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ORIGINAL RESEARCH

Results of a Multimodal Program During Hospitalization in Obese COPD Exacerbated Patients

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Abstract

The objective of this study was to analyze the results of a multimodal therapeutic program during hospitalization in obese AECOPD patients. This was a randomized, single-blind clinical trial conducted at two university hospitals in Granada, Spain. Forty-nine patients hospitalized due to AECOPD were randomly allocated to a control group (CG), in which patients received standard care, or to an intervention group (IG), in which patients were included in a multimodal therapeutic program, added to the standard care. The main outcome measures were pulmonary, physical (strength and exercise capacity) and perceived (dyspnea, quality of life and psychological distress) variables. Within-group significant improvements ($p < 0.05$) were found in physical and perceived variables in the IG after the treatment. In the CG, a significant decrease was found in lower limb strength and a significant improvement in dyspnea and in three subscales of the EuroQol-5D questionnaire. The between-groups analysis showed significant differences after the treatment on lower limb strength and exercise capacity values ($p < 0.05$), in three of the EuroQol-5D subscales, and in the total score and the depression subscale of the Hospital Anxiety and Depression Scale. A multimodal therapeutic program has a beneficial effect on physical functioning and perceived variables in hospitalized obese patients with AECOPD.

Introduction

Obesity in COPD has increased in the last decades and its prevalence varies from 10–20% in the European countries (1). Obesity would be expected to amplify the abnormalities of dynamic ventilatory mechanics and ventilatory demand that characterise COPD. The combination of restrictive/obstructive deficits in obese patients with COPD increase the symptomatology and activity limitation (2). Seres et al. (3) determined that the reduced exercise capacity in morbid obesity was associated with greater oxygen uptake, heart rate, systolic blood pressure and minute ventilation. The American Thoracic Society/European Respiratory Society Statement on Pulmonary Rehabilitation (PR) published in 2006, addressed the importance of the nutritional status. After this publication, different studies (4,5) have focused on the assessment and rehabilitation of obese COPD patients.

It has been reported a poorer exercise performance, a higher degree of functional impairment and fatigue levels in obese compared to non-obese COPD patients (5). As reported by the recent review of Chittal et al. (6), over

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the last decade, there has been substantial focus on the paradox that exists among the obese with chronic diseases, where overweight and at least mild-moderately obese with these chronic diseases appear to have a better prognosis than do their leaner counterparts. Despite the growing interest on COPD therapeutics and obesity, to our knowledge, no previous studies have been focused on PR during acute exacerbation in obese COPD inpatients.

Most patients hospitalized due to acute COPD exacerbation (approximately 75%) show a progressive deterioration of muscle strength and endurance in both peripheral and respiratory muscles (7). This has been attributed to prolonged bed rest and treatment with steroids (8). Although numerous therapeutic programs have been proposed (9, 10) for AECOPD inpatients, the results of a multimodal program in obese COPD exacerbated patients have not been previously assessed. The objective of this study was to evaluate the results of a multimodal therapeutic program including breathing training and lower and upper limb exercises during hospitalization due to acute exacerbation in obese COPD patients.

Methods

Study design

Randomized, single-blind clinical trial

The research assistant who collected the data was blinded to the hypothesis of the study and to the patient's allocation. The study was approved by the Hospital Ethics Committee (approval number 1107) and all the participants gave their written consent. The study was registered in www.clinicaltrials.gov, reference NCT01826682.

Randomization procedure

An independent nurse assigned the participants to the IG or CG according to a computer-generated randomization list. The nurse informed the physiotherapist once the participants had given their approval to participate in the study. The distribution of the participants is shown in the flow diagram (Figure 1) (11).

