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The Effects of 1 Year of Specific Inspiratory Muscle Training in Patients With COPD*

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Aim: **We assessed the long-term benefits of inspiratory muscle training (IMT) on inspiratory muscle strength, exercise capacity, the perception of dyspnea, quality of life, primary care use, and hospitalizations in patients with significant COPD.**

Patients: **Forty-two consecutive COPD patients with FEV_1 < 50% of predicted were randomized into a group that received IMT for 1 year, and a control group that received training with a very low load.**

Results: **There was a statistically significant increase in inspiratory muscle strength (at the end of the third month of training) as assessed by maximal inspiratory pressure (from 71 ± 4.9 to 90 ± 5.1 cm H_2O [± SEM], p < 0.005) and 6-min walk distance (at the end of the third month of training; from 256 ± 41 to 312 ± 54 m; p < 0.005), a decrease in the mean Borg score during breathing against resistance (at the end of the ninth month of training), improvement in the health-related quality-of-life scores (at the end of the sixth month of training) in the training group but not in the control group. At the end of the training year, these changes were maintained; in addition, a decrease in primary health-care use and hospitalization days was observed.**

Conclusions: **Our study shows that during IMT in patients with significant COPD, there is an increase in exercise capacity, improvement in quality of life, and decrease in dyspnea. Our study also provides evidence that long-term IMT can decrease the use of health services and hospitalization days.** ***(CHEST 2005; 128:3177–3182)***

Key words: COPD; inspiratory muscle training

Abbreviations: 6MWT = 6-min walk test; IMT = inspiratory muscle training; PImax = maximal inspiratory pressure; POD = perception of dyspnea; SGRQ = St. George's Respiratory Questionnaire

COPD is a major public health problem. It limits normal physical activities of daily living, affects quality of life, and is a major cause for hospital admissions.[1] Although there are many reasons to hospitalize patients with COPD, acute exacerbation due to bronchial infection is the major cause.[2] In addition, once a COPD patient is hospitalized and discharged, approximately one half of the patients are readmitted to the hospital during the following year.[3] Although medication may provide limited subjective benefit, many patients remain symptomatic with impaired quality of life.

The role of rehabilitation programs for improving health status in patients with COPD has been well established, and guidelines for rehabilitation have been published.[4,5] Despite the documented benefits of inspiratory muscle training (IMT) in a rehabilitation program, most rehabilitation programs are short term and last 4 to 12 weeks. Longer-term effects were less clearly defined, but it has been shown that the improvement in health status achieved during the training period gradually declines between 6 months and 12 months after the training program.[6–8] Long-term programs of rehabilitation are much less popular, and maintenance training is not applied.

Patients with significant COPD have inspiratory muscle weakness that may contribute to dyspnea and exercise intolerance.[9,10] Inspiratory muscle dysfunction appears to be the result of geometric changes of the thorax and diaphragm, systemic factors, and

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potential structural changes of the muscles.[11,12] Therefore, it was rational to try ventilatory muscle training in these patients in order to enhance respiratory muscle function and potentially reduce the severity of breathlessness and improve exercise tolerance.

IMT was extensively investigated in patients with COPD. The Joint American College of Chest Physicians/American Association of Cardiovascular and Pulmonary Rehabilitation Committee[4] declared that when the stimulus or load placed on the respiratory muscles during training is sufficient to augment inspiratory muscle strength, there is an associated increase in exercise capacity and decrease in dyspnea. However, as in the major rehabilitation programs, most of the IMT programs are short term and are not performed as a maintenance training. In a recent study[13] performed by our group, we showed that the benefits of the intensive basic IMT were not maintained beyond 6 months without maintenance training. Our study was not designed to determine whether domiciliary IMT reduced exacerbations or hospital admissions in COPD patients. In the present study, we hypothesized that long-term IMT for 1 year could significantly improve inspiratory muscle performance, the sensation of dyspnea, exercise performance, quality of life, and reduce use of health services and hospital admissions in patients with significant COPD.

Materials and Methods

Subjects

Forty-two consecutive patients, 32 men and 10 women, with spirometric evidence of significant chronic airflow limitation (FEV_1 < 50% of predicted, FEV_1/FVC < 70% of predicted) with a diagnosis of COPD according to the criteria of the American Thoracic Society[14] were recruited from the community. The patients were all new to an IMT program, and none were receiving additional regular exercise or dietary supplements. All were receiving regular long-acting bronchodilators, and 34 patients were receiving regular inhaled corticosteroids. The patients were observed during a 4-week run-in period, when their regular treatment was maintained, to verify stability in their clinical and functional status. Their characteristics are summarized in Table 1. Patients with cardiac disease and poor compliance and needing supplemental oxygen were excluded from the study.

