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The effects of a physiotherapy programme on patients with a pleural effusion: a randomized controlled trial

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Abstract

Objective: To investigate the effects of a physiotherapy protocol on patients with pleural effusion.
Design: Randomized controlled trial.
Setting: University hospital.
Participants: A total of 104 consecutive inpatients with a medical diagnosis of pleural effusion.
Intervention: Patients were randomly allocated to a control group receiving standard treatment (medical treatment and drainage) or an intervention group treated with physiotherapy added to standard treatment. The physiotherapy programme included deep breathing exercises, mobilizations and incentive spirometry.
Main outcome measures: Spirometric predicted values and chest radiographs were measured before treatment and at discharge and the length of hospital stay was recorded. Assessors were blinded to the intervention.
Results: A comparative analysis showed a significant improvement of spirometric parameters in the intervention group; pre-to-post hospitalization predicted values showed significant changes in vital capacity (73.1 ± 12.6% to 72.13 ± 13.7 %, $P<0.001$), forced expiratory volume in first second (72.13 ± 13.7% to 78.98 ± 16.9%, $P<0.001$) and forced expiratory flow at 25-75 % (64.8 ± 35.1% to 76.78 ± 35.3%, $P=0.198$) compared to the control group that showed no significant changes across treatment. The radiographic findings showed better scores on the affected side of the thorax at discharge in the physiotherapy group. Length of hospital stay was also significantly ($P=0.014$) shorter in the intervention group (26.7 ± 8.8 days) compared to the control group (38.6 ± 10.7 days).
Conclusions: A physiotherapy programme added to standard treatment improves the spirometric parameters and the radiological findings and reduces the hospital stay in patients with a pleural effusion.

Keywords

Pleural effusion, physiotherapy, length of stay, spirometry

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Introduction

Pleural effusion is an accumulation of fluid in the pleural space. It is a common medical condition caused by an underlying disease. It often causes dyspnea, pleuritic chest pain, non-productive cough and fever, although their clinical manifestations largely depend on the underlying disease. Regardless of its cause, it has significant effects on the respiratory system, aggravating the normal age-related changes.[1]

In the management of pleural effusion, the aim is to provide symptomatic relief by removing the fluid from the pleural space and to allow the treatment of the underlying disease. Management options often depend on the pathophysiology of pleural effusion, its evolutionary stage and the underlying condition. The most common care priorities in pleural effusion include, but are not limited to dyspnea, localized pain, ineffective breathing pattern, activity intolerance and anxiety.[2]

A number of treatment strategies for the pleural effusion are currently discussed. The most common treatment used when the amount of fluid is more than 100 ml is to drain the liquid and antibiotic treatment. The total resolution of the effusion with this treatment has been reported to range between 18 and 91%.[3] Fibrinolitic agents combined with the drainage are shown to be effective to prevent the infections and the residual pleural fibrosis and to improve the pulmonary function.[4,5]

Additionally, pleurodesis for the treatment of pleural effusion offers the most effective control of fluid recurrence. It has been reported to have an overall success rate around 60-70%.[6] When attempting to explain this wide range of success rates cited in the literature for pleurodesis, some points to mention are the eligibility criteria for patient selection, the pleura design agent used, the methods and the definition of success.

Physiotherapy has been previously proposed as a possible therapeutic approach added to other surgical and non-surgical treatments.[7] This is an important intervention that prevents and reduces the negative effects of prolonged bed rest during hospitalization and improves the respiratory function. Respiratory physiotherapy usually includes breathing control exercises, postural exercises and mobilizations, sputum clearance techniques and education.[8] It is recommended and should be applied during the first weeks of treatment. But while some authors[9,10] propose treatment with respiratory physiotherapy, no definitive conclusions could be drawn about the success of this treatment relative to improvement in pleural effusion symptoms. To date, the most common approach is medical treatment combined with pleural fluid removal by thoracentesis.[3]

The complexity of diagnosis and treatment of pleural effusion makes it challenging to plan and deliver care. The aim of the present study was to investigate the effects of a respiratory physiotherapy protocol added to standard treatment on patients with pleural effusion.

