Effect of airway vibratory mucus disintegration on clinical morbidity and management of chronic obstructive pulmonary disease patients

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Background Chronic obstructive pulmonary disease (COPD) is the fifth cause of morbidity and mortality in the developed world and represents a substantial economic and social burden. Patients experience a progressive deterioration characterized by airflow limitation, limited and declining performance status with chronic respiratory failure, and severe systemic manifestations/complications.

Aim of study The aim of the study was to evaluate the effect of airway vibratory mucus disintegration on clinical morbidity and management of COPD patients.

Patients and methods This prospective study was conducted on 30 COPD patients admitted to the Chest Department, Main University Hospital in Alexandria during the period from January 2012 to November 2012. The patients were subdivided into two groups: group I included 15 patients with COPD subjected to conventional treatment and group II included 15 patients with COPD subjected to conventional treatment and mucus disintegration by mechanical vibration.

Results A general improvement in cough and dyspnea was observed in the two groups after treatment. Six-minute walking distance was improved after treatment in both groups, but the improvement was statistically significant only in group II after treatment. Partial pressure of oxygen in the blood (PaO_2), partial pressure of CO_2 in the blood ($PaCO_2$), and bicarbonate (HCO_3) and oxygen saturation (SaO_2) showed significant differences before and after treatment among group II patients. The total duration of hospital stay was significantly lower in group II patients than in group I patients.

Conclusion We can conclude that there were no adverse effects. Flutter is simple to use, inexpensive, and fully portable, and once the patient and family are instructed its use, it does not require the assistance of a caregiver.

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Introduction

Chronic obstructive pulmonary disease (COPD) is the fifth cause of morbidity and mortality in the developed world and represents a substantial economic and social burden. Patients experience a progressive deterioration characterized by airflow limitation, limited and declining performance status with chronic respiratory failure, and severe systemic manifestations/complications [1].

Today, COPD develops earlier in life and is less sex specific. Tobacco smoking is the major risk factor for COPD followed by occupation and air pollution. Severe deficiency of α1-antitrypsin is rare; several phenotypes are being associated with the elevated risk for COPD in the presence of risk factor exposure. Any patient presenting with cough, sputum production, or dyspnea should be assessed using standardized spirometry.

Continued exposure to noxious agents promotes a more rapid decline in lung function and increases the risk for repeated exacerbations, eventually leading to end-stage disease. Without major efforts in prevention, there will be an increasing proportion of end-stage patients who can live longer through long-term oxygen therapy and assisted ventilation but with elevated suffering and huge costs. Prevention and cessation of smoking are the most important epidemiological measures to counteract COPD epidemics [1].

In 1998, in an effort to draw more attention to COPD, its management, and its prevention, a committed group of scientists encouraged the US National Heart, Lung, and Blood Institute and the WHO to form the Global Initiative for Chronic Obstructive Lung Disease (GOLD). The important objectives of GOLD are to increase awareness of COPD and to help millions of people who suffer from this disease and die prematurely because of it or its complications [2].

The under-recognition and underdiagnosis of COPD lead to significant under-reporting. The extent of under-reporting varies across countries and depends on the level of awareness and understanding of COPD among health professionals, on the organization of healthcare services to cope with chronic diseases, and

on the availability of medications for the treatment of COPD [3].

COPD in its early stages (stages I and II) is usually not recognized, diagnosed, or treated, and therefore may not be included as a diagnosis in a patient's medical record. Morbidity from COPD may be affected by other comorbid chronic conditions that are not directly related to COPD; nevertheless, it may have an impact on the patient's health status or may interfere with COPD management. In patients with more advanced disease (stages III and IV), morbidity from COPD may be misattributed to another comorbid condition [4–6].

Identification of cigarette smoking as the most commonly encountered risk factor for COPD has led to the incorporation of smoking cessation programs as a key element of COPD prevention as well as an important intervention for patients who already have the disease [7,8]. Cigarette smokers have a higher prevalence of respiratory symptoms and lung function abnormalities, a greater annual rate of decline in FEV1, and a greater COPD mortality rate compared with nonsmokers. Pipe and cigar smokers have greater COPD morbidity and mortality rates than nonsmokers, although their rates are lower than those for cigarette smokers [9]. Other types of tobacco smoking popular in various countries are also risk factors for COPD [10,11].

Aim of the study

The aim of the study was to evaluate the effect of airway vibratory mucus disintegration on clinical morbidity and management of COPD patients.

