

Randomized Application of Low-Frequency Electrostatic Field and General Magnetic Therapy after Surgical Treatment of Breast Cancer

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Abstract

Background: Various methods of physical therapy are widely used in the rehabilitation of patients with cancer (magnetotherapy, pneumocompression, electrotherapy, laser therapy). The goal of such rehabilitation is to minimize side effects and complications after radical treatment. However, a staged approach to the appointment of physiotherapeutic factors in the early period after surgical treatment of breast cancer has not been developed enough.

Aim: To develop a staged approach to the appointment of physiotherapeutic factors at different times after surgical treatment of breast cancer.

Design: a randomized-placebo-controlled study.

Location: the clinic named after professor Yu. N. Kasatkin of the Russian Medical Academy of Continuing Professional Education of the Ministry of Health of the Russian Federation, Moscow.

Population: Examination and treatment of 78 patients aged 30-70 after surgery for breast cancer were performed. The main group of 39 patients underwent a 2-stage course of medical rehabilitation: the first course on days 2-4 after surgery and the second course after 1-1.5 months against the background of adjuvanted radiation therapy. The control group of 39 patients underwent physiotherapy placebo procedures.

Methods: All the patients underwent medical rehabilitation: individual exercise therapy, balance-therapy, sessions with a medical psychologist, course exposure to an alternating low-frequency electrostatic field and general magnetic therapy.

Results: two-stage physical rehabilitation improves the quality of life, decreases swelling, increases the range of motion, decreases pain, decreases the number of postoperative complications, and shortens the duration of lymphorrhea.

Conclusions: It is advisable to include general magnetic therapy procedures and exposure to an alternating low-frequency electrostatic field in combination with physiotherapy exercises, balance-therapy and individual lessons from a medical psychologist in rehabilitation courses.

Clinical Rehabilitation Impact: Prescribing two courses of medical rehabilitation after breast cancer surgeries in the early stages (on days 2-4) and 1-1.5 months after surgery contributed to a decrease in pain and postoperative edema, and an increase in the range of motion in the shoulder joint, preventing severe lymphostasis and improving the quality of life.

Key-words: Medical Rehabilitation, General Magnetic Therapy, Low-frequency Electrostatic Therapy, Physiotherapy Exercises, Balance-therapy, Breast Cancer, Early Postoperative Period.

1. Introduction

Background. Medical rehabilitation of patients after radical treatment of breast cancer (BC) is one of the priority areas^[1] due to advances in BC treatment which increase the life expectancy of patients^[2, 3]. Radical treatment of BC, which includes several types of therapeutic effects (radiation therapy, polychemotherapy, surgery), often leads to a complex of functional and psychological disorders. As a result, patients faced a number of medical, social and psycho-emotional problems^[4, 5]. One of the main functional disorders in patients after radical treatment of breast cancer is the scalenus syndrome (up to 99% of cases) which develops within the first year after radical treatment^[6]. Common complications (up to 87%) include lymphatic edema of the upper limb on the side of the operation (postmastectomy lymphedema)^[7, 8, 9]. Limitation of the range of motion in the shoulder joint and damage to the nerve fibers of the brachial plexus occurs in 67% of patients^[10, 11, 12]. The causes of these complications are impaired venous outflow, and cicatricial deformities and brachioplexitis due to the excessive formation of fibrous tissue in the axillary, subclavian and subscapular regions. Cicatricial changes are enhanced due to prolonged and profuse lymphorrhea and a prolonged inflammatory process in the area of the postoperative wound^[13, 14]. Radiation therapy, in turn, also increases postoperative complications. Radiation fibrosis develops in the areas of distant radiation therapy (axillary, subclavian and postoperative scar), which leads to compression of blood vessels and nerve fibers, resulting in circulatory disorders, ischemia, and trophic changes in tissues^[15, 16].

Currently, various methods of physical therapy are widely used in the rehabilitation of patients with cancer^[17, 18, 19, 20, 21]. The successful use of magnetic therapy, pneumocompression, various types of electrotherapy and laser therapy in this category of patients is well known. Magnetic

therapy in this category of patients is accompanied by a decrease in complications and the time and volume of lymphorrhea^[22].

There are separate reports on general magnetic therapy in patients with breast cancer. During preoperative radiation therapy, general magnetic therapy procedures were prescribed, and after completing the course of radiation therapy, a radical Madden mastectomy was performed. On the 5th day after the surgical treatment, the general magnetic therapy procedures were resumed. The present study revealed that the patients had reduced terms and volumes of lymphorrhea^[23, 24]. In addition, the effect of general magnetic therapy on T and B lymphocytes was established, altering their number, function, and regulation of cellular and humoral immunity^[24].

There is experience in the use of a low-energy vortex magnetic field in patients with grade III BC^[25]. The results showed that during rehabilitation according to the chemotherapy and radiation therapy scheme, additional exposure to the magnetic field increases the effectiveness of the therapeutic effect on the primary tumor, and especially on metastases in the regional lymph nodes, with a higher level of therapeutic pathomorphosis.