Table 1—*Characteristics of Patients With COPD

Characteristics	IMT (n = 21)	Control (n = 21)
Age, yr	67.7 ± 3.6	66.9 ± 3.3
Male/female gender	17/4	15/6
Weight, kg	76.8 ± 3.2	74.3 ± 3.4
Height, m	1.69 ± 3.2	1.69 ± 3.4
FVC, L	2.31 ± 1.0	2.34 ± 0.9
% predicted	65 ± 4.4	68 ± 4.6
FEV_1, L	1.21 ± 0.4	1.26 ± 0.4
% predicted	42 ± 2.6	43 ± 2.5
Six-minute walk distance, m	256 ± 41	268 ± 43
PImax, cm H_2O	71 ± 4.9	67 ± 4.9
Current smokers	4	2
Ex-smokers	16	17
Previous admissions		
Patients	12	14
Total	22	20

*Values are expressed as mean ± SEM or No.

Study Design

All tests were performed before, and 3 months, 6 months, 9 months, and 12 months after starting the training period. The patients were randomized using a random-numbers table into two groups: a group of 21 patients assigned to receive IMT for the next year, and a group of 21 patients assigned as a control group who received training with very low load. In all patients, several practice tests were performed before the baseline value in order to correct a possible training and learning effect. All the data were collected by the same investigator, who was blinded to the training group, as well as by the patients themselves, who were also blinded to the mode of treatment. The study protocol was approved by the institutional ethics committee, and informed consent was obtained from all the subjects. The information about primary care consultation, hospital admissions, and length of hospitalization were self-reported by the patients and/or family members during the daily call by the physiotherapist.

Tests

Spirometry: FVC and the FEV_1 were measured three times on a computerized spirometer (Compact; Vitalograph; Buckingham, UK), and the best trial is reported.

Six-Minute Walk Test: The distance the patient was able to walk in 6 min was determined in a measured corridor as described for the 12-min walk test by McGavin and coworkers.[15] The patients were instructed to walk at their fastest pace and cover the longest possible distance over 6 min under the supervision of a physiotherapist. The test was performed twice, and the best result is reported.

Inspiratory Muscle Strength: Inspiratory muscle strength was assessed by measuring the maximal inspiratory pressure (PImax) at residual volume, as previously described by Black and Hyatt.[16] Mouth pressures were measured with a vacuumed mouthpiece (1002 mouthpiece; Vista; Ventura, CA), which has a small air leak to prevent pressure generation by glottis closure, connected to a pressure transducer (1050 BP transducer; Biopac Systems; Goleta, CA) and recorded on a strip chart recorder. The value obtained from the best of at least three efforts was used.

Dyspnea: The perception of dyspnea (POD) was measured while the patient breathed through the same device proposed by Nickerson and Keens.[17] The patients breathed against progressive resistance at 1-min intervals in order to achieve mouth pressures of 0 (no resistance), 5, 10, 20, and 30 cm H_2O. After breathing for 1 min in each inspiratory load, in a protocol similar to the one previously described by our group,[18] the patients rated the sensation of difficulty in breathing (dyspnea) using a modified Borg scale,[19] a linear scale of numbers ranking the magnitude of difficulty in breathing, ranging from 0 (none) to 10 (maximal).

Health-Related Quality of Life: Health-related quality of life was measured by the St. George's Respiratory Questionnaire (SGRQ).[20]

Training Protocol

All subjects trained daily in two sessions of 15 min each, six times a week for 12 months. The training was performed using a threshold inspiratory muscle trainer (POWERbreathe; Gaiam Ltd; Southam, Warwickshire, UK). The subjects started breathing at a resistance that required generation of 15% of PImax for 1 week. The load was then increased incrementally, 5 to 10% each session, to reach generation of 60% of PImax at the end of the first month. IMT was then continued at 60% of the PImax adjusted monthly to the new PImax achieved.

The training was performed in our rehabilitation center for 1 month under the supervision of a respiratory therapist followed by home training, verified by a respiratory therapist daily by phone and once weekly by a personal visit, for the next 11 months. The control group trained for the same sessions with a fixed load that required generation of mouth pressure of 7 cm H_2O.

