Evaluation of the effectiveness of bioresonance therapy in patients with chronic lumbosacral dorsopathy

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It is now generally accepted that when assessing the severity of the disease, choosing the methods of therapy and assessing their effectiveness, it is necessary to rely on indicators of quality of life (QOL) [1, 15]. According to statistical studies, the pathology of the lumbosacral spine accounts for about 30% of the total morbidity, 20-30% of all diseases of the nervous system and more than 80% of diseases of the peripheral nervous system [2, 16]. Most often, clinical manifestations due to degenerative changes occur in the lumbar spine (62%), less often- in the cervical (36%) and only 2% - in the thoracic region. Lumbosacral dorsopathy (PCD) is characterized by low back pain- LBP) and significantly reduces the quality of life, and the existing treatment programs for patients are extremely diverse and expensive [3, 17]. For example, in the United States, the treatment of this disease accounts for up to 80% of health care costs. Such high costs of society for treatment concern, first of all, that small category of patients (4% of the population) who do not recover from the first episode within a month from the onset of the disease and become chronic patients [18]. Myofascial pain syndromes (MFPS), represented by myofascial trigger points (MFTP), are among the main causes of back pain [4, 5, 6]. In chronic pain syndrome PKD, rehabilitation methods come to the fore in the treatment of patients, which are aimed at preventing exacerbations of the disease and slowing the progression of the degenerative-dystrophic process in the spine [7, 8]. The high risk of side effects of ongoing drug therapy and surgical treatment in patients with PKD and a significant decrease in the quality of life of patients make it urgent to search for new promising methods of non-drug treatment [9]. In the era of development of biophysical technologies, a promising direction is the use of adaptive

bioresonance therapy (BRT), using low-intensity pulsed electrical influences [10, 11, low-frequency 12].

Modern principles of integrated treatment PKD include and usage slow-acting modifying agents: chondroprotectors, which contain glucosamine and chondroitin sulfate for external, injection, oral administration [13, 14, 19]. From the group of chondroprotectors, the biotechnological drug Alflutop (Biotechnos, Romania), which has a positive ten-year experience of clinical use, and Teraflex (Sagmel, Inc., USA) are increasingly being used.

Purpose of the study: to analyze the effectiveness of the use of BRT and Alflutop local therapy (ALT) on an outpatient basis in patients with PKD, both in monotherapy and in combination.

Material and research methods

In a controlled open study of the effectiveness of the use of biophysical technologies in patients with lumbosacral dorsopathy, 110 patients (39 men and 71 women) with degenerative-dystrophic PCD were examined. Patients were aged from 27 to 62 years (average 43.1 ± 5.2 years), with a disease duration from 1 to 8 years (average 3.7 ± 2.4 years) and current exacerbation from 1 to 5 months. ... (on average 2.5 ± 0.9 months). Patients complained of pain at the level of the lumbosacral spine and lower extremities, limited mobility in the spine, numbness of the extremities, fatigue, irritability, sleep disturbance.

Clinical neurological examination was carried out to investigate the detection of pain syndrome of varying intensity in the lumbosacral region, with positive symptoms of tension Lasegue, Wasserman, Neri, Matskevich. In cases of discogenic radiculopathy, a decrease or loss of the corresponding reflexes, muscle weakness and hypesthesia in the innervation zone of the affected nerve roots were revealed. Depending on the severity of the disease, ultrasound, radiography, CTG, MRI of the spine, RVG, electropuncture diagnostics (EPD) using the method of autonomic resonance test (VRT), visual palpation diagnostics (VPD) were performed in order to identify the sources of pain and determine the pain pattern specific to each the patient before and after treatment [11, 12].

Depending on the therapy used, all patients were divided into 4 groups, matched by sex, age, clinical picture, and duration of the disease.

