AerobiKA®

Oscillating Positive
Expiratory Pressure Device

Study Summary

2026

50 Cited publications.
10+ Studies ongoing and planned.

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.

• Clinical Studies Using the Aerobika* OPEP Device

Papers and posters supporting the use and efficacy of the Aerobika* OPEP device in COPD, bronchiectasis, cystic fibrosis and post-operative settings.

• Studies Comparing OPEP Devices and Airway Clearance Techniques

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.

• Guidelines and Recommendations

International guidelines recommending the use of OPEP and PEP therapy for the management of mucus hypersecretion.

Executive Summary

Clinical Studies Using The Aerobika* OPEP Device

CHRONIC OBSTRUCTIVE PULMONARY DISEASE – PAPERS

CHRONIC OBSTRUCTIVE PULMONARY DISEASE – POSTERS

BRONCHIECTASIS – PAPERS

BRONCHIECTASIS – POSTERS

CYSTIC FIBROSIS – POSTERS

PRIMARY CILIARY DYSKINESIA – PAPERS

POST-OPERATIVE PULMONARY COMPLICATIONS – PAPERS

POST-OPERATIVE PULMONARY COMPLICATIONS – POSTERS

Studies Comparing OPEP Devices and Airway Clearance Techniques

THE DIFFERENCE IS CLEAR: OPEP DEVICES ARE NOT ALL THE SAME

GUIDELINES AND RECOMMENDATIONS

CHRONIC OBSTRUCTIVE PULMONARY DISEASE

BRONCHIECTASIS

CYSTIC FIBROSIS

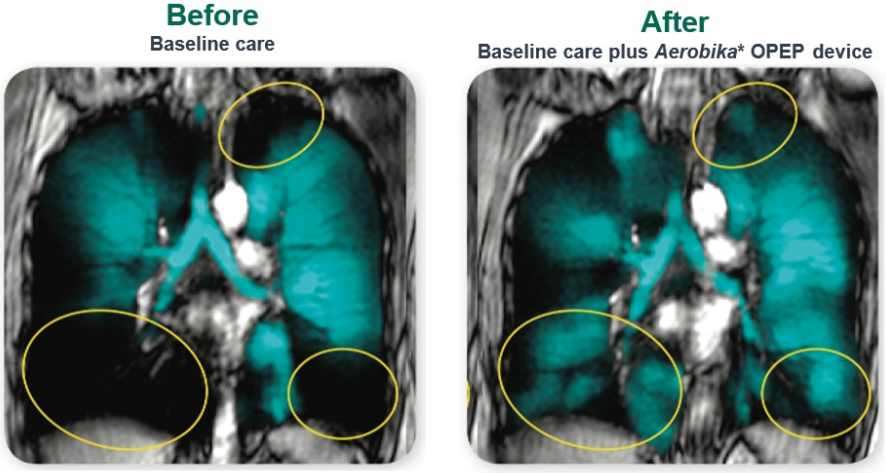
Executive Summary

1 Oscillating Positive Expiratory Pressure in Chronic Obstructive Pulmonary Disease

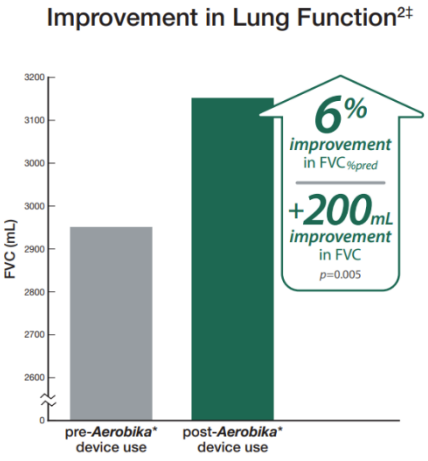
S Svenningsen, GA Paulin, K Sheihk, F Guo, A Hasany, M Kirby, R Etemad-Rezai, DG McCormack, G Parraga. Journal of COPD 2016;13(1):66-74. https://doi.org/10.3109/15412555.2015.1043523

Clinical Study Paper

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 FEV_1 (r=-0.50, p=0.009). In COPD patients with chronic sputum production, PEQ and SGRQ scores, FVC and 6MWD improved post-oPEP. **FEV_1 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).



‡ Sputum-producing COPD cohort.

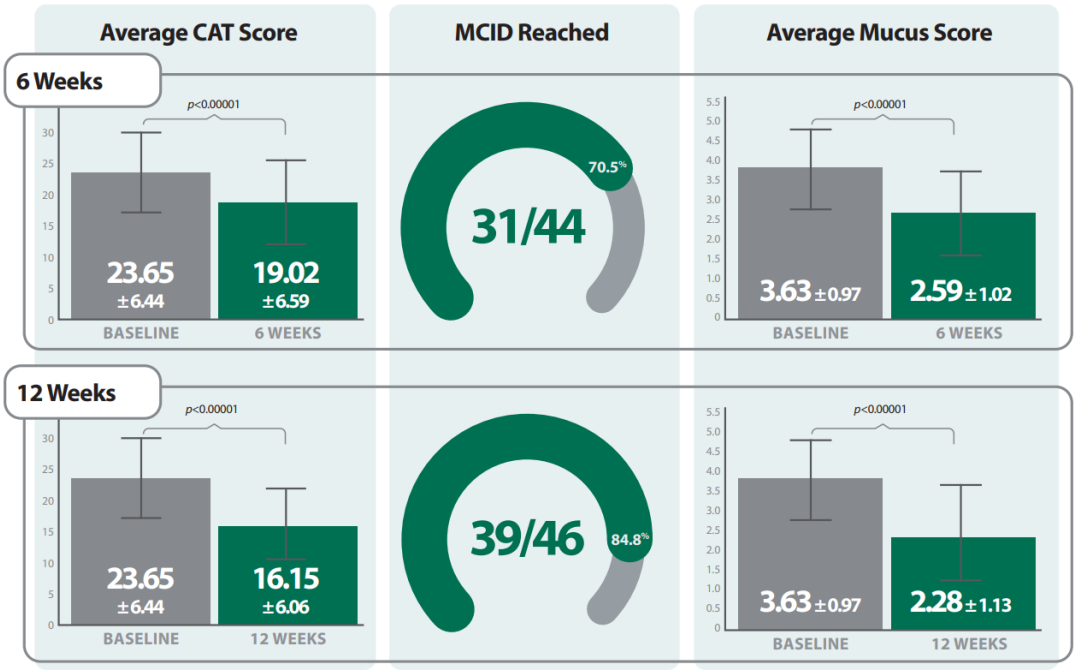
The Aerobika* OPEP device significantly improved lung function in COPD patients.
Use of the Aerobika* device led to a +200mL improvement in FVC.

2 The Impact of an Oscillating Positive Expiratory Pressure Device on Quality of Life in COPD Patient

Poirier, C., Menard, P., Wang, S., & Suggett, J. The impact of an oscillating positive expiratory pressure device on quality of life in COPD patients. 2025 Canadian Respiratory Conference Abstracts. (2025). Canadian Journal of Respiratory, Critical Care, and Sleep Medicine, 9(sup1), S1-S68. https://doi.org/10.1080/24745332.2025.2501877

Clinical Study Poster | *Peer reviewed with journal citation*

Rationale: Clinical benefits of Oscillating Positive Expiratory Pressure (OPEP) devices have been previously demonstrated. This study aimed to provide patient-reported outcomes of OPEP treatment in chronic obstructive pulmonary disease (COPD) patients in Québec, Canada. **Methods:** Recruitment took place across 3 sites in Québec. Included COPD patients had a baseline COPD Assessment Test (CAT) score greater than 10, and a baseline mucus score of 2 or greater for item 2 of the CAT. Aerobika* OPEP (TMI) devices were provided, along with instructions on usage and technique. Patients were to complete at least 2 sessions daily, with each session lasting 10-20 minutes. CAT assessments were collected at the initial baseline visit, and at 6 and 12-week follow-up visits. At the final 12- week visit, patients were also asked whether they would continue to use the device and gave 1 (bad) to 5 (great) ratings on usability and satisfaction. **Results:** Data was analyzed from 46 patients. The average CAT score at 6 weeks was significantly lower compared to baseline (19.02 ± 6.59 vs. 23.65 ± 6.44, p<0.00001), with 31/44 patients (70.5%) reaching the minimum clinically important difference (MCID). CAT scores decreased further at 12 weeks (16.15 ± 6.06), a significant improvement from the 6-week results (p=0.0052). MCID was reached by 39/46 patients (84.8%) after 12 weeks of treatment. Average mucus scores at 6 and 12 weeks (2.59 ± 1.02 and 2.28 ± 1.13, respectively) were both significantly lower than the average baseline score (3.63 ± 0.97; p<0.00001 at both 6 and 12 weeks). Regarding device feedback, 43/44 patients (97.7%) would continue to use the device. The proportion of patients that provided 4/5 or 5/5 satisfaction ratings were 40/45 (88.9%), 43/45 (95.6%), and 40/45 (88.9%) for ease of use, quality, and overall satisfaction, respectively. No device-related adverse events were reported.



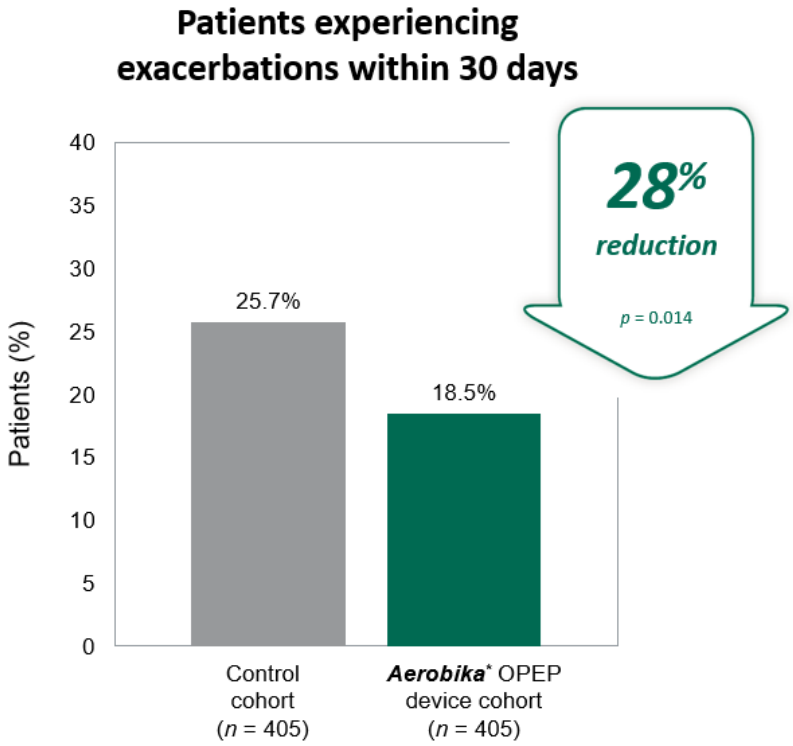
Conclusions: Statistically significant and clinically meaningful improvements were observed following 6- and 12-weeks use of the OPEP intervention. This study supports the use of the Aerobika* OPEP device in conjunction with standard of care therapy in COPD patients to manage symptoms and enhance quality of life. Patient feedback shows high levels of acceptable and perceived value of the device.

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

Clinical Study Paper

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.



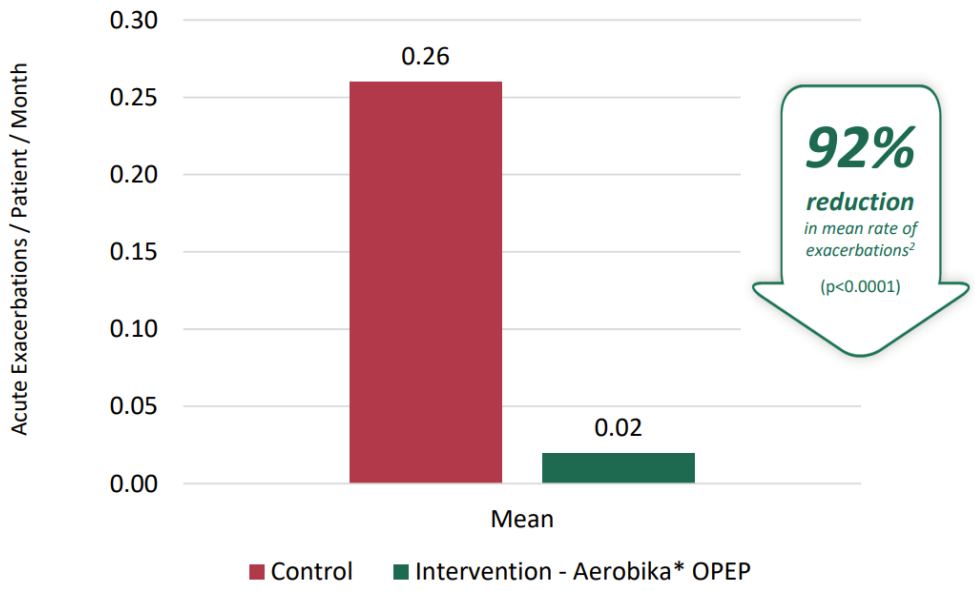
Conclusions: Study findings suggest that using Aerobika* OPEP as part of a treatment regimen may help reduce ED visits, hospital re-admissions and related costs in COPD patients who have a history of exacerbations.

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.

Clinical Study Paper

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.



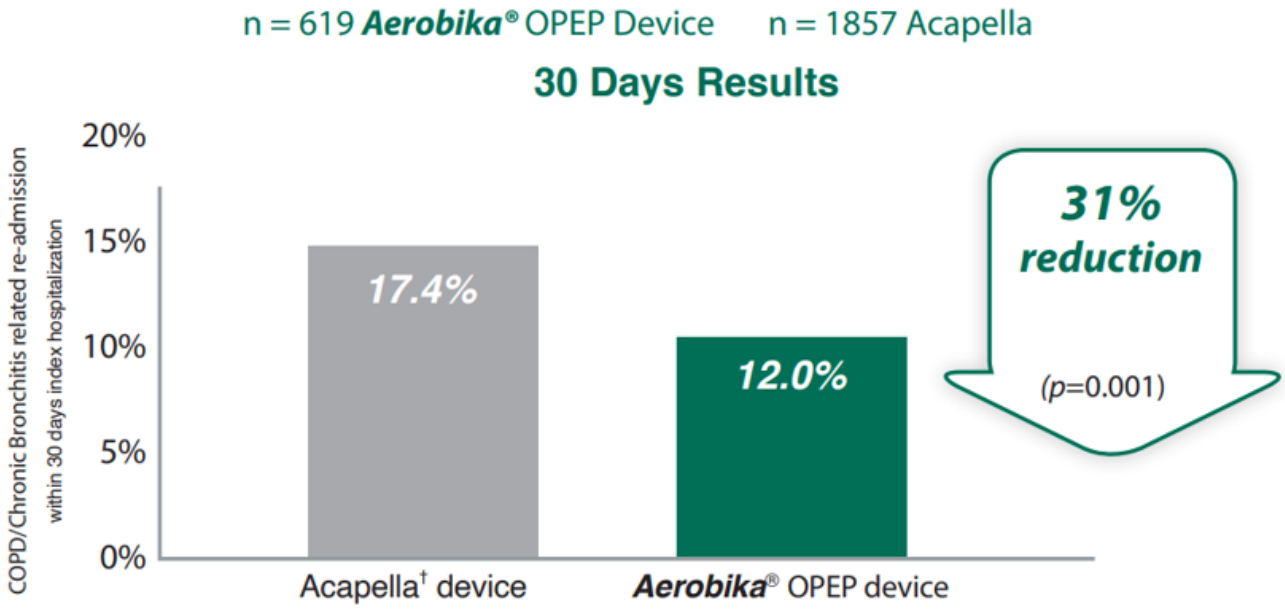
Conclusion: Twice-daily physiotherapy with the OPEP device in patients with bronchiectasis who have frequent exacerbations may facilitate symptomatic improvement and prevention of acute exacerbations without serious adverse events.