A promising direction in the rehabilitation of patients with oncological diseases is the use of a low-frequency electrostatic field. Administration of this factor to the upper limb area of patients after radical mastectomy contributes to a good lymphatic drainage effect^[26]. The electrostatic field generated by the apparatus and created between the hand of a medical worker and the surface of the patient's body creates varying degrees of vibration in the tissues, spreading to a considerable depth^[27]. These electrostatic impulses in superficial and deep tissues have anesthetic, antispastic and anti-edema effect, improve tissue trophism and enhance regenerative processes in them. This increases the effectiveness of manual massage techniques, enhances local hemodynamics and lymph circulation. This is due to the effect of a low-frequency electrostatic field both on the skin, subcutaneous fat and connective tissue, and on the vascular network and neuromuscular structures^[28].

Goals and Hypotheses. At present, various methods of physical therapy are proposed in the rehabilitation of patients with BC. However, a staged approach to prescribing physiotherapeutic factors in the early period after BC surgery is not developed enough.

The goal of such rehabilitation is to minimize side effects and complications after radical treatment.

2. Methods

Study design. This was a multicenter, randomized, blind, placebo-controlled study in two groups. The patients were divided into 2 groups by simple randomization: the main group and the control group, comparable in age, clinical and functional indicators, and differing only in the purpose of physiotherapy methods in a 2-stage course of medical rehabilitation.

Study design changes. None.

Participant selection criteria. The criteria for the inclusion of patients in the study were: established diagnosis of BC stage IIB (T_2, N_1, M_0 ; T_3, N_0, M_0), stage IIIA (T_3, N_1, M_0 , T_{1-2}, N_2, M_0), and the age of 25-70. Criteria for exclusion in the study: age under 25 and over 70, concomitant acute infectious diseases, severe concomitant somatic pathology, mental illness (schizophrenia, schizotypal and delusional disorders, Alzheimer's disease, dementia, severe behavioral and social adaptation disorders, all forms of drug addiction and chronic alcoholism), individual intolerance to procedures.

Study settings. The study was carried out at the Russian Medical Academy of Continuous Professional Education of the Ministry of Healthcare of the Russian Federation.

Interventions. The study included 78 women aged 30-70 who underwent surgical treatment for the established diagnosis of breast cancer stage IIB (T_2, N_1, M_0 ; T_3, N_0, M_0) and stage IIIA (T_3, N_1, M_0 , T_{1-2}, N_2, M_0). The main group $n = 39$ included women who, against the background of standard therapy, underwent a 2-stage course of medical rehabilitation: first course on days 2-4 after BC surgery and second course after 1-1.5 months against the background of radiation therapy. Each course included procedures for general magnetic therapy, alternating electrostatic field, physiotherapy exercises (exercise therapy), balance-therapy and individual sessions with a medical psychologist.

The control group $n = 39$ included women who, against the background of standard therapy, underwent exercise therapy, balance-therapy, individual sessions with a medical psychologist, physiotherapy placebo procedures (patients underwent procedures according to the general protocol, except for the application of a magnetic field and electrostatic field).

To assess the quality of life in both groups, the Russian version of MOSSF-36 (Medical Outcomes Study – ShortForm) health questionnaire was used. It contained 36 questions combined into 8 scales: physical functioning (PF), role functioning (RF); pain intensity (PI); general health (GH); vitality (V); social functioning (SF); role-based emotional functioning (RBEF); mental health (MH). Indicators PF, RF, PI, GH characterize physical health, indicators V, SF, RBEF, MZ – psychological health. The scores on each scale range between 0 and 100, with 100 representing overall health. The patients either filled out the offered cards on their own or were interviewed.

For an objective assessment of the condition and its dynamics, patients of both groups underwent anthropometric measurements: determining the degree of edema based on the circumference of the middle third of the shoulder and forearm on both upper limbs at symmetrical levels (the same distance to the fingertips in centimeters). The range of motion in the shoulder joints was determined with a protractor, and the range of the following movements in the shoulder joint was also determined – abduction in the frontal plane, flexion and extension in the sagittal plane.

When studying the hemostasis system, the following indicators were determined: thrombin time; plasma fibrinogen concentration, and complete blood count.

An ultrasound examination of the skin and subcutaneous tissue in the area of the postoperative suture and of the thickness of the tissues of the edematous upper limb in comparison with similar tissues of the healthy limb was carried out. For diagnostics, Skinscanner DUB 22-30 MHz (TPM, Germany; registration certificate No. RZN 2016/5165 dated April 26, 2017) was used.

The study of microcirculation in the shoulder-scapular region, the postoperative region and the upper limb on the side of the surgical rehabilitation was carried out using the LDF ‘LAKK-OP’ apparatus (SPA LAZMA, Russia; registration certificate No. FSR 2010/07442 dated April 22, 2010). The microvascular tone was assessed using the amplitude-frequency analysis of blood flow fluctuations.