Group I - BRT the main one, 30 patients (9 men and 21 women, mean age 42.1 ± 4.9 years) received an optimized version of BRT using an IMEDIS device for autonomous BRT [11,12];

Group II - ALT Comparison, 30 patients (12 men and 18 women, mean age 42.9 ± 4.4 years) received ALT - Alflutop, locally subcutaneously 1.0 ml in 4-5 most pronounced MPTP, every other day, depending on the severity of the pain syndrome;

Group III - ALT + BRT comparison, 30 patients (10 men 20 women, mean age 43.4 ± 4.6 years) - received ALT - Alflutop, locally, s / c in 4-5 MPTP, followed by simultaneous BRT, after 1-2 days or 1-2 times per week.

IV group - A + NSAIDs control, 20 patients (8 men and 12 women, mean age 42.4 ± 5.0 years) received NSAIDs Dicloberl (Dicloberl, Berlin Chemie Menarini Group, intramuscularly) up to No. 5-10 and Alflutop (Biotechnos, Romania), 1 ml intramuscularly, daily, No. 20.

The bioresonance effect was provided with the help of the hardware-software complex (APC) "IMEDIS-EXPERT" or the apparatus for adaptive BRT "IMEDIS-BRT-A". All patients received simultaneously drug therapy, which included B vitamins, chondroprotectors (oral and external), anticholinesterase agents and angioprotectors, if indicated.

The effectiveness of the treatment was assessed on the basis of a clinical and neurological study: an increase in the range of motion in the spine (symptoms of Schober and Thomayer), the severity of muscle-tonic syndrome (MTS), the severity of the radicular syndrome, the index of muscle syndrome (IMS), and data on the scale of general clinical impression ... For a subjective assessment of the intensity of pain, a special examination was carried out using questionnaire methods using a visual analogue scale (VAS), an assessment of the level of vital activity with the Oswestry questionnaire (ODI, The Oswestry Low Back Pain Disability Questionnaire, ODQ according to J. Fairbank. 1980), Roland's questionnaire - Morris "Pain in the lower back and disability" (M. Roland, R. Morris, 1983) and medical and psychological testing using the Luscher color test.

The study was conducted before and after treatment.

The inclusion criteria were:

1) age from 20 to 65 years;

2) an established diagnosis of lumboischialgia due to herniated lumbosacral discs, spondyloarthropathy or spondylosis, radiographically confirmed;

3) moderate or severe pain syndrome;

4) chronic recurrent or persistent course with a prescription of the current exacerbation at least 1 month

The exclusion criteria were:

1) the duration of the exacerbation is less than 1 month;

2) severe deformity of the spine and herniated discs, complicated by compression of the root;

3) diseases of the spine requiring special treatment (tumors, infections);

4) concomitant somatic diseases of the cardiovascular system, liver, kidneys; diabetes;

5) taking drugs with a chondroprotective focus for 6 months to the present research.

Results and discussion

A total of 110 patients were included in the study, aged from 27 to 62 years (average 43.1 ± 5.2 years). Neurological examination before the start of the study revealed pain syndrome of varying intensity in the lumbosacral region (in 71 - moderate, in 29 - significant). When comparing groups by age, gender, ODI and VAS, no statistically significant differences were found.

The VAS questionnaire for the patient's self-assessment of the severity of pain is a straight horizontal line 10 cm long, on which the patient marks the level of pain with a vertical line from 0 cm - no pain, up to 10 cm - unbearable pain.

Table 1

VAS scores in patients before and after treatment on day 14

No.	Patient groups (type of therapy)	before treatment	14 day of treatment	% improvement
I	BRT n = 30	6.3 ± 2.3 (100%)	2.1 ± 1.3	66.7
II	ALT n = 30	6.1 ± 2.2 (100%)	2.2 ± 1.7	63.7
III	ALT + BRT n = 30	6.4 ± 2.2 (100%)	1.4 ± 1.4	81.3
IV	A + NSAIDs n = 20	6.2 ± 2.4 (100%)	2.1 ± 1.4	66.1

Analysis of the indices of subjective sensations of pain intensity according to VAS shows that the effectiveness of the applied methods of therapy for PKD in all groups was determined as high (p <0.05). Before treatment, the level of pain syndrome, assessed by the VAS, was 6.3 mm (from 48 to 82 mm).