Data Analysis

Comparisons of lung function, respiratory muscle strength and endurance, 6-min walk test (6MWT), and rating of dyspnea within and between the two groups were carried out using two-way analysis of variance with repeated measures. The results are expressed as mean ± SEM.

Results

There were no significant differences between the two groups in age, height, weight, mean baseline FEV_1 and FVC, PImax, 6MWT, and prior hospital admissions at the beginning of the study. Eleven patients dropped out of the study during the training period: 4 patients from the training group (2 of whom died) and 7 patients from the control group (4 of whom died). The attendance rate of the study was 63 ± 7% in the training group and 59 ± 8% in the control group ($p = 0.082$)

Spirometry

There was no statistically significant change in FEV_1 or FVC in the training and control groups.

Inspiratory Muscle Strength

After 3 month of training, there was a statistically significant increase in PImax in the training group (from 71 ± 4.9 to 90 ± 5.1 cm H_2O, $p < 0.005$) but not in the control group (from 66.7 ± 4.3 to 69.8 ± 4.5 cm H_2O, $p = 0.216$). During the next 9 months of the study, the training group continued to show a small increase in PImax (to 94.7 ± 5.0 cm H_2O, 97.2 ± 5.2 cm H_2O, 100.8 ± 5.1 cm H_2O after 6, 9, and 12 months, respectively), while there was almost no change in PImax in the control group, with a significant difference between the groups ($p < 0.01$). This difference was maintained until the end of the study period (Fig 1).

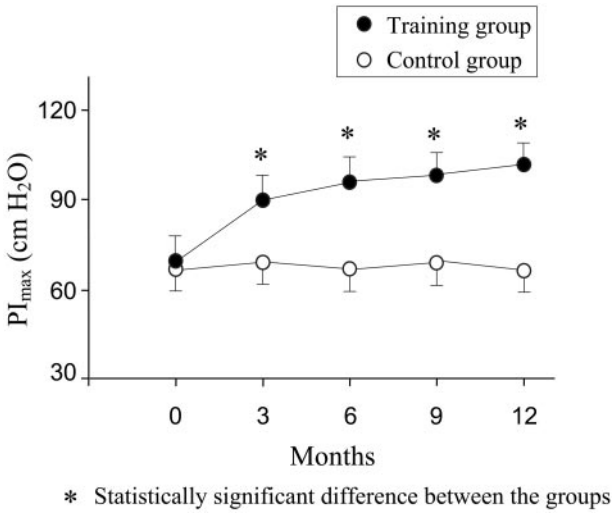

FIGURE 1. Inspiratory muscle strength as assessed by the PImax before and after the training period in the study group and in the control group. Already at the 3-month period, there was a significant difference between the groups ($p < 0.01$).

6MWT

After 3 months of training, there was a statistically significant increase in the 6MWT in the training group (from 256 ± 41 to 312 ± 54 m, $p < 0.005$) but not in the control group (from 268 ± 43 to 252 ± 44 m, $p < 0.005$). During the next 9 months of the study, the training group continued to show a small increase in the 6MWT (to 319 ± 47 after 6 months, 324 ± 47 after 9 months, and 328 ± 49 m at the end of the year), while there was almost no change in the 6MWT in the control group with a significant difference between the groups ($p < 0.01$). This difference

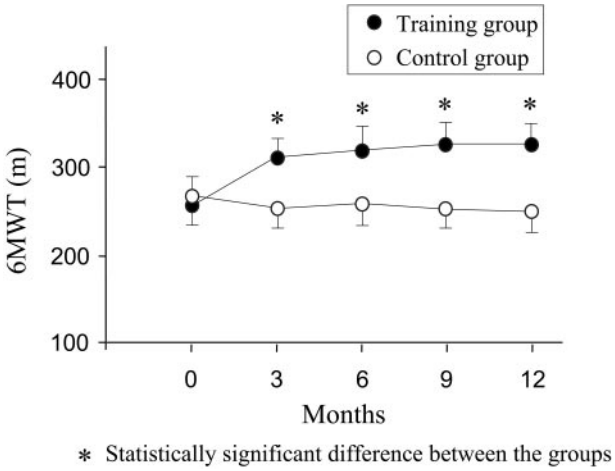

FIGURE 2. The mean ± SEM distance walked in 6 min before and after the training period in the study group and in the control group. Already at the 3-month period there was a significant difference between the groups ($p < 0.05$).

was maintained until the end of the study period (Fig 2). There was no statistical difference between the results after 6, 9, and 12 months and the results after 3 months.

