

Aerobika* Oscillating PEP Therapy System

Study Summary



FOREWORD

TMI has an enviable history of strong leadership in creating innovative medical devices that enhance the quality of life for people of all ages. We focus our efforts on the well-being of our employees and customers, and provide safe, valuable and easy to use devices for a global market.

The **Aerobika*** Oscillating Positive Expiratory Pressure (PEP) device is a drug-free, easy to use, hand-held device that helps people with COPD and other respiratory conditions breathe easier and live better. Clinical evaluations conducted at Robarts Research Institute (Western University, London) demonstrated use of the device could significantly improve mucus clearance, decrease cough frequency, reduce breathlessness, increase exercise tolerance and improve quality of life.

The following sections are included in the summary:

- **The Problem with Mucus in Chronic Obstructive Pulmonary Disease**
An overview of the effect mucus has on the airways of patients with COPD
- **Studies Using the Aerobika* Oscillating PEP Therapy System**
In vitro and *in vivo* studies supporting the efficacy of the **Aerobika*** Oscillating PEP device
- **Airway Clearance Techniques in COPD, Bronchiectasis and Cystic Fibrosis**
Articles addressing the use and efficacy of Airway Clearance Techniques as part of an overall therapy program in Chronic Obstructive Pulmonary Disease, Bronchiectasis and Cystic Fibrosis
- **Guidelines**
International guidelines recommending the use of PEP and Oscillating PEP

THE PROBLEM WITH MUCUS IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Physiologic Characterization of the Chronic Bronchitis Phenotype in GOLD Grade IB COPD

AF Elbehairy, N Raghavan, S Cheng, L Yang, KA Webb, JA Neder, JA Guenette, MI Mahmoud, DE O'Donnell. *Chest* 2015;147(5):1235-1245.

Background: Smokers with persistent cough and sputum production (chronic bronchitis [CB]) represent a distinct clinical phenotype, consistently linked to negative clinical outcomes. However, the mechanistic link between physiologic impairment, dyspnea, and exercise intolerance in CB has not been studied, particularly in those with mild airway obstruction. We, therefore, compared physiologic abnormalities during rest and exercise in CB to those in patients without symptoms of mucus hypersecretion (non-CB) but with similar mild airway obstruction. **Methods:** Twenty patients with CB (≥ 3 months cough/sputum in 2 consecutive years), 20 patients without CB but with GOLD (Global Initiative for Chronic Obstructive Lung Disease) grade IB COPD, and 20 age- and sex-matched healthy control subjects underwent detailed physiologic testing, including tests of small airway function and a symptom-limited incremental cycle exercise test. **Results:** Patients with CB (mean \pm SD postbronchodilator FEV₁, 93% \pm 12% predicted) had greater chronic activity-related dyspnea, poorer health-related quality of life, and reduced habitual physical activity compared with patients without CB and control subjects (all $P < .05$). The degree of peripheral airway dysfunction and pulmonary gas trapping was comparable in both patient groups. Peak oxygen uptake was similarly reduced in patients with CB and those without compared with control subjects (% predicted \pm SD, 70 \pm 26, 71 \pm 29 and 106 \pm 43, respectively), but those with CB had higher exertional dyspnea ratings and greater respiratory mechanical constraints at a standardized work rate than patients without CB ($P < .05$). **Conclusions:** Patients with CB reported greater chronic dyspnea and activity restriction than patients without CB and with similar mild airway obstruction. The CB group had greater dynamic respiratory mechanical impairment and dyspnea during exercise than patients without CB, which may help explain some differences in important patient-centered outcomes between the groups.

Chronic Bronchitis is Associated with Worse Symptoms and Quality of Life than Chronic Airflow Obstruction

P Meek, H Petersen, GR Washko, AA Diaz, V Kim, A Sood, Y Tesfaigzi. *Chest* 2015. Epub ahead of print.

Background: Chronic obstructive pulmonary disease (COPD) includes the chronic bronchitis (CB) and emphysema phenotypes. While it is generally assumed that emphysema or chronic airway obstruction (CAO) is associated with worse quality of life than CB, this assumption has not been tested. **Methods:** The present study, analyses from the Lovelace Smokers' Cohort (LSC) were validated in the COPDGene Cohort. CB without CAO (CB only) was defined by self-reported cough productive of phlegm for at least 3 months/year for 2 consecutive years and postbronchodilator FEV₁/FVC \geq 70%. CAO without CB (CAO only) was defined by a postbronchodilator FEV₁/FVC $<$ 70% with no evidence of CB. Quality of life outcomes were obtained from the SGRQ and SF-36 questionnaires. A Priori Covariates included age, sex, pack-years of smoking, current smoking, and FEV1. **Results:** Smokers with CB without CAO (LSC $n=341$; COPDGene=523) were younger, had a greater BMI, and less smoking exposure than those with CAO only (LSC $n=302$; COPDGene=2208). Compared to the latter group, quality of life scores were worse for those with CB only. Despite similar SGRQ Activity and SF-36 Role physical and physical functioning, SGRQ Symptoms and Impact scores and SF-36 Emotional and Social measures were worse in the CB only group, in both cohorts. After adjustment for covariates, CB only group remained a significant predictor for 'worse' symptoms, and emotional and social measures. **Conclusions:** This analysis is the first study to suggest that among subjects with COPD those with CB only present worse quality of life, symptoms and mental well-being than those with CAO only.

Clinical Issues of Mucus Accumulation in COPD

FL Ramos, JS Krahnke, V Kim. *International Journal of COPD* 2014;9:139–150.

Airway mucus is part of the lung's native immune function that traps particulates and microorganisms, enabling their clearance from the lung by ciliary transport and cough. Mucus hypersecretion and chronic productive cough are the features of the chronic bronchitis and chronic obstructive pulmonary disease (COPD). Overproduction and hypersecretion by goblet cells and the decreased elimination of mucus are the primary mechanisms responsible for excessive mucus in chronic bronchitis. Mucus accumulation in COPD patients affects several important outcomes such as lung function, health-related quality of life, COPD exacerbations, hospitalizations, and mortality. Nonpharmacologic options for the treatment of mucus accumulation in COPD are smoking cessation and physical measures used to promote mucus clearance. Pharmacologic therapies include expectorants, mucolytics, methylxanthines, beta-adrenergic receptor agonists, anticholinergics, glucocorticoids, phosphodiesterase-4 inhibitors, antioxidants, and antibiotics.

Chronic Bronchitis in COPD Patients is Associated with Increased Risk of Exacerbations: a Cross-Sectional Multicentre Study

JL Corhay, W Vincken, M Schlessler, P Bossuyt, J. Imschoot. *Int J Clin Pract* 2013;67(12):1294-1301.

