AerobiKA®

Oscillating Positive
Expiratory Pressure Device

Study Summary

JANUARY 2024

TRUDELL MEDICAL INTERNATIONAL

Helping people breathe better and live fuller lives.

STUDY SUMMARY OUTLINE

The ***Aerobika**** Oscillating Positive Expiratory Pressure (OPEP) device is a hand-held, easy-to-use, and drug-free device for airway clearance therapy. When a patient exhales through the device, intermittent resistance creates a unique pressure – oscillation dynamic, which expands the airways and helps to mobilize mucus to the upper airways where it can be coughed out. The ***Aerobika**** OPEP device has demonstrated efficacy in managing respiratory conditions such as Chronic Obstructive Pulmonary Disease (COPD), Bronchiectasis, and Cystic Fibrosis, as well as providing benefits as an intervention in post-operative care.

The following sections are included in this summary:

- **Executive Summary**
  Highlighting the critical pieces of evidence that support the clinical efficacy and use of the ***Aerobika**** OPEP device in managing patients with mucus hypersecretion.

- **The Problem with Airway Maintenance in Chronic Obstructive Pulmonary Disease**
  An overview of the effect that structure-function decline has on the airways of patients with COPD.

- **Studies Using the *Aerobika**** **OPEP Device**
  In vitro and in vivo studies supporting the use and efficacy of the ***Aerobika**** device in COPD, Bronchiectasis, Cystic Fibrosis, and Post-Operative Pulmonary Complications.

- **Studies Comparing OPEP Devices and Airway Clearance Techniques**
  The Difference Is Clear: OPEP Devices Are Not All the Same
  In vitro and in vivo studies evaluating the differences between various OPEP devices and airway clearance techniques, highlighting the importance of selecting a device/therapy based on the existence of clinical evidence supporting efficacy, and patient usability factors.

- **Studies Evaluating Airway Clearance Techniques in COPD, Bronchiectasis and Cystic Fibrosis *(Non Aerobika**** *OPEP Studies)***
  Articles addressing the use and efficacy of airway clearance techniques as part of an overall therapy program in COPD, Bronchiectasis and Cystic Fibrosis.

- **Positive Outcomes in Post-Operative Pulmonary Complications Using OPEP and PEP**
  Evidence highlighting that using the ***Aerobika**** OPEP device and other positive expiratory pressure therapies shows positive outcomes in post-operative patients.

- **Guidelines**
  International guidelines recommending the use of OPEP and PEP.

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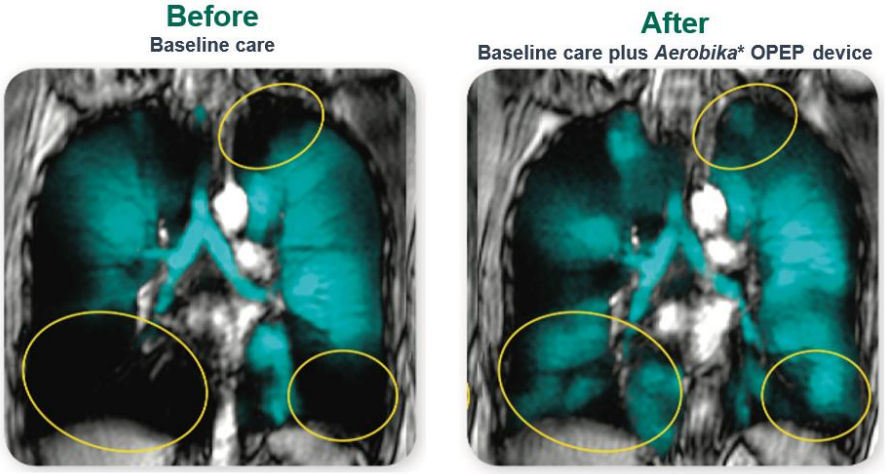
EXECUTIVE SUMMARY

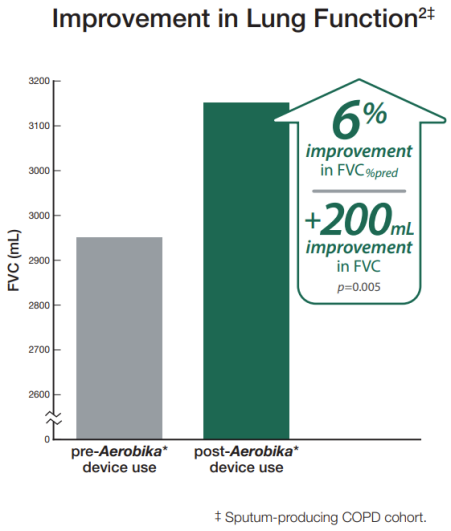
1. *Oscillating Positive Expiratory Pressure in Chronic Obstructive Pulmonary Disease*

S Svenningsen, GA Paulin, K Sheihk, F Guo, A Hasany, M Kirby, R Etemad-Rezai, DG McCormack, G Parraga. Journal of COPD 2016;13(1):66-74. https://doi.org/10.3109/15412555.2015.1043523

Evidence-based guidance for the use of airway clearance techniques (ACT) in chronic obstructive pulmonary disease (COPD) is lacking in-part because well-established measurements of pulmonary function such as the forced expiratory volume in 1s (FEV_1) are relatively insensitive to ACT. The objective of this crossover study was to evaluate daily use of an oscillatory positive expiratory pressure (oPEP) device for 21–28 days in COPD patients who were self-identified as sputum-producers or non-sputum-producers. COPD volunteers provided written informed consent to daily oPEP use in a randomized crossover fashion. Participants completed baseline, crossover and study-end pulmonary function tests, St. George's Respiratory Questionnaire (SGRQ), Patient Evaluation Questionnaire (PEQ), Six-Minute Walk Test and ^{3}He magnetic resonance imaging (MRI) for the measurement of ventilation abnormalities using the ventilation defect percent (VDP). Fourteen COPD patients, self-identified as sputum-producers and 13 COPD-non-sputum producers completed the study. Post-oPEP, the PEQ-ease-bringing-up-sputum was improved for sputum-producers (p=0.005) and non-sputum-producers (p=0.04), the magnitude of which was greater for sputum-producers (p=0.03). **There were significant post-oPEP improvements for sputum-producers only for FVC (p=0.01), 6MWD (p=0.04), SGRQ total score (p=0.01) as well as PEQ-patient-global assessment (p=0.02).** Clinically relevant post-oPEP improvements for PEQ-ease-bringing-up-sputum/PEQ-patient-global-assessment/SGRQ/VDP were observed in 8/7/9/6 of 14 sputum-producers and 2/0/3/3 of 13 non-sputum-producers. The post-oPEP change in ^{3}He MRI VDP was related to the change in PEQ-ease-bringing-up-sputum (r=0.65, p=0.0004) and FEV1 (r=-0.50, p=0.009). In COPD patients with chronic sputum production, PEQ and SGRQ scores, FVC and 6MWD improved post-oPEP. **FEV1 and PEQ-ease-bringing-up-sputum improvements were related to improved ventilation providing mechanistic evidence to support oPEP use in COPD.**



Teal colour and intensity show areas with gas distribution. Yellow circles represent areas of greatest change after 3-4 weeks of ***Aerobika**** OPEP device use.
Demonstrated by hyperpolarized ^{3}He magnetic resonance imaging (MRI).

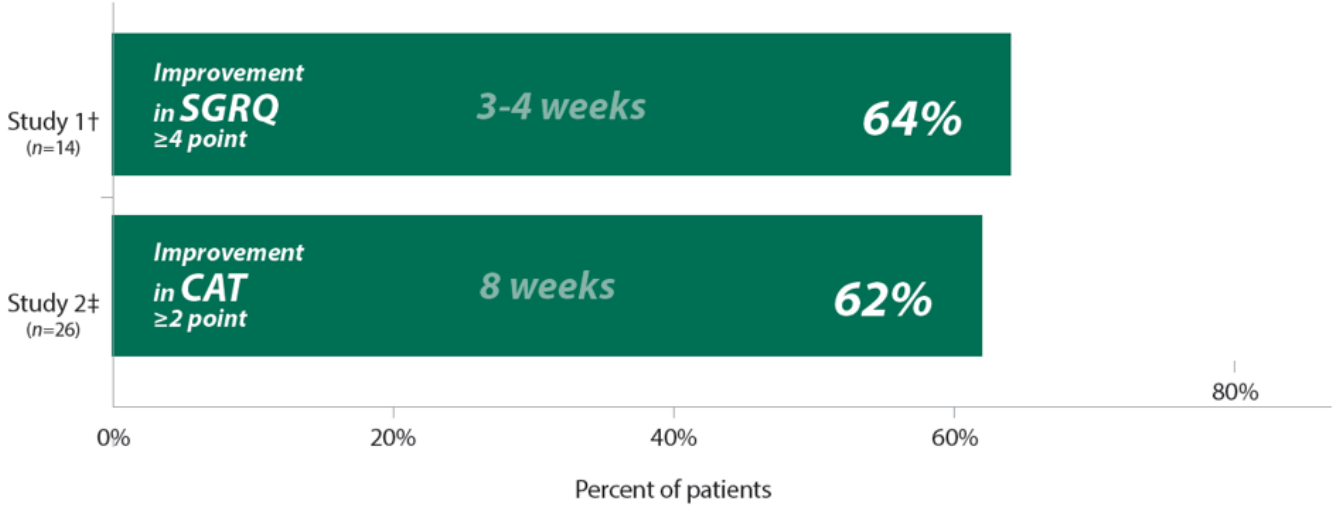


The *Aerobika** OPEP device significantly improved lung function in COPD patients. Use of the ***Aerobika**** device led to a +200mL improvement in FVC.

2. *Review of Quality of Life Outcomes Following Use of an Oscillating Positive Expiratory Pressure Device for Chronic Obstructive Pulmonary Disease: 8 Week Field Study Using the COPD Assessment Test*

RA Stockley. Abstract presentations: COPD10, Birmingham, United Kingdom, 2016. Chronic Obstructive Pulmonary Diseases: Journal of the COPD Foundation. 2017; 4(3): 225-246.
http://doi.org/10.15326/jcopdf.4.3.2017.0137

Background: The ***Aerobika**** OPEP device has been reported to improve quality of life outcomes for COPD patients with chronic bronchitis[1,2]. This abstract compares the responder rates from two separate studies using the same device, one with the St George's Respiratory Questionnaire (SGRQ) and the other with the COPD assessment test (CAT). **Methods:** Study 1[1], a randomized cross-over study in 27 COPD patients (n=14 sputum-producers) for 3-4 weeks, used the SGRQ. Study 2[2], a clinical assessment of 37 COPD patients over an 8-week period, used the CAT. Taking clinically significant measures of improvement of greater than 4 and at least 2 (for the SGRQ and CAT respectively), responder rates were calculated for the COPD patients with chronic bronchitis. **Results**: In study 1, the mean SGRQ value for the 14 COPD patients with chronic bronchitis significantly improved from 49 to 40 (p=0.01, paired t-test) following OPEP therapy. In study 2, the mean CAT value for the 26 COPD patients with chronic bronchitis significantly improved from 19.7 to 17.4 (p=0.01, paired t-test) following OPEP therapy. In terms of responder rate analysis, using the recognized improvement thresholds noted above, 64% of the COPD patients with chronic bronchitis from study 1 showed a clinically significant improvement in Quality of Life compared to 62% from study 2.



† Randomized, cross-over study evaluating the efficacy of the ***Aerobika**** OPEP device after 3-4 weeks of treatment in patients with COPD and chronic bronchitis.[2]
‡ Clinical assessment of patients with COPD and chronic bronchitis over 8 weeks of treatment with the ***Aerobika**** OPEP device.[3]

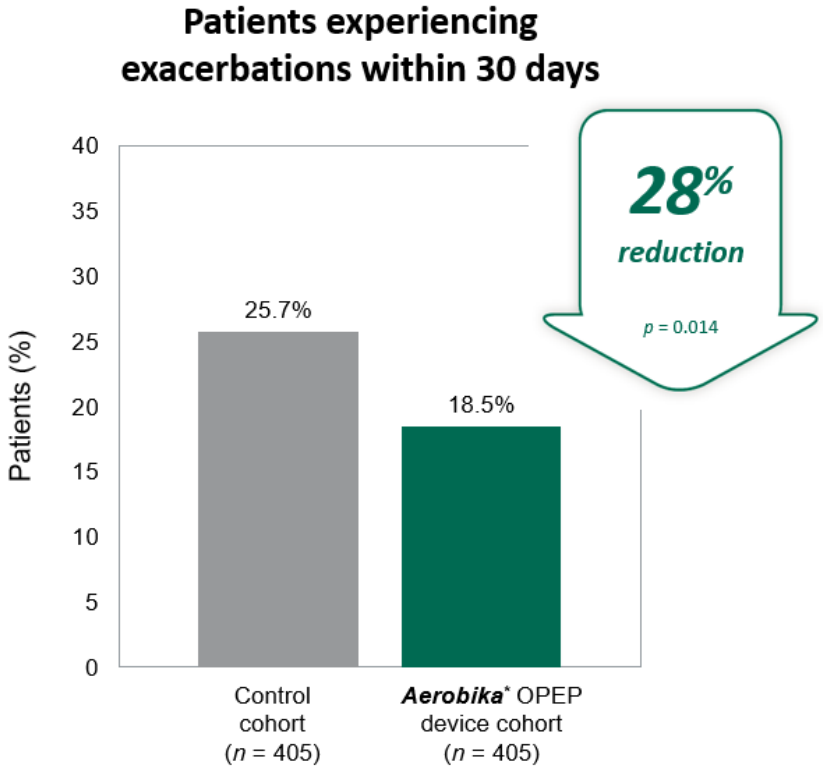
Conclusions: The results from the two separate studies (using different validated QoL instruments) show good agreement, with nearly two thirds of COPD patients with chronic bronchitis exhibiting clinically significant improvements in Quality of Life following self-administered treatment with the ***Aerobika**** OPEP device.

1. Svenningsen S, Paulin GA, Sheikh K, *et al*. Oscillatory Positive Expiratory Pressure in Chronic Obstructive Pulmonary Disease. COPD. 2015 Oct 2:1-9.
2. Suggett J. Review of Quality of Life outcomes following use of an Oscillating Positive Expiratory Pressure (OPEP) device for Chronic Obstructive Pulmonary Disease (COPD): 8 weeks field study using the COPD Assessment Test (CAT), ATS 2016.

3. *Real-World Study of 30-Day Exacerbation Outcomes in Chronic Obstructive Pulmonary Disease (COPD) Patients Managed with Aerobika* OPEP*

C Burudpakdee, A Seetasith, P Dunne, G Kauffman, B Carlin, D Coppolo, J Suggett. Pulmonary Therapy 2017;3(163);DOI 10.1007/s41030-017-0027-5 (Published online: 06 February 2017).
https://doi.org/10.1007/s41030-017-0027-5

Introduction: Oscillating positive expiratory pressure (OPEP) devices may reduce chronic symptoms in patients with obstructive pulmonary disease (COPD); however, no real-world studies have been performed to evaluate the benefits of these devices. The objective of this study was to measure the rate of early (30-day) moderate-to-severe exacerbations and related costs in COPD patients treated with **Aerobika***, an OPEP device, vs. a matched control group in a real-world setting. **Methods**: The study utilized data from the QuintilesIMS' CDM hospital database. COPD patients treated with **Aerobika*** OPEP between 9/2013 and 8/2015 were propensity score matched to COPD patients who did not use any positive expiratory pressure device. Severe exacerbation was defined as a hospital admission with a diagnosis for chronic bronchitis or COPD. Moderate-to-severe exacerbation was defined as a hospitalization or an ED visit with a diagnosis for chronic bronchitis or COPD. Exacerbations and costs were compared between cohorts at 30 days. A generalized linear model (GLM) was used to estimate the marginal effect of **Aerobika*** OPEP on the cost of ED visits and hospitalizations due to COPD exacerbations. **Results**: A total of 405 **Aerobika*** OPEP patients were matched to 405 controls. At 30 days, 18.5% of subjects using the **Aerobika*** OPEP vs. 25.7% of controls had a moderate-to-severe exacerbation (p=0.014); 13.8% of subjects with **Aerobika*** OPEP vs. 19.0% of controls had a severe exacerbation (p=0.046). The mean per patient cost of moderate-to-severe exacerbations and severe exacerbations in the **Aerobika*** OPEP group was significantly lower than controls ($2975 vs. $6065; p=0.008, and $2838 vs. $5871; p=0.009, respectively). In the GLM, the per-patient cost of moderate-to-severe exacerbations in the **Aerobika*** OPEP group was 34% lower (p=0.012) than the control group.

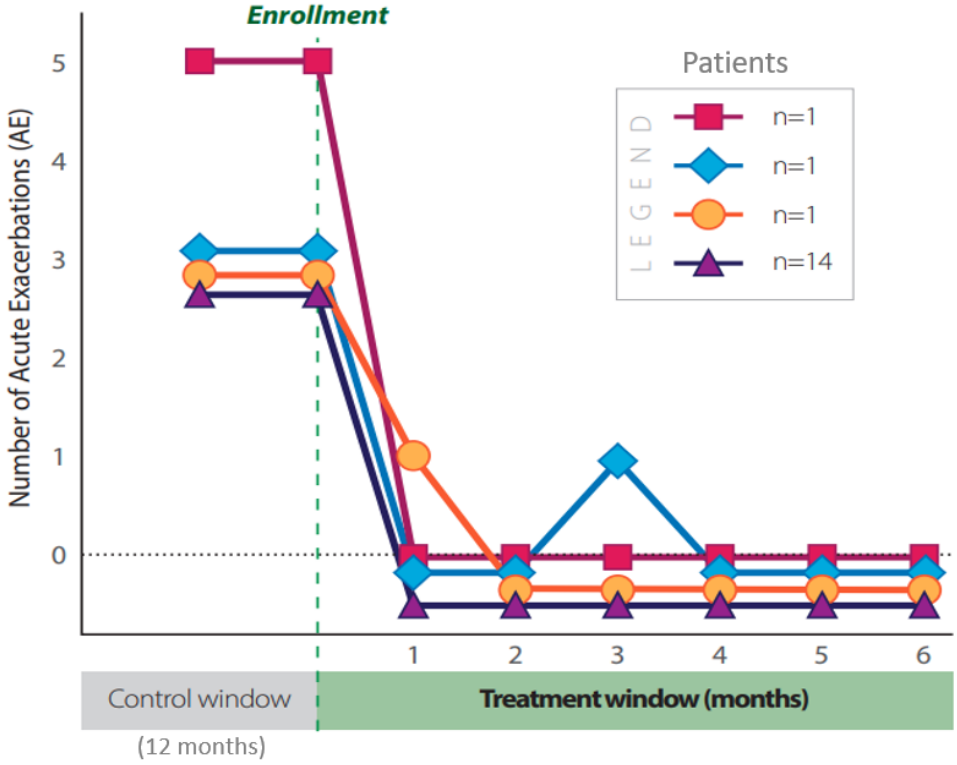


Conclusions: Study findings suggest that using **Aerobika*** OPEP as part of a treatment regimen may help reduce ED visits, hospital re-admissions and related costs in COPD patients who have a history of exacerbations.

4. *Effectiveness of the Use of an Oscillating Positive Expiratory Pressure Device in Bronchiectasis with Frequent Exacerbations: A Single-Arm Pilot Study*

Kim SR, Kim SH, Kim GH, Cho JY, Choi H, Lee H, Ra SW, Lee KM, Choe KH, Oh YM, Shin YM, Yang B. Front Med (Lausanne). 2023 May 12;10:1159227. doi: 10.3389/fmed.2023.1159227. PMID: 37250647; PMCID: PMC10213442.

Introduction: Impaired airway clearance in patients with non-cystic fibrosis bronchiectasis causes frequent bacterial infection, chronic inflammation, and progressive tissue destruction. We aimed to evaluate whether an oscillating positive expiratory pressure (OPEP) device could allow effective sputum expectoration and prevent acute exacerbations in patients with bronchiectasis who had frequent acute exacerbations. **Methods:** This open-label, single-arm, prospective study included 17 patients who experienced three or more acute exacerbations in the past year. We evaluated the prevention of acute exacerbations, subjective symptom improvement, and change in sputum amount during the use of the Aerobika (Trudell Medical International, London, ON) OPEP device twice daily for 6 months. Each session was defined as 10-20 blows into the device with a few huffs at the end of the session. Patients were doing prior drainage techniques such as active cycle of breathing and autogenic drainage as trained by their physician. Patients were instructed to continue prior methods. **Results:** Of all enrolled patients, only two acute exacerbations occurred during the study period, indicating a significant decrease compared with the number of acute exacerbations before the device use ($p < 0.001$). Additionally, Bronchiectasis Health Questionnaire score changed from 58.7 to 66.6, showing significant improvement over the treatment period ($p<0.001$). The largest sputum volume was observed 3 months after OPEP device use (baseline: 10 ml, 3rd month 25 ml, $p = 0.325$). There were no major adverse events related to the use of OPEP devices.

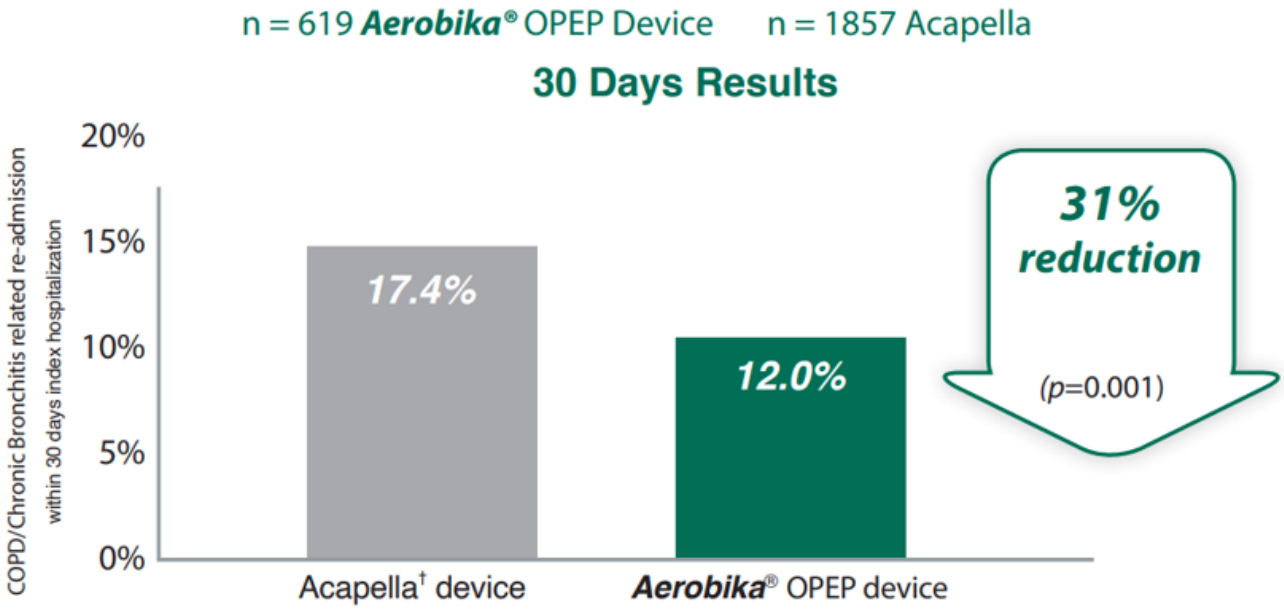


Conclusion: Twice-daily physiotherapy with the OPEP device in patients with bronchiectasis who have frequent exacerbations may facilitate symptomatic improvement and prevention of acute exacerbations without serious adverse events.

5. *Impact of Oscillating Positive Expiratory Pressure Device Use on Post-Discharge Hospitalizations: A Retrospective Cohort Study Comparing Patients with COPD or Chronic Bronchitis Using the Aerobika® and Acapella® Devices*

Jenny Tse, Keiko Wada, Yi Wang, Dominic Coppolo, Vladimir Kushnarev, Jason Suggett. International Journal of Chronic Obstructive Pulmonary Disease 2020:15 2527–2538 https://www.dovepress.com/impact-of-oscillating-positive-expiratory-pressure-device-use-on-post--peer-reviewed-fulltext-article-COPD

Background: Managing and preventing disease exacerbations are key goals of COPD care. Oscillating positive expiratory pressure (OPEP) devices have been shown to improve clinical outcomes when added to COPD standard of care. This retrospective database study compared real-world resource use and disease exacerbation among patients with COPD or chronic bronchitis prescribed either of two commonly used OPEP devices. **Patients and methods:** Patients using the Aerobika® (Trudell Medical International, London, ON, Canada) or Acapella® (Smiths Medical, Wampsville, New York, USA) OPEP device for COPD or chronic bronchitis were identified from hospital claims linked to medical and prescription claims between September 2013 and April 2018; the index date was the first hospital visit with an OPEP device. Severe disease exacerbation, defined as an inpatient visit with a COPD or chronic bronchitis diagnosis, and all-cause healthcare resource utilization over 30 days and 12 months post-discharge were compared in propensity score (PS)-matched Aerobika device and Acapella device users. **Results:** In total, 619 Aerobika device and 1857 Acapella device users remained after PS matching. After discharge from the index visit, Aerobika device users were less likely to have ≥1 severe exacerbation within 30 days (12.0% vs 17.4%, p=0.01) and/or 12 months (39.6% vs 45.3%, p=0.01) and had fewer 12-month severe exacerbations (mean, 0.7 vs 0.9 per patient per year, p=0.01), with significantly longer time to first severe exacerbation than Acapella users (log-rank p=0.01). Aerobika device users were also less likely to have ≥1 all cause inpatient visit within 30 days (13.9% vs 20.3%, p<0.001) and 12 months (44.9% vs 51.8%, p=0.003) than Acapella users.

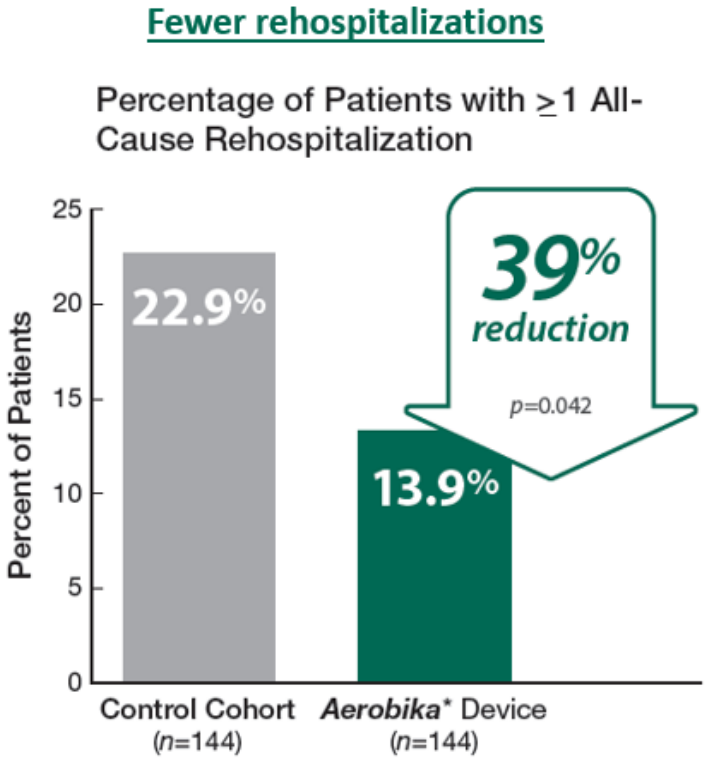


Conclusion: Patients receiving the Aerobika OPEP device, compared to the Acapella device, had lower rates of subsequent severe disease exacerbation and all-cause inpatient admission. This suggests that Aerobika OPEP device may be a beneficial add-on to usual care and that OPEP devices may vary in clinical effectiveness.

6. *A Real-World Evidence Study Assessing the Impact of Adding the Aerobika Oscillating Positive Expiratory Pressure Device to Standard of Care Upon Healthcare Resource Utilization and Costs in Post-Operative Patients*

Chakkarin Burudpakdee . Aimee M. Near . Huan Huang . Dominic Coppolo . Vladimir Kushnarev . Jason Suggett Pulm Ther 2018. https://doi.org/10.6084/m9.figshare.6188678

Introduction: The aim of this real-world study was to measure the benefit of the Aerobika oscillating positive expiratory pressure (OPEP) device when added to standard of care (defined as incentive spirometry [IS]) for post-operative patients. **Methods**: Adults aged ≥ 18 years who were hospitalized for cardiac, thoracic or upper abdominal surgery between 1 September 2013 and 30 April 2017 were identified from IQVIA's Hospital Charge Detail Master (CDM) database; the index date was the date of the first hospitalization for surgery. The control cohort (IS) included patients who had ≥ 1 CDM record within 12 months prior to the index date and ≥ 1 record after discharge, evidence of IS use during index hospitalization and no evidence of use of a PEP or OPEP device at any time during the study period. The Aerobika OPEP cohort was selected in a similar manner, except that patients were required to have evidence of Aerobika OPEP use during the index hospitalization. Aerobika OPEP patients were 1:1 matched to IS patients using propensity score (PS) matching. Hospital readmissions and costs were measured at 30 days post-discharge from the index hospitalization. **Results**: After PS matching, 144 patients were included in each cohort. At 30 days post-discharge, compared to the control (IS) cohort there were significantly fewer patients in the Aerobika OPEP cohort with ≥ 1 all-cause rehospitalizations (13.9 vs. 22.9%; p = 0.042). The patients in the Aerobika OPEP cohort also had a shorter mean length of stay (± standard deviation) (1.25 ± 4.04 vs. 2.60 ± 8.24 days; p = 0.047) and lower total unadjusted mean all-cause cost per patient ($3670 ± $13,894 vs. $13,775 ± $84,238; p = 0.057). Adjusted analyses suggested that hospitalization costs were 80% lower for the Aerobika OPEP cohort versus the IS cohort (p = 0.001).



Conclusion: Our results suggest that the addition of the Aerobika OPEP device to standard of care (IS) is beneficial in the post-operative setting.

7. *Cost-Effectiveness of the Aerobika* Oscillating Positive Expiratory Pressure Device in the Management of Chronic Obstructive Pulmonary Disease Exacerbations in Canada*

N.X. Thanh, P. Jacobs, J. Suggett, A. McIvor, A. Kaplan. Canadian Respiratory Journal. Volume 2019, Article ID 9176504, 7 pages, 2019. https://doi.org/10.1155/2019/9176504

Background: The Aerobika® oscillating positive expiratory pressure (OPEP) device is a hand-held, drug-free medical device that has been shown to improve lung function and improve health-related quality of life in patients with chronic obstructive pulmonary disease (COPD). We estimated the cost-effectiveness of this device among post exacerbation COPD patients in the Canadian healthcare system. **Methods:** We performed a cost-utility analysis using a Markov model to compare both costs and outcome of patients with COPD who had recently experienced an exacerbation between 2 treatment arms: patients who used the Aerobika® device and patients who did not use the Aerobika® device. This cost-utility analysis included costs based on the Alberta healthcare system perspective as these represent Canadian experience. A one-year horizon with 12 monthly cycles was used. **Results:** For a patient after 1 year, the use of the Aerobika® device would save $694 in healthcare costs and produce 0.04 more in quality-adjusted life years (QALYs) in comparison with no positive expiratory pressure (PEP)/OPEP therapy. In other words, the economic outcome of the device was dominant (i.e., more effective and less costly). The probability for this device to be the dominant strategy was 72%. With a willingness to pay (WTP) threshold of $50,000 per QALY gained, the probability for the Aerobika® device to be cost-effective was 77%. **Conclusions:** Given one of the major treatment goals in the GOLD guidelines is to minimize the negative impact of exacerbations and prevent re-exacerbations, the Aerobika® OPEP device should be viewed as a potential component of a treatment strategy to improve symptom control and reduce the risk of re-exacerbations in patients with COPD.

8. *Global Strategy for Prevention, Diagnosis and Management of COPD: GOLD 2024 Report*

Global Initiative for Chronic Obstructive Lung Disease (GOLD): 2024 Report.

Management of Mucus Hypersecretion: Treatment goals for patients with chronic bronchitis (CB) include: 1) reducing the overproduction of mucus; 2) decreasing mucus hypersecretion by reducing inflammation; 3) facilitating elimination of mucus by increasing ciliary transport; 4) decreasing mucus viscosity and 5) facilitating cough mechanisms. Mucus clearance treatments that promote mechanical movement through the airway such as oscillating positive expiratory pressure (OPEP) therapy may improve mucus mobilization, symptoms and quality of life in people with COPD who produce sputum daily or most days. The use of nebulized hypertonic saline for copious mucus has been used in obstructive lung disease and cystic fibrosis with beneficial effects. However, in patients with COPD, current studies are limited, and results are inconsistent.

