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Original Scientific Paper

EFFECT OF INTRADIALYTIC THERAPEUTIC EXERCISES AND ELECTRICAL STIMULATION ON LEG FUNCTIONAL ABILITY, DIALYSIS EFFICACY AND INTRADIALYTIC HYPOTENSION IN PATIENTS ON CHRONIC HEMODIALYSIS

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SUMMARY – Chronic inflammation and protein energy malnutrition in patients on hemodialysis lead to decrease in muscle mass and impaired functional ability. Our goal was to evaluate the effect of a combination of electrical stimulation (ES) with intradialytic therapeutic exercises on dialysis efficacy, arterial blood pressure, and functional ability of lower extremities. The study involved 35 patients who were on chronic hemodialysis. The study consisted of two phases. During the first month, no intervention was performed. It was followed by a therapeutic program combining intradialytic resistance exercises with ES on quadriceps muscle, which was performed 3 times a week for 3 months. Functional tests for lower extremity and body composition analysis were obtained at baseline and at the end of the study. Arterial pressure, dialysis efficacy and laboratory parameters were monitored. Functional tests showed significant improvement after the intervention. A significant positive correlation was found in patients who had shown improvement in functional tests, with less intradialytic episodes of hypotension and improvement in dialysis efficacy. This study found a positive effect of combining resistance exercises and ES on dialysis efficacy and functional ability of lower extremities in patients on chronic hemodialysis.

Key words: *Hemodialysis; Intradialytic exercises; Dialysis efficacy; Intradialytic hypotension; Leg functional ability; Electrical stimulation*

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Introduction

Chronic kidney disease is a growing problem worldwide, with the number of patients receiving renal replacement therapy (dialysis or kidney transplantation) exceeding 2.5 million and it is projected that the number will be doubled by 2030[1]. In patients with chronic kidney disease, muscle mass is reduced due to the severe chronic condition often associated with numerous comorbidities, as well as protein energy malnutrition[2]. Poor physical performance and sedentary behavior lead to impairment of the cardiovascular system, which eventually contributes to the increased mortality of these patients[3]. In general, there are numerous positive effects of therapeutic exercises. It is known that electrical stimulation (ES) can improve muscle size and strength[4-6] and accelerates venous circulation of lower extremities[7,8]. Resistance training can significantly increase muscular strength[9]. A very important aspect of intradialytic exercises is improvement of muscle strength and functional capacity[10], as well as positive impact on dialysis efficacy[11-14] and arterial blood pressure[15,16]. A recent meta-analysis has revealed that most of the research used stationary cycling as a way of exercising[11], but it is usually inaccessible at most hemodialysis units, which is why we decided to design a different rehabilitation program. An animal model by Sun *et al.* confirmed the results on the effectiveness of resistance exercises[17], as well as on the skeletal muscle myostatin expression to be increased in uremia but falling with increase in work load. In other words, work overload seems to correct uremic muscle atrophy[17]. Moraes *et al.* showed a decrease in inflammatory marker levels (C-reactive protein [CRP], ICAM-1, VCAM-1) in hemodialysis patients after 6 months of resistance exercise program[18].

The aim of our study was to evaluate the effect of combining quadriceps ES with resistance therapeutic exercises performed during hemodialysis on functional ability of lower extremities, bioimpedance, dialysis efficacy, and arterial blood pressure in patients on chronic hemodialysis. It can be assumed that this combination may have positive effects on these outcomes.

Patients and Methods

Study design

This was a prospective, non-blinded, single-center, pre- and post-interventional study where the participants served as their own controls. The study was divided in two phases. In the first phase, which lasted for one month, there was no specific intervention and it was used to collect relevant baseline parameters. In the next, second phase, which lasted for 3 months, patients performed resistance exercises for lower extremities in combination with ES of both quadriceps muscles during the process of hemodialysis. The before mentioned parameters from the first and second phase were compared.

Tests of functional ability of lower extremities, as well as body composition analysis by bioimpedance were performed at baseline and at the end of the intervention part. The overall flow-chart of the study design is shown in Figure 1.