2.2 was obtained in group II (ALT monotherapy) and the efficacy rate was 63.7%. A significant decrease in the intensity of pain syndrome from 6.4 points to 1.4 was obtained in group III (complex therapy of ALT and BRT) and the efficiency indicator was 81.3%, which is 17.6% more than in group II (p <0, 05). The indicators in groups I (monotherapy with BRT) and IV (A + NSAIDs) are comparable, respectively, 66.7% and 66.1%. Assessment of pain perception according to VAS after 1 month was in group I - 76.7%, in group II - 73.2%, in group III - 87.6%, in group IV - 76.0%.

The revealed side effects when using Alflutop: soreness at the injection site - 4 cases and headache, dizziness - 1 case, disappeared on their own, against the background of ongoing treatment.

Side effects in the form of pain in the epigastric region and dyspeptic manifestations were noted by 7 patients (35%) of group IV (A + NSAIDs). When conducting FGS, ultrasound, all these patients were found to have gastropathy, of which 2 (10%) had erosive, which makes it possible to interpret these disorders as a complication: NSAIDs - gastropathy.

The Oswestry Questionnaire (ODI) for PCD was used to identify impairments to the patient's daily physical functioning. The total score can range from 0 (best performance) to 50 (worst performance).

table 2

Indicators of the ODI questionnaire in points before and after treatment on day 14

No.	Patient groups (type of therapy)	before treatment	14 day of treatment	% improvement
I	BRT n = 30	31.3 ± 2.5 (100%)	12.3 ± 1.4	60.7
II	ALT n = 30	30.4 ± 2.3 (100%)	12.0 ± 1.3	60.4
III	ALT + BRT n = 30 A	31.5 ± 2.2 (100%)	8.5 ± 1.6	73.0
IV	+ NSAIDs n = 20	31.2 ± 2.7 (100%)	12.3 ± 1.5	60.5

The quality of life according to ODI was 31.1% (24 to 57%). QoL improvement based on results ODI questionnaire was observed in all groups. The smallest downward trend in this indicator was found in group II (ALT) to 12.0 points (60.4%). The best dynamics of the indicator was determined in group III (ALT + BRT) from 31.5 to 8.5 points (73%), which is 12.6% more than in group II. There is a statistically comparable decrease in indicators in groups I (12.3 - 60.7%), II (12.0 - 60.4%) and IV (12.3 - 60.5%). The ODI questionnaire indices after one month were 72.5% in group I, and group II - 73.3%, group III - 88.0%, group IV - 72.6%.

Table 3

Indicators of the Roland-Morris questionnaire in points before and after treatment on day 14

No.	Groups patients (type therapy)	before treatment	14 day of treatment	% efficiency
I	BRT n = 30	12.3 ± 2.2 (100%)	2.9 ± 1.1	94
II	ALT n = 30	12.3 ± 2.3 (100%)	3.1 ± 1.2	92
III	ALT + BRT n = 30 12.6 ± 2.2 (100%) A +		2.1 ± 1.1	105
IV	NSAID n = 2 12.2 ± 2.1 (100%)		3.3 ± 1.2	89

According to the Roland-Morris questionnaire, the average score of the pain self-assessment level in patients before treatment was 12.3 ± 2.2, significantly decreased: from 12.3 to 2.9, which shows the high efficiency of the therapy (p <0.05). A more pronounced decrease in the level of pain in patients of group III - 105% efficiency and less pronounced in group IV - 89% (results between groups are statistically significant, p <0.05). Roland-Morris scores correlate with ODI scores. A month later, positive trends persisted in all groups and increased by the third month.