Patients and methods

Patients

The study population included 30 patients with COPD, subdivided into two groups. The study was approved by the institutional ethics committee.

Group I: Patients were subjected to conventional treatment.

Group II: Patients were subjected to conventional treatment and mucus disintegration by mechanical vibration using Flutter mucus clearance device (Axcan Scandipharm Inc., Birmingham, Alabama, USA). The Flutter is a handheld device designed to facilitate the clearance of mucus in hypersecretory lung disorders. Exhalation through the Flutter results in oscillations of expiratory pressure and airflow, which vibrate the airway walls (loosening mucus), decrease the collapsibility of the airways, and accelerate airflow, facilitating movement of mucus up the airways.

Materials and Methods

All patients were subjected to the following before and after the procedure:

(1) Thorough history taking, full clinical examination, and routine laboratory investigations were carried out.
(2) Duration of the hospital stay was determined.
(3) Pulmonary function test was performed.
(4) Six-minute walking distance test and oxygen saturation (SaO_2) test were performed.
(5) Frequency of daytime and nocturnal cough was noted.
(6) Need for rescue short-acting B2-agonist was determined.
(7) Quality of life questionnaire (CAT questionnaire) was used.

Flutter mucus clearance device [12]

Product description

The Flutter mucus clearance device is pipe shaped with a hardened plastic mouthpiece at one end, a plastic-protective perforated cover at the other end, and a high-density stainless steel ball resting in a plastic circular cone inside (Figs 1 and 2).

Principle of operation

The principle of the Flutter as a mucus clearance device is based on its ability to (a) vibrate the airways (which loosens mucus from the airway walls); (b) intermittently increase endobronchial pressure (which helps maintain the patency of the airways during exhalation so that mucus does not become trapped as it moves up the airways); and (c) accelerate expiratory airflow (which facilitates the upward movement of mucus through the airways so that it can be more easily cleared). The Flutter effect occurs during the expiratory phase of respiration. Before exhalation, the steel ball blocks the conical canal of the Flutter. During exhalation, the actual position of the steel ball is the result of equilibrium between the pressure of the exhaled air, the force of gravity on the

Fig. 1

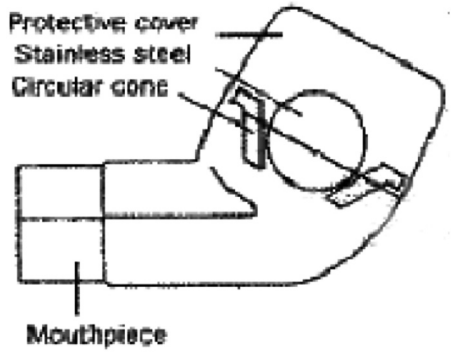
FLUTTER® mucus clearance device: Product description 1.

ball, and the angle of the cone where the contact with the ball occurs. As the steel ball rolls and bounces up and down, it creates an opening and closing cycle, which repeats itself many times throughout each exhalation (Fig. 3). The net result is that oscillations in expiratory pressure and airflow are produced. When the oscillation frequency approximates the resonance frequency of the pulmonary system, endobronchial pressure oscillations are amplified and result in vibrations of the airways. The vibrations produced by these oscillations cause the 'fluttering' sensation from which the Flutter derived its name. These vibrations loosen mucus from the airway walls. The intermittent increase in endobronchial pressure decreases the collapsibility of the airways during exhalation, increasing the likelihood of clearing mucus from the tracheobronchial tract. The airflow accelerations increase the velocity of the air being exhaled, facilitating the movement of mucus up the airways (Fig. 4).

