Application of the Simeox airway clearance technology

in the treatment of

Cystic Fibrosis

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COPD and BRONCHIECTASIS

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Simeox Clinical Notebook n°2

Introduction

Airway clearance techniques (ACTs) represent a panel of various techniques performed by the external application of forces to clear bronchial secretions from the lungs[1]. ACTs facilitate sputum transport via manipulation of lung volumes, gas flow, pulmonary pressures and compressive forces. A combination of these factors exerts shearing forces onto sputum at the air-liquid interface, and the resulting energy transfer shifts secretions towards the mouth. This mechanism is well known as two-phase gas-liquid flow and is considered essential for lung clearance in patients with mucociliary dysfunction to improve ventilation[2].
Several types of ACTs are used in clinical practice: conventional therapy (postural drainage, percussion, vibration), breathing exercises (ACBT, autogenic drainage), Positive Expiratory Pressure (PEP devices) and mechanical devices applied externally to the chest wall (HFCWO).

Cystic fibrosis (CF) is a disorder that interrupts the lungs' normal mucus secretion, causing excessive production of viscid mucus, which leads to mucus plugging, recurrent infections, and inflammation, followed by airway damage and lung function deterioration.
ACTs have the short-term effect of increasing mucus transport in CF[3]. Available clinical evidences showed that no ACTs demonstrated to be superior to others and that the prescription of ACTs should be individualized based on patient preference[5,6,7] although some devices seem to reduce rate of long term respiratory exacerbation[8].

Chronic obstructive pulmonary disease (COPD) is an umbrella term used to described progressive lung diseases including emphysema, chronic bronchitis, and refractory asthma as Asthma-COPD Overlap Syndrome (ACOS). COPD patients often experience dyspnea, cough, sputum and chest tightness which may worsen during acute exacerbation of COPD (AECOPD). Patients with bronchiectasis have more severe symptoms, purulent sputum expectoration and acute exacerbation, and may be good responders to ACTs[9].
ACTs are safe and enhance mucus clearance in COPD[1, 4]. Performing ACTs reduced during an AECOPD the likelihood of needing mechanical ventilation, as well as the length of time for which it was required[4]. There are a few evidences to suggest some benefits on future exacerbation or health-related quality of life[10, 11]. Performing ACTs during stable COPD do not affect exacerbation or hospitalizations but may improve health-related quality of life[4].

Simeox (Physio-Assist, France) technology is an innovative ACT which mobilizes mucus in the distal tracts to change its rheology and transport it to the proximal tract for expectoration. The device generates a succession of very short air depressions of constant volume at a frequency similar to that of the vibratory cilia of the bronchial epithelium by disseminating a vibratory pneumatic signal in the bronchial tree during relaxed exhalation. This signal allows a direct intrapulmonary action on the dynamic viscosity and mobilization of the bronchial mucus.
The viscosity decreases sharply by the shear thinning property and thixotropy of mucus. Relaxed exhalation is ensured by the device with an aid for preventing airway collapse and increasing the expiratory time.
The main target diseases of Simeox are CF, COPD, bronchiectasis and primary ciliary dyskinesia.
Simeox can be used as part of a bronchial drainage session after the patient has been trained by a physiotherapist. The touch screen interface allows biofeedback that facilitates real-time visualization of the progress of patient treatment..

This clinical documentation brings together the experience with the Simeox technology of several recognized national centers of medical expertise and research from different EU countries (France, Poland, Czech Republic, Romania, Slovakia and Russian federation) in the management of patients with various obstructive lung diseases (Cystic fibrosis, COPD, non-CF bronchiectasis, pulmonary fibrosis, ILD) suffering from pulmonary congestion and requiring airway clearance.
Each center performed a pilot prospective study with the aim of assessing short-term benefits and safety of Simeox technology compared to conventional physiotherapy in patients hospitalized for either acute pulmonary exacerbation of chronic lung disease or routine medical checkup. Patients with acute exacerbation were treated for chest congestion with Simeox for 5-7 days (1 or 2 sessions per day) during hospitalization while receiving optimal drug therapy. Pulmonary function tests, symptoms, mucus clearance, SpO2, usability, quality of life and adverse events were evaluated during the study.

Cystic Fibrosis

Clinical and Scientific Evidences

Simetol prospective cohort study

Evaluating safety, tolerability and efficacy of Simeox compared to usual chest physiotherapy techniques for airway secretion clearance

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Introduction

According to the 2018 standards of cares for Cystic fibrosis (CF), meticulous daily management of lung disease is essential to prevent infection and preserve lung function in CF. However, daily chest physiotherapy may be a burden for patients and relatives and prescription of a suitable airway clearance technique (ACT) should therefore be tailored to patient preference.

SIMETOL study aims to assess through a multidisciplinary approach, the feasibility, safety and efficacy of Simeox (PhysioAssist, France) in patients with stable chronic obstructive pulmonary disease and requiring airway secretion clearance.

Clinical study

This prospective open monocentric crossover clinical trial was approved by a French National Ethic Committee (Comité de Protection des Personnes Sud-Méditerranée 1) and authorized by the French National Competent Health Authority (ANSM).
All patients gave informed consent before any study procedure. The study was conducted in accordance with Good Clinical Practice and the principles of the Declaration of Helsinki. The study was registered at ClinicalTrials.gov registry (NCT02061852).

The data presented below are derived from a statistical subgroup analysis of patients with Cystic Fibrosis (CF) recruited in the study.

Patients

Subset of adult CF patients, male or female, with stable lung function and FVC and/or FEV1 <85% of predicted and requiring a hospitalization duration of 5 to 8 days for routine medical checkup including airway clearance therapy.

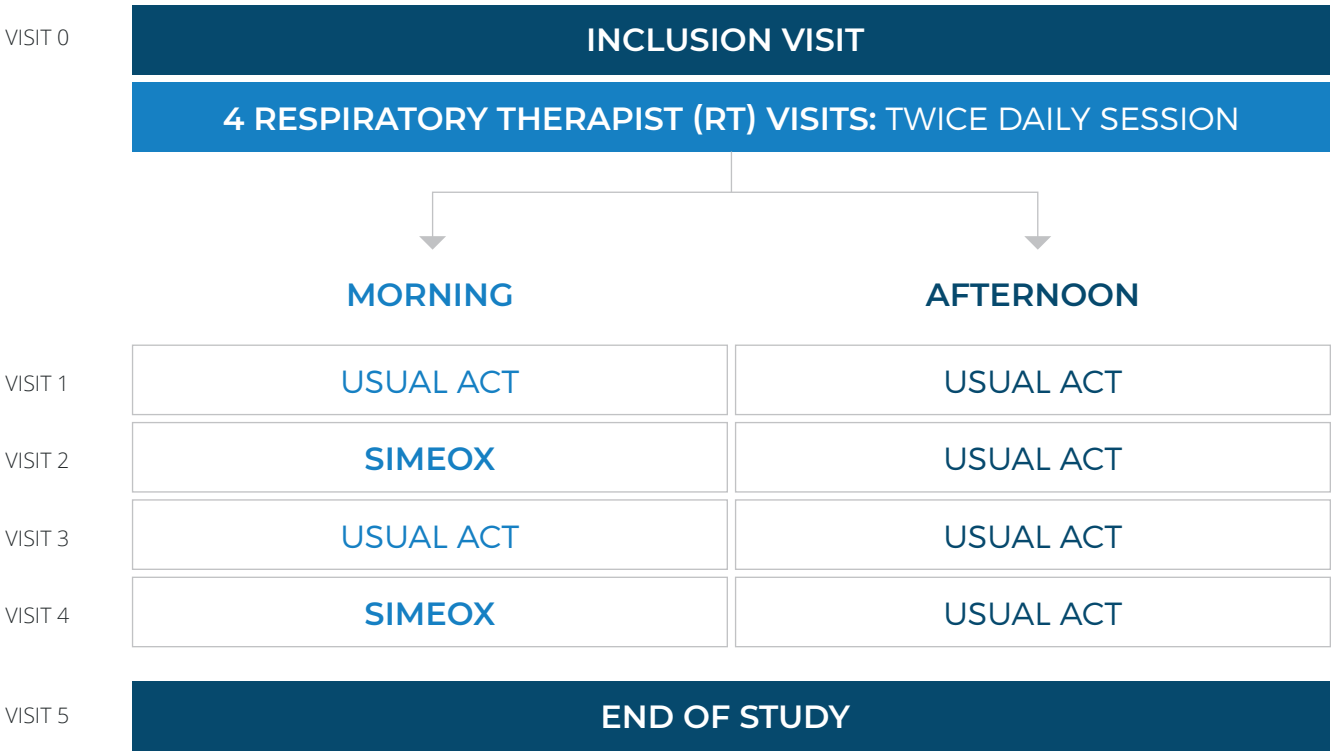
Patients were excluded if they had contraindication to chest physiotherapy, non-productive bronchial drainage session, required more than 2 chest physiotherapy sessions per day, had lung transplant, >8 hours per day of mechanical ventilation, hemoptysis or pneumothorax within last month, pan-drug-resistant bacteria, or were participating in another trial.