Patients

Eighty-five patients among those admitted to the respiratory ward in San Cecilio and Virgen de las Nieves Hospitals, in Granada, Spain, were recruited during a 4-month period (July-October 2013). Thirty-six patients

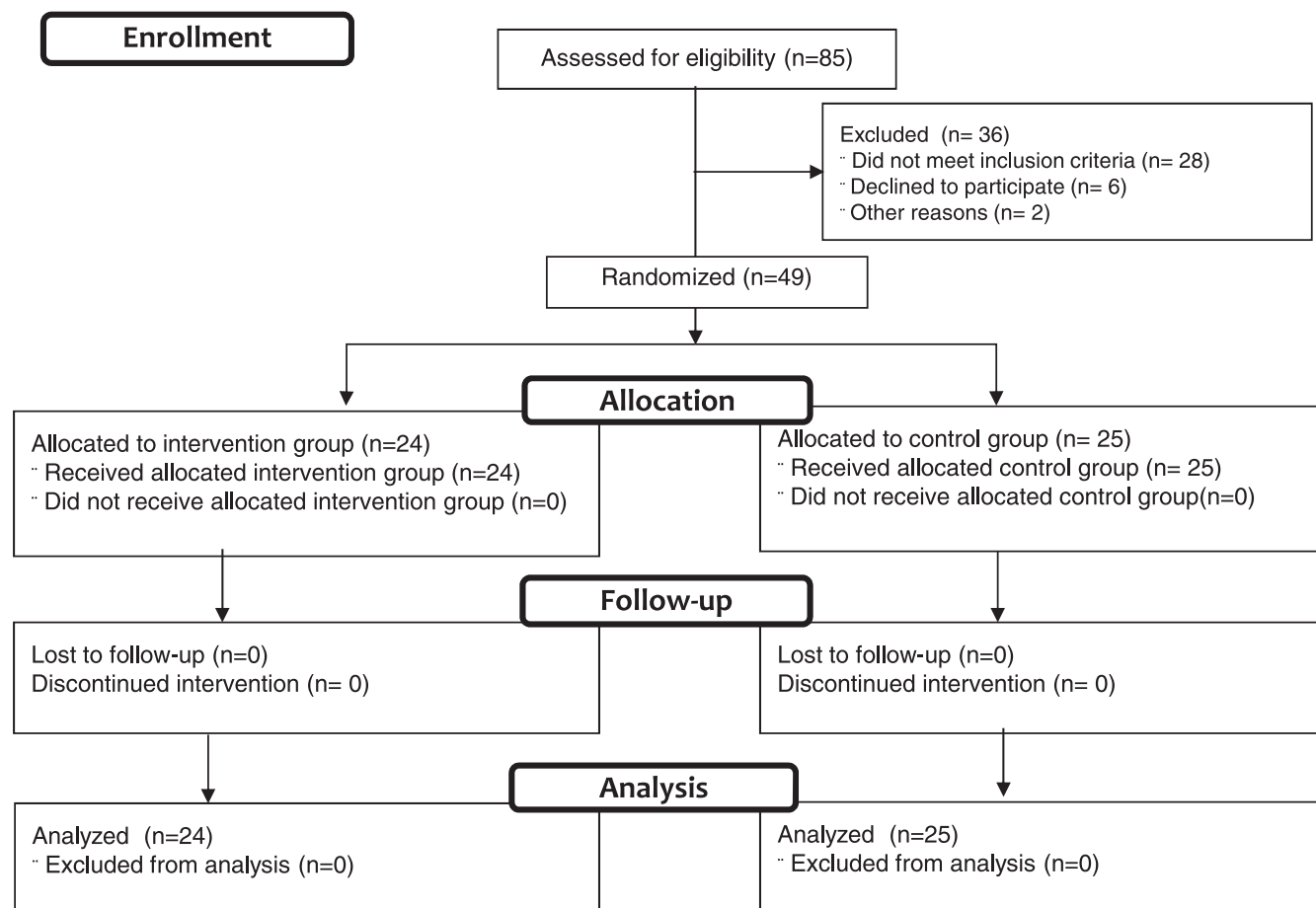


Figure 1. CONSORT 2010 flow diagram.

were excluded and finally forty-nine patients were randomized into the IG or the CG (Figure 1).

