International Journal of Health Sciences and Research
Vol.10; Issue: 10; October 2020
Website: www.ijhsr.org
Original Research Article *ISSN: 2249-9571*

Comparison of Lung Flute Device versus Flutter Device for Sputum Clearance in Bronchiectasis: A Randomized Crossover Trial

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ABSTRACT

Purpose: The main clinical manifestation of bronchiectasis is productive cough. In recent years, there is a development of large number of devices to assist airway clearance and allow self-administration therapy. There are no studies to our knowledge that have compared Lung Flute device with Flutter device. Hence, a study was undertaken to compare the effect of Lung Flute device over Flutter device in mucous clearance and establish patient preference in bronchiectasis patients.
Methods: 46 subjects diagnosed with bronchiectasis with sputum volume >30ml were selected according to inclusion criteria. A pre-treatment 24 hour sputum volume was measured. They were randomized into Lung Flute group and Flutter group wherein each group were administered 3 sessions/day. Post treatment 24 hour sputum volume was measured and the subjects were crossed over after a 24 hour washout period.
Results: Lung Flute device and Flutter device showed statistically significant increase in expectorated sputum volume with p values 0.001 and 0.000 respectively. Between the two devices, there was no statistical (p=0.369) or clinical (r=0.09) significant change on sputum volume. On Likert scale analysis, it was observed that significant difference was noted on "level of comfort to use the device" and "ease of removal of secretions" with Flutter device being better than Lung Flute device.
Conclusion: It can be concluded that Lung Flute device and Flutter device have comparable efficacies in regards to sputum clearance in bronchiectasis with patient preference to Flutter device for the comfort of use and for ease of removal of secretions.

Keywords: Bronchiectasis, Flutter, Lung Flute, Sputum clearance.

INTRODUCTION

Bronchiectasis is defined as abnormal, irreversible dilatation of the bronchi.[1] It is not a disease in itself but the end stage of a variety of pathologic processes leading to repeated respiratory infections requiring antibiotics, disabling productive cough, shortness of breath and occasional haemoptysis.[2]

The abnormal dilatation of airways occurs patchily due to scarring and is usually associated with mucosal thickening, mucus plugging and a variable degree of lung hyperinflation.[3] Thus altered airway anatomy, impaired mucociliary system and repeated infections lead to a decline in respiratory function.

Prevalence of bronchiectasis is not well defined worldwide. Due to large geographical variation, ethnic, religious, socioeconomic and cultural parameters in India establishing true prevalence by epidemiological studies poses a challenge and is not well estimated in Indian scenario.[4]

The causes of bronchiectasis can vary from infections, primary ciliary dyskinesia, immunodeficiency, cystic

fibrosis to connective tissue disorders like rheumatoid arthritis and inflammatory bowel diseases. The most common cause of bronchiectasis mentioned in the literature is infection.

Bacterial pathogens exert a number of direct effects on the respiratory tract that impairs host defence. The mediators released by the bacteria may directly interfere with ciliary functions, damage ciliated epithelium and inhibit mucous transport.[5] Glycoproteins secreted by the bacteria attract neutrophils which leads to damage of the respiratory mucosa as well as stimulation of mucous secreting glands in airways . Thus excess sputum production and impaired mucociliary clearance system together lead to a vicious cycle which induces and perpetuates the inflammatory process thus causing progressive damage to the airways. This leads to chronic inflammation, further disrupting mucociliary function, tissue damage and remodelling and a cycle of infection and inflammation (King 2005).[6]

This profile of sputum retention, together with airway damage lends support to application of techniques that facilitate sputum removal as treatment goal. Foundations of treatment for bronchiectasis include identification of acute exacerbations and administration of antibiotics, suppression of microbial loads, treatment of underlying conditions, promotion of bronchial hygiene and surgical removal of extremely damaged segments or lobes.[7]

