

Airway Clearance in Bronchiectasis: A Randomized Crossover Trial of Active Cycle of Breathing Techniques versus Acapella®

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Key Words

Bronchiectasis · Airway clearance techniques ·
Acapella® · Active cycle of breathing techniques

Abstract

Background: The efficacy of a new airway clearance device (Acapella®) has not been previously investigated. Active cycle of breathing techniques (ACBT) is the standard airway clearance technique used in patients with bronchiectasis. **Objective:** The objective of this study was to compare the efficacy of ACBT with Acapella as methods of airway clearance in adults with stable, productive bronchiectasis. **Methods:** Twenty patients (7 males), age 58 ± 11 years (mean \pm SD), FEV₁ $64 \pm 22\%$ predicted with stable (change of not greater than FEV₁ 10% predicted during 3 months prior to study), productive (history of expectoration of half an egg cup sputum/day) bronchiectasis attended the respiratory clinic on 3 days. Day 1: 40-min training session on ACBT and Acapella. Days 2 and 3: 30-min treatment session of either ACBT or Acapella. Treatment order was determined by a concealed randomization procedure. The following outcomes were measured before and after treatment spirometry, SpO₂ and breathlessness by an independent assessor who was blinded to treatment order. Weight of sputum (during treatment plus 30 min after treatment),

number of coughs and patient preference were also recorded. **Results:** No significant differences were found at baseline indicating that patients were stable. No significant differences were found between weight of sputum expectorated with ACBT treatment and weight of sputum expectorated with Acapella treatment – mean difference 0.54 g (95% CI –0.39 to 1.46). A greater proportion of patients preferred Acapella (14/20). **Conclusion:** Acapella is as effective a method of airway clearance as ACBT and may offer a user-friendly alternative to ACBT for patients with bronchiectasis.

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Introduction

Bronchiectasis is characterized by repeated pulmonary infections requiring antibiotics, disabling productive cough, shortness of breath and occasional haemoptysis [1]. Impaired clearance of sputum results in a vicious cycle of colonization and infection of bronchi with pathogenic organisms, dilation of bronchi and further production of sputum [1, 2]. Airway clearance techniques (ACTs) are an important component of the management of patients with bronchiectasis. A recent UK survey showed that the active cycle of breathing techniques (ACBT) is the most frequently used ACT [3]. A number of other ad-

juncts are also available for airway clearance (for example, positive expiratory pressure and Flutter); however, there is limited evidence of their effectiveness in bronchiectasis.

The Acapella® (DHD Healthcare, Wampsville, N.Y., USA; CE approved) is a small hand-held device, which combines positive expiratory pressure and high-frequency oscillation therapy. A laboratory study compared the Acapella and Flutter in terms of mean pressure, pressure amplitude and frequency and found the devices to have similar performance characteristics [4]. The manufacturers suggest that Acapella may offer a beneficial alternative to other ACTs as it requires less therapist time, is self performed, can be used in any postural drainage position and is suitable to patients with a wide range of pulmonary function (www.dhd.com). No clinical trials have been conducted to investigate the effectiveness of Acapella in patients with bronchiectasis. Therefore, the purpose of this study was to compare the efficacy of Acapella with ACBT in adults with stable, productive bronchiectasis and to determine patient preference between the two techniques.

Materials and Methods

Patients

Twenty consecutive adult patients with stable (change of not greater than FEV₁ 10% predicted during 3 months prior to study), productive (history of expectoration of half an egg cup sputum/day) bronchiectasis (diagnosis by CT scan) were recruited from a specialist respiratory clinic at the Belfast City Hospital. The sample size in this study was based on a power calculation using sputum weight as the primary outcome measure [5]. A sample size of 16 is required to detect a difference of at least 3.8 g (4.23), with 90% power, using an α value of 0.05 and a two-tailed test. To allow for a drop-out rate, 20 patients were recruited into this study. Written informed consent was obtained from all participants. The study was approved by the local ethics committee.