Inclusion criteria were defined as follows: diagnosis of COPD made according to the criteria of the American Thoracic Society (ATS) (12); patients clinically diagnosed with AECOPD; patients with more than 30 kg/cm² of BMI, patients free from exacerbations for at least 10 days prior to the AECOPD; patients with a hospital stay of at least 7 days. Patients with other organ failure, cancer or inability to cooperate were excluded.

Evaluation

For descriptive purposes, anthropometric measures and previous clinical history data were recorded at baseline. Additionally, a spirometry was performed in all the subjects following the criteria of the American Thoracic Society (13). Other variables assessed at baseline were the quality of life measured by the St. George's Respiratory Questionnaire (SGRQ) (14) and the level of independence (Barthel Index) (15).

Outcome measures included physical (lower and upper limbs strength and exercise capacity) and perceived variables (dyspnea, quality of life and psychological distress).

Pulmonary, physical and perceived outcome measures were assessed at hospital admission and discharge.

Pulmonary outcomes

Respiratory function

The respiratory function was evaluated in all the patients following the criteria of the American Thoracic Society (16). Forced expiratory volume in the first second (FEV₁) % predicted and resting oxygen saturation (SO₂) were assessed.

Physical outcomes

Lower limb strength

Quadriceps strength was assessed according to previous studies (17, 18) with a portable hand-held dynamometer (Lafayette Manual Muscle Testing System, model 01163, Lafayette, IN, USA). The test was performed with the patient seated with his/her knees and hips flexed at 90°. Resistance was applied to the anterior tibia during 5 seconds of maximal muscle contraction. The test was repeated alternatively 3 times on the leg, allowing participants to rest between measurements. The highest value in Newton was selected for the analysis. This test has been previously used to assess muscle strength in COPD patients.

Upper limb strength

Handgrip strength is a reliable marker of peripheral muscle strength. The measurements were made with a handgrip dynamometer (TEC-60; Productos Técnicos, EE.UU.) individually adjusted for the size of the subject's handgrip. Three measurements were made in the hand; the peak force was recorded in each case (19). There was

a time to rest between measurements. This test has been previously used to measure muscle strength in people with COPD (20).

Exercise capacity

Aerobic endurance was measured using the two-minute step-in-place (2MSP) test. This test can be used when there are space limitations or weather conditions that make difficult to perform the 6-minute walk test (21). The patients were asked to raise each knee to a point midway between the patella (i.e., kneecap) and the iliac crest (i.e., top hip bone). The score of this test is the number of times that the right knee reaches the required height in 2 minutes.

Perceived outcomes

Dyspnea perception

Dyspnea was assessed at rest using the modified Borg scale. Patients classified their breathlessness from 0 to 10 (22). This measure has been validated in healthy subjects and COPD patients.

Quality of life (QoL) measure

We used the Spanish version of the EuroQol-5D (EQ-5D) questionnaire (23). Two values were obtained: the EQ-5D Visual Analogue Scale (VAS) and the EQ-5D index. The VAS consists of a rating scale of 0 to 100 points, taken as 0–100% (0%, death/worst possible health; 100%, best possible health). The EQ-5D index is a questionnaire composed of five items (mobility, self-care, usual activity, pain/discomfort and anxiety/depression). For each item, the patient selects one of three descriptive health states (from good to poor) and the number and percentage of patients selecting each state is recorded. The questionnaire has been previously used in COPD patients.

Psychological distress

It was measured with the Hospital Anxiety and Depression Scale (HADS). The HADS is a 14-items self-report questionnaire designed to detect psychological morbidity in medically ill patients (24). It contains depression and anxiety subscales, each with scores ranging from 0 to 21.

Intervention

We compared the effects of a multimodal intervention program combined with standard medical and pharmacological care with those of a standard care intervention in obese patients hospitalized due to AECOPD. During the exacerbation, all patients were treated with standard medical therapy including systemic steroids (76%), inhaled bronchodilators (100%) and oxygen.

The IG received twice daily individualized multimodal PR during 30–45 minutes. The program included 15 minutes of deep breathing exercises and 20–30 minutes of limb exercises. The duration of the intervention was determined by the length of hospital stay of

each patient, and all the sessions were conducted by a physiotherapist.

