Clinical experience in the management of patients with bronchiectasis and other pulmonary pathologies with bronchial hypersecretion.

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Simeox Clinical Notebook No. 6

EN

General information

Bronchiectasis is usually defined as the permanent dilatation of bronchi or bronchioli diagnosed based on high-resolution computer tomography (HRCT) (1). Mucus hypersecretion is present in 70% of cases suffering from bronchiectasis (1,2). Although, mucus hypersecretion may occur in a patient without bronchiectasis (2).

The prevalence of bronchiectasis has been estimated at 53-566 per 100.000 inhabitants. Prevalence increases with age and is higher in females. The rate of bronchiectasis cases is rising by 8% each year. According to observational studies, the risk of death has been described as up to 30% at one year following an exacerbation. Half of the European bronchiectasis patients have more than two exacerbations yearly, and one-third require at least one hospitalization per year. More than 75% of patients are diagnosed in their fifties or later (3,4). Approximately 40% of non-cystic fibrosis (non-CF) bronchiectasis are idiopathic. The leading known cause of non-CF bronchiectasis in Europe is chronic obstructive pulmonary disease (COPD) (3). Bronchiectasis prevalence is around 50% in moderate-to-severe COPD. Those patients more often experience exacerbations, and their quality of life and prognosis is worse than without them (4,5,6).

There are many different classifications of bronchiectasis. It may be categorized based on pathogenesis, radiological pattern, and extension. Variety of classifications reflects the heterogeneity of this clinical entity. The most useful classification for clinicians is the one based on clinical symptoms. According to ERS Guidelines, we should divide patients into symptomatic and asymptomatic groups (1). The main symptoms of bronchiectasis are:

- cough,
- sputum production,
- breathlessness,
- rhinosinusitis,
- fatigue,
- hemoptysis,
- thoracic pain.

Our treatment aims at reducing those symptoms while improving quality of life, preventing exacerbations and stopping disease progression. New advances in diagnosis and management are helping to treat acute or advanced disease stages. To achieve these goals, patients require individualized treatment (1).

First and foremost, everything should be done to estimate the cause of bronchiectasis to implement a causative treatment (e.g. cystic fibrosis). The mucus overproduction always demands regular symptom monitoring (1,8,9).

The pathogenesis of bronchiectasis in individual patient may be complex and is generally poorly investigated (1,2,8,9). Chronic bronchial infection, neutrophilic inflammation, impaired mucociliary clearance, and structural lung and bronchi/bronchioli deformation are responsible for symptoms and disease progression. Complex therapy and individual approach are always recommended.

Airway clearance is a mainstay of this complex therapy in symptomatic bronchiectasis (1,2,8,9). Both clinical practice and ERS practice guidelines (1) underline importance of proper order and diversity in management. If the sputum is thick, mucolytic treatment is recommended. Then bronchodilation in obstructive diseases and oxygen therapy in respiratory insufficiency should be applied. Finally, postural drainage and other physiotherapeutic maneuvers help to evacuate mucus. Effective treatment may demand the association of conventional medicine with innovative techniques. The more effective airway clearance, the more effective therapy with inhaled drugs, i.e. antibiotics. The complex therapy is essential in prevention of exacerbations and disease progression (1,2,6, 8,9).

SIMEOX Therapy

Bronchial clearance with the Simeox vibratory signal liquefies the mucus and transports it from the distal to the central airways. Through a succession of relaxed expirations assisted by the Simeox medical device, the patient mobilizes their mucus, often abundant and viscous in targeted lung pathologies. At the end of the session, the patient can easily expectorate it with a productive cough.

Thanks to the Simeox therapy, the patient can mobilize and clear their mucus autonomously within 15 to 20 minutes without any fatigue. Their quality of life improves significantly.

This innovative method of airway clearance has been used in patients both in stable conditions and during a pulmonary exacerbation. This "tailor-made therapy" allows changing the operating parameters of the device depending on the patient's needs. Its effectiveness leads to clinical improvement and an improvement in the parameters of pulmonary function tests. It is a safe, easy-to-use and well-tolerated method of chest physiotherapy and can be considered as an option in the chronic treatment in conjunction with conventional pharmacotherapy.

The Simeox device is the only medical device which mechanically assists the expiration of the patient, promoting the reduction of hyperinflation and flow limitations (12).

Patients can use SIMEOX therapy on their own at home, when medically advised and after training by a physiotherapist.

Indications to Simeox therapy

1. Diseases with bronchiectasis and chronic mucous hypersecretion in the airways

- cystic fibrosis (CF)
- chronic obstructive lung disease (COPD)
- chronic bronchitis (CB)
- rhinosinusitis
- asthma
- interstitial lung disease (ILD)
- allergic bronchopulmonary aspergillosis (ABPA)
- primary ciliary dyskinesia
- idiopathic bronchiectasis
- post-inflammation adhesions (e.g., POST COVID)
- postoperative scaring/adhesions within the respiratory system
- tuberculosis
- mycobacteriosis
- bronchiectasis in sarcoidosis
- yellow nail band
- silicosis
- bronchiectasis in connective tissue diseases (CTD)

2. Acute diseases with mucous hypersecretion

- severe pneumonia
- COVID-19
- fungal infections in the respiratory system
- exacerbation in immunodeficiency syndromes
- acute bronchitis
- whooping cough
- hypereosinophilic syndrome

3. Difficulties in airway clearance due to abnormal respiratory system or chest anatomy

- ankylosing spondylitis
- kyphoscoliosis
- vocal cord paralysis
- post-trauma chest deformation

