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REPETITIVE PERIPHERAL MAGNETIC STIMULATION AS PAIN MANAGEMENT SOLUTION IN MUSCULOSKELETAL AND NEUROLOGICAL DISORDERS - A PILOT STUDY

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ABSTRACT

Background: Non-invasive therapeutic approaches without negative side-effects are desirable in pain condition treatment where the mobility limiting factor is also there. Repetitive peripheral magnetic stimulation (rPMS) is considered a promising curative method from different perspectives. Because of wide range of therapeutic effects, therapy is mainly indicated in musculoskeletal and neurological disorders. Aim of this study was to investigate pain relief effect and improving of the difficulties in performing Activities of Daily Living (ADL) achived byrPMS among patients with acute and chronic conditions assosiated with musculoskeletal and neurological painful disorders.

Methods: 40 patients (n=23 women, n=17 men) with acute and chronics painful condition and difficulty to perform ADL accompanying musculoskeletal or neurological disorders were comprised in the study. All patients were treated with rPMS. The therapy parameters were adjusted to patient´s condition. Patients with acute pain underwent daily treatments (n=5). Patients with chronic pain underwent treatments three times per week (n=10). The Pain presence was evaluated by a 10-point Visual Analog Scale (VAS) for Pain Presence (refer to Appendix 1). Difficulties to perform ADL were evaluated by Patient Functional Assessment Questionnaire (PFAQ) for ADL (refer to Appendix 2). A three-month follow-up was completed. All collected data were further evaluated.

Results: There was a statistically significant difference ($p<0.05$) in the before/after condition comparison. Majority of participants described pain decrease (87.33%) on VAS for Pain and improvement (41.33%) in ability to perform ADL after the course of treatment. A three-month follow up showed persisting improvement (to 42.04% (vs. before treatment condition)) in ADL performing abilities.

Conclusion: Similar results proved that rPMS therapy can be used as an effective and non-invasive treatment of painful condition with ADL limiting factor accompanying musculoskeletal and neurological disorders. Persisting pain relief effect and ameliorating patient quality of life were observed.

Keywords: musculoskeletal, neurological, disorders, intensive pulse magnetic stimulation, pain relief effect.

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INTRODUCTION

The International Association for the Study of Pain describes pain as a subjective unpleasant sensory and emotional experience associated with tissue damage, [1] and it is usually accompanied with limited mobility. Physiological mechanisms producing pain usually include nociceptive irritation, structural brain reorganization and decreased inhibition [1-5]. Pain is produced as a consequence of a neurological disorder and canbe a direct (neuropathicpain) or an indirect (musculoskeletal) [6]. Direct pain is initiated by a primary lesion or dysfunction in the nervous system and affects the somatosensory [7]. The indirect consequence of neurological disorders is musculoskeletal pain causing both short- and long-term disabilities. The muscoloskeletal pain is further categorized in various types e.g. depending on the persistance - acute and chronic; on the pathophysiological mechanisms - nociceptive and neuropathic; on anatomical localization - sholders, back, head, face etc [8].

Worldwide chronic pain incidence is estimated between 20-25%. Commonly, drug treatment is considered a pain management solution. However, negative side effects such as addiction and temporal character are often overlooked. More than 50% of treated patients describe the drug treatment as inadequate, whereas only few percents of them regain non-painful condition [9,10]. Therefore, non-invasive solution without negative side-effects is desirable for providing high-quality healthcare to the patients.

Basics of repetitive magnetic stimulation have been known since 19th century, however, curative effect has been applied in the early 1980´s. The originally known as transcranial magnetic stimulation (TMS) was '*centrally*' applicable in neuro-psychiatry. Repetitive *peripheral* magnetic stimulation´ (rPMS) with curative effect has been proven in many medical branches for pain relief [11-19]. Comparing to negative side-effects of drug treatment, rPMS is non-invasive therapeutic approach that could have pain relief effect.

Both TMS and rPMS share very similar principles of action, where electromagnetic induction is used to generate an electric current across the tissue without a physical contact. An activated coil (plastic enclosed) placed next to the treated region, produces a magnetic field (ones of Tesla), orthogonal to the plane of the coil. The field creates (inducts) electric currents that interact with neuromuscular tissue (in the very same way if currents are applied directly on the treated area). The occurred depolarization of the neuronal cells causes muscle contraction. Therapeutic effects are pain relief, myostimulative, myorelaxative, swelling release effect and circulation improvement [19]. Therefore, the rPMS therapy is indicated in acute (optimally with its high frequency field)and chronic (usually with its low frequency field) painful conditions of the musculoskeletal and neurological disorders.

Aim of this study was to evaluate the pain relief effect of rPMS among patients with acute and chronic painful conditions and difficulties to perform ADL accompanying musculoskeletal or neurological disorders.

