).

The illness prognosis was evaluated through the BODE Index,²⁰ following the recommendation of the "Strategy in COPD of the National Health System" document published by the Ministry of Health and Social Politics of Spain (2009) (http://www.msssi.gob.es/organizacion/sns/planCalidadSNS/docs/EstrategiaEPOCSNS.

pdf., accessed January 18, 2011). The BODE Index is a multidimensional evaluation system for COPD patients which predicts the risk of death from any cause and from respiratory causes. This index, whose scores range from 0 to 10, takes into account airway obstruction (as measured by FEV1), exercise tolerance (as measured by the 6MWT), Body Mass Index (BMI) and dyspnea (as measured by the Modified Medical Research Council Dyspnea Scale (MMRC).¹⁴ A higher BODE score indicates negative values of FEV1, walking distance, IMC and dyspnea.

Sample size calculation

Estimating as clinically significant a minimum difference in the exercise tolerance of 54 metres²⁴ (SD±80),²⁵ requiring a 95% capability to detect that difference, if it exists, alpha risk of 0.05%, and a correlation coefficient of 0.6, for a bilateral hypothesis, we estimated the number of subjects to be studied as 25.

Randomization

Participants were selected by consecutive sampling of a hospital ward.

Statistical analysis

A descriptive analysis was performed. The quantitative data is presented as mean and standard deviation (\pm SD). The Wilcoxon test was used for the comparison of the two means. The data was analysed through the statistical package SPSS.19.

Results

Demographic and clinical characteristic of patients are presented in Table I.

All subjects improved their HRQoL in the SGRQ (mean difference of the total score by - 12.5 P<0.001), the CRDQ (0.9 P<0.001) and the AQ20 (-3.1 P<0.001) questionnaires (Table II). This statistically significant improvement is demonstrated in each one of the evaluated dimensions.

Table III shows the results of the 6MWT and the BODE Index, before and after the muscular training program. Following the program subjects walked an average of 56 meters more (P<0.001).

Discussion

The most significant findings of this clinical trial were: a greater exercise tolerance, an improvement in the HRQoL, and a better illness prognosis as measured by the BODE index.

The HRQoL improvement experienced by subjects following the muscular training sessions is consistent with that found by other authors.^{6,26,27} Murphy et al. evaluated quality of life with SGRQ comparing a group of subjects that received pulmonary rehabilitation with another one on the waiting list for transplantation who received routine treatment. These authors did not find an improvement in the subscales of symptoms as our study did in all questionnaire subscales. This difference could result from Murphy's training program being shorter (6 weeks) than ours (8 weeks). Moreover, the subjects in Murphy's study had initiated the pulmonary rehabilitation program immediately following hospital discharge. Because of that and the functional deterioration that characterized COPD patients immediately after an exacerbation,²⁸ they may have needed more recovery time. Therefore, the key to improving quality of life could be in the development of more extended muscular training programs such as ours.

Man et al.⁶ in a randomized controlled trial employed the SGRQ and CRDQ questionnaires to measure the quality of life in subjects with recent exacerbation involved in a 3 months pulmonary rehabilitation program. Compared with our program, they have obtained a better scoring for the dimensions impact of the illness and the total score in the SGRQ and for the dimensions of illness control and emotional function in the CRDQ. These results may be justified because their rehabilitation program was developed by an interdisciplinary team that has placed great importance on patient education whereas in our study the physiotherapist emphasized the education sessions mainly during the first week of the program.

In the systematic review carried out by Puhan et al.⁵ effects of pulmonary rehabilitation on subjects with stable COPD were compared with those with acute exacerbation. Their research has shown that the effect on HRQoL seems to be similar in both groups. That finding does not relate to the findings of other authors ^{28,29} who consider that the potential for improvement of a patient is higher after an exacerbation due to the initial damage of exacerbations on exercise capability and quality of life.