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

Clinical Study Paper

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.



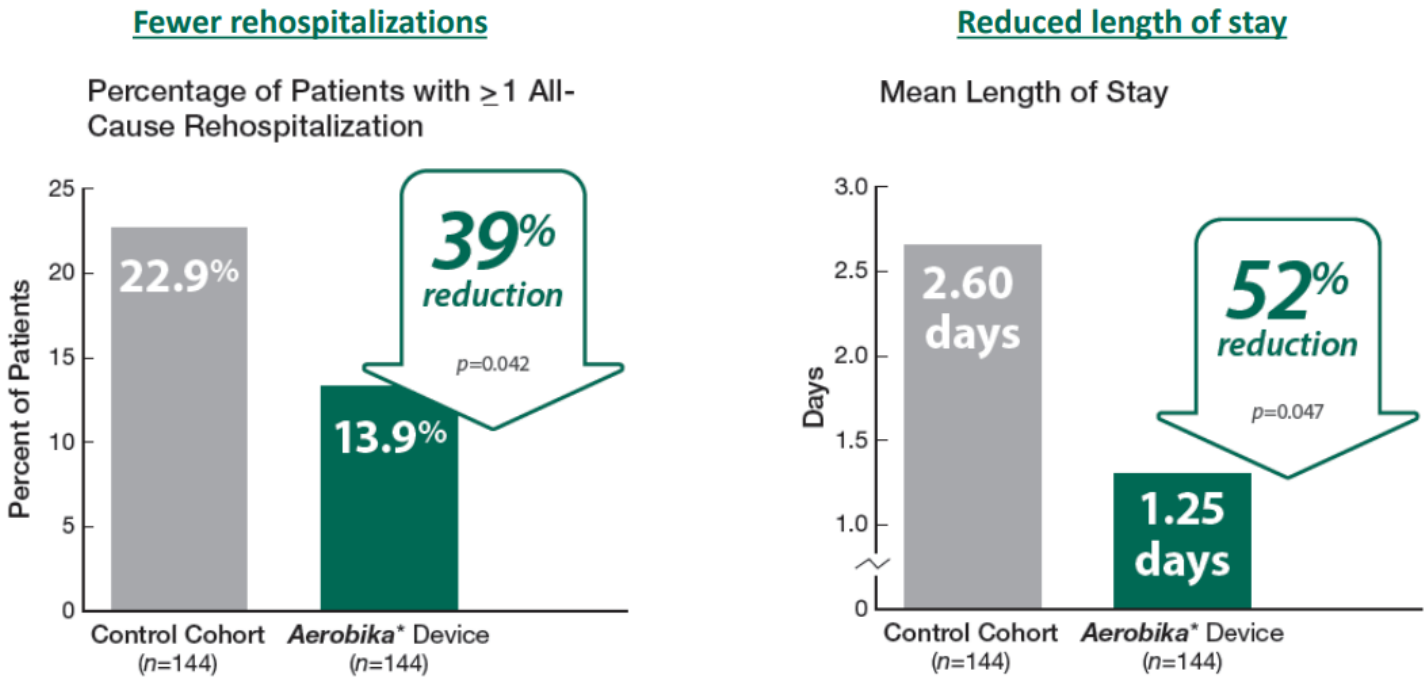
Conclusion: Patients receiving the Aerobika* OPEP device, compared to the Acapella device, had lower rates of subsequent severe disease exacerbation and all-cause inpatient admission. This suggests that Aerobika* OPEP device may be a beneficial add-on to usual care and that OPEP devices may vary in clinical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

Clinical Study Paper

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

Health Economic Paper

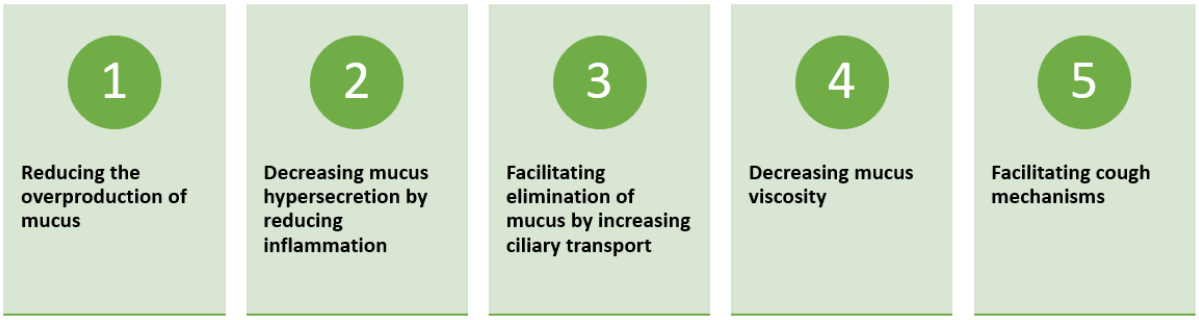
Background: The Aerobika* oscillating positive expiratory pressure (OPEP) device is a hand-held, drug-free medical device that has been shown to improve lung function and improve health-related quality of life in patients with chronic obstructive pulmonary disease (COPD). We estimated the cost-effectiveness 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 the Diagnosis, Management, and Prevention of COPD: GOLD 2025 Report

Global Initiative for Chronic Obstructive Lung Disease (GOLD): 2025 Report.

Guideline

Management of Mucus Hypersecretion: Treatment goals for patients with chronic bronchitis (CB) include:



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 Clinical Practice Guideline for the Management of Adult Bronchiectasis

Chalmers JD, Haworth CS, Flume P, et al. European Respiratory Society Clinical Practice Guideline for the Management of Adult Bronchiectasis. Eur Respir J 2025; in press (https://doi.org/10.1183/13993003.01126-2025).

Guideline

Should airway clearance techniques be used (compared to no airway clearance techniques) in adults with bronchiectasis?

Recommendation

We recommend that patients with bronchiectasis should be taught airway clearance techniques (strong recommendation for the intervention, very low certainty of evidence).

- Previous ERS guidelines limited ACTs to patients with chronic productive cough. The current recommendation acknowledges that some patients with a dry cough, particularly those with mucus plugging on chest CT, may benefit from ACTs. Instruction in ACTs may also assist patients during periods of increased symptoms, such as exacerbations.

Justification of Recommendations

ACTs are associated with improved quality of life and symptoms and may reduce exacerbations. Airway clearance is a key component of daily bronchiectasis management. Despite the very low certainty of evidence, the panel issued a strong recommendation based on the following: i) ACTs are self-administered, low-cost, and accessible; ii) Patients widely recognize their benefits; iii) The recommendation was strongly supported by patient representatives. Although adverse effects and harms were not systematically reported or collected, ACTs are widely believed to be safe and low risk of adverse events. These factors outweigh the limitations of the evidence base and highlight a need for broader implementation. Airway clearance is underutilized in clinical practice, and this recommendation should encourage increased uptake among healthcare professionals and policy.

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/

Guideline

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).

Clinical Studies Using The Aerobika* OPEP Device

CHRONIC OBSTRUCTIVE PULMONARY DISEASE – PAPERS

1 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

Clinical Study Paper

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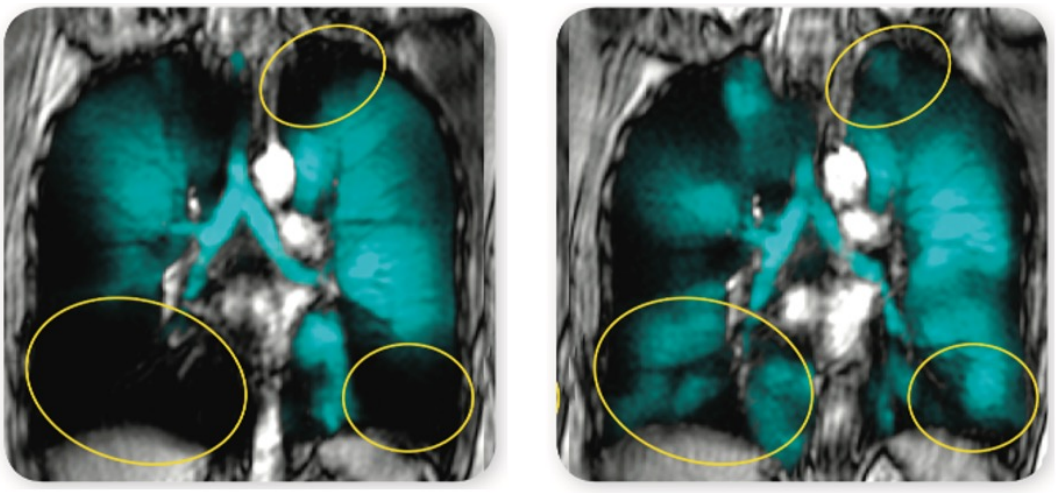
Before
Baseline care

After
Baseline care plus ***Aerobika**** OPEP device



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).

2 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

Clinical Study Paper

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.

3 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

Clinical Study Paper

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.

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

Clinical Study Paper

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 FEV_1, FVC, 6MWD from baseline in group A was significantly more as compared to group B (FEV_1: $P < 0.001$; 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 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/

Clinical Study Paper

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.

6 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.

Clinical Study Paper

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 $p = 0.001$), FEF25-75, L (12-week $p = 0.023$, 24-week $p = 0.002$), and FEF25-75% 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.

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

Health Economic Paper

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 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

Health Economic Paper

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.

9 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

Clinical Study Paper

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.

Table 4 Summary of Patient reported outcome measures (PROM) data before and after participation in the airway clearance service (ACS)

		All completed participant questionnaires		Participants who completed both Pre ACS and Post ACS questionnaires	
		Pre ACS	Post ACS	Difference Pre-post	Number meeting or exceeding MCID
Outcome measure	**Domain scores**	**N (%) Mean (SD)**	**N (%) Mean (SD)**	**N (%) Mean (SD)**	**N (% of those who completed pre and post)**
Leicester Cough Questionnaire (*n* = 1155) *(MCID 1.3 points higher)*	Total score	775 (67) 14.6 (4.1)	280 (24) 16.4 (3.4)	273 (24) 1.7 (3.3)	137 (50)
COPD Assessment Tool (*n* = 344) *(MCID 2 points lower)*	Total score	309 (90) 22.8 (7.4)	107 (35) 16.0 (7.8)	101 (33) 2.7 (7.1)	54 (53)
Depression Anxiety Stress Scale (*n* = 1155) *(MCID 5 points lower)*	Total score	716 (62) 14.2 (12.0)	260 (23) 13.1 (11.3)	251 (22) 0.8 (9.4)	68 (27)
Quality of Life – Bronchiectasis (*n* = 579) *(MCID – see individual domain)*	Physical (≥ 10.0 points)	378 (65) 49.8 (32.0)	161 (43) 55.8 (34.1)	132 (35) -3.7 (18.3)	63 (48)
	Role functioning (≥ 8.0 points)	378 (65) 54.9 (12.8)	161 (43) 57.6 (12.6)	132 (35) -1.6 (14.2)	52 (39)
	Vitality (≥ 10.0 points)	378 (65) 58.7 (13.9)	161 (43) 60.6 (11.6)	132 (35) -0.1 (14.8)	40 (30)
	Emotion (≥ 7.0 points)	378 (65) 79.5 (21.3)	161 (43) 84.3 (18.3)	132 (35) -3.2 (15.5)	51 (39)
	Social (≥ 9.0 points)	378 (65) 57.5 (26.1)	161 (43) 64.1 (23.0	132 (35) -7.3 (22.8)	71 (54)
	Treatment Burden (≥ 9.0 points)	204[a] (35) 36.3 (14.9)	127[b] (22) 34.1 (12.8)	77 (13) 1.9 (20.8)	20 (15)
	Health perception (≥ 8.0 points)	378 (65) 49.8 (14.9)	161 (43) 45.5 (15.3)	132 (35) 1.2 (15.2)	53 (40)
	Respiration (≥ 8.0 points)	378 (65) 60.4 (19.2)	161 (43) 67.3 (15.0)	132 (35) -5.0 (15.6)	81 (61)

Leicester Cough Questionnaire and Depression Anxiety Stress Scale provided to all participants; COPD Assessment Tool provided only to those with a referral diagnosis of COPD; Quality of Life – Bronchiectasis provided only to those with a referral diagnosis of bronchiectasis

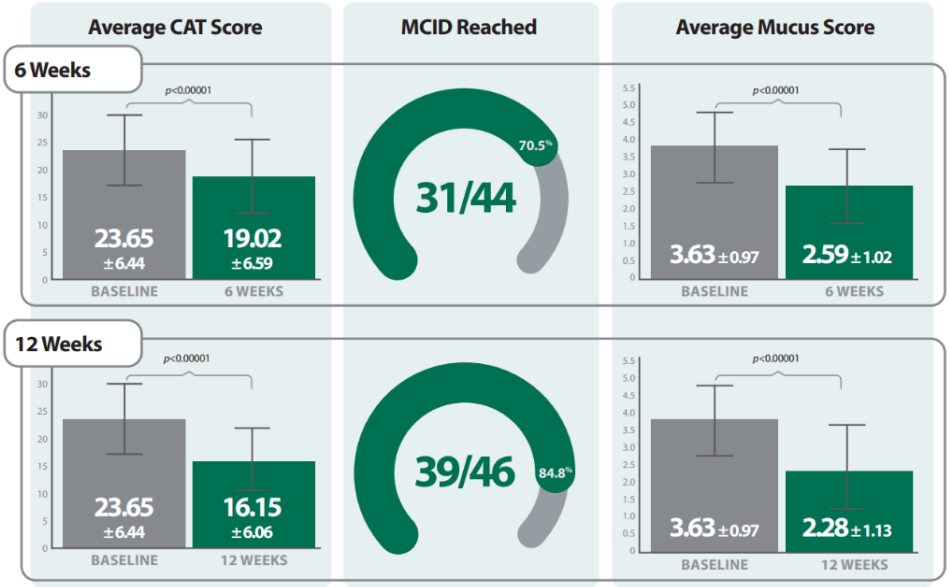
Conclusions: This evaluation describes an airway clearance service as it exists, providing an example from which airway clearance services can be planned, implemented and improved.

10 The Impact of an Oscillating Positive Expiratory Pressure Device on Quality of Life in COPD Patients

Poirier, C., Menard, P., Wang, S., & Suggett, J. The impact of an oscillating positive expiratory pressure device on quality of life in COPD patients. 2025 Canadian Respiratory Conference Abstracts. (2025). Canadian Journal of Respiratory, Critical Care, and Sleep Medicine, 9(sup1), S1-S68. https://doi.org/10.1080/24745332.2025.2501877

Clinical Study Poster | *Peer reviewed with journal citation*

Rationale: Clinical benefits of Oscillating Positive Expiratory Pressure (OPEP) devices have been previously demonstrated. This study aimed to provide patient-reported outcomes of OPEP treatment in chronic obstructive pulmonary disease (COPD) patients in Québec, Canada. **Methods:** Recruitment took place across 3 sites in Québec. Included COPD patients had a baseline COPD Assessment Test (CAT) score greater than 10, and a baseline mucus score of 2 or greater for item 2 of the CAT. Aerobika* OPEP (TMI) devices were provided, along with instructions on usage and technique. Patients were to complete at least 2 sessions daily, with each session lasting 10-20 minutes. CAT assessments were collected at the initial baseline visit, and at 6 and 12-week follow-up visits. At the final 12- week visit, patients were also asked whether they would continue to use the device and gave 1 (bad) to 5 (great) ratings on usability and satisfaction. **Results:** Data was analyzed from 46 patients. The average CAT score at 6 weeks was significantly lower compared to baseline (19.02 ± 6.59 vs. 23.65 ± 6.44, p<0.00001), with 31/44 patients (70.5%) reaching the minimum clinically important difference (MCID). CAT scores decreased further at 12 weeks (16.15 ± 6.06), a significant improvement from the 6-week results (*p*=0.0052). MCID was reached by 39/46 patients (84.8%) after 12 weeks of treatment. Average mucus scores at 6 and 12 weeks (2.59 ± 1.02 and 2.28 ± 1.13, respectively) were both significantly lower than the average baseline score (3.63 ± 0.97; p<0.00001 at both 6 and 12 weeks). Regarding device feedback, 43/44 patients (97.7%) would continue to use the device. The proportion of patients that provided 4/5 or 5/5 satisfaction ratings were 40/45 (88.9%), 43/45 (95.6%), and 40/45 (88.9%) for ease of use, quality, and overall satisfaction, respectively. No device-related adverse events were reported.



