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ORIGINAL ARTICLE

# NEUROMUSCULAR ELECTRICAL STIMULATION AND TRANSCUTANEOUS ELECTRICAL DIAPHRAGMATIC STIMULATION IN HOSPITALIZED PATIENTS WITH CHRONIC CARDIORESPIRATORY DISEASES: A RANDOMIZED CLINICAL TRIAL

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**KEYWORDS:**
**Electric Stimulation;**
**Muscle strength;**
**Functionality**

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**Objective:** To evaluate and compare the effects of two modalities of respiratory and peripheral muscle training in patients with chronic cardiorespiratory diseases. **Methodology:** A randomized clinical trial performed from September 2015 to December 2016 at the University Hospital of Canoas/RS, Brazil. Patients were randomized into 2 groups: Group I (Intervention) - transcutaneous electrical diaphragmatic stimulation (TEDS) and neuromuscular electrical stimulation (NMES) associated with voluntary contraction; and Group II (Conventional) - peripheral muscle training through mechanical resources and respiratory training through Power Breathe®. Both groups performed a respiratory and motor physiotherapy protocol standardized by the research team. The evaluation consisted of assessing respiratory muscle strength through MIP and MEP, peripheral muscle strength through the Medical Research Council (MRC) score and functionality through the Functional Independence Measure (FIM) scale. The level of significance was set at $p \leq 0.05$ and the analyzes were performed in the SPSS program version 21.0. **Results:** Twenty patients were included in the study, 11 belonging to Group I and 9 to Group II. The mean age was 68.7 ± 12.1 years, with a prevalence of the female gender (65%). The intervention group had a significant increase in MEP ($p = 0.011$), functional independence ($p = 0.024$), left palmar grip strength ($p = 0.017$) and peripheral muscle strength ($p = 0.012$). **Conclusion:** Both training modalities improved expiratory and peripheral muscle strength. In addition, there was only an increase in functional independence in the intervention group (NMES + TEDS).

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**INTRODUCTON**

The main chronic cardiorespiratory diseases are Heart Failure (HF) and Chronic Obstructive Pulmonary Disease (COPD), which directly influence the quality of life and survival of patients[1]. In addition to pulmonary involvement, many patients with COPD develop several systemic manifestations that result in decreased functional capacity, worsening dyspnea, decreased quality of life and increased mortality[2]. HF is a chronic disease in which patients present exercise intolerance which is directly associated with dyspnea symptoms, inspiratory muscle weakness, and muscle fatigue[3]. Chronic cardiorespiratory diseases have high prevalence and great impact on morbidity and mortality worldwide, and are currently considered a serious public health problem in epidemic proportions[3].

Muscle training is currently recommended in both chronic cardiorespiratory diseases, with the aim of increasing inspiratory and peripheral muscle strength, resulting in effects on the cardiovascular and respiratory systems[4]. Among the implemented techniques, conventional inspiratory muscle training and the use of electrotherapeutic resources, both for peripheral musculature and specific for the inspiratory musculature in the Transcutaneous Electrical Diaphragmatic Stimulation (TEDS) modality may help the respiratory musculature function and also improve muscle strength[5,6].

Neuromuscular electrical stimulation (NMES) is a technique that may be effective in these patients, since it implies a low overload to the cardiorespiratory system and has been used as an alternative to active exercise and mobilization in bedridden patients, demonstrating beneficial effects in patients with COPD and HF in the hospital scope6. TEDS promotes increased diaphragmatic muscle strength in patients with diaphragmatic dysfunctions through recruitment of muscle fibers, even if the stimulus is transcutaneously applied. This technique consists in applying pulse trains to the motor points of the phrenic nerve, which is responsible for the innervation of the diaphragmatic muscle7. The main objective is to prevent hypotrophy or reduced respiratory muscle strength and lung volumes through muscle contractions by electrical stimuli[8].

In a study in patients with exacerbated COPD, NMES was effective in preventing muscle atrophy and increasing muscle strength, also improving anabolic/catabolic balance[9]. Randomized controlled trials (RCTs) demonstrated the effects of inspiratory muscle training (IMT) on inspiratory muscle strength and muscle endurance, which resulted in improved peak oxygen consumption, dyspnea, and quality of life[10,11].

