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THE EFFECTS OF COMBINED PHYSICAL PROCEDURES ON THE FUNCTIONAL STATUS OF PATIENTS WITH DIABETIC POLYNEUROPATHY

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Abstract
Introduction: Diabetic polyneuropathy is a common chronic complication in patients with diabetes mellitus. This study aimed to determine the importance of applied physical procedures on the functional status in diabetic polyneuropathy patients in comparison to the group of respondents with the applied alpha-lipoic acid.

Materials and Methods: 60 subjects were divided into two groups: group A - diabetic polyneuropathy patient’s treatment with physical procedures; and group B – diabetic polyneuropathy patient’s treatment with alpha-lipoic acid. The study protocol implied that the study has lasted for three diagnostic and therapeutic cycles, each lasting for 16 days with the time between cycles of 6 weeks.

Results: Manual muscle test, range of motion, Michigan Neuropathy Screening Instrument and Berg balance scale values showed statistically significant improvement at the end of testing the group A respondents, while in the group B respondents there was not any improvement shown.

Conclusions: The application of the combined physical procedures shows clear benefit for improvement of muscle strength and mobility of the ankle joint in respondents with diabetic polyneuropathy.

**Keywords:** diabetic polyneuropathy, physical procedures, alpha-lipoic acid
Abstrakt

Uvod: Djabetesna polineuropatija je česta hronična, komplikacija kod pacijenata sa dijabetes melitusom. Cilj ove studije bio je da se utvrdi značaj primenjenih fizikalnih postupaka na funkcionalni status pacijenata sa dijabetesnom polineuropatijom u poređenju sa grupom ispitanika sa primenjenom alfa-lipoičnom kiselinom.

Materijal i metode: 60 ispitanika je podeljeno u dve grupe: Grupa A - lečenje pacijenata sa dijabetičkom polineuropatijom fizičkim postupcima; i B grupa - lečenje pacijenta sa dijabetičnom polineuropatijom alfa-lipoičnom kiselinom. Protokol studije podrazumijeva da je studija sprovedena tokom tri dijagnostička i terapijska ciklusa, od kojih je svaki trajao 16 dana, a period između ciklusa bio je 6 nedelja.

Rezultati: Manuelni mišićni test, obim pokreta, Michigan Neuropathy Screening Instrument i Bergove skale ravnoteže pokazale su statistički značajno poboljšanje na kraju testiranja ispitanika grupe A, dok kod ispitanika grupe B nije pokazano poboljšanje.

Zaključak: Primena kombinovane fizikalne terapije pozitivno utiče na poboljšanje mišićne snage i pokretljivosti skočnog zgloba kod pacijenata sa dijabetesnom polineuropatijom.

Ključne reči: dijabetička polineuropatija, fizikalni postupci, alfa-lipoična kiselina
Introduction

The common chronic complication in patients with diabetes mellitus (DM) (in more than 50% it occurs after 25 years’ disease duration) is diabetic polyneuropathy (DPN) or distal sensorimotor polyneuropathy (DSP) [1]. There are approximately 600 000 people in Serbia suffering from DM or 8.2% of the population (out of which 95% of that population accounts for patients with type 2 diabetes), and 5.9% has diabetic neuropathy [2]. There is an increased risk of deformity, ulceration and amputation in these patients [3].

DSP leads to postural balance disorders and increased susceptibility to falls [4]. Deterioration of motor nerve fibers weakens the intensity of stimulation of the muscles which become hypotrophic. Injuries related to falls in these patients are 15 times more often compared to healthy respondents of the same age [5]. Also, muscle weakness and limitations of mobility in the ankles and the small joints of the foot occur over time. These disorders result in functional foot impairment, changing pressure points on the foot and the creation of ulceration [6]. Even 30% of diabetics have limited movements of small or large joints. Limited mobility in the ankle joint and metatarsophalangeal (MTPH) joint is caused by thickening and shortening of the ligaments and tendons, leading to increased plantar pressure of the forefoot [7]. Muscle weakness mainly dominates in the distal segments of the lower limb, thus threatening gait and other activities in daily life [8, 9].