Background and aims: Chronic bronchitis (CB) in chronic obstructive pulmonary disease (COPD) patients is associated with increased mortality, frequent exacerbations and faster disease progression. This study investigates the prevalence of CB in a large population of COPD patients to identify features associated with CB. **Methods:** Cross-sectional multicentre study in patients with Global Initiative for Chronic Obstructive Lung Disease (GOLD) stages 2–4 from Belgium and Luxembourg. Results: The 974 patients included were on average 67.8 ± 9.6 years old; 72% were male, FEV₁ was $52.5 \pm 15.8\%$ of predicted. The prevalence of CB was 64% (622/974). In patients with CB, the number of pack-years smoked and the prevalence of chronic respiratory failure, cachexia and skeletal muscle wasting were significantly higher, whereas FEV₁ and FEV₁/VC were lower. The prevalence of CB increased with GOLD stage and was higher in patients with emphysema and those exposed to occupational risk factors. The CB group had more exacerbations, a higher percentage of patients with frequent exacerbations (37.3% vs. 14.2% of patients; $p < 0.0001$), increased COPD-related, non-intensive care unit hospitalizations and all-cause hospitalisation rates. In multiple logistic regression analysis, frequent exacerbation was the most important independent variable associated with CB, followed by current smoking, chronic respiratory failure, COPD duration and age. Conclusions: CB prevalence in GOLD stage 2–4 COPD patients is high. CB is related to current tobacco smoking, and prevalence increases with COPD severity and duration, emphysema and age. CB could be the hallmark of a subtype of COPD easy to identify in clinical practice, associated with increased disease severity and increased risk of exacerbation.

Airway Mucus Function and Dysfunction

JV Fahy, BF Dickey. *N Engl J Med* 2010;363(23):2233-2247.

The lungs are remarkably resistant to environmental injury, despite continuous exposure to pathogens, particles, and toxic chemicals in inhaled air. Their resistance depends on a highly effective defense provided by airway mucus, an extracellular gel in which water and mucins (heavily glycosylated proteins) are the most important components. Airway mucus traps inhaled toxins and transports them out of the lungs by means of ciliary beating and cough. Paradoxically, although a deficient mucous barrier leaves the lungs vulnerable to injury, excessive mucus or impaired clearance contributes to the pathogenesis of all the common airway diseases. This review examines the normal formulation and clearance of airway mucus, the formation of pathologic mucus, the failure of mucus clearance that results in symptoms and abnormal lung function, and the therapy of mucus dysfunction.

Revisited Role for Mucus Hypersecretion in the Pathogenesis of COPD

I Cerveri, V Brusasco. Eur Respir Rev 2010;19(116):109-112.

Chronic obstructive pulmonary disease (COPD) is a heterogeneous and complex disease of which the basic pathophysiological mechanisms remain largely unknown. On the basis of recent results from pathological studies and large clinical trials, the presence of airway inflammation does not seem to be sufficient to explain the complexity of the disease and the relatively poor response to treatment. It is probably time to abandon the concept of COPD as a unique disease and define, identify and treat the various aspects, which may differ between individuals. Among the different phenotypic distinctions, the classical distinction “chronic bronchitis” has mucus hypersecretion as the key presenting symptom. Its role in COPD has been the subject of an ongoing debate; however, it now appears to be being re-evaluated due to findings from recent epidemiological and pathological studies. In this context, the view that chronic mucus hypersecretion plays a secondary role in the pathogenesis of COPD should be abandoned and instead, drugs targeting mucus hypersecretion should be considered as a treatment option.

Mucus Hypersecretion in COPD: Should We Only Rely on Symptoms?

PR Burgel, C Martin. Eur Respir Rev 2010;19(116):94–96. Editorial comment on ‘Revisited Role for Mucus Hypersecretion in the Pathogenesis of COPD’.

Concluding Statement: In conclusion, current COPD therapies have limited effects in modifying the natural history of the disease. Mucus hypersecretion occurs in all COPD subjects and increases with airflow limitation. Pathological and physiological studies suggest that chronic cough and sputum production is a manifestation of mucus hypersecretion in proximal airways, but that mucus hypersecretion in small airways is not necessarily associated with symptoms. These major findings suggest that therapies targeting mucus hypersecretion in COPD could be beneficial regardless of the presence of chronic cough and sputum production. Proof of this concept will require carefully designed clinical trials evaluating the impact of novel therapies on mucus hypersecretion and COPD relevant outcomes.

Cough and Sputum Production are Associated with Frequent Exacerbations and Hospitalizations in COPD Subjects

PR Burgel, P Nesme-Meyer, P Chanez, D Caillaud, P Carré, T Perez, N Roche; on behalf of the Initiatives Bronchopneumopathie Chronique Obstructive (BPCO) Scientific Committee. Chest 2009;135(4):975-982.

Background: Epidemiologic studies indicate that chronic cough and sputum production are associated with increased mortality and disease progression in COPD subjects. Our objective was to identify features associated with chronic cough and sputum production in COPD subjects. **Methods:** Cross-sectional analysis of data were obtained in a multicenter (17 university hospitals in France) cohort of COPD patients. The cohort comprised 433 COPD subjects (65±11 years; FEV₁, 50±20% predicted). Subjects with (*n*=321) and without (*n*=112) chronic cough and sputum production were compared. **Results:** No significant difference was observed between groups for age, FEV₁, body mass index, and comorbidities. Subjects with chronic cough and sputum production had increased total mean numbers of exacerbations per patient per year (2.20±2.20 vs 0.97±1.19, respectively; *p* < 0.0001), moderate exacerbations (1.80±2.07 vs 0.66±0.85, respectively; *p* < 0.0001), and severe exacerbations requiring hospitalizations (0.43±0.95 vs 0.22±0.56, respectively; *p* < 0.02). The total number of exacerbations per patient per year was the only variable independently associated with chronic cough and sputum production. Frequent exacerbations (two or more per patient per year) occurred in 55% vs 22% of subjects, respectively, with and without chronic cough and sputum production (*p* < 0.0001). Chronic cough and sputum production and decreased FEV₁ were independently associated with an increased risk of frequent exacerbations and frequent hospitalizations. **Conclusions:** Chronic cough and sputum production are associated with frequent COPD exacerbations, including severe exacerbations requiring hospitalizations.

Exacerbations of Chronic Obstructive Pulmonary Disease and Chronic Mucus Hypersecretion

Y Tesfaigzi, P Meek, S Lareau. Clinical and Applied Immunology Reviews 2006;6:21-36.

Chronic obstructive pulmonary disease (COPD) exacerbations are an important cause of the considerable morbidity and mortality found in COPD. COPD exacerbations increase with increasing severity of COPD, and some patients are prone to frequent exacerbations leading to hospital admission and readmission. These frequent exacerbations may have considerable impact on quality of life and activities of daily living. Factors that increase the risk for COPD exacerbations are associated with increased airway inflammation caused by common pollutants and bacterial and/or viral infections. These inflammatory responses cause mucus hypersecretion and, thereby, airway obstruction and associated exacerbations. While chronic mucus hypersecretion is a significant risk factor for frequent and severe exacerbations, patients with chronic mucus hypersecretion have a lower rate of relapse after initial treatment for acute exacerbation. The benefit of antibiotics for treatment of COPD exacerbations is small but significant. While the mechanisms of actions are not clear, mucolytic agents reduce the number of days of disability in subjects with exacerbations. Reducing mucous cell numbers in small airways could be a useful way to reduce chronic mucus hypersecretion. Our studies suggest that programmed cell death is crucial in the resolution of metaplastic mucous cells, and understanding these mechanisms may provide novel therapies to reduce the risk of COPD exacerbations.