The first day of the treatment begins with the patient in bed and consisted of breathing exercises, active range of motion (ROM) exercises and muscle strengthening. From the second to the fourth day the breathing program continues and the exercise treatment consisted of active ROM exercises and muscle strengthening while the patient is seated, including knee flexion-extension, and hip abduction-adduction and flexion-extension exercises. Upper limbs flexion-extension and abduction-adduction exercises were also included.

From fifth day to last hospitalization day, in addition to breathing exercises, treatment included all the exercises done from second to fourth day and additionally they were encouraged to do standing exercises including knee flexion-extension, and hip flexion-extension and abduction-adduction exercises, they also had to do single leg stance, and sit to stand exercises, they had to try exercises with arms stationary at the beginning and try to raise hands to make it more difficult to keep standing.

A physiotherapist supervised these exercises. The number of repetitions was adapted to the subject's response taken into account the perceived dyspnea and fatigue during the exercise performance. The exercise program was based on methods that have been reported to increase the strength, the flexibility and the ROM (25). The subjects were examined for adverse signs and symptoms such as increased pain, severe dyspnea, desaturation and increased skin temperature at each session. If any soreness lasted more than a few hours after the intervention, the regimen was decreased accordingly for that subject. Only were included in the analysis the patients who received at least 7 sessions of treatment.

Sample size calculation and power

The primary outcome measure for the study was the lower limb strength. On the basis of previous audit data (26, 27), a small positive effect (10 Nm) was anticipated in the training group. Hence, in order to have 80% power using a two-sided $\alpha = 0.05$, and a hypothetical drop-out rate of 20%, 20 patients in each group would be needed to show statistically significant differences in lower limb strength between the two groups.

Statistical analyses

Data were analyzed using SPSS software version 20.0. Descriptive statistics were used to determine the participant's characteristics. The Kolmogorov–Smirnov test was performed to assess the normality of continuous data prior to the statistical analysis. Normally distributed demographic variables were compared using Student's *t*-test. Non-normally distributed variables were compared using the Kruskal–Wallis test with an alpha level of 0.05. For each outcome variable measured, we performed a 2 (baseline and discharge) \times 2 (multimodal therapeutic program + standard care vs. standard care group) two-way mixed ANOVA. If the two-way

ANOVA showed a significant interaction for each variable, Scheffe's post-hoc test was used to identify the specific mean differences. Statistical significance was accepted at a *p*-value of 0.05.

Results

The final sample was composed of 49 patients (Figure 1). The sample was composed of 4.8% ($n = 2$) women and 95.2% ($n = 47$) men. Age values were similar between intervention (72.36 ± 8.91) and control groups (73.7 ± 7.10), $p = 0.597$. The groups were statistically equivalent on the clinical measures and importantly on the length of hospital stay. Means and standard deviations for pre-intervention sociodemographic and clinical characteristics of the sample are reported in Table 1.

Table 1 shows the characteristics of the patients included at the beginning of the study and randomly allocated in two groups. Outcome measures at baseline in the intervention and control groups are shown in Table 2.

Table 2 shows both groups' main outcome values. Not significant between groups differences were found at baseline. Within-group changes and between-group differences after the intervention on physical outcomes are shown in Table 3.

Pulmonary variables improved significantly in both groups ($p < 0.05$). Physical variables improved significantly in the IG while lower limb strength showed a significant impairment in the CG ($p < 0.05$) (see Table 4). First callout Table 4. Between groups significant differences were found on lower limb strength and exercise capacity ($p < 0.05$).

