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Лазеротерапия в комплексном лечении пациентов с лимфедемой нижних конечностей

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АННОТАЦИЯ

Введение. Применение методов физиотерапевтического воздействия с использованием внутривенного лазерного освечивание крови (ВЛОК), влияющего на различные звенья патогенеза лимфедемы, позволяет получить необходимый лечебный эффект и свидетельствует о его перспективности.

Цель. Оценка эффективности применения ВЛОК для уменьшения лимфедемного объема на нижних конечностях.

Материалы и методы. В 2020–2022 гг. проведено комплексное консервативное лечение, включающее компрессионную терапию, фармакотерапию и ВЛОК 60 пациентам с I–III стадиями лимфедемы, средний возраст 45,3 ± 1,6 лет. В 1 группу включены пациенты с первичной (n = 8), во 2 — со вторичной (n = 52) лимфедемой нижних конечностей. Применялось излучение длиной волны 632 нм по стандартизированным параметрам: мощностью от 3 до 15 мВт, частотой импульсов от 80 до 2000 Гц, длительностью процедуры от 5 до 15 мин., с курсовой (до 10 раз), ежедневной или интервальной нагрузкой (через 1 день). Для динамической оценки лимфооттока, микроциркуляции, мягких тканей пораженной конечности использовались электрокоагулография, ультразвуковое исследование паховых лимфатических узлов и мягких тканей, триплексное сканирование, тепловидение и проба Мак-Клюра и Олдрича.

Результаты. Отмечалось уменьшение периметров конечности на уровне средней трети голени на 14,8 ± 0,7% (от 48,7 ± 5,3 см до 41,4 ± 0,9 см) в конце курса лечения. Электрокоагулографически после 4 сеансов и курса лечения выявлялась гипокоагуляция с формированием рыхлого сгустка с ранней ретракцией. Анализ Спирмена показал прямую взаимосвязь между изменениями фибринолитической активности крови и данными периметра на голени у пациентов 2 группы I–II стадии заболевания ($p < 0{,}005$). При термографии нижних конечностей установлено повышение уровня инфракрасного излучения со статистически значимым ($p < 0{,}001$) увеличением площади гипертермии в дистальной части голеней и внутренней поверхности бедер. По результатам пробы Мак-Клюра и Олдрича после окончания ВЛОК во 2 группе зафиксировано статистически значимое замедление рассасывания кожной папулы в дистальной части голени с 27,13 ± 2,77 мин. до 35,72 ± 3,11 мин. ($p < 0{,}05$) в I стадии заболевания.

Заключение. ВЛОК воздействует на внутренние факторы лимфооттока и способствует его оптимизации в комплексном лечении пациентов в начальной стадии вторичной лимфедемы нижних конечностей.

Ключевые слова: *лимфедема нижних конечностей; внутривенное лазерное облучение крови; ультразвуковое исследование; термография; гидрофильная проба*

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Laser Therapy in Comprehensive Treatment of Patients with Lymphedema of Lower Limbs

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ABSTRACT

INTRODUCTION: Methods of physiotherapy using intravenous laser irradiation of blood (ILIB) that affects various pathogenetic factors of lymphedema, permits to achieve the required therapeutic effect and shows its promising perspectives.

AIM: Evaluation of the effectiveness of ILIB to reduce the lymphedema volume in the lower limbs.

MATERIALS AND METHODS: In 2020–2022, a comprehensive conservative treatment including compression therapy, pharmacotherapy and ILIB, was conducted in 60 patients of the mean age 45.3 ± 1.6 years with I–III stage lymphedema. Group 1 included patients with primary (n = 8) and group 2 (n = 52) with secondary lymphedema of the lower limbs. Laser radiation at 632 nm wavelength was used with standardized parameters: power 3 to 15 mW, pulse rate 80 to 2,000 Hz, exposure time 5 to 15 min, with a course (up to 10 sessions), daily, or interval (every 2nd day) load. Lymph outflow, microcirculation, soft tissues of the affected limb were evaluated using electrocoagulography, ultrasound examination of inguinal lymph nodes and soft tissues, triplex scanning, thermal imaging and McClure-Aldrich test.

