



ORIGINAL

CYSTIC FIBROSIS: COMPARISON BETWEEN CONVENTIONAL CHEST PHYSICAL THERAPY AND POSITIVE EXPIRATORY PRESSURE IN HOSPITALIZED PATIENTS

FIBROSE CÍSTICA: COMPARAÇÃO ENTRE FISIOTERAPIA TORÁCICA CONVENCIONAL E PRESSÃO EXPIRATÓRIA POSITIVA EM PACIENTES HOSPITALIZADOS

Jefferson VERONEZI¹

Rafael VERCELINO²

Cristina MADRUGA³

Kamile BORBA⁴

Patrícia KAMINSKI³

Paulo José Cauduro MAROSTICA⁵

ABSTRACT

Objective

To compare the efficacy of Conventional Chest Physical Therapy with Positive Expiratory Pressure in the treatment of cystic fibrosis patients during hospital treatment of exacerbation.

Methods

Randomized clinical trial with 29 patients at the *Hospital de Clínicas de Porto Alegre*. Thirteen patients were randomly assigned to Group A (Positive Expiratory Pressure) in which the seated patient went through 15 breathing cycles using a

¹ Centro Universitário Metodista IPA. Rua Joaquim Pedro Salgado, 80, Porto Alegre, RS, Brasil. Correspondência para/Correspondence to: J. VERONEZI. E-mail: <jeffveronezi@ig.com.br>.

² Laboratório de Fisiologia e Hepatologia, Universidade Federal do Rio Grande do Sul. Porto Alegre, RS, Brasil.

³ Complexo Hospitalar Irmandade Santa Casa de Misericórdia de Porto Alegre. Porto Alegre, RS, Brasil.

⁴ Hospital Moinhos de Vento. Porto Alegre, RS, Brasil.

⁵ Emergência do Hospital de Clínicas de Porto Alegre. Porto Alegre, RS, Brasil.

mask with a positive end-expiratory pressure of 13 cmH₂O, followed by huffing without the mask along with coughing and expectoration. This sequence was repeated 7 times during 30 minutes. Sixteen patients were included in group B (Conventional Chest Physical Therapy) where patients assumed five postural drainage positions. In each position, the chest was submitted to manual clapping for three minutes associated with vibration, deep breathing, huffing, coughing and expectoration. Each position was maintained for five to seven minutes for a total of 30 minutes, twice daily. The patients were evaluated before and after the treatment using pulmonary function tests, peak expiratory flow, measurement of the arterial oxyhemoglobin saturation and determination of the Shwachmann radiographic score.

Results

In a comparison of the outcomes of the two groups using the Student t test and analysis of covariance, there were no statistically significant differences between the two groups with respect to outcome ($p < 0.05$).

Conclusion

The results indicated no differences between the techniques evaluated. Further studies are necessary since PEP gives more autonomy to the patients.

Indexing terms: cystic fibrosis; conventional chest physical therapy; positive-pressure respiration.

RESUMO

Objetivo

Comparar a eficácia da Fisioterapia Torácica Convencional versus a Pressão Expiratória Positiva no tratamento de fibrocísticos internados para tratamento da exacerbação.

Métodos

Ensaio clínico randomizado em 29 pacientes do Hospital de Clínicas de Porto Alegre, divididos em Grupo A (13 pacientes) e Grupo B (16 pacientes). Os pacientes do Grupo A foram tratados por meio de pressão expiratória positiva e, sentados, realizavam 15 ciclos respiratórios dentro da máscara, com pressão expiratória positiva final de 13 cmH₂O seguidos de 2 a 3 huffing fora da máscara com tosse e expectoração; esta seqüência foi repetida 7 vezes durante 30 minutos. Os pacientes do Grupo B, tratados por meio de fisioterapia torácica convencional, assumiram 5 posições de drenagem postural, mantidas de 5 a 7 minutos, totalizando meia hora, 2 vezes ao dia. Em cada posição, o tórax foi submetido a tapotagem associada à vibração, respiração profunda, huffing, tosse e expectoração por 3 minutos. Os pacientes eram avaliados antes e após o tratamento por meio das provas de função pulmonar, pico de fluxo expiratório, saturação da hemoglobina por oxigênio e escore radiológico de Shwachman.