Contraindications for Simeox therapy

Based on previous studies, absolute contradictions for Simeox therapy have not been found. It is essential to underline that every patient needs to be individually qualified for the therapy and educated in its usage. There is a list of uncommon side effects that are usually temporarily connected with the underlying disease. There are some relative contraindications where it is necessary to be cautious with Simeox therapy and proof a favorable benefit-risk ratio before use:

- severe hemoptysis
- unstable cardiac disease
- pleural disease
- current or susceptibility to pneumothorax/pneumomediastinum
- acute lung injury
- recent lung surgery
- uncontrolled GERD
- cardiac pacemaker/defibrillator

List of expected side effects for Simeox

Some uncommon (less than 1% of cases) side effects may occur during or after a drainage session with the SIMEOX device. Most of these side effects are transient and mild, and may include:

- hemoptysis,
- cough and excessive sputum production,
- chest discomfort or pain,
- laryngitis,
- dry throat,
- shortness of breath,
- bronchial irritation,
- gastric reflux.

Other uncommon side effects (less than 1% of cases) are of moderate intensity and may be more persistent under treatment:

- increase in pre-existing hemoptysis,
- nausea or vomiting, particularly in pregnant women, low back pain,
- increase in gastric reflux in patients with a history of gastroesophageal reflux,
- possible arrhythmias in patients with a history of rhythm disorders or with a pacemaker or defibrillator.

Most of these side effects cease rapidly after the treatment is stopped.
Some situations, like old age, poor concentration or muscle weakness require more attention from a health caregiver.
Simeox therapy is only one element of a complex therapy that should be monitored and individually adjusted.

Therapy monitoring

Monitoring covers several areas of therapy described below.

A. Treatment correctness monitoring

It should be individualized according to the patient's ability to manage treatment.

To be assessed at least once every four weeks.

B. Vital signs monitoring

It should always refer to the results of measurements made before starting therapy.
The frequency of measurements should be individualized and depend on the clinical situation.
Monitoring should include the following:

Respiratory rate (breaths/min)

Arterial blood pressure (mmHg)

Pulse rate (beats/min)

SpO_2 measured by pulse oximetry (%)

C. Monitoring the safety of therapy

Simeox therapy is safe (see side effects). The acceptance of the treatment is also related to its tolerability, which such symptoms as fatigue, pain, and ventilatory adaptation may influence. One should always be aware that similar clinical symptoms may result from the patient's condition or may be due to the disease itself.
The monitoring strategy should be elaborated for an individual patient. For this reason, simple scales may be applied. The Visual Analog Scale (VAS) is a 10-point scale. It is a straight horizontal line of fixed length, usually 100 mm. The ends are defined as the extreme limits of the parameter to be measured, orientated from the left (worst) to the right (best) (10). A 4-point scale (1 easy > 4 difficult) may be more suitable for some parameters.

Monitoring may include:

- Pain during treatment (VAS)
- Ease of sputum expectoration (4-score scale)
- Fatigue during treatment (VAS)
- Ease of breathing during treatment (4-score scale)
- Dyspnea during treatment (VAS)
- Expectorated sputum characteristics (4-score scale:1 copious sputum > 4 scanty and foamy sputum)
- Cough during treatment (VAS)
- SpO_2 measured by pulse oximetry (%) during treatment (oxygen desaturations in weak patients or severe disease)

D. Monitoring of therapy effectiveness

Monitoring of therapy effectiveness should occur not earlier than after dozen days of therapy. Scales commonly used to monitor specific disease features, e.g., CAT (COPD assessment test) for COPD and bronchiectasis or ACT (asthma control test) for asthma, can be used. CAT is a valid, responsive symptom assessment tool in bronchiectasis (11).
The measurements listed below remain the standard means of monitoring:

- Lung function tests: spirometry, body plethysmography, 6-minute walking distance test (6MWT), or oscillometry.
- SpO_2 measured by pulse oximetry (%)
- 24-hour collected mucus amount (ml)
- Dyspnea (VAS)
- Cough (VAS)
- Disease exacerbations
- Quality of life questionnaire, e.g., St. George's Respiratory
- Questionnaire (SGRQ)

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Clinical experience in the management of patients with bronchiectasis and other pulmonary pathologies at Department of Pneumology, Medical University of Lodz, Poland

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Introduction

According to the 2017 European Respiratory Society (ERS) guidelines for management of adult bronchiectasis, meticulous daily management of lung disease is essential to prevent exacerbation, preserve lung function and decrease mortality in adult bronchiectasis (1). Observational studies and data from worldwide records underline that quality of life, mortality and economic burden is similar to chronic obstructive lung disease (COPD) or idiopathic pulmonary fibrosis (IPF)(1,3,7). However, no therapies are currently specifically licensed by regulatory authorities, most of them are extrapolated from cystic fibrosis (1). The cohorts vary considerably in many ways e.g., age, sex, comorbidities, cognitive ability. There is need to evaluate the usefulness of therapies currently used. In both diseases mucociliary clearance is impaired. Treatment is to prevent mucus stasis and the associated mucus plugging, airflow obstruction and progressive lung damage (1).

SIMEOX study aims to assess through a multidisciplinary approach, the feasibility, safety and efficacy of Simeox (PhysioAssist, France) in patients with exacerbation of non-cystic fibrosis (NCF) bronchiectasis and other pulmonary pathologies.

