Long-Term Treatment of Chronic Bronchitis
with Positive Expiratory Pressure Mask and
Chest Physiotherapy*
Erika Frischknecht Christensen, M.D.; Tonny Nedergaard; and
Ronald Dahl, M.D.

Long-term treatment of chronic bronchitis with chest physiotherapy with or without positive expiratory pressure (PEP) by mask was studied in 43 patients randomly allocated to PEP treatment (PEP group, 20 patients) and conventional chest physiotherapy (control group, 23 patients). After instruction, the treatments were self-administered twice daily for 12 months (34 patients) and 5 months (9 patients). Twice weekly, patients filled in a diary concerning symptoms. The PEP group had significantly less cough and less mucus production. The number of acute exacerbations were calculated from the diaries and were lower in the PEP group compared to the control group, and 85 percent of the patients in the PEP group were free from acute exacerbations versus 48 percent in the control group. The PEP group also used less antibiotics and mucolytics. The PEP group had a small increase in FEV₁ of mean 62 ml compared to a small decrease of 43 ml for the control group. Treatment with a simple PEP device can reduce morbidity in patients with chronic bronchitis and may preserve lung function from a more rapid decline. (Chest 1990; 97:645-50)

PEP = continuous positive airway pressure; PEP = positive expiratory pressure

Positive expiratory pressure is used in patients breathing spontaneously as continuous positive airway pressure mostly applied by mask. The CPAP is used in the treatment of respiratory failure and in conditions with impaired clearing of airway secretions, for example, after abdominal surgery.¹

The CPAP is not suitable for home treatments because of the high airflow needed.² A simplified positive expiratory pressure system has been developed as a PEP mask (Fig 1). This system is more convenient for self administration and home treatment. It consists of a facemask connected to a T-tube where inspiratory and expiratory airflow are separated by a valve. Variable expiratory resistances can be applied onto the expiratory tube as connections of different diameters, causing positive airway pressure only during expiration.

The use of PEP-mask has been studied in patients with cystic fibrosis with conflicting results concerning clearing of secretions from the airways and improvement of arterial oxygen saturation compared to conventional chest physiotherapy, ie, postural drainage, percussion, and forced expirations and breathing exercises.³,⁴

In a recent study, the use of PEP-mask was shown to be comparable to CPAP in prevention of pulmonary complications after abdominal surgery.⁵

Chest physiotherapy is used also in chronic bronchitis. Its main indication seems to be acute exacerbations of chronic bronchitis with increased mucus production, whereas the value of regular chest physiotherapy during chronic phases is uncertain.⁶ However, the effect of long-term treatment with chest physiotherapy combined with PEP has not been studied. The purpose of this study was to compare the prophylactic effect of diaphragmatic breathing and forced expirations with and without PEP-mask in the

*From the Department of Respiratory Diseases, University Hospital of Aarhus, the Institute of Experimental Clinical Research and Department of Theoretical Statistics, Institute of Mathematics University of Aarhus, Denmark.

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FIGURE 1. PEP mask is a face mask connected to a T-tube where inspiratory and expiratory airflow are separated by a valve. Variable expiratory resistances can be applied onto the expiratory tube as connections of different diameters. In this way, a positive airway pressure is created during expiration. The pressure can be controlled by a manometer.
home treatment of patients with chronic bronchitis. The effect was evaluated with respect to symptoms, number of acute exacerbations, number of sick-leaves, need for additional medication (including antibiotics), and by lung function tests.

Patients and Methods

Criteria for Inclusion

Patients with a history of chronic bronchitis, ie, cough daily and expectation for at least three consecutive months for the last two years were included in the study. They were recruited among the outpatients of the clinic. They should be cooperative and capable to follow the instructions for the treatment. Smokers and nonsmokers were included; exsmokers were included only if they had stopped smoking at least two years prior to the study. Patients with bronchial asthma, heart failure, or lung cancer were not included.

Asthma was defined as a 20 percent or higher increase in forced expiratory volume in the first second (FEV1) after inhalation of 1.25 mg of terbutaline through a 750 ml volume cone spacer. Patients who already used a PEP mask, used prophylactic mucolytic drugs, or received more than 10 mg prednisolone (or equivalent doses of corticosteroids) daily could not take part in the study. A total of 44 patients were included in the study in the months of January or February and followed for 12 months, and 10 patients were included in October and followed for 4 to 5 months.

Criteria for Exclusion During the Study

Death, diseases or hospitalization interfering with the treatment, or discontinued treatment during the study lead to exclusion from the data analysis. Data from patients receiving antibiotics for more than two weeks because of diseases other than exacerbations of chronic bronchitis, more than 10 mg prednisolone (or equivalent) daily, or mucolytics daily for more than four consecutive weeks were excluded.