9. *European Respiratory Society Guidelines for the Management of Adult Bronchiectasis*

Polverino E, Goeminne PC, McDonnell MJ, et al. European Respiratory Society guidelines for the management of adult bronchiectasis. Eur Respir J 2017; 50: 1700629
https://doi.org/10.1183/13993003.00629-2017

Regular physiotherapy (airway clearance and/or pulmonary rehabilitation) is more beneficial than control (no physiotherapy treatment) in adult bronchiectasis patients.
Recommendations: We suggest that patients with chronic productive cough or difficulty to expectorate sputum should be taught an airway clearance technique (ACT) by a trained respiratory physiotherapist to perform once or twice daily (weak recommendation, low quality of evidence). We recommend that adult patients with bronchiectasis and impaired exercise capacity should participate in a pulmonary rehabilitation program and take regular exercise. All interventions should be tailored to the patient's symptoms, physical capability and disease characteristics (strong recommendation, high quality of evidence).
Summary of the evidence: In bronchiectasis, it is a common belief that physiotherapy can improve mucus clearance and reduce lung inflammation and risk of infection. In addition, it is well accepted by patients. Respiratory physiotherapy includes ACTs and pulmonary rehabilitation. ACTs consist of breathing techniques, e.g. active cycle of breathing and autogenic drainage, sometimes combined with an instrument, e.g. OPEP devices, that modify expiratory flow and volumes or produce chest wall oscillations in order to increase mucus clearance. The principal effect obtained by ACTs is an increase in sputum volume and a reduced impact of cough on quality of life. Interesting, but still preliminary data, shows reduced peripheral

airways obstruction, less inflammatory cells in sputum and improved exercise capacity after ACTs. The aim of a pulmonary rehabilitation program is to improve exercise tolerance and quality of life through a tailored standardized exercise protocol.

10. British Thoracic Society Guideline for Bronchiectasis in Adults

British Thoracic Society Guideline for Bronchiectasis in Adults. Thorax. Jan 2019, Vol 74. https://www.brit-thoracic.org.uk/document-library/guidelines/bronchiectasis/bts-guideline-for-bronchiectasis-in-adults/

Which airway clearance techniques should be taught?
Recommendation: Offer active cycle of breathing techniques or oscillating positive expiratory pressure to individuals with bronchiectasis.
A systematic review evaluated OPEP devices in bronchiectasis. In the seven studies reviewed (n=146 patients), OPEP therapy was associated with improvements in sputum expectoration and quality of life measures compared with no treatment. Moreover, they concluded that compared with other ACTs, the effects in terms of sputum expectoration, lung function, gas exchange, and symptoms were equivalent. However, the authors did suggest a greater patient preference for oscillating PEP compared with ACBT with or without Gravity Assisted Positioning (GAP).

THE PROBLEM WITH AIRWAY MAINTENANCE IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE

1. COPD Readmissions: Addressing COPD in the Era of Value-Based Healthcare

T Shah, VG Press, M Huisingh-Scheetz, SR White. CHEST 2016;150(4):916-926. *https://doi.org/10.1016/j.chest.2016.05.002*

Of those patients hospitalized for an exacerbation of COPD, one in five will require rehospitalization within 30 days. Many developed countries are now implementing policies to increase care quality while controlling costs for COPD, known as value-based health care. In the United States, COPD is part of Medicare's Hospital Readmissions Reduction Program (HRRP), which penalizes hospitals for excess 30-day, all-cause readmissions after a hospitalization for an acute exacerbation of COPD, despite minimal evidence to guide hospitals on how to reduce readmissions. This review outlines challenges for improving overall COPD care quality and specifically for the HRRP. These challenges include heterogeneity in the literature for how COPD and readmissions are defined, difficulty finding the target population during hospitalizations, and a lack of literature to guide evidence-based programs for COPD readmissions as defined by the HRRP in the hospital setting. It then identifies risk factors for early readmissions after acute exacerbation of COPD and discusses tested and emerging strategies to reduce these readmissions. Finally, we evaluate the current HRRP and future policy changes and their effect on the goal to deliver value-based COPD care. COPD remains a chronic disease with a high prevalence that has finally garnered the attention of health systems and policy makers, but we still have a long way to go to truly deliver value-based care to patients.

2. 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. https://doi.org/10.1378/chest.14-1491

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 ± SD post-bronchodilator FEV_1, 93% ± 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 ± SD, 70 ± 26, 71 ± 29 and 106 ± 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.

3. *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;148(2):408-416. https://doi.org/10.1378/chest.14-2240

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 COPD Gene 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 post-bronchodilator $FEV_1/FVC \geq 70\%$. CAO without CB (CAO only) was defined by a post-bronchodilator $FEV_1/FVC < 70\%$ 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.

4. *Clinical Issues of Mucus Accumulation in COPD*

FL Ramos, JS Krahnke, V Kim. International Journal of COPD 2014;9:139-150. https://doi.org/10.2147/COPD.S38938

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.

5. *Chronic Bronchitis in COPD Patients is Associated with Increased Risk of Exacerbations: A Cross-Sectional Multicentre Study*

JL Corhay, W Vincken, M Schlesser, P Bossuyt, J. Imschoot. International Journal of Clinical Practice 2013;67(12):1294-1301. https://doi.org/10.1111/ijcp.12248

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±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.

6. Airway Mucus Function and Dysfunction

JV Fahy, BF Dickey. New England Journal of Medicine 2010;363(23):2233-2247.
https://doi.org/10.1056/NEJMra0910061

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.

7. Revisited Role for Mucus Hypersecretion in the Pathogenesis of COPD

I Cerveri, V Brusasco. European Respiratory Review 2010;19(116):109-112.
https://doi.org/10.1183/09059180.00002710

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.

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

PR Burgel, C Martin. European Respiratory Review 2010;19(116):94-96. Editorial comment on ‘Revisited Role for Mucus Hypersecretion in the Pathogenesis of COPD’. https://doi.org/10.1183/09059180.00004410

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.

9. 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.
https://doi.org/10.1378/chest.08-2062

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.

10. 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. https://doi.org/10.1016/j.cair.2006.02.001

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.

11. COPD Exacerbations • 3: Pathophysiology

DE O'Donnell, CM Parker. Thorax 2006;61:354-361. http://dx.doi.org/10.1136/thx.2005.041830

Exacerbations of chronic obstructive pulmonary disease (COPD) are associated with increased morbidity and mortality. The effective management of COPD exacerbations awaits a better understanding of underlying pathophysiological mechanisms that shape its clinical expression. The clinical presentation of exacerbations of COPD is highly variable and ranges from episodic symptomatic deterioration that is poorly responsive to usual treatment, to devastating life threatening events. This underscores the heterogeneous physiological mechanisms of this complex disease, as well as the variation in response to the provoking stimulus. The derangements in ventilatory mechanics, muscle function, and gas exchange that characterise severe COPD exacerbations with respiratory failure are now well understood. Critical expiratory flow limitation and the consequent dynamic lung hyperinflation appear to be the proximate deleterious events. Similar basic mechanisms probably explain the clinical manifestations of less severe exacerbations of COPS, but this needs further scientific validation. In this review we summarise what we have learned about the natural history of COPD exacerbations from clinical studies that have incorporated physiological measurements. We discuss the pathophysiology of clinically stable COPD and examine the impact of acutely increased expiratory flow limitation on the compromised respiratory system. Finally, we review the chain of physiological events that leads to acute ventilator insufficiency in severe exacerbations.

12. 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. Respiratory Research 2005;6:98. https://doi.org/10.1186/1465-9921-6-98

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).

13. 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 Sciurba, HO Coxson, PD Paré. New England Journal of Medicine 2004;350(26):2645-2653. https://doi.org/10.1056/NEJMoa032158

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.

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

R Pistelli, P Lange, DL Miller. European Respiratory Journal 2003;21(40s):10s-14s. https://doi.org/10.1183/09031936.03.00403403

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 (FEV1) values, but not with an accelerated decline of FEV1 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.

15. Epidemiological Studies in Mucus Hypersecretion

J Vestbo. 2002 Mucus hypersecretion in respiratory disease. Wiley, Chichester (Novartis Foundation Symposium 248) p 3-19. https://doi.org/10.1002/0470860790.ch2

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.

16. *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. American Journal of Respiratory and Critical Care Medicine 1996;153: 1530-1535. https://doi.org/10.1164/ajrccm.153.5.8630597

The aim of this study was to examine the association between chronic mucus hypersecretion and FEV_1 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 FEV_1 decline; the effect was most prominent among men, where chronic mucus hypersecretion at both surveys was associated with an excess FEV_1 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 FEV_1 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 FEV_1 decline and an increased risk of subsequent hospitalization because of COPD.

17. *Chronic Mucus Hypersecretion in COPD and Death from Pulmonary Infection*

E Prescott, P Lange, J Vestbo. European Respiratory Journal 1995;8:1333-1338.
https://doi.org/10.1183/09031936.95.08081333

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** OPEP DEVICE

STUDIES USING THE AEROBIKA OPEP IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE*

1. **NEW** *A Feasibility Randomised Control Trial (RCT) of OPEP Versus Active Cycle of Breathing Technique (ACBT) in People with Chronic Obstructive Pulmonary Disease (COPD)*

*[1]CG Bridges, [2]L Graham-Wollard, [1]H Morris, [2]J Annandale, [2,3]KE Lewis. [1]Cardiff and Vale UHB, Cardiff, UK; [2]Hywel Dda UHB, Carmarthen, UK; [3]Respiratory Innovation Wales, Llanelli, Carmarthenshire, UK. Thorax 2023; **78**: A43-A44. https://doi.org/10.1136/thorax-2023-BTSabstracts.62*

NICE guideline NG115 for COPD recommend Airways Clearance Techniques (ACTs) for people with excessive sputum but there have been no studies comparing different ACTs. **Aim:** To compare Oscillatory Positive Expiratory Pressure (OPEP, Aerobika*) vs Active Cycle of Breathing Technique (ACBT) following exacerbations of COPD. **Method:** A pilot, feasibility randomised controlled trial (ClinicalTrials.gov Identifier: NCT05548036). **Patient:** With confirmed COPD (GOLD 2023) and chronic bronchitis symptoms, who had not received ACTs previously. They were recruited in hospital or through community COPD nurses during (or within 4 days) of starting a moderate-severe exacerbation. Randomisation via sealed envelope determined whether they received 30–60 minutes of training on OPEP or ACBT by respiratory physiotherapists, face-to-face. All participants received antibiotics, steroids, nebulisers and oxygen in the acute phase according to clinical discretion. All were already prescribed optimal inhaled treatments. Participants were advised to continue twice daily OPEP or ACBT at home for at least 6 months. Groups were similar at baseline (all p=N.S). See table 1.

Abstract S56 Table 1 Participant characteristics at base line

Variable	OPEP (n=19)	ACBT n=23
Age	66 (10.3) yrs	69.7 (7.3) yrs
Male	37%	48%
Smokers	32%	13%
FEV_1% pp	50%	44%
MRC	3.4 (1.0)	3.5 (0.7)
CAT	31.0 (5.4)	32.6 (4.7)
LCQ-Total	63.8 (25.0)	61.2 (17.6)

Primary Outcome: Leicester Cough Questionnaire (LCQ) at 3 months post-intervention (via intention to treat analysis). **Results:** Mean (SD) Total LCQ at 3 months in the OPEP group was 87.3 (27.3) vs 91.9 (29.2) in the ACBT group, p=0.73, 95% CI -33 to +23.8. **Conclusion:** Both groups showed statistically significant and clinically important improvement in LCQ, post-exacerbation (MDCID 1.5–2 LCQ) but there is no significant difference in LCQ scores between OPEP (Aerobika*) vs ACBT groups at 3 months.

2. **NEW** *Impact of Aerobika® Oscillating Positive Expiratory Pressure in Improving Small Airway Resistance, Lung Function, Symptoms and Exercise Capacity in Chronic Obstructive Pulmonary Disease*

Sahardin SN, Jailaini MFM, Abeed NNN, Ban AY, Hau NB, Azmel AA, Shah SA, Hamid MFA. Front Med (Lausanne). 2023 Jun 2;10:1202380. doi: 10.3389/fmed.2023.1202380. PMID: 37332765; PMCID: PMC10272579.

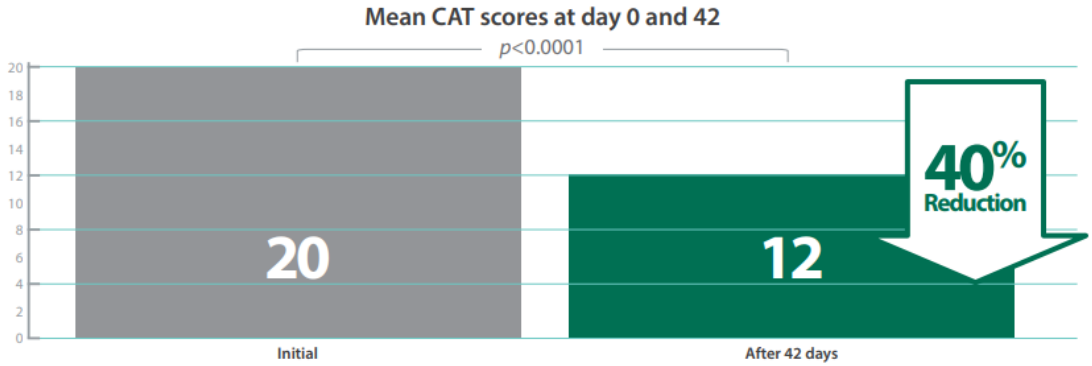
Background: Aerobika® oscillating positive expiratory pressure (OPEP) device promotes airway clearance in many respiratory diseases. However, studies have yet to focus on its effectiveness in improving small airway resistance *via* impulse oscillometry (IOS) measurement in COPD subjects. We aim to evaluate the improvement of small airway resistance (*via* IOS), lung function (spirometry), exercise capacity [*via* 6-min walking test (6MWT)], symptoms [COPD assessment test (CAT)] and severe exacerbation events among COPD subjects using Aerobika® OPEP. **Methods:** This was a prospective, single-arm interventional study among COPD subjects with small airway disease. Subjects were instructed to use twice daily Aerobika® OPEP (10 min each session); for 24 weeks; as an addition to standard therapy. IOS, spirometry, 6MWT, CAT score and severe exacerbation events were evaluated at baseline, 12 weeks and 24 weeks. **Results:** Fifty-three subjects completed the study. Aerobika® usage

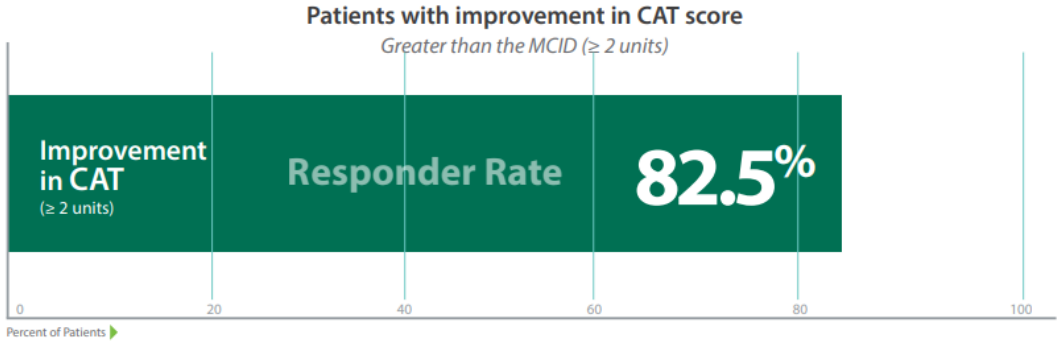
showed improvement of IOS parameters; e.g. measurement of airway resistance at 5 Hz (R5), cmH20/L/s, (12-week p = 0.008, 24-week p < 0.001), R5% predicted (12-week p = 0.007, 24-week p < 0.001) and small airway resistance (R5-R20), cmH20/L/s, (12-week p = 0.021, 24-week p < 0.001). There was improvement of lung function; e.g. FEV_1, L (12-week p = 0.018, 24-week p = 0.001), FEV_1% predicted (12-week p = 0.025, 24-week p = 0.001), FEF_{25-75}, L (12-week p = 0.023, 24-week p = 0.002), and FEF_{25-75}% predicted (12-week p = 0.024, 24-week p < 0.001). CAT score improved at 12 weeks (p < 0.001) and 24 weeks (p < 0.001). Subjects had improved exercise capacity (6MWT, metres) after 24 weeks (p = 0.016). However, there was no significant difference in severe exacerbation events 24 weeks before and after Aerobika® usage. **Conclusions:** Aerobika® OPEP demonstrated significant improvement in small airway resistance as early as 12 weeks of usage, with sustained improvement at 24 weeks. Aerobika® OPEP administration had significantly improved lung function, 6MWT, and CAT scores over 24 weeks. There was no difference in severe exacerbation events.

3. **NEW** *Assessment of the Clinical Value of an Oscillating Positive Expiratory Pressure (OPEP) Device for Chronic Obstructive Pulmonary Disease (COPD) Patients in India: a 6 week field study using the COPD Assessment Test (CAT)*

Suggett J[1], Bansal A[2], Patel K[2], Katakwar, M[2]. [1]Trudell Medical International, Canada. [2]Lupin, Ltd, India. American Thoracic Society Conference. May 19 – 24, 2023. https://doi.org/10.1164/ajrccm-conference.2023.207.1_MeetingAbstracts.A4681

Background: Despite multiple drug treatment options available, many COPD patients still suffer from a poor quality of life, often as a result of excess mucus. This study assessed the quality of life outcomes for COPD patients with mucus hypersecretion in India following treatment with a handheld, easy-to-use OPEP device, using the CAT over a 6 week duration. **Methods:** The clinical assessment was undertaken through 21 pulmonologists across India. COPD patients with mucus hypersecretion (determined via patient consultation) were selected between 40-85 years, having been admitted to hospital with a COPD exacerbation, and who were willing and able to be trained with the OPEP device. Patients with active cancer, any other chronic disease, history of epilepsy or pregnant/breast feeding were excluded. All standard of care COPD therapy was maintained during the study. Included patients were prescribed the OPEP device (Aerobika* OPEP, Trudell Medical International) upon discharge, with the CAT being performed via a remote call 2 days following discharge (day 0) and six weeks later (day 42). **Results:** 40 patients (29 male) were included in the study. The mean CAT total score for the 40 COPD patients improved from 20.0 (initial) to 12.0 (p<0.0001) after 42 days. Furthermore, responder rate analysis showed that 82.5% of patients (33/40) had a clinically significant improvement in their total CAT score (at least 2 units). This improvement was evident regardless of gender.





Conclusions: For COPD patients being discharged from hospital following exacerbation, the addition of the Aerobika* OPEP device to standard of care was associated with a clinically and statistically significant improvement in CAT scores from baseline to 6 weeks. Notwithstanding the limitations of a relatively small study size and lack of a

control, the results further support the efficacy of this drug free OPEP device with respect to improved quality of life in COPD patients.

4. *Therapeutic Efficacy of Oscillating Positive Expiratory Pressure Therapy in Stable Chronic Obstructive Pulmonary Disease*

Aayushi Gupta, Mandeep Kaur Sodhi, Surabhi Jaggi, Deepak Aggarwal, Varinder Saini. Lung India. 39(5):p 449-454, Sep-Oct 2022. DOI: 10.4103/lungindia.lungindia_218_22

Background: Chronic obstructive pulmonary disease (COPD) is characterized by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airway and the lung to noxious particles or gases. Sputum production is a cardinal feature in COPD. Airway clearance techniques have been the mainstay of management. Oscillating positive expiratory pressure (OPEP) devices are handheld devices that provide a combination of positive expiratory pressure (PEP) with high frequency oscillations which involve exhaling against a resistance that is fluctuating. It encourages airflow within secretions, whereas oscillations induce vibrations within airway wall to displace secretions into airway lumen and help in expectoration. **Methods:** A randomized control trial was conducted at the department of pulmonary medicine, Government Medical College & Hospital, Chandigarh, in which 50 patients with stable COPD were enrolled for one- and- half years. After taking proper history, they were subjected to spirometry, six- minute walk test, and were asked to fill the St. George's Respiratory Questionnaire (SGRQ) and COPD Assessment Test (CAT). These patients were randomized into group A (intervention group) and group B (control group), where group A was prescribed Aerobika OPEP device for daily use for a period of three months. After three months of use of device, the patients were again subjected to assessment parameters and inquired about any exacerbation within the three- month period. **Results:** At the end of three months were compared with baseline results. The median change in FEV1, FVC, 6MWD from baseline in group A was significantly more as compared to group B (FEV1: $P < 0.001$; FVC: $P < 0.001$; 6MWD: $P = 0.08$), whereas SGRQ score showed a significant improvement in both the intervention and control groups ($P < 0.001$) and CAT score showed significant improvement in comparison to the control group ($P < 0.001$). The median change in 6MWD and CAT from baseline in group A was significantly more as compared to group B (SGRQ: $P < 0.001$; CAT: $P < 0.001$), whereas it was not significant in case of SGRQ ($P = 0.233$). There was no significant difference in the incidence of exacerbation in the two groups ($P = 0.19$). The device did not help in controlling the rate of exacerbation in the present study at three months. **Conclusion:** Stable COPD patients who were given OPEP therapy as an adjunct to the standard drug therapy showed improvement in the spirometry parameters, exercise capacity and symptom burden in comparison to the drug only group.

5. *A Retrospective Cohort Study Comparing an Oscillating Positive Expiratory Pressure (OPEP) Device vs Positive Expiratory Pressure (PEP) Devices in Patients with Chronic Obstructive Pulmonary Disease (COPD) or Chronic Bronchitis on Hospital Readmissions at 30 Days*

J. Suggett[1], V. Kushnarev[1], D. P. Coppolo[2], J. Tse[3], K. Wada[3]. American Journal of Respiratory and Critical Care Medicine. 2021;203:A2264.
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https://doi.org/10.1164/ajrccm-conference.2021.203.1_MeetingAbstracts.A2264

Rationale: For patients with COPD, acute exacerbations are the most common reason for hospital admissions, with approximately 1 in 5 patients requiring re-hospitalization within 30 days of discharge. The Aerobika* OPEP device has previously been shown to significantly improve outcomes such as ease in bringing up sputum, forced vital capacity, quality of life, and exacerbations, when added to standard of care. This retrospective cohort study described real-world outcomes among patients with COPD or chronic bronchitis, comparing the Aerobika* OPEP device to the similar, but more basic PEP device, which does not generate pressure pulses. **Methods:** IQVIA's Charge Detail Master (CDM) hospital claims database linked to medical (Dx) and prescription claims (LRx) data were used to identify patients receiving the Aerobika* (Trudell Medical International) OPEP device or any PEP device between September 2013 and November 2018; the index date was the first CDM record with an OPEP/PEP device. Patients were required to be ≥18 years of age and have ≥1 hospital and LRx/Dx records within 12 months before and after index, ≥1 COPD/chronic bronchitis diagnosis during the index visit and no asthma diagnosis before index or post-operative device use within 30 days before index. Patients receiving the Aerobika* OPEP device were propensity score (PS) matched to patients receiving a PEP device based on demographics and baseline comorbidities, history of exacerbations and drug therapy. The proportion of patients experiencing a COPD/chronic bronchitis related readmission within 30 days of the index visit was evaluated. **Results:** After 1:1 PS matching, 588 patients receiving Aerobika* and 588 receiving PEP were compared. Baseline characteristics were well-balanced. Patients using Aerobika* OPEP had a 31% reduction in COPD/chronic bronchitis related readmission within 30 days of the index hospitalization compared to those patients with a PEP device (12.4% vs. 17.9%; p=0.006). **Conclusions:** Results

from this study demonstrate a reduction in COPD/chronic bronchitis related readmissions within 30 days of Aerobika* OPEP device therapy initiation compared to PEP therapy. This further supports the use of the Aerobika* OPEP device as an add-on to usual care to manage COPD/chronic bronchitis patients post-exacerbation and provides some evidence as to the additional benefit of pressure oscillations over standard PEP.

6. *Impact of Oscillating Positive Expiratory Pressure Device Use on Post-Discharge Hospitalizations: A Retrospective Cohort Study Comparing Patients with COPD or Chronic Bronchitis Using the Aerobika® and Acapella® Devices*

Jenny Tse, Keiko Wada, Yi Wang, Dominic Coppolo, Vladimir Kushnarev, Jason Suggett. International Journal of Chronic Obstructive Pulmonary Disease 2020:15 2527–2538 https://www.dovepress.com/impact-of-oscillating-positive-expiratory-pressure-device-use-on-post--peer-reviewed-fulltext-article-COPD

Background: Managing and preventing disease exacerbations are key goals of COPD care. Oscillating positive expiratory pressure (OPEP) devices have been shown to improve clinical outcomes when added to COPD standard of care. This retrospective database study compared real-world resource use and disease exacerbation among patients with COPD or chronic bronchitis prescribed either of two commonly used OPEP devices. **Patients and methods:** Patients using the Aerobika® (Trudell Medical International, London, ON, Canada) or Acapella® (Smiths Medical, Wampsville, New York, USA) OPEP device for COPD or chronic bronchitis were identified from hospital claims linked to medical and prescription claims between September 2013 and April 2018; the index date was the first hospital visit with an OPEP device. Severe disease exacerbation, defined as an inpatient visit with a COPD or chronic bronchitis diagnosis, and all-cause healthcare resource utilization over 30 days and 12 months post-discharge were compared in propensity score (PS)-matched Aerobika device and Acapella device users. **Results:** In total, 619 Aerobika device and 1857 Acapella device users remained after PS matching. After discharge from the index visit, Aerobika device users were less likely to have ≥1 severe exacerbation within 30 days (12.0% vs 17.4%, p=0.01) and/or 12 months(39.6% vs 45.3%, p=0.01) and had fewer 12-month severe exacerbations (mean, 0.7 vs 0.9 per patient per year, p=0.01), with significantly longer time to first severe exacerbation than Acapella users (log-rank p=0.01). Aerobika device users were also less likely to have ≥1 all cause inpatient visit within 30 days (13.9% vs 20.3%, p<0.001) and 12 months (44.9% vs 51.8%, p=0.003) than Acapella users. **Conclusion:** Patients receiving the Aerobika OPEP device, compared to the Acapella device, had lower rates of subsequent severe disease exacerbation and all-cause inpatient admission. This suggests that Aerobika OPEP device may be a beneficial add-on to usual care and that OPEP devices may vary in clinical effectiveness.

7. *A Functional Respiratory Imaging Approach to the Effect of an Oscillating Positive Expiratory Pressure Device in Chronic Obstructive Pulmonary Disease*

Glenn Leemans, Dennis Belmans, Cedric Van Holsbeke, Vladimir Kushnarev, Jason Suggest, Kris Ides, Dirk Vissers, Wilfried De Backer International Journal of Chronic Obstructive Pulmonary Disease 2020:15 1261–1268
https://pubmed.ncbi.nlm.nih.gov/32581531/

Background: It has recently been reported that COPD patients with chronic bronchitis have a significant improvement in sputum expectoration and clearance after 21 to 28 days of daily ***Aerobika**** Oscillating Positive Expiratory Pressure (OPEP) device utilization, coupled with some progress towards a better regional ventilation. Moreover, sputum- producer patients were shown to have improvements in a number of other parameters, namely forced vital capacity (FVC), 6-minute walk test, Saint George's Respiratory Questionnaire (SGRQ) and Patient Evaluation Questionnaire (PEQ).7 Additionally, patients were also shown to benefit from Aerobika in terms of HRQoL: 64% and 62% COPD patients with chronic bronchitis had a clinically-meaningful improvement in SGRQ and COPD Assessment Test (CAT) after using this device for three to four or eight weeks, respectively.8 Finally, the rate of moderate- to-severe and severe COPD exacerbations (at 30 days) was shown to be significantly lower in patients using Aerobika when compared to matched controls, as were the exacerbations-related mean per patient costs (data from a real-world study).9 In spite of the accumulating evidence suggesting the benefits of Aerobika utilization among the COPD population, its physiological basis remains scarcely characterized. Our aim was to tackle that issue by applying Functional Respiratory Imaging (FRI) to assess the effect of the Aerobika or oPEP device, in addition to standard of care medication, on the lung dynamics and aerosol deposition patterns of COPD patients. **Methods:** In this single-arm pilot study, patients were assessed using standard spirometry tests and functional respiratory imaging (FRI) before and after a period of 15±3 days of using the oPEP device twice daily (before their standard medication). **Results:** The utilization of the oPEP device led to a significant increase of 2.88% in specific airway volume after two weeks (1.44 (SE: 0.18) vs 1.48 (SE: 0.19); 95% CI = [0.03%,5.81%]; p=0.048). Moreover, the internal airflow distribution (IAD) was affected by the treatment: patients' changes ranged from −6.74% to 4.51%. Furthermore, IAD changes at the lower lobes were also directly correlated with variations in forced expiratory volume in one second and peak expiratory flow; conversely, IAD changes at the upper lobes were inversely correlated with these clinical parameters. Interestingly, this change in IAD was significantly correlated with changes in lobar drug deposition

(r2=0.30, p<0.001). **Conclusion:** Our results support that the Aerobika device utilization leads to an improved airflow, which in turn causes a shift in IAD and impacts the drug deposition patterns of the concomitant medication in patients with COPD.

8. *How Can Time to COPD Exacerbation Be Delayed? A Real-World Study Comparing Two Oscillating Positive Expiratory Pressure (OPEP) Devices in Patients with Chronic Obstructive Pulmonary Disease (COPD) Or Chronic Bronchitis*

J. Suggett1, V. Kushnarev1, D. Coppolo2, J. Tse3, K. Wada3 1Trudell Medical International, London, ON, Canada. 2Monaghan Medical Corporation, NY, US 3IQVIA, Medical and Scientific Services, VA, US. Presented at ERS 2020 https://www.trudellmed.com/ERS-2020

Rationale: Acute COPD exacerbations are common and a main driver of hospitalizations. This retrospective study compared disease-related hospital readmission in COPD/chronic bronchitis patients using two OPEP devices. **Method:** Patients were identified with either the Aerobika* (Trudell Medical International) or Acapella† (Smiths Medical) OPEP devices from September 2013 to April 2018 in IQVIA's hospital claims data linked to medical (Dx) and prescription claims (LRx); the first COPD/chronic bronchitis hospital visit with an OPEP device was index. Patients were ≥18 years old, had ≥1 hospital, LRx, and Dx record within 12 months before and after index, and had no asthma diagnosis before index or post-operative OPEP device use within 30 days before index. Kaplan-Meier survival analysis was used to compare time from discharge to disease-related readmission, and readmission rates were also determined at 30 days and 12 months post-discharge for 1:3 propensity score (PS)-matched Aerobika and Acapella users. **Results:** 619 Aerobika users were matched to 1,857 Acapella users (mean age 72 years). Aerobika* users had a significantly longer time to readmission than Acapella† users (p=0.01). Readmission rates (proportion of patients having at least one) were lower for Aerobika users at 30 days (11% vs 17%) and 12 months (40% vs 45%). **Conclusion:** COPD/chronic bronchitis patients given an Aerobika* OPEP device compared to an alternative OPEP device had delayed time to readmission. This supports use of the Aerobika* OPEP device as an add-on to usual care post-exacerbation and highlights differences in OPEP device effectiveness.

9. *A National Audit of The Aerobika* Oscillatory Positive Pressure (OPEP) Device When Used to Assist Airway Clearance for Those with Cystic Fibrosis, Bronchiectasis and COPD*

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Rationale: Oscillating positive expiratory pressure (OPEP) devices are used by physiotherapists to support airway clearance techniques (ACTs) with the objectives of improving sputum clearance and thus potentially increasing airway ventilation and quality of life. The use of the Aerobika* OPEP (Aerobika*Trudell Medical UK)device was evaluated in 23 UK hospitals to gain a better understanding of effectiveness and acceptability. **Methods:** Those with adult Cystic Fibrosis (CF), Bronchiectasis, Chronic Obstructive pulmonary patients (COPD) and 18 defined by Physiotherapists as other patients with excess sputum were evaluated over a one month period using the Aerobika* OPEP device. Evaluation was via a 5 point questionnaire, which included feedback from both patients and physiotherapists. A COPD assessment test (CAT) was performed at the start and end of the evaluation period for those with COPD. **Results:** Evaluation was completed by 176 patients. For the COPD patients 82% had complete CAT scores with 60% of these demonstrating a clinically significant decrease (improvement) of 2 points or more on OPEP therapy. Acceptability: 92% of all patients wished to continue using this OPEP device, 87% of HCPs were happy or very happy with the device with the most popular feature noted was that the device was not position dependent. **Conclusion:** The Aerobika* OPEP device was found to be acceptable for patients and therapists. Improvement in CAT scores were observed in 60% of COPD patients. Inclusion of the Aerobika* should be considered as an acceptable adjunct to ACT physiotherapy regimes for those with CF, bronchiectasis or COPD.