The aim of the present study was to evaluate and compare the effects of two modalities of respiratory and peripheral muscle training in patients with chronic cardiorespiratory diseases.

**METHODS**

**Study type**

Randomized clinical trial.

**Sample**

The sample consisted of individuals with chronic cardiorespiratory diseases hospitalized at the University Hospital of Canoas from September 2015 to December 2016. The calculation of the sample size was based on the results of Nordon-Craft[12]. The sample size estimated by the statistical program WinPepi version 11.43 was 84 patients, with a minimum effect size of 0.4 standard deviations between evaluations, significance level of 5%, and power of 90%.

**Elegibility criteria**

The study included individuals with a minimum age of 18 years and a maximum of 90 years, both genders, with chronic cardiorespiratory diseases, with a maximum of 48 hours of hospital stay, and after being invited and advised about the study signed the Free and Informed Consent Form (ICF), drafted according to the Guidelines and Norms Regulating research involving human beings, set forth in Resolution of the National Health Council No. 466/12. Patients who were hemodynamically unstable, obese (BMI>30kg/m$^2$), who had neuromuscular diseases, or who had lesions on the skin at the place to be electrostimulated were excluded from the study.

The patients were randomized via *Random Allocation Software* - version 2.0 (HTTP://www.randomization.com), into two groups: Group I (Intervention) and Group II (Control). The evaluation was performed before the first treatment and after the last session (on the day of hospital discharge), consisting of maximum inspiratory pressure (MIP) and maximal expiratory pressure (MEP) through a manovacuometer and dynamometry, and application of the Medical Research Council (MRC) and Functional Independence Measure (FIM) scales.

**Respiratory muscle strength**

Respiratory muscle strength was evaluated through a Medical Commercial manovacuometer (Famabras Brazilian industry). For verifying MIP, the patient was instructed to expire to the residual volume after a maximal inspiratory effort, while for MEP analysis the patient underwent a deep inspiration up to their total lung capacity and then a maximum expiratory effort until the residual volume. MEP and MIP were maintained under maximum pressure for at least two seconds and were tested three times, with an interval of two minutes between measurements, and with the highest measure achieved being recorded[13]. In this study, the MIP and MEP values found were compared to the values predicted by the equations of Neder et al.[14].

**Peripheral muscle strength**

The Medical Research Council (MRC) score was used to assess the peripheral muscle strength. The test consists of six bilateral, distal to proximal movements. The movements evaluated are: shoulder abduction, elbow flexion, wrist extension, hip flexion, knee extension and ankle dorsiflexion. Individuals who received total score between 48 and 37 points on the MRC scale were considered to have significant muscle weakness, while those who received 36 points or less were classified as severely weak[15].

The test for determining 1RM was performed as follows: a brief 5-minute warm-up with free active upper limb exercises (flexion/adduction/external rotation with elbow flexion), followed by a growing protocol where loads were increased progressively until obtaining the largest displaced load in total joint amplitude. Up to five attempts were made to determine the 1RM[16]

**Palm grip muscle strength**

Palm grip muscle strength was evaluated using an EH 101 E-clear DayHome® Digital Hand Dynamometer, measuring 19 x 12 cm, 1"(2.5 cm) with an LCD display weighing 0.1 kg. The patient was instructed to press the appliance with the greatest contraction possible for 30 seconds, and three repetitions were performed with intervals between them. The best result of the patient was collected for the database.[17] According to Hodgson et al.[18], scores less than 7 Kgf for women and 11 Kgf for men are considered as muscle weakness.

**Functional independence**

The Functional Independence Measurement (FIM)[12] scale was applied to evaluate functional independence. It is an evaluation tool used to quantify the functional independence of a recovering individual. Its minimum score is 18 and indicates total dependence of the individual, and its maximum score is 126, indicating complete functional independence. Daily life situations such as personal care, sphincter control, transfers, movement, communication, expression, social cognition and memory are evaluated by the items of this scale.

