The Super Inductive System - A New Approach in Treatment of Denerved Muscle

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ABSTRACT

Background and objectives: The repetitive pulse magnetic stimulation (rPMS) is considered a promising innovative means in physiotherapy and medicine. The method has wide range of therapeutic effects that address mainly musculoskeletal and neurological disorders. Aim of this study was to evaluate its effectiveness for treating muscles with damaged innervations.

Materials and methods: 30 patients randomized into the treatment and control groups. The treatment group received rPMS therapy. The Control group received electrotherapy. Manual Muscle Testing (MMT) and Patient Functional Assessment Questionnaire (PFAQ) were applied at both pre- and post-treatment stages for assessing the results.

Results: The level of improvement from MMT examination was 67 % in the treatment and 47 % in the Control group. The PFAQ results showed improvements in all domains respectively for the Treatment and Control group. The biggest improvement was observed in Carry/Move/Handle objects domain for the Treatment group: 35.22 %, whereas the respective value for the Control group was 23.33 %. All results were deemed statistically significant with $p<0.05$.

Conclusion: rPMS is an effective and safe non-invasive method that allows contactless treatment of denerved muscles and further ameliorating the ability to perform Activities of Daily Living among patients suffering from conditions associated with denerved muscles.

KEY WORDS: muscle strength, denerved muscles, repetitive pulse magnetic stimulation

INTRODUCTION

An increasing part of the population is affected by neurological diseases and in some cases the muscle innervations can be affected. Causes could be trauma to the nerve structures (1-4 grades), neurological disorders with inflammatory or intoxication characteristics.[1]–[3] Neurological inflammatory disorders are mostly caused by constant repetitive movements, affecting a single or group of nerves.[2] Intoxication neurological diseases are consequences of toxic substances such as alcohol or others with harm effects to the kidneys and liver.[3] Regardless of the main reason, the greatest changes are muscle strength and mass, which also decrease the cross sectional area of the limb (decrease in muscle fiber diameter).[4], [5] The described changes result in weakened strength, metabolic processes and trophic inhibition.[6] The direct result on patients is mobility limiting factor that affect their ability to perform activities of daily living (ADL).[7] One of the commonly used conventional approaches for treating muscles with damaged innervation and decreased strength include low-frequency electrical stimulation. Depending on the severity of the harm, muscles are treated by low-frequency current with slowly rising forefronts and longer pauses between impulses. The necessity of direct contact between tissue and electrode, the risk of adverse events such as burns, the tissue adaptability factor, are still present.[8]

Therefore, finding more effective and safe approaches is invariably beneficial for patients and healthcare as a whole. The repetitive pulse magnetic stimulation (rPMS) might be one possibility. The therapy is based on the interaction between the high intensity electromagnetic field and neuromuscular tissue. Electromagnetic field, with induction intensity measured in units of Tesla, passes through the neuromuscular tissue, in which electric currents are induced and depolarization of the neuronal cells occurs. This leads to selective muscle contractions. rPMS passes into deeply lying tissues without need of direct skin contact of the patient. The therapeutic effects include myostimulation, blood circulation enhancement, pain and swelling relief.[9] - [18]

MATERIALS AND METHODS

Study design and aim:

Controlled, randomized study conducted in order to evaluate the efficacy of rPMS in treatment of muscle dysfunction associated with denerved muscles.

Subjects:

30 subjects (n=12 women and n=18 men), aged between 35 and 67 years (49.10 ± 9.58, median 49), diagnosed with denerved muscles (grade of affection of the respective muscle nerve: 1 and 2) led by diagnosis as described in Figure 1, were enrolled in this study. All participants experienced weakened muscle strength and difficulties to perform ADL. All participants were enrolled after their voluntarily agreement. Participants with cardiac disorders, implants, neurological seizures or psychiatric conditions were not enrolled in this study.