10. *Cost-Effectiveness of the Aerobika* Oscillating Positive Expiratory Pressure Device in the Management of Chronic Obstructive Pulmonary Disease Exacerbations in Canada*

N.X. Thanh, P. Jacobs, J. Suggett, A. McIvor, A. Kaplan. Canadian Respiratory Journal. Volume 2019, Article ID 9176504, 7 pages, 2019. https://doi.org/10.1155/2019/9176504

Background: The Aerobika® oscillating positive expiratory pressure (OPEP) device is a hand-held, drug-free medical device that has been shown to improve lung function and improve health-related quality of life in patients with chronic obstructive pulmonary disease (COPD). We estimated the cost-effectiveness of this device among post exacerbation COPD patients in the Canadian healthcare system. **Methods:** We performed a cost-utility analysis using a Markov model to compare both costs and outcome of patients with COPD who had recently experienced an

exacerbation between 2 treatment arms: patients who used the Aerobika® device and patients who did not use the Aerobika® device. This cost-utility analysis included costs based on the Alberta healthcare system perspective as these represent Canadian experience. A one-year horizon with 12 monthly cycles was used. **Results:** For a patient after 1 year, the use of the Aerobika® device would save $694 in healthcare costs and produce 0.04 more in quality-adjusted life years (QALYs) in comparison with no positive expiratory pressure (PEP)/OPEP therapy. In other words, the economic outcome of the device was dominant (i.e., more effective and less costly). The probability for this device to be the dominant strategy was 72%. With a willingness to pay (WTP) threshold of $50,000 per QALY gained, the probability for the Aerobika® device to be cost-effective was 77%. **Conclusions:** Given one of the major treatment goals in the GOLD guidelines is to minimize the negative impact of exacerbations and prevent re-exacerbations, the Aerobika® OPEP device should be viewed as a potential component of a treatment strategy to improve symptom control and reduce the risk of re-exacerbations in patients with COPD.

11. A Retrospective Cohort Study Comparing the Impact of Two Oscillating Positive Expiratory Pressure (OPEP) Devices in Patients with Chronic Obstructive Pulmonary Disease (COPD) or Chronic Bronchitis on Hospital Readmissions at 30 Days and 12 Months

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Rationale: In patients with COPD, acute exacerbations are the most common reason for hospital admissions, with approximately 1 in 5 patients requiring re-hospitalization within 30 days of discharge. The Aerobika OPEP device has previously been shown to signi_cantly improve outcomes such as ease in bringing up sputum, forced vital capacity, quality of life, and exacerbations, when added to standard of care. This retrospective cohort study describes real-world outcomes among patients with COPD or chronic bronchitis, comparing the Aerobika OPEP device to a commonly used alternative OPEP device. **Methods**: IQVIA's Charge Detail Master (CDM) hospital claims database linked to medical (Dx) and prescription claims (LRx) data were used to identify patients receiving the Aerobika* (Trudell Medical International) or the Acapella (Smiths Medical) OPEP device between September 2013 and April 2018; the index date was the _rst CDM record with an OPEP device. Patients were required to be ≥18 years of age and have ≥1 hospital and LRx/Dx records within 12 months before and after index, ≥1 COPD/chronic bronchitis diagnosis during the index visit and no asthma diagnosis before index or post-operative OPEP device use within 30 days of index. Patients receiving the Aerobika* OPEP device were propensity score (PS) matched to patients receiving the Acapella device based on demographics, baseline comorbidities, history of exacerbations and drug therapy. Study measures included proportion of patients experiencing COPD/chronic bronchitis related readmission within 30 days and 12 months of the index visit. **Results:** After 1:3 PS matching, 619 patients receiving Aerobika* and 1,857 receiving Acapella were compared (mean age 72 years). Baseline characteristics were well-balanced. Patients using Aerobika* OPEP had a 31% reduction in COPD/chronic bronchitis related readmission within 30 days of the index hospitalization (12.0% vs. 17.4%; p=0.001) compared to Acapella. This signi_cant di□erence persisted over a 12-month duration, with a smaller proportion of Aerobika* patients having a hospitalization (39.6% vs. 45.3%; p=0.013) and fewer hospitalizations per patient (mean, 0.75 vs. 0.90; p=0.010). **Conclusions**: Results from this study demonstrate a reduction in the proportion of patients requiring COPD/chronic bronchitis related readmission within 30 days and 12 months of Aerobika* OPEP device therapy initiation compared to an alternative OPEP device. This further supports the use of the Aerobika* OPEP device as an add-on to usual care to manage COPD/chronic bronchitis patients post-exacerbation and highlights that not all OPEP devices are the same in terms of 30-day and 12-month readmissions.

12. The Use of Functional Respiratory Imaging to Investigate the Impact of an Oscillating Positive Expiratory Pressure Device on Lung Dynamics and Drug Deposition

V Kushnarev, G Leemans, C Van Holsbeke, D Belmans, J De Backer, J Suggett. Presented at ERS 2018.
https://www.trudellmed.com/sites/default/files/inline-files/MD_174A_0618.pdf

Background: The ***Aerobika**** Oscillating Positive Expiratory Pressure (OPEP) device has previously been reported as providing benefits to Chronic Obstructive Pulmonary Disease (COPD) patients in terms of lung ventilation, lung capacity, quality of life and reduced exacerbations. This abstract reports the results of a pilot Functional Respiratory Imaging (FRI) study which attempts to provide some lung dynamics understanding following use of the device, as well as how such lung dynamics might relate to drug deposition. **Methods**: A single center, prospective study, was performed in COPD patients whereby subjects were instructed to use the ***Aerobika**** device for 10 minutes, then take their standard of care medication, continuing to use the device twice daily for 15 +/- 3 days. Ten subjects were investigated: • 7 male, 3 female; mean age 67.3 ± 9.6 years; mean FEV1 55 ± 18.0% predicted. Paired inspiratory-expiratory high-resolution CT (HRCT) scans were taken before and after the start of the treatment period. Afterwards, FRI was used to evaluate changes in the lung dynamics and deposition of concomitant medication. **Results**: Analysis

of individual lobes indicated a shift in internal airflow distribution (IAD) between - 7% and + 5%, significantly correlating to airway deposition of the concomitant medication. Additionally, it was observed that patients in whom the airflow was redistributed towards the lower lobes exhibited increased FEV1 values. **Conclusions**: These pilot study results provide evidence supporting the theory that this specific OPEP device enables airflow redistribution and influences drug deposition patterns. Further research is required to investigate the lower lobar ventilation relationship with FEV1. The resultant airflow redistribution following use of the device may well be a contributing factor to the previously reported[1,3] improved clinical outcomes, and the specific nature of the redistribution might also be related to the level of clinical response observed.

1 Svenningsen S, Paulin GA, Sheikh K, *et al*. Oscillatory Positive Expiratory Pressure in Chronic Obstructive Pulmonary Disease. Journal of COPD 2016;13(1):66-74. 2 Stockley RA. Abstract presentations: COPD10, Birmingham, United Kingdom, 2016. Chronic Obstr Pulm Dis. 2017; 4(3): 225-

doi: http://doi.org/10.15326/jcopdf.4.3.2017.0137. 3 Burudpakadee C, Seetasith A, Dunne P, *et al*. A real-world study of 30-day exacerbation outcomes in chronic obstructive pulmonary disease (COPD) patients managed with ***Aerobika**** OPEP. Pulmonary Therapy. 2017;3(1):163-171. 4 Adapted from Svenningsen S, Paulin GA, Sheikh K, *et al*. Oscillatory Positive Expiratory Pressure in Chronic Obstructive Pulmonary Disease. Journal of COPD 2016;13(1):66-74.

13. *Understanding Lung Physiological Dynamics Following Use of an Oscillating Positive Expiratory Pressure (OPEP) Device for Chronic Obstructive Pulmonary Disease (COPD)*

J Suggett, V Kushnarev, C Van Holsbeke, J De Backer, W De Backer, G Leemans. Presented at COPD11 2018.

Background: The Aerobika* OPEP device has been reported to reduce incidence of re-hospitalization following exacerbation1 and improve quality of life outcomes for COPD patients with chronic bronchitis2. This abstract reports a pilot functional respiratory imaging (FRI) study which attempts to understand further the lung dynamics at play when using such as device. Methods: A single center, prospective study, was performed in COPD patients. Subjects were instructed to use the Aerobika* (TMI, London, ON) OPEP device for 10 minutes, then take their standard of care medication, continuing to use the device twice daily for 15 +/- 3 days. Paired inspiratory-expiratory HRCT scans were taken before and after the start of the treatment period. Afterwards, FRI was used to evaluate changes in the lung dynamics and deposition of concomitant medication. Results: Ten subjects were investigated (7M/3F, mean age 67.3±9.6 years, mean FEV1 55±18.0%predicted). Analysis of individual lobes indicated a shift in internal airflow distribution between -7% and +5%, significantly correlating to airway deposition of the concomitant medication. Additionally, it was observed that patients in whom the airflow was redistributed towards the lower lobes exhibited increased FEV1 values. Conclusions: These pilot study results provide evidence supporting the theory that this specific OPEP device enables airflow redistribution and influences drug deposition patterns. Further research is required to investigate the lower lobar ventilation relationship with FEV1. The resultant airflow redistribution following use of the device may well be a contributing factor to the previously reported improved clinical outcomes and the specific nature of the redistribution might also be related to the level of clinical response observed.

1 Burudpakdee C, Seetasith A, Dunne P, *et al*. A real-world study of 30-day exacerbation outcomes in chronic obstructive pulmonary disease (COPD) patient managed with ***Aerobika**** OPEP. Pulmonary Therapeutics. 2017. DOI 10.1007/s41030-017-0027-5. 2 Svenningsen S, Paulin GA, Sheikh K, *et al*. Oscillatory Positive Expiratory Pressure in Chronic Obstructive Pulmonary Disease. COPD. 2015 Oct 2:1-9.

14. *Cost-Effectiveness of the Aerobika* Oscillating Positive Expiratory Pressure Device in the Management of COPD Exacerbations*

S Khoudigian-Sinani, S Kowal, JA Suggett, DP Coppolo. International Journal of COPD 2017;12:3065-3073. https://doi.org/10.2147/COPD.S143334

Introduction: COPD places a huge clinical and economic burden on the US health care system, with acute exacerbations representing a key driver of direct medical costs. Current treatments, although effective in reducing symptoms and limiting exacerbations, do not adequately target the underlying disease processes that drive exacerbation development. The Aerobika* oscillating positive expiratory pressure (OPEP) device has been shown in a real-world effectiveness study to lower the frequency of moderate-to-severe exacerbations during a 30-day post-exacerbation period. This study sought to determine the impact on exacerbations and costs and to determine the cost-effectiveness of the Aerobika* device. Methods: Data from published literature and national fee schedules were used to model the cost-effectiveness of the Aerobika* device in patients who had experienced an exacerbation in the previous month, or a post-exacerbation care population. Exacerbation trends and the impact of the Aerobika* deviceon reducing exacerbation frequency were modeled using a one-year Markov model with monthly cycles and three health states: (i) no exacerbation, (ii) exacerbation, and (iii) death. Scenario analysis and one-way sensitivity analysis (OWSA) were also performed. Results: When the effect of Aerobika* device was assumed to last 30 days, use of the device resulted in cost-savings ($553 per patient) and improved outcomes (ie, six fewer exacerbations per 100 patients per year) compared to no OPEP/positive expiratory pressure therapy. When the effect of the Aerobika* device was assumed to extend beyond the conservative 30-day time frame, the Aerobika* device remained the dominant strategy (21 fewer exacerbations per 100 patients per year; cost savings of $1,952 per patient). Consistency in findings after performing OWSAs indicates the robustness of results. Conclusion: The Aerobika* device is a cost-effective treatment option that provides clinical benefit and results in direct medical cost savings in a post-exacerbation care COPD population.

15. *Real-World Study of 30-Day Exacerbation Outcomes in Chronic Obstructive Pulmonary Disease (COPD) Patients Managed with Aerobika* OPEP*

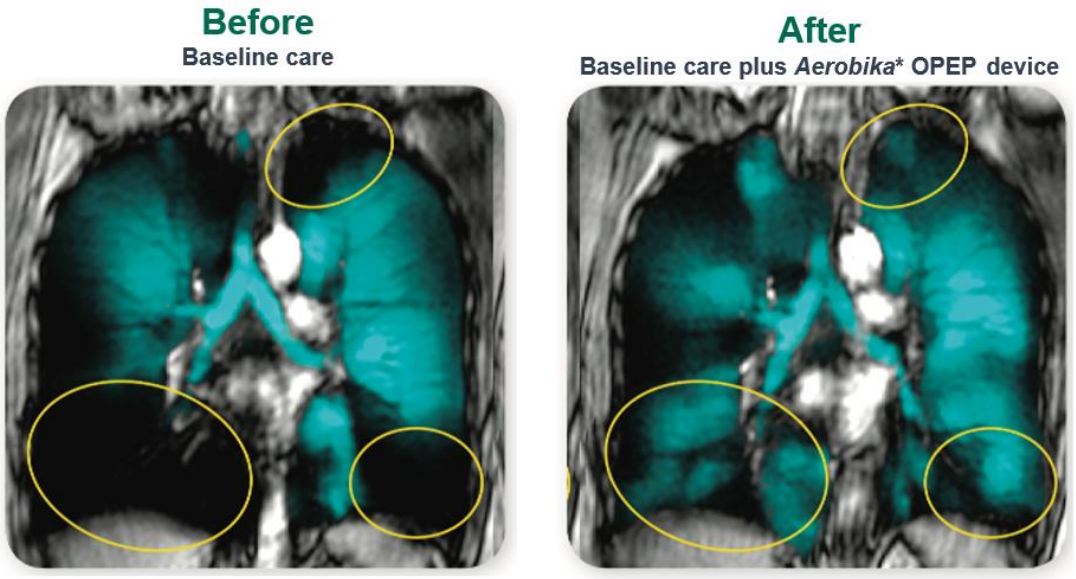
C Burudpakdee, A Seetasith, P Dunne, G Kauffman, B Carlin, D Coppolo, J Suggett. Pulmonary Therapy 2017;3(163);DOI 10.1007/s41030-017-0027-5 (Published online: 06 February 2017). https://doi.org/10.1007/s41030-017-0027-5

Introduction: Oscillating positive expiratory pressure (OPEP) devices may reduce chronic symptoms in patients with obstructive pulmonary disease (COPD); however, no real-world studies have been performed to evaluate the benefits of these devices. The objective of this study was to measure the rate of early (30-day) moderate-to-severe exacerbations and related costs in COPD patients treated with Aerobika*, an OPEP device, vs. a matched control group in a real-world setting. Methods: The study utilized data from the QuintilesIMS' CDM hospital database. COPD patients treated with Aerobika* OPEP between 9/2013 and 8/2015 were propensity score matched to COPD patients who did not use any positive expiratory pressure device. Severe exacerbation was defined as a hospital admission with a diagnosis for chronic bronchitis or COPD. Moderate-to-severe exacerbation was defined as a hospitalization or an ED visit with a diagnosis for chronic bronchitis or COPD. Exacerbations and costs were compared between cohorts at 30 days. A generalized linear model (GLM) was used to estimate the marginal effect of Aerobika* OPEP on the cost of ED visits and hospitalizations due to COPD exacerbations. Results: A total of 405 Aerobika* OPEP patients were matched to 405 controls. At 30 days, 18.5% of subjects using the Aerobika* OPEP vs. 25.7% of controls had a moderate-to-severe exacerbation (p=0.014); 13.8% of subjects with Aerobika* OPEP vs. 19.0% of controls had a severe exacerbation (p=0.046). The mean per patient cost of moderate-to-severe exacerbations and severe exacerbations in the Aerobika* OPEP group was significantly lower than controls ($2975 vs. $6065; p=0.008, and $2838 vs. $5871; p=0.009, respectively). In the GLM, the per-patient cost of moderate-to-severe exacerbations in the Aerobika* OPEP group was 34% lower (p=0.012) than the control group. Conclusions: Study findings suggest that using Aerobika* OPEP as part of a treatment regimen may help reduce ED visits, hospital re-admissions and related costs in COPD patients who have a history of exacerbations.

16. *Oscillatory Positive Expiratory Pressure in Chronic Obstructive Pulmonary Disease*

S Svenningsen, GA Paulin, K Sheihk, F Guo, A Hasany, M Kirby, R Etemad-Rezai, DG McCormack, G Parraga. Journal of COPD 2016;13(1):66-74. https://doi.org/10.3109/15412555.2015.1043523

Evidence-based guidance for the use of airway clearance techniques (ACT) in chronic obstructive pulmonary disease (COPD) is lacking in-part because well-established measurements of pulmonary function such as the forced expiratory volume in 1s (FEV_1) are relatively insensitive to ACT. The objective of this crossover study was to evaluate daily use of an oscillatory positive expiratory pressure (oPEP) device for 21–28 days in COPD patients who were self-identified as sputum-producers or non-sputum-producers. COPD volunteers provided written informed consent to daily oPEP use in a randomized crossover fashion. Participants completed baseline, crossover and study-end pulmonary function tests, St. George's Respiratory Questionnaire (SGRQ), Patient Evaluation Questionnaire (PEQ), Six-Minute Walk Test and ^{3}He magnetic resonance imaging (MRI) for the measurement of ventilation abnormalities using the ventilation defect percent (VDP). Fourteen COPD patients, self-identified as sputum-producers and 13 COPD-non-sputum producers completed the study. Post-oPEP, the PEQ-ease-bringing-up-sputum was improved for sputum-producers (p=0.005) and non-sputum-producers (p=0.04), the magnitude of which was greater for sputum-producers (p=0.03). There were significant post-oPEP improvements for sputum-producers only for FVC (p=0.01), 6MWD (p=0.04), SGRQ total score (p=0.01) as well as PEQ-patient-global assessment (p=0.02). Clinically relevant post-oPEP improvements for PEQ-easebringing-up-sputum/PEQ-patient-global-assessment/SGRQ/VDP were observed in 8/7/9/6 of 14 sputum-producers and 2/0/3/3 of 13 non-sputum-producers. The post-oPEP change in ^{3}He MRI VDP was related to the change in PEQ-ease-bringing-up-sputum (r=0.65, p=0.0004) and FEV1 (r=-0.50, p=0.009). In COPD patients with chronic sputum production, PEQ and SGRQ scores, FVC and 6MWD improved post-oPEP. FEV1 and PEQ-ease-bringing-up-sputum improvements were related to improved ventilation providing mechanistic evidence to support oPEP use in COPD.



Teal colour and intensity show areas with gas distribution. Yellow circles represent areas of greatest change after 3-4 weeks of ***Aerobika**** OPEP device use. Demonstrated by hyperpolarized 3He magnetic resonance imaging (MRI).

17. *Analysis of Acute Drug Usage from a Retrospective Cohort Study on the Impact of an OPEP Device in COPD Patients with Chronic Bronchitis*

J Suggett, B Carlin, P Dunne, G Kauffman, D Coppolo. CHEST 2016;150(4):837A. Presented at CHEST 2016.
https://journal.chestnet.org/article/S0012-3692(16)57136-0/pdf

Purpose: In Chronic Obstructive Pulmonary Disease (COPD) patients with Chronic Bronchitis (CB) the ***Aerobika**** Oscillating Positive Expiratory Pressure (OPEP) device has been shown to significantly improve measures such as[1] ease-bringing-up-sputum, Forced Vital Capacity, quality of life, and 6 Minute Walk Distance. This abstract reports acute drug usage data from a real-world study over 6 months among COPD patients with CB. **Background:** Antibiotics and oral corticosteroids (OCS) are commonly prescribed drug therapies used in treatment of acute COPD exacerbations[2]. Antibiotic-resistant infections add considerable and avoidable costs to the already overburdened healthcare system[3]. **Methods:** A retrospective cohort study of the CDM hospital claims database was conducted between September 2013 and August 2015. Moderate to severe exacerbations were defined as requiring either a hospital ER visit or hospital admission. Study participants *n*=810; patients who used the ***Aerobika**** device *n*=405; propensity score matched controls *n*=405; Propensity score matches included, amongst others, demographics, history of exacerbations, comorbidities and drug usage. Inclusion Criteria included CDM record with CB diagnosis [ICD-9 491.xx] from 01/01/2011– 09/30/2015, documented ***Aerobika**** device use, newly initiated, ≥1 CDM record before and after their index date and at least ≥35 years old in the year of index visit. Exclusion Criteria included incomplete demographic data (age, gender), use of ***Aerobika**** device before their index date, and use of PEP or other OPEP devices at any time during the study period. **Results**: The proportion of patients prescribed OCS and antibiotics in the hospital setting during the postindex period was significantly lower for patients using the ***Aerobika**** device compared to their matched controls: Oral Corticosteroids: 1.5% vs 13.3%, $p<0.001$; Antibiotics: 14.1% vs 32.6%, $p<0.001$. Decreased need for short-term drug therapies including OCS and antibiotics, may reflect better disease control. **Conclusions:** There was a significant reduction in the requirement for OCS and antibiotics in the hospital setting for patients receiving the ***Aerobika**** device. These findings provide additional evidence that the drug-free ***Aerobika**** device may be an effective addition to a disease management plan for COPD patients with chronic bronchitis and a history of exacerbations.

1 Svenningsen S, Paulin GA, Sheikh K, et al. *Oscillatory Positive Expiratory Pressure in Chronic Obstructive Pulmonary Disease. COPD 2016;13(1):66-74. 2 Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. 2015. 3 Antibiotic Resistance Threats in the United States, 2013. US Department of Health and Human Services: Centers for Disease Control and Prevention. 4 Wolkove N* et al*. Use of a mucus clearance device enhances the bronchodilator response in patients with stable COPD. CHEST 2002;121(3):702-7. 5 Suggett J. A Retrospective Cohort Study Demonstrating the Impact of an OPEP Device on Exacerbations in COPD Patients with Chronic Bronchitis. Presented at ERS 2016. CDM = Charge Description Master.*

18. *A Retrospective Cohort Study Demonstrating the Impact of an OPEP Device on Exacerbation Related Healthcare Costs in COPD Patients with Chronic Bronchitis*

D Coppolo, BW Carlin, P Dunne, G Kauffman, J Suggett. Presented at CHEST 2016.
https://erj.ersjournals.com/content/48/suppl_60/PA3780

Purpose: In Chronic Obstructive Pulmonary Disease (COPD) patients with Chronic Bronchitis (CB) the ***Aerobika***** Oscillating Positive Expiratory Pressure (OPEP) device has been shown to significantly improve measures such as[1] Ease-bringing-up-sputum, Forced Vital Capacity, Quality of life and 6 Minute Walk Distance. This abstract reports moderate-to-severe exacerbation related healthcare cost data from a real-world study over 6 months among COPD patients with CB. **Background:** COPD exacerbations account for the greatest proportion of the total COPD burden on the healthcare system.[2] In the US, the estimated direct cost is $30 billion and the indirect cost is approximately $20 billion.[2] The US national average 30 day readmission rate for patients hospitalized with a COPD exacerbation is 23%[3]. The US Centers for Medicare and Medicaid Services (CMS) has introduced 30 day readmission reimbursement penalties with the goal of reducing 30 day readmission rates. COPD cases are projected to increase 155% from 2010 to 2030[4]. There is a predicted epidemic of COPD hospitalizations over the next 15 years[4]. **Methods:** A retrospective cohort study of the CDM hospital claims database was conducted between September 2013 and August 2015. Moderate to severe exacerbations were defined as requiring either a hospital ER visit or hospital admission. Study participants *n*=810; patients who used the ***Aerobika***** device *n*=405; propensity score matched controls *n*=405; Propensity score matches included, amongst others, demographics, history of exacerbations, comorbidities and drug usage. Inclusion Criteria included CDM record with CB diagnosis [ICD-9 491.xx] from 01/01/2011– 09/30/2015, documented ***Aerobika***** device use, newly initiated, ≥1 CDM record before and after their index date and at least ≥35 years old in the year of index visit. Exclusion Criteria included incomplete demographic data (age, gender), use of ***Aerobika***** device before their index date, and use of PEP or other OPEP devices at any time during the study period. **Results:** The mean cost of moderate-to-severe exacerbations per patient was significantly reduced in patients who used the ***Aerobika***** device plus baseline care.

	Cost Reduction		
Length of Time	30 Days	3 Months	6 Months
Mean Cost (USD)	-$6,347 (*p*=0.008)	-$6,600 (*p*=0.031)	-$9,936 (*p*=0.018)

The device cost is included in the calculation; the mean cost reductions show significant savings to the healthcare system. **Conclusions:** Patients in the ***Aerobika***** device cohort exhibited significantly lower costs throughout the 6 month study period. These findings provide additional evidence that the drug-free ***Aerobika***** device may be an effective addition to a disease management plan for COPD patients with chronic bronchitis and a history of exacerbations.

1 Svenningsen S, Paulin GA, Sheikh K, *et al*. Oscillatory Positive Expiratory Pressure in Chronic Obstructive Pulmonary Disease. COPD 2016;13(1):66-74. 2 Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. 2015. 3 Jenks S, Williams M, Coleman E. Re-hospitalization among patients in the Medicare fee-for-service program. N Eng J Med. 2009; 360:14. 4 Khakban A, *et al*. Am J Respir Crit Care Med. 2016 Sep 14. [Epub ahead of print]. 5 Wolkove N, *et al*. Use of a mucus clearance device enhances the bronchodilator response in patients with stable COPD. CHEST 2002;121(3):702-7. 6 Suggett J. A Retrospective Cohort Study Demonstrating the Impact of an OPEP Device on Exacerbations in COPD Patients with Chronic Bronchitis. Presented at ERS 2016. CDM = Charge Description Master.

19. *A Retrospective Cohort Study Demonstrating the Impact of an OPEP Device on Exacerbations in COPD Patients with Chronic Bronchitis*

J Suggett. Presented at ERS 2016. https://erj.ersjournals.com/content/48/suppl_60/PA3780

Rationale: In Chronic Obstructive Pulmonary Disease (COPD) patients with Chronic Bronchitis (CB) the ***Aerobika***** Oscillating Positive Expiratory Pressure (OPEP) device has been shown to significantly improve measures such as Ease-bringing-up-sputum, FVC, Quality of life, and 6MWD.[1] To date, its effectiveness in reducing exacerbations in the real-world had not been reported in COPD patients. This abstract reports 30 day exacerbation data from real-world outcomes over 6 months among COPD patients with CB. **Background:** Acute exacerbations are the most common reason for medical visits, hospital admissions, and death in patients with COPD[2]. 1 in 5 patients hospitalized for a COPD exacerbation require re-hospitalization within 30 days[3]. During an exacerbation, airways are compromised by inflammation, mucus buildup, and dynamic lung hyperinflation[4]. Patients with compromised airways are poorly responsive to usual COPD treatments, and are at increased risk of recurrent exacerbations[4]. According to guidelines, the goal is to minimize the impact of the current exacerbation and to prevent the development of subsequent exacerbations5. **Methods**: Inclusion Criteria were CDM record with chronic bronchitis diagnosis [491.xx]

from 01/01/2011 – 09/30/2015, Documented ***Aerobika**** OPEP device use, ≥1 CDM record before their index date and after their index date, ≥1 CDM record of chronic bronchitis diagnosis (ICD-9 491.xx any position) on or before index date, at least ≥35 years old in the year of index visit. Exclusion Criteria included incomplete demographic data (age, gender), ***Aerobika**** device use before their index date and use of PEP or other OPEP devices at any time during the study period. **Statistical Analysis:** Study participants *n*=810; patients who used ***Aerobika**** device *n*=405; propensity score-matched controls *n*=405. Propensity score matching is a statistical technique that balances baseline differences between groups under non-randomized conditions. Patients who used the ***Aerobika**** device were propensity score matched 1:1 to COPD patients who did not use any positive expiratory pressure device, based on demographics, exacerbation history, and treatment history. **Results:** In the ***Aerobika**** cohort there was a statistically significant 28% reduction in patients with a moderate-to-severe exacerbation within 30 days (25.7% to 18.5%, *p*=0.014). Results determined the Number Needed to Treat (NNT) was 14. **Conclusions:** Patients in the ***Aerobika**** device cohort, experienced a significant reduction in moderate-to-severe exacerbations within 30 days (–28%, *p*=0.014). This translates to a NNT of 14 which compares favorably to several drug product studies. These findings provide additional evidence that the drug-free ***Aerobika**** device may be an effective addition to a disease management plan for COPD patients with Chronic Bronchitis.

1 Svenningsen S, Paulin GA, Sheikh K, *et al*. Oscillatory Positive Expiratory Pressure in Chronic Obstructive Pulmonary Disease. COPD 2016;13(1):66-74. 2 O'Donnell DE, *et al*. Can Respir J. 2007;14(Suppl B):5B-32B. 3 Shah T, *et al*. CHEST. 2016 May 7. doi: 10.1016/j.chest.2016.05.002. [Epub ahead of print]. 4 O'Donnell DE, Parker CM. Thorax. 2006;61(4):354-61. 5 Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. 2015. 6 Marks JH. Paediatr. Respir. Rev. 2007;8:17-23. 7 Strickland SL. Respir. Care 2013:on line Nov 12. 8 Pasteur MC, Bilton D, Hill AT. Thorax 2010.65(Suppl 1):i1-i58. CDM = Charge Description Master.

20. *Quality of Life (QoL) Responder Rate Analysis Following Use of an Oscillating Positive Expiratory Pressure (OPEP) Device for Chronic Obstructive Pulmonary Disease (COPD): SGRQ v CAT Assessments*

RA Stockley. Abstract presentations: COPD10, Birmingham, United Kingdom, 2016. Chronic Obstructive Pulmonary Diseases: Journal of the COPD Foundation. 2017; 4(3): 225-246.
http://doi.org/10.15326/jcopdf.4.3.2017.0137

Background: The ***Aerobika**** OPEP device has been reported to improve quality of life outcomes for COPD patients with chronic bronchitis[1,2]. This abstract compares the responder rates from two separate studies using the same device, one with the St George's Respiratory Questionnaire (SGRQ) and the other with the COPD assessment test (CAT). **Methods:** Study 1[1], a randomized cross-over study in 27 COPD patients for 3-4 weeks, used the SGRQ. Study 2[2], a clinical assessment of 37 COPD patients over an 8-week period, used the CAT. Taking clinically significant measures of improvement of greater than 4 and at least 2 (for the SGRQ and CAT respectively), responder rates were calculated for the COPD patients with chronic bronchitis. **Results**: In study 1, the mean SGRQ value for the 14 COPD patients with chronic bronchitis significantly improved from 49 to 40 (*p*=0.01, paired t-test) following OPEP therapy. In study 2, the mean CAT value for the 26 COPD patients with chronic bronchitis significantly improved from 19.7 to 17.4 (*p*=0.01, paired t-test) following OPEP therapy. In terms of responder rate analysis, using the recognized improvement thresholds noted above, 64% of the COPD patients with chronic bronchitis from study 1 showed a clinically significant improvement in Quality of Life compared to 62% from study 2. **Conclusions**: The results from the two separate studies (using different validated QoL instruments) show good agreement, with nearly two thirds of COPD patients with chronic bronchitis exhibiting clinically significant improvements in Quality of Life following self-administered treatment with the ***Aerobika**** OPEP device.

Svenningsen S, Paulin GA, Sheikh K, *et al*. Oscillatory Positive Expiratory Pressure in Chronic Obstructive Pulmonary Disease. COPD. 2015 Oct 2:1-9. 2. Suggett J. Review of Quality of Life outcomes following use of an Oscillating Positive Expiratory Pressure (OPEP) device for Chronic Obstructive Pulmonary Disease (COPD): 8 weeks field study using the COPD Assessment Test (CAT), ATS 2016.

21. *Review of Quality of Life Outcomes Following Use of an Oscillating Positive Expiratory Pressure Device for Chronic Obstructive Pulmonary Disease: 8 Weeks Field Study Using the COPD Assessment Test*

J Suggett. Presented at ATS 2016. https://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2016.193.1_MeetingAbstracts.A6888

Background: Despite the multiple treatment options available, many Chronic Obstructive Pulmonary Disease (COPD) patients still suffer from a poor quality of life. We assessed the quality of life outcomes for COPD patients with chronic bronchitis following treatment with a handheld, easy-to-use Oscillating Positive Expiratory Pressure (OPEP) device, using the COPD Assessment Test (CAT) over an 8 week duration. **Methods:** A clinical assessment was undertaken in 37 COPD patients in southwestern Ontario, Canada, who received the ***Aerobika**** device (Trudell Medical International) via their healthcare provider. Patients were monitored using the CAT survey over an 8 week period of daily use. The 37 patients were stable on prescribed therapy which included oxygen therapy. The CAT was

administered by an attending Respiratory Therapist in their home at 0, 4 and 8 weeks of OPEP use. **Results**: 26 of the 37 COPD patients were diagnosed with Chronic Bronchitis (CB). Note: Review of the patient records of the original 37 patients identified 11 of whom had a diagnosis of emphysema, and therefore these were excluded from the analysis. The mean CAT total score for the 26 COPD patients with CB changed from 19.7 (initial) to 18.2 (4 weeks) and 17.4 (8 weeks) with a clinically (at least 2 units1) and statistically (p=0.011, paired two-tailed t test) significant reduction over the 8 weeks OPEP use. Furthermore, 62% of patients had a clinically significant improvement in their total CAT after 8 weeks. **Conclusions**: For stable COPD patients already on prescribed therapy, the addition of the ***Aerobika**** device delivered a clinically and statistically significant improvement in CAT scores from baseline to 8 weeks. Notwithstanding the limitations of a relatively small study size and lack of a control, the results further support the efficacy of this device with respect to improved quality of life in these patients. Given the reported poor quality of life for many COPD patients, it is worth consideration to include an easy-to-use, drug-free OPEP device such as the ***Aerobika**** device as part of the disease treatment plan for COPD patients with chronic bronchitis.