Mortality in GOLD stages of COPD and its dependence on symptoms of chronic bronchitis

M Ekberg-Aronsson, K Pehrsson, J Nilsson, PM Nilsson, C Löfdahl. Resp Res 2005;6:98.

Background: The GOLD classification of COPD severity introduces a stage 0 (at risk) comprising individuals with productive cough and normal lung function. The aims of this study were to investigate total mortality risks in GOLD stages 0–4 with special focus on stage 0, and furthermore to assess the influence of symptoms of chronic bronchitis on mortality risks in GOLD stages 1–4. **Method:** Between 1974 and 1992, a total of 22,044 middle-aged individuals participated in a health screening, which included a spirometry as well as recording of respiratory symptoms and smoking habits. Individuals with comorbidity at baseline (diabetes, stroke, cancer, angina pectoris, or heart infarction) were excluded from the analyses. Hazard ratios (HR 95% CI) of total mortality were analyzed in GOLD stages 0–4 with individuals with normal lung function and without symptoms of chronic bronchitis as a reference group. HR:s in smoking individuals with symptoms of chronic bronchitis within the stages 1–4 were calculated with individuals with the same GOLD stage but without symptoms of chronic bronchitis as reference. **Results:** The number of deaths was 3674 for men and 832 for women based on 352,324 and 150,050 person-years respectively. The proportion of smokers among men was 50% and among women 40%. Self reported comorbidity was present in 4.6% of the men and 6.6% of the women. Among smoking men, Stage 0 was associated with an increased mortality risk, HR; 1.65 (1.32–2.08), of similar magnitude as in stage 2, HR; 1.41 (1.31–1.70). The hazard ratio in stage 0 was significantly higher than in stage 1 HR; 1.13 (0.98–1.29). Among male smokers with stage 1; HR: 2.04 (1.34–3.11), and among female smokers with stage 2 disease; HR: 3.16 (1.38–7.23), increased HR:s were found in individuals with symptoms of chronic bronchitis as compared to those without symptoms of chronic bronchitis. **Conclusion:** Symptoms fulfilling the definition of chronic bronchitis were associated with an increased mortality risk among male smokers with normal pulmonary function (stage 0) and also with an increased risk of death among smoking individuals with mild to moderate COPD (stage 1 and 2).

The Nature of Small-Airway Obstruction in Chronic Obstructive Pulmonary Disease

JC Hogg, FC Chu, S Utokaparch, R Woods, WM Elliott, L Buzatu, RM Cherniack, RM Rogers, FC Scirba, HO Coxson, PD Paré. New Eng J Med 2004;350(26):2645-2653.

Background: Chronic obstructive pulmonary disease (COPD) is a major public health problem associated with long-term exposure to toxic gases and particles. We examined the evolution of the

pathological effects of airway obstruction in patients with COPD. **Methods:** The small airways were assessed in surgically resected lung tissue from 159 patients — 39 with stage 0 (at risk), 39 with stage 1, 22 with stage 2, 16 with stage 3, and 43 with stage 4 (very severe) COPD, according to the classification of the Global Initiative for Chronic Obstructive Lung Disease (GOLD). **Results:** The progression of COPD was strongly associated with an increase in the volume of tissue in the wall ($P<0.001$) and the accumulation of inflammatory mucous exudates in the lumen ($P<0.001$) of the small airways. The percentage of the airways that contained polymorphonuclear neutrophils ($P<0.001$), macrophages ($P<0.001$), CD4 cells ($P=0.02$), CD8 cells ($P=0.038$), B cells ($P<0.001$), and lymphoid aggregates containing follicles ($P=0.003$) and the absolute volume of B cells ($P=0.03$) and CD8 cells ($P=0.02$) also increased as COPD progressed. **Conclusions:** Progression of COPD is associated with the accumulation of inflammatory mucous exudates in the lumen and infiltration of the wall by innate and adaptive inflammatory immune cells that form lymphoid follicles. These changes are coupled to a repair or remodeling process that thickens the walls of these airways.

Determinants of Prognosis of COPD in the Elderly: Mucus Hypersecretion, Infections, Cardiovascular Comorbidity

R Pistelli, P Lange, DL Miller. Eur Respir J 2003;21(40s):10s-14s.

In this paper, the authors update the present knowledge about three risk factors for the prognosis of chronic obstructive pulmonary disease (COPD), which may be particularly relevant in elderly people: mucus hypersecretion, respiratory infections, and cardiovascular comorbidity. Chronic mucus hypersecretion (CMH) is a common respiratory symptom in old age, the relevance of which is analysed on the basis of data and collected during the first three rounds of the Copenhagen City Heart Study. In subjects aged ≥ 65 yrs, CMH was a strong predictor of the incidence of respiratory infections in a 10-yr follow-up period and it was also a strong predictor of death from COPD (relative risk=2.5). However, CMH was associated with consistently lower forced expiratory volume in one second (FEV_1) values, but not with an accelerated decline of FEV_1 in this sample of an elderly population. Acute respiratory infections (ARI) are extremely common at all ages, mostly mild self-limiting illnesses at a young age, but severe often fatal illnesses in elderly people already affected by a chronic disease such as COPD. This paper summarises the present knowledge about aetiology, pathology, prognostic relevance, and prevention of ARI. Furthermore, the areas in which further research is needed are listed. Clinical cohort studies clearly support the relevance of cardiovascular comorbidity for the short- and long-term prognosis of elderly subjects affected by severe COPD. In this paper, the recently demonstrated association between particulate air pollution and cardiovascular events is reported to suggest the presence of an extremely susceptible cluster of elderly subjects in the population identified by the copresence of chronic obstructive pulmonary disease and cardiovascular comorbidity.

Epidemiological Studies in Mucus Hypersecretion

J Vestbo. 2002 Mucus hypersecretion in respiratory disease. Wiley, Chichester (Novartis Foundation Symposium 248) p 3-19.

Respiratory mucus in epidemiology has mainly been studied using standardized questionnaires including questions on cough and phlegm. In chronic obstructive pulmonary disease (COPD) much controversy exists regarding the importance of mucus hypersecretion. From being the key element in the 'British hypothesis' it was reduced to being an innocent disorder in the 1980s but is now again recognized as a potential risk factor for an accelerated loss of lung function. Whereas early studies in mainly occupational cohorts showed no effect of chronic mucus hypersecretion on decline in lung function, such an effect has been shown in subsequent studies on general population samples. Chronic mucus hypersecretion also increases risk of hospital admission which may be due to an increased risk of lower respiratory tract infection. In severe COPD this may explain the increased mortality associated with the presence of mucus. In asthma recent findings suggest that in epidemiology chronic mucus hypersecretion may indicate lack of control which leads to an accelerated loss of lung function and increased mortality in subjects with self-reported asthma.

