PROLONGED INTRAVENOUS INFUSION THERAPY OF LIDOCAINE IN TREATMENT OF CHRONIC VENOUS INSUFFICIENCY IN C6 AND C6R STAGE

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Abstract

Chronic venous disease (CEAP stage C2 - C3) is found in approximately 25% of the population, and trophic skin changes, including leg ulcers (C4 - C6), up to 5%.

The aim of the work was to develop an effective dose and concentration of lidocaine and the optimal method of its administration for the treatment of chronic venous disease in the stage of active trophic wounds and accelerate the healing process.

Materials and methods. The results of treatment of 97 patients with chronic venous insufficiency in stage C6 and C6r were evaluated, which were divided into two clinical groups: retrospective (n= 50) in which classical surgical treatment was performed (Coquette veins ligation, Narat phlebectomy) and prospective (n=47) in which classical surgical intervention (crosssectiony + Bebcock and / or Narat phlebectomy) was used in combination with the prolonged intravenous infusion therapy of lidocaine.

Research results and their discussion. In the period of 3-6 months, complete healing of trophic wounds was observed in the prospective group. At the same time, in 25.53% of patients in this group complete healing was observed up to 7 days. Whereas, in patients of the retrospective group, this was observed between 6-9 months. In addition, the rate of decrease
in the area of trophic wound for the first month in the prospective group was 23.72% higher than in the retrospective group (p<0.05). We did not observe a recurrence of a trophic wound in the follow-up period up to 1 year in the prospective group.

**Key words: chronic venous insufficiency; trophic wounds; lidocaine**

**Introduction**

Chronic venous insufficiency is one of the most common, often unrecognized and underestimated problems worldwide [15]. Usually the spread of this pathology in the age aspect is clearly traced. Thus, the prevalence of chronic venous disease (CVD) among people under 30 is <10% among men and women, while among men and women ≥70 years it is already 57% and 77% [11]. However, in recent years there has been a significant rejuvenation of this disease [6].

In general, CVD with or without edema (CEAP stage C2 - C3) is found in approximately 25% of the population, and trophic skin changes, including leg ulcers (C4 - C6), up to 5% [9]. The number of people in Africa is staggering, estimated at 25 to 135 million people with chronic injuries, in Europe up to 2.2 million people, and in the US more than 6 million people [2]. The average duration of ulcers is 9 months, 20% of ulcers do not heal within 2 years, and 66% of patients have ulcers lasting more than 5 years [5]. Long-term ulcers significantly impair a person's ability to social and professional activities, reduce the quality of life and impose financial constraints. [10].

The most common method of treatment today is surgery. Compared with conservative measures, it is much faster in significantly reducing symptoms and improving the quality of life of patients [1]. However, the use of all modern treatments does not provide the expected rapid wound healing. Even with a combination of surgical treatment and compression therapy, healing lasts an average of up to 6 months. Histological and structural studies have shown that the vessel wall of varicose veins has areas with reduced collagen content, alternating with areas of reduced levels of elastin and laminin [13]. Disorders in collagen metabolism were observed in chronic venous wounds [8]. In recent years, there have been studies to determine the role of lidocaine solution in regenerative injection therapy [14] confirming the clinical effect caused by induction of fibroblast proliferation and enhanced collagen synthesis.

**The aim of the work** was to develop an effective dose and concentration of lidocaine and the optimal method of its administration for the treatment of chronic venous disease in the stage of active trophic wounds and accelerate the healing process.
Materials and methods

The results of treatment of 97 patients with chronic venous insufficiency in stage C6 and C6r were evaluated, which were divided into two clinical groups: retrospective (n=50) in which classical surgical treatment was performed (Coquette veins ligation, Narat phlebectomy) and prospective (n=47) in which classical surgical intervention (crossectomy + Bebcock and / or Narat phlebectomy) was used in combination with the developed method of treatment of trophic wounds [12]. Both groups were representative by age, sex, study and comorbidities, risk factors, features of medical history, as well as conditions of surgical treatment (surgical treatment was performed in one hospital).

For clinical evaluation used the classification of CEAP (2020) [7]. Thus, according to the purpose of the study, patients of both groups were: with C6 (open trophic wound) and C6r (recurrence of open trophic wound) class; the presence of subjective symptoms - S (itching, pain, distension, heaviness); by etiology of secondary disease - Es; by the anatomy of the lesion - As (subcutaneous veins), Ad (deep veins), Ap (perforating veins); on a pathophysiological basis - with sonographically confirmed refluxes Pr and / or obstruction of the vein Po; by the level of diagnostic actions - L1 (clinical examination + ultrasound Doppler).

In addition to the standard clinical examination of pathology of the venous system (clinical+duplex ultrasound) of the lower extremities, trophic wounds were evaluated: their number, location, area, duration of wound anamnesis were determined.

Research results discussion

Among the examined patients of both groups, complaints of: stabbing pain and heaviness in the lower extremities, periodic, often systematic edema, nocturnal cramps in the leg muscles, the presence of trophic wounds on the lower extremities (Table 1).

Objective examination revealed the presence of two main symptom complexes: varicose veins in combination with persistent edema in 63.83% of prospective groups and 72.0% - retrospective and trophic disorders of trophic wounds in 100% of patients in both groups on the background of hyperpigmentation. (100.0%), lipodermatosclerosis (100.0%). Localization of a trophic ulcer on the left was observed almost three times more often, than on the right at men, and at women twice.

Trophic wounds were localized in the distal parts of the tibia in 78.72 % of patients, in the middle third of the tibia in 21.28 %. Trophic wound area is shown in Table 2.
Table 1. The structure of typical complaints of the two study groups (n = 97)

| Complaints                  | Prospective group (n=47) | Retrospective group (n=50) |
|-----------------------------|--------------------------|---------------------------|
| Heaviness                   | 80,85 %                  | 84,0 %                    |
| Bursting pain               | 100,0 %                  | 100,0 %                   |
| Night cramps                | 14,89 %                  | 18,0 %                    |
| Persistent edema            | 63,83 %                  | 72,0 %                    |
| Transient edema             | 36,17 %                  | 28,0 %                    |
| Varicose veins              | 100,0 %                  | 100,0 %                   |
| Hyperpigmentation           | 100,0 %                  | 100,0 %                   |
| Lipodermatosclerosis        | 100,0 %                  | 100,0 %                   |
| Skin exfoliation            | 10,64 %                  | 8,0 %                     |
| Active wounds               | 100,0 %                  | 100,0 %                   |
| Recurrence of an active wound | 29,79 %              | 16,0 %                    |
| Scars from ulcers           | 10,64 %                  | 24,0 %                    |

Table 2. Trophic wound area of the two study groups (n = 97)

| Wound area     | Prospective group (n=47) | Retrospective group (n=50) |
|----------------|--------------------------|---------------------------|
| up to 10 sm²   | 51,06 %                  | 44,0 %                    |
| 11-20 sm²      | 19,15 %                  | 30,0 %                    |
| more than 20 sm² | 29,79 %              | 26,0 %                    |

In patients of the prospective group (n=47), after crossectomy and / or stripping of the great saphen vein (GSV) (short or long), subfascial ligation of the perforated vein in the area of the trophic ulcer, a subclavian catheter into a perforate vein was installed, in which prolonged infusion therapy of Lidocaine 10% 20 ml and 0.9% NaCl solution 200 ml was performed using the Exadrop-infusion system at a rate of 1-4 mg / min 3 hours for 7 days period.

For