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Original Article

An editorial comment on this article is available at page 101

The Efficacy of Flutter® and Active Cycle of Breathing Techniques in Patients with Bronchiectasis: A Prospective, Randomized, Comparative Study

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Abstract

OBJECTIVES: The objective of the study was to compare the efficacy of an oscillating positive expiratory device and the active cycle of breathing techniques (ACBT) in patients with bronchiectasis.

MATERIALS AND METHODS: A home-based study that lasted for 4 weeks was designed to compare the oscillating physiotherapy device Flutter® and the ACBT in 40 patients, who were randomly assigned into two groups containing 20 patients each. The effect of the two methods of physiotherapy on sputum production, pulmonary functions, and the quality of life was compared.

RESULTS: The results of the present study indicate that both the methods were associated with a reduced number of patients complaining of cough and fatigue and increased sputum production (p=0.000, p=0.004, and p=0.002, respectively). In addition, statistically significant reductions were determined by the Medical Research Council and Borg Dyspnea scores (p=0.001 and 0.002, respectively). The Flutter® device caused a more significant effect on the perception of dyspnea. Overall, there was an improvement in the physical sub-scale of the Short Form (SF)-36 Quality of Life Questionnaire scores of 36 patients who completed the study (p=0.001). During the physiotherapy period, no changes in pulmonary functions were observed. Exacerbations were recorded in 3 patients in the ACBT group and in 1 patient in the Flutter® group.

CONCLUSION: The Flutter® device and ACBT represent effective home-based physiotherapeutic methods. The Flutter® device appears to be more effective with regard to sputum production.

KEYWORDS: Bronchiectasis, pulmonary rehabilitation, oscillating physiotherapy device, active cycle of breathing techniques

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INTRODUCTION

There are no definitive treatments of bronchiectasis. The objectives of treatment include achieving symptom control, preventing or reducing exacerbations, decelerating the progression of pulmonary injury, maintaining airway patency, and improving the quality of life, all of which are the factors to be accomplished merely by decreasing bronchial infection and inflammation and by increasing the mucociliary clearance [1]. Traditional physiotherapeutic methods used in patients with chronic pulmonary conditions such as bronchiectasis or cystic fibrosis increase the expectorated sputum volume as well as alveolar ventilation and decrease the frequency of infections. However, these conventional techniques have also been reported to result in temporary adverse effects on physiological parameters during the treatment phase and require the assistance of others [2]. In this regard, the Flutter® device represents an alternative to traditional physiotherapeutic modalities and has been increasingly used in the management of respiratory conditions characterized by chronic sputum production. Flutter® is a simple handheld device that allows removal of mucus from the airways using positive expiratory pressure (Figure 1) [3]. Active cycle of breathing techniques (ACBT) is a standard technique, and it bears some advantages. It is flexible, requires patient's active participation, and requires neither the use of any specific devices nor any specific positioning. While breathing control prevents or diminishes airway narrowing, thoracic expansion exercises prevent deleterious effects of percussion (Figure 2) [2].

The objective of the present study was to compare the efficacy of home-based respiratory physiotherapy, either by means of the Flutter® device or by ACBT, on symptoms, sputum production, and perception of dyspnea, pulmonary functions, and health-related quality of life in patients with bronchiectasis. A study comparing autogenous drainage with Flutter® reported no differences in the amount of sputum produced by application of either of the two methods [4]; however, the Flutter® device was reported to be more effective in reducing viscoelasticity of the secretion. The positive expiratory pres-

This study was presented in the European Respiratory Society (ERS) 2012 Annual Congress, September 1-5, 2012, Vienna, Austria.
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sure was shown to be more effective than Flutter® in terms of preserving pulmonary function, hospital admissions, and antibiotic use in patients, who were followed up for 1 year [5]. Daily use of the Flutter® device at home was as effective as ACBT in patients with non-CF bronchiectasis, and it leads to higher levels of adherence by patients [3]. To our knowledge, there have not been many trials on evaluating effectiveness of home-based physiotherapy program. The aim of the study was to compare the efficacy of ACBT techniques with the Flutter® device in bronchiectasis patients.

