ORIGINAL ARTICLE

Comparison of 2 Methods for Inspiratory Muscle Training in Patients With Chronic Obstructive Pulmonary Disease

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OBJECTIVE: The aim of this study was to compare the use of threshold and resistive load devices for inspiratory muscle training in patients with chronic obstructive pulmonary disease (COPD). A randomized prospective trial was designed to compare use of the 2 devices under training or control conditions.

PATIENTS AND METHODS: Thirty-three patients with moderate or severe COPD were randomly assigned to home treatment with a threshold device, a resistive load device, or a control situation in which either of those devices was maintained at a minimum load throughout the study. Training was performed daily in 2 sessions of 15 minutes each for 6 weeks. In the patients who underwent training with threshold (n=12) and resistive load (n=11) devices, the loads used were adjusted weekly until the maximum tolerated load was reached to ensure that the interventions were as equivalent as possible. Respiratory function, respiratory muscle function, and quality of life were assessed before and after training and the different inspiratory pressure profiles were compared between training groups.

RESULTS: Both peak inspiratory pressure and scores on the Chronic Respiratory Questionnaire (CRQ) improved in the groups that received inspiratory muscle training compared with control subjects: maximal static inspiratory pressure increased from 86 cm H_2O to 104.25 cm H_2O (P<.01) in the threshold device group and from 91.36 cm H_2O to 105.7 cm H_2O (P<.01) in the resistive load device group. The resistive load group showed the largest increase in CRQ quality-of-life scores. Differences between the dyspnea score on the CRQ at the beginning and end of the training period were as follows: 3 points in the resistive load group, 2.58 in the threshold group, and 2.5 in the control group. Significant differences in duty cycle measured during training sessions were observed between groups at the end of training (0.31 in the threshold group and 0.557 in the resistive load group), but the mean pressure–time index was similar (0.11) in both groups because of the greater peak and mean inspiratory pressures in the threshold device group.

CONCLUSIONS: Load readjustment allowed equivalent training intensities to be achieved with different inspiratory pressure profiles. Our study demonstrated the effectiveness of inspiratory muscle training without control of breathing pattern but showed no superiority of one training method over another.

Key words: *Respiratory muscle training. COPD. Respiratory muscles. Quality of life. Rehabilitation.*

Comparación de 2 métodos de entrenamiento muscular inspiratorio en pacientes con EPOC

OBJETIVO: Con el objetivo de comparar el entrenamiento muscular respiratorio (EMR) con dispositivos de umbral de presión (U) y de carga resistiva (CR) en pacientes con enfermedad pulmonar obstructiva crónica (EPOC), se ha diseñado un estudio prospectivo y aleatorizado que incluyó ambas modalidades y un grupo control (C).

PACIENTES Y MÉTODOS: Los 33 pacientes con EPOC grave-moderada incluidos se asignaron aleatoriamente a realizar entrenamiento en el domicilio con un dispositivo de U, de CR o un nivel mínimo de ambos durante 6 semanas, a razón de 2 sesiones diarias de 15 min. En los grupos U (n = 12) y CR (n = 11) se ajustó semanalmente la carga hasta la máxima tolerada como estrategia más equitativa para no favorecer a ningún grupo. Se exploraron medidas de función respiratoria, musculares y de calidad de vida antes y después del EMR y se compararon los patrones de presión en el entrenamiento.

RESULTADOS: Mejoraron las presiones inspiratorias máximas y las puntuaciones del cuestionario para enfermedad respiratoria crónica (CRQ) en U y CR respecto a C: la presión inspiratoria estática máxima pasó de 86 a 104,25 cmH_2O ($p < 0,01$) en el grupo U, y de 91,36 a 105,7 cmH_2O ($p < 0,01$) en CR, que fue el grupo que presentó mayores incrementos en áreas de calidad de vida del CRQ. La diferencia respecto a la disnea fue de 3 puntos en CR, de 2,58 en U y de 2,5 en C. Se observaron diferencias significativas entre grupos en el ciclo respiratorio durante el EMR (de 0,31 en U, frente a 0,557 de CR), si bien las mayores presiones pico y media en U rindieron índices presión-tiempo finales equivalentes: de 0,11 en U y de 0,11 en CR.

CONCLUSIONES: Mediante el reajuste de carga se consiguieron intensidades de entrenamiento equivalentes con patrones de presión diferentes. Nuestro planteamiento demostró la eficacia de un EMR no controlado, pero no la superioridad de una modalidad de entrenamiento sobre otra.

