Long-term comparative trial of conventional postural drainage and percussion versus positive expiratory pressure physiotherapy in the treatment of cystic fibrosis

P. Maggie McIlwaine, MCSP, CPA, Lawrence T. Wong, MB, BS, FRCPC, Donlim Peacock, MB, ChB, FRCPC, and A. George F. Davidson, BSc, MD, FRCPC

We report the results of a long-term comparative trial of physiotherapy by the positive expiratory pressure (PEP) technique with a PEP mask (Astra Meditec) versus conventional postural drainage and percussion (PD&P). Forty patients, ages 6 to 17 years, with Shwachman scores between 52 and 93, attending the cystic fibrosis clinic were enrolled in the study and randomly assigned to one of two groups. Group A (control) continued to perform physiotherapy by using PD&P for a 1-year period, whereas patients assigned to group B performed physiotherapy with the PEP technique for the same period. Compliance with physiotherapy was closely monitored for both groups throughout the study. Clinical status and pulmonary function (forced vital capacity [FVC], FEV_1, and FEF_{25-75}) were measured at 3-month intervals. Group B (PEP) demonstrated improved pulmonary function in all parameters as measured by change in percent predicted value for age, gender, and height. The changes in pulmonary function over the study period were: FVC, +6.57; FEV_1, +5.98; and FEF_{25-75}, +3.32. This improvement was significantly different from that of group A (PD&P) whose pulmonary function declined in all parameters (FVC, –2.17; FEV_1, –2.28; FEF_{25-75}, –0.24). The differences between treatment groups were statistically significant for the changes in FVC ($p = 0.02$) and FEV_1 ($p = 0.04$). Our results indicate that for our patients with cystic fibrosis, pulmonary physiotherapy with the PEP technique was superior to conventional physiotherapy with the PD&P technique. (J Pediatr 1997;131:570-4)

Since the 1950s, the standard treatment in North America for pulmonary manifestations of cystic fibrosis has used the physiotherapy techniques of postural drainage, percussion, deep breathing, vibration, and cough.[1] These techniques, often collectively called conventional physiotherapy or postural drainage and percussion therapy, are designed to improve the clearance of viscous secretions from the lungs. Although there is good evidence for the efficacy of PD&P in cystic fibrosis,[2-6] there are significant problems with the use of this therapy. The time required, the need for assistance from a second party, and the discomfort that many experience during therapy all contribute to a high degree of noncompliance, which may be more than 40%.[7,8] Hypoxia may be a significant problem during PD&P in patients with CF and severe lung disease[9,10]; and aspiration from gastroesophageal reflux may occur during the head-down postural drainage positions.[11] Therefore various alternative airway clearance techniques have been advocated; unfortunately, few have been adequately evaluated, and there have been no long-term comparative trials with PD&P as the standard of care.[12]

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Positive expiratory pressure was initially used postoperatively as a method to reinflate collapsed parts of lungs by increasing collateral ventilation.[13,14] However, it was also found to have a secretion removal effect. Falk et al.[15] combined this with forced expiration (huffing) and coughing to mobilize secretions, thus developing the PEP technique. Studies have shown that physiotherapy with PEP is at least as effective as conventional PD&P in mobilizing secretions in patients with CF.[15-20] PEP can be performed without aid from a second party and is effective without need for postural drainage (head-down) positions.[15,18,19] PEP physiotherapy therefore appears to offer potential advantages for patients with CF.[12] In the study reported here, we have determined whether PEP mask physiotherapy in the long term is as effective as conventional PD&P therapy currently in use in North America.

CF	Cystic fibrosis
FEF_{25-75}	Forced expiratory flow between 25% and 75% of vital capacity
FEV_1	Forced expiratory volume in 1 second
FVC	Forced vital capacity
PD&P	Postural drainage and percussion
PEP	Positive expiratory pressure

From Department of Paediatrics, University of British Columbia; and the Department of Physiotherapy and the Cystic Fibrosis Clinic, B.C.'s Children's Hospital, Vancouver, British Columbia, Canada.

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Reprint requests: A. George F. Davidson, BSc, MD, FRCPC, Cystic Fibrosis Clinic, B.C.'s Children's Hospital, 4480 Oak St., Room 2C66, Vancouver, B.C. V6H 3V4, Canada.

