

New Medicine Assessment

Oscillating Positive Expiratory Pressure Devices for Non – Cystic Fibrosis Bronchiectasis

RAG recommendation

Red – Oscillating positive expiratory pressure devices should be provided directly from respiratory services.

Background

There are currently six oscillating positive expiratory pressure devices listed in the Drug Tariff and available on prescription.

Device Name	NHS List Price (Oct 2019)
Acapella	£40.50
Aerobika	£45.50
Flutter	£40.50
Lungflute	£37.50
Pari O-PEP	£27.78
RC - Cornet	£39.95

It is unclear how long a device lasts and more than one would probably be needed each year with regular use.

The device is intended for use in medical conditions where there is excessive production of mucus and / or where mucus clearance is reduced e.g. bronchiectasis.

The devices are contraindicated in pneumothorax, severe TB, haemoptysis and right sided heart failure.

Evidence Summaries

The British Thoracic Society Guideline for Bronchiectasis in Adults¹

The BTS Guideline states that respiratory physiotherapy aims to mobilise secretions and aid effective expectoration, improving airways clearance and providing some control of cough.

The BTS Guidelines includes reference to various small studies.

It cites a single randomised crossover trial that has been published which assesses the efficacy of regular respiratory physiotherapy versus no respiratory physiotherapy in patients with bronchiectasis and chronic sputum expectoration.² Twenty stable outpatients who did not practice regular respiratory physiotherapy were included. The intervention comprised of twice daily 20-30minute sessions of respiratory physiotherapy using an oscillating positive expiratory pressure device (Acapella Choice) over a 3 month period compared with 3 months of no respiratory physiotherapy. The primary end-point was the Leicester Cough Questionnaire (LCQ). Additional outcomes included 24-hr sputum volume, forced expiratory volume in 1 s (FEV(1)), forced vital capacity (FVC), forced expiratory flow at 25-75% of FVC (FEF(25-75%)), maximum inspiratory pressure (MIP), maximum expiratory pressure (MEP), exercise capacity, sputum microbiology and St George's Respiratory Questionnaire (SGRQ). The treatment effect was estimated using the differences of the pairs of observations from

each patient. There was a significant improvement in all domains and total LCQ score with regular chest physiotherapy (median (interquartile range) total score improvement 1.3 (-0.17-3.25) units; $p = 0.002$). 24-h sputum volume increased significantly with regular chest physiotherapy (2 (0-6) mL; $p = 0.02$), as did exercise capacity (40 (15-80) m; $p = 0.001$) and SGRQ total score (7.77 (-0.99-14.5) unit improvement; $p = 0.004$). No significant differences were seen in sputum bacteriology, FEV(1), FVC, FEF(25-75%), MIP or MEP. The conclusion being that regular chest physiotherapy in non-cystic fibrosis bronchiectasis has small, but significant benefits.

The BTS Guidelines also look at the Flutter device, concluding based on the result of a study by Volsko³ that Acapella and Flutter have similar performance characteristics and that in a 4 week crossover trial, the Flutter (combined with the Forced Expiratory Technique (FET) and Postural Drainage (PD) as necessary) was shown to be as effective as the Active Cycle of Breathing Techniques (ACBT) and PD for median weekly sputum weight when used twice daily⁴. Neither of the techniques (ACBT or Flutter) had an adverse effect on Peak Expiratory Flow (PEF) or breathlessness. Eleven of the seventeen subjects expressed a preference for Flutter.

In other studies looking at the Flutter device included within the BTS Guidelines it would appear that although there is little or no difference in effectiveness between ACBT and Flutter groups, the patients preference lay with the Flutter device^{5 6}

A separate study considered the Aerobika device. This was a study in 15 stable bronchiectasis patients which looked at outcomes before and after 3 weeks of daily oscillating positive expiratory pressure (OPEP) (Aerobika) use. This showed significant improvements in Patient Evaluation Questionnaire (PEQ) – ease in bringing up sputum ($p=0.048$) and PEQ -global assessment ($p=0.01$)⁷.

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. However, it was concluded that compared with other Airway Clearance Techniques (ACTs), the effects in terms of sputum expectoration, lung function, gas exchange and symptoms were equivalent. Although the authors suggested a greater patient preference for the oscillating PEP compared with ACBT with or without Gravity Assisted Positioning (GAP)⁸.

