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# Evaluation of the Effects of Neuromuscular Electrical Stimulation of The Lower Limbs Combined with Pulmonary Rehabilitation on Exercise Tolerance in Patients with Chronic Obstructive Pulmonary Disease

*by*
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*Chronic obstructive pulmonary disease (COPD) is a systemic disease with multiple extrapulmonary manifestations including impeded skeletal muscle function, leading to decreased muscular strength and endurance in patients with COPD. Pulmonary rehabilitation eases the symptoms of the condition and produces increased muscular endurance. Neuromuscular electrical stimulation (NMES) may serve as a treatment alternative to traditional pulmonary rehabilitation. The aim of the study was to assess the effects of NMES combined with pulmonary rehabilitation on exercise tolerance in patients in comparison with pulmonary rehabilitation alone. The subjects included 30 patients with COPD randomly assigned to one of the two groups. The first group consisted of 15 patients who were treated with neuromuscular electrical stimulation at frequency of 35Hz and pulmonary rehabilitation (NMES+RP). The second group comprised 15 patients treated with pulmonary rehabilitation only (RP). Pre- and post-study assessments were performed. The retrospective evaluation including an exercise tolerance test (i.e. six minute walk test (6MWT)), spirometry and blood gasometry was carried out after 3 weeks. Twenty-eight patients in total completed the study. In the NMES+RP group, an increase in exercise tolerance manifested by a longer distance walked in the 6MWT was observed in comparison to the pulmonary rehabilitation group. No effects of NMES combined with pulmonary rehabilitation on selected spirometric and gasometric parameters in patients with COPD were observed in comparison with traditional pulmonary rehabilitation. The acquired results suggest that NMES of the lower limbs may be applied as an additional form of pulmonary rehabilitation in patients with COPD.*

***Key words**: COPD, neuromuscular electrical stimulation, exercise tolerance.*

## Introduction

Chronic obstructive pulmonary disease (COPD) is characterized by sustained limitation of the airflow in the lower respiratory tract, usually of progressive nature, caused by excessive inflammatory response in the bronchial passages and lungs in reaction to gases and dust. Main symptoms of COPD include decreased exercise tolerance related to dyspnea and fatigue during physical exercise. At first, these symptoms occur only during intense physical exercise. However, as the condition progresses, the symptoms begin to appear also during casual activities, thus reducing the patient's self-support. Therefore, COPD is not only a medical issue, but also a social challenge to the patient due to factors such as decreased quality of life, disablement and social isolation. Moreover, exacerbation of COPD symptoms leads to hospitalization of the patients

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and thus, demands greater funds to support treatment (Decramer, 2015).

Currently, COPD is perceived not only as a pulmonary disease, but more as a systemic disease affecting functioning of other organs, including locomotor system. Impaired functioning of skeletal muscles is among the most common extrapulmonary manifestations of COPD. The impairment of skeletal muscle function appears regardless of physical function of the respiratory tract, as demonstrated by the evaluation of patients after lung transplant surgery (including one and both lungs transplant patients) (Decramer, 2015). Progressive muscle impairment leads to decreased strength, endurance, exercise tolerance and in turn, decreased quality of life. Moreover, increased exercise and resting dyspnea, as well as greater fatigue during exercise are observed. The impairment of skeletal muscles in COPD is of structural, metabolic and functional character (Allaire, 2004; Gosker, 2003).

Lately, in numerous reports it has been suggested that applying physical training in rehabilitation of patients with COPD is safe and beneficial. Increased exercise tolerance and peak oxygen consumption were observed as a result of applying protocols utilizing physical training (Bolton, 2013; Decramer, 2015).

Physical training not only induces increased exercise tolerance, but also improves quality of life, a measure directly related to the state of one's health. Patients report improved physical and mental shape, ability to perform daily tasks with more ease and thus, greater self-reliance and decreased sensation of illness (Puhan, 2006).