To assess the state of motion disorders and of sensitive innervation, the patients underwent a study of the excitability of the neuromuscular system using a multifunctional portable AsEtM-01/6 ‘Elesculap Med TeKo’ apparatus for stimulation and electrotherapy (LLC Med TeKo, Russia registration certificate No. FSR 2011/09988 dated February 04, 2011). To analyze the damage to nerve fibers, the study was carried out first on the healthy side, then on the side of the surgical intervention. For an objective study, Erb's points and tables of electrical excitability of motor points of various nerves (Stinzing tables) were used, which show the average values of electrical excitability for each nerve and muscle, extreme higher and lower numbers still within the normal range, and the difference in electrical excitability between the nerves and muscles of both sides. The excitability of the neuromuscular apparatus was determined using the bipolar technique.

The rehabilitation course was carried out on 2-4 day after the operation and after 1-1.5 months. In patients of both groups, the rehabilitation program included daily exercise therapy (breathing exercises and a complex aimed at increasing mobility in the shoulder joint and the range of motion of the upper limbs with a gradually increasing load) and training with biofeedback on the support reaction (balance-therapy, which is based on self-control of the pose). All the patients underwent a course of individual lessons from a medical psychologist.

Patients of the main group, against the background of complex therapy in the early postoperative period (2-4 days), underwent consistent procedures (all in one day) of alternating electrostatic field on both upper limbs (hand, forearm, shoulder), on the back (scapular and subscapular areas) excluding the axillary area, and the area of the postoperative suture on the ELGOS apparatus (LLC SPC Rehabilitation Technologies, Russia; registration certificate No. FSR 2012/13738 dated August 13, 2012), starting with the healthy arm from the hand and spreading movements (stroking without pressure) distally in the direction of the natural flow of body fluids. The intensity of exposure ranged from 50% to 80%. Mode 3 (pulse duration/pause duration ratio 1:1) was used. Exposure frequency was 10 min (120 Hz) and 5 min (80 Hz); 5 times a week, 12 procedures per course. The procedures were carried out in special gloves (Fig. 1).

Then, without interruption, general magnetic therapy was carried out on a unit with frequency, modulation and induction of a rotating magnetic field control 'Magnitoturbotron' (LLC SPC 'MMTs MADIN', Russia; registration certificate No. FSR 2016/3707 dated February 19, 2016), creating pulsed magnetic fields uniformly rotating around the patient's longitudinal axis with induction variations from 0-3.5 mT (frequency 50-150 Hz). The first 3 procedures were carried out at the maximum induction of 1 mT (frequency 150 Hz), then the induction increased to 2 mT (frequency 100 Hz), and 12-15 procedures were performed (frequency 80 Hz) with the magnetic field induction of 2 mT. The duration of the procedure was 30 minutes, 5 times a week for a course of 12 daily procedures. After 1-1.5 months, against the background of complex therapy (which included postoperative radiation therapy), this group of patients underwent the second stage of rehabilitation including the following physiotherapeutic procedures: variable electrostatic field on both upper limbs (hand, forearm, shoulder), the back (scapular and subscapular areas) excluding the axillary area, and the area of the postoperative suture starting from the healthy arm from the hand and spreading movements (stroking without pressure) distally in the direction of the natural flow of body fluids. The intensity of exposure ranged from 60% to 90%. Mode 3 (pulse duration/pause duration ratio 1:1) was used. Exposure frequency was 10 min (70 Hz) and 10 min (25 Hz) 5 times a week, 12 procedures per course. The procedures were carried out in special gloves.

Then, without interruption, general magnetic therapy was carried out on the UMTI-3F 'Kolibri-expert' apparatus (LLC SPC 'MMTs MADIN', Russia; registration certificate No. FSR 2011/11030 dated June 21, 2011). A low-frequency pulsed 'running' magnetic field (frequency 100 Hz) was used with the rotation of the field 1-2-3 in one direction (mode I on the apparatus). In 1-2 procedures, the value of magnetic induction was 30% of the maximum value of 3.5 mT, then the induction increased to 75% of the maximum value of 3.5 mT, and starting from the 12-15th

procedure, the value of magnetic induction was 50% of the maximum value of 3.5 mT, the duration of the procedure was 20 minutes. The procedures were carried out 5 times a week, 15 procedures per course.

Patients of the control group underwent physiotherapeutic placebo procedures against the background of complex therapy in the early postoperative period (2-4 days) and after 1-1.5 months against the background of radiation therapy (without including the magnetic induction and alternating electrostatic field).

Informed consent. All the patients have given their informed consent for participation in the research study.

Data availability. The data associated with the paper are not publicly available but are available from the corresponding author on reasonable request.

Results. The entire treatment complex was well tolerated by the patients. The procedures did not cause any negative reactions. In none of the cases, interruption or cancellation of the course of therapy was required.