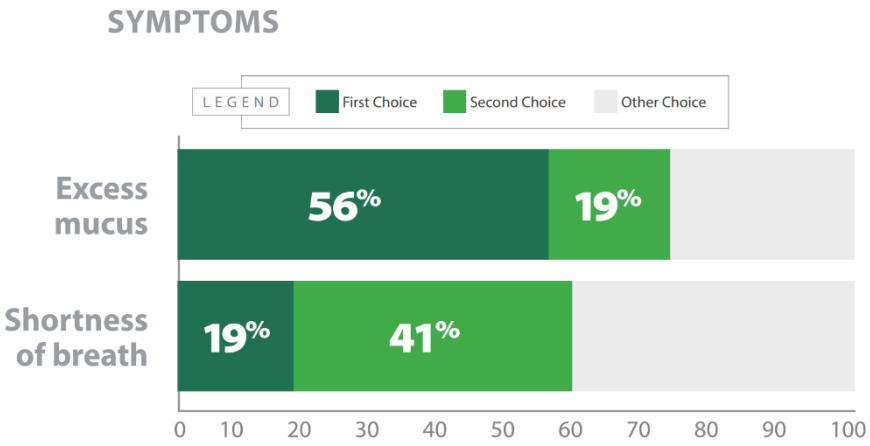
Conclusions: Statistically significant and clinically meaningful improvements were observed following 6- and 12-weeks use of the OPEP intervention. This study supports the use of the Aerobika* OPEP device in conjunction with standard of care therapy in COPD patients to manage symptoms and enhance quality of life. Patient feedback shows high levels of acceptable and perceived value of the device.

11 Acceptability of an Oscillating Positive Expiratory Pressure (OPEP) Device by Respiratory Disease Patients

Wang, S., Sydor, D., & Suggett, J. Acceptability of an Oscillating Positive Expiratory Pressure (OPEP) Device by Respiratory Disease Patients. Presented at the European Respiratory Society International Conference. Sept 26 – Oct 2, 2025.

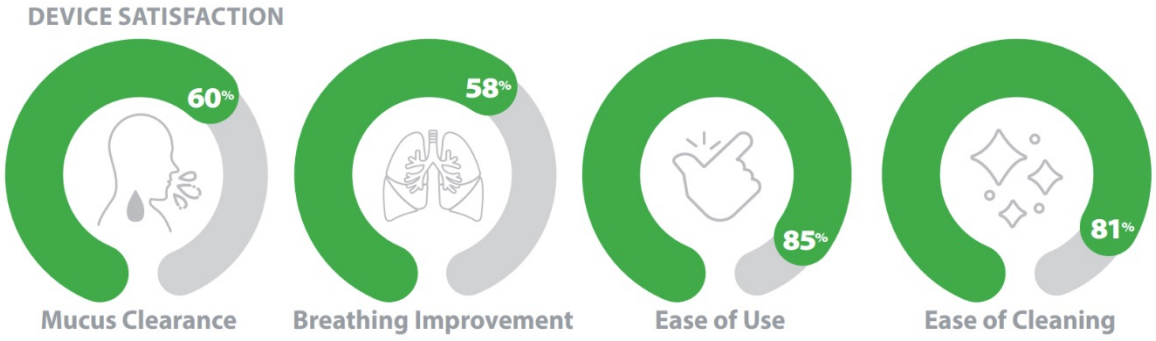
Clinical Study Poster | *Peer reviewed with journal citation*

Introduction: Despite OPEP therapy being an established treatment in the management of chronic respiratory disease, device satisfaction among users is not well understood. In this study, we investigated whether the Aerobika* OPEP device (TMI) is considered effective and accepted by patients with various respiratory diseases. **Methods:** A survey was sent out to patients across Canada who were registered with myAerobika*, a voluntary platform for Aerobika* OPEP users. Questions included asking which symptoms patients found most bothersome, which device attributes were most important, and device satisfaction. Depending on the question, patients were to select one or multiple provided responses. **Results:** Data was analyzed from 151 patients. Conditions included: COPD/chronic bronchitis, n = 75; bronchiectasis, n = 31; asthma, n = 13; respiratory infection, n = 12; cystic fibrosis, n = 5; and other, n = 15.



With regard to symptoms, 75% of patients selected excess mucus as their first or second most bothersome symptom, while 60% selected shortness of breath. This finding was generally independent of disease type.

Regarding device satisfaction, 60% of patients were extremely satisfied or very satisfied with the device's ability to clear mucus, and 58% reported such satisfaction for ability to improve breathing. 85% and 81% of patients were extremely or very satisfied with the device being easy to use and easy to clean, respectively.



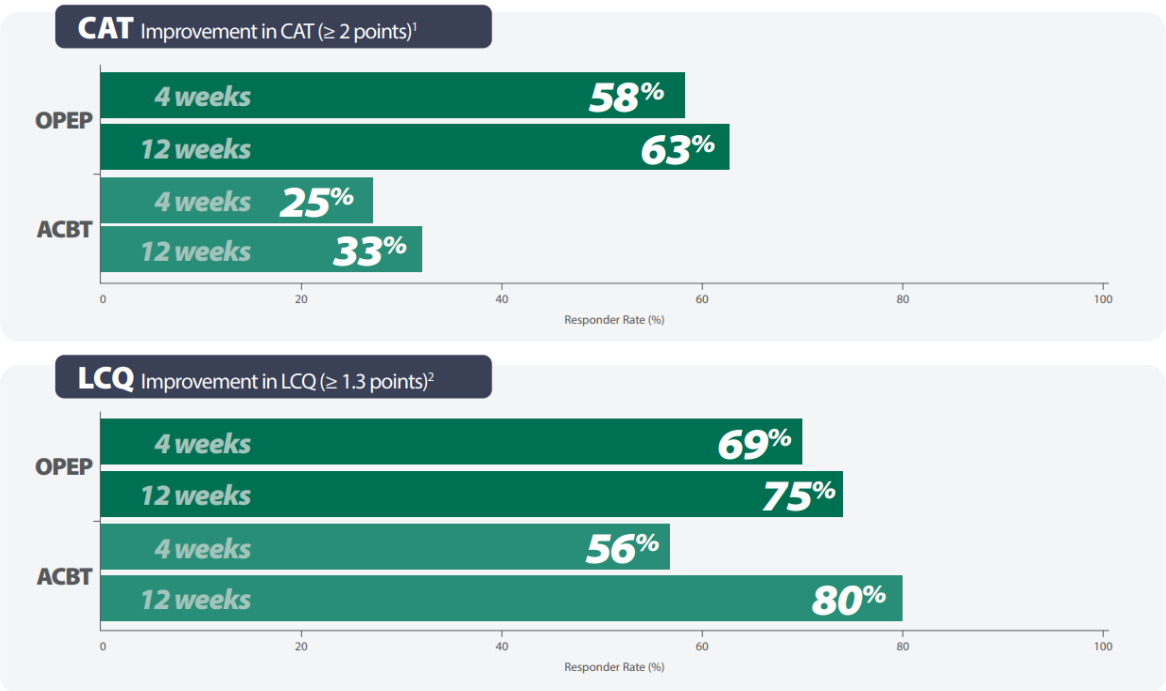
In terms of the most important device attributes, 70% of patients valued being easy to use and clean. The device scored 8.3/10 in terms of likelihood of continued use. **Conclusions:** Respiratory disease patients provided favorable feedback for the OPEP device, in terms of both addressing symptom concerns and usability.

12 Assessment of the Clinical value of an Oscillating Positive Expiratory Pressure (OPEP) Device and Active Cycle of Breathing (ACBT) for Chronic Obstructive Pulmonary Disease (COPD) Post Exacerbation: a 12 Week Prospective Randomized Study using Leicester Cough Questionnaire (LCQ) and COPD Assessment Test (CAT)

C. Bridges, J. Suggett, K. Lewis. Presented at American Thoracic Society Conference. May 17 – 22, 2024.
md-357a-0124-opep_v_acbt_poster-62x36-en.pdf

Clinical Study Poster | *Peer reviewed with journal citation*

Rationale: Despite multiple drug treatment options available, many people with COPD still suffer from poor quality of life, often as a result of excess mucus. This is further exaggerated as a result of exacerbations. This study assessed people with COPD suffering with mucus hypersecretion, post exacerbation in Wales, UK, following treatment with a handheld, OPEP device or the ACBT breathing technique. **Methods:** Inclusion criteria: • People with COPD aged 40-90 years old • Chronic Bronchitis (CB) phenotype • Gold E • FEV_1 / FVC Ratio <0.7 • >10 pack year history • Regular sputum producers • >15 CAT • On guideline pharmacological therapy • Exacerbation treated with antibiotics or steroids. Exclusion criteria: • Patients with life expectancy < 12 months • Unstable cardiac conditions • OPEP contraindications. All standard of care COPD therapy was maintained during the study. Participants were randomized to either OPEP (Aerobika* OPEP, Trudell Medical International) or ACBT, with LCQ and CAT data collected at 0, 4, and 12 weeks. Responder rates - % of patients having MCID (minimum clinically important difference) improvement - were assessed for each. **Results:** 29 patients (11 male) were included in the study. All participants were assessed at 4 weeks and 18 participants at 12 weeks. Responder rates for the two interventions are reported in the table.



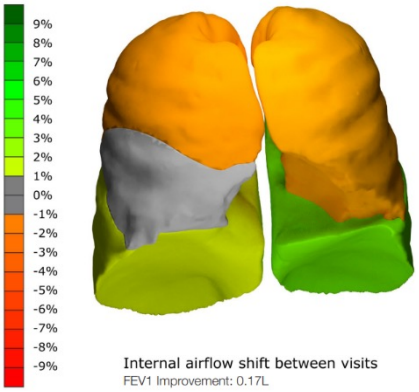
Conclusions: For COPD patients being discharged from hospital following exacerbation, the first 30 days recovery period is critical. Both interventions were associated with clinically important improvements in cough and quality of life for a number of patients, with OPEP having responder rates of 69% (LCQ) and 58% (CAT) respectively and ACBT 56% and 25%. Such improvements were generally maintained or improved further after 12 weeks. Notwithstanding the relatively small sample size, the results of this study provide evidence to support the potential use of the interventions in CB COPD patient.

13 The Impact of an Oscillating Positive Expiratory Pressure (OPEP) Device on Mucus Plugs: A Case Study Using Functional Respiratory Imaging (FRI) and a COPD Patient

J. Suggett, A. Cortes, C. Mussche, J.D. Backer. Presented at American Thoracic Society Conference. May 17 – 22, 2024. The Impact of an Oscillating Positive Expiratory Pressure (OPEP) Device on Mucus Plugs: A Case Study Using Functional Respiratory Imaging (FRI) and a COPD patient | trudellmed.com

Clinical Study Poster | *Peer reviewed with journal citation*

Rationale: A previously published FRI clinical study[1] had reported a shift in internal airflow distribution (IAD) to the lower lobes of a COPD patient following use of an OPEP (Aerobika*) device for 3 weeks. This shift was subsequently associated with an increase in FEV_1. Given the more recent availability of mucus plug detection as part of the FRI technology, we wanted to investigate this association further. **Methods:** The IAD and pulmonary function test (PFT) data for the COPD patient in the referenced study were evaluated in detail to understand IAD values in different lobes pre and post OPEP intervention, as were the results for FEV_1 and FVC. The FRI technology was also used to re-examine the CT images of the patient to assess location, number and volume of mucus plugs before and after OPEP intervention. **Results:** The patient's upper lobe IAD decreased from 39.7% to 32.8% after OPEP contrasting to an increase in lower lobe IAD from 60.3% to 67.2%. The FEV_1 for the same patient had a clinically significant increase from 2.48L to 2.65L and their FVC increased from 4.41L to 4.48L.

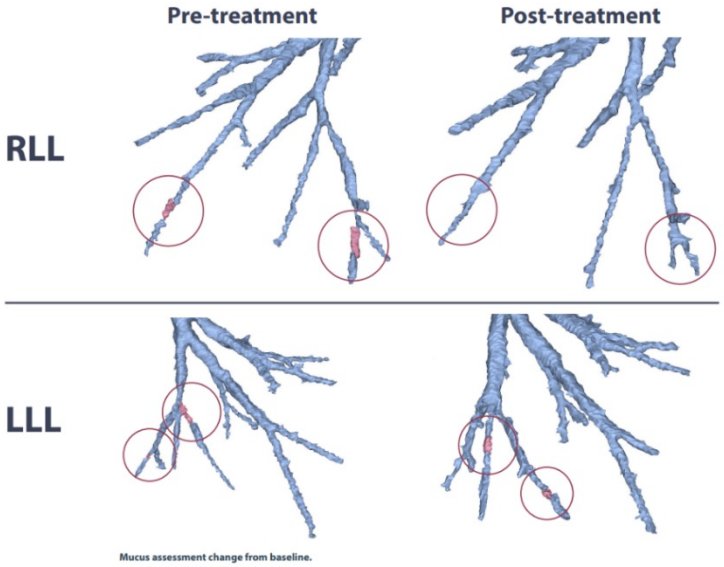


Analysis of the mucus plugs is reported in the table below.

Lobe location	UCSF Mucus Score[2] (before / after OPEP)	Mucus Volume (ml) (before / after OPEP)
Right-Upper Lobe	0 / 0	0 / 0
Right-Middle Lobe	0 / 0	0 / 0
Right-Lower Lobe	**2 / 0**	**0.033 / 0**
Left-Upper Lobe	0 / 0	0 / 0
Left-Lower Lobe	2 / 2	0.035 / 0.034
Total	**4 / 2**	**0.068 / 0.034**

Conclusions: The FRI analysis of mucus plug presence (and associated visual images) indicated that both mucus plugs originally present in the right lower lobe of the patient were no longer present post OPEP. This was linked to a decrease in mucus volume of 0.033ml in the same lobe. This evaluation shows the utility of the mucus detection technology within the FRI assessment, proposes a potential explanation for the increase in lower lobe airflow distribution and increased FEV_1 and FVC following OPEP therapy in this patient, and highlights the potential value of OPEP therapy in clearing the airways of excess secretions / plugs.

Associated lung images were also generated.



14 Nurse led oscillating positive expiratory pressure (OPEP) and the impact on quality of life using the St George's Respiratory Questionnaire (SGRQ)

Rickards, E., Kearney, C., & Jones, E. European Respiratory Journal 2024 64(suppl 68): PA3213; DOI: https://doi.org/10.1183/13993003.congress-2024.PA3213

Clinical Study Poster | *Peer reviewed with journal citation*

Introduction: The Knowsley Community Respiratory Team is a multidisciplinary team that diversifies traditional roles within health care to enhance and complement patient care. Nurse led OPEP was proposed to enable holistic treatment for patients as an adjunct to traditionally initiated pharmacological interventions. The nursing staff were trained by the physiotherapy team, which allowed patients to be treated promptly within one consultation. Methods : A total of 40 patients with COPD (27) and bronchiectasis (13) were included. Male : 31; Female : 9. Ex-smoker: 30; Current smokers: 7; Never smokers : 3. Patients were reviewed in the community setting. Following clinical assessment and established mucopurulent or purulent sputum, which was difficult to expectorate, OPEP was initiated. A SGRQ at baseline and again at week two was completed on all 40 patients. The Active Cycle of Breathing Technique (fig[1]) was advised pre and post OPEP 2 – 3 times daily (or as tolerated). Settings were adjusted according to patient preference/ tolerance. **Results:** Clinically meaningful improvements in SGRQ total score between baseline and week 2 favoured the initiation of OPEP, (total score, symptoms score, activity score and impact score) ($p<0.005$). Patient feedback was also positive in all 40 patients: 'Changed my life' 'Feel I can breathe so much better' 'My chest feels relieved and clear'. **Conclusion:** This study demonstrates that in patients with COPD and bronchiectasis, Nurse led OPEP in conjunction with the Active Cycle of Breathing Technique, improves quality of life and symptom burden.

