Effects of a Flutter Mucus-Clearance Device on Pulmonary Function Test Results in Healthy People 85 Years and Older in China

Qi-xing Wang, Xiang-yu Zhang MD, and Qiang Li MD

OBJECTIVE: To investigate the impact of a new flutter-type mucus-clearance device on pulmonary function test results in people ≥ 85 years old. METHODS: We conducted a randomized controlled trial with 60 people ≥ 85 years old. The subjects were distributed randomly into an intervention group and a control group. Spirometry was performed at baseline and after 28 days of using the flutter mucus-clearance device. We recorded peak expiratory flow (PEF), FEV_1, forced vital capacity (FVC), and FEV_1/FVC. The intervention group used the flutter mucus-clearance device during pulmonary exercises. The control group had no interventions other than routine healthcare. We recorded episodes of fever, antibiotic therapy, and hospital visits during the 28 days of the study. RESULTS: PEF, FEV_1, FVC and FEV_1/FVC showed no significant differences between the 2 groups at baseline. The mean ± SD baseline values were: PEF 103.2 ± 43.0 L/min, FEV_1 0.98 ± 0.43 L, and FVC 1.76 ± 0.68 L. Compared to baseline, on day 28 there was no significant difference in PEF, FEV_1, or FEV_1/FVC, in either group. The mean ± SD difference in FVC between baseline and day 28 was 0.33 ± 0.30 L in the intervention group, and 0.20 ± 0.14 L in the control group ($P = .03$). There were no significant differences in the number of cases of fever, antibiotic therapy, or hospital visits between the groups. CONCLUSIONS: The new flutter mucus-clearance device improved elderly patients' FVC. (Clinicaltrials.gov registration NCT00881335.) *Key words: geriatrics; pulmonary function; mucus-clearance; flutter; physiotherapy; vital capacity; China.* [Respir Care 2010;55(11):1449–1452. © 2010 Daedalus Enterprises]

Introduction

As a population ages, quality of life related to decreased pulmonary function in elderly people becomes a common concern. Previous studies have shown important benefits from pulmonary rehabilitation,[1-3] including increased exercise tolerance,[4] exercise capacity, and quality of life.[5] However, few studies have looked at pulmonary function and physiotherapy in people ≥ 85 years old.[6,7]

See the Related Editorial on Page 1506

The flutter-type mucus-clearance device is a simple handhold apparatus (Fig. 1) that contains a steel ball positioned in the air flow way. The exhaled air passing through the device makes the ball vibrate and generates vibrations. Since the vibration depends on the force of gravity, the angle at which the flutter device is held affects the vibration frequency and amplitude.[8]

Flutter-type mucus-clearance devices have been used most extensively in patients with cystic fibrosis and bronchiectasis in the United States.[9] We hypothesized that it might also be efficacious in people ≥ 85 years old without diagnosed chronic pulmonary disease and residing at a geriatric facility, in improving pulmonary function and

Qi-xing Wang and Xiang-yu Zhang MD are affiliated with the Department of Emergency and Critical Care Medicine, Shanghai Tenth People's Hospital, Tongji University School of Medicine, Shanghai, People's Republic of China. Ms Wang is certified in rehabilitation care by the Ministry of Health, People's Republic of China. Qiang LI MD is affiliated with the Department of Pulmonology, Shanghai Kongjiang Hospital, Shanghai, People's Republic of China.

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Correspondence: Zhang Xiang-yu MD, Department of Emergency and Critical Care Medicine, Shanghai Tenth People's Hospital, Tongji University School of Medicine, 301 Yanchang Road, Shanghai, 200072, People's Republic of China. E-mail: xiangyu62@126.com.

decreasing the occurrence of respiratory infection. Mucus clearance from small airways may directly improve diffused air-flow obstruction.

Methods

Study Design

In this randomized controlled single-center study we investigated the impact of 28 days of use of a new flutter-type mucus-clearance device on pulmonary function, fever, antibiotic therapy and hospital visits in people ≥ 85 years old. Sixty people ≥ 85 years old, and without diagnosed pulmonary or heart disease, were invited to participate. Pulmonary function tests were conducted at baseline and on study day 28. The subjects were randomized via sealed envelopes and were distributed to either the intervention group or the control group. Only the intervention group did the pulmonary exercises with the flutter device. The control group had no interventions other than routine healthcare.

The eligibility criteria were: ≥ 85 years old and capable of using the flutter device. The exclusion criteria were: untreated pneumothorax; diffuse interstitial lung disease; acute coronary syndrome; third-stage hypertension; advanced cancer; severe heart problems; liver, renal, blood system, or and endocrine system dysfunction; active hemoptysis; and receiving noninvasive mechanical ventilation.

The research and ethics committee of Shanghai Tenth People's Hospital approved the study. The protocol was explained to all subjects, and written informed consent was obtained from all participants prior to participation in the study.

