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Respiratory training with a specific device in cystic fibrosis: A prospective study

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Abstract

Introduction: Chest physiotherapy (CP) is used in cystic fibrosis (CF) even if there is no robust scientific evidence of a beneficial effect. We investigated the effects of a training with a specific device (SpiroTiger®) in a group of CF patients. This device, developed for respiratory training through maximal inspirations and espirations without hypocarbia, may improve respiratory function and mucus clearance. Patients where instructed and trained by a physiotherapist with individualized settings of training parameters.

Methods: Twenty-four patients were enrolled in an open-label 1 year observational study. Baseline and post intervention measurements were determined by lung function (FVC, FEV1, FEF 25-75), patients' opinions on physiotherapy (questionnaires), need for antibiotic treatment (clinical follow-up and records) and perception of physical fitness (questionnaires) in the year before and in the year of intervention. Adherence to physiotherapy was monitored by means of a specific device software.

Results: Increased lung function (FEV1 $p<0.01$), perception of physical fitness ($p<0.001$) and a reduction in the need for intravenous antibiotic treatment ($p<0.001$) were reported. Adherence to treatment was good/acceptable in 92% of patients.

Conclusions: This study shows an association between training through a specific device and improved lung function. Further trials are needed to confirm this report.

Keywords: Respiratory training; Lung function; Antibiotic treatment; SpiroTiger®

1. Introduction

Chest physiotherapy (CP) is widely used in patients with CF [1]. However, there is no strong evidence to support the assumption that CP has a beneficial effect [2,3]. High pressure positive expiratory pressure (HiPEP) mask therapy, carried out with the AstraTech PEP mask system [4] is the most used physiotherapy technique in our centre. There is no evidence that positive expiratory pressure it is more or less effective than other forms of physiotherapy [5].

Chronic obstructive lung disease causes hyperinflation with alterations in chest structure and muscle function [6]. The loss of fat-free mass has been associated with a reduction in skeletal muscle mass which reduces the inspiratory muscle function [7–9]. There is considerable variability in published data regarding respiratory muscles strength in CF. Some authors report that strength is preserved or even increased, while others report significant reduction [6,10]. In the latter hypothesis skeletal muscle alterations and the interaction between the pattern of thoracic adaptation and the function of respiratory muscles may play a role in worsening the lung function and in hyperinflation [6,8,9]. Therefore a physiotherapy targeted at improving specifically chest function may also improve lung function [11].

Respiratory muscle training may also work by removing secretions thus effectively lowering residual volume and functional residual capacity levels, which allows the muscles to work effectively on more advantageous parts of the length tension curve.

We selected a specifically designed respiratory device (SpiroTiger®, MVM, Bologna, Italy) that has been used with athletes to train breathing muscles and improve pulmonary function. One advantage of a respiratory device in comparison

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to physical exercise is represented by the fact that training is not dependent on endurance of inferior limb muscles.

Our hypothesis was that the specific properties of the device could not only provide respiratory muscles training but also achieve an improvement of the whole lung function. Training through this device may induce high flows by mean of maximal inspirations with radial traction on airways and, at the same time, avoid hypocarbia and dynamic hyperinflation. Increased air flow could also mobilize secretions and improve mucus clearance.

We performed a prospective clinical trial in order to assess the efficacy of respiratory training with SpiroTiger®. This is a pilot study aimed at confirming the positive results obtained in our Hospital in few subjects, in preparation for a multi-centre controlled clinical trial.

2. Materials and methods

The study was conducted in one CF centre of a Tertiary University Hospital (Institute of Child Health IRCCS Burlo Garofolo, Trieste, Italy) between January 2004 and December 2006.