**Treatment protocols**

**Group I:** Muscle training through the NMES method associated with voluntary contraction - peripheral musculature, and TEDS - respiratory musculature. A low frequency current was used through FesVif 995 dual QUARK® equipment (Piracicaba, Brazil), where two 3x5cm carbon silicon electrodes were placed with conductive gel and fixed with micropore tape at the points to be electrostimulated. The patient was placed in dorsal decubitus position, bedside at 30° with their upper limbs extended along their body. The protocol was performed once a day.

For the TEDS application, diaphragmatic motor points were located at the sixth, seventh and eighth intercostal spaces and paraxiphoid region (application of pulse trains at the motor points of the phrenic nerve). For the parameters, a carrier frequency was used at 1,000Hz, a stimulation frequency of 50Hz, on and off time of two seconds, with the total stimulation time being thirty minutes. The current intensity was the maximum necessary to promote a visible and comfortable diaphragmatic contraction. The NMES was bilaterally applied to the upper and lower limbs, associating the voluntary contraction of the respective muscles: biceps brachii, deltoid, quadriceps and anterior tibialis. The electrodes were positioned in the muscular

belly of each muscle group. The parameters used were a carrier frequency at 1,000Hz, stimulation frequency of 50Hz, pulse width of 250μs, on time of ten seconds and off time of twenty seconds. The total stimulation time was 20 minutes for each muscle group (initial 10 minutes, with 1 minute per day of hospitalization added). The current intensity was the maximum needed to promote a visible and comfortable muscular contraction.

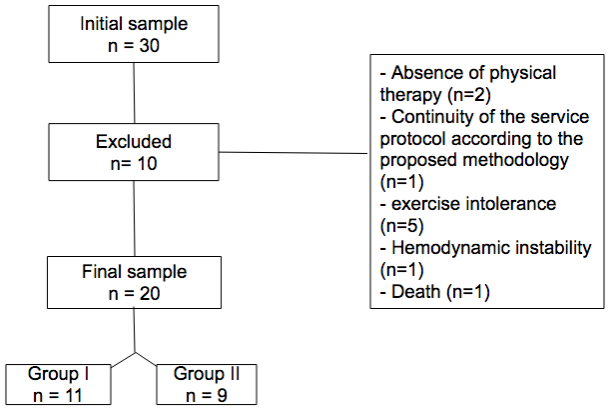
**Group II:** Conventional muscle training through kinesiotherapy with the aid of mechanical resources. The protocol was performed once a day with the patient sitting in a comfortable position. An ACTE® cycle ergometer (São Paulo/Brazil) was used for the lower limb muscle training, during which the patient performed a cycle of 20 revolutions per minute for 15 minutes. The 1RM test was used to determine the load on the upper limb during muscle training. The patient was instructed to perform the abduction and flexion movements of the shoulder joint and flex-extension of the elbow joint with dumbbells, with each movement being performed three series of ten repetitions with intervals of thirty seconds between them. Any sign of discomfort or fatigue observed by the therapist (desaturation, tachycardia, and tachypnea) caused the protocol to be interrupted for as long as necessary, so that the patient could recover.

Respiratory muscular training was performed through the POWERBreathe® exerciser from Brazil (Barueri/Brazil) once a day, in which the patient was instructed to perform 30 inspiratory efforts, and for every 10 inspiratory efforts they rested for one minute[19], using a load of 30% of MIP. Both groups performed standardized care, which consisted of motor physiotherapy (ambulation, active exercises of upper and lower limbs) and respiratory physiotherapy (reexpansive and/or unobstructive techniques) twice a day.

**Data analysis**

Quantitative variables were described by mean and standard deviation or median and amplitude of variation. Qualitative variables were described by absolute and relative frequencies. In order to compare the intragroup means, the paired Student's t-test was used, and the Wilcoxon test was performed in the case of asymmetry. To compare means between groups, the Student's t-test for independent samples was applied, and the Wilcoxon-Mann-Whitney test was used in case of asymmetry. For comparisons of intra and intergroup ratios, the McNemar and Pearson chi-square tests were applied, respectively.

**Figure 1.** Study flowchart




A 5% ($p \leq 0.05$) significance level was adopted and the analyzes were performed in the IBM® SPSS® Statistics Base program version 21.0/Brazil.