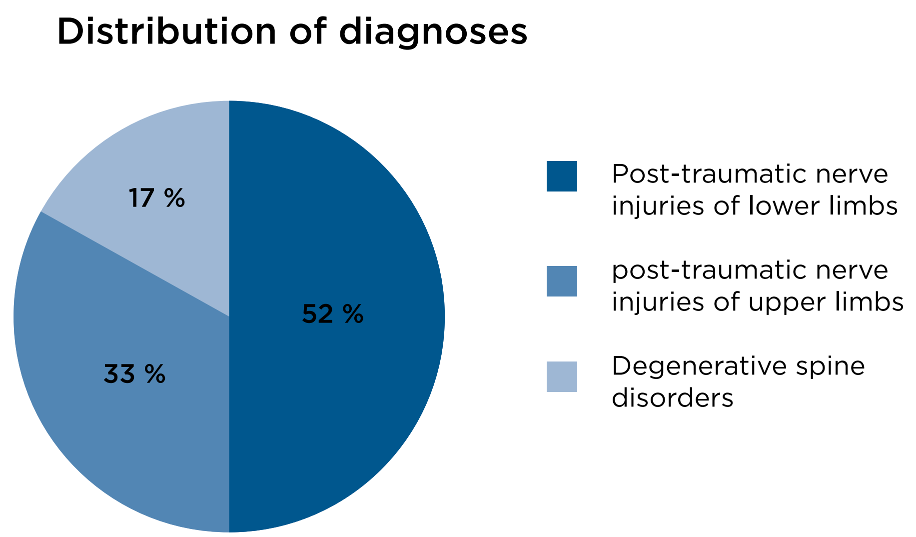

Figure 1. Distribution of diagnoses

Data collection:

Before treatments, patients underwent an evaluation of muscle strength – manual muscle strength (MMT) and filled-in a Patient Functional Assessment Questionnaire (PFAQ) for evaluation of their ability to perform ADL. MMT was performed by one and the same physiotherapist to avoid measurement mistake or subjectivity. Muscle strength was evaluated and scored by MMT in accordance to protocols by Kendall for the respective muscles, where a scale from 0 to 5, as described in Table 1. was applied. [19]

Grade	Explanation	Muscle Strength
5	Normal	Complete ROM against gravity, with full resistance
4	Good	Complete ROM against gravity, with some resistance
3	Fair	Complete ROM against gravity, with no resistance
2	Poor	Complete ROM with gravity omitted
1	Trace	Evidence of slight contractility, with no joint motion
0	Zero	No evidence of muscle contractility

Table 1: Manual Muscle Test

In PFAQ (Version 001, Copyright © 2013 U.S. Physical Therapy, Inc.)., all subjects were asked to fill 24-part (each part is graded from 0 to 6). The main domains in the questionnaire with the respective sub domains are presented in Table 2., whereas the grades are presented in Table 3.

MOBILITY/WALKING	Walking short distances
	Walking long distances
	Walking outdoors
	Climbing stairs
	Hopping
	Running
CHANGE/ MAINTAIN BODY POSITION	Rolling over
	Moving - lying to sitting
	Sitting
	Bending/Stooping
	Kneeling
	Standing
CARRY/ MOVE/ HANDLE OBJECTS	Pushing
	Pulling
	Reaching
	Grasping
	Lifting
	Carrying
SELF CARE	Dressing/ Clasp b/h back
	Doing light housework
	Prep meals/ kitchen tasks
	Bathroom activities
	Sleeping abilities
	Hygiene (comb hair/ brush teeth)

Table 2. PFAQ Domains

Grade	Corresponding Ability
0	Absolute no difficulty
1	Able to do with little difficulty
2	Able to do with little to moderate difficulty
3	Able to do with moderate difficulty
4	Able to do with moderate to significant difficulty
5	Able to do with significant difficulty
6	Unable to do at all

Table 3. PFAQ Grades

Consequently, the subjects were randomly assigned into two groups: Treatment and Control. The Treatment group (n=15 subjects, see Figure 2) were delivered 8 therapies with rPMS (BTL-6000 Super Inductive System, BTL Industries Ltd.) with a total duration of 3 weeks (except for the weekends). The therapy was delivered after placing the applicator above the pathological area (contactless delivery), with following parameters: 13-minute therapy, sinusoid type of pulse, frequency range between 15 - 50 Hz, frequency and amplitude trapezoid modulation were used to achieve gradual motor unit recruitment. To avoid weakened muscle fatigue the ratio of stimulation and pause was set to 1:3. The intensity of the therapy was set at the beginning of the therapy to patient´s motor up to above the motor threshold.