Directions for use

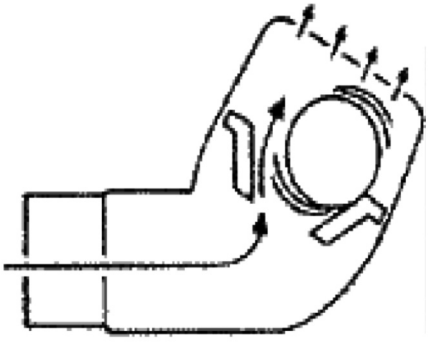
The patient was seated with back straight and head slightly tilted upward; hence, the upper airway was wide open (Fig. 5). This allowed exhaled air to flow smoothly from the lungs and out through the Flutter. As an alternative, the patient may be seated with elbows resting on a table at a comfortable level and head position as described above. The angle at which the patient holds the Flutter is critical (Fig. 6). Initially, the Flutter was held so that the stem is horizontal to the floor, which places the cone at a slight tilt. The tilt ensures that the ball not only bounces, but also rolls during exhalation. This combined rolling and bouncing of the steel ball produces the vibrations that dislodge mucus from the airways. The Flutter then needs to be adjusted to the patient's pulmonary resonance frequency, which was carried out by moving the Flutter slightly up or down to achieve the maximum 'fluttering' effect (Fig. 7). This resonance was evidenced by the vibrations within the chest that can be felt by the patients. The healthcare professional determined whether the patient had achieved the 'fluttering' effect by placing one hand on the patient's back and the other hand on the patient's chest. The vibrations in the lungs were felt as the patient exhaled. After the patient had established a comfortable position and selected the proper tilt to maximize 'fluttering', the therapy may begin.

Fig. 2



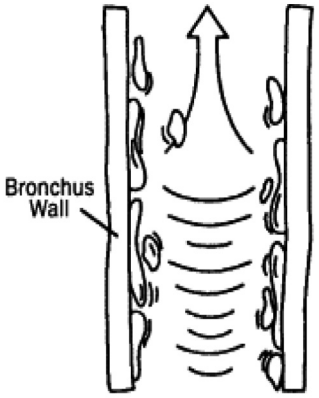
FLUTTER® mucus clearance device: Product description 2.

Fig. 3



FLUTTER® during exhalation.

Fig. 4

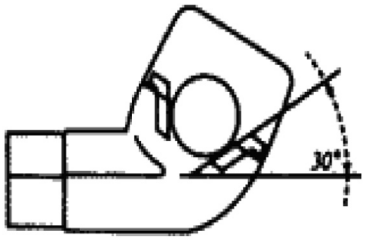


Movement of mucus up the airways.

Fig. 5

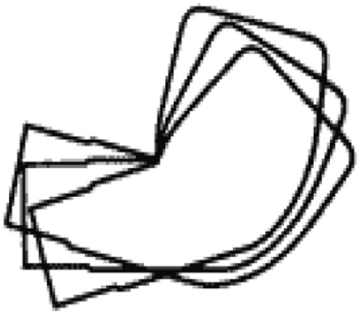
Position of patients during FLUTTER® use.

Fig. 6



The angle at which the patient holds the FLUTTER®.

Fig. 7



Movement of the FLUTTER® slightly up or down to achieve the maximum "fluttering" effect.

Frequency and duration of use

Flutter therapy was completed when no further mucus could be expectorated following several diligent sequences. Frequency of use and duration of each session were determined by the healthcare professional. Flutter therapy is a more 'goal-based' than 'time-based' therapy, and experience has shown that successful clearing of the airways in most patients occurs in ~5–15 min. Generally, morning and late afternoon or evening sessions were performed. Patients were avoided becoming overtired by adding a session instead of extending any session to a point of discomfort.

Results

The present study included 30 patients diagnosed as COPD. The results revealed that the highest prevalence (78.3%) was among the age group 50–60 years. All patients among the two studied groups were male patients representing 100%.

With respect to the patient's occupation, it was obvious that manual work was the most common occupation encountered among the two groups (45%); some had occupational exposure to cotton dust (22%) and lower percentage of the study groups were exposed to vehicle vapors, chemical, and other materials.

The main complaints in the patients among group I and group II were cough (72 and 74%, respectively), dyspnea (68 and 66%, respectively), and chest pain (54 and 66%, respectively). A general improvement in cough and dyspnea was observed in the two groups after treatment, but this improvement was not statistically significant (P = 0.019 and 0.018, respectively).

Six-minute walking distance was improved after treatment in both groups, but the improvement was statistically significant in only group II patients after treatment (Table 1).

A general improvement in the frequency of daytime and nocturnal cough could be observed in the two groups after treatment, but this improvement was not statistically significant either in the same group or between the two groups.

With respect to the need for rescue short-acting B2-agonist, there was a significant decrease in the use of rescue short-acting B2-agonist among patients in group II.

With respect to arterial blood gases result before and after treatment in the two studied groups, the arterial pH did not show any significant difference either between the two groups or in the same group before and after treatment. However, partial pressure of oxygen in the blood (PaO_2), $PaCO_2$, and bicarbonate (HCO_3) showed significant differences before and after treatment among group II patients. In addition, $SPaO_2$ showed significant improvement before and after treatment among group II patients (Table 2).