15 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*

Clinical Study Poster | *Peer reviewed with journal citation*

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.

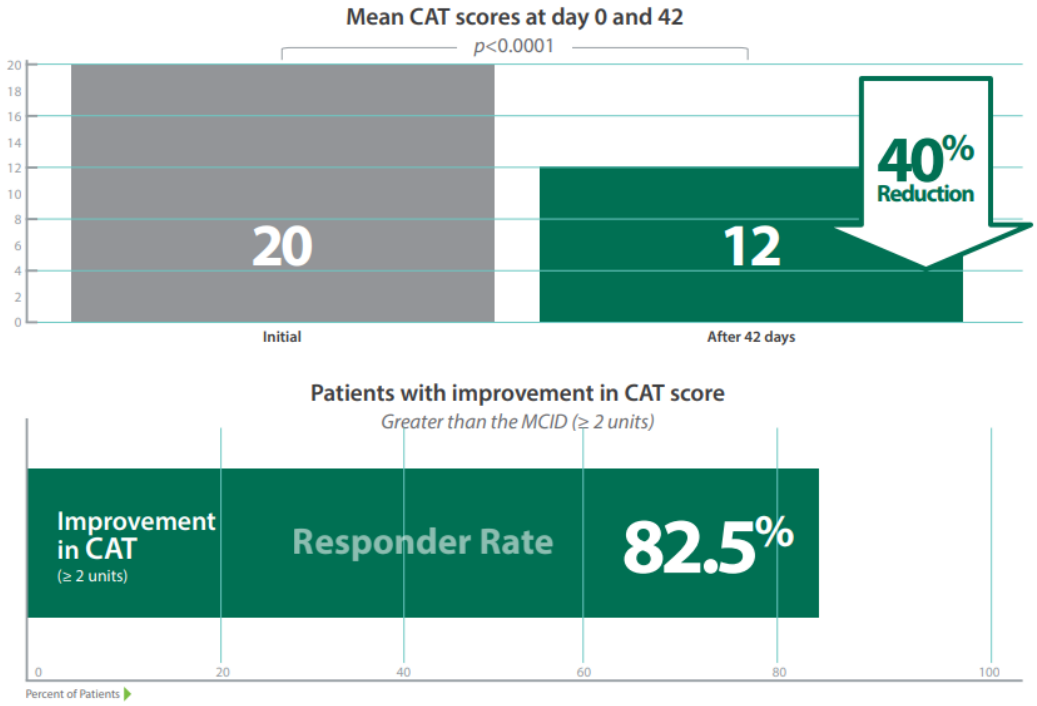
Primary Outcome: Leicester Cough Questionnaire (LCQ) at 3 months post-intervention (via intention to treat analysis). **Results:** Mean (SD) Total LCQ at 3 months in the OPEP group was 87.3 (27.3) vs 91.9 (29.2) in the ACBT group, p=0.73, 95% CI -33 to +23.8. **Conclusion:** Both groups showed statistically 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.

16 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*

Clinical Study Poster | *Peer reviewed with journal citation*

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.

17 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.https://doi.org/10.1164/ajrccm-conference.2021.203.1_MeetingAbstracts.A2264

Clinical Study Poster | *Peer reviewed with journal citation*

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.

18 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

J. Suggett[1], V. Kushnarev[1], D. P. Coppolo[2], J. Tse[3], K. Wada[3]; [1]Trudell Medical International, London, ON, Canada, [2]Monaghan Medical, Syracuse, NY, United States, [3]IQVIA, Virginia, VA, United States. Presented at ATS 2020. https://doi.org/10.1164/ajrccm-conference.2020.201.1_MeetingAbstracts.A7390

Clinical Study Poster | *Peer reviewed with journal citation*

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 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 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 first 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 significant difference 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.

19 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. Suggett[1], V. Kushnarev[1], D. Coppolo[2], J. Tse[3], K. Wada[3] [1]Trudell Medical International, London, ON, Canada. [2]Monaghan Medical Corporation, NY, US [3]IQVIA, Medical and Scientific Services, VA, US. *Presented at ERS 2020. European Respiratory Journal 2020 56(suppl 64): 631; DOI: https://doi.org/10.1183/13993003.congress-2020.631*

Clinical Study Poster | *Peer reviewed with journal citation*

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.

20 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. Bracey[1], J. Suggett[2], J. Conway[3]
[1]Trudell Medical UK - Basingstoke (United Kingdom), [2]Trudell Medical International - London Ontario (Canada), [3]Southampton NIHR Respiratory and Critical Care Biomedical Research Centre - Southampton (United Kingdom). *Presented at ERS International congress 2019 https://doi.org/10.1183/13993003.congress-2019.PA5267*

Clinical Study Poster | *Peer reviewed with journal citation*

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.

21 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. European Respiratory Journal 2018 52(suppl 62): PA3885; DOI: https://doi.org/10.1183/13993003.congress-2018.PA3885

Clinical Study Poster | *Peer reviewed with journal citation*

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 FEV_1 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 FEV_1 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 FEV_1. 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.

22 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.

Clinical Study Poster

Background: The Aerobika* OPEP device has been reported to reduce incidence of re-hospitalization following exacerbation[1] and improve quality of life outcomes for COPD patients with chronic bronchitis[2]. 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 FEV_1 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 FEV_1 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 FEV_1. 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.

23 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

Clinical Study Poster | *Peer reviewed with journal citation*

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 post-index 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.

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

J Suggett. Presented at ERS 2016. https://doi.org/10.1183/13993003.congress-2016.PA3780
https://erj.ersjournals.com/content/48/suppl_60/PA3780

Health Economic Poster | *Peer reviewed with journal citation*

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 20304. 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.

25 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

Clinical Study Poster | *Peer reviewed with journal citation*

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 COPD2. 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 exacerbations[5]. **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.

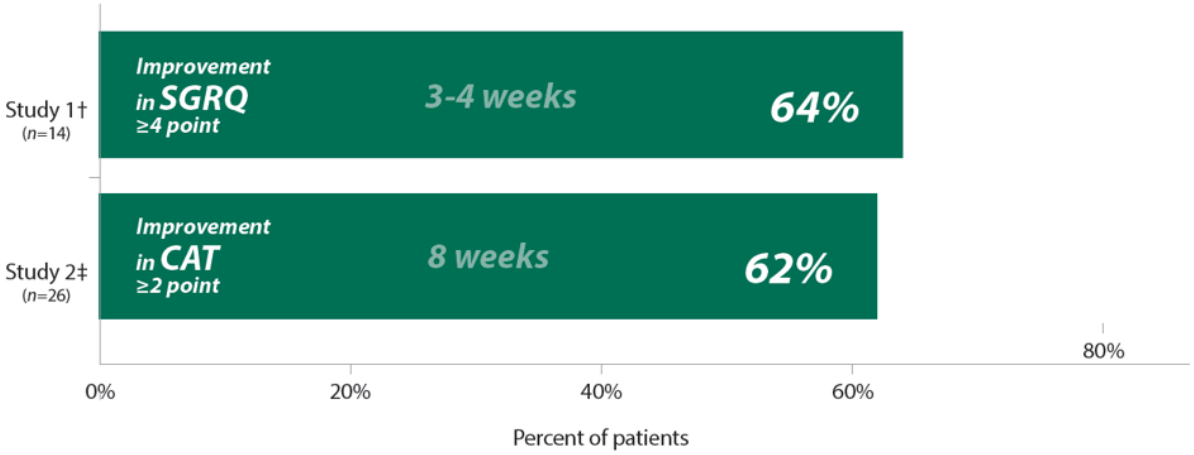
1 Svenningsen S, Paulin GA, Sheikh K, et al. Oscillatory Positive Expiratory Pressure in Chronic Obstructive Pulmonary Disease. COPD 2016;13(1):66-74. 2 O'Donnell DE, et al. Can Respir J. 2007;14(Suppl B):5B-32B. 3 Shah T, et al. CHEST. 2016 May 7. doi: 10.1016/j.chest.2016.05.002. [Epub ahead of print]. 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.

26 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

Clinical Study Poster | *Peer reviewed with journal citation*

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 11, a randomized cross-over study in 27 COPD patients (*n*=14 sputum-producers) for 3-4 weeks, used the SGRQ. Study 22, 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 assesment 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.

27 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

Clinical Study Poster | *Peer reviewed with journal citation*

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 units[1]) 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.

28 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

Clinical Study Poster | *Peer reviewed with journal citation*

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.

29 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.

Clinical Study Poster

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.

30 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

Clinical Study Poster | *Peer reviewed with journal citation*

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).

31 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

Clinical Study Poster | *Peer reviewed with journal citation*

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 ^{3}He 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.

32 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

Clinical Study Poster | *Peer reviewed with journal citation*

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.

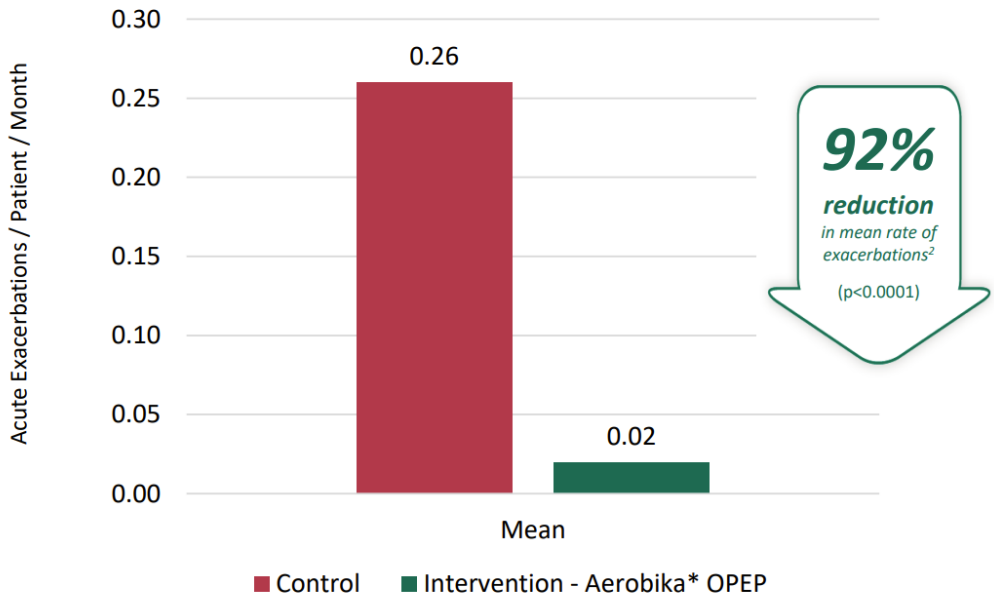
Petty TL. The National Mucolytic Study: Results of a Randomized, Double-Blind, Placebo-Controlled Study of Iodinated Glycerol in Chronic Obstructive Bronchitis. CHEST. 1990 Jan;97(1):75-83. 2. Kirby M et al. Hyperpolarized ^{3}He magnetic resonance functional imaging semi-automated segmentation. Acad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

1 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.

Clinical Study Paper

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.

2 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

Clinical Study Paper

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.

3 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

Clinical Study Paper

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.

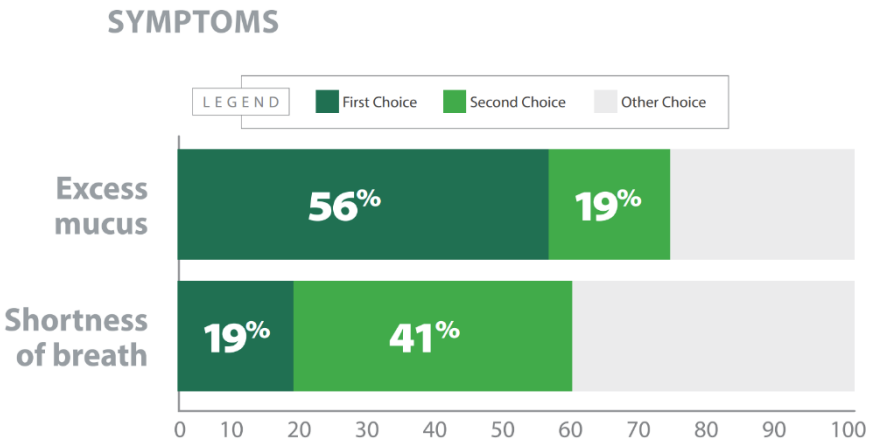
Conclusions: This evaluation describes an airway clearance service as it exists, providing an example from which airway clearance services can be planned, implemented and improved.

4 Acceptability of an Oscillating Positive Expiratory Pressure (OPEP) Device by Respiratory Disease Patients

Wang, S., Sydor, D., & Suggett, J. Acceptability of an Oscillating Positive Expiratory Pressure (OPEP) Device by Respiratory Disease Patients. Presented at the European Respiratory Society International Conference. Sept 26 – Oct 2, 2025.

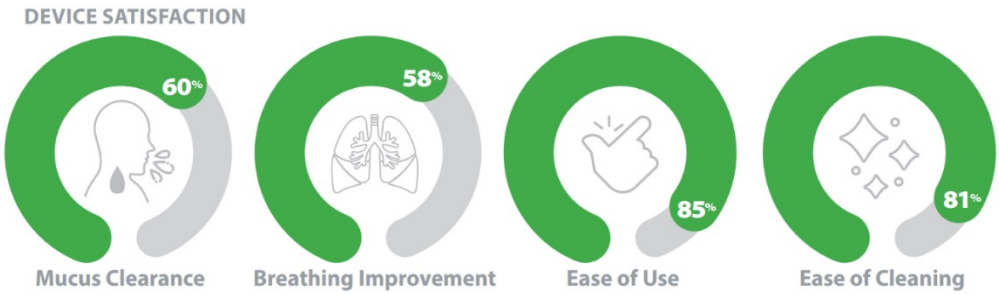
Clinical Study Poster | *Peer reviewed with journal citation*

Introduction: Despite OPEP therapy being an established treatment in the management of chronic respiratory disease, device satisfaction among users is not well understood. In this study, we investigated whether the Aerobika* OPEP device (TMI) is considered effective and accepted by patients with various respiratory diseases. **Methods:** A survey was sent out to patients across Canada who were registered with myAerobika*, a voluntary platform for Aerobika* OPEP users. Questions included asking which symptoms patients found most bothersome, which device attributes were most important, and device satisfaction. Depending on the question, patients were to select one or multiple provided responses. **Results:** Data was analyzed from 151 patients. Conditions included: COPD/chronic bronchitis, n = 75; bronchiectasis, n = 31; asthma, n = 13; respiratory infection, n = 12; cystic fibrosis, n = 5; and other, n = 15.



With regard to symptoms, 75% of patients selected excess mucus as their first or second most bothersome symptom, while 60% selected shortness of breath. This finding was generally independent of disease type.

Regarding device satisfaction, 60% of patients were extremely satisfied or very satisfied with the device's ability to clear mucus, and 58% reported such satisfaction for ability to improve breathing. 85% and 81% of patients were extremely or very satisfied with the device being easy to use and easy to clean, respectively.



