

Inspiratory Muscle Training with a Pressure Threshold Breathing Device in Patients with Chronic Obstructive Pulmonary Disease¹⁻³

JANET L. LARSON,⁴ MI JA KIM, JOHN T. SHARP, and DOUGLAS A. LARSON

Introduction

Inspiratory muscle training (IMT) with inspiratory loading is designed to improve strength and/or endurance of the inspiratory muscles in an attempt to improve respiratory muscle function in patients with chronic obstructive pulmonary disease (COPD). Recent research suggested that inspiratory muscle fatigue may limit exercise tolerance in these patients (1-3). If inspiratory muscle fatigue limits exercise tolerance, then improved strength and endurance of the inspiratory muscles may delay the onset of respiratory muscle fatigue and increase activity tolerance.

However, the effects of IMT have not been adequately tested, and findings have been inconsistent with respect to its effects on inspiratory muscle strength, respiratory muscle endurance, and general exercise tolerance. Some investigators reported an increase in both inspiratory muscle endurance and general exercise tolerance (4) but no change in inspiratory muscle strength (5). One investigator reported an improvement in dyspnea and general exercise endurance (6). In contrast, other investigators reported an increase in inspiratory muscle strength with no change in exercise tolerance (7-10), an increase in respiratory muscle endurance and no change in inspiratory muscle strength (11), no change in respiratory muscle endurance (12), and no change in either inspiratory muscle strength or respiratory muscle endurance (13). These inconsistencies can be explained in part because none of the above studies controlled for the magnitude of the inspiratory pressure load during training.

All of the above studies trained patients with nonlinear resistive breathing devices, which produce unreliable inspiratory pressure loads. With these devices, the inspiratory pressure load varies according to the size of the inspiratory orifice and the rate of inspiratory

SUMMARY The inspiratory pressure load is an important variable in inspiratory muscle training (IMT), but previous studies with chronic obstructive pulmonary disease (COPD) patients have not controlled for this variable. We compared the effects of two months of IMT with a pressure threshold breathing device at inspiratory pressure loads equal to either 15 or 30% of each patient's maximal inspiratory pressure ($P_{I_{max}}$). This study was double blind and patients were randomly assigned to the treatment groups, 12 in the 15% group and ten in the 30% group. Dependent variables were measured at baseline, and after one and two months of IMT. Patients who exercised with the 30% load improved the following: $P_{I_{max}}$ by a mean of -12 ± 9 cm H₂O ($p < 0.01$), endurance time while breathing against an inspiratory pressure load equal to 66% of $P_{I_{max}}$ by 5 ± 9 min ($p < 0.01$), and 12-min distance walk (12MD) by 199 ± 90 feet ($p < 0.01$). Patients who exercised with the 15% load demonstrated no improvements in $P_{I_{max}}$, endurance time, and 12MD. There were no changes in patients' report of functional impairment (Sickness Impact Profile), mood (Profile of Mood States), health status (Health Perceptions Questionnaire), and pulmonary symptoms (respiratory symptom log). We conclude that the 30% load was more effective than the 15% load in this sample.

AM REV RESPIR DIS 1988; 138:689-696

airflow. Two people training with the same size inspiratory orifice would be training with different inspiratory pressure loads if they used different inspiratory airflow rates. Consequently, with the nonlinear resistive breathing devices, there is no easy way to establish the magnitude of the inspiratory pressure load when patients train at home because their inspiratory airflow is likely to vary (13).

In the present study, we solved this problem by training patients with a pressure threshold breathing device, which produces reliable inspiratory pressure loads that were independent of airflow. The purpose of this study was to compare the effects of IMT with two inspiratory pressure loads, one equal to 15% and the other equal to 30% of the patient's maximal inspiratory pressure ($P_{I_{max}}$).

Methods

Patients with moderate to very severe COPD were recruited from the pulmonary clinic of a midwestern Veterans Administration Hospital and from the community by newspaper advertisements. The purpose, risks, and potential benefits of the study were explained to all patients, and they gave written consent to participate.

Patients were randomly assigned to train

with a threshold pressure breathing device at an inspiratory pressure load equal to either 15 or 30% of their individual $P_{I_{max}}$, and the investigator was blinded to patients' assignment to treatment group (table 1). The following dependent variables were measured at baseline, after one month of IMT, and after two months of IMT: $P_{I_{max}}$, endurance time while breathing against an inspiratory pressure load equal to 66% of $P_{I_{max}}$, and 12-min distance walk (12MD) (14). Patients also completed the following questionnaires at baseline and monthly throughout the study: Profile of Mood States (15), Sickness Impact

(Received in original form October 19, 1987 and in revised form March 22, 1988)

¹ From the College of Nursing, University of Illinois at Chicago, Chicago; the Pulmonary Division, Hines Veterans Administration Hospital, Hines; and Loyola Stritch School of Medicine, Loyola University Medical Center, Maywood, Illinois.

² Supported in part by Grant No. HL-31558 from the National Institutes of Health and by a grant from Sigma Theta Tau, Psi Chapter.

³ Requests for reprints should be addressed to Janet L. Larson, Ph.D., R.N., College of Nursing, University of Illinois at Chicago, 845 S. Damen Avenue, Chicago, IL 60612.

⁴ Recipient of National Research Service Award 5 F31 NU 05675-02, Division of Nursing, Public Health Service, U.S. Department of Health and Human Services.

TABLE 1
INSPIRATORY LOADS FOR INSPIRATORY
MUSCLE TRAINING*

	15% Group (cm H ₂ O)	30% Group (cm H ₂ O)
Month 1	-8 (2)	-18 (5)
Month 2	-9 (3)	-21 (6)

* All values are means (SD).

Profile (16), and Health Perceptions Questionnaire (17). Patients reported specific clinical symptoms on a daily log.

Additionally, we measured demographic data and pulmonary function tests, including lung volumes by helium dilution (Stead-Wells Modular Spirometer, Warren E. Collins, Braintree, MA) (18), spirometry (Gould 500 IV Computerized Pulmonary Function Lab; Gould Medical Products Division, Dayton, OH) (19), and arterial blood gases (Instrumentation Laboratory System 1303 pH/blood gas analyzer and the Instrumentation Laboratory System Co-Oximeter 282, Lexington, MA). We remeasured spirometry at the end of the study. Upon entry into the study, patients underwent a 2-wk control period during which they practiced the following tests: $P_{I_{max}}$, endurance time, and 12MD. During this period, patients performed these tests once a week for 3 wk and the third repetition was taken as the baseline measure.