Intervention

Patients were treated during hospitalization for 4 consecutive days (2 x 20-45 min session per day, one in the morning and one in the afternoon) with their usual conventional chest physiotherapy (autogenic drainage, active cycle of breathing techniques, forced expiration techniques, controlled coughing, airway clearance devices).

Simeox technology was introduced in the morning of Day 2 and 4 in replacement of usual chest physiotherapy session. As a result, patient received usual physiotherapy alone on day 1 and 3 and combined physiotherapy techniques (usual and Simeox) on day 2 and 4.

Side effects (excessive fatigue, dizziness due to hyperventilation, headache, cervical pain, nausea, sore throat), tolerability (fatigue, pain, ventilatory adaptation) and usability of Simeox device was assessed during the study. 24h-wet sputum weight and pulse oximetry (SpO_2) before/after each session were compared between therapies.



Results

11 adult CF patients were included in the subgroup analysis. Mean age was 34±9 years, 7 male and 4 women, BMI 19.8±3.2. Mean rate of usual chest physiotherapy session was 31±16/month.
Baseline PFTs: FEV1 1015±401 ml, FVC 1919±641 ml, FEV1% 31±13%, FEV1/FVC% 52±6%,

Median duration of sessions was similar (30 min) between Simeox and usual chest physiotherapy. All patients completed the study. No side effect nor decrease of SpO2 was reported during both interventions. There was no significant difference in SpO2 change between Simeox and usual chest physiotherapy alone (morning session with/without Simeox) or between combined ACTs and usual physiotherapy alone (days with/without Simeox).

Daily secretion clearance was significantly improved with combined ACTs (median [Q1-Q3]: 38 [19-48] vs 26 [17-38]g, p=0.025) compared to usual chest physiotherapy alone.

No patient discontinued device therapy. Simeox therapy was not painful in 9 patients. 2 patients reported moderate pain and 2 patients experienced very tiring sessions with Simeox compared to usual chest physiotherapy.
After the second Simeox session, 9 patients were satisfied with device therapy and 7 patients preferred use of Simeox alone or combined therapy rather than usual chest physiotherapy alone.

Conclusions

These data suggest that Simeox therapy alone or combined with chest physiotherapy is safe and feasible in adult CF with good tolerability for most of patients.

Simeox therapy may provide additional benefits on lung clearance in term of comfort and perceived efficiency.

Pilot Safety and Feasibility Study

of Simeox Physiotherapy vs. Traditional Physiotherapy in Adult Cystic Fibrosis Patients in Clinical Setting

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Aim of the study

To assess safety and feasibility of Simeox physiotherapy during the pulmonary exacerbation treatment in adult Cystic Fibrosis patients in clinical setting compared to conventional physiotherapy.

Materials and Methods

Patients. Adult Cystic Fibrosis patients, having an in-patient pulmonary exacerbation treatment were included in prospective, monocentric, randomized controlled study.

The Study group was formed of 5 patients randomized to have Simeox (physio-Assist, France) physiotherapy together with standard medical treatment of CF pulmonary exacerbation in pulmonology department. 5 patients were randomized for the Control group and were treated with standard CF pulmonary exacerbation medical treatment together with traditional manual physiotherapy technique.

The groups were comparable by main anthropometric, microbiological and functional characteristics *(Table 1)*. In all cases Cystic Fibrosis was diagnosed in early childhood and was confirmed by clinical findings, positive sweat test and CFTR genotyping. The patients had chronic respiratory infection with non-fermenting gram-negative bacteria and were pancreatic insufficient mostly. No one of the patients included had recent hemoptysis, pneumothorax 6 months or less prior to the study, all of them could perform spirometry, had no contra-indication to manual or instrumental physiotherapy and did not participate in another clinical trial.

Table 1 | *The Study and Control group characteristics*

	Study group, n=5	Control group, n=5	P
Age, Med (IQR), years	25.0 (5.0)	24.0 (7.0)	0.753
Gender, M/F	1/4	2/3	0.783
P.aeruginosa, n	5	5	1.0
BMI, Med (IQR), kg/m2	18.0 (6.3)	20 (5.7)	0.602
FEV1, Med (IQR), % pred	45.0 (21.5)	50 (9.0)	0.527

IQR: Interquartile range; Med: median

The clinical and functional assessment of the patients was performed before the start and after 5 days of treatment.

The questionnaire (provided by PhysioAssist company), reporting the ability of the patient to use the device, adverse events, reported outcomes, as well as the chest expansion and SpO2 measurement, spirometry and expectorated sputum volume were evaluated.

Questionnaire evaluation:

Simeox physiotherapy was evaluated by 5 patients as follows:

- Pain during treatment – 2.7 by 10-score scale (0 no pain > 10 painful)
- Was it easy to relax during passive exhalation? – 2.5 by 4-score scale (1 easy > 4 difficult)
- Fatigue – 3.5 by 10-score scale (0 low > 10 high)
- Is it easier to breathe? – 2.5 by 4-score scale (1 easy > 4 difficult)
- Expectorated sputum characteristics? –1.5 by 4-score scale (1 copious sputum > 4 scanty and foamy sputum)

Format was performed to all Study group patients with a treatment duration of 20 – 25 minutes : 2 sessions per day, 1 morning and 1 evening, for 5 days.
Control group patients had traditional manual physiotherapy technique : 2 sessions per day, 1 morning and 1 evening, for 5 days.

Results

There was no adverse events in both groups during 5-day course of treatment, and no withdrawal from Simeox physiotherapy.

Questionnaire results in both groups. **Tables 2 – 8**
There was no significant difference between the groups in questionnaire results.