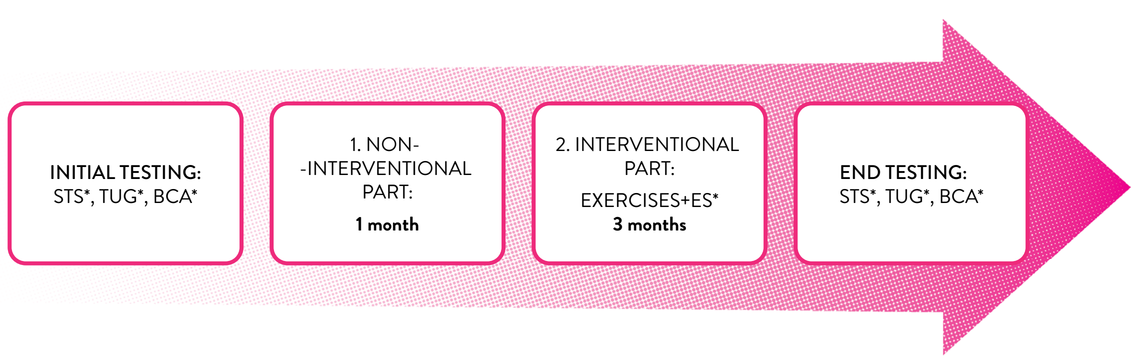

Fig. 1. Study design flow-chart.

STS = sit-to-stand test; TUG = timed up and go test; BCA = body composition analysis; ES = electrical stimulation

Setting

The study was conducted in patients who were on chronic hemodialysis in Dialysis Unit, Department of Nephrology, Sestre milosrdnice University Hospital Center in Zagreb, Croatia. It was performed in collaboration with the Department of Rheumatology, Physical and Rehabilitation Medicine of the same hospital. The study was conducted from March until the end of June 2018. The study was conducted after approval of the institutional Ethics Committee and in concordance with the Declaration of Helsinki[19].

Patients

Thirty-five patients (17 female, 18 male) who met the inclusion and exclusion criteria and agreed to take part in the study were enrolled. Their median age was 68 (range from 33 to 90) years. Inclusion criteria were: subjects aged 18 years and above, as well as dialysis vintage for at least 6 months. Exclusion criteria were: lower extremity amputation, myocardial infarction or coronary bypass graft surgery in the last 3 months, cerebral vascular incident or transient ischemic attack in the last 3 months, thrombophlebitis, pulmonary or heart disease that requires oxygen therapy, heart pacemaker, subdiaphragmatic electrical device, current immunosuppressive therapy, acute infectious disease or acute disease of the locomotor system in the previous month. All patients signed the informed consent prior to study start.

Intervention

Exercise program was supervised by a physiotherapist. All exercises were performed for 30 minutes in a supine position. The exercise program started with breathing exercises and simple warm-up exercises for lower extremities, followed by resistance exercise using 1 kg weights affixed around both ankles. Each exercise was performed in 2 series with 6-8 repetitions, depending on patient ability. After 30 minutes of workout, ES was applied on both quadriceps muscles for 15 minutes (EV-906 TENS/EMS, Everyway Medical Instruments CO., Ltd., New Taipei City, Taiwan). Silicone-rubber electrodes, size 4x4 cm, were placed over gel and affixed with Micropore surgical tape on the distal part of *m. vastus medialis* and middle-lateral part of *m. vastus lateralis* of both legs. Stimulation current was increased up to patient tolerability and visible muscle contractions (occurring typically at a current of 20 to 40 mA). The highest tolerable current frequency was applied ranging from 20 Hz to 80 Hz, with pulse width of 300 μs. Contraction phase lasted for 10 s, while relaxation period lasted for 20 s. Patients were encouraged to make voluntary contraction of quadriceps during ES contraction phase. Therapeutic exercises and ES were performed during the initial 2 hours of hemodialysis.

Assessment

At baseline, tests for functional ability of lower extremities, timed up and go (TUG) test[20] and 30-second sit-to-stand (STS) test[21], were performed in each patient. Both of these clinical tests are widely used in clinical trials, and are explained in detail elsewhere[20,21]. Briefly, TUG test is performed in a way that patient from the starting position sitting on the chair on command stands up and walks ahead for 3 meters, turns around, walks back to the chair and sits down, while the time to perform the test is recorded. In 30-second STS test, starting position is seated, too, and on command the patient should do as many as possible full stands and sits within 30 seconds. Body composition was measured by a bioimpedance measuring device (Body Composition Monitor (BCM), Fresenius Medical Care GmbH, Germany), where muscle mass was expressed as the lean tissue index (LTI) defined as a quotient of lean mass and square of height.