Ethics

The patients were included after informed consent and both verbal and written information was given. The study was approved by the Ethics Committee of Aarhus and was in accordance with the Helsinki Declaration II.

Treatment

The patients were randomly allocated to treatment with self-administered diaphragmatic breathing followed by forced expirations and cough until expectation succeeded (control group) or PEP treatment where diaphragmatic breathing was performed through a PEP mask followed by forced expirations and cough. The patients were taught a respiratory force to create a pressure of 12 to 20 cm H2O, and the expiratory pressure was measured by a manometer. The patients were instructed by a specialized and trained physiotherapist. The actual pressure level was individually determined according to the capability to breathe 10 to 15 times in the mask. The patients were instructed to use either treatment every morning and evening for 10 to 15 breaths repeated until expectation had stopped. They were allowed use the treatments more often if needed. The patients continued their treatment with beta-agonist, theophylline, and corticosteroid. Acute exacerbations were treated with antibiotics, mucolytics, and adjustment of bronchodilators and corticosteroids when needed.

Diary

Twice a week, the patients filled in a diary card with questions concerning symptoms. The following was answered by yes or no: Do you feel ill? Is your temperature (rectal) more than 38°C? Are you on sick leave from work? Are you being treated with antibiotics? The following questions were graded from 0-3 according to specified qualities in the grades: severity of cough, severity of dyspnea, amount of secretion, color of secretion, thickness of secretion, and difficulty in expectoration. The patients also wrote the number of treatments used daily. Finally, every month, the patients answered questions graded from 0-2 according to severity (more, equal or less) of dyspnea, cough, and expectation during the last month compared to these symptoms at the start of the study. The diary was modified from a multicenter study that found it very suitable for assessment of the rate of exacerbation. The diary cards were collected every month. From the diaries, the subjective symptoms, the number of acute exacerbations, the number of sick leaves, and days with antibiotics were evaluated.

An acute exacerbation was defined as the appearance of mucopurulent or purulent sputum and increasing cough and one or more of the following symptoms: temperature >38°C, general malaise, increased dyspnea, increased mucus production, increased mucus thickness, or increased difficulty in expectoration.

Clinical Control

At the start of the study, a clinical history, physical examination, ECG, and chest x-ray film were done. Lung function tests were performed with measurement of FEV1, forced vital capacity, and vital capacity (dry spirometer) before and 20 minutes after 1.25 mg terbutaline inhaled through a 750 ml cone spacer.

The patients were seen at the clinic every month the first three months and then every second or third month during the summer period. In autumn and winter, they were again seen every month, giving a total of a minimum of seven visits. They were interviewed concerning symptoms and medical treatment. After one month and at the end of the study, the patients were asked to give an overall assessment of the treatment (definitely useful, useful, not useful, harmful, or definitely harmful).

Lung function tests were performed at the start and at the end of the study. Physical examination and chest x-ray film were done after six months and when needed.

The physiotherapist instructed the patients in the technique of diaphragmatic breathing, forced expirations, and use of PEP mask and regularly controlled how the patients performed. Initially, they were instructed twice a week, then once a week during the first month. After this period of introduction, they were seen by the physiotherapist every second or third month during the summer. At the start of the winter period, the patients were again seen once or twice a week for the first month and then every second month.

Statistical Methods

Descriptive data for the patients were compared by means of unpaired Student’s t-test (continuous variable) or chi-square statistics (categorical variables). Data from the clinical control visits (medical treatment, assessment) were analyzed by chi-square statistics. The individual change in lung function from the first to the last visit was compared between the groups by Student’s t-test, and the changes in lung function in the two groups were compared by one-way analysis of variance.

From the diary, an individual average score for symptoms was calculated and the two groups compared by using the nonparametric Mann-Whitney test.

Concerning the number of acute exacerbations and use of antibiotics, the two groups were compared by calculating an average incidence rate, ie, the total number of events divided by the total number of fulfilled diary days (the observation time). Then the expected number of events in the groups was calculated and compared with the observed number of events by means of a chi-square statistic with DF = 1.