This study aimed to determine the importance of applied physical procedures on muscle strength and range of motion (ROM) in patients with DPN in comparison to the group of respondents with the applied alpha-lipoic acid (control group). It also aimed to determine if there is a statistically significant difference in the values of Michigan test for examining the neuropathy at the beginning and at the end of the study, between the group of respondents who underwent the combined physical therapy and the group of respondents who took alpha-lipoic acid.
Materials and Methods

This prospective, the study was done on 60 randomized patients, older than 18 years, at the Center for Physical Medicine and Rehabilitation, Clinical Center, Kragujevac, and was approved by the local Ethics Committee of the Clinical Center Kragujevac. This study is part of the previously published studies by Grbovic et al. [10-11].

Inclusion criteria were following: DPN with timeframe longer than 2 months with DPN signs and symptoms defined as pain, muscular weakness, paresthesia, hyperesthesia to anaesthesia and electromyoneurographic (EMNG) findings; without changes in antidiabetic treatment for at least of 6 months and who signed consent for participation in the study.

Patients who had following exclusion criteria were excluded from the study: deficiency of vitamin B12, moderate/severe use of alcohol, chronic kidney disease, dysfunction of the thyroid gland, any state of immunodeficiency, diseases of systemic connective tissues, severe damage of the liver, any kind of cerebrovascular ischemia, decompensation of heart failure, presence of acute coronary syndrome in the previous 6 months, uncontrolled high blood pressure (defined as values of systolic blood pressure higher than 160 mmHg and diastolic blood pressure higher than 80 mmHg), chemotherapy in the last decade, severe polytrauma or state after it, use of peripheral nerves damaging drugs (e.g. nitrofurantoin, paclitaxel, vincristine, cisplatin, indomethacin, emetine, streptomycin, dapsone, chloroquine, ethionamide, isoniazid, carbamazepine, phenytoin, hydralazine, metronidazole, amiodarone,); any sort of contraindication for the usage any of the arranged physical therapy agents (acute infectious disease, fever, pregnancy, malignancy, any acute vital organ failure, the presence of metal in body); or hypersensitivity to galactose, alpha-lipoic acid, Lapp lactose deficiency or glucose-galactose malabsorption.

The investigation was organized during 3 cycles of diagnostics and therapeutics, each lasting for 16 days with the timeframe between cycles of 6 ± 1 week (total study duration of six months).

Each subject was randomized into two groups of 30 patients each, with diabetes mellitus type 2 and DSMP, in light of clinical indications and signs, just as the parameters of EMNG discoveries. Utilizing computer randomization, every patient was arbitrarily assigned to one group (therapeutical arms): Group A or B.
Group A was treated with combined physical procedures that included pulsed electromagnetic field, exercise, stable galvanization and transcutaneous electrical nerve stimulation while group B was treated with alpha-lipoic acid as per conditions specified in the marketing license in Serbia. Detailed methods applied in these groups can be found in our previously published study [10].

On admission and after completion of the last diagnostical-therapeutical cycle (after 6 months), the EMNG of the lower extremities, Michigan Neuropathy Screening Instrument (MNSI), evaluation of functionality (manual muscle test - MMT and of range of motion - ROM) and Berg balance scale were done. EMNG examination was made with Medtronic Keypoint device (Denmark, Skovlunde, www.medtronic.com). MNSI comprises two parts. The first part is a questionnaire that consisted of 15 questions, and the second part included the examination of the patient, as follows: inspection of the foot (to determine if there are any changes on the feet, ulcerations, infections, calluses, deformities, etc.), the examination of muscle tendon reflexes, vibratory sensibility testing and examination of monofilaments. The score ranged from 0 (best result) to 10 (worst result) and the score is the result of marks for both legs. Diagnosis of diabetic peripheral neuropathy with a physical examination score higher than 2.5 was established [12]. The examined MMT are m. triceps surae, m. peroneus longus, m. tibialis posterior, m. tibialis anterior and m. peroneus brevis, based on factors of manual loading and gravity. Gradation of muscle strength was performed according to Kendall, namely: 10 points = grade 5 on MMT; 9 = 4+; 8 = 4; 7 = 4--; 6 = 3+; 5 = 3; 4 = 3--; 3 = 2+; 2 = 2; 1 = 2--; 0 = 0), whereby grade 5 matches the strength of a normal muscle which can make a full range of motion against gravity and a maximum of manual loading; grade 0 means that during the attempt of a movement, a muscle does not show any visible or palpation sensitive contraction [13].