Against the background of ongoing rehabilitation, in the early postoperative period (on the 5th day) in patients from the main group, the daily volume of lymphorrhea through the drainage and the daily volume of lymphorrhea evacuated with syringes after removing the drainage was less than in the control group (Fig. 2). This pattern persisted after the rehabilitation ($p < 0.05$). On examination one month after the surgical treatment, the patients from the main group did not show any fluid in the area of the postoperative scar, while the patients of the control group (7 people, 20%) had an accumulation of fluid which was evacuated with a syringe.

1-1.5 months after the surgical treatment, all the patients had difference in the circumference between the healthy limb and the limb from the side of the surgery. In the patients of the main group who underwent physiotherapy, these indicators were less than in the control group. Reliable indicators of the difference in the circumference were observed in the long term after two courses of rehabilitation.

In all the patients after surgical treatment for BC, the range of motion in the shoulder joint on the side of the surgery was reduced compared to normal values in the postoperative period. Thus, in the patients of the main group, the following indicators were recorded: flexion amplitude – $60 \pm 1.3^\circ$, extension – $18 \pm 0.5^\circ$ and abduction – $65 \pm 1.4^\circ$. The indicators in the control group were: flexion amplitude – $62 \pm 1.3^\circ$, extension – $19 \pm 0.5^\circ$ and abduction – $66 \pm 1.4^\circ$. After the first course of rehabilitation, these functions significantly improved in patients from the main group, namely: flexion – up to $118 \pm 2.4^{*}$, extension – $24 \pm 0.8^{*}$, abduction – up to $100 \pm 1.5^{*}$; while in the control

group the indicators were: flexion – up to $74 \pm 1.8^{\circ}$ #, extension – $22 \pm 0.8^{\circ}$, abduction – up to $90 \pm 2.5^{\circ}$ #. Before the second course of medical rehabilitation, the movement functions in the patients of the main group were significantly better than in the control group: flexion in the shoulder joint $130 \pm 2.2^{\circ}$ and $90 \pm 1.8^{\circ}$ #, extension – $40.0 \pm 0.8^{\circ}$ and $32 \pm 0.5^{\circ}$ #, abduction – $145 \pm 1.8^{\circ}$ * and $100 \pm 1.8^{\circ}$ * # (* – significant differences $-p < 0.05$ for all indicators before and after rehabilitation, # – significant differences $-p < 0.05$ between the indicators of the main and control groups). After the second course of rehabilitation, the indicators in the main group continued to increase up to the normal values of $175 \pm 1.5^{\circ}$ (flexion and abduction) and $43 \pm 1.2^{\circ}$ (extension), while in the control group these indicators were below $145 \pm 1.8^{\circ}$ # (flexion), $130 \pm 1.5^{\circ}$ # (abduction), $33 \pm 1.2^{\circ}$ (extension). Additional evidence of dysfunctions of the upper limb on the side of radical surgery is a decrease in hand strength which was assessed using the dynamometric method. This indicator was significantly (2-2.5 times) lower than the corresponding values for the strength of the hand on the healthy side.

Therefore, the range of motion in the shoulder joint on the side of the surgical intervention was better in the patients of the main group. This testifies to the expediency of an early start of rehabilitation measures including physical factors and to continuing the next course 1-1.5 months after the operation.

The clinical effect was also expressed in a decrease in pain in the upper limb and in the area of the postoperative suture, in a decrease or disappearance of puffiness in the postoperative area and in the upper limb, an increase in the volume and quality of movements, decreased sensitivity disorders in the upper limb, an improvement in general well-being, mood, and normalization of sleep. The dynamics of indicators of health-related quality of life in patients after BC surgery are presented in Table 1.

Table 1- Dynamics of indicators of the quality of life of patients after BC surgery according to the MOSSF-36 questionnaire (M \pm SD, points)