Pulmonary function test before and after treatment within the same group as well as between the two studied groups showed an improvement in all parameters, but this improvement was not statistically significant either in the same group or between the two groups (Table 3).

The total duration of hospital stay was significantly lower in group II than in group I (Table 4).

Discussion

COPD is a major cause of disability that dramatically alters the well-being of the patients and their quality of life. Historically, the management of COPD has focused on the strategies to prevent further deterioration of lung function, such as smoking cessation and standard medical treatment to try to improve symptoms.

Functional abilities were improved by introducing strategies to help them cope with their condition; hence, a comprehensive care program including pulmonary

rehabilitation was described. The rehabilitation nurse plays an important role in providing care, education, and support to patients and their families. In addition, nurses can advocate patients in establishing a plan of care consistent with patient's values and beliefs [13].

In the present study, it was found that the majority of patient's age ranged from 50 to 60 years. This may be explained by the fact that the occurrence of COPD increases with age as the airspaces get bigger and lose their elasticity, indicating that there is less area for gases to be exchanged across, and also the strength of the respiratory muscle decreases. This is in agreement with the result of Kim *et al*. [14], who conducted a Korean survey and concluded that the prevalence of COPD was 17.2% among patients above 45 years of age and with the result of Stang [15] who argued that 15.3 million people who are above 40 years of age in the USA have COPD.

Table 1 Six-minute walking distance before and after treatment in studied groups

	Group I		Group II	
	Before treatment	After treatment	Before treatment	After treatment
6-MWD	180 + 24	210 + 27	175 + 33	260 + 37
	T=1.399 *P*=0.167		*T*=3.476 *P*=0.03*	

6-MWD, six-minute walking distance; *Significant difference at $P < 0.05$.

The residence may give an idea about the circumstances in which the patients live. The majority of the patients in the present study were living in the rural area; this is in agreement with the study conducted by Tazanakis *et al*. [16] to determine the prevalence of COPD in Greece, which concluded that the prevalence of COPD was significantly higher in the rural areas compared with the urban areas, and also with the study by Gunen *et al*. [17] who studied the prevalence of COPD in Turkey and reported that biomass exposure as a sole reason for COPD was significantly common among female patients living in the rural areas (54.5%). However, Inversen *et al*. 18], who conducted a study in Scotland concluded that the prevalence of COPD did not differ between the rural and urban areas.

Smoking is recognized as the most important causative factor for COPD, and its cessation is the single most important intervention to prevent disease progression. Helping COPD patients to stop smoking is vital [19]. In this study, all the patients were smokers; either they had a history of smoking or were currently smokers.

The present study portrays that all patients used bronchodilators; this is because the bronchodilators remain the mainstay of COPD management and are recommended for the treatment of symptomatic

Table 2 Arterial blood gases before and after treatment in both groups

	Patients (*N* = 30)			
	Group I (*N* = 15)		Group II (*N* = 15)	
Arterial blood gases parameters	Before treatment	After treatment	Before treatment	After treatment
pH	7.30 ± 18.1	7.3=50 ± 10.2	7.28 ± 18.1	7.36 ± 19
	T=1.399 *P*=0.167		*T*=0.852 *P*=0.398	
PaO_2	64.5 ± 11.08	76.6 ± 8.66	66.6 ± 10.67	82.5 ± 9.76
	T=4.664 *P*=0.000*		*T*=4.260 *P*=0.000*	
$PaCO_2$	55.6 ± 9.68	44.8 ± 8.06	54.41 ± 8.96	42.66 ± 5.72
	T=3.331 *P*=0.002*		*T*=4.757 *P*=0.000*	
HCO_3	33.75 ± 5.51	28.12 ± 3.37	33.58 ± 5.37	27.53 ± 2.98
	T=3.467 *P*=0.001*		*T*=3.965 *P*=0.000*	
SaO_2	91.93 ± 1.20	94.00 ± 4.71	91.7 ± 2.33	96.94 ± 1.96
	T=7.818 *P*=0.000*		*T*=5.849 *P*=0.000*	

HCO_3, bicarbonate; $PaCO_2$, partial pressure of CO_2 in the blood; PaO_2, partial pressure of oxygen in the blood; SaO_2, oxygen saturation; *Significant difference at $P < 0.05$.

