Efficacy Evaluation of Targeted Radiofrequency Therapy in Trigger Points and Functional Muscle Spasms Treatment

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Background and objectives: Trigger points and muscle spasms are painful symptoms of fibromyalgia syndrome. They result in difficulties for performing Activities of Daily Living (ADL). An effective treatment of trigger points and muscle spasms decreases the pain and further results into mobility restoration. The aim of this controlled study was to evaluate the effect of the Targeted Radiofrequency Therapy (TR-Therapy) at 500 kHz for treating painful conditions caused by trigger points and functional muscle spasms compared to the methods of the conventional physiotherapy.

Methods: 40 subjects (n=22 female and n=18 male) diagnosed with trigger points and functional muscle spasms completed the study. They were assigned into two groups – Treatment and Control group. The Treatment group (subjects n=20) were delivered TR-therapy. The Control group (subjects n=20) were treated with conventional physiotherapy (electrotherapy, ultrasound therapy, magneto-therapy, microwave therapy). The primary outcome measure was pain perception evaluation. For the purpose a 10-point Visual Analogue Scale (VAS) for Pain was used (see Appendix 1.). The secondary outcome measure was a detailed assessment of the experienced difficulties to perform ADL. For the purpose a 24-part (each part is graded from 0 to 6) Patient Functional Assessment Questionnaire (PFAQ) was used (see Appendix 2.). The data were collected at pre- and post-treatment stage (right before the first and right after the last therapy).

Results: The average decrease of the pain perception in the Treatment group was 77 % and 63% in the Control group. The average improvement of the abilities to perform ADL in the Treatment group was 41 % and 21% in the Control group. A further statistical evaluation (Student's t-test) proved a significant difference between the post-treatment results of both groups. The evaluation of the results from VAS for Pain perception of both groups showed a statistical difference with p= 3,42E-03. The evaluation of the results from PFAQ for ADL showed a statistical difference with p=7,07E-03.

Conclusions: Similar results proved the TR-Therapy as more effective solution in treatment of painful conditions with ADL limiting factor (led by trigger points and functional muscle spasms) compared to the conventional physiotherapy methods. The results could also be interpreted in a manner that TR-Therapy is a quality of life increasing solution.

Key words: Trigger Points, Muscle Spasms, Pain relief, Activities of Daily Living, Radiofrequency Therapy

Introduction

Trigger points and functional muscle spasms - common symptoms of fibromyalgia syndrome, are either associated or could lead to musculoskeletal disorders. [1],[2]

Trigger points are discrete, focal, hyperirritable spots located in a taut band of skeletal muscle. The spots are painful on compression and can produce referred pain, referred tenderness, motor dysfunction, and autonomic phenomena. [3] Trigger points are classified to active and passive. An active trigger point causes pain in rest. It is sensitive to palpation. The pain pattern is described as spreading or radiating. A passive trigger point does not cause spontaneous pain. It is movement restricting and muscle weakness causing. [4]

Patients with trigger points often report regional, persistent pain usually resulting in a decreased range of motion of the joint supported by the relevant muscle. The usually affected muscles are the ones that are maintaining the body posture, in the region of the neck and shoulders: m. Trapezius, mm. Scalenii, m. Sternocleidomastoideus, m. Levator Scapulae, m. Quadratus Lumborum. [5]

Other painful symptom that could lead to musculoskeletal disorders, or is already associated, as mentioned, are muscle spasms. A muscle spasm is an involuntary contraction of a muscle. [6] There is a variety of causes of muscle spasms (structural change, Magnesium deficit on a cell level etc.) and in the most generalized manner they could be divided into structural and functional. [6], [7]

The most unwanted direct effects on the patients, lead by trigger points and muscle spasms are pain and difficulties to perform ADL. [8], [9] Conventional physiotherapy methods (such as electrotherapy, ultrasound therapy, magneto-therapy, microwave therapy etc.) have an effect on improvement of the mentioned conditions in most of the cases. However there is a field for improvement. Therefore finding more effective, non-invasive and harmless solutions for treating the described conditions is essential for healthcare.