MOS SF-36	GH	PF	RF	PI	V	SF	RBEF	MH
Main group (n=39)								
Before the 1st course	25.1 \pm 2.2	22.2 \pm 2.1	33.9 \pm 1.2	24.5 \pm 4.5	29.2 \pm 3.2	41.1 \pm 4.2	29.2 \pm 3.2	33.9 \pm 4.1
After the 1st course	39.9 \pm 1.5*	43.9 \pm 1.2*	49.7 \pm 3.9*	42.7 \pm 3.9*	42.2 \pm 4.5*	57.5 \pm 1.7*	44.7 \pm 3.9*	48.7 \pm 4.2*
Before the 2nd course	54.2 \pm 2.1*	44.3 \pm 1.5*	55.2 \pm 2.7*	72.3 \pm 6.3*	65.1 \pm 2.3*	76.9 \pm 3.7*	57.4 \pm 2.8*	59.8 \pm 5.1*
After the 2nd course	74.6 \pm 1.9*	56.3 \pm 1.8*	76.2 \pm 1.7*	82.5 \pm 4.3*	76.1 \pm 4.3*	81.9 \pm 2.7	74.5 \pm 2.2*	68.5 \pm 3.4*
In 3 months	85.2 \pm 1.1*	78.3 \pm 1.6*	85.2 \pm 2.7*	91.3 \pm 2.3*	81.1 \pm 1.3*	89.9 \pm 3.7*	85.4 \pm 1.8*	75.2 \pm 3.5*
Control group (n=39)								
Before the 1st course	25.4 \pm 1.2	21.9 \pm 2.3	33.2 \pm 1.1	25.7 \pm 3.2	28.8 \pm 2.1	40.8 \pm 3.5	29.5 \pm 3.1	33.7 \pm 3.8
After the 1st course	33.5 \pm 1.5*	35.9 \pm 1.4*	36.7 \pm 3.9*	35.7 \pm 2.8*	30.3 \pm 4.7	41.2 \pm 3.9	38.6 \pm 6.3	41.6 \pm 6.3
Before the 2nd course	37.4 \pm 4.4	53.4 \pm 7.3	39.8 \pm 4.2	44.2 \pm 3.2	42.2 \pm 4.5*	57.5 \pm 1.7*	44.7 \pm 3.9*	48.7 \pm 5.2*
After the 2nd course	53.5 \pm 1.7*	72.1 \pm 3.9*	48.6 \pm 3.2*	62.1 \pm 4.7*	53.4 \pm 5.3*	65.8 \pm 3.7*	51.1 \pm 2.3*	50.4 \pm 3.8*
In 3 months	68.3 \pm 1.5*	79.1 \pm 4.1	58.6 \pm 3.4*	79.1 \pm 4.5*	63.5 \pm 4.4*	75.8 \pm 3.9	74.1 \pm 2.5*	53.5 \pm 1.7*

Note: * - significant differences ($p < 0.05$) between the main and control groups

Table 1 shows that after the rehabilitation in patients of both groups, compared with the initial level, the indicators of the quality of life increased, probably because various specialists began working with the patients (oncologist surgeon, physiotherapist, exercise therapy doctor, medical psychologist). Notably, after the rehabilitation in the patients of the main group such indicators as GH, PF, RF, PI, and V were higher ($p < 0.05$) than in the control group and continued to increase 1.3-1.5 times 3 months after the second course of rehabilitation.

For an objective diagnosis of the condition of the scars, of the area of postoperative inflammation and post-radiation fibrosis, modern methods of instrumental diagnostics were used: laser Doppler flowmetry, ultrasound diagnostics of the skin, electrodiagnostics of the pectoralis major muscle, deltoid muscle, and biceps brachii.

Analysis of the results of laser Doppler flowmetry on the upper limb from the side of surgery in both groups of patients in the early postoperative period (2-4 days) revealed a hyperemic-stagnant type of microcirculation. In both studied groups, before the beginning of rehabilitation in the area of the focus, an increase in the values of the microcirculation index (M) on average to 4.57 ± 0.33 was recorded (apparently due to stagnant disturbances of blood flow, primarily along the capillary bed) and a decrease in the value of the Kv index to $8.65 \pm 0.67\%$, which characterizes certain disorders of blood flow and disorders of vasomotor activity of vessels. Analysis of the parameters of the amplitude-frequency spectrum of vasomotor oscillations revealed a stagnant form of microcirculation disorders in the overwhelming majority of patients. In the structure of the amplitude-frequency spectrum, there was a significant decrease in the relative value of the active component of microcirculatory blood flow ($A_{\max.LF} \cdot 100\% / M = 16.05 \pm 1.32\%$) with a simultaneous increase in the share of passive mechanisms of microhemodynamics: respiratory ($A_{\max.HF} - 0.31 \pm 0.04$ relative units) and cardiac ($A_{\max.CF} - 0.41 \pm 0.04$ relative units) components of vasomotor oscillations, indicating a decrease in the inflow and expansion of venules with congestion. These changes were reflected in the value of the integral indicator of microhemodynamics – index of microcirculation efficiency which was significantly lower (0.58 ± 0.07 relative units; $p < 0.05$) than in the corresponding area of the unaffected limb.

In the study of the neuromuscular system (determination of the electrical excitability of the pectoral, deltoid and biceps brachii muscles from the side of the operation in the early postoperative period – in patients of both groups an increase in the threshold current strength (rheobase) for galvanic current up to 40 mA and an exponential type of current up to 58 mA, chronaxy 1.5-1.8 ms, muscle contractions with increased muscle fatigue and damped contraction were revealed, while the Brenner-Pflugger formula was equalized, which is characteristic of quantitative and qualitative damage

to myofibrils and corresponds to the performed surgical intervention. On the opposite side, no significant deviations from normal indicators of electroexcitability were found.

After the first course of rehabilitation, in the main group there was an improvement in the indicators of electrical excitability, namely, a decrease in the rheobase for galvanic current to 29* mA, for exponential current up to 42* mA, while in the control group, the indicators did not change significantly compared to the initial state (response to galvanic current up to 36 mA and exponential form of current up to 52 mA). Before the second course of rehabilitation, the indicators of electroexcitability in both groups showed a slight decrease. After the second course of rehabilitation in patients of the main group, the excitability of the neuromuscular apparatus of the deltoid and biceps muscles of the shoulder approached the upper norm, and the electrical excitability of the pectoral muscle remained elevated but below the previous data (rheobase for galvanic current up to 21 mA and for exponential current up to 32* mA, chronaxy 1.1*).