The BCM employs bioimpedance spectroscopy techniques. It measures body composition at 50 frequencies over a range from 5 to 1000 kHz.

Throughout the study, hemodialysis parameters were measured, i.e., arterial blood pressure before, during and after hemodialysis, as well as dialysis efficacy (Kt/v) and urea reduction ratio (URR), which were performed 3 times a week. Calculations of Kt/v and URR as measures of dialysis efficacy are well known in the literature[22]. Laboratory parameters analyzed throughout the study were CRP (mg/L), albumin (g/L), hemoglobin (g/L), phosphate (mmol/L), and creatinine (μmol/L).

Study size

Participation was offered to every patient attending chronic hemodialysis in Dialysis Unit, Sestre milosrdnice University Hospital Center. Patients who met the inclusion and exclusion criteria and agreed to take part in the study were enrolled (N=35).

Statistical analysis

We included demographic, clinical and laboratory data, as well as dialysis adequacy parameters. All patients were exposed to the same treatment (as described above), and baseline and end-study results were compared.

Differences in repeated measurements (at different time points) were tested using paired samples T-test and Wilcoxon test, depending on the normality of distribution. Correlations were assessed using Pearson correlation for normally distributed and Spearman rank correlation test for non-normally distributed variables. Associations were evaluated using multivariate logistic regression. Independent variables in logistic models were selected for inclusion using clinical rational judgment.

End-study values of STS, TUG and LTI were used as dependent variables in regression models. We constructed several models which included potential confounders, modifiers and predictors. A two-tailed $p<0.05$ was used as an indicator of statistical significance. Missing data were not substantial and were not explored further. Patients with loss-to-follow up were included in baseline, but not end-study analyses. All analyses were done in SPSS v. 23 (IBM).

Continuous variables were tested for normality of distribution using D'Agostino-Pearson test. Categorical variables were presented as absolute value (percentage). Normally distributed continuous variables were presented as mean (standard deviation) and non-normally distributed ones as median (interquartile range, IQR).

Results

Seven patients withdrew from the study. The reasons for discontinuing participation in the study were a kidney transplant (two patients), some other pre-arranged surgery (one patient) or general fatigue (three patients) while one patient died due to complications of the terminal phase of malignant disseminated disease. Ten (29%) patients had diabetes. Median patient age was 68 (IQR 62 to 79) years and mean dialysis vintage 45±39 months (Table 1).

In STS test, the mean number of stands increased significantly after intervention (baseline *vs*. end-study, 10.1±5.5 *vs*. 12.7±6.7 stands, p=0.0001) (Table 2, Fig. 2). Median increase in STS test was 2 stands (delta STS=2 (IQR 0-3)). TUG test improved after intervention (baseline *vs*. end-study, 9.5 (IQR 6.9 to 11.7) vs. 8.5 (IQR 6.1-10.0) seconds, p=0.004) (Table 2, Fig. 3). Median decrease in TUG test was -0.93 seconds (delta TUG=-0.93, IQR -2.29 to -0.11). Similar improvement in STS and TUG was seen in both patients younger than 65 and those aged ³65, as well as in

Table 1. Demographic and laboratory characteristics of patients with or without improvement on functional test

	Whole group (continuous data expressed as median (range) and count as frequency (percent, %))	**Improvement in functional tests**	
		Yes	**No**
Age (years)	68/32-89	69 (62-80)	67 (60-74)
Mean dialysis vintage (months)	36/2-150	36 (10-61)	43 (13-69)
Gender, male/female	18 (51%)/17 (49%)	12/14	2/0
Diabetic/non-diabetic	10 (29%)/25 (71%)	5	5
Hb (g/L)	107/77-127	110 (100-118)	108 (102-118)
CRP (mg/L)	3.8/0.3-30.9	2.6 (1.4-4.6)	3.9 (2.9-5.8)
Phosphate (mmol/L)	1.45 (1.25-1.69)	1.65 (1.45-1.77)*	1.29 (1.18-1.42)
Albumin (g/L)	38.7 (37.5-42.9)	38.4 (47.5-43.5)	40.8 (38.3-42.9)
Creatinine (μmol/L)	774 (673-934)	916 (759-986)	(629-785)