The principles of action of TR-Therapy are based on the transfer of high frequency electromagnetic energy through the tissues of the body. The technology features capacitive and resistive modes of action. The result is creating selective tissue hyperthermy, which bring therapeutic effects such as immediate and intense pain relief, muscle relaxation, edema reduction and supporting tissue regeneration and healing. The described effects further result in decrease of the ADL difficulties.

The aim of this controlled study was to prove the effectiveness of the TR-Therapy at 500 kHz in treating painful conditions and improving of the abilities to perform ADL, led by trigger points and functional muscle spasms. The results were compared to results achieved by conventional physiotherapy methods.

Materials and Methods

Study design: One-site, two-arm, controlled, randomized study conducted in order to evaluate the efficacy of the TR-Therapy at 500 kHz in treatment of painful conditions and improving the ability to perform ADL, led by trigger points and functional muscle spasms.

Subjects: 40 subjects (n=22 female and n=18 male), aged between 40 and 66 years (mean age 51.4 ± 7.8), diagnosed with trigger points and functional muscle spasms, who experienced pain and difficulties to perform ADL, were enrolled in the study. The pre-treatment average outcome data for all subjects were: 5.66±1.25 pain perception ('Depressing, miserable pain') and 0.99±1.20 difficulty to perform ADL ('Able to do with a little difficulty').

The patients were randomly assigned into two groups: Treatment and Control.

The Treatment group (n=20 participants) were delivered 10 daily therapies with the TR-Therapy (BTL−6000 TR-Therapy Elite device was used) with total duration 2 weeks (except for the weekends).

The therapy parameters were set as follow:

Mode: Capacitive
Total Time: 15 min
Frequency: 500 Hz
Duty Factor: 100%
Applicator: 30mm, capacitive + neutral electrode
Subjective Intensity Valuation: II

The physiotherapist was present during the sessions. All subjects were familiarized with Subjective Intensity Valuation (SIV) scale and communicate it with the physiotherapist. The SIV scale was based on the heat perception by the patient, using a scale developed by Schliephake (I – no heat perception, very low intensity;
II – moderate heat perception, low intensity;
III – evident heat perception, medium intensity;
IV – strong, but not unpleasant, heat perception, high intensity).

The Control group (n=20 participants) were delivered 10 daily conventional physiotherapy treatments with total duration 2 weeks (except for weekends). The types of the treatments in the Control group were iontophoresis, ultrasound therapy, pulsed magnetic field therapy, microwave therapy, ultra-high frequency current therapy, interference current therapy.

Results evaluation and statistics: The primary outcome measure was pain perception evaluation. All subjects were asked to rank the level of the pain they experience on a 10-point Visual Analog Scale (VAS) for Pain (see Appendix 1.). The data were collected at pre- and post-treatment (right before the first and right after the last therapy) stage and further evaluated.

The secondary outcome measure was improvement of the abilities to perform ADL. All subjects were asked to fill a 24-part (each part is graded from 0 to 6) Patient Functional Assessment Questionnaire for evaluation of their ability to perform ADL (see Appendix 2.). The data were collected at pre- and post-treatment (right before the first and right after the last therapy) stage and further evaluated.

The outcome results were presented in format (Mean ± S.D.). The improvements were presented in format (Mean ± S.D.) and in relative value.

For further statistical comparison Student's t-test was used to evaluate the post-treatment data between both groups. The purpose of the test is to compare outcome data of two similar statistical sets and prove / disprove the statistical significance (the quality of being worthy of attention; importance). Values of $p<0.05$ were considered statistically significant.

Results

All subjects completed the study. No abnormal findings were observed.

The collected during the study pain perception data and the decrease are presented in Table 1. / on Figure 1: Pain Perception Results. The average decrease of the pain perception in the Treatment group was (4.50 ± 1.00) in absolute points and 77% in relative aspect. The average decrease of the pain perception in the Control group was (3.50 ± 1.10) in absolute points and 63% in relative aspect.

The results of both groups were tested for statistical significance (Student's t-test) and confirmed statistical significance with p= 3,42E-03.