2.1. Selection of patients

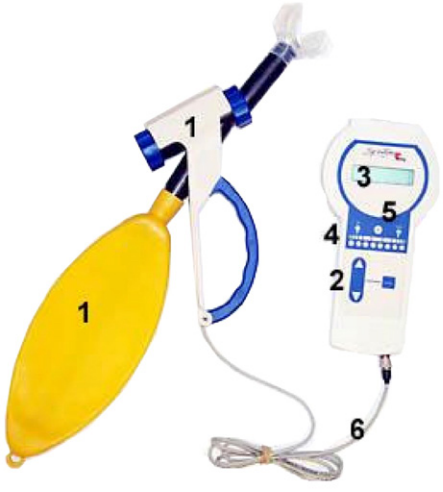
All patients with the following characteristics were enrolled:

1) Former diagnosis of CF based on clinical criteria, pathologic sweat test (Na and Cl levels >70 mmol/L) and CF genotype.
2) Regular attendance of the CF centre with at least 3 visits per year. All subjects had complete medical records relative to the 2 years preceding the enrolment with clinical reports, height, weight, BMI, pulmonary function tests, sputum cultures, blood tests, specific aspergillum IgE titer, record of antibiotic and steroid treatment. Perception of fitness and attitudes towards physiotherapy were routinely checked and reported in medical records by means of questionnaires. All patients had received the prescription of physiotherapy with HiPEP.
3) At least one antibiotic treatment administered orally or intravenously in the last 6 months for an acute respiratory exacerbation, with a decrease of at least 10% FEV1 of their best usual values.

Exclusion criteria were: less than 9 years of age, dyspnoea at rest, recent clinically significant haemoptoe, need for additional oxygen, cor pulmonale.

2.2. Trial design

Each subject enrolled served as his/her own control. All patients who matched the inclusion criteria were consecutively enrolled over a 2 year period, with 1 year of scheduled post intervention follow-up. Upon enrolment, SpiroTiger was offered instead of HiPEP. Data related to study outcomes collected in the year before enrolment (data from clinical records) were compared with data collected during the year of follow-up. Post intervention measures were taken at least three



Description:

1. Held unit with specific valve and respiratory pouch.
2. personal training target values are entered into the basic unit and serve to monitor the breathing frequency and depth during training.
3. The display provides instruction such as "breathe faster" and a bar shows the respiration depth.
4. The breathing frequency is paced by a moving light and brief sounds.
5. In case of substantial deviation from the ideal training frequency, the Spiro Tiger ® issues optical and acoustic warnings
6. The data collected during a training session are passed by cable to the basic station where they are monitored and stored.

Fig. 1. Spiro Tiger. Description: Held unit with specific valve and respiratory pouch. Personal training target values are entered into the basic unit and serve to monitor the breathing frequency and depth during training. The display provides instruction such as "breathe faster" and a bar shows the respiration depth. The breathing frequency is paced by a moving light and brief sounds. In case of substantial deviation from the ideal training frequency, the Spiro Tiger ® issues optical and acoustic warnings. The data collected during a training session are passed by cable to the basic station where they are monitored and stored.

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times during the year of intervention, starting after a minimum of 3 months from the end of the training. We decided to wait 3 months to obtain measures because there is evidence that the placebo effect takes approximately 12 weeks to recede [12].

Patients were free to drop out from the study at any time and go back to HiPEP or choose to have no physiotherapy. They were also allowed to continue respiratory training for any length of time they chose after the first year of follow-up.

Written informed consent was obtained before enrolment from each patient or from the patient's legal guardian, when younger than 18 years of age.

The Local ethical committee approved the study.

2.3. Training device

The SpiroTiger® training device consists of a hand-held unit with a respiratory pouch and a base station (Fig. 1). The specific properties of the device allow for personalized respiratory training through maximal inspirations and expirations without hypocarbia, and without the limitation of lower limbs muscles involvement. To avoid hypocarbia despite hyperventilation the Spiro Tiger® features a two way piston valve connecting to a rebreathing bag. As the patient breathes out through the mouthpiece, the rebreathing bag stores part of the expired air, which contains increased concentrations of carbon dioxide. Once the rebreathing bag is filled to its capacity, a valve opens and allows the rest of the expired air to be released into the environment. The valve shuts when expiration finishes and inspiration starts. Inspiration empties the rebreathing bag first (containing increased concentrations of carbon dioxide), then the valve opens and some fresh outside air is inspired at the end of each inspiration.