22. *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. Presented at ATS 2015. https://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2015.191.1_MeetingAbstracts.A3981

Background: Airway clearance therapy can be used to help mobilize and clear excess mucus secretions in the lungs. Excess mucus is a common complaint for Chronic Obstructive Pulmonary Disease (COPD) patients with chronic bronchitis. Contributes to breathlessness, chronic cough and difficulty performing daily tasks resulting in poor quality of life. Effective airway clearance can result in an improved quality of life. We compared the quality of life outcomes for COPD patients following treatment with a new Oscillating Positive Expiratory Pressure (OPEP) device (***Aerobika**** OPEP, Trudell Medical International, Canada), both in a cross-over clinical study using the validated St. George's Respiratory Questionnaire (SGRQ) and in a much larger non-validated patient survey. **Methods:** Randomized, 6 week cross-over study of 14 COPD (Chronic Bronchitis) patients.[1] Difference in SGRQ scores pre and post OPEP therapy were compared. In a separate evaluation, ***Aerobika**** OPEP devices and associated surveys were supplied to non-phenotyped COPD patients in Ontario, Canada via their healthcare provider. Feedback was received from 461 patients following 1 month's use. **Results**: Clinical study results[1]: The mean SGRQ Total Score for the 14 COPD patients in the 6 week cross-over study changed from 45 pre-OPEP to 36 post-OPEP. A decrease in score relates to an improvement. Highlighting a statistically (p=0.009, paired two tailed t test) and clinically significant reduction of 9 points - more than 2 times the Minimum Clinically Important Difference (MCID). 97% of patients wanted to continue using the device. **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 non-phenotyped 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.

1 Svenningsen S *et al.* Oscillating Positive Pressure Therapy in Chronic Obstructive Pulmonary Disease and Bronchiectasis. Presented at ERS 2014.

23. *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. Presented at CRC 2015.

Rationale: Chronic Obstructive Pulmonary Disease (COPD) is the fourth leading cause of death in Canada and is the only chronic condition where the affected population continues to grow. Studies have shown the ***Aerobika**** Oscillating Positive Expiratory Pressure (OPEP) device to have positive patient outcomes in clinical evaluations,[1,2] but assessment of home-based user experience was not known. A survey was undertaken with patients to determine if using the device had any impact on patient reported outcomes, compliance, and satisfaction. **Background:** Patients with COPD experience symptoms including breathlessness, chronic cough, excess mucus, and the inability to perform daily activities. COPD is characterized by a number of interrelated physiological changes in the lungs. Airflow limitation and chronic inflammation create excess mucus within the airways. Airway damage inhibits the natural ability of the lungs to clear excess mucus. Pharmacological treatments have been unable to demonstrate effect on mucus clearance.[3] **Method**: Patients were counselled on the proper use of the ***Aerobika**** OPEP device. Each patient was asked to use the device twice daily for at least 3 weeks prior to completing the survey. Survey responses were captured via an online portal requiring a unique ID to prevent duplicate entries. **Results**: 812 unique survey responses were collected. 90% of patients had COPD (non-phenotyped). 8% had Bronchiectasis. 2% Cystic Fibrosis. Compliance to therapy was high with 97% indicating they would continue to use the device. Patient

satisfaction was 94% for the device overall with 96% it easy to use. **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.

1 Svenningsen S *et al*. Hyperpolarized ^{3}HE magnetic resonance imaging following oscillatory positive expiratory pressure treatment in GOLD stage & III COPD. Presented at ATS 2013. 2 Svenningsen S *et al*. Oscillating Positive Expiratory Pressure Therapy in Chronic Obstructive Pulmonary Disease and Bronchiectasis. Presented at ERS 2014 (Munich, Germany). 3 Perry RJ *et al*. Journal of Aerosol Medicine 1990;3(3):187-196. Hogg JC *et al*. American Journal of Respiratory and Critical Care Medicine 2007;176(5):454. Burgel PR *et al*. European Respiratory Journal 2004;24(4):594- 600. Ramos FL *et al*. International Journal of COPD 2014;9:139-150. Pavia D *et al*. European journal of respiratory diseases 1983;128(Suppl):304. Hasani A *et al*. CHEST 2004;125(5):1726-1734. Baraniuk JN *et al*. Clinical & Experimental Allergy Reviews 2010;10(1):12-19. Rogers D *et al*. Annals of medicine 2006;38(2):116- 125. Salathe M *et al*. CHEST 1996; 110(4):1048-1057. Poole PJ. International Journal of Chronic Obstructive Pulmonary Disease 2006;1(2):123 Rogers DF. Pulmonary Pharmacology & Therapeutics 2005;18(1):1-8. 4. Marks JH. Paediatr. Respir. Rev. 2007;8:17-23. 5 Strickland SL. Respir Care. 2013;58(12):2187-93.

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

S Svenningsen, G Paulin, A Wheatley, D Pike, J Suggett, D McCormack, G Parraga. Presented at ERS 2014.
https://erj.ersjournals.com/content/44/Suppl_58/P3679

Background / Rationale: Cough and sputum production are common in Chronic Obstructive Pulmonary Disease (COPD) and Bronchiectasis, both of which are associated with increased rates of mortality and other adverse clinical outcomes.[1] Airway Clearance Therapies (ACT) such as Oscillating Positive Expiratory Pressure (OPEP) aim to facilitate mucus transport and sputum expectoration, however clinical evidence of their efficacy is lacking.[2] To test the effects of daily OPEP use over a 3 week period, a hand-held device was evaluated in COPD and Bronchiectasis. **Hypothesis:** Daily use of OPEP over a 3-week period results in significantly improved mucus clearance and symptom scores in subjects with COPD and Bronchiectasis. **Research Objective:** To evaluate the safety and efficacy of four-times daily OPEP over 3 weeks in COPD and Bronchiectasis with Chronic Bronchitis/chronic sputum production. METHODS: **Study Subjects and Design**: Subjects with COPD (n=14) and non-CF Bronchiectasis (n=14) were randomized to perform OPEP four-times daily in a cross-over controlled study; 3 weeks on/3 weeks off (or vice versa). Study evaluations (start/cross-over/end): Pulmonary Function Tests, Six Minute Walk Test (6MWT), St. George's Respiratory Questionnaire (SGRQ), Patient Evaluation Questionnaire (PEQ), Hyperpolarized Helium-3 Magnetic Resonance Imaging (^{3}He MRI). **Discussion:** Following use of the OPEP device for all subjects there were statistically significant improvements in: 6MWD (p=0.02), SGRQ (p=0.02), PEQ Cough Frequency (p=0.009), PEQ Dyspnea (p=0.04), PEQ Ease in Bringing up Sputum (p<0.0001). Both COPD and Bronchiectasis subjects had improved ease in bringing up sputum. SGRQ was improved in COPD but not Bronchiectasis. 6MWD was improved in Bronchiectasis. In a subset of both COPD and Bronchiectasis subjects, ventilation defects (as measured by ^{3}He) were diminished post-OPEP. **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.

1 Ekberg-Aronsson *et al*. Respir Res (2005); 2 van der Schans *et al*. Paediatr Respir Rev (2002).

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

J Suggett, J Mitchell. Presented at Respiratory Drug Delivery 2014.
https://www.researchgate.net/publication/288490436_More_than_Drug_Delivery_A_New_Airway_Clearance_Therapy_Evaluated_Clinically_using_MRI

Background: The creation of Oscillating Positive Expiratory Pressure (OPEP) is a recognized Airway Clearance Therapy (ACT) to mobilize secretions associated with lung diseases in pulmonary rehabilitation, in particular in association with Chronic Obstructive Pulmonary Disease (COPD) and cystic fibrosis. Chest physiotherapy with bronchial drainage, which is the traditional method for maintaining bronchial hygiene, is very time consuming and labour intensive, so there is a strong incentive to move to more efficient techniques. With OPEP, expiratory pressure stents the airways open and helps fill under-inflated or collapsed alveoli while oscillation creates short bursts of increased expiratory airflow to thin, dislodge and move mucus to the central/upper airways where it can be coughed out. To date, there has been relatively little clinical data supporting this type of therapy in COPD, and it is also difficult to evaluate regional lung effects following ACT. A new hand-held Oscillatory Positive Expiratory Pressure device (***Aerobika****) has been developed that can be used by patients in any orientation. We report the outcome of an *in vivo* study performed in collaboration with Robarts Research Institute and the Department of Medicine, University of Western Ontario, London, Canada, that used Magnetic Resonance Imaging (MRI) with hyperpolarized helium (^{3}He) to assess the influence of the ***Aerobika**** OPEP device on lung ventilation in COPD patients. **Materials and Methods**: The ***Aerobika**** OPEP device was evaluated in patients with varying stages of COPD, in an 8 week, longitudinal, cross-over study design; 14 patients (ages 62-81); Group split to receive 4 weeks on OPEP therapy followed by 4 weeks off or vice versa. ^{3}He MRI was performed at the start of the study, cross-over week and end of study.

Additionally, pulmonary function testing (PFT) was performed and a validated patient evaluation questionnaire (PEQ) completed at 2 week intervals. **Results**: There were no adverse events judged related to the use of the ***Aerobika***** OPEP device, nor were there any serious/severe adverse events or COPD exacerbations during the study. Given the relatively small number of patients and the fact that they were not phenotyped as an entry criteria, the focus of the study was mainly on the MRI methodology and its application to assess ACT in COPD. Notwithstanding, analysis of all patients showed a statistically significant (paired two tailed t-test) improvement in dyspnea (p=0.03), measured as part of the PEQ, following use of the OPEP device. The MRI analysis produced both a visual regional representation as well as the ability to determine a Ventilation Defect Percentage (VDP). The VDP measurement enabled the identification of six patients exhibiting a detectable improvement (>2%). Analysis of this subgroup showed that following OPEP therapy there was a significant improvement in (1) Forced vital capacity (FVC%pred) [p=0.04] (2) From the PEQ, ease in bringing up sputum [p=0.02]. The use of 3He MRI provided a clear indication of specific areas of the lungs in which ventilation is present and absent. The presence and intensity of coloration relates to ventilation, whereas no color, black, represents nonventilated areas. This methodology therefore allows identification of specific regions of the lungs in which ventilation has improved following OPEP therapy, potentially due to the removal of mucus plugs in the airways. **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* and ease in bringing up sputum, for a subgroup of patients demonstrating imaging improvements. The use of ^{3}He MRI has also been shown to be a promising tool with which to interpret visually the physiological effects of ACT.

26. 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. Presented at ATS 2013. https://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2013.187.1_MeetingAbstracts.A4885

Introduction: Airway clearance techniques are thought to help improve mucus clearance and dyspnea in chronic pulmonary diseases such as CF and bronchiectasis. The effect of positive expiratory pressure and oscillatory positive expiratory pressure (oPEP) in COPD is not well-understood. To test the effects of oPEP, a hand-held prototype device (Trudell Medical International) was evaluated in COPD ex-smokers. **Goal**: To determine the effect of oPEP on pulmonary function, imaging biomarkers of airway function, St Georges Respiratory Questionnaire (SGRQ) and a mucous clearance questionnaire. **Hypothesis**: oPEP use results in significantly improved mucous clearance and symptom scores in COPD ex-smokers. **Research Objective:** To evaluate the safety and efficacy of four-times daily oPEP over 4 weeks in COPD ex-smokers using pulmonary function tests (PFTs), hyperpolarized ^{3}He magnetic resonance imaging (MRI), six minute walk test (6MWT), the St. Georges Respiratory Questionnaire (SGRQ), and a validated symptom diary[1]. **Study Subjects and Design:** 17 COPD ex-smokers were randomized to 4 weeks of oPEP or no therapy in a cross-over study. Pulmonary function tests (spirometry, plethysmography, DLCO) were acquired on an EasyOne spirometer (ndd Medizintechnik AG, Zurich, CH) according to ATS guidelines. 6MWT, SGRQ, and mucous clearance symptom questionnaire were acquired at each visit. **Image Acquisition and Analysis:** MRI performed on 3T Discovery 750MR (GEHC, Milwaukee, USA) ^{3}He MRI ventilation defect percent (VDP)[2] generated for images acquired after a 15s breath-hold (FRC+1L). 14 subjects completed the study and two cases are presented – a single self-reported non-responder and self-reported responder. **Discussion:** In a single self-reported responder, SGRQ total score and ease of mucous clearance was improved, cough frequency was increased and FVC, RV, TLC and RV/TLC were also improved suggesting improved gas trapping and this was consistent with a very modest improvement in ^{3}He MRI VDP. In a single self-reported non-responder, there were no improvements in SGRQ, dyspnea or ease of bringing up sputum and there was no change in any PFT measurement, and ^{3}He MRI increased or worsened (15%-20%). **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, mucous 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, ^{3}He MRI VDP, SGRQ and ease in bringing up sputum that were in agreement with self-reported response.

Petty TL. The National Mucolytic Study: Results of a Randomized, Double-Blind, Placebo-Controlled Study of Iodinated Glycerol in Chronic Obstructive Bronchitis. CHEST. 1990 Jan;97(1):75-83. 2. Kirby M *et al.* Hyperpolarized ^{3}He magnetic resonance functional imaging semi-automated segmentation. Acad Radiol. 2012 Feb;19(2):141-52.

27. *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. Presented at Respiratory Drug Delivery 2013.
https://www.researchgate.net/publication/288496569_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

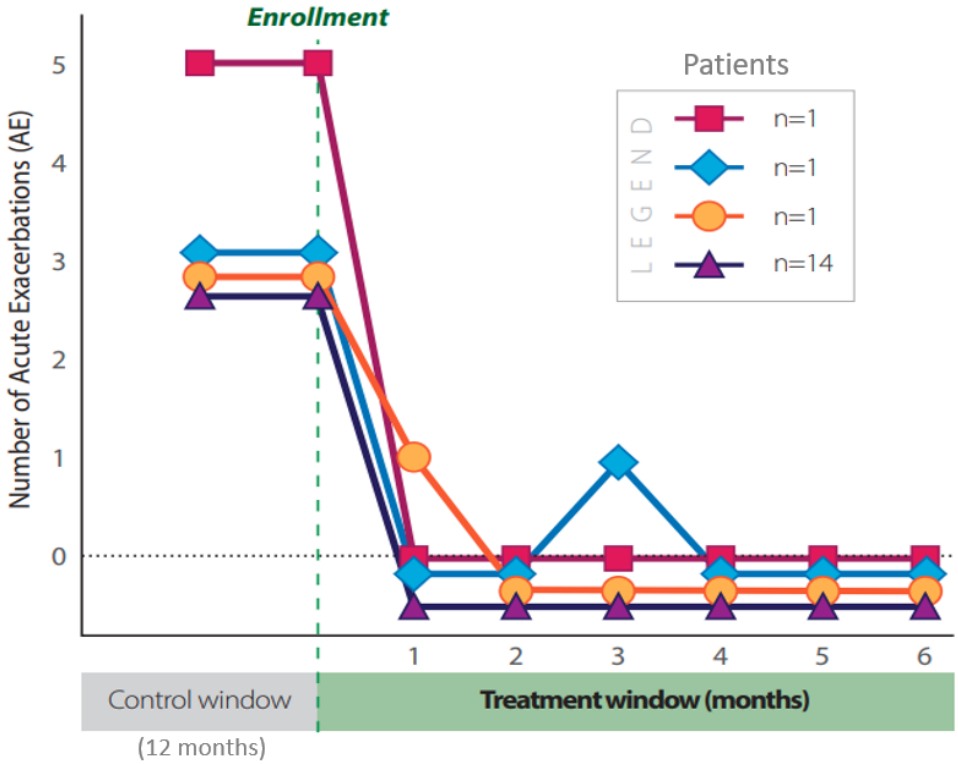
Background: Oscillating Positive Expiratory Pressure (OPEP) is a well-established therapy to mobilize secretions associated with lung diseases in pulmonary rehabilitation, in particular in association with COPD and Cystic Fibrosis. To date, OPEP therapy has usually been given at a separate time following initial delivery of inhaled medical aerosol therapy. The most likely reason is that the former is associated with exhalation, whereas the latter can only be done effectively during inhalation. **Study Purpose:** A new hand-held Oscillatory Positive Expiratory Pressure device (***Aerobika***** OPEP, Trudell Medical International (TMI), London, Canada) can be connected directly to the ***AEROECLIPSE***** II Breath Actuated Nebulizer (BAN, TMI). The patient can thereby receive aerosol therapy and secretion mobilization simultaneously. The ***Aerobika***** OPEP device might also be used with a small volume nebulizer with a 22 mm adapter. We report the outcome of *in vitro* measurements of BAN performance as part of research into the overall capability for the new OPEP device. The medication-containing aerosol generated from the BAN upon inhalation passes through the OPEP device via a short, low resistance pathway containing an open one-way valve before being inhaled. In this configuration, the aerosol flow path is linear with minimal restriction to mitigate internal losses caused by inertial impaction. When the patient exhales, the one-way valve closes, diverting the flow through the body of the OPEP device mechanically operating the vane that generates oscillatory pressure pulsations that are transmitted back to the patient. Initial results from a clinical study involving patients with COPD, using the ***Aerobika***** OPEP device alone performed at the Robarts Research Institute, London, Canada have indicated positive findings. The to be reported data demonstrated a statistically significant improvement in dyspnea after OPEP therapy, with improvements also noted in lung ventilation dejects and ease of mucus clearance. **Materials and Methods:** Measurements were made (9 replicates) of total and fine droplet mass < 5.4 µm by Next Generation Impactor (NGI) equipped with a Ph.Eur./USP induction port and operated at 15.0 L/min ± 5%. The BAN on test was operated by compressed air delivered at 50 psig and filled with 4-ml ipratropium bromide solution for nebulization (0.5 mg/mL). This product is widely used as an anticholinergic in the treatment of COPD. The BAN alone was initially tested connected directly to the inlet of the cascade impactor system via a leak-tight fitting. The measurements were repeated with the ***Aerobika***** OPEP device inserted between the BAN and impactor system. The BAN on test was run to onset of sputter, and the total mass of ipratropium bromide (TM*ipr*), recovered and assayed by a validated HPLC-UV spectrophotometric method. Measurements were also made with the acapella† vibratory PEP device. This OPEP device is widely available for lung secretion mobilization. The purpose of this arm was to examine what might happen if a clinician was to make this substitution. Fine Particle Mass <5.4µm aerodynamic diameter (FMipr) was evaluated. **Results**: TM*ipr* (mean ± SD) via the BAN alone for the ***AEROECLIPSE***** II BAN – ***Aerobika***** OPEP, and for the BAN – acapella† OPEP systems were 582±30, 515±28 and 178±21 µg respectively. These are equivalent to delivery rates of 1.9±0.1, 1.6±0.1 and 0.4±0.05 µg/s. Corresponding values of the therapeutically more important fine droplet mass < 5.4 µm for bronchodilation of the airways of the lungs (FM*ipr*) were 452±28, 426±27 and 177±21 µg respectively. **Conclusions**: The delivery of medication as fine particles from the ***AEROECLIPSE***** II BAN is comparable by combining the BAN with the ***Aerobika***** OPEP 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.

STUDIES USING THE AEROBIKA OPEP IN BRONCHIECTASIS*

1. **NEW** *Effectiveness of the Use of an Oscillating Positive Expiratory Pressure Device in Bronchiectasis with Frequent Exacerbations: A Single-Arm Pilot Study*

Kim SR, Kim SH, Kim GH, Cho JY, Choi H, Lee H, Ra SW, Lee KM, Choe KH, Oh YM, Shin YM, Yang B. Front Med (Lausanne). 2023 May 12;10:1159227. doi: 10.3389/fmed.2023.1159227. PMID: 37250647; PMCID: PMC10213442.

Introduction: Impaired airway clearance in patients with non-cystic fibrosis bronchiectasis causes frequent bacterial infection, chronic inflammation, and progressive tissue destruction. We aimed to evaluate whether an oscillating positive expiratory pressure (OPEP) device could allow effective sputum expectoration and prevent acute exacerbations in patients with bronchiectasis who had frequent acute exacerbations. **Methods:** This open-label, single-arm, prospective study included 17 patients who experienced three or more acute exacerbations in the past year. We evaluated the prevention of acute exacerbations, subjective symptom improvement, and change in sputum amount during the use of the Aerobika (Trudell Medical International, London, ON) OPEP device twice daily for 6 months. Each session was defined as 10-20 blows into the device with a few huffs at the end of the session. Patients were doing prior drainage techniques such as active cycle of breathing and autogenic drainage as trained by their physician. Patients were instructed to continue prior method. **Results:** Of all enrolled patients, only two acute exacerbations occurred during the study period, indicating a significant decrease compared with the number of acute exacerbations before the device use ($p < 0.001$). Additionally, Bronchiectasis Health Questionnaire score changed from 58.7 to 66.6, showing significant improvement over the treatment period ($p<0.001$). The largest sputum volume was observed 3 months after OPEP device use (baseline: 10 ml, 3rd month 25 ml, $p = 0.325$). There were no major adverse events related to the use of OPEP devices.

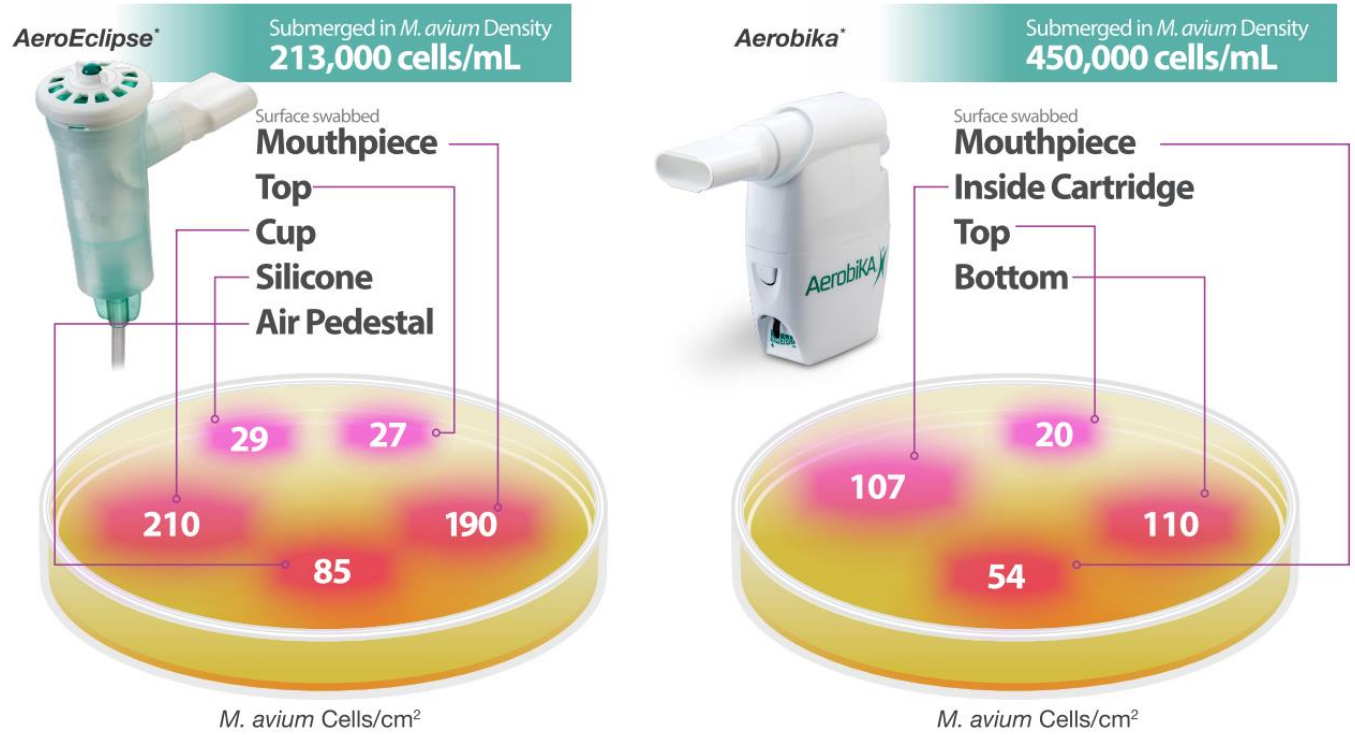


Conclusion: Twice-daily physiotherapy with OPEP device in patients with bronchiectasis who have frequent exacerbations may facilitate symptomatic improvement and prevention of acute exacerbations without serious adverse events.

2. **NEW** *Failure of Mycobacterium avium to Adhere to Interior Surfaces of Oscillating Positive Expiratory Pressure (OPEP) and Nebulizer Devices*

Falkinham, J.[1], Schloss, J.[2], Suggett, J.[3], Coppolo, D.[2] [1]Department of Biological Sciences, Virginia Tech. [2]Monghan Medical Corporation, New York, USA. [3]Trudell Medical International, London, Canada. 6th World Bronchiectasis & NTM Conference. July 18 – 20, 2023. https://evidence.monaghanmed.com/wp-content/uploads/2023/08/MD-295A-0423-corrected-poster-sm.pdf

Background: Risk of respiratory infection is a common concern for bronchiectasis patients often leading to caution involving use of medical devices for inhalation. *M. avium* is a major cause of lung infection in bronchiectasis patients and is common in household drinking water that could be used to rinse respiratory devices. Accordingly, the object of this study was to measure the adherence of *M. avium* cells to the interior walls of two commonly used respiratory devices. **Methods:** One OPEP device (Aerobika*, Monaghan Medical) and one nebulizer device (AeroEclipse* XL BAN* Nebulizer, Monaghan Medical) were evaluated. Each device was disassembled and separately submerged in a one-liter high density suspension of *M. avium* for 24 hours and then air dried. A 4-cm^2 area of each device part was swabbed. The swab was placed in 2 mL of sterile distilled water and vortexed to release and suspend *M. avium* cells. Cells were counted as colony-forming units on Middlebrook 7H10 agar media after 10 days incubation at 37 degrees Celsius. **Results:**



Conclusion: The test was designed to provide a worst-case scenario, with a very high-density suspension of *M. avium* cells and a long 24-h period to allow for adherence. Compared to copper, stainless steel, galvanized steel, and PVC surfaces (average > 2,000 cells/cm^2 in 24 hr.), the number of adherence *M. avium* cells on the surfaces of the ***AeroEclipse* XL BAN*** Nebulizer and ***Aerobika**** OPEP device is minimal. Thus, even under a worst-case scenario, the measurements indicate the materials comprising the Aerobika* OPEP and AeroEclipse* XL BAN* Nebulizer devices fail to collect adherent *M. avium* cells. This provides some assurance to patients that the risk of infection from such microorganisms will be low in the event that cleaning and disinfection is not performed robustly.

3. **NEW** *A Prospective Study to Identify the Benefits of Using an Oscillatory Positive Expiratory Pressure Device in the Management of Bronchiectasis*

Towers B, Kendrick C. Physiotherapy Dept, Blackpool Teaching Hospitals NHS Foundation Trust, Blackpool, UK. Chartered Society of Physiotherapy (CSP) Annual Conference. Abstract No. 266. November 1st, 2023.

Purpose: A main symptom of bronchiectasis is sputum production and expectoration. The British Thoracic Society (2019) advise that airway clearance techniques should be taught by a respiratory physiotherapist. Frequency and duration of airway clearance techniques should be tailored to the individual and a self-management plan should be created. Self-management plans should be individualised, incorporating daily airway clearance techniques, including a wide range of treatments, for example the active cycle of breathing technique (ACBT), postural drainage, and use of an OPEP device, such as an Aerobika. We wanted to explore the use of an Aerobika for symptom management of a

cohort of patients with bronchiectasis. **Methods:** A prospective study, including qualitative and quantitative data, was collected over an 8-month period. Using clinical judgement, appropriate patients were identified and provided with an Aerobika. Patients were considered appropriate if they displayed good compliance with all aspects of their self-management plan, however, continued to struggle with expectorating sputum. An initial sample size of 20 patients was identified, 11 were able to participate in the full study and therefore included. Prescriptions and instructions were given verbally or hand-written. Patients were advised to complete 10 minutes of Aerobika use daily, consisting of 5-10 breaths followed by 2-3 x forced expiratory technique. An initial telephone questionnaire was completed 1 month after provision of the device. A second questionnaire was then completed at the subsequent clinic appointment. **Results:** The initial questionnaire results indicated the following: 7/11 patients were utilising the Aerobika as prescribed. All patients reported it was easy to use. On a scale of 0-5, 0 indicating no benefit and 5 indicating extremely beneficial, an average of 3.3/5 was scored, regarding the benefits it provided in clearing sputum. **9/11 patients reported the Aerobika to be more beneficial than ACBT as a standalone treatment, 2/11 patients felt unsure. Overall, 10/11 patients would recommend the use of an Aerobika to other individuals with bronchiectasis.** At clinic reviews, 9/11 patients were using the device as prescribed, identifying an increase in compliance. 6/11 patients felt a further improvement in their sputum clearance, and 5/11 felt their ability remained the same. 5/11 patients had no infections since device provision, and 6/11 patients had 1-2 infections within this period. 8/11 patients felt that using an Aerobika had a positive impact on their quality of life. Finally, all patients would continue to use the Aerobika once discharged from the service. **Conclusion:** Overall, the findings indicate that using an Aerobika can provide patients with bronchiectasis some benefits to managing their symptoms. In the future, it would be useful to create an inclusion and exclusion criteria to ensure that the whole cohort of appropriate patients is captured. To remove any risk of inconsistency, a standardised prescription could be created for each therapist to utilise when providing an Aerobika. **Impact:** For the future, as this study has identified the positive impacts of using an Aerobika, there is scope to consider whether patients should be given an Aerobika as a standard treatment modality within the Adult Bronchiectasis Service.

4. *A Randomized Controlled Trial of 4 Weeks of Airway Clearance with Oscillating Positive End Expiratory Pressure Device Versus Autogenic Drainage in People with Bronchiectasis*

Michal Shteinberg, Naama Yaari, Nili Stein, Lea Bentur, Galit Livnat, Yochai Adir
European Respiratory Journal 2020 56: 4103; DOI: 10.1183/13993003.congress-2020.4103

Background: Airway clearance (AWC) is a fundamental component of care in bronchiectasis, but evidence of efficacy are few. Lung clearance index (LCI) is a promising measurement of ventilation inhomogeneity. Its responsiveness to AWC has not been demonstrated. **Aim:** To compare effects of two methods of AWC- Autogenic Drainage (AD) and Oscillating Positive Airway Pressure (oPEP) on LCI, spirometry, sputum quantity, and quality of life. **Methods:** Adult patients with bronchiectasis, naive to airway clearance, were randomized and instructed to daily AWC with either AD or oPEP (Aerobika, Trudell pharma, Canada). Weekly phone calls were performed to evaluate adherence to AWC. Multiple breath washout, spirometry, sputum volume and purulence, and QOL- B questionnaire were measured at randomization and after 4 weeks of AWC. **Results:** 51 patients were randomized and 49 completed the study (25 AD, 24 oPEP). Adherence was 87% (oPEP) and 88% (AD). LCI and FEV1 did not change between visits in either groups. Sputum quantity decreased in 12/24 of the oPEP group, and in 6/25 (24%) of the AD group, (p=0.044). 'Treatment burden' was worsened or unchanged in 70% of participants randomized to AD and 55% randomized to oPEP (p=0.038). During the study, 11 participants experienced a pulmonary exacerbation (6 AD, 5 oPEP). When these participants were excluded from the analysis, LCI improved in the oPEP group only (-0.59 vs. -0.1 in the AD group), without statistical significance (p=0.45). **Conclusions:** Sputum quantity was improved after one month of oPEP, without an increase in treatment burden. No change in LCI was seen with AWC.