MATERIALS AND METHODS

Design:

One –site, one-arm, before-after study, conducted in order to investigate pain relief effect of rPMS among patients with painful conditions and difficulties to perform ADL accompanying musculoskeletal or neurological disorders.

Participants:

40 patients, aged from 13 to 74 years (n=23 women, n=17 men; mean age 54.6 ± 11.6 years) were comprised in this study. All participants experienced pain and difficulties to perform ADL, led by musculoskeletal or neurological disorders (Participants with heart disorders, any contraindicating implants, seizure neurological or psychiatric conditions etc. were considered disqualified for this study). All participants agreed to voluntarily join the study. A proportional percentage representation (including additional data concerning the ‚before' condition of the patients) is listed in the Table 1, Figure 1.

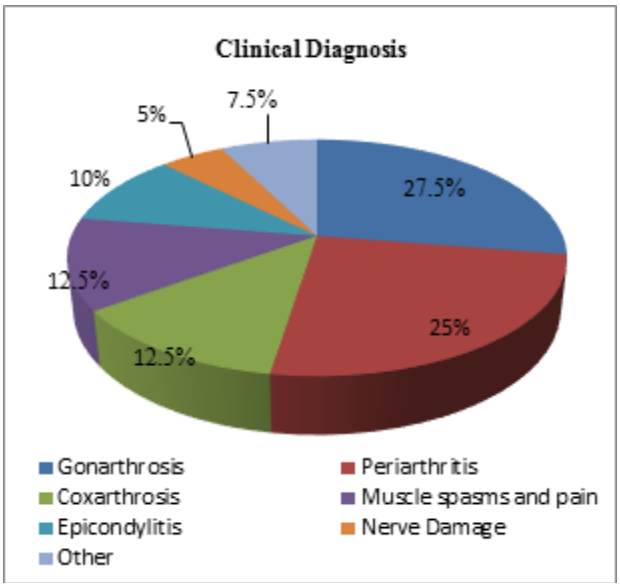

Figure1: Chart of Clinical Diagnosis

Age (years)		
Mean±SD	54.6±11.5	
Range	13 - 74	
Clinical Diagnosis	Share	Patients, n
Gonarthrosis	27.50%	11
Periarthritis	25%	10
Coxarthrosis	12.50%	5
Muscle spasms and pain	12.50%	5
Epicondylitis	10%	4
Nerve Damage	5.00%	3
Other	7.50%	2
Total	100%	40
Pain (VAS)		
Mean±SD	7.6 ± 1.9	

Table 1: Pre-treatment Clinical Condition

Patient assessment and therapies were provided by the investigator and research assistants. The device (BTL-6000 Super Inductive System, BTL Industries Ltd.) parameters were stated as follows: magnetic field intensity – up to 2.5T, range of frequency up to 150 Hz and adjustable relative intensity up to 100%. The therapy procedure was followed by manufacturer´s recommendation. The patients with acute pain underwent daily treatments (n=5) with single therapy duration 12 minutes, whereas the patients with acute pain underwent therapy three times per week (n=10) with single therapy duration 10:20 minutes. Therapy frequency was determined by patient´s condition (low frequency field for chronic conditions and high freqeuncy field for patient with acute pain). The intensity was dependent on patient´s subjective perception: the intensity range varied from patient´s *lower than* up to *motor threshold* intensity, based on communication between therapist and patient.

Outcome measures and Statistics evaluation:

A primary outcome measure was Pain presence evaluation. A 10-point (0-10; *No pain* to *Worst possible pain*) Visual Analog Scale (VAS) for Pain was used to evaluate presence of pain (refer to Appendix 1). The patients were asked to evaluate the level of the pain they experienced right before the first and right after the last treatment (respectively the outcome data were collected right before the first and right after the last treatment). The following question was asked: *'How would you rank the level of your pain?'*. Mean improvements in absolute points (Mean ± SD) and levels of improvement (%) were calculated.

A secondary outcome measure was evaluation of ability to perform ADL. The evaluation was performed by the means of 24-part (each activity with grade from 0 to 6) Patient Functional Assessment Questionnaire (PFAQ) - refer to Appendix 2. Patients were instructed to circle the level of difficulty per each activity. The score range was varying from 0 to 6, where 0 means that a patient is able to perform activity without any difficulties, whereas 6 means inability to perform such a task. Data were collected right before and right after the last treatment, and at the 3-month follow up. Mean improvements in absolute points (Mean ± SD) and levels of improvement (%) were calculated.

A further statistical analysis of 'before' and 'after' conditions was performed by the means of Student's t-test – the purpose was to be proved a statistical significance between the results, signifying a quality to be worthy of attention, importance. Values of $p < 0.05$ were accepted for statistically significant.

RESULTS

40 subjects with acute and chronic painful conditions accompanying musculoskeletal and neurological disorders, which experienced difficulty to perform ADL, ssuccessfully finished a course of treatment with rPMS. During the course of treatments no abnormalities, no side-effects and no aggravation of patient´s condition were observed.