Mucociliary clearance depends upon the viscoelasticity of secretions, the amount of airflow for mobilisation of secretions and extent of mucous production. Bronchopulmonary hygiene consists of pharmacological and non-pharmacological measures to assist the patients in removal of secretions. Airway Clearance Techniques (ACT) also form the mainstay of treatment of bronchiectasis. ACTs have evolved over the years, using strategies such as high-frequency chest wall compressions using an inflatable vest connected to an air compressor, hand-held expiratory vibratory devices and more recently acoustic waves to vibrate the mucus from the airway walls. Also conventional methods like positioning, gravity assisted drainage, manual manoeuvres like cupping, percussions and vibrations, various breathing strategies like Active Cycle of Breathing Strategies (ACBT) and Autogenic Drainage (AD) are also effective. New techniques like positive expiratory pressure (PEP) devices have been developed. The theoretical benefits of PEP therapy is the ability to enhance and promote mucous clearance by either preventing airway collapse or stenting the airways or increasing the intra thoracic pressure distal to retained secretions by collateral ventilation or by increasing functional residual capacity.[8] Whereas the OPEP devices combines the above mentioned benefits with airway vibrations or oscillations. Oscillations reportedly decrease the viscoelastic properties of mucous which make it easier to mobilise mucous up the airways which can later be cleared using huffing or coughing techniques.

Different PEP and OPEP devices have been introduced claiming to improve mucociliary clearance. Flutter is one such hand-held OPEP device shaped like a pipe which contains a high density stainless steel ball that sits in a circular cone inside the bowl of the ‘pipe’. The cover over the ball has perforations that allow expiratory airflow to pass through the device. The Flutter can be used with the patient sitting upright or lying on either sides. The Flutter device must be held pointing upwards for maximum efficacy and proper operation.

The Lung Flute is a new small self-powered audio device that has been classified by the FDA to the family of oscillatory positive expiratory pressure (OPEP) devices which includes Flutter and Acapella. The Lung Flute has a unique mechanism of action based on acoustic energy unlike traditional oscillatory backpressures used in OPEP devices. When an expiratory flow of enough force is passed through the mouthpiece, the reed within the

rectangular hardened plastic tube oscillates to produce a sound wave. This sound wave has the ability to travel down tracheobronchial tree and vibrate tracheobronchial secretions. Lung Flute being a novel technique there is a need of further exploration of this device. Also we need to establish its efficacy as compared to already established devices.

As per our knowledge, there has been no published study comparing the effect of Lung Flute device versus Flutter device in sputum clearance in bronchiectasis.

MATERIALS AND METHODOLOGY

The study was approved by the institutional ethical committee before its commencement. Patients diagnosed with bronchiectasis and those having sputum production more than 30ml/day were selected for the study. Informed written consent was taken from the patient after explaining the study procedure and the benefits of the study in the language best understood by them.

The basic demographic data like Age, Gender, Height, and Weight was taken from which the Body mass index was calculated. Other information like the duration of bronchiectasis, past history of tuberculosis, current or past history of smoking, current medications, daily intake of water were recorded.

Patients were instructed not to change their medications throughout the course of the study and not to miss their daily medications. Daily intake of water of the patients was also kept constant, as not to affect the amount of sputum production.

The primary outcome measurement of sputum volume was recorded 24 hours prior to each treatment device. Patients were asked to maintain a sputum diary and the volume expectorated in the calibrated cups provided to them, was noted in the diary. The total volume of the sputum expectorated for 24 hours was recorded.

The sequence of airway clearance device was randomized using simple chit method.

Post allocation to their respective groups, patients performed either Flutter device or Lung Flute device. Familiarization with the technique was done by demonstration of the technique of each device.

Lung Flute Arm:

Patients performing Lung Flute device were instructed to hold the device pointing downwards, and take a little deep inspiration than normal, place the lips completely around the mouthpiece and blow out gently into the device. While doing so, they will hear a gentle Fluttering of the reed as it vibrates. The patient was instructed to remove the mouthpiece and inhale again and quickly replace the mouthpiece and exhale into the device. This was followed by a 5-7 seconds break wherein several normal breaths were taken. Patients were instructed to do this for 20 sets or maximum possible by the patient with 2 blows per set. Then patients were instructed to cough out the secretions.[13] 3 sessions were given per day and 24 hour sputum volume was recorded using calibrated sputum cups. A Likert scale was provided to rate the treatment session on the basis of comfort level of the device, ease of expectoration and ease to follow the instructions.

Flutter Arm:

Patients performing Flutter device were instructed to hold the stem of the Flutter device horizontal to the ground, which was latter adjusted to achieve maximum vibrations by tilting it slightly upwards or downwards.

While keeping the Flutter at the angle wherein maximum vibrations were felt, patients were asked to keep their cheeks firm.

Slow inhalation was followed by a breath hold of 2-3 seconds followed by fast but not too forceful exhalation. The patients were instructed to take 10 breaths followed by huffing and then again to repeat the cycle.