Pulmonary Function Testing

The pulmonary function tests were conducted with a hand-held spirometer (One Flow FVC Memo, Clement Clarke International, Harlow, Essex, United Kingdom) with disposable mouthpiece. All subjects sat upright in a chair during the testing and were instructed on how to perform the test. The test was repeated until 3 acceptable and reproducible results were obtained. Spirometry was performed at baseline and on study day 28. The peak expiratory flow (PEF), FEV_1, forced vital capacity (FVC), the FEV_1/FVC were recorded for the best of the 3 valid expiratory efforts.

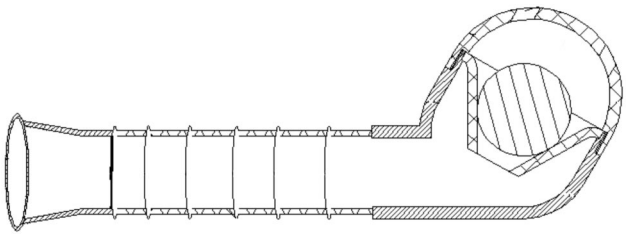

Fig. 1. Longitudinal cross-section of the flutter-type mucus-clearance device.

Flutter Mucus-Clearance Device and Regimen

The flutter mucus-clearance device we used in this study is a new design (patent number ZL2008 2 0055589.5), and was used only by the intervention group. Each intervention-group subject was instructed how to place the flutter device in the mouth and to exhale through the device actively with deep breaths, but not forcefully, and how to adjust the device angle to obtain better air-flow vibrations. The subject was instructed to repeat the procedure for 5–10 breaths, in three 5-min sessions per day. Each session allowed the subject to rest as needed for comfort. The recommend times for the 3 daily sessions were: after getting up in the morning; after midday nap; and before going to the bed in the evening.

Measurement

We recorded age, sex, height, and weight at baseline. Medical care outcomes data (cases of fever [temperature > 38°C], antibiotic therapy, and hospital visits) were collected on day 28 from the nursing home medical care records, and also confirmed via questionnaire to the subjects on day 28. Adverse events were determined and recorded via questionnaire on day 28.

Statistical Analysis

All data analysis and group comparisons were with the independent-samples *t* test. All the variational data are presented as mean ± SD. Numeration data were analyzed with the chi-square test. We used double-tailed tests for all statistical tests. A P value $< .05$ was considered statistically significant. Data analysis was performed with statistics software (SPSS 16.0, SPSS, Chicago, Illinois).

Results

Baseline Characteristics

We prospectively screened elderly people at a nursing home in Shanghai, China, between April 19 and May 17, 2009. Sixty elderly adults were included and randomly distributed to the intervention group ($n = 30$) and the control group ($n = 30$). On day 28 the intervention group had lost 2 to follow-up and 1 was disqualified. The intervention-group subjects' age range was 85–95 years (mean ± SD age 86.8 ± 2.1 y), and the intervention group had 8 males and 19 females.

Table 1. Baseline Characteristics

	Intervention Group (n = 27) (mean ± SD)	Control Group (n = 28) (mean ± SD)	Total (n = 55) (mean ± SD)	P
Age (y)	86.8 ± 2.1	87.6 ± 3.0	87.2 ± 2.6	.15
Height (cm)	163 ± 6	160 ± 6	161 ± 6	.46
Weight (kg)	57.4 ± 9.2	56.4 ± 9.4	56.8 ± 9.3	.86
PEF (L/min)	102.2 ± 39.7	104.1 ± 46.8	103.2 ± 43.0	.20
FEV_1 (L)	0.92 ± 0.38	1.05 ± 0.47	0.98 ± 0.43	.36
FVC (L)	1.78 ± 0.72	1.74 ± 0.66	1.76 ± 0.68	.84
FEV_1/FVC (%)	53 ± 16	61 ± 16	57 ± 16	.88

PEF = peak expiratory flow
FVC = forced vital capacity

Table 2. Pulmonary Function on Day 28

	Intervention Group (n = 27) (mean ± SD)	Control Group (n = 28) (mean ± SD)	P
PEF (L/min)	117.6 ± 50.4	103.9 ± 41.5	.20
FEV_1 (L)	1.01 ± 0.37	1.02 ± 0.35	.96
FVC (L)	2.06 ± 0.73	1.77 ± 0.63	.79
FEV_1/FVC (%)	51 ± 17	59 ± 14	.24

PEF = peak expiratory flow
FVC = forced vital capacity

Table 3. Pulmonary Function Differences Between Baseline and Day 28

	Intervention Group (n = 27) (mean ± SD)	Control Group (n = 28) (mean ± SD)	P
ΔPEF (L/min)	26.8 ± 18.3	24.1 ± 19.3	.70
ΔFEV_1 (L)	0.20 ± 0.14	0.21 ± 0.16	.73
ΔFVC (L)	0.33 ± 0.30	0.20 ± 0.14	.03
ΔFEV_1/FVC (%)	8 ± 7	9 ± 6	.67

PEF = peak expiratory flow
FVC = forced vital capacity

On day 28 the control group had lost 1 to follow-up, and 1 was disqualified. The control-group subjects' age range was 85–95 years (mean ± SD age 87.8 ± 3.0 y), and the control group had 5 males and 23 females. There were no significant differences in the groups' baseline characteristics (Table 1).