Methods

A randomized controlled trial was conducted in the University Hospital San Cecilio (Granada, Spain). The study was carried out from February 2009 to March 2012. It received ethical approval from the University of Granada Ethics Committee and was registered in www.clinicaltrials.gov, reference NCT01756742.

One hundred and four consecutive inpatients with pleural effusion were screened and invited to participate on the basis of the following inclusion criteria: be clinically diagnosed with pleural effusion. The diagnosis was based on the presence of consistent radiological findings in posteroanterior and lateral chest radiographs in addition to the clinical presentation (dyspnea, pleuritic chest pain, non-productive cough and fever, depending on the underlying disease), to be aged between 18 and 80 years and to have a life expectancy higher than three months. Patients were excluded if they had visual impairments, severe cognitive impairment or comprehension deficits that prevented them from following verbal commands, other concomitant neurological or cardiorrespiratory disease and recent trauma or surgery in the thoracic spine.

Before being included in the study, patients were informed about the purpose and the course of

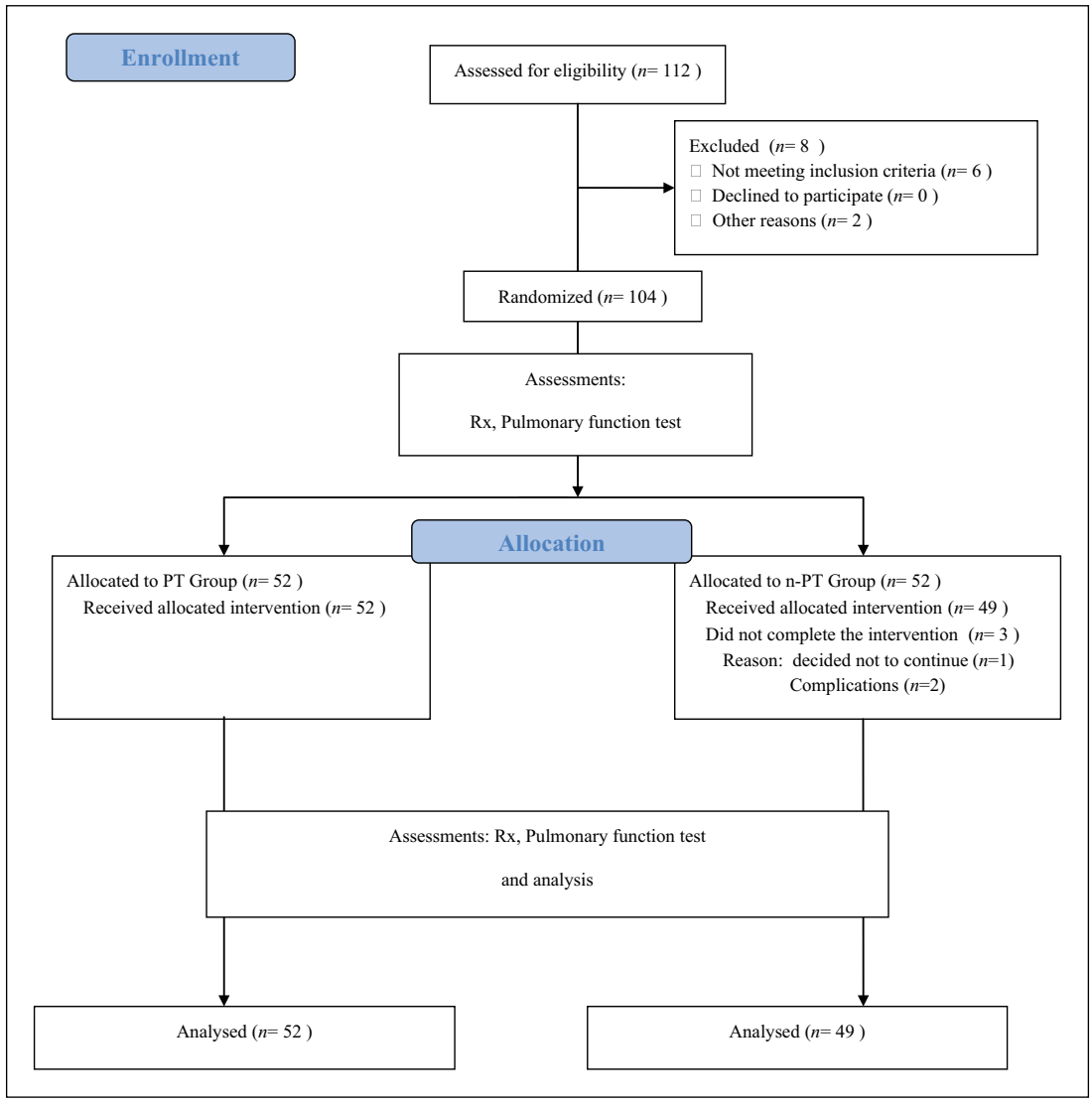

Figure 1. Flow diagram representing the recruitment, inclusion, assignment and subsequent follow-up of the study patients.

the study, after which they gave their informed written consent to participate.

Patients were randomized to the intervention group (physical therapy added to standard treatment) or to the control group (medical treatment and drainage). To ensure concealment of allocation, eligibility was determined by a blinded assessor (a nurse) not involved in the randomization process. The randomization sequence was drawn up and kept off-site by an independent body, using a random number generator in blocks of eight with no stratification. The sequence of subjects included in every treatment group was mailed from the independent body to the recruiter. The design of the study and participants' distribution between groups is shown in Figure 1.[11]

After the allocation, baseline measures were taken. All the data were collected by an independent researcher who was blinded to the allocation group of the patients.