Table 3 Pulmonary function test parameters before and after treatment in both groups

	Patients (*N* = 30)			
	Group I (*N* = 15)		Group II (*N* = 15)	
Pulmonary function test parameters	Before treatment	After treatment	Before treatment	After treatment
FVC (% predicted)	84.31 ± 9.85	87.12 ± 8.50	87.10 ± 10.81	87.81 ± 10.94
	T=1.399 *P*=0.258		*T*=0.873 *P*=0.258	
FEV1 (% predicted)	56.22 ± 13.27	56.81 ± 10.75	57.21 ± 14.61	57.83 ± 13.25
	T=1.112 *P*=0.271		*T*=0.943 *P*=0.349	
FEV1%	65 ± 9.68	66 ± 8.06	64 ± 8.96	65 ± 5.72
	T=1.029 *P*=0.308		*T*=0.854 *P*=0.397	

patients at all the stages of this disease. It is also explained by the fact that dyspnea is the predominant complaint in COPD patients, which distresses them. In addition, it was revealed that antibiotics were used by all patients; this is explained by the fact that although there are many reasons to hospitalize COPD patients, acute exacerbation due to infection is the major cause for hospital admission [20,21].

Expiratory flow limitation is the hallmark of COPD, which promotes air trapping and dynamic hyperinflation and appears to be the main cause of exertional breathlessness and exercise intolerance. Mucus extraction can help to control the respiratory rate and breathing patterns thus decreasing air trapping. It also attempts to decrease the work of breathing and improve the position and function of the respiratory muscles [22,23].

Pulmonary function tests are the primary diagnostic tools for COPD. These tests demonstrate characteristic abnormalities in the lung function, confirm or support the diagnosis of COPD, and give some idea of the degree of impairment and prognosis. With respect to pulmonary function tests, the present study reported a general improvement in forced expiratory volume in one seconed (FEV1), forced vital capacity (FVC), peak expiratory flow (PEF), and maximum volantory ventilation (MVV), but this improvement was not statistically significant either in the same group or between the two groups. This could be explained by the fact that COPD is a progressive disease, unlike bronchial asthma; hence, it is not expected that pulmonary function parameters will improve.

Blood gas analyses are an essential part of COPD patient care, as it assesses the ventilator status, oxygenation, acid–base status, and the response to an intervention [24]. Although it is an invasive and painful procedure, it is one of the important procedures that assess the effect of the current study. The present study revealed that there was an improvement in PaO_2 and $SPaO_2$ and a decrease in $PaCO_2$ in group II patients, and this improvement was statistically significant and may be attributed to the improvement in the *V/Q* due to rapid intrabronchial clearance of secretions.

The COPD assessment test (CAT questions) consists of eight items. Patients read the two statements for each item, which described the best and worst scenario, and decided where on the scale (0–5) they fit. This system was chosen because it is reliable and simple to use. Scores for each of the eight items were summed to give a single, final score (minimum 0, maximum 40). This is a measure of the overall impact of the patient's condition on their life [25].

Scores for the individual items within the questionnaire provide insight into the relative influence that the different components of COPD have on its overall impact on a patient's life; thus, they will highlight the problematic areas that can be explored further during consultation and ultimately addressed through intervention [1,2]. With respect to the 6-minute walking distance and quality of life questionnaire (CAT), there was a general improvement in both the groups before and after treatment, but this improvement was statistically significant only in group II (P = 0.03 and 0.05, respectively). This could be explained by the fact that mucus extraction causes more clearance of secretions, which leads to improvement in intrabronchial obstruction and hence decreases air trapping and dynamic hyperinflation, and also improvement in the *V/Q* with an improvement in dyspnea and hence the quality of life and 6-minute walking distance.

Table 4 Total duration of hospital stay after treatment in both groups

	Group I	Group II
	Before treatment	After treatment
Duration of hospital stay	230 ± 27	190 ± 33
	T=3.476 P=0.03*	

*Significant difference at $P < 0.05$.

Table 5 Chronic obstructive pulmonary disease assessment test (CAT questions)

	Group I		Group II	
	Before treatment	After treatment	Before treatment	After treatment
CAT	32 ± 8	28 ± 7	34 ± 6	35 ± 8
	T=1.399 P=0.167		T=3.476 P=0.05*	

*Significant difference at $P < 0.05$.

Conclusion

There were no adverse effects. Flutter is simple to use, inexpensive, and fully portable, and once the patient and family are instructed its use, it does not require the assistance of a caregiver (Table 5).

Acknowledgements

Conflicts of interest

None declared.

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