Ethical aspects of the study

This study was approved by the Ethics and Research Committee of the Lutheran University of Brazil (*ULBRA*) under opinion no. 1,375,884 and CAAE: 46056215.9.0000.5349.

**RESULTS**

Thirty (30) patients were included in the protocol between September 2015 and December 2016. Of these, 20 concluded the study, and the others were excluded due to the following criteria: absence of Physiotherapy prescription (n=2), non-continuity of the care protocol according to the proposed methodology (n=1), exercise intolerance (n=5), hemodynamic instability (n=1) and death (n=1), as shown in Figure 1. The mean age between the groups was 68.7 ± 12.1 years, with a higher prevalence of females (65 %). Table 1 shows the characterization of the sample, in which homogeneity is observed in relation to the demographic and anthropometric characteristics and number of visits between the groups.

**Table 1.** Sample data

| Variables | Total sample (n=20) | Intervention Group (n=11) | Control Group (n=9) | *p-value* |
|---|---|---|---|---|
| Age (years) - mean ± SD | 68.7 ± 12.1 | 72.3 ± 13.1 | 64.2 ± 9.5 | 0.142 |
| Gender - n(%) | | | | 0.374 |
| Female | 13 (65.0) | 6 (54.5) | 7 (77.8) | |
| Male | 7 (35.0) | 5 (45.5) | 2 (22.2) | |
| Weight (kg) - mean ± SD | 73.4 ± 19.8 | 71.9 ± 19.9 | 75.2 ± 20.8 | 0.721 |
| Height (m) - mean ± SD | 1.63 ± 0.08 | 1.64 ± 0.09 | 1.61 ± 0.07 | 0.398 |
| BMI (kg/m²) - mean ± SD | 27.4 ± 6.6 | 26.3 ± 5.9 | 28.7 ± 7.6 | 0.434 |
| No. of treatments - md (min – max) | 7.5 (3 – 26) | 7 (3 – 26) | 8 (3 – 12) | 0.656 |
| | | | | |

Legend: SD=standard deviation; BMI= Body mass Index; md=median; min=minimum value; max=maximum value

When intra-group comparisons were performed regarding respiratory muscle strength, a significant increase in MEP values was observed in both groups at hospital discharge (p = 0.011 and p = 0.047, respectively), and the increase was significant (p = 0.012) when the predicted percentage of the same variable was evaluated only in the Intervention group. Moreover, there was no increase regarding MIP in both groups when the initial and final evaluations were compared, while the differences were not statistically significant (p> 0.05) in the intergroup comparisons. Table 2 shows the performance of respiratory muscle strength between groups.

**Table 2.** Analysis of respiratory muscle strength

| Variables | Intervention Group (n=11) | Control Group (n=9) | *p-value* |
|---|---|---|---|
| | Median (Min – Max) | Median (Min – Max) | |
| MIP ($cmH_2O$) | | | |
| Initial | 50 (20 - 100) | 50 (25 – 150) | 0.656 |
| Final | 50 (25 – 150) | 50 (25 – 150) | 0.656 |
| *p* | 0.173 | 0.336 | |
| MEP ($cmH_2O$) | | | |
| Initial | 75 (15 – 125) | 50 (25 – 100) | 0.941 |
| Final | 80 (20 – 150) | 75 (25 – 150) | 0.941 |
| *p* | 0.011 | 0.047 | |
| MIP (predicted%) | | | |
| Initial | 73 (29.8 – 179) | 79.2 (35 – 249) | 0.941 |
| Final | 93.7 (37.3 – 218) | 83.7 (39.6 – 249) | 0.941 |
| *p* | 0.128 | 0.500 | |
| MEP (predicted%) | | | |
| Initial | 93.3 (24.3 – 156.8) | 97.1 (30.7 – 185) | 0.766 |
| Final | 111 (32.3 – 173) | 117 (47.4 – 231) | 0.882 |
| *p* | 0.012 | 0.066 | |

Legend: min=minimum value; max=maximum value

As shown in Table 3, it was only possible to observe a significant increase in muscle strength in the right hemiside in the control group (p = 0.003) when the peripheral muscle strength was analyzed through dynamometry (palm grip strength); however, the increase was only significant in the intervention group (p = 0.017) with respect to the left hemiside. When the

number of patients with muscle weakness (≤ 7 kgf for women and ≤11 kgf for men) was analyzed, no patient presented this condition in the right hemiside, and it was not possible to perform statistical tests on this hemiside.

