Original Article

Beyond postural drainage and percussion: Airway clearance in people with cystic fibrosis

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Abstract

Background: Evidence indicates that there are no statistically significant differences in effectiveness among the airway clearance techniques (ACTs) of active cycle of breathing, autogenic drainage, positive expiratory pressure (PEP) or oscillating PEP in the short-term, but are there differences in the long-term (one year)? The objective of the study was to demonstrate non-inferiority in the long-term.
Methods: Seventy-five people with cystic fibrosis entered the prospective, randomised controlled trial of these five different ACTs. The primary outcome measure was forced expiratory volume in one second (FEV_1). Secondary outcome measures included exercise capacity and health related quality of life.
Results: Using intention to treat, data were available on 65 subjects at the end of the study period. There were no statistically significant differences among the regimens in the primary outcome measurement of FEV_1 ($p = 0.35$).
Conclusion: In different countries either one or several airway clearance regimens are used. This study provides evidence in support of current practices.
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Keywords: Cystic fibrosis; Airway clearance techniques

1. Introduction

The use of airway clearance techniques (ACTs) in chronic suppurative lung disease is based on the hypothesis that facilitation of the clearance of infected bronchial secretions reduces the bacterial load in the airways, 'has a major influence in limiting the adult consequences of CF' [1] and is felt to be of benefit by the patient during a pulmonary exacerbation of infection [2]. There are few clinicians and patients today who would advocate a control arm of no airway clearance in the presence of excess and infected bronchial secretions in people with cystic fibrosis (CF). The literature contains many short-term studies comparing one airway clearance regimen with another and a few longer term studies [3–5] but the regimens used, especially in the short-term studies, have not always been undertaken as advocated by the proponents.

The clinical signs and symptoms of respiratory disease in CF are variable, but at some point cough becomes prominent, is usually associated with sputum and respiratory failure is the most common cause of death [6]. Cochrane reviews [7–10] have concluded that airway clearance techniques have the short-term effect of increasing mucus transport and there appears to be no advantage of either 'conventional' chest physiotherapy or oscillating devices over other airway clearance techniques in the primary outcome measure of lung function, but there is little evidence on which to draw conclusions concerning the long-term effects. The objective of the current study was to demonstrate non-inferiority in the long-term.

With improvements in health, quality of life and longevity [11] in people with CF and the development of PEP and oscillating PEP devices, airway clearance in the sitting position

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replaced the head-down tipped positioning in many countries. In this study the airway clearance techniques (ACTs) of the active cycle of breathing techniques (ACBT) [12], autogenic drainage (AD) [13], positive expiratory pressure (PEP) [14] and the oscillating PEP devices of the Flutter® (Flutter) [15] and R-C Cornet® (Cornet) [16] were used in the sitting position and compared over a period of one year. It was also hoped to identify objective indicators as to when a particular regimen should be recommended.

2. Methods

During formulation of the study proposal, the lead researcher (JP) visited and worked with the internationally recognised experts of the different airway clearance regimens: Jean Chevaillier (AD, Belgium), Lynne Gumery (LG) (AD, United Kingdom), Ulrich Cegla (Cornet, Germany), Jim Bolek (Flutter, United States of America) and Mette Kelstrup (PEP, Denmark). The lead researcher had been associated with the ACBT since the 1960s. LG and Esta-Lee Tannenbaum (ET) trained the subjects randomised to AD.

2.1. Subjects

All adult patients registered at Royal Brompton Hospital with CF were considered for entry to the study.

Inclusion criteria: diagnosis of CF (genotype, sweat chloride concentration >60 mmol per litre or sweat sodium concentration >70 mmol per litre), 16 years of age or over and FEV_1 of 25% predicted or greater on assessment for entry to the study.
Exclusion criteria: evidence of a current respiratory exacerbation [17], past history of pneumothorax, current severe haemoptysis, awaiting lung/heart–lung transplantation, pregnancy and recent (within three months) acquisition of *Burkholderia cepacia*.

2.2. Ethics

The study was approved by Royal Brompton & Harefield NHS Trust and National Heart & Lung Institute Ethics Committee. All subjects gave written, informed consent.

2.3. Randomisation

Randomisation was computerised and used a random number sequence stratified by FEV_1% predicted (FEV_1 less than 50%; FEV_1 greater than or=50%) and sputum expectorated (less than one cupful per day; greater than or=one cupful per day). The subjects were randomised to one of the five regimens of the ACBT, AD, Cornet, Flutter or PEP.