RESULTS: At the end of the treatment course, a reduction of the limb perimeter at the level of the middle third of the lower leg by 14.8 ± 0.7% was noted (from 48.7 ± 5.3 cm to 41.4 ± 0.9 cm). After 4 sessions and a treatment course, electrocoagulography revealed hypocoagulation with the formation of a loose clot with early retraction. Spearman test showed a direct relationship between changes in the fibrinolytic activity of blood and the perimeter of the lower leg in patients of group 2 with I–II stage of the disease ($p < 0.005$). Thermography of the lower limbs showed increased IR radiation with a statistically significant increase ($p < 0.001$) in the area of hyperthermia in the distal parts of the lower legs and the inner surface of the thighs. The results of McClure-Aldrich test showed a statistically significant slowdown of a skin papule resolution in the distal part of the lower legs from 27.13 ± 2.77 min to 35.72 ± 3.11 min ($p < 0.05$) after ILIB in I stage of the disease.

CONCLUSION: ILIB affects the internal factors of lymph outflow and contributes to its optimization in the comprehensive treatment of patients in the initial stage of secondary lymphedema of the lower limbs.

Keywords: *lymphedema of the lower limbs; intravenous laser irradiation of blood; ultrasound examination; thermography; hydrophilic test*

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LIST OF ABBREVIATIONS

CDI — color Doppler imaging
ILIB — intravenous laser irradiation of blood
LL — lower limbs
US — ultrasound examination

INTRODUCTION

Lymphedema is a common, complex and underappreciated human disease [1]. According to Stanford Center for Lymphatic and Venous Disorders, about 200 thousand cases of lymphedema are diagnosed annually. The disease affects about 90 million people worldwide, and in combination with chronic venous insufficiency, the number of patients reaches 300 million [2]. This pathology most commonly affects (80%–90%) women and young individuals.

In the last decade, there has been a significant increase in the insight into the pathogenesis and approaches to the problem of treatment of lymphedema. Significant advances have been achieved in experimental studies, diagnostics and clinical methods of treatment. This progress owes the advances in the field of genetics, lymphatic imaging and lymphatic surgery. New molecular ideas of lymphedema pathogenesis are being studied, as well as their connection with future molecular [3] and cell therapy [4].

The lymphatic system is one of the most complex systems of the body. It performs 3 main functions: maintaining the fluid balance, nutritional function (fat absorption), and protective function. Lymphatic vessels return the capillary ultrafiltrate and plasma proteins escaped from the most tissues, back into the bloodstream. Therefore, lymphatic system is responsible for maintaining the tissue (and plasma) volume homeostasis. Impairment of lymph outflow results in peripheral edema (lymphedema) and can have serious consequences for cardiovascular diseases (in particular, arterial hypertension and atherosclerosis), infections and immune status, cancer and obesity — the four main healthcare problems of the XXIst century [5].

Preventive surgical methods, biopsy of signaling lymph nodes, microsurgical preventive approach to the treatment of lymphedema, reduce the morbidity, but do not always bring the desired result [6, 7]. Lymphedema is a chronic disease that requires a combination of surgical and conservative treatment (combined therapy). Standardization of lymphedema staging, key outcome parameters and quantitative data will be crucial for establishing the best methods of its diagnosis and treatment [8, 9].

The list of conservative treatment methods includes physiotherapy providing a complex decongestant effect [10, 11]. Currently, there is a wide use of such methods as pneumatic compression, sinusoidal simulated currents, electrophoresis with enzymes (lidase, ronidase, trypsin), radiofrequency stimulation of the lymphangion contractility, barotherapy (chamber in chamber), gravity therapy, as well as low-intensity intravenous laser therapy [12, 13]. In the complex treatment of patients with pathological edema of the lower limbs (LL), a combination of simultaneously performed manual massage, electromechanical lymphatic massage and elastic compression is used [14].

However, improving the effectiveness of treatment of patients with lymphatic LL edema remains a relevant task. The physiotherapeutic methods, first of all those using ILIB, affect various pathogenetic factors of lymphedema, activate the contractile ability of lymphangion, affect fibrinolytic activity and microvasculature, which permits to achieve the required therapeutic effect and shows the prospects of this direction.

The **aim** of this study assessment of the effectiveness of intravenous laser irradiation of blood to reduce lymphedema volume in the lower limbs.