It is widely known that numerous COPD patients also suffer from locomotor disorders which impede performance of physical exercise. Moreover, COPD patients cannot undergo physical training due to advanced heart failure and/or respiratory failure. Also, some of the patients abandon physical exercise because of the discomfort related to dyspnea.

Current studies suggest that neuromuscular electrical stimulation (NMES) of the lower limbs may serve as an alternative to traditional physical training in patients with COPD in periods of exacerbation of symptoms or with locomotor disorders which hinder the performance of traditional physical exercises (Banerjee, 2010). As presented in contemporary studies, NMES can be applied safely in patients with COPD during periods of exacerbation of symptoms, in advanced stages of COPD or even in patients undergoing respiratory therapy. Another important aspect of NMES is that patients feel less anxious during and post-exercise in comparison to traditional physical training (Bourjeily-Habr, 2002; Dal Corso, 2007; Neder, 2002; Vivodtzev, 2006; Vivodtzev, 2012).

Presently, there are no rehabilitation protocols utilizing a combination of traditional pulmonary rehabilitation and neuromuscular electrical stimulation in patients with COPD.

The aim of this study was to evaluate the effect of a rehabilitation protocol consisting of traditional pulmonary treatment combined with neuromuscular electrical stimulation of lower limbs at a frequency of 35Hz in comparison with standard pulmonary rehabilitation on exercise tolerance and quality of life in patients with COPD.

## Material and Methods

***Research material choice and plan of experiment***

The study involved 30 hospitalized patients with COPD submitted to stationary pulmonary rehabilitation at the Pulmonary Rehabilitation Division for a 3-week period. Inclusive and exclusive criteria regarding the participants of the experiment were applied (Table 1). Approval from the Bioethics Committee at the Jerzy Kukuczka Academy of Physical Education in Katowice (No. 6/2010) was granted. All participants were informed about the aim of the experiment as well as the methods of evaluation and provided their written consent to participate in the study. The patient's refusal to participate in the study did not affect further treatment procedures.

Patients that fulfilled the inclusive criteria were randomly assigned to one of the two groups:

- Study group (NMES + PR) consisting of 15 patients, who apart from pharmacological treatment and traditional pulmonary rehabilitation were treated with electrical stimulation (NMES) of the lower limbs,
- Control group (PR) consisting of 15 patients, who apart from pharmacological treatment were treated with traditional pulmonary

rehabilitation only.

Basic characteristics of the subjects are presented in Table 2. The following values were measured both pre- and post-experiment:

1. Exercise tolerance (measured with the use of the 6 minute walk test (6MWT)),
2. Selected spirometric parameters (forced expiratory volume, forced vital capacity, forced expiratory volume to forced vital capacity percentage ratio, peak expiratory flow) measured through spirometric evaluation,
3. Selected blood gasometry parameters (partial oxygen pressure, partial carbon dioxide pressure).

***Pulmonary rehabilitation***

Patients from both groups received standard pulmonary rehabilitation. Therapy was applied 6 times a week under medical and physiotherapeutic supervision. The rehabilitation protocol included breathing exercises activating the chest consisting of upper limb movements during the breathing cycle, thus increasing breathing efficiency and the diaphragm pathway, basic physical conditioning, fundamental training for COPD patients, i.e. 30 min sessions of treadmill training with applied resistance performed in accordance with the rule of not exceeding 60% of the patient's peak exercise tolerance level, relaxation exercises. Safety of patients was monitored during the rehabilitation process. Each day before the rehabilitation session an objective and subjective evaluation was performed including blood pressure and heart rate measurements.

***Neuromuscular electrical stimulation of the lower limbs (NMES)***

Neuromuscular electrical stimulation (NMES) was performed with the use of a double-canaled Astar Aries S device. The procedure consisted of applying the electrodes to closer and distal endpoints of the muscle belly of the quadriceps and gastrocnemius muscles. A commutative, symmetric rectangular current of 35 Hz frequency was used. The impulse duration amounted to 0.3 ms. Duration of a series of impulses (duration of muscle contraction) amounted to 2 s, whereas the pause between the series of impulses lasted 4 s.