Resultados

Comparando-se as variáveis entre os grupos com o teste "t" Student e análise de covariância, não houve diferença estatisticamente significativa ($p < 0,05$).

Conclusão

Esses resultados não demonstraram diferença entre as técnicas avaliadas. A pressão expiratória positiva é um método que justifica estudos adicionais, pois propicia aos pacientes maior autonomia.

Termos de indexação: *fibrose cística; fisioterapia torácica convencional; respiração com pressão positiva.*

INTRODUCTION

Cystic Fibrosis (CF) or mucoviscidosis is an autosomic recessive, potentially lethal disease, more common amongst Caucasians. It is multisystemic, primarily compromising the epithelial organs¹. The estimated incidence of CF in white individuals ranges from 1:2000 to 1:2600 live newborns. In Brazil, 1983, Raskin et al.² estimated a variable occurrence according to the geographical area and the degree of miscegenation amongst the people, being 1:2000 in the State of *Rio Grande do Sul* but going down to 1:10000 in the State of *São Paulo*.

The classic clinical description of CF is chronic obstructive pulmonary disease, failure to thrive as a secondary response to malabsorption, pancreatic insufficiency and salty sweat.

The respiratory symptoms are usually a chronic cough, excessive production of thick sputum due to dehydration of the cell surface caused by malfunctioning of the chloride channel in the apical membranes of the epithelial cells, inflammation and infection¹.

The treatment includes daily respiratory physical therapy, frequent use of antibiotics, anti-inflammatory drugs, bronchodilators, mucolytics, psychological and social support, pancreatic enzyme supplements and nutritional support to ensure the best possible nutritional condition^{2,3}.

Decreased mucociliar clearance leads to bacterial infection, possibly causing atelectasis of a section or lobe of a lung and if not treated, the final result will be a seriously bronchiectasic segment or lobe^{4,5}.

Since 1950, physical therapy for pulmonary manifestations of CF has been conventional chest physical therapy (CPT) (postural drainage position, clapping, deep breathing, vibration and coughing) aiming at better clearance of lung secretions⁶.

Though these techniques are recommended at most CF treatment centers, there are significant difficulties involved in using this therapy. An assistant is necessary, it requires time and room, it produces

discomfort, which contributes to poor compliance to the treatment, besides the possibility of causing hypoxia in patients with severe pulmonary disease, where the gastroesophageal reflux can occur during postural drainage^{7,8}. To overcome these problems, alternatives have been suggested, with varied results.

Recently, new methods of respiratory physical therapy have been developed, including the active cycle of breathing (ACB), positive expiratory pressure (PEP) and autogenic drainage⁹.

Developed in Denmark, the therapy using PEP involves expiration against a resistance to a variable flow. In theory, PEP helps move the secretions in the airways via collateral ventilation⁹. A maneuver during huffing subsequently allows the patient to produce the necessary flow to expel the mucus from the obstructed airways. Most of the clinical studies using PEP therapy involved patients with CF, and when compared to other methods of bronchial hygiene (postural drainage associated with percussion and vibration, autogenic drainage and ACB), produces a comparable mucociliar clearance⁹. Amongst the advantages of this technique are easy understanding, no need for an assistant after a learning period, adaptability to different facilities and postures, besides the feasibility of using for children as from three years old.

Due to the issue of autonomy, PEP could become an alternative, since evidence of its effectiveness is already available. With this purpose, a study was carried out, which compared the efficacy of CPT to PEP in the bronchial clearance of patients admitted for clinical treatment of pulmonary exacerbation.

METHODS

A randomized clinical trial was carried out in a consecutive sample of 29 CF patients admitted for clinical treatment at the Pediatric and Adult Pulmonology Units from March 2000 to March 2002.

Cystic fibrosis patients over 6 years old, admitted with pulmonary exacerbation according to

standard criteria, were eligible. Every patient included was submitted to intravenous and inhaled antibiotics, besides the use of inhaled 3% hypertonic saline.

Pulmonary exacerbation was defined as an increase in the amount or frequency of cough or sputum production, new crackles, hemoptysis, decrease in pulmonary function, loss of weight or a renewed acquisition of *Pseudomonas aeruginosa* in pulmonary secretions¹⁰. Patients needing oxygen therapy, colonized with *Burkholderia cepacia*, those with FEV₁ <40% according to the last pulmonary function test and those considered clinically unstable as evaluated by the assistant physician, were excluded.