Independent Variable

Inspiratory muscle training. Patients trained with a pressure threshold breathing device that could be adjusted to produce reliable inspiratory pressure loads (figure 1). This device was designed by an engineer, D. Larson, specifically for this study. In contrast to the currently available nonlinear resistive breathing devices, its major advantage is that it produces consistent inspiratory pressure loads regardless of the inspiratory flow rate.



Fig. 1. Pressure threshold breathing device.

The pressure threshold breathing device was constructed with a spring-loaded poppet valve that could be adjusted to produce inspiratory pressure loads ranging from -5 cm H₂O to -35 cm H₂O. To train with this device, patients had to generate a predetermined negative pressure with each inspiration to open the poppet valve and allow airflow. This pressure threshold breathing device had sufficient flow capacity to maintain a relatively constant inspiratory pressure load with flow rates as high as 3 L/s. At higher flows, the inspiratory pressure load increased by a maximum of 1 to 2 cm H₂O (figure 2).

Patients trained with this device for 15 min a day during the first week. They gradually increased the duration of each training session to 30 min a day for the remaining 7 wk. We monitored this process by asking them to record the duration of each training session on a daily log and we telephoned patients once a week until they reported they could accomplish the full 30 min with ease. This was de-

signed to both assist patients in performing the exercises and encourage compliance with the protocol. Patients were instructed to use a noseclip for all training sessions.

Dependent Variables

Inspiratory muscle strength. We measured the $P_{I_{max}}$ as an indicator of inspiratory muscle strength. The $P_{I_{max}}$ was defined as the maximal negative pressure that could be measured at the mouth when patients performed a maximal inspiratory effort against an occluded airway (20). Measurements were taken with a 2000-200-CM magnehelic pressure gauge (Dwyer Instruments, Michigan City, IN) with thick rubber tubing and a mouthpiece attached to its negative port. An 18-gauge needle was inserted in the proximal end of the tubing to assist patients in maintaining an open glottis during the maneuver. Calibration of the pressure gauge was verified against a water manometer. We measured $P_{I_{max}}$ from residual volume, and negative pressures

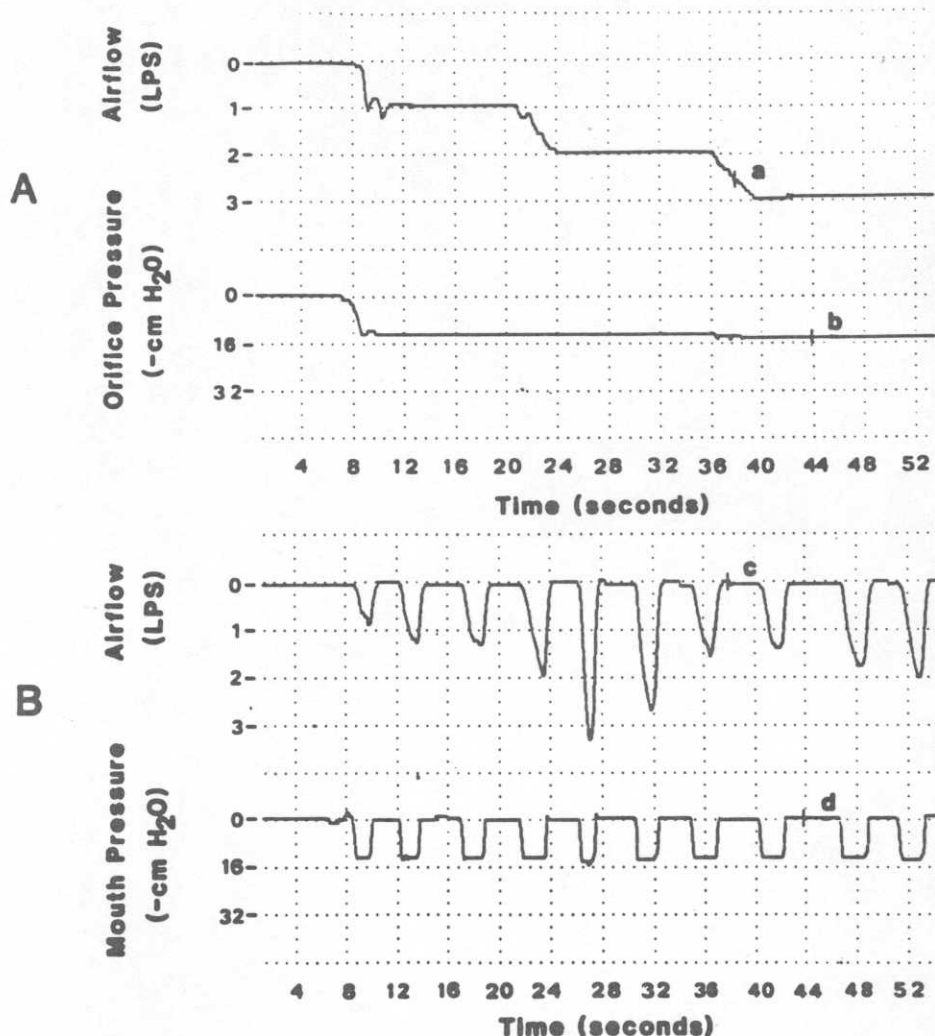


Fig. 2. Relationship between airflow and inspiratory pressure load of the pressure threshold breathing device. In Panel A, airflow was generated through the pressure threshold breathing device with a constant airflow generator, and pressure measured at the mouthpiece remained relatively constant despite a large increase in airflow. In Panel B, airflow was varied during normal breathing through the pressure threshold breathing device, and mouth pressure remained relatively constant.

had to be sustained for a minimum of one full second. Each measurement was taken a minimum of five times.

Respiratory muscle endurance. We measured the endurance time as an indicator of respiratory muscle endurance. The endurance time was defined as the maximal duration for which patients could breathe against an inspiratory pressure load equal to 66% of their $P_{I_{max}}$. The absolute inspiratory pressure load for this test increased as $P_{I_{max}}$ increased throughout the study. We used the device designed by Nickerson and Keens (21). This device is a pressure threshold breathing device, and its inspiratory orifice is occluded by a weighted plunger so patients must generate enough negative pressure to lift the plunger and allow inspiratory flow. It can be adjusted to produce inspiratory pressure loads ranging from -5 cm H_2O to -90 cm H_2O .