Clinical study

This prospective open monocentric observational study was conducted in the Department of Pneumology, Medical University of Lodz, Poland. The study protocol was presented to the local Ethical Committee, which decided that the character of the study obviate the need for further approval and obtaining informed consent from the subjects.
The study was conducted in accordance with Good Clinical Practice and the principles of the Declaration of Helsinki.
The data presented below are derived from a statistical subgroup analysis of patients with NCF bronchiectasis recruited in the study.

Materials and Methods

Patients with NCF bronchiectasis diagnosed according to high resolution computer tomography (HRCT) were enrolled to the study from July 2022 to September 2022.
The main criterion was an exacerbation requiring hospitalization with mucus hypersecretion. All patients had to obtain positive result in training with the use of Simeox (PhysioAssist, France).
Patients were excluded if they were diagnosed with cystic fibrosis, had contraindication to chest physiotherapy, non-productive bronchial drainage session, hemoptysis or pneumothorax within last month, pan-drug-resistant bacteria, or were participating in another trial.

Patients were treated during hospitalization for 2 to 7 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. As a result, patient in hospital received combined physiotherapy techniques (usual and Simeox), the training in the use of Simeox was obtained. After the discharge, the patient operated only with Simeox therapy, without assistance.
Clinical evaluation according to CAT score, tolerability (pain, easy relaxation, tiredness, breathing fluidity during session, sputum quality and aspect) and usability of Simeox device was assessed during the study.

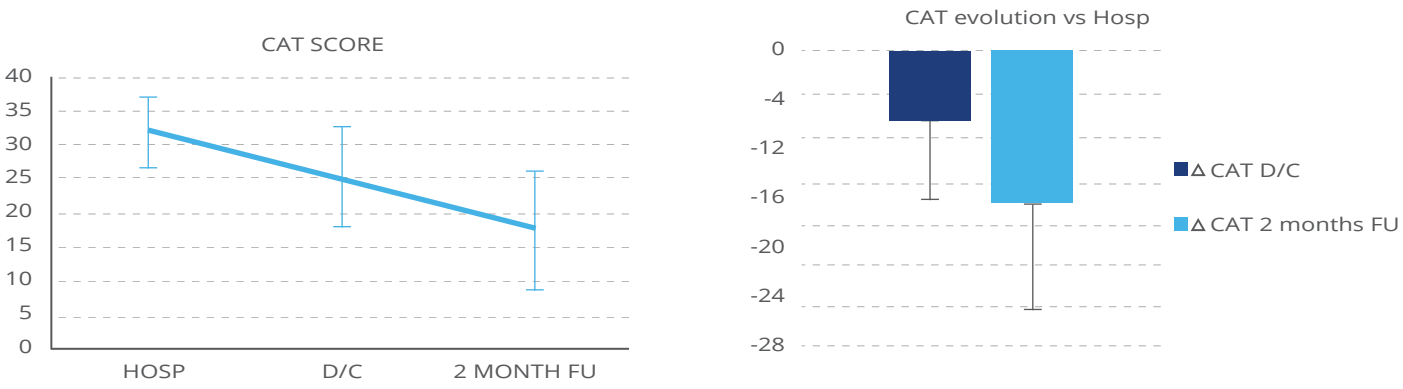
Results

Six patients were enrolled in study at the Department of Pneumology, Medical University of Lodz, Poland. They were diagnosed with COPD, post infectious bronchiectasis, hipereozynophilic syndrome, Kartegener's syndrome, CTD-ILD, and idiopathic bronchiectasis.

CAT score and all subscores of the test significantly decreased over time during the 2 months treatment (Figure 1 and Figure 2). Patients reported low level of pain and fatigue during the Simeox therapy. Additionally, they observed lower amount of sputum and better breathing fluidity over time (Figure 3). Due to better ventilation, patients reduced time of every session and lower daily use of Simeox at the end of the study (Figure 4). Both patients and health professionals demonstrated high level of satisfaction of two months therapy (Figure5). None of the patients had an exacerbation at home therapy at the time of the study.

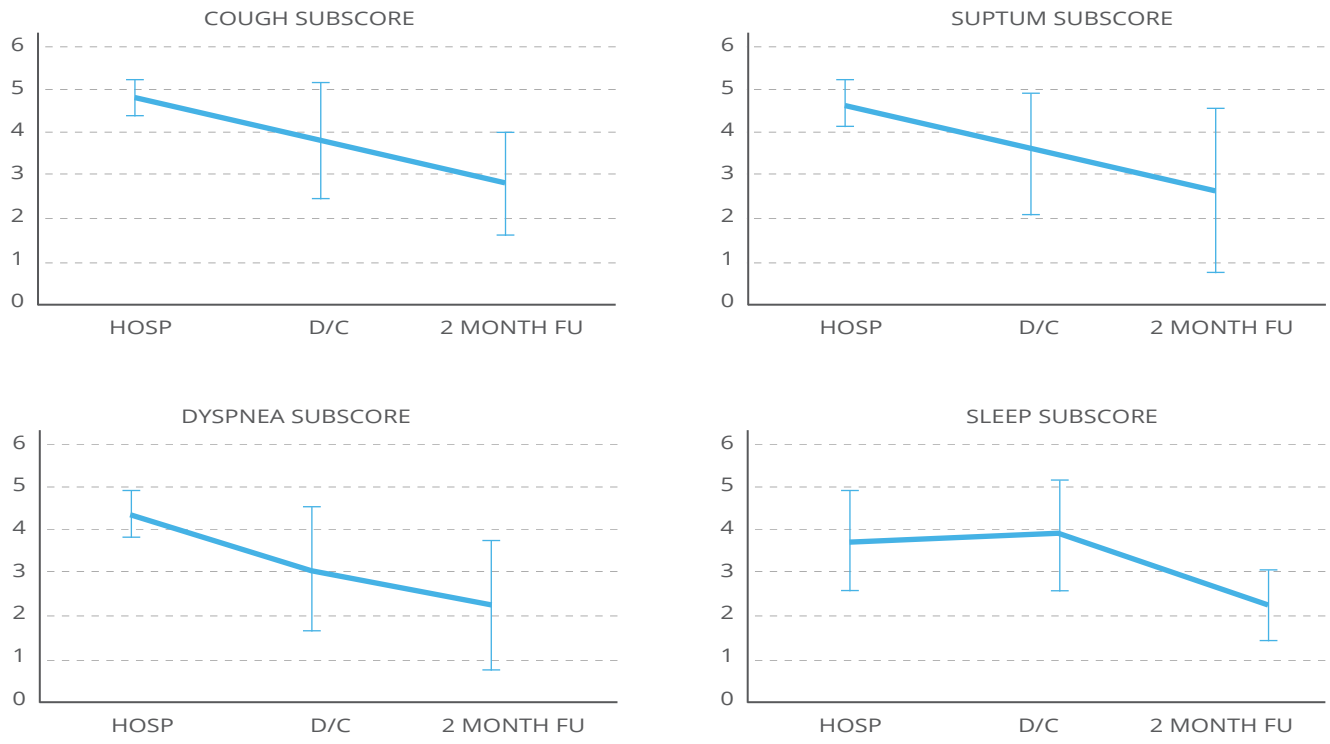
Figure 1. CAT score evaluation in 6 patients during 2 months therapy at the Department of Pneumology, Medical University of Lodz, Poland.