Study Design

Patients attended the respiratory clinic on 3 days. Day 1: 40-min assessment/training session which included determination by auscultation of two postural drainage positions, selection of the correct Acapella device (green Acapella for patients able to sustain an expiratory flow of greater than 15 l/min for at least 3 s and blue Acapella for patients with an expiratory flow of less than 15 l/min), determination of the correct Acapella settings and training on ACBT and Acapella.

Days 2 and 3: patients performed either ACBT or Acapella at the same time on 2 consecutive days in a respiratory out-patient clinic. Patients were instructed to administer their medication (short-acting bronchodilators, long-acting bronchodilators and steroids, where applicable) at least 1 h before treatment and at the same time on both study days. The same physiotherapist adminis-

tered all treatment sessions. Treatment order was determined by a concealed computerized randomization procedure. End of treatment was determined when the patient was treated for a maximum of 15 min in each postural drainage position, the patient was no longer expectorating sputum or when the patient became too tired to continue treatment. An independent assessor conducted pre- and post-treatment (10 min after completion) measures of spirometric lung function (Micro Lab, 3500 UK), pulse oximetry (Nellcor Puritan Bennett NPB-40) and 15-count breathlessness score [6]. Weight of sputum expectorated (during treatment plus 30 min after treatment), number of coughs and patient preference after treatment day 2 were also recorded. Preference was assessed using a standardized questionnaire [7].

ACBT

ACBT was performed in the two predetermined postural drainage positions. The components of ACBT included breathing control, thoracic expansion exercises (percussion and/or vibration was added) and forced expiration (huff) in a set cycle [8].

Acapella

Acapella consists of a counterweighted plug and metal strip attached to a lever, and a magnet. Airflow oscillations are created by the breaking and reforming of a magnetic attraction by the plug as it intermittently occludes air passing through the device. The device incorporates a frequency/resistance dial which adjusts the proximity of the magnet to the metal strip, thereby regulating expiratory pressure and amplitude and frequency of oscillations. During the initial training session, patients were taught to exhale through the device (with frequency/resistance dial set at minimum setting) in a 3- to 4-second timeframe. If exhalation was too slow or too fast, patients were encouraged to exhale more or less forcefully. A manometer was then included in the circuit and the frequency/resistance dial increased until the expiratory pressure reading was maintained between 10 and 20 cm H₂O. Acapella was performed in the two predetermined postural drainage positions. The components of Acapella treatment included breathing control, 10 breaths through the Acapella device inhaling to three-quarter maximum breathing capacity, 2–3 s breath hold, active exhalation to functional residual capacity and cough or forced expiration (huff) in a set cycle.

Statistical Analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS version 11.0). The *t* test for paired samples was used to compare pre- and post-treatment outcome measures within each group. Differences in preference were analysed using a method proposed by Newcombe [9]. A *p* value of <0.05 was considered statistically significant.

Results

All twenty patients (7 males), age 58 ± 11 years (mean ± SD), FEV₁ 64 ± 22% predicted completed the study. No significant differences were found between baseline measures of lung function, SpO₂ or breathlessness score between study days indicating that patients were stable.

No significant differences were found between weight of sputum expectorated (during treatment plus 30 min after treatment) in ACBT treatment or Acapella treatment – mean difference 0.54 g (95% CI –0.39 to 1.46) (fig. 1). There were no significant differences between pre- and post-treatment measures of lung function, SpO₂ or breathlessness for either technique indicating that neither ACBT nor Acapella caused airway obstruction (table 1). No significant differences were found between treatment times of ACBT and Acapella – mean difference –0.3 min (95% CI –1.44 to 0.84). A greater proportion of patients preferred Acapella to ACBT; however, this was not significant – mean difference 0.4 (95% CI –0.04 to 0.71).

