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Feasibility and Safety evaluation of Simeox Airway Clearance Technique in patients with Bronchiectasis

ERS 2019, Madrid

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Introduction

Airway Clearance Techniques (ACTs) improve bronchial drainage in various obstructive lung diseases with sticky and viscid mucus. Patients with bronchiectasis (BE) are a good indication for airway clearance therapy but new techniques required to be evaluated.

Aim

Goal of this pilot study was to assess feasibility and safety of an innovative ACT compared to manual chest physiotherapy (CPT) for airway clearance management of hospitalized patients suffering from bronchiectasis.

Methods

12 consecutive patients with BE (non-CF or CF) hospitalized for acute pulmonary exacerbation were randomized 1:1 to CPT (Control) or a new airway clearance device (Simeox, Physio-Assist).

Simeox device generates a precise pneumatic vibratory signal that disseminates during relaxed exhalation in the bronchial tree a succession of very short negative air pressure pulses of adjustable constant volume at a frequency of 12 Hz. The signal modifies mucus viscosity and elasticity, and mobilizes mucus secretions from distal airways to the proximal tract for productive expectoration.

Patients were treated 5 days (2 sessions of 20 min each per day) during hospitalization with either device or CPT (6 patients in each group).

Pulmonary function test, chest expansion, sputum collection and SpO2 were performed before and after ACT procedure, and compared between the 2 groups (Intent-To-Treat analysis).

Data were compared using non-parametric test (Man-Whitney-Wilcoxon or Wilcoxon signed rank test). All statistical analyses were performed using IBM SPSS Statistics for Windows. A p-value of <0.05 was considered to indicate statistical significance.

Results

12 patients were included from March to April 2018. 7 men, 5 women; Mean age 46.5 y. Lung diseases: 7 CF+BE (Control: 5, Device: 2), 3 COPD+BE (Control: 1, Device: 2); 2 IPF+BE (Control:0, Device:2).

After 5 days of therapy, there was a similar trend in FEV1 improvement between Simeox (+2.5%; +70ml) and Control (+1.5%; +40ml). Chest expansion and SpO2 increased significantly to a similar extent in both groups. Total sputum production (median [Min; Max]) seemed to be higher with the device (+143ml [25; 300]) than Control (+30ml [20; 180]) but the difference between groups was not statistically significant.

A longitudinal rise of SpO2 pre-therapy leading to less negative SpO2 variations between ACT sessions was observed during the 5 days in the device group only (R^2=0.705; p = 0.002), suggesting a persistent effect of therapy with the device on oxygen saturation.

The device was well tolerated by all patients and no safety signal was detected. Functions of Simeox were easily understood and proper handling was simple for every patient. Patients appreciated the device and found it comfortable.

EVOLUTION OF PULMONARY FUNCTION

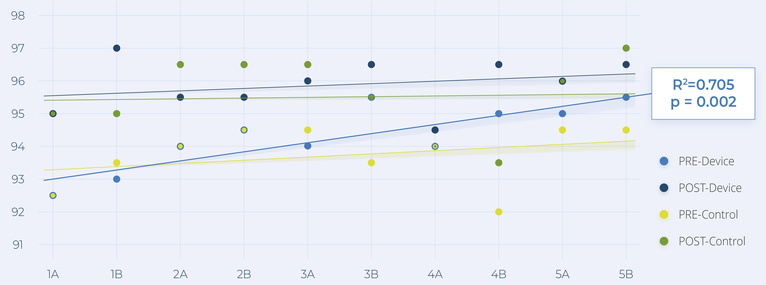
Parameters	Device (N=6)			Control (N=6)			P *value*
	Median	Minimum	Maximum	Median	Minimum	Maximum	
FEV1 before	1.54	0.88	2.08	1.30	0.93	1.64	0.337
FEV1 after	1.84	0.83	2.22	1.42	0.93	1.64	0.200
ΔFEV1	**0.07**	**-0.07**	**0.87**	**0.04**	**-0.28**	**0.50**	**0.872**
FEV1% before	57.0%	28.0%	75.0%	39.0%	22.0%	100.0%	0.173
FEV1% after	59.5%	39.0%	84.0%	35.5%	23.0%	108.0%	0.078
ΔFEV1%	**2.5%**	**-3.0%**	**21.0%**	**1.5%**	**-7.0%**	**10.0%**	**0.872**
RV% before	152.0	51.0%	386%	213%	135%	342%	0.109
RV% after	176.0	52.0%	263%	228%	128%	297%	0.200
ΔRV%	**4.5**	**-123%**	**56%**	**-11%**	**-72%**	**48%**	**0.423**
Chest mobility before (cm)	3.5	1.5	5.0	2.0	2.0	3.0	0.070
Chest mobility after (cm)	4.3	1.5	6.0	3.0	2.5	4.0	0.145
ΔChest mobility (cm)	**0.8**	**0.0**	**1.0**	**1.0**	**0.5**	**1.5**	**0.337**

FEV1: force expiratory volume in 1 second (liter);
FEV1%: % predicted FEV1; RV%: % predicted residual volume

EVOLUTION OF SPUTUM PRODUCTION

Parameters	Device (N=6)			Control (N=6)			P *value*
	Median	Minimum	Maximum	Median	Minimum	Maximum	
Sputum day 1 (ml)	15.0	5.0	40.0	7.5	0.0	20.0	0.247
Sputum day 2 (ml)	10.0	0.0	90.0	5.0	5.0	80.0	0.412
Sputum day 3 (ml)	20.0	10.0	70.0	10.0	0.0	30.0	0.134
Sputum day 4 (ml)	42.5	5.0	90.0	7.5	0.0	40.0	0.146
Sputum day 5 (ml)	20.0	5.0	70.0	5.0	5.0	30.0	0.113
Total Sputum (ml)	**142.5**	**25.0**	**300.0**	**30.0**	**20.0**	**180.0**	**0.126**

EVOLUTION OF SPO2 (%)



Day 1- 5 (A: morning; B: afternoon)

Conclusions

These preliminary data showed non-inferiority of device procedure compared to manual chest physiotherapy in patients with bronchiectasis.

Simeox technology was considered safe and feasible for airway clearance management during hospitalization of different lung diseases with mucus retention.

PhysioAssist

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