2.4. Treatment regimens

All treatments were undertaken in the sitting position and independent of an assistant, but if a subject was to be admitted

to hospital with an acute, infective pulmonary exacerbation, the patient and the medical team were to optimise treatment, as appropriate. For the study, the number of airway clearance sessions in a day and the length of time for treatment was individualised in agreement with each patient. One of the researchers (JP, ET or LG) discussed and explained the regimen to which the subject had been randomised. The subject practised the technique, with the researcher/s, until he/she felt confident to continue at home. Written instructions were given to each subject with the regimens agreed and signed by the experts above. When a device was used, cleaning of the device was discussed, demonstrated and the instructions, approved by the Infection Control Nurse at Royal Brompton Hospital, given to the subject in writing.

2.5. Measurements

The primary outcome measure was forced expiratory volume in one second (FEV_1). Secondary outcome measures were:

– Other measures of lung function (forced vital capacity (FVC), maximal expiratory flow at 25% of forced vital capacity (MEF_{25}) and residual volume as a percent of total lung capacity (RV%TLC)
– Body mass index
– Modified shuttle test [18]
– Chronic respiratory questionnaire [19]
– Short form-36 registered with the Medical Outcomes Trust, Boston, Massachusetts, USA
– Number of courses of intravenous antibiotics.

Subjects were requested to attend monthly, for a review of their ACT and to record the outcome measurements. The measurements of lung function and body mass index at 0, 6 and 12 months and the statistical analyses were undertaken by observers (physiologists and statistician) blind to the regimen to which the subjects had been randomised.

2.6. Statistical analysis

Sample size calculation was based on the only available data at the time of setting up the study and was from short-term airway clearance studies [12,20]. For 80% power and 5% level of significance, 16 subjects would be required per group. Intention to treat was used for the primary outcome measure of FEV_1. Mixed model analysis of variance (SAS®) was used in the analysis of the data with comparisons made between two points in time (0 months and 12 months) and among the five groups.

3. Results

3.1. Patient demographics

Four hundred and sixty-three adult patients with CF (aged 16 years and over) were registered at Royal Brompton Hospital at the start of the study (Fig. 1). Of these 344 were within a commutable distance of London or willing to travel. Two
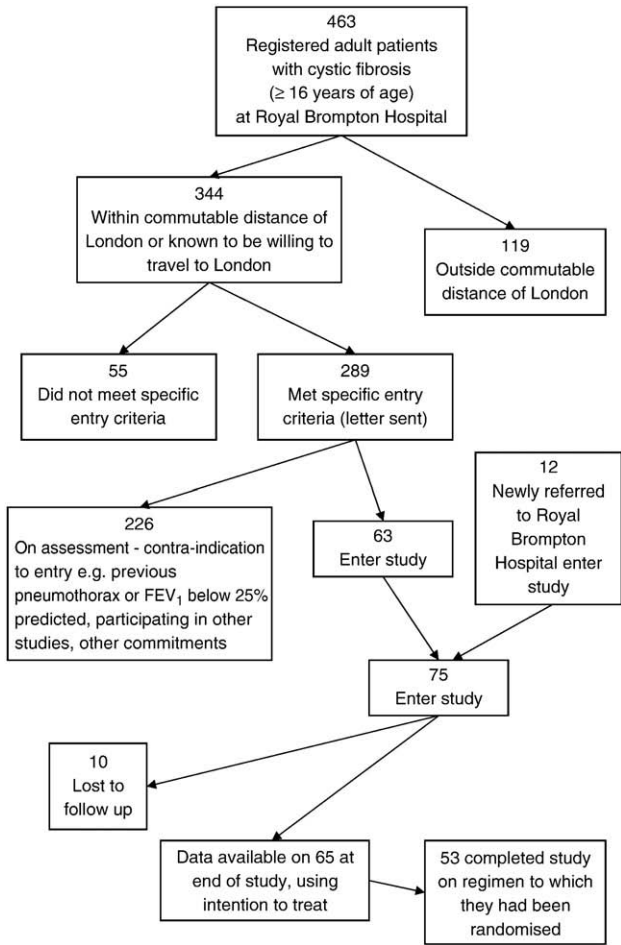
Fig. 1. Study profile.

referred to the Hospital agreed to enter which led to 75 entering at month 0.

