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ABSTRACT

of the dissertation for the degree of Doctor of Philosophy

THE EFFECTIVENESS OF THE COMBINED APPLICATION OF LASER THERAPY AND "VENOCORYL" OINTMENT IN THE TREATMENT OF CHRONIC VENOUS ULCERS OF THE LOWER EXTREMITIES

Specialty: 3213.01- Surgery

Field of science: Medicine

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The research was conducted at the Department of General Surgery of Azerbaijan Medical University and the Gazakh District Central Hospital, under the Public Legal Entity "Management Union of Medical Territorial Units".

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GENERAL CHARACTERISTICS OF THE WORK

Relevance of the Topic: Trophic disorders occurring as a complication of venous insufficiency in the lower extremities occupy an important place among vascular diseases and pathologies of the extremities, accounting for 10-30%[1].

Venous ulcers have been the most common cause of lower extremity ulcers in developed countries, occurring in a ratio of 1.5-3.0 per 1000 in people under 65 years old. The prevalence increases with age and is recorded at a rate of 20 per 1000 in people over 80 years old[2].

Despite certain advancements in the diagnosis and treatment of venous ulcers, their healing still requires an average of 6 months, and the recurrence rate exceeds 58% within 5 years[3].

Pathologies such as diabetes, arterial hypertension, and chronic arterial insufficiency aggravate the disease and prolong its duration [4].

The high costs of treatment are due to the prolonged duration of treatment, the high cost of medical materials, and the frequent recurrence [5].

The recurrence of varicose veins in the lower extremities is considered a complex issue after varicose vein surgery, including

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ligation and resection, as well as endovenous procedures [6]. Genetic factors related to height have been reported to play a major role in the development of venous ulcers[7].

The incidence of complications and recurrences of trophic ulcers remains high. Taking this into account, many authors have developed complex treatment methods that integrate surgical interventions and conservative approaches [8].

Early identification of these patients at high risk of infection, prevention of complications, and reduction of the incidence of adverse outcomes are essential. This leads to prolonged treatment, delayed recovery, and negatively impacts patients' quality of life, the healthcare system, and society [9].

In this regard, the treatment of varicose veins of the lower extremities remains a pressing issue. Traditional treatments such as mechanical and elastic bandage dressings and topical antibiotics for infection are often ineffective [10].

Recently, the use of endovenous laser ablation (EVLA) in the treatment of varicose veins of the lower extremities has become

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widespread. When EVLA is performed, it is possible to prevent the closure of communicating veins without additional trauma[11].

In addition, the combined application of plant-derived biologically active agents helps eliminate the inflammatory process and accelerate healing in the ulcerated area and surrounding tissues[12]. One such preparation is the 5% "Venocoryl" ointment, which is made from flavonoids extracted from the leaves of Corylus avellana L., and has anti-inflammatory, anti-swelling, and vein-strengthening effects[13].

Thus, the high incidence of trophic ulcers caused by varicose veins of the lower extremities in patients, along with the insufficient effectiveness of existing conservative and surgical treatment methods, are the main reasons for the continued attention to this issue. Taking this into account, the conduct of a study based on a comparative analysis of the results of the combined application of EVLA and "Venocoryl" ointment has been proposed as an important scientific and practical issue.

Object of the research. The study included 75 patients with trophic ulcers on the background of varicose veins of the extremities who sought treatment at the Educational Surgical Clinic by Azerbaijan Medical University and the Gazakh District Central Hospital between 2019 and 2023. The patients were divided into 3 groups based on the treatment measures: Group I – EVLA+mini-phlebectomy (n=25); Group II – EVLA + mini-phlebectomy + “Venocoryl” (n=25); Group III – EVLA + low-intensity laser radiation + “Venocoryl” (n=25).

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Purpose of the research. Improving treatment outcomes through the combined use of laser technologies and Venocoryl ointment in patients with trophic ulcers caused by varicose veins of the lower extremities.

Research objectives:

1. Study of the dynamic effect of Venocoryl on the course of the wound process after its application in clinical studies.
2. Clinical evaluation of the effect of the combined application of Venocoryl and low-intensity laser radiation on the course of the wound process.
3. Comparative study of morphological changes in inflamed tissues after the combined application of low-intensity laser radiation.
4. To comparatively study the short-term and long-term results of the application of Venocoryl and low-intensity laser radiation in the treatment of chronic venous ulcers of the lower extremities.

Scientific novelty of the research. For the first time, the local combined effect of low-intensity laser irradiation and Venocoryl ointment in the treatment of trophic ulcers was studied in clinical research in a complex manner with endovenous ablation of lower extremity veins. The effectiveness of the proposed methods for the treatment of trophic ulcers in various combinations was evaluated using clinical-instrumental markers.

Practical significance of the research:

1. When using the treatment combination of EVLA, Venocoryl, and low-intensity laser radiation, proposed by us, in patients with varicose veins and trophic ulcers of the lower extremities, the symptomatic outcomes were more favorable compared to other treatment combinations.
2. Considering the higher dynamic improvement in patients' quality of life indicators with the proposed treatment combinations, their practical application is recommended.
3. The same situation was observed in the dynamics of trophic ulcers and surgical site area indicators after interventions, supporting the conclusion that this combination is a more practical treatment approach.

Research methods.

- Clinical-anamnestic
- Instrumental
- Histological examination
- Quality of life
- Mathematical and statistical analysis methods

Main provisions of the dissertatin submitted for defense:

1. The good treatment outcomes with the use of endovenous laser ablation of the greater saphenous veins are ensured by a thorough approach to the patients. The results of ultrasound (USM) should be absolutely considered regarding the nature and length of changes in the superficial veins.
2. To eliminate the altered flow of the greater saphenous veins due to varicose veins, it is more appropriate to use the mini-phlebectomy method or perform phlebosclerotherapy in the postoperative period.
3. The catheterization of the greater saphenous vein during endovenous laser ablation is performed through a small incision above the medial malleolus or by puncturing the skin. It is essential to subject the segment of the vein, where reflux was detected during the preoperative ultrasound examination, to obliteration.
4. The complex treatment consisting of EVLA + Venocoryl + low-intensity laser radiation for the treatment of varicose veins and trophic ulcers of the lower extremities shows better results compared to other combinational treatments, as demonstrated by clinical indicators, quality of life surveys, and histomorphological evaluation.