*statistically significant result; Hb = hemoglobin; CRP = C-reactive protein

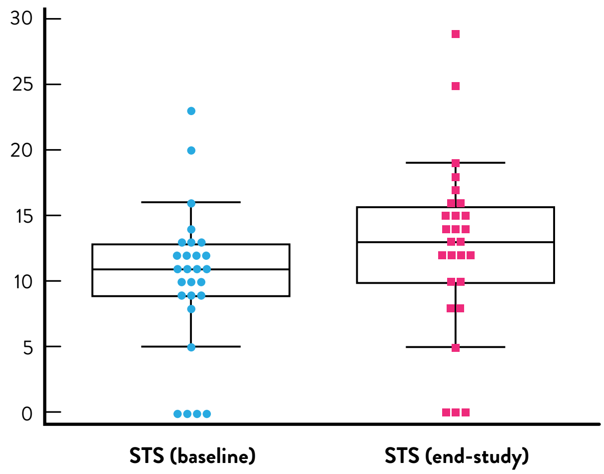

Fig. 2. Baseline vs. end-study STS.

STS = sit-to-stand test

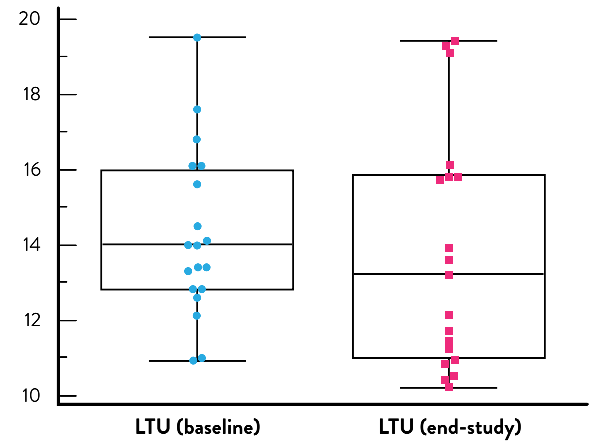

Fig. 4. Baseline vs. end-study LTI.

LTI = lean tissue index

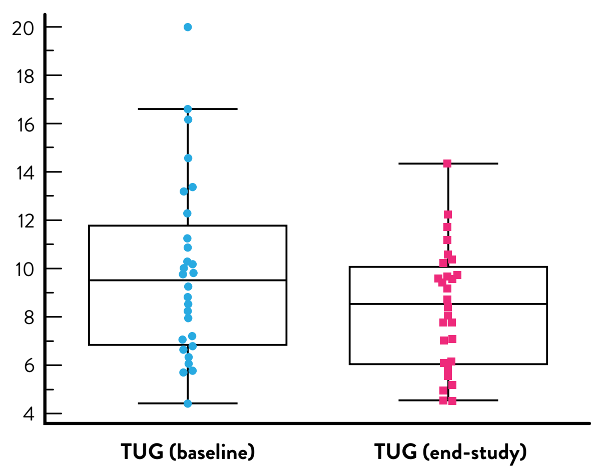

Fig. 3. Baseline vs. end-study TUG.

TUG = timed up and go test

Table 2. Baseline vs. final results of functional tests, dialysis dose and muscle mass

	Baseline	End of study	p
URR (%)	68.7 (7.7)	69.3 (6.0)	0.52
Kt/v	1.36 (0.27)	1.30 (0.21)	0.24
STS test (stands)	10.1 (5.5)	12.7 (6.7)	<0.001
TUG (s)	9.5 (6.9-11.7)	8.5 (6.1-10.0)	0.004
LTI (kg/m^2)	14.2 (2.2)	13.7 (3.2)	0.24

URR = urea reduction ratio; Kt/v = urea clearance; STS = sit-to-stand test; TUG = timed up and go test; LTI = lean tissue index; values in parentheses are standard deviation except for TUG (interquartile range).

diabetic *vs*. non-diabetic patients. A total of 6 diabetic patients required 4 or more interventions for hypotension compared to 6 (24%) non-diabetics (p=0.059). As shown in Table 3, patients who improved in STS had less interventions for hypotension in comparison to those who had no improvement on STS. There were no differences in baseline *vs*. end-study results of LTI (14.2±2.2 *vs*. 13.7±3.2, p=0.24) (Table 2, Fig. 4). End-study LTI was positively correlated with baseline and end-study STS, and negatively with baseline and end-study TUG and age.