To perform the test, patients first warmed up by breathing against an inspiratory pressure load equal to 15% of their $P_{I_{max}}$ for 5 min. After the warm-up, they were presented with the test load (66% of $P_{I_{max}}$) and instructed to breathe against that load for as long as they could, until they became so tired they could not continue or until they were unable to get enough air. In either case, they were to perform the best they could for that day. The same precise directions were given at each test. During the test, we monitored oxygen saturation by ear oximetry (Biox IIA; Biox Technology, Denver, CO) and we asked patients to rate their perceived effort on a Borg Scale every 3 min (22).

Because performance on the endurance test could vary depending on the breathing pattern adopted (23, 24), we measured inspiratory time (T_i) and total duration of each respiratory cycle (T_{tot}) to verify that there were no significant differences in breathing patterns from test to test. These data were measured from graphic recordings of airflow as measured at the mouth with a Fleisch pneumotachograph and Validyne differential pressure transducer, DP45-16 (Validyne Engineering Corp., Northridge, CA), which was connected in series with the Nickerson and Keens pressure threshold breathing device. These data were used to calculate a tension time index (TTI) for the inspiratory muscles during each endurance test. The TTI was calculated as the product of the mean inspiratory mouth pressure (expressed as a fraction of $P_{I_{max}}$) and the ratio of T_i/T_{tot} in a manner similar to Bellemare and Grassino (23).

General exercise tolerance. We assessed patients' exercise tolerance or ability to function physically by measuring the maximal distance each patient could walk on a level surface in 12 min according to the method of McGavin and coworkers (14). This test required a prolonged submaximal effort that reflected patients' functional ability. It tested patients with an activity that was familiar, and it could be used even in severely limited patients.

The 12MD was conducted in a quiet, temperature-controlled hospital corridor

where the investigator instructed patients to walk as far as possible in 12 min. Patients were allowed to slow down or stop and rest if necessary, but rest time was included as part of the 12 min. Oxygen saturation was assessed at the beginning and end of the first practice test, and further tests were conducted with oxygen if oxygen saturation fell below 85%.

Affective moods. We administered the Profile of Mood States questionnaire to determine if IMT would improve patients' moods. The Profile of Mood States questionnaire reflects patients' perception of the following affective states: Tension-Anxiety, Depression-Dejection, Anger-Hostility, Vigor, Fatigue-Inertia, and Confusion-Bewilderment. It is a list of 65 adjectives, each with a 5-point rating scale (not at all, a little, moderately, quite a bit, extremely) to which patients respond by selecting the modifier that best describes how they felt over the past week. This instrument has been used extensively and is both reliable and valid (15).

Functional impairment. The Sickness Impact Profile was administered to determine if patients' perception of their functional impairment was influenced by IMT. The Sickness Impact Profile consists of 136 items in 12 scales: Ambulation, Mobility, Body Care and Movement, Social Interaction, Communication, Alertness Behavior, Emotional Behavior, Sleep and Rest, Eating, Work, Home Management, Recreation and Pastimes. Items describe dysfunctional behaviors, and patients identify those dysfunctional behaviors that describe them and are related to their state of health. Reliability was established with test-retest reliability coefficients of $r = 0.92$, and validity was established in a variety of populations (16).

General health status. The Health Perceptions Questionnaire was administered to evaluate the effects of training on patients' perception of their general health status. The Health Perceptions Questionnaire contains 35 items that reflect patients' assessment of six constructs of general health: Current Health, Prior Health, Health Outlook, Resistance to Illness, Health Worry/Concern, and Sickness Orientation (17). The reliability and validity of this instrument was established in a large national sample that supported its ability to evaluate changes in health over time (17).

Clinical symptoms. Patients reported their clinical symptoms and use of the pressure threshold breathing device on a daily log. They rated the intensity of each of the following symptoms on a 5-point scale (0 = none, 1 = a little, 2 = moderate, 3 = quite a bit, 4 = severe, 5 = most severe): shortness of breath, wheezing, cough, difficulty expectorating sputum, and fatigue. In addition, they reported the duration of each training session.

Sample

Patients meeting the following criteria were eligible for participation: (1) FEV₁ < 65% predicted, and (2) stable condition. Patients with a recent history of exacerbation were allowed to enter the study only after they report-

ed that their ability to function and day-to-day symptoms had returned to baseline. All patients were enrolled more than two months after recovery from an exacerbation except one who enrolled one month after recovery from an exacerbation because he insisted that his breathing would not improve any further. Patients were advised against participation if they indicated that the 12MD was too strenuous. Patients were excluded if they demonstrated evidence of restrictive lung disease based on lung volumes, if they had a history of asthma, and if they had a history of cardiovascular disease or musculoskeletal conditions that could interfere with either the training or testing maneuvers. Patients were also excluded if they were taking psychotropic drugs or abusing alcohol. Patients were dropped from the study if they: experienced an exacerbation, required a change in their pharmacologic regimen, or reported less than 80% compliance with the training protocol.

All pulmonary function tests were conducted with patients taking their routine pharmacologic regimens because many patients could not tolerate withholding medication prior to testing. All pulmonary function tests and measures of the dependent variables were taken at the same time of day for each individual patient. This was necessary to avoid the effects of fluctuating drug levels throughout the day.

Procedures

At each visit, data were collected in the same sequence. The $P_{I_{max}}$ was measured first and this was followed by the test of endurance time. Patients were then given a minimum of 20 min of rest prior to performing the 12MD. All tests were conducted by one investigator, and the same precise directions were given with each test. All appointments were made for the same time of day, and the time was determined by each patient's report of when they felt the best.

The baseline Profile of Mood States questionnaire was administered at the first visit, and the remaining questionnaires were administered in random order during the 20-min rest periods of subsequent visits. When this time was not sufficient, questionnaires were sent home and patients were instructed to keep their answers confidential from family members and return them via mail within two days. The same procedures were followed after 1 and 2 months of IMT. By sending questionnaires home with patients, we limited the duration of each visit and reduced the potential confounding effects of fatigue on the questionnaire data. All questionnaires were completed and returned in a timely manner.

Random assignment to the treatment group was conducted by a person who was not involved with the study, and patients were instructed about the double-blind nature of the study.