The assessment included a complete clinical history review and a physical examination.

The outcome measures recorded were the spirometry and the chest radiograph at baseline and at discharge and the length of hospital stay.

Spirometry

Spirometry was used to assess the severity of individual patients' respiratory disease and their response to therapy.[12] It is regarded as the gold standard measure of respiratory function.[13] A Medical International Research (MIR) Spirolab II spirometer was used to collect data using Knudson et al.[14] predicted spirometric values as the normal reference values. The following variables were recorded: 1) forced vital capacity (FVC), 2) forced expiratory volume achieved in the first second (FEV_1), and 3) forced expiratory flow at 25 -75 % (FEF_{25-75}). These variables were calculated according to the methods defined in the Medical International Research manual.[15]

Chest radiographs

Posteroanterior and lateral chest radiographs were used to confirm the diagnosis at baseline and as an outcome measure of severity. Lateral radiographs are able to identify a small amount of fluid. The diagnosis criteria was based on some radiological findings including the following features: on the lateral chest radiograph, pleural effusions became visible as a meniscus at a volume of approximately 50 ml.[16] At a volume of 200 ml, the meniscus is also identified on the posteroanterior radiograph and at a volume of about 500 ml the hemidiaphragm appear to be obscured. Other radiologic findings are blunting of the costophrenic angle and in case of a large volume of fluid a mediastinal shift could be appreciated.[17]

The severity was scored using a numeric scale as shown in previous studies.[18] A radiologist with more than eight years of experience graded the pleural effusion severity from 0 (no pleural effusion) to 10 (massive pleural effusion).

Length of hospital stay

Length of hospital stay (LOS) is defined as the number of days between hospital admission and discharge. Over recent years, LOS has been shown to be an outcome variable in several therapeutic strategies and practical guidelines.[19]

All the patients included in the study received standard treatment. This was based on medical treatment including management and clinical care, pharmacologist approach and drainage (if necessary) during the hospital stay.