There was no significant change in dialysis efficacy expressed as URR or Kt/V (baseline URR *vs*. end-study URR 71% *vs*. 70%, p=0.71, and baseline Kt/V *vs*. end-study Kt/V 1.36 *vs*. 1.37, p=0.44). While we failed to detect a significant between-group difference, there was a clear statistically significant trend between STS and URR as demonstrated by Spearman rank

Table 3. Final results according to functional test outcomes

	Better functional tests at the end of the examination					
	Yes			No		
	Before	After	p	Before	After	p
URR (%)	69.1(8.2)	68.3(7.1)	0.67	67.7(7.6)	69.5(5.3)	0.09
Kt/v	1.31 (0.18)	1.30 (0.19)	0.78	1.36 (0.35)	1.30 (0.24)	0.32
Number of interventions for hypotension	1 (0-4)			2 (1-8)		
STS test (stands)	10.9 (4.9)	14.0 (4.6)	<0.001	9.3 (6.4)	11.0 (8.5)	0.13
TUG test (s)	9.8 (3.3)	8.1 (2.4)	0.001	9.9 (4.3)	8.7 (2.7)	0.19
LTI (kg/m^2)	14.1 (2.6)	13.9 (3.5)	0.64	14.4 (2.0)	13.6 (3.0)	0.28

URR = urea reduction ratio; Kt/V = dialysis efficacy; STS test = sit to stand test; TUG test = timed up and go test; LTI = lean tissue index

correlation test (end STS test *vs*. URR delta, p=0.019 *vs*. p=0,008). A total of 11 (31%) patients showed improvement in bioimpedance and they had lower baseline CRP levels compared to those with deterioration or stable muscle mass (2.4, IQR: 1.3-2.9 *vs*. 4.6, IQR 3.6-10.9, p=0.03). There was a trend in correlation between baseline CRP and end-study LTI, but results did not reach statistical significance.

Discussion

In this study, we combined therapeutic resistance exercises and ES on quadriceps in order to get positive effect on muscular strength, mobility and blood flow velocity, resulting in improvement of dialysis efficacy and reduced intradialytic hypotension in patients on chronic hemodialysis. The results showed an increased mean number of stands in STS test, as well as significantly better results of TUG test at 12 weeks of intervention. However, there was no improvement in baseline *vs*. end-study LTI, probably because of short duration of the intervention. Yet, STS and LTI positively correlated in the whole group. That leads us to a conclusion that patients who exercised properly, eventually had an increase in their muscle mass. It is important to emphasize that those patients who had improvement in LTI had lower baseline CRP. So, it can be inferred that patients who had elevated CRP due to chronic inflammation had difficulties in gaining muscle mass. There was no significance in baseline *vs*. end-study Kt/V or URR. While we failed to detect a significant between-group difference, there was a clear statistically significant trend between STS and URR as demonstrated by Spearman rank correlation test.

It is still uncertain which is the best way to improve dialysis efficacy, and therapeutic exercises could be the answer because of their ability to accelerate muscle blood flow, which opens capillary vessels and facilitates the flux of urea and other waste products from the body. There is some evidence that therapeutic exercises improve dialysis efficacy[11,12,23]. In the study of Giannaki *et al*., patients exercised (stationary cycling) during hemodialysis for 3 hours at 40% of their maximal capacity, which resulted in significant improvement in Kt/v by 20%, URR by 11%, and creatinine reduction ratio by 26%[23]. In the study by Parsons *et al*., 5 months of intradialytic exercises (stationary cycling and mini stepper) which lasted for 30 min 3 times a week significantly increased Kt/v (18%-19%)[12]. The results were impressive, but on a small sample size (n=13).