POD

There was no difference in the POD between the two groups before training. Following training, there was a gradual decrease in the mean Borg score during breathing against resistance in the study group but not in the control group. The difference between the groups became statistically significant at the end of the ninth month ($p < 0.05$). This difference was maintained until the end of the study period (Fig 3).

Health-Related Quality of Life

Baseline health-related quality-of-life scores on the SGRQ were comparable between the groups. The total score significantly improved in the study group at the sixth month compared to baseline ($p < 0.05$) and compared to the control group ($p < 0.01$). This difference was maintained until the end of the study period (Fig 4).

There was no good correlation between the baseline PImax and the outcomes of the POD and 6MWT. However, there was a close correlation between the increase in PImax and the decrease in the mean Borg score during breathing against resistance ($r = 0.762$, $p < 0.01$) and between the increase in PImax and the increase in the 6MWT ($r = 0.536$, $p < 0.05$) in the training group.

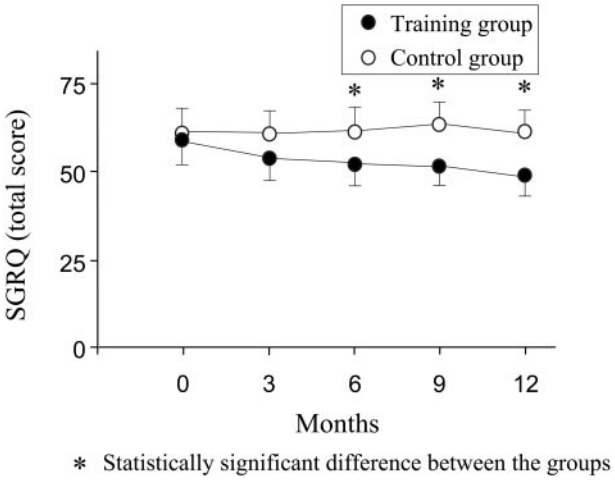

FIGURE 4. Changes in health-related quality-of-life scores determined by the SGRQ before and after the training period in the study group and in the control group. Already at the 6-month period there was a significant difference between the groups ($p < 0.05$).

Primary Care Consultation and Hospital Admissions

Eleven patients in the study group (18 admissions) and 13 patients in the control group (20 admissions) were hospitalized at least once during the study period. This difference did not reach statistical significance (Fig 5). There was a significant difference between the groups in the average days spent in the hospital (8.6 ± 1.0 days in the study group vs 11.1 ± 1.1 days in the control group, $p < 0.05$). The total time spent in the hospital was 156 days in the study group, compared to 222 days in the control

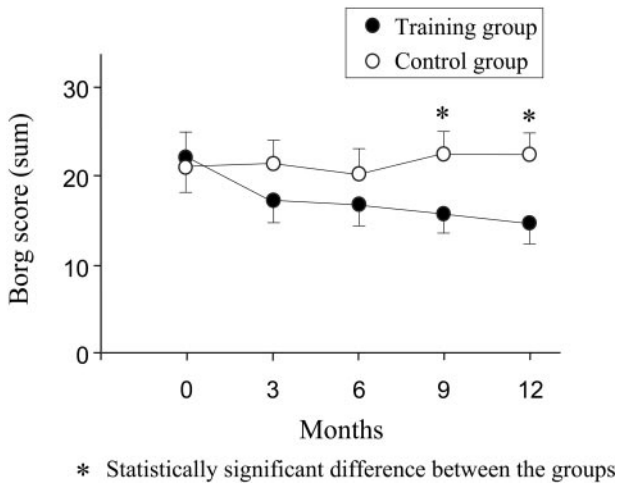

FIGURE 3. The mean ± SEM perception of dyspnea (Borg score) during breathing against load in all COPD patients before and after the training period. The difference between the groups became evident at the 9-month period ($p < 0.05$).