MATERIALS AND METHODS

A prospective, randomized study was conducted to compare Flutter® and ACBT methods in patients with bronchiectasis. An approval by the Ethics Committee of the Trakya University School of Medicine, protocol no was 2009/153 and registered under the number 12/08, was obtained before commencing the study. A total of 40 patients, who were diagnosed with bronchiectasis and admitted to the Chest Diseases Department at the University Medical Faculty Hospital between December 2009 and March 2010 were included in this study if they complied with the inclusion criteria and met none of the exclusion criteria. The diagnosis of bronchiectasis was confirmed both clinically and by HRCT. Twenty patients in each group, namely the ACBT and Flutter® groups, practiced home-based respiratory physiotherapy while continuing to receive their current treatment regimens. Patients were randomized into two separate study groups by a faculty member at the Department of Statistics of University using the MedCalc 11.5.1 package program. Figure 3 presents the flowchart for the study.

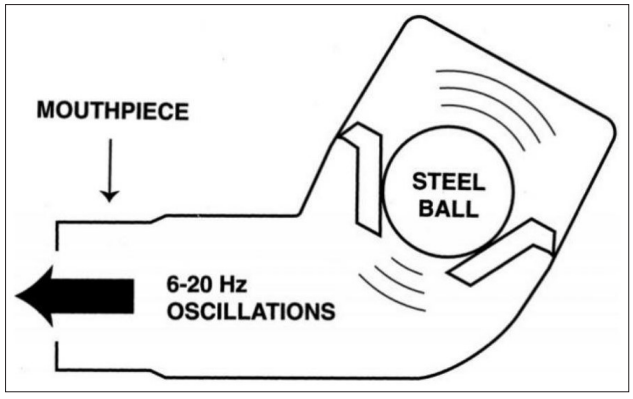

Figure 1. Parts of the Flutter device and the rate of oscillation (http://www.flutter.gen.tr/index.php?id=26)

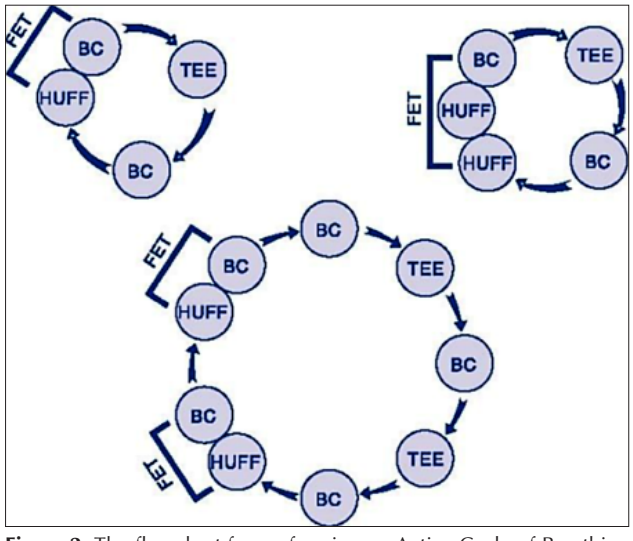

Figure 2. The flowchart for performing an Active Cycle of Breathing Technique: BC, breathing control; TEE, thoracic expansion exercise; FET: forced expiration technique (http://bronchiectasis.com.au/physiotherapy/techniques/the-active-cycle-of-breathing-technique)

Inclusion criteria:

- Clinically stable patients
- A diagnosis of bronchiectasis due to non-CF conditions in patients older than 18 years
- Absence of acute and/or respiratory failure
- No contraindication(s) for the physiotherapeutic method to be employed

Exclusion criteria:

- A history of pneumothorax
- Presence of cor pulmonale and/or heart failure
- Presence of hemoptysis
- Recent history of acute myocardial infarction
- Presence of vertebral injury
- Unstable intervertebral disc hernia and/or costal fracture
- Severe osteoporosis
- Respiratory distress requiring hospitalization

Patients were evaluated by a symptom assessment form, pulmonary function, and reversibility tests, the "Medical Research Council" scale, Borg Dyspnea Scale, and Short Form (SF)-36 Quality of Life Questionnaire. The assessments were performed at baseline and on days 10, 20, and 30.