Approbation of the dissertation. The results of the research were discussed at the following conferences:

1. The proceedings of the International Practical Conference on "Current Problems of Medicine-2022" dedicated to the “270th anniversary of Shusha” in the Republic of Azerbaijan (Baku, May 24-25, 2022);

2. Current Issues in Education and Science: Proceedings of the International Scientific and Practical Conference (Penza, July 31, 2022).

The results of the dissertation were presented and discussed at the interdepartmental meeting of AMU on July 5, 2023, at meeting No. 12, and at the scientific seminar of the Dissertation Council ED 2.06 operating under AMU, held on June 10, 2024, at meeting No. 06.

Publications. 12 scientific works dedicated to the results and fragments of the dissertation were published. Of these, 8 were articles (2 articles in journals included in international abstracting and indexing databases), and 4 were theses (one abroad).

Application of research results. The results of the dissertation were included in the scientific research plan of the Educational Surgery Clinic by the Azerbaijan Medical University, the Gazakh District Central Hospital under the Public Legal Entity "Management Union of Medical Territorial Units, and the Center of Scientific Surgery named after Academician M.A. Topchubashov under the Public Legal Entity "Management Union of Medical Territorial Units".

The organization where the dissertation work was performed. The research was conducted at the Educational Surgery Clinic by the Azerbaijan Medical University and the Gazakh District Central Hospital under the Public Legal Entity "Management Union of Medical Territorial Units."

The structure and volume of the dissertation. The dissertation consists of 153 printed pages (200,139 characters) and includes an introduction (11,106 characters), Chapter I (52,958 characters), Chapter II (19,451 characters), Chapter III (65,386 characters), conclusion (49,128 characters), results (1,596 characters), practical recommendations (516 characters), and a list of references. The dissertation includes 25 tables, 24 graphs, and 15 figures. The list of references includes 148 sources, of which 8 were by local authors, 26 by Russian authors, and 114 by foreign authors.

MATERIALS AND METHODS OF THE RESEARCH

The research included 75 patients with trophic ulcers that developed due to varicose veins in the extremities, who sought treatment at the Educational Surgery Clinic by the Azerbaijan Medical University and the Gazakh District Central Hospital between 2019 and 2023. The patients were divided into groups based on the applied complex treatment methods. The average age of the patients included in the research was 42.4 years (ranging from 15 to 75). Of these, 28 (37.3%) were men and 47 (62.4%) were women.

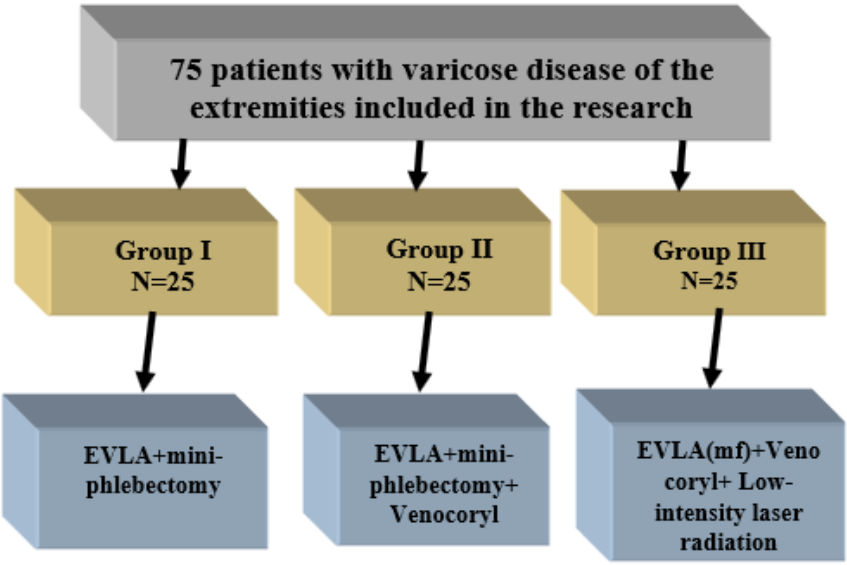


Figure 1. The design of the research

The patients had ulcers measuring 14-48 mm in their lower extremities, which developed due to chronic venous insufficiency.

The inclusion criteria for the patients in the research are as follows:

- Age between 15 and 75 years;
- Patients with small stage 2 ulcers in the lower extremities;
- Patients with medium-sized ulcers.

The exclusion criteria for the research are as follows:

- Patients with connective tissue and blood disorders
- Patients with diabetes mellitus, and oncological diseases
- Pregnant women
- Deep vein thrombosis (Post-Thrombotic Syndrome)

The size of the ulcers in the patients included in the research ranged from 14 to 48 mm.

In this stage of the study, the presence of characteristic symptoms such as “discomfort in the legs”, “increased fatigue in the legs”, “heaviness in the legs at night”, “throbbing, burning pain in the lower extremities”, “swelling of the ankles in the evening”, and “calf muscle cramps” was assessed in the patients before the treatment and 6 months after the completion of treatment for varicose veins in the lower extremities.

During the study, it was recorded that 13 of the total patients with trophic ulcers due to varicose veins in the lower extremities had ulcers for approximately 3 months, which accounts for 17.3% of the corresponding group. However, the number of patients with trophic ulcers that developed within 4 months and 5-6 months was 5 (6.7%) and 6 (8.0%).

In the second stage, it was determined that the trophic ulcers were on average in the following size intervals: 1-3 cm^2, 4-7 cm^2, 8-11 cm^2, 12-16 cm^2, 17-21 cm^2, and 22-25 cm^2.

At the stage of the study where we determined the area of trophic ulcers in the total patients, 17 of them, or 22.7%, had ulcers with an area in the range of 1-3 cm^2. In the corresponding stage, changes in the area of trophic ulcers within the ranges of 4-7 cm^2 and 8-11 cm^2 were recorded in 26 and 9 patients, accounting for 34.7% and 12.0% of the total patients, respectively.

