



## Physical Factors in the Treatment of Chronic Venous Insufficiency of the Lower Extremities

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### Abstract

Trophic ulcers are one of the most severe complications of chronic venous diseases, leading to functional insufficiency of the lower extremities and a sharp decline in the life quality. Complex of preoperative preparation and combination with various methods of surgical correction are essential in this case. Higher results can be obtained with combined application of several techniques. Topical application of combined low-intensity laser radiation and micro dispersed drug irrigation is a pathogenetically substantiated non-invasive method of conservative treatment and preoperative preparation of trophic ulcers in patients of the C6 class.

**Keywords:** *Bactericidal therapy, Pain syndrome, Varicose veins, Trophic ulcers.*

### Introduction

In the ill venous system or in the event of a pump failure for the calf muscles, the venous pressure in the deep system during movement may either fall minimally or not at all. This sustained outpatient pressure has been called venous hypertension. Ultimately, venous hypertension in deep veins can be transmitted to the superficial system [1].

Venous hypertension is also called “chronic venous insufficiency” and occurs through one of 4 pathophysiological mechanisms: [1] valve dysfunction on the surface and/or communicating veins due to congenital or acquired incompetence; [2] valve dysfunction in the deep system due to congenital absence, congenital weakness or thrombotic damage; [3] deep venous obstruction, not valve incompetence; and [4] muscle dysfunction and malnutrition of the calf muscles due to inflammatory conditions of the joints or muscles, fibrosis, or neuropathies. Chronic venous insufficiency (CVI) is a common problem in Western societies. It covers a wide range of conditions, from symptoms without any signs, to telangiectasias and varicose veins, to skin changes and ulceration of the legs [2].

This complex clinical expression is described in the CEAP classification, created in 1994, which has since gained universal acceptance. Despite the fact that few epidemiological studies have been conducted in non-Western countries, the prevalence of CVI in these areas is considered low. It is not known whether the prevalence, clinical severity and risk factors for cardiovascular diseases are the same in Eastern Europe and in Western Europe. Trophic ulcers are one of the most severe complications of chronic vein diseases [3], which lead to functional insufficiency of the lower limbs and a sharp decline in the quality of life of patients [4,6].

Chronic venous disease is very common in developed countries and affects up to a third of the adult population. Manifestations are ranging from edema and varicose veins to non-healing leg ulcers, which require months of wound care.

Regardless of pathophysiology, reflux or obstruction, compression remains the basis of therapy. Compression stockings are used because they are believed to compensate for increased venous pressure, prevent deep and superficial vein thrombosis, and reduce inflammation, swelling and pain.

Through surgical intervention it stays impossible to eliminate all CVI pathogenetic mechanisms. Therefore, development and implementation of modern methods of treating trophic ulcers, their inclusion in the complex of preoperative preparation and combination with various methods of CVI surgical correction is relevant. Purpose .To improve the treatment results of patients with CVI of lower limbs of C6 clinical class with the use of combined use of surgical correction methods, autodermoplasty and the combined effects of low-intensity laser radiation and finely dispersed medicinal irrigation of trophic ulcers.

## Materials and Methods

160 patients of C6 class (age range 20-85, mean age  $61.7 \pm 2.4$  years) were examined and treated. Women prevailed - 96 (60%). 111 patients had varicose (69.4%), and 49 patients had post-thrombophlebitic (30.6%) diseases. 18 (11.2%) patients had anamnesis up to 5 years, 65 (40.6%) - from 5 to 10 years, 56 (35%) from 10 to 20 years and 21 (13.2%) patients - 20+ years.