Palabras clave: *Entrenamiento muscular respiratorio. EPOC. Músculos respiratorios. Calidad de vida. Rehabilitación..*

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Introduction

Airflow limitation in patients with chronic obstructive pulmonary disease (COPD) occurs as a result of impaired respiratory mechanics. The relationship between inspiratory muscle overload and the perception of peripheral feedback is interpreted neuropsychologically by the patient as dyspnea,[1-3] the symptom that has the greatest impact on daily life. Increasing the power and resistance of the muscles should, in theory, improve the capacity of patients with COPD to perform physical tasks and should, as a result, improve their quality of life. Consequently, inspiratory muscle training has been discussed as a possible method for rehabilitation in these patients. The meta-analyses carried out by Smith et al[4] and Lötters et al,[5] as well as the opinions of other expert panels,[6,7] have established level B evidence for the use of this technique in patients with COPD. However, taking into account the large methodological differences between the different studies, Smith et al[4] established that only studies with control of breathing pattern guaranteed the effectiveness of respiratory muscle training, a condition that places serious limitations on efforts to establish generalized use of this treatment.

Based on general principles of respiratory muscle training,[8,9] it seems that the absence of sufficient muscle load must be the most plausible explanation for the ineffectiveness of protocols not involving control of breathing pattern. In addition, the possibility of loading muscles with resistive load or threshold devices adds further complexity to this question. Although exhaustive functional studies have been published that differentiate respiratory muscle training characteristics in terms of velocity of shortening, pressure, and time,[10] there is no known correspondence of load values, nor are appropriate studies available comparing the two methods, as highlighted in the American Thoracic Society document on pulmonary rehabilitation.[6] We hypothesized that the maximum load that the patient is capable of sustaining during respiratory muscle training would be a representative indicator free of problems of subjective comparisons of equivalence of intensity.

Thus, we undertook a study in which load was supervised without control of breathing pattern to allow the independent use of respiratory muscle training devices in patients with COPD, ensuring that sufficient load was used by periodic readjustment, in order to observe the adaptations of the patient to the device when used freely.

TABLE 1
Baseline Characteristics of the Patients in the 3 Groups: General Characteristics, Lung Function, Arterial Blood Gases, and Respiratory Muscle Function*

Parameter	Threshold Group (n=12)	Resistive Load Group (n=11)	Controls (n=10)
Age, y	62 (13.7)	66 (7.2)	61.5 (8.6)
BMI, kg/m^2	26.03 (3.46)	28.03 (4.08)	26.9 (4.41)
FVC, L	3.16 (0.52)	3.31 (0.71)	2.9 (0.52)
FEV_1, L	1.33 (0.27)	1.34 (0.33)	1.48 (0.48)
FEV_1, % predicted	45 (9)	47 (11.6)	49 (7.4)
FEV_1/FVC	0.43 (0.08)	0.4 (0.066)	0.46 (0.057)
TLC, L	8 (1.57)	8.99 (2.12)	7.53 (1.79)
TLC, % predicted	115 (28.9)	141 (22)	123 (21)
RV/TLC, %	58.8 (8.81)	59.26 (10.84)	57.9 (7.5)
PaO_2, mm Hg	68.9 (59-89)	76.4 (63-94)	75.4 (63-85)
$PaCO_2$, mm Hg	41.2 (36-47)	41.4 (38-50)	40.7 (36-48)
P_{Imax}, cm H_20	86 (18)	91 (22.6)	88.5 (27.7)

*Data are shown as means (SD) or median (range).
FEV_1 indicates forced expiratory volume in 1 minute; FVC, forced vital capacity; BMI, body mass index; P_{Imax}, maximum static inspiratory pressure; RV, residual volume; TLC, total lung capacity.
There were no statistically significant differences between the groups for any of the parameters.

Patients and Methods

A randomized comparative study was performed including a control group.

Patients

The study included 34 patients with a diagnosis of moderate–severe COPD who were attended in the outpatient clinics serving the catchment area of our hospital. Candidates were assessed as being clinically stable in the month prior to inclusion in the study. The following exclusion criteria were applied: severe hypoxemia (PaO_2<60 mm Hg), diagnosis of asthma, coronary disease, chronic metabolic disease, musculoskeletal disease, recent thoracic or abdominal surgery, and treatment with corticosteroids, hormones, or chemotherapy. The study was approved by the ethics committee of the hospital. The patients were distributed in 3 groups: *1)* training with a threshold device (n=12; *2)* training with a resistive load device (n=11); and *3)* a control group (n=10). Patient characteristics are shown in Table 1. The training period lasted 6 weeks.

