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Improving the ketchup bottle method with positive expiratory pressure, PEP, in cystic fibrosis

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Abstract: We studied the acute effects of 4 different chest physical therapy regimens using a randomised cross-over design in 14 patients with cystic fibrosis. Treatment A consisted of postural drainage, percussion and vibration; treatment B of postural drainage and periodic application of a face mask with positive expiratory pressure (PEP); treatment C of PEP in the sitting position; treatment D of the forced expiration technique in the sitting position. In terms of sputum expectorated, treatments B and C were superior to treatment D and especially to treatment A ($p<0.05$). Skin oxygen tension, PsO_2, was monitored continuously during and for 35 min after treatment. A substantial and prolonged decay in PsO_2 was observed during treatment A, quite different from other patterns seen. During and even following treatment C, an increase in PsO_2 was noted. PEP was well accepted by the patients, who preferred treatment C, and we suggest it is incorporated in chest physical therapy regimens if the therapeutic objective is to increase expectoration.

La methode de la bouteille de ketchup "amerliorec" avec pression positive expiratoire. Etude contrôlée chez des patients atteints de fibrose kystique.

Résumé: Dans une étude randomisée avec double permutation, portant sur 14 patients atteints de fibrose kystique, nous avons étudié les effets aigus de 4 régimes différents de traitement physique thoracique. Le traitement A a consisté en drainage postural, percussion et vibration; le traitement B en drainage postural, avec application périodique d'un masque facial avec pression positive expiratoire (PEP); le traitement C d'une PEP isolée en position assise; et le traitement D d'une technique d'expiration forcée en position assise. En termes de volume expectoré, les traitements B et C s'avérèrent supérieurs au traitement D et spécialement au traitement A ($p<0.05$). La tension d'oxygène cutanée (PsO_2) a été suivie de façon continue pendant le traitement et les 35 minutes qui lui faisaient suite. On a observé une chute substantielle et prolongée de PsO_2 pendant le traitement A, à l'opposé de ce qui se produisait dans les autres schémas. Pendant, et même après le traitement C, on a relevé une augmentation de la PsO_2. La PEP fut bien acceptée par les patients, qui préféraient le traitement C. Nous suggérons donc qu'elle soit incorporée dans les traitements physiques thoraciques lorsque l'objectif thérapeutique est d'augmenter l'expectoration.

Key words: airway obstruction - chest physical therapy - cystic fibrosis - positive expiratory pressure.

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Assuming that it is important in patients with cystic fibrosis to get excessive secretions out of the bronchial tree, the most efficient way of achieving this has long puzzled the clinician and challenged the investigator. Usually "the ketchup bottle method", i.e., postural drainage, percussion, vibration and some sort of cough assistance is prescribed (13). Unfortunately, this treatment, apart from the coughing involved, seems to be more a state of mind; physiological background and proven efficiency in randomised controlled studies are sorely lacking (13, 16, 18). Morphologists and physiologists claim that airway obstruction with diffuse airway narrowing will improve if resting lung volume increases (11), air can get behind secretions, and, conveivably, that coughing will become more effective. Application of some sort of positive expiratory pressure, usually referred to as continuous positive airway pressure, CPAP, or positive end expiratory pressure, PEEP, is a modern well-documented key stone in the treatment of patients with acute respiratory failure (14), where low resting lung volumes and diffuse airway obstruction is usually present. We, therefore, found it of interest to evaluate in a randomised controlled study whether positive expiratory pressure, PEP, applied with a face mask, would be of advantage to patients with cystic fibrosis.

TABLE 1. *Morphometric and lung function data for the 14 patients (4 females & 10 males) studied. All values are given as median and range.*

Age	18 years	(14-30)
Weight	51 kg	(30.5-67.5)
Height	170 cm	(147-190)
FVC measured	2.1 l	(0.8-4.4)
FVC % predicted	54%	(26-98)
FEV_1 measured	1.3 l	(0.4-2.6)
FEV_1 % predicted	34%	(15-55)
PEF measured	360 l/min	(180-606)
PEF % predicted	75%	(63-105)

PATIENTS AND METHODS

Fourteen patients with cystic fibrosis and chronic pseudomonas infection entered the study after informed consent had been obtained. Seven of the patients were studied during admission for their usual anti-pseudomonas treatment and the other 7 at least one month after their treatment.