Personal training target values are entered into the base unit and are used to monitor the breathing frequency and depth during training.

The base station in the hand-held computer monitors the breathing frequency, sets threshold limits for breathing patterns, and displays visual and acoustic feedback so as to allow the subject to breathe within the threshold values for isocapnia.

The base station also stores time and frequency of each exercise session, thus allowing the patient and his/her health care provider to retrieve and review the data.

2.4. Setting of training sessions and training parameters

Training parameters were established by the respiratory physiotherapist, based on the patient's respiratory tests, clinical conditions and on the results of a preliminary test on the training machine. Rebreathing bag size and respiratory frequency are crucial in ensuring end-expiratory CO_2 concentrations within acceptable physiological parameters. All sessions are dedicated to a single clinically stable patient and performed in the CF clinic by the physiotherapist who has been in charge of the treatment in previous years. Four training sessions of 30 min each over a 3 month period were performed:

- First session: theory, explanations, demonstration, and 10 min training.
- Second session: breathing co-ordination and choice of the rebreathing bag.
- Third session: targeting patients' outcomes in terms of respiratory frequencies, volume of the pouch, feed-back levels.
- Fourth session: two minute warm-up at 26–27 breaths/min, followed by a 14 min training at 29–30 breaths/min. Training sessions are strictly tailored on patients' respiratory function. Patients with more severe respiratory conditions were trained with lower frequencies to avoid the risk of shortening expiratory time with hyperinflation.

- The choice of the rebreathing bag's volume was based on the patient's forced vital capacity (FVC), starting with a rebreathing bag size roughly equivalent to half the patient's FVC.
- The respiratory rate was initially set at 24 breaths/min for 2 min, eventually using 2 min of maximal inspiratory and expiratory breaths at an increasing breathing frequency.
- Frequency and length of training cycle: a daily training session was performed for the first week at a frequency of 27–28 breaths/min for a period of 10 min then increased to at least 14 min, at least 4 days a week.
- Intensifying the training: this was obtained by increasing the rebreathing bag volume by 10% in the last 3–4 min in order to increase the work load. Increasing the rebreathing bag volume is preferable to increasing the respiratory frequency in patients with important lung involvement who are at risk of delayed emptying of alveolar units with lower constant of time.

2.5. Antibiotic treatment policy

Oral antibiotic treatment was prescribed for minor respiratory exacerbations (increased cough, increased sputum expectoration,

Table 2
Main characteristics of enrolled population ($n=24$)

Male sex $n=24$ (%)	58%
Age (mean, SD)	21.3 (6.6)
BMI (mean, SD)	20 (3.1)
Height (mean, SD)	165.2 (9.9)
Weight (mean, SD)	55.9 (13.2)
Colonized with $n=24$ (%):	
Pseudomonas	17 (70.8)
Cepacia	5 (20.8)
MRSA	7 (29.2)
Serratia	1 (4.2)
Steroid treatment for aspergillosis $n=24$ (%)	2 (8.3)

Table 1
Patients' perception of physical fitness

1. Choose three physical activities you like to do, and that represent your well being status (e.g. Swimming, playing soccer, going for a walk)
2. Give a mark from 0 to 10 to each activity based on the difficulties you experience in performing it. 10 is the best desirable result (no difficulty), 0 the worst (I can't do it).

Example of the questionnaires used.