ROM was tested by dorsal flexion, plantar flexion, eversion and inversion of the foot. The range of motions was measured by a manual goniometer. Active dorsal flexion is normally up to 30°, plantar flexion to 45°, inversion to 35° and eversion up to 10° [14].

Berg balance scale examined the balance in elderly people with vestibular disorders, assessing it through specific functional tasks. This is a valid instrument which is used to evaluate the efficiency of treatment, the quantitative description of the function in the clinical practice as well as the researches. The scale includes 14 functional tasks for assessing the balance in adults in clinical conditions with grades from 0 (the worst result) to
4 (the best result). The full value of 41 - 56 indicates a low level of the risk of falling; 21 - 40 = medium level of the risk of falling; 0 - 20 = high level of the risk of falling. 8 - points difference is enough to show a change in function between the two measurements [15].

Distribution of all continuous variables was determined, using the Shapiro-Wilk test, the median value, minimum and maximum values, standard deviation (SD). Paired T-test was used for comparison of the mean values of continuous variables within the tested groups with normal distribution or Wilcoxon's test of matched pairs. Independent T-test or the Mann-Whitney test for datasets without a normal distribution were used for comparison of differences between the groups. For comparison of the frequency (incidence) of categorical (dichotomous) variables, the $\chi^2$ test was used. P values less than 0.05 were considered as statistically significant. SPSS version 20.0 was used for statistical calculations. The statistics procedures were the same as in our previously published study [10-11].

**Results**

The baseline characteristics of respondents in group A and group B are given in Table 1. Since this study is part of previously published studies by Grbovic et al., the detailed baseline characteristics of respondents from group A and group B are given those manuscripts [10-11].

MNSI showed statistically significant improvement at the end of testing the group A respondents (p<0.001), while in the group B respondents there was not any improvement shown (p=0.169). Berg balance scale examination showed that there was a statistically significant improvement at the end of testing the group A respondents (p=0.001), while in the group B there was no significant improvement shown (p≈1.000).

At the end of the treatment, there was a significant improvement of the dorsal flexion (p<0.001) and plantar flexion (p=0.022) in the group A respondents. At the start of the study, no significant differences were observed in the measures in the range of motion (homogeneous in dorsal flexion, $p=0.884$; plantar flexion $p=0.557$; inversion and eversion of the foot $p≈1.000$). At the end of the intervention, the A group respondents and B group respondents also did not significantly differ in the observed measures in the range of motion (they were homogeneous in dorsal flexion, $p=0.055$; plantar flexion $p≈1.000$, inversion of the foot $p=0.634$ and eversion of the foot $p≈1.000$) (Table 2.).
Table 3. shows the analyzed muscles of the lower extremities. After the intervention, the A group respondents showed significant improvement in muscle strength of *m. tibialis anterior* (*p*=0.002); *m. tibialis posterior* (*p*<0.001); *m. triceps surae* (*p*=0.004) and *m. peronei* (*p*<0.001). At the beginning of the study, the group A and group B respondents were not significantly different in the followed parameters (homogeneous in muscle strength of *m. tibialis anterior* *p*=0.55; *m. tibialis posterior* *p*=0.32; and *m. triceps surae* *p*=0.915), except in muscle strength of *m. peronei* (*p*=0.024). At the end of the intervention, the group A respondents and group B respondents did not differ significantly in muscle strength of observed muscles (anterior *m. tibialis* *p*=0.276; *m. tibialis posterior* *p*=0.457; *m. triceps surae* *p*=0.58; *m. peronei* *p*=0.098).
Discussion

Our study shows the clear benefits of the combined application of physical procedures for improvement of muscle strength and mobility of the ankle joint in respondents with DPN.

The 2014 study indicated the importance of the implementation of exercise in patients with diabetic neuropathy. The testing included 55 respondents with DPN, 26 of which had exercise (2x per week, 12 weeks), while 29 respondents were the control group. After 12 and 24 weeks it led to an improvement in foot functionalities in the intervention group [16].