The duration of Flutter arm extended for 10-15 minutes or till no more secretions were expectorated by the patient. 3 sessions were given per day and 24 hour sputum volume was recorded using calibrated sputum cups. Likert scale was provided at the end of the treatment to rate the device on following three components, ease to follow the instructions, comfort level of the device and ease of sputum expectoration following the treatment.

Post treatment after the respective device a 24 hour washout period was maintained to neutralize the effect of each intervention before the patients were crossed over to the other group.

STATISTICAL ANALYSIS:

- All the data was analysed using IBM SPSS 20 version for windows.
- Normality tests were performed for all the outcomes in both the groups.
- All non-parametric data within same group was analysed using Wilcoxon signed ranks test and between two groups was analysed using Mann-Whitney U test.
- All parametric data was analysed using an independent t test.
- The level of significance was set at $p<0.05$.

RESULTS

Table 1: This table gives the descriptive data of all the subjects in the study on the basis of their gender, age, BMI, history of tuberculosis and bronchial asthma, smoking history and medications.

Demographic analysis:

Baseline characteristics	n=46
Gender Male/Female	28/18
Age	57.04±6.93
BMI	22.21±2.56
Duration of bronchiectasis	7.21±3.06
Smokers	21
H/o tuberculosis	28
H/o Bronchial Asthma	9
Daily intake of water	2.29±1.03
Medications	
B_2 agonist	41
Inhaled corticosteroid	35
Theophylline	35
Anticholinergic	33

Table 2: This table shows the median and confidence interval of Lung Flute group and Flutter group before treatment

Device	Median	Confidence Interval
Lung Flute	80.00	73.61-88.78
Flutter	80.00	72.22-87.34

Inference: The pre sputum volume comparison showed statistically non-significant change and hence the groups were comparable.

Table 3: This table shows the median and confidence interval of pre and post sputum volume in Lung Flute group.

Lung Flute Device	Pre	Post	Z value	p value
Median	80.00	100.00		
CI	73.61-88.78	82.9.-100.57	-3.343	0.001

Inference: The pre and post sputum volume comparison after Lung Flute device intervention showed statistically significant difference (p=0.001).

Table 4: This table shows the median and confidence interval of pre and post sputum volume in Flutter group

Flutter	Pre	Post	Z value	p value
Median	80.00	95.00		0.000
CI	72.22-87.34	88.63-105.93	-4.891	

Inference: The pre and post sputum volume showed statistically very significant change (p=0.000) following Flutter device use.

Table 5: This table reveals the mean, standard deviation and p values of sputum volume post Flutter device and Lung Flute device.

Device	Mean	SD	p value
Lung Flute	91.13	29.16	
Flutter	97.28	29.76	0.369

Inference: This graph shows that the treatment groups after Lung Flute and Flutter device were statistically not significant (p=0.369).

Table 6: This table gives mean, standard deviation and p values of all 3 components of the Likert scale.

Device	Easy instructions	Comfort to use	Easy removal
Flute	42.11	40.86	27.23
Flutter	50.89	52.14	65.77
Z value	-1.772	-2.172	-7.281
P value	0.08	0.03	0.00

Inference: There was no significant change for the understanding of the instructions to use the device (p=0.08).
However significant change was seen for the level of comfort during the device (p=0.03) and the ease of removal of the

secretions (p=0.00) post the devices wherein Flutter device showed better removal as compared to Lung Flute device

Table 7: As the data did not show any statistically significant change between both the groups of treatment intervention, the clinical significance was estimated.

Flutter		Lung Flute		Cohen's d	Effect size *r*
Mean	SD	Mean	SD		
97.28	29.13	91.73	29.76	-0.19	0.09

Inference: Our study has r = -0.09(trivial effect), thus it can be concluded that our treatment interventions had no significant difference statistically as well as clinically.

DISCUSSION

Bronchiectasis is always defined with the presence of chronic productive sputum. As bacterial colonization and irreversible damage occurs most frequently in the peripheral airways it is important to utilize a modality that treats all regions of the lungs and reliably mobilizes mucus from small as well as large airways .[14] A change in technique or introduction of a device may improve adherence to treatment as it is important to introduce the concept of self-treatment at an early stage. Lifelong techniques for mucus clearance are advised to these patients. In this study, two such devices that is Flutter and Lung Flute were compared for their efficacy in mucus clearance.

The measurement of expectorated sputum volume might be useful to evaluate the effectiveness of therapeutic interventions meant to improve mucus clearance. However, sputum volume may be influenced by a person's reticence to expectorate, saliva contamination or swallowing of secretions[15] but it is a highly pertinent, non-invasive marker and has been selected as a relevant outcome measure in previous studies. Hence only sputum volume was considered to be the primary outcome measure in this study.