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Table 3
Main results ($n=24$)

	Before	After	P
FVC % predicted (mean, SD)	93.2 (17.3)	98.5 (14.3)	0.003
FEV1 % predicted (mean, SD)	75.9 (20.5)	81.3 (24.4)	0.002
FEF 25–75 % predicted (mean, SD)	54.1 (33)	57.1 (37.8)	0.5
Oral antibiotics (cycles/year) (mean, SD)	2 (1.3)	1.96 (1.2)	0.8
Intravenous antibiotics (cycles/year) (mean, SD)	1.8 (1.4)	1 (1.3)	0.001
Perception of physical fitness (mean, SD)	6.1 (1.2)	9.1 (0.8)	<0.001

diminished appetite, lower viral respiratory infections, decrease in FEV1 above 10%, increased CRP). Intravenous antibiotics were prescribed for more important respiratory exacerbations, or in the case of inadequate response to oral treatment. Inhaled antibiotic treatment was prescribed to maintain stable pulmonary function in patients who were more likely to have a faster decrease in FEV1 and FVC, requiring frequent intravenous treatments. This antibiotic treatment policy did not change over the study period.

2.6. Measures of outcomes

Lung function (FVC, FEV1, FEF 25-75) was measured at 3 to 4 months intervals in the year before and during treatment using a dry wedge SensorMedics Vmax 22 spirometer (SensorMedics®, Milano, Italy). For each lung function outcome data was calculated as average value before and during treatment. All parameters were expressed as percentage prediction according to age, height and gender.

The number of antibiotics treatments was recorded before and during the period of the study.

The perception of physical fitness was routinely measured by means of an analogue scale at every control visit. Patients were asked to specify three physical activities that could represent their physical fitness. Patients were then instructed to assign a mark from 0 to 10 based on the difficulty to carry out physical activities due to dispnoea or other pulmonary symptoms (0 being the worst value and 10 the best). For each patient we calculated the average scores on a minimum of three controls before and during treatment. An example of the questionnaires is shown in Table 1.

Adherence to treatment was assessed using the software included in the training device. Adherence to treatment was arbitrarily defined as good for evidence of training 6 days out of 7 for at least 16 min, as low for evidence of training more than 3 days out of 7 for at least 16 min, and as absent (no adherence) below 3 days a week.

Patients' opinions on the amount of cough, on easiness in mucus expectoration and on dyspnoea were investigated by means of a questionnaire administered before the beginning of the study and repeated after 6 months of treatment. Patients were asked to assign a mark from 0 to 10 on a visual analogue scale, 0 being the worst value and 10 the best.

2.7. Statistical analysis

We did not perform an "a priori" sample size calculation due to the characteristics of the study (pilot study). We also estimated to enrol all subjects who matched the above reported inclusion criteria in the study period. Furthermore, there were no previous studies on SpiroTiger in CF patients.

Data presented in the results are referred to the whole year before and after the enrolment. Categorical data are presented as numbers and percentages, continuous variables as means and standard deviations (SD). Differences between continuous variables were evaluated using a non-parametric test for paired data (Wilcoxon Signed Ranks Test), assuming a non-normal distribution of data. The statistical analysis was carried out with SPSS 11.0 statistical software.

