

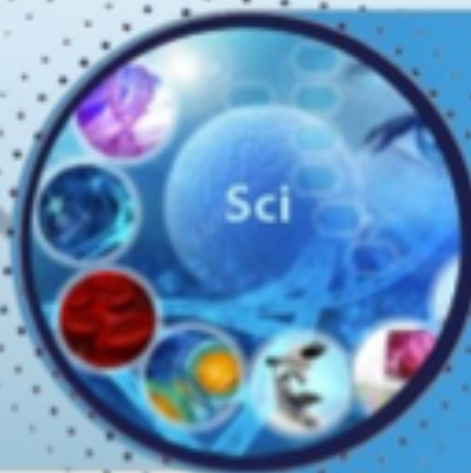


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## New Approaches in the Treatment of Trophic Ulcers of Venous Etiology

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### ABSTRACT

**Background.** The prevalence of trophic leg ulcers of venous etiology is a real social disaster. Tuberculosis, rheumatism, diabetes mellitus, injuries - all these diseases taken together lead to less disability than trophic ulcers.

**Material and methods.** The present work is based on the analysis of the treatment of 89 patients with trophic ulcers of the lower extremities of venous etiology in the multidisciplinary clinic of the Tashkent Medical Academy. Depending on the types of methods prescribed, all patients were divided into 3 groups.

**Results.** The combined method of treatment of trophic ulcers, consisting of the use of phlebosclectomy and the wound healing agent "FARGALS", helps to reduce the time for clearing ulcers from purulent-necrotic masses, accelerates epithelialization, which leads to a reduction in the duration of patients' stay in the hospital. The pronounced effectiveness of this method is due to the pharmacological activity of "FARGALS", and its ability to have an anti-inflammatory, antimicrobial, and regenerative effect.

**Conclusion.** For the first time, a complex method of treatment of patients with trophic ulcers of the lower extremities was developed using phlebosclectomy and wound healing agent "FARGALS". It has been stopped that under the influence of sclerotherapy and "FARGALS" there is an early cleansing of the ulcerative surface, weakening of inflammation and activation of reparative processes.

**Keywords:** Chronic venous insufficiency, "FARGALS", chronic ulcers

### INTRODUCTION

Chronic venous insufficiency of the lower extremities due to varicose or post-thrombophlebotic disease is one of the most common vascular pathologies.

Treatment of trophic leg and foot ulcers is one of the urgent tasks of medical science and practical health care.

There are still many unresolved issues in the treatment of such patients.

The severity of this pathology, especially among people of working age, leads to a high degree of disability,

and inability to stable self-epithelialization of wounds, associated with the insufficient effectiveness of modern means and methods of treatment.

In addition, the treatment of such patients is the most important medical and social problem, since the economic damage as a result of disability is large, amounting to millions of rubles [1].

Patients with trophic ulcers are regular, sometimes lifelong, visitors to polyclinics and surgical departments, accounting for about 10% of all patients in general surgical hospitals [2].

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The prevalence of trophic leg ulcers of venous etiology is a real social disaster. Tuberculosis, rheumatism, diabetes mellitus, injuries - all these diseases together lead to less disability than trophic ulcers [3].

Currently, more than 200 methods of conservative treatment of ulcers have been proposed, which are used both independently and in combination [4].

To date, there are several principal approaches to solving this issue: treatment aimed at correcting venous outflow; and treatment aimed at complete epithelialization of the trophic ulcer. In addition, there are treatment methods that combine the correction of venous blood flow and the healing of trophic ulcers [5].

To date, the question of local treatment of trophic ulcers remains debatable: the expediency of excision of trophic ulcers is questionable; the question of the method of closing a trophic ulcer by skin grafting has not been resolved; Recurrences of trophic ulcers are largely due to inadequate correction of venous blood flow [6].

The relevance of treatment of trophic leg ulcers is associated not so much with the huge range of methods offered (from conservative to surgical with complete excision of the ulcer and plastic surgery of the defect) but with the recurrence of the disease, which reaches 38% - 100% [7,8].

An important factor in the local treatment of trophic ulcers is that many recognized methods are expensive and ineffective. In this regard, there is an urgent need to improve them and to develop new methods of treatment with the use of drugs.