The patients' characteristics are summarised in Table 1. At baseline the only statistically significant difference was sex. There were more men than women in each of the groups. When FEV_1 was adjusted for sex, using the mixed model of analysis of variance, there were no differences among the five treatment groups ($p = 0.31$). When adjusted for sex using FEV_1 as a percent of predicted FEV_1, sex was not a significant predictor.

Using intention to treat, data for the primary outcome measure were available on 65 of the subjects at the end of the 12-month study period. Fifty-three subjects completed the 12-month study period on the regimen to which they had been randomised. Of the 22 patients who did not complete the study, one had died, one was accepted on to the transplantation list, one required a limited pleurodesis for a pneumothorax, three were lost to follow up, three withdrew (one giving no reason (Cornet), one did not wish to undergo any more tests (Flutter) and one started a new job outside London (PEP)). Thirteen did not like the regimen to which they had been randomised and withdrew either to revert to their original regimen (9) or to a different one of their choosing (4).

3.2. Lung function

There were no significant differences among the regimens in the primary outcome measure of FEV_1 ($p = 0.35$) (Fig. 2). Overall there was a significant deterioration in FEV_1 over the 12-month period ($p = 0.02$). Expressed as change in FEV_1 percent predicted, for the group as a whole, this was -1.8%. There were no significant differences in FVC among the five groups ($p = 0.54$), MEF_{25} ($p = 0.54$) or RV%TLC ($p = 0.24$).

3.3. Body mass index

There were no significant differences in body mass index among the five groups ($p = 0.94$).

hundred and eighty-nine met the entry criteria and of these 63 entered the study. Reasons for not entering included participating in other studies, too busy with work or home commitments, found to have contra-indications to entry, on the transplantation waiting list, not contactable, transferred to another cystic fibrosis centre and not interested. In addition to the 63, 12 newly

Table 1
Demographic data ($n = 75$).

|		ACBT $n=15$	AD $n=15$	Cornet $n=15$	Flutter $n=15$	PEP $n=15$
Age (years)	Mean ($\pm$SD)	31.1 ($\pm$9.7)	25.9 ($\pm$6.5)	25.3 ($\pm$8.3)	32.1 ($\pm$7.5)	29.3 ($\pm$12.0)
		Range: 17–52	Range: 17–39	Range: 17–49	Range: 19–41	Range: 18–63
	Median ($\pm$Interquartile range)	30.0 ($\pm$16.0)	25.0 ($\pm$6.0)	24.0 ($\pm$8.0)	34.0 ($\pm$13.0)	25.0 ($\pm$13.0)
Sex		Male: 11	Male: 10	Male: 8	Male: 10	Male: 8
		73.3%	66.7%	53.3%	66.7%	53.3%
		Female: 4	Female: 5	Female: 7	Female: 5	Female: 7
		26.7%	33.3%	46.7%	33.3%	46.7%
FEV_1 (litres)	Mean ($\pm$SD)	2.0 ($\pm$0.8)	2.6 ($\pm$1.3)	1.9 ($\pm$0.8)	2.4 ($\pm$0.9)	2.1 ($\pm$1.1)
	Median ($\pm$Interquartile range)	1.6 ($\pm$1.3)	2.4 ($\pm$2.3)	1.7 ($\pm$1.2)	2.1 ($\pm$1.7)	1.8 ($\pm$1.5)
Median value SpO_2(%)	Mean ($\pm$SD)	96.2 ($\pm$1.5)	96.8 ($\pm$2.0)	96.3 ($\pm$1.6)	97.2 ($\pm$1.8)	96.4 ($\pm$1.6)
	Median ($\pm$Interquartile range)	97.0 ($\pm$2.0)	97.0 ($\pm$1.8)	97.0 ($\pm$3.0)	97.0 ($\pm$3.0)	96.0 ($\pm$3.0)
Modified shuttle distance	Mean ($\pm$SD)	1005.4 ($\pm$317.0)	985.0 ($\pm$445.9)	906.7 ($\pm$311.5)	1044.3 ($\pm$292.2)	887.9 ($\pm$358.3)
(metres)	Median ($\pm$Interquartile range)	1010.0 ($\pm$445.0)	900.0 ($\pm$445.0)	930.0 ($\pm$350.0)	975.0 ($\pm$520.0)	880.0 ($\pm$597.5)
BMI (weight in kilograms/	Mean ($\pm$SD)	21.1 ($\pm$3.0)	22.6 ($\pm$3.2)	20.9 ($\pm$3.0)	22.8 ($\pm$3.1)	21.5 ($\pm$3.3)
height in metres^2)	Median ($\pm$Interquartile range)	20.5 ($\pm$3.7)	22.7 ($\pm$4.0)	21.5 ($\pm$6.0)	22.8 ($\pm$3.2)	20.6 ($\pm$4.6)
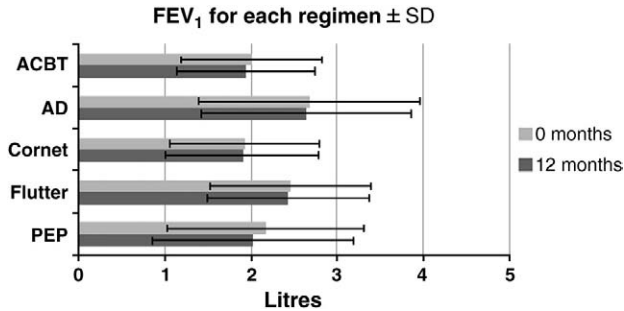
Fig. 2. FEV$_1$ for each regimen. Mean FEV$_1$±SD: ACBT ($n=13$) at 0 months 2.01±0.82, at 12 months 1.94±0.80; AD ($n=13$) at 0 months 2.68±1.29, at 12 months 2.64±1.22; Cornet ($n=14$) at 0 months 1.93±0.87, at 12 months 1.90±0.89; Flutter ($n=12$) at 0 months 2.46±0.94, at 12 months 2.43±0.94; PEP ($n=13$) at 0 months 2.17±1.14, at 12 months 2.02±1.17. There were no significant differences among the regimens at 0 months or 12 months.