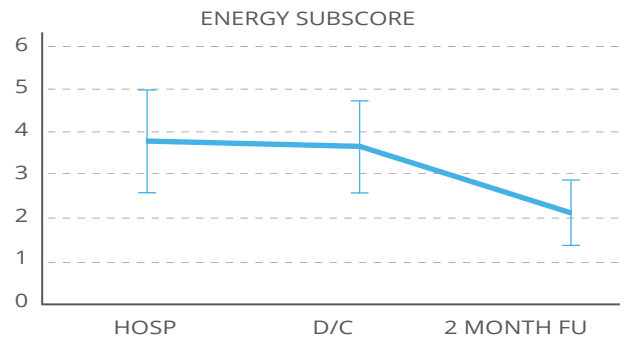
Clinical evaluation in 6 first cases (Lodz): CAT score

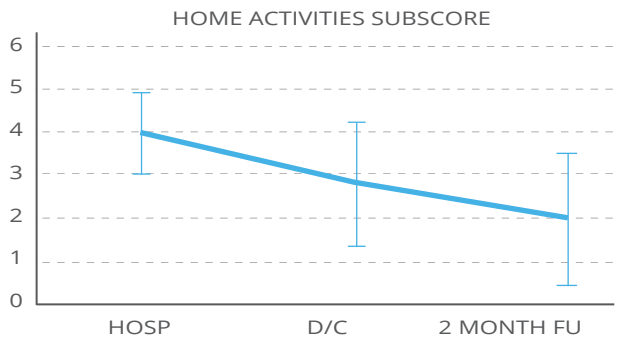


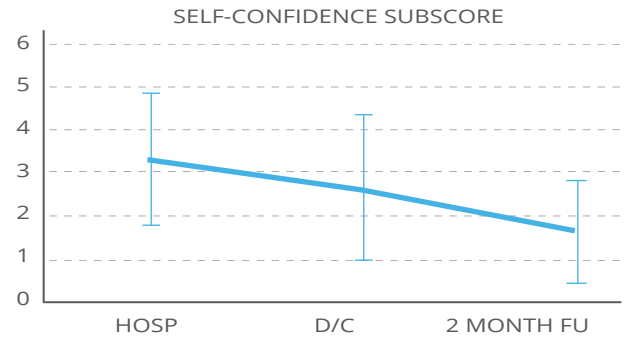
Significant improvement of CAT score over time during hosp and at home

