5TH WORLD BRONCHIECTASIS & NTM CONFERENCE, PRAGUE 30.06-02.07 2022

Feasibility of implementing an innovative airway clearance technology

at home by telecare in patients with non-cystic fibrosis bronchiectasis

Marlene Murris-Espin [3], Sylvie Leroy [2], Marie Mahot [1], Raphael Abouly [1], Hughes Gauchez [4], Sophie Jacques [5], Jean-Christian Borel [1], Eloise Joffray [1], Nathalie Arnol [1], Laurent Morin [6] and Rebecca Hamidfar [7]

[1] AGIR à dom, MEYLAN, France
[2] Hôpital Pasteur CHU Nice, NICE, France
[3] Hôpital Larrey, CHU Toulouse, TOULOUSE, France
[4] Cabinet de Kinésithérapie, Marcq-en-Barœul, France
[5] Cabinet de Kinésithérapie, Rennes, France
[6] Physio-Assist, Aix en Provence, France
[7] Hôpital Michallon, CHU Grenoble, France

*Auteur(s) correspondant(s) :
Adresse email : j.borel@agiradom.com (J.C.Borel)
Adresse email : morin@physio-assist.com (L.Morin)

INTRODUCTION

Chest physiotherapy is a key component of bronchial drainage in patients with non-cystic fibrosis bronchiectasis (NCFB) and chronic mucus hypersecretion (CMH). The guidelines (ERS 2017) recommend that patients who have difficulty clearing their bronchial secretions should have one or more daily drainage sessions. **However, regular access to a respiratory physiotherapist can be very limited for various reasons:** geographical restrictions, accessibility to health care professionals, patient availability, and exceptional situations such as the Covid 19 pandemic.

SIMEOX (PhysioAssist) is an innovative bronchial drainage device that can provide patients **with technical assistance in autonomy at home.** The device delivers an intermittent vibratory pneumatic signal at a frequency of 12 Hz into the bronchial tree during exhalation, which increases the mobilization of mucus from the peripheral lung to the central bronchi to promote expectoration of secretions.

However, the use of SIMEOX requires specific training beforehand. We hypothesized that telecare could allow remote training of NCFB patients and promote the autonomous use of the device over time at home.

The primary objective of this study was to **evaluate the frequency of use of SIMEOX in autonomy during 3 months after training and regular follow-up by telecare.**

The secondary objectives were to evaluate the evolution of adherence during the 3 months of therapy, the search for factors correlated with adherence, the feasibility during the study of a regular telecare follow-up and weekly collection of secretion weight, the patients' satisfaction with the combined solution SIMEOX + telecare, the evolution of several quality-of-life scores and spirometry data, and the safety of the device.

Flow chart

Inclusion V0	Inclusion (hospital) **N=22**	SIMEOX device presented (first use) and delivered to patients for home use
TELECARE	D1-D15 Remote SIMEOX training Motivational enhancement therapy every 10 days **N=22**	SIMEOX therapy at home Device data exported on web (tablet) Diary completed after each use Sputum weight once a week
3-month FU	Follow-up visit – End of study (hospital) **N=22**	
Analysis	ITT PP ITT Population **N=22** PP Population **N=21**	1 patient with 2 major deviations : - Differential diagnostic (CF) - No self-reported session

METHODS

We conducted a prospective, multicentre, open-labeled study **in adult NCFB patients with CMH** (bronchorrhea > 10 ml/d) who had difficulties in accessing chest physiotherapy.

A SIMEOX was provided at inclusion to each patient in the investigating center; **training in device use was carried out by videoconference** (up to 5 sessions in the first 2 weeks) by a physiotherapist expert in the use of device.

Patients were then contacted by the physiotherapist by phone call every 10 days **to reinforce their motivation.**

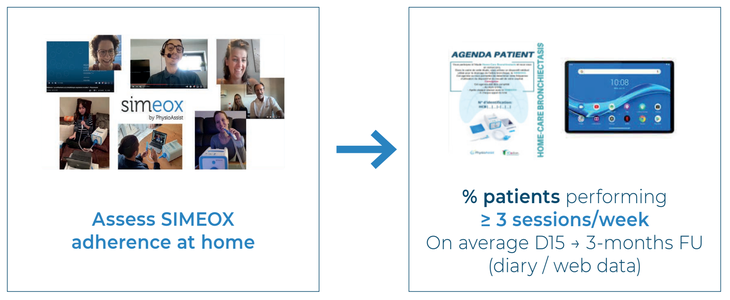
The primary endpoint was **the percentage of patients who completed at least 3 SIMEOX sessions/week between the end of the training (2 weeks) and the 3-month FU visit.** Adherence data was collected by patients on a diary, and automatically transferred to a secure IT server via a tablet connected to the device via Bluetooth during drainage sessions.