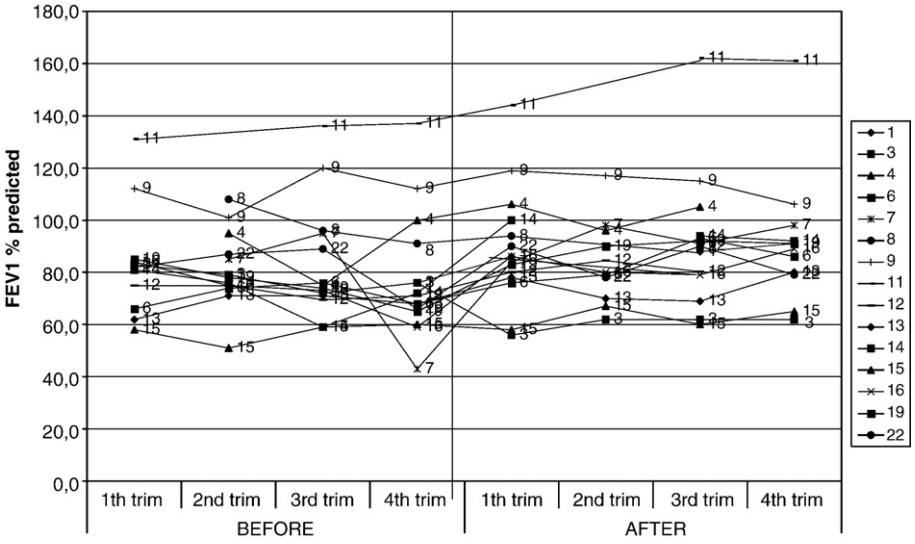

Fig. 2. Graphical representation of FEV1 values in patients with good compliance. Each number represents a patient.

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3. Results

3.1. Study group characteristics

SpiroTiger training was offered to 24 patients and all accepted to enter the study. Demographic and clinical data are shown in Table 2.

All patients started the initial training, 2 patients did not regularly attended the first 4 scheduled training sessions; none decided to stop training and returned the training device or went back to HiPEP. All patient were followed up for 1 year after enrolment. The data presented are referred to the complete year before and after the enrolment. Lung function tests, cycles of oral and intravenous antibiotics treatments, perception of physical fitness before and after the period of the study are all shown in Table 3. Graphical representation of FEV1 over the study period is shown in Figs. 2 and 3.

3.2. Inhaled antibiotic treatment

5 out of 24 patients received inhaled antibiotic during the study period: 2 patients in the year before and during intervention, 1 only in the year before intervention, and 1 started inhaled antibiotics treatment in the year of intervention. 1 patient who was assuming inhaled treatment in the year before intervention stopped it while using Spiro Tiger®.

3.3. Adherence to treatment

15/24 patients (63%) showed good adherence to the treatment with SpiroTiger; 7/24 (29%) low adherence; 2/24 (8%) no adherence.

Patients' opinions: questionnaire results are shown in Table 4. Data were available for 23/24 patient. One patient with insufficient adherence to treatment did not answer the questionnaire.

Table 4
Patients' opinions ($n=23$)

	hiPEP mask	STM (Spiro Tiger Medical)	P
Efficacy of treatment in reducing the amount of cough (mean, SD)	0.7 (0.5)	8.4 (1.4)	<0.001
Efficacy of treatment in mucus drainage (mean, SD)	2.9 (1.7)	9.3 (0.8)	<0.001
Efficacy of treatment in reducing dyspnoea with effort (mean, SD)	0	9.3 (0.6)	<0.001

Results are expressed in terms of 0–10 on a visual analogue scale (0 is the worst value, 10 is the best).

4. Discussion

In this experience respiratory training through a specific commercial device in CF patients was associated with improved lung function and perception of physical fitness.

The study has some limitations, in particular the lack of a measure of respiratory muscle strength, the design without a control group, and the possible bias due to the increased attendance in CF clinic required for the training. To limit these possible biases we chose a long term follow-up, and strong parameters of outcome such as respiratory function and adherence to physiotherapy. We didn't measure quality of life using a specific questionnaire (e.g. St. George Respiratory Questionnaire or AQ20). According to the literature it is difficult to administer standardised questionnaires to an extremely variable population such as that of patients with CF