Association of Chronic Mucus Hypersecretion with FEV₁ Decline and Chronic Obstructive Pulmonary Disease Morbidity

J Vestbo, E Prescott, P Lange, Copenhagen City Heart Study Group. Am J Respir Crit Med 1996;153:1530-1535.

The aim of this study was to examine the association between chronic mucus hypersecretion and FEV₁ decline, and subsequent hospitalization from chronic obstructive pulmonary disease (COPD). We used data from The Copenhagen City Heart Study on 5,354 women and 4,081 men 30 to 79 yr of age with assessment of smoking habits, respiratory symptoms, and spirometry at two surveys 5 yr apart. Information on COPD hospitalization during 8 to 10 yr of subsequent follow-up was obtained from a nationwide register. Chronic mucus hypersecretion was significantly associated with FEV₁ decline; the effect was most prominent among men, where chronic mucus hypersecretion at both surveys was associated with an excess FEV₁ decline of 22.8 ml/yr (95% confidence interval, 8.2 to 37.4) compared with men without mucus hypersecretion, after adjusting for age and smoking; relative risk was 5.3 (2.9 to 9.6) among men and 5.1 (2.5 to 10.3) among women. After further adjusting for FEV₁ at the second survey, the relative risk was reduced to 2.4 (1.3 to 4.5) for men and 2.6 (1.2 to 5.3) for women. Chronic mucus hypersecretion was significantly and consistently associated with both an excess FEV₁ decline and an increased risk of subsequent hospitalization because of COPD.

Chronic Mucus Hypersecretion in COPD and Death From Pulmonary Infection

E Prescott, P Lange, J Vestbo. Eru. Resp. J. 1995;8:1333-1338.

The association of chronic mucus hypersecretion and mortality is a matter of debate. We wished to determine whether the relationship between chronic mucus hypersecretion and chronic obstructive pulmonary disease (COPD)-related mortality could be explained by proneness to pulmonary infection. We followed 14,223 subjects of both sexes for 10-12 yrs. Cases where COPD was an underlying or contributory cause of death (n=214) were included, and hospital records were obtained where possible (n=101). From the presence of increased mucus, purulent mucus, fever, leucocytosis and infiltration on chest radiography, death was classified as either due to pulmonary infection (n=38), or other causes (n=51), or unclassifiable (n=12). Of subjects reporting chronic mucus hypersecretion at the initial examination, pulmonary infection was implicated in 54% of deaths, whereas this only occurred in 28% of subjects without chronic mucus hypersecretion. Controlling for covariates, in particular smoking habits, a Cox analysis showed a strong inverse relationship between ventilatory function and COPD-related mortality. Chronic mucus hypersecretion was found to be a significant predictor of COPD-related death with pulmonary infection implicated (relative risk (RR) 3.5) but not of death without pulmonary infection (RR 0.9). We consider that subjects with COPD and chronic mucus hypersecretion are more likely to die from pulmonary infections than subjects without chronic mucus hypersecretion. This may explain the excess mortality in subjects with COPD and chronic mucus hypersecretion found in previous studies.

STUDIES USING THE **AEROBIKA*** OSCILLATING POSITIVE EXPIRATORY PRESSURE THERAPY SYSTEM

Review of Quality of Life Outcomes Following Use of an Oscillating Positive Expiratory Pressure Device for Chronic Obstructive Pulmonary Disease: Comparison of Small n Clinically Controlled and Validated Measures to Large n Patient Survey Data

J. Suggett. ATS 2015.

Conclusions: “A highly significant improvement (both statistical and clinical) in SGRQ score was observed by patients following use of the **Aerobika*** OPEP device within the 3 week cross-over clinical study. Although the large n patient survey was in nonphenotyped COPD patients using a non-validated survey, with therefore recognized limitations, there was still a degree of correlation to the clinical study outcomes with subjective improvements related to mucus clearance, ease of breathing, quality of life and coughing reported for a large number of patients.”

Survey of Patients Using an Oscillating Positive Expiratory Pressure Device Indicates Improvement in Well-Being and Compliance to Therapy

H Harkness, C Patrick and J Lefebvre. CRC 2015.

Conclusions: “Results from this patient feedback survey indicate that the **Aerobika*** OPEP device has a high degree of acceptance within the COPD population because it is easy to use, helps clear mucus and reduces feelings of breathlessness. Responses demonstrated a high degree of satisfaction with the **Aerobika*** OPEP device, specifically in assisting with mucus clearance and decreased breathlessness (may lead to better therapeutic benefit). The addition of the **Aerobika*** OPEP is associated with improved symptom relief.”

Oscillating Positive Expiratory Pressure Therapy in Chronic Obstructive Pulmonary Disease and Bronchiectasis

Svenningsen S, Paulin G, Wheatley A, Pike D, Suggett J, McCormack D and Parraga G. ERS 2014.

Conclusions: “In subjects with COPD and Bronchiectasis, three weeks of OPEP therapy was well-tolerated and there was improved dyspnea, quality of life, exercise capacity and ease in bringing up sputum.”

Assessment of Oscillating Positive Expiratory Pressure Devices By Means Of Adult Expiratory Waveforms: A Laboratory Study

J Suggett, A Meyer, S Costella, R Morton, J Mitchell. Poster presented at ATS 2014.

Conclusions: “Duration of oscillations per expiratory portion of each respiratory cycle is important as a measure of device efficiency for the clinical management of mucus secretion mobilization. Measures of t_{osc} [% of exhalation time with oscillations] with the **Aerobika*** OPEP device were >75% at all PEF [Peak Expiratory Flow Rate] settings and were generally consistent. The other OPEP systems exhibited lower and much more variable t_{osc} values, ranging from 30% to 63%. Duration of oscillations for **Aerobika*** OPEP was 52-60% greater on average compared to other devices.”

Comparative Laboratory Study of Oscillating Positive Expiratory Pressure Waveforms from Commercially Available Devices Used In Airway Clearance Therapy

J Suggett, A Meyer, S Costella, J Mitchell. Respiratory Drug Delivery 2014.

Conclusions: “The oscillation frequencies determined for the **Aerobika*** OPEP [Oscillating Positive Expiratory Pressure] device were closest to the reported optimum range for airway clearance. Furthermore, initial clinical studies with COPD patients support its efficacy.”

More than Drug Delivery: A New Airway Clearance Therapy Evaluated Clinically Using MRI

J Suggett, J Mitchell. Respiratory Drug Delivery 2014.

Conclusions: “The **Aerobika*** OPEP device was shown to be well tolerated in use with this cohort of COPD patients. There was a statistically significant improvement in dyspnea following use of the device, with additional statistically significant improvements in FVC%_{pred} [Forced Vital Capacity percent of predicted] and ease in bringing up sputum, for a subgroup of patients demonstrating imaging improvements. The use of ³He MRI [Hyperpolarized Helium-3 Magnetic Resonance Imaging] has also been shown to be a promising tool with which to interpret visually the physiological effects of ACT [Airway Clearance Therapy].”