	GROUP	
	Treatment Group	Control Group
Pre-treatment	5.90 ± 1.33	5.45 ± 1.15
Post-treatment	1.40 ± 0.60	1.95 ± 0.51
Decrease	**4.50 ± 1.00**	**3.50 ± 1.10**
Decrease, %	**77%**	**63%**

Table 1.: Pain Perception Results

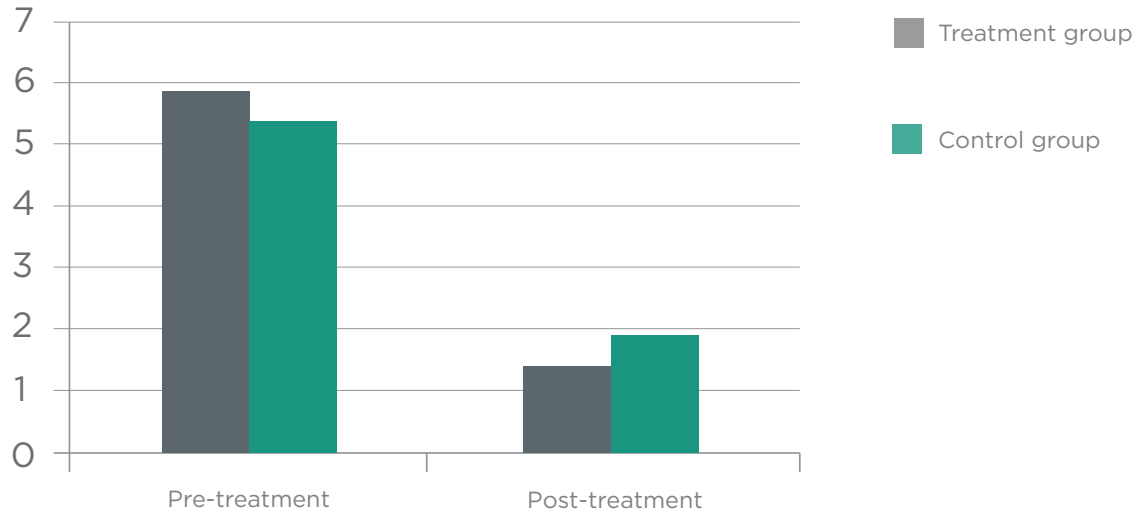

Figure 1.: Pain Perception Results (absolute points)

The outcome data and results assessing the abilities to perform ADL, collected during the study, are presented in Table 2. and on Figure 2.: ADL Performing Assessment Improvement (*treat. stands for treatment). The average increase of the abilities to perform ADL in the Treatment group was (0.78 ± 1.01) in absolute points and 41% in relative aspect. The average increase of the abilities to perform ADL in the Control group was (0.54 ± 0.82) in absolute points and 25% in relative aspect. The results of both groups were tested for statistical significance (Student's t-test) and confirmed statistical significance with p=7,07E-03.

ADL	Treatment group				Control group			
	Pre-treat.*	Post-treat.	Improve--ment	Improve--ment, %	Pre-treat.	Post-treat.	Improve--ment	Improve--ment, %
MOBILITY WALKING	1.28±1.64	0.33±0.47	0.94±1.21	37%	1.00±1.24	0.46±0.50	0.54±0.84	20%
CHANGE MAINTAIN BODY POSITION	0.79±0.93	0.19±0.42	0.60±0.76	40%	0.78±0.95	0.34±0.48	0.44±0.75	25%
CARRY MOVE HANDLE OBJECTS	0.72±1.24	0.14±0.35	0.58±1.07	23%	0.53±0.95	0.33±0.65	0.23±0.48	12%
SELF CARE	1.29±1.07	0.30±0.50	0.99±0.79	62%	1.52±1.06	0.59±0.60	0.93±0.99	45%
Average Improvement	1.02±1.27	0.24±0.44	0.78±1.01	41%	0.97±1.12	0.43±0.57	0.54±0.82	25%

