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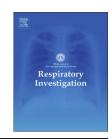
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### Original article

## A new method for enhanced expectoration of sputum by vibratory stimulation of the cervical trachea

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#### ABSTRACT

Background: Expectoration of sputum can be difficult for patients with respiratory conditions such as chronic obstructive pulmonary disease, chronic bronchitis, or bronchiectasis because of the effects of decreased pulmonary function, respiratory muscle fatigue, altered sputum properties, and impaired ciliary function. We developed a new method for the vibratory stimulation of the cervical trachea and this study aimed to compare it with the Acapella (a current oscillation device) method.

Methods: Patients with chronic productive cough and difficulty with expectoration were recruited for the study. The tracheal vibration and Acapella methods were applied for 4 weeks each, according to a crossover design with an intervening 4-week washout period. To perform the tracheal vibration method, an electronic artificial larynx (Yourtone®) was applied to the cervical trachea for up to 5 minutes. Patient preference for the two devices was determined from the performance scores recorded for each device and by using a visual analogue scale. Results: Twelve patients were recruited in the study. According to the performance scores assigned by the subjects, the tracheal vibration method was effective in 9 patients, while the Acapella method was effective in 10 patients. Both methods were effective in 8 patients, among whom the tracheal vibration method was more effective in 5 patients. Both methods were found to be ineffective in 1 patient.

Conclusions: The tracheal vibration method may be effective at removing central airway sputum and does not require repeated forced expiratory effort, which can otherwise cause exhaustion in patients with decreased lung function. Further investigation is required to confirm its use as a new oscillation technique.

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Abbreviations: COPD, chronic obstructive pulmonary disease; TV, tracheal vibration; VAS, visual analogue scale \*Corresponding author. Fax: +81 42 526 5535.

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#### 1. Introduction

Patients with chronic respiratory failure, such as chronic obstructive pulmonary disease (COPD), chronic bronchitis, or bronchiectasis, often find the expectoration of sputum difficult because of decreased pulmonary function, respiratory muscle fatigue, sputum property changes, and/or impaired ciliary function [1]. In general, strategies for improving airway clearance include pharmacotherapy with nebulizers or expectorants, chest physiotherapy, or cough-assisted maneuvers such as oscillatory techniques [2-6]. Airway clearance techniques based on oscillation (vibration) involve the use of oscillating positive expiratory pressure devices such as the Acapella, Flutter, and Cornet [7-9] that apply vibration to the airways during expiration and SmartVest that allows high-frequency chest wall oscillation [6]. We recently found that direct vibratory stimulation of the trachea might assist airway clearance. The cervical trachea is the only part of the lower airway where an external device can be readily employed for vibratory stimulation, but the effects of tracheal stimulation have not been reported. The aim of the present study was to investigate the safety of a new tracheal vibration (TV) method and to compare its efficacy at clearing sputum with the Acapella method in patients with chronic respiratory disease.

#### 2. Material and methods

#### 2.1. Patients

Patients with chronic respiratory disease and chronic productive cough who had difficulty with expectoration were recruited to participate in our study at the Pulmonology Outpatient Department of the National Hospital Organization Disaster Medical Center (Tokyo, Japan) from June 2012 to July 2014. The eligibility criteria were as follows: age > 18 years, expectoration of sputum >5 times/day, complete expectoration requiring >30 s, and stable medication for 4 weeks before the study. Exclusion criteria were the presence of any of the following within 4 weeks before enrollment: acute exacerbation requiring an increase of steroid therapy, common cold, reflux esophagitis, musculoskeletal disorders, uncontrolled asthma, heart failure, upper/lower airway bleeding, pneumothorax, and surgery in the trunk area. Patients were also excluded for pregnancy or breast-feeding and if they were inappropriate for any other reason according to the attending physician. This study was approved by the ethics committee of the National Hospital Organization Disaster Medical Center (date of approval, 20 January 2012, approval number 2011-40) and written informed consent was obtained from all participants. This study was registered with the University Hospital Medical Information Network clinical trials registry (registration number: UMIN000017425; date of registration, May 7, 2015).

#### 2.2. Study design

A randomized crossover design was employed in this study. During the 2-week run-in period, patients recorded the daily frequency and difficulty of expectoration (scored on a visual analogue scale [VAS]) in a "sputum diary." In the 4-week



Fig. 1 – Tracheal vibration method. An electronic larynx (Yourtone) is applied to the cervical trachea.

Phase 1, patients were randomly divided between the Acapella and the TV groups. In the TV group, an electronic larynx (Yourtone, Densei Communications Inc., Hokkaido, Japan) that is normally used to create an artificial voice after laryngectomy was applied to the cervical trachea to generate continuous transcutaneous vibration at 80 Hz for up to 5 min per session (Fig. 1).

#### 2.3. Methods

Each treatment was performed at least twice a day (morning and evening) or more often, as needed. The frequency of expectoration, number of treatments, and difficulty of expectoration (a higher VAS score indicated that expectoration was more difficult) were recorded daily in the sputum diary. After Phase 1, a 4-week washout period was included, following which patients switched to the other method for Phase 2 of the study. During the washout period, patients maintained the sputum diary. Two weeks after completing Phase 2, patients rated the efficacy of each device on a scale of 0-100 (a higher score indicating superior efficacy), expressed their preference for the Acapella or Yourtone method using a VAS with the Acapella and Yourtone at opposite ends (a higher score indicating a stronger preference), and wrote comments on both devices. The patients also underwent lung function tests and completed a quality of life (QOL) questionnaire at the start and end of Phases 1 and 2. The QOL questionnaire was based on the St. George's Respiratory Questionnaire [10] to assess respiratory function and the Japanese version of the SF36 Health Survey [11,12] to assess general health.

#### 2.4. Analysis

The primary endpoints of this study were the scores (0–100) assigned by the patients to each device and their preference for the Acapella or the Yourtone methods. The secondary endpoints included the safety of the device, QOL, respiratory function, frequency of expectoration, and the VAS score for expectoration.

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