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METHODS

Subjects

Forty patients with CF, aged 6 to 17 years, were enrolled in the study after informed consent was obtained as approved by the University of British Columbia Ethical Review Committee. The diagnosis of CF was confirmed by sweat test with the Gibson-Cooke method.[21] At entry to the study all patients were judged to be competent and compliant in performing daily conventional PD&P physiotherapy at home. This was based on the clinical impression from long-term follow-up at the CF clinic, repeated assessment of the patient's knowledge of physiotherapy techniques, and the patient's reported adherence to physiotherapy at home. Patients also had to be competent in performing pulmonary function tests. At entry to the study each patient's condition was stable as judged by clinical evaluation, chest radiograph, and pulmonary function. No patient entered the study during or within 1 month of discharge from hospital or use of intravenous antibiotics or other intensive therapy for a pulmonary exacerbation. No study patient was receiving DNase or inhaled antimicrobials during the study period. Patients using inhaled β_2-bronchodilators or inhaled corticosteroids before commencement of the study were advised not to change any of these treatments during the 1-year study period.

Study Design

To provide balanced study groups, we paired patients according to their FEV_1 (within 15% of predicted value), sex, and age (within 3 years). Subjects within each pair were randomly assigned by computer to either group A or group B (Table I). Group A continued their prestudy chest physiotherapy using PD&P, and group B replaced their prestudy PD&P treatment with the PEP method. The study period was 1 year. On entering the study and at 3-month intervals, each patient had a full clinical assessment, including Shwachman and Huang scores,[22] performed at the CF clinic by physicians blinded to the method of physiotherapy the patient was performing. Sputum specimens for bacteriologic culture were obtained. Pulmonary function was determined by using standardized equipment, and results are reported as percent predicted value for age, gender, and height. The pulmonary function technician was also blinded as to which method of physiotherapy the patient was performing. The following indices were measured: forced vital capacity, FEV_1, and FEF_{25-75}. A chest radiograph was taken at the beginning and end of the study, and results were reported by a radiologist blinded to the study. Chest radiographs were also scored by using the Brasfield scoring system[23] by two clinic physicians in consultation with the radiologist, who were blinded to the patient's name, date of radiograph, and method of physiotherapy. Patients kept a daily record of treatment adherence and completed a monthly questionnaire. This questionnaire was used to record physical activity level, how the patient was feeling, amount of cough, sputum productivity, and patient's impression of the physiotherapy technique he or she was performing or adverse reaction to the technique; and it summarized compliance or reasons for noncompliance with physiotherapy. A level of less than 85% compliance with performance of twice daily physiotherapy over a 1-month period was considered the end point for noncompliance and a reason for the patient to be removed from the study. Patients were instructed to maintain their prestudy level of physical activity throughout the study period.

The primary outcome measured was the change in FEV_1, standardized for percentage predicted for gender, age, and height.[24] Secondary outcomes measured were FVC, FEF_{25-75}, number of hospitalizations, Shwachman and Huang scores, chest radiographs, and the patients' own evaluation of the technique.

Statistical analysis was carried out by using the Statistical Analysis Systems SAS/PC program[25] and the nonparametric routine in the NCSS computer program. Least squares regression was used to calculate the slope for rates of decline in each pulmonary function parameter and clinical score for each patient. A two-tailed t test for independent groups was then used to compare the mean slopes of decline. The significance level was set at 0.05 before the study. The secondary outcome of number of hospitalizations was analyzed by using a sign test.

Table I. Characteristics of patients on enrollment

	Group A PD&P	Group B PEP
Mean FVC (%)	94.95 ± 14.04	93.20 ± 14.99
Mean FEV_1 (%)	80.85 ± 15.97	80.10 ± 17.67
Mean FEF_{25-75} (%)	58.95 ± 22.24	54.85 ± 22.93
Mean age (yr)	9.75	10.40
Range (yr)	6-14	6-17
Male/female	12/8	10/10

Values for FVC, FEV_1, and FEF_{25-75} are expressed as means ± SD.
All pulmonary function test results are expressed as percent predicted based on age, gender, and height.

Treatment Techniques

CONVENTIONAL PD&P

During PD&P the patient assumed each of five or six postural drainage positions. In each position the chest wall was percussed for 3 to 5 minutes, followed by deep-breathing exercises combined with vibration on expiration, forced expirations, and vigorous coughing.[26,27] This required an average of 5 to 7 minutes to be spent in each PD&P position. Completion of this sequence for all drainage positions required approximately 30 minutes and was repeated twice daily. This regimen conforms to international standards[26,27] and to standard practice as reported by over 80% of North American CF centers (McIlwaine. Unpublished data).