Training Systems

Two training systems were used:

1. Threshold inspiratory muscle trainer (Threshold, Healthscan, Cedar Grove, USA). This is an inspiratory device that can be adjusted with a spring. The tension in the spring determines the aperture of the valve at a fixed pressure, with a range of between 0 and 45 cm H_20. The device is designed so that there is no significant flow below the threshold pressure; once that pressure is exceeded the valve opens and the linear resistance to inspiratory flow should be unappreciable (Figure 1).

2. Resistive load device (Pflex resistive trainer, Respironics HealthScan Inc, Cedar Grove, USA). The device has 6 inspiratory resistors or orifices that control the entry of air into the body of the device. The measured diameters were as follows: orifice 6, 0.45mm; orifice 5, 1.9 mm; orifice 4, 2.7 mm; orifice 3, 3.5 mm; orifice 2, 4.5 mm; and orifice 1, 5.35 mm. These nonlinear resistances generate parabolic pressure–flow curves (Figure 1).

The progressive limitation of flow fits expressions of the following type: $Fl(pr) = a\sqrt{pr}$ (where Fl indicates flow and pr, pressure), with each level (orifice) characterized by a different value of the coefficient a (Figure 1).

Figure 1 shows graphs of pressure against flow in the devices when connected to a vacuum pump capable of generating stable flows. These measurements were performed using the program LABDAT-ANADAT (RHT-Infodat Inc, Montreal, Canada).

Respiratory Muscle Training Protocol

The following measurements were made at the beginning and end of the 6-week training period:

– *Lung function tests:* forced spirometry was performed with a Masterlab spirometer (Jaeger, Würzburg, Germany) and

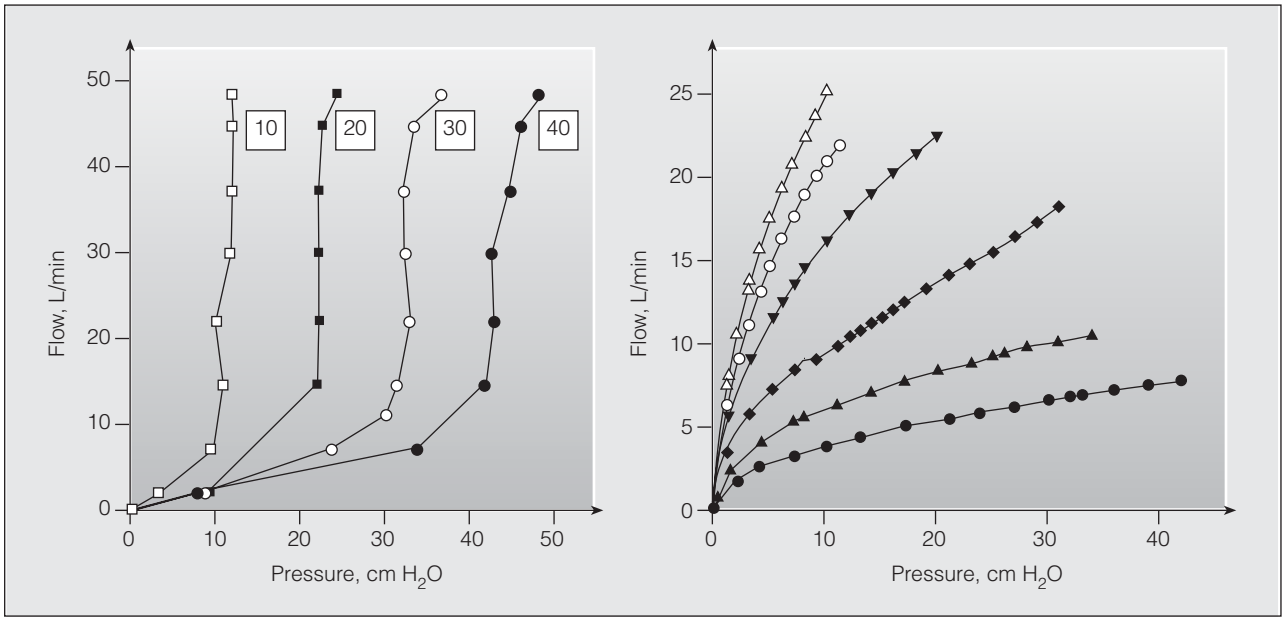

Figure 1.Pressure plotted against flow in the threshold device (left), adjusted to 10, 20, 30, and 40 cm H_20, and the resistive load device (right), where the lower curve corresponds to orifice 6, the next orifice 5, and onwards up to orifice 1.
The curves on the right fit a square root function of flow (Fl) in relation to pressure (pr): $Fl(pr)=a\sqrt{pr}$, where a has a specific value for each orifice from 1 to 6. For orifices 1 to 6, the coefficient a corresponds to 7.836, 6.58, 5.04, 3.102, 1.788, and 1.17, respectively; always with $r^2>0.998$, expressing an ideal fit.

included static lung volumes and airway resistance, diffusing capacity of lung for carbon monoxide (DLCO) measured by the single-breath method, according to procedures[11] and reference values[12-14] of the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR).