Table 2 | *During the last 2 weeks how difficult it was to:*

Patient	Group	To do vigorous exercise (running etc.)		To carry or lift heavy objects		To walk one floor up the stairs	
		Day 1	Day 5	Day 1	Day 5	Day 1	Day 5
1	Simeox	4	3	2	2	2	1
2	Simeox	4	4	4	4	4	4
3	Simeox	3	2	2	3	2	1
4	Simeox	3	3	1	1	1	1
5	Simeox	3	2	3	3	2	2
6	Control	3	3	3	3	2	2
7	Control	3	3	3	3	3	2
8	Control	4	4	2	2	3	3
9	Control	4	3	4	4	2	2
10	Control	4	3	4	4	4	4

4-very difficult, 3-difficult, 2-a bit difficult, 1-not difficult

Table 3 | *During the last 2 weeks how often:*

Patient	Group	You felt in good shape		You felt tired		You felt full of energy		You felt exhausted	
		Day 1	Day 5	Day 1	Day 5	Day 1	Day 5	Day 1	Day 5
1	Simeox	2	3	3	2	2	2	3	1
2	Simeox	2	1	4	4	1	1	4	4
3	Simeox	2	2	3	4	2	2	4	3
4	Simeox	2	2	2	3	2	2	3	3
5	Simeox	3	3	3	3	3	3	3	2
6	Control	2	2	3	3	3	3	4	4
7	Control	3	3	3	3	2	2	4	3
8	Control	2	2	3	3	2	2	3	3
9	Control	3	3	4	4	2	2	3	3
10	Control	2	2	2	2	2	2	3	3

4-always, 3-often, 2-sometimes, 1-never

Table 4

Patient	Group	How difficult is it for you to walk? *		How difficult is it for you follow the course of treatment? **	
		Day 1	Day 5	Day 1	Day 5
1	Simeox	3	2	2	1
2	Simeox	4	4	2	3
3	Simeox	2	2	2	3
4	Simeox	2	2	2	2
5	Simeox	2	2	2	2
6	Control	2	2	2	2
7	Control	3	3	3	3
8	Control	2	2	2	2
9	Control	2	2	2	2
10	Control	2	2	2	2

** 1- You can walk for a long time without fatigue, 2- You can walk for a long time, but you get tired, 3- You can't walk for a long time because you get tired, 4- You refrain from walking, because you get tired quickly.*

*** 1- not difficult at all, 2- a bit difficult, 3- moderately difficult, 4- very difficult*

Table 5 | *What statement is right for you?*

Patient	Group	I have to limit vigorous exercise (running, sports, etc.)		I have to bring myself to eat		I have to stay at home more often than I would like to		I think my cough is a nuisance to others	
		Day 1	Day 5	Day 1	Day 5	Day 1	Day 5	Day 1	Day 5
1	Simeox	4	3	3	2	4	2	3	2
2	Simeox	4	4	4	4	3	3	4	4
3	Simeox	1	1	3	3	1	1	3	3
4	Simeox	3	3	2	2	1	1	4	3
5	Simeox	2	2	2	2	2	2	3	3
6	Control	2	2	3	3	1	1	3	3
7	Control	3	3	2	2	2	2	4	1
8	Control	3	3	3	2	2	2	3	3
9	Control	4	4	3	3	4	3	3	3
10	Control	2	2	3	3	3	3	3	2

4- completely agree, 3- partially agree,2- partially disagree,1- completely disagree

Table 6 | *During the last 2 weeks:*

Patient	Group	Your airways were congested		You coughed during the day		You coughed to drain the sputum	
		Day 1	Day 5	Day 1	Day 5	Day 1	Day 5
1	Simeox	4	2	3	2	4	3
2	Simeox	4	3	4	2	4	3
3	Simeox	4	4	4	3	4	2
4	Simeox	2	2	4	4	3	3
5	Simeox	3	3	2	2	3	2
6	Control	4	3	3	2	4	3
7	Control	2	2	3	2	3	2
8	Control	3	3	3	3	3	3
9	Control	4	3	4	4	2	2
10	Control	2	2	3	2	2	2

4-very much so, 3- probably yes,2-not much,1-not at all

Table 7

Patient	Group	Your sputum was most often	
		Day 1	Day 5
1	Simeox	3	3
2	Simeox	3	3
3	Simeox	3	3
4	Simeox	3	3
5	Simeox	3	3
6	Control	3	3
7	Control	3	3
8	Control	3	3
9	Control	3	3
10	Control	3	3

1-transparent, 2- transparent yellow, 3-green, 4 - green with traces of blood, 5 - I don' know

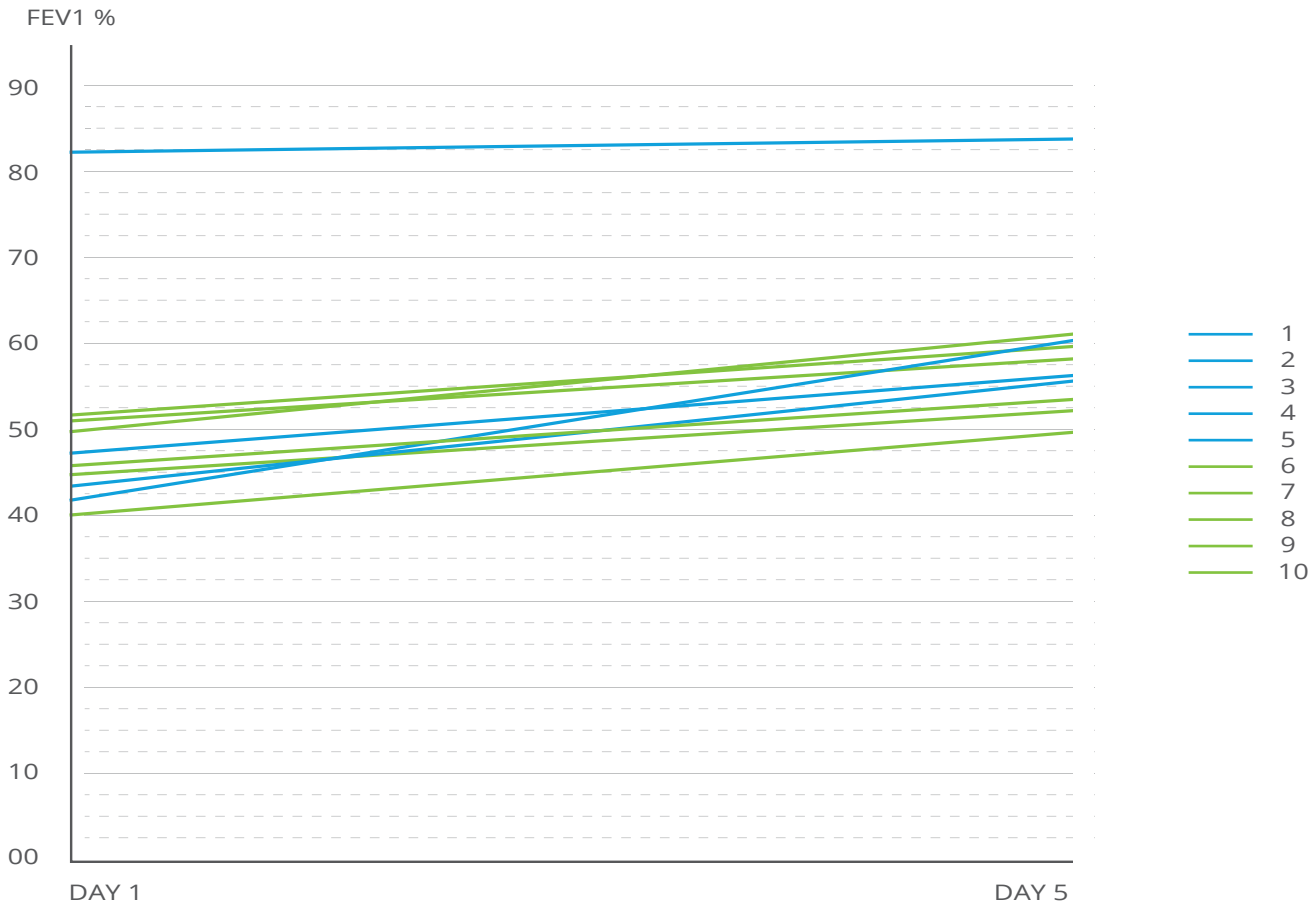
Table 8 | *How often during the last 2 weeks:*