**Table 3.** Analysis of palmar grip muscle strength

| Variables | Intervention Group (n=11) | Control Group (n=9) | *p-value* |
|---|---|---|---|
| | Mean ± SD | Mean ± SD | |
| Right Hemiside (kgf) | | | |
| Initial | 16.4 ± 4.5 | 16.8 ± 5.9 | 0.871 |
| Final | 17.8 ± 3.1 | 20.6 ± 6.7 | 0.235 |
| *p* | 0.102 | 0.003 | |
| Left Hemiside (kgf) | | | |
| Initial | 14.3 ± 4.7 | 17.2 ± 7.9 | 0.321 |
| Final | 17.0 ± 5.6 | 19.6 ± 8.5 | 0.435 |
| *p* | 0.017 | 0.063 | |
| Muscle weakness Right Hemiside (kgf) - n(%) | | | |
| Initial | 0 (0.0) | 0 (0.0) | - |
| Final | 0 (0.0) | 0 (0.0) | - |
| *p* | - | - | |
| Muscle weakness Left Hemiside (kgf) - n(%) | | | |
| Initial | 2 (18.2) | 1 (11.1) | 1.000 |
| Final | 1 (9.1) | 0 (0.0) | 1.000 |
| *p* | 1.000 | 1.000 | |

Legend: SD=standard deviation

When the muscle strength in the left hemiside was analyzed in the Intervention group, it can be observed that 2 patients initially presented muscular weakness, and after the intervention protocol, meaning in the final evaluation, only 1 remained with muscle weakness, but without significant difference (p = 1.000). Only 1 patient initially presented muscular weakness in the control group, but with recovery in the final evaluation, and without significant difference (p = 1.000). The differences were not statistically significant in the intergroup comparisons (p> 0.05).

Regarding the FIM and MRC scores, there was a significant increase in the functionality in the intragroup comparisons according to the FIM values in the Intervention group (p = 0.024), as presented in Table 4. Regarding the MRC score, the increase in muscle strength was significant in both groups (p = 0.012 and p = 0.010, respectively), while the differences were not statistically significant in the intergroup comparisons (p>0.05).

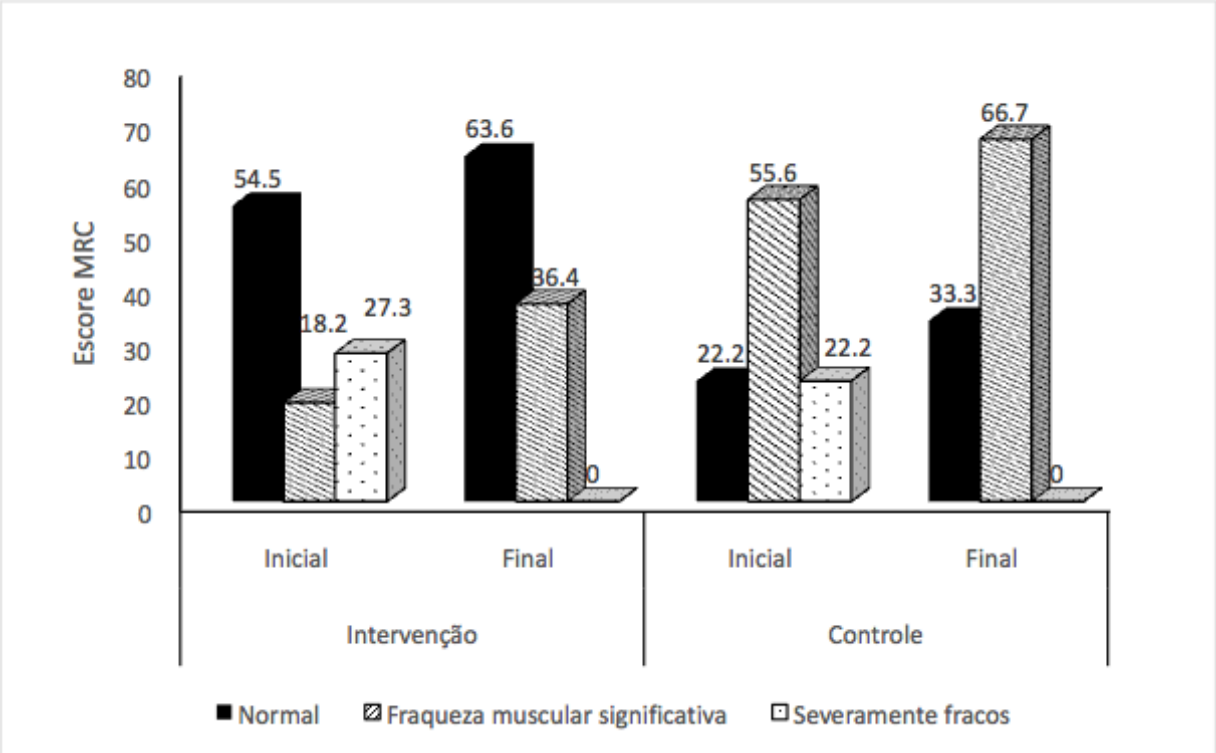
**Table 4** - Analysis of FIM and MRC scores.