Clinical evaluation in 6 first cases (Lodz): CAT subscores





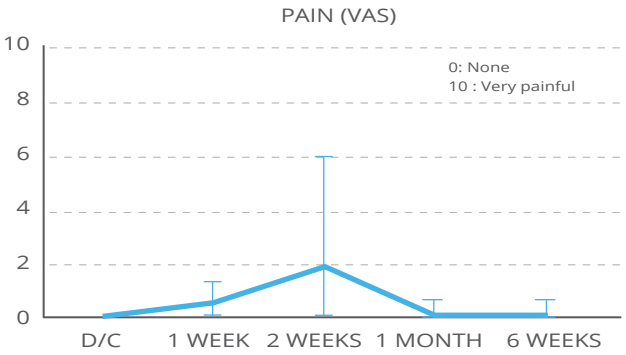


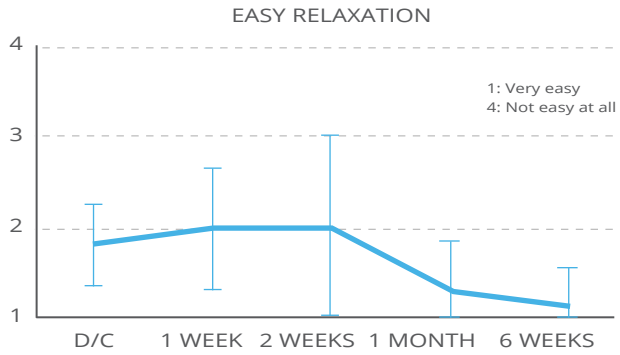


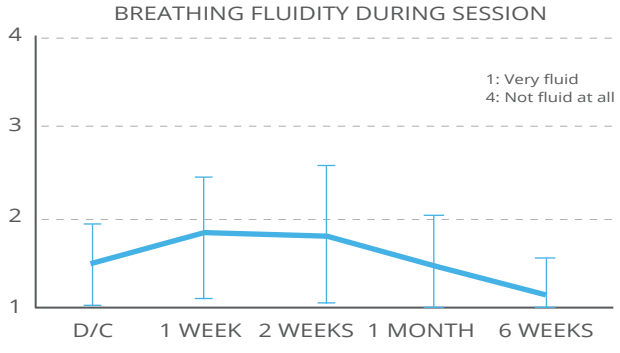
Significant improvement of CAT subscores over time especially during therapy at home

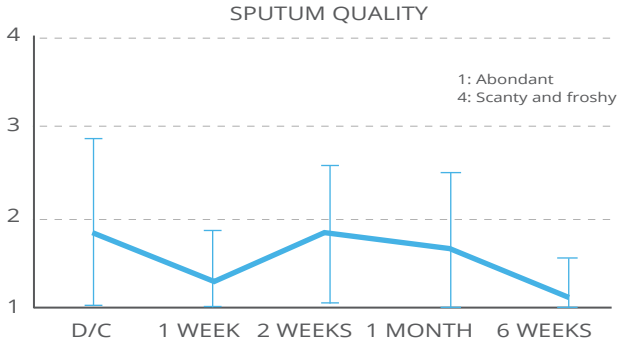
Figure 3. Tolerability of Simeox therapy in 6 patients during 2 months therapy at the Department of Pneumology, Medical University of Lodz, Poland

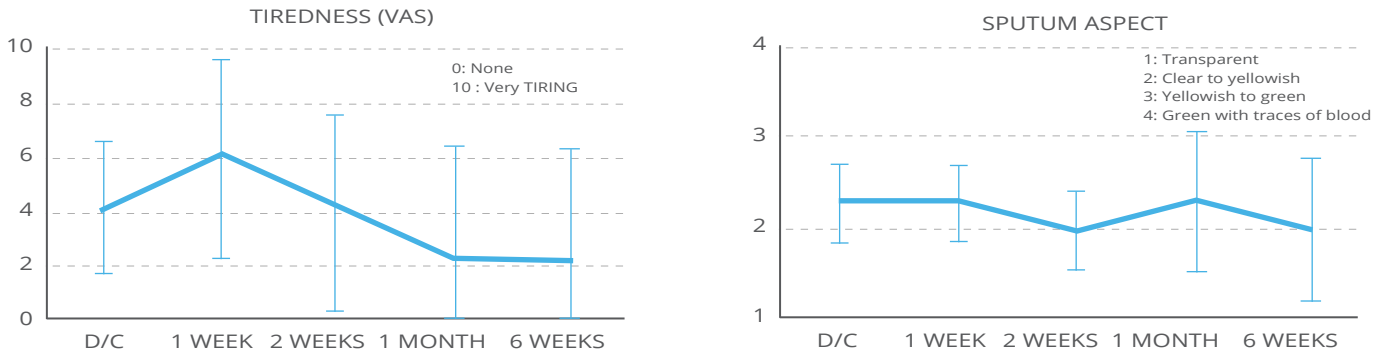
Clinical evaluation in 6 first cases (Lodz): Tolerability







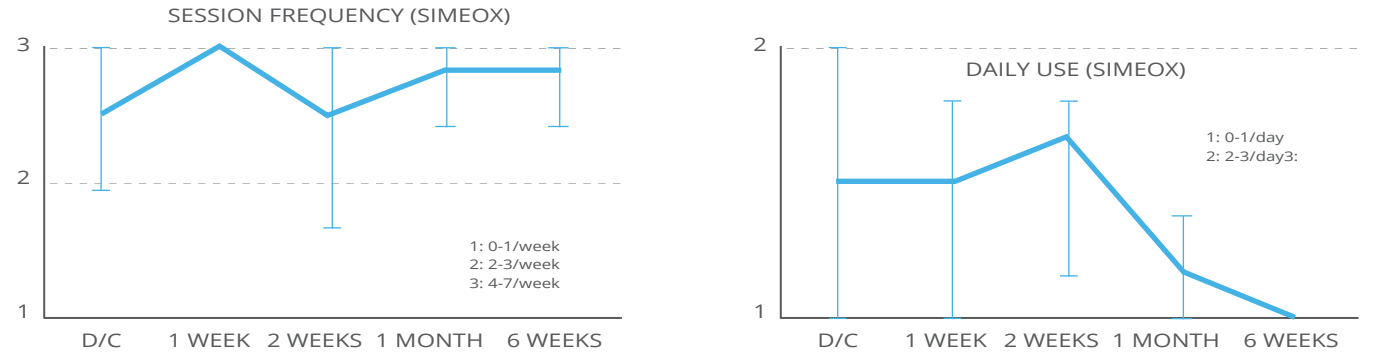




Very good tolerability and safety profile

Figure 4. Adherence of the 2 months therapy in 6 patients at the Department of Pneumology, Medical University of Lodz, Poland