Patient	Group	You had wheezing?		You had breathing difficulties?		You woke up at night because of the cough?	
		Day 1	Day 5	Day 1	Day 5	Day 1	Day 5
1	Simeox	2	2	3	2	3	2
2	Simeox	4	2	4	3	3	2
3	Simeox	4	3	4	1	2	2
4	Simeox	3	3	2	2	2	2
5	Simeox	4	4	4	4	3	2
6	Control	3	3	4	4	4	3
7	Control	2	2	3	3	2	2
8	Control	3	2	2	2	2	2
9	Control	3	3	3	2	3	3
10	Control	3	3	3	3	3	3

4-always, 3-often, 2-sometimes, 1-never

There was no significant difference between the groups in FEV1 increase as well:
+9.0±6.0% pred. in the Study Simeox group and + 8.0 ± 2.9 % pred. in the Control group (p=0.751) **(Fig.1)**

Fig.1 FEV1 changes (%pred) in the Study group (blue) and the Control group (green) after 5-day course of treatment.



In the Study (Simeox) group the expectorated sputum volume decrease after 5 days of treatment was significantly lower than the expectorated sputum volume decrease after 5 days of treatment in the Control group that may be related to positive draining effect of Simeox physiotherapy **(Fig.2,3).**

Fig.2 | *Study group. Expectorated sputum volume decrease (ml) during 5 days of treatment*

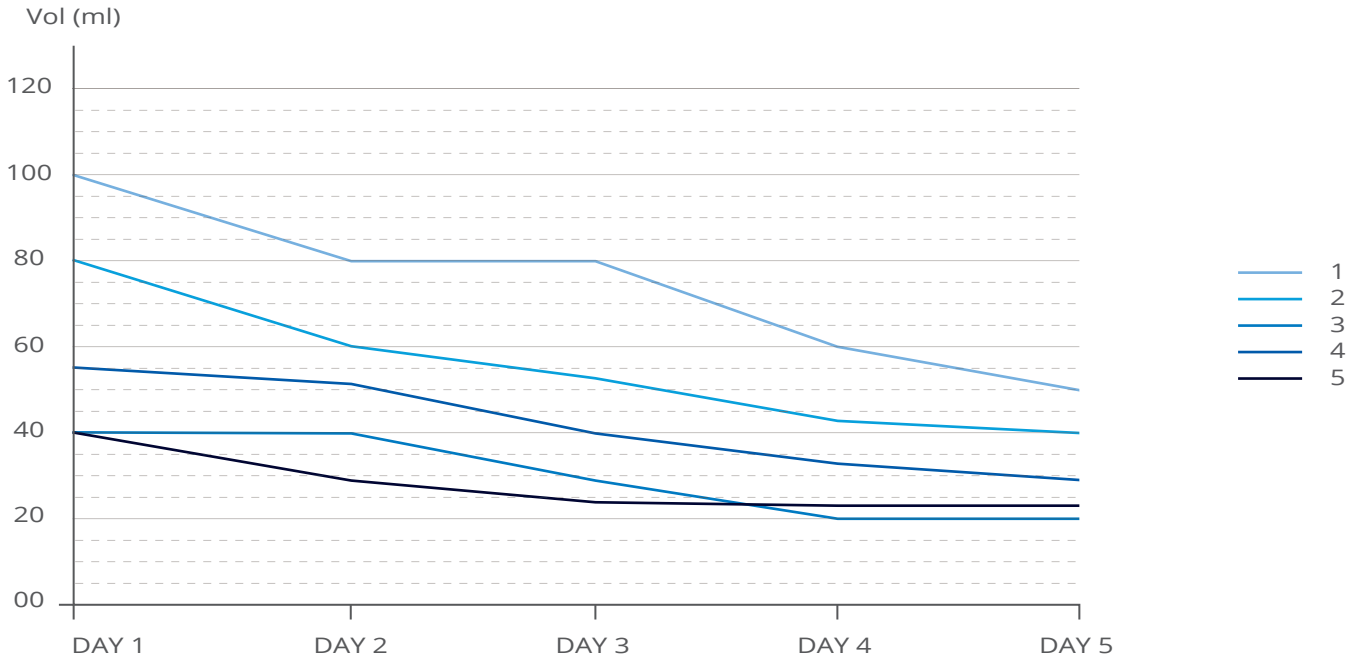
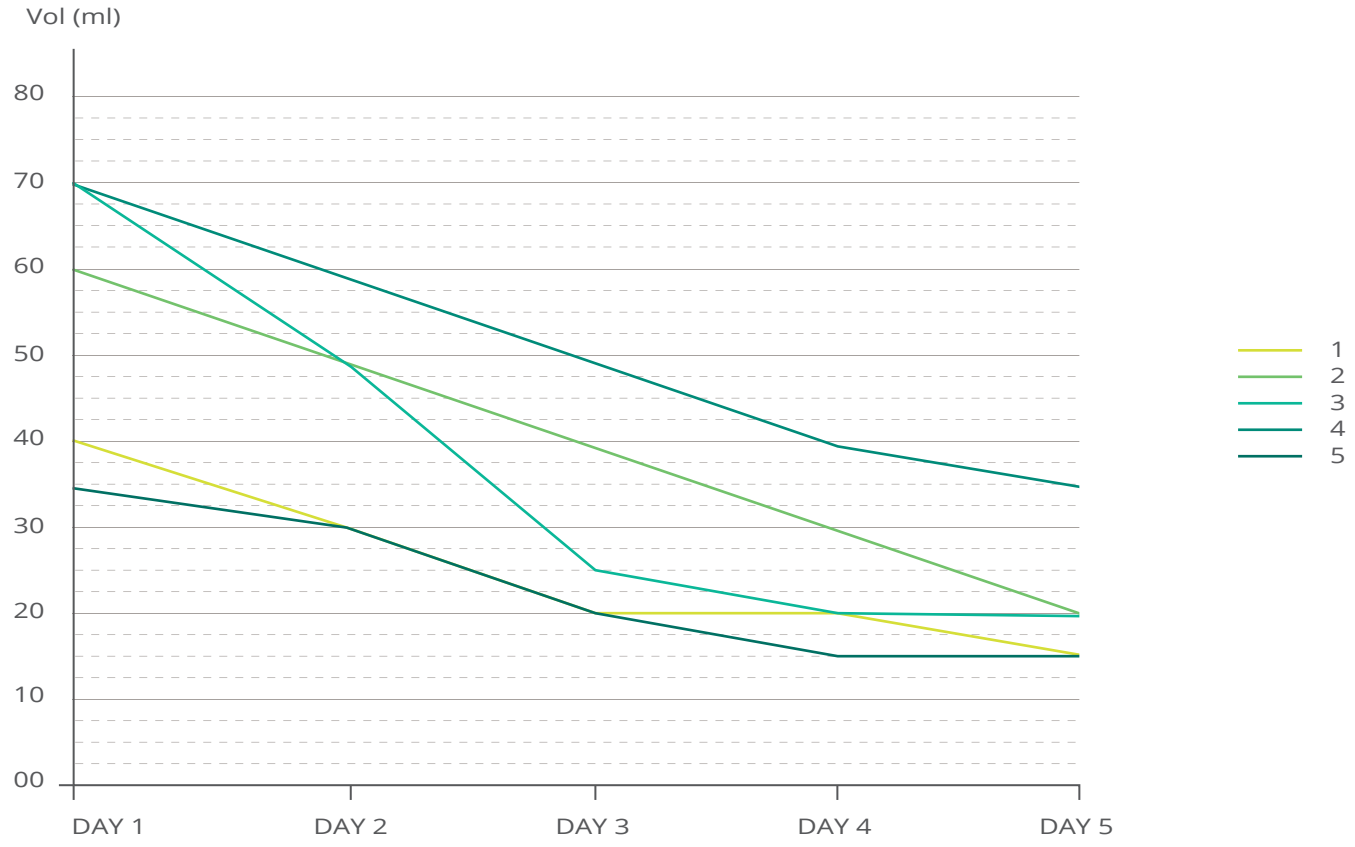