The results of VAS for Pain evaluation are summarized in Table 2:

Before	After	Improvement		Level of Improvement	
	Mean±SD		p	%	p
7.60±1.87	1.05±0.86	6.55±1.60	<0.05	87.33	<0.05

Table 2: VAS Pain evaluation results

The mean value of the experienced pain at before treatment condition was 7.60 (S.D.±1.89. This value is matching with a *severe pain* level on the VAS for Pain (refer to Appendix 1). The mean value of the pain at after treatment condition was 1.05 (S.D.±1.61) in absolute points. This value is matching with a *mild pain* level on the VAS for Pain (refer to Appendix 1). The mean level of improvement was 87.33 %. A further data analysis by t-test (Paired Two Samples for Means) of before and after treatment VAS for Pain scores showed a statistical significance with $p<0.05$.

The results of PFAQ for difficulties to perform ADL are presented in Table3

Activity	Before	After	3-month follow up	Before Vs. After		Before Vs. 3-month follow up		After Vs. 3-month follow up	
				Level of Improvement, %					
Mobility, Walking	1.74 ± 2.04	0.57 ± 0.91	0.51 ± 0.83	41.47	p<0.05	42.68	p<0.05	1.21	p<0.05
Change/ Maintain body position	1.13 ± 1.53	0.25 ± 0.58	0.23 ± 0.52	37.49	p<0.05	37.91	p<0.05	0.42	p<0.05
Carry / Move/ Handle objects	1.46 ± 1.96	0.38 ± 0.72	0.35 ± 0.64	30.58	p<0.05	31.39	p<0.05	0.81	p<0.05
Self-care	2.00 ± 1.79	0.35 ± 0.78	0.35 ± 0.78	55.76	p<0.05	56.17	p<0.05	0.41	p<0.05
MEAN	**1.50 ± 1.85**	**0.39 ± 0.77**	**0.36 ± 0.71**	**41.33**		**42.04**		**0.71**	

Table 3: Data from PFAQ

The patients recorded difficulties to perform tasks such as *walking, changing body position, handle objects and self-care*. The range of values at before treatment condition varied from 1.54 to 2.03, mean 1.50 ± 1.85. This value is matching to *little moderate difficulties* performing such activities (refer to Appendix 2). The range of the values at after-treatment condition varied from 0.58 to 0.91, mean 0.39 ± 0.77. This value is matching to ability to perform ADL *with little difficulties (refer to Appendix 2).* A major clinical improvement of 55.76% in the after treatment condition occurs in category ´self-care´. The overall improvement in the abilities to perform ADL is 41.33%. A further data analysis (t-test Paired Two Samples for Means) showed a statistical significance between the before- and after- treatment condition with $p<0.05$. The 3-month follow up with PFAQ was completed. Results showed that post-treatment condition was retained and increased up to 42.04% (versus pre-treatment), respective value of $p<0.05$.

DISCUSSIONS

Pujol et al. 1998 has studied the pain relief effect of the direct application of rPMS on the painful limb with a placebo controlled trial among 30 patients in total. The active group experienced 59% pain relief effect while the 14% pain relief was experienced in the control group. However, the mechanism of action remained not clear [11]. *Smania et al. 2005* conducted a study researching the pain relief effect of the method among 53 patient with myofascial trigger points randomized as follows: 17 patients were treated by the means of the rPMS , 18 patients received transcutaneous electrical nerve stimulation (TENS) nad the remaining 18 patients were terated with placebo. The rPMS group demonstrated most significant improvement in all studied outcome measures ("neck pain and disability visual analogue scale" (NPDVAS), algometry) [13]. Research on the pain relief effect of the rPMS has been conducted by *Lo et al. 2011* among 20 patients randomized in active and control group assuming that the 62.3% pain decrease in the active group (whereas the result in the control group was 6.1%) is resulting from disrupting afferent nerve fibers or activation of spinal and/ or supra spinal inhibitory neurons [15].

Statistical evaluation of the data from the current study proved an immediate pain relief effect from *severe level* of pain to *mild level* of pain in post treatment condition of the participants. The 87% *pain decrease* is resulting in average 41% *improvement in performing ADL* (from *little moderate* to *little difficulties*) and thus affecting the patients quality of life in a positive manner. A persisting improvement to 42% in the ADL scores at 3-month follow up results (vs. pre-treatment condition) is there (see Figure 2.) signifies for long-lasting therapy effect. Further data analysis by the means of Student's t-test proved a significant pain relief effect resulting in persisting quality of life amelioration among patients with acute and chronic pain associated with musculoskeletal and neurological disorders. This effect is assumed to be led by local circulation improvement.

CONCLUSIONS

The results obtained during the current study provide evidence of effectiveness from rPMS therapy in pain management. The therapy appears effective non-invasive treatment foracute and chronic pain condition and mobility restoration, ameliorating patient quality of life.

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