After a 10-week exercise program, the 2012 study showed a statistically significant improvement in neuropathic symptoms measured by MNSI (p=0.01), while there was no improvement made in electroneurographic parameters of n. peroneus, n. tibialis and n. suralis. This study was completed by 17 respondents with DPN (8 males/9 females; age 58.4±5.98; diabetes duration of 12.4±12.2 years) or 63.3% of respondents who started the program [17], which correlates with the results obtained in our study. However, our study also showed improvement not only in manual muscle test but also in some electroneurographic parameters [10] which could be a results of combined effect of different physical procedures, rather than just exercises used in the study by Kluding et al. Results of the tests conducted in the Bossi et al. study on the effect of pulsed electromagnetic fields in the treatment of diabetic neuropathy, which included 101 respondents (the first group consisting of 50 respondents with the applied pulse magnetic field and the second group consisting of 51 respondents who received placebo). MNSI was being examined and at the end of the study (3 months later) showed no significant differences between the two groups [18]. Since this study used only the pulse magnetic field and we used multiple physical procedures, again we could hypothesize that improvement in MNSI score in our study is the result of the combined physical procedures.

The 2007 study examined the effect of alpha-lipoic acid in diabetic neuropathy. It included 95 respondents with DPN. The first group included 52 respondents who had been receiving alpha-lipoic acid (600 mg, parenterally) for 14 days, and the second group included 43 respondents with placebo treatment applied. MNSI was examined 7 and 14 days later. There were statistically significant reduced values of Michigan questionnaire for
testing neuropathy in a group of respondents with the applied alpha-lipoic acid (p<0.01) [19]. In our study, we found that multiple physical procedures had a significant effect on MNSI score, however not for patients treated with alpha-lipoic acid. However, patients treated with alpha-lipoic acid had significantly lower MNSI score before starting with the treatment than patients treated with physical procedures.

Songet al. study indicated the importance of the application of exercise on balance improvement in patients with DPN. After the 8-week exercise implementation (60 min, 2x per week), a statistically significant improvement in balance was made (BBS, p <0.05)[20]. As in this study, our study showed that in patients treated with physical procedures a statistically significant improvement was made in postural equipoise and balance measured by Berg's balance scale (p=0.001). The group B respondents showed no statistically significant improvements.

Other study indicated the weakness of the muscles of the foot and limited mobility of the joints of the foot and ankle joint in patients with DPN, which later become risk factors for foot deformities and ulceration [21]. At the end of our study, the clear effects of the combined application of physical procedures were shown on increasing range of motion in ankles (dorsal and plantar flexion), while in the second group such an effect was not achieved.

The Anderson et al. study was also dealing with the examination of muscle strength in patients with DM. The study involved two respondent groups, 36 respondents each (the first group consisted of those suffering from DM, the second control group consisted of healthy respondents). Muscle strength was determined by using an isokinetic dynamometer. At the end of the study, it was concluded that the first group respondents have the decreased muscle strength of flexor and extensor of knee, ankle, wrist and elbow joint and that it is associated with neuropathy [22]. Importance of exercise applied in patients with DPN was confirmed in the Francia et al. study. The study included 26 patients with DM, and 17 patients were the control group. After 12 weeks of an exercise program, there has been an increase in muscle strength, mobility and walking speed, thus preventing the occurrence of disabilities [23].

Similarly to the results of these studies, in our study, at the end of the treatment, we found a significant increase in muscle strength of tested muscles (m. tibialis anterior, m.
*tibialis posterior, m. triceps surae* and *m. peronei*), while in the group B respondents with the alpha-lipoic acid applied there was no improvement made.

**Conclusion**

The application of the combined physical procedures (pulsed electromagnetic field, exercise, stable galvanization and transcutaneous electrical nerve stimulation) shows a clear benefit of the combined application of physical procedures for improvement of muscle strength and mobility of the ankle joint in respondents with DPN. This is reflected in a significant improvement of neurological symptoms and signs (MNSI), while the importance of applied physical procedures shows the clear effects in strengthening muscles and increasing mobility of the respondents as well as in improving postural balance.

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**Conflict of interest**

The authors declare that there are no conflicts of interest.