In the third stage of the study, the average daily epithelialization rate of the ulcers was studied on the 30th day, the 60th day, and in total after the initiation of the planned treatment measures in the patients of the groups.

Histological examination was performed on the patients. The SF-36 health survey was used to assess the patients' quality of life.

Student's t-test was used to assess the initial difference between variance ranks, while the mean difference between selected indicators for paired variants and the difference between proportions were evaluated. For verifying and refining the results, non-parametric tests such as the Wilcoxon (Mann-Whitney) U test and Pearson's $\chi 2$ test for frequency analysis were used. For the statistical analysis of the obtained numerical indicators, Pearson's $\chi 2$ test (Pearson Chi-Square) was used. The statistical analysis of the results obtained during the study was conducted using the Statistica 7.0 software package.

RESULTS OF PERSONAL RESEARCH

As a result of the study, we determined the duration of the presence or onset of trophic ulcers in the total patient group. In this regard, the patients were grouped as follows: 6 weeks, 2 months, 3 months, 4 months, 5-6 months, 7-12 months, 13-24 months, and 25 months or more. In most patients, 18 (24%) developed ulcers within 6 weeks, while only 2 patients (2.7%) had ulcers that developed after more than 25 months. The number of patients with ulcers that developed in 2 months (20.0%), 3 months (17.3%), and 7-12 months (14.7%) was also significant.

The characteristics of symptoms in the patients included in the study were quantitatively compared before treatment and 6 months after treatment in each group. The presence or absence of symptoms such as discomfort in the legs, fatigue, heaviness in the legs at night, throbbing pain, swelling in the ankles, and cramps in the calf area was determined in the patients.

It was found that in Group I, although a reduction in symptoms was observed after treatment, statistically significant differences were identified in terms of the presence of symptoms ($p=0.0377$), discomfort in the legs ($p=0.6092$), fatigue ($p=0.0377$), heaviness at night ($p=0.1706$), throbbing pain ($p=0.1963$), and swelling ($p=0.3487$).

In Group II, a reduction in symptoms was also observed after treatment. However, no statistical significance was found for the following: the presence of symptoms ($p=0.0005$), discomfort in the legs ($p=0.3487$), fatigue ($p=0.0006$), heaviness at night ($p=0.1383$), throbbing pain ($p=0.0106$), swelling ($p=0.3487$), and cramps ($p=0.2347$).

In Group III, reductions in symptoms were more pronounced after treatment. Before treatment, 5 (20.0%) patients had no symptoms, while 6 months after treatment, 21 (84.0%) patients had no symptoms. A statistically significant difference was observed between the indicators (p=0,0001). In other indicators: discomfort in the legs (p=0.4898), fatigue (p=0.0002), heaviness at night (p=0.0096), throbbing pain (p=0.0106), swelling (p=0.1895), and cramps (p=0.1098) were observed.

Thus, in patients treated with EVLA + Venocoryl + low-intensity laser radiation, more symptoms of the disease were eliminated.

In the patients included in the study, we determined the areas covered by trophic ulcers. The areas of the ulcers were classified as follows: 1-3 cm², 4-7 cm², 8-11 cm², 12-16 cm², 17-21 cm², 22-25 cm². The majority of patients had an ulcer area of 4-7 cm², with 26 (34.7%) patients recorded. The fewest patients had an ulcer area of 22-25 cm², with 5 (6.7%) patients recorded.

Table 1.

The daily average epithelialization rate (cm²/day) of the wound site 30 days after treatment with different methods

Research groups	After 30 days	After 45 days	After 60 days
Group I (n=25)	0.068±0.005	0.072±0.004	0.065±0.005
Group II (n=25)	0.152±0.009 $p_{I\ gr.}$ = 0.0001	0.125±0.007 $p_{I\ gr.}$= 0.0001	0.133±0.009 $p_{I\ gr.}$ = 0.0001
Group III (n=25)	0.239±0.010 $p_{I\ gr.}$ = 0.0001 $p_{II\ gr.}$ = 0.0001	0.131±0.008 $p_{I\ gr.}$= 0.5583 $p_{II\ gr.}$= 0.0001	0.125±0.009 $p_{I\ gr.}$= 0.5266 $p_{II\ gr.}$ = 0.0001

Daily ulcer epithelialization rates were determined for patients in the research groups during the first 30 days, the second 30 days, and a total of 60 days after treatment (Table 1).

In this case, in Group III, where EVLA, Venocryl ointment, and low-intensity laser radiation were combined for the treatment of lower extremity varicose veins and trophic ulcers, the daily epithelialization rate after 30 days of treatment was on average 0.239±0.010 cm²/day. In this case, it was statistically significantly higher than the indicators

of Groups I and II (p=0.0001) (Table 1). In Group II, the average daily epithelialization rate of trophic ulcers 30 days after the treatment (0.152±0.009 cm²/day) was statistically significantly higher than in Group I (0.068±0.005 cm²/day) (p=0.0001). This indicator was statistically insignificant compared to the patients' pre-treatment indicators (p=0.1234). Thus, patients treated with EVLA + Venocryl + low-intensity laser radiation for trophic ulcers achieved the highest daily epithelialization rate 30 days after treatment.

The ulcer area was examined in dynamics before treatment and 10, 15, 20 and 25 days after treatment. (Table 2).

Table 2

The average quantitative indicators of ulcer areas before and after treatment in the research groups. (cm^2)

Group	Before treatment	10 days after	15 days after	20 days after	25 days after
Group I	25.4±0.44	25.2±0.46	24.6±0.35	23.5±0.31	22.3±0.29
Group II	24.7±0.53	24.5±0.49	22.2±0.25	20.3±0.43	19.2±0.33
P_1	0.0065	0.3466	0.0001	0.0001	0.0001
Group III	23.6±0.45	22.4±0.41	18.0±0.32	13.60±0.18	6.6±0.24
P_1	0.3034	0.0001	0.001	0.0001	0.0001
P_2	0.1235	0.0018	0.0001	0.0001	0.0001

Note: P_1 and P_2 represent the statistical significance for Groups I and II, respectively, according to the Mann-Whitney U test.