The following selection criteria were used:

1) Excessive secretions, i.e., at least 1.5 g/h expectorated under controlled circumstances
2) No patient was studied during or immediately after anti-pseudomonas treatment, or other change in basic medication
3) All should abstain from inhalation theaapy (beta$_2$ stimulants, urea, etc.) for at least 5 h prior to the study periods

The actual amounts of sputum expectorated by the selected patients are given as median and range 61.1 g (9.5-136.8) collected in 9 h ($6\frac{1}{2}$-$9\frac{1}{2}$).

Morphometric and lung function data from the 14 patients are shown in Table 1. Twelve patients had a reversible component in their airflow limitation, defined as at least a 15% increase in FCV, FEV_1 or PEF following inhalation of salbutamol.

All patients were accustomed to chest physical therapy including postural drainage, percussion and the forced expiration technique (FET), and received this modality for 1-3 h daily. During this study the usual treatment was suspended.

Each patient was subjected to 4 different chest physical therapy regimens, A, B, C, D, in 2 days. One treatment was given in the

morning and one in the afternoon, with an interval of at least 5 h. The order of treatments was randomised and allocation of a specific treatment was after test parameters (*vide infra*) had been obtained.

Components of the different regimens

Postural drainage in 7 different positions; 4 for the lower and 1 for the middle lobe all given with the foot of the bed elevated 30°. In addition, 2 sitting positions for the upper lobes were used. The order of positions was always the same. Each position was maintained for 4-5 min.

Percussion was performed by manually clapping the thoracic cage over the non-dependent lung area, and completed by 3 deep inspirations and vibration on expiration.

FET (15) consisted of forced expirations with the glottis open from midway between functional residual capacity and total lung capacity to midway between functional residual capacity and residual volume.

Pursed lip breathing (12) was used with a slow diaphragmatic inspiration and expiration through pursed lips.

PEP was given by the apparatus shown in Fig. 1 and consists of a face mask and a one-way valve, to which expiratory resistances can be attached. In the figure a manometer, that easily can be removed, is inserted to monitor the actual value of PEP. The system is commercially available (Astra Meditec, Denmark).

The PEP level used was determined as follows: sitting comfortably with arms resting on a table, the patient holding the mask tightly over nose and mouth, used diaphragmatic breathing with a slight active

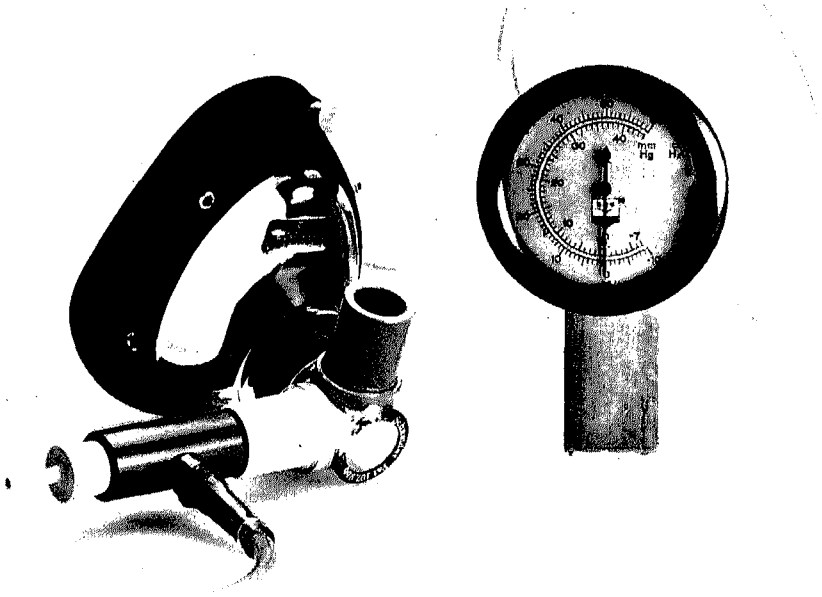

Figure 1. The PEP mask with a manometer mounted to measure the exact pressure produced during expiration.

expiration. The expiratory resistance used was that with which the patient could maintain a steady PEP for 2 min without exertion. The appropriate connections for these patients were found to be 3 or 3.5 mm, producing a PEP in the middle third of expiration of 17 cm H_2O (15-30).