Fig.3 | *Control group. Expectorated sputum volume decrease (ml) during 5 days of treatment*



On the Day 1 of treatment the expectorated sputum volume (Med, IQR) in the Study group was -55.0 (50.0) ml, in the Control group -70.0 (22.5) ml. **(Table 9).**

On the Day 5 of treatment the expectorated sputum volume (Med, IQR) was 30.0 (22.5) ml in the study group, in the Control group 20.0 (20.0) ml, p=0.243.
The expectorated sputum volume in the Study group decreased 2.0 (0.28) times, it is significantly lower (p=0.034) than in the Control group, where the sputum volume decreased 2.3 (1.25) times.

Table 9 | *Expectorated sputum volume (ml) in both groups during 5 days of treatment*

Patient	Group	Day 1	Day 2	Day 3	Day 4	Day 5	Expectorated sputum volume decrease in 5 days therapy: X times
1	Simeox	100	80	80	60	50	2
2	Simeox	80	60	55	45	40	2
3	Simeox	40	40	30	20	20	2
4	Simeox	55	50	40	35	30	1.8
5	Simeox	40	30	25	25	25	1.6
6	Control	70	50	25	20	20	3.5
7	Control	60	50	40	30	20	3
8	Control	70	60	50	40	35	2
9	Control	70	40	40	40	35	2
10	Control	35	30	20	15	15	2.3

4-very much so, 3- probably yes, 2- not much, 1- not at all

The Study (Simeox) group patients have pointed out the ease of training and the convenience of use of the device, all of them gave a positive answer to the question if they could use the device at home and if they would recommend this technique to another patient.

Conclusion

The pilot study of Simeox physiotherapy in adult Cystic Fibrosis patients has demonstrated safety, feasibility and positive airway clearance effect in clinical setting.

COPD and BRONCHIECTASIS

Clinical and Scientific Evidences

Simeox feasibility and safety

evaluation in patients with bronchiectasis

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The main goal of our monocentric randomized controlled trial was to evaluate the feasibility and safety of airway clearance with Simeox technology (Physio-Assist, France) and show non-inferiority of this technique compared to conventional manual physiotherapy in the treatment of hospitalized patients suffering from bronchiectasis. Patients were recruited from 1st March to 30th April 2018.

Objectives of the study

To show the non-inferiority of the Simeox device compared to traditional manual physiotherapy technique related to the airway clearance management of hospitalized patients suffering from bronchiectasis in cystic fibrosis, COPD and idiopathic pulmonary fibrosis.

To evaluate clinical outcomes of Simeox procedure measured by pulmonary functional tests.
To consider daily autonomous use of Simeox technology in patients with various obstructive lung diseases.

Endpoints

Primary endpoint: feasibility of Simeox procedure
Secondary endpoints:

- Safety of the procedure in regards of respiratory and other complications
- PFTs results (FEV1, RV)
- Chest expansion measured on xiphoid processus level (in cm)
- SpO2 mesured by pulse oximetry (%)
- 24-hour collected mucus amount (ml)

Inclusion criteria

Patients between 18-75 years, with bronchiectasis and diagnosis of cystic fibrosis, COPD or idiopathic pulmonary fibrosis (IPF), reporting symptoms of excessive mucus production and difficulties to clear the mucus.

Methodology

Consecutive patients were randomized to reference therapy - manual physiotherapy technique performed by the physiotherapist or Simeox procedure. Both procedures lasted 5 days with 2 sessions per day (morning and afternoon). Each session lasted 20 minutes as a minimum (plus instructions).
Measurement of pulmonary function tests, chest expansion, oxygen saturation of haemoglobin was measured before and after session, mucus was collected every day of the procedures.

Statistics

Median, minimal and maximal values were calculated as descriptive parameters. Two nonparametric methods were used: Mann-Whitney U-test for independent values of two groups, paired Wilcoxon test for timely depended values. Limit of significance was $p < 0.05$. Statistical software IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp was used.

Recruitment

12 patients were included, 6 in each arm. All of them achieved planned procedures. 7 men and 5 women. Mean age was 46.5 years (53.1 and 39.3 years in Simeox and manual physiotherapy groups, respectively).
7 patients had cystic fibrosis (2 in Simeox group), 3 had COPD (2 in Simeox group), and 2 patients had IPF (both in Simeox group).

Results

Table 1 shows PFTs results in both arms. There were no statistical difference inside the groups despite a trend in FEV1 improvement. Chest expansion increased both after Simeox and manual physiotherapy.
There were also no significant difference in pulmonary function tests or sputum production, between both groups **(Table 2).**
SpO2 increased in both arms. The changes were partially significant ($p<0.01$) as shown in **table 3.** The changes of SpO2 were not statistically different between the two groups **(Table 4)**. However, regression analysis showed a longitudinal rise of SpO2 median assessed before procedure in the Simeox group only **(Graph 1, Table 5).**

Safety and feasibility

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

Conclusions

Our prospective study showed noninferiority of Simeox procedure compared to manual physiotherapy technique. After 5 days of therapy similar results were achieved by both methods. Significant improvement of chest expansion and oxygen saturation of haemoglobin were observed in both study groups. A positive longitudinal trend of SpO2 median before procedure was observed only in the Simeox group.
Simeox procedure was well tolerated by all patients and the device was considered safe and feasibile for treatment of various lung diseases with mucus retention.