5. *A National Audit of The Aerobika* Oscillatory Positive Pressure (OPEP) Device When Used to Assist Airway Clearance for Those with Cystic Fibrosis, Bronchiectasis and COPD*

A. Bracey1, J. Suggett2, J. Conway3
1Trudell Medical UK - Basingstoke (United Kingdom), 2Trudell Medical International - London Ontario (Canada), 3Southampton NIHR Respiratory and Critical Care Biomedical Research Centre - Southampton (United Kingdom).
Presented at ERS International congress 2019 https://erj.ersjournals.com/content/54/suppl_63/PA5267

Rationale: Oscillating positive expiratory pressure (OPEP) devices are used by physiotherapists to support airway clearance techniques (ACTs) with the objectives of improving sputum clearance and thus potentially increasing airway ventilation and quality of life. The use of the Aerobika* OPEP (Aerobika*Trudell Medical UK)device was evaluated in 23 UK hospitals to gain a better understanding of effectiveness and acceptability. **Methods:** Those with adult Cystic Fibrosis (CF), Bronchiectasis, Chronic Obstructive pulmonary patients (COPD) and 18 defined by Physiotherapists as other patients with excess sputum were evaluated over a one month period using the Aerobika* OPEP device. Evaluation was via a 5 point questionnaire, which included feedback from both patients and physiotherapists. A COPD assessment test (CAT) was performed at the start and end of the evaluation period for

those with COPD. **Results:** Evaluation was completed by 176 patients. For the COPD patients 82% had complete CAT scores with 60% of these demonstrating a clinically significant decrease (improvement) of 2 points or more on OPEP therapy. Acceptability: 92% of all patients wished to continue using this OPEP device, 87% of HCPs were happy or very happy with the device with the most popular feature noted was that the device was not position dependent. **Conclusion:** The Aerobika* OPEP device was found to be acceptable for patients and therapists. Improvement in CAT scores were observed in 60% of COPD patients. Inclusion of the Aerobika* should be considered as an acceptable adjunct to ACT physiotherapy regimes for those with CF, bronchiectasis or COPD

6. *Noncystic Fibrosis Bronchiectasis: Regional Abnormalities and Response to Airway Clearance Therapy Using Pulmonary Functional Magnetic Resonance Imaging*

S Svenningsen, F Guo, DG McCormack, G Parraga. Academic Radiology 2017;24(1):4-12. https://doi.org/10.1016/j.acra.2016.08.021

Rationale and Objectives: Evidence-based treatment and management for patients with bronchiectasis remain challenging. There is a need for regional disease measurements as focal distribution of disease is common. Our objective was to evaluate the ability of magnetic resonance imaging (MRI) to detect regional ventilation impairment and response to airway clearance therapy (ACT) in patients with noncystic fibrosis (CF) bronchiectasis, providing a new way to objectively and regionally evaluate response to therapy. **Materials and Methods:** Fifteen participants with non-CF bronchiectasis and 15 age-matched healthy volunteers provided written informed consent to an ethics board-approved Health Insurance Portability and Accountability Act-compliant protocol and underwent spirometry, plethysmography, computed tomography (CT), and hyperpolarized ^{3}He MRI. Bronchiectasis patients also completed a Six-Minute Walk Test, the St. George's Respiratory questionnaire, and Patient Evaluation Questionnaire (PEQ), and returned for a follow-up visit after 3 weeks of daily oscillatory positive expiratory pressure use. CT evidence of bronchiectasis was qualitatively reported by lobe, and MRI ventilation defect percent (VDP) was measured for the entire lung and individual lobes. **Results:** CT evidence of bronchiectasis and abnormal VDP (14 ± 7%) was observed for all bronchiectasis patients and no healthy volunteers. There was CT evidence of bronchiectasis in all lobes for 3 patients and in 3 ± 1 lobes (range = 1–4) for 12 patients. VDP in lobes with CT evidence of bronchiectasis (19 ± 12%) was significantly higher than in lobes without CT evidence of bronchiectasis (8 ± 5%, P = .001). For patients, VDP in lung lobes with (P < .0001) and without CT evidence of bronchiectasis (P = .006) was higher than in healthy volunteers (3 ± 1%). For all patients, mean PEQ-ease-bringing-up-sputum (P = .048) and PEQ-patient-global-assessment (P =.01) were significantly improved post-oscillatory positive expiratory pressure. An improvement in regional VDP greater than the minimum clinical important difference was observed for 8 of the 14 patients evaluated. **Conclusions:** There was CT and MRI evidence of structure-function abnormalities in patients with bronchiectasis; in approximately half, there was evidence of ventilation improvements after airway clearance therapy.

STUDIES USING THE AEROBIKA OPEP IN CYSTIC FIBROSIS*

1. *Effect of Aerobika* an Oscillating Positive Expiratory Pressure Device, on Lung Function in Pediatric CF Patients: A Longitudinal Analysis*

Elizabeth H. Baker, PhD[1]; Hector H. Gutierrez, MD[2]; Stephanie Gamble, RT[2]; Gabriela R. Oates, PhD[2]. NACFC 2022. [1]Department of Sociology; [2]Divison of Pulmonary and Sleep Medicine, Department of Pediatrics of Alabama at Birmingham

Background: Airway clearance therapy (ACT) is a cornerstone of cystic fibrosis (CF) care. Multiple ACT modalities are available, but little evidence exists to support the use of one over another. **Objective:** Examine the effect of Aerobika*, an Oscillatory Positive Expiratory Pressure device (OPEP), on lung function over time in a pediatric CF clinic. **Methods:** Retrospective longitudinal study of lung function in pediatric patients at a single CF center, stratified by Aerobika* use. Measures: Lung function – ppFEV$_1$. Exposure: Aerobika*, use alone or concurrently with a high frequency chest wall oscillating (HFCWO) vest, vs no Aerobika*. Study period: 2016-2021. Study population: N=146. Statistical Analysis: Longitudinal analysis used mixed modeling, which contains both fixed effects and random effects. We allow for a random intercept and slope. Stata 15. **Results:** Aerobika* use is associated with 7.2 higher ppFEV$_1$ (p=0.009). The association is stronger for children and adolescents whose parents do not have a college degree (11.2, p=0.007). **Conclusions:** Aerobika*, used alone or with a HFCWO best, may help preserve lung function. Effect size may be larger for older patients, 1.5% (p=0.074) less annual ppFEV$_1$ decline in patients 9 and older. The benefit is greater in less-educated families; may help reduce inequities in outcomes. **Implications:** Evaluate clinical efficacy in a randomized controlled trial. Identify most appropriate age for introducing the device. Take steps to address inequities in use.

2. A National Audit of The Aerobika* Oscillatory Positive Pressure (OPEP) Device When Used to Assist Airway Clearance for Those with Cystic Fibrosis, Bronchiectasis and COPD

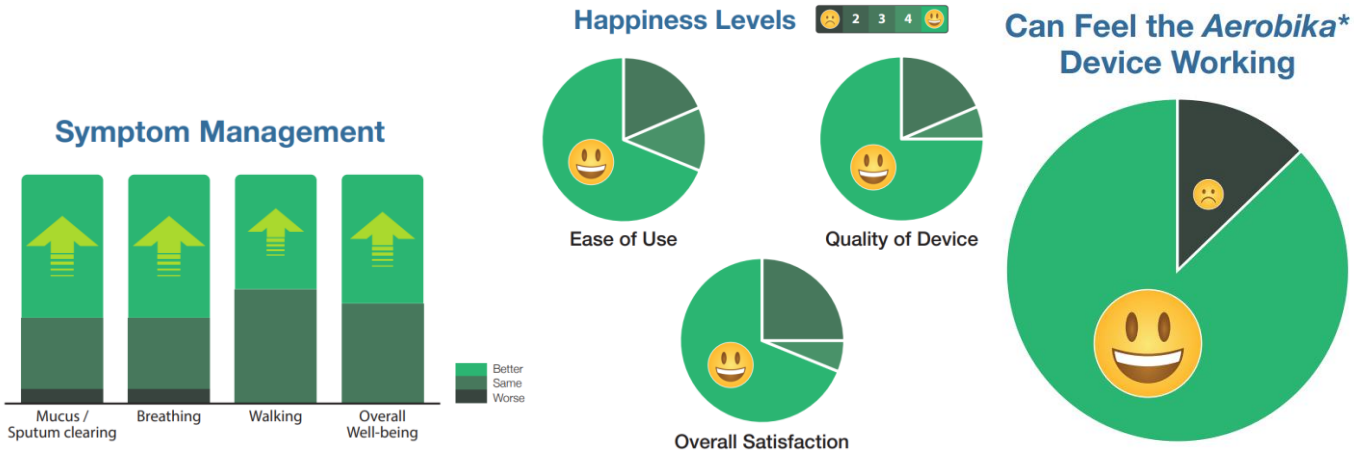
A. Bracey1, J. Suggett2, J. Conway3
1Trudell Medical UK - Basingstoke (United Kingdom), 2Trudell Medical International - London Ontario (Canada), 3Southampton NIHR Respiratory and Critical Care Biomedical Research Centre - Southampton (United Kingdom).
Presented at ERS International congress 2019 https://erj.ersjournals.com/content/54/suppl_63/PA5267

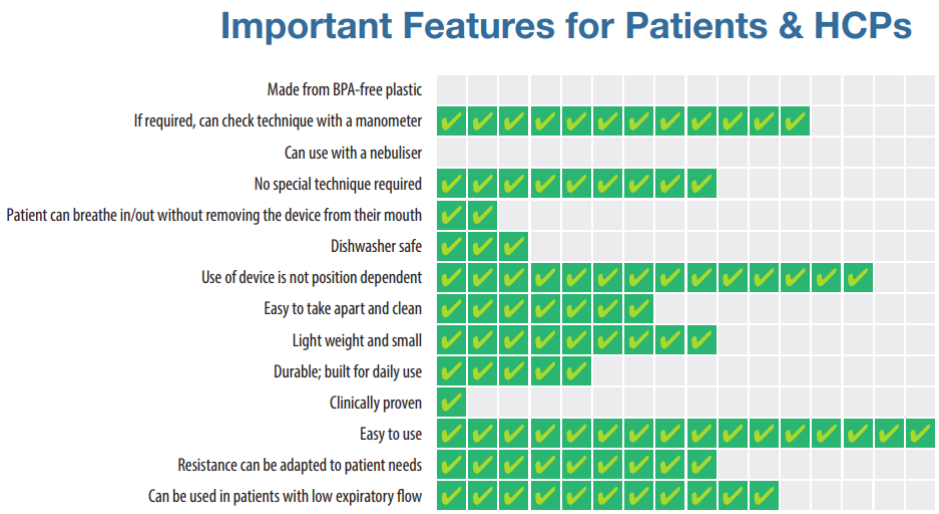
Rationale: Oscillating positive expiratory pressure (OPEP) devices are used by physiotherapists to support airway clearance techniques (ACTs) with the objectives of improving sputum clearance and thus potentially increasing airway ventilation and quality of life. The use of the Aerobika* OPEP (Aerobika*Trudell Medical UK)device was evaluated in 23 UK hospitals to gain a better understanding of effectiveness and acceptability. **Methods:** Those with adult Cystic Fibrosis (CF), Bronchiectasis, Chronic Obstructive pulmonary patients (COPD) and 18 defined by Physiotherapists as other patients with excess sputum were evaluated over a one month period using the Aerobika* OPEP device. Evaluation was via a 5 point questionnaire, which included feedback from both patients and physiotherapists. A COPD assessment test (CAT) was performed at the start and end of the evaluation period for those with COPD. **Results:** Evaluation was completed by 176 patients. For the COPD patients 82% had complete CAT scores with 60% of these demonstrating a clinically significant decrease (improvement) of 2 points or more on OPEP therapy. Acceptability: 92% of all patients wished to continue using this OPEP device, 87% of HCPs were happy or very happy with the device with the most popular feature noted was that the device was not position dependent. **Conclusion:** The Aerobika* OPEP device was found to be acceptable for patients and therapists. Improvement in CAT scores were observed in 60% of COPD patients. Inclusion of the Aerobika* should be considered as an acceptable adjunct to ACT physiotherapy regimes for those with CF, bronchiectasis or COPD

3. Evaluating the Use of an Oscillatory Positive Expiratory Pressure Device as Part of Airway Clearance in Paediatric Patients with Cystic Fibrosis

L. Newell1, A. Martin1, A. Pitman2, P. McCormack2, K. Southern2, Y.Y. Matthews1.
1 Wrexham Maelor Hospital BCUHB Trust. 2 Alderhey Children's Hospital. *Presented at 42 nd European Cystic Fibrosis Conference. UK 2019*

Objectives: It is necessary for children with Cystic Fibrosis (CF) to undertake regular Airway Clearance Techniques (ACT) due to increased secretions, inflammation, and potential deficits in lung function. Maintaining adherence to ACTs is a challenge for all people with CF. In order to improve adherence and quality of care, we introduced and evaluated the use of an Oscillatory Positive Expiratory Pressure (OPEP) device in addition to current ACT techniques. **Methods:** 16 patients were recruited from a paediatric CF clinic in North Wales to evaluate the Aerobika* OPEP device • Age 6-16 yrs • 10 male, 6 female • 3-month period. Patients were advised on implementing the use of the Aerobika* device for 15 breaths over 9 minutes in conjunction with their own individual ACT which included Active Cycle of Breathing (ACBT, 3 cycles), Forced Expiratory Techniques (FET) and in some cases Autogenic Drainage (AD). A pressure manometer was provided for some patients, depending on age and capacity prior to the trial. Telephone follow-up at 1 month post initiation was undertaken and a 5-point questionnaire including feedback from both patient/parent and physiotherapist at 3 months. Results: Evaluations were completed by 10 patients and 6 parents. All respondents (16) reported that they would continue using the device. Frequency of use was typically 3x daily and duration of use was an average of 9 minutes.





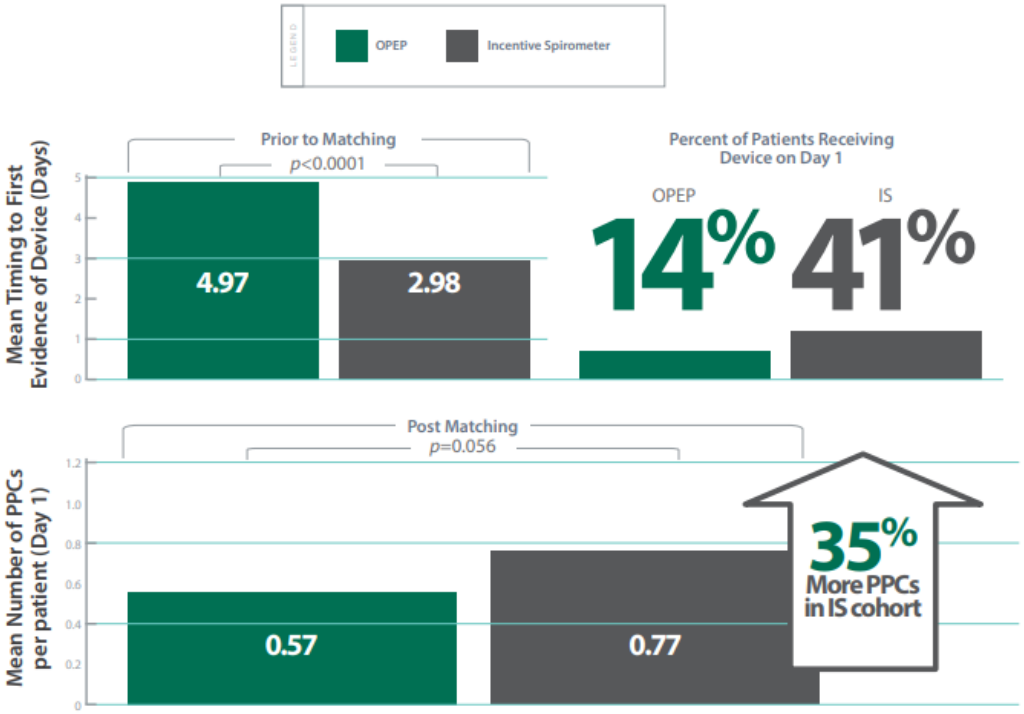
Conclusion: All 16 participating patients benefited from the use of the Aerobika* device to supplement their individual evidence-based regime of Airway Clearance Techniques (ACT). The Aerobika8 OPEP device was found to be a useful device for supplementing ACT for this Paediatric patient group with CF. Dependent on age, it was particularly useful to use the manometer device to regulate and modify changes to patient treatments dependent on their symptoms and disease progression. Both patients and parents reported improved adherence and frequency of treatment within their ACT.

STUDIES USING THE AEROBIKA OPEP IN POST-OPERATIVE PULMONARY COMPLICATIONS*

1. **NEW** *Assessment of Airway Clearance Therapy Usage and Outcomes in Post-operative Care – A Real World Evidence Study*

Suggett J[1], Coppolo D[2], Schloss J[2], Near A[3], Fu M[3], Tse, J[3]. [1]Trudell Medical International, Canada. [2]Monaghan Medical Corporation, USA. [3]IQVIA Medical and Scientific Services, USA. American Thoracic Society Conference. May 19 – 24, 2023. https://www.trudellmed.com/global/en-CA/news/airway-clearance-therapy-usage-and-outcomes-post-operative-care

Rationale: Post-operative pulmonary complications (PPCs) are a variety of conditions adversely affecting the respiratory system after anesthesia and surgery. Strategies to prevent and treat PPCs include techniques of lung re-expansion using incentive spirometry (IS), which is typically standard of care in the US, and oscillating positive expiratory pressure (OPEP) devices. However, recent systematic reviews concluded that there is a lack of evidence regarding the effectiveness of IS for the prevention of PPCs in cardiac, thoracic, or upper abdominal surgery. Previous studies have shown that the addition of an OPEP device to standard of care (IS) reduced all cause rehospitalizations and mean length of stay.1 This real-world retrospective study aimed to assess usage patterns of IS vs an OPEP device, and the impact on post-surgery PPCs. **Methods:** Adults ≥18 years of age with ≥1 hospitalization for cardiac, thoracic or upper abdominal surgery between 9/1/2013 and 7/1/2021 were identified from IQVIA's Hospital Charge Detail Master (CDM) database and linked to IQVIA's prescription (LRx) and medical claims (Dx); index visit was the first hospitalization for surgery. The IS only cohort included patients who had ≥1 CDM, Dx, and LRx record within 12 months prior to index visit and ≥1 CDM and Dx record after discharge, evidence of IS use and one surgery type during index hospitalization, and no evidence of any PEP or OPEP any time during or up to 3 months before index visit. The OPEP only cohort was selected similarly, except that patients were required to have evidence of a specific OPEP device (Aerobika*, Monaghan Medical) use during index hospitalization and no evidence of IS, OPEP, or PEP use up to 3 months before index visit. OPEP patients were 1:1 matched to IS patients using propensity score (PS) matching on age, gender, region, payer type, surgical procedure, index year, baseline comorbidity profile, and index visit duration. The timing of the device introduction during the index visit was assessed, as were the incidence of PPCs during the visit. **Results:** Prior to matching, 477 OPEP only patients and 65,506 IS only patients were identified; 477 patients remained in each cohort after PS-matching. Before matching, the mean timing during index visit with first evidence of device was day **4.97 and 2.98 (p<0.0001) for OPEP and IS respectively, with 14% of patients getting OPEP on day 1 vs 41% getting IS**. After matching, the mean timing of OPEP and IS were similar (day 4.97 and 4.56, p=0.205). The **mean number of PPCs per patient among patients with access to devices on day 1 was 0.57 and 0.77 (p=0.056) for OPEP and IS, respectively**. If the OPEP device was not given until day 3 or later, the mean number of PPCs increased to 1.12 (p=0.001).



Conclusions: This real-world study highlights that current US hospital practice favors the introduction of IS earlier than OPEP for post operative care. The hypothesis being that OPEP is given more commonly as a reaction measure to observed complications. When matched patient groups were compared, there was a trend towards less PPCs for the Aerobika* OPEP vs IS if each device was given on day 1. There was a significant increase in PPCs if the introduction of the OPEP device was delayed to day 3 or later. This study suggests that there could be benefits if the OPEP device was provided earlier and instead of IS when managing post operative care.

2. *A Real-World Evidence Study Assessing the Impact of Adding the Aerobika* Oscillating Positive Expiratory Pressure Device to Standard of Care Upon Healthcare Resource Utilization and Costs in Post-Operative Patients*

C Burudpakdee, AM Near, H Huang, D Coppolo, V Kushnarev, J Suggett. Pulmonary Therapy 2018;4(1):87-101.
https://doi.org/10.1007/s41030-018-0055-9

Introduction: The aim of this real-world study was to measure the benefit of the ***Aerobika****** oscillating positive expiratory pressure (OPEP) device when added to standard of care (defined as incentive spirometry [IS]) for post-operative patients. **Methods**: Adults aged ≥ 18 years who were hospitalized for cardiac, thoracic or upper abdominal surgery between 1 September 2013 and 30 April 2017 were identified from IQVIA's Hospital Charge Detail Master (CDM) database; the index date was the date of the first hospitalization for surgery. The control cohort (IS) included patients who had ≥ 1 CDM record within 12 months prior to the index date and ≥ 1 record after discharge, evidence of IS use during index hospitalization and no evidence of use of a PEP or OPEP device at any time during the study period. The ***Aerobika**** OPEP cohort was selected in a similar manner, except that patients were required to have evidence of ***Aerobika**** OPEP use during the index hospitalization. ***Aerobika**** OPEP patients were 1:1 matched to IS patients using propensity score (PS) matching. Hospital readmissions and costs were measured at 30 days post-discharge from the index hospitalization. **Results**: After PS matching, 144 patients were included in each cohort. At 30 days post-discharge, compared to the control (IS) cohort there were significantly fewer patients in the ***Aerobika**** OPEP cohort with ≥ 1 all-cause re-hospitalizations (13.9 vs. 22.9%; p = 0.042). The patients in the ***Aerobika**** OPEP cohort also had a shorter mean length of stay (± standard deviation) (1.25 ± 4.04 vs. 2.60 ± 8.24 days; p = 0.047) and lower total unadjusted mean all-cause cost per patient ($3670 ± $13,894 vs. $13,775 ± $84,238; p = 0.057). Adjusted analyses suggested that hospitalization costs were 80% lower for the ***Aerobika**** OPEP cohort versus the IS cohort (p = 0.001). **Conclusion**: Our results suggest that the addition of the ***Aerobika**** OPEP device to standard of care (IS) is beneficial in the post-operative setting.

STUDIES COMPARING OPEP DEVICES AND AIRWAY CLEARANCE TECHNIQUES.

The Difference Is Clear: OPEP Devices Are NOT All the Same

1. *Impact of Oscillating Positive Expiratory Pressure Device Use on Post-Discharge Hospitalizations: A Retrospective Cohort Study Comparing Patients with COPD or Chronic Bronchitis Using the Aerobika® and Acapella® Devices*

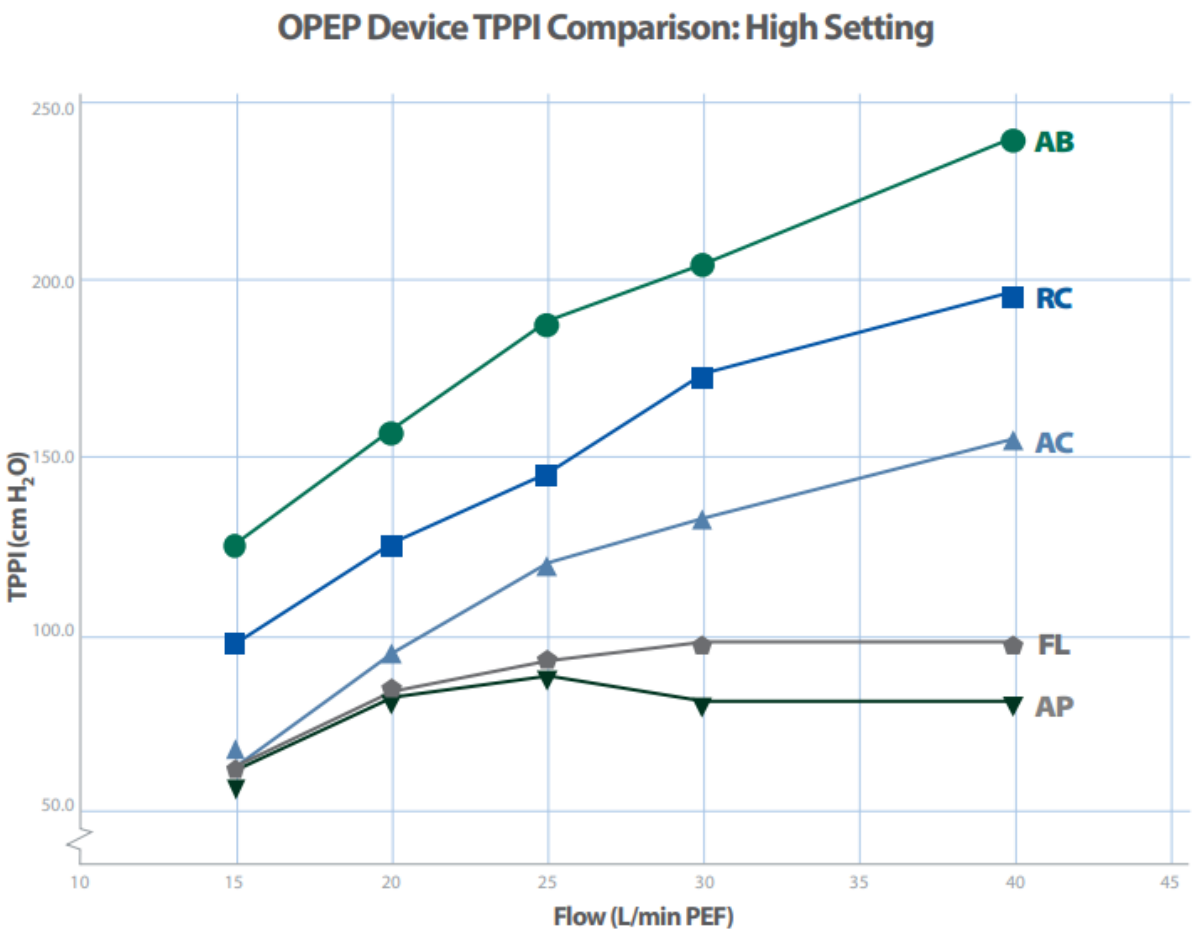
Jenny Tse, Keiko Wada, Yi Wang, Dominic Coppolo, Vladimir Kushnarev, Jason Suggett. International Journal of Chronic Obstructive Pulmonary Disease 2020:15 2527–2538 https://www.dovepress.com/impact-of-oscillating-positive-expiratory-pressure-device-use-on-post--peer-reviewed-fulltext-article-COPD

Background: Managing and preventing disease exacerbations are key goals of COPD care. Oscillating positive expiratory pressure (OPEP) devices have been shown to improve clinical outcomes when added to COPD standard of care. This retrospective database study compared real-world resource use and disease exacerbation among patients with COPD or chronic bronchitis prescribed either of two commonly used OPEP devices. **Patients and methods:** Patients using the Aerobika® (Trudell Medical International, London, ON, Canada) or Acapella® (Smiths Medical, Wampsville, New York, USA) OPEP device for COPD or chronic bronchitis were identified from hospital claims linked to medical and prescription claims between September 2013 and April 2018; the index date was the first hospital visit with an OPEP device. Severe disease exacerbation, defined as an inpatient visit with a COPD or chronic bronchitis diagnosis, and all-cause healthcare resource utilization over 30 days and 12 months post-discharge were compared in propensity score (PS)-matched Aerobika device and Acapella device users. **Results:** In total, 619 Aerobika device and 1857 Acapella device users remained after PS matching. After discharge from the index visit, Aerobika device users were less likely to have ≥1 severe exacerbation within 30 days (12.0% vs 17.4%, p=0.01) and/or 12 months(39.6% vs 45.3%, p=0.01) and had fewer 12-month severe exacerbations (mean, 0.7 vs 0.9 per patient per year, p=0.01), with significantly longer time to first severe exacerbation than Acapella users (log-rank p=0.01). Aerobika device users were also less likely to have ≥1 all cause inpatient visit within 30 days (13.9% vs 20.3%, p<0.001) and 12 months (44.9% vs 51.8%, p=0.003) than Acapella users. **Conclusion:** Patients receiving the Aerobika OPEP device, compared to the Acapella device, had lower rates of subsequent severe disease exacerbation and all-cause inpatient admission. This suggests that Aerobika OPEP device may be a beneficial add-on to usual care and that OPEP devices may vary in clinical effectiveness.

2. ***NEW*** *Effectiveness Assessment of Oscillating Positive Expiratory Pressure (OPEP) Devices: Using a Clinically Relevant Laboratory Measure*

Suggett, J.[1], & Costa, R.[1] [1]Trudell Medical International, London, ON, Canada. European Respiratory Society International Congress. September 9 – 13, 2023. *https://www.trudellmed.com/global/en-CA/news/effectiveness-assessment-oscillating-positive-expiratory-pressure-opep-devices-using*

Background: OPEP devices are used therapeutically to aid airway clearance where excess mucus is a challenge, such as in bronchiectasis, cystic fibrosis and COPD. The mechanism of device action can differ greatly between different OPEP devices and therefore clinical data is important to demonstrate the effectiveness of each device. A clinically relevant laboratory metric such as the one utilized in this study can provide additional insights into likely differences in effectiveness. **Methods:** Aerobika* (TMI), AirPhysio† (AirPhysio), Flutter† (Allergan), Acapella Choice† (ICU Medical) and RC Cornet† Plus (Cegla) OPEP devices (n=3, 3 repeats for each) were assessed at their highest resistance setting, utilizing simulated OPEP expiratory breathing patterns at various different peak expiratory flows (PEFs), using a pressure wave generator (Pulmonary Waveform Generator System – Model: wPWG). The total pressure pulse impact (TPPI), calculated as the sum of pressure pulse amplitudes for all discernible pulses (> 1.0 cm H2O) in a single exhalation, was determined for each pattern and each device. **Results:** The average TPPI values for each device are shown in the figure below.



Discussion/Conclusion: The therapeutic effectiveness of the air flow pulses, as assessed here via the laboratory TPPI value, is considered to be dependent on the ability of the device to generate and maintain significant pressure pulses throughout the exhalation. Higher pressure pulse amplitudes indicate greater changes in pressure differentials which can create stronger shear forces that reduce the viscoelastic properties of bronchial secretions, enabling secretions to be cleared from the airways.[1,2] The different mechanisms of OPEP device function appear to significantly impact the extent to which the pressure pulses are generated. The Aerobika* OPEP device (AB) demonstrated significantly larger TPPI values at all PEFs than other devices ($p<0.05$). The two devices with metal ball mechanism (AP, FL) had the lowest. Such differences highlight the risk of assuming that all devices will perform the same clinically and the importance of reviewing clinical efficacy and real-life usability when selecting an OPEP device.

[1]Coppolo D, Schloss J, Suggett J, Mitchell, J. Non-Pharmaceutical techniques for obstructive airway clearance focusing on the role of oscillating positive expiratory pressure (OPEP): a narrative review. Pulm Ther. 2021.
[2]Van Fleet H, et al. Respiratory Care. 2017;62(4):451-458

3. ****NEW**** *A Feasibility Randomised Control Trial (RCT) of OPEP Versus Active Cycle of Breathing Technique (ACBT) in People with Chronic Obstructive Pulmonary Disease (COPD)*

[1]CG Bridges, [2]L Graham-Wollard, [1]H Morris, [2]J Annandale, [2,3]KE Lewis. [1]Cardiff and Vale UHB, Cardiff, UK; [2]Hywel Dda UHB, Carmarthen, UK; [3]Respiratory Innovation Wales, Llanelli, Carmarthenshire, UK. *Thorax 2023; **78**: A43-A44. https://doi.org/10.1136/thorax-2023-BTSabstracts.62*

NICE guideline NG115 for COPD recommend Airways Clearance Techniques (ACTs) for people with excessive sputum but there have been no studies comparing different ACTs. **Aim:** To compare Oscillatory Positive Expiratory Pressure (OPEP, Aerobika*) vs Active Cycle of Breathing Technique (ACBT) following exacerbations of COPD. **Method:** A pilot, feasibility randomised controlled trial (ClinicalTrials.gov Identifier: NCT05548036). **Patient:** With confirmed COPD (GOLD 2023) and chronic bronchitis symptoms, who had not received ACTs previously. They were recruited in hospital or through community COPD nurses during (or within 4 days) of starting a moderate-severe exacerbation. Randomisation via sealed envelope determined whether they received 30–60 minutes of training on OPEP or ACBT by respiratory physiotherapists, face-to-face. All participants received antibiotics, steroids, nebulisers and oxygen in the acute phase according to clinical discretion. All were already prescribed optimal inhaled treatments. Participants were advised to continue twice daily OPEP or ACBT at home for at least 6 months. Groups were similar at baseline (all p=N.S). See table 1.

Abstract S56 Table 1 Participant characteristics at base line

Variable	OPEP (n=19)	ACBT n=23
Age	66 (10.3) yrs	69.7 (7.3) yrs
Male	37%	48%
Smokers	32%	13%
FEV_1% pp	50%	44%
MRC	3.4 (1.0)	3.5 (0.7)
CAT	31.0 (5.4)	32.6 (4.7)
LCQ-Total	63.8 (25.0)	61.2 (17.6)

Primary Outcome: Leicester Cough Questionnaire (LCQ) at 3 months post-intervention (via intention to treat analysis). **Results:** Mean (SD) Total LCQ at 3 months in the OPEP group was 87.3 (27.3) vs 91.9 (29.2) in the ACBT group, p=0.73, 95% CI -33 to +23.8. **Conclusion:** Both groups showed statistically significant and clinically important improvement in LCQ, post-exacerbation (MDCID 1.5–2 LCQ) but there is no significant difference in LCQ scores between OPEP (Aerobika*) vs ACBT groups at 3 months.