The patients collected once a week the weight of the secretions removed after a drainage session (scale provided).

Patients completed the satisfaction questionnaire at the end of the study and the quality-of-life questionnaires (QOL-B, SGRQ, LCQ and CAT) at inclusion and 3-month FU visit. Adverse events were collected throughout the study.

Clinicaltrial.gov NCT04742270.

SIMEOX® + TELECARE feasibility (setting up / follow-up of patients)



RESULTS

22 patients were included and evaluated in ITT analysis; one patient was excluded in Per Protocol analysis (PP n=21) for differential diagnosis of cystic fibrosis after the study. The PP population characteristics are presented (Table 1).

Adherence reported in the diary: 14 patients **(67%) performed at least 3 SIMEOX sessions per week** (3.8 ± 2.2 / week); this number increased to 17 patients (81%, 4.4 ± 1.8 / week) considering the adherence data transferred to the server. The diary and server data were well correlated (R=0.73, p<0.001).

Adherence was stable over the course of the study (median: 3-5 sessions/week). None of the predicted factors were associated with adherence (demographics, smoking, BSI, etiology of bronchiectasis, comorbidities, adherence to other therapies, social-professional categories, or physical activity). However mean adherence was significantly correlated with number of FU phone call during the study (Pearson's coeff. correlation r=0.45, p=0.043) suggesting that adherence for Simeox therapy seems to be better in patients having more contact with PT by telecare.

In practice, patients collected sputum weight 0.7 [0.2; 1.0] / week confirming the feasibility of sputum collection during the study. The median sputum weight was stable during the follow-up.

However, at the end of the follow-up there was **a significant reduction in the weight of the largest sputum (Q75**).

The mean time between phone calls was 14±6 days. At three months, **patient satisfaction with SIMEOX + telecare was very high (median [Q1;Q3]): 9.0 [7.9;10.0]** on a 10-point visual analog scale.

There was no change in spirometry data at 3 months in this population.

There was a significant improvement in the QOL-B vitality and treatment burden scores (p<0.05) and a positive trend in health perception (p=0.08) and social functioning (p=0.07) scores.

The SGQR was improved by >4 units (MCID) for the total score (p<0.05) and each of the 3 domains (symptoms, activity limitation and psychosocial impact). The evolution of the LCQ was close to statistical significance: improvement > 1.3 and > 0.4 units (MCID) respectively for the total score and each of the 3 domains (physical, psychological, and social impact). **The CAT score was improved by > 4 MCID units for the total score (p=0.005).**

Four patients were hospitalized for pulmonary exacerbation during the 3-month period (time to first PEx: 50 ± 32 days). Only one patient was permanently discontinued from device therapy at home. 3 patients had an exacerbation that did not require a change in treatment.

No severe or serious adverse events were reported. 3 patients experienced increased chest pain during coughing. 4 patients reported increased bleeding in sputum, and one patient experienced worsening of GERD symptoms (after 9 weeks of device treatment). **These adverse events were temporary and all resolved quickly,** except for the patient with a history of GERD.

These adverse events led to only one temporary discontinuation (48h) of therapy for haemoptysis (no permanent discontinuation).

CONCLUSION

NCFB patients with CMH have a high level of mid-term adherence to SIMEOX technology at home and very high satisfaction with its use combined with telecare.

Both remote training in SIMEOX use and therapeutic FU by telecare are therefore feasible.

These results suggest that SIMEOX therapy is safe and efficient in improving airway clearance and as a result respiratory symptoms and quality of life.

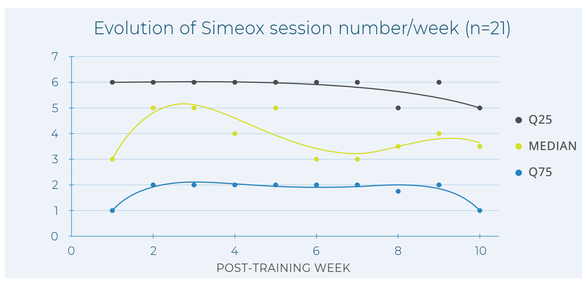
The clinical effectiveness of this procedure in NCFB needs to be evaluated in a long-term randomized controlled trial.