Examination included Doppler USI and angioscanning, functional electroneuromyography, computed tomography, classical microbiological and cytological methods, planimetry using standard contact techniques. 102 (63.7%) patients of group I had a combined effect of laser radiation and fine-dispersed medicinal irrigation Octenidine dihydrochloride applied on the trophic defect surface. In group II (n=58), treatment was carried out according to standard methods. Trophic ulcers size in both groups ranged from 2.1 to 52.6 cm<sup>2</sup>. For 141 (88.1%) patients, the area did not exceed

20 cm<sup>2</sup>. In the main group, for 42 patients ulcerative defect area was less than 5 cm<sup>2</sup>, in 49 - 5-20 cm<sup>2</sup> and in 11 cases - 20+ cm<sup>2</sup>, on average:  $4.8 \pm 0.9$  cm<sup>2</sup>,  $18.7 \pm 1.4$  cm<sup>2</sup> and  $46.2 \pm 2.6$  cm<sup>2</sup> respectively. Control group showed results as follows: in 24 patients ulcerative defect area was less than 5 cm<sup>2</sup>, in 28 - 5-20 cm<sup>2</sup> and in 6 - 20+ cm<sup>2</sup>, on average:  $4.7 \pm 0.2$  cm<sup>2</sup>,  $19.1 \pm 1.1$  cm<sup>2</sup> and  $58.6 \pm 2.4$  cm<sup>2</sup> respectively. Ulcers course lasted up to 1 year in 52 (32.5%), for 2-5 years - in 40 (25%), for 6-10 years - in 46 (28.7%), for 11+ in 22 (13.8%) patients. 70 (68.6%) patients in Group I and 34 (58.6%) patients from Group II had operation in medical records. Phlebectomy was performed in conjunction with Cockett's operations - 25 (24.5%), Linton - 20 (19.6%), SEPS - 32 (31.4%), SEPS and fasciotomy - 17 (16.7%), with autodermoplasty - 94 (58.7%). Evaluation of the combined treatment long-term results was carried out in terms from 3 months to 3 years.

## Results

Clinical picture was characterized by a significant severity of all pathological signs and functional insufficiency of lower limbs with significant impairments of static-dynamic function. Chronic venous compartment syndrome was formed with frequent recurrences and a long course of trophic ulcers. The results of bacteriological studies indicated the need to include antimicrobials in the complex treatment. Pain relief in patients of group I (in 89 (87.3%) after 5 and in all cases after 10 sessions) and burning and itching (in 76 (74.5%) after 5 and in 94 (92.2%) after 10 sessions) showed the treatment analgesic and sedative effects.

**Table 1: Groups of patients studied and the medical care effect**

Group number	Number of patients	Effect
I	102	1) pain syndrome is decreased or absent (87.3-100% of patients) 2) No burning or itching sensation (74.5-92.2%)
II	58	1) Pain syndrome is decreased or absent (65.5-90%) 2) No burning or itching sensation (47.5-80.0%)
Control	24	1) Pain syndrome is decreased or absent (30-45%) 2) No burning or itching sensation (25-45%)

Decrease in the growth of microbial flora and the microbial contamination level of ulcers in group I ( $p < 0.05$ ) as well as the absence of degenerative-inflammatory and identification of inflammatory-regenerative cytogram types (75%), recorded for 10 days, allowed us to conclude about bacteriostatic and bactericidal

therapy effects and a more pronounced positive treatment result. Positive dynamics of trophic ulcers healing statistically ( $p < 0.05$ ) prevailed in the I group, more than 2 times exceeding of control group results. Resulting reduction in epithelialization in group I, in our opinion, is explained by the

effectiveness of the combined effect of low-intensity laser radiation and fine dispersion of the medicinal solution, which allows obtaining bactericidal, bacteriostatic, analgesic and sedative effects on the course of exudation and reparation of the ulcer process. Fine drug dispersion eliminates damage to the developing granulation tissue. After 12 months, number of relapses for Group I was 8 (34.8%), and in the control group - 12 (66.7%), which is explained by the lack of prompt correction of pronounced disorders of venous hemodynamics characteristic of C6 class. Results obtained in the postoperative period indicate that an undoubted improvement in venous hemodynamic parameters does not reach the parameters of practically healthy individuals.