3.4. Exercise capacity

There were no significant differences in the modified shuttle test among the five groups ($p=0.52$).

3.5. Health related quality of life

The *Short Form-36* was analysed in the aggregate domains of physical and mental. There were no significant differences in the physical domain among the five groups ($p=0.99$). Overall there was a trend towards a deterioration over time ($p=0.05$). In the mental domain, there were no significant differences among the five groups ($p=0.27$) but there was a significant deterioration over time ($p=0.002$).

The *Chronic Respiratory Questionnaire* (CRQ) was analysed for the four domains of dyspnoea, fatigue, emotion and mastery. Dyspnoea: There were no significant differences in dyspnoea among the five groups ($p=0.7$). Overall there was a significant improvement over time ($p=0.01$) in the group as a whole. Fatigue: There were no significant differences in fatigue among the 5 groups ($p=0.85$). Overall there was no significant difference over time ($p=0.69$). Emotion: There were no significant differences in emotion among the five groups ($p=0.39$). Overall there was no significant difference over time ($p=0.44$). Mastery: There were no significant differences in mastery among the five groups ($p=0.82$). Overall there was no significant difference over time ($p=0.37$). However there were clinical, minimal important differences [21] (improvements) in dyspnoea in four of the five groups at 12 months (Table 2).

Table 2
Minimal important differences in the Chronic Respiratory Questionnaire.

Dyspsnoea		
ACBT	0–12 months	Small improvement (0.7)
AD	0–12 months	Small improvement (0.5)
Cornet	0–12 months	No difference (<0.5)
Flutter	0–12 months	Moderate improvement (1.3)
PEP	0–12 months	Small improvement (0.8)

A change of 0.5 represents a small difference in symptoms, 1.0 a moderate difference and 1.5 a large difference [21].

3.6. Intravenous antibiotics

Some patients in each of the regimens required intravenous antibiotics during the 12-month period. The median number of courses ranged from 1.0 to 1.5. Owing to the small numbers and the scattered nature of the data, it was not appropriate to analyse this data statistically.

4. Discussion

A reduction in FEV$_1$ has been recognised as a predictor of mortality in people with CF [22] although with improvements in the management of these people, this is becoming a less sensitive indicator. Sputum would not have been a valid outcome measure for a long-term airway clearance study and more recently available non-invasive measurements had not been validated at the time of designing the study protocol. Also at the time of setting up the study protocol, CF disease specific quality of life questionnaires [23,24] were not in the public domain. The Short Form-36 was selected as the generic health related questionnaire and the Chronic Respiratory Disease Questionnaire as the disease specific questionnaire.