Patients allocated in the intervention group received physiotherapy added to standard treatment. The physiotherapy programme started when the patient was considered clinically stable by the medical doctor. A trained physiotherapist provided 40–60 minute sessions five times per week during the hospital stay. The physiotherapy protocol was supervised and individually adapted, according to the patient response to treatment. Patients were monitored during the exercise performance in order to detect increased pain, severe dyspnea, desaturation and/or increased skin temperature at each session.

The physiotherapy protocol included mobilization techniques and exercises, deep breathing exercises and incentive spirometry. The proposed exercises have been reported to increase strength, flexibility, and range of motion.[20,21]

Mobilization techniques and exercises

Limb exercises (i.e., passive, active assisted, or active) were performed in bed or in a seated position, depending on medical advice, with the aim of maintaining joint range of motion, improving soft-tissue length, muscle strength and function, and decreasing the risk of thromboembolism. The deep breathing programme included pursed lips breathing, active expiration and incentive spirometry, as follows:

- *Pursed lips breathing*: Pursed lips breathing works to improve expiration, requiring active and prolonged expiration and to prevent airway collapse.[22] It has been found to have a more marked increase of tidal volume and a decrease of breathing frequency.[23]
- *Active expiration*: The active expiration lengthens the diaphragm and contributes to make it operate close to its optimal length.[24,25] In addition, active expiration increases elastic recoil pressure of the diaphragm and the rib cage.[25]
- *Incentive spirometry*: Incentive spirometry was used as a lung expansion therapy, and it was administered supervised by a physiotherapist during 10 to 15 minutes per day.[26,27] The device used was the Coach spirometer (Kendall; Neustadt, Germany)

The inpatients allocated to the control group did not receive any physiotherapy. They received only the standard treatment.

Sample size calculation was based on the primary outcomes: spirometry results and radiographic score. An increase in FVC and FEV_1 (-12±3.3 and -15±8.2) was expected in the control group, as previously reported[28] and a greater positive effect (-3 in FVC and -5 in FEV_1) was anticipated in the intervention group.

Hence, in order to have 80% power using a two-sided α=0.05 and a hypothetical dropout rate of 10%, 48 patients in each group were required to show statistically significant differences between both groups in FVC and FEV_1.

Data were entered into Statistical Package for the Social Sciences, version 20.0 (SPSS Inc., Chicago, IL, USA) for analysis. Descriptive statistics (mean ± standard deviation) were used to determine participant characteristics. Prior to statistical analysis, the Kolmogorov-Smirnov test was performed to assess the normality of continuous data. The statistical distribution of the data was initially analyzed using the Shapiro Wilks test. The demographic data and initial assessment results were compared using the Student's *t*-test. The *t*-test for paired samples was used to compare the results of the assessment before and after treatment for parametric data. The Wilcoxon signed rank test was used to perform such comparisons with non-parametric data. Differences between groups were analyzed with the independent *t*-test for parametric data and the Mann-Whitney U-test for non-parametric data. The alpha level was set at 0.05.

Results

A total of 112 patients who fulfilled the criteria for pleural effusion were included in the study. Finally, a total of 104 patients were enrolled and randomly assigned to the intervention or to the control group. Figure 1[11] shows the recruitment, inclusion, assignment, and subsequent follow-up of the patients.

Demographic and clinical data for the study groups are shown in Table 1. No significant differences between-groups were found for any of the variables. Most participants had left side and exudate pleural effusion (Table 1).

No significant differences were found between the two groups for the dependant variables of severity and the spirometric values at baseline. (Table 1).

Table 2 shows the outcome measures (radiographic pleural effusion score, spirometric values and length of hospital stay) at baseline and at discharge.

The intervention group showed a significant pre-to-post hospital stay improvement (P<0.001) in spirometric values (FVC and FEV_1) and in radiographic severity. Student's *t*-test showed a significant difference between groups in length of hospital stay, being shorter in the physiotherapy group.

Discussion

The objective of this study was to investigate the effects of a respiratory physical therapy programme added to standard treatment on spirometric parameters, chest radiographs and length of hospital stay in inpatients with a pleural effusion.