The results of these studies have led to the following evidence statements in the BTS Guidelines for airways clearance techniques:

- The active cycle of breathing techniques is as effective as oscillating PEP (Flutter and Acapella) at clearing sputum
- The active cycle of breathing techniques plus PD enhances the quantity of sputum expectorated compared with the active cycle of breathing techniques in the sitting position or oscillating PEP (Flutter) in the sitting position
- Oscillating PEP (Acapella) is more effective at clearing sputum than a threshold inspiratory muscle trainer
- Oscillating PEP (Acapella) improves QoL, sputum volume expectorated and exercise capacity compared with no airways clearance technique over a 3 month period
- Oscillating PEP (Acapella) (plus postural drainage) is effective and safe to use during an acute exacerbation

With the recommendations that:

- Offer active cycle of breathing techniques **or** oscillating positive expiratory pressure to individuals with bronchiectasis
- Consider gravity assisted positioning (where not contraindicated) to enhance the effectiveness of an airways clearance technique.

Cochrane Review : Positive expiratory pressure therapy versus other airway clearance techniques for bronchiectasis (Review) 2017⁹

The primary aim of this review was to determine the effects of PEP therapy compared with other ACTs on health-related quality of life (HRQOL), rate of acute exacerbations, and incidence of hospitalisation in individuals with stable or an acute exacerbation of bronchiectasis. Secondary aims included determining the effects of PEP therapy upon physiological outcomes and clinical signs and symptoms compared with other ACTs in individuals with stable or an acute exacerbation of bronchiectasis.

Nine studies involving 213 participants met the inclusion criteria, of which seven were cross-over in design. All studies included adults with bronchiectasis, with eight including participants in a stable clinical state and one including participants experiencing an acute exacerbation. Eight studies used oscillatory PEP therapy, using either a Flutter or Acapella device and one study used Minimal PEP therapy. The comparison intervention differed between studies. The methodological quality of studies was poor, with cross-over studies including suboptimal or no washout period, and a lack of blinding of participants, therapists or personnel for outcome measure assessment in most studies. Clinical heterogeneity between studies limited meta-analysis. Daily use of oscillatory PEP therapy for four weeks was associated with improved general health according to the Short-Form 36 questionnaire compared to the active cycle of breathing technique (ACBT). When applied for three sessions over one week, minimal PEP therapy resulted in similar improvement in cough-related quality of life as autogenic drainage (AD) and L'expiration Lente Totale Glotte Ouverte en Décubitus Latéral (ELTGOL).

Oscillatory PEP therapy twice daily for four weeks had similar effects on disease-specific HRQOL (MD -0.09, 95% CI -0.37 to 0.19; low-quality evidence). Data were not available to determine the incidence of hospitalisation or rate of exacerbation in clinically stable participants. Two studies of a single session comparison of oscillatory PEP therapy and gravity-assisted drainage (GAD) with ACBT had contrasting findings. One study found a similar sputum weight produced with both techniques (SMD 0.54g (-0.38 to 1.46; 20 participants); the other found greater sputum expectoration with GAD and ACBT (SMD 5.6 g (95% CI 2.91 to 8.29; 36 participants). There was no difference in sputum weight yielded between oscillatory PEP therapy and ACBT with GAD when applied daily for four weeks or during an acute exacerbation. Although a single session of oscillatory PEP therapy was associated with less sputum compared to AD (median difference 3.1 g (95% CI 1.5 to 4.8 g; one study, 31 participants), no difference between oscillatory PEP therapy and seated ACBT was evident. PEP therapy had a similar effect on dynamic and static measures of lung volumes and gas exchange as all other ACTs. A single session of oscillatory PEP therapy (Flutter) generated a similar level of fatigue as ACBT with GAD, but greater fatigue was noted with oscillatory PEP therapy compared to ACBT alone. The degree of breathlessness experienced with PEP therapy did not differ from other techniques. Among studies exploring adverse events, only one study reported nausea with use of oscillatory PEP therapy.

The Cochrane review concluded that PEP therapy appears to have similar effects on HRQOL, symptoms of breathlessness, sputum expectoration, and lung volumes compared to other ACTs when prescribed within a stable clinical state or during an acute exacerbation. The number of studies and the overall quality of the evidence were both low. The following information is necessary to provide further guidance for prescription of PEP therapy for people with bronchiectasis:

- Evidence to establish the long-term clinical effects of PEP therapy over other ACTs for outcomes that are important to people with bronchiectasis
- Evidence on clinical parameters which impact on disease progression and patient morbidity in individuals with stable bronchiectasis.
- Evidence on the role of PEP therapy during an acute exacerbations.

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