In particular, phlebosclectherapy is becoming more and more common for the treatment of varicose veins of the lower extremities.

The main advantage of this method is simplicity, affordability and a fairly good cosmetic result. At the same time, folk medicine has long used preparations from medicinal plants as means that have regenerative, anti-inflammatory and other effects on organs and tissues. Based on traditional medical sources, the drug «FARGALS» has been developed.

In this regard, a very promising direction in this search is the development and implementation of new pharmacological drugs, as well as effective combined methods for the treatment of varicose veins of the lower extremities complicated by trophic ulcers [9-12].

The study aimed to increase the effectiveness of treatment of patients with chronic venous insufficiency of the lower extremities, complicated by trophic leg ulcer by improving phlebosclectherapy and using a new wound healing agent «FARGALS».

## MATERIAL AND METHODS

The present work is based on the analysis of the treatment of 89 patients with trophic ulcers of the lower extremities of venous etiology in the multidisciplinary clinic of the Tashkent Medical Academy.

Depending on the types of methods prescribed, all patients were divided into 3 groups.

In the first group (control) 15 patients were treated with conventional methods with the use of various medications and a dressing with furacillin. The ulcerated surface was treated with a 3% solution of hydrogen peroxide and antiseptic solutions. In the presence of purulent necrotic masses, IRUKSOL, aqueous solution of chlorhexidine, and boric acid were used, and then a dressing with furacillin was applied. With the appearance of granulations, the beginning of focal epithelialization, the latter was replaced with ointment dressings - with SOLCOSERIL, sea buckthorn or rosehip oil. For the prevention of severe allergic dermatitis, eczema, and inflammation, medications with antimycotic activity were used, most often CLOTRIMAZOLE ointment, NYS-TATIN, and less often sulfur ointment.

The second group consisted of 29 patients whose wound surface was treated with a single antiseptic, and more often with a 0.9% sodium chloride solution. After that, a 0.2% solution of CURIOSIN was applied to the wound at the rate of 1 drop per 1 cm<sup>2</sup> of the wound. After a two-minute exposure, parchment paper was placed on top of a gauze pad and the limb was bandaged with an elastic bandage. Dressing was performed 1 time a day.

The third group included 45 patients who underwent complex treatment: a combination of sclerosing therapy of superficial veins of the lower leg with the use of the wound healing agent «FARGALS». This drug has not previously been used in the treatment of trophic ulcers, and its effect has not been compared with other wound coverings.

The safety and tolerability of the drug were determined experimentally and in the clinic by general clinical, biochemical methods, and glycemic level, as well as by thermometry. In addition, we did not find any works in the available literature where a combination of phlebosclectherapy and «FARGALS» would be used.

To fill this gap, we used this combined method in 45 patients (group 3).

For phlebosclectherapy, we used a 3% thrombovar solution at the rate of 2.0 ml per session (per leg). If both lower legs were interested, the total dose was 4.0 mL. The patient was in an upright position. Sclerosing was

started with veins located in the area of the trophic ulcer or located in trophic-altered tissues, which were determined visually or palpably.

For the injection, insulin syringes with 30 GA needles from Becton Dickinson (which allow precise and painless puncture of the vein) were used. In the control of the needle in the vein (blood in the syringe), the tip of the needle was pressed tightly against the wall of the vein and the sclerosant was slowly injected. After removing the needle from the vein, the puncture site was pressed down with a gauze ball and tightly bandaged with an elastic bandage. During 1 session, 3-4 injections were carried out in one lower leg.

Next, the bandage was removed and an elastic compression bandage was applied (the limb is bandaged from the foot to the knee joint) and the patient was advised to walk or perform movements in the ankle joints for at least 2 hours after the procedure. The bandage is allowed to be removed no earlier than 5-6 days.

If the patient had tissue edema, induration, or hyperpigmentation, there were no varicose veins due to edema or lymphostasis, then a blockade with lidocaine 2% - 5.0 ml was performed next to the trophic ulcer. If blood appeared in the needle during the block, then a thrombovar 3% - 0.5 ml was injected into the same place and elastic compression of the lower leg was performed.

When performing technically correct puncture sclerotherapy, deep vein thrombosis, and necrosis of subcutaneous fat in the area of sclerosant injection were not observed.