– *Arterial blood gases:* arterial blood was obtained from the radial artery according to SEPAR guidelines[14] and processed using an ABL-500 analyzer (Radiometer, Copenhagen, Denmark).

– *Respiratory muscle function:* Maximum static inspiratory (P_{Imax}) and expiratory mouth pressures were recorded using standard techniques[15] and a specifically designed manometer (Sibelmed 163, SIBEL, Barcelona, Spain). Maximum esophageal pressures were measured using maximal sniff tests and Müller maneuvers[15,16] and recorded following insertion of an esophageal balloon connected via a catheter to a pressure transducer (Transpac II, Abbott Critical Care Systems, North Chicago, USA) with a range of ±150 cm H_20 calibrated with a water column. The best of 3 values with a variation of less than 10% were considered maximum values of P_{Imax}, maximal expiratory pressure, and esophageal pressures in the sniff test and Müller maneuver.

The endurance time at a threshold load of 66% of P_{Imax} ($T_{lim66\%}$) was assessed with the Healthscan threshold device if 66% of the P_{Imax} was within the range of the device, or with an inspiratory valve loaded with weights, as described by Nickerson and Keens.[17] This time limit was reached if the patient was unable to continue after 3 consecutive ineffective efforts in which they did not succeed in opening the threshold valve, or if a reduction in oxygen saturation was observed (less than 90% or a reduction of more than 4% from the baseline value). No breathing pattern was imposed during the resistance maneuvers and the limit for the maximum sustainable time was set at 15 minutes.

– *Quality of life.* Quality of life was measured using the Chronic Respiratory Questionnaire (CRQ) developed by Guyatt et al[18] and validated in Spanish by Guell et al.[19] The minimum difference between the results of 2 questionnaires that was considered clinically significant was 0.5 points per item[20] in any of the domains (dyspnea, fatigue, emotional function, and mastery of the disease).

Respiratory Muscle Training Load

A minimum load (7 cm H_20 or orifice 1) was applied for 1 week. In the control group, this load remained unchanged for the rest of the study, while in the threshold and resistive load groups it was increased until the maximum tolerated load was reached, following a similar procedure: The training session was initiated with the device at the maximum load (orifice 6 or 45 cm H_20). If the patient could not sustain this load for 15 minutes, either for the same reasons as in the $T_{lim66\%}$ or due to an intolerable sensation of being unable to breathe, the device was adjusted to a lower level of difficulty by moving to the next size of orifice or by reducing the pressure threshold by 4 cm H_20. Following a 20-minute rest period, another test was begun. Once again, the level was reduced if the patient could not sustain the load, and so on until the maximum load that could be sustained for 15 minutes was reached, always observing a 20-minute rest period between one test and the next.

Each week, the load was adjusted in the reverse direction, adding 4 cm H_20 to the threshold or changing to the orifice with a diameter immediately below that which was sustained previously. In these supervised sessions in the hospital, the patients were asked about symptoms and compliance with training, in addition to measuring their P_{Imax}.[15] The initial and final loads are shown in Table 2.

Only in 1 patient was the device altered to exceed the maximum threshold in the range, since in that patient 45 cm H_20 was sustainable from the beginning. So as not to distort the assessment of the commercial devices, it was decided not to make any further alterations.

Training Parameters

During the first and last hospital visits, the pressure in the device (mouth pressure) was measured during training with a pressure transducer (Abbot, Transpac 11, North Chicago, USA; range ±150 cm H_20) and recorded digitally on a computer using

LABDAT-ANADAT software. The signal was processed to determine the breathing rate, duty cycle, mean and peak inspiratory pressures, the integral of the inspiratory pressure, and the pressure–time index (PTI, [inspiratory pressure/P_{Imax}] × [inspiratory time/total time]).[21,22]

Individual changes in the load applied during training are shown in Table 2, which contains the loads applied weekly and maintained until the following appointment. The level of training corresponds to the number of the resistive load orifice or the threshold value. In the initial training and at the end of the training period, the PTI was measured as an expression of the effective load, taking into account the training profile.