Data Analysis

Data for $P_{I_{max}}$, endurance time, 12MD, and questionnaires were analyzed by analysis of

TABLE 2
SAMPLE CHARACTERISTICS*

	15% Group	30% Group	p Value
Age, yr	68 (3)	60 (6)	< 0.01
FEV ₁ , % pred	27 (11)	36 (20)	NS
FEV ₁ /FVC	33 (9)	38 (11)	NS
FRC, % pred	135 (35)	130 (34)	NS
TLC, % pred	109 (19)	112 (20)	NS
Oxyhemoglobin, % saturation	92 (3)	94 (2)	NS
PaO ₂ , mm Hg	67 (9)	76 (6)	< 0.05
PaCO ₂ , mm Hg	42 (5)	40 (5)	NS
Weight/height, pounds/inches	2.3 (0.3)	2.2 (0.4)	NS

* All values are means (SD).

variance for repeated measures with one grouping factor and one within factor (25, 26). Data were grouped according to treatment group (grouping factor) and duration of treatment (within factor). The total variance in each dependent variable was broken down into effects accounted for by the treatment group, and effects accounted for by the duration of treatment. Interactions between the two main effects of treatment group and duration of treatment were examined to identify changes that occurred over time in one group but not the other. When significant differences were found, unplanned post hoc comparisons were conducted with the T-method (26). Some data were missing because it was not always possible to reschedule tests when patients failed to perform at maximal level.

Data from baseline pulmonary function tests were analyzed with descriptive statistics, and the relationships between baseline pulmonary function tests and improvement after IMT were analyzed with Pearson's correlation (26). Pulmonary function tests at baseline and after two months of IMT were compared with paired *t* tests.

Data from patient's daily log of clinical symptoms were collapsed into weekly averages for each symptom. Log data collected during the first control week were discarded to avoid confounding effects associated with the novelty of completing the logs. The col-

lapsed data from control Week 2 and training Weeks 1 through 8 were analyzed with Friedman's test for multiple matched groups (27).

Results

A total of 22 patients (20 men, 2 women) completed the study. Twelve trained with the lighter inspiratory pressure load (15% P_Imax), and ten trained with the heavier inspiratory pressure load (30% P_Imax). There were few significant differences between the two groups at baseline, and these data are summarized in table 2. The sample was middle class as indicated by the Hollingshead Four Factor Index of socioeconomic status (28). Most patients had severe COPD, and most patients were taking standard pharmacologic regimens such as inhaled beta agonists, oral beta agonists, and methylxanthines. One patient used home oxygen, and four patients had arterial CO₂ greater than 45 mm Hg (two in each group). There were no significant differences between the two groups for questionnaire data at baseline, so both groups were combined and only selected scales are reported in table 3 because of space limitations.

The analysis of variance demonstrated no significant difference for P_Imax between treatment groups or for the interactions between treatment group and duration of treatment. However, there was a significant difference for the duration of treatment (*p* < 0.01). Post hoc comparisons with the T-method demonstrated no significant change in P_Imax for the group that trained with the 15% load, but there was a significant increase in P_Imax for the group that trained with the 30% inspiratory load (*p* < 0.01) (figure 3, table 4). Patients who trained with the 30% inspiratory pressure load increased their P_Imax by a mean of -12 cm H₂O after one month of training, with no further increase after the second month of training. Post hoc comparisons demonstrated no significant difference between the groups for P_Imax at baseline, but after both one month and two months of inspiratory training, the patients who exercised with the 30% inspiratory load had significantly higher P_Imax than did the patients who exercised with the 15% load (*p* < 0.01).

The data for the test of endurance time were transformed with a log transformation to meet the assumptions of analysis of variance (26). For the transformed data, there was no significant difference between treatment groups and no significant difference for interaction between treatment group and duration of treatment. However, there was a significant difference for the duration of treatment (*p* < 0.01). Post hoc comparisons with the T-method demonstrated no significant change in endurance time for the group that trained with the 15% inspiratory pressure load, but there was a significant increase in endurance time for the group that trained with the 30% in-

TABLE 3

SAMPLE CHARACTERISTICS AS REPORTED BY PATIENTS ON QUESTIONNAIRES*†

Hollingshead Index	35 (9)
Sickness Impact Profile (% functional impairment)	
Psychosocial dimension	7 (6)
Physical dimension	4 (4)
Total sickness impact profile	9 (6)
Profile of Mood States (raw score)	
Tension-anxiety	10 (6)
Depression-dejection	10 (10)
Anger-hostility	10 (7)
Health Perceptions Questionnaire (raw score)	
Current health	24 (3)
Prior health	9 (2)

* All values are means (SD).

† Selected scales were reported here, but complete data available upon request to the first author.

TABLE 4
DESCRIPTIVE STATISTICS FOR MAXIMAL INSPIRATORY PRESSURE, ENDURANCE TIME, AND 12-MIN DISTANCE WALK*

	n	Baseline	Month 1 IMT†	Month 2 IMT†
Maximal inspiratory pressure, cm H ₂ O				
15% group	11	-53 (16)	-61 (16)	-60 (15)
30% group	10	-61 (17)	-75 (18)‡§	-73 (19)‡§
Endurance time, min				
15% group	10	5.4 (4.9)	5.1 (5.4)	6.8 (4.0)
30% group	9	6.7 (5.5)	9.3 (8.0)	12.1 (12.2)¶
12-min distance walk, feet				
15% group	12	2,549 (420)	2,544 (466)	2,601 (437)
30% group	8	2,588 (471)	2,813 (497)¶¶	2,787 (467)¶¶

* All values are means (SD).

† Inspiratory muscle training (IMT).

‡ Baseline compared to either one or two months of IMT; *p* < 0.01.

§ 30% group compared to 15% group; *p* < 0.01.

¶ 30% group compared to 15% group; *p* < 0.05.

¶¶ Baseline compared to either one or two months of IMT; *p* < 0.05.

