

The influence of high tone power therapy on the functional status of patients with multiple sclerosis

Multiple sclerosis (MS) is a chronic inflammatory demyelinating disease of the central nervous system, where there is a multifocal damage (demyelination and degradation of axons) nerve tissue. In 1868, the French neurologist Jean Charcot -Martin, as first described the pathology and symptoms of the disease [6].

It is believed that a key role in the formation of lesions play both autoimmune processes, common environmental factors and genetic factors. The lesions relate to the cortex and gray matter, including basal ganglia and cerebellar cortex [16]. The process of inflammation, which is related to proinflammatory cytokines, macrophages and T lymphocytes, causes a disturbance of the blood-brain barrier, which involves the malfunction of neurons, swelling, and hence may be the occurrence of relapse [14]. MS is a disease, which touches the population of young people. The disease affects people of working age, leading to their disability.

The largest number of cases is observed between 20 and 40 years of age. The MS cases also are diagnosed in children. They are called childish form of MS. There are as well cases of people aged 50 and older, referred to as late SM [13].

The most vulnerable population is Caucasian race. The occurrence of the disease in the world is very diverse, it is related to latitude. It is observed increase in the MS incidence with increasing latitude, and decrease when approaching the equator. This relationship is a confirmation of a reduced or increased exposure to the sun. Currently, the MS in the world suffer from approx. 2.5 million people and still is observed increase in the number of cases. The incidence eg. In Europe or the US is 40 - 150 patients per 100 000 inhabitants. In Poland, this number is 55 - 57 per 100 000 inhabitants, which means that the country is under high risk of developing MS [4].

MS is a complex disease because of the difficulty in determining the appropriate treatment and its wide range of symptoms. This suggests a comprehensive approach to the patient including both pharmacology and neurorehabilitation. Rehabilitation, which includes psychotherapy and symptomatic therapy, is regarded today as the best form of treatment in multiple sclerosis. An element of rehabilitation is a physiotherapy, which consists of treatments in kinesis, physiotherapy, massage and spas [5]. All treatments included in the physiotherapy should be recommended in such a way as to act upon the greatest possible number of motor deficits [3].

One of the new physical methods of the electrotherapy, which was used in patients with MS is the High Tone Power Therapy. Improvement of the functional status of the mentioned patients requires a comprehensive approach and the High Tone Power Therapy involves not only symptomatic but also causal treatment.

The High Tone Power Therapy (HiToP) is a modern method of electrotherapy, whose operation is based on the fact that the bioelectric changes occurring in cells always involve biochemical changes [2]. The main objective of therapy is a direct action on cell metabolism. Normalization of metabolism is a consequence of energy introduced into the body, which increases the energetic potential of the cell and cellular structures oscillation. This method is based on bi-directional medium frequency (from 4096 to 32768 Hz) currents [9]. In contrast to the classical electrotherapy, this method allows a therapist to change the amplitude and frequency depending on the individually set sensory threshold curve, which the manufacturer describes as SimulFAM®i. Classic electrotherapy allows the amplitude modulation, which means that the current is modulated at a fixed frequency or uses the frequency modulation only. Another distinctive aspect of the treatment with use of the High Tone Power Therapy in comparison with the classic electrotherapy is the fact that the procedure can take up to 60 minutes, using 4 channels of at least 10 electrodes.

For the therapy can be used the above-mentioned, non stimulus mode of operation - SimulFAM®, as well

as the stimulus mode - SimulFAM ® X.

In the first mode of operation we do not get muscle stimulation, but the metabolism improvement, analgesic and revitalization of the organism. This is caused by the resonance vibration, which aims at improving the metabolic processes and pain reduction. Revitalization involves the whole body of the patient, which is of great therapeutic importance, since the disease rarely is limited to one part of the body only. A particular effectiveness can be identified in patients with MS, where the demyelinating process causes dysfunctions within the upper and lower limbs, leading to disability. Vitalization also strengthens the immune system throughout the whole body [18].

In the second mode of operation SimulFAM ® X brings stimulation of nerves and muscles, where "X" means exceeding the threshold curve. This action is similar to the classical electrotherapy, but at a higher energy level. The following are the ranges of electric current used in the High Tone Power Therapy:

- 0.1-0.5 Hz - the slow movements of the muscles to relax, activating muscle pump
- 3 Hz - stimulation of lipolysis
- 10 Hz - vasoconstriction, treatment of oedema, congestion reduction
- 20 Hz - muscle stimulation to contract with interruptions - 100 Hz - the reduction of pain according to the "gate control" theory.