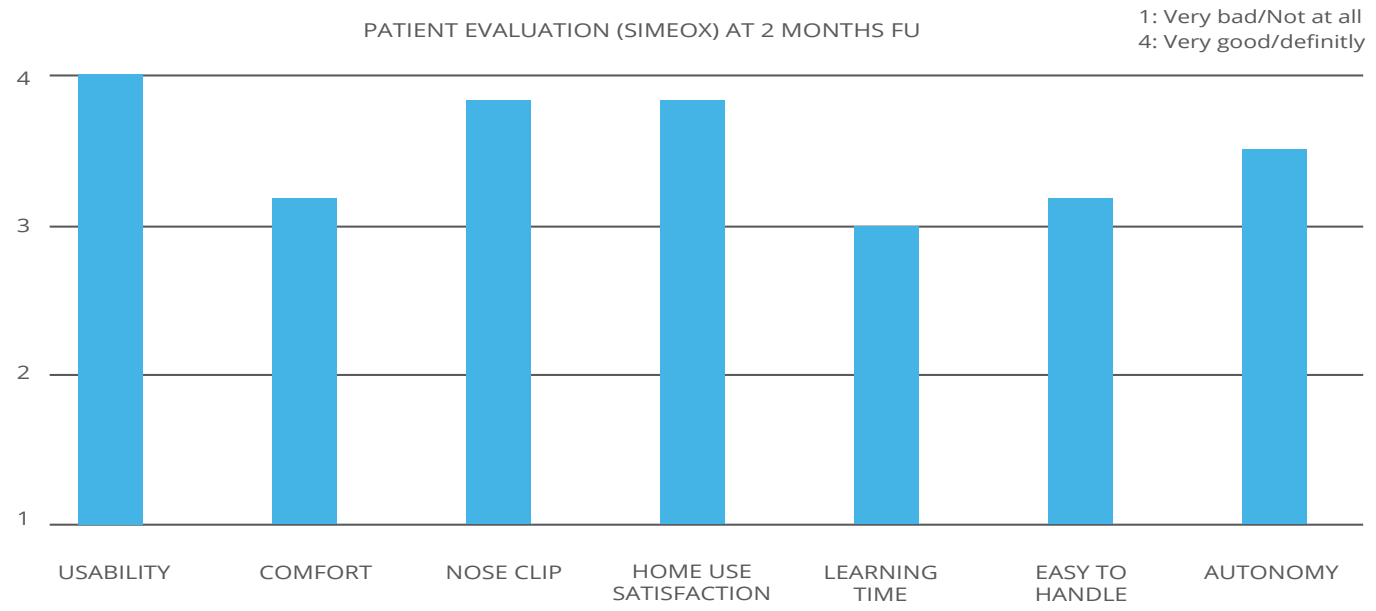
Clinical evaluation in 6 first cases (Lodz): adherence

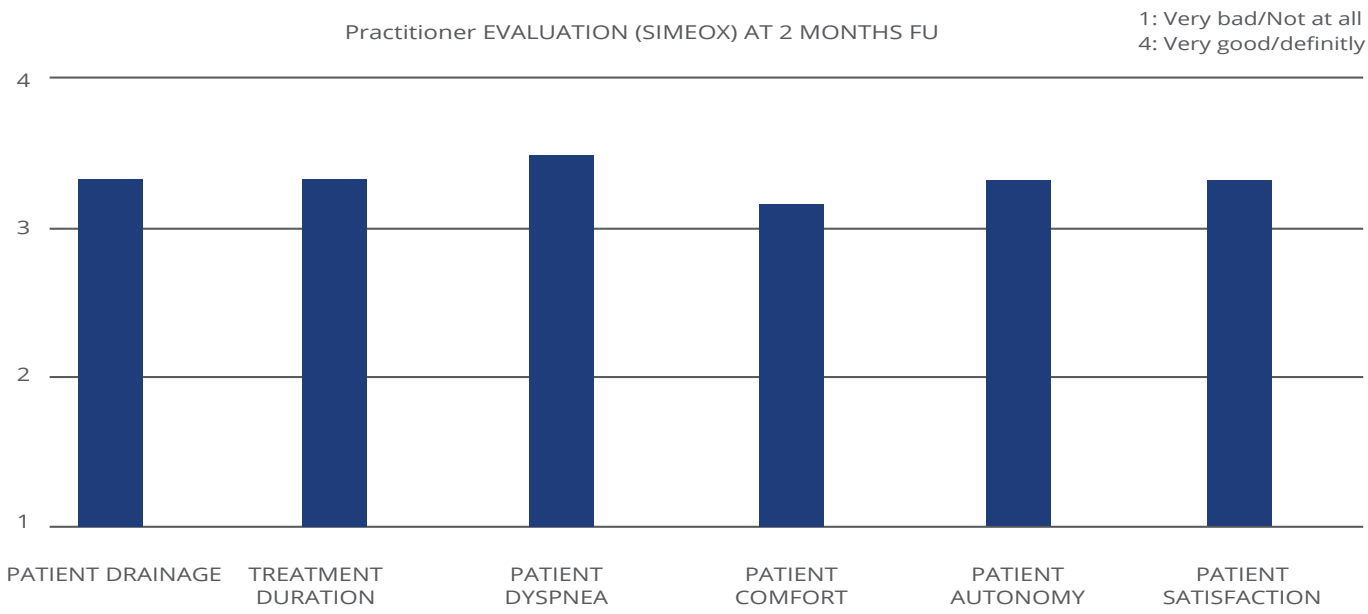


High level of Simeox adherence (weekly frequency and daily use)
Stable frequency of use / week; reduction of daily use at the end of the study

Figure 5. Satisfaction of the 2 months therapy in 6 patients at the Department of Pneumology, Medical University of Lodz, Poland