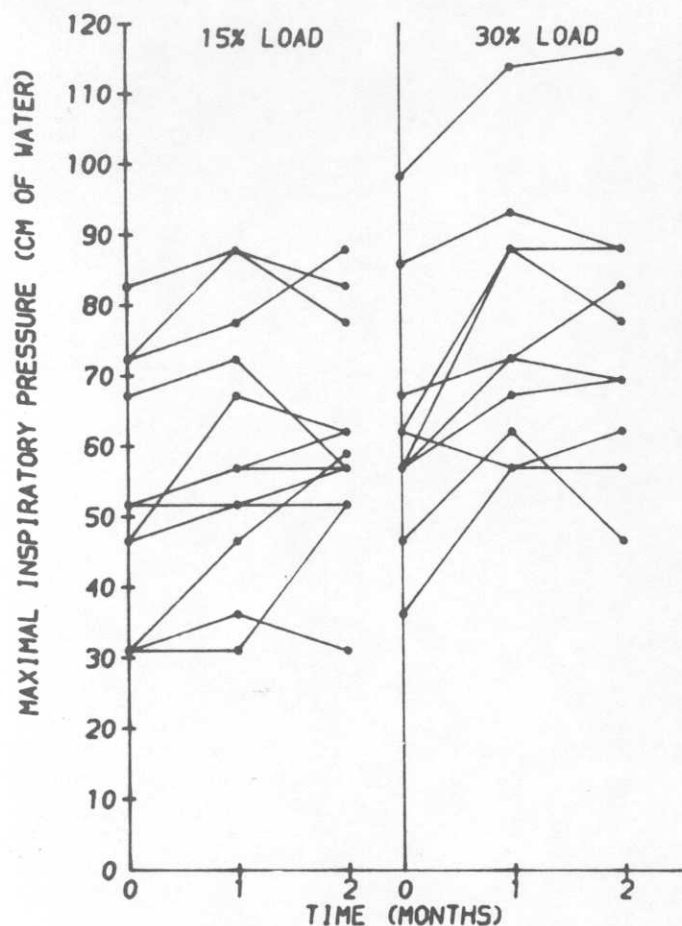


Fig. 3 (left). Repeated measures of P_Imax in both groups of patients.

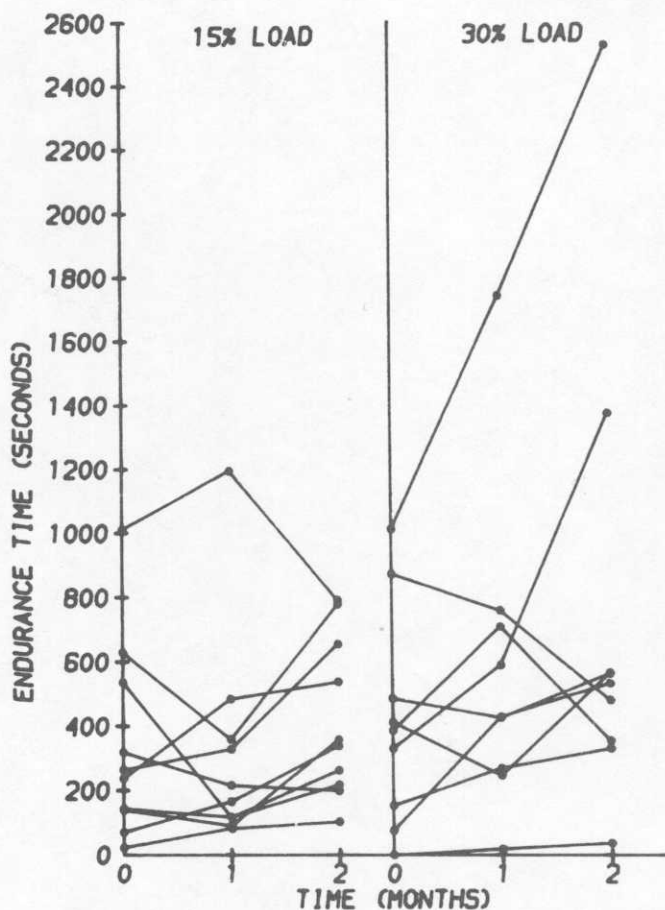


Fig. 4 (right). Repeated measures of endurance time in both groups of patients.

spiratory pressure load (figure 4, table 4). Patients who trained with the 30% load had no change in endurance time after one month of IMT, but increased endurance time by a mean of 5 min after two months of IMT ($p < 0.05$). Repeated measures analysis of variance demonstrated no significant differences in the breathing pattern during repeated tests of endurance time (table 5).

The oxyhemoglobin saturation routinely increased during the test of endurance time, but it often declined by 1 or 2% just before patients terminated the test. At the point where they terminated the test, patients reported an average intensity of effort between strong and very strong on the Borg Category-Ratio Scale.

For 12MD there was no significant difference between groups, but there was a significant difference for duration of treatment ($p < 0.01$) and for the interaction between treatment group and duration of treatment ($p < 0.01$). Post hoc comparisons demonstrated no change in 12MD for the group that trained with the 15% inspiratory pressure load, but there

was a significant increase in 12MD for the group that trained with the 30% inspiratory pressure load (figure 5). Patients who trained with the 30% load increased their 12MD after one month of IMT ($p < 0.05$), with no further increase at the end of two months of IMT. Their 12MD increased by a mean of 199 feet. There was no significant difference be-

tween the groups at baseline for 12MD, but after both one and two months of IMT, the groups that trained with the 30% load had significantly higher 12MD than the group that trained with the 15% inspiratory load ($p < 0.05$). In the group that trained with the 15% inspiratory pressure load, one patient desaturated during the initial practice test and was

TABLE 5
MOUTH PRESSURE AND BREATHING PATTERNS MEASURED DURING THE TEST OF ENDURANCE TIME*†

Exercise Group	n	Baseline	Month 1 IMT	Month 2 IMT	p Value
Mouth pressure, cm H ₂ O					
15% load	9	-37 (10.7)	-42 (10.1)	-42 (8.6)	< 0.05
30% load	9	-40 (11.8)	-51 (11.8)	-49 (12.4)	< 0.01
Ti/Ttot					
15% load	9	0.349 (0.116)	0.320 (0.081)	0.295 (0.075)	NS
30% load	9	0.302 (0.085)	0.256 (0.077)	0.255 (0.080)	NS
Tension-time index					
15% load	9	0.230 (0.077)	0.212 (0.053)	0.195 (0.049)	NS
30% load	9	0.195 (0.058)	0.165 (0.043)	0.163 (0.048)	NS

* All data are means (SD).

† Tension-time index was calculated as the product of Ti/Ttot and the inspiratory load (expressed as a fraction of P_Imax).