The number of fulfilled diary cards was put in relation to the
Table 1—Morphometric Details, History, and Lung Function at Start of Study (Mean ± SD)

<table>
<thead>
<tr>
<th></th>
<th>PEP</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients, number</td>
<td>20</td>
<td>23</td>
</tr>
<tr>
<td>Still working, number</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>Age, yr</td>
<td>61.7 (4.6)</td>
<td>62.7 (5.2)</td>
</tr>
<tr>
<td>FEV₁, L*</td>
<td>1.72 (0.73)</td>
<td>2.07 (0.57)</td>
</tr>
<tr>
<td>FEV₁, in percent of predicted FEV₁*,</td>
<td>62.5 (23.9)</td>
<td>77.4 (20.7)</td>
</tr>
<tr>
<td>FVC, L*</td>
<td>2.60 (0.82)</td>
<td>2.91 (0.54)</td>
</tr>
<tr>
<td>FEV₁/FVC*</td>
<td>0.65 (0.14)</td>
<td>0.71 (0.11)</td>
</tr>
<tr>
<td>Smokers, number</td>
<td>16</td>
<td>17</td>
</tr>
<tr>
<td>Nonsmokers or exsmokers, number</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Duration of disease, yr</td>
<td>18.4 (15.7)</td>
<td>12.6 (10.7)</td>
</tr>
<tr>
<td>Number of acute exacerbations during the previous 12 months</td>
<td>2.3 (2.3)</td>
<td>1.4 (1.4)</td>
</tr>
<tr>
<td>Number of acute exacerbations treated with antibiotics during the previous 12 months</td>
<td>1.5 (1.5)</td>
<td>0.8 (1.3)</td>
</tr>
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*n = 20 in the PEP group, n = 22 in the control group.

Results

Clinical History and Lung Function

Fifty four patients were included in the study, and 43 completed the study. The reasons for exclusion were malignant lung tumors in three patients (all in the PEP group), long-term use of acetylcysteine in one patient (in the PEP group), discontinued treatment in seven patients (three in the PEP group and four patients in the control group). There was no significant difference between the control group and the PEP group with respect to age, smoking habits, duration of disease, number of acute exacerbations during the previous year, number of treatments with antibiotics during the previous year, and medication (corticosteroid, beta₂-agonist, parasympatholytic and theophylline) (Table 1). About one-third of the patients used theophylline or beta₂-agonist, only one patient in each group used oral corticosteroid, two patients in the PEP group used low-dose inhaled corticosteroid.

The majority of the patients had retired from work because of age. One patient in the PEP group and three patients in the control group had stopped working because of lung disease.

The lung function was normal or moderately reduced (Table 1), and there was no difference between the groups concerning the initial values of FEV₁, FVC, and VC. The FEV₁ in relation to predicted normal was significantly lower in the PEP group compared to control group (p<0.025, Student’s t-test).

The 11 patients not completing the study did not differ concerning baseline data. They were mean age 61.4 years, ten patients were smokers, one patient was an exsmoker. The mean duration of chronic bronchitis was 16.2 years and they had, as a mean, one acute exacerbation during the previous 12 months. Mean FEV₁ and FVC was 1.95 and 2.99 L.

Cooperation of the Patients

A part of the information collected in this study was based on the diary cards, which makes it important to evaluate the patient’s cooperation. The patients receiving treatment for 12 months had a maximum of 96 diary days, and the patients treated only during the winter had a maximum of 40 diary days. The actual number of days with completed diary (the observation time), divided by the maximum possible number of diary days are shown in Table 2. There was no difference between the groups in this respect.

Discontinued treatment was defined as less than eight completed diary days (treatment for less than one month) and/or missing more than one of the control visits. Four patients did not show up after the first visit, one patient had less than eight diary days and stayed away from more than one control visit, two patients stayed away from more than one visit, giving a total of seven patients who discontinued the treatment. The data from these patients were not included in the data analysis. One patient was not able to perform the lung function tests correctly (because of cough) but otherwise cooperated very well, so the data from this patient, except lung function values, were included in analysis.

From the diary cards, the actual daily use of treatments was calculated. The PEP group had a mean daily use of the mask of 2.5 times (range 1.8 to 4.6), and the control group had a mean daily use of physiotherapy of 2.5 times (range 0.7 to 6.1). Fourteen patients in the PEP group and 13 in the control group used the treatments more than twice daily; the mean values were 2.8 and 3.4 times daily, respectively.

Symptoms

According to the diary answers, the PEP group reported significantly less cough (p = 0.025, Mann-Whitney test) and less mucus production (p = 0.013) than the control group. There was a tendency of less dyspnea in the PEP group, but this was not statistically significant (p = 0.33).
The overall assessment of the treatment after one month of treatment and at the end of the study was significantly more positive in the PEP group (p<.05 and p = 0.0001, chi-square test) where a majority of the patients called it definitely useful. But the control group also found the treatment useful. Only a few patients found the treatments useless, and none found them harmful. The patients who found the treatment useful were asked to describe the effect. A majority in the PEP group (13 patients) found the main effect to be a facilitation of expectoration compared to the control group where most patients (16) could not describe the effect and five found it to facilitate expectoration.