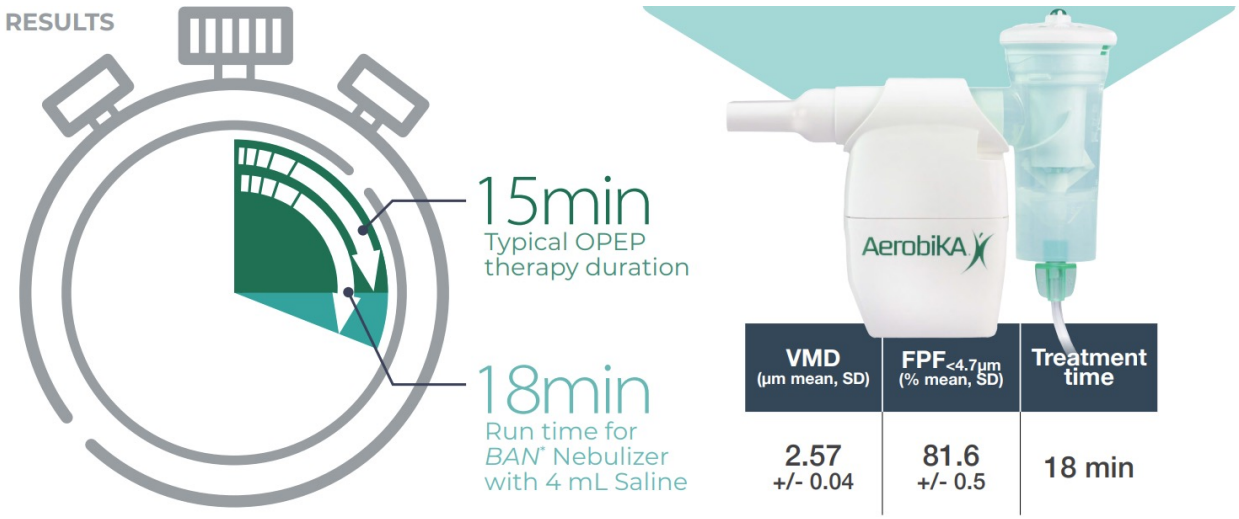
In terms of the most important device attributes, 70% of patients valued being easy to use and clean. The device scored 8.3/10 in terms of likelihood of continued use. **Conclusions:** Respiratory disease patients provided favorable feedback for the OPEP device, in terms of both addressing symptom concerns and usability.

5 Combination Therapy (OPEP and Nebulizer) to Provide Focus to Mucus Clearance – Results from a Lab Study Using Hypertonic Saline

Suggett J.[1], Schloss J.[2], Coppolo D.[2] Presented at the World Bronchiectasis Conference. July 4 – 6, 2024.
[1]Trudell Medical International, London, ON, Canada. [2]Monaghan Medical Corporation, Plattsburgh, NY, USA.

Laboratory Study Poster

Introduction: Management of excess mucus is a major treatment goal for bronchiectasis patients. Inhaled, nebulized mucolytics such as hypertonic saline are often used with other modalities, such as Oscillating Positive Expiratory Pressure (OPEP) devices. The treatment time burden is significant and therefore being able to combine therapies offers potential benefits to the patient in terms of reduced treatment duration. This study evaluated the medication delivery performance of hypertonic saline when delivered via a nebulizer with breath actuated technology (inhalation) attached to an OPEP device (exhalation). **Methods:** An AeroEclipse* XL BAN* Nebulizer / Ombra* Compressor (TMI) was connected to an Aerobika* OPEP device (TMI), n = 5. A 4 mL fill of hypertonic saline (7% NaCl) was delivered through the combination system and a laser diffractometer was used to determine the volume median diameter (VMD) as well as the fraction of delivered medication that was <4.7 microns (fine particle fraction, FPF<4.7µm). Treatment time was also determined when operating the combination therapy using an adult USP breathing pattern with the nebulizer in breath actuated mode.



Discussion/Conclusions: A typical treatment time for a single session of OPEP therapy is approximately 15 minutes. This laboratory study showed that with combination therapy there was a similar time associated with the completion of OPEP therapy and nebulized hypertonic saline, with more than 80% of the delivered medication being in the respirable droplet size range to work therapeutically in the lung. It has also previously been reported that such combination of these devices did not appreciably change the respirable mass delivered using the nebulizer alone.[1] In addition to providing the benefit of treatment time savings, this combination of devices reduces both medication wastage / fugitive emissions and has the potential to provide dual benefits of airway clearance compared to only performing one individual therapy. Given the efficiency of hypertonic saline delivery demonstrated in the study, as well as the good degree of alignment between ideal OPEP therapy time and nebulizer run time, this type of combination therapy should be considered to reduce the burden of therapy and for mucus management in bronchiectasis patients.

[1]M Nagel, et al. Pediatric Pulmonology 2019;54(S2):183

6 Nurse led oscillating positive expiratory pressure (OPEP) and the impact on quality of life using the St George's Respiratory Questionnaire (SGRQ)

Rickards, E., Kearney, C., & Jones, E. European Respiratory Journal 2024 64(suppl 68): PA3213; DOI: https://doi.org/10.1183/13993003.congress-2024.PA3213

Clinical Study Poster | *Peer reviewed with journal citation*

Introduction: The Knowsley Community Respiratory Team is a multidisciplinary team that diversifies traditional roles within health care to enhance and complement patient care. Nurse led OPEP was proposed to enable holistic treatment for patients as an adjunct to traditionally initiated pharmacological interventions. The nursing staff were trained by the physiotherapy team, which allowed patients to be treated promptly within one consultation. **Methods:** A total of 40 patients with COPD (27) and bronchiectasis (13) were included. **Male:** 31; **Female:** 9. Ex-smoker: 30; Current smokers: 7; Never smokers: 3. Patients were reviewed in the community setting. Following clinical assessment and established mucopurulent or purulent sputum, which was difficult to expectorate, OPEP was initiated. A SGRQ at baseline and again at week two was completed on all 40 patients. The Active Cycle of Breathing Technique (fig[1]) was advised pre and post OPEP 2 – 3 times daily (or as tolerated). Settings were adjusted according to patient preference/tolerance. **Results:** Clinically meaningful improvements in SGRQ total score between baseline and week 2 favoured the initiation of OPEP, (total score, symptoms score, activity score and impact score) ($p<0.005$). Patient feedback was also positive in all 40 patients: 'Changed my life' 'Feel I can breathe so much better' 'My chest feels relieved and clear'. **Conclusion:** This study demonstrates that in patients with COPD and bronchiectasis, Nurse led OPEP in conjunction with the Active Cycle of Breathing Technique, improves quality of life and symptom burden.

7 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.

Clinical Study Poster

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**

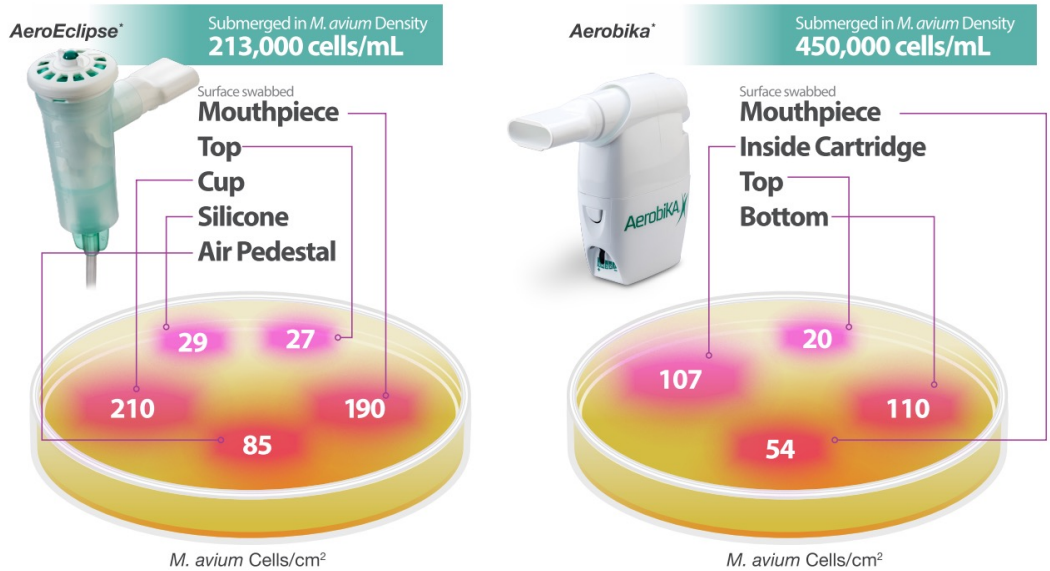
be more beneficial than ACBT as a standalone treatment, 2/11 patients felt unsure. Overall, 10/11 patients would recommend the use of an Aerobika* to other individuals with bronchiectasis. At clinic reviews, 9/11 patients were using the device as prescribed, identifying an increase in compliance. 6/11 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.

8 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

Laboratory Study Poster

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.

9 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

Clinical Study Poster | *Peer reviewed with journal citation*

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 AWCAutogenic 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 FEV_1 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.

10 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. Bracey[1], J. Suggett[2], J. Conway[3]
[1]Trudell Medical UK - Basingstoke (United Kingdom), [2]Trudell Medical International - London Ontario (Canada), [3]Southampton 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

Clinical Study Poster | *Peer reviewed with journal citation*

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.

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

Elizabeth H. Baker, PhD1; Hector H. Gutierrez, MD2; Stephanie Gamble, RT2; Gabriela R. Oates, PhD2. NACFC 2022.
[1]Department of Sociology; [2]Divison of Pulmonary and Sleep Medicine, Department of Pediatrics of Alabama at Birmingham

Clinical Study Poster

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. Bracey[1], J. Suggett[2], J. Conway[3]
[1]Trudell Medical UK - Basingstoke (United Kingdom), [2]Trudell Medical International - London Ontario (Canada), [3]Southampton 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

Clinical Study Poster | *Peer reviewed with journal citation*

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

L. Newell[1], A. Martin[1], A. Pitman[2], P. McCormack[2], K. Southern[2], Y.Y. Matthews[1]. Presented at 42nd European Cystic Fibrosis Conference. UK 2019. Journal of Cystic Fibrosis. 18:S162. DOI:10.1016/S1569-1993(19)30662-9
[1]Wrexham Maelor Hospital BCUHB Trust. [2]Alderhey Children's Hospital.

Clinical Study Poster | *Peer reviewed with journal citation*

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.

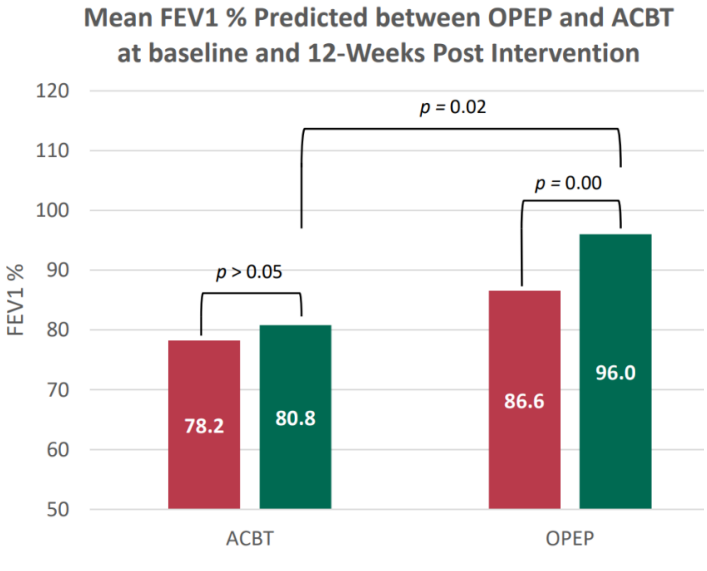
Conclusion: All 16 participating patients benefited from the use of the Aerobika* device to supplement their individual evidence-based regime of Airway Clearance Techniques (ACT). The Aerobika*8 OPEP device was found to be a useful device for supplementing ACT for this Paediatric patient group with CF. 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.

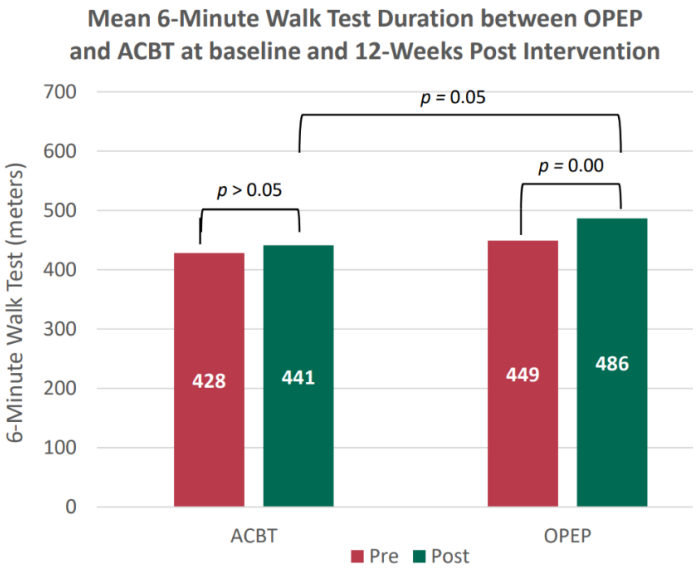
1 Active cycle of breathing technique versus oscillating positive expiratory pressure therapy: Effect on lung function in children with primary ciliary dyskinesia; A feasibility study

Fashho B, Rumman N, Lucas J, Halaweh H. Active cycle of breathing technique versus oscillating positive expiratory pressure therapy: Effect on lung function in children with primary ciliary dyskinesia; A feasibility study. Chronic Respiratory Disease. 2025;22. doi:10.1177/14799731251314872

Clinical Study Paper

Background: Primary Ciliary Dyskinesia (PCD) is a rare genetic disorder requiring airway clearance techniques for mucus removal. We aimed to evaluate the feasibility and the effect of the active cycle of breathing technique (ACBT) versus oscillating positive expiratory pressure therapy (OPEP) in improving lung function and functional exercise capacity among children with PCD in Palestine. **Methods:** 32 PCD children (6–18 years) were included in a 12-week home-based feasibility study. They were assigned randomly into two groups: ACBT and OPEP. Data collection included spirometry measurements, and the six-minute walk test (6MWT). **Results:** After 12 weeks of regular airway clearance techniques (ACT), the FEV_1, MEF25-75%, and the 6MWT demonstrated statistically significant differences ($p = .02$, $p = .04$, and $p = .05$ respectively) between the two groups, in favor of the OPEP group with the effect size of Cohen's d (0.86, 0.76, and 0.71) respectively. However, there was no significant difference ($p > .05$) between the two groups in FVC and FEV_1/FVC. Additionally, only in the OPEP group, significant differences were recorded between pre and post-tests for FEV_1 and 6MWT ($p < .05$).





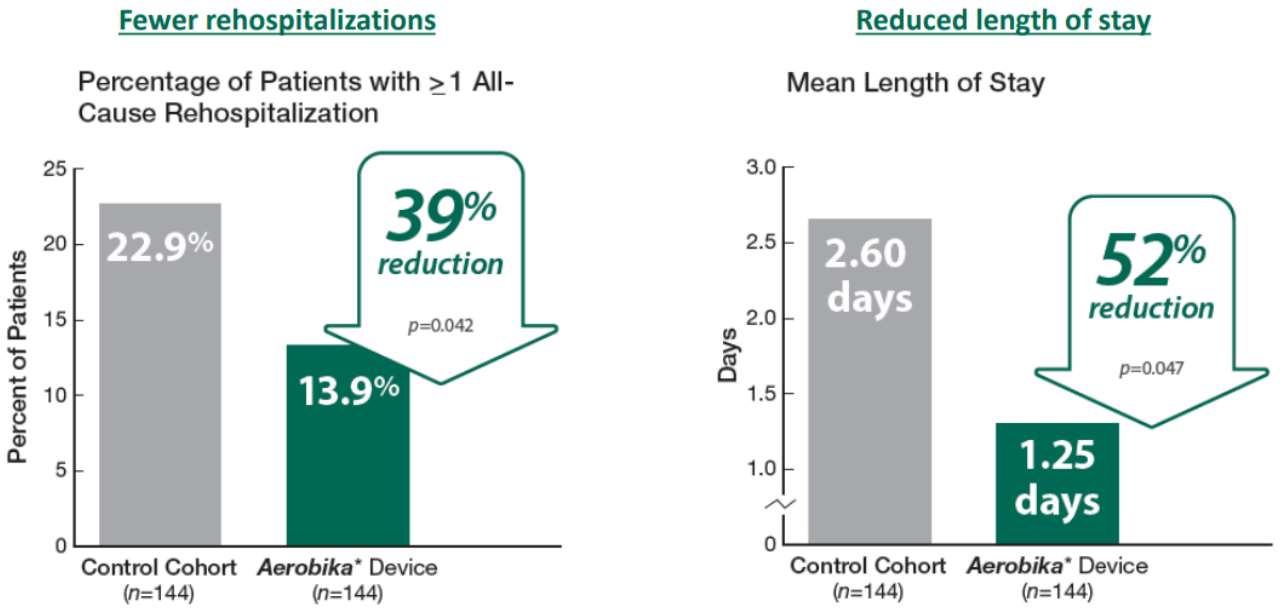
Conclusion: The randomized study design comparing ACBT and OPEP was feasible and acceptable to patients. OPEP demonstrates potential for managing respiratory health; however, treatments should be individualized to address each patient's specific needs. Further research with larger cohorts is needed to assess the effectiveness of both methods.