Combining Oscillating Positive Expiratory Pressure Therapy with Inhalation of Bronchodilator Via a Breath-Actuated Nebulizer: Initial Evaluation of *In Vitro* Data to Determine Nebulizer Performance

J Schmidt, M Nagel, H Schneider, V Avvakoumova, C Doyle, V Wang, R Ali, A Meyer, R Kopala, JP Mitchell. Respiratory Drug Delivery 2013.

Conclusions: “The delivery of medication as fine particles from the **AeroEclipse*** II BAN [Breath Actuated Nebulizer] is comparable by combining the BAN with the **Aerobika*** OPEP [Oscillating Positive Expiratory Pressure] device, offering the patient the opportunity for combined aerosol/OPEP therapy. Substitution by OPEP devices that do not allow incoming aerosol to be transported directly to the patient, are likely to result in substantial loss of aerosol from this nebulizer that may be clinically significant.”

Hyperpolarized ³He Magnetic Resonance Imaging Following Oscillatory Positive Expiratory Pressure Treatment in Gold Stage II & III COPD

S Svenningsen, BN Jobse, A Hasany, N Kanhere, M Kirby, J Suggett, DG McCormack, G Parraga. American Thoracic Society 2013.

Conclusions: “In this pilot, proof-of-concept study, self-administered oPEP therapy over 4 weeks variably affected lung volumes, VDP and symptoms in two cases with stable advanced COPD. One COPD ex-smoker case exhibited clear improvements in Spirometry and plethysmography measurements, mucus clearance and SGRQ, whereas the other case showed no or little change during the treatment period. Future work will involve careful patient phenotyping using MRI and CT to help stratify subjects to oPEP therapy and to better understand therapy responses. Results in all subjects are currently being evaluated to determine the effect of 4 weeks oPEP in 14 COPD ex-smokers who completed therapy. For two COPD ex-smokers, one a self-reported non-responder and the other a self-reported responder to oPEP, there were changes in PFTs, ³HE MRI, SGRQ and ease in bringing up sputum that were in agreement with self-reported response.”

AIRWAY CLEARANCE TECHNIQUES IN COPD

Advances in Airway Clearance Technologies for Chronic Obstructive Pulmonary Disease

CR Osadnik, CF McDonald, AE Holland. *Expert Rev Resp Med.* 2013;7(6):673-685.

Techniques to promote clearance of sputum from the airways (airway clearance techniques: ACTs) have existed in clinical practice for more than a century. This review examines current evidence and clinical recommendations regarding ACTs for individuals with chronic obstructive pulmonary disease. Comparisons between this literature and reports of current practice suggest that discrepancies may exist in relation to the clinical management of sputum in individuals with COPD. The novel application of newer technologies has enhanced our ability to assess the complex physiological processes underpinning airway clearance therapy. The potential for physiologically tailored ACT prescription may, however, depend on the capacity for translation of such technology from the research setting in the clinical environment. Future directions regarding this common form of therapy will be discussed, including identification of the key research priorities to optimize evidence-based practice in this area.

Airway Clearance Techniques for Chronic Obstructive Pulmonary Disease

CR Osadnik, CF McDonald, AP Jones, AE Holland. *Cochrane Database Syst Rev.* 2012.

Background: Cough and sputum production are common in chronic obstructive pulmonary disease (COPD) and are associated with adverse clinical outcomes. Airway clearance techniques (ACTs) aim to remove sputum from the lungs, however evidence of their efficacy during acute exacerbations of COPD (AECOPD) or stable disease is unclear. **Objectives:** To assess the safety and efficacy of ACTs for individuals with AECOPD and stable COPD. **Search Methods:** We searched the Cochrane Airways Group Specialised Register of trials from inception to October 2011, and PEDro in October 2009. **Selection Criteria:** We included randomised parallel trials and randomised cross-over trials which compared an ACT to no treatment, cough or sham ACT in participants with investigator-defined COPD, emphysema or chronic bronchitis. **Data Collection and Analysis:** Two review authors independently conducted data extraction and assessed the risk of bias. We analysed data from studies of AECOPD separately from stable COPD, and classified the effects of ACTs as 'immediate' (less than 24 hours), 'short-term' (24 hours to eight weeks) or 'long-term' (greater than eight weeks). One subgroup analysis compared the effects of ACTs that use positive expiratory pressure (PEP) to those that do not. **Main Results:** Twenty-eight studies on 907 participants were included in the review. Study sample size was generally small (range 5 to 96 people) and overall quality was generally poor due to inadequate blinding and allocation procedures. Meta-analyses were limited by heterogeneity of outcome measurement and inadequate reporting of data. In people experiencing AECOPD, ACT use was associated with small but significant short-term reductions in the need for increased ventilatory assistance (odds ratio (OR) 0.21, 95% confidence interval (CI) 0.05 to 0.85; data from four studies on 171 people), the duration of ventilatory assistance (mean difference (MD) -2.05 days, 95% CI -2.60 to -1.51; mean duration for control groups seven days; data from two studies on 54 people) and hospital length of stay (MD -0.75 days, 95% CI -1.38 to -0.11; mean duration for control groups nine days; one study on 35 people). Data from a limited number of studies revealed no significant long-term benefits of ACTs on the number of exacerbations or hospitalisations, nor any short-term beneficial effect on health-related quality of life (HRQoL) as measured by the St. George's Respiratory Questionnaire (SGRQ) total score (MD -2.30, 95% CI -11.80 to 7.20; one study on 59 people). In people with stable COPD, data from single studies revealed no significant short-term benefit of ACTs on the number of people with exacerbations (OR 3.21, 95% CI 0.12 to 85.20; one study on 30 people), significant short-term improvements in HRQoL as measured by the SGRQ total score (MD -6.10, 95% CI -8.93 to -3.27; one study on 15 people) and a reduced long-term need for respiratory-related hospitalisation (OR 0.27, 95% CI 0.08 to 0.95; one study on 35 participants). The magnitude of effect of PEP-based ACTs on the need for increased ventilatory assistance and hospital length of stay was greater than for non-PEP ACTs, however we found no statistically significant subgroup differences. There was one report of vomiting during treatment with postural drainage and head-down tilt. **Authors' Conclusions:** Evidence from this

review indicates that airway clearance techniques are safe for individuals with COPD and confer small beneficial effects on some clinical outcomes. Consideration may be given to the use of airway clearance techniques for patients with COPD in both acute and stable disease, however current studies suggest that the benefits achieved may be small.

Effect of airway clearance techniques in patients experiencing an acute exacerbation of chronic obstructive pulmonary disease: a systematic review

K Hill, S Patman, D Brooks. Chron Respir Dis. 2010;7(1):9-17.