Table 1 | *Pulmonary function changes inside groups during therapy*

Parameter	SIMEOX (N=6)			P	Manual physiotherapy (N=6)			P
	Median	Minimum	Maximum		Median	Minimum	Maximum	
FEV1 before	1.54	0.88	2.08	0.225	1.30	0.93	1.64	0.465
FEV1 after	1.84	0.83	2.22		1.42	0.93	1.64	
FEV1 (%) before	57	28	75	0.225	39	22	100	0.273
FEV1 (%) after	60	39	84		36	23	108	
RV (%) before	152	51	386	0.600	213	135	342	0.600
RV (%) after	176	52	263		228	128	297	
Chest expansion before	3.5	1.5	5.0	0.038	2.0	2.0	3.0	0.026
Chest expansion after	4.3	1.5	6.0		3.0	2.5	4.0	

FEV1 – forced expiratory volume in the first second, RV – residual volume

Table 2 | *Pulmonary function changes and sputum production - between both groups*

Parameter	SIMEOX (N=6)			Manual physiotherapy (N=6)			P
	Median	Minimum	Maximum	Median	Minimum	Maximum	
FEV1 difference	0.07	-0.07	0.87	0.04	-0.04	0.50	0.872
FEV1 (%) difference	2.5	-3.0	21.0	1.5	-7.0	10.0	0.872
RV (%) difference	4.5	-123.0	56.0	-10.5	-72.0	48.0	0.423
Chest expansion change	0.8	0.0	1.0	1.0	0.5	1.5	0.337
Sputum 1 (ml)	15.0	5.0	40.0	7.5	0.0	20.0	0.247
Sputum 2	10.0	0.0	90.0	5.0	5.0	80.0	0.247
Sputum 3	10.0	10.0	70.0	10.0	0.0	30.0	0.134
Sputum 4	42.5	5.0	90.0	7.5	0.0	40.0	0.146
Sputum 5	20.0	5.0	70.0	5.0	5.0	30.0	0.113
Sputum total (ml)	142.5	25.0	300.0	30.0	20.0	180.0	0.126

FEV1 – forced expiratory volume in the first second, RV – residual volume

Table 3 | *Oxygen saturation of haemoglobin - SpO2 (%) changes inside the groups*

Before / After	SIMEOX (N=6)			P	Manual physiotherapy (N=6)			P
	Median	Minimum	Maximum		Median	Minimum	Maximum	
1A	93	80	96	0.027	93	88	95	0.026
1A	95	85	99		95	89	97	
1B	93	88	96	0.046	94	87	95	0.0042
1B	97	87	99		95	90	99	
2A	94	84	98	0.026	94	88	96	0.024
2A	96	85	100		97	92	99	
2B	95	87	99	0.111	95	89	97	0.026
2B	96	84	98		97	92	100	
3A	94	80	99	0.111	95	90	97	0.026
3A	96	84	98		97	92	100	
3B	96	83	98	0.066	94	88	97	0.039
3B	97	86	98		96	93	97	
4A	94	79	97	0.221	94	87	96	0.026
4A	95	84	98		94	91	98	
4B	95	90	98	0.408	92	88	95	0.026
4B	97	88	98		94	91	98	
5A	95	82	97	0.167	95	90	97	0.041
5A	96	83	98		96	92	99	
5B	96	85	98	0.074	95	90	97	0.114
5B	97	87	98		97	90	98	

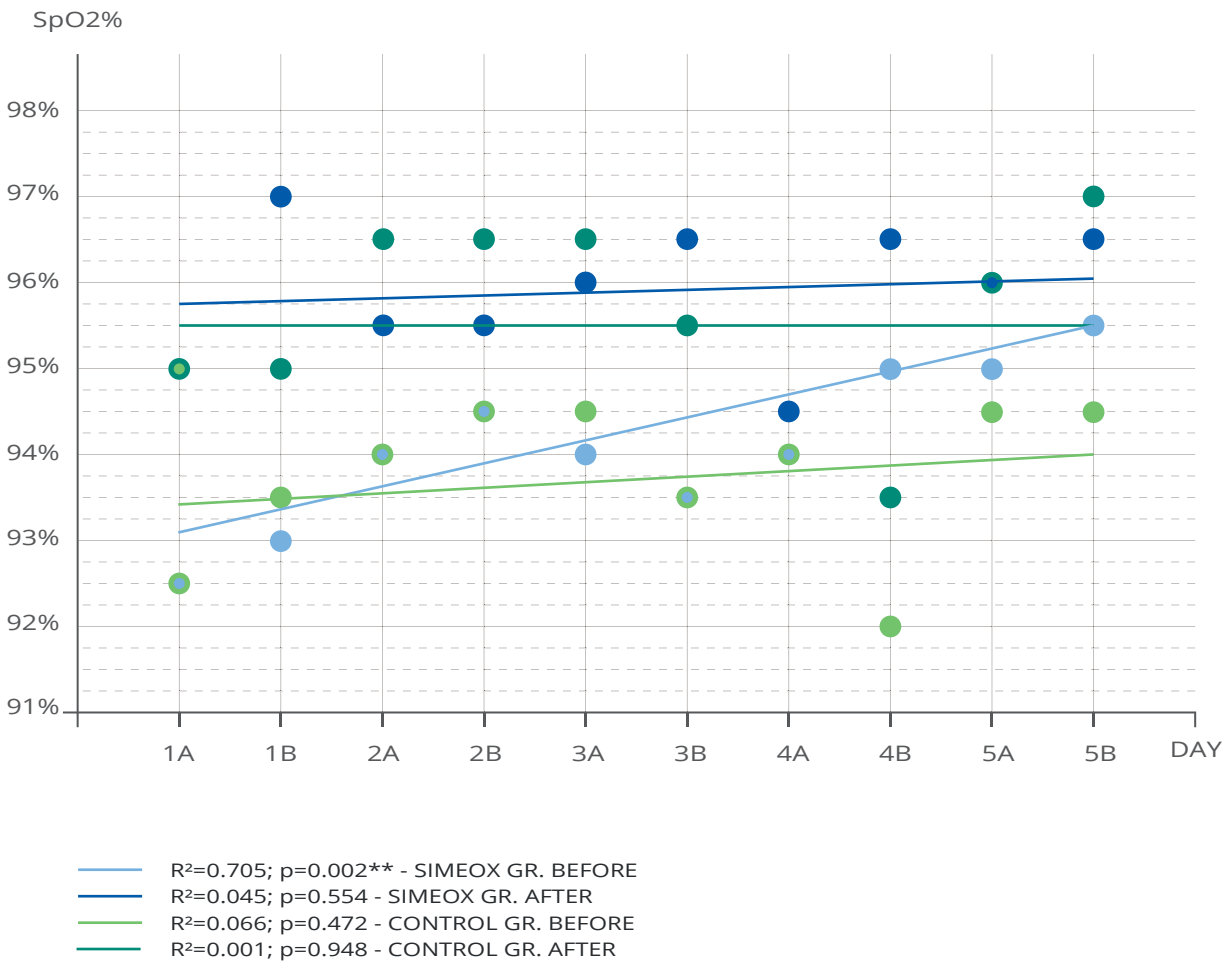
A – in the morning, B in the afternoon, 1 - 5 - day 1-5

Table 4 | *Oxygen saturation of haemoglobin - SpO2 (%) changes between both groups*

	GROUPS										P
	SIMEOX (N=6)					Manual physiotherapy (N=6)					
	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	
dif 1A	3.0	1	6	3.3	1.9	2.0	1	3	2.0	0.9	0.186
dif 1B	2.5	-1	6	2.7	2.3	1.5	0	4	1.8	1.5	0.418
dif 2A	2.0	1	3	1.8	0.8	2.5	2	4	2.7	0.8	0.101
dif 2B	0.5	0	4	1.2	1.6	3.0	1	4	2.8	1.0	0.070
dif 3A	2.0	-1	4	1.3	2.0	2.5	1	3	2.3	0.8	0.315
dif 3B	1.0	0	3	1.2	1.2	2.0	0	5	2.0	1.7	0.363
dif 4A	1.0	-1	5	1.2	2.3	1.0	-1	4	1.2	1.7	0.935
dif 4B	1.0	-2	2	0.5	1.4	1.5	1	4	2.2	1.5	0.086
dif 5A	1.0	-2	3	1.2	1.8	2.0	0	3	1.8	1.2	0.560
dif 5B	2.0	-1	3	1.3	1.5	2.5	-1	4	1.7	2.2	0.563