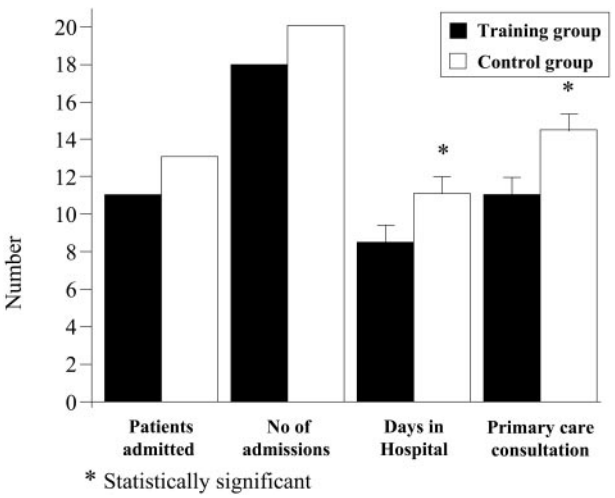

FIGURE 5. Hospital admissions, days spent in the hospital, and the use of primary-care consultations during the training period in the study group and in the control group.

group ($p < 0.01$). There was also a difference between the groups in the number of primary care use applications (11.2 ± 0.9 applications in the study group vs 14.5 ± 1.1 applications in the control group, $p < 0.05$).

Discussion

This study shows that in patients with significant COPD, long-term IMT results in an increase in the inspiratory muscle strength. This increase is associated with improved exercise performance, decrease in the sensation of dyspnea while breathing against resistance, improved quality of life, lower rate of primary care consultation, and fewer hospitalization days.

IMT has been extensively investigated in patients with COPD. More than a decade ago, Smith et al[21] published the first meta-analysis of IMT in patients with COPD. Their primary conclusion was that, "Overall, there is little evidence of clinically important benefit of respiratory muscle training in patients with chronic airflow limitation." However, Smith et al[21] did identify a moderate treatment effect for improved functional exercise capacity in five studies in which respiratory strength or endurance were improved.

Five years later, the Joint American College of Chest Physicians/American Association of Cardiovascular and Pulmonary Rehabilitation Committee[4] concluded that there was sufficient evidence to recommend IMT as part of a program of pulmonary rehabilitation. They concluded that in studies in which the stimulus or load placed on the respiratory muscles during training was sufficient to augment inspiratory muscle strength, there was an associated increase in exercise capacity and a decrease in dyspnea. Similarly, the findings of the most recent meta-analysis[22] of IMT in patients with COPD suggest that IMT reduces exertional dyspnea in patients with COPD.

Furthermore, and perhaps unsurprisingly, when dyspnea is attenuated, an associated effect of IMT is improved functional exercise capacity. In studies[23–27] that used appropriate selection criteria and in which post-IMT changes in exercise tolerance were assessed, most have found a significant improvement. The approximate 60-m increase in the 6-min walking distance observed in these studies was large enough to be considered as clinically relevant.[28] Overall, the literature suggests that when patients with ventilation limitation (minute ventilation/maximum voluntary ventilation > 75%, for example) undergo respiratory muscle training, a significant increase in functional exercise capacity is observed. Our results are in accordance with these results and with a previous study[13] of our group on the long-term effect of IMT on dyspnea and exercise tolerance in patients with significant COPD. In addition, these improvements were translated by the patients to a better quality of life following training.

A previous uncontrolled and retrospective study[29] found a significant decrease in hospitalization days after a rehabilitation program. However, no such differences in hospitalization days were demonstrated by others.[30] All of the data in the literature on the effect of rehabilitation program on hospital admissions of patients with COPD are related to a general rehabilitation program mixing different types of exercise. There are no data in the literature on the effect of long-term IMT alone on hospitalization of COPD patients.

Our results show that the number of days spent in the hospital by the training group was 30% less than the number of days spent by the control group. This difference was mainly due to the difference of 23% in the duration of hospitalization, while there was almost no difference in the number of patients admitted or in the total number of admissions.

The number of days spent in hospital was approximately one half in patients involved in rehabilitation as compared to a control group.[31] However, in this study,[31] the patients received a 6-week rehabilitation program, so on follow-up the difference between the control and rehabilitation groups became smaller with time. A domiciliary program such as ours may provide more sustained benefit over time.

We have also noticed a decreased rate of primary care consultations in the trained subjects. We could not distinguish between respiratory-related and nonrespiratory-related consultations. We are also unable to analyze the national health service implication of our results.

In conclusion, IMT has been extensively investigated in patients with COPD. It is now well established that when the training stimulus is adequate to augment inspiratory muscle strength, there is an associated increase in exercise capacity, improvement in quality of life, and decrease in dyspnea. Our study also provides evidence that long-term IMT can have benefits in terms of health status in patients with significant COPD, and to decrease the use of health services that might translate to economic benefits as well. Most patients will benefit from participating in a pulmonary rehabilitation program, and IMT should be integrated in such a program.

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