The dyspnea values showed a significant improvement in both groups (2.20 ± 2.6 ; $p < 0.001$ in the IG vs. 3.6 ± 2.21 ; $p < 0.001$ in the CG) with no between group differences ($p = 0.785$). In the IG, the quality of life measured with the EuroQol-5D questionnaire also showed a significant improvement ($p < 0.05$) in all the subscales. The CG improved significantly only in self-care, pain/discomfort and anxiety/

Table 1. Descriptive characteristics of the sample at baseline

	IG ($n = 24$)	CG ($n = 25$)	<i>p</i> -value
Age (years)	72.36 (± 8.91)	73.7 (± 7.10)	0.597
Sex n (% women)	0(0)	2 (9.1)	0.268
BMI (kg/m^2)	33.56 (± 1.11)	34.33 (± 2.04)	0.271
Ex-smoker n (%)	18 (81.8)	22 (100)	0.065
Length of hospital stay (days)	8.7 (± 2)	8.8 (± 2)	0.801
Resting SO_2 (% O_2)	88.4 (± 4)	90.3 (± 4)	0.480
FEV ₁ (l)	0.78 (± 0.2)	0.80 (± 0.7)	0.317
FEV ₁ predicted (%)	39%	41%	0.453
SGRQ total score	64 (± 13)	63 (± 13)	0.760

Non-categorical variables are expressed as mean (\pm SD); SD: Standard deviation; IG: intervention group; CG: control group; n: Number of participants per group; BMI: Body mass index; FEV₁: Forced expiratory volume in the first second; SGRQ: St. George's Respiratory Questionnaire.

Table 2. Outcome measures at baseline in the patients included in the study

	PT group (n = 24)	SC group (n = 25)	p-value
Physical variables			
Lower limb strength (N)	126.9 (± 36.2)	153.5 (± 75.0)	0.146
Handgrip strength (N)	251.5 (± 60.0)	284.5 (± 83.1)	0.146
2MSP (number of times)	46.82 (± 23.68)	46.63 (± 21.62)	0.980
Perceived variables			
Dyspnea perception	5.50 (± 2.06)	6.60 (± 2.16)	0.108
EuroQol-5D Mobility	1.82 (± 0.66)	1.70 (± 0.47)	0.514
EuroQol-5D Self-care	1.91 (± 0.81)	1.80 (± 0.89)	0.681
EuroQol-5D Usual activities	2.00 (± 0.75)	1.90 (± 0.71)	0.663
EuroQol-5D Pain/discomfort	1.82 (± 0.85)	1.80 (± 0.89)	0.947
EuroQol-5D Anxiety/depression	1.82 (± 0.85)	2.00 (± 0.64)	0.445
EuroQol-5D VAS	59.55 (± 17.5)	53.5 (± 20.52)	0.309
HADS anxiety subscore	8.45 (± 4.64)	6.80 (± 3.07)	0.186
HADS depression subscore	6.00 (± 2.86)	4.90 (± 2.84)	0.218
HADS total	14.45 (± 5.81)	11.7 (± 4.94)	0.108

Note the end of the Table Body coding for Table 2 cannot be seen but it is there.

* $p < 0.05$; ** $p < 0.001$; Values are expressed as mean (±SD) (SD: Standard deviation);

n: Number of participants per group; IG: Intervention group; CG: Control group; 2MSP: 2-minute step-in-place; VAS: Visual Analogue Scale; HADS: Hospital Anxiety and Depression Scale.

depression subscales ($p < 0.05$). An improvement in the values of the EuroQol-5D VAS was recorded in both groups, although it was only significant in the IG (17.45 [−30.190, −4.920]; $p = 0.006$). Between-groups comparisons showed significant differences in the EuroQol-5D self-care, usual activities, anxiety and depression subscores and the EuroQol-5D VAS, with higher improvements in the IG ($p < 0.05$). The HADS subscores and the total score showed significant improvements in the IG after the treatment ($p < 0.05$). The CG also reported improvements but the differences were not significant. Between-groups comparisons also showed significant differences in HAD depression subscore and total score ($p < 0.05$).

Discussion

The objective of this study was to analyze the results of a multimodal therapeutic program during hospitalization in obese COPD exacerbated patients. Our results revealed that the patients who received a multimodal program consisting of breathing training and limb exercises experienced an improvement on strength, exercise capacity and psychological distress during AECOPD hospitalization. Moreover, our study showed a beneficial effect of physical treatment on QoL measures and dyspnea. The sample of subjects included in this study was representative of the general population with COPD and obesity (i.e., similar age range, and COPD severity). This homogeneity was useful in order to reduce the possibilities of including confounding factors that could have affected the value of our results. Additionally, the final sample of participants was similar to previous studies (28).