When the walls of the vein are contacted by elastic compression, the very mechanism of action of the drug excludes the possibility of complications. In our observations, we also did not note allergic reactions.

Depending on the degree of trophic altered tissues, the size of the ulcer, the number of varicose veins surrounding the latter, and the loose or main nature of varicose veins of the lower extremities, the number of sessions corresponded from 3 to 9 (on average 4.2).

Puncture therapy was terminated after the obliteration of all varicose veins located in trophic altered tissues was achieved.

The treatment was carried out under strict control of the general condition and well-being of the patients with the measurement of blood pressure, pulse, and body temperature.

Differences in the nature and severity of the lesion, the age of the disease, and the age of the patients in the groups were statistically insignificant ( $p > 0.05$ ).

## RESULTS

**A**mnestic data and assessment of the condition of the lower extremities made it possible to identify the main causes that led to the formation of trophic ulcers. In 57.3% of patients, the main cause of trophic disorders was postthrombotic disease of the lower extremities, in 42.7% complicated primary varicose veins of the lower extremities. The duration of the disease ranged from 3 months to 30 years (mean 6.23).

The occurrence or recurrence of ulcers was noted in terms of 3 weeks to 5 years before the last hospitalization and in 82% of cases from 1.5 months to 2 years. As a rule, all patients were treated with various methods and means before admission to the hospital, which led to a temporary improvement in the patient's condition, and even to the closure of the ulcer. After some time (from 1-3 weeks to 1 year), the ulcer recurred. In 38% of patients, ulcers did not close within one month to 5 years, in terms of 5 to 10 years - in 2.7%, in terms of more than 10 years - in 2.1% of observations. The size of the ulcers ranged from 3 cm<sup>2</sup> to 200 cm<sup>2</sup> (on average 32.7 cm<sup>2</sup>) and most of them were covered with purulent-necrotic masses, with hyperemia, pigmentation and thickening around them. Lymphangitis and regional lymphadenitis have been observed. In 25.8% of patients, trophic ulcers were accompanied by allergic dermatitis, and in 10.1% - eczema. And in 26.9% of patients with erysipelas with a recurrent course.

Concomitant diseases were detected in 76.4%: coronary heart disease - 33.7%; hypertension, 23.5 per cent; obesity, 44.1 per cent; diabetes mellitus - 10.2%); chronic diseases of the respiratory system, 5.7 per cent; obliterating vascular diseases of the lower extremities, 4.4 per cent; kidney disease, 2.8 per cent.

When assessing the effectiveness of treatment, first of all, the clinical course of the disease was taken into account: reduction or disappearance of pain and edema in the lower extremity, attention was paid to the rate of purification of the ulcer lesion, the timing of the appearance of granulations and epithelialization of the ulcer. In the group of patients treated in a well-known way (group I), a decrease in the severity of symptoms (pain, flushing, edema, etc.) occurred on days 13-16; Clearing of the ulcerative surface, the appearance of granulations on the 19th day, and partial epithelialization by 75-80% were observed on the 39th-40th day.

In the group of patients in whom the ulcerative surface was treated with «CURIOSIN», granulations ap-

peared on day 10; Partial epithelialization by 75-80% occurred on days 18-20.

In the third group of patients, a decrease in the severity of symptoms was observed on days 2-4, and partial epithelialization of the wound by 75-80% on days 9-11.

In 2% of patients, after the administration of thrombovar 3% - 2.0, chills, and a rise in body temperature to 38-38.3 °C were observed, but after taking aspirin (0.5) the above phenomena disappeared, and the well-being of the patients did not suffer.

In patients of the 2nd and 3rd groups, 2-3 days after the start of treatment, well-being improved, and pain in the area of the pathological focus decreased. There was a tendency to reduce swelling, hyperemia and inflammatory infiltration along the periphery of the ulcer lesion. By the end of 5-12 days from the beginning of treatment, the wound surface was gradually cleared of necrotic tissues, healthy juicy granulations appeared, inflammatory phenomena around ulcers abruptly subsided, and a pale pink corolla of young epithelial tissue appeared along the periphery of the ulcer surface.