Statistical Analysis

Based on previous studies and taking P_{Imax} as the primary outcome measure, the minimum sample size was calculated as 18 patients for the intervention groups and 10 control patients (power, 0.95; α=.05; for an expected difference in P_{Imax} in the intervention groups following training of 18 cm H_20 compared with controls, SD=20). We included 12 patients in the resistive load and threshold groups to take into account possible losses and to allow comparisons between the groups (Student *t* test). In each group, the results before and after the intervention were assessed with the Student *t* test. A *P* value less than .05 was considered significant.

Results

No differences were observed between the 3 groups in terms of spirometry variables, diffusion, or static lung volumes either at the beginning or end of training.

Muscle Variables and Quality of Life

The changes in muscle variables and quality of life are shown in Table 3. The threshold group, in which P_{Imax} increased from 86 to 104.26 cm H_20 with equivalent increases in esophageal pressures, was the only group in which an increase was observed in $T_{lim66\%}$, from 4.67 to 10.22 minutes. In the resistive load group, the P_{Imax} increased from 91 to 105.7 cm H_20, and that group also showed the greatest increase in terms of quality of life. On the CRQ, there was an improvement in the dyspnea domain in all 3 groups, but the most notable changes were in the resistive load group. Although greater differences were observed in all domains in this group, the differences were not statistically significant between the groups. It is worth noting that when considered together, the control group did not exhibit parallel changes compared with the treatment groups.

Training Parameters

As shown in Table 2, the mean (SD) value for the threshold pressure increased from 33.33 (9.22) to 41.17 (5.41) mm H_20 and the resistive loads employed increased from a mode of orifice 4 to orifice 5. A significant number of patients reached the maximum load, although it was also observed that the PTI decreased in 2 patients in the threshold group, due to increases in P_{Imax} and changes in the breathing pattern.

Figure 2 shows sample recordings from the training period for each device. Table 4 shows the defining parameters for pressure and respiratory cycle. The peaks in inspiratory pressure (troughs in Figure 2) were deeper and shorter with the threshold device than when using a resistive load: at the end of the training protocol, the duty cycle (inspiratory time/total respiratory cycle length) in the threshold group was 0.31, compared with 0.557 in the resistive load group. In contrast, the mean inspiratory pressure in the threshold group was much higher, and we did not observe differences in breathing rate between the two groups (between 14 and 17 breaths per minute, Table 4), with little variation throughout the protocol.

TABLE 2
Outcome of Training in the Resistive Load and Threshold Groups: Training Level at the Beginning and End of the Protocol and Corresponding Values for the Pressure–Time Index*

	Resistive Load				Threshold			
	Weeks†		PTI		Weeks‡		PTI	
	1	6	Initial	Final	1	6	Initial	Final
Case 1	5	6	0.08	0.07	50	50	0.10	0.07
Case 2	5	6	0.14	0.15	27	36	0.18	0.25
Case 3	4	6	0.16	0.21	45	45	0.11	0.04
Case 4	4	5	0.11	0.12	39	40	0.13	0.12
Case 5	2	5	0.06	0.09	30	43	0.11	0.12
Case 6	4	5	0.13	0.13	24	38	0.09	0.14
Case 7	6	6	0.12	0.22	30	43	0.05	0.07
Case 8	4	5	0.05	0.11	25	35	0.1	0.1
Case 9	4	6	0.04	0.04	25	39	0.07	0.08
Case 10	2	5	0.02	0.04	27	37	0.27	0.18
Case 11	3	5	0.13	0.08	16	33	0.08	0.07
Case 12	–	–	–	–	39	45	0.07	0.10
Mode	4	5	–	–	–	–	–	–
Mean (SD)	–	–	0.1 (0.04)	0.11 (0.06) (NS)	33.33 (9.22)	41.17 (5.41)§	0.11 (0.06)	0.11 (0.06) (NS)

*NS indicates not significant; PTI, pressure–time index.
†Training level shown as the orifice in the resistive load device.
‡Training level shown as the resistive load, cm H_20.
§*P*<.001 compared with week 1.