MATERIALS AND METHODS

In 2020–2022, on the base of Hospital Surgery Clinic of Samara State Medical University, a comprehensive conservative treatment was conducted including III class compression therapy, pharmacotherapy and ILIB. Lymphatic drainage massage was not used. Before implementation of medical interventions, a written informed consent to participation in the study was received from each patient. The study is approved Ethics Committee of Samara State Medical University (Protocol No. 12 of November 11, 2020).

Therapeutic irradiation of blood was performed with a Matrix-ILIB device (Lasermedservis, Russia) in 60 patients (of them 7 men (11.7%)) of the mean age 45.3 ± 1.6 years, body mass index from 23.4 to 36.8 (28.8 ± 3.3) kg/cm^2.

Inclusion criteria: age above 18; confirmed diagnosis of LL lymphedema, a voluntary informed consent to participate in the study.

Exclusion criteria: refusal of a patient from participation in any stage of treatment; existence of any type of diabetes mellitus; clinically significant arterial pathology of LL; breakage of the integrity of skin of any genesis; pregnancy; renal pathology; thrombotic complications.

Preconditions to lymphedema were surgeries followed by radiotherapy on the regional lymph nodes or their removal — in 7 (23.1%) patients, traumas and fractures — in 3 (5.8%), pregnancy and childbirth, gynecological diseases in 2 (3.8%) female patients. Most patients with secondary lymphatic edema of LL had a past erysipelatous inflammation of LL — 35 (67.3%). The degree of LL lymphedema depended on the form and frequency of erysipelatous inflammation. An unspecified cause of lymphatic edema was also registered (n = 5, 9.6%).

The patients were divided into 2 groups. *Group 1* — (primary lymphedema established on the basis of anamnesis and genetic analysis data) included only patients (n = 8) with III stage of the disease with duration of 24.4 ± 8.2 years. *Group 2* — (secondary LL lymphedema, Table 1) included 52 patients (5 patients with I stage, 29 with II stage and 18 with III stage) with the average duration of the disease 15.2 ± 7.1 years.

Table 1. Causes of Secondary Lymphedema in Group 2 Patients (n = 52), n (%)

Cause of Lymphedema	Unilateral Lesion	Bilateral Lesion
Post-irradiation sclerosis of inguinal lymph nodes	3 (5.8)	4 (7.7)
Fractures and injuries	3 (5.8)	–
Pregnancy, childbirth	2 (3.8)	–
Unspecified cause	2 (3.8)	3 (5.8)
Erysipelatous inflammation	35 (67.3)	–

Before inclusion in the study, the patients of both groups had not been given any regular standardized pathogenetic treatment, but only its separate elements, because of the absence of qualified recommendations at the outpatient level and low adherence to treatment.

A complex of therapeutic measures included drug treatment. Conservative therapy was selected individually for each patient and depended on the stage of LL lymphedema with obligatory consideration of the somatic state. The list of medications for all patients included drugs improving the rheological properties of blood, facilitating metabolic, neuroprotective and microcirculatory effects, antiplatelet drugs, benzopyrons, nonsteroidal anti-inflammatory drugs, antihistamines, as well as therapeutic gymnastics and obligatory class III elastic compression. Immunocorrectors, auto-ultraviolet blood irradiation and antibacterial agents were prescribed on indications. In patients with primary LL lymphedema, the treatment was aimed at a possible increase in passive lymph outflow, and in patients with secondary lymphedema — at stimulating the motility of preserved lymphangions. All patients of the comparison groups were prescribed ILIB according to the scheme.

ILIB was used at 632 nm wavelength, power from 3 mW to 15 mW, pulse rate from 80 Hz to 2000 Hz, exposure from 5 minutes to 15 minutes, with a course (up to 10 times), daily or interval load (after 1 day). The procedure was performed using sterile lightguides connected to the device, with power control and digital indication of the procedure.

The study included:

1) history taking;

2) examination of the patient by a lymphologist;

3) measurement of the limb cirumference at standard levels;

4) color Doppler imaging (CDI) of LL vessels (Aloka SSD 1700, Japan and Logic 7, USA devices);

5) general clinical and biochemical blood analysis;

6) electrocoagulography (N-334 self-recording portable coagulograph (Etalon, Russia);

7) McClure-Aldrich resorption test;

8) ultrasound (US) of the skin, soft tissues and lymph nodes of the affected limb (Aloka SSD 1700, Japan and Logic 7, USA);

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9) thermal imaging in dynamics on a computer thermograph IRTIS-2000 IU (Irtis, Russia);

10) dynamics of the disease regression — assessment of lymphatic edema on the 12th day after ILIB;

11) study of the outcome of the disease — assessment of clinical manifestations on the 14th day (end of inpatient treatment) and on an outpatient examination after 1 month. The follow-up period was 14.0 ± 2.4 days of inpatient treatment and further examinations according to the study program.