In our study the dimensions of dyspnea and fatigue of the CRDQ have shown a higher scoring following muscular training compared to the data presented by Lacasse for the exacerbation group. We have also found an improvement in all dimensions of the CRDQ similar to the findings in the Ghaem et al.³⁰ randomized trial.

López et al.³ in a clinical trial where they assessed the functional status and the survival of COPD subjects following respiratory rehabilitation have found an increase in the total scoring of the SGRQ. However, its separate dimensions (symptoms, activity and impact of the illness) did not achieve a clinically significant difference as happened in our research. A feasible explanation to this data could be in the fact that the Lopez study patients showed a lower deterioration in HRQoL and exercise tolerance in comparison to our study patients. This would support the hypothesis that the greater the patient's functional deterioration, the greater the benefits to be expected from this type of program,³¹ as occurred with our group.

It is important to note that our study has demonstrated the benefits of pulmonary rehabilitation programs in HRQoL in all the questionnaires used. This is the first research to confirm the utility of a brief questionnaire such as the AQ20 to measure sensitivity to change in muscular training programs.

The exercise tolerance improvement achieved, following our intervention program, agrees with that found by other authors 3,32,33 a lower degree of dyspnea and a better effort capacity measured through the 6MWT. In our study, subjects gain 55.9 meters in walking distance in relation to the pretraining value. This is not only statistically significant (P<0.001) but also clinically relevant.

Our result is clearly superior to the 31 meters of improvement achieved by López et al.³ Perhaps this difference could be explained by the limited physical deterioration of the experimental group at the beginning of the training program. Subjects in the López research showed an initial average of 412 (SD \pm 79.4) meters in the 6MWT, despite the degree of COPD severity according to spyrometric data. In our study, subjects showed a lower capability with an average of 312.8 (SD \pm 77.8) meters pretraining 6MWT. This finding reinforces the theory that the greater the deterioration in the patient's physical

condition, the greater the improvements to be obtained from a muscular training program. Participants in our study had presented exacerbations that contributed to a reduction in muscular function which could be ameliorated through a muscular training program.

The improvement reached in the 6MWT corresponds with the results obtained by the Takigawaa research group ³⁴ in which the average increase in walking distance following the training program was around 50 meters for all subjects with differing degrees of COPD. Moreover, it is slightly lower than the 77 meters average referred in the Cochrane review.³⁵ However, it is necessary to signal the heterogeneity of the revised studies. Two out of these six analysed studies did not show an increase in walking distance. The findings of the Nava³⁶ and the Trooster³⁷ studies were similar to our research result, with 68 meters and 64 meters respectively for a similar population (severe COPD patients). Subjects in the Trooster study carried out a longer training program than in ours (6 months versus 2), but our subject improvement in the walking distance was similar (55.9 meters versus 64). This fact could lead us to believe that there are no significant differences between longer and shorter length programs in terms of exercise tolerance improvement. However this hypothesis contrasts with the results obtained by Behnke et al.³⁸ in their 2003 clinical trial. They demonstrated a 215 meters increase in the 6MWT after an 18 months training program with patients with severe COPD. This positive result could be justified by the constant control that was implemented during the development of the program and included hospital and home-based phases with regular visits to patients from health professionals and periodic telephone control. This demonstrates the relevance of supervision and follow-up of patients in these types of training programs.

In relation to illness prognosis, our study results show an improvement in the BODE Index of 1.5 points. There are few publications that pay reference to this index for the assessment of illness prognosis. López et al.³ tried to show the effects of a respiratory rehabilitation program on the survival of COPD subjects. Although they obtained an improvement in the BODE Index, the relationship with survival did not achieve statistical significance. Their study highlighted that positive values of the BODE Index does not necessarily correlate with greater survival. In this sense, it differs from the affirmation by Celli et al.²⁰ which considered the BODE Index as a good predictor of the risk of death from any cause and from respiratory causes in COPD patients. In our research, the BODE

Index improves but we do not have the data on a long-term basis to check the relationship of this improvement to a greater survival.