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Table 1. Characteristics of the patients with DPN [10-11].

| Characteristic           | Group A (n = 30) | Group B (n = 30) | p-value     |
|--------------------------|------------------|------------------|-------------|
|                          | Male             | Female           |             |
| Sex                      | 11 (36.67%)      | 19 (63.33%)      | 0.598<sup>a</sup> |
| Heredity for DM          | Yes              | No               | ≈1.000<sup>a</sup> |
| Age (years)              | 63.17±7.68       | 62.77±8.35       | 0.09<sup>c</sup> |
| Duration of diabetes (yr)| 12.22±7.58       | 11.70±5.75       | 0.09<sup>c</sup> |
| HbA1c (%)                | 7.80±1.87        | 7.30±1.21        | 0.403<sup>c</sup> |
| MNSI questionnaire       | 8.57±1.23        | 7.83±0.79        | 0.008<sup>c*</sup> |
| MNSI examination         | Before           | After            | p-value     |
|                          | 6.32±0.23        | 5.95±0.21        | <0.001<sup>b*</sup> |
|                          | 5.82±0.23        | 5.87±0.20        | 0.169<sup>b</sup> |
|                          | ≈1.000<sup>b</sup> | 0.244<sup>c</sup> | 0.34<sup>c</sup> |
| Berg balance scale       | Before           | After            | p-value     |
|                          | 43.23±1.28       | 43.60±1.13       | 0.244<sup>c</sup> |
|                          | 43.87±1.28       | 44.67±1.56       | ≈1.000<sup>b</sup> |

Statistical test used: a – Chi-square test; b – Paired Sample T-test; c – Independent Sample T-test; * significance at p-value < 0.05
Table 2. Range of motion in the ankle joint

| Parameter                  | Group A (n = 30) | Group B (n = 30) | p-value |
|----------------------------|-----------------|-----------------|--------|
| Ankle dorsal flexion       |                 |                 |        |
| Before                     | 16.33±4.90      | 16.17±3.87      | 0.884<sup>b</sup> |
| After                      | 19.50±1.52      | 18.50±2.33      | 0.055<sup>b</sup> |
| p-value                    | <0.001<sup>a,</sup>* | 0.659<sup>a</sup> |        |
| Ankle plantar flexion      |                 |                 |        |
| Before                     | 40.50±9.50      | 41.83±7.93      | 0.557<sup>b</sup> |
| After                      | 42.17±6.39      | 42.17±7.39      | ≈1.000<sup>b</sup> |
| p-value                    | 0.022<sup>a,</sup>* | ≈1.000<sup>a</sup> |        |
| Foot inversion             |                 |                 |        |
| Before                     | 22.67±6.40      | 22.67±6.12      | ≈1.000<sup>b</sup> |
| After                      | 23.33±3.56      | 22.83±4.49      | 0.634<sup>b</sup> |
| p-value                    | 0.058<sup>a</sup> | 0.083<sup>a</sup> |        |
| Foot eversion              |                 |                 |        |
| Before                     | 4.33±1.73       | 4.33±1.73       | ≈1.000<sup>b</sup> |
| After                      | 4.67±1.27       | 4.67±1.27       | ≈1.000<sup>b</sup> |
| p-value                    | ≈1.000<sup>a</sup> | ≈1.000<sup>a</sup> |        |

The statistical test used: a – Paired Sample T-test; b – Independent Sample T-test;

* significance at p-value < 0.05
Table 3. Manual muscle test of muscles of the lower extremities

| Parameter                     | Group A (n = 30) | Group B (n = 30) | p-value |
|-------------------------------|-----------------|-----------------|---------|
| *m.triceps surae*             |                 |                 |         |
| Before                        | 4.47±1.14       | 4.47±0.97       | 0.276 b |
| After                         | 5.00±1.29       | 5.03±1.13       | 0.915 b |
| p-value                       | **0.004 a**     | 0.742 a         |         |
| *m.tibialis posterior*        |                 |                 |         |
| Before                        | 4.60±0.97       | 4.80±1.09       | 0.457 b |
| After                         | 5.03±1.00       | 5.03±1.29       | 0.32 b  |
| p-value                       | **0.001 a**     | 0.321 a         |         |
| *m.tibialis anterior*         |                 |                 |         |
| Before                        | 5.20±1.32       | 5.40±1.43       | 0.58 b  |
| After                         | 5.40±1.38       | 5.63±1.61       | 0.55 b  |
| p-value                       | **0.002 a**     | 0.096 a         |         |
| *m.peroneus longus et brevis* |                 |                 |         |
| Before                        | 5.00±1.39       | 4.47±1.04       | 0.098 b |
| After                         | 5.73±1.64       | 4.83±1.34       | 0.024 b |
| p-value                       | <**0.001 a**    | 0.419 a         |         |

Statistical test used: a – Paired Sample T-test; b – Independent Sample T-test;
* significance at p-value < 0.05

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