At the end of the two-week treatment period, the surface of the ulcer was completely covered with epithelium, in patients treated with «CURIOSIN», epithelialization of wounds (ulcers) occurred 18-20 days after the start of treatment.

One of the important criteria for the effectiveness of any treatment method is the percentage of healing of trophic ulcers at the hospital stage. The analysis of our data showed that the highest clinical effect was achieved with combined treatment with phlebosclectherapy and «FARGALS». In this group (group 3) of patients there were also the shortest treatment periods (3.3±0.44 days). Information on clinical indicators and healing of trophic ulcers depending on the type of treatment is presented.

In general, all this testifies to the high efficiency of the proposed method of treatment of trophic ulcers of venous etiology.

Results of cytological, cytochemical, cytological bacteriological and morphological studies.

In parallel with clinical and planimetric data, cytological study of smears of imprints from the surface of trophic ulcers was carried out before the start of treatment, on the 3rd, 7th, 14th, 21st days of treatment, as well as histological and histochemical study of biopsies from these ulcers in the terms of 7, 14, 21 days for the severity of anti-inflammatory effect and stimulation of regeneration with the combined use of sclerotherapy and «FARGALS».

Before the start of treatment, smears showed a pronounced bacterial infection of trophic ulcers, consisting mainly of coccal and rod microflora.

Taking into account the high risk of purulent complications in patients with trophic ulcers, microbiological studies of the qualitative and quantitative composition of the microflora were performed in 30 patients.

The smear cytogram was characterized by neutrophils (89.3%), with the majority of them (91.2%) in a state of decay, most of the microflora lying freely.

In the first group of patients, cytological examination of wound discharge smears indicated a slight decrease in microbial contamination, increased phagocytosis of microbes, and a slight increase in macrophages and fibroblasts only on 15-21 days. However, infection and inflammatory reaction remained pronounced (81.7±3.09 neutrophils in the smear).

«CURIOSIN» promotes the healing of trophic ulcers (group 2). The exudate was cleared of dystrophic altered and necrotic neutrophils much faster, the number of immature mononuclear elements and macrophages increased rapidly (from the 5th day), the phagocytosis of microbes and detritus increased, the fibroblastic elements increased. Epithelial cells increased from 1 4-1 to 8 days.

Morphological examination of biopsies before treatment revealed that the bottom and edges of trophic ulcers were dominated by necrotic masses and fibrinous-purulent exudate, granulation tissue with pronounced structural changes. Thus, the combination of areas of granulation tissue with cicatricial inclusions was noted. Microcirculatory disorders (stasis, sludge of erythrocytes, microthrombosis, infiltrative-productive endovasculitis, plasma impregnation and fibrinous necrosis of the walls, erythrocyte diapedesis and leukodiapedesis) were pronounced.

There was marked edema and lymphedema of the tissue, and neutrophilic infiltration. The reaction of macrophages and mast cells is sharply inhibited and perverted.

## DISCUSSION

**P**athomorphological examination in group 1 suggests that only by the 20th day did focal typical granulation tissue appear, necrosis, edema and inflammatory infiltration of tissues decrease, and there was a proliferative reaction. The wound-healing process was inhibited, and microcirculatory disorders and the inflammatory process remained pronounced [13].

By 21 days after treatment, the morphological picture indicated low efficacy of treatment in group 1 patients.

In the 2nd group of patients, according to pathomorphological data, reparative processes were activated on day 7, as evidenced by the proliferation of fibroblasts, maturation of granulation tissue, and traces of epithelialization. The pattern of inflammatory manifestations decreased, granulation tissue matured and by 14 days it filled the tissue defect, and by 21 days there was a rapid growth of epithelial layers.

Acceleration of the reparative process was obtained in patients of the 3rd group.

Due to the summation of the mechanisms of therapeutic action of sclerosing therapy and «FARGALS», according to the data of cytological and pathomorphological studies, the results obtained are significantly superior to those achieved in the treatment in other groups.

Combined treatment led to rapid clearing of the ulcerated surface from necrotic substrate and fibrinous-purulent exudate, early appearance of granulation tissue of typical structure and its maturation ( $5.5\pm 0.31$ ), scarring, epithelialization and closure of the defect ( $10.6\pm 0.33$ ). This occurs as a result of activation of bacterial phagocytosis, detritus by neutrophils and macrophages, improvement of microcirculation, removal of edema and other inflammatory manifestations, stimulation of the reparative process, fibrillogenesis and regeneration of the epithelium.