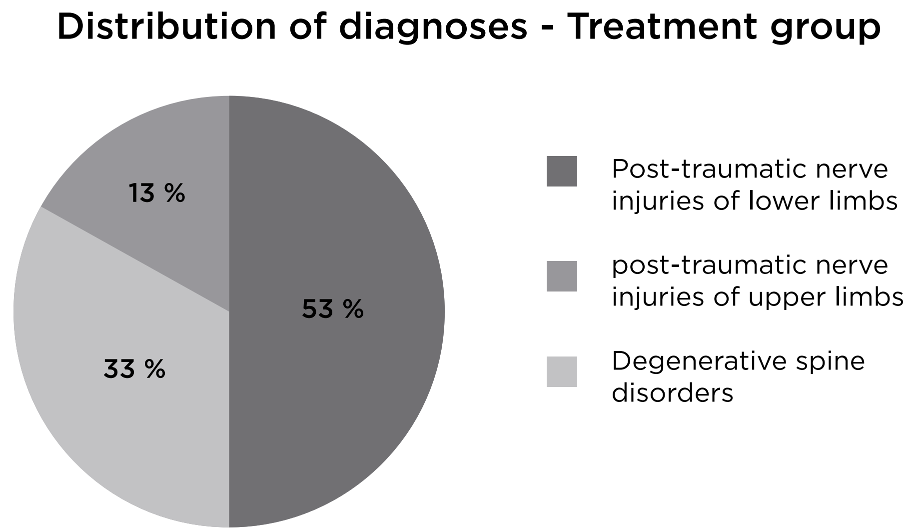

Figure 2. Distribution of diagnoses - Treatment group

For muscle strengthening with electrotherapy - Control group (n=15 subjects, see Figure 3) used 10-minute therapy, which parameters differed according to patient´s condition. The electrodes were attached directly to a subject´s skin and responding to the affected muscles. Triangle pulse type with a frequency range between 1 - 30 Hz was used. The ratio of stimulation and pause was set to 1:3. To prevent patient´s adaptation, the intensity of the therapy was set at the beginning and adjusted during the therapy to the patient´s motor threshold.

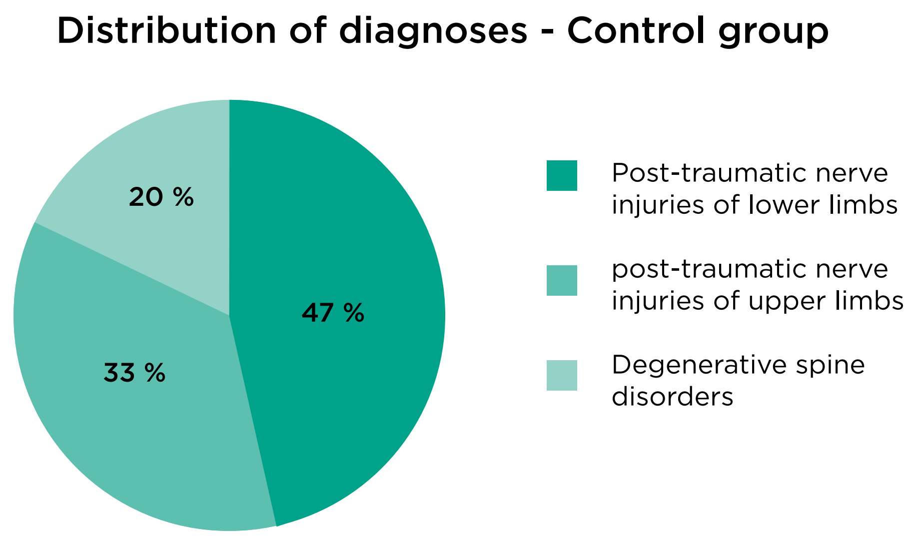

Figure 3. Distribution of diagnoses - Control group

The outcome data was collected before the first and after the last therapy for both groups. Improvements and levels of improvements were calculated. Further statistical analysis was done by means of Student's t-test (MS Excel was used), where levels of $p<0.05$ were deemed statistically significant.