Therefore, surgical correction should be purposefully combined with conservative treatment methods. Combined effect of these factors allowed us to reduce the preoperative period by 2.8 times and to perform autodermoplasty in group I on day  $6.1 \pm 1.1$ , while group II patients only by  $17.2 \pm 1.3$  days from the start of hospitalization. Moreover, the complete engraftment of the auto dermal graft was observed in 45 (75%) patients in group I and only on day 11 (32.3%) in group II, which we consider to be due to the preoperative trophic defect preparation.

## Discussion

In this section, we discuss some methodological aspects of treating venous insufficiency and lower extremities ulcers as a consequence.

### Wound Debridement

Leg ulcers are considered to be cleared of necrotic and fibrinous residues in order to form good granulation tissue and adequate epithelialization [1, 7] however, some authors have recently questioned the need for this procedure. An unequivocal confirmation does not exist to prove the benefit of treating venous ulcers; nonetheless, it remains patient care standard. There are several methods for treating wounds, including autolytic, chemical, mechanical, surgical, and biological [8, 9, 6].

### Autolithic Processing

Compression therapy is the key to the healing of venous ulcers, and the role of special dressings under compression bandage

is not entirely clear [10]. For venous ulcers, there may still be a chance that wound occlusion on itself contributes to its re-epithelization and reduces accompanying pain, strengthens autolytic sanitization and provides an additional barrier to bacteria [9, 6].

There have been several randomized trials comparing bandages, but most doctors agree that maintaining a moist environment in a wound accelerates wound healing compared to a dry environment caused by air exposure [11]. Five basic types of occlusive dressings are available, each with its own advantages and disadvantages.

These include hydrogels (for example, Intra Site gel, Nu-Gel, Vigilon), alginates (for example, Sorbsan, Kaltostat, Algiderm), hydrocolloids (for example, Comfeel, DuoDerm, Restore), foams (for example, Allevyn, Curafoam, Lyofoam) and films (for example, OpSite, Tegaderm). The dressing choice is usually determined according to the type of wound, amount of exudate, cost and patient and physician preferences. In two randomized controlled trials of various contact dressings in combination with a multi-layered dressing, no significant material was found better than a simple non-adherent dressing.

### Chemical Processing

To promote the necrotic tissue removal and formation of healthy granulation tissue, several enzymes have been recommended. The use of specific proteolytic enzymes to venous ulcers can accelerate the removal of fibrin cuffs and the capture of other macromolecules. In particular, several enzyme degrading agents are commercially available in the United States, including collagenase (Santyl, Knoll Pharmaceuticals), papain (Panafil, Rystan Company, Inc. and Accuzyme, HealthPoint) and trypsin (Granulex, Dow Hickham). Bandages were changed from one to several times a day in accordance with manufacturer recommendations. A recently published report on a double-blind, randomized trial showed that Elase was ineffective for removing venous ulcers [11].

Topical application of tissue plasminogen activator may be a promising therapy; however, it is unclear whether this treatment works by removing fibrin. There is no

conclusive evidence of the clinical efficacy of these drugs in randomized, large-scale, controlled trials yet [9, 6].

### **Mechanical Restoration**

There are several methods of mechanical treatment, including wet and dry dressings, hydrotherapy, irrigation and dextranomers [9, 6]. The main disadvantage of machining is the non-discriminatory removal of viable tissue along with necrotic material [1]. There are no studies indicating that hydrotherapy or irrigation actually promotes healing of wounds, although many doctors claim that they are useful. Dextranomer is a very hydrophilic structure with a high absorption capacity, especially useful for severe exudative wounds. Its main disadvantage is the ability to cause wound layer dehydration.

### **Topical Antibiotics**

Any local drug should be taken with caution, as patients with CVI have an increased susceptibility to contact dermatitis. If severe contact dermatitis develops, systemic steroids in a short course may be required. Topical antibiotics use is controversial, with the possibility of developing bacterial resistance. Topical antiseptics have cellular toxicity, which exceeds their bactericidal activity and violate wound epithelialization, sanitation, stimulation of granulation tissue and general wound healing.