4. ****NEW**** *A Prospective Study to Identify the Benefits of Using an Oscillatory Positive Expiratory Pressure Device in the Management of Bronchiectasis*

Towers B, Kendrick C. Physiotherapy Dept, Blackpool Teaching Hospitals NHS Foundation Trust, Blackpool, UK. Chartered Society of Physiotherapy (CSP) Annual Conference. Abstract No. 266. November 1st, 2023.

Purpose: A main symptom of bronchiectasis is sputum production and expectoration. The British Thoracic Society (2019) advise that airway clearance techniques should be taught by a respiratory physiotherapist. Frequency and duration of airway clearance techniques should be tailored to the individual and a self-management plan should be created. Self-management plans should be individualised, incorporating daily airway clearance techniques, including a wide range of treatments, for example the active cycle of breathing technique (ACBT), postural drainage, and use of an OPEP device, such as an Aerobika. We wanted to explore the use of an Aerobika for symptom management of a cohort of patients with bronchiectasis. **Methods:** A prospective study, including qualitative and quantitative data, was collected over an 8-month period. Using clinical judgement, appropriate patients were identified and provided with an Aerobika. Patients were considered appropriate if they displayed good compliance with all aspects of their self-management plan, however, continued to struggle with expectorating sputum. An initial sample size of 20 patients was identified, 11 were able to participate in the full study and therefore included. Prescriptions and instructions were given verbally or hand-written. Patients were advised to complete 10 minutes of Aerobika use daily, consisting of 5-10 breaths followed by 2-3 x forced expiratory technique. An initial telephone questionnaire was completed 1 month after provision of the device. A second questionnaire was then completed at the subsequent clinic appointment. **Results:** The initial questionnaire results indicated the following: 7/11 patients were utilising the Aerobika as prescribed. All patients reported it was easy to use. On a scale of 0-5, 0 indicating no benefit and 5 indicating extremely beneficial, an average of 3.3/5 was scored, regarding the benefits it provided in clearing sputum. **9/11 patients reported the Aerobika to be more beneficial than ACBT as a standalone treatment, 2/11 patients felt unsure. Overall, 10/11 patients would recommend the use of an Aerobika to other individuals with bronchiectasis.** At clinic reviews, 9/11 patients were using the device as prescribed, identifying an increase in compliance. 6/11 patients felt a further improvement in their sputum clearance, and 5/11 felt their ability remained the same. 5/11 patients had no infections since device provision, and 6/11 patients had 1-2 infections within this period. 8/11 patients felt that using an Aerobika had a positive impact on their quality of life. Finally, all patients would continue to use the Aerobika once discharged from the service. **Conclusion:** Overall, the findings indicate that using an Aerobika can provide patients with bronchiectasis some benefits to managing their symptoms. In the future, it would be useful to create an inclusion and exclusion criteria to ensure that the whole cohort of appropriate patients is captured. To remove any risk of inconsistency, a standardised prescription could be created for each therapist to utilise when providing an Aerobika. **Impact:** For the future, as this study has identified the positive impacts of using an Aerobika, there is scope to consider whether patients should be given an Aerobika as a standard treatment modality within the Adult Bronchiectasis Service.

5. *Assessment of Two Oscillating Positive Expiratory Pressure (OPEP) Devices (Aerobika* v.s. AirPhysio): How do the Differing Mechanisms of Action Impact Lab Performance*

J. Suggett[1], R. Costa[1], J. Patel[2], A. Meyer[1]. Thorax 2022;77:A64.
[1]Trudell Medical International, London, ON, Canada. [2]Trudell Medical UK Limited, Grove House, Lutyens Close Chineham Court, Basingstoke, Hampshire
http://dx.doi.org/10.1136/thorax-2022-BTSabstracts.108

Rationale: OPEP devices are often used therapeutically in order to aid airway clearance where excess mucus is a challenge, such as in bronchiectasis, CF and COPD. Ease of use, ability to clean and adaptability to use with nebulizers are real world differentiators for different types of OPEP device, however the mechanism of device action can also differ. This laboratory study compared an established, clinically supported OPEP device with a recently introduced one that is based on older technology. Key in-vitro performance parameters were compared. **Methods:** Aerobika* (Trudell Medical International, Canada) and AirPhysio (AirPhysio, Australia) OPEP devices (n=3) were assessed at steady expiratory flows of 10–30L/min using a flow generator (Resmed VPAP III), flow meter (TSI 4000), pressure tap and computer for data collection and analysis. Average positive pressure, pulse amplitude and pulse frequency were determined for each device. **Results:** As each device can be operated at different resistances, the values at medium resistance are reported in figure 1. **Discussion/Conclusions:** For effective performance, frequency is typically desired to be in the 10–15 Hz range, mean pressure ideally between 10–20 cm H_2O, and pulse amplitude as large as possible. The results for the two devices show that although mean pressures are similar across the range of flow rates, the amplitudes are higher for the Aerobika* OPEP device and the frequencies are more often in the desired range. The observed differences are probably due to the fact that each device operates according to a different mechanical principle. What is clear from these results is that, in addition to real world usability assessments, it is important to understand that each OPEP device can perform differently mechanically. Hence, when selecting an OPEP device for a patient, the existence of clinical evidence supporting efficacy, as well as patient preference, should be considered. All devices will not perform the same.

6. *A Retrospective Cohort Study Comparing an Oscillating Positive Expiratory Pressure (OPEP) Device vs Positive Expiratory Pressure (PEP) Devices in Patients with Chronic Obstructive Pulmonary Disease (COPD) or Chronic Bronchitis on Hospital Readmissions at 30 Days*

J. Suggett[1], V. Kushnarev[1], D. P. Coppolo[2], J. Tse[3], K. Wada[3]. American Journal of Respiratory and Critical Care Medicine. 2021;203:A2264.
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https://doi.org/10.1164/ajrccm-conference.2021.203.1_MeetingAbstracts.A2264

Rationale: For patients with COPD, acute exacerbations are the most common reason for hospital admissions, with approximately 1 in 5 patients requiring re-hospitalization within 30 days of discharge. The Aerobika* OPEP device has previously been shown to significantly improve outcomes such as ease in bringing up sputum, forced vital capacity, quality of life, and exacerbations, when added to standard of care. This retrospective cohort study described real-world outcomes among patients with COPD or chronic bronchitis, comparing the Aerobika* OPEP device to the similar, but more basic PEP device, which does not generate pressure pulses. **Methods:** IQVIA's Charge Detail Master (CDM) hospital claims database linked to medical (Dx) and prescription claims (LRx) data were used to identify patients receiving the Aerobika* (Trudell Medical International) OPEP device or any PEP device between September 2013 and November 2018; the index date was the first CDM record with an OPEP/PEP device. Patients were required to be ≥18 years of age and have ≥1 hospital and LRx/Dx records within 12 months before and after index, ≥1 COPD/chronic bronchitis diagnosis during the index visit and no asthma diagnosis before index or post-operative device use within 30 days before index. Patients receiving the Aerobika* OPEP device were propensity score (PS) matched to patients receiving a PEP device based on demographics and baseline comorbidities, history of exacerbations and drug therapy. The proportion of patients experiencing a COPD/chronic bronchitis related readmission within 30 days of the index visit was evaluated. **Results:** After 1:1 PS matching, 588 patients receiving Aerobika* and 588 receiving PEP were compared. Baseline characteristics were well-balanced. Patients using Aerobika* OPEP had a 31% reduction in COPD/chronic bronchitis related readmission within 30 days of the index hospitalization compared to those patients with a PEP device (12.4% vs. 17.9%; p=0.006). **Conclusions:** Results from this study demonstrate a reduction in COPD/chronic bronchitis related readmissions within 30 days of Aerobika* OPEP device therapy initiation compared to PEP therapy. This further supports the use of the Aerobika* OPEP device as an add-on to usual care to manage COPD/chronic bronchitis patients post-exacerbation and provides some evidence as to the additional benefit of pressure oscillations over standard PEP.

7. *A Laboratory Assessment into the Efficiency and Effectiveness of Different Oscillating Positive Expiratory Pressure Devices by Means of Patient Simulated Expiratory Waveforms*

A Meyer, J Suggett. Presented at CHEST 2017. https://www.trudellmed.com/sites/default/files/inline-files/aerobika-chest-2017.pdf

Rationale: Oscillating Positive Expiratory Pressure (OPEP) devices can be used to manage a variety of conditions, such as CF, COPD, bronchiectasis and post-surgical recovery. OPEP devices function through a general mechanism of opening / vibrating airways and loosening mucus, however, the specific mechanism by which this is achieved differs between different devices. This investigation assesses the positive pressure oscillation waveforms of various devices and evaluates each critically in terms of consequential efficiency and effectiveness of action. **Materials and Methods**: A simulated OPEP exhalation maneuver was generated based on previous research[1] in which a flowmeter (TSI4040 TSI, US) was used to record the waveforms of 5 healthy adults. An average profile was then scaled so the Peak Expiratory Flow rate (PEF) was 30 L/min, thereby being more patient representative. This patient representative waveform was then used to operate, via a breathing simulator (ASL5000 IngMar, US), a range of different OPEP devices; *n* = 3 devices, 3 replicates of each. The pressure / time waveforms were recorded (Pressure Transducer, Honeywell, USA) for each device, set at their highest resistance to enable direct comparison. In addition, various critical performance parameters were determined: percentage of exhaled breath with discernable oscillations (> 1.0 cm H_2O), t_{osc} [%]; average oscillation amplitude; Total Pressure Pulse Impact (TPPI) = sum of discernable pressure amplitudes in a single exhalation. **Results**: Each device waveform had its own unique pattern, as summarized in Table 1. In terms of the percentage of breath with oscillations and the average oscillation pressure amplitude, the ***Aerobika****** OPEP device exhibited the highest values for both, with the vPEP† and Flutter† devices the lowest for each respectively.

Table 1: Device Performance Comparison

Device	t_{osc}[%]	Avg Amp [cm H_2O]	# of osc	TPPI [H_2O]
Aerobika* OPEP	81%	13.9	36	495
vibraPEP†	69%	9.4	27	256
Acapella Choice†	67%	5.8	41	236
Flutter†	62%	3.0	46	139
vPEP†	45%	4.5	25	112

Conclusions: TPPI assesses both efficiency and effectiveness of the device: efficiency relates to the percentage of breath with oscillations; effectiveness relates to the number and amplitude of the oscillations. The therapeutic effectiveness of the air flow oscillations, as assessed here via the TPPI value, is considered to be dependent, in part, on the ability of the device to generate and maintain a pressure amplitude or turbulent spike throughout the maneuver.[2] The TPPI values showed the ***Aerobika**** OPEP device to be the most effective, with double the value of the second ranking device.

1 Meyer A *et al*, Assessment of Oscillating Positive Pressure Devices by Means of Adult Expiratory Waveforms: A Laboratory Study, Am J Respir Crit Care Med 2014; 189:A3036. 2 Van Fleet *et al*, Evaluation of Functional Characteristics of 4 Oscillatory Positive Pressure Devices in a Simulated Cystic Fibrosis Model, Resp Care 2017;62(4):451-458.

8. *Patient Centered Considerations when Selecting an Oscillating Positive Expiratory Pressure (OPEP) Device*

J. Suggett[1], J. Schloss[2]. North American Cystic Fibrosis Conference. November 3-5, 2022.
[1]Trudell Medical International, London, Canada. [2]Monaghan Medical Corp., Plattsburgh, NY, USA.
https://www.trudellmed.com/ca/en-CA/news/patient-centered-considerations-when-selecting-oscillating-positive-expiratory-pressure-opep

Introduction: Efficacy is a major aspect when selecting an OPEP device for airway clearance. However, usability of the device is also another very important aspect to consider in device selection as this may affect adherence to the therapy. This study compares patient use factors for several different OPEP devices (covering design improvements introduced over time) with the aim of highlighting usability differences, as it may help with device selection. **Methods:** Four different OPEP devices were evaluated. These were: 1. Aerobika® (Monaghan Medical) 2. Acapella Choice Blue† (Smiths Medical) 3. Flutter† and similar (multiple manufacturers – e.g. Pari OPEP, AirPhysio, Gelomuc†) 4.

vPEP† (DR Burton). Previous studies have outlined the performance differences between devices, due to differences in mechanical action, which are likely to result in different patient outcomes. The patient 'friendly' factors that were assessed to evaluate usability of each device were: A. Orientation independent use, B. Ability to change exhalation resistance, C. Ease of cleaning, D. Ease of disinfecting, E. Life span of device, and F. Ability to use connected to a nebulizer. For each factor, a score of either 1, 3 or 5 (the higher the better) was assigned, enabling a total score to be calculated. The scoring justification is supported from device leaflet content and previous publications. **Results:** See attached table. **Conclusions:** The many differences in device ease of use and flexibility that are shown in the table will hopefully provide some guidance when selecting the best device for each patient. Combining usability findings with evidence of likely efficacy when adherent will enable a more objective selection of device. Notwithstanding that the patient themselves will provide good validation of the correct choice.

9. A Laboratory Assessment of Nebulized Medication Delivery Through Different Oscillating Positive Expiratory Pressure (OPEP) Devices – Not all Devices are the Same

J. Suggett1. 5th World Bronchiectasis & NTM Conference. Prague, 30 June – 2 July, 2022.
1Trudell Medical International, London, Canada.
https://www.trudellmed.com/ca/en-CA/news/laboratory-assessment-nebulized-medication-delivery-through-different-oscillating-positive

Introduction: Medications to manage care of bronchiectasis and NTM patients are often delivered via a nebulizer, as they are easy to use. OPEP devices are also often used for airway clearance by the same group of patients and the two treatments can be combined allowing medication delivery on inhalation and OPEP therapy on exhalation. This study compares a number of different OPEP / Nebulizer combinations using salbutamol as the modelled medication. **Methods:** Four different OPEP / Nebulizer systems were evaluated. These were: A. AEROBIKA* OPEP with AEROECLIPSE* II BAN* Nebulizer at back of OPEP, B. acapella† Choice OPEP with VixOne† nebulizer using t-piece at front of OPEP, C. acapella† Choice Blue OPEP with AEROECLIPSE* II BAN* Nebulizer at back of OPEP, D. acapella† Choice Blue OPEP with Salter Labs† 8900 nebulizer using t-piece at front of nebulizer. Medication delivery (total emitted mass until sputter) of salbutamol 2.5 mg in 3 ml was determined in the lab for each system using a breathing simulator and filter collection at mouthpiece (settings: 600 ml tidal volume, 1:3 I:E ratio, 2s pause after inhalation). **Results:** See attached table. **Conclusions:** The results show that OPEP/Neb combination selection can have a large impact on the amount of drug delivered. The AEROBIKA* OPEP / AEROECLIPSE* breath actuated device combination delivered more than 3x as much salbutamol in a treatment compared to the other combinations. Combining OPEP and nebulizer therapy has advantages in terms of patient efficiencies, convenience, and adherence, however care should be taken to ensure the drug delivery is not compromised.

10. Non-Pharmaceutical Techniques for Obstructive Airway Clearance Focusing on the Role of Oscillating Positive Expiratory Pressure (OPEP): A Narrative Review.

D.P., Coppolo, J. Schloss, J. Suggett, J. Mitchell. Pulm. Ther. ***8****, 1-41 (2022).* *https://doi.org/10.1007/s41030-021-00178-1*

Abstract: Mucus secretion in the lungs is a natural process that protects the airways from inhaled insoluble particle accumulation by capture and removal via the mucociliary escalator. Diseases such as cystic fibrosis (CF) and associated bronchiectasis, as well as chronic obstructive pulmonary disease (COPD), result in mucus layer thickening, associated with high viscosity in CF, which can eventually lead to complete airway obstruction. These processes severely impair the delivery of inhaled medications to obstructed regions of the lungs, resulting in poorly controlled disease with associated increased morbidity and mortality. This narrative review article focuses on the use of non-pharmacological airway clearance therapies (ACTs) that promote mechanical movement from the obstructed airway. Particular attention is given to the evolving application of oscillating positive expiratory pressure (OPEP) therapy via a variety of devices. Advice is provided as to the features that appear to be the most effective at mucus mobilization.

11. A Randomized Controlled Trial of 4 Weeks of Airway Clearance with Oscillating Positive End Expiratory Pressure Device Versus Autogenic Drainage in People with Bronchiectasis

Michal Shteinberg, Naama Yaari, Nili Stein, Lea Bentur, Galit Livnat, Yochai Adir
European Respiratory Journal 2020 56: 4103; DOI: 10.1183/13993003.congress-2020.4103

Background: Airway clearance (AWC) is a fundamental component of care in bronchiectasis, but evidence of efficacy are few. Lung clearance index (LCI) is a promising measurement of ventilation inhomogeneity. Its responsiveness to AWC has not been demonstrated.
Aim: To compare effects of two methods of AWC- Autogenic Drainage (AD) and Oscillating Positive Airway Pressure (oPEP) on LCI, spirometry, sputum quantity, and quality of life.

Methods: Adult patients with bronchiectasis, naive to airway clearance, were randomized and instructed to daily AWC with either AD or oPEP (Aerobika, Trudell pharma, Canada). Weekly phone calls were performed to evaluate adherence to AWC. Multiple breath washout, spirometry, sputum volume and purulence, and QOL- B questionnaire were measured at randomization and after 4 weeks of AWC.
Results: 51 patients were randomized and 49 completed the study (25 AD, 24 oPEP). Adherence was 87% (oPEP) and 88% (AD). LCI and FEV1 did not change between visits in either groups. Sputum quantity decreased in 12/24 of the oPEP group, and in 6/25 (24%) of the AD group, (p=0.044). 'Treatment burden' was worsened or unchanged in 70% of participants randomized to AD and 55% randomized to oPEP (p=0.038). During the study, 11 participants experienced a pulmonary exacerbation (6 AD, 5 oPEP). When these participants were excluded from the analysis, LCI improved in the oPEP group only (-0.59 vs. -0.1 in the AD group), without statistical significance (p=0.45).
Conclusions: Sputum quantity was improved after one month of oPEP, without an increase in treatment burden. No change in LCI was seen with AWC.

12. 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.
https://thorax.bmj.com/content/thoraxjnl/early/2013/02/12/thoraxjnl-2012-202915.full.pdf

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, haemaptysis, 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."

13. Evaluation of Functional Characteristics of 4 Oscillatory Positive Pressure Devices in a Simulated Cystic Fibrosis Model

H Van Fleet, DK Dunn, NL McNinch, TA Volsko. Respiratory Care 2017;62(4):451-458.
https://doi.org/10.4187/respcare.04570

Background: Oscillatory positive expiratory pressure (OPEP) is an airway clearance therapy that delivers positive pressure and air-flow oscillations during exhalation. This study described functional characteristic differences of 4 OPEP devices during an active exhalation in a simulated model. We hypothesized peak pressure (Ppeak), positive expiratory pressure (PEP), oscillatory frequency (f), and pressure amplitude will differ, depending upon the device used, device resistance setting, and time (repeated consecutive active exhalations through the device). **Methods**: The ASL 5000 was scripted to simulate pulmonary mechanics of a pediatric cystic fibrosis patient with moderate to severe lung disease. Airway resistance was standardized at 17.1 cm H_2O/L/s, pulmonary compliance at 42.1 mL/cm H_2O, active exhalation at 22 breaths/min, and tidal volume at 409 mL. Resistance settings for the Acapella, RC-Cornet, Flutter, and ***Aerobika***** were adjusted to low, medium, and high. Values for f, Ppeak, PEP, and pressure amplitude were recorded for 1 min and graphically displayed. **Results**: Significant effects for time, device, and resistance ($P < .01$) were noted for Ppeak, PEP, and pressure amplitude at each resistance level, demonstrating that the devices functioned differently as more than one repetition of a series of consecutive active exhalations are performed. Significant interaction effects for device, resistance level, and time indicate inconsistent output for Ppeak ($P < .01$), PEP ($P < .01$), and pressure amplitude ($P < .01$). Oscillatory f values fell within the respective manufacturers' operational parameters. The ***Aerobika***** provided the most consistent pressure amplitude across resistance settings and produced the highest mean pressure amplitude at medium and high resistance settings. **Conclusions**: Statistically significant and clinically relevant variations in Ppeak, PEP, and pressure amplitude occurred between devices and within a device, as the resistance setting changed. The combination of device, time, and resistance settings affects OPEP device output for pressure, amplitude, and oscillatory frequency. Functional variations may impact therapeutic effectiveness, warranting additional study to determine clinical impact.

14. *Comparing the Performance Characteristics of Different Positive Expiratory Pressure Devices*

Lisa J Franks, James R Walsh, Kathleen Hall, Guillermo Jacuinde, Stephanie Yerkovich, and Norman R Morris. Respir Care. 2019 Apr;64(4):434-444. doi: 10.4187/respcare.06410. Epub 2019 Jan 22. PMID: 30670668.

Background: Positive expiratory pressure (PEP) devices are widely used in clinical settings, yet the performance characteristics of these devices remain relatively unknown. This study compared the performance characteristics of 6 airway clearance devices by varying resistance and flow. **Methods:** Mean PEP, peak PEP, oscillation frequency, and amplitude PEP of the Flutter, Pari PEP S, Acapella Choice, Acapella DM, Acapella DH, and Aerobika devices were obtained across flows of 5, 10, 15, 20, 25 and 30 L/min and at low, medium, and high resistance using an experimental apparatus custom-built for this bench study. **Results:** Performance characteristics of the devices differed across flows and resistance settings (device × flow/resistance interaction; $P < .001$). At a fixed resistance, increasing flows increased mean PEP produced by the Acapella Choice, Acapella DH, Aerobika, and Pari PEP S. Increasing flow resulted in minimal change in mean PEP produced by the Flutter and Acapella DM. Increasing flow increased peak PEP and amplitude PEP produced by all devices except the Acapella DH and Acapella Choice. Increasing flow maintained or increased oscillation frequency for all devices except the Flutter. At a fixed flow, increasing resistance increased mean PEP produced by all devices except the Acapella Choice. Increasing resistance increased peak PEP produced by the Acapella DM, Aerobika, and Pari PEP S but resulted in minimal change in peak PEP for the Flutter and Acapella Choice. Increasing resistance either maintained or increased oscillation frequency for all devices. Amplitude PEP was either maintained or increased during oscillations when increasing resistance for all devices except the Flutter. **Conclusions:** PEP devices produced small but statistically significant variations in performance characteristics across a range of flows and resistance settings. There appear to be flow-dependent and non-flow-dependent devices. Varying flow or resistance typically maintained or increased the production of mean, peak, and amplitude PEP and oscillation frequency.

15. *Performance Characteristics of Positive Expiratory Pressure Devices*

Demchuk AM, Chatburn RL. Performance Characteristics of Positive Expiratory Pressure Devices. Respir Care. 2021 Mar;66(3):482-493. doi: 10.4187/respcare.08150. Epub 2020 Sep 15. PMID: 32934102.

Background: Positive expiratory pressure (PEP) therapy imposes expiratory flow resistance to increase airway diameter and enhance mucus clearance. PEP is achieved several ways. Oscillatory PEP devices (OPEP) generate repeated occlusions that are known to reduce mucus viscosity. There are many marketed devices, but comparative performance is mostly unreported. The purpose of this study was to evaluate performance characteristics of many PEP/OPEP devices. For OPEP devices, we defined an optimal performance metric by creating an oscillation index that combines the OPEP performance characteristics. **Methods:** PEP devices (TheraPEP, EzPAP, VersaPAP, Resistex, AccuPEP, AccuPAP, and Threshold PEP) and OPEP devices (Acapella DH, Acapella DM, Acapella Choice, ShurClear, Aerobika, VibraPEP, vPEP, and PocketPEP with and without the Oxyjet attachment) were tested by adjusting simulated expiratory flow from 5 L/min to 30 L/min in increments of 5 L/min using a standard flow meter. **Results:** All devices showed varying performance characteristics. As expiratory flow increased, mean PEP increased for most devices. The TheraPEP showed a mean PEP of 13 cm H2O across all settings. For OPEP devices, there was a major difference between pressure and flow waveforms. The Acapella DH, ShurClear, and Aerobika showed the highest flow amplitude, flow frequency, and oscillation index. **Conclusions:** PEP devices behaved similarly and as expected, with increased pressure with increased flow (flow resistors) or flow independence (threshold resistors). There was much greater variation in the performance of the OPEP devices. A higher oscillation index indicates better mechanical performance characteristics. Many devices have similar characteristics. However, the devices with the highest oscillation index have the highest flow amplitude and frequency, which may indicate better clinical performance.

16. *Assessment of a New Pressure Manometer for Use with an Oscillating Positive Expiratory Pressure Device*

J Suggett, N Alizoti, A Meyer. Presented at ERS 2015 https://erj.ersjournals.com/content/46/suppl_59/PA715

Rationale: Airway clearance therapy using Oscillating Positive Expiratory Pressure (OPEP) devices can be used to help mobilize and clear excess mucus secretions in the lungs. The desired therapeutic positive expiratory pressure range is often considered to be between 10 and 20 cm H2O. Confirmation of this therapeutic pressure range can be achieved using a manometer attachment with an OPEP device. This investigation assessed how a new pressure manometer incorporated onto the ***Aerobika**** OPEP device might influence the frequency of oscillations. **Materials and Methods:** A new pressure manometer was assessed with the ***Aerobika**** OPEP device. The manometer accessory can be attached directly to the OPEP device and is visible to the user during device use**.** Seven healthy volunteers were instructed to exhale through the OPEP device (without manometer attachment) according to the instructions for use (3 replicate exhalations per subject) and the average frequency of all oscillations per breath were

calculated for each subject. Pressure oscillations were recorded by means of a sensitive pressure transducer (Honeywell, Morristown, NJ) – from these profiles, oscillation frequencies in Hz could be determined. The same seven volunteers then repeated the exercise with the manometer attached to the OPEP device and were instructed to target the middle of the desired pressure range on the manometer (green zone, or 5 – 20 cm H2O). The relationship between pressure and frequency is independent of the user and therefore would be expected to be the same if patients were using the device rather than healthy volunteers. **Results:** The average frequencies of OPEP oscillations determined for each volunteer, with and without the manometer, are represented in the table below. A theoretical optimum frequency range is 12 –15Hz (King *et al*, 1983; Silva *et al*, 2009).

Participant	Without Manometer	With Manometer
1	11.3	13.0
2	15.5	13.8
3	12.5	13.7
4	17.3	14.8
5	9.8	13.6
6	14.0	13.9
7	13.7	15.3
Mean	13.4	14.0
SD	2.3	0.7
Range	9.8 – 17.3	13.0 – 15.3

Discussion & Conclusions: The manometer attachment was able to be used quickly and effectively by all seven volunteers. With the manometer attachment connected and the instruction to target a level in the middle of desired pressure range the oscillation frequencies were more consistent, and interestingly, were even closer aligned to the reported optimum Hz range. For patients uncertain of the amount of exhalation effort to use, the OPEP with manometer attachment provided feedback as to the safe and effective positive pressure level to stay within during the therapy. The use of such a manometer may therefore be useful as part of routine therapy or as a training aid.

17. *Combining Inhalation by a Breath Actuated Nebulizer and Exhalation with Oscillating Positive Expiratory Pressure Device Offers Potential for Simultaneous Therapy: A Laboratory Study*

R Sharpe, J Suggett, V Avvakoumova, H Schneider, R Ali and MW Nagel. Presented at the European Cystic Fibrosis Conference 2015. https://www.sciencedirect.com/science/article/pii/S1569199315303453

Background: Oscillating Positive Expiratory Pressure (OPEP) therapy is used to mobilize secretions associated with lung diseases for pulmonary rehabilitation, like Cystic Fibrosis. Traditionally, OPEP therapy has been conducted separately from aerosol therapy. **Study Purpose**: An innovative hand-held oscillatory positive expiratory pressure device (***Aerobika***** OPEP) can be connected directly to the ***AEROECLIPSE***** II Breath Actuated Nebulizer (BAN). The patient can thereby receive aerosol therapy and secretion mobilization simultaneously. The ***Aerobika***** OPEP device can also be used with any continuous nebulizer with a 22 mm adapter. *In vitro* measurements of BAN aerosol delivery performance when connected with the ***Aerobika***** OPEP device. In this configuration (Inhalation), the aerosol flow path is linear with minimal restriction to mitigate internal losses caused by inertial impaction. When the patient exhales (Exhalation), the one-way valve closes, diverting the flow through the body of the OPEP device mechanically operating the vane that generates oscillatory pressure pulsations that are transmitted back to the patient. **Materials and Methods**: Measurements were made (9 replicates) of total and fine droplet mass < 5.4 µm by Next Generation Impactor (NGI) equipped with a Ph.Eur./USP induction port and operated at 15.0 L/min ± 5%. The BAN on test was operated by compressed air delivered at 50 psig and filled with 4-ml ipratropium bromide solution for nebulization (0.5 mg/mL). The BAN was initially tested connected directly to the induction port via a leak-tight fitting. The measurements were repeated with the ***Aerobika***** OPEP device inserted between the BAN and induction port. The BAN on test was run to onset of sputter, and the Total Mass of ipratropium bromide (TM_{ipr}) recovered and assayed by a validated HPLC-UV spectrophotometric method. Measurements were also made with the acapella† duet † Vibratory PEP Therapy System (Smiths Medical North America, Dublin, OH). The purpose of this arm was to examine what might happen if a clinician was to make this substitution.

Results (mean ± SD):

	BAN Alone	BAN – *Aerobika** device	BAN – acapella† duet†
TM*ipr* (ug)	582 ± 30	515 ± 28	308 ± 23
FM*ipr* (ug)	452	426	196

Conclusions: Offering the patient the opportunity to combine aerosol and OPEP therapy will reduce the overall length of treatment time. The delivery of medication from the ***AEROECLIPSE**** II BAN is only marginally reduced by combining the BAN with the ***Aerobika**** OPEP device. Substitution by devices that do not allow incoming aerosol to be transported directly to the patient, are likely to result in substantial loss of aerosol.

18. *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. Presented at ATS 2014.
https://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2014.189.1_MeetingAbstracts.A3036

Background: The development of the new ***Aerobika**** Oscillating Positive Expiratory Pressure (OPEP) device (Trudell Medical International), required assessment of performance under realistic conditions of adult use to aid prescribing clinicians. At the same time, comparative measurements were made with other commercially available OPEP devices to gather benchmark data against which to compare the ***Aerobika**** OPEP device. **Materials and Methods:** A healthy adult volunteer exhaled into the ***Aerobika**** OPEP device set to the high resistance setting. The subject followed typical instructions for an OPEP device: exhale actively but not forcefully, achieve exhalation durations between 3 – 4 times the duration of inhalation, and replicate exhalation patterns (*n*=5) were recorded and the average profile was then scaled so that the Peak Expiratory Flow rate (PEF) ranged from 15 to 40 L/min. These patient representative scaled profiles were then used to operate the ***Aerobika**** OPEP device by means of a programmable flow generator (modified Pulmonary Waveform Generator using Hoyt – PWG hardware). The pressure oscillations were recorded by means of a sensitive pressure transducer (Honeywell, Morristown, NJ, USA). The percentage of each simulated exhalation profile during which discernable pressure oscillations (>1.0 cm H2O) were evident (*tosc*) was calculated. The procedure was repeated with other prescribed OPEP devices (green-DM acapella†; Smiths Medical North America, Norwell, MA, USA vibratory PEP (vPEP) devices and RC-Cornet†; Curaplex, Dublin, OH, USA. **Results:** The Comparative Values of tosc at different adult PEFs for Simulated Exhalation Profiles are summarized in the Table below.

			***tosc* (%)**		
PEF (L/min)	**15**	**20**	**25**	**30**	**40**
Aerobika*	76.0	77.0	79.5	81.0	81.5
acapella† green-DH	34.5	51.0	53.0	58.5	62.5
RC Cornet†	30.0	47.0	50.0	60.5	59.0

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 *tosc* [% 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 *tosc* values, ranging from 30% to 63%. Duration of oscillations for ***Aerobika**** OPEP was 52-60% greater on average compared to other devices.