The quasi-experimental feature of the study and the lack of a control group must be pointed out as a research limitation. The study design was conditioned by the difficulty of finding a sample that fulfils the inclusion criteria due to the co-morbidity and mortality in this population group. Nevertheless, the agreement of our findings with those published endorses their external validity.

Conclusions

Our data indicates that the implementation of a muscular training program does contribute to an improvement in quality of life, exercise tolerance and illness prognosis in COPD patients with moderate or severe exacerbations.

However, there has been an inadequate implementation of this type of treatment as part of the non pharmacological management of COPD patients.³⁹ It is essential, therefore, to increase the levels of evidence that strongly support the benefits of these programs for COPD patients with moderate or severe exacerbations.

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	Mean (±SD)		%
Age	68.88 (±8.53)		
Sex (%)		Male	92%
		Female	8%
Smoking habit (%)		Smoker	12%
		Ex -smokers	88%
COPD degree (GOLD)		Degree II	4%
		Degree III	56%
		Degree IV	40%
FEV ₁ (l/s)*	1.0 (0.3)		
FEV ₁ (%)	33.9 (10.2)		
FVC (%)†	60.6 (15.5)		
FEV1/ FVC (%)	42.7 (9.3)		
COPD exacerbations	2,4 (±1,38)		
Exacerbation type (%)		Moderate	32%
		Severe	68%
Body Max Index 2	5,5 (± 4,4)		
Dyspnea (MMRC) ‡	2,92 (± 1,11)		

Table I.—Demographic and clinical characteristics of patients at baseline

*Forced expiratory volume in the first second; †forced vital capacity; ‡Modified Medical Research Council Dyspnea Scale.

	Pretraining		Postraining		Diference			Р
	Mean (±SD)	Median	Mean (±SD)	Median	Mean (±SD)	P ₅	P ₉₅	
SGRQ*								
Total	54.7 (12.5)	54.1	42.1 (14.4)	39.3	-12.5 (10)	-5.2	27.9	< 0.001
Symptoms	57.8 (16.8)	60.2	46.8 (17.8)	46.6	-10.8 (13.5)	-6.5	38.5	< 0.001
Activity	76.9 (14.8)	79.0	63.5 (17.0)	59.5	-13.4 (12.5)	-4.9	42.2	< 0.001
Impact	41.2 (15.1)	42.4	28.5 (15.9)	26.3	-12.7 (14.6)	-12.9	43.2	< 0.001
CRDQ †								
Гotal	3.9 (0.8)	3.9	4,8 (1.1)	4.7	0.9	0.0	1.8	< 0.001
Dyspnea	3.2 (0.8)	3.2	4.4 (1.1)	4.2	1.1	-0.1	2.5	< 0.001
Fatigue	3.8 (0.9)	3.8	4.7 (1.1)	4.5	0.9	-0.4	2.9	< 0.001
Emotional Function	4.2 (1.0)	4.1	5.0 (1.4)	4.4	0.7	-1.5	2.0	0.001
llness Control	4.2 (1.2)	4.0	5.1 (1.4)	5.0	0.9	-1.3	2.6	0.001
AQ20‡	9.84 (3.4)	9.0	6.7 (3.9)	6.0	-3.1	-9.7	2.1	< 0.00

Table II.—Health Related Quality of life before and after muscular training

*St. George's Respiratory Questionnaire; †Chronic Respiratory Disease Questionnaire; ‡AQ20: Airways Questionnaire.

	Pretraining		Postraining	Postraining		Diference		
	Mean (±SD)	Median	Mean (±SD)	Median	Mean (±SD)	P ₅	P ₉₅	
6MWT*	312.8 (77.8)	317	368.8 (60.5)	361	56 (41)	-7	151.7	< 0.001
BODE †	5.1 (1.7)	5	3.6 (1.6)	3	-1.5 (1.3)	-4	0.0	< 0.001

Table III.—Exercise tolerance and BODE Index before and after muscular training

*Six-minute walking test; †COPD Prognosis Index.