Graves and Zheng [1] reported a mean reduction in venous ulcer size by 34% with iodine cadexomer, while wounds in the control group actually increased in size. Similarly, Holloway et al [12]. Evaluating wound closure in 75 patients with venous disease, reported a double healing rate for cadexomer iodine treatment compared with the control group.

### **Systemic Therapy**

Systemic pharmacotherapy for veins ulceration may be useful as an adjunct to standard compression therapy. Most drugs used as adjuvant therapy have mechanisms of action that address the elimination of factors identified in the pathophysiology of venous leg ulceration [13]. It is a common dilemma to determine whether an ulcer is infected or simply colonized by bacteria, because poly-microbial growth is usually observed in tampon cultures on a wound. Tissue quantitative cultures are useful

though not usually available. More than  $10^5$  bacteria present per gram of tissue may interfere with wound healing and regeneration [14]. Systemic antibiotics do not improve the healing of venous ulcers and should be used for ulcers with clinically pronounced cellulitis. An additional difficulty is differentiate the infection from contact dermatitis in the edematous and erythematous leg. Although elevated CRP levels correlated with clinical signs of infection due to venous ulceration, test significance requires further evaluation. Considering the constancy and importance of systemic fibrinolytic abnormalities and the presence of pericapillary fibrin cuffs in ulcerative veins, fibrinolytic therapeutic methods are of great research interest.

Stanozolol, an androgenic steroid with fibrinolytic properties, is useful in the treatment of acute and chronic lipodermatosclerosis [15]. Burnand et al [16] showed clinical improvement and increased fibrinolysis in 3 patients after 3 months of therapy. Burnand et al [16]. Also reported a reduction in pain and hardening of the skin in 14 patients with lipodermatosclerosis, treated with stanozolol and compression stockings. Burnand et al [16] compared stanozolol with elastic stockings and placebo with elastic stockings.

Both treatments showed to be useful for reducing the thickness and pain from lipodermatosclerosis, but stanozolol and compression had better results. Although stanozolol has a positive effect on lipodermatosclerosis, no study has demonstrated an increase in healing of ulcers of the skin affected [11]. Stanozolol is a safe drug, and most of its side effects are minor and reversible. Peliosis, hepatitis and hepatocellular carcinoma are probably the most rare of them, but still concerns about serious side effects remain [17].

Other side effects include sodium retention with concomitant edema and hypertension, hirsutism, acne, liver and lipid abnormalities, and dysmenorrhea, all of which are reversible. Patients treated with stanozolol must undergo a blood pressure measurement, prostate exam, liver function tests, lipid profile, a prostate-specific antigen test, a complete blood cell test and kidney function tests. If ban, an antagonist of the thromboxane receptor, is expected stimulate

the healing of venous ulcers. However, a double-blind, randomized study with 150 patients was not able to demonstrate the increased efficacy of this therapy compared to compression therapy only. Pentoxifylline effectiveness for venous ulcers can be explained partially by its fibrinolytic effect. Pentoxifylline can also act by reducing the adhesion of white blood cells to the vascular endothelium and due to its antithrombotic effects. These actions of pentoxifylline are probably mediated by cytokine production. In a controlled study [14], a complete healing of a target ulcer was reported in 23 of 38 patients who received pentoxifylline 400 mg 3 times a day.

However, in a more recent randomized, double-blind, placebo-controlled study with 200 patients with confirmed venous ulcers, administration of pentoxifylline 400 mg 3 times a day was no more effective than placebo [17]. Higher doses of pentoxifylline are probably required. A recent study of 131 patients showed that pentoxifylline 800 mg 3 times a day accelerated the venous ulcers healing and was more effective than the usual dose (400 mg 3 times a day) [11]. An increase in the rate of healing of venous ulcers was reported with daily use of aspirin (300 mg) with an enteric coating. Promotion ulcer healing by inhibiting platelet aggregation or reducing inflammation remains to be determined.