The CF patients were admitted to the hospital for at least 14 days. After admission, the subjects involved in the study were submitted, on the first day, to chest radiographs and a pulmonary evaluation (SpO₂ and PEF) carried out by a physical therapist, who was not aware to which group the patient had been randomized to. Spirometry was carried out during the first half of the hospitalization period, soon after the release of the sputum bacteriological test results, in accordance with the hospital infection control policy. On the 14th day of hospitalization, a pulmonary reevaluation was performed, when all the outcomes were rechecked.

The pulmonary function testing was done at the Pulmonary Physiology Unit of the Pulmonology Service. Spirometry was performed in a sitting position using a Jaeger™ - v4.31^a equipment (Jaeger, Wuertzburg, Germany) and the technical acceptability criteria of the guidelines for pulmonary function testing¹⁰. FVC, FEV₁, the FEV₁/FVC ratio and FEF_{25-75%} were measured. The values were expressed as percentages of the expected value according to gender, age and height¹¹.

Oxygen hemoglobin saturation (SpO₂) was checked using a portable oxymeter, model 9500™ (Nonin Medical, Inc, Minneapolis, MN, USA).

PEF was checked by a physical therapist using a STECH™ peak flow meter (Center Laboratories, Healthscan Products Inc., USA) according to conventional standards, recording the best of three efforts.

Conventional chest radiographs in the frontal and side positions were interpreted blindly (with no identification, clinical information or pulmonary function tests) by a pediatric pulmonologist, using the radiographic column of the Shwachmann score system¹².

Patients eligible for treatment were allocated to group A (PEP) or group B (CPT) according to a table with random numbers.

Group A (PEP): the seated patient went through 15 breathing cycles using a spring load valved mask with a PEEP of 13 cm H₂O, followed by two or three huffings without the mask by coughing and expectoration. The patient was then allowed to breathe calmly for one minute. This sequence was repeated seven times during 30 minutes, twice daily.

Group B (CPT): The patients were put in five different positions for postural drainage aiming at clearing the most usually compromised pulmonary lobes and segments. In each position, three-minute sequences of manual clapping, followed by deep breathing and expiratory vibration (10 movements), huffing, coughing and expectoration were carried out. Each position was maintained for five to seven minutes, for a total of 30 minutes, twice daily.

The patients were kept in the study protocol for 12 days of hospitalization (from the second to the thirteenth day) independent of their length of stay, which was determined by the assistant physician according to the patient's improvement.

Before starting the study, four physical therapists were trained by the Head of their CF center. The study was only begun when they were considered adequately trained for the assignment.

The study was evaluated and approved by the Research and Ethics Committee, HCPA. All patients, or their legal guardians, were informed of the study objectives and signed a consent form.

The database was in Excel and the analyses were done using the Statistical Package for Social Sciences (SPSS)¹⁰.

The data collected were analyzed by descriptive statistics using the means, standard

deviations, differences, confidence interval, standardized effect size (ES) and levels of significance. A comparison between the groups of the continuous variables was done using the Student "t" test and analysis of covariance. The differences were considered significant when $p < 0.05$.

RESULTS

Of the 29 patients included in this study, 12 (41.38%) were male. Thirteen (44.82%) patients were allocated to group A (PEP) and 16 (55.17%) to group B (CPT). Except for age and FEV₁, which were greater in Group A (PEP) (10 ± 5 years old *versus* 9 ± 3 ; $P = 0.048$) and ($67 \pm 17\%$ of the expected value *versus* $82 \pm 22\%$, $P = 0.049$) respectively, the other variables were not statistically different at the baseline evaluation (Table 1).

Comparing all patients from both treatment groups, there was an improvement in SpO₂

($95.69\% \pm 2.80\%$ to $97.10\% \pm 1.52$, $p < 0.01$), in PEF (192.93 ± 100.29 to 255.17 ± 130.93 , $p < 0.001$) and in the radiologic score (13.06 ± 3.94 to 14.79 ± 3.76 , $p < 0.001$) from the first measurement done on the day of admission to the 12th day. On the other hand, comparing the spirometric data from the 6th to the 12th days, no significant differences were found.