POSITIVE EXPIRATORY PRESSURE

Physiotherapy by PEP was performed as described by Falk et al.,[15,26] using the

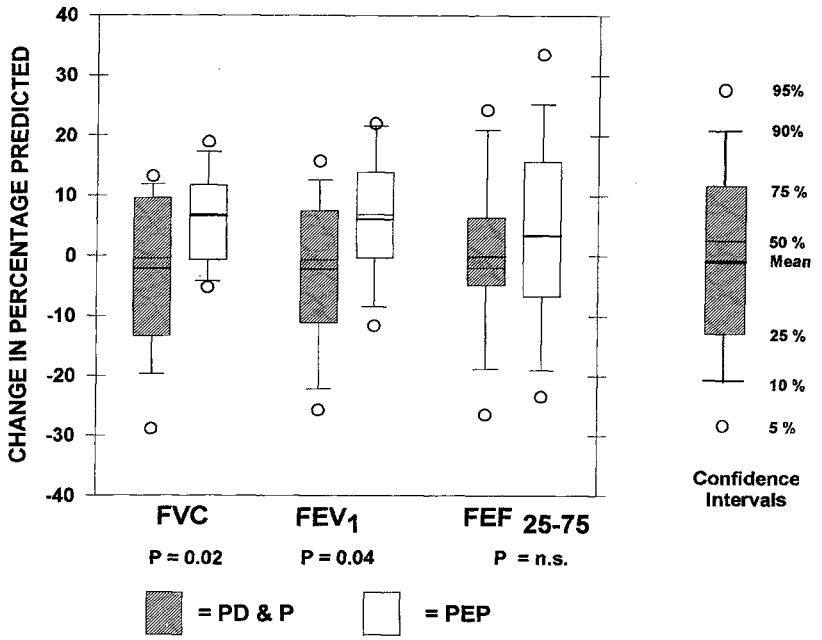

Fig. 1. Comparison of change in percentage predicted for pulmonary function parameters over a 12-month period between group A, performing PD&P, and group B, performing PEP.

Astra Meditec PEP set as follows. The PEP system consists of a mask and a one-way valve to which a resistor is attached at the expiratory orifice. A manometer inserted just proximal to the expiratory resistor was used to determine which resistor would create a steady PEP of 10 to 20 cm H_2O during the middle part of expiration. This was the resistor the patient then used during treatment. Treatment was carried out in a sitting position; the patient breathed in and out through the mask 15 times (approximately 2 minutes). Depth of inspiration was tidal volume, and expiration was slightly active against the mask. The patient then removed the mask and performed two or three forced expirations, followed by a cough to clear secretions that had been mobilized to the central airways. This was followed by a 1- to 2-minute period of relaxed controlled breathing. The above sequence was repeated six times and required approximately 20 minutes to complete. The patient was instructed to perform the regimen twice daily.

Results

Between January and April of 1994, 40 patients (22 boys), aged 6 to 17 years, were enrolled in the study and randomly assigned to either group A or B (Table I). The patients in both groups were evenly matched for pulmonary function and age. A broad range of pulmonary dysfunction was represented (FEV_1, 37% to 115% of predicted value). Thirty-six patients completed the 1-year study period. Two from each group dropped out because of noncompliance with treatment (performance of prescribed physiotherapy regimen less than 85% of the time) or nonattendance at clinic. There were no reported adverse effects from use of the PEP mask. No patient in either group had pneumothorax. Other adjunctive therapies at home remained stable, with 45% in group A and 35% in group B using inhaled β2-bronchodilators before physiotherapy. Twenty-five percent of patients in group A and 5% in group B used inhaled corticosteroids after physiotherapy.

The change in pulmonary function during the study period was determined from the regression slope over the study period for each pulmonary function parameter (FVC, FEV_1, and FEF_{25-75}), measured at 3-month intervals. In group A pulmonary function declined in all parameters, whereas in group B (who performed PEP) improvement in all pulmonary function parameters was demonstrated (Fig. 1). This improvement achieved statistical significance for FVC ($p = 0.02$) and FEV_1 ($p = 0.04$).

The number of hospitalizations was not significantly different (11 for group A and 13 for group B). No patient was receiving home intravenous antibiotic therapy during the treatment period. There were no significant differences between the groups with respect to prestudy and poststudy Shwachman and Huang scores, chest radiograph reports, or changes in bacteriologic cultures. In addition, there was no significant difference between the two groups with respect to prestudy Brasfield scores (7:00/25 [PD] 8:02/25 [PEP]) or to the change in score after study (0.37 ± 1.80 [PD] vs 0.37 ± 1.86 [PEP], $p = 1.0$). Patients in group B (PEP group) who had performed PD&P as their prestudy physiotherapy technique reported on the patient questionnaire that they preferred using PEP. Subjectively, they felt PEP mobilized greater quantities of mucus than PD&P and was easier to perform. The levels of compliance as recorded by the patients were 92% in group A and 96% in group B.