Abstract: Answers were sought to the following question: Are techniques, applied predominantly with the aim of clearing secretions from the airways, to patients during an acute exacerbation of chronic obstructive pulmonary disease (AECOPD), safe and effective? A systematic review was undertaken of studies that (i) were either randomized controlled or randomized cross-over trials, (ii) recruited patients during an AECOPD, (iii) reported the results of between-group analyses and (iv) investigated the effect of techniques applied primarily with the aim of clearing secretions from the airways. Studies that examined non-invasive positive pressure ventilation (NIPPV) and early rehabilitation were excluded. Data were extracted pertaining to resting lung function, gas exchange, sputum expectoration, symptoms, NIPPV use and hospital stay. Five studies were included with a mean Physiotherapy Evidence Database (PEDro) score of 4.4 +/- 1.1 (range: 3-6). The main findings were that (i) airway clearance techniques did not improve measures of resting lung function or produce any consistent change in measures of gas exchange, (ii) the application of 5 min of continuous chest wall percussion reduced forced expiratory volume in 1 second (FEV₁), (iii) in people with copious secretions, mechanical vibration, and non-oscillating positive expiratory pressure (PEP) mask therapy increased sputum expectoration and (iv) in patients with hypercapnic respiratory failure, intrapulmonary percussive ventilation (IPV) and PEP mask therapy reduced the need for, and duration of, NIPPV, respectively. With the exception of continuous chest wall percussion, airway clearance techniques were safe in patients during an AECOPD. Vibration and non-oscillating PEP facilitated sputum expectoration in patients characterized by copious airway secretions. In patients with respiratory failure, techniques that apply a positive pressure to the airways may reduce either the need for, or duration of, NIPPV and hospital length of stay.

Chest physiotherapy for patients admitted to hospital with an acute exacerbation of chronic obstructive pulmonary disease (COPD): a systematic review

CY Tang, NF Taylor, FC Blackstock. Physiotherapy 2010 Mar;96(1):1-13.

Objectives: To examine the effectiveness of chest physiotherapy for patients admitted to hospital with an acute exacerbation of chronic obstructive pulmonary disease (COPD). **Data Source:** CINAHL, MEDLINE, Embase, Cochrane, Expanded Academic Index, Clinical Evidence, PEDro, Pubmed, Web of Knowledge and Proquest were searched from the earliest available time to September 2007, using the key elements of COPD, acute exacerbation and chest physiotherapy interventions. **Review Methods:** To be included, trials had to investigate patients during admission to hospital with an acute exacerbation of COPD, and to evaluate at least one physiotherapy intervention. Two reviewers independently applied the inclusion criteria, and assessed trial quality using the PEDro scale. Results were expressed as standardised mean differences and analysed qualitatively with a best-evidence synthesis. **Results:** Thirteen trials were identified. There was moderate evidence that intermittent positive pressure ventilation and positive expiratory pressure were effective in improving sputum expectoration. In addition, there was moderate evidence that walking programmes led to benefits in arterial blood gases, lung function, dyspnoea and quality of life. No evidence was found supporting the use of any other chest physiotherapy techniques to change lung function, arterial blood gases, perceived level of dyspnoea or quality of life. **Conclusions:** Chest physiotherapy techniques such as intermittent positive pressure ventilation and positive expiratory pressure may benefit patients with COPD requiring assistance with sputum clearance, while walking programmes may have wider benefits for patients admitted with an exacerbation of COPD. Chest physiotherapy techniques other than percussion are safe for administration to this patient population.

Efficacy of Physical Therapy Methods in Airway Clearance in Patients With Chronic Obstructive Pulmonary Disease: A Critical Review

R Nowobilski, T Włoch, M Płaszewski, A Szczekliak. Polskie Archiwum Medycyny Wewnętrznej 2010;120(11):468-477.

Abstract: Multiplicity and variety of chest physical therapy (CPT) methods for increasing bronchial clearance in patients with chronic obstructive pulmonary disease (COPD) require an assessment of validity and reliability of the available clinical evidence. The aim of the review was to evaluate publications on CPT in COPD patients and to establish the basis (objective criteria) on which given methods and techniques are recommended or refuted. Systematic reviews, narrative reviews, and clinical practice guidelines, published in English between January 1, 2000 and July 1, 2010, were identified from the PubMed/MEDLINE and Cochrane (DARE, CRD, The Cochrane Airways Review Group Register) databases. The PEDro and SIGN scales were used to assess the quality and grade of recommendations for selected papers. Generally, the papers that we identified were based on small studies, limited to short-term outcomes, mostly using crossover designs, and rarely including sham therapy. Recommendations from clinical guidelines were mainly grade C or D. Health-related quality-of-life analyses, including working and exercise capacity, are lacking. The evidence from the studies in patients with cystic fibrosis cannot be directly extrapolated to COPD subjects. Despite the lack of convincing evidence, clinical practice supports the value of CPT in COPD. However, when making a clinical decision, potential side effects should be considered.

Positive Expiratory Pressure in Patients with Chronic Obstructive Pulmonary Disease – A Systematic Review

MF Olsén, E Westerdahl. Respiration 2009;77:110-118.

Background: Breathing exercises against a resistance during expiration are often used as treatment for patients with chronic obstructive pulmonary disease (COPD). Controversy still exists regarding the clinical application and efficacy. **Objectives:** The aim of this systematic review was to determine the effects of chest physiotherapy techniques with positive expiratory pressure (PEP) for the prevention and treatment of pulmonary impairment in adults with COPD. **Methods:** The review was conducted on randomised, controlled clinical trials in which breathing exercises with positive expiratory pressure were compared with other chest physical therapy techniques or with no treatment, in adult patients with COPD. A computer-assisted literature search of available databases from 1970 to January 2008 was performed. Two reviewers extracted data independently and assessed the trials systematically with an instrument for measuring methodological quality. **Results:** In total, 11 trials met the inclusion criteria, of which 5 reached an adequate level of internal validity. Several kinds of PEP techniques with a diversity of intensities and durations of treatment have been evaluated with different outcome measures and follow-up periods. Benefits of PEP were found in isolated outcome measures in separate studies with a follow-up period <1 month. Concerning long-term effects, the results are contradictory. **Conclusion:** Prior to widespread prescription of long-term PEP treatment, more research is required to establish the benefit of the technique in patients with COPD.

Improving mucociliary clearance in chronic obstructive pulmonary disease

A Bhowmik, K Chahal, G Austin, I Chakravorty. Resp Med 2009;103:496-502.

Patients with COPD usually experience mucus hypersecretion as a result of airway inflammation and response to noxious stimuli. These in turn lead to worsening airway resistance, impaired airflow, increased work of breathing, dyspnoea and exercise intolerance. Mucus hypersecretion may also lead to increased exacerbations and poor health related quality of life (HRQL). Institution based pulmonary rehabilitation programs incorporating airway clearance techniques have been shown to improve HRQL, reduce dyspnoea and improve exercise tolerance but are often difficult to provide due to restricted accessibility and resource implications. This review examines the current evidence base and best clinical practice in the area of airway clearance. Mechanical devices such as the flutter valves, positive end expiratory pressure and high frequency chest wall oscillation (HFCWO) may be able to provide the benefits of improved airway clearance in the patient's home potentially with reduced demands on healthcare resources.

Use of Mucus Clearance Devices Enhances the Bronchodilator Response in Patients with Stable COPD

N Wolkove, H Kamel, M Rotaple, MA Baltzan. Chest 2002;121:702-707.

