A NEW ADJUNCTIVE THERAPY TO SUPPORT MULTI-MORBID GERIATRIC PATIENTS WITH COPD AND IMPROVE THEIR QUALITY OF LIFE

Jörg Pötzsch[1], Jörg Schulz[2], Zisi Fotev[1], Barbara Ludwig[2]

[1] *Satina Medical UG, Berlin*
[2] *Paracelsus-Klinik, Adorf/Schöneck*

Correspondence address:
Dr. Jörg Pötzsch, Dr. Zisi Fotev, Satina Medical UG, Robert-Rössle-Str. 10, 13125 Berlin, E-mail: jp@satina-medical.com
Professor Dr. med. Jörg Schulz, Dr. med. B. Ludwig, Paracelsus-Klinik, Adorf/Schöneck, Sorger Straße 51, 08626 Adorf

Dr. Jörg Pötzsch

Prof. Dr. med. Jörg Schulz

Dr. Zisi Fotev

Dr. med. Barbara Ludwig

ABSTRACT — In a pilot study, the clinical effects on ten multi-morbid geriatric patients with COPD was examined over 5 days using a new novel device that is worn around the waist that specifically stimulates the diaphragm muscle. The device induced slow deep rhythmic breathing in all the patients resulting in an increase in partial oxygen pressure (by 1.7%), decreased heart (by 5.8%) and breathing (by 13.8%) rates. All changes were statistically significant ($p<0,05$). There was a clear improvement of their general condition and feeling and therefore this device offers great potential to be used as a safe, easy to use alternative adjunctive treatment for COPD patients.

ZUSAMMENFASSUNG — In einer Pilotstudie an 10 multimorbiden geriatrischen Patienten mit COPD wurden die klinischen Effekte eines neuartigen Gerätes untersucht, das um die Taille getragen wird und spezifisch das Zwerchfell stimuliert. Das Gerät rief bei allen Patienten tiefe, langsame und rhythmische Atmung hervor, woraufhin der Sauerstoffpartialdruck um 1,7% stieg, die Herzfrequenz um 5,8% und die Atemrate um 13,8% sanken. Es wurde eine klare Verbesserung des Allgemeinzustandes erreicht. Das Gerät hat somit das Potential, als sichere und einfach anzuwendende adjuvante Therapie für COPD eingesetzt zu werden.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is characterized by persistent airflow limitation that is usually progressive. It is associated with a chronic inflammatory response in the airways and lungs to noxious particles or gases. The persistent airflow limitation results from a combination of diffuse small airway disease and destruction of the lung parenchyma (emphysema). 5–10% of adults aged over 40 years have COPD, and its prevalence is expected to continue increasing in the next decade. The key risk factor for COPD is tobacco smoke, but occupational exposure, pollution and genetic factors also play a role. The most important symptoms of COPD are breathlessness on exertion and chronic cough with or without phlegm. Fatigue, anorexia and weight loss can arise as the disease progresses. Treatment is multimodal, including smoking cessation, treatment with bronchodilators as well as inhibitors of inflammation, physical exercise and oxygen therapy. Overall, the COPD mortality rate for men and women in Europe, age standardized to the European Standard Population, is about 18 per 100.000 inhabitants per year.

Although the progressive decline of lung function in COPD patients is irreversible using pharmacotherapy, medications can prevent and control symptoms, and reduce the incidence of COPD exacerbations.1) Medication adherence levels for COPD medications

have been found to be well below the levels typically observed for treatments for other conditions.

Furthermore, COPD patients typically have multiple chronic comorbidities including conditions such as hypertension, coronary atherosclerosis, other heart diseases, lipid disorders, diabetes, osteoporosis, and sleep apnea [2].

Comorbidities contribute to the overall severity and manifestations of the disease. They can occur in mild, moderate or severe COPD and they increase the risks of hospitalization and mortality of COPD independently [3–8].

A major factor contributing to the poor compliance of COPD medication is the multiple side-effects that users suffer, such as headaches, shakiness, fast irregular heart beat, cramping of limbs, mood swings and weight gain [9]. Moreover, these patients have extreme difficulty to breathe deeply as is conditional for the use and effectiveness of the inhaled bronchodilators.

Therefore, it is of utmost importance from the patient perspective to provide an alternative treatment that can be used as a support to the prescribed medication that can increase the quality of life of these patients.

In this study we examined the use of a new active wearable diaphragm stimulating device. It is a belt-shaped device that generates mechanical impulses (not electrical) with a defined frequency. It is placed around the abdominal region, adjacent to the costal arch. Within a few minutes of operation, it activates the diaphragm to contract in a rhythmic manner and induces deep abdominal breathing thereby facilitating a more efficient exchange of gases in the lungs without any effort on behalf of the patient. Furthermore, abdominal breathing is known to be accompanied by increased parasympathetic activity [10]. This activity is characterized by an improved oxygen consumption, decreased heart rate, and decreased blood pressure, as well as increased theta wave amplitude in EEG recordings, accompanied by the experience of alertness and reinvigoration [10].

STUDY OBJECTIVES

It was the primary objective of the study to investigate the effects on patients of the device on several clinical parameters (changes to breathing, heart rate and partial oxygen pressure). The secondary objective was to report global clinical impressions.

STUDY SYNOPSIS

The study was conducted at the Geriatric department of the Paracelsus-Clinic, in Adorf, Germany from April 2014 to May 2014. The number of planned and analyzed patients was 10, all female, between the ages of 71 and 92 and all signed a patient consent form. Patients had COPD with multi-morbid indications varying from diabetes Type II, hypertension, stroke, obesity and congestive heart failure. The device was used twice a day for 20 minutes for 5 days. Clinical parameters were reported at the end of each day from 5 days.

RESULTS

Using the device resulted in an increase in partial oxygen pressure by 1.7%, decreased heart rate by 5.8% and breathing rate by 13.8%. These beneficial effects were already visible at the end of the first day of treatment. All changes were statistically significant ($p<0,05$).

All (except one) patients reported an improvement in general condition and feeling. The one patient reported an unpleasant feeling caused by the impulse pattern in the abdomen.

Two patients had bowel movement again. No safety issues were observed.

Table 1. *Effect of using the Belt Device on clinical parameters*

	Heart Rate		Breathing Rate		Saturated Oxygen Levels (%)	
	Before	After	Before	After	Before	After
Mean	83,8	78,9	17,7	15,2	93,7	95,2
SD	15,9	13,5	1,8	1,7	1,3	1,9

N=10
Before = prior to using device on Day 1
After = following 2nd treatment with device on Day 5

CONCLUSION

The diaphragm stimulating device demonstrated an improvement in the tested parameters of co-morbid COPD patients, especially in slowing the breathing rate and increasing the blood oxygen saturation levels. These effects were already observable with the first day of use and remained constant throughout the study.

The results strongly underscore the importance of diaphragmatic breathing and its multiple physiological benefits to the health of patients suffering from COPD and other co-morbidities.

The device also showed that it is easy to use, comfortable for patients and without concern for unwanted side-effects.

Further studies are needed to confirm these findings and to evaluate the benefits of the device in the therapy of COPD.

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