The time for a treatment session was not standardised as the time required, by an individual with CF, for effective airway clearance will vary. A longer time for treatment is usually required during an exacerbation of pulmonary infection and in the presence of bronchospasm. Standardisation of time is difficult in a long-term study and would not have reflected clinical practice. Some people prefer more frequent and shorter treatment sessions, others longer but less frequent sessions dependent on life-style.

The assessment of the impact of physiotherapy on lung disease is difficult in long-term studies as other treatment strategies in the package of care are continuously under development [25]. It is well recognised that distinction among the airway clearance regimens has become blurred in clinical practice. In this study considerable effort was taken to involve the original proponents of the regimens in order that the regimens used in the study were as described and undertaken by the proponents.

The objective to demonstrate that no one regimen of the airway clearance techniques of the ACBT, AD, Cornet, Flutter and PEP was inferior, over a period of one year, was supported by the results. There were no statistically significant differences, over the period of 12 months, among the regimens in the primary outcome measure of FEV$_1$ ($p=0.35$). Overall there was a significant deterioration in FEV$_1$ over time ($p=0.02$), but this deterioration of -1.8% (as a percent of predicted FEV$_1$) was within the international average of -2.0% at the time of the study.

The Short Form-36 identified a significant deterioration in both the physical ($p=0.05$) and mental ($p=0.002$) domains over time, but there were no significant differences among the regimens. The Chronic Respiratory Questionnaire identified an improvement over time in the domain of dyspnoea. The statistical difference was reflected in the minimal important difference in all regimens except the Cornet (Table 2). More

regular airway clearance may reduce the sensation of dyspnoea without a corresponding improvement in lung function, or the subjective sensation of dyspnoea may be influenced by changes in the subject's internal locus of control.

It was important to monitor closely the lung function in the subjects on the study as McIlwaine et al. [4] in their long-term study comparing the airway clearance regimens of PEP and Flutter had identified, for those on the Flutter regimen, a reduction in lung function, increased hospitalisation and increased use of antibiotics after six months. There were no clinical concerns regarding any of the regimens in the present study at six months. The differences in outcome between the two studies may be a reflection of the different age groups, but this requires further investigation.

Accurso et al. [3] undertook a three-year multi-centre randomised controlled study to assess the long-term effects of the airway clearance techniques of postural drainage and percussion, Flutter and high frequency chest wall oscillation. It would seem that both single centre and multi-centre airway clearance trials experience similar problems in recruitment and retention with long-term studies. High frequency chest wall oscillation had not been included as one of the regimens of the current airway clearance study as it was not, at the time, registered for use as a medical device in Europe.

Which technique for which patient? It was hoped to identify objective indicators as to which technique should be recommended [26], but none were identified during the study period. Each regimen can and should be adapted to suit the individual patient and each patient should be able to adapt his/her regimen at the time of each treatment session and during a treatment session. 'Patient satisfaction and perceived efficacy are probably intimately related to adherence to a technique' [26] and Langenderfer [27] has said, 'Which alternative to recommend depends on the ability, motivation, preference, needs, and resources of each patient.'

This study provides additional evidence for international practice and concurs with the evidence available, but highlights the problem of recruitment and retention to long-term studies. It would have been desirable to have undertaken the study with larger numbers, but recruitment took place over four years and with increasing time between the start and finish of a study other variables begin to bias long-term results, for example changes in medical management.

The study did not attempt to answer the question as to which regimen should be used during an acute exacerbation of pulmonary infection. New measurement tools for example lung clearance indices as measurements of ventilation inhomogeneities, non-invasive chest wall imaging techniques which allow calculation of lung volumes, lung compliance measurements and electrical impedance tomography may provide greater insight to differences which may exist among the regimens.

5. Conclusion

This study suggests that there are no statistically significant differences among the airway clearance regimens of the ACBT, AD, Cornet, Flutter and PEP when used over a period of one year, in the sitting position, by adults with cystic fibrosis. It is likely that to optimise adherence to treatment and consequently improvements in morbidity and mortality, the patient should be involved in the selection of his/her airway clearance regimen.

The findings of this study must be limited to people with CF. The study does not suggest that people with non-CF bronchiectasis or other conditions with excess bronchial secretions can effectively use an airway clearance regimen in the sitting position. Survival and quality of life for people with CF has improved, but the prognosis is still poor. Gene therapy and other new treatments may benefit most those with the minimal lung destruction. Physiotherapy and in particular airway clearance will therefore remain an important component in the management of people with CF in the foreseeable future.

Acknowledgments

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