The effectiveness of treatment of patients was controlled by the electrocoagulography (as a method of express diagnostics of the functional state of the hemostasis system), measurement of limb circumferences at previously established levels (foot, shin at 3 standard levels, hip at 3 standard levels). The state of venous outflow was evaluated by ultrasound duplex scanning of venous trunks with CDI in real time with the determination of their geometry, patency, developmental abnormalities, velocity and direction of blood flow. Soft tissue US was conducted to study the condition of the skin, subcutaneous tissue of the lower legs (in the middle and lower third), inguinal lymph nodes (linear size and structural composition) [15, 16]. The microvasculature of the LL was studied by thermography of a limb or a part of it with registration of hyperthermia areas, calculation of their area in pixels, contrast in the desired gradient range with the construction of diagrams and dynamic analysis. Experimentally, the ratio of the number of pixels per 1 cm^2 was determined to be 22.73 [17]. The thermal imaging study was carried out at a room temperature of 23.0 ± 1.0°C, air velocity of no more than 0.25 m/sec, relative humidity of 50%–75%, in the morning hours. The control of reliability of the obtained results was a 'black body' with a constant temperature of 33.0°C. The examination was carried out in a standing position, at the distance from the device 1.5–2.0 meters, depending on the area of study. The resorptive effect of lymph outflow from the affected limb was determined by McClure–Aldrich hydrophilic test.

Statistical data processing was carried out using parametric Student's test and Spearman's rank correlation analysis.

RESULTS

In the complex treatment of LL lymphedema using ILIB, all the patients noted a subjectively positive effect characterized by a decrease in a heavy feeling and swelling in the affected limb. When using ILIB, no systemic or local side effects were identified. When measuring the circumference of the affected limb at standard levels before and immediately after the laser therapy session, no positive dynamics was detected, but after 4 sessions, a decrease in the circumference of the foot, lower third and middle third of the lower leg by 1.6 ± 0.32 cm was noted in Group 2 patients with the initial stages (I–II) of lymphedema. In patients with anatomically preserved lymph node basin, the circumferences of the affected limb at standard levels at the end of the course of complex treatment statistically reduced by 14.8 ± 0.7% (from 48.7 ± 5.3 cm to 41.4 ± 0.9 cm), and insignificantly reduced by 5.2 ± 0.8% in patients with stage III secondary LL lymphedema with significant transformations. All of the above changes were not registered in Group 1 patients.

US of the soft tissues of the limbs performed in 18 patients after the 4th and final ILIB session, showed reduction of echogenicity of the subcutaneous tissue at the level of foot and in distal part of medial surface of the lower leg, and also reduction of extension and size of interlymphatic spaces in the subcutaneous tissue. When studying the external inguinal lymph node structure of the lower group, the paracortical layer was reduced and the medullary layer was statistically increased ($p < 0.05$) and was located in the central part without hypoechoic and hyperechoic inclusions, with the linear dimensions of the lymph node remaining the same (Table 2).

All the above manifestations were observed only in patients of Group 2 at I and II stages of secondary lymphedema of LL. US of patients with III stage showed that thickness of soft tissues decreased only in 4 patients, which indicates a buildup of fibrous restructure, although lymphatic lacunae between the areas of sclerosed tissues changed in size and shape.

Electrocoagulography conducted in all patients before, after 4 sessions and at the end of ILIB, showed a statistically significant ($p < 0.001$) tendency to hypocoagulation with formation of a loose clot with early retraction.

Using Spearman correlation analysis, we established a direct close relationship between changes in the blood coagulation system (fibrinolytic activity) and the circumferences of lower and middle third of shin in Group 2 patients with I–II stage of the disease. The required coefficient was 0.96 with the critical Spearman criterion value of 0.573 ($p < 0.005$). In Group 1, no significant effect was found.