Discussion

This study demonstrates that the Acapella device is as effective a method of airway clearance as ACBT in patients with bronchiectasis during single treatment sessions. The efficacy of Acapella has not been previously investigated, and therefore, this study was conducted in the form of a single-session crossover trial. The study was originally designed to detect a clinically important difference of 3.8 g in sputum weight. Since the upper limit of the 95% CI (1.46 g) for the actual difference in sputum weight in this study – mean difference 0.54 g (95% CI –0.39 to 1.46) – lies well below 3.8 g, it is appropriate to conclude that a difference as large as 3.8 g is very unlikely.

ACBT is the standard ACT used in patients with bronchiectasis. Evidence for the use of ACTs in bronchiectasis is limited and focuses on four randomized controlled trials. In two trials, only a small proportion of the patients had bronchiectasis (50%) [10, 11]. A single intervention study demonstrated ACBT to be more effective than an

inspiratory muscle training technique advocated as an ACT in patients with bronchiectasis [12]. A randomized controlled trial compared the efficacy of ACBT with Flutter in 17 patients, for 4 weeks of each technique in a crossover design. No significant differences were found in daily sputum weight produced between treatments [13].

A bench study has shown that the Acapella has performance characteristics similar to Flutter [4]. A range of flow rates compatible with the pulmonary function of respiratory patients were artificially created from a compressed oxygen source. The devices were compared in terms of mean pressure, pressure amplitude and frequency. Acapella was found to produce higher amplitude oscillations at lower flow rates and therefore has the potential to be useful in patients with more severe lung function. This study demonstrated that although Acapella and

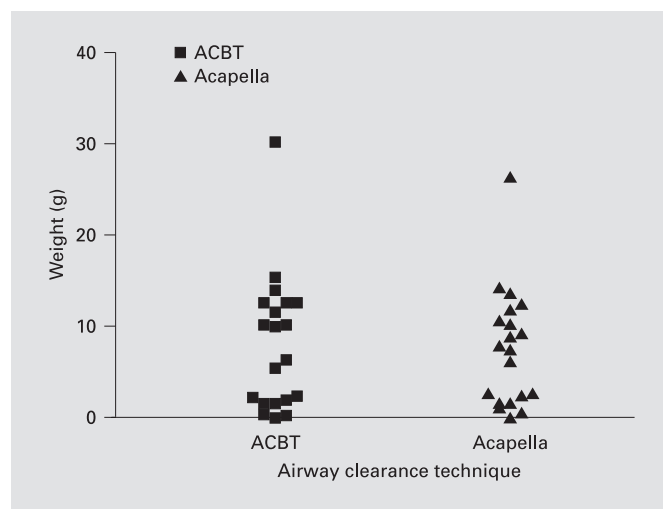


Fig. 1. Weights of sputum expectorated with ACBT and Acapella.

Table 1. Pre- and post-treatment measures of lung function and SpO₂

	ACBT before treatment mean ± SD	ACBT after treatment mean ± SD	p value (95% CI)	Acapella before treatment mean ± SD	Acapella after treatment mean ± SD	p value (95% CI)
FEV ₁ , % predicted	65±20	65±22	0.56 (–2.02 to 1.12)	65±22	65±22	0.88 (–2.42 to 2.82)
FVC, % predicted	81±20	81±20	0.40 (–2.23 to 0.93)	80±19	81±20	0.48 (–3.42 to 1.82)
PEF, % predicted	67±19	68±19	0.89 (–3.50 to 2.20)	69±20	70±18	0.34 (–5.48 to 1.98)
SpO ₂ , %	97±1	96±2	0.23 (–0.18 to 0.68)	97±1	97±1	0.06 (–0.81 to 1.31)

FVC = Forced vital capacity; PEF = peak expiratory flow.

ACBT were similar in terms of sputum production, a greater proportion of patients preferred Acapella. This may have been due to the experience of using a novel device or the benefits of being able to perform treatment independently.

In conclusion, this single intervention study indicates that Acapella is as effective a method of airway clearance as ACBT. It was found to be the preferred method of airway clearance and provides a technique that can be administered independently.

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