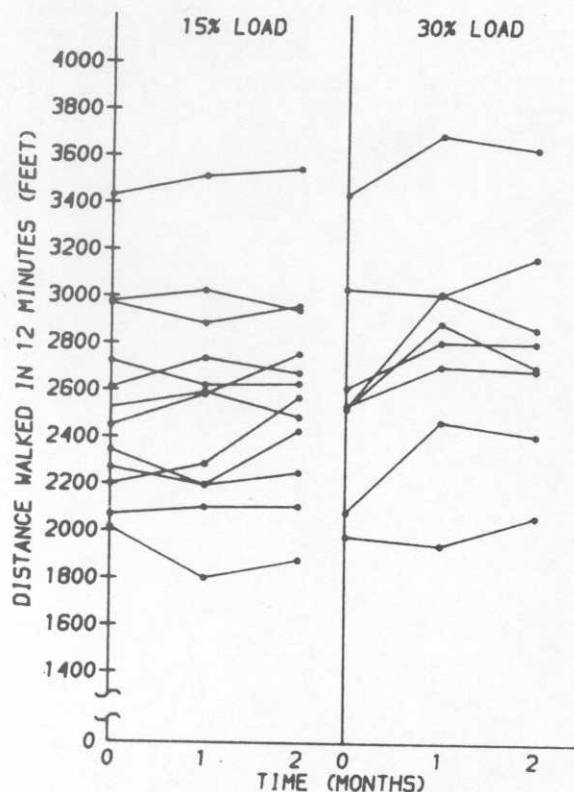


Fig. 5. Repeated measures of 12-min distance walk in both groups of patients.

walked on subsequent tests with O_2 at 2 L/min.

There were no significant differences in FEV_1 or FVC following IMT. Change scores were calculated for $P_{I_{max}}$, endurance time, and 12MD by subtracting baseline measures from those taken after two months of IMT. In patients who trained with the 30% inspiratory pressure load, baseline FRC correlated positively with improvement in $P_{I_{max}}$ ($r = 0.51$, $p > 0.05$) and 12MD ($r = 0.69$, $p < 0.05$), but it correlated negatively with improvement in endurance time ($r = -0.70$, $p < 0.05$).

For both groups, there were no changes in the following: Profile of Mood States, Sickness Impact Profile, and Health Perceptions Questionnaire. There were no significant differences in either group among scores at baseline and during each week of IMT on the symptoms of shortness of breath, wheezing, coughing, difficulty expectorating sputum, and fatigue ($p > 0.05$) as reported in the daily log.

Forty-five patients completed the control period, but only 22 completed the study. Of the 23 who did not finish, 15 dropped out before completing one month of IMT, four dropped out before completing two months of IMT, and four completed two months of IMT but their data were discarded either because of exacerbations or insufficient compliance. Most patients dropped out during IMT

for reasons that were beyond their control, including exacerbations of COPD and unrelated health problems.

The dropouts were compared to those who completed the study to determine if there were significant differences in patient characteristics that would explain the high dropout rate. Independent t tests identified no significant differences in the means for the following variables: age, FEV_1 , percent predicted, TLC percent predicted, P_{aCO_2} , P_{aO_2} , 12MD, $P_{I_{max}}$, endurance time; Profile of Mood States scales for Fatigue-Inertia, Vigor, Depression-Dejection, Tension-Anxiety; Sickness Impact Profile scores for the Physical Dimension, Psychosocial Dimension, and Total Sickness Impact Profile; and Health Perceptions Questionnaire scale for Current Health. Furthermore, the dropout rate was not affected by the assigned training load because similar numbers dropped out of each group. Of the 19 who dropped out before the end of two months of IMT, nine were assigned to train with the 30% inspiratory pressure load and ten were assigned to train with the 15% inspiratory pressure load.

Discussion

Patients who trained with the lighter inspiratory pressure load demonstrated no improvement in inspiratory muscle strength, respiratory muscle endurance,

and general exercise tolerance. However, patients who trained with the heavier inspiratory pressure load increased all three parameters.

At the time of this report, we are aware of only two studies that trained the inspiratory muscles with a pressure threshold breathing device. The first was Clanton and coworkers (29), who trained normal subjects for strength by training them with heavy inspiratory pressure loads for very brief periods. They increased the training load with each training session as long as subjects could maintain adequate tidal volumes. This protocol was so different that it cannot be compared to the present study. The second was Goldstein and colleagues (30), who trained COPD patients with the highest inspiratory pressure load that could be tolerated for 10 min. They have not yet published their work in detail, hence results cannot be compared. However, our results can be compared to the effects of IMT with nonlinear resistive breathing devices.

Our results are generally consistent with some of the findings of previous investigators who trained patients with nonlinear resistive breathing devices. As indicated earlier, investigators reported inconsistent improvements in inspiratory muscle strength, respiratory muscle endurance, and general exercise tolerance, but the present study is the first to demonstrate an increase in inspiratory muscle strength, respiratory muscle endurance, and general exercise tolerance in the same group of patients. This may in part be accounted for by the nature of the training. With the threshold pressure breathing device, patients trained with a consistent inspiratory pressure load, whereas with the nonlinear resistive breathing devices, patients could adjust their inspiratory pressure load by adjusting their airflow, so their inspiratory pressure load was not precisely known (13). Because it is difficult to quantify the actual inspiratory pressure load of a nonlinear resistive breathing device in the home setting, it is possible that our patients trained with heavier pressure loads.

The two groups of patients in this study were significantly different from each other with respect to age and P_{aO_2} . The group that trained with the 15% inspiratory pressure load was slightly older and their resting P_{aO_2} was slightly lower than the other group. However, it is unlikely that the difference in P_{aO_2} affected results because O_2 saturation increased as patients hyperventilated during tests of respiratory muscle endurance

and during the IMT exercises. The lower P_{aO_2} could have influenced the 12MD if those subjects were prone to desaturate, but we monitored this and administered O_2 during all 12MD tests to the one subject in the group with the 15% inspiratory load who desaturated. Moreover, in the group that exercised with the 30% inspiratory pressure load, there were no significant correlations between age and changes in 12MD ($r = -0.45$), $P_{I_{max}}$ ($r = -0.46$), and endurance time ($r = 0.14$). Similarly, there were no significant correlations between P_{aO_2} and changes in 12MD ($r = 0.16$), $P_{I_{max}}$ ($r = -0.19$), and endurance time ($r = 0.15$). Similar relationships were observed for the group that exercised with the 15% load and for the combined groups. Because the differences in both age and P_{aO_2} were relatively small and there were no differences in other variables such as spirometry and lung volumes, it is not plausible that these differences influenced the results.