Table 2: ADL Performing Assessment Results

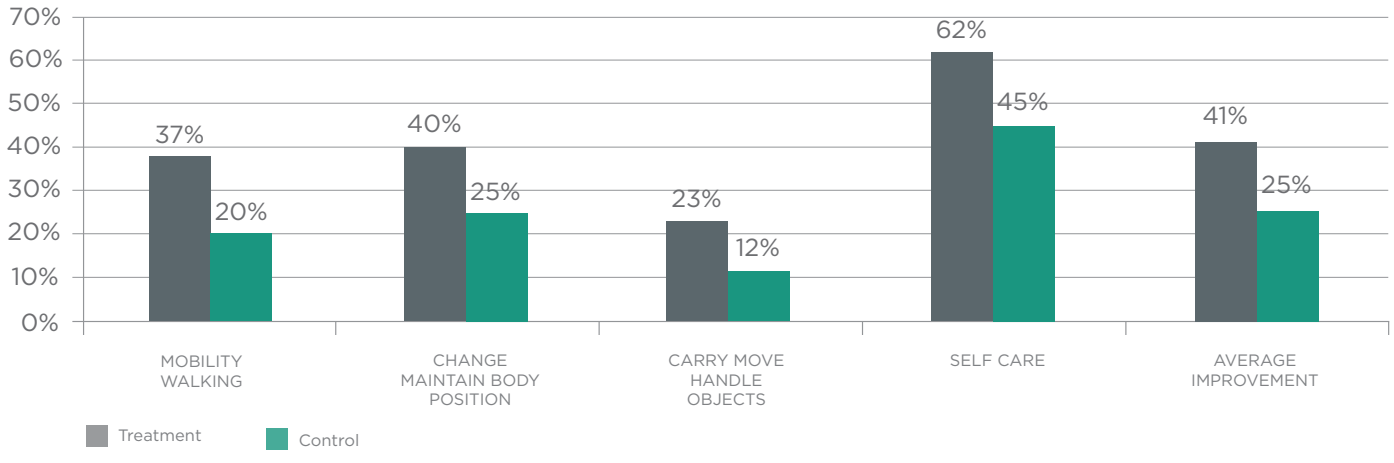

Figure 2: ADL Performing Assessment Improvement (%)

Discussion

The results proved pain decrease effect from both studied methods: TR-Therapy and conventional physiotherapy, in the relevant groups. The greater pain decrease is observed in the Treatment group. The 77% - pain decrease result in the Treated group correlates with improvement of the pain perception from 'Depressing, miserable pain' to 'No pain'. The 63% - pain decrease result in the Control group correlates with improvement of the pain perception from 'Depressing, miserable pain' to 'Mild, annoying pain'.

Increase of the abilities to perform ADL in both groups was observed, yet greater in the Treatment group. The 41% improvement result of the abilities to perform ADL in the Treatment group correlates to improvement from 'Able to do with little difficulty' to 'Absolute no difficulty' (mean 0.24±0.44 at post-treatment stage). The 21% improvement result of the abilities to perform ADL in the Control group correlates to improvement from 'Able to do with little difficulty' to mid-grade 'Able to do with little difficulty' – 'Absolute no difficulty'. (mean 0.54±0.82 at post-treatment stage).

The statistical analysis between the improvement results for both groups showed a significant difference with p=3,42E-03 for pain perception data comparison and p=7,07E-03 for abilities to perform ADL data comparison. Similar results are providing statistical prove that TR-Therapy is more effective in treating painful conditions and decreasing the difficulties to perform ADL compared to the methods of the conventional physiotherapy.

Conclusion

The presented results proved the TR-Therapy as an effective solution for treating painful conditions with ADL limiting factor (led by trigger points and muscle spasms) and more effective in comparison to the conventional physiotherapy methods. The therapy was proved as a quality of life increasing solution among patients experiencing pain and difficulties to perform ADL caused by trigger points and functional muscle spasms.

References:

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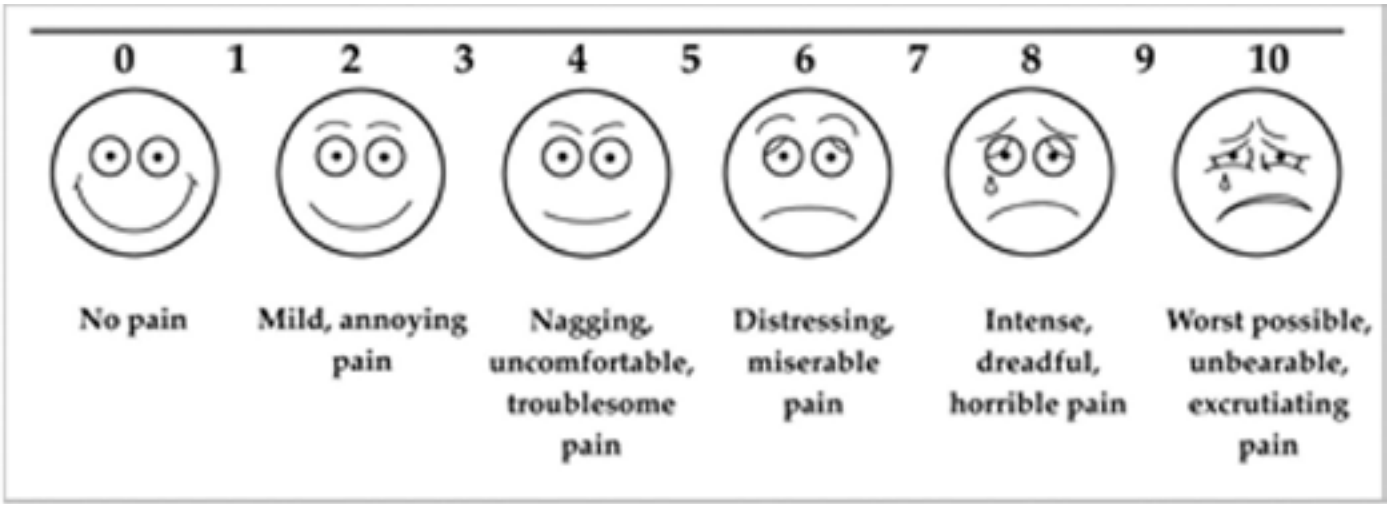
Appendix 1:

Visual Analog Scale for Pain



Appendix 2:

Patient Functional Assessment Questionnaire:

PATIENT FUNCTIONAL ASSESSMENT QUESTIONNAIRE

PATIENT NAME: _____ DATE: _____

		INSTRUCTIONS: Circle the level of difficulty for each activity.	0 = Absolute no difficulty	1 = Able to do w little difficulty	2 = Able to do w lit-mod difficulty	3 = Able to do w mod difficulty	4 = Able to do w mod-signif difficulty	5 = Able to do w signif difficulty	6 = Unable to do at all	Not applicable
MOBILITY/WALKING	1	Walking short distances	0	1	2	3	4	5	6	n/a
	2	Walking long distances	0	1	2	3	4	5	6	n/a
	3	Walking outdoors	0	1	2	3	4	5	6	n/a
	4	Climbing stairs	0	1	2	3	4	5	6	n/a
	5	Hopping	0	1	2	3	4	5	6	n/a
	6	Running	0	1	2	3	4	5	6	n/a
CHANGE/MAINTAIN BODY POSITION	1	Rolling over	0	1	2	3	4	5	6	n/a
	2	Moving - lying to sitting	0	1	2	3	4	5	6	n/a
	3	Sitting	0	1	2	3	4	5	6	n/a
	4	Bending/Stooping	0	1	2	3	4	5	6	n/a
	5	Kneeling	0	1	2	3	4	5	6	n/a
	6	Standing	0	1	2	3	4	5	6	n/a
CARRY/MOVE/ HANDLE OBJECTS	1	Pushing	0	1	2	3	4	5	6	n/a
	2	Pulling	0	1	2	3	4	5	6	n/a
	3	Reaching	0	1	2	3	4	5	6	n/a
	4	Grasping	0	1	2	3	4	5	6	n/a
	5	Lifting	0	1	2	3	4	5	6	n/a
	6	Carrying	0	1	2	3	4	5	6	n/a
SELF CARE	1	Dressing/Clasp b/h back	0	1	2	3	4	5	6	n/a
	2	Doing light housework	0	1	2	3	4	5	6	n/a
	3	Prep meals/kitchen tasks	0	1	2	3	4	5	6	n/a
	4	Bathroom activities	0	1	2	3	4	5	6	n/a
	5	Sleeping Ability	0	1	2	3	4	5	6	n/a
	6	Hygiene (comb hair/brush teeth)	0	1	2	3	4	5	6	n/a

_____ _____

PATIENT SIGNATURE DATE

_____ _____

REVIEWED BY THERAPIST / CREDENTIALS DATE