Lung Flute device has shown effective sputum clearance between its pre and post sputum volume (table 2). Lung Flute device also classified in the family of oscillatory positive expiratory pressure devices generates a sound wave of 16-22Hz with an output of 110-115 dB using 2.5cmH_2O of pressure. This sound wave has ability to travel down the tracheobronchial tree and vibrate tracheobronchial secretions.[16] These vibrations enhances the mucociliary clearance from the lower airways thus aiding mucus removal. The sound wave generated is approximately equivalent to ciliary beat frequency thus enhancing the mucociliary clearance. Resonance frequency generated when the subject blows into the Lung Flute device is said to alter the rheology of the mucus making it thinner and easier to expectorate .This finding is supported by very few studies as Lung Flute is comparatively a new device its efficacy over other treatment options is yet to be established.

Flutter device showed significant increase in the expectorated sputum volume in this study (table 3). The primary mechanism of airway oscillatory device is to provide a splinting effect on the airways, improving a collateral ventilation and altering sputum rheology.[17] In a study on mechanical behaviours of Flutter VRP1, Shaker and Acapella devices they found that Flutter VRP1 showed values closer to those favouring better transport of mucus in all the airflows. It has been shown in other studies that high frequency oscillations produced by Flutter device can break down the mucus macromolecules, making mucus less thick and consequently more easily transported through the airways. Flutter device creates a PEP between 5-35cmH_2O and vibrations typically between 8-26Hz. This is an acceptable frequency value for the best transport of bronchial mucus. The post sputum volumes of Flutter device and Lung Flute device were not statistically different (table 4). Also there was no clinical significance between the two (table 7). Thus this study shows that both the devices were comparable with regards to their efficacy in mucus clearance.

This study is first of its kind to establish comparable efficacies of Flutter

device and Lung Flute device in bronchiectasis patients for mucus clearance.

Establishing patient preference was secondary objective of this study. It is suggested by Timothy Myers (2007) that if the therapies are equivalent, based on scientific reviews, then other factors like treatment cost or patient preference may need to be factored into airway clearance regimen decisions.[18]

Patient preference in this study was established using a 7- point Likert scale wherein the components ranged from strongly disagree (0) to strongly agree (7). Likert scale is a psychometric scale to determine the individual's response regarding a certain statement or preferences. This scale helps to establish a patient centred approach to focus on the use of the device and patients view regarding the device. Three components of the device were rated by the patients that are the ease of understanding the instructions, the comfort level achieved during execution of the device and the ease of removal of secretions.

There was no significant difference between understanding and execution of the instructions between the two devices as both the devices comprised for simple instructions.

But for second and the third component, that is comfort level of the device and easy removal of secretions a significant difference was noted suggesting that patients preferred Flutter device over Lung Flute device for these components (table 6).

Since, patient preference is established entirely on the patients view about the device it can be affected by the Fluttering effect which is felt during use of Flutter device due to vibration of the high density stainless steel ball giving it more preference over the Lung Flute device which uses acoustic waves not felt by the patient. The vibrations felt by the patient while using Flutter device may act as a psychological feedback thus increasing the patient's perception of the mucus clearance.

Similarly along with these two outcome measures other factors like maintenance of the device, feasibility and transportability of the device and cost issues should also be considered during prescription of the device as these issues will play an important role as the patients diagnosed with bronchiectasis will require long term bronchial hygiene therapies for home use.

The therapist will need to concentrate on all the factors before prescribing the device to the patient. Especially the need and expectations of the patients from their therapist and their bronchial hygiene regimen will play an important role for patient's compliance to the treatment regime for long term use.

However limitations of the study were that blinding of the therapist was not done, limited outcomes were included in the study and dry weight of the sputum or rheological study was not undertaken. In-spite of the instructions, the sputum volume which may be swallowed by the patient cannot be accounted for.

CONCLUSION

According to patient's preference and availability either of the devices can be prescribed as an adjunct therapy for sputum clearance in bronchiectasis. To get further clarity on the efficacy of the devices, long term effects of these devices should be assessed and their impact on Quality of Life and PFT values ought to be checked.

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How to cite this article: Ghodge S, Dangi A, Deo M. Comparison of lung flute device versus flutter device for sputum clearance in bronchiectasis: a randomized crossover trial. Int J Health Sci Res. 2020; 10(10):204-210.

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