Thus, the cytological and pathomorphological picture testifies to the high efficiency of the method developed by us for the treatment of trophic ulcers of venous etiology using sclerosing therapy and «FARGALS» applications.

In a complex pathophysiological chain, the occurrence of trophic skin disorders and ulcers, the main role is played by distal venous hypertension due to perforating vein insufficiency [13-16].

Continued exposure to venous hypertension leads to decompensation of not only venous but also lymphatic drainage.

The compensatory capabilities of the latter are exhausted, and the resulting tissue edema contributes to the development and progression of trophic changes.

In this regard, a great prospect in the treatment of chronic venous insufficiency complicated by trophic ulcers is opened up by sclerosing therapy with the local use of «FARGALS», which has a strong stimulating property of tissue regeneration.

## CONCLUSION

The use of «FARGALS» in combination with phlebosclectomy is a highly effective method of treatment

of trophic ulcers of the lower extremities. The accelerated wound-healing effect of «FARGALS» is based on its ability to stimulate tissue regeneration. According to cytological, cytochemical and morphological studies, the use of «FARGALS» in the local treatment of trophic ulcers of the lower extremities leads to the stimulation of phagocytosis, activation of macrophage and fibroblastic reaction with subsequent epithelialization. A microbiological study of trophic ulcer imprints showed that with the combined use of sclerotherapy and «FARGALS», patients have a complete cleansing of the ulcer surface on the 5th day from the beginning of treatment. The combined use of sclerotherapy and «FARGALS» helps to reduce the length of stay of patients in hospitals.

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**Data availability statement** - The original contributions presented in the study are included in the article material, further inquiries can be directed to the corresponding authors.

**Ethics approval and consent to participate** - All patients gave written informed consent to participate in the study.

**Consent for publication** - The study is valid, and recognition by the organization is not required. The authors agree to open the publication.

**Availability of data and material** - Available

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## **VENOZ ETIOLOGIYANING TROFIK YARALAR- INI DAVOLASHDA YANGI YONDASHUVLAR**

**Atakov S.S.**

**Toshkent tibbiyot akademiyasi**

### **ABSTRAKT**

**Dolzarbliqi.** Venoz etiologiyaning trofik oyoq yaralarining keng tarqalganligi haqiqiy ijtimoiy falokatdir. Tuberkulyoz, revmatizm, diabet, jarohatlar - bu kasalliklarning barchasi trofik yaralarga qaraganda kamroq nogironlikka olib keladi.

**Material va usullar.** Hozirgi kunda faoliyat Toshkent tibbiyot akademiyasining ko'p tarmoqli klinikasida venoz etiologiyaning pastki ekstremitalari bo'lgan 89 nafar bemorni davolashni tahlil qilish asosida tashkil etilgan. Buyurilgan usullarning turlariga qarab barcha bemorlar 3 guruhga bo'lingan.

**Natijalar.** Fleboskleroterapiya va yara shifobaxsh vosita "FARGALS" dan foydalanishdan iborat trofik

yaralarni davolashning birlashgan usuli yaralarni yiringli-nekrotik massalardan tozalash vaqtini qisqartirishga yordam beradi, epitelizatsiyani tezlashtiradi, bu bemorlarning kasalxonada qolish muddatini qisqartirishga olib keladi. Ushbu usulning aniq samaradorligi "FARGALS" ning farmakologik faoliyati, yallig'lanishga qarshi, mikroblarga qarshi, regenerativ ta'sirga ega bo'lish qobiliyati bilan bog'liq.

**Xulosa.** Birinchi marotaba pastki ekstremitalarning trofik yarasi bo'lgan bemorlarni kompleks davolash usuli "FARGALS" fleboskleroterapiya va yaralarni davolash agenti yordamida ishlab chiqildi. Skleroterapiya va "FARGALS" ta'siri ostida yiringli yuzani erta tozalash, yallig'lanishning zaiflashuvi va reparativ jarayonlarning faollashishi to'xtatildi.

**Tayanch iboralar:** Surunkali venoz insferentsiya, "FARGALS", surunkali yaralar