Training on the Flutter® Device and ACBT Physiotherapy Method

All patients received basic information and training on bronchiectasis and respiratory physiotherapy on an individual ba-

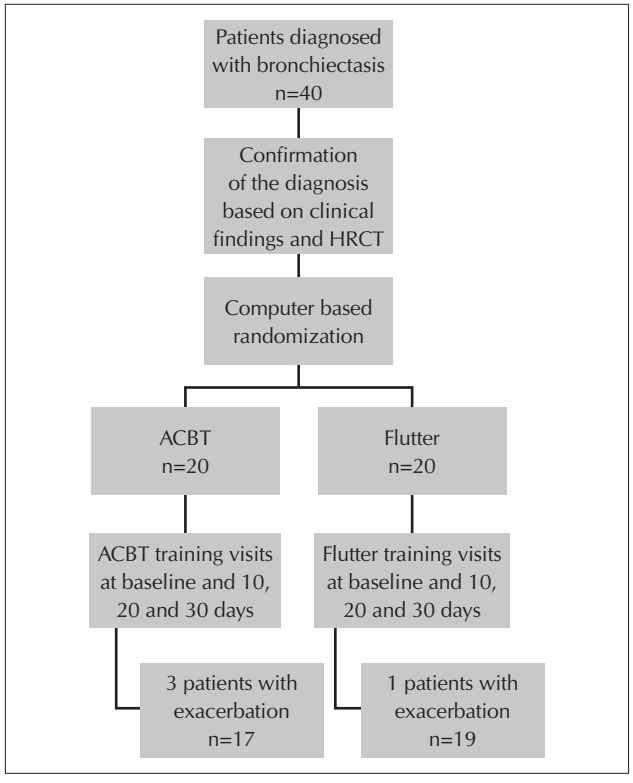

Figure 3. The flowchart for the study

sis. Following theoretical training, each patient in the ACBT group received practical training, individually.

The active cycle breathing chest physiotherapy technique with postural drainage consists of 3 steps (subjects were comfortably sitting in a standard chair): 1. Breathing control: The subject breathes at a normal rate and depth using the lower chest. 2. By resting one hand on the epigastrium, allow the subject to breath in slowly and deeply using the lower chest (pause), then breathe out fully, but not forcefully. Repeat 2 to 3 times. Return to breathing control. 3. Sputum removal: The subject takes a slightly bigger-than-normal breath in, while keeping the mouth open and O shaped. The subject breathes out more forcefully by contracting the abdominal muscles while keeping the mouth and throat open. It should sound like a forced sigh as huffing (Figure 2) [6]. Return to breathing control till the patient is ready to begin another cycle. The patient is advised to start coughing out any sputum if necessary [7,8]. Each standardized ACBT cycle lasted approximately for 2 min and was repeated for 15-20 min with postural drainage/gravity assisted drainage i.e., the use of specific positioning in which gravity enhances mucus transport from distal bronchi. The procedure was repeated twice daily with a minimum 6-h duration [9].

The training courses were planned and carried out with a specialist from the Department of Physical Therapy and Rehabilitation. After ascertaining that each patient fully understood the instructions for the therapy, the physiotherapy sessions were commenced. Similarly, following the commencement of treatment, each patient received training on the use of the device in the Flutter® group, which would be practiced for 15-20 min twice daily. During each of the three follow-up visits after baseline, it was accessed whether the patients' practice of the physiotherapeutic technique was performed properly i.e., as it was described during the training sessions. The practice of physiotherapy was followed up by the Physiotherapy Practice Checklist, which included physiotherapy steps, the duration of physiotherapy, and how many times a day it was practiced. In case of inappropriate practices, training was repeated. For patients who could not attend the hospital visits, a telephone call was made or the patient was visited in his or her home to ascertain the proper use of the physiotherapeutic technique. An explanatory brochure was prepared and delivered to each patient for effective home-based physiotherapy. Both therapy methods were performed twice daily by the patients.

Patient Assessment Form

A "Bronchiectasis Patient Assessment Form" was made for all 40 study patients to collect and record information on personal data, demographic characteristics, past history, duration of disease, symptoms, follow-up of the changes in sputum production, and physical examination findings of the patients. The pulmonary function test (PFT) results, HRCT findings, the HRCT scores, Borg Dyspnea Scale, MRC Scale, and bronchodilator treatments received by the patients were recorded as well.