There were no statistically significant differences in ulcer area between Groups I, II, and III before treatment (25.4±0.44 cm², 24.7±0.53 cm², 23.6±0.45 cm², respectively), and this parameter was approximately the same in the groups. The ulcer area in group II was

statistically significantly smaller than in group I at all post-treatment periods (p=0.0001). In Group III (22.4±0.41 cm²), the ulcer area decreased 10 days after treatment. Compared to Group II (24.5±0.49 cm²), the difference was statistically non-significant (p=0.0018), while a statistically significant reduction was observed compared to Group I (25.2±0.46 cm²). 15 days after treatment, the reduction in ulcer area in Group III (18.0±0.32 cm²) compared to Group II (22.2±0.25 cm²) was statistically non-significant (p=0.001). 20 and 25 days after treatment, the ulcer area in Group III was statistically significantly smaller compared to Groups I and II (p=0.0001).

We determined the changes in the size of the areas of trophic ulcers by groups. In Group I (n=25), before treatment, or in other words, before surgery, the average area was 16.7±0.38 cm², whereas on the 10th day of treatment, this value decreased to 15.6±0.22 cm². The average area indicators also decreased on the 15th and 20th days of treatment. Thus, on the 15th day after the start of treatment measures in Group II, the total average area of trophic ulcers on the lower extremities of the patients decreased to 14.8±0.28 cm², and by the 20th day, it further decreased to an average of 12.9±0.21 cm² in the group. In Group III, when surgical interventions were started, the total average area of ulcer-like lesion elemets on the lower extremities of the study objects was 12.2±0.36 cm² ($P_{I\ gr.}$=0.0001). However, during the repeated measurements conducted on the 10th day of treatment, we observed a decrease in the average area of trophic ulcers in the group, with the area reducing to 8.2±0.23 cm² ($P_{I\ gr}$ =0.0001). On the 25th day after the start of treatment measures or the day following the completion of the treatment procedures, a reduction in the average area size of trophic ulcers in the lower extremities of the patients in the main group continued. The average area was determined to be 5.5±0.30 cm² ($P_{I\ gr}$ =0.0001). In Group III, as the epithelialization and healing of trophic ulcers continued in the following periods after treatment measures, the ulcer areas continued to decrease. On the 20th day after starting treatment measures, the average ulcer area in the group decreased to 3.5±0.22 cm² ($P_{I\ gr.}$=0.0001).

Table 3.

The average reduction in trophic ulcers by days after starting treatment measures in the research groups (cm²)

Groups	10 days after	15 days after	20 days after
Group I	15.6±0.22	14.8±0.28	12.9±0.21
Group II	13.3±0.25	11.6±0.25	8.3±0.19
P_1	0.0001	0.0001	0.0001
Group III	8.2±0.23	5.5±0.30	3.5±0.22
P_1	0.001	0.0001	0.0001
P_2	0.0001	0.0001	0.0001

Note: P_1 and P_2 represent the statistical significance for Groups I and II, respectively, according to the Mann-Whitney U test

It should be noted that the combined treatment measures for this group also lasted a total of 14 days. On the 15th day of treatment, we observed a reduction in the total average area of trophic ulcers in the lower extremities of the patients, decreasing to 11.6±0.25 cm² ($P_{II\ gr.}$=0.0001, $P_{III\ gr.}$=0.0001) On the 20th day of treatment, or on the 6th day, the average area of trophic ulcers on the lower extremities of the patients further decreased to 8.3±0.19 cm² ($P_{I\ gr.}$=0.0001, $P_{III\ gr.}$=0.0001).

In the second stage of the study, where the occurrence of granulation, marginal epithelialization, and complete epithelialization (healing) was studied by days in the control, comparison, and main groups, using various combinations of methods for the elimination of varicose veins and trophic ulcers in lower extremities, in Group I, where the combination of EVLA + mini-phlebectomy was used for treatment, the presence of granulation in the ulcers lasted an average of 14.9±0.27 days. In the corresponding group, marginal epithelialization of trophic ulcers occurred on an average of 20.7±0.43 days. The duration of complete epithelialization of trophic ulcers in the lower extremities due to the effect of treatment measures was an average of 44.3±0.44 days in the group (Table 4)

Table 4 .

The duration of the healing process in stages (days) after treatment of trophic ulcers of the lower extremities in the research groups

Research groups	Granulation	Marginal epithelialization	Complete epithelialization
Group I	14.9±0.27	20.7±0.43	44.3±0.44
Group II	10.3±0.30	17.3±0.26	40.2±0.27
P_1	0.0001	0.0001	0.0001
Group III	5.9±0.19	9.5±0.29	25.9±0.35
P_1	0.0001	0.0001	0.0001
P_2	0.0001	0.0001	0.0001

Note: P_1 and P_2 represent the statistical significance for Groups I and II, respectively, according to the Mann-Whitney U test

In Group II, granulation lasted an average of 10.3±0.30 days, marginal epithelialization 17.3±0.26 days, and complete epithelialization lasted 40.2±0.27 days. These processes took less time compared to Group I and were statistically significantly lower (p=0.0001). In Group III, granulation lasted 5.9±0.19 days, marginal epithelialization 9.5±0.29 days, and complete epithelialization took 25.9±0.35 days. In Group III, these indicators were statistically significantly lower compared to Groups II and I (p=0.0001). The application of the combination of EVLA, Venocoryl ointment, and low-intensity laser radiation resulted in faster granulation and epithelialization processes in ulcers.

51 patients (68%) experienced recurrence after full recovery 6 months after treatment. Although the ulcers were completely closed in these patients, recurrence occurred. At this time, complete healing of ulcers was observed in 21 (84%) of the study objects (n=25) in group III, who received treatment with the EVLA+Venocryl+low-intensity laser radiation (Table 5).

Table 5.

Healing outcomes after 6 months of treatment of trophic ulcers in the groups

Research groups	Patients with complete epithelialization		Patients with recurrences after healing	
	Absolute number	%	Absolute number	%
Group I (n=25)	13	52	3	23.1
Group II (n=25)	17	68	2	11.8
Group II(n=25)	21	84	2	9.5

In group II (n=25), 17 (68%) patients were recorded with complete resolution of trophic ulcers 6 months after treatment. In the same group, six months after treatment, complete epithelialization of trophic ulcers was observed in 13 patients, accounting for 52% of the total patients.