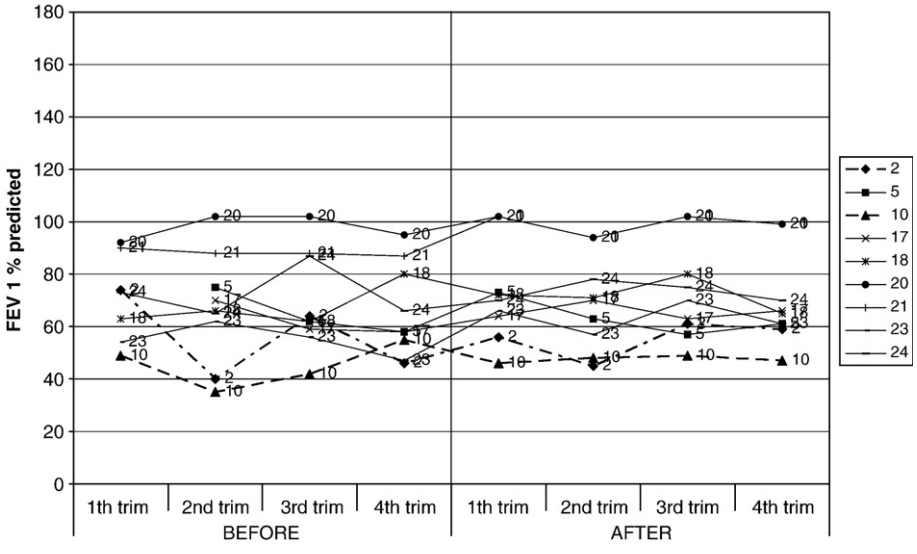

Fig. 3. Graphical representation of FEV1 values in patients with low and no compliance. Each number represents a patient, the two patient with no adherence are represented in dotted lines.

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[13,14]. This is why we preferred to simply measure the perception of physical fitness.

In CF patients, the lung disease and the secondary chest and muscle alterations are associated with a reduction in compliance and elastic recoil, with an increase in respiratory resistance and hyperinflation. With time, the loss of fat-free mass in chest muscles further reduces inspiratory muscle function. It has been demonstrated that the force that a skeletal muscle can generate depends on its effective cross-sectional area and on the geometry with which it applies its tensile force [15]. For this reason the increase of the cross-sectional area of the inspiratory muscles due to hypertrophy may reverse or delay the consequences of impaired inspiratory muscle function.

In our experience a specific respiratory training device led to an increase in ventilation without hypocarbia, at the same time allowing for feed-back during exercise, good focusing and flexibility of the training, and control of adherence to treatment through the software. No breathing resistances are used in this device, while it allows for maximal inspirations and expirations which are usually rarely experienced by CF patients who are limited by scarce endurance of inferior limb muscles. The hypothesis is that this kind of respiratory training, which is made possible by the design of the device, produces an advantageous stretching effect on chest wall.

Enright et al. [11] demonstrated that inspiratory muscle training over an 8 week program improves lung function and exercise capacity in adults. Keens et al. in 4 weeks of normocapnic-hyperpnea and resistive breathing showed an improvement of endurance and strength, but the effects were no grater than those obtained by general aerobic exercise training [16]. Asher et al. after 6 weeks with low-intensity inspiratory threshold loading at 40% of maximal inspiratory pressure, showed an improvement in inspiratory muscle endurance but no effects on pulmonary function [17]. It has been demonstrated that in CF patients, greater levels of aerobic fitness and exercise capacity are associated with lower levels of mortality [18] and improved psychosocial status [19] respectively. The hypothesis is that the specific properties of the device provide respiratory training and increase mucus clearance. To the best of our knowledge, no previous studies have addressed both these issues at the same time.

Since these activities involve building up muscle mass, specific care to ensure adequate nutrition should be taken with these patients [20].

Given the long follow-up and the expected decline in lung function in time in CF patients [21,22], our positive results are encouraging in terms of pulmonary tests, perception of physical fitness and, to a lesser extent, reduced requirement for intravenous antibiotic treatment.

Indeed, patients' opinions showed a preference for respiratory training with this device with respect to HiPEP, with a relevant subjective perception of benefit in several every day life aspects. It is well known [23] that adherence to physiotherapy is variable in CF patients, the percentage of adult patients carrying out daily chest physiotherapy being lower than 30%. Our series is limited to 24 patients and more data are needed, but the percentage of patients maintaining good adherence to the treatment argues in favour of the perception of benefit and efficacy of this approach.

In conclusion this study shows an association between respiratory training through a specific commercial device and improved lung function. Further well designed trials are needed to confirm this preliminary report.

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