Symptoms

Cough, sputum, hemoptysis, wheezing, chest pain, fatigue, loss of appetite, sweating, and reflux were assessed before and after physiotherapy, and they were recorded in the assessment form.

Changes in Sputum Production

Sputum production was evaluated in each patient before physiotherapy, and changes in sputum production were recorded for each visit. A 4-category was used to determine the status of sputum production: 0, no sputum production; 1, reduced sputum production; 2, no change in sputum production; and 3, increased sputum production.

Pulmonary Function Tests (PFT)

To assess the pulmonary functions, a Vmax 22 device (Sensormedics, USA) was used.

Dyspnea Scales

The MRC and Modified Borg Dyspnea Scale were used. Scores before and after physiotherapy were recorded.

Short Form-36 Quality of Life Questionnaire

This 36-item measure is divided into the following 8 subscales providing information on 36 items: physical functioning (10 items), social functions (2 items), role limitations due to physical problems (4 items), role limitations due to emotional problems (3 items), general mental health (5 items), vitality and fatigue (4 items), pain (2 items), general health perception (5 items), and health transition (1 item). Items within subscales are summed up to provide a total score ranging from 0 (negative health) to 100 (positive health) [10,11]. SF-36 was completed by our patients both at the time-point when they provided informed consent and at the completion of visit 4. Assessments and scoring were performed at the end of the study period. Written informed consent was obtained from each patient after providing detailed information on the nature of the study. The study was supported by the Scientific Research Project Council (project no 2009/121, with the project approval date of October 21, 2009).

Statistical Analyses

For the statistical analyses, Statistica 7.0 (Serial no: 31N6YUCV38) software pack was used. The difference between the groups with regard to categorical variables was tested with Chi-square test, and nonparametric measurements were compared with the Mc Nemar test. The Wilcoxon paired two-sample test was used for the statistical analysis of the change between the parameters. The difference in variables in pairwise group comparisons was assessed with the Bonferroni test. Data have been expressed as the mean±standard deviation, minimum, and maximum. The statistical significance was set at a p-value of <0.05.

RESULTS

A total of 22 females (55%) and 18 males (45%) patients with a mean age of 54.18±11 were included in the study. Three patients in the ACBT group and 1 in the Flutter® group discontinued participation due to exacerbations, while 17 and 19 patients in these two groups completed the study, respectively. The two groups were comparable with regard to demographic characteristics, symptoms, sputum change, dyspnea scores, pulmonary function tests, and the SF-36 Quality of Life scores before physiotherapy (Table 1).

After 4 weeks of physiotherapy, the change in symptoms were compared both in all of the study patients as well as between the groups. Physiotherapy was associated with a decrease in the number of patients who had cough, wheezing, and fatigue, as well as an increase in the number of patients with improved appetite. A comparison between the groups demonstrated a significant reduction in the number of patients with cough in the ACBT group after physiotherapy, whereas a significant reduction was found in the number of patients with fatigue in the Flutter® group. Wheezing was reduced in the ACBT group; however, no changes were observed in the Flutter® group. The decrease in wheezing was not significant (Table 2). A within- and between-group comparison of the sputum production and of the changes in sputum revealed that there were 23 patients with and 13 patients without sputum production. Among all study patients, 4 patients, who could not produce sputum, started production, and 9 patients had increased sputum production with physiotherapy. Increased sputum production was detected in 4 patients in ACBT group and in 5 patients in the Flutter® group. In both groups, the increase in sputum production was statistically significant (Table 3). A comparison of the PFT before and after physiotherapy showed significant decreases in both groups. Inter- and intra-group comparisons in terms of the change in the PFT before and after physiotherapy in the Flutter® and ACBT groups did not show any significant differences.

Comparison of dyspnea scores before and after physiotherapy revealed significant reductions in both dyspnea scale scores of all study patients (Table 4). In the Flutter® group, the scores of both MRC and Borg dyspnea scales demonstrated significant decreases compared to baseline scores before physiotherapy (p=0.012 and p=0.006, respectively); however, a significant decrease in the MRC was detected only in the ACBT group (p=0.021). A comparison of the dyspnea scale scores before and after physiotherapy showed no differences between the groups (Table 4).