In the stage of the study where recurrence cases were determined six months after the planned treatment measures were implemented in patients across the groups, a total of 7 (13.7%) patients experienced recurrent ulcers. In group III, 2 (9.5%) patients whose ulcers had completely healed and epithelized 6 months after treatment experienced recurrence with ulcers (Table 5).

During the study, in Group I, where trophic ulcers developed due to varicose veins of the lower extremities and the EVLA+mini phlebectomy+Venocryl scheme was used for treatment, recurrence was recorded in 2 (11.8%) patients after complete healing.

In Group I (n=13), where the EVLA+mini phlebectomy scheme was used, recurrences occurred at the site of healed ulcers in 3 (23.1%) patients after complete healing.

Analysis of the patients' physical condition. The quality of life was analyzed in a comparative aspect based on the SF-43 health survey before treatment, and 3 and 6 months after treatment. The physical condition of the patients was assessed based on the following parameters: physical functioning (PF), role physical (RP), bodily pain (BP), and general health (GH). The psychological condition of the patients was assessed based on

the following parameters: vitality (VT), social functioning (SF), role emotional (RE), and mental health status (MH).

In group III, the PF score before treatment was on average 64.4±1.36 points, after 3 months it increased to 74.8±1.51 points (p=0.001), and after 6 months, the PF score was 90.4±1.00 points (p=0.001).

While the PF score in group I was on average 65.0±1.44, the corresponding score increased to 70.4±1.80 in the 3rd month, and reached 72.6±1.76 (p=0.0016) in the 6th month.

In group II, the PF score before treatment was 65.2±1.65, and by the 3rd month, the score increased to 75.4±1.71 (p=0.001). By the 6th month, it reached 84.6±1.19 (p=0.0001).

While the mean score of the role physical parameter (RP) in group III was calculated to be 25.0±3.54, during the repeated examinations in the 3rd month, the corresponding score increased to 62.0±3.27, and in the 6th month, it increased further to 91.0±2.84 (p=0.0001).

In group I, the RP score was 28.0±3.00 before treatment, increased to 35.0±4.33 in the 3rd month, and further increased to 38.0±4.36 (p=0.0648) in the 6th month.

In group II, the RP score was 28.0±2.20 before treatment, increased to 61.0±2.92 in the 3rd month, and further increased to 81.0±3.89 (p=0.0001) in the 6th month.

In group III, the mean BP score was 62.8±1.99 before treatment, increased to 75.3±1.82 in the 3rd month (p=0.001), and further increased to 82.7±2.04 (p=0.0001) in the 6th month.

The physical functioning scores were recorded as 64.4±1.36 before treatment, 74.8±1.51 (p=0.001) in the 3rd month, and 90.4±1.00 (p=0.001) in the 6th month. The improvement in physical functions is significant, and a marked difference was observed both in the 3rd and 6th months. The role physical was 25.0±3.54 before treatment, 62.0±3.27 (p=0.0001) in the 3rd month, and 91.0±2.84 (p=0.0001) in the 6th month. The bodily pain (BP) score was 62.8±1.99 before treatment, 75.3±1.82 (p = 0.001) in the 3rd month, and 82.7±2.04 (p = 0.0001) in the 6th month. The general health score was 30.6±1.13 at the start of treatment,

37.4±1.29 (p = 0.002) in the 3rd month, and 70.2±1.21 (p = 0.0001) in the 6th month. RE score was 33.3±4.30 before treatment, increased to 66.7±4.71 (p = 0.0001) in the 3rd month, and further increased to 81.3±4.34 (p = 0.0001) in the 6th month. The MH score was 64.2±2.12 before treatment, 63.8±1.87 (p=0.910) in the 3rd month, and 65.3±1.68 (p=0.681) in the 6th month.

In group I, the BP score was 65.2±1.70 before treatment, increased to 71.3±1.57 (p=0.0113) in the 3rd month, and further increased to 76.8±1.17 (p=0.0001) six months after treatment.

In group II (n=25), the BP score was 65.7±1.53 before treatment, increased to 75.1±1.90 (p=0.003) in the 3rd month, and reached 81.8±2.15 (p=0.0001) six months after treatment. Overall, a positive development trend was observed in physical and mental health parameters between the 3rd and 6th months of treatment.

In group III, the general health (GH) score was observed to be 30.6±1.13 before the treatment, 37.4±1.29 (p=0.002) in the 3rd month, and 70.2±1.21 (p=0.0001) in the 6th month.

In group I, the GH score before treatment was 33.2±1.25, increased to 45.6±1.42 (p=0.0001) in the 3rd month, and reached 49.0±1.22 (p=0.0001) in the 6th month.

In the comparison group, the GH score before treatment was 32.4±1.23, but in the 3rd and 6th months, the corresponding values were 37.0±1.29 (p=0.013) and 63.4±1.41 (p=0.0001), respectively.

In group III, the VT score was 35.4±1.44 before treatment, while it was 55.2±1.34 in the 3rd month and 65.2±0.98 in the 6th month (p=0.0001). In group I (n=25), although the score was 35.8±0.94 before treatment, it was 44.2±0.85 (p=0.001) and 44.0±0.96 (p=0.001) in the 3rd and 6th months, respectively. In group II, the score before treatment was 36.0±1.47, and after 3 and 6 months of treatment, this indicator was calculated as 55.4±1.41 and 62.0±1.00, respectively. The difference between these indicators was statistically significant (p=0.0001).

In group III, before the treatment, the relevant parameter was determined to be 49.5±2.34, but after 3 months, it was calculated as 62.5±2.28 (p=0.0001), and after 6 months, it was 75.5±1.69 (p=0.0001).

In group I, before treatment, the SF score was 52.0±2.36, and during the repeat calculations at the end of the 3rd and 6th months, it was recorded as 56.0±1.79 (p=0.1826) and 59.0±2.11 (p=0.0316), respectively.