Regarding venous hemodynamics, some research found its improvement using ES when applied on legs[7,8]. It could contribute to faster venous back flow and improvement in dialysis efficacy. Suzuki *et al*. demonstrated that 8 weeks of ES could improve muscle size measured using magnetic resonance imaging[4]. Moreover, Cabric *et al*. performed biopsies of gastrocnemius muscle before and 3 weeks after ES, and found significant increase in fiber size and nuclear number and size[5]. Considering all of the above mentioned, we evaluated a combination of therapeutic exercises and ES as a method to improve dialysis efficacy, as well as muscle size and strength.

Considering a significant trend between STS and URR, we can infer that not all patients did their best while exercising, but those who did, had improvement in dialysis efficacy. The same group of patients who had improvement in STS or TUG test also required less interventions with 0.9% NaCl for dialysis-induced hypotension. So, those who exercised more vigorously had improved leg function and, moreover, experienced fewer blood pressure drops that required saline intervention.

The strength of this study is that it was done in a group of real-life patients with well-defined inclusion and exclusion criteria. Another positive aspect is that we presented a new training program, which has not been examined in patients on HD yet. The peculiarity of this program lies in a positive synergistic effect of resistance therapeutic exercises and ES on the functional ability of lower extremities, body composition, dialysis efficacy, and dialysis-induced hypotension.

This study had several limitations. First of all, our sample size was only 35 subjects, which hampered us to perform additional sub-analysis. Secondly, we did not unify stimulation intensity of ES, but applied the highest tolerable intensity in each session, which on the other hand is the most likely way to obtain the best result. Also, the length of the intervention part with therapeutic exercises was 3 months, which may not be enough to see all the benefits of it.

Using the novel approach of combining intradialytic resistance therapeutic exercises with ES, there was a positive effect on the functional ability of lower extremities of patients, as well as on dialysis efficacy and a smaller number of necessary interventions for dialysis-induced hypotension. However, intradialytic exercises are still not part of standard therapy in the majority of dialysis centers, so all of them should aim to incorporate this exercise approach in everyday practice, since it has the power to improve and prolong patient functioning and eventually their life expectancy. Additional studies with a larger sample of patients are warranted to corroborate our results.

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Sažetak

UTJECAJ INTRADIJALIZNIH TERAPIJSKIH VJEŽBI I ELEKTRIČNE STIMULACIJE NA FUNKCIONALNU SPOSOBNOST NOGU, UČINKOVITOST DIJALIZE I INTRADIJALIZNU HIPOTENZIJU U BOLESNIKA NA KRONIČNOJ HEMODIJALIZI

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Kronična upala i proteinsko energetska pothranjenost u bolesnika na hemodijalizi dovode do smanjenja mišićne mase te smanjene funkcionalne sposobnosti. Cilj istraživanja je bio procijeniti učinak kombinacije elektrostimulacije (ES) s intradijaliznim terapijskim vježbama na učinkovitost dijalize, arterijski tlak i funkcionalnu sposobnost donjih ekstremiteta. U istraživanju je sudjelovalo 35 bolesnika koji su bili na kroničnom programu hemodijalize. Istraživanje se sastojalo od dvije faze. Tijekom prvog mjeseca nije bilo intervencije. Slijedio je terapijski program kombinacije intradijaliznih vježba s otporom i ES na kvadricepsima, koji je provođen 3 puta na tjedan tijekom 3 mjeseca. Funkcionalni testovi za donje ekstremitete i analiza sastava tijela mjereni su na početku i na kraju istraživanja. Tijekom istraživanja praćen je arterijski tlak, djelotvornost dijalize i laboratorijski parametri. Funkcionalni testovi za donje ekstremitete pokazali su značajno poboljšanje nakon intervencije. U bolesnika koji su postigli poboljšanje funkcionalnih testova pronađena je značajna pozitivna korelacija s manje intradijaliznih epizoda hipotenzije i poboljšanjem djelotvornosti dijalize. Ovo istraživanje je utvrdilo pozitivan učinak kombinacije vježba otpora i ES na djelotvornost dijalize i funkcionalnu sposobnost donjih ekstremiteta u bolesnika na kroničnoj hemodijalizi.

Ključne riječi: *Hemodijaliza; Intradijalizne vježbe; Učinkovitost dijalize; Intradijalizna hipotenzija; Funkcionalna sposobnost nogu; Elektrostimulacija*