With a high level of objectification, the following changes of the quantitative parameters of infrared radiation of a pathologically altered limb were obtained: left inguinal region — 39.02 ± 0.17°C, popliteal region 37.86 ± 0.13°C, respective regions on the right — 37.93 ± 0.16°C and 38.96 ± 0.19°C. The thermal asymmetry was characterized by peculiarities of arrangement of vessel trunks and innervation of the limb (Table 4). Evaluation of thermography parameters

Table 2. Changes in Size and Structure of Lymph Nodes in Group 2 Patients after Irradiation of Blood with Low-Intensity Laser Light, M ± σ

Parameters	Before ILIB		After ILIB	
Parameter	M	m	M	m
Length	1.84	0.07	1.75	0.10
Width	1.0	0.05	0.58	0.06
Paracortical layer	0.29	0.03	0.2	0.04
Medullary layer	0.32	0.03	0.44*	0.05

Notes: ILIB — Low-Intensity Laser Light; *— compared with the parameters of lymph nodes before ILIB, $p < 0.05$, $t = 2.101$

Table 3. Condition of Hemostasis in Patients with Secondary LL Lymphedema (Group 2, n = 52), M ± σ

Parameters	Before Laser Therapy		After Laser Therapy	
	M	**m**	**M**	**m**
Hematocrit	0.41	0.13	0.42	0.08
Blood coagulation time, min	5.05	0.29	12.24*	1.37
Clot retraction time, min	10.55	1.84	12.73	2.09
Clot density	0.09	0.01	0.16	0.03
Fibrinolytic activity	4.30	0.91	12.29*	3.84

Note: * — relative to the initial hemostatic parameters of patients, $p < 0.001$, $t = 3.48$

Table 4. Changes in Thermal Profile in Projection of Inguinal Lymph Nodes and Area of Hyperthermia in Distal Part of Lower Leg during ILIB Treatment of Patients with Secondary Lower Limb Lymphedema (Group 2, n = 52), M ± σ

Period of Parameter Evaluation	Temperature, degrees		Area, cm^2	
	M	**m**	**M**	**m**
Before laser therapy	39.14	0.34	16.83	0.59
After laser therapy	38.11	0.28	31.20*	2.86

Notes: ILIB — Low-Intensity Laser Light; * — increase in the area of hyperthermia in patients of Group 2 after ILIB, $p < 0.001$; $t = 3.488$

of LL showed increase in the level of IR radiation only in Group 2. Increase ($p < 0.001$) in the area of hyperthermia in the distal part of lower legs and along the inner surface of thighs was recorded evidencing improvement of microcirculation (Figure 1).

In McClure–Aldrich tests, a statistically significant slowdown of a skin papule resolution in a distal part of the lower leg from 27.13 ± 2.77 min to 35.72 ± 3.11 min ($p < 0.05$) was recorded in I stage of the disease only after completion of ILIB treatment. In II and III stage of secondary LL lymphedema, a mild increase in the time of a skin papule resolution was noted, which, nevertheless, evidences a reduction of lymphatic edema and improvement of resorption-transport function of lymph node basin of the affected limb, and of the functional activity of lymphangion. In Group 1, no such regularities were recorded.