Finally, the patients were asked both in the diary and at the clinic visits about any side effects of the treatment. A few patients complained of dizziness, especially in the PEP group. This was caused by hyperventilation, and the complaints ceased after repeated instruction.

**Acute Exacerbations**

The PEP group had fewer acute exacerbations compared to the control group (six vs 28). Also, the number of patients who experienced acute exacerbations were smaller in the PEP group compared to the control group (three vs 12). In the PEP group, 85 percent of the patients remained free from acute exacerbations, compared to 48 percent in the control group (p = 0.011, chi-square). No patient in the PEP group and three patients in the control group had more than three acute exacerbations (Fig 2).

The exacerbation rate defined as the number of acute exacerbations divided by the observation time was calculated for each patient, and this value was significantly lower in the PEP group compared to the control group (p<0.0005, chi-square test).

**Sick Leaves**

Only a few of the patients actually were still working. Five patients in the control group and four patients in the PEP group stayed home from work because of acute exacerbations. There was a large difference between the number of days on the sick list: 17 in the PEP group and 64 in the control group, but 36 of the sick list days were accorded to one patient, who left work during the study period.

**Antibiotics**

The number of diary days with use of antibiotic was less in the PEP group compared to the control group (21 vs 74 days). The antibiotic rate, defined as the number of days when the patients used antibiotics divided by the observation time, was significantly lower in the PEP group compared to the control group (p<0.005, chi-square test). The patient with 36 days of sick leaves had antibiotics for 19 days, and when the data from this patient were excluded from the analysis, the PEP group still had significantly less use of antibiotics (p<0.05).

**Mucolytics**

At the control visits, the patients were questioned about use of mucolytic medication (acetylcysteine or other). Only a few positive answers were given. In the PEP group, there was one occasion when acetylcysteine was used and two occasions for other mucolytics. In the control group, the corresponding figures were eight and nine. An incidence rate for use of mucolytics was defined as the number of occasions when mucolytics were used divided by the total number of occasions and the rates were then compared between the groups. The use of acetylcysteine and other mucolytic drugs was, in this manner, significantly lower in the PEP group compared to the control group (p<0.025 and p<0.05, chi-square test).

**Other Medical Treatment During the Study**

Treatment with corticosteroids, beta2-agonists, parasympatholytics, and theophyllines did not change significantly during the study and was similar in the PEP group and the control group.

**Lung Function**

At the start of the study, FEV1, FVC, and VC for the PEP group was lower than in the control group but without significant difference between the groups.
At the end of the study, a similar pattern was seen, and again, without significant difference between the groups.

However, the PEP group had a small, insignificant increase in FEV₁, FVC, and VC during the study, whereas the control group had a small, insignificant decline in these parameters (Table 3). This difference between the groups was more pronounced when the analysis was done with only the patients treated for 12 months included. Then the increase in FEV₁ for the PEP group during the study was found significantly different from the decrease in FEV₁ found in the control group (p = 0.039, analysis of variance) (Table 3). In the PEP group, a majority of the patients (13) had an increase in FEV₁ from the start to the end of the study, compared to six in the control group. Seven patients in the PEP group had unchanged or decreased FEV₁ compared to 16 patients in the control group, (p<0.025, chi-square test).

### Discussion

The significantly fewer symptoms, the significantly smaller number of acute exacerbations, and the rate of exacerbations in the PEP group showed that the use of PEP by PEP-mask relieved the symptoms and had a prophylactic effect on acute exacerbations in patients with chronic bronchitis. In this respect, PEP treatment was superior to conventional chest physiotherapy with diaphragmatic breathing and forced expiration technique. The reduced rate of acute exacerbations in the PEP group was reflected in a reduced use of antibiotics and mucolytics compared to the control group.

The conclusions may be limited by the fact that the study was not double blind. It is not possible to design this kind of study in a double blind manner. It could be argued that the control group should use a mask without expiratory resistance, but an expiratory resistance will be felt by the patient using it. Furthermore, we found that breathing through the mask without expiratory resistance could give a positive airway pressure of less than 5 cm H₂O (unpublished). We were very anxious to attend the control group as carefully as the PEP group, giving repeated instructions, etc. The control group, in fact, found the treatment useful by the final assessment, which was not supported by the other results of the study.