In group I, the PF score was 65.0±1.44 before treatment, 70.4±1.80 (p=0.0235) three months after treatment, and 72.6±1.76 (p=0.0016) six months after treatment. The RP score was found to be 28.0±3.00 before treatment, 35.0±4.33 (p=0.1902) after 3 months of treatment, and 38.0±4.36 (p=0.0648) after 6 months of treatment. The BP score was 65.2±1.70 before treatment, 71.3±1.57 (p=0.0113) after 3 months, and 76.8±1.17 (p=0.0001) after 6 months. The GH score was 33.2±1.25 before treatment, 45.6±1.42 (p=0.0001) after 3 months, and 49.0±1.22 (p=0.0001) after 6 months. The VT score was observed to be 35.8±0.94 before treatment, increased to 44.2±0.85 (p=0.001) after 3 months, and reached 44.0±0.96 (p=0.001) after 6 months. SF was determined as 52.0±2.36 before treatment, 56.0±1.79 (p=0.1826) after 3 months, and 59.0±2.11 (p=0.0316) after 6 months. The RE score was 33.3±4.71 before treatment, increased to 52.0±5.47 (P=0.0128) after 3 months, and reached 64.0±5.06 (P=0.0001) after 6 months.

In the comparison group, the SF score was determined to be 52.5±3.46, 63.0±2.45 (p=0.017) in the 3rd month, and 77.5±1.77 (p=0.0001) in the 6th month.

A positive effect of treatment on the parameters of the physical component was observed. In the mental component, there were positive changes in VT, SF and RE parameters. However, the MH parameter did not show any changes (P>0.05). These results indicate that EVLA and mini phlebectomy treatment affect patients' quality of life.

In group III, although the RE parameter was calculated as 33.3±4.30 before treatment, it was determined as 66.7±4.71 and 81.3±4.34 in the 3rd and 6th months, respectively (p=0.0001 for both indicators). In group I, the score was 33.3±4.71 before treatment, 52.0±5.47 (p=0.0128) at the end of the 3rd month, and 64.0±5.06 in the 6th month (p=0.0001). In group II, the RE score was 33.3±4.30 before treatment, increased to 66.7±4.30 (p=0.0001) in the 3rd month, and was calculated as 78.7±3.27 (p=0.0001) in the 6th month.

In group III, the MH parameter score before treatment was calculated as 64.2±2.12, but in the 3rd month, this score slightly decreased to 63.8±1.87 (p=0.910). By the 6th month, it increased to 65.3±1.68 (p=0.681).

In group II (n=25), PF was determined as 65.2±1.65 before treatment, 75.4±1.71 (p=0.001) after 3 months, and 84.6±1.19 (p=0.0001) after 6 months. The RP score was 28.0±2.20 before treatment, increased to 61.0±2.92 (p=0.0001) after 3 months, and reached 81.0±3.89 (p=0.0001) after 6 months. The bodily pain (BP) score was 65.7±1.53 before treatment, increased to 75.1±1.90 (P=0.003) after 3 months, and reached 81.8±2.15 (p=0.0001) after 6 months. The GH score was 32.4±1.23 before treatment, increased to 37.0±1.29 (p=0.013) after 3 months, and reached 63.4±1.41 (p=0.0001) after 6 months. The VT score was 36.0±1.47 before treatment, 55.4±1.41 (P=0.0001) after 3 months, and 62.0±1.00 (P=0.0001) after 6 months. Social functioning (SF) was determined as 52.5±3.46 before treatment, 63.0±2.45 (p=0.017) after 3 months, and 77.5±1.77 (p=0.0001) after 6 months. The RE score was 33.3±4.30 before treatment, increased to 66.7±4.30 (p=0.0001) after 3 months, and reached 78.7±3.27 (p=0.0001) after 6 months. The MH score was 64.8±1.85 before treatment, 64.3±2.04 (p=0.862) after 3 months, and 64.2±1.74 (p=0.802) after 6 months.

In group II (n=25), the MH parameter score before treatment was 65.1±1.49, 65.3±1.26 (p=0.935) in the 3rd month, and 64.3±1.20 (p=0.6773) in the 6th month.

Thus, significant improvements were observed in all parameters related to physical components (PF, RP, BP, GH) during all three periods of treatment. Furthermore, these improvements became even more apparent after 6 months. Positive changes were also recorded in the mental components (VT, SF, RE), with particularly noticeable improvements in the VT and RE parameters in the 3rd and 6th months of treatment. The MH parameter, however, remained unchanged. In group II, the treatment shows a positive effect on both physical and mental health.

The analysis of the results of morphohistological examinations was carried out based on subepithelial parameters. All changes in mesenchymal tissues seen in the skin and subcutaneous tissue in the

examined tissue samples were analyzed in this section. These parameters include the infiltration of mononuclear leukocytes (lymphocytes and plasma cells), infiltration of neutrophils, infiltration of eosinophils, necrosis in tissue samples, proliferation of fibrous tissue and collagen fibers, and changes in microcirculation.

Infiltration of mononuclear leukocytes (lymphocytes and plasma cells): Lymphocyte and plasma cell infiltration in the skin and subcutaneous tissues were mainly seen in biopsies taken on the first day and the 7th day of the experiment. (Figure 2). Lymphocytes and plasma cells were predominantly accumulated in the papillary dermis, located just beneath the epithelial layer, or in perivascular areas. In the majority of cases, lymphocytes were more abundant in intensity compared to plasma cells. The samples, which were rated with 3 points, showed aggregates consisting of lymphocytes and partially plasma cells, where mononuclear leukocytes were most intensive. As a rule, the number of mononuclear leukocytes in the samples decreased as they descended into deeper tissues. In the last biopsy sample taken, the average number of mononuclear leukocytes was minimal, especially in group III.