1 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

Clinical Study Paper

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.

2 Effect of Aerobika* Device in Sputum Induction, Pulmonary Function and Thoracic Expansion in Phase One Cardiac Rehabilitation for Post CABG Subjects: A Randomized Prospective Controlled Trial

Varun, N., & Paramshetti , A. (2025). Nepalese Heart Journal, 22(1), 3–9. https://doi.org/10.3126/nhj.v22i1.78198

Clinical Study Paper

Background: Patients who undergo coronary artery bypass graft (CABG) surgery frequently experienced pulmonary complications shortly after the procedure due to reduced lung function and a weakened cough reflex. The recent study aimed to determine and evaluate the effects of Aerobika* device on sputum induction, pulmonary function and thoracic expansion in phase one cardiac rehabilitation for post CABG subjects. **Methods:** A Randomized prospective controlled trail was conducted on 36 participants with median sternotomy. Participants were assigned to either Group A (*n*=18) or Group B (*n*=18). The session was carried for 30 minutes twice a day for a week. Outcome measures in the present study were sputum volume, thoracic expansion measurements, peak expiratory flow meter and maximal inspiratory pressure. The outcome measures were evaluated on daily basis, i.e., pre and post of every session. Statistical analysis used: Statistical analysis was done using SPSS 23. Wilcoxon test was used for within group pre test and post test comparison whereas Mann Whitney Test was used for between the group comparison. The level of significance was set at 5%. **Results:** Within-group analysis indicated that both groups demonstrated statistically significant improvements in all parameters individually (p-value = 0.001< 0.05). Between group comparison demonstrated that the experimental group was more effective in enhancing secretion clearance, thoracic expansion, maximal inspiratory pressure and peak expiratory flow meter as evidenced by significant differences (p-value = 0.001<0.05). **Conclusions:** The study concluded that phase one cardiac rehabilitation along with the use of Aerobika* device are effective in improving the sputum induction, pulmonary function and thoracic expansion of the lung.

POST-OPERATIVE PULMONARY COMPLICATIONS – POSTERS

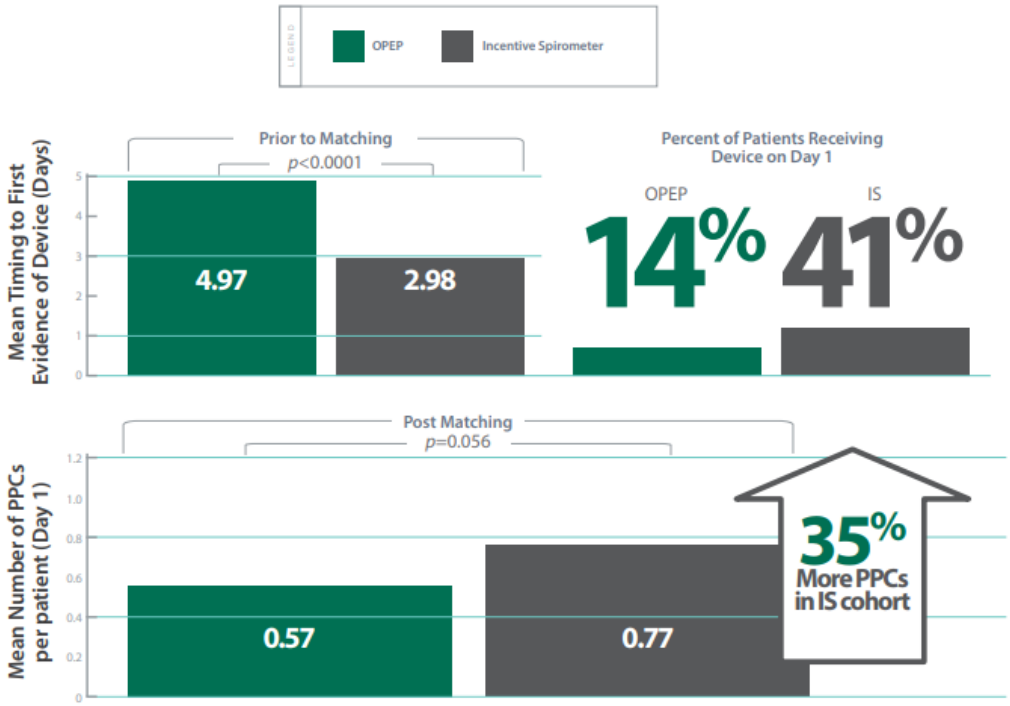
3 Assessment of Airway Clearance Therapy Usage and Outcomes in Post-operative Care – A Real World Evidence Study

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. Am J Respir Crit Care Med 2023;207:A2977. https://doi.org/10.1164/ajrccm-conference.2023.207.1_MeetingAbstracts.A2977*
https://www.trudellmed.com/global/en-CA/news/airway-clearance-therapy-usage-and-outcomes-post-operative-care

Clinical Study Poster | *Peer reviewed with journal citation*

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.

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

Clinical Study Paper

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 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

Laboratory Study Paper

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.

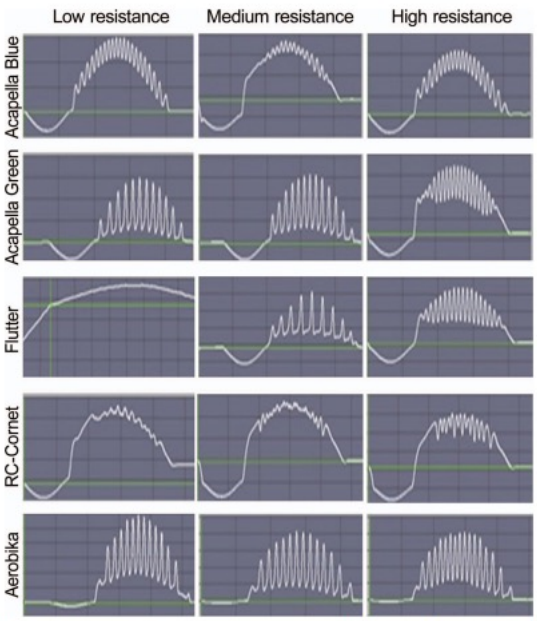


Fig. 5. Representative waveforms for each of the devices tested from which the oscillatory f was counted. The x axis represents the total cycle time of 2.7 s. Each representative waveform begins with inspiration (lasting 0.6 s). The oscillations occur during the active exhalation, which lasts 1.7 s. The y axis represents peak pressure, measured in cm H_2O. The ASL 5000 automatically adjusts the pressure scale range, resulting in differently scaled y axes for each of the graphs. The height of the y axes varies in magnitude from a minimum of 4 cm H_2O to a maximum of 25 cm H_2O. The green lines denote the reference 0 cm H_2O.

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.

3 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.

Laboratory Study Paper

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.

Table 2. Mean PEP, Peak PEP, Amplitude PEP, and Oscillation Frequency for Different Devices at Different Flows

Flow, L/min	Acapella Choice	Acapella DM	Acapella DH	Flutter	Aerobika	Pari PEP S
Mean PEP						
5		4.1 ± 0.05		5.8 ± 0.01	2.6 ± 0.02	1.3 ± 0.01
10	3.4 ± 0.05	5.7 ± 0.02		6.1 ± 0.07	5.8 ± 0.07	5.4 ± 0.05
15	4.9 ± 0.03	6.7 ± 0.04		6.0 ± 0.04	9.7 ± 0.06	10.5 ± 0.08
20	6.7 ± 0.06		6.5 ± 0.10	6.2 ± 0.03	14.4 ± 0.08	19.8 ± 0.15
25	8.5 ± 0.08		11.7 ± 0.08	6.7 ± 0.03	17.1 ± 0.12	28.5 ± 0.25
30	16.6 ± 0.13		17.0 ± 0.14	7.4 ± 0.19	21.6 ± 0.20	47.2 ± 0.47
Peak PEP						
5		12.1 ± 0.04		9.9 ± 0.03	15.7 ± 0.18	1.5 ± 0.00
10	13.7 ± 0.10	22.1 ± 0.04		16.0 ± 0.22	27.5 ± 0.12	5.5 ± 0.04
15	20.7 ± 0.08	26.6 ± 0.09		21.3 ± 0.07	38.6 ± 0.15	10.7 ± 0.06
20	26.8 ± 0.08		28.1 ± 0.26	26.9 ± 0.15	48.9 ± 0.18	19.9 ± 0.12
25	29.9 ± 0.44		14.4 ± 0.49	32.5 ± 0.16	52.6 ± 0.28	28.8 ± 0.26
30	21.1 ± 1.04		18.6 ± 0.16	39.2 ± 0.64	62.7 ± 0.52	47.4 ± 0.45
Oscillation Frequency						
5		10.3 ± 0.18		23.2 ± 0.08	6.5 ± 0.01	
10	10.0 ± 0.19	13.8 ± 0.03		23.1 ± 0.18	10.3 ± 0.07	
15	10.5 ± 0.10	12.9 ± 0.09		20.0 ± 0.02	11.5 ± 0.04	
20	10.9 ± 0.16		12.2 ± 0.44	17.6 ± 0.07	13.9 ± 0.13	
25	11.5 ± 0.25		17.6 ± 0.40	16.4 ± 0.03	16.0 ± 0.33	
30	19.1 ± 0.58		23.2 ± 1.10	15.3 ± 0.50	16.0 ± 0.51	
Amplitude PEP						
5		14.1 ± 0.89		9.9 ± 0.71	27.1 ± 1.72	
10	15.2 ± 0.91	23.4 ± 0.68		18.1 ± 1.21	29.3 ± 0.45	
15	22.3 ± 0.44	27.0 ± 0.41		23.3 ± 0.75	39.6 ± 0.18	
20	28.3 ± 0.45		30.9 ± 0.58	28.6 ± 2.26	50.6 ± 0.33	
25	31.4 ± 0.44		15.1 ± 1.89	34.6 ± 2.12	56.9 ± 0.70	
30	19.6 ± 1.95		13.9 ± 1.04	41.3 ± 2.62	65.5 ± 0.43	

All data represent mean ± SD values from 9 trials collected at a fixed medium resistance setting
PEP = positive expiratory pressure

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.

4 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.

Laboratory Study Paper

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 H_2O 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.

5 Comparison of 6 Oscillatory Positive Expiratory Pressure Devices During Active Expiratory Flow

Poncin W, Reychler G, Liistro M, Liistro G. Comparison of 6 Oscillatory Positive Expiratory Pressure Devices During Active Expiratory Flow. Respir Care. 2020 Apr;65(4):492-499. doi: 10.4187/respcare.07271. Epub 2019 Nov 19. PMID: 31744866.

Laboratory Study Paper

Background: Air-flow oscillations generated by exhaling through oscillatory positive expiratory pressure (OPEP) devices favor airway clearance. Variations in mechanical properties between different devices may influence therapeutic efficacy. The objective of this study was to assess mechanical properties in vitro and to compare the performance of 6 OPEP devices at different resistance levels under active expiratory flow patterns. **Methods:** 4 gravity-dependent OPEP devices (ie, Flutter, Gelomuc, Pari O-PEP, Shaker Medic Plus) and 2 gravity-independent OPEP devices (ie, Acapella Choice and Aerobika*) were each tested at low, medium, and high resistance settings. All devices were independently connected to a pulmonary waveform generator that reproduced active exhalation flows. Expiratory flow-volume curves were retrieved from 4 subjects with different stages of obstruction severity and were scaled according to either peak expiratory flow (4, 6, and 8 L/s) or volumes (2, 3 and 4 L), thus amounting to 24 active exhalations. Resulting waveforms were divided into 4 parts and the 2 middle parts were used to extract the following mechanical data: positive expiratory pressure (PEP), maximum expiratory pressure (Ppeak), oscillation frequency, and flow oscillation amplitude. The percentage of tests achieving oscillation frequencies ≥ 12 Hz and PEP ≥ 10 cm H_2O was calculated for each device. **Results:** Mechanistic effects of the Acapella, Aerobika*, and Shaker devices were not comparable. The Flutter, Gelomuc, and Pari devices behaved similarly and achieved more tests with optimum oscillation frequency and PEP values than the other devices. These 3 devices also produced the highest oscillation amplitudes at the low-resistance level, whereas the Aerobika* elicited higher and

consistent oscillation amplitudes at medium and high resistance settings. **Conclusions:** Operational parameters differed between and within devices, yet the Flutter, Gelomuc, and Pari devices were similar in many aspects. Therapeutic efficacy may depend on the selected OPEP device and set resistance.

6 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

Clinical Review Paper

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.

7 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

Clinical Study Paper

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."

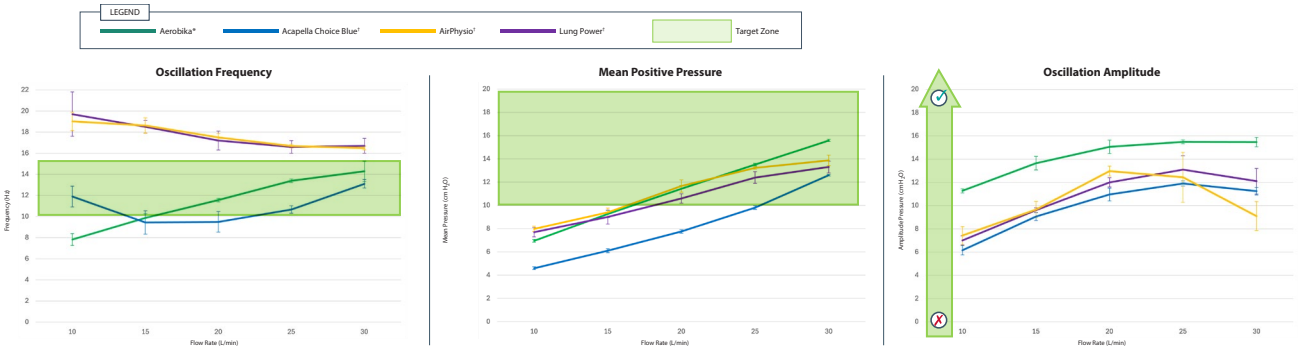
- "Treatment time was significantly shorter in the PEP group."
- "There were significantly more adverse events related to the lower airways in the HFCWO group than in the PEP group (mean 2.46 vs 1.72, p=0.023). These included increased cough, chest infection, haemaptysis, decreased lung function and 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."

8 Laboratory Assessment of Four Oscillating Positive Expiratory Pressure (OPEP) Devices: How do the Differing Mechanisms of Action Impact Performance

Suggett J.[1] Presented at the Asian Pacific Society of Respiratory Congress. November 7 – 10, 2024.
[1]Trudell Medical International, London, Ontario, Canada.