Peripheral muscle weakness is a well-known systemic feature in patients with clinically stable COPD (29) that became more important with obesity (4). Different studies (6, 30) focused on PR have found a relationship in obese COPD patients with baseline status, but this seems not to affect PR outcomes: lower extremity exercise performance, health status, and functional status. Garrod et al. (30) showed that BMI was not related to changes in the 6 minute walking distance (6MWD) or health status following PR. These studies have compared the results of PR by BMI groups but no previous studies have been focused on specific therapeutic proposals for obese COPD patients. This study evaluates the results of a multimodal therapeutic program on AECOPD patients.

The study of Spruit et al. (26) showed a detrimental effect of hospitalization on peripheral muscle strength and systemic inflammation on the third day of hospitalization in AECOPD patients compared to stable COPD patients and healthy elderly subjects. That study also revealed a significant decrease in peripheral muscle

Table 3. Mean changes on pulmonary function, strength and exercise capacity by group.

	IG (n = 24)	CG (n = 25)	Between-group [95% CI]	Between-group differences (p-value)
Pulmonary variables				
Δ Resting SO ₂ (% O ₂)	5.8 (± 4.6) ^a	4.7 (± 5.2) ^a	[4.89 to 5.41]	0.412
Δ FEV ₁ (l)	0.59 (± 0.9) ^a	0.34 (± 0.6) ^a	[0.41 to 0.56]	0.123
Δ FEV ₁ predicted (%)	7 (± 0.8) ^a	9 (± 0.5) ^a	[7.89 to 14.41]	0.264
Physical variables				
Δ Handgrip strength (N)	23.3 (± 52.0) ^a	0.33 (± 3.67)	[12.89 to 14.41]	0.376
Δ Lower limb strength (N)	16.5 (± 9.7) ^a	−31.0 (± 44.1) ^a	[−20.95 to 9.76]	0.038*
Δ 2MSP (number of times)	17.59 (± 6.69) ^a	4.87 (± 16.12)	[−17.59 to 6.69]	0.013*

Data are presented as mean (± SD). ^a $p < 0.05$, (within-group differences). * $p < 0.05$; ** $p < 0.001$; (between-group differences). IG: intervention group; CG: Control group; CI: Confidence interval; n: Number of participants per group; 2MSP: 2-minute step-in-place.

FEV₁: Forced Expiratory Volume in the first second.

Table 4. Mean changes on perceived outcomes by group

	IG (<i>n</i> = 24)	CG (<i>n</i> = 25)	Between-groups 95% CI [95% CI]	Between group <i>p</i> -value
Δ Dyspnea perception	2.20 (± 2.6) ^a	3.6 (± 2.21) ^a	[-1.15 to 1.51]	0.785
Δ EuroQol-5D Mobility	0.71 (± 0.72) ^a	0.30 (± 0.65)	[-0.06 to 0.49]	0.124
Δ EuroQol-5D Self-care	0.57 (± 0.81) ^a	0.30 (± 0.47) ^a	[0.14 to 0.85]	0.007*
Δ EuroQol-5D Usual activities	0.71 (± 0.75) ^a	0.30 (± 0.65)	[0.24 to 0.95]	0.001*
Δ EuroQol-5D Pain/discomfort	0.47 (± 0.90) ^a	0.50 (± 0.68) ^a	[-0.15 to 0.38]	0.381
Δ EuroQol-5D Anxiety/depression	0.62 (± 0.65) ^a	0.50 (± 0.51) ^a	[0.34 to 0.60]	0.029*
Δ EuroQol-5D VAS	17.45 (± 23.51) ^a	9.00 (± 20.87)	[-28.29 to -0.70]	0.040*
Δ HAD anxiety subscore	3.81 (± 3.59) ^a	0.80 (± 2.9)	[-0.83 to 3.56]	0.218
Δ HAD depression subscore	4.18 (± 2.53) ^a	0.20 (± 3.5)	[1.26 to 4.49]	0.001*
Δ HAD total	8.00 (± 4.51) ^a	1.0 (± 4.9)	[1.40 to 7.08]	0.004*