The clinical significance of the observed changes remains to be determined. The -12 cm H_2O increase in $P_{I_{max}}$ for the group that trained with the 30% inspiratory pressure load was a modest improvement. It is not plausible that these data represent a learning effect in performing the $P_{I_{max}}$ maneuver because of the practice sessions. During the first and second visit of the control period, $P_{I_{max}}$ increased significantly ($p \leq 0.05$), but there was no further increase with the third visit.

Improvement in $P_{I_{max}}$ plateaued after one month of IMT and this may be explained by the nature of the inspiratory load. For every 10 cm H_2O increase in $P_{I_{max}}$, the training load was increased by approximately 3 cm H_2O to maintain the training load at 30% of $P_{I_{max}}$. Hence, patients were given relatively small increases in training load, and it is possible that further improvements in strength may have been elicited by heavier training loads. However, clinical impressions lead us to believe that an inspiratory pressure load equal to 30% of the $P_{I_{max}}$ was a substantial training load. These impressions were verified by patients at the end of the study when asked if they would like to train with a heavier load. All patients who trained with the heavier load said they did not want to increase the training load, whereas most patients who trained with the lighter load said they would like to increase the training load.

The increase in endurance time was modest, but the inspiratory pressure load on this test was increased as individual patients increased their $P_{I_{max}}$. This was

done to isolate the effects of muscle strength and endurance. Hence, patients improved their performance on the test of endurance time while breathing against higher absolute inspiratory pressure loads. The magnitude of improvement was similar to the findings of Chen and coworkers (31) with a similar test following a combination of bicycle training and IMT with a nonlinear resistive breathing device. There were no significant differences between the two groups after IMT, and this suggests that the improvements observed in the group that trained with the 30% inspiratory pressure load were not dramatic.

Performance on the test of endurance time could improve if patients used a shorter duty cycle and lower inspiratory flow rates during the test (23, 32). The work of Clanton and colleagues suggests that the most important of these two variables is duty cycle (24). We observed no significant change in duty cycle from test to test; hence, this could not account for the improved performance. We did not monitor inspiratory airflow, but patients were given identical directions for performing the test and we have no reason to believe that it would have changed from test to test. However, we recognize this as a limitation of our data.

With endurance tests of this nature, one must always be concerned with the effects of motivation on performance. We limited the effects of this variable by giving the same precise directions to each patient, randomly assigning subjects to their training group, and blinding both the investigator and patients to group assignment. In general, our subjects were highly motivated, and the fact that all subjects were training with an inspiratory pressure load helped maintain the high level of motivation and limit the risk of demoralization in the control group.

The change in 12MD was modest, but it was consistent with the changes observed by others after IMT (4, 5, 9, 10). The improvement in 12MD was also similar to the improvement observed after other forms of therapies such as oxygen (33, 34), aminophylline and salbutamol (35), promethazine (36), and general exercise rehabilitation (37-39). It remains unclear though whether the effects of any of these interventions would be additive. In contrast, it could be that any one of the above interventions will improve performance to this level but no further.

Patients' moods were measured because it has been reported that patients with COPD have disturbances in their moods (40), and it was anticipated that

moods may improve if patients felt better after IMT. However, when compared to published normative data, this sample of COPD patients did not report significant mood disturbance on the baseline Profile of Mood States questionnaire (15). Hence, it is understandable that they would not experience improvements. This data must be interpreted with caution, though, because the published norms are for psychiatric outpatients and college-age students.

This sample reported moderate levels of functional impairment on the Sickness Impact Profile at baseline, and they reported lower scores for Current Health than the general population (17). Even though there was no systematic improvement in reported functional impairment, health status, or symptoms, many patients reported anecdotally that the training was helpful. We suspect that if any of these factors improved with IMT the improvements were very subtle and the instruments that we used were not sensitive enough to detect them.

The dropout rate was high in this study, but it was similar to the experiences of other investigators (5, 13). We found no difference between those who completed the study and those who dropped out. Hence, it seemed to be a problem associated with longitudinal research in this elderly chronically ill population rather than a response to the experimental intervention.

For the patients who trained with the 30% inspiratory pressure load, the FRC was positively associated with improvement in inspiratory muscle strength and general exercise tolerance, but negatively associated with improvement in respiratory muscle endurance. This suggests that factors such as hyperinflation may influence the patients' response to IMT, but this was a small group of patients and no generalizations can be made. Further work needs to be done in this area to determine which patients are most likely to benefit from this type of training.

We used an experimental design that was double blind with patients randomly assigned to treatment groups, and this strengthens our claim that the differences between the groups were a result of the differences in inspiratory pressure loads during training. However, it is not sufficient evidence to claim that the improved strength and endurance of the respiratory muscles accounted for the improvements in 12MD. There are other mechanisms that may also account for the observed results. Inspiratory muscle training may improve neuromuscular coordina-

tion, so patients can consciously breathe deeper and slower when exerting themselves. This would decrease inspiratory time and increase the time available for expiration. Inspiratory muscle training may desensitize patients to the fear of dyspnea, so they are no longer afraid to push themselves to higher levels of activity. These issues were not addressed by the present study, but they need to be explored further.

In summary, we trained patients with a pressure threshold breathing device that allowed us to compare the effects of IMT with two inspiratory pressure loads. Those who trained with the heavier inspiratory load improved their ability to perform tests of inspiratory muscle strength, respiratory muscle endurance, and general exercise tolerance. These results are promising, but many questions remain unanswered regarding the effects of IMT. We feel that a reliable inspiratory pressure training load is very important and remaining questions about the potential effects of IMT will best be answered with further research that employs IMT devices similar to the one we used.