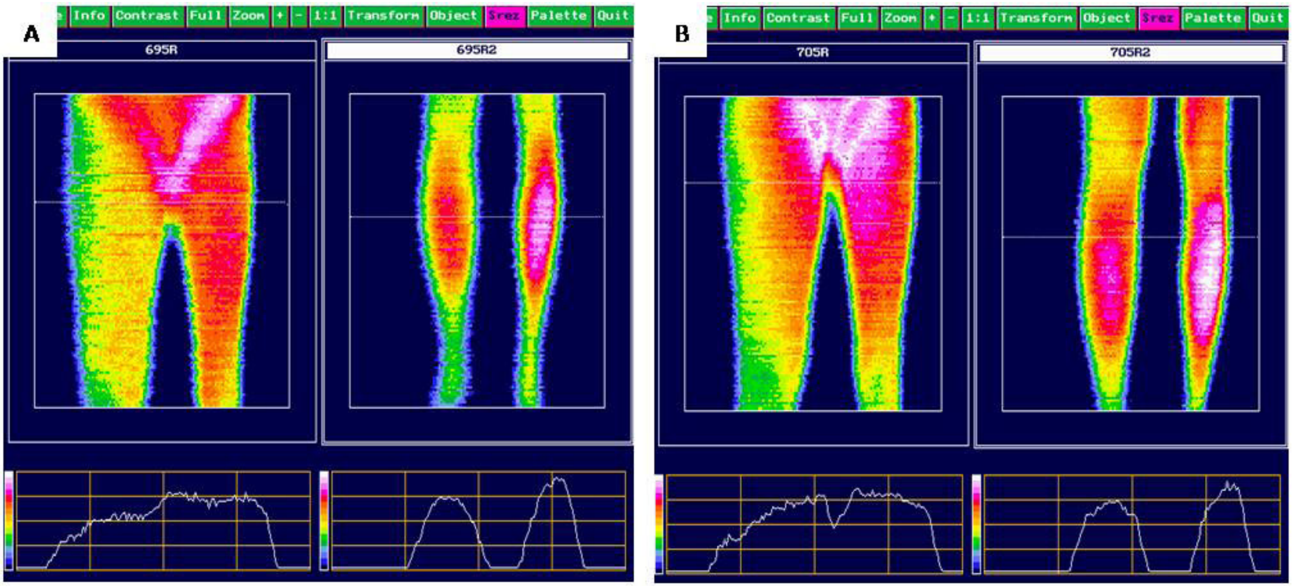

Fig. 1. Clinical example: Thermograms of lower limbs of a female patient S., 58 years old, with III stage secondary lymphedema before (A) and after (B) comprehensive treatment.

DISCUSSION

The main focus of treatment for secondary and primary lymphedema is conservative therapy including gymnastics in water with a positive effect, especially in the short term [18], acupuncture in a healthy limb in case of lymphedema of an upper limb [19], the use of orthopedic insoles, restoration of mobility of the foot and ankle joint [20]. The comprehensive treatment should include the following methods: mechanical (therapeutic gymnastics, massage, compression therapy, body weight control), physical (ampliimpulse, electrophoresis, electrostimulation, pneumocompression, barotherapy, ultraviolet irradiation of blood) and pharmacological (drugs to improve lymph flow, normalize the contractile activity of lymph vessels, prevent relapses of erysipelas, improve venous outflow, correct inflammatory and trophic tissue changes) [9], and also successive manual lymphatic drainage, kinesiotaping, therapeutic gymnastics in the gym hall [20].

Laser light is proved to stimulate lymphogenesis, restore lymph drainage through increase in the motility of lymphatic vessels and reduction of interstitial fluid production, and has a favorable effect on the endothelial dysfunction of blood vessels. Additional effects of laser light are reduction of fibrosis and sclerosis of lymphedematous tissues due to protective effect of fibroblasts, as well as stimulation of immunity through activation of macrophages [13]. In our study, mechanical and pharmacological methods in combination with ILIB were used.

In our opinion, it is reasonable that a comprehensive therapy of patients with lymphatic edema of limbs be combined with ILIB. The ILIB effectiveness is explained by the effect on the platelet aggregation rate, the time of dense clot formation and the degree of blood clot disaggregation, that is, recovery of platelet aggregation ability, which is directly related to viscosity and fluidity of lymph, and is confirmed by a close direct Spearman correlation relationship ($p < 0.005$). ILIB stimulates microcirculation (which is confirmed by thermal imaging), lymphatic pump function at the capillary level and the functionality of preserved lymphangions, which influences the ‘dehydration’ of the interstitial tissue, reducing the severity of dystrophic transformation (confirmed by a positive hydrophilic test). The effectiveness of hydrophilic test was established to be directly proportional to the degree of sclerotic alterations in soft tissues and the stage of lymphedema. ILIB method improves the effectiveness of comprehensive treatment of patients with secondary LL lymphedema, especially at the initial stages of the disease with the preserved lymphangion function.

CONCLUSION

Irradiation of blood with low-intensity laser light is reasonable for application in patients with I-II stage of secondary lymphedema with functionally preserved lymphatic vessels.

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Вклад авторов: *Яровенко Г. В.* — концепция и дизайн исследования, статистическая обработка, написание текста; *Каторкин С. Е.* — концепция и дизайн исследования, редактирование. Все авторы подтверждают соответствие своего авторства международным критериям ICMJE (все авторы внесли существенный вклад в разработку концепции, проведение исследования и подготовку статьи, прочли и одобрили финальную версию перед публикацией).

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