TABLE 3
Changes in Muscle Function and Quality of Life*

	Threshold			Resistive Load			Control		
Muscle Parameters	**Initial**	**Final**	**Difference, %**	**Initial**	**Final**	**Increase, %**	**Initial**	**Final**	**Difference, %**
P_{Imax}, cm H_20	86 (18.1)	104.3 (22.4)†	21	91.4 (22.6)	105.7 (20.4)†	16	88.5 (27.7)	86.7 (23.5) (NS)	–2
$T_{eim66\%}$, min	4.67 (2.61)	10.22 (5.56)†t	118.8	4.77 (4.15)	5.21 (4.94) (NS)	9.2	3.71 (3.27)	6.71 (5.9) (NS)	80.9
PES Müller, cm H_20	76.7 (26.2)	100.3 (27.4)†	30.8	81.8 (22.2)	99.2 (20.8)†	21.3	82.3 (26.8)	91 (37.3) (NS)	10.6
PES sniff, cm H_20	74 (26.6)	100.3 (21.6)†	35.5	79 (21.3)	96.9 (19.39)†	22.7	86.9 (24) (NS)	91.7 (40.7)	5.5
Quality of Life	**Initial**	**Final**	**Difference**	**Initial**	**Final**	**Difference**	**Initial**	**Final**	**Difference**
Dyspnea	11.67 (4.23)	14.25 (5.66)‡	2.58	16.2 (5.27)	19.2 (5.07)‡	3	12.9 (6)	15.4 (7.49)‡	2.5
Fatigue	18.16 (5.88)	19.7 (4.85) (NS)	1.54	16.8 (5.12)	19 (4.16)§	2.2	20.2 (4.52)	20.7 (5.72) (NS)	0.5
Emotional function	35.67 (8.3)	38.5 (7.65)§	2.83	34.1 (8.08)	37.7 (6.68)‡	3.6	35.1 (8.86)	36.7 (10.1) (NS)	1.6
Mastery of the disease	21.5 (5.2)	22.3 (4.94) (NS)	0.8	18.8 (6.53)	20.6 (5.87)§	1.8	22.2 (5.53)	22.8 (5.94) (NS)	0.6

*Data are shown as mean (SD).
NS indicates not significant; PES, esophageal pressure; P_{Imax}, maximum static inspiratory pressure; $T_{lim66\%}$, endurance time at a threshold load of 66% of the P_{IMAX}.
†P<.001. ‡P<.01.§ P<.05.

Discussion

Based on the results obtained in this study, the most important conclusions can be summarized in the following points:

1. The two respiratory muscle training devices display different and opposite pressure–flow behaviors and may therefore lead to different effort saving strategies. These adaptations should be taken into account in relation to training without control of breathing pattern when considering why training is ineffective.

2. Using a protocol without strict control of breathing pattern, through the use of a simple weekly adjustment in both types of training, a similar degree of respiratory muscle overload was achieved in both training groups,

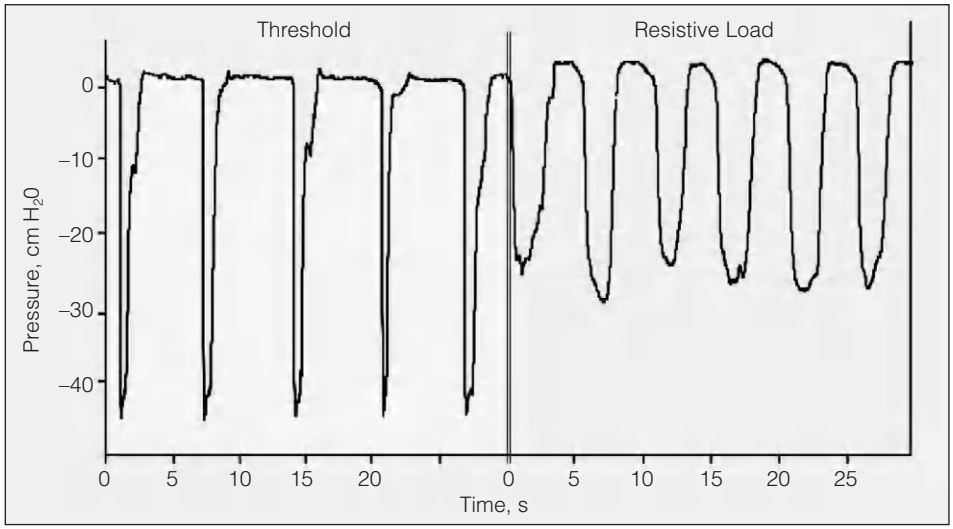

Figure 2. Differences in breathing patterns during training. Representative examples for threshold pressure (left), displaying a pattern of sharp and brief descents, compared with efforts that were more limited in terms of pressure but sustained with the resistive load device (right).