The different chest physical therapy treatments.

Treatment A. Postural drainage, percussion, FET maneuvers and cough as needed. Time alloted≈35 min.

Treatment B. Postural drainage with PEP for 6-12 respirations followed by FET maneuvers and cough as needed (35 min).

Treatment C. Sitting position. PEP for 6-12 respirations followed by FET maneuvers and cough as needed. Procedure repeated for 20 min.

Treatment D. Pursed lip breathing for 5-8 respirations followed by FET maneuvers and cough as needed. Time schedule and position as treatment C.

During every treatment the exact numbers of coughs and FET maneuvers were recorded.

Test parameters

Immediately before and 50 min after each treatment FVC and FEV_1 were obtained from Vitalograph® tracings and PEF was measured on a mini peak-flow meter®.

Expectorated sputum was collected separately during and until 50 min after treatment. A precision balance was used to get the exact weight within 0.05 g.

Peripheral oxygen delivery was monitored transcutaneously from skin oxygen tension, PsO_2, during treatment and in the observation period with Radiometer® equipment. An area of skin on the ventral portion of the left lower arm was vigorously rubbed with petrol for medical use, allowed to dry and 2 transcutaneous electrodes were placed. Both were heated to 45°. Calibration and application were according to the manufacturer's specification. At least 30 min were allowed for stabilisation.

Following the treatments, the patients filled in a questionnaire evaluating the subjective assessment of efficiency and acceptability. Radiographs in 2 projections were taken before and after the study (all 4 treatments). They were presented to the same radiologist twice with an interval of 5 days. The order of presentation was random and interest primarily focused on the local and the overall degree of inflation, air-bronchogram, infiltrations and atelectasis. Lung function data, PsO_2 values and the radiographs were all evaluated blindly.

Statistical methods

Non-parametric statistics were used with determination of median and range, and for the PsO_2 data 1. and 3. quartiles, $p<0.05$ was considered significant. The method of Koch (9), described for non-statisticians by Hills & Armitage (6), using the Mann-Whitney test for different randomization groups, were applied to take into account any influence of periodic and carry-over effects. Following exclusion of the two last, Friedman's test was used (4).

RESULTS

All patients completed the treatment schedules as planned. No differences were observed in pretreatment test parameters ($p>0.15$). None of the treatments had any effect on FEV_1 and PEF ($p>0.1$); consistent changes were only seen in FVC. Following treatment A, FVC decreased by 6.6% (0-11), ($p<0.01$), and following treatment C, it increased 4.7% (0-7.9) ($p<0.01$). Periodic and carry over effects were not observed.

TABLE 2. *Result on sputum yield during and up to 50 min following treatment comparing treatment A ("the classical") with the newer methods, treatments B, C & D. Only patient data from the same day are used in the analysis.*

Treatment seq.	Patient no.	Period 1	Period 2	I. (carry-over effect) Period 1+2	rank	II. (treatment effect) Period 1-2	rank	III. (periodic effect) Treatment A-X	rank
A-X	2	51.1 g	50.7 g	101.8 g	14	0.4 g	5	0.4 g	13
A-X	3	2.4 g	10.7 g	13.1 g	2	−8.3 g	2	−8.3 g	8
A-X	4	6.6 g	12.5 g	19.1 g	3	−5.9 g	3	−5.9 g	9
A-X	8	1.9 g	5.8 g	7.7 g	1	−3.9 g	4	−3.9 g	11
A-X	9	7.9 g	35.2 g	43.1 g	8	−27.3 g	1	−27.3 g	4
A-X	13	23.0 g	18.8 g	41.8 g	7	4.2 g	7	4.2 g	14
X-A	1	15.3 g	12.4 g	27.7 g	5	2.9 g	6	−2.9 g	12
X-A	5	44.9 g	13.7 g	58.6 g	11	31.2 g	14	−31.2 g	1
X-A	6	44.9 g	16.2 g	61.1 g	13	28.7 g	12	−28.7 g	3
X-A	7	33.0 g	28.0 g	61.0 g	12	5.0 g	8	−5.0 g	10
X-A	10	22.2 g	9.6 g	31.8 g	6	12.6 g	9	−12.6 g	7
X-A	11	36.1 g	20.8 g	56.9 g	10	15.3 g	10	−15.3 g	6
X-A	12	21.6 g	3.3 g	24.9 g	4	18.3 g	11	−18.3 g	5
X-A	14	39.7 g	10.0 g	49.7 g	9	29.7 g	13	−29.7 g	2
		Rank sum A-X:			35		22		59
		Rank sum X-A:			70		83		46
		Conclusion:		N.S.		$p<0.01$		N.S.	