A comparison of the SF-36 Quality of Life Questionnaire scores before and after physiotherapy demonstrated a statistically significant improvement in physical function and physical role subscales, whereas the increase in physical

Table 1. Baseline patient characteristics

Characteristic	ACBT n:20	Flutter® n:20
Age (years) mean SD	54.9±9.1	53.5±5.9
Female n, (%)	12(60)	10(50)
Smoking n, (%)		
Nonsmoker	11(55)	11(55)
Ex	8(40)	9(45)
Smoker	1(5)	0(0)
Previous disease n, (%)		
Measles	3(15)	3(15)
Pertussis	0 (0)	1 (5)
Pneumonia	3(15)	10(50)
Pleuritis	0 (0)	2(10)
Tuberculosis	7(35)	1 (5)
Measles and pneumonia	2(10)	2(10)
Tuberculosis and pneumonia	0 (0)	2(10)
No history	6(30)	2(10)
Symptoms n, (%)		
Cough	17(85)	11(55)
Sputum	14(72)	12(60)
Wheezing	8(40)	8(40)
Chest pain	3(15)	2(10)
Fatigue	13(65)	13(65)
Loss of appetite	3(15)	2(10)
Sweating	2(10)	3(15)
Reflux	7(35)	7(35)
PFT mean SD		
FVC (%)	67.8±18.6	62.0±16.7
FEV_1 (%)	70.8±28.2	60.6±23.4
FEV_1/FVC	82.1±12.8	77.6±12.0
PEF (%)	85.5±55.9	65.0±23.4

PFT: pulmonary function test; SD: standard deviation; FVC: forced vital capacity; FEV_1:1 expiratory volume at 1 sec; PEF: peak expiratory flow

Table 3. Distribution of patients with increased sputum after physiotherapy

	ACBT (n:17)		Flutter (n:19)	
	After physiotherapy (n)	p	After physiotherapy (n)	p
Sputum increase	4	*0.004	5	*0.003

ACBT: active cycle of breathing technique; *: p<0.05

Table 2. Changes in symptoms after physiotherapy in study groups

	ACBT (n:17)			Flutter (n:19)		
	Before physiotherapy (n)	After physiotherapy (n)	p	Before physiotherapy (n)	After physiotherapy (n)	p
Cough	14	4	*0.002	10	5	0.13
Wheezing	5	2	0.38	8	8	1.0
Fatigue	11	7	0.22	12	4	*0.021
Loss of appetite	3	1	0.50	2	0	-

ACBT: active cycle of breathing technique, *: p<0.05

status score was also significant (Table 4). Comparison of the subscales of general health, physical functions, physical role, emotional role, social functions, pain, energy level, and general mental health showed an improvement in the general health, physical function, physical role, emotional role, social function, pain, and energy in the Flutter® group; however, only the improvement in the emotional role and pain yielded in statistically significant results. A comparison between the groups before and after physiotherapy showed no differences in subscale scores other than those of general health and pain subscales. While there was no improvement after physiotherapy in the ACBT group with regard to physical assessments (physical functions, physical role, pain, and general health) and mental health (energy, social functions, emotional role, and mental health), patients in the Flutter® group had partial and statistically significant improvement in physical status. However, the comparison between the groups did not reveal statistically significant results (Table 5).

Table 4. Changes in dyspnea and the SF-36 Quality of Life Questionnaire after physiotherapy as compared to baseline

	Before physiotherapy n:36 Mean±SD	After physiotherapy n:36 Mean±SD	p
Dyspnea Score			
MRC Score	1.8±1.1	1.3±1.1	*0.001
Borg Score	2.8±1.9	1.9±1.7	*0.002
SF-36 QoL Questionnaire			
General health	36.2±24.9	37.9±24.5	0.45
Physical functioning	69.4±24.6	74.6±23.1	*0.031
Physical role	63.9±39.4	75.7±35.6	0.036
Emotional role	48.2±30.3	53.7±22.9	0.44
Social functioning	62.2±19.9	58.0±19.2	0.19
Pain	73.7±23.6	78.8±23.0	0.23
Vitality	49.6±20.8	45.7±19.2	043
Mental health	67.0±19.7	64.0±18.9	0.78
SF-36 Outcome Score			
Physical state assessment	43.5±10.4	46.6±10.8	*0.001
Mental state assessment	42.0±9.8	39.9±10.1	0.63