In the control group, after the second course of rehabilitation, an improvement in the indicators of electrical excitability was observed, for example, adequate muscle contraction appeared in all the muscle groups, although the electrical excitability of the pectoral muscle remained elevated but below the previous data (rheobase for galvanic current up to 31 mA and for exponential current up to 42* mA, chronaxy 1.3). When examined 3 months after the two courses of rehabilitation, the indicators of neuromuscular excitability continued to recover, while in the control group there were quantitative changes in the electrical excitability of all the muscle groups, and the increased electrical fatigue of myofibrils remained.

On days 2-4 after the operation, during ultrasound examination of the skin and subcutaneous tissue in the area of the postoperative suture and the upper limb in comparison with similar tissues of the healthy limb, edema was detected in patients of both groups, determined by local reduced echogenicity of soft tissues with uneven and indistinct contours and unexpressed fluid strokes (the main group of 27 people (70%), the control group of 26 people (68%). In 10 (26%) patients of the main group and 8 (22%) of the control group, hematomas were diagnosed in the area of the postoperative scar, defined as a polycyclic formation with clear or indistinct contours, hypoechoic, heterogeneous structure. After the first course of rehabilitation, edema of the upper limb persisted in 10 (26%) people in the main group, and 21 (55%) people in the control group ($p < 0.05$); in the area of the postoperative suture, signs of hematoma remained in 3 (8%) people in the main group, and in 8 (22%) people in the control group ($p < 0.05$).

Before the second course of rehabilitation, edema was observed in the area of the postoperative scar and the shoulder-scapular area in 3 (8%) patients from the main group and 13

(35%) from the control group; after the second course of rehabilitation, signs of soft tissue edema were practically not observed in the main group, whereas in the control group, edema persisted in the area of the postoperative suture and the shoulder-scapular region in 6 (16%) people. 3 months after 2 courses of rehabilitation, the patients showed signs of tissue fibrosis and damage to blood and lymph vessels in the area of external beam radiation therapy, but in the main group, patients with such complications comprised less than 3 (8%), compared to 15 (38%) in the control group.

Biochemical parameters of blood, such as total protein, protein fractions, ALT, AspAT, alkaline phosphatase, calcium, creatinine, urea, glucose, bilirubin, gamma-GT were within the reference values. These indicators remained after the completion of the two-stage course of rehabilitation, and did not change significantly in the long term.

The present study analyzed the dynamics of a number of indicators of the blood coagulation system in women after BC surgery, since an increase in blood viscosity can aggravate the pathological process due to a decrease in the oxygen delivery, and magnetotherapy and a low-frequency electrostatic field contribute to the normalization of the fluid-viscous properties of blood, which was confirmed by the study (Fig. 3, 4).

In the main group, after the first and second courses of general magnetic therapy and alternating low-frequency electrostatic field, a decrease in blood viscosity (namely, in fibrinogen) and an increase in thrombin time was observed, probably due to the mechanism of the physical factors used.

Sample Size: To find a reduction in the recovery time after BC surgery (which is consistent with the study by S.V. Strazhev with the two-sided significance level of 4% and the degree of 83%), a sample size of 39 patients per group was necessary given an expected dropout rate of 5%.

Interim Analysis and Stop Recommendations: None.

Randomization: The study was conducted in accordance with the GCP principles and applicable national regulations, respecting the rights and ensuring the safety and well-being of study participants, who were protected by the ethical principles set forth in the Declaration of Helsinki. Before the start of the study, voluntary written informed consent was obtained from each patient. Each study participant was informed in writing about the nature, duration of treatment measures and expected results of rehabilitation.

Distribution Concealment Mechanism: Patients of the control group underwent physiotherapeutic placebo procedures against the background of complex therapy in the early postoperative period (2-4 days) and after 1-1.5 months against the background of radiation therapy (without including the magnetic induction and alternating electrostatic field).

Randomization implementation. Information about the highlighted group was presented on the map and numbered 2.

Blinding. While physicians were aware of the allocated group, outcome evaluators and data analysts were unaware of the distribution.

Similarity of Interventions. The patients underwent procedures according to the general protocol, except for the application of a magnetic field and an electrostatic field.

Statistical Methods. The results were evaluated immediately before the rehabilitation (2-4 days after the operation), after the end of the first course of rehabilitation, before the second course of rehabilitation (1-1.5 months after the operation), immediately after and 3 months after the second course of rehabilitation. All the data were processed using Microsoft Office Excel (2010) and the Statistica 10.0/W RUS package of applied statistical programs for medical and biological research. For the analysis of quantitative variables, the method of one-way analysis of variance and the Mann-Whitney test were used. The analysis of categorical variables was carried out using Pearson's chi-squared test. The significance of differences within the group, obtained during the observation period, was assessed using The Wilcoxon signed-rank test. Differences were considered significant at $p < 0.05$.