Our results show greater improvement in all the variables measured in the physiotherapy intervention group. More specifically, this group improved the pulmonary function, decreased the severity and

Table 1. Characteristics of the subjects included in the study.

Variables	Intervention group (*n*=52)	Control group (*n*=49)	*P*-value
Sex *n* (%) males	15 (28.84)	19 (38.77)	0.072
Age (years) mean ± SD	56.4 ± 16.2	57.04 ± 17.0	0.683
Weight (kg) (mean ± SD)	68.3 ± 13.03	67.6 ± 13.2	0.741
Height (cm) (mean ± SD)	164 ± 22.14	166.8 ± 15.3	0.322
BMI (kg/cm2) (mean ± SD)	25 ± 11.9	27.5 ± 18.3	0.567
Effusion side, *n* (%):			0.188
Right side	19 (36.5)	16 (32.65)	
Left side	28 (53.8)	29 (59.18)	
Bilateral	5 (9.7)	4 (8.27)	
Type of pleural effusion, *n* (%):			0.206
Malignancy	25 (48.07)	23 (46.93)	
Parapneumonia	11 (21.15)	9 (18.36)	
Tuberculosis	8 (15.38)	6 (12.24)	
Other exudates	5 (9.61)	7 (14.28)	
Transudates	3 (5.82)	4 (8.19)	
Severity of pleural effusion (mean ± SD)	4.84 ± 1.73	4.79 ± 1.61	0.810
Drainage *n* (%)	31 (59.62)	29 (59.18)	0.859
Spirometric values (% predicted values) (mean±SD):			0.667
FVC	73.1 ± 12.6	72.7 ± 13.1	
FEV_1	72.13 ± 13.7	72.5 ± 11.8	
FEF 25-75%	64.8 ± 35.1	61.8 ± 30.2	

FVC %: predicted forced vital capacity, FEV_1%: predicted forced expiratory volume in first second, FEF_{25-75}: forced expiratory flow 25%-75%, SD: standard deviation, BMI: body mass index, *n*: number of subjects allocated in a group.

the length of hospital stay was shorter compared with the control group.

Several studies have shown physical therapy to be effective in the treatment of various respiratory conditions.[9,10,29,30] The general aim of a physiotherapy programme in critical areas is to apply advanced and cost-effective therapeutic modalities, decrease the dependence of patients, improve residual function, reduce the risk of new hospitalization and improve the quality of life.[31]

Physiotherapy has been proposed by some authors[32-34] as part of the treatment of a pleural effusion regardless of the etiology. In fact, various studies[33,34] have suggested that patients with pleural effusion should be included in a respiratory physiotherapy programme as early as possible. Yet, to our knowledge, no clinical trials focused on the effects of a physiotherapy programme in hospitalized patients due to a pleural effusion are available in the literature.

One of the most important goals of physical therapy related to hospitalization due to respiratory pathologies, even in highly compromised patients is to enhance their functional capacity and to decrease

Table 2. Outcome measures at baseline and after the intervention.

Clinical variables	Intervention group (n=52)				Control group (n=49)				Between groups *P*-value
	Pre-intervention	Post-intervention	Mean difference (95% CI)	Within group *P*-value	Pre-intervention	Post-intervention	Mean difference (95% CI)	Within group *P*-value	
Spirometric values (%predicted values)									
FVC	73.1 ± 12.6	81.66 ± 13.7	8.9 (−11.4, −6.47)	p<0.001	72.7 ± 13.1	73.6 ± 13.3	1.1(−2.3, 0.065)	0.062	0.001
FEV_1	72.13 ± 13.7	78.98 ± 16.9	6.77 (−9.6, −3.8)	p<0.001	72.5 ± 11.8	72.9 ± 12.6	0.068 (−2.3, 2.2)	0.952	0.198
FEF_{25-75}	64.8 ± 35.1	76.78 ± 35.3	14.8 (−39.3, 9.5)	0.198	61.8 ± 30.2	58.7 ± 29.8	3.04 (−0.76, 6.80)	0.114	0.001
X-ray severity of pleural efusión (0-10)	4.84 ± 1.73	2.78 ± 1.98	2.05 (1.35, 2.76)	p<0.001	4.79 ± 1.61	2.85 ± 1.39	1.94 (1.28, 2.6)	0.221	0.042
LOS (days)	–	26.7 ± 8.8	–	–	–	38.6±10.7	–	–	0.014