TABLE 4
Defining Parameters of the Respiratory Pattern: Differences Between Groups and Within Groups at the Beginning and End of

	Threshold		Resistive Load		*P* Between Training Groups
	Initial	Final	Initial	Final	
PTI	0.11 (0.06)	0.11 (0.06)	0.1 (0.044)	0.11 (0.06)	NS
P_I/P_{Imax}	0.3 (0.103)	0.36 (0.071)†	0.17 (0.065)	0.21 (0.11)†	<.001
T_I/T_{tot}	0.358 (0.125)	0.31 (0.123)‡	0.55 (0.11)	0.56 (0.08)	<.001
Breathing rate	14.45 (6.92)	15.19 (7.09)	17.32 (6.97)	15.15 (5.59)	NS

*Data are shown as mean (SD).
P_I indicates inspiratory pressure; P_{Imax}, maximum static inspiratory pressure; PTI, pressure–time index; T_I/T_{TOT}, inspiratory time/total time; NS, not significant.
†*P*<.1 between initial and final values.
‡*P*<.05 between initial and final values.
The mean P_I (in relation to P_{Imax}) increased as a result of load adjustment but PTI remained constant with the changes in the breathing pattern and upon increasing P_{Imax}.

despite the patients adapting with different patterns of exercise.

3. This free approach led to improvements in respiratory muscle variables and to changes in quality of life, both of which were better in the intervention groups than in the control group.

4. The observation that there were no significant differences between the two training groups and the similarity of the level of effort achieved does not allow us to draw conclusions regarding the superiority of one type of training over another.

Our assessment of the devices revealed pressure–flow curves (Figure 1) that were similar to previous reports, both for resistive load devices[23] and threshold devices loaded with weights[17] or with a spring mechanism.[24,25] We confirmed that the defining characteristic of the threshold device was met, that is, the absence of significant flow—less than 0.1 L/s, a flow signal attributed by Gosselink et al[25] to decompression of air close to the valve—below the threshold value. With the resistive load devices, the pressure–flow profile can be predicted across its range via a mathematical expression, a square root (as described in Patients and Methods). This constant relationship reflects the relationship between laminar flow and turbulent flow according to the classical Rohrer equation, in which the turbulent component increases with increasing flow or resistance. The possibility of adjusting flow or pressure could help to facilitate easier monitoring of training involving simple substitution or to plan training regimens with control of breathing pattern.

The design involving free training with no control of breathing pattern allowed us to observe the different strategies that were used with each device in similar groups of patients (Table 1) and in the same context. Adaptation to maximal training did not appear to be limited by hypoventilation in any of the patients. No arterial desaturations were recorded, even in the most hypoxemic patients, the number of whom was not significantly higher in the threshold group, despite the difference shown in Table 1, a finding that could be linked to the absence of hypercapnia. The distribution of inspiratory time and pressure and the duty cycle tended to reduce the effort by limiting its duration in the case of the threshold device (shorter inspiratory time) or by limiting the pressure in the case of resistive loads (Figure 2). Gosselink et al[25] tested a threshold device in healthy individuals and patients with COPD in 5-minute sessions and observed that the healthy individuals maintained a duty cycle of 0.5 while in the COPD patients the cycle was 0.36 to 0.39, with a breathing rate that increased with increasing load.

This finding in "naïve" subjects may indicate that patients with COPD are used to this breathing strategy before using a threshold device for the first time. We found that in the threshold group there was a tendency towards an even shorter inspiratory time, with a mean duty cycle of 0.31 and the presence of extreme cases (case 3 in Table 2 or Figure 2), explaining the low PTI despite maximum threshold levels. On the other hand, the duty cycle reached 0.55 in the resistive load group. For these reasons, we suggest that it is the lengthening of the inspiratory time that should be considered atypical, since it reverses the natural tendency of patients towards a more prolonged expiratory time to prevent dynamic hyperinflation. Such an adaptation lacks clear "perceptual" advantages that could influence quality of life independently of respiratory muscle rehabilitation.

The adaptations observed in this study may explain why studies without control of breathing pattern prove to be ineffective. Any long-term or short-term training strategy designed with or without control of breathing pattern should take into account these interactions between the patient and the device in order to be effective. In our study, we found that the mean inspiratory pressure during training fluctuated between 30% and 35.7% of the patient's P_{Imax}, higher than the 30% established by Larson et al[24] as an effective level for training (Table 4). It may have been even higher if that had been permitted by the device, following the strategy designed rather than the alternative used by other authors of increasing the breathing rate.[10,25] In terms of the resistive loads, previous studies have demonstrated that training with control of breathing pattern guarantees the necessary intensity of training.[23] Our approach would represent an alternative to the use of devices with feedback systems, which are more expensive.