A – in the morning, B in the afternoon

Graph 1 | *Longitudinal trends of SpO2 (%) medians during therapy*



A: morning, B: afternoon, R2 – determination coeficient ,
***p<0.01 Significant increase of SpO2 in Simeox group before procedure.*

Table 5 | *D1-D5 longitudinal trends of Sp O2 (%) medians*

Median	1A	1B	2A	2B	3A	3B	4A	1B	5A	5B
SIMEOX before	92.5	93	94	94.5	94	95.5	94	95	95	95.5
Control before	92.5	93.5	94	94.5	94.5	93.5	94	92	94.5	94.5
SIMEOX after	95	97	95.5	95.5	96	96.5	94.5	96.5	96	96.5
Control after	95	95	96.5	96.5	96.5	95.5	94	93.5	96	97

A: morning, B: afternoon

Benefits of SIMEOX

airway clearance technology in non-CF patients with bronchiectasis

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Introduction

Bronchiectasis is classified as an obstructive lung disease with typical symptoms including chronic cough with excessive mucus production and dyspnea on exertion. The cause is unknow in almost a half of patients.

Airway Clearance Techniques (ACTs) improve bronchial clearance in obstructive lung diseases complicated by excessive secretion of sticky and viscous mucus. ACTs are therefore widely recommended as a part of the comprehensive management in a such cases. Especially patients with bronchiectasis are a very good candidates for airway clearance therapy. New techniques have been recently developed, e.g. the Simeox device which facilitates mucus clearance by generating successive low-frequency depressions during passive exhalation.

Methods

A prospective series of 13 non-CF patients with previously confirmed diagnosis of bronchiectasis were hospitalized due to an acute exacerbation. Routine pharmacological therapy including antibiotics, inhaled bronchodilators and mucolytics was supported by ACT using the Simeox device in the morning for 20 minutes every day for 7 consecutive days.

Respiratory symptoms, lung function (body plethysmography), disease-specific quality of life questionnaire (CAT score) and 6 minute walking distance test (6MWT) were assessed before and after the seven-day intervention.
Statistical analysis was performed with non-parametric paired Wilcoxon's test.

Results

Thirteen patients, 5 females and 8 males, with a mean age of 65±6 years were enrolled into the study. Underlying/coexisting respiratory diseases consisted of: moderate-to-severe COPD in 5 patients, asthma in 2 patients, interstitial pulmonary disease with fibrosis in one patient, emphysema in one patient and unspecified pleural condition in one patient.

Vast majority of patients complained of severe dyspnea, intense cough and were full of phlegm at admission. Respiratory symptoms intensity assessed by the COPD Assessment Test (CAT) at entry and after seven days of therapy are shown in the **table 1.**

Table 1 | *The Study and Control group characteristics*

	Total score	Dyspnea domain	Cough domain	Expectoration domain
At admission	23.9±7.9	3.8±1.5	3.3±1.2	3.7±1.4
after 7 days	14.8±9.4	2.5±1.7	1.9±1.0	1.7±1.2
p value	0.008			

Statistically (p=0.008) and clinically (CAT score change by >2 points) significant improvement in total CAT score by 9 points was observed. Also cough intensity, chest congestion and perceived dyspnea decreased significantly.

Selected ventilatory parameters at baseline are shown in the **table 2.**

Table 2 | *Baseline ventilatory parameters.*

Variable	Value	Variable	Value
FEV_1 (L)	1.58±0.75	RV (L)	2.39±1.20
FEV_1 %pred.	62±29	RV %pred.	108±49
FVC (L)	2.80±1.92	Raw (kPa/L/sec)	0.54±0.21
FVC %pred.	83±22	Raw %pred.	181±69
FEV_1/FVC	0.58±0.20	sGaw (1/kPa*sec)	0.61±0.30
TLC (L)	5.14±1.30	sGaw %pred.	65±31
TLC %pred.	92±18		

Unfortunately we were not able to repeat assessment of ventilatory parameters in all 13 patients after 7 days of ACT with Simeox. In 6 patients who performed the second pulmonary function test measurements, FEV1 and FVC slightly increased by 60 mL and 180 mL respectively and Raw slightly decreased by 0.05 units after 7 days of therapy.
Results of 6 minute walking distance test (6MWT) before and after 7 days of ACT with Simeox available for 10 pts are presented in the **table 3**.

Table 3 | *Result of 6MWT before and after 7 days of ACT with Simeox.*

	Desaturation during exercise, ΔSaO2 (%)	Distance (m)	Dyspnea (Borg scale)	
			at rest	the end of walk
At admission	4.82±7.15	333.8±118.7	0.42±1.00	1.17±1.95
after 7 days	4.40±7.60	411.6±87.1	0.00±0.00	1.10±2.28
p value	<0.05	0.036		

At baseline 6MWT distance covered and desaturation (ΔSaO2) during exercise were 333.8±118.7 m and 4.82±7.15 % respectively. Management of bronchiectasis exacerbation including ACT with Simeox resulted in significant prolongation by 74±117 m (23%) of distance covered and reduction of oxygen desaturation during exercise by 0.9±1.2 % compared to baseline ($p<0.05$).

Conclusions

Patients with non-CF bronchiectasis of different origin may benefit from the use of airway clearance technique during acute exacerbation in hospital setting. Easy to use and efficient airway clearance technology may quickly and significantly improve quality of life and exercise capacity of these patients. Simeox device was well tolerated by all studied patients and proved to be safe and easy to handle even for older and disabled person.

Effects of a new ACT

versus manual physiotherapy in COPD

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Introduction

COPD patients with bronchiectasis or chronic bronchitis report more severe symptoms, purulent sputum expectoration and acute exacerbation. Airway Clearance Techniques (ACTs) may improve quality of life and reduce morbidity and mortality.

Aim

Study objective was to evaluate the effects of a new ACT technology (Simeox, Physio-Assist, France) in hospitalized COPD patients suffering of chest congestion compared to manual physiotherapy.

Methods

10 COPD patients (FEV1>20%) with AECOPD who reported excessive mucus congestion and difficulties to clear airways despite bronchodilator therapy were treated 5 days (2 sessions of 20-min/day) during hospitalization with either Simeox device or manual physiotherapy (5 patients in each group). Patients were excluded if they had recent pneumothorax, severe cardiac health issues, recent haemoptysis or inability to perform spirometry.
Spirometry, symptoms, CAT score, usability and safety were compared between the 2 groups.

Results

Age 65±8ys, 7 men and 3 women, 7 with bronchiectasis and 8 had lung crackles, BMI 27.1±6.1kg/m2, Borg scale 4.5±1.8, SpO2 96.3±1.7%, FEV1% 42±19.