FVC: forced vital capacity, FEV_1: forced expiratory volume in first second, FEF_{25-75}: forced expiratory flow 25%-75%, LOS: length of hospital stay, *n*: number of subjects allocated in a group, CI: confidence interval, SD: standard deviation.

the risks associated with intensive care and bed rest.[35] In order to that, we included mobilization techniques and exercises to reduce the musculoskeletal complications due to the bed rest, and respiratory exercises to improve respiratory function.

The standard treatment includes drainage of the fluid accumulated in the pleural space. The aspiration of pleural fluid is associated with increase in the static lung volumes which were lower than the volume of fluid removed.[23,35] This indicates that pleural effusion cause a decrease in lung volume and chest wall expansion.[36] According to that, pulmonary function was included as a main outcome measure. No previous study has demonstrated that physiotherapy added to medical treatment and drainage improve the spirometric values. These results might be attributed to the effect of respiratory exercises on lung volume and chest wall expansion. The physical therapy intervention also induces an intrathoracic pressure generated in pursed lip breathing and in the incentive spirometry that may help the drainage.[23] It was shown a significant improvement in the severity of the pleural effusion based on chest radiographic findings in the intervention group.

Another point to mention is related to the length of hospital stay. Our study showed a reduced hospital stay in the intervention group compared with a control group. According to a number of studies, the reported mean length of hospital stay of patients with different pleural effusion etiologies ranges from 17 to 37 days.[37-39]

Ferguson et al.[37] analyzed 119 patients with purulent fluid; the mean time to discharge was 21 days when the drainage tube or the aspiration intervention was successful and 26 days when treatment was unsuccessful. Alfageme et al.[39] studied 82 patients with purulent or non-purulent fluid with a positive culture. The mean length of stay was 37 days, but patients with nosocomial infections or a bronchopleural fistula required significantly longer hospitalization. Interestingly, Ruiza et al.[5] explained the differences between the length of hospital stay in the different studies. The first important point to mention is the duration of the drainage and the second is the underlying and associated diseases.

Although no studies have assessed the influence of a physiotherapy intervention in length of stay,

our results showed a positive effect of respiratory physiotherapy on fluid removal and respiratory function and consequently, the length of stay was reduced.

A number of factors limit the general applicability of our study's findings regarding the efficacy of physiotherapy in patients with a pleural effusion. First, the diagnosis and evolution of pleural effusion was based on the presence of consistent radiological findings in posteroanterior and lateral chest and decubitus lateral radiographs[16,17] evaluated by a trained radiologist. However, previous research has shown this method to be accurate and reliable. A second limitation of our study was the lack of drainage duration and surgical procedures data. A third limitation of the current study was the absence of follow up after discharge. It is only reported the effectiveness pre to post intervention during the hospital stay.

In conclusion, this study shows that physiotherapy (deep breathing exercises, and mobilization techniques) combined with medical treatment and drainage in inpatients with a pleural effusion was associated to a reduced length of hospital stay and a better recovery (i.e., radiological repercussions and pulmonary function). These differences should be taken into account because they are both significant and clinically relevant.

Clinical messages

- A physiotherapy treatment based on mobilizations, deep breathing exercises and incentive spirometry, added to the standard treatment is feasible for patients with a pleural effusion, increasing the pulmonary function and reducing the hospital stay.
- There is an evidence of radiographic benefit of treatment with physiotherapy in patients with pleural effusion, decreasing the severity of this condition.

Conflict of interest

The authors declare that there is no conflict of interest.

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