The use of the latter frequency of 100 Hz is an important part of therapy because the pain information is transmitted to the brain by sensory nerves, at a rate of 100 pulses per second, which causes superposition of the information about hyperalgesia. This results in a lack of receive of this stimulus in the brain. Analgetic effect can be used locally, or generally in cervical spinal cord. The advantage of the overall analgesic effect is to block pain information to the spinal cord and its lack of flow to the brain. The treatment is based on applying electrodes in the places of pain in order to activate the local cells with SimulFAM®i, and then a local or general application of the electrodes in order to reduce pain with SimulFAM®X 100Hz [2].

Basic therapeutic procedure takes 60 minutes, during which following treatments are used: causal treatment with an SimulFAM®i - enhancing vitality and symptomatic therapy with SimulFAM®X of analgesic nature. The method has been used in the treatment of back pain, soft tissue injuries, disorders of the microcirculation, as well as in disturbances of the psyche. The advantage of the method is the possibility of its application in patients with metal implants, or varicose veins. Contraindication for treatment are general ongoing inflammatory processes in the body, bacterial infections, a pacemaker, as well as pregnant women.

1. Materials and methods

The study included 20 patients of both sexes: 13 women and 7 men aged from 23 to 77 years (mean 53.8 ± 12.27) suffering from MS who were treated in the Department of Rehabilitation and Physical Medicine, University Hospital WAM - central Veterans Hospital in Lodz, Poland. Patients were included in the project after the subject and object audit, namely the diagnosis of MS on the basis of clinical MRI. The exclusion criteria were common contraindications for electrotherapy and obtaining Kurtzke's scale (EDSS) score above 7.5.

Patients were randomly divided into two study groups. Group I consisted of 10 MS patients aged 32 to 65 years (mean 50.9 ± 10.6) who were applied the High Tone Power Therapy. Group II consisted of 10 patients also with MS at the age of 23 to 77 years (mean 56.7 ± 13.67), who used treatments in kinesis. Both the I and II test group 15 days of treatment were used.

In the group I the High Tone Power Therapy was used with the device HiToP 4 Touch. The operating time was 60 minutes. The device generates a frequency in the range of 4096 and 32768 Hz, which pass through the body of the patient in the form of an electric field. The electric field causes molecules vibration, which consequences have been described in the introduction. The High Tone Power Therapy has two possible

effects, causal and symptomatic. The patients received three different application techniques:

- The red channel of the device - the whole body - two electrodes on the plantar of the foot (black plugs), 2 electrodes on the outside of the forearm (white plugs) - SimulFAM®i;
- The green channel - 1 electrode transversely at the level of the lumbar spine (black plug), 2 electrodes laterally on the abdominal wall (white plugs) - SimulFAM®i;
- The yellow channel (one electrode at the level of the cervical spine, two electrodes on the eyeballs) - SimulFAM®X 100Hz.

Flat rubber electrodes were used for the treatment, moistened with the "Aloe Vera" aloe spray to avoid skin irritation. Moreover, the application of the spray ensures long-lasting moisturization of the skin, which is needed for 60 minutes of the High Tone Power Therapy treatment. The electrodes used to stimulate the eyeballs were applied with the sterile gauze backing. All electrodes were attached with the Velcro rubber straps. Electrodes were attached in the following order: the green channel, the yellow channel, the red channel, which means that the current in the two channels operating in the same time were tuned in the same order, and vitalization of the body was connected last. The current was tuned two times at a frequency of 4096 Hz and at a frequency of 16384 Hz, until obtaining a clear sense of tingling sensation by the patient.

In the group II the were used exercises in classical kinetic therapy, together with and elements of neurophysiological methods such as PNF (Proprioceptive Neurmuscular Facilitation) and NDT Bobath (Neuro-Developmental Treatment - Bobath). Patients used mainly active relieving exercises on upper and lower limbs, balance exercises, coordination exercises, walking re-education, postural muscles exercise and re-creation normal movement patterns.

To assess the functional state of the patients was used the Kurtzke's Enlarged Scale Physical Failure (EDSS) and the Index of ADL by Barthel. Quality of life assessment was made using the Questionnaire MSQOL-54. For the evaluation of gait and balance Tinetti scale was used, and the pain was evaluated in the VAS and Laitinen scale. Assessment of changes in muscle tension was determined according to the Ashworth scale [10]. Verification of the patient's condition was carried out twice, before the start of rehabilitation and immediately after the period of rehabilitation.

The results were statistically analysed by adopting the significance level of $p < 0.05$. The Student t-test was used for independent samples. Assessment of the normal distribution was verified by the Shapiro-Wilk test. In analysis of the results the Statistica PL 10.0 software was used.