***Exercise tolerance***

Exercise tolerance of the participants was evaluated with the 6 minute walk test (6MWT). The object of assessment was the distance walked by the patient during a 6 min period. The experiment was carried out on a previously measured segment of a hospital floor of 30 meters. The segment was then further divided into 1 m parts. The room in which the experiment took place was well ventilated beforehand. The temperature in the room ranged from 20 to 23$^0$C. The equipment used for the experiment consisted of a stop-watch, a blood pressure meter, a pulse oximeter.

***Spirometric test***

The spirometric test was performed using the MES-1000 system. The following parameters were evaluated: forced expiratory volume ($FEV_1$), forced vital capacity (VC), forced expiratory volume to forced vital capacity percentage ratio ($FEV_1$/VC), peak expiratory flow (PEF).

***Gasometric test***

The capillary blood gasometric test was performed utilizing the Bayer HealthCare RapidLab 348 apparatus. The procedure consisted of the following: after applying and rubbing small amounts of Histadermin into the ear lobe and after puncturing it using a disposable needle, blood slowly flowing out was collected into a heparinised glass capillary. The capillary was then secured with a glass cap for needs of transportation. Afterwards, the RapidLab apparatus was used to collect samples into the analysing system.

***Statistical analysis***

Measures of location and dispersion of the evaluated parameters were set for the research material. In order to determine the effect of the applied treatment as well as the actual need of applying rehabilitation statistical analyses were performed. The level of significance was set at 0,05. The typical repetitive measure scheme was implemented to the experiment, consisting in an assessment of the patients pre- and post-rehabilitation. In case of meeting the conditions of the parametric tests (normality of variable distribution – results of the Shapiro-Wilk test statistically irrelevant and variance unity – results of the Leven's test statistically irrelevant), the Student's t-test for independent samples was used to evaluate the differences between the groups. Due to repetitive measurements resulting from

control check-ups of the same patients after an established period of rehabilitation, the Student's t-test was utilized. For variables of normal distribution not meeting the conditions, calculations were made with the use of non-parametric methods: the Mann-Whitney U-test and the Wilcoxon's test. Statistica PL software was used for all statistical calculations.

## Results

A total of 28 patients completed the study. The reasons for withdrawing from the study by 2 patients were: (1) exacerbation of chronic obstructive pulmonary disease symptoms and (2) acciddental event. The patients who resigned were from the pulmonary rehabilitation group. Therefore, the statistical analysis included 28 patients, who completed the pulmonary rehabilitation programme. The studied groups did not differ significantly in terms of body height and BMI. The NMES+PR group, however, were noticeably older (Table 2).

***Exercise tolerance***

All of the participants were evaluated with the use the 6MWT before and after the pulmonary rehabilitation. Pre-rehabilitation, the distance walked amounted to 397.2 ± 70.65 m and 421.4 ± 69.4 m in the studied groups and did not differ significantly between the groups (Table 3). Post-rehabilitation, a significant increase of distance walked in the 6MWT was observed only in the NMES+PR group (a median of 6.1% increase in the distance walked). The increase in the distance walked amounted to 24.1m in the NMES+PR group and 10.3 in the PR group. In the PR group, a minor increase in walked distance was noted (2.4%), not differing significantly from the measurements taken before the treatment.

***Spirometric test***

A spirometric test was performed in both groups pre- and post-rehabilitation. The following parameters were evaluated: forced vital capacity (FVC), forced expiratory volume ($FEV_1$), forced expiratory volume to forced vital capacity percentage ratio ($FEV_1/FVC$) and peak expiratory flow (PEF).

No statistically significant differences were noted in the selected spirometric values between the studied groups both pre- and post-rehab. Also, no statistically significant effect of pulmonary rehab and pulmonary rehab combined with neuromuscular electrical stimulation (NMES) of the lower limbs was observed (Table 4).