After a 12-day treatment period, there were no statistically significant differences between the groups, after controlling the initial differences in age and FEV₁ by analyses of covariance (Table 2).

Also, on evaluating the changes in the outcome parameters, before and after treatment, no significant differences were observed between the two groups (Table 3).

The power of the sample size used to detect a difference of 20% in FEV₁ was 60%.

Table 1. Clinical, functional and radiographic baseline features of the patients.

	Group A (PEP)		Group B (CPT)		p^*
	M	± DP	M	± DP	
Age (years)	10	± 5	9	± 3	0.048
FVC (%)	82	± 23	69	± 15	0.080
FEV1 (%)	82	± 22	67	± 17	0.049
FEC1 (%)	99	± 14	95	± 14	0.500
FEMF (%)	77	± 32	56	± 30	0.080
PEF (L/min)	229	± 129	163	± 56	0.080
SaO ₂ (%)	96	± 2	94	± 3	0.110
Score Rx	12	± 5	13	± 3	0.830

Values were expressed as mean and standard deviation. Pulmonary function test results are expressed in the expected percentage for the age, gender and height. * Student "t" test.

Table 2. Functional variables and radiographic score after treatment.

	Group A (PEP)		Group B (CPT)		p^*
	M	± DP	M	± DP	
FVC (%)	80	± 18	75	± 14	0.42
FEV1 (%)	79	± 17	71	± 18	0.27
FEC1 (%)	98	± 9	94	± 14	0.43
FEMF (%)	73	± 27	56	± 29	0.12
PEF (L/min)	303	± 166	215	± 78	0.07
SaO ₂ (%)	97	± 2	96	± 1	0.17
Score Rx	15	± 4	14	± 3	0.70

The values were expressed in mean and standard deviation. * Student "t" test.

Table 3. Variables changes (before and after treatment) for groups.

	Group A (PEP)	Group B (CPT)	DIF	ES*	p^{**}		
FVC (%)	-2.53	± 13	5.43	± 11	-7.97	0.66	0.09
FEV1 (%)	-3.46	± 11	4.50	± 8	-4.64	0.89	0.19
FEC1 (%)	-0.69	± 7	-0.62	± 6	-0.07	0.01	0.98
FEMF (%)	-4.00	± 15	0.19	± 10	-4.18	0.39	0.39
PEF (L/min)	74.00	± 102	52.00	± 43	21.73	0.27	0.50
SaO ₂ (%)	0.92	± 2	1.81	± 3	-0.89	0.35	0.40
Score Rx	2.27	± 2	1.33	± 1	0.94	0.54	0.17

The values above are expressed as mean, standard deviation, effect and size difference. ES* – Standard Effect Size. **Student "t" test.

DISCUSSION

The results of this study demonstrated that both techniques were potential tools for use in bronchial clearance in patients with CF, especially during pulmonary exacerbation periods, no differences between the treatments being observed.

It is known that during pulmonary exacerbation, clinical, functional and radiographic changes occur, associated with an increase in airflow obstruction initially located in the distal airways and progressing to the intermediate and proximal ones⁹.

The subjects involved in this study were evaluated for 12 days. PEP was the alternative therapy chosen because it is a technique widely recommended in the international literature for CF treatment, despite the scarcity of supporting studies. Furthermore, it is a technique that gives autonomy to the patient, without depending on technicians or family members to help apply it^{7,13-16}. A level of 13 cm H₂O of PEEP was chosen because this is the recommended pressure level to recruit collapsed pulmonary areas^{17,18}.

Huffing was associated with the treatment in both groups, since it has been shown to be one of the most effective techniques for respiratory physical therapy, based on the physiological concept of equal pressure points (EPP)¹⁵ and, above all, because it also gives the patients more autonomy. EPP occurs at some point along the airways, where the inner pressure is the same as the outer pressure in the pleural space. In this technique, the EPP migrates from the larger airways towards the smaller ones, as the lungs are emptied¹⁹. In CF, hypertrophy and hyperplasia of the calciform mucus secretory cells occur in the smaller airways²⁰. It is believed that mucus produced in the lower airways is led to the upper ones through the mucociliary layer, which moves in the cephalic direction⁴. The use of PEP involves expiration against a variable flow resistance. Theoretically, PEP helps to mobilize large airway secretions by filling hypo or non-ventilated segments through collateral ventilation and by preventing airway collapse during expiration⁹. Huffing is associated so that the patient can expel the mucus.