2. Findings

Based on the data collected, the results have been developed. They are graphically depicted in Tables 1 - 3, and Figures 1 - 5. After the series of 15 treatments and re-examination of the MS patients were found positive impact of the therapy on all the parameters of the study.

In the group I, which used the High Tone Power Therapy an improvement occurred, statistically significant at $p < 0.05$ in terms of functional status, balance and gait, quality of life and pain, as shown in Table 1 and figures 1 - 5. There was also obtained improvement in terms of muscle tone in Ashworth scale assessed in comparison with the test performed before the start of rehabilitation, but this value was not statistically significant. The mean value of pain intensity in the Laitinen scale was 5.7 before treatment and 3.7 after treatment. Similar results were obtained in the visual analogue scale VAS, where the average value was 39.9 before treatment and after finished therapy it was 19.3. Mean values are shown in Figure 4. Thus, there was confirmed reduction of pain, which is one of the symptoms associated with MS.

It is worth mentioning that all patients in group I showed an improvement in terms of scale MSQOL-54, evaluating the quality of life, both in terms of physical and mental. Patients reported significant improvement after treatment in the field of energy, pain, sexual function, or social, and cognitive limitations and deficiencies due to emotional problems, which resulted in an improvement in the overall

quality of life. The results are shown in Figure 5. It can be concluded that this could contribute to the SimulFAM®i program, aimed at revitalization of the whole organism. The results indicate primarily improving the general functional condition, manifesting in the results in the EDSS scale and Barthel ADL Index (Figs. 1 and 2). Positive results were also reported in the Tinetti scale that assesses balance and gait, where the average value before treatment was 13.4, and after treatment it was 16.9. It is therefore a higher score obtained after the High Tone Power Therapy (Fig. 3).

In the group II, wherein patients underwent exercise within the scope of classic physiotherapy a statistically significant improvement was also achieved, but not in all the examined parameters, as shown in Table 2. There was no additional progress in the field of EDSS, Ashworth, and Tinetti scale, evaluating one of the components - namely the balance. Other results show an improvement in quality of life, less pain, and also better gait parameters achieved.

Also the results obtained before and after treatment the patients of Group I and II were correlated. There were no statistically significant differences. This means that both treatments carried out in group I and II bring favourable results in patients with MS and should be included in the basic program of rehabilitation. The results are shown in Table. 3. The High Tone Power Therapy used in patients in group I helped to get a statistically significant improvement in all parameters studied, which have a significant impact on the daily functioning of patients with MS.

Evaluation of the used High Tone Power Therapy is mainly based on subjective tests. However, the information obtained from patients during treatment and immediately after its completion, indicates positive, comprehensive impact of this type of therapy on the organism. Despite the long-lasting (60 minutes) treatment, patients reported the recovery of vitality, and general relaxation.

Table 1. The significance of differences between arithmetic means obtained in group I before and after the test

Variable	n	Standard deviation (difference)	t	p
EDSS	10	0,258	3,674	0,005121*
ADL Barthel Index	10	0,667	-4,743	0,001054*
Ashworth	10	0,422	1,500	0,167851**
Tinetti: - Balance - Gait	10	1,716	-6,450	0,000118*
	10	2,098	-4,221	0,002236*
	10	1,033	-5,511	0,000375*
Laitinen	10	1,886	3,354	0,008468*
VAS	10	20,619	3,159	0,011563*
MSQOL-54 (ZP)	10	1,015	-7,077	0,000058*
MSQOL-54 (ZF)	10	0,425	-9,528	0,000005*

Explanation:

* - Statistically significant difference $p < 0,05$

** - Statistically insignificant difference $p > 0,05$

Table 2. The significance of differences between arithmetic means obtained in group II before and after the test

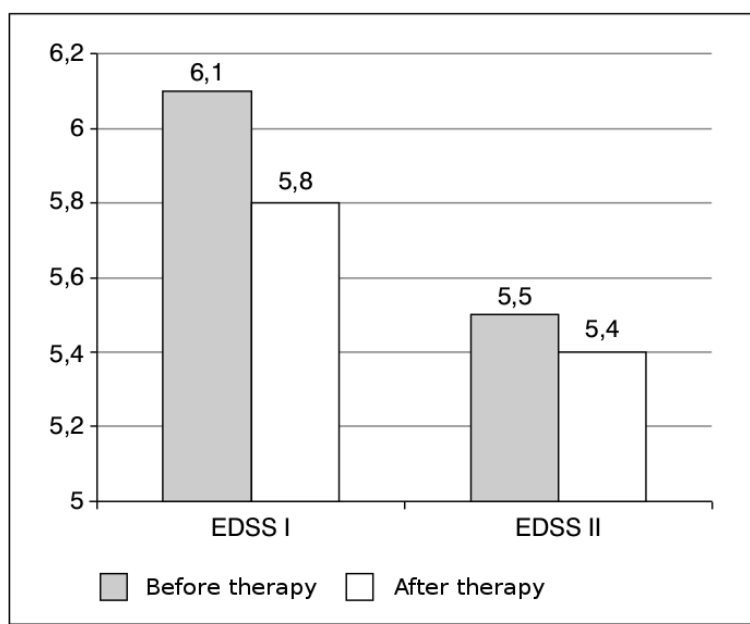
Variable	n	Standard deviation (difference)	t	p
EDSS	10	0,211	1,500	0,17
ADL Barthel Index	10	0,516	-3,674	0,005121*
Ashworth	10	0,350	1,809	0,1