***Gasometric test***

In both studied groups a gasometric test was performed both pre- and post-rehab. Two indicators were recorded for further analysis: oxygen pressure ($pO_2$) and carbon dioxide pressure ($pCO_2$) in capillary blood.

No statistically significant changes in $pO_2$ and $pCO_2$ values were noted in the studied groups pre- and post- treatment. Moreover, no statistically significant influence of pulmonary rehab and pulmonary rehab combined with neuromuscular electrical stimulation on $pO_2$ and $pCO_2$ values was observed (Table 4).

**Table 1**

*Inclusion and exclusion criteria*

| Inclusion criteria | Exclusion criteria |
|---|---|
| 1. documented case of COPD,<br>2. clinical stability pre-study,<br>3. consent to partake in the study. | 1. unstable coronary disease,<br>2. revelant hemodynamic narrowing of the aortic valve,<br>3. acute myocarditis or pericarditis,<br>4. pacemaker implant, cardioverter-defibrillator implant (ICD), cardiac resynchronization therapy<br>defibrillator implant (CRT),<br>5. liver and kidney disease during insufficiency periods,<br>6. venous thrombo-embolism,<br>7. lack of consent to partake in the study. |

**Table 2**

*Basic chasracteristics of the participants (median ± SD)*

| Variable | Experimental group (NMES+PR) (n = 15) | Control group (PR) (n = 13) |
|---|---|---|
| Sex (female/male) | 4/11 | 5/10 |
| Age (years) | 68.3 ± 6.35* | 61.3 ± 7.78 |
| Body height (m) | 1.66 ± 0.08 | 1.66 ± 0.1 |
| Body mass (kg) | 79.0 ± 15.34 | 79.7 ± 21.4 |
| BMI (kg/m$^2$) | 28.8 ± 5.75 | 28.7 ± 7.49 |

**p = 0.012 in comparison with the control group; NMES+PR – neuromuscular electrical stimulation of the lower limbs in combination with standard pulmonary rehabilitation; PR – pulmonary rehabilitation only*

**Table 3**

*Pre- and post-treatment exercise tolerance in both studied groups (median ± SD)*

| Variable | Experimental group (NMES+PR) (n = 15) | Control group (PR) (n = 13) |
|---|---|---|
| 6MWT 1 (m) | 397.2 ± 70.65 | 421.4 ± 69.4 |
| 6MWT 2 (m) | 421.3 ± 69.76* | 431.7 ± 53.7 |

**p = 0.001 in comparison with pre-study results; 1 – pre-study results; 2 – post-study results; 6MWT – the Six-Minute Walk Test*

**Table 4**

*Spirometric and gasometric evalutation (of capillary blood): results pre- and post-study in both of the studied groups (median ± SD).*

| Variable | Experimental group (NMES+PR) (n = 15) | Control group (PR) (n = 13) |
|---|---|---|
| FVC 1 (l) | 3.18 ± 124 | 3.44 ± 2.2 |
| FVC 2 (l) | 2.81 ± 1.02 | 3.23 ± 2.4 |
| $FEV_1$%FVC 1 (%) | 53.1 ± 10.75 | 52.8 ± 36.28 |
| $FEV_1$%FVC 2 (%) | 52.5 ± 12.75 | 53.6 ± 36.99 |
| $FEV_1$ 1 (l/s) | 1.66 ± 0.69 | 1.78 ± 0.78 |
| $FEV_1$ 2 (l/s) | 1.45 ± 059 | 1.76 ± 0.91 |
| PEF 1 (l/s) | 4.94 ± 1.7 | 4.75 ± 2.3 |
| PEF 2 (l/s) | 4.65 ± 1.485 | 4.89 ± 2.29 |
| $pO_2$ 1 (mmHg) | 63.3 ± 6.94 | 63.3 ± 6.83 |
| $pO_2$ 2 (mmHg) | 59.3 ± 5.98 | 67.0 ± 13.11 |
| $pCO_2$ 1 (mmHg) | 38.1 ± 5.09 | 39.4 ± 3.69 |
| $pCO_2$ 2 (mmHg) | 39.0 ± 4.91 | 38.6 ± 3.71 |