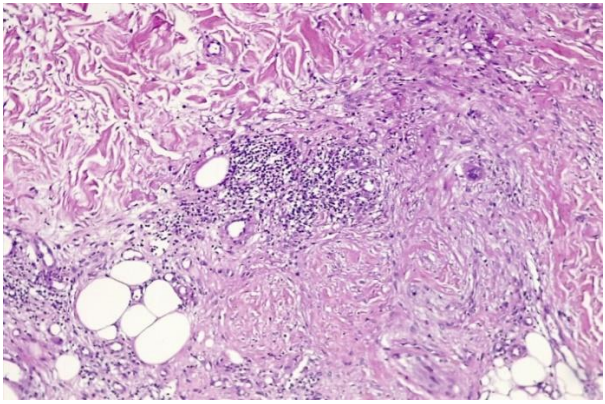


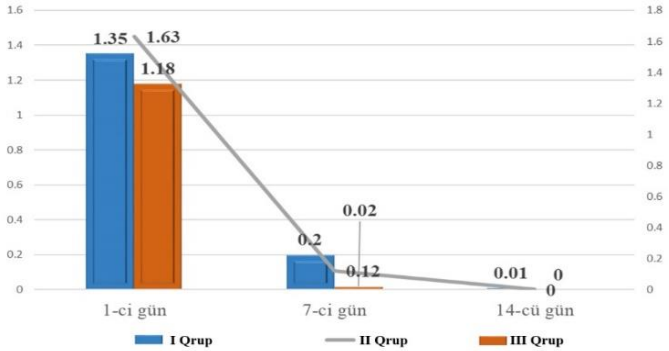
Figure 2. Chronic inflammation composed of mononuclear leukocytes in the skin; Group III, 7th day of the experiment (x400, HE).

Table 6.

Average intensity of mononuclear leukocytes (lymphocyte and plasma cell) infiltration in different groups

Groups	1st day	7th day	14th day
Group I	2.16±0.76	1.04±0.91	0.36±0.16
Group II	1.92±0.93	0.88±0.71	0.09±0.36
Group III	2.41±1.13	0.73±0.59	0.03±0.24

Infiltration of neutrophils: Neutrophil infiltration was mainly observed in samples taken on the first day of the experiment. In many samples, isolated neutrophils were detected in the skin and subcutaneous tissues. Like other cells involved in inflammation, neutrophils were mainly seen in perivascular areas or in the vessel walls of patients with developing vasculitis. When we compare the groups, in dynamic observation, on the 7th day of biopsy, a sharp decrease in neutrophil counts and, indirectly, in acute inflammatory signs was seen in all three groups. In the final biopsies obtained, neutrophil infiltration was not detected in almost any group (Graph 1).



Graph 1. Dynamic description of the average intensity of neutrophil infiltration by groups

Eosinophilic infiltration, which is more characteristic of allergic lesions, was almost not recorded in the biopsies taken during the experiment.

Necrotic changes: Necrosis paralleled the intensity of neutrophil infiltration in the samples and was mainly seen in samples taken on the first day of the experiment. Necrotic changes were recorded in subepithelial tissue in samples with epidermal erosion, and in the vessel walls and perivascular tissue in cases with developing vasculitis in capillary vessels (Figure 3). In samples taken at a later stage of the experiment (7th and 14th days), necrosis was almost completely eliminated, and no neutrophil infiltration was detected in any group in the final biopsies taken (Graph 2).

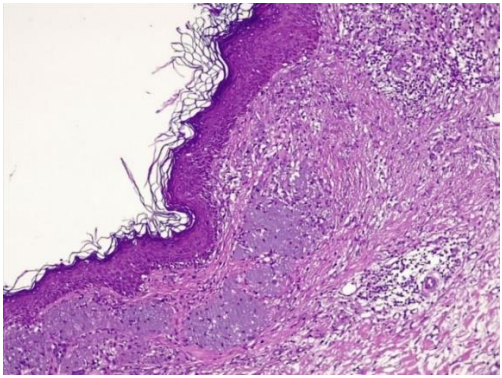
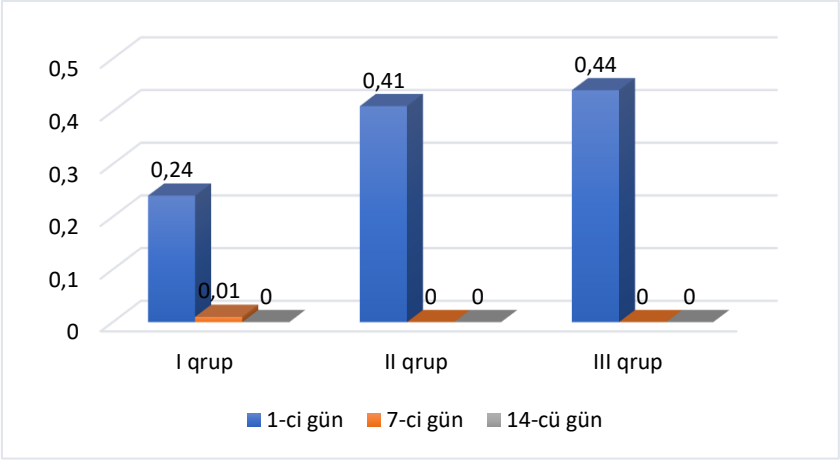


Figure 3. Focal coagulative necrosis and chronic active inflammation in the skin; Group II, first day of the experiment (x 200, HE)

The proliferation of fibrous tissue and collagen fibers increased during dynamic observation in the samples. As inflammatory parameters decreased, an increase in the volume of fibrous tissue and proliferation of collagen fibers was recorded. These changes were more intensively recorded in the tissues beneath the epidermis in biopsies (Figure 4). Fibrous tissue and collagen proliferation were more frequently observed in samples with epidermal erosion and neutrophil-rich inflammation. The intensity of fibrous tissue and collagen fibers generally decreased towards the deeper tissues. In the final biopsy samples obtained, intense collagen proliferation and fibrous tissue were recorded in all groups. This parameter was particularly high in group III ($p<0.05$).