The severity of muscle-tonic syndrome (MTS) was determined by calculating the muscle syndrome index (IMS): I severity of spontaneous pain, II muscle tone,

IV duration of pain, V degree of pain irradiation on palpation. IMS is assessed by the sum of points of the named signs: I degree (mild) - IMS up to 5 points; II (medium, moderate) - from 5 to 12 points; III (severe, pronounced) - more than 12 points [15].

Table 4

Index of muscle syndrome in patients before and after treatment on day 14

No.	Patient groups (type of therapy	before treatment	Day 14 treatment	% improvement
I	BRT n = 30	12.4 ± 2.3 (100%)	3.1 ± 2.2	75
II	ALT n = 30	12.1 ± 2.4 (100%)	3.7 ± 2.2	69.4
III	ALT + BRT n = 30 A	12.9 ± 2.1 (100%)	2.1 ± 0.2	83.4
IV	+ NSAIDs n = 20	12.4 ± 2.3 (100%)	3.3 ± 2.2	73.4

IMS during an objective examination was defined as pronounced (12.5 ± 0.2 points in 34 patients - 31%) and average (7.6 ± 0.2 points; in 76 people - 69%). IMS after 5 days of treatment was no more than 4.8 ± 0.2 points ($p < 0.05$); after 10 days it decreased to 2.0 ± 0.2 ($p < 0.05$) and remained during the next month. In group III, relief of pain syndrome was observed after the 1st or 2nd session, and in group IV - after the 4-5th session ($p < 0.05$) and a statistically significant decrease in IMS in 5-7 sessions, which is 2 , 6 times less than in group IV ($p < 0.05$). Patients I – III subsequently underwent therapy sessions 1–2 times a week, 1–2 times a month, according to indications. The course of therapy for women was 5.5 sessions, for men - 8.2. The average session duration was 10–40 minutes. Stable IMS indicators for more than 3 months were observed in all groups, however, in groups III they persisted from 6 months to a year, and in groups I, II, IV they increased during the first 3 months and depleted by 6 months.

Medical and psychological testing using the Luscher color test revealed a violation of emotional stability (ES) 34%, the level of anxiety (UT) 31%. As a result of therapy in group III (ALT and BRT), there was a decrease in UT to low values and an increase in stress resistance in 69% of patients. With monotherapy, unambiguous results were obtained, indicating an increase in stress resistance in 54% of cases (the differences between the groups are statistically insignificant). In 4 cases, women who had a history of significant psycho-emotional upheavals, against the background of clear positive tests in the dynamics of VAS, ODI, Roland-Morris, no positive changes were observed in the Luscher test. In all these cases, the pain relief was short-term.

The most common symptom of Lasegue tension on examination was positive in all patients. The average value of the angle of elevation of the limb when checking the Lasegue symptom in patients of groups I and II was 45.0 ± 14.3 °, in III and IV - 41 ± 12.0 °. It should also be said that most often in patients of all groups, the interest of the S1 root was revealed, less often L5. The dynamics of the functional state of the spine (Schober and Thomayer test) during therapy had positive and statistically significant changes by 1 month of treatment (p, 0.05). Thomayer's test before treatment averaged 27.2 ± 5.7 cm, after treatment - 5.1 ± 3.8 cm, Schober's test before treatment - 5.4 ± 3.5 and after - 12.5 ± 2.5 cm.

With EPD by the ART technique, the level of lesions of the spinal column, plexuses, roots was revealed using the electronic selector of the APK "IMEDIS-EXPERT" and / or the parameters of the problem areas directly were measured before treatment and during a treatment session. They had the value of the zone where the corridor of numbers was registered: from 0-40. The duration of the BRT session is determined by the achievement of the norm of EPD indicators (80 cu) during the session and the regression of the activity of the pain source. The duration of the session is 10-40 minutes.

Evaluation of the results on the scale of general clinical impression (Clinical Global Impression - CGI) was used with the following gradations: "-" 1 point - deterioration; 0 points - no effect; 1 point - slightly pronounced effect; 2 points - moderate effect; 3 points - significant effect.