*1 – pre-rehab results; 2 – post-rehab results; FVC – forced vital capacity; $FEV_1$% FVC – forced expiratory volume to forced vital capacity percentage ratio; $FEV_1$ – forced expiratory volume; PEF – peak expiratory flow; 1 – pre-rehab results; $pO_2$ – oxygen pressure in capillary blood; $pCO_2$ – carbon dioxide pressure in capillary blood.*

## Discussion

Pulmonary rehabilitation supports pharmacological therapy in COPD treatment and is a fundamental element of the recovery process in terms of self-reliance and activity on the labour market of patients. Pulmonary rehabilitation should be aimed at reducing symptoms of the disease, improving exercise tolerance and promoting a healthy lifestyle. Such endeavours lead to lower rates of hospitalization of COPD patients.

Physical exercise results in decreased symptoms of skeletal muscles function disorders, which constitute the most common extrapulmonary symptoms of COPD. Physical training prevents further muscle damage which leads to decreased strength and endurance, while at the same time increasing exercise tolerance of clinical COPD symptom responsible for dyspnea and exercise intolerance.

Physical training helps to break the vicious cycle of dyspnea in patients, which consists in occurrence of a increasing sensation of dyspnea as a result of, inter alia, muscle conditioning, hindered muscle oxygen metabolism, increased oxygen need as well as increased respiratory effort burdening the patient during physical activity.

Current, limited scientific data on the topic suggests that a remedy for this issue alternative to physical exercise may be neuromuscular electrical stimulation (NMES) of the lower limbs. However, varying methodologies, different groups of patients partaking in the studies as well as the obtained results do provide contradictory conclusions with regard to the application of NMES in rehabilitation of patients with COPD.

The results of this study indicate that due to the application of traditional pulmonary rehabilitation in combination with neuromuscular electrical stimulation of 35 Hz frequency, a substantial increase of distance walked in the 6MWT in relation to the distance covered pre-study was observed. On the other hand, in the group where only traditional pulmonary rehabilitation methods were applied, no relevant improvement was noted with regard to the distance walked. Therefore, it could be concluded that applying a treatment protocol consisting of a combination of classical pulmonary rehabilitation with NMES of the lower limbs caused increased exercise tolerance in patients. The aforementioned increase in exercise tolerance does not correlate with improvements in selected spirometric (FVC, FEV1, FEV1%FVC i PEF) as well as gasometric (pO2 and pCO2) parameters. However, the observed improvement of exercise tolerance results from increased strength and endurance of skeletal muscles of lower limbs subjected to NMES therapy.

Vivodtzev et al. (2006) in a study evaluating the effects of pulmonary rehabilitation combined with NMES compared to standard pulmonary rehabilitation also demonstrated a significant increase in exercise tolerance measured with the 6MWT in the NMES group. Nevertheless, no statistically significant intergroup differences were noted in the 6MWT post-study ($p = 0.12$). Nine of the participants were treated with pulmonary rehabilitation and NMES, whereas the remaining 8 patients underwent pulmonary rehabilitation only. The NMES therapy was applied in 30 min sessions, 4 days a week, for a period of 4 weeks. A current of 35Hz frequency was applied only to the quadriceps muscles. The treatment plan included active mobilisation of the limbs performed by a physiotherapist with the use of a therapeutic table, training on a treadmill, workout engaging the upper limbs. It needs to be highlighted that the aforementioned study lasted a week longer, the number of total days remained similar and the NMES therapy was applied exclusively to the quadriceps muscles. Apart from the substantial effect of NMES combined with pulmonary rehab on exercise tolerance, a positive influence of this protocol was noted regarding maximal voluntary contraction of the quadriceps muscle in both of the groups, however, the increase in maximal voluntary contraction was twofold in the NMES group in comparison to the pulmonary rehab group.