References

1. Bye PTP, Esau SA, Walley KR, Macklem PT, Pardy RL. Ventilatory muscles during exercise in air and oxygen in normal men. *J Appl Physiol* 1984; 56:464-71.
2. Grassino A, Gross D, Macklem PT, Roussos C, Zigelbaum G. Inspiratory muscle fatigue as a factor limiting exercise. *Bull Eur Physiopathol Respir* 1979; 15:105-11.
3. Martin B, Heintzelman M, Chen H-I. Exercise performance after ventilatory work. *J Appl Physiol* 1982; 52:1581-5.
4. Sonne LJ, Davis JA. Increased exercise performance in patients with severe COPD following inspiratory resistive training. *Chest* 1982; 81:436-9.
5. Pardy RL, Rivington RN, Despas PJ, Macklem PT. Inspiratory muscle training compared with physiotherapy in patients with chronic airflow limitation. *Am Rev Respir Dis* 1981; 123:421-5.
6. Falk P, Eriksen A-M, Kolliker K, Andersen JB. Relieving dyspnea with an inexpensive and simple method in patients with severe chronic airflow limitation. *Eur J Respir Dis* 1985; 66:181-6.
7. Williams M, Kim MJ, Larson J, Semerdjian RA. The effects of resistive breathing training on strength and endurance of the respiratory muscles (abstract). *Am Rev Respir Dis* 1984; 129(Suppl:A128).
8. Altose MD, Kendis C, Connors AF, DiMarco AF. Comparison of the effects of inspiratory muscle training and physical reconditioning on exercise capacity and dyspnea in chronic obstructive lung disease (COLD) (abstract). *Am Rev Respir Dis* 1986; 133(Suppl:A102).
9. Kim MJ, Larson M, Sachs P, Sharp JT. Respiratory muscle training in patients with chronic obstructive pulmonary disease (abstract). *Am Rev Respir Dis* 1984; 129(Suppl:A129).
10. Larson M, Kim MJ. Respiratory muscle training with the incentive spirometer resistive breathing device. *Heart Lung* 1984; 13:341-5.
11. Nochomovitz ML, Murray S, Vasco K, Wood J, Braun B, Klein L. Monitoring respiratory timing and oxygen saturation during inspiratory muscle training (IMT) with resistive breathing (RB) in chronic obstructive lung disease (COLD) (abstract). *Am Rev Respir Dis* 1986; 133(Suppl:A102).
12. Jederlinic P, Muspratt JA, Miller MJ. Inspiratory muscle training in clinical practice. *Chest* 1984; 86:870-3.
13. Belman MJ, Thomas SG, Lewis MI. Resistive breathing training in patients with chronic obstructive pulmonary disease. *Chest* 1986; 90:662-9.
14. McGavin CR, Gupta SP, McHardy GJR. Twelve-minute walking test for assessing disability in chronic bronchitis. *Br Med J* 1976; 1:822-3.
15. McNair DM, Lorr M, Droppleman LF. Profile of mood states. San Diego: Educational and Industrial Testing Services, 1981.
16. Bergner M, Bobbitt RA, Carter WB, Gilson BS. The sickness impact profile: development and final revision of a health status measure. *Med Care* 1981; 19:787-805.
17. Davies AR, Ware JE. Measuring health perceptions in the health insurance experiment. Santa Monica, CA: Rand, 1981.
18. Meneely GR, Ball COT, Kory RC, et al. A simplified closed circuit helium dilution method for the determination of the residual volume of the lungs. *Am J Med* 1960; 28:824-31.
19. Zamel N, Altose MD, Speir WA. Statement on spirometry: a report of the section of respiratory pathophysiology. *Chest* 1983; 83:547-50.
20. Black LF, Hyatt RE. Maximal respiratory pressures: normal values and relationship to age and sex. *Am Rev Respir Dis* 1969; 99:696-702.
21. Nickerson BG, Keens TG. Measuring ventilatory muscle endurance in humans as sustainable inspiratory pressure. *J Appl Physiol* 1982; 52:768-72.
22. Borg G, Holmgren A, Lindblad I. Quantitative evaluation of chest pain. *Acta Med Scand* (Suppl) 1981; 644:43-5.
23. Bellemare F, Grassino A. Effect of pressure and timing of contraction on human diaphragm fatigue. *J Appl Physiol* 1982; 53:1190-5.
24. Clanton TL, Dixon GF, Drake J, Gadek JE. Effects of breathing pattern on inspiratory muscle endurance in humans. *J Appl Physiol* 1985; 59:1834-41.
25. Dixon WJ, ed. BMDP statistical software. Berkeley: University of California Press, 1985.
26. Sokal RR, Rohlf FJ. Biometry. 2nd ed. San Francisco: WH Freeman, 1981.
27. Siegel S. Nonparametric statistics for the behavioral sciences. New York: McGraw-Hill, 1956.
28. Hollingshead AB. Four factor index of social status. New Haven, CT: Yale University, 1975.
29. Clanton TL, Dixon G, Drake J, Gadek JE. Inspiratory muscle conditioning using a threshold loading device. *Chest* 1985; 87:62-6.
30. Goldstein RS, De Rosie J, Contreras M, Long S. Specificity of inspiratory muscle training (abstract). *Am Rev Respir Dis* 1986; 133(Suppl:A102).
31. Chen H-I, Dukes R, Martin BJ. Inspiratory muscle training in patients with chronic obstructive pulmonary disease. *Am Rev Respir Dis* 1985; 131:251-5.
32. McCool FD, McCann DR, Leith DE, Hopkin FG. Pressure-flow effects on endurance of inspiratory muscles. *J Appl Physiol* 1986; 60:299-303.
33. Leggett RJE, Flenley DC. Portable oxygen and exercise tolerance in patients with chronic hypoxic cor pulmonale. *Br Med J* 1977; 2:84-6.
34. Woodcock AA, Gross ER, Geddes DM. Oxygen relieves breathlessness in "pink puffers." *Lancet* 1981; 1:907-9.
35. Leitch AG, Morgan A, Ellis DA, Bell G, Haslett C, McHardy GJR. Effect of oral salbutamol and slow-release aminophylline on exercise tolerance in chronic bronchitis. *Thorax* 1981; 36:787-9.
36. Woodcock AA, Gross ER, Geddes DM. Drug treatment of breathlessness: contrasting effects of diazepam and promethazine in pink puffers. *Br Med J* 1981; 283:343-6.
37. McGavin CR, Gupta SP, Lloyd EL, McHardy GJR. Physical rehabilitation for the chronic bronchitic: results of a controlled trial of exercises in the home. *Thorax* 1977; 32:307-11.
38. Cockcroft AE, Saunders MJ, Berry G. Randomised controlled trial of rehabilitation in chronic respiratory disability. *Thorax* 1981; 36:200-3.
39. Mungall IPF, Hainsworth R. An objective assessment of the value of exercise training to patients with chronic obstructive airways disease. *Q J Med* 1980; 49:77-85.
40. Prigatano GP, Wright EC, Levin D. Quality of life and its predictors in patients with mild hypoxemia and chronic obstructive pulmonary disease. *Arch Intern Med* 1984; 144:1613-9.