MRC: Medical Research Council; SD: standard deviation; *: p<0.05

DISCUSSION

Our study, comparing two different physiotherapeutic techniques scheduled to be practiced at home, determined that both techniques were effective in removing phlegm. We evaluated the changes in symptoms after the physiotherapy. Evaluation of symptoms experienced on a daily or intermittent basis by the patients may provide a measure of the success of physiotherapy. A symptomatic improvement observed in both groups is supportive of the efficacy of the physiotherapy programs used in this study. However, this warrants further studies. One of the aim of the physiotherapy should include a reduction in the symptoms that influence the quality of life of the patients. The effects of respiratory physiotherapy modalities on the volume of sputum have been subject to previous research. Despite the use of a variety of techniques, many

Table 5. The distribution and comparison of dyspnea score and the Quality of Life Questionnaire scores within and between the ACBT and Flutter® groups

	ACBT (n:17)		Flutter® (n:19)		
	After physiotherapy Mean±SD	p^1	After physiotherapy Mean±SD	p^1	p^2
Dyspnea Score					
MRC Score	1.1 ±1.1	*0.021	1.1±1.1	*0.006	0.97-
Borg Score	1.8±1.8	0.11	2.1±1.5	*0.012	0.39-
SF-36 QoL Questionnaire					
General health	35.6±27.9	0.22	40.0±21.6	0.09	*0.048
Physical functioning	72.9±22.9	0.21	76.1±24.0	0.07	0.87
Physical role	76.5±25.8	0.16	75.0±43.3	0.12	0.81
Emotional role	47.1±26.5	0.64	56.7±17.9	*0.048	0.07
Social functioning	57.4±21.7	0.12	58.5±17.2	0.72	0.51
Pain	69.9±25.4	0.51	86.7±17.8	*0.005	*0.011
Vitality	42.4±21.9	0.28	48.7±16.4	0.95	0.13
Mental health	61.4±22.4	0.67	66.3±15.5	0.90	0.30
SF-36 Outcome Score					
Physical state assessment	45.5±10.7	0.08	47.5±11.1	*0.005	0.28
Mental state assessment	38.4±11.2	0.26	39.9±8.3	0.43	0.16

ACBT: active cycle of breathing technique; SD: standard deviation; MRC: medical research council; SF: short form; p^1: within group comparisons before and after physiotherapy in the ACBT and Flutter groups; p^2: between-group comparisons for the change in scores after physiotherapy as compared to baseline *:p<0.05

studies found an increased sputum production as well as a positive effect on the airway clearance with the use of a single method or combined modalities [2,12-15]. Similarly, we also observed increased sputum production in our patient group. Recent studies have particularly focused on the comparative efficacy of ACBT and Flutter® in patients with cystic fibrosis (CF) or bronchiectasis. In one of these studies, no difference in the amount of daily sputum production could be detected, and no clear-cut data were provided concerning whether the intervention was carried out at home or at the hospital settings [3]. Similar to our study, ACBT and an oscillation device were compared in a study that lasted 3 days, and the device was found to be as effective as ACBT in terms of sputum production [16]. In another hospital-based study, the Flutter® device was reported to be superior for postural drainage with respect to the amount of sputum produced [17].

Since our study involved a relatively longer duration compared to previous studies i.e., 4 weeks, and the study design included a home-based therapy program, an objective assessment of the sputum volume could not be performed as opposed to other studies. This represents one potential limitation of our study. On the contrary, the intervention was performed in home settings in our study. Our findings not only are supportive of the efficacy of respiratory physiotherapy in bronchiectasis of non-CF origin but also have shown that the Flutter® device was as equally effective as ACBT. Furthermore, the results support the notion that this approach may be as effective as a hospital-based intervention and feasible home settings. Studies examining the perception of dyspnea in patients with bronchiectasis are scarce in number. Dyspnea occurring early in the course of the disease results in avoidance of physical activity because patients feel gradually more discouraged to be physically active with the presence of dyspnea. Thus, dyspnea represents an important symptom [18]. In one study, pulmonary rehabilitation was found to improve dyspneic symptoms in patients with chronic pulmonary disease [19]. In different studies utilizing the ACBT, ACBT-Postural Drainage (PD), and oscillation devices, no effect of physiotherapy on dyspnea was observed [14,16]. In contrast, both techniques were associated with improved scores of both the MRC and Borg dyspnea scale of the patients in our study. The improvement in dyspnea by the Flutter® device was detected not only during exercise but also at rest, suggesting that this technique is more efficacious. Since the clinical course of bronchiectasis may display significant variability, prediction of respiratory function abnormalities is not possible. Patients with airway obstruction comprise the majority of cases [20]. Also, the effect of physiotherapy on PFT is a matter of controversy. In studies utilizing oscillation devices and ACBT techniques, no change in PFTs have been reported [3,14,21], similar to our observations. This may be explained on the basis of the irreversible damage and bronchial dilatation despite the achievement of effective airway clearance in bronchiectasis.