Laboratory Study Poster

Background & Aims: OPEP devices are crucial for airway clearance in patients with excessive mucus production, including those with bronchiectasis, CF and COPD. Ease of use, cleaning options, and ability to use in combination with a nebulizer are real world factors that differentiate various OPEP devices. OPEP devices often have differing mechanisms of action. This laboratory study compared four different OPEP devices, each with a distinctly different mechanism of action in producing oscillatory pressure. Key in-vitro performance parameters were compared to investigate whether mechanism of action has an impact on performance parameters. **Methods:** Four OPEP devices - Aerobika* (TMI), Acapella Choice Blue (ICU Medical), AirPhysio (AirPhysio) and Lung Power (Dream Air) 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. The average positive pressure, oscillation amplitude and oscillation frequency were determined for each device. **Results:** Each device can be operated at different resistances. The values at a medium resistance are reported in this study as this is typically the recommended starting setting. For effective performance, frequency is typically desired to be in the 10-15 Hz range[1], mean pressure ideally between 10-20 cm H_2O[2], and oscillation amplitude as large as possible[3]. Higher oscillation amplitudes indicate greater changes in pressure differentials which can create stronger shear forces, reducing the viscoelasticity of bronchial secretions[2] and enabling mobilization and clearance[3]. The results for the four devices show that for frequency, Aerobika* and Acapella were mostly in the desired range but AirPhysio and Lung Power were outside. For average pressure, Aerobika*, AirPhysio and Lung Power were mostly in the desired range while Acapella was below. For oscillation amplitude, Aerobika* was the highest across all flow rates with other devices lower and similar to one another. The observed differences are probably due to the different mechanical principles of each device.



Conclusions: 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 operate differently mechanically and that this may impact device performance and potentially the clinical benefit of the device. In this study the Aerobika* OPEP device performed the best overall. Hence, when selecting an OPEP device, it is crucial to consider not only the clinical evidence supporting its efficacy and patient preferences but also the variations in mechanical action that can influence device performance. All devices will not perform the same.

[1]Silva C, et al. Respiratory Care 2009;54(11):1480-1487. [2]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. [3]Van Fleet H, et al. Respiratory Care. 2017;62(4):451-458.

9 Laboratory Investigation into the Effect of Flow Rate on the Performance of Four Oscillating Positive Expiratory Pressure (OPEP) Devices: Does Mechanism of Action Matter and Considerations for Clinical Relevance

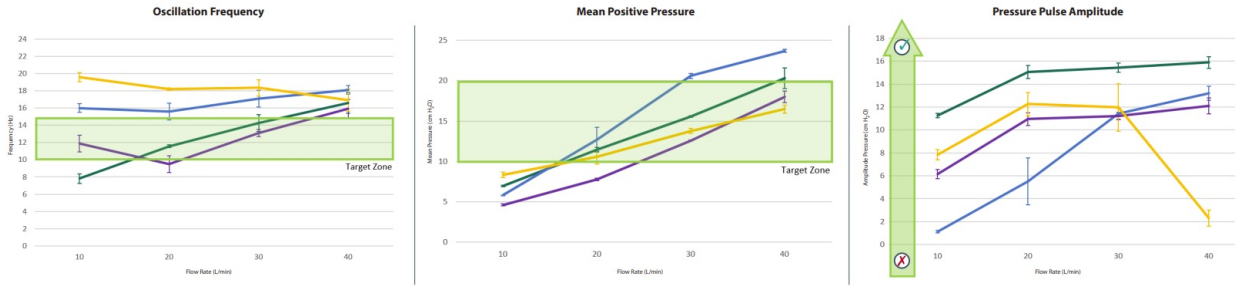
Suggett J, Costa R, Sydor D. European Respiratory Journal 2024 64(suppl 68): PA1368; DOI: https://doi.org/10.1183/13993003.congress-2024.PA1368

Laboratory Study Poster | *Peer reviewed with journal citation*

Introduction: OPEP devices are used therapeutically to aid airway clearance where excess mucus is a challenge, such as in bronchiectasis, CF and COPD. Ease of use, cleaning options, and ability to use in combination with a nebulizer are real world factors that differentiate various OPEP devices. OPEP devices often have differing mechanisms of action. This laboratory study compared four different OPEP devices, each with a distinctly different mechanism of action in producing the OPEP, to investigate whether mechanism of action has an impact on key in-vitro performance parameters. **Methods:** Aerobika* (Trudell Medical International), Acapella Choice Blue† (ICU Medical), GeloMuc† (Pohl Boskamp), and RC Cornet Plus† (Cegla) OPEP devices (*n*=3) were assessed at steady expiratory flows of 10-40L/ min using a flow generator (Resmed VPAP III), flow meter (TSI 4000), pressure tap and computer for data collection and analysis. Average positive pressure, pressure pulse amplitude and pulse frequency were determined for each device.

Results: Each device can be operated at different resistances. The values at a medium resistance are reported in this study as this is typically the recommended starting setting. For effective performance, frequency is typically desired to be in the 10-15 Hz range[1], mean pressure ideally between 10-20 cm H_2O[2], and pulse amplitude as large as possible[3]. Higher amplitudes indicate greater changes in pressure differentials which can create stronger shear forces that reduce the viscoelasticity of bronchial secretions[2], enabling mobilization and clearance[3]. The results for the four devices show that for frequency, Aerobika* and Acapella† are mostly in the desired range while GeloMuc† and RC Cornet Plus† are outside. For average pressure, all devices start a little below the desired range at 10 L/min before increasing, with the RC Cornet Plus† having pressures above the desired range at higher flow rates. For pulse amplitude, Aerobika* is the highest across all flow rates. GeloMuc† and Acapella† are lower and similar to each other (until GeloMuc† drops appreciably at 40 L/min). RC Cornet Plus† has the lowest pulse amplitude until flow rates reach 30 L/ min where it matches Acapella† and GeloMuc.† The observed differences are probably due to the different mechanical principles of each device.

Aerobika*, Acapella Choice Blue†, GeloMuc†, RC Cornet Plus†



Conclusion: It is important to understand that OPEP devices can operate differently mechanically and that this may impact device performance and potentially the clinical benefit of the device. In this study the Aerobika* OPEP device performed the best overall. 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.

[1]Silva C, et al. Respiratory Care 2009;54(11):1480-1487. [2]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. [3]Van Fleet H, et al. Respiratory Care. 2017;62(4):451-458.

10 Laboratory Assessment of Three Oscillating Positive Expiratory Pressure (OPEP) Devices: How do the Differing Mechanisms of Action Impact Performance with Considerations for Clinical Relevance

Suggett J.[1], Pinto T.[2], Favand P.[2]. Presented at the Journées Francophone Alvéole. March 21 – 22, 2024.
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Laboratory Study Poster

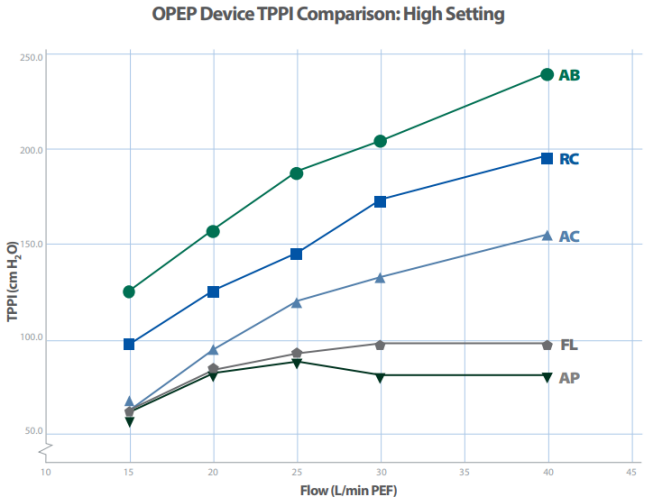
Introduction: OPEP devices are often used therapeutically to aid airway clearance where excess mucus is a challenge, such as in COPD, bronchiectasis, and cystic fibrosis. Ease of use, cleaning options, adjustable resistance, and ability to use in combination with a nebulizer are real world factors that differentiate various OPEP devices. In addition, OPEP devices often have differing mechanisms of action. This laboratory study compared three different OPEP devices, each with a distinctly different mechanism of action in producing the OPEP. Key in-vitro performance parameters were compared. **Methods:** Aerobika* (Trudell Medical International), Acapella Choice Blue† (ICU Medical), and GeloMuc† (Pohl Boskamp) 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. Pulse frequency, average positive pressure, and pressure pulse amplitude were determined for each device. **Results/Discussion:** Each device can be operated at different resistances. The values at medium resistance are reported in this study as this is typically the recommended starting setting. 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. Higher amplitudes indicate greater changes in pressure differentials which can create stronger shear forces that reduce the viscoelasticity of bronchial secretions and the adhesion of secretions to the bronchial walls, enabling mobilization and clearance. The results for the three devices show that for frequency, Aerobika* and Acapella are mostly in the desired range while GeloMuc is outside. For average pressure, Aerobika* and GeloMuc are mostly in the desired range while Acapella is below. For pressure pulse amplitude, Aerobika* is the highest across all flow rates with GeloMuc and Acapella lower and similar to each other. The observed differences are probably due to the fact that each device operates according to a different mechanical principle. Study limitations include the fact that this study is lab based (rather than clinical) and that flow rates above 30 L/min were not tested. However, as a comparative study, the results still have value. **Conclusions:** 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, and that this may impact device performance and potentially the clinical benefit of the device. In this study, the Aerobika* OPEP device performed the best overall as it was most often in the desired range for frequency and mean pressure, and produced the greatest pressure pulse amplitudes. 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.

11 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. European Respiratory Journal 2023 62(suppl 67): PA504; DOI: https://doi.org/10.1183/13993003.congress-2023.PA504*

Laboratory Study Poster | *Peer reviewed with journal citation*

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* (AB) (TMI), AirPhysio† (AP) (AirPhysio), Flutter† (FL) (Allergan), Acapella Choice† (AC) (ICU Medical) and RC Cornet† Plus (RC) (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 H_2O) 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.

12 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*

Clinical Study Poster | *Peer reviewed with journal citation*

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). **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.

13 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.*

Clinical Study Poster

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.

14 Assessment of Two Oscillating Positive Expiratory Pressure (OPEP) Devices (Aerobika* vs. 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

Laboratory Study Poster | *Peer reviewed with journal citation*

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.

15 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

Laboratory Study Poster

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.

	AEROBIKA®	ACAPELLA CHOICE BLUE†	FLUTTER† and Similar	vPEP†
Orientation independence Does device angle impact performance?	5 Mechanism not gravity dependent	5 Mechanism not gravity dependent	1 Internal metal ball mechanism -gravity dependent	3 Mechanism only allows some angle or pitch movement
Exhalation resistance variability Does adjustment change resistance?	5 5 resistance settings / good differentiation	5 Multiple resistance settings / good differentiation	1 Needs to be held at specific angles	3 3 resistance settings / poor differentiation
Ease of cleaning Are there multiple cleaning methods?	5 Easy to take apart and reassemble (4 parts). Dishwasher safe	5 Easy to take apart and reassemble (4 parts). Dishwasher safe	3 Easy to take apart and reassemble (3 parts). Dishwasher safety not always assured	3 Easy to take apart and reassemble (4 parts). Dishwasher safety not noted for cleared device
Ease of disinfection Are there multiple disinfection methods?	5 Includes steam sterilization, microwave, boiling, alcohol, hydrogen peroxide, bleach	3 Includes boiling, alcohol, hydrogen peroxide (contains metal parts)	1 No disinfection methods noted for most versions (contains metal parts)	3 Includes alcohol and hydrogen peroxide (contains metal parts)
Life span of device 12 mo., 6 mo. or undocumented lifespan	5 12 months	3 6 months	3 Variable – from no information to 6 months	1 No information - unclear
Ability to use with nebulizer Delivery of aerosol equal to nebulizer alone?	5 Yes - with good neb delivery	3 Yes - but potential to lose drug	1 Not possible	3 Yes - but not included in the intended use
Total Scores	30	24	10	16

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

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

Laboratory Study Poster

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.

17 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.
[1]Science and Technology, Trudell Medical International, London, ON, Canada. [2]Monaghan Medical, Syracuse, NY, United States. [3]Medical and Scientific Services, IQVIA, Falls Church, VA, United States.
https://doi.org/10.1164/ajrccm-conference.2021.203.1_MeetingAbstracts.A2264

Clinical Study Poster | *Peer reviewed with journal citation*

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.

18 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

Clinical Study Poster | *Peer reviewed with journal citation*

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 AWCAutogenic 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 FEV_1 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.

19 Assessing the Waveforms of Different Oscillating Positive Expiratory Pressure Devices: A Clinically Relevant Pressure Pulse Laboratory Study

Suggett J.[1], Coppolo D.[2], Meyer A.[1] Presented at the North American Cystic Fibrosis Conference. October 18 – 20, 2018.
[1]Trudell Medical International, London, Canada. [2]Monaghan Medical Corporation, Plattsburgh, NY, USA.

Laboratory Study Poster

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 links the critical performance attributes of pressure pulse amplitude and frequency in order to compare potential effectiveness. **Materials & Methods:** A simulated OPEP exhalation maneuver was generated based on previous research[1] in which a flow meter (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. Analysis of each device waveform was performed in order to determine the Total Pressure Pulse Impact around optimum oscillation frequency ($TPPI_f$).

Results: $TPPI_f$ = SUM of all amplitudes >1.0 cm H_2O in single exhalation, that are in frequency range 10-15 Hz.

Device	$TPPI_f$ [cm H_2O]
Aerobika*	88
vPEP†	57
Flutter†	51
Acapella Choice†	29
VibraPEP†	19

Discussions & Conclusions: The use of the $TPPI_f$ value to assess the therapeutic effectiveness of air flow oscillations is supported by the twin assumptions of

- Effectiveness is dependent, in part, on the ability of the device to generate and maintain a pressure amplitude / spike throughout the maneuver[2]
- Effectiveness is optimized at a frequency of approximately 13 Hz[3]

The $TPPI_f$ values showed the Aerobika* device to be the most effective, with a 54% higher value than the second ranking device and more than four times the value of the lowest performing device. The combination of pressure and frequency in assessing device performance also supports the value of a pressure manometer attachment to OPEP devices. It is recognized that the implications of these reported laboratory differences should be assessed in a clinical setting also, however they do provide useful relevant insights when selecting a device for clinical practice.

[1]Meyer A et al, Am J Respir Crit Care Med 2014;189:A3036. [2]Van Fleet H et al, Resp Care 2017;62(4):451-458. [3]Silva CEA et al, Resp Care 2009;54(11):1480-1487

20 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. CHEST, Volume 152, Issue 4, A970.

Laboratory Study Poster | *Peer reviewed with journal citation*

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.

21 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

Laboratory Study Poster | *Peer reviewed with journal citation*

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 H_2O. 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 H_2O). 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.

22 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

Laboratory Study Poster | *Peer reviewed with journal citation*

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 (TMipr) 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†
TMipr (ug)	582 ± 30	515 ± 28	308 ± 23
FMipr (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.

23 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

Laboratory Study Poster | *Peer reviewed with journal citation*

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 H_2O) 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. **Results:** The Comparative Values of t_{osc} at different adult PEFs for Simulated Exhalation Profiles are summarized in the Table below.

	t_{osc} (%)				
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 t_{osc} [% of exhalation time with oscillations] with the Aerobika* OPEP device were >75% at all PEF [Peak Expiratory Flow Rate] settings and were generally consistent. The other OPEP systems exhibited lower and much more variable t_{osc} values, ranging from 30% to 63%. Duration of oscillations for Aerobika* OPEP was 52-60% greater on average compared to other devices.

24 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

Laboratory Study Poster | *Peer reviewed with journal citation*

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 H_2O) 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.

GUIDELINES AND RECOMMENDATIONS

CHRONIC OBSTRUCTIVE PULMONARY DISEASE

1 Global Strategy for the Diagnosis, Management, and Prevention of COPD: GOLD 2025 Report

Global Initiative for Chronic Obstructive Lung Disease (GOLD): 2025 Report.