The use of the patient’s assessment from diary cards as the main effect parameter might be another limitation. Chronic bronchitis and chronic airflow limitation are regarded as independent diseases. Chronic bronchitis, although associated with morbidity, it is not always associated with chronic airflow limitation. Most patients in the present study had normal or moderately reduced lung function, and their morbidity was caused by the symptoms and acute exacerbations. Several studies, recently reviewed by Sutton et al. and Demedics, show that changes in lung function indices after various regimens of chest physiotherapy are minor and mostly found as an immediate and short-term effect after the therapy. On this background, we did not expect significant changes in lung function as a long-term effect and chose the major effect parameters to be the symptomatic relief and the number of acute exacerbations.

Because of the inability to perform a double blind study and the subjective effect parameters, we found it particularly important to use an assessment independent of the investigators. The method of calculating the number of acute exacerbations by standardized diary cards was described by Boman et al who used this method in a multicenter trial and found that the inevitable differences in assessment of acute exacerbations by the investigators in this way could be ruled out. This method of assessment of acute exacerbations was recommended for future studies. The randomization of the patients turned out with a tendency towards less disease severity in the control group, but no statistically significant differences were found. However, this supports our findings of fewer symptoms and acute exacerbations in the PEP group. Only four patients, all in the PEP group, had severe pulmonary obstruction (FEV₁ <1.0 L). This partly explains the difference concerning baseline lung function in the two groups. The small increase in FEV₁, FVC, and VC in the PEP group compared to the decrease in the same parameters in the control group is remarkable because the FEV₁, FVC, and VC usually declines over time, especially in patients with chronic bronchitis. The variation of the measured values were large and to ascertain an influence of PEP treatment on lung function, more patients or a longer study period is required.

The value of a study based on reports from the patients will be dependent on the cooperation of the patients. We found good cooperation in filling out the diaries; only seven patients discontinued the study for this reason. They should use the treatments every
morning and evening, but most patients used the treatments more often. This indicates that they felt an immediate benefit from the maneuvers.

The physiologic effects of PEP cannot be explained by our study. It is possible that PEP worked by loosening secretions, improving ventilation, and/or dilating airways. To our knowledge, the present study is the first concerning long-term treatment of chronic bronchitis with PEP. The acute effect of PEP has been studied in the treatment of cystic fibrosis. These studies compared more vigorous regimens including postural drainage with percussion, and the effect parameters were the amount of expectoration and oxygen saturation during and after the treatment. Furthermore, the studied regimens were different, which make comparison difficult. Falk et al found PEP to be more effective concerning the amount mucus expectorated, whereas Hofmeyr et al found postural drainage with breathing exercises and forced expiration technique to be the most effective regimen. The PEP might enhance the effect of forced expiration by moving the equal pressure point of dynamic compression peripherally, thereby removing mucus from smaller bronchi.

Studies have shown that both expiratory positive airway pressure (equal to PEP) and CPAP increase functional residual capacity in healthy subjects and in diseases accompanied by reduced resting lung volume. This was supported by a study of patients undergoing abdominal surgery where the use of PEP-mask was found to be as effective as CPAP in reducing the incidence of atelectasis and in restoring pulmonary function. This effect is probably explained by an increase in closing capacity, thus improving the ability to mobilize secretions from the peripheral airways.

Similarly, the study of Groth et al confirmed the increase in FRC with positive expiratory pressure by PEP-mask in patients with cystic fibrosis, and this study also showed improvement in ventilation and reduction in volume of trapped gas. The mechanism of PEP might be a redistribution of the ventilation and airflow, thus loosening secretions and dilating obstructed airways. The possibility of a bronchodilating effect of positive airway pressure was recently supported by the finding of decrease in airway resistance during application of CPAP in induced asthma.

It would be interesting to contrast our results with the results of one of the most important long-term studies of patients with chronic obstructive pulmonary disease, the multicenter trial of the IPPB-group, where no significant changes in pulmonary function, mortality, rate, and duration of hospitalizations and life quality indices were found. A comparison is difficult because the patients in the IPPB study had significantly more airways obstruction with predicted FEV₁ of mean 36 percent. The treatments in the IPPB study were quite different from ours and consisted of nebulized bronchodilator with or without IPPB applied by a Bennett ventilator giving a standardized tidal volume, thus giving inspiratory assistance instead of expiratory resistance as PEP.

Though the physiologic effects of positive expiratory pressure are still not clearly understood, new clinical applications are found. The present study shows that treatment with a simple and inexpensive PEP device without side effects can reduce morbidity in patients with chronic bronchitis and may preserve lung function from a more rapid decline.

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