"Significant effect." A significant improvement was understood as a rapid relief of the main symptoms of the disease, as well as a pronounced positive dynamics of special research methods.

"Moderate effect". Improvement was understood as a determined significant regression of clinical symptoms, with a positive dynamics of the results of special research methods.

"No effect" assessed the therapeutic effect in the absence of reliably significant positive changes on the part of subjective and objective clinical signs and

special research methods.

Table 5

Overall Clinical Impression Scale

No.	Patient groups (type of therapy)	deterioration, %	No effect,%	insignificantly expressed the effect, %	moderate. the effect, %	significant the effect, %
I	BRT n = 30	-	-	nineteen	65.7	15.3
II	ALT n = 30	-	-	18	68.7	13.3
III	ALT + BRT n = 30 A	-	-	13.3	fifty	36.7
IV	+ NSAIDs n = 20	25	-	fifteen	55	five

On the scale of general clinical impression, functionally significant improvement in patients (moderate + significant) was 86.7% in group III, in group I - 81%, in group II - 82%, in group IV - 60%. In group III, patients who received complex therapy ALT + BRT have the maximum indicator in the column "significant improvement" - 36.7%. In group IV, deterioration was recorded in 5 patients (25%), due to the development of NSAID gastropathy. The use of NSAIDs does not always eliminate pain syndrome, has a negative effect on bone metabolism and increases the risk of side effects on the gastrointestinal tract. Groups I and II are statistically comparable and have no significant differences. Younger patients (20–29, 30–39) years old showed better results with ALT and / or ALT + BRT, and patients over 50 years old, respectively - during BRT and ALT + BRT. Alflutop was more effective in young and middle-aged patients with a relatively short duration of illness and current exacerbation. It is important to note that the therapeutic effect of alflutop was also manifested in a decrease in the patients' need for non-steroidal anti-inflammatory drugs.

In all groups, as a result of the therapy, there was a normalization of the neurological status: regression of symptoms of tension and emotional sensation of pain, vegetative-trophic disorders, sensory and motor disorders; improvement of the functional activity of patients, primarily of such parameters of mobility as the ability to flexion-extension and standing. A positive trend was revealed, which was more significant and distinct in patients of group III who received complex therapy: ALT + BRT. The average duration of one course of treatment was 16.8 in the 1st group; in the second - 18.8; in the third - 13.9; in the 4th - 20 days. Stable positive follow-up up to 6 months in patients in groups I, II, IV; from 6 months to a year or more in patients of group III. Repeated courses of therapy are recommended in groups I, II, III 1-2 times a year; IV - 2 times a year.

Conclusions:

1. The effectiveness of the applied methods of therapy on an outpatient basis in patients with PKD during all groups turned out to be significantly high.

2. The most effective method of therapy that improves QoL in patients with PKD was complex therapy using an optimized BRT and ALT method, which is reliably confirmed by indicators of the physical and mental health of patients in all age categories: visual analogue scale (VAS) - 81.3%, ODI questionnaire - 73.0%, Roland-Morris questionnaire - 105 %, muscle syndrome index (IMS) - 83.4; Luscher color test - increased stress resistance -69%; the degree of decrease in severity with. Lasegue, range of motion in the spine - Schober's test 12.5 ± 2.5; Thomayer's test - 5.1 ± 3.8; scale of general clinical impression - 87.7%, treatment time - 13.9 days, follow-up from 6 months. up to 1 year.

3. Methods of monotherapy - BRT, ALT effectively affect the quality of life of patients and can considered by the methods of choice for PKD, to a greater extent in young people.

4. The use of a combination of A + NSAIDs has a positive effect on the QoL of patients with PKD, but to a lesser extent. degree and due to the side effects (NSAID gastropathy) has limitations.

5. The use of adaptive BRT and ALT both in monotherapy and in combination can reduce drug load, prevent polypharmacy, allergization of patients, reduce the need for NSAIDs, and can be recommended for widespread use in patients with PKD on an outpatient basis.

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