A reduced frequency of exacerbations by physiotherapy has previously been reported [22]. A smaller number of patients with exacerbations in the Flutter® group as compared to the ACBT group in our study suggest that colonization may be reduced via removal of secretions, leading to a decrease in the risk of infective exacerbation episodes. However, because our study did not primarily target to assess the efficacy of physiotherapy on exacerbation frequency, further and longer-term studies would be warranted to reach more definite conclusions on this subject. Studies examining the perception of dyspnea in patients with bronchiectasis are scarce in number. However, dyspnea occurring early in the course of the disease results in the avoidance of physical activity because patients gradually feel more discouraged to be physically active when affected by dyspnea. Thus, dyspnea represents an important symptom [18]. In one study, pulmonary rehabilitation was found to improve dyspneic symptoms in patients with chronic pulmonary disease [19]. In different studies utilizing ACBT, ACBT-PD, and oscillation devices, no effect of physiotherapy on dyspnea was observed [14,16]. In contrast, both techniques were associated with improved MRC and Borg dyspnea scale scores of the study patients.

Bronchiectasis is associated with significant reductions in the quality of life as a result of the natural course of the disease leading to cough and production of purulent sputum, which may cause severe restrictions on social life. Studies examining the effect of physiotherapy on the quality of life in patients with bronchiectasis are very scarce in number, and only one study, which assessed the effect of the Flutter® and ACBT on the quality of life, is reported in the literature [3].

Previous studies examined the effect of the sputum volume and exercise capacity on the quality of life and found associations between these factors. In our study, the effect of the quality of life on the exercise capacity was not evaluated, again representing a potential limitation for our study. Parameters such as dyspnea, exercise capacity, and sputum production may well be affected by increases or decreases in the quality of life in patients with bronchiectasis. Although physiotherapy was effective in improving the quality of life, the Flutter® device had even a more significant positive effect on this parameter. This latter finding may be associated with the number of factors such as the ease of use, patient comfort, and better adherence to the therapy.

The limitations of our study are as follows: the patient number was low; the amount of sputum was not measured by objective methods; the following parameters, namely patients' exercise capacity, exercise adherence, physical activity levels could not be compared; and there was no control group. Nevertheless, home-based physiotherapy during a follow-up period of 1 month in bronchiectasis patients revealed successful results. None of our patients presented with absenteeism due to physiotherapy. A reduction in coughing, ease of sputum removal, decreased dyspnea perception, and perhaps an increase in the quality of life associated with the former are important results of our study in terms of demonstrating and supporting the success of physiotherapy.

Our results have demonstrated that physiotherapy represents an effective contribution to the management of patients with bronchiectasis. Higher efficacy of the Flutter® device in certain parameters may be associated with its easy of use and the subsequent improvements in treatment compliance. Further studies are warranted to support these findings.

Ethics Committee Approval: Ethics committee approval was received for this study from the Ethics Committee of Trakya University School of Medicine (Approval Date: 25.06.2009; Approval No: 2009/153).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author contributions: Concept - B.U., G.A.; Design - B.U., G.A.; Supervision - G.A., H.T.; Resource - B.U., L.O.; Materials -B.U., L.O., G.A. ; Data Collection and/or Processing - B.U.; Analysis and/or Interpretation - B.U., N.S.; Literature Search - B.U., L.O.; Writing -B.U. ; Critical Reviews - G.A., H.T., L.O.

Conflict of Interest: The authors have no conflicts of interest to declare.

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