19. *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. Presented at Respiratory Drug Delivery 2014.
https://www.researchgate.net/publication/288490455_COMPARATIVE_LABORATORY_STUDY_OF_OSCILLATING_POSITIVE_EXPIRATORY_PRESSURE_WAVEFORMS_FROM_COMMERCIALLY_AVAILABLE_DEVICES_USED_IN_AIRWAY_CLEARANCE_THERAPY

Background: Oscillating Positive Expiratory Pressure (OPEP) based treatment is becoming widely adopted in pulmonary rehabilitation as an alternative to postural drainage of mucus-based secretions for Airway Clearance Therapy (ACT). These devices are useful for patients unable to mobilize secretions by coughing alone, associated with diseases such as Chronic Obstructive Pulmonary Disease (COPD), bronchiectasis and cystic fibrosis. The ***Aerobika**** hand-held OPEP device (Trudell Medical, London, Canada) has the following features: can be used by patients in any orientation, has adjustable resistance settings to enable, patients to set according to their specific requirements, can be taken apart and cleaned at home daily. With OPEP, expiratory pressure stents the airways

open and helps fill under-inflated or collapsed alveoli while oscillation creates short bursts of increased expiratory airflow to thin, dislodge and move mucus to the central/upper airways where it can be coughed out. **Materials and Methods**: In order to develop exhalation breathing profiles representative of the OPEP maneuver an ***Aerobika***** OPEP device (*n*=1) was connected to pressure (Honeywell, Morristown, NJ) and flow (model 4000, TSI Corp., St Paul, MN) sensors. A series of exhalation flow rate waveforms as a function of elapsed time from the start of exhalation were recorded from adult volunteers (*n*=5), who had been trained to use the device in accordance with instructions: exhale actively but not forcefully, achieve exhalation durations between 3 to 4 times the duration of inhalation, replicate exhalation patterns (*n*=5) were recorded and the average profile was then scaled so that the Peak Expiratory Flow rate (PEF) ranged from 15 to 40 L/min. These patient representative scaled profiles were then used to operate the ***Aerobika***** OPEP device by means of a programmable flow generator (MH Custom Design & Manufacturing, Midvale, UT). The percentage of each simulated exhalation profile during which discernable pressure oscillations (>1.0 cm H2O) were evident (t*osc*) was calculated. The procedure was repeated with other prescribed OPEP devices (green-DM acapella†; Smiths Medical North America, Norwell, MA, USA vibratory PEP (vPEP) devices and RC-Cornet†; Curaplex, Dublin, OH, USA. Three devices of each type were each tested once. **Results:** Comparative values of t*osc* at different adult PEFs for simulated exhalation profiles were summarized. This range was deemed likely to encompass the achievable performance of most users of these devices. Measures of t*osc* with the ***Aerobika***** OPEP device were >75% at all PEF settings and were generally consistent. The other OPEP systems exhibited lower and much more variable t*osc* values ranging from 30% to 63%. The frequencies of the oscillations for each device using the 30 L/min PEF exhalation profile were 15.2 Hz, 18.6 Hz, and 28.7 Hz for the ***Aerobika***** OPEP, acapella† and RC Cornet † devices, respectively. It has been reported that a frequency range of 12-15 Hz is optimal, due to the correlation with average frequency of ciliary beating in the upper airways hence enabling easier expectoration. **Conclusions:** It is intuitive to associate higher values of t*osc* at a given PEF with improved efficacy of secretion mobilization. On this basis, the ***Aerobika***** OPEP device performed well, especially at lower values of PEF likely to be encountered with patients having more obstructed airways. The oscillation frequencies determined for the ***Aerobika***** OPEP device were closest to the reported optimum range for airway clearance. Furthermore, initial clinical studies[1] with COPD patients support these *in vitro* results.

1 Kanhere, N, Hasany, A, Kirby, M, Suggett, J, McCormack, DG, Parraga, G: Hyperpolarized ^{3}He magnetic resonance imaging following oscillatory positive expiratory pressure treatment in GOLD Stage II and III chronic obstructive pulmonary disease, Proc Am J Respir Crit Care Med 2013, 187: A4884.

STUDIES EVALUATING AIRWAY CLEARANCE IN COPD, BRONCHIECTASIS, AND CYSTIC FIBROSIS *(NON-AEROBIKA* OPEP STUDIES)*

STUDIES EVALUATING AIRWAY CLEARANCE TECHNIQUES IN COPD

*1. **NEW** Physiotherapy-Led, Community-Based Airway Clearance Services for People with Chronic Lung Conditions: A Retrospective Descriptive Evaluation of an Existing Model of Care*

Cooper, L., Johnston, K. & Williams, M. Physiotherapy-led, community-based airway clearance services for people with chronic lung conditions: a retrospective descriptive evaluation of an existing model of care. BMC Health Serv Res ***24****, 98 (2024).* https://doi.org/10.1186/s12913-024-10550-x

Objectives: Airway clearance interventions are recommended for people with chronic lung conditions and mucus hypersecretion, but there are few published models of care or descriptions of airway clearance service provision. This evaluation describes a dedicated, physiotherapy-led, community-based airway clearance service in a metropolitan local health network. **Design:** Retrospective evaluation using existing airway clearance service administrative database. **Participants:** All first referrals to the airway clearance service in a 5-year period (1/1/2017 to 31/12/2021). **Main Outcome Measures:** Available service data grouped into four domains: participant demographics, referral demographics, service provision and outcomes. **Results:** Of the 1335 first referrals eligible for inclusion, 1157 (87%) people attended. Bronchiectasis was the commonest condition (n = 649/1135, 49%). A total of 2996 occasions of service (face to face clinic n = 2108, 70%, phone n = 736, 25%, telehealth n = 99, 3%, home visit n = 53, 2%) were delivered. Airway clearance devices frequently prescribed were the Aerobika (525/1157, 45%), bubble-positive expiratory pressure (263/1157, 23%) and the Acapella (127/1157, 11%). On average, initial appointment with the airway clearance service occurred within 36 days of referral and people attended the service three times. Individuals voluntarily completed both pre/post service questionnaires around a third of the time. At least half of responders reported an improvement in respiratory symptom outcome measures consistent with the minimum clinically important difference. **Conclusions:** This evaluation describes an airway clearance service as it exists, providing an example from which airway clearance services can be planned, implemented and improved.

2. Oscillating Positive Expiratory Pressure (OPEP) Device Therapy in Canadian Respiratory Disease Management: Review, Care Gaps and Suggestion for Use

Jean Bourbeau, R. Andrew McIvor, Hollie M. Devlin & Alan Kaplan. CANADIAN JOURNAL OF RESPIRATORY, CRITICAL CARE, AND SLEEP MEDICINE
https://doi.org/10.1080/24745332.2018.1558426

Abstract: Oscillating positive expiratory pressure (OPEP) devices are a non-pharmacologic therapy that can increase mobilization and elimination of airway mucus hypersecretions. In respiratory diseases such as chronic obstructive pulmonary disease, cystic fibrosis and others, mucus clearance can improve pulmonary mechanics and facilitate gas exchange, reduce breathlessness, prevent recurring infection, reduce exacerbations and hospitalization and improve quality of life. Several OPEP devices are available, although only a few have published evidence of efficacy, cost effectiveness and benefit to patients. We review the evidence and provide suggestions on inclusion of some OPEP devices in mucus clearance therapy regimens.

3. 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.
https://doi.org/10.1586/17476348.2013.847368

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.

4. *Airway Clearance Techniques for Chronic Obstructive Pulmonary Disease*

CR Osadnik, CF McDonald, AP Jones, AE Holland. Cochrane Database of Systematic Reviews 2012. https://doi.org//10.1002/14651858.CD008328.pub2

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.

5. *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. Chronic Respiratory Disease 2010;7(1):9-17. https://doi.org/10.1177/1479972309348659

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 (FEV(1)), (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.

6. *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. https://doi.org/10.1016/j.physio.2009.06.008

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.

7. *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 Szczeklik. Polskie Archiwum Medycyny Wewnętrznej 2010;120(11):468-477.
https://pdfs.semanticscholar.org/94c7/8697933caf1b1de926ded898be727de01616.pdf

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.

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

MF Olsén, E Westerdahl. Respiration 2009;77:110-118. https://doi.org/10.1159/000163062

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.

9. *Improving Mucociliary Clearance in Chronic Obstructive Pulmonary Disease*

A Bhowmik, K Chahal, G Austin, I Chakravorty. Respiratory Medicine 2009;103:496-502. https://doi.org/10.1016/j.rmed.2008.10.014

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.

10. *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. https://doi.org/10.1378/chest.121.3.702

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.

11. *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. Archives of Physical Medicine and Rehabilitation 2000;81:558-560. https://doi.org/10.1016/S0003-9993(00)90034-0

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 ±8.6g to 19.0± 9.3g, $p < .01$) and ELTGOL (from 17.0± 7.0g to 20.6 ±6.9g, $p < .02$) than with PD (from 15.5± 4.0g to 17.5 ±3.7g, 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.

STUDIES EVALUATING AIRWAY CLEARANCE TECHNIQUES IN BRONCHIECTASIS

*1. **NEW** Physiotherapy-Led, Community-Based Airway Clearance Services for People with Chronic Lung Conditions: A Retrospective Descriptive Evaluation of an Existing Model of Care*

Cooper, L., Johnston, K. & Williams, M. Physiotherapy-led, community-based airway clearance services for people with chronic lung conditions: a retrospective descriptive evaluation of an existing model of care. BMC Health Serv Res ***24****, 98 (2024).* https://doi.org/10.1186/s12913-024-10550-x

Objectives: Airway clearance interventions are recommended for people with chronic lung conditions and mucus hypersecretion, but there are few published models of care or descriptions of airway clearance service provision. This evaluation describes a dedicated, physiotherapy-led, community-based airway clearance service in a metropolitan local health network. **Design:** Retrospective evaluation using existing airway clearance service administrative database. **Participants:** All first referrals to the airway clearance service in a 5-year period (1/1/2017 to 31/12/2021). **Main Outcome Measures:** Available service data grouped into four domains: participant demographics, referral demographics, service provision and outcomes. **Results:** Of the 1335 first referrals eligible for inclusion, 1157 (87%) people attended. Bronchiectasis was the commonest condition (n = 649/1135, 49%). A total of 2996 occasions of service (face to face clinic n = 2108, 70%, phone n = 736, 25%, telehealth n = 99, 3%, home visit n = 53, 2%) were delivered. Airway clearance devices frequently prescribed were the Aerobika (525/1157, 45%), bubble-positive expiratory pressure (263/1157, 23%) and the Acapella (127/1157, 11%). On average, initial appointment with the airway clearance service occurred within 36 days of referral and people attended the service three times. Individuals voluntarily completed both pre/post service questionnaires around a third of the time. At least half of responders reported an improvement in respiratory symptom outcome measures consistent with the minimum clinically important difference. **Conclusions:** This evaluation describes an airway clearance service as it exists, providing an example from which airway clearance services can be planned, implemented and improved.

*2. **NEW** European Respiratory Society Statement on Airway Clearance Techniques in Adults with Bronchiectasis*

Herrero-Cortina B, Lee AL, Oliveira A, O'Neill B, Jácome C, Dal Corso S, Poncin W, Muñoz G, Inal-Ince D, Alcaraz-Serrano V, Reychler G, Bellofiore A, Posthumus A; Patient representative; Tonia T, Chalmers JD, Spinou A. Eur Respir J. 2023 Jul 20;62(1):2202053. doi: 10.1183/13993003.02053-2022. PMID: 37142337.

Airway clearance techniques (ACTs) are part of the main management strategy for patients with bronchiectasis. Despite being a priority for patients, accessibility, implementation and reporting of ACTs are variable in clinical settings and research studies. This European Respiratory Society statement summarises current knowledge about ACTs in adults with bronchiectasis and makes recommendations to improve the future evidence base. A task force of 14 experts and two patient representatives (10 countries) determined the scope of this statement through consensus and defined six questions. The questions were answered based on systematic searches of the literature. The statement provides a comprehensive review of the physiological rationale for ACTs in adults with bronchiectasis, and the mechanisms of action along with the advantages and disadvantages of each ACT. Evidence on ACTs in clinical practice indicates that the most frequently used techniques are active cycle of breathing techniques, positive expiratory pressure devices and gravity-assisted drainage, although there is limited evidence on the type of ACTs used in specific countries. A review of 30 randomised trials for the effectiveness of ACTs shows that these interventions increase sputum clearance during or after treatment, reduce the impact of cough and the risk of exacerbations, and improve health-related quality of life. Furthermore, strategies for reducing the risk of bias in future studies are proposed. Finally, an exploration of patients' perceptions, barriers and enablers related to this treatment is also included to facilitate implementation and adherence to ACTs.

	FET	ACBT	Manual percussions	Manual vibrations or shaking	GAD	HFCWO	IPV	AD	ELTGOL	PEP	O-PEP
Advantages											
Can be performed independently.	✓	✓	≈ (anterior lung regions)	≈ (anterior lung regions)	✓	✓		✓	✓	✓	✓
Can be combined with some other ACTs	✓ (e.g., GAD)	✓ (e.g., GAD)	✓ (e.g., GAD)	✓ (e.g., ACBT)	✓ (e.g., ACBT)	✓ (e.g., GAD)	✓ (e.g., GAD)	✓ (e.g., O-PEP)	✓ (e.g., O-PEP)	✓ (e.g., AD or ELTGOL)	✓ (e.g., AD or ELTGOL)
Easy to perform in different environments / easy to transport (e.g., when travelling).	✓	✓	✓	✓	✓	≈ (if using a portable HFCWO device)		✓	✓	✓	✓ (except TPEP)
Easy to teach (respiratory physiotherapist) and easy to learn how to perform (patients).	✓	✓				✓				✓	✓
Patient does not require concentration or effort			✓	✓	✓	✓	✓				
Technique can be applied passively, which can be appropriate when patients are too unwell to do independent techniques.			✓	✓	✓	✓	✓				
Generate ventilatory support (e.g., recommended for exacerbations or in more severe patients)							✓				
Patients may prefer this technique compared to other techniques.								✓		✓	✓
Disadvantages											
Less commonly used as a standalone technique because a prolonged treatment time may be needed, especially when the goal is to enhance sputum clearance from peripheral airways.	X			X	X						
Likelihood of airway dynamic collapse using low inspiratory lung volumes [57].	X	X									
Usually, assistance is required from a respiratory physiotherapist or another person (e.g., caregiver).			X	X			≈ (preferably used in clinical settings)				
It may be difficult for the respiratory physiotherapist or caregiver to perform long sessions while still achieving optimal performance.			X	X					X (if it is assisted)		
Patients may experience discomfort (especially those who are frail) or present adverse events (e.g., gastroesophageal reflux, shortness of breath, ventilation/perfusion mismatch, increase intracranial pressure), particularly in severe disease or during acute exacerbations.			X	X	X (especially downward positions)	X			X (if side-lying position was not tolerated)		
Devices that are difficult to transport (size or weight) and required electrical source if a battery-operated device is not available.						X	X				X (only TPEP)
Cost associated with the device (the prize or because needed to replace periodically)						X	X			X	X
Device does not provide feedback on whether it is used correctly or not (e.g., target pressure unless a manometer is used)						X	X			X (except TheraPEP)	X (except TPEP)
Noisy						X	X				X
Time required for cleaning and disinfection							X			X	X
Can take time to master the technique and requires concentration and effort compared to other techniques.								X	X		

✓ for advantages; X for disadvantages; ≈ yes, but with exceptions. FET, forced expiratory technique; ACBT, active cycle of breathing techniques; GAD, gravity-assisted drainage; HFCWO, high-frequency chest wall oscillation; IPV, intrapulmonary percussive ventilation; PEEP, positive end expiratory pressure; O-PEP, oscillating positive expiratory pressure; ELTGOL, slow expiration with glottis opened in lateral posture; PEP, positive expiratory pressure; TPEP, temporary positive expiratory pressure.

*3. **NEW** Patient Experiences Living with Bronchiectasis – Results from a U.S. Focused Online Survey*

Esposito, L.[1], Suggett, J.[2], Coppolo, D.[3], & Schloss, J.[3] [1]BE CLEAR with Bronchiectasis, LLC. [2]Trudell Medical International, London, Canada. [3]Monaghan Medical Corporation, New York, USA. *6th World Bronchiectasis & NTM Conference. July 18 – 20, 2023.*

Background: The diagnosis of bronchiectasis is challenging and the burden of treatment can be high. This study looked to understand themes around time to bronchiectasis diagnosis, treatment burden and maintenance of therapeutic devices. **Methods:** An online survey was shared via social media platforms to bronchiectasis patients by

a patient advocate. Questions related to: a) time to diagnosis b) time spent performing pulmonary therapy and use of device combinations c) lung infections, and d) ways to clean/disinfect and the time spent doing that. **Results: O**f the 122 detailed responses received, some headline results are reported here. Almost 50% of patients had been diagnosed within the last 5 years with 30% of all patients having symptoms for >5 years prior to diagnosis. A little over 70% of respondents spent more than 30 mins per day on nebulizer/ airway clearance therapy (34% more than 1 hour). Different device combinations were used to reduce treatment duration (eg. nebulizer/OPEP/vest). Bacterial infections (various types) were reported by the majority of patients. 97% of patients cleaned or disinfected their devices, with almost 50% of patients spending more than 1 hour a week performing such cleaning/disinfecting. Boiling on the stove was the most commonly used method of disinfecting, however many different methods of cleaning were reported. **Conclusions:** The results from the survey confirmed that a large proportion of patients experience significant time from onset of symptoms to formal diagnosis. Despite patients utilizing combination therapy in various forms, the burden of therapy along with cleaning / disinfecting their devices remains high. Based on these results, in addition to continuing to raise the awareness of bronchiectasis within the HCP community, there remains an onus on therapy manufacturers to develop time efficient and easy to clean/disinfect devices for these patients.

4. Airway Clearance Techniques for Bronchiectasis

AL Lee, A Burge, AE Holland. Cochrane Database of Systematic Reviews 2013, Issue 5. Art. No.: CD008351. https://doi.org//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.

5. A Comparison of the Acapella and a Threshold Inspiratory Muscle Trainer for Sputum Clearance in Bronchiectasis-A Pilot Study

S Naraparaju, K Vaishali, P Venkatesan, V Acharya. Physiotherapy Theory and Practice 2010;26(6):353-357. https://doi.org/10.3109/09593981003596616

Conclusion: "The present study demonstrated increased sputum clearance following the use of the Acapella when compared to the threshold inspiratory muscle trainer. In addition, the Acapella was preferred by patients who judged that it was more useful in clearing secretions."

6. 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. Jornal Brasileiro de Pneumologia 2009;35(12):1190-1197. http://dx.doi.org/10.1590/S1806-37132009001200005

- **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."

7. Randomized Crossover Study of the Flutter Device and the Active Cycle of Breathing Technique in Non-Cystic Fibrosis Bronchiectasis

CS Thompson, S Harrison, J Ashley, K Day, DL Smith. Thorax 2002;57:446-448. *http://dx.doi.org/10.1136/thorax.57.5.446*

Conclusions: "Daily use of the Flutter device in the home is as effective as ACBT in patients with noncystic fibrosis bronchiectasis and has a high level of patient acceptability."

STUDIES EVALUATING AIRWAY CLEARANCE TECHNIQUES IN CYSTIC FIBROSIS

1. Effects of Quantity and Quality of Daily Airway Clearance Treatments on Lung Function in Children and Young People with Cystic Fibrosis: Results from Project Fizzyo

E. Raywood, N. Filipow, S. Stanojevic, H. Shannon, H. Douglas, G. Tanriver, N. Murray, R. O'Connor, L. Hill, C. Dawson, G. Davies, L. Stott, G. Saul, T. Kuzhagaliyev, T. van Schaik, B. Furtuna, O. Liakhovich, J. Booth, K. Kapoor and E. Main. NACFC 2022. Philadelphia, USA.

Introduction: People with CF are advised to do daily physiotherapy airway clearance techniques (ACTs). 76% of UK Children and young people with CF (CYPwCF) use positive expiratory pressure (PEP) devices for ACTs. Little is known about the quantity or quality of daily ACT treatments at home or the effects on lung function over time. **Methods:** Project Fizzyo used electronic pressure sensors to record breath-by-breath data during usual ACTs at home over 16 months by CYPwCF using one of four PEP ACT devices (Acapella Choice, Aerobika, AstraTech PEP, Pari PEP). Treatments were labelled in terms of quantity and quality. The *number* of ACT treatments per day and breaths per ACT were counted. Treatments were defined as:

- *Good quality ACTs* if breaths met: a) a recommended mid-expiratory pressure between 10 and 20 cmH_2O (+/-5) and b) an expired breath length between 1.5 and 3 seconds.
- *Poor quality ACTS* if breaths did not meet criteria above for breath pressure and length (higher or lower).
- *No ACTs* when no treatments were recorded in a day.

Outcome: FEV_1%pred from an extrapolated individualized polynomial regression. A linear mixed-effect model (LMER) was used to evaluate the effect of different components of ACT quantity and quality on FEV_1. The model accounted for disease severity, age, intravenous antibiotics, and modulatory therapy use. **Results:** 145 CYPwCF were recruited from three U.K. CF centers. Overall, doing more ACTs per week did not result in better lung function. 22% of treatments were categorized as good quality and 46% as poor quality. Although ACTs were prescribed, 32% of days had no ACTs. When CYPwCF performed *good quality ACTs*, there was a significant impact of ACT quality on FEV_1 (extrapolated >5%pred per year) compared with those doing no ACTs or poor quality ACTs. These effects were observed after adjusting for disease severity, age, antibiotics, and modulator therapies. Quantity of ACTs modified the effects on FEV_1% pred after ACTs were categorized by quality. Those weeks with more good quality ACTs had better FEV_1 than those with fewer. Conversely, weeks with more poor quality ACTs (or no ACTs) had worse FEV_1 than those with fewer. **Conclusions:** Regular good-quality ACTs were more important than quantity in improving FEV_1. The vast majority of CYPwCF did not regularly achieve good quality ACTs. CYPwCF who do ACTs every day may not realize when their techniques are poor. These new findings have important implications for how clinicians teach, measure, and monitor effective ACTs.

2. 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. https://thorax.bmj.com/content/thoraxjnl/early/2013/02/12/thoraxjnl-2012-202915.full.pdf

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, haemaptysis, 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."

3. 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.*https://doi.org/10.4187/respcare.01389

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."

4. *Acapella vs. PEP Mask Therapy: A Randomized Trial in Children with Cystic Fibrosis during Respiratory Exacerbation*

K West, M Wallen, J Follett. Physiotherapy Theory and Practice 2010;26(3):143-149. https://doi.org/10.3109/09593980903015268

"This study investigated the effectiveness of the Acapella in comparison to PEP mask therapy. Twenty-three participants with cystic fibrosis (CF) with a median age of 12 years (range 7–18 years), who were admitted to hospital for a respiratory exacerbation were randomised to either the PEP mask or Acapella treatment group. Both groups completed two treatment sessions each day (10 sets of 10 breaths in sitting) over a 10-day period. Outcome measures were change in lung function (FEV1, FVC, FEF25–75, and PEF) and exercise performance (modified 10-metre shuttle). In addition, total sputum production during treatment (wet weight) and patient satisfaction were assessed over the 10-day period. At the end of 10 days there were no statistically significant differences between the groups for any of the outcome measures. Participants were highly satisfied with both devices. The results suggest that there is no statistically significant difference between the Acapella device and the PEP mask for use in CF during an acute exacerbation. Larger studies are required to determine whether differences between PEP mask and Acapella noted in this trial are clinically worthwhile."

5. *Airway Clearance Devices in Cystic Fibrosis*

JH Marks. Paediatric Respiratory Reviews 2007;8:17-23. https://doi.org/10.1016/j.prrv.2007.02.003

- "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."

6. *Positive Expiratory Pressure and Oscillatory Positive Expiratory Pressure Therapies*

TR Myers. Respiratory Care 2007;52(10):1308-1327. http://rc.rcjournal.com/content/52/10/1308

- "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."

7. *Physiotherapy and Airway Clearance Techniques and Devices*

M McIlwaine. Paediatric Respiratory Reviews 2006;7S:S220-S222. https://doi.org/10.1016/j.prrv.2006.04.197

- "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."

8. *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. https://doi.org/10.3138/ptc.57.3.199

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."

9. *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. https://doi.org/10.1016/j.rmed.2005.11.028

- "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."

10. *Performance Comparison of Two Oscillating Positive Expiratory Pressure Devices: Acapella Versus Flutter*

TA Volsko, JM DiFiore, RL Chatburn. Respiratory Care 2003;48(2):124-130.
http://rc.rcjournal.com/content/48/2/124.short

- **Conclusion:** "Acapella and Flutter have similar performance characteristics. Acapella's performance is not gravity-dependent (ie, dependent on device orientation) and may be easier to use for some patients, particularly at low expiratory flows."

11. *Long-Term Comparative Trial of Positive Expiratory Pressure versus Oscillating Positive Expiratory Pressure (Flutter) Physiotherapy in the Treatment of Cystic Fibrosis*

PM McIlwaine, LT Wong, D Peacock, AG Davidson. Journal of Pediatrics 2001;138(6):845-850.
https://doi.org/10.1067/mpd.2001.114017

- **Conclusion:** "Flutter was not as effective in maintaining pulmonary function in this group of patients with CF compared with PEP and was more costly because of the increased number of hospitalizations and antibiotic use."

12. *Comparison of Flutter Device and Chest Physical Therapy in the Treatment of Cystic Fibrosis Pulmonary Exacerbation*

M Gondor, PA Nixon, R Mutich, P Rebovich, DM Orenstein. Pediatric Pulmonology 1999;28(4):255-260.
https://doi.org/10.1002/(SICI)1099-0496(199910)28:4<255::AID-PPUL4>3.0.CO;2-K

- "This study demonstrated that patients using the Flutter® device had better pulmonary function after 1 week of therapy and similar improvement in pulmonary function and exercise tolerance compared to CPT after 2 weeks of therapy, suggesting that Flutter® valve therapy is an acceptable alternative to standard CPT during in-hospital care of patients with CF."

13. *Comparison of the Flutter Device to Standard Chest Physiotherapy in Hospitalized Patients with Cystic Fibrosis*

*DN Homnick, K Anderson, JH Marks. CHEST 1998;114(4):993-997.*https://doi.org/10.1378/chest.114.4.993

- **Results:** "The groups (CPT and Flutter) did not differ at baseline in demographics or Shwachman score, nor was length of hospitalization different. Significant improvements were noted from admission to discharge in CS and PFT results within each group. Mean percent change in CS and PFT results between CPT and Flutter groups showed no significant difference from hospital admission to discharge. Subsequent power analysis using the observed difference in percent change from admission to discharge for FEV1 indicated that to attain 80% power at $\alpha = 0.05$, a sample of 219 subjects in each group would be necessary."
- **Summary:** "Comparative trials of airway clearance techniques with sufficient sample size are lacking. Although the Flutter appears to be a useful device for independent, cost-effective, and safe administration of CPT in this pilot study, a much larger clinical trial would be necessary to make definitive conclusions."

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

TA Scherer, J Barandun, E Martinez, A Wanner, EM Rubin. CHEST 1998;113(4):1019-1027.
https://doi.org/10.1378/chest.113.4.1019

- “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.”

15. Efficacy of the Flutter Device for Airway Mucus Clearance in Patients with Cystic Fibrosis

MW Konstan, RC Stern, CF Doershuk. Journal of Pediatrics 1994;124:689-693.
https://www.ncbi.nlm.nih.gov/pubmed/8176554

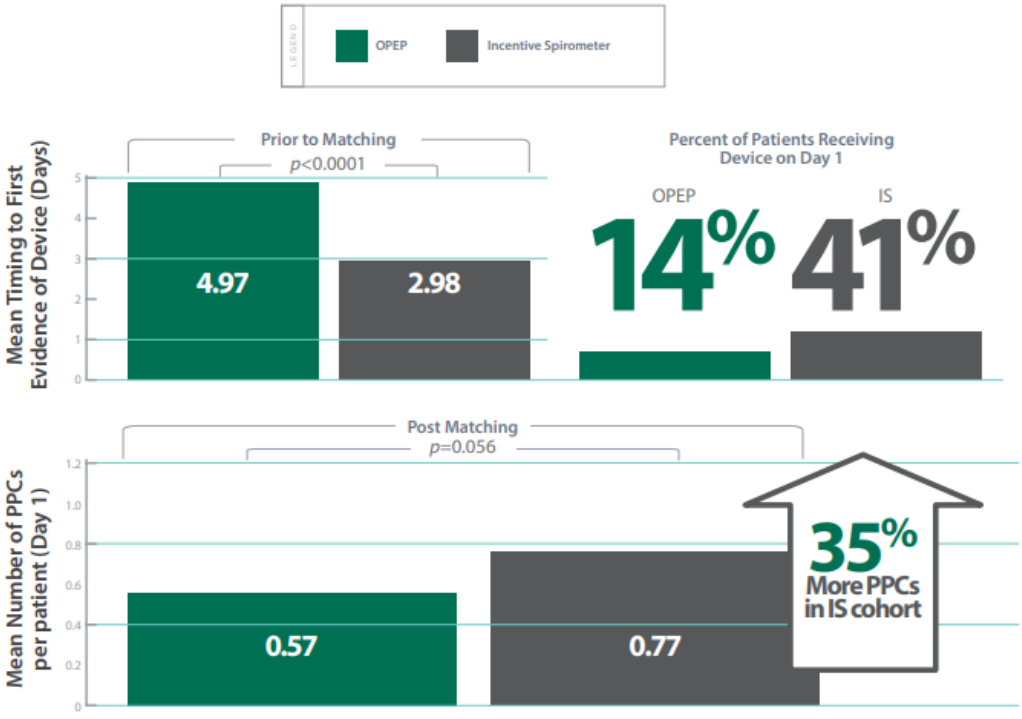
- “We studied 18 patients with cystic fibrosis and mild to moderate lung disease to determine the efficacy of the Flutter in clearing mucus from the airways. The amount of sputum expectorated (measured by weight) when the Flutter was used was compared with the amount expectorated with vigorous voluntary coughing and with postural drainage (chest percussion and vibration). The amount of sputum expectorated by subjects using the Flutter was more than three times the amount expectorated with either voluntary cough or postural drainage ($p < 0.001$). There were no adverse effects.”

POSITIVE OUTCOMES IN POST-OPERATIVE PULMONARY COMPLICATIONS USING OPEP AND PEP

1. **NEW** *Assessment of Airway Clearance Therapy Usage and Outcomes in Post-operative Care – A Real World Evidence Study*

Suggett J[1], Coppolo D[2], Schloss J[2], Near A[3], Fu M[3], Tse, J[3]. [1]Trudell Medical International, Canada. [2]Monaghan Medical Corporation, USA. [3]IQVIA Medical and Scientific Services, USA. American Thoracic Society Conference. May 19 – 24, 2023. https://www.trudellmed.com/global/en-CA/news/airway-clearance-therapy-usage-and-outcomes-post-operative-care

Rationale: Post-operative pulmonary complications (PPCs) are a variety of conditions adversely affecting the respiratory system after anesthesia and surgery. Strategies to prevent and treat PPCs include techniques of lung re-expansion using incentive spirometry (IS), which is typically standard of care in the US, and oscillating positive expiratory pressure (OPEP) devices. However, recent systematic reviews concluded that there is a lack of evidence regarding the effectiveness of IS for the prevention of PPCs in cardiac, thoracic, or upper abdominal surgery. Previous studies have shown that the addition of an OPEP device to standard of care (IS) reduced all cause rehospitalizations and mean length of stay.1 This real-world retrospective study aimed to assess usage patterns of IS vs an OPEP device, and the impact on post-surgery PPCs. **Methods:** Adults ≥18 years of age with ≥1 hospitalization for cardiac, thoracic or upper abdominal surgery between 9/1/2013 and 7/1/2021 were identified from IQVIA's Hospital Charge Detail Master (CDM) database and linked to IQVIA's prescription (LRx) and medical claims (Dx); index visit was the first hospitalization for surgery. The IS only cohort included patients who had ≥1 CDM, Dx, and LRx record within 12 months prior to index visit and ≥1 CDM and Dx record after discharge, evidence of IS use and one surgery type during index hospitalization, and no evidence of any PEP or OPEP any time during or up to 3 months before index visit. The OPEP only cohort was selected similarly, except that patients were required to have evidence of a specific OPEP device (Aerobika*, Monaghan Medical) use during index hospitalization and no evidence of IS, OPEP, or PEP use up to 3 months before index visit. OPEP patients were 1:1 matched to IS patients using propensity score (PS) matching on age, gender, region, payer type, surgical procedure, index year, baseline comorbidity profile, and index visit duration. The timing of the device introduction during the index visit was assessed, as were the incidence of PPCs during the visit. **Results:** Prior to matching, 477 OPEP only patients and 65,506 IS only patients were identified; 477 patients remained in each cohort after PS-matching. Before matching, the mean timing during index visit with first evidence of device was day **4.97 and 2.98 (p<0.0001) for OPEP and IS respectively, with 14% of patients getting OPEP on day 1 vs 41% getting IS**. After matching, the mean timing of OPEP and IS were similar (day 4.97 and 4.56, p=0.205). The **mean number of PPCs per patient among patients with access to devices on day 1 was 0.57 and 0.77 (p=0.056) for OPEP and IS, respectively**. If the OPEP device was not given until day 3 or later, the mean number of PPCs increased to 1.12 (p=0.001).



Conclusions: This real-world study highlights that current US hospital practice favors the introduction of IS earlier than OPEP for post operative care. The hypothesis being that OPEP is given more commonly as a reaction measure to observed complications. When matched patient groups were compared, there was a trend towards less PPCs for the Aerobika* OPEP vs IS if each device was given on day 1. There was a significant increase in PPCs if the introduction of the OPEP device was delayed to day 3 or later. This study suggests that there could be benefits if the OPEP device was provided earlier an instead of IS when managing post operative care.