Our study assumes that the patients adapt to the pressure–flow relationships of the devices. The design of our training protocol was aimed at preempting strategies used by the patients to reduce effort. In our study, the intensity of the effort had to be maintained to treat both groups in parallel, without a known correspondence in terms of load. Our findings have confirmed that such a

correspondence does not exist unless we take into account the duration of the effort, which is highly variable according to the duty cycle, especially with threshold devices, as reported by Gosselink et al.[25] Consequently, the PTI, as used in our study, is an index that confirms that the load is similar in both training groups. Compared with the original study of Bellemare and Grassino,[26] the values observed would represent high additional loads, close to the threshold for muscle fatigue. Although those authors used transdiaphragmatic pressures to calculate PTI, mouth pressures are thought to be an acceptable indicator of diaphragmatic activity.[22]

One of the limitations of our protocol was the low pressure range of the threshold device used, especially for this type of strategy, in which the training pattern is determined by the patient. This was less apparent in the case of the resistive load device, despite the fact that 5 of the 11 patients completed the maximum training level, probably because the possibility of altering the training strategy is more limited. Given that the study sought to evaluate a particular type of commercial device, we deliberately chose not to manipulate the device by adding new springs[25] or lengthening the existing ones. However, we believe that various patients could have sustained much greater loads, especially those in whom PTI was reduced over the duration of the protocol (cases 1 and 3). Therefore, we feel that this limitation should be taken into account and that the model should be chosen according to the range required by the patient in the protocol.

Our results are consistent with those obtained in previous studies with control of breathing pattern and coincide in particular with the conclusions of the meta-analysis of Lötters et al,[5] which mainly confirmed the effectiveness in terms of quality of life and muscle function, particularly in debilitated patients. Although our patients did not exhibit severe muscular dysfunction, as indicated by the static pressures obtained, we consider them to be a valid reflection of what occurs in patients with COPD. Given that this was a pilot comparative study and having opted for training with maximal loads, patients with severe dysfunction due to COPD and muscle weakness were not included; instead, we selected patients from the outpatient population who were sufficiently independent to be able to visit the hospital each week. Nevertheless, a benefit was observed in terms of muscle parameters in both training groups but not in the control patients, a finding which is attributable to muscle exercise.

It can not be ruled out that the differences simply represent an effect of learning: the P_{Imax} and esophageal pressures improved in the threshold group more significantly than in the resistive load group, in which exercise does not fit a pattern of short and intense inspiration, similar to the dynamics of maximal maneuvers. Furthermore, the $T_{lim66\%}$, described by Nickerson and Keens[17] as a parameter of resistance, was significantly lengthened in the patients in the threshold group.

The results of our study show that inspiratory training can have a direct effect on symptoms and quality of life, as shown in Table 3, especially in the resistive load group, as described previously,[27] an effect to which inspiratory muscle reinforcement and a certain sensory desensitization would contribute.[28,29] Since both types of training act on a similar substrate, it seemed unlikely that they would give very different results, even though they might give rise to different adaptations.

The similarity of the results obtained does not allow conclusions to be drawn regarding the superiority of one training method over another. Since the devices are used within a training protocol, it will be the protocol and the effective overload of the musculature that are likely to influence the results. Since the protocol involved adjustable maximum loads, both systems produced similar values for PTI and similar results. Using the threshold device, we know the level of pressure associated with inspiratory effort, although the breathing pattern displays a high level of variation between the patients. Respiratory muscle training with resistive loads does not carry the same potential for variation of the load but in a free training protocol it leads to "less physiological" lengthening of the inspiratory time. It is not clear whether either modality exhibits a more specific effectiveness in muscle strengthening or in terms of perception. We can postulate that training using threshold devices could have a more specific effect on the force component, in contrast to a more sustained effort with resistive loads, which would act on resistance. We will limit ourselves to presenting the data and highlighting that, as reported by others,[4,5,24] muscle reinforcement was achieved in both training groups, despite limitations in terms of the threshold values that could be applied and the resistive loads generating peak pressures lower than those in the threshold group. It is possible that the two modalities could have different and even complementary indications. Furthermore, the possibility of using training without strict control of breathing patterns would facilitate protocols that are more accessible and appropriate for longer periods, a clear need given the reversibility of the effects of training.[30]

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