Baseline characteristics

Variables	Global Group values (N=10)	SIMEOX group values (N=5)	Manual physiotherapy group values (N=5)
Age (years) mean ± SD	65±8	65.8±7.3	64.2±9.4
Male (N / %)	7 (70%)	4 (80%)	3 (60%)
Body mass index (kg/m²) mean ± SD	27.1±6.1	28.1±6.1	26.1±6.6
CAT score mean ± SD	21.6±5.9	20.2±6.4	17.2±5.4
Dyspnea (BORG scale) mean ± SD	4.5±1.8	3±0.7	6±1.2

Clinical characteristics

Variables	SIMEOX group values (N=5)		Manual Physiotherapy group values (N=5)	
	Baseline	EOS**	Baseline	EOS*
CAT score Mean ± SD	20.2±6.4	17.0±4.6	17.2±5.4	18.6±4.0
Drainage improvement (N, %)	5 (100%)		4 (80%)	
Dyspnea improvement (N, %)	4 (80%)		4 (80%)	
Fatigue improvement (N, %)	4 (80%)		4 (80%)	
Autonomy in execution	5 (100%)		4 (80%)	

** End of Study (EOS) : 2 sessions of 20 minutes per day, for 5 days*
*** End of Study (EOS) : 2 sessions of 20 minutes per day, intensity 50-75%, for 5 days*

All the patients of device group acquired quickly autonomous usage. No adverse event nor pain was reported.
Improvement of mucus clearance and symptoms were similar between groups. FEV1(L) improved by +0.15±0.10L (FEV1% +5±2%) and FEV1/FVC increased from 52.5±2.4% to 58.0±12.8% in the device group but remained stable in the manual physiotherapy group. CAT score improved in the device group only from 20.2±6.4 to 17.0±4.6.

PFTs characteristics

Variables	Groupe values (N=10)	SIMEOX group values (N=5)		Manual Physiotherapy group values (N=5)	
		Baseline	EOS**	Baseline	EOS*
FVC (L)	1.97±0.89	2.01±0.82	2.19±0.77	1.93±1.05	1.99±0.90
FVC (%)	55.7±17.5	55.5±18.4	60.6±15.9	55.9±18.7	60.2±18.0
FEV1 (L)	1.14±0.59	1.12±0.44	1.27±0.54	1.16±0.77	1.12±0.66
FEV1 (%)	42.2±19.0	39.5±13.5	44.6±15.8	45.0±24.8	44.8±24.9
FEV1/FVC%	53.2±7.5	52.5±2.4	58.0±12.1	55.4±10.7	51.7±14.1

All parameters ▲ ▲ in FVC; ▼ in FEV1, FEV1/FVC%
FEV1 ▲ with 150±100 ml and 5.2±2.3% FEV1 ▼ with 40±110 ml and 0.02±0.08%

** End of Study (EOS) : 2 sessions of 20 minutes per day, for 5 days*
*** End of Study (EOS) : 2 sessions of 20 minutes per day, intensity 50-75%, for 5 days*

Conclusions

These preliminary data suggest safety and additional benefits of Simeox airway clearance technology for COPD with severe chronic bronchitis symptoms or bronchiectasis. There is a need in further randomised studies including more patients for a longer follow-up.

SIMEOX therapy

in patients with COPD and Asthma

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Introduction

Asthma COPD Overlap Syndrome (ACOS) is a COPD phenotype with worse prognosis. Airway clearance techniques (ACTs) may improve symptoms and reduce hospitalization and exacerbation in COPD and ACOS but need to be evaluated.

Aim

Aim of our monocentric study was to assess feasibility and effects of an innovative ACT (Simeox, Physio-Assist, France) in COPD/ACOS with chest congestion despite adherent medication and conventional physiotherapy.

Patients were included from 13 March to 23 April 2018.

Methods

Primary endpoint was ability to properly use the device as evaluated by patient preference.

Secondary endpoints were safety, tolerance, patients reported outcomes, changes in mucus production, spirometry and ABG.

Inclusion criteria were: age >18yr, COPD or overlap COPD-asthma (ACOS), patient reporting symptoms of excessive mucus and difficulties to clear the mucus despite conventional manual physiotherapy technique performed by the physiotherapist.

Simeox device training was performed after patient inclusion. Patient had usually one daily Simeox session for 6 days.

Blood gases and acid-base balance were assessed before and after each session. 3 successive programs were performed during each session: Program 1: 6 expiratory cycles, Program 2: 8 expiratory cycles and Program 3: 10 expiratory cycles. Power selection was 25 or 50%. Expectoration were monitored by clinical team during each session and the patient monitored himself the expectoration after the session.

Results

15 COPD/ACOS patients hospitalized for AECOPD who reported symptoms of excessive mucus congestion were treated with Simeox device. The duration of clearance therapy session with Simeox was between 15-25 min.

Age was 67.9±10.5, 10 men and 5 women, 10 COPD and 5 ACOS, 8 GOLD 3-4, 13 very symptomatic (GOLD B/D) and 11 with high risk (GOLD C/D). 5 had LABA/LAMA and 7 had ICS/LABA/LAMA **(Table 1).**

Patients were able to use the device after a 15-min of training during the first session. No adverse event nor pain was reported.

Mucus clearance was improved (++/+++) in all patients compared to previous manual physiotherapy **(Table 1)**. Pa02 increased by + 0.4-1.4 kPa. FEV1 improved by +200±56 ml and +142±29 ml in COPD and ACOS, respectively. In the patients GOLD 3-4, FEV1 improved by +158±30 ml

Conclusion

These results confirmed the feasibility of managing airway clearance in COPD/ACOS with Simeox device. This technology may contribute to lung function improvement without worsening fatigue or pain during chest physiotherapy.

Table 1

	Gender	Age	Diagnosis	Medication	LFT FEV1 (l) before and after sessions	Nbre of sessions (mucus clearance)
1	W	72	3D+ACOS	ICS+LABA+LAMA	1.05/1.18	6(+++)
2	M	81	2C	LABA+LAMA	1.58/1.72	5(++)
3	W	36	2B deficit A1AT	LABA+LAMA	2.10/2.35	6(+++)
4	M	68	2D	ICS+LABA+LAMA	1.25/1.58	6(++)
5	M	64	4D	ICS+LABA+LAMA Roflumilast	0.58/0.80	6(+++)
6	M	72	3D	LABA+LAMA	1.80/1.97	6(++)
7	M	81	2B	LAMA	1.05/1.25	6(+++)
8	W	66	4D+ACOS	ICS+LABA+LAMA Roflumilast	0.65/0.78	6(++)
9	W	64	3D+ACOS	ICS+LABA+LAMA	0.84/0.98	6(+++)
10	M	62	2B+ACOS	ICS+LABA	2.05/2.23	6(+++)
11	M	72	2D+ACOS	ICS+LABA+LAMA	1.82/1.99	6(++)
12	W	79	2B	LAMA	2.46/2.68	6(+++)
13	M	72	3C	LABA+LAMA	1.88/2.01	6(+++)
14	M	62	4D	LABA+LAMA Roflumilast	0.86/1.02	6(+++)
15	M	68	4D	ICS+LABA+LAMA Roflumilast	1.10/1.28	6(+++)

Conclusions

Patients with various chronic obstructive lung diseases acquired quickly autonomous usage of the device during hospitalization after a short training by physiotherapists. The technology was very well tolerated in all patients who find it comfortable and easy to use. No significant side effect related to Simeox device was reported in the series. These data confirm the feasibility and safety of Simeox technology in patients suffering of bronchial congestion and requiring chest physiotherapy.
Mucus clearance and respiratory symptoms improved to the same extent as manual physiotherapy after a few days of therapy. In some series, mucus production was increased with Simeox after manual physiotherapy trial. These results suggest that Simeox can do as much or better than conventional physiotherapy for airway clearance management in patients hospitalized for acute exacerbation and are in favor of promoting this technology as an alternative of conventional ACTs.
Moreover, Simeox device may provide also additional benefits on lung function and quality of life in patients with COPD and/or bronchiectasis. These interesting data deserve to be investigated in more detail in the near future to understand deeply the benefits of Simeox technology.

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