Data are presented as mean (± SD). ^a*p* < 0.05, (within group differences). **p* < 0.05; ***p* < 0.001; (between-group differences). PT group: Physical therapy group; SC group: Standard care group CI: Confidence interval; VAS: Visual Analogue Scale; HADS: Hospital anxiety and depression scale.

strength during hospitalization. Similar results were shown in the studies of Martínez-Llorensa *et al.* (7) and Pitta *et al.* (27). Our results in the control group are in the same line, showing a decrease on muscle strength during hospitalization. No previous studies have compared the repercussion of inactivity and hospitalization in COPD by BMI group, but obese COPD patients seem to have poorer prediction after hospitalization due to the negative influence of their increased metabolic and ventilatory requirements (31).

In this study we proposed a multimodal therapeutic program to prevent hospital impairment. Other authors (29, 32) have suggested various interventions in order to prevent such impairment. As demonstrated in the study conducted by Giavedoni *et al.* (32), neuromuscular electrical stimulation (NMES) is a feasible and effective treatment to prevent the impairment of lower limb strength during AECOPD and may be used to supplement early post-exacerbation PR. Electrical stimulation may be an useful alternative treatment in patients with severe COPD, who are unable to perform usual exercise on a regular basis, as required in rehabilitation programs (17).

Troosters *et al.* (33) concluded that resistance training during AECOPD is a safe and effective strategy to counterbalance loss of musculoskeletal function. Resistance training does generate a protective stimulus to the muscle and may facilitate functional recovery after an acute exacerbation. In their study, they found a significant increase in lower limb strength compared to a control group.

Our treatment proved to be effective not only in preventing hospital impairment but also improving muscle strength and exercise capacity in hospitalized obese AECOPD patients. This treatment is cost-efficient, taking into account that other treatments that have been proposed (e.g., neuromuscular electrical stimulation programs) imply a greater cost.

While it has been well established that pulmonary rehabilitation improves quality of life, exercise toler-

ance and dyspnea, these recommendations do not support pulmonary rehabilitation for the prevention of hospitalizations in COPD patients >4 weeks post recent hospitalization (35). However, our study has shown an additional effect of a multimodal therapeutic program on psychological distress during AECOPD. Psychological distress has been related to AECOPD influencing its clinical course (34). The effectiveness of a PR program in reducing stress and depressive symptoms experienced by patients with COPD has been proven regardless of disease stage, patients' gender, age or education level (36).

Our study shows similar results in psychological distress, with higher improvements in depression compared to the anxiety levels. This improvement in our study may be influenced by the hospitalization "per se," the more aggressive pharmacological treatment and the clinical profile of the obese COPD subjects. However, no previous studies have compared the effects of a rehabilitation program on psychological distress during acute exacerbation in obese COPD patients.

The limitations of this study include the variability of the length of hospital stay of the patients and the imbalance in the sex distribution. In addition, we used a dynamometer to measure muscle condition, while other studies used a biopsy.

Conclusion

A multimodal therapeutic program has a beneficial effect on muscle strength and exercise capacity in obese AECOPD hospitalized patients, also improving the perceived variables. Future research should explore other modalities of physical therapy in obese COPD subjects.

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Declaration of Interest Statement

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper. ITS: contributed to the acquisition and interpretation of the data. MCV: contributed to the analysis and interpretation of the data; drafting of the manuscript and revising it for important intellectual content; and approving the final manuscript. GVD: contributed to the study concept and design, revising the manuscript for important intellectual content, and approving the final version. GSR: contributed to the acquisition of the data and to the study concept and design. ICM: contributed to the study concept and design, acquisition and interpretation of the data, revision of the manuscript for important intellectual content, and approving the final version. LMM: contributed to the revision of the manuscript for important intellectual content, and approving the final version.

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