| Variables | Intervention Group (n=11) | Control Group (n=9) | *p-value* |
|---|---|---|---|
| | Mean ± SD | Mean ± SD | |
| FIM | | | |
| Initial | 114.1 ± 15.2 | 120.2 ± 6.4 | 0.275 |
| Final | 119.0 ± 13.4 | 122.9 ± 3.8 | 0.412 |
| *p* | 0.024 | 0.161 | |
| MRC | | | |
| Initial | 47.7 ± 10.5 | 44.0 ± 7.4 | 0.382 |
| Final | 54.1 ± 8.0 | 50.3 ± 6.7 | 0.275 |
| *p* | 0.012 | 0.010 | |

Legend: SD=standard deviation; FIM=Functional Independence Measure; MRC=Medical Research Council.

As shown in Figure 2, despite the evident improvement in peripheral muscle strength in both groups according to the MRC score, where no patient presented severe weakness after the interventions, the differences were not significant in the intervention or control groups (p = 0.102 and p = 0.083, respectively). The differences were also not significant between the groups either at baseline or at the end (p = 0.190 and p = 0.370, respectively).

**Figure 2** - MRC (*Medical Research Council)* before and after the intervention in both groups.




**DISCUSSION**

In the present study, both groups had improved expiratory muscle strength, peripheral muscle strength and palm grip at the time of hospital discharge. There was an increase in functional independence only in the intervention group.

When intra-group comparisons were performed regarding respiratory muscle strength, a significant increase in MEP values could be observed in both groups, but only the intervention group presented a significant difference when the predicted percentage of this variable was evaluated, which corroborates a study that demonstrated an increase in expiratory force, noting that although TEDS is a specific resource for improving inspiratory muscle performance, the expiratory force may also be altered, most likely due to the overlap of the stimulated region, since the high density of the current in the electric field generated may have generated a sufficiently wide electric field to stimulate both compartments[20].

In the case of TEDS, the electric current may also stimulate the abdominal wall by the location of the electrodes, a fact which justifies the increase in expiratory muscle strength[20]. From the results of a study that evaluated pulmonary function and respiratory muscle strength, it can be concluded that these are impaired in patients with HF, and that those with functional class III have a significant decrease in MEP[21].

In this study we did not obtain an increase in MIP when comparing the initial and final evaluations in both groups, thus presenting a result that contrasts a study by Huang et al.[22] with a sample composed of patients diagnosed with COPD using Threshold IMT® during six consecutive weeks, five times a week, although with higher loads (75%-85% of MIP) and duration of the inferior therapy (ten minutes), wherein they found a 39% increase in MIP.