2. *A Real-World Evidence Study Assessing the Impact of Adding the Aerobika Oscillating Positive Expiratory Pressure Device to Standard of Care Upon Healthcare Resource Utilization and Costs in Post-Operative Patients*

Chakkarin Burudpakdee . Aimee M. Near . Huan Huang . Dominic Coppolo . Vladimir Kushnarev . Jason Suggett Pulm Ther 2018. https://doi.org/10.6084/m9.figshare.6188678

Introduction: The aim of this real-world study was to measure the benefit of the Aerobika oscillating positive expiratory pressure (OPEP) device when added to standard of care (defined as incentive spirometry [IS]) for post-operative patients. **Methods**: Adults aged ≥ 18 years who were hospitalized for cardiac, thoracic or upper abdominal surgery between 1 September 2013 and 30 April 2017 were identified from IQVIA's Hospital Charge Detail Master (CDM) database; the index date was the date of the first hospitalization for surgery. The control cohort (IS) included patients who had ≥ 1 CDM record within 12 months prior to the index date and ≥ 1 record after discharge, evidence of IS use during index hospitalization and no evidence of use of a PEP or OPEP device at any time during the study period. The Aerobika OPEP cohort was selected in a similar manner, except that patients were required to have evidence of Aerobika OPEP use during the index hospitalization. Aerobika OPEP patients were 1:1 matched to IS patients using propensity score (PS) matching. Hospital readmissions and costs were measured at 30 days post-discharge from the index hospitalization. **Results**: After PS matching, 144 patients were included in each cohort. At 30 days post-discharge, compared to the control (IS) cohort there were significantly fewer patients in the Aerobika OPEP cohort with ≥ 1 all-cause rehospitalizations (13.9 vs. 22.9%; p = 0.042). The patients in the Aerobika OPEP cohort also had a shorter mean length of stay (± standard deviation) (1.25 ± 4.04 vs. 2.60 ± 8.24 days; p = 0.047) and lower total unadjusted mean all-cause cost per patient ($3670 ± $13,894 vs. $13,775 ± $84,238; p = 0.057). Adjusted analyses suggested that hospitalization costs were 80% lower for the Aerobika OPEP cohort versus the IS cohort (p = 0.001). **Conclusion:** Our results suggest that the addition of the Aerobika OPEP device to standard of care (IS) is beneficial in the post-operative setting.

3. *The Use of a Modified, Oscillating Positive Expiratory Pressure Device Reduced Fever and Length of Hospital Stay in Patients after Thoracic and Upper Abdominal Surgery: A Randomised Trial*

Zhang X, Wang Q, Zhang S, Tan W, Wang Z, Li J. Journal of Physiotherapy 2015;61:16-20

Question: Does the use of an oscillating positive expiratory pressure (PEP) device reduce postoperative pulmonary complications in thoracic and upper abdominal surgical patients? **Design:** A multi-centre, parallel-group, randomised controlled trial with intention-to-treat analysis, blinding of some outcomes, and concealed allocation. **Participants:** A total of 203 adults after thoracic or upper abdominal surgery with general anaesthesia. **Intervention:** Participants in the experimental group used an oscillating PEP device, thrice daily for 5 postoperative days. Both the experimental and control groups received standard medical postoperative management and early mobilisation. **Outcome measures:** Fever, days of antibiotic therapy, length of hospital stay, white blood cell count, and possible adverse events were recorded for 28 days or until hospital discharge**. Results:** The 99 participants in the experimental group and 104 in the control group were well matched at baseline and there was no loss to follow-up. Fever affected a significantly lower percentage of the experimental group (22%) than the control group (42%), with a RR of 0.56 (95% CI 0.36 to 0.87, NNT 6). Similarly, length of hospital stay was significantly shorter in the experimental group, at 10.7 days (SD 8.1), than in the control group, at 13.3 days (SD 11.1); the mean difference was 2.6 days (95% CI 0.4 to 4.8). The groups did not differ significantly in the need for antibiotic therapy, white blood cell count or total expense of treatment. **Conclusion:** In adults undergoing thoracic and upper abdominal surgery, postoperative use of an oscillating PEP device resulted in fewer cases of fever and shorter hospital stay. However, antibiotic therapy and total hospital expenses were not significantly reduced by this intervention.

4. *Longitudinal Evaluation of the Pulmonary Function of the Pre and Postoperative Periods in the Coronary Artery Bypass Graft Surgery of Patients Treated with a Physiotherapy Protocol*

Moreno AM, Castro RR, Sorares PP, Sant' Anna M, Cravo SL, Nóbrega AC. J Cardiothorac Surg. 2011;6:62.

Background: The treatment of coronary artery disease (CAD) seeks to reduce or prevent its complications and decrease morbidity and mortality. For certain subgroups of patients, coronary artery bypass graft surgery (CABG) may accomplish these goals. The objective of this study was to assess the pulmonary function in the CABG postoperative period of patients treated with a physiotherapy protocol. **Methods:** Forty-two volunteers with an average age of 63 ± 2 years were included and separated into three groups: healthy volunteers (*n* = 9), patients with CAD (*n* = 9) and patients who underwent CABG (*n* = 20). Patients from the CABG group received preoperative and postoperative evaluations on days 3, 6, 15 and 30. Patients from the CAD group had evaluations on days 1 and 30 of the study, and the healthy volunteers were evaluated on day 1. Pulmonary function was evaluated by measuring forced vital capacity (FVC), maximum expiratory pressure (MEP) and Maximum inspiratory pressure (MIP). **Results:** After CABG, there was a significant decrease in pulmonary function ($p < 0.05$), which was the worst on postoperative day 3 and returned to the preoperative baseline on postoperative day 30. **Conclusion:** Pulmonary function decreased after CABG. Pulmonary function was the worst on postoperative day 3 and began to improve on postoperative day 15. Pulmonary function returned to the preoperative baseline on postoperative day 30.

5. *Incentive Spirometry with Expiratory Positive Airway Pressure Reduces Pulmonary Complications, Improves Pulmonary Function and 6-Minute Walk Distance in Patients Undergoing Coronary Artery Bypass Graft Surgery*

Haeffener MP, Ferreira GM, Barreto SSM, Arena R, Dall'Ago P. American Heart Journal 2008;156(5):900.e1-900.e8.

Background: The use of the incentive spirometry (IS) with expiratory positive airway pressure (EPAP) to prevent postoperative pulmonary complications (PPC) after coronary artery bypass graft (CABG) is not well established. This study sought to determine the effects of IS + EPAP after CABG. **Methods**: Thirty-four patients undergoing CABG were randomly assigned to a control group or IS + EPAP group. Maximal respiratory pressures, pulmonary function test, 6-minute walk test and chest x-ray were performed at baseline as well as 1 week and 1 month after CABG. **Results:** Maximal inspiratory pressure was significantly higher in the IS + EPAP group compared to controls at both 1 week and 1 month ($P < .001$). Maximal expiratory pressure was significantly higher at 1 month compared to 1 week in IS + EPAP group ($P < .01$). At 1 month, forced vital capacity and forced expiratory volume in 1 second was significantly higher in IS + EPAP compared to controls ($P < .05$). Inspiratory capacity was higher at 1 month in IS + EPAP group compared to controls ($P < .05$). The distance walked in 6-minute walk test was higher at 1 month in IS + EPAP group ($P < .001$) compared to controls. Lastly, radiological injury score at 1 week was lower in IS + EPAP compared to controls ($P < .004$). **Conclusions:** In patients undergoing CABG, IS + EPAP results in improved pulmonary function and 6-minute walk distance as well as a reduction in PPC.

GUIDELINES AND RECOMMENDATIONS

1. **NEW** *Global Strategy for Prevention, Diagnosis and Management of COPD: 2024 Report*

Global Initiative for Chronic Obstructive Lung Disease (GOLD): 2024 Report.

Management of Mucus Hypersecretion: Treatment goals for patients with chronic bronchitis (CB) include: 1) reducing the overproduction of mucus; 2) decreasing mucus hypersecretion by reducing inflammation; 3) facilitating elimination of mucus by increasing ciliary transport; 4) decreasing mucus viscosity and 5) facilitating cough mechanisms. **Mucus clearance treatments that promote mechanical movement through the airway such as oscillating positive expiratory pressure (OPEP) therapy may improve mucus mobilization, symptoms and quality of life in people with COPD who produce sputum daily or most days.** The use of nebulized hypertonic saline for copious mucus has been used in obstructive lung disease and cystic fibrosis with beneficial effects. However, in patients with COPD, current studies are limited, and results are inconsistent.

2. The COPD-X Plan: Australian and New Zealand Guidelines for the Management of Chronic Obstructive Pulmonary Disease 2022

Yang IA, George J, McDonald CF, McDonald V, O'Brien M, Craig S, Smith B, McNamara R, Zwar N, Dabscheck E. The COPD-X Plan: Australian and New Zealand Guidelines for the management of Chronic Obstructive Pulmonary Disease 2025. Version 2.66, April 2022.

Chest Physiotherapy (Airway Clearance Techniques):
Airway clearance techniques (ACTs) are only indicated for patients with COPD who have evidence of sputum. This is likely to include individuals who have the clinical features of chronic bronchitis, those with co-existent bronchiectasis and some patients during an exacerbation.
The aims of ACTs in patients with COPD are to assist sputum clearance in an attempt to reduce symptoms and paroxysmal coughing, slow the decline in lung function, reduce exacerbation frequency and hasten the recovery from exacerbations.
A variety of techniques are available that vary in terms of ease of learning and equipment related cost. These include the active cycle of breathing techniques (ACBT), (a cycle of breathing control, thoracic expansion exercises and the forced expiration technique), positive expiratory pressure (PEP) therapy (e.g. Astra PEP® or Pari PEP®), devices that combine PEP and an oscillatory vibration of the air within the airways (e.g. Flutter®, Acapella® or Aerobika ®) and autogenic drainage (AD).

3. INESSS: Chronic Obstructive Pulmonary Disease

Institut National d'Excellence en Santé et en Services Sociaux Québec. Gouvernement du Québec, novembre 2022.
https://www.inesss.qc.ca/fileadmin/doc/INESSS/Rapports/Usage_optimal/INESSS_MPOC_GUO_FR.pdf

The goals of comprehensive COPD management include:

- Relief of dyspnea and respiratory symptoms that interfere with daily activities;
- The decrease in the frequency and severity of acute exacerbations of COPD (AECOPD);
- Slowing the progression of the disease;
- Maintaining quality of life and autonomy; and
- Reduced risk of morbidity and mortality

Comprehensive management of COPD includes non-pharmacological and pharmacological measures. The application of non-pharmacological measure is necessary to optimize pharmacological treatment.

Comprehensive Management of COPD	
Intervention	**Indication**
Technique for clearing the airways: • Especially oscillatory positive expiratory pressure devices (e.g., Aerobika*)	In the presence of sputum, usually if chronic bronchitis or concomitant bronchiectasis • To clear the airways and to reduce the frequency of AECOPD (Acute Exacerbations of COPD)

4. National (France) Diagnosis and Care Protocol: Bronchiectasis in Children, Diagnosis and Management (Excluding Cystic Fibrosis and Primary Ciliary Dyskinesia)

Drafted under the coordination of Pr Ralph EPAUD. RespiRare, reference center for rare respiratory diseases. September 2021.

Facilitate bronchial drainage: Respiratory physiotherapy with bronchial drainage is an essential and consensual element of care (30, 55). The hygiene conditions are the same as for the cystic fibrosis. Manual and instrumental techniques such as flutter (Gelomuc®, Aerobika®, etc.) and incentive spirometry (Voldyne®, Tri flow®, etc.) can be offered, adapted to the patient. The pace of the sessions depends on the clinical condition of the patient, multi-weekly to multi-daily. In adolescents and adults, education self-drainage facilitates additional care at home, with or without instrument. Regular physical activity contributes to bronchial drainage and improvement of QOL and should be encouraged. Programs of exercise rehabilitation can support the most severe patients with deconditioning during exercise.

5. British Thoracic Society Guideline for Bronchiectasis in Adults

British Thoracic Society Guideline for Bronchiectasis in Adults. Thorax. Jan 2019, Vol 74. https://www.brit-thoracic.org.uk/document-library/guidelines/bronchiectasis/bts-guideline-for-bronchiectasis-in-adults/

Which airway clearance techniques should be taught?
Recommendation: Offer active cycle of breathing techniques or oscillating positive expiratory pressure to individuals with bronchiectasis.
A systematic review evaluated OPEP devices in bronchiectasis. In the seven studies reviewed (n=146 patients), OPEP therapy was associated with improvements in sputum expectoration and quality of life measures compared with no treatment. Moreover, they concluded that compared with other ACTs, the effects in terms of sputum expectoration, lung function, gas exchange, and symptoms were equivalent. However, the authors did suggest a greater patient preference for oscillating PEP compared with ACBT with or without Gravity Assisted Positioning (GAP).

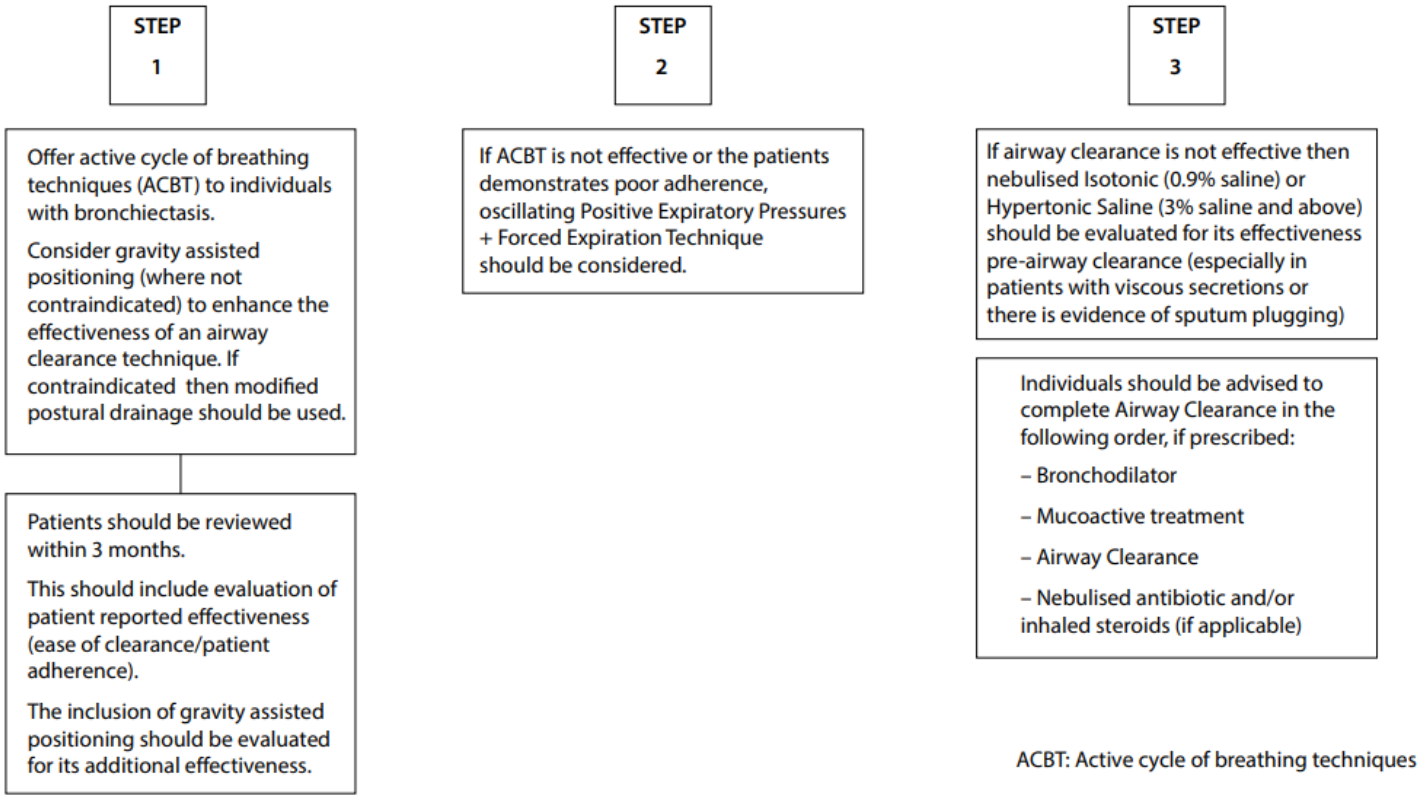


Figure 3 Physiotherapy management-stepwise airway clearance.

6. Spanish Guidelines on Treatment of Bronchiectasis in Adults

Martínez-García MÁ, Máiz L, Olveira C, Girón RM, de la Rosa D, Blanco M, Cantón R, Vendrell M, Polverino E, de Gracia J, Prados C. Spanish Guidelines on Treatment of Bronchiectasis in Adults. Arch Bronconeumol (Engl Ed). 2018 Feb;54(2):88-98. English, Spanish. doi: 10.1016/j.arbres.2017.07.016

Airway Clearance

Airway Clearance [AC] techniques are safe and recommended in adult patients with clinically stable bronchiectasis [BE] with productive cough, because they significantly improve quality of life, especially hypersecretory patients or those with frequent exacerbations (*Strong recommendation. Low quality evidence*).

The choice of technique should be based on the patient's preference, their ability, comorbidity, and interference in daily life.

AC should form part of an overall training program and should be carried out at least once daily or as required. AC techniques can be either manual (autogenic drainage, slow expiration with glottis opened and active cycle of breathing techniques [ACBT]) or instrumental (positive expiratory pressure [PEP], oscillating positive expiratory pressure [OPEP] and high frequency chest wall oscillation [HFCWO]). All reduce the symptoms of dyspnea and cough and facilitate expectoration. The use of OPEP also increases the volume of expectoration and may reduce the number of exacerbations.

Table 5
Standard Physiotherapy Techniques in Bronchiectasis.

	Technique	For	Against	Improvements
Manual techniques:				
(a) Slow expiration maneuver	Autogenic drainage ELTGOL	– Control of flow rate and respiratory volume	– Requires patient collaboration and training – May require assistance	– Increase the expectoration volume – Reduce cough and dyspnea and facilitate mucus transport and expectoration – Improve quality of life related to cough
(b) Fast expiration maneuver	Active cycle of breathing techniques (ACBT)	– Control of flow rate and respiratory volume	– Requires patient collaboration and training	– Facilitate expectoration
(c) Positioning	Conventional respiratory physiotherapy (postural drainage, clapping)	– Use in uncooperative patients	– Needs assistance – Uncomfortable positions – May cause hypoxemia or worsen gastroesophageal reflux – Limited by pain	– May facilitate expectoration
Instrumental techniques:	PEP (TheraPEP®, PiPED®; PEP mask®)	– Prevent alveolar collapse during expiration	– Cleaning of device required – Good breathing coordination important to increase efficacy	– Reduce hyperinflation and RFC
	Oscillating PEP-(Flutter®, Acapella®, Cornet®, Aerobika®)	– Prevent alveolar collapse during expiration – Oscillation in the airways modifies the rheology of the mucus	– Cleaning of device required – Good breathing coordination important to increase efficacy	– Increase the volume of expectoration – Reduce cough and dyspnea – May reduce the number of exacerbations – Reduction in RFC
	HFCWO (Vest®, SmartVest®)	– In the case of poor expectoration that requires additional chest maneuvers	– Very expensive – Limited by pain	– Reduce cough and dyspnea and facilitate expectoration – Improve FEV_1, FVC

FVC: forced vital capacity; ELTGOL: slow expiration with the glottis open in a lateral posture; FEV_1: forced expiratory volume in the first second; RFC: residual functional capacity; HFCWO: high frequency chest wall oscillation; OPEP: oscillating positive expiratory pressure techniques; PEP: positive expiratory pressure techniques.

7. European Respiratory Society Guidelines for the Management of Adult Bronchiectasis

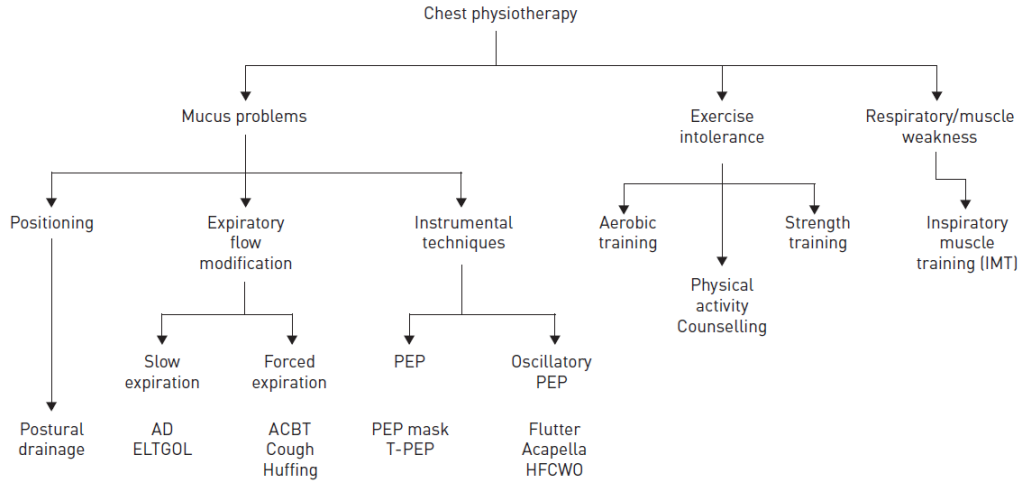
Polverino E, Goeminne PC, McDonnell MJ, et al. European Respiratory Society guidelines for the management of adult bronchiectasis. Eur Respir J 2017; 50: 1700629 https://doi.org/10.1183/13993003.00629-2017

Regular physiotherapy (airway clearance and/or pulmonary rehabilitation) more beneficial than control (no physiotherapy treatment) in adult bronchiectasis patients.

Recommendations: We suggest that patients with chronic productive cough or difficulty to expectorate sputum should be taught an airway clearance technique (ACT) by a trained respiratory physiotherapist to perform once or twice daily (weak recommendation, low quality of evidence). We recommend that adult patients with bronchiectasis and impaired exercise capacity should participate in a pulmonary rehabilitation program and take regular exercise. All interventions should be tailored to the patient's symptoms, physical capability and disease characteristics (strong recommendation, high quality of evidence).

Summary of the evidence: In bronchiectasis, it is a common belief that physiotherapy can improve mucus clearance and reduce lung inflammation and risk of infection. In addition, it is well accepted by patients. Respiratory physiotherapy includes ACTs and pulmonary rehabilitation. ACTs consist of breathing techniques, e.g. active cycle of breathing and autogenic drainage, sometimes combined with an instrument, e.g. OPEP devices, that modify

expiratory flow and volumes or produce chest wall oscillations in order to increase mucus clearance. The principal effect obtained by ACTs is an increase in sputum volume and a reduced impact of cough on quality of life. Interesting, but still preliminary data, shows reduced peripheral airways obstruction, less inflammatory cells in sputum and improved exercise capacity after ACTs. The aim of a pulmonary rehabilitation program is to improve exercise tolerance and quality of life through a tailored standardized exercise protocol.



8. *The Saudi Thoracic Society Guideline for Diagnosis and Management of Non-CF Bronchiectasis*

Al-Jahdali H, Alshimemeri A, et al. The Saudi Thoracic Society guidelines for diagnosis and management of noncystic fibrosis bronchiectasis. Ann Thorac Med. 2017 Jul-Sep;12(3):135-161. doi: 10.4103/atm.ATM_171_17.

Airway Clearance: The main pathophysiology of bronchiectasis is a vicious circle of airway infection and inflammation, leading to alteration of the cilia and impairing mucociliary clearance. Therefore, the main principle of management, in addition to antibiotics, is to improve mucus clearance, which is considered essential in optimizing respiratory function, facilitating expectoration of sputum, and reducing the progression of lung disease. There are a variety of pharmacological and nonpharmacological techniques used to clear the airway from secretions. Pharmacological agents include nebulized hypertonic saline solution, mannitol, and mucolytic agents while nonpharmacological agents include airway clearance techniques (ACTs).

Airway Clearance Techniques: ACTs include respiratory exercises, directed cough, forced expiration, chest physical therapy with postural drainage, hand or mechanical chest-clapping, positive expiratory pressure (PEP), oscillatory PEP (e.g., flutter valve device), and high-frequency chest wall compression. These ACT techniques can be used in isolation or in combination. There is limited evidence that the active breathing cycles and flutter are superior in the gravity-assisted position compared with the sitting position.

Recommendations:

- There is lack of data about the role of ACT in the management of acute bronchiectasis exacerbation; thus, it may be used if there are no contraindications.
- ACT is safe and recommended as it may improve sputum expectoration, lung function, and health-related QoL in stable bronchiectasis patients.
- Taking in account patient's preference and adherence to treatment, the patient or their caregiver should be taught and encouraged to use ACT and appropriate device.

9. *Guidelines for the Physiotherapy Management of the Adult, Medical, Spontaneously Breathing Patient (Status: Archived 2017) British Thoracic Society Physiotherapy Guideline Development Group/ Association of Chartered Physiotherapists in Respiratory Care*

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. https://www.brit-thoracic.org.uk/document-library/clinical-information/physiotherapy/physiotherapy-guidelines/physiotherapy-guideline/

- "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."

10. *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, Clinical Practice Guidelines for Pulmonary Therapies Committee. Respiratory Care 2009;54(4):522-537.
http://rc.rcjournal.com/content/54/4/522

- "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)."

11. *Standards of Care and Good Clinical Practice for the Physiotherapy Management of Cystic Fibrosis Cystic Fibrosis Trust*

T Daniels, L Morrison, N Harnett, and S Lewis, Editorial Board. Third Edition, 2017.
https://www.cysticfibrosis.org.uk/~/media/documents/life-with-cf/publications/consensus-on-physiotherapy-management--third-edition-2017.ashx?la=en

Good practice points:

- No single treatment technique is suitable for all patients and the therapist delivering airway clearance must be well-educated in all aspects of airway clearance and associated therapy techniques.
- Oscillating PEP has not been proven to be more or less effective overall than other airway clearance techniques. There is no evidence that one device is superior to another.
- Consider patient preference and their health beliefs when selecting an appropriate airway clearance technique for a patient with CF.
- Consider the age-appropriateness of specific airway clearance devices when recommending them for use as an airway clearance technique.
- Patients must be instructed in appropriate cleaning regimens of oscillatory PEP devices as per manufacturer guidelines.

Recommendations:

- Consider oscillatory devices when recommending an appropriate airway clearance technique for a patient with CF (QoE – low).

GUIDELINES AND RECOMMENDATIONS: COVID-19

1. *Pulmonary rehabilitation for patients with coronavirus disease 2019 (COVID-19)*

Lu-Lu Yang [1] , Ting Yang[2]. 1. Capital Medical University, Beijing 100069, China. 2.Department of Pulmonary and Critical Care Medicine, Center of Respiratory Medicine, China-Japan Friendship Hospital, Beijing 100029, China
Chronic Diseases and Translational Medicine 6 (2020) 79e86. https://doi.org/10.1016/j.cdtm.2020.05.002

Abstract: As a highly infectious respiratory tract disease, coronavirus disease 2019 (COVID-19) can cause respiratory, physical, and psychological dysfunction in patients. Therefore, pulmonary rehabilitation is crucial for both admitted and discharged patients of COVID-19. In this study, based on the newly released pulmonary rehabilitation guidelines for patients with COVID-19, as well as evidence from the pulmonary rehabilitation of patients with severe acute respiratory syndrome, we investigated pulmonary rehabilitation for patients with COVID-19 having complications, such as chronic pulmonary shed an intelligent respiratory rehabilitation model for these patients.

Thoughts on pulmonary rehabilitation of patients with COVID-19 complicated with chronic pulmonary diseases

For patients with COVID-19 complicated with chronic pulmonary diseases, such as COPD, bronchial asthma, and pulmonary interstitial fibrosis, in addition to performing an assessment and developing a prescription based on the rehabilitation guidelines, the following instructions should be followed: (1) Ensure the continuation of standardized basic medications and a reasonable diet. (2) Promote smoking cessation, flu vaccination, and Streptococcus pneumoniae vaccination. (3) As patients with COVID-19 having chronic pulmonary diseases often have excessive airway secretions, expiration exercises should be performed in addition to general airway clearance exercises to facilitate sputum excretion and reduce the exhaustion due to coughing. In addition, auxiliary techniques, such as the application of oscillatory positive expiratory pressure (OPEP), can be utilized. (4) Appropriate oxygen therapy should be provided during exercises. Patients with chronic pulmonary diseases can develop hypoxemia at rest. Subsequently, when exercising, as the interval for red blood cells to pass through the alveolar capillaries is shortened, the ventilation flow rate disorder increases, and oxygen intake decreases. Meanwhile, an escalated breathing rate causes pulmonary dynamic hyperinflation and gas trapping, which increases the end-expiratory lung volume, dead space ventilation and work of breathing, thereby further reducing blood oxygen saturation. In contrast, introducing oxygen therapy during exercise can meet the elevated metabolic demands, prevent hypoxemia, and reduce pulmonary dynamic hyperinflation, thereby improving the effect of exercise, while allowing an increase in the intensity and duration of the exercise. Hypoxemia during exercise is regarded as the indication for requirement of oxygen therapy (SpO2 at 88%e90% or a relative reduction of 2%e5%, lasting for 0.5e5.0 min). The goal of oxygen therapy is to adjust the oxygen flow rate to maintain the SpO2 within the range of 90%e92%. In order to increase the exercise effect, the oxygen flow rate can be increased according to the exercise intensity to maintain the SpO2 at about 95%.29 (5) Thoracic kyphosis correction: Due to long-term dyspnea, cough, etc., the work of breathing in patients with chronic pulmonary diseases often increases, which leads to the formation of abnormal breathing patterns. The resultant chronic pulmonary hyperinflation usually causes enlargement of the anterior and posterior diameters of the chest, thereby resulting in barrel chest or other chest deformities. A study of 143 young patients with cystic fibrosis showed that in patients over 15 years old, the condition of 77% of females and 36% of males was complicated with thoracic kyphosis deformity of more than 40.30 Since this deformity can inhibit airway clearance and increase the work of breathing, it is important to incorporate physiotherapy, such as chest and muscle stretching and intensive training, in a comprehensive pulmonary rehabilitation program for thoracic kyphosis correction.

2. *Physiotherapy management for COVID-19 in the acute hospital setting: clinical practice recommendations*

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This document outlines recommendations for physiotherapy management for COVID-19 in the acute hospital setting. It includes: recommendations for physiotherapy workforce planning and preparation; a screening tool for determining requirement for physiotherapy; and recommendations for the selection of physiotherapy treatments and personal protective equipment. It is intended for use by physiotherapists and other relevant stakeholders in the acute care setting caring for adult patients with confirmed or suspected COVID-19.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a new coronavirus that emerged in 2019 and causes coronavirus disease 2019 (COVID-19).1,2 SARS-CoV-2 is highly contagious. It differs from other respiratory viruses in that it appears that human-tohuman transmission occurs approximately 2 to 10 days prior to the individual becoming symptomatic.2–4 The virus is transmitted from person to person through respiratory secretions. Large droplets from coughing, sneezing or rhinorrhoea land on surfaces within 2 m of the infected person. SARS-CoV-2 remains viable for at least 24 hours on hard surfaces and up to 8 hours on soft surfaces.5 The virus is transferred to another person through hand contact on a contaminated surface followed by touching the mouth, nose or eyes. Aerosol airborne infected particles created during a sneeze or cough remain viable in the air for 3 hours.5 These airborne particles of SARS-CoV- 2 can then be inhaled by another person or land on the mucosal membranes of the eyes. Individuals with COVID-19 can present with an influenza-like illness and respiratory tract infection demonstrating fever (89%), cough (68%), fatigue (38%), **sputum production (34%)** and/or shortness of breath (19%).

Recommendations for the delivery of physiotherapy interventions, including personal protective equipment requirements Physiotherapy management principles – respiratory care

Examples of physiotherapy-led respiratory interventions (or chest physiotherapy) are provided below.
Airway clearance techniques:
Airway clearance techniques include positioning, active cycle of breathing, manual and/or ventilator hyperinflation, percussion and vibrations, positive expiratory pressure therapy (PEP) and mechanical insufflation-exsufflation.
Non-invasive ventilation and inspiratory positive pressure breathing
Physiotherapists may use inspiratory positive pressure breathing (eg, for patients with rib fractures). Non-invasive ventilation may be applied as part of airway clearance strategies in the management of respiratory failure or during exercise.

Techniques to facilitate secretion clearance
Techniques to facilitate secretion clearance include assisted or stimulated cough maneuvers and airway suctioning.

Other
Physiotherapists prescribe exercise and assist patients to mobilise. Physiotherapists also play an integral role in the management of patients with a tracheostomy. COVID-19 poses significant considerations for respiratory physiotherapy interventions due to their aerosol-generating procedures.