Clinical evaluation in 6 first cases (Lodz): device settings





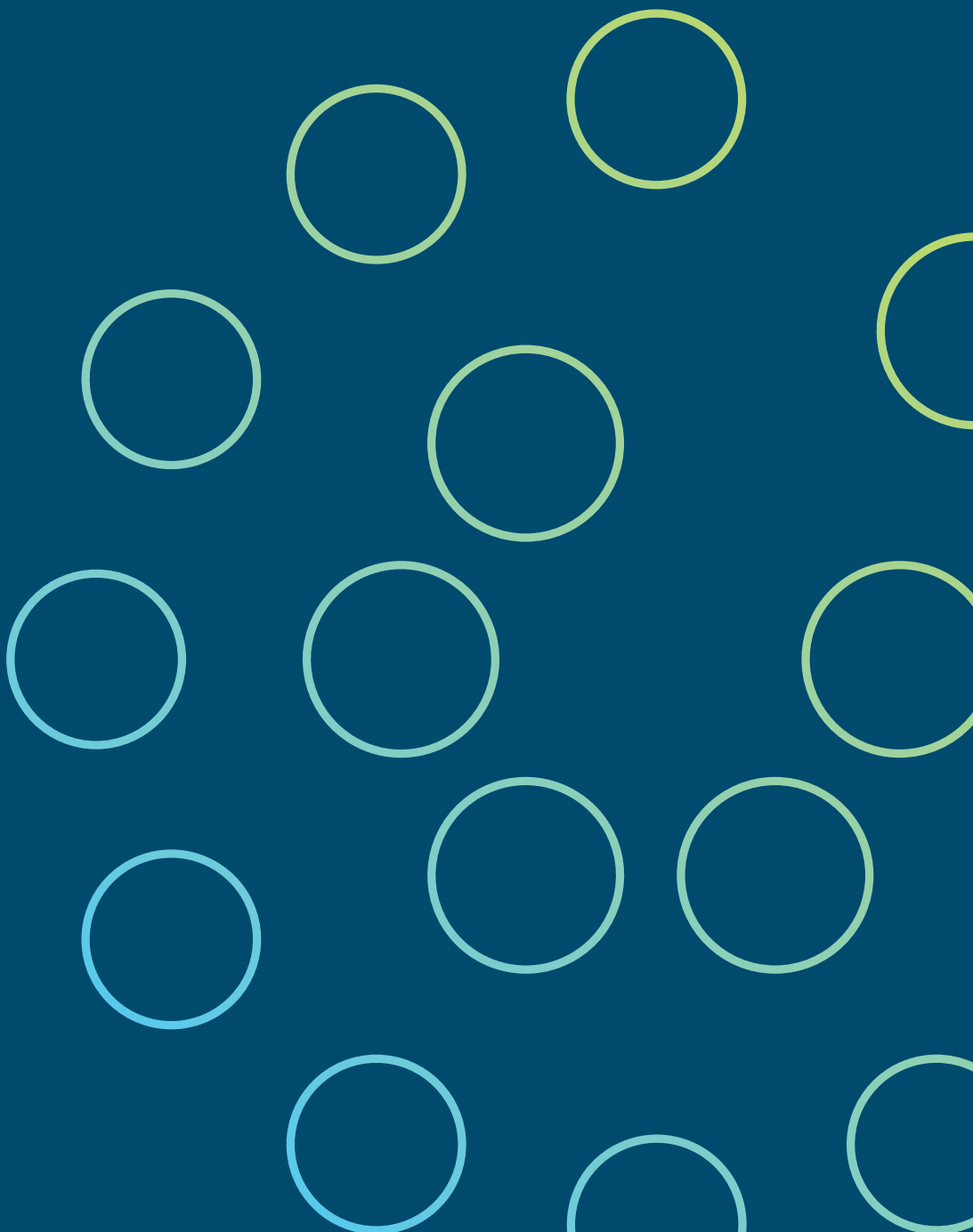
High level of patient and practitioner satisfaction

Conclusions

These data suggest that Simeox therapy is safe and feasible in adult NCF bronchiectasis with good tolerability and adherence at home for most of patients and their healthcare professionals.

Clinical experience in the management of patients

with bronchiectasis and others pulmonary pathologies



MEDICAL UNIVERSITY OF LODZ

CASE 1

15.07.2022 - At the beginning of the study

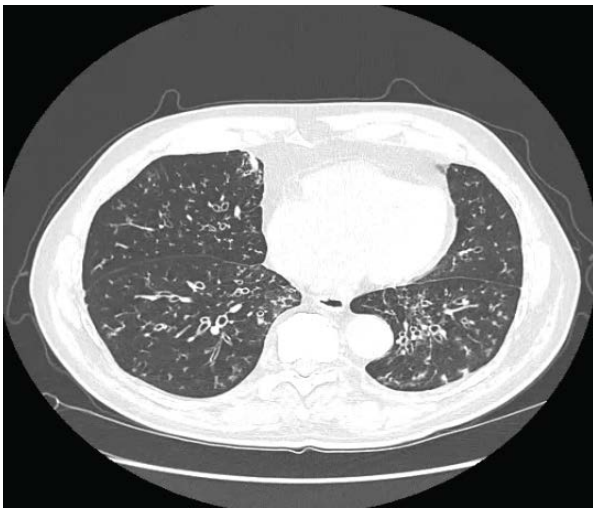
NON-CF-bronchiectasis

COPD

- 77-year old man
- 2 exacerbations of COPD required hospitalisations.
- mMRC=4, CAT=37