Study objective: To determine whether the use of a mucus clearance device (MCD) [Flutter; Axcan Scandipharm; Birmingham, AL] could improve the bronchodilator response to inhaled ipratropium and salbutamol delivered by a metered-dose inhaler in patients with stable, severe COPD. **Patients:** Twenty-three patients with severe COPD were studied. Mean SD age was 71.7±6.3 years. Mean FEV₁ was 0.74±0.28 L or 34.5±12.7% predicted. **Methods:** Patients were tested in random order on 2 subsequent days after using an MCD or a sham MCD. A bronchodilator (four puffs; each puff delivering 20 µg of ipratropium bromide and 120 µg of salbutamol sulfate) was administered by metered-dose inhaler with a holding chamber after use of the MCD or sham MCD. Spirometry was performed before and after use of the MCD or sham MCD, and at 30 min, 60 min, and 120 min after the bronchodilator. Six-minute walk distance was tested between 30 min and 60 min; oxygen saturation, pulse, and a dyspnea score were recorded before and after walking. **Results:** Immediately after use of the MCD, but not the sham MCD, there was a statistically significant ($p < 0.05$) improvement in FEV₁ and FVC (11±24% vs 1±7% and 18±33% vs 6±18%, respectively). Whether patients were pretreated with the MCD or sham MCD, there was a significant improvement in FEV₁ and FVC compared to baseline with combined bronchodilator therapy. At 120 min, the change in FEV₁ after treatment with the MCD was greater than with the sham MCD (186±110 mL vs 130±120 mL; $p < 0.05$). When comparing the MCD to the sham MCD, 6-min walk distance was greater (174±92 m vs 162±86 m; $p < 0.05$), with less dyspnea before and at the end of walking. **Conclusion:** Patients with severe COPD may demonstrate a significant bronchodilator response to combined ipratropium and salbutamol delivered by metered-dose inhaler. This response may be enhanced and additional functional improvement obtained with the prior use of a bronchial MCD.

Chest Physical Therapy in Patients With Acute Exacerbation of Chronic Bronchitis: Effectiveness [sic] of Three Methods

A Bellone, R Lascioli, S Raschi, L Guzzi, R Adone. Arch Phys Med Rehabil 2000;81:558-560

Objective: To compare the short-term effects of postural drainage (PD), oscillating positive expiratory pressure (using the FLUTTER device), and expiration with the glottis open in the lateral posture (ELTGOL) on oxygen saturation, pulmonary function, and sputum production in patients with an acute exacerbation of chronic bronchitis. **Design:** A prospective, randomized study. **Setting:** A clinical ward. **Patients:** Ten patients with chronic bronchitis exacerbation received PD, FLUTTER, and ELTGOL by the same respiratory therapist at about the same time of day on separate days and in random order. **Main Outcome Measures:** Oxygen saturation and pulmonary function were measured before, immediately after, and 15 minutes and 1 hour after each treatment. Improvement in sputum production was measured by total sputum wet weight immediately after and for 1 hour after treatment. **Interventions:** PD consisted of positioning the patients in a posture that allows bronchial drainage by gravity. FLUTTER is a device that is claimed to combine oscillating positive expiratory pressure with oscillations of the airflow. ELTGOL is an airway clearance technique that uses lateral posture and different lung volumes to control expiratory flow rate to avoid airway compression. The total time spent for treatments was 30 minutes. **Results:** All techniques were well tolerated, and oxygen saturation and pulmonary function did not change significantly during and after treatments. Thirty minutes after the beginning of treatment, sputum production increased significantly with all techniques, but during the 1 hour after the end of treatment, it was significantly larger with FLUTTER (from $15.0 \pm 8.6\text{g}$ to $19.0 \pm 9.3\text{g}$, $p < .01$) and ELTGOL (from $17.0 \pm 7.0\text{g}$ to $20.6 \pm 6.9\text{g}$, $p < .02$) than with PD (from $15.5 \pm 4.0\text{g}$ to $17.5 \pm 3.7\text{g}$, NS). **Conclusions:** All three treatments were safe and effective in removing secretions without causing undesirable effects on oxygen saturation, but FLUTTER and ELTGOL techniques were more effective in prolonging secretion removal in chronic bronchitis exacerbation than was the PD method.

AIRWAY CLEARANCE TECHNIQUES IN BRONCHIECTASIS

Airway Clearance Techniques for Bronchiectasis

AL Lee, A Burge, AE Holland. *Cochrane Database of Systematic Reviews 2013, Issue 5. Art. No.: CD008351. DOI: 10.1002/14651858.CD008351.pub2.*

Authors' conclusions: ACTs appear to be safe for individuals (adults and children) with stable bronchiectasis, where there may be improvements in sputum expectoration, selected measures of lung function and health-related quality of life. The role of these techniques in people with an acute exacerbation of bronchiectasis is unknown. In view of the chronic nature of bronchiectasis, more data are needed to establish the clinical value of ACTs over the short and long term on patient-important outcomes, including symptoms, on physiological outcomes which may clarify the rationale for each technique and on long-term parameters that impact on disease progression in individuals with stable bronchiectasis. This is necessary in order to provide further guidance of specific ACT prescription for people with bronchiectasis. It may also be important to establish the comparative effect of different types of ACTs in people with bronchiectasis.

Influence that Oscillating Positive Expiratory Pressure Using Predetermined Expiratory Pressures has on the Viscosity and Transportability of Sputum in Patients with Bronchiectasis

EMC Ramos, D Ramos, DM Iyomasa, GL Moreira, KCT Melegati, LCM Vanderlei, JR Jardim, AS de Oliveira. *J Bras Pneumol 2009;35(12):1190-1197.*

Conclusions: "The fact that sputum viscosity decreased whether OPEP was performed at P15 or P25 suggests that there is no need to generate high expiratory pressure to achieve the desired result."

- "...mechanisms that promote the displacement and removal of secretions are essential to maintain the respiratory tract defenses against infections and the proliferation of bacteria."
- "...the decreased sputum viscosity after the sessions at P15 and P25 suggests a better rheological profile and greater sputum thinning after the use of the [OPEP] device."

AIRWAY CLEARANCE TECHNIQUES IN CYSTIC FIBROSIS

Long-Term Multicentre Randomised Controlled Study of High Frequency Chest Wall Oscillation Versus Positive Expiratory Pressure Mask in Cystic Fibrosis

MP McIlwaine, N Alarie, GF Davidson, LC Lands, F Ratjen, R Milner, B Owen, JL Agnew. *Thorax* 2013;0:1-6.

Conclusions: “The results of this study favour PEP and do not support the use of HFCWO as the primary form of AC in patients with CF.”