Efficacy of treatment in terms of sputum expectorated per min clearance rate, showed that treatment A gave 209 mg/min (57-409), treatment B 557 mg/min (386-910), treatment C 681 mg/min (472-896) and treatment D 607 mg/min (388-1017). Table 2 presents the results of the aforementioned statistical analysis for expectorated sputum during and up to 50 min after treatment comparing A with B, C & D. Only data from the same day are used in the analysis. No carry-over or periodic effects are observed, but a statistically significant treatment difference in favour of B, C, & D emerges ($p<0.01$). Using the Friedman test on all the data showed the same ($p<0.01$). The total sputum yields during this period were: treatment A 10.0 g (1.9-51.1), treatment B 21.6 g (12.5-53.5), treatment C 17.4 g (5.8-50.7) and treatment D 15.0 g (5.4-44.9). Approximately 60% of the sputum was expectorated during treatment A, while the result for B was 90%, for C 85% and for D 55%. Table 3 evaluates treatments using PEP (B&C) with treatment D. Carry over and periodic effects are insignificant, but treatment D is less effective than treatments B&C ($p<0.05$).

The number of spontaneous cough manoeuvers varied between the different treatments; A was associated with the lowest number, 28(12-52), B 100(28-156), C 88(16-128) and D 64(12-168). No carry-over or periodic effects were observed. Treatment A showed significantly lower numbers than treatments B, C, & D ($p<0.01$). Treatment D was associated with less frequent coughs than treatments B & C ($p<0.05$).

The PsO_2 data were analysed by calculating for both electrode tracings the percentage deviation from baseline value.

TABLE 3. *Result on sputum yield during and up to 50 min following treatment comparing B & C (methods using PEP) with treatment D (forced expiration technique). Only patient data from the same day are used in the analysis.*

Treatment seq.	Patient no.	Period 1	Period 2	I. (carry over effects) Period 1+2	rank	II. (treatment effects) Period 1−2	rank	III. (periodic effects) Treatment D-Y	rank
D-Y	1	13.0 g	32.8 g	45.8 g	6	−19.8 g	1	−19.8 g	1
D-Y	4	5.5 g	5.5 g	11.0 g	1	0.0 g	4	0.0 g	8
D-Y	8	8.4 g	13.2 g	21.6 g	3	−4.8 g	3	−4.8 g	6
D-Y	13	18.8 g	25.9 g	44.7 g	5	−7.1 g	2	−7.1 g	5
Y-D	2	53.5 g	37.9 g	91.4 g	8	15.6 g	8	−15.6 g	3
Y-D	3	13.9 g	9.7 g	23.6 g	4	4.2 g	7	−4.2 g	7
Y-D	7	38.0 g	19.8 g	57.8 g	7	18.2 g	6	−18.2 g	2
Y-D	12	14.2 g	5.8 g	20.0 g	2	8.4 g	5	−8.4 g	4
		Rank sum D-Y:			15		10		20
		Rank sum Y-D:			21		26		16
		Conclusion:		N.S.		$p<0.05$		N.S.	

This was done with ½ min increments for the treatment periods and in the final 15 min of the observation period. The detailed result of this analysis is shown in Table 4, where the duration of the different treatments is also presented. The transcutaneous electrode tracings gave results within 2.5% (0-7½). Periodic and carry-over effects were not significant, but only treatment C showed a gain in PsO_2 following treatment ($p<0.01$). The time spent below baseline was significantly longer for treatment A than for treatments B, C, & D ($p<0.01$) and even the change in PsO_2 was greater ($p<0.01$). A considerable increase in PsO_2 was observed during treatments B, C, & D ($p<0.01$). This is shown in more detail in Fig. 2, where the raw PsO_2 data from a patient with minor expectoration, I, and another with a very high sputum yield, II, is

TABLE 4. *Results calculated from the PsO_2* data during treatments. Median and 1. & 3. quartiles.