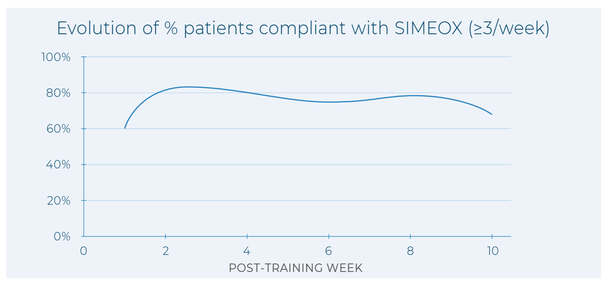
Table 1: Demographic characteristics (PP n=21)

Age (y)	53 ± 18
Gender (M)	8 (38%)
BMI (kg/m²)	21.4 ± 3.4
Passive/former smoking	9 (45%)
mMRC	1 [1 ; 1]
FEV1 (L)	2.4 ± 0.8
FVC (L)	3.4 ± 1.0
FEV1/FVC (%)	66.4 ± 14.7
BSI	6.6 ± 3.5
≥3 lobes or cystic BE	18 (90%)
PA colonization	10 (50%)
Yellow/green sputum (n=17)	14 (82%)
> 1 tablespoon (> 15 ml)	17 (81%)

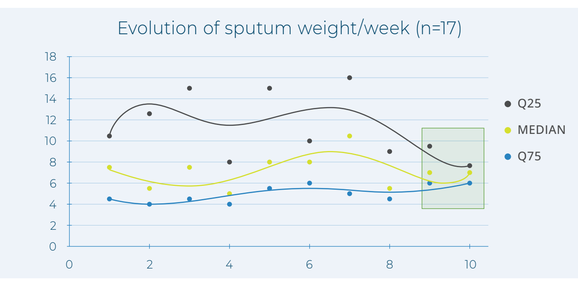
ETIOLOGY :	
Idiopathic	6 (33%)
PCD	3 (17%)
Child infection	3 (17%)
ABPA	3 (17%)
Other	3 (17%)
COMORBIDITY:	
Asthma	5 (24%)
COPD	2 (10%)
Chronic rhinosinusitis	11 (55%)
Nasal polyps	2 (11%)
CVD	1 (5%)
Diabetes	1 (5%)
Anxiety/depression	4 (19%)

Evolution of adherence

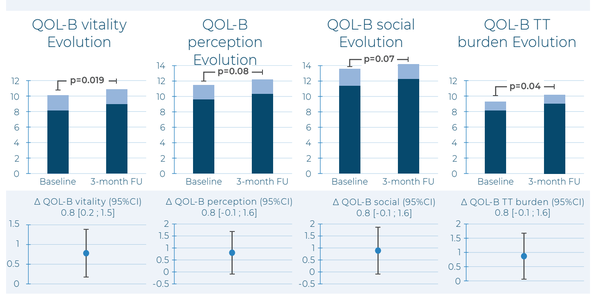




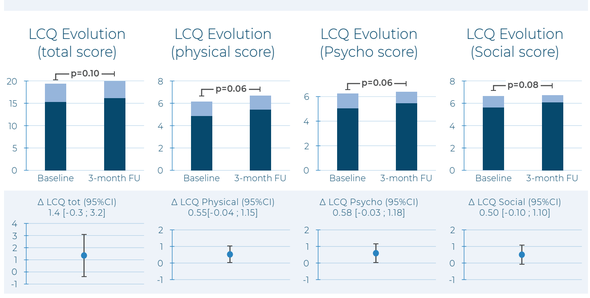
Evolution of sputum collection



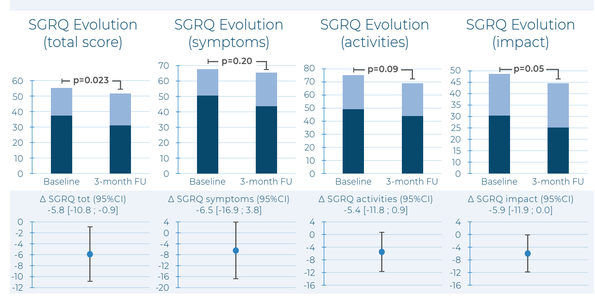
QOL-B questionnaire



LCQ questionnaire



SGRQ questionnaire



CAT score