Guideline

Management of Mucus Hypersecretion: Treatment goals for patients with chronic bronchitis (CB) include:

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 Recommandations pour la prise en charge de l'encombrement des voies aériennes par les techniques de désencombrement (Guidelines for the management of airway mucus secretions by airway clearance techniques)

Reychler G, Audag N, Prieur G, Poncin W, Contal O; Groupe « Kinésithérapie Respiratoire » de la Société de pneumologie en langue française. Recommandations pour la prise en charge de l'encombrement des voies aériennes par les techniques de désencombrement [Guidelines for the management of airway mucus secretions by airway clearance techniques]. Rev Mal Respir. 2024 Sep;41(7):512-537. French. doi: 10.1016/j.rmr.2024.06.001. Epub 2024 Jul 17. PMID: 39025771.

Guideline

Recommendations:

- It is recommended that oscillating positive expiratory pressure techniques be used in comparison with standard care in order to increase the amount of expectorated secretions in patients with stable COPD
- It is recommended that OPEP and PEP techniques be used in patients with exacerbating COPD to facilitate sputum clearance

3 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.

Guideline

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).

4 Institut National d'Excellence en Santé et en Services Sociaux (INESSS) COPD Optimal Usage Guide

Institut National d'Excellence en Santé et en Services Sociaux Québec. Gouvernement du Québec, Novembre 2022.

Guideline

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

The goals of comprehensive COPD management include:

- Relieving dyspnea and respiratory symptoms that interfere with daily activities
- Decreasing the frequency and severity of acute exacerbations of COPD (AECOPD)
- Slowing the progression of the disease
- Maintaining quality of life and autonomy
- Reducing the risk of morbidity and mortality

INESSS recommends airway clearance techniques and in particular oscillating positive expiratory pressure devices such as Aerobika* OPEP for the presence of sputum to clear the airways and reduce the frequency of acute exacerbations of chronic obstructive pulmonary disease.

5 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 (2019): Oscillating positive expiratory pressure (OPEP) device therapy in Canadian respiratory disease management: Review, care gaps and suggestion for use, Canadian Journal of Respiratory, Critical Care, and Sleep Medicine, DOI: 10.1080/24745332.2018.1558426

Clinical Review Paper

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.

Figure 1. Oscillating positive expiratory pressure mode of action model.

Recommendations and future research: Based on the literature and the authors' clinical experience, we offer the following recommendations for clinical practice:

- Given the low-risk safety profile and body of evidence now available across a number of different devices, we believe that the incorporation of an OPEP device into treatment plans of COPD, bronchiectasis and CF patients could be considered when airway clearance therapy is thought to be of value. Notwithstanding the lack of large randomized controlled trials (RCTs) for any device in any patient population, there is a relatively large body of clinical evidence supporting the benefit of the Aerobika* device for COPD patients and some evidence supporting the Flutter device. The clinical evidence supporting the use of OPEP devices in CF and bronchiectasis, while mixed, does suggest their benefit in some cases. They may be considered in addition to standard of care given the low safety risk.
- OPEP devices do not all provide the same benefits to patients and may not be interchangeable. They operate differently, produce different pressure pulse waveforms, differ in terms of usability and cleaning, and are supported by varying levels of clinical evidence
- The choice of an OPEP device should be based on the published evidence, cost and patient preference. When OPEP devices are prescribed, patients should be taught which benefits to expect, and how to use and clean the device (eg, as per product instructions). Furthermore, training should be provided in performing a huff cough to expel the mucus that may have been loosened and mobilized by the device.

Summary: Although the number of large, controlled clinical studies published investigating OPEP devices is still small (and this is somewhat reflected in the lack of visibility in many guidelines), there is a growing body

of evidence supporting the effectiveness of some OPEP devices in specific patient populations. Published clinical trials for one OPEP device confirm that in COPD there is evidence of benefit to patients in terms of reduction of exacerbations, improved lung function and a positive impact on quality of life. OPEP devices have a range of strengths and weaknesses and may not be interchangeable. More studies that include OPEP devices are needed in stable disease and in acute exacerbation of bronchiectasis or COPD to better define their safety profile and efficacy at short and long term when combined with optimal medication treatment. We trust this article will provide clinicians an up-to-date guide of the potential use of OPEP while waiting for more data.

6 NICE: Chronic Obstructive Pulmonary Disease in Over 16s: Diagnosis and Management

National Institute for Health and Care Excellence (NICE) (2018). Chronic Obstructive Pulmonary Disease in Over 16s: Diagnosis and Management (NICE Guideline NG115). Available at: https://www.nice.org.uk/guidance/ng115

Guideline

Managing Stable COPD

Physiotherapy: If people with excessive sputum, they should be taught:

- How to use positive expiratory pressure devices
- Active cycle of breathing techniques

Oral prophylactic antibiotic therapy: Before offering prophylactic antibiotics, ensure that the person has had:

- Sputum culture and sensitivity (including tuberculosis culture), to identify other possible causes of persistent or recurrent infection that may need specific treatment (for example, antibiotic-resistant organisms, atypical mycobacteria or Pseudomonas aeruginosa)
- Training in airway clearance techniques to optimize sputum clearance
- A CT scan of the thorax to rule out bronchiectasis and other lung pathologies

Managing Exacerbations of COPD

Respiratory physiotherapy and exacerbations: Consider physiotherapy using positive expiratory pressure devices for selected people with exacerbations of COPD, to help with clearing sputum.

7 Chronic Obstructive Pulmonary Disease: Singapore Ministry of Health Clinical Practice Guidelines

Singapore Ministry of Health. Chronic Obstructive Pulmonary Disease – Ministry of Health Clinical Practice Guidelines. February 2017.

Guideline

Management of Acute Exacerbations

Discharge from hospitalization for exacerbations: Clearance of secretions

- Patients who regularly expectorate sputum or those with tenacious sputum may benefit from airway clearance techniques during an exacerbation. In individuals with copious secretions, mechanical vibration and positive expiratory therapy (PEP) increased sputum expectoration.

8 European Respiratory Society Clinical Practice Guideline for the Management of Adult Bronchiectasis

Chalmers JD, Haworth CS, Flume P, et al. European Respiratory Society Clinical Practice Guideline for the Management of Adult Bronchiectasis. Eur Respir J 2025; in press (https://doi.org/10.1183/13993003.01126-2025).

Guideline

Should airway clearance techniques be used (compared to no airway clearance techniques) in adults with bronchiectasis?

Recommendation

We recommend that patients with bronchiectasis should be taught airway clearance techniques (strong recommendation for the intervention, very low certainty of evidence).

- Previous ERS guidelines limited ACTs to patients with chronic productive cough. The current recommendation acknowledges that some patients with a dry cough, particularly those with mucus plugging on chest CT, may benefit from ACTs. Instruction in ACTs may also assist patients during periods of increased symptoms, such as exacerbations.

Justification of Recommendations

ACTs are associated with improved quality of life and symptoms and may reduce exacerbations. Airway clearance is a key component of daily bronchiectasis management. Despite the very low certainty of evidence, the panel issued a strong recommendation based on the following: i) ACTs are self-administered, low-cost, and accessible; ii) Patients widely recognize their benefits; iii) The recommendation was strongly supported by patient representatives. Although adverse effects and harms were not systematically reported or collected, ACTs are widely believed to be safe and low risk of adverse events. These factors outweigh the limitations of the evidence base and highlight a need for broader implementation. Airway clearance is underutilized in clinical practice, and this recommendation should encourage increased uptake among healthcare professionals and policy.

Implementation Considerations

Patients should receive appropriate training and personalized guidance in selecting the most suitable ACTs for their individual needs by a specialist respiratory physiotherapist. It is acknowledged that not all patients will have access to a respiratory physiotherapist and other healthcare professionals may be involved in teaching airway clearance. Although direct comparative studies are lacking, clinical experience from the panel members suggest starting treatment with independent ACTs (defined as methods used to clear mucus and secretions from the airways that can be performed by an individual without the need for assistance from another person or specialized equipment). Adjuvant airway clearance devices may be considered to enhance sputum properties, facilitate consistent treatment, and increase adherence and tolerability. These devices may not be equally accessible in low- and middle-income settings, and patients typically bear the costs due to limited coverage by health systems. Although the acceptability of remote delivery for this intervention is uncertain, it may offer an opportunity to enhance accessibility. Additionally, the panel supports implementing ACTs alongside an educational approach that identifies the benefits of this intervention and addresses barriers and facilitators to promote long-term adherence. Finally, when inhaled mucoactive agents or bronchodilators are administered alongside ACTs, the timing of administration in relation to ACTs should be carefully managed to maximize treatment synergy. There are no head-to-head studies comparing different ACTs, and the consensus is that no one technique is superior to others. Therefore, techniques should be chosen based on individual preference and effectiveness.

9 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. European Respiratory Society statement on airway clearance techniques in adults with bronchiectasis. Eur Respir J. 2023 Jul 20;62(1):2202053. doi: 10.1183/13993003.02053-2022. PMID: 37142337.

Clinical Review Paper

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 summarizes current knowledge about ACTs in adults with bronchiectasis and makes recommendations to improve the future evidence base.

A review of 30 randomized 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.

What is the physiological rationale of each one of the ACTs and what are the advantages and limitations of each technique?

	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

10 Management erwachsener Patientinnen und Patienten mit Bronchiektasen-Erkrankung (Management of adult patients with bronchiectasis)

Ringshausen FC, Baumann I, de Roux A, Dettmer S, Diel R, Eichinger M, Ewig S, Flick H, Hanitsch L, Hillmann T, Koczulla R, Köhler M, Koitschev A, Kugler C, Nüßlein T, Ott SR, Pink I, Pletz M, Rohde G, Sedlacek L, Slevogt H, Sommerwerck U, Sutharsan S, von Weihe S, Welte T, Wilken M, Rademacher J, Mertsch P. Management erwachsener Patientinnen und Patienten mit Bronchiektasen-Erkrankung [Management of adult bronchiectasis - Consensus-based Guidelines for the German Respiratory Society (DGP) e.V. (AWMF registration number 020-030)]. Pneumologie. 2024 Nov;78(11):833-899. German. doi: 10.1055/a-2311-9450. Epub 2024 Nov 8. PMID: 39515342.

Guideline

Physiotherapeutic treatment supports secretion mobilization, promotes physical activity and is a central component of pulmonary rehabilitation. The respiratory therapy techniques used make use of physical-mechanical effects such as increasing the expiratory flow rate, changing airway pressures, generating oscillations and gravity. In combination with efficient and energy-saving coughing as a compensation mechanism for the impaired mucociliary clearance, higher expiratory and inspiratory flows and ultimately better ventilation of the lung areas obstructed by bronchial mucus accumulation can be achieved.

The goals of secretion mobilization are, on the one hand, to reduce the amount of secretion and cough and, with it, airway inflammation and the risk of future exacerbations. On the other hand, an improvement in lung function and health-related quality of life of those affected can often be achieved.

A systematic literature search by the ERS Taskforce on the use of physiotherapeutic respiratory therapy in adults with bronchiectasis in 2023 found that the most frequently used techniques in studies were active cycle of breathing, postural drainage and oscillating positive expiratory pressure (PEP) therapy. Active techniques are preferred for patients with bronchiectasis, also because they allow for independent performance of the treatment and low-threshold implementation in everyday life. However, disadvantages include the effort and concentration required, as well as the possible need to clean and purchase spare parts for the equipment and the associated costs. In addition, there is no evidence for the superiority of a particular respiratory physiotherapeutic technique for secretion mobilization and clearance of the airways compared to others or for their effectiveness in improving disease severity and survival or health economic effects.

11 Recommandations pour la prise en charge de l'encombrement des voies aériennes par les techniques de désencombrement (Guidelines for the management of airway mucus secretions by airway clearance techniques)

Reychler G, Audag N, Prieur G, Poncin W, Contal O; Groupe « Kinésithérapie Respiratoire » de la Société de pneumologie en langue française. Recommandations pour la prise en charge de l'encombrement des voies aériennes par les techniques de désencombrement [Guidelines for the management of airway mucus secretions by airway clearance techniques]. Rev Mal Respir. 2024 Sep;41(7):512-537. French. doi: 10.1016/j.rmr.2024.06.001. Epub 2024 Jul 17. PMID: 39025771.

Guideline

Recommendation

- It is recommended that oscillating positive expiratory pressure techniques be used in comparison with standard care to increase the amount of expectorated secretions in patients with bronchiectasis in stable condition.

12 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/

Guideline

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).

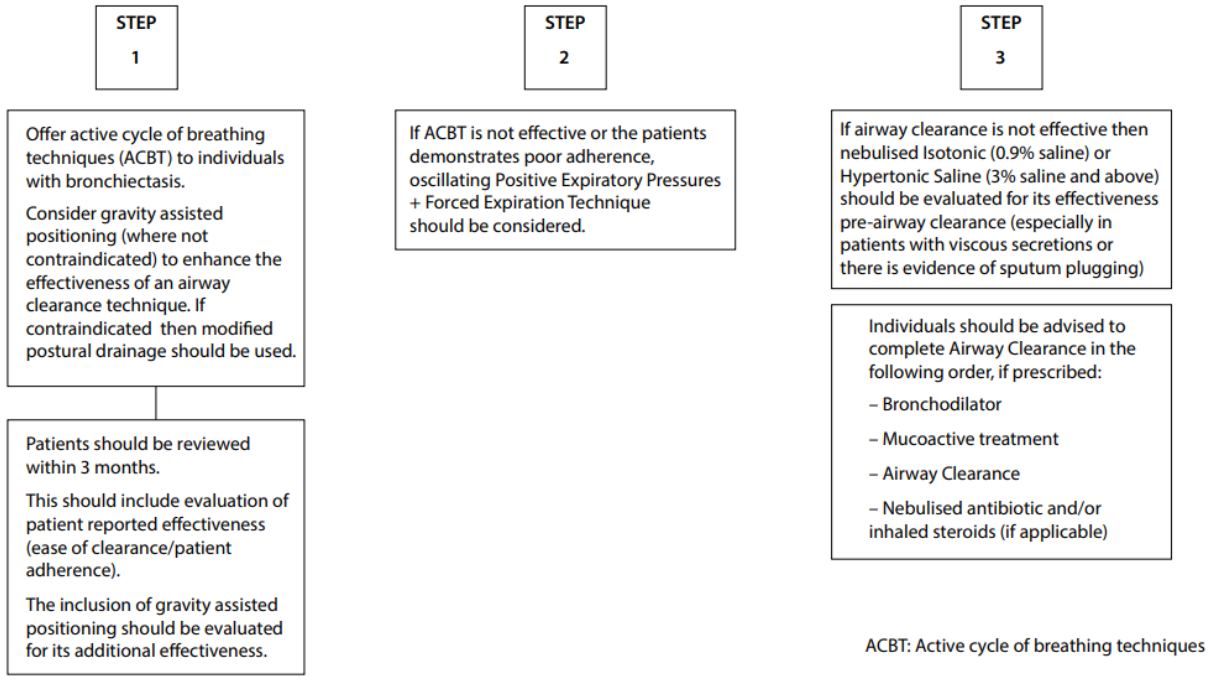


Figure 3 Physiotherapy management-stepwise airway clearance.

13 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

Guideline

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.

14 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.

Guideline

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.

15 Cystic Fibrosis Canada: Cystic Fibrosis Airway Clearance Therapy Recommendations in an Era of Modulators

Cystic Fibrosis Canada. https://cysticfibrosis.ca/resource/cf-airway-clearance-therapy-recommendations Accessed 22Sep2025.

Guideline

With the significant improvements in lung function and quality of life for people with CF who are taking modulators (e.g. Trikafta), **the Canadian Cystic Fibrosis Physiotherapy Advisory Group (CCFPAG) strongly recommends regular airway clearance therapy to keep the lungs healthy and maximize the impact of the modulator therapy.** More long-term evidence for people on modulator treatment is required to determine if the improvement in lung function can be sustained over time and if airway clearance routines can be reduced. For individuals who are not on modulator therapy, daily airway clearance remains one of the key foundational treatments to decrease the progression of CF lung disease.