Variable	n	Standard deviation (difference)	t	p
Tinetti:	10	1,581	-3,000	0,01
- Balance	10	2,415	-1,964	0,08
- Gait	10	0,876	-3,250	0,009991*
Laitinen	10	2,877	3,847	0,003925*
VAS	10	15,986	3,422	0,007603*
MSQOL-54 (ZP)	10	0,978	-7,179	0,000052*
MSQOL-54 (ZF)	10	0,354	-10,828	0,,000002*

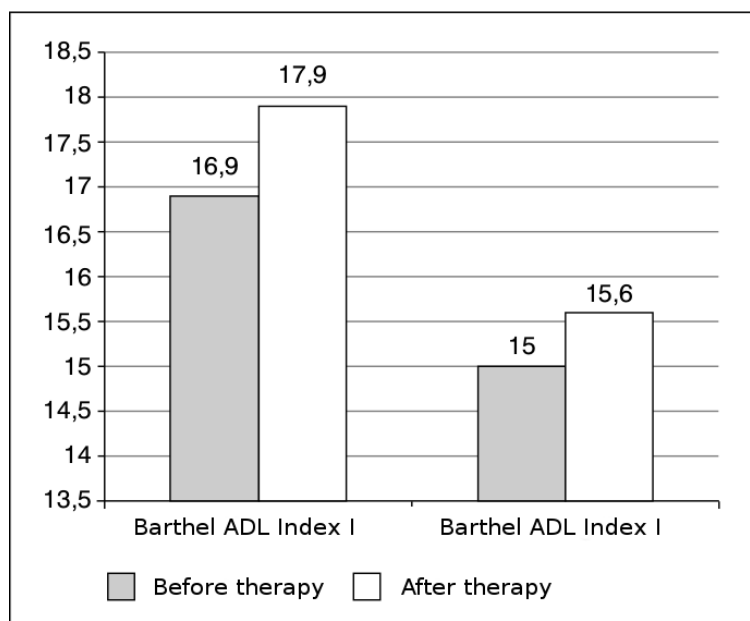
Explanation:

* - Statistically significant difference $p < 0,05$

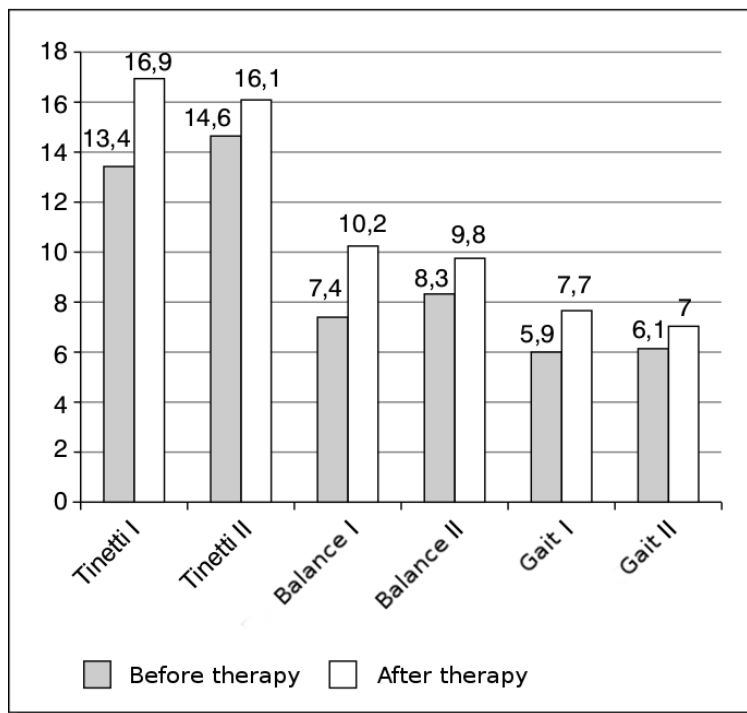
** - Statistically insignificant difference $p > 0,05$