- Treated:
  - LAMA+LABA+ICS
  - Mucolytics
- No routine daily rehabilitation

FVC %	42
FEV1%	23
FEV1/FVC	41
PEF	36 l/s



15.07 - 09.09.2022 - Time of observation

SIMEOX

- No pain
- No tiredness
- Exhalation – improved (VAS 2 in scale 0-4)
- 2 x daily
- Sputum white

After 7 days
of rehabilitation with SIMEOX:

mMRC=4
CAT=22

Treated:

- LAMA+LABA+ICS
- Mucolytics
- Gentamycin in nebulizations

After 8 weeks
of rehabilitation with SIMEOX:

mMRC=2
CAT=14

Treated:

- LAMA+LABA+ICS
- Mucolytics
- Gentamycin in nebulizations

CASE 2

08.08.2022 - At the beginning of the study

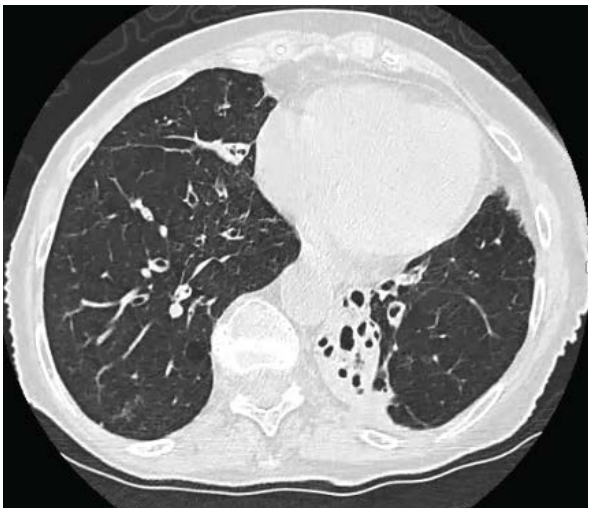
NON-CF-bronchiectasis

CIRROSIS OF THE LUNG'S LOBE, Asthma

- 82-year old woman
- 2-4 exacerbations of chronic diseases required hospitalisations.
- mMRC=3, CAT=20

- Treated:
  - LAMA+LABA+ICS
  - Mucolytics
  - Azythromycin 3x a week
- Every day exercise of the diaphragm

FVC %	50
FEV1%	70
FEV1/FVC	59,6
PEF	2,46 l/s



08.08 - 29.09.2022 - Time of observation

SIMEOX

- Pain 1 (0-10)
- Tiredness 7 later 1 (0-10)
- Exhalation – improved (VAS 2 in scale 0-4)
- 2 x daily
- Sputum white/yellow
- Time 30min > 25 min

After 7 days
of rehabilitation with SIMEOX:

mMRC=3
CAT=22

Treated:

- LAMA+LABA+ICS
- Mucolytics
- Gentamycin in nebulizations

After 8 weeks
of rehabilitation with SIMEOX:

mMRC=2
CAT=14

Treated:

- LAMA+LABA+ICS
- Mucolytics
- Gentamycin in nebulizations

CASE 3

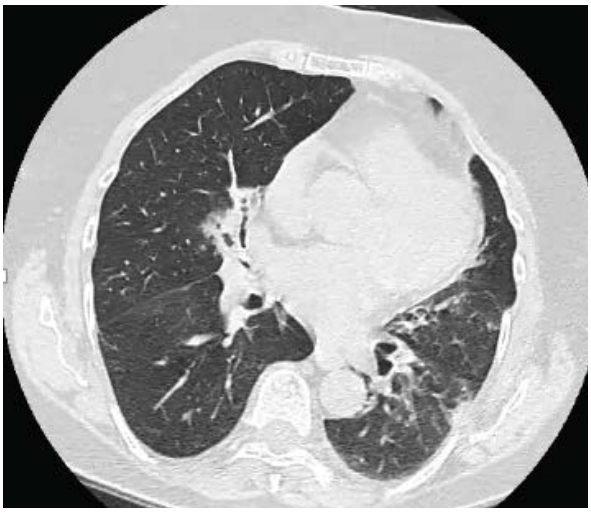
22.07.2022 - At the beginning of the study

NON-CF-bronchiectasis

IDIOPATIC BRONCHIESTASIS, RHINOSINUSITIS

- 67-year old woman
- 2 exacerbations of chronic diseases without hospitalisations.
- mMRC=2, CAT=24
- No spirometry because of the cough

- Treated:
  - LABA+SABA
  - Mucolytics
  - Kolistin in nebulization 3x
- No routine every day rehabilitation



22.07 - 17.10.2022 - Time of observation

SIMEOX

- Pain 2 > 0 (0-10)
- Tiredness 4 later 0 (0-10)
- Exhalation – improved (VAS 2 in scale 0-4)
- 0-2 x daily
- Sputum white/yellow
- Time 10min > 13 min

After 7 days

of rehabilitation with SIMEOX:

mMRC=2
CAT=19

Treated:

- SABA+LABA
- Mucolytics
- Kolistin in nebulizations
- Autogenic drenage

After 8 weeks

of rehabilitation with SIMEOX:

mMRC=1
CAT=18

Treated:

- SABA
- Mucolytics

CASE 3

NON-CF-bronchiectasis

IDIOPATIC BRONCHIESTASIS, RHINOSINUSITIS

Spirometry values

	1 day of exacerbation	7 day of treatment	12 weeks of treatment
FEV1	--	56	65
FVC	--	53	68
FEV1/FVC	--	81,82	74
PEF	--	3,82 l/s	4,43 l/s

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