	Treatment A	Treatment B	Treatment C	Treatment D
Duration	37 min (33-43)	39 min (28-45)	20 min (18-32)	21 min (16-32)
Time below baseline	25 min (13-35)	13 min (2-18)	0 min (0-1)	1 min (0-6)
% change in PsO_2	14.3% (4.2-19.2)	9.7% (0-14.1)	0% (0-2.8)	2.4% (0-50.1)
Time at or over baseline	12 min (2-24)	26 min (21-37)	20 min (19-20)	20 min (15-21)
% change in PsO_2	11.3% (2.1-25)	24.6% (19.3-39.5)	27.1% (16.1-40.0)	21.5% (12.8-29.9)
Gain in PsO_2 at 35 min after treatment	4.3% (−9.4-12.1)	3.2% (0-15.4)	14.4% (4.6-27.4)	2.4% (−8.0-11.3)

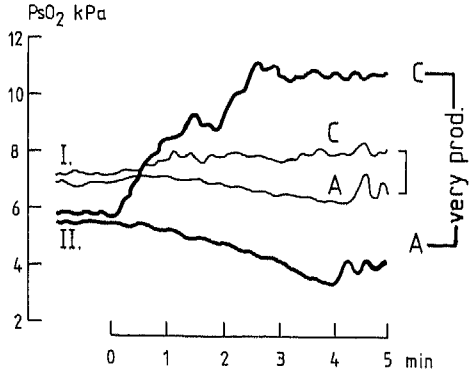

Figure 2. Evolution of PsO_2 during the initial parts of treatment A and treatment C for 2 different patients, I & II with low (A: 1g, C: 5.2g) and high (A: 29.7g, C: 44.5g) sputum yields during treatments.

presented for the initial periods of treatment A and treatment C. During A, a progressive decline in PsO_2 is observed with some recovery during coughing. Treatment C on the other hand increases PsO_2. Baseline values before treatments were started were 56% (37-81) of normal.

The subjective assessment of acceptability showed that 11 patients preferred treatment C finding it easy to perform, non-tiring and effective. In addition the possibility of self-administration was praised. Treatment D on the other hand was considered unacceptable by 11 patients, comments given being that it was exhausting with a clear imbalance between effort and result. Treatments involving postural drainage (A & B) were rejected by 7 and 9 patients respectively. It was uncomfortable, time consuming, ineffective and dependent on help from others. Several patients pointed out that FET maneuvers were less fatiguing when combined with PEP treatment. No correlation was found between patient evaluation of efficiency and actual expectorated sputum weight. No changes were observed in the radiological examination. No hazards were recorded during and following treatments that involved PEP.

DISCUSSION

This study demonstrates that in patients with cystic fibrosis sputum yields can be significantly increased by periodic application of PEP administered with a face mask. Furthermore, this treatment is accepted well by the patients, who find it less time consuming, and point out they can do it themselves. No hazards were observed, and a substantial increase in peripheral oxygen delivery as measured with skin oxygen tension was noted. The PEP mask-set is simple, rather inexpensive and easy to clean. The findings will be discussed under different headings.

Pulmonary function indices.

Only minor and, presumably, not clinically relevant changes were seen in FVC with a decrease following treatment A and an increase following treatment C. Other studies have shown a decrease in FEV_1 following percussion in patients with bronchospasm (5), while yet another documented an increase in FVC (20). The reason for this difference is not quite obvious. It is conceivable that lung function tests, which more specifically look at small airways might show some effects of PEP, as it has been shown in excised human lungs that application of this modality has a pronounced effect on small airways and collateral channels (1). Furthermore, PEP increases resting lung volume (14), while percussion will rather tend to have the opposite effect (11).