Discussion

Our results indicate that physiotherapy with the PEP technique was significantly superior to PD&P in maintaining or improving pulmonary function in patients with CF. In the group performing PD&P, the annual rate of decline in pulmonary function (FEV_1 of –2.28% predicted per year) was similar to the reported North American rate of decline (FEV_1 of –2% predicted per year [S. Fitzsimmons, The American CF Registry; personal communication, July 1996). Reisman et al.[6] also reported a similar rate of decline (FEV_1 of –1.9% predicted per year) in their PD&P group during a 3-year study in which PD&P was compared with huffing alone. In the latter study PD&P was found to be superior, because when PD&P was discontinued in favor of huffing alone, FEV_1 fell by –4.7% predicted per year. In our study the group performing PEP showed an improvement in all pulmonary func-

tion parameters measured, (FVC, +6.57%; FEV_1, +5.98%; FEF_{25-75}, +3.3% predicted per year). These results suggest that PEP is a superior form of physiotherapy for patients with CF and should be considered an important advance in the management of pulmonary manifestations of CF.

The physiologic theories on which PEP therapy are based suggest that it may help mobilize peripheral lung secretions more than conventional physiotherapy. In our previous studies we found that PEP produced more secretions than PD&P, though this difference did not reach statistical significance.[20] Groth et al.[28] demonstrated that the application of PEP reduced the volume of trapped gas in patients with CF and promoted a more even intrapulmonary distribution of ventilation as a result of opening up of regions that were otherwise closed off during tidal volume breathing. Although we did not measure the volume of trapped gas in this study, it can be hypothesized that the increases in FVC and FEV_1 may be due to decreases in air trapping, as well as decreases in airway obstruction. In these patients airway obstruction can also cause airways to close during expiration as a result of the Bernoulli effect, causing an increased pressure gradient. Positive intraluminal pressure prevents airway collapse and allows expiratory airflow to move the secretions centrally. Forced expirations are then used to mobilize secretions to where they may be effectively expectorated.

Although we could not mask ("blind") the patient or physiotherapist as to which technique the patient with CF was performing, the clinic physicians assessing the patients and the respiratory therapist performing the pulmonary function tests were blinded as to which physiotherapy technique the patients were using. We also controlled for compliance (or adherence); two patients were withdrawn from the study because they did not meet the 85% compliance level.

The patients in this study also reported in their questionnaire a preference for PEP over PD&P; this was matched to superior efficacy, demonstrated by improved FVC and FEV_1.

The number of positions used for PD (five to six) and the 3 to 5 minutes for percussion conformed to the "standard" for PD&P, as determined from a survey in 1993 of CF centers across North America (McIlwaine. Unpublished data). Of 81 centers that responded to this survey, 81% used 3 to 5 minutes of percussion in each position, 9% used less than 3 minutes, and 10% used more than 5 minutes; 60% of centers used four to eight postural drainage positions per session, with 20% using fewer than four positions and 20% using more than eight positions. We therefore consider the PD&P used in this study as conforming to standard procedures used in North America.

In considering the results of this long-term study, it is important to note the specific equipment used for PEP therapy and the specific technique (i.e., 15 breaths, followed by forced expirations and relaxed controlled breathing). Some authors have suggested that PEP alone did not always clear the secretions adequately. However, in these studies either PEP was performed for fewer than 10 breaths, or it was not combined with forced expirations. In our study we applied the same PEP technique and equipment as developed by Falk et al.[15]; since these original studies,[26,29] a variety of modifications to the original PEP techniques and mask have been suggested. These modifications may affect treatment performance, as well as outcome, and warrant separate investigation.

An oscillating PEP device called "the flutter device" has also been advocated as an alternative to PD&P. It combines PEP with an oscillation in the airflow, which is presumed to assist in the loosening of mucus from airway walls. Konstan et al.[30] demonstrated a threefold increase in mucus expectoration with the flutter device compared with cough alone or with only 1 minute of percussion in postural drainage positions. However, it was not compared with the standard PD&P as used in our study. To date, no studies have been conducted to assess the effect of oscillation on the airway walls, and there is some concern that it may cause hypersecretion of mucus as a result of airway irritability.

In conclusion, PEP physiotherapy, performed as described in this study, is superior to PD&P physiotherapy in maintaining pulmonary function in patients with CF. The PEP technique appears to be preferred by patients with CF; it requires less time to perform, and assistance from a second person is not required. Regular use of PEP as described should be considered an important advance in the management of the pulmonary manifestations of CF.

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