Pic. 1. Average values obtained on a scale EDSS in group I and II, before and after therapy



Pic. 2. Average values obtained on a scale ADL Barthel in group I and II, before and after therapy



Pic. 3. Average values obtained on a scale Tinetti in group I and II, before and after therapy

Table 3. The significance of differences between arithmetic means obtained in group I and II before and after the test

Variable	n	Before			After		
		t	p	variances	t	p	variances
EDSS	20	0,930	0,367**	0,093	0,656	0,520**	0,064
ADL Barthel Index	20	1,116	0,279**	0,340	1,393	0,181**	0,306
Ashworth	20	-0,761	0,457**	0,706	-0,728	0,476**	0,278
Tinetti:	20	-0,458	0,652**	0,018	0,301	0,767**	0,103
- Balance	20	-0,570	0,576**	0,000	0,219	0,829**	0,088
- Gait	20	-0,165	0,871**	0,444	0,611	0,549**	0,806
Laitinen	20	0,284	0,780**	0,614	1,573	0,133**	0,260
VAS	20	0,104	0,918**	0,538	-0,198	0,845**	0,904
MSQOL-54 (ZP)	20	0,451	0,658**	0,578	0,531	0,602**	0,540
MSQOL-54 (ZF)	20	0,600	0,556**	0,576	0,702	0,491**	0,455

Explanation:

* - Statistically significant difference $p < 0,05$

** - Statistically insignificant difference $p > 0,05$

3. Discussion

The MS is still an incurable illness, which causes disability. A growing number of patients, especially at a young age, triggers researchers to search for new therapies to alleviate the negative effects of the disease. Patients suffering from MS have problems with the performance of the basic activities of daily living. This is a result of a number of neurological deficits resulting from the disease. It has been shown the

relationship between the degree of disability, and quality of life of patients. Rośc proved that quality of life is dependent on the degree of disability as assessed by Kurtzke's EDSS [12]. Broła et al., confirmed a clear relationship between the degree of disability, and the severity of depression and the consequent reduction in quality of life [1]. Cited studies, but also many others, evaluating the quality of life indicate the negative impact of the disease on physical and mental functioning of patients with MS. The role of doctors and physiotherapists is to implement new methods of therapy to alleviate the symptoms and, consequently, improve the quality of life.

Due to the favourable results of the High Tone Power Therapy in other disease entities, there was an attempt to assess the efficacy of the High Tone Power Therapy on the functional status of patients with MS. Unfortunately, cannot compare the results observed by other researchers, due to the lack of reports in the literature on the use of the treatment of demyelinating diseases. The performed to date studies with use of the High Tone Power Therapy indicate positive effects in the treatment of symptoms of peripheral joints and spine, which manifest in less pain [7,17]. Similar results were observed in patients with diabetic neuropathy, as well as in the chronic pelvic pain [11,19]. In patients with cerebral palsy have shown improvement in gait parameters, as well as the operations manual hand [15]. Studied patients with chronic venous insufficiency and obtained relief of symptoms, ie. Swelling and pain. The therapy applied in patients suffering from peripheral vascular disease in examining the effect on peripheral microcirculation lower limbs. The results confirmed the beneficial effects of therapy energetycznej changes in microvascular flow dynamics of the lower limbs [8].

The above reports confirm the effectiveness of the High Tone Power Therapy as a method of healing, also in terms of prevention. The method may be particularly useful for patients with MS, improving their functional status, and thereby improving the overall quality of life. Achieving results in terms of number of tested parameters allows the use of this therapy in the comprehensive improvement of MS patients. Because of the tests were performed on a small number of patients it is advisable to continue treatment for a larger population.

4. Conclusions

The High Tone Power Therapy has a beneficial effect on the functional state and is well tolerated by patients with MS. The use of a series of 15 treatments with the High Tone Power Therapy had statistically significant impact on the improvement in the parameters studied, except for the changes in muscle tension. Both the High Tone Power Therapy and exercises of the classic kinesytherapy had a positive influence on the existing neurological deficits in patients with MS. No adverse event indicates a high level of safety the High Tone Power Therapy.

Obtain promising results in a few groups of patients suggests the need for a follow-up to a larger population.

5. Bibliography

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Contact:

Anna Kubsik

Uniwersytet Medyczny w Łodzi, Klinika Rehabilitacji i Medycyny Fizykalnej,

PL 90-647 Łódź, Plac Hallera 1, phone / fax +48 (42) 63 93 064,

e-mail: anna.kubsik@wp.pl