Borst et al.[23] analyzed the respiratory muscle dysfunction in patients with HF, and patients with class III presented

impairment of respiratory muscle strength for both MIP and MEP when compared to patients with class II, with a greater difference in MIP when compared to MEP. Evans et al.[24] found a decrease in MIP and MEP in patients with HF, with MIP more significant. The study demonstrates the correlation between MIP and cardiac indexes, suggesting that muscle perfusion is involved in the etiology of diseases related to respiratory muscles. According to Meyer et al.[25], the decrease in respiratory muscle strength and lung function may be a consequence of reduced muscle mass. This fact can also lead to capillary density and oxidative enzyme activity, which could be the main factor responsible for diaphragm atrophy.

In this study it was only possible to observe a significant increase in the palm grip muscle strength in the right hemiside in the control group, and this result can be justified because both groups did not show muscle weakness in the R hemiside. This corroborates a study by Emmanouilidis et al.[26], in which palm grip strength in the dominant hand presented higher values in relation to the non-dominant hand in a sample of COPD patients. According to the literature, palmar pressure force is approximately 10% higher in the dominant hand than in the non-dominant hand[18].

Thus, with muscular strength preserved in the R-hemiside and insertion in the control group, which has the use of mechanical resources as the treatment protocol (which are more usual), the patients only maintained increasing the palm grip muscle strength on the dominant side. Regarding left hemiside, the increase was only significant in the intervention group; a result that corroborates the efficacy of NMES in increasing peripheral muscle strength, since the left hemiside was not the dominant member of the study participants, but presented significant strength improvement.

Regarding the MRC score, the increase in peripheral muscle strength was significant in both groups, but the differences in the intergroup comparisons were not statistically significant. According to Jones S et al.[27] and Kaymaz D et al. [28], NMES may be an effective treatment for peripheral muscle weakness in adults with advanced progressive disease, and may be considered as an exercise treatment for use within rehabilitation programs.

In a systematic review with meta-analysis of randomized clinical trials[29], the beneficial effects of NMES were demonstrated in patients with heart failure, such as increased walking distance in the six-minute walk test (6MWT) and peripheral muscle strength similar to conventional aerobic exercise. An increase in maximal oxygen uptake was also observed when NMES treatment was compared to a control group (placebo NMES). Thus, it was concluded that NMES may be an alternative to conventional aerobic exercise for patients with heart failure who cannot perform exercise in a conventional way.

Despite the improvement in peripheral muscle strength in both groups according to the MRC score, in which no patient presented severe weakness after the interventions, the differences were not significant in the intervention and control groups. The limitation in exercise capacity in patients with chronic cardiorespiratory diseases has a multifactorial origin, being composed of factors involving ventilation, gas exchange, cardiovascular system and abnormalities of the peripheral musculature[30].

Considering skeletal muscle impairment in HF patients who present a decrease in type I and II fiber diameter, and pulmonary involvement in patients with COPD who tend to reduce their level of physical activity due to exertional dyspnea[2], in this case study it was possible to observe that the implementation of a muscle training protocol may result in increased peripheral strength, corroborating the decrease in the diagnosis of severe weakness in patients with chronic cardiorespiratory diseases.

Regarding the FIM score in the intragroup comparison, there was a significant increase in functionality in the Intervention group. This result is according to another study in which NMES was used as an alternative to active exercise and showed beneficial effects in patients with COPD and HF in the hospital environment, so that the use of new technologies such as NMES stands out both in maintenance and in the gain of mass and muscular strength, with consequent improvement in the functionality of patients in the hospital environment[31]. Increased muscle strength of the lower limbs, improved exercise capacity and functional capacity after NMES in COPD patients were observed in a study by increasing the distance walked on the 6MWT[32].

The main limitation of this study is due to the limited sample size, which did not reach the estimated sample estimate, even though results presenting statistical relevance are of great importance to the continuity of the present study in order to increase the sample size. Another limiting factor was the number of exclusions due to non-continuity of the care protocol according to the proposed methodology and by exercise intolerance.

**CONCLUSION**

In the present study, it was possible to observe improvement in the expiratory and peripheral muscular strength in both groups and an increase in the functional capacity only in the intervention group. Thus, we can conclude that in addition to conventional muscle training, the use of electrotherapeutic resources such as NMES and TEDS may be an effective treatment strategy in hospital-based cardiopulmonary rehabilitation programs for respiratory and peripheral muscle training in patients with chronic cardiorespiratory diseases.

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