On day 28 there were no significant differences between the intervention and control groups in PEF, FEV_1, FVC, or FEV_1/FVC (Table 2). Table 3 shows the differences between the baseline and day-28 PEF, FEV_1, FVC, or FEV_1/FVC values. Only the FVC difference was significantly different (0.33 ± 0.30 L in the intervention group vs 0.20 ± 0.14 L in the control group, P = .03)

Table 4. Number of Cases With Fever, Antibiotic Therapy, and Hospital Visits

	Intervention Group (n = 27)	Control Group (n = 28)	P
Fever	0	2	.49
Antibiotic therapy	1	3	.63
Hospital visit	2	3	> .99

Outcomes

All the subjects reported no adverse events. There were no significant differences in the number of cases of fever, antibiotic therapy, or hospital visits (Table 4).

Discussion

Pulmonary function test results decrease with age, primarily because of a decrease in lung elasticity and respiratory muscle strength, and an increase in stiffness of the chest wall. FVC and FEV_1 decrease, and residual volume increases with age. The FEV_1 decline may approach 65–70% in the elderly. Static maximum expiratory and inspiratory pressures also decline with age.[10,11]

Previous investigations reported average yearly decreases of 0.032 L/y in FVC, and 0.141 L/y in FEV_1 in healthy older people.[12,13] All of the subjects in our study were ≥ 85 years old (mean ± SD age 87.2 ± 3.0 y). The overall FVC and FEV_1 at baseline were 1.76 ± 0.68 L and 0.98 ± 0.43 L, respectively, which is an important decrease in respiratory function in people of this age range.

Spirometry measures air flow from fully inflated lungs. The 2 most important measurements are FVC and FEV_1. FVC is the maximum amount of air that can be forcefully exhaled from a fully inflated lung.

Flutter mucus-clearance devices have been used in many countries for many years. The basic mechanism is resonance vibration during expiratory flow, which loosens and thereby helps remove airway secretions.[14,15] Many flutter devices are designed so that they need to be held at a certain angle that is only effective if the patient is in a sitting position.[16] Patients need to adjust body position to get a better vibration angle. The new flutter mucus-clearance device we used in this study has a flexible adapter between the flutter vibration generator and the mouthpiece (see Fig. 1), so it works with any patient body-position and eliminates the uncomfortable vibration of the teeth that occurred with earlier flutter devices. The new flutter device is transparent, which helps the user find the best position for maximum vibration and comfort.

Previous studies found that older adults' pulmonary function improves with respiratory exercises. Pulmonary rehabilitation exercises can increase exercise tolerance[17] and FVC. The present study found that the FVC improvement at day 28 was significantly better ($P = .03$) in the intervention group.

PEF measures how fast a person can exhale air, and is a simple method of measuring airway obstruction and thus can detect moderate to severe respiratory disease. The reproducibility of PEF depends on patient effort, which is a potential limitation of this study. However, we used the same model of spirometer in all the tests, and all the tests were conducted by the same clinician, who has respiratory care certification; PEF showed no significant difference ($P = .70$) between the 2 groups.

FEV_1 and FEV_1/FVC indicate the degree of air-flow obstruction, and are important predictors of disease progression and prognosis in COPD patients. The subjects in our study were healthy but 85–95 years old. FEV_1 and FEV_1/FVC showed no significant difference between the intervention and control groups.

There were no cases of fever in the intervention group, whereas there were 2 cases in the control group. In the intervention group, 1 patient received antibiotic therapy, and 2 patients required hospital visits. There were no significant differences in the number of cases of fever, antibiotic therapy, or hospital visits between the 2 groups.

Limitations

Fifty-five subjects is a very small sample for a pulmonary function investigation. However, this study does draw attention to the substantially decreased pulmonary function in healthy people $\geq$ 85 years old. The use of the flutter device for respiratory exercise to improve pulmonary function in elderly people is based on various studies that have described the benefits of respiratory exercise. But our findings may be limited by the small sample size and short study period (28 days).

Conclusions

Elderly people may improve pulmonary function and vital capacity by doing pulmonary rehabilitation exercises. A flutter-type mucus-clearance device can improve some components of pulmonary function in healthy elderly people. Further study is needed on improving pulmonary function via respiratory exercises in elderly people.

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