- “Treatment time was significantly shorter in the PEP group.”
- “There were significantly more adverse events related to the lower airways in the HFCWO group than in the PEP group (mean 2.46 vs 1.72, $p=0.023$). These included increased cough, chest infection, haemoptysis, decreased lung function and chest pain”.
- “The number of hospitalisations for PE in this study was three times more in the HFCWO group than in the PEP group (19 vs 6). The cost of hospitalisation is significant for our health economy and also causes a significant burden for the family of people with CF. Thus, at a time when we are looking to reduce health costs, unless there is strong evidence to support the use of more expensive equipment we cannot justify the cost.”
- “The relatively lower PE rates and their later onset in patients performing PEP therapy compared with HFCWO supports the use of PEP as the primary ACT in patients with CF aged > 6 years.”

Adherence to Airway Clearance Therapies By Adult Cystic Fibrosis Patients

JS Flores, FA Teixeira, PME Rovedder, B Ziegler, PTR Dalcin. *Respiratory Care* 2013;58(2):279-285.

Conclusions: “Treatment recommendations and self-reported subject adherence were in best agreement when positive expiratory pressure and flutter devices were used. Healthcare professionals should consider these outcomes as potentially applicable to their own clinical practices.”

Airway Clearance Devices in Cystic Fibrosis

JH Marks. *Paediatric Respiratory Reviews* 2007;8:17-23.

- “Airway clearance devices as alternatives to CCPT [Conventional Chest Physiotherapy] allow CF patients to choose the therapy that best fits their lifestyle and allows greatest independence
- “Airway clearance devices are preferred by many patients compared to CCPT and may result in better adherence.”
- “PEP may be more effective for airway clearance than CCPT.”
- “Oscillating positive expiratory pressure devices and HFCWO [High Frequency Chest Wall Oscillation] appear to be at least as effective as CCPT.”

Positive Expiratory Pressure and Oscillatory Positive Expiratory Pressure Therapies

TR Myers. *Respiratory Care* 2007;52(10):1308-1327.

- “In addition to enhanced secretion mobilization and elimination, the secondary objective of these airway-clearance devices is to prevent recurring infection, atelectasis, and disease progression, or to improve pulmonary mechanics and facilitate gas exchange.”
- “Oscillations reportedly decrease the viscoelastic properties of mucus, which makes it easier to mobilize mucus up the airways, and create short bursts of increased expiratory airflow that assist in mobilizing secretions up the airways.”

Physiotherapy and Airway Clearance Techniques and Devices

M McIlwaine. Paediatric Respiratory Reviews 2006;7S:S220-S222.

- “Oscillation has been shown to decrease the viscoelastic properties of mucus hence making it easier to mobilize up the airways. The second effect of the oscillations is to cause short bursts of increased acceleration of the expiratory airflow which assist in mobilizing the secretions up the airways.”

The Flutter Device Versus the PEP Mask in the Treatment of Adults with Cystic Fibrosis

ME Newbold, E Tullis, M Corey, B Ross, D Brooks. Physiotherapy Canada 2005; 57(3):199-207.

Conclusions: “When comparing the Flutter device and the PEP Mask in the treatment of adults with CF over a 13-month period, there were no significant differences in pulmonary function or health-related quality of life. A much larger sample would be needed to conclude with confidence that there were no between-group differences. Therefore, additional research is needed to further examine the effectiveness of the Flutter device and the PEP Mask.”

Evidence for Physical Therapies (Airway Clearance and Physical Training) in Cystic Fibrosis: An Overview of Five Cochrane Systematic Reviews

JM Bradley, FM Moran, JS Elborn. Respiratory Medicine 2006;100:191-201.

- “Patients tended to prefer techniques that promoted independence to CCPT”
- “Single, short and longer term trials show that PEP is at least as effective as other forms of airway clearance”
- “Evidence from the Cochrane systematic reviews support current expert opinion that no one airway clearance regimen is better than another.”
- “Data are consistent that treatment factors (the duration and the complexity of the treatment) or trait factors (worry and confidence in medical practitioners) are important determinants of adherence.”
- “As current evidence suggests that physical therapy interventions are equally beneficial, treatment duration, patient preference and patient adherence may be important primary outcomes.”

Effect of High-Frequency Oral Airway and Chest Wall Oscillation and Conventional Chest Physical Therapy on Expectorations in Patients with Stable Cystic Fibrosis

TA Scherer, J Barandun, E Martinez, A Wanner, EM Rubin. Chest 1998;113(4):1019-1027.

- “It is conceivable that compliance can be improved by the availability of simple, effective, and easy-to-use devices that allow independent treatment at home. Devices to apply oral airway and chest wall oscillation fit these criteria. Considering their effectiveness and their potential to reduce health-care costs by permitting self-administration, they appear to represent a useful alternative to conventional CPT.”

GUIDELINES

Guidelines for the Physiotherapy Management of the Adult, Medical, Spontaneously Breathing Patient

British Thoracic Society Physiotherapy Guideline Development Group

J Bott, S Blumenthal, M Buxton, S Ellum, C Falconer, R Garrod, A Harvey, T Hughes, M Lincoln, C Mikelsons, C Potter, J Pryor, L Rimington, F Sinfield, C Thompson, P Vaughn, J White; Thorax. 2009;64(1):i1-51.

- “Consider the active cycle of breathing techniques (which includes the forced expiration technique), autogenic drainage and plain or oscillating positive expiratory pressure for patients with stable COPD who need an airway clearance technique to assist in the removal of secretions.”
- “Consider oscillating positive expiratory pressure devices when recommending an airway clearance technique for adults with cystic fibrosis.”
- “Consider oscillating positive expiratory pressure when recommending an airway clearance technique for adults with noncystic fibrosis related bronchiectasis.”
- “PEP and oscillating PEP devices have been shown to be equally effective as traditional chest physiotherapy in sputum clearance, and are recognised as useful techniques in the NICE guidelines on COPD. There may be a patient preference for PEP devices, with or without an oscillatory function, over traditional methods of postural drainage and manual techniques, due to the convenience they offer to the patient. No difference in benefit has been shown between devices in aiding sputum clearance.”

British Thoracic Society Guideline for Non-CF Bronchiectasis – A Quick Reference Guide

MC Pasteur, D Bilton, AT Hill. British Thoracic Society Reports 2010;2(2).

- “The active cycle of breathing techniques (plus postural drainage) and oscillating positive expiratory devices (plus postural drainage and the forced expiration technique) should be considered when offering individuals with non-CF bronchiectasis effective airway clearance techniques.”

Cystic Fibrosis Pulmonary Guidelines: Airway Clearance Therapies

American Association of Respiratory Care (AARC)

PA Flume, KA Robinson, BP O’Sullivan, JD Finder, RL Vender, D Willey-Courand, TB White, BC Marshall and the Clinical Practice Guidelines for Pulmonary Therapies Committee. Respiratory Care 2009;54(4):522-537.

- “There are no ACTs [Airway Clearance Therapies] demonstrated to be superior to others, so the prescription of ACTs should be individualized.”
- “There are advantages and disadvantages of each of the therapeutic options...and decisions regarding prescription of airway clearance may include age of the patient, patient preference, severity of disease, availability of a partner, and observed efficacy based on patient reporting (subjective measures) and objective measures (eg, lung function).”

Note: GOLD, ATS and CTS Guidelines do not include Airway Clearance Therapies at time of print.