Additional analyzes. None.

Stream of participants.

Losses and exclusions. None.

Set. The patients were examined from February 2018 to January 2019. The results obtained were assessed immediately before the beginning of rehabilitation (2-4 days after the operation), after the end of the 1st course of rehabilitation, before the 2nd course of rehabilitation (1-1.5 months after the operation), after the end of the 2nd course of rehabilitation and in the long-term after 3 months after completion of the 2nd course of rehabilitation.

Table 2- Initial data

	Magnetic field Electrostatic field n=39	Placebo n=39
Age	48±	48±
Sex	female	female
Lymphorrhea	130±1.2 ml	129±1.1 ml
Difference in circumference between the upper limbs	7.3±0.2	7.24±0.2
Shoulder flexion angle	60±1.3°	62±1.3°
Shoulder extension angle	18±0.5°	19±0.5°
Shoulder abduction angle	65±1.4°	66±1.4°
Increase in the microcirculation index values (MI)	4.58±0.32	4.57±0.33
Decrease in Kv value	8.65±0.67%	8.65±0.67%
Reobase for galvanic current	40±0.02 mA	40 ±0.04 mA
Rheobase for exponential current	58 ±0.04 mA	58 ±0.06 mA
Chronaxie	1.5±0.04 ms	1.5±0.03 ms
Fibrinogen	4.1±0.14 g/L	4.2±0.18 g/L
Prothrombin time	15.8±0.19s	15.9±0.13s

Analyzed numbers. The primary analysis was directed to treatment and included all patients who were randomly assigned.

3. Results and Evaluation

Figure 1. Reduction of the daily volume of lymphorrhea in patients in the early postoperative period

Table 3- Difference in circumference between healthy and affected limbs (M±SD, cm)

Measurement level	5 cm above the elbow	At the level of the middle third of the forearm	At the level of the middle of the hand through the base of the <i>m.thenar</i>
Main group (n=39)			
Before the 1st course	7.3±0.2	5.2±0.1	3.9±0.1
After the 1st course	5.5±0.1*	3.9±0.1	2.1±0.1
Before the 2nd course	4.2±0.1*	3.5±0.2*	1.83±0.2*
After the 2nd course	1.4±0.1*	1.6±0.1	1.5±0.2
In 3 months	0.2±0.1*	0.2±0.1*	0.2±0.1*
Control group (n=39)			
Before the 1st course	7.24±0.2	5.1±0.3	4.2±0.2
After the 1st course	6.9±0.2*	4.3±0.3	2.6±0.1
Before the 2nd course	5.5±0.1*	3.9±0.3*	2.9±0.1*
After the 2nd course	2.9±0.1*	2.1±0.1	1.8±0.2
In 3 months	1.2±0.2*	1.2±0.3*	0.9±0.2*

Note: * - significant differences (p <0.05) between the indicators in the main and control groups.

Table 4- Dynamics of indicators of the quality of life of patients after BC surgery according to the MOSSF-36 questionnaire (M±SD, points)

MOS SF-36	GH	PF	RF	PI	V	SF	RBEF	MH
Main group (n=39)								
Before the 1st course	25.1±2.2	22.2±2.1	33.9±1.2	24.5±4.5	29.2±3.2	41.1±4.2	29.2±3.2	33.9±4.1
After the 1st course	39.9±1.5*	43.9±1.2*	49.7±3.9*	42.7±3.9*	42.2±4.5*	57.5±1.7*	44.7±3.9*	48.7±4.2
Before the 2nd course	54.2±2.1*	44.3±1.5*	55.2±2.7*	72.3±6.3*	65.1±2.3*	76.9±3.7*	57.4±2.8*	59.8±5.1*
After the 2nd course	74.6±1.9*	56.3±1.8*	76.2±1.7*	82.5±4.3*	76.1±4.3*	81.9±2.7	74.5±2.2*	68.5±3.4*
In 3 months	85.2±1.1*	78.3±1.6*	85.2±2.7*	91.3±2.3*	81.1±1.3*	89.9±3.7*	85.4±1.8*	75.2±3.5*
Control group (n=39)								
Before the 1st course	25.4±1.2	21.9±2.3	33.2±1.1	25.7±3.2	28.8±2.1	40.8±3.5	29.5±3.1	33.7±3.8
After the 1st course	33.5±1.5*	35.9±1.4*	36.7±3.9*	35.7±2.8*	30.3±4.7	41.2±3.9	38.6±6.3	41.6±6.3
Before the 2nd course	37.4±4.4	53.4±7.3	39.8±4.2	44.2±3.2	42.2±4.5*	57.5±1.7*	44.7±3.9*	48.7±5.2*
After the 2nd course	53.5±1.7*	72.1±3.9*	48.6±3.2*	62.1±4.7*	53.4±5.3*	65.8±3.7*	51.1±2.3*	50.4±3.8*
In 3 months	68.3±1.5*	79.1±4.1	58.6±3.4*	79.1±4.5*	63.5±4.4*	75.8±3.9	74.1±2.5*	53.5±1.7*

Note: * - significant differences (p <0.05) between the main and control groups

Additional analyses. None.