Graph 2. Schematic representation of the average intensity of the necrosis parameter by different groups

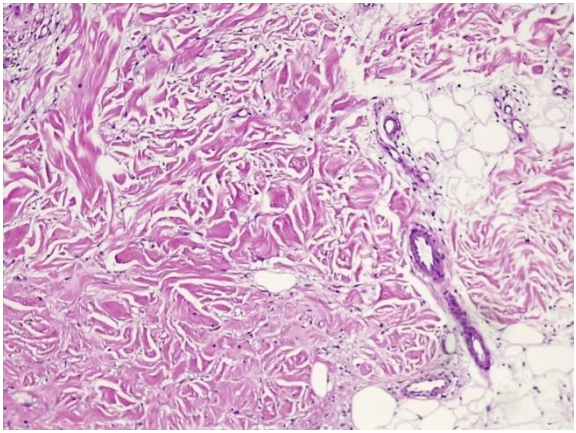


Figure 4. The proliferation of fibrous tissue and collagen fibers in the skin; Group III, 14th day of the experiment (x200, HE)

Accumulation of fibrin fibers on the surface of the epidermis: It was only detected in samples with epidermal damage and was recorded

in the biopsies taken on the first day of the experiment. The intensity of fibrin fiber accumulation varied depending on the depth of the epidermal damage. In some samples, a thick diphtheritic-type fibrin layer was observed, whereas, in others, a thin croupous (diphtheroid) fibrin layer was identified. In some samples, infiltration of monomorphic leukocytes and neutrophils was observed on the fibrin layer. The visibility of the fibrin layer was dramatically reduced in biopsies taken on day 7 and completely eliminated in biopsies taken on day 14. When looking at the indicators in separate groups, no statistically significant difference was found ($p>0.05$).

Thus, the morphological changes recorded in different groups during the experimental period were mostly similar, and their dynamics were parallel. During this period, many morphological parameters representing tissue damage disappeared, especially in biopsies taken on the 7th day. Although no statistically significant difference was found, inflammatory parameters resolved relatively faster in the main group. Also, in the microcirculation, hyaline thrombi in the capillary lumens decreased more rapidly in the main group ($p<0.05$). In addition, more intense fibrosis and proliferation of collagen fibers were observed in the biopsies taken on the last day of the experiment (14th day) in the main group ($p<0.05$). Based on the above indicators, it can be concluded that in dynamic observation, the combined application of EVLA, Venocoryl ointment, and low-intensity laser radiation in the main group has almost the same effect as other treatment methods. However, the faster reduction of thrombi in the microcirculation in the main group suggests that this treatment approach ensures an earlier restoration of microcirculation. Therefore, it can be successfully applied as an alternative treatment plan for the treatment of varicose veins.

Thus, based on the results of the clinical and morphohistological studies, the combined application of Venocoryl ointment with Endovenous laser ablation in the treatment of trophic ulcer wounds facilitates the rapid resolution of the inflammatory process around the wound and intensifies the regeneration process, significantly accelerating the healing process.

RESULTS

1. During clinical studies, in the second group (n=25) of patients, where EVLA and Venocoryl ointment were combined for treatment, the average daily epithelialization rate of trophic ulcers in the first 30 days after the corresponding treatment measures was 0.152±0.009 cm²/day, while in the first group (n=25), after the application of EVLA, the average epithelialization rate was determined as 0.068±0.005 cm²/day.[3;5;10]
2. During clinical studies, in group 3 (n=25) patients, who received a combination of EVLA, Venocoryl ointment and low-intensity laser radiation for treatment, the average daily epithelialization rate of trophic ulcers in the first 30 days after the implementation of appropriate treatment measures was 0.239±0.010 cm^2/day.[2;6;8]
3. As a result of morphological studies, at the end of the 2nd week, while abundant erosions were observed in the surface epithelium against the background of neutrophil infiltration in group 1, reactive hyperplasia and fibrous tissue were observed in the surface epithelium against the background of sparse lymphocyte infiltration in group 2. In the third group, more intense epithelial hyperplasia and an increase in fibrous tissue were observed. [1;4;11]
4. During the clinical study, we calculated the physical functioning (PF) parameter of the SF-36 health survey in the first group of patients with varicose veins of the lower extremities (EVLA). The corresponding score was 65.0±1.44 before the intended treatment measures and increased to 72.6±1.76 in the 6th month. In the second group (EVLA + Venocoryl), the corresponding score for the physical functioning (PF) parameter was 84.6±1.19 in the 6th month. In the third group (EVLA + Venocoryl + low-intensity laser radiation), the score for the physical functioning (PF) parameter was 91.0±2.84 six months after the treatment measures. [7;9;12]

PRACTICAL RECOMMENDATIONS

1. Based on the results obtained during the study, the combination of EVLA, Venocoryl ointment, and low-intensity laser radiation proved to be more effective in treating varicose veins and trophic ulcers of the lower extremities. It was recommended to incorporate this treatment approach into practical clinical practice for better patient outcomes.
2. The application of the appropriate treatment combination also showed high quality of life indicators in patients. Considering the role of the method in the restoration of patients' work capacity, it should be noted that it is a suitable tactic.

LIST OF PUBLICATIONS ON THE TOPIC OF THE DISSERTATION

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7. B.B. Abbasəliyev, R.Ə. Məmmədov, T.A. Suleymanov, M.O. Yusubov, A.Ş. Hümmətova Xroniki venoz çatışmazlıq fonunda yaranmış trofik xoraların müalicəsində lazeroterapiyanın tətbiqinin effektivliyi // – Bakı: Cərrahiyyə, – 2022, №4(1), – s.23-28.
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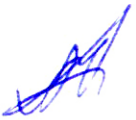
11. Məmmədov R. Ə., Abbasəliyev B.B. Aşağı ətraflarda xroniki venoz xoraların müalicəsində lazeroterapiya və “venocoryl” məlhəminin müştərək tətbiqinin effektivliyi, Tibb və elm. Əziz Əliyev adına elmi-praktik jurnal, 2024, №2. S.43-48
12. Məmmədov R. Ə., Abbasəliyev B.B.. Aşağı ətraflarda xronik venoz xoraların müalicəsində lazeroterapiya və “venocoryl” məlhəminin müştərək tətbiqinin effektivliyi // Bakı: Sağlamlıq, – 2024. №4, – s.65-70.

LIST OF ABBREVIATIONS

BP	–	Bodily pain
EVLA	–	Endovenous laser ablation
GH	–	General health
MH	–	Mental health
PF	–	Physical functioning
RE	–	Role emotional
RP	–	Role physical
SF	–	Short form survey
USM	–	Ultrasound examination
VT	–	Vitality



The defense of the dissertation will be held on «22» april 2025 at 14 he meeting of the Dissertation Council ED 2.06

Address: AZ 1022, Baku, 14 A. Gasimzadeh Street (conference hall)

The dissertation is accessible in the library of the Azerbaijan Medical University.

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