Sputum weight

Most studies have used sputum volume rather than sputum weight to assess the

efficiency of chest physical therapy (13, 16). Because of the difficulties in determining the exact volume, we have no confidence in this approach. Sputum weight seems to be a more accurate reflection of both quantity and quality. Others have used both wet and dry weight to exclude contamination with saliva (19); there was no demonstrable difference using either. In this study sputum was inspected carefully and we found that only minor contamination was present and that most of the expectorate must have come from the bronchial tree. It is important though, that patients are carefully observed during sputum collection and this is the reason why only data from such periods are used. Further information presumably can be gained using such techniques as the inhaled radioaerosol method (3), or more specific tests for determining mucociliary clearance.

In terms of sputum yield, treatments B & C are more effective than treatment D and especially than treatment A. Apparently postural drainage is not mandatory when PEP is used. This could be explained by the higher functional residual capacity in the sitting position, which is further increased with PEP. It is noteworthy and clinically important that with treatments using PEP the major part of secretions are expectorated during the procedure.

Skin oxygen tension

Previous studies (7, 16, 18) have shown that arterial hypoxemia can accompany chest percussion. This of course is only acceptable if the treatment is effective and the magnitude and duration of induced hypoxemia is small. PsO_2 has been shown to be a reliable monitor of arterial oxygen tension in patients with lung disease both at rest and during exercise (17). But as perfusion is, to some extent, involved in this parameter, we would like to advance the hypothesis that it also contains information on peripheral oxygen delivery. If this is true, the observed hypoxemia during treatment A is unacceptable and we think that percussion should be stopped in patients who beforehand are close to the knee of the oxygen dissociation curve. This view is further enhanced by the availability of more efficient treatments with no side effects and even a gain in PsO_2.

Subjective assessment

Even though all patients had received postural drainage and percussion as an integral part of treatment, they did not hesitate to accept treatment C, which was easier, less time consuming and could be used when needed.

Radiographs

No changes were seen in this short-term study. This comes as no surprise as most of the radiologic manifestations of disease were chronic and not acute. Another modality of positive expiratory pressure, CPAP, has been shown to be an effective therapy for acute atelectasis (2).

Theoretical considerations

The therapeutic objective of the ketchup bottle method is to obtain more secretions from the bronchial tree than would be obtained from the unattended patient. Clearly, the bottle must contain some ketchup before it can be emptied, but another mandatory point is that air gets behind the secretions to get them out. Thus, modalities that increase both overall, as well as regional lung volume, in obstructed areas must be sought for. There is ample evidence that this happens with PEP (1, 14). The classical method, (i.e., percussion) at best seems to have the opposite effect; decreasing

functional residual capacity and, at least theoretically, opposing influx of available air behind obstructions.

Coughing and FET are only effective in airways where dynamic compression occurs, i.e., central airways down to generation 7 (10, 18). PEP on the other hand also has an effect on peripheral airways and collateral channels (1). Thus, it seems that combining the techniques will give access to the whole bronchial tree.

This study only evaluates the acute effects of different chest physical therapy regimens. The long-term effect is at present under investigation. It has now been used in patients with cystic fibrosis for nearly 3 years. We have seen no hazards and it is our impression that the beneficial effects of the acute study could be substantiated by more prolonged studies.

The commonly held belief that it is dangerous to increase the airways pressure above atmospheric is not well documented (14). Furthermore, it is noteworthy that the pressure created during a cough is around 200 cm H_2O (10). We use approximately 10% of this, and then, only periodically.

The apparatus used to give PEP is cheap, small, easy to clean, and, following careful instruction by a chest physical therapist, not difficult to use. It should be recognized that individual determination of the expiratory resistance is essential.

Can these data be extrapolated to other patients with excessive secretions? We think they can. Mucus in patients with cystic fibrosis is not different from mucus in other patients with obstructive disease, though usually, it is more infected (8). Thus, there is no reason to believe that the treatment will not work in other patients.

We look forward to studies which examine the long-range consequences of a transient increase in sputum expectoration in relation to total production and removal, improvement in pulmonary function, changes in psychosocial well-being, prevention of complications and effect on the natural history of the underlying disease (13). For the interim, we suggest that the PEP mask be used as a "wind instrument", "--- *which to the tune of flutes kept stroke, and made the water* follow faster" (Antony & Cleopatra).

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