In one of the earlier studies conducted by Neder et al. (2002), 15 patients with advanced COPD were observed, of whom 9 received home NMES treatment of 50Hz frequency and 6 were qualified to a group receiving standard medical treatment. The study lasted 6 weeks and consisted of 30 min sessions. The duration of NMES sessions amounted to 15 min in the first week and then 30 min in the following weeks. After the 6

weeks, NMES was applied also to the control group. The stimulation was applied to quadriceps muscles only. After the 6-week period, a significant improvement of exercise tolerance measured with a spiroergometric exercise test consisting of increased endurance and later onset of fatigue of lower limbs was observed in the NMES group.

In a randomized prospective study by Bourjeily et al. (2002), 9 patients were qualified to a group in which NMES of 50 Hz frequency was applied, while the other 9 patients were assigned to a control group in which electrical stimulation was used. Popliteus, quadriceps and calf muscles were stimulated in 20 min sessions, 3 times a week for 6 weeks. The patients were evaluated by the Incremental Shuttle Walk Test – exercise tolerance variables were assessed pre- and post-study. After the 6-week period, a significant improvement in exercise tolerance ($p = 0.007$) was noted in the NMES group.

Dal Corso et al. (2007) observed 17 patients with COPD. Nine patients received home NMES treatment of quadriceps muscles of 50Hz frequency 5 times a week for 6 weeks and 8 were assigned to a control group in which electrical stimulation was applied. In contradiction to the aforementioned studies, no significant changes were noted in the 6MWT regarding exercise tolerance of the patients. Moreover, no changes in muscle mass measured with dual energy X-ray absorptiometry and peak exercise tolerance (CPET) were observed.

Vivodtzev et al. (2012) lately conducted a study including 12 patients treated with NMES at home and 8 patients who underwent electrical stimulation. NMES was applied to the quadriceps muscle for 35 min and then to the calf muscle for 25 min with a frequency of 50 Hz for a period of 6 weeks, 5 times a week. Strength and endurance of the quadriceps muscles, cross-section of the quadriceps and calf muscles (CSA), exercise tolerance measured with the Endurance Shuttle Walk Test (ESWT) through selected cardiovascular and respiratory parameters were assessed. A significant increase of distance walked in the 6MWT in 6 of the NMES group patients was noted. The observed changes were correlated with a progressive increase of the current used for electrical stimulation. Moreover, a substantial increase ($p < 0.05$) of quadriceps and calf muscles in cross-section, as well as a significant increase in strength and endurance of the quadriceps muscles were registered ($p < 0.03$). The increase in strength of quadriceps muscles correlated with the frequency of the electrical current used for the NMES therapy and CSA of the thigh.

*Limitations of the study*

The fundamental limitation of the conducted study was the short period of observation of patients with COPD. The Polish National Health Fund provided financial support for a three-week inpatient pulmonary rehabilitation programme only. In contrast, as shown in the literature on the subject, the current studies on the benefits of NMES rehabilitation in COPD patients lasted around 4 to 6 weeks. Another important limitation of the study which may have affected the analysis of the achieved results was the low number of participants (15 patients in each group) due to the inclusion and exclusion criteria. Moreover, the NMES+PR group was significantly older than the PR group. The above mentioned constraints provide an incentive for researchers to conduct further studies on the effects of merging NMES with traditional pulmonary rehabilitation of COPD patients not only with regard to exercise tolerance, but also on the number of further hospitalizations due to exacerbation of COPD and median survival time.

## Summary

The effect of a protocol combining standard pulmonary rehabilitation (physical training) and neuromuscular electrical stimulation (NMES) of the lower limbs of 35 Hz frequency observed in this study may suggest that including NMES in a protocol for treating COPD results in improved exercise tolerance in patients in comparison to pulmonary rehabilitation only. Moreover, the obtained results suggest that NMES of 35 Hz frequency may be used as a supplemental form of pulmonary rehabilitation in COPD patients or in patients who cannot undertake physical training due to locomotor disorders.

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