Daflon, a micronized and purified flavonoid fraction, has proven to be useful in symptomatic disorders of venolymphatic origin. This drug works by reducing the blockage of endothelial cells by white blood cells, reducing capillary permeability and increasing the speed of red blood cells. Daflon daily dose of 1000 mg was used in addition to compression stockings in 105 patients with venous ulcers in the study for a 2-month period. This study showed that Daflon is useful for patients with venous ulceration, accelerating the healing of ulcers smaller than 10 cm [17]. However, for further evaluation of the drug effectiveness requires a longer observation.

Recent studies by Italian researchers have shown that sulodexide, a heparin-like molecule with profibrinolytic and antithrombotic activity accelerates the healing of venous ulcers in combination with compression therapy than compared to

compression only [15]. Some authors have confirmed that patients with varicose veins of the lower extremities of clinical classes C4 and C6 have impaired immunity in the pattern recognition receptors system, in the natural cytotoxicity system and in the adaptive immunity system that leads to chronic inflammation. The additional use of systemic enzyme therapy in complex treatment of venous trophic ulcers, along with elastic compression, systemic, pharmacotherapy with phleboactive drugs and modern dressings, contributes to the correction of immunological disorders and leads to a rapid CVI regression, as well as reducing epithelialization time of the ulcer defect.

### Surgery

Surgical treatment of venous ulcers can be directed to changing the venous hypertension cause or treating the ulcer itself with a graft. There is no specific indication for skin grafts for lower limb ulcers. Larger or refractory ulcers are two cases in which grafts should be considered. Even if transplants are rejected by the patient's body, they are likely to stimulate wound healing, and in case of very painful ulcerations, skin grafts can relieve pain quickly and noticeably. However, grafted ulcers are at risk because they are usually contaminated, prone to injuries, and they may have a vascular compromise in a dependent position [17].

However, split-thickness skin grafts (STSG) have been successfully used for treating chronic leg ulcers with healing rates up to 75% [18, 11]. Kirsner et al [18]. Used STSG for treating 36 ulcers of various natures and noted that 78% of them were fully or partially healed during follow-up. It is important to note that if patients remained cured for 3 months, long-term success improves. In a study of 100 patients, conducted for 17 years by Trier, Peacock, Madden [19], the complete healing rate was 54%. Similarly, they reported that in case graft was intact for a similar critical 3-month post-grafting period, it usually remained so.

Harrison [20] treated 34 patients with venous ulcers with STSG and a long follow-up of 28 years. He found that major medical problem / medications, multiple hospitalizations, immobility, local foot problems such as dermatitis, chronic ulcer, and living alone were risk factors that

predispose patients to a less successful outcome [21, 22]. Despite the success rates of STSG treatment for chronic wounds, there are a significant percentage of patients whose wounds do not heal after transplantation performed. Possible contributing factors include non-compliance with local fibrin deficiency in the wound bed, preventing graft adhesion, or the presence of micro thrombi in dermal vessels, which leads to ischemia and deterioration of the transplant process [23]. Grafting small-sized grafts is a useful option for small wounds [24].

Their advantage is a space of several millimeters remains between each graft, allowing the exudate to drain and to avoid elevation of the graft from the ulcer surface. Mesh grafts are useful for large, highly exudative ulcers, as they also allow exudates to pass through the interstitial graft [9]. Superficial vein surgery (ligation or sclerosis of long and short subcutaneous systems with/without vein ligation or sclerosis) proved its value for reducing the recurrence rate only if deep veins are competent, but this

advantage is not confirmed in case the deep veins are incompetent. Surface vein surgery didn't improve the healing rate of venous ulcers. Radical excision of the ulcerative bed, fibrous suprafascial tissue and affected superficial and perforating veins, as well as covering a large soft tissue defect with a free flap have been successfully used in several cases [1]. However the need for this intervention is questionable. Its use is limited to the surgical technique scale [9, 6].

## Conclusions

The techniques considered have shown the absence of the full treatment effect when taken separately. At the same time, better results can be obtained by the joint application of several techniques. Our data confirmed this thesis. Topical application of combined low-intensity laser radiation and micro dispersed drug irrigation is a pathogenetically substantiated non-invasive method of conservative treatment and preoperative preparation of trophic ulcers in patients of C6 class.

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