RESULTS

All subjects completed the study and were able to tolerate the applied therapies. No abnormal finding or adverse events were observed. The outcome data and results collected during the study, are presented in Table 4.

Parameter	Treatment group (n=15)				Control group (n=15)			
	Pre-	Post-	Δ, %	p	Pre-	Post-	Δ, %	p
	Mean ± SD				Mean ± SD			
MMT	2.47±0.64	4.00±0.85	67.00%	<0.05	2.40±0.51	3.33±0.82	47.00%	<0.05
MOBILITY/WALKING	2.52±2.17	1.38±1.25	27.11%	<0.05	2.50±2.13	1.87±1.62	15.43%	<0.05
CHANGE/ MAINTAIN BODY POSITION	1.20±1.51	0.52±0.81	29.57%	<0.05	1.33±1.59	1.00±1.17	10.17%	<0.05
CARRY/ MOVE/ HANDLE OBJECTS	1.49±1.94	0.90±1.82	35.22%	<0.05	1.47±1.43	0.94±1.00	23.33%	<0.05
SELF CARE	1.90±1.93	0.73±1.42	23.80%	<0.05	1.34±1.72	0.94±1.28	12.11%	<0.05

Table 4. Outcome data

The outcome muscle strength in both groups was poor according to the applied scale for MMT. According to the applied scale in the PFAQ the outcome data was as follows: Mobility/ Walking - with moderate difficulty, the abilities to Change maintain body position and Carry/Move/Handle objects was with little difficulty in both groups. Self-care in the treatment group was performed with little to moderate difficulty and with little difficulty in the control group. No statistical difference was observed between the outcome data in both groups.

The levels of improvement and their comparison between both groups are represented in Table 5.

Parameter	Pre-treatment (T0)			Post-treatment(T1)		
	Treatment	Control	p	Treatment	Control	p
	mean ± SD			ΔT1-T0%		
MMT	2.53±0.74	2.40±0.51	NS	67.00%	47.00%	<0.05
MOBILITY/WALKING	2.52±2.17	2.50±2.13	NS	27.11%	15.43%	<0.05
CHANGE/ MAINTAIN BODY POSITION	1.20±1.51	1.33±1.59	NS	29.57%	10.17%	<0.05
CARRY/ MOVE/ HANDLE OBJECTS	1.49±1.94	1.47±1.43	NS	35.22%	23.33%	<0.05
SELF CARE	1.90±1.93	1.34±1.72	NS	23.80%	12.11%	<0.05

Table 5. Results comparison

DISCUSSIONS

The rPMS method has previously been studied mainly for mobility restoration - Strupppler et al. 2007, Kouloulas et al. 2016, and pain relief - Zarkovic et al. 2016, and its effectiveness is present. The therapeutic effects are assumed to be led by improved tissue elasticity and increased local circulation.[20]-[23]] Evidence of the myostimulative effect of the therapy has been recently presented by Zarkovic 2016, and the method has been considered effective.[24] Statistical assessment of the data from the current study showed that both studied methods are effective in treatment of weakened muscles led by damaged innervation. A greater effect of increased muscle strength – 67 % was observed in the treatment group. The result in the control group was 47 %. The results are deemed statistically different with level of $p<0.05$. The greater effect in the treatment group is suggested to be led by the myostimulative effect of the therapy. The described effect of increased muscle strength is further resulting in increased abilities to performing ADL (with levels of improvement as per tables Table 1 and Table 2 with the respective levels of significance $p<0.05$) and hence leading to amelioration of patient´s quality of life.

CONCLUSION

The obtained study results provide evidence of effectiveness from rPMS in treatment of denerved muscles. The clinical effects are assumed to be due to neuronal cell depolarization. Further research on the latter should be conducted, however. In conclusion, the therapy appears to be effective method for increasing the muscle strength and ameliorating the abilities to perform ADL among patients who suffer from conditions associated with denerved muscles.

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