Harms. None.

4. Discussion

Restrictions. None.

Generalizability

The present study revealed that low-frequency alternating electrostatic field and general magnetic therapy in the complex of rehabilitation measures decreases the volume and timing of lymphorrhea, decreases and, with long-term observation, eliminates the edema of the upper limb and the area of the postoperative scar. The increase in the range of motion in the shoulder joint after two courses of rehabilitation was significantly higher in the main group and persisted for a long time, and a significant improvement in the range of motion was observed after the first course of rehabilitation. Objectively, these indicators are confirmed by the data of neuromuscular diagnostics of the thoracic, deltoid and biceps brachii muscles on the side of the surgery. The indicators of life quality, such as physical functioning, pain intensity, general health, vitality, were better in the main group, probably due to the effect of general magnetic therapy which has analgesic, anti-inflammatory, and decongestant effects, decreases situational and personal anxiety, eliminates asthenovegetative manifestations, and improves sleep due to the correction of capillary insufficiency, both venous and arterial. Perivascular tissue edema decreased, the microvasculature opened, and tissue hypoxia decreased. In the course of rehabilitation, the correction of venous and arterial capillary insufficiency occurs, which is clinically expressed by a decrease in various pathological symptoms and syndromes based on vascular disorders and similar to the previously obtained data^[23, 25].

Interpretation

After BC surgery, it is advisable to prescribe a course of general magnetic therapy in combination with a low-frequency alternating electrostatic field in the early postoperative period and after 1-1.5 months against the background of radiation therapy with physiotherapy exercises with balance-therapy and classes with a medical psychologist. The rationale for these rehabilitation measures is their substantiated pathogenetic effect on postmastectomy syndrome, where disorders of

vascular microcirculation, reduction of inflammation syndrome (edema, hyperemia, pain, dysfunction), improvement of regeneration of various tissues (normalized healing rate, reduced inflammation phase, improved quality of scarring), improved general well-being in the early postoperative period are important, since a prolonged inflammatory process and lymphorrhea leads to pronounced cicatricial changes in the lymphadenectomy areas and directly influences the development of postmastectomy edema in patients who did not receive medical rehabilitation. General magnetic therapy reduces early radiation reactions, the general toxic effect of chemotherapy and the number of complications decrease in the postoperative period, and the duration and volume of lymphorrhea are reduced. Analysis of the long-term results of rehabilitation of this category of patients revealed that when magnetic therapy and alternating electrostatic field are included in the treatment complex, the likelihood of complications of radical treatment of breast cancer decreases.

Lymphedema is a typical high-protein edema which leads to insufficient tissue oxygenation due to the disruption of intercellular contacts necessary for the unimpeded circulation of gas. Hypoxia, in turn, slows down the functioning of cells. In lymphedema, excess protein concentration acts as an activator of chronic inflammation. The magnetic field has the property of increasing the number of lymphatic collaterals, it stimulates lymph drainage, increases tissue oxygenation, has a hypocoagulant, anti-edema, anti-inflammatory effect and has a sedative effect^[27]. General magnetic therapy prolongs the anti-edema effect; this is due the combination with the effect of a low-frequency alternating electrostatic field. The activation of nonspecific adaptive reactions of the immune, humoral and nervous systems occurs. General magnetic therapy has a normalizing effect on the vegetative and psychoemotional status due to the elective effect on the excitability of the hypothalamus of the cortical and subcortical structures of the brain. A low-frequency electrostatic field (due to the body's responses in the form of physicochemical changes in the primary mechanisms of homeostasis) leads to a decrease in protein edema and to normalization of the functional electroexcitability of the neuromuscular apparatus of the operated area.

Using a low-frequency alternating electrostatic field in patients with lymphedema (with adequately selected exposure parameters) helped restore elasticity and improve the functional state of tissues and enhance local hemodynamics and microcirculation, which in turn led to a decrease in edema of the upper limb on the side of surgery.

5. Conclusion

Two courses of medical rehabilitation at the early stages (on days 2-4) and 1-1.5 months after BC surgery decreased pain and postoperative edema and increased movements in the shoulder joint, preventing severe lymphostasis and improving the quality of life.

The need to include in the rehabilitation courses the procedures of general magnetic therapy and exposure to an alternating low-frequency electrostatic field in combination with physiotherapy exercises, balance-therapy, individual classes with a medical psychologist was revealed. In the main group, a pronounced and long-term clinical effect was obtained, compared with the group of patients who were prescribed physiotherapeutic placebo procedures, which emphasizes the advisability of exposure to physical factors in patients with breast cancer at the stages of rehabilitation.

Registration. None.

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