Most of the subjects were admitted to the study based on a clinical evaluation that took into account clinical variables like coughing, sputum production, shortness of breath and fever, amongst others. Spirometry was usually performed on about the 6th day after admission, when the results of the sputum culture would be available, in accordance with the local Infection Control Committee policy that advises against treating together patients with different germs. This is the reason why some of the patients showed no significant improvement in the spirometric variables. It is probable that improvement would have been detected if the spirometry values had been measured on admission and then on the 13th day, since there was a significant increase in PEF, SpO₂ and the radiologic score during this period.

In 1984, Falk et al.¹⁴ studied the effects of four physical therapeutic techniques in a randomized crossover study with 14 CF patients. The patients who used the PEP mask showed better results than those who did not, with respect to FVC and sputum weight. They used PEEP levels of 17cmH₂O, which were higher than those used in the present study, which may explain the differences in the findings.

In 2004, Darbee et al.¹⁵ demonstrated the efficacy of PEP in five CF patients with moderate to severe pulmonary involvement. There was a greater improvement in the physiological parameters as well as in the sputum volume in these patients, who were also treated with higher levels of PEP than our patients.

In 1986, Oberwaldner et al.¹³ carried out a study with 20 CF patients. One group used the PEP mask and the other, conventional chest physical therapy (CPT). In the group using the PEP mask, the patients removed a larger volume of secretion than those in the CPT group. There was a significant increase in expiratory flow and decrease in hyperinsufflation with the use of the PEP mask. There was a decrease in pulmonary function when the mask was not used. They concluded that this method increased pulmonary function and bronchial clearance in CF patients. Differently from this study, the patients were not necessarily exacerbated, and

were treated for a period of ten months. It is reasonable to suppose that, outside the hospital environment as a long-term management measure, the use of the PEP mask would be more effective, due to being easier to accept than CPT.

In 1991, Steen et al.¹⁶ made a random, crossover study using 38 CF patients. They compared five physical therapeutic techniques, three of which used the PEP mask, and evaluated the spirometric variables, secretion weight and radiographic scores. No significant differences were found between the groups.

In 1997, McIlwaine et al.⁷ compared postural drainage and percussion (DP & P) versus PEP in 40 CF patients, in a similar design to that of the present study.

The spirometric variables were better in the PEP group. However, the patients were ambulatory, in a stable condition and with mild pulmonary involvement. It is possible that exacerbated patients, with an increase in intrinsic inflammatory processes, respond differently as compared to those in a more stable condition.

In 2001, McIlwaine et al.¹⁷ made a clinical experiment at random, comparing the PEP mask to the Flutter in 40 CF children. They found that the Flutter was the least effective in maintaining pulmonary function and with respect to the number of hospital admissions. Different from our study, no patient had CPT.

In a systematic review, Elkins et al.²¹ showed that the PEP technique was as effective as other standard techniques in patients with CF. These results are in agreement with ours.

It is important to mention that, in the present study, the small sample size might have interfered with the results, leading to a β type error. On the other hand, the size of the sample was similar to others reported in the literature, in which the intention was to evaluate physical therapeutic techniques^{13,14}.

This limitation is justified by the relatively low prevalence of CF, and ineligibility of severely ill patients. Another study design including ambulatory

patients could solve this issue, but our intention was to evaluate patients in a hospital setting.

In conclusion, the PEP mask was as effective as CPT in the management of patients with exacerbated CF. Further studies with more patients are recommended.

A C K N O W L E D G M E N T S

To the Pulmonology and Pediatric Pulmonology Staff of HCPA for the allocation of patients for this study.

To the Research and Graduate Staff of HCPA for the epidemiological supervision and statistical analyses.

R E F E R E N C E S

1. Marostica PJ, Raskin S, Abreu-e-Silva FA. Analysis of the deltaF508 mutation in a Brazilian cystic fibrosis population: comparison of pulmonary status of homozygotes with other patients. *Braz J Biol Res.* 1998; 31(4):529-32.
2. Andrade EF, Abreu-e-Silva FA. Fibrose cística. In: Corrêa da Silva LC. *Conduas em pneumologia.* Porto Alegre: Revinter; 2001. p.919-21.
3. Ribeiro JD, Ribeiro MAGO, Ribeiro AF. Controvérsias na fibrose cística: do pediatra ao especialista. *J Pediatría.* 2002; 78(2):171-86.
4. Robinson C, Scanlin FT. Cystic fibrosis. In: Fishmann AP, Elias JÁ, Fishman JÁ. *Fishman's Pulmonary diseases and disorders.* New York: McGraw-Hill, 1998. p. 803-24.
5. Houtmeyers E, Gosselink R, Gayan-Ramirez G, Decramer M. Regulation of mucociliary clearance in health and disease. *Eur Resp J.* 1999; 13(5):1177-88.
6. Webber BA, Pryor JA. Physiotherapy. In: Hodson ME, Geddes DM. *Cystic fibrosis.* London: Chapman & Hall Medical; 1995. p.349-57.
7. McIlwaine PM, Wong LT, Peacock D, Davidson GF. Long-term comparative trial of conventional postural drainage and percussion versus positive expiratory pressure physiotherapy in the treatment of cystic fibrosis. *J Pediatría.* 1997; 131(4):570-4.
8. Miller S, Hall DO, Clayton CB, Nelson R. Chest physiotherapy in cystic fibrosis: a comparative study of autogenic drainage and the active age of breathing techniques with postural drainage. *Thorax.* 1995. 50(2):165-9.

9. Scanlan C, Myslinski MJ. Terapia de higiene brônquica. São Paulo: Manole; 2000. p. 817-43.
10. Rabin HR, Butler SM, Wohl MEB, et al. Pulmonary exacerbation in cystic fibrosis. *Pediatric Pulmonol.* 2004; 37:400-6.
11. Sociedades Brasileira de Pneumologia e Tisiologia. Diretrizes para testes de função pulmonar. *J Pneumol.* 2002;1-82.
12. Shwachman H, Kulczycki LL. Long-term study of one hundred five patients with cystic fibrosis; studies made over a five-to-fourteen-year period. *Am J Dis Child.* 1958; 96(1):6-15.
13. Oberwaldner B, Evans JC, Zach MS. Forced expirations against a variable resistance: a new chest physiotherapy method in cystic fibrosis. *Pediatr Pulmonol.* 1986; 2(6):358-67.
14. Falk M, Kelstrup M, Andersen JB, Kinoshita T, Falk P, Stovring S, Gothgen I. Improving the bottle ketchup bottle method with positive expiratory pressure, PEP, in cystic fibrosis. *Eur J Respir Dis.* 1984; 65(6):423-32.
15. Darbee JC, Ohtake PJ, Grant BJ. Physiologic evidence for the efficacy of positive expiratory pressure as an airway clearance technique in patients with Cystic Fibrosis. *Physical Therapy.* 2004; 84(6):524-37.
16. Steen HJ, Redmond AOB, O'Neill D, Beattie F. Evaluation of the PEP mask in cystic fibrosis. *Acta Paediatr Scand.* 1991; 80(1):51-6.
17. McIlwaine PM, Wong LT, Peacock D, Davidson AG. Long-term comparative trial of expiratory pressure *versus* oscillating positive expiratory pressure (flutter) physiotherapy in the treatment of cystic fibrosis. *J Pediatr.* 2001; 138(6):845-50.
18. Azeredo CAC. Pressão expiratória positiva. In: Azeredo CAC. *Fisioterapia respiratória moderna.* São Paulo: Manole; 1993. p.56.
19. Levitzky MG. Mecânica da respiração. In: Levitzky MG. *Pulmonary physiology.* 6th. New York: McGraw-Hill; 2004. p.39.
20. Boat TF. Cystic fibrosis. In: Behrman RE, Kliegman RM, Jenson HB. *Tratado de pediatria.* 16. ed. Rio de Janeiro: Guanabara Koogan; 2002. p.1296-308.
21. Elkins MR, Jones A, Schans C. Positive expiratory pressure physiotherapy for airway clearance in people with Cystic Fibrosis. *Cochrane Database Syst Rev.* 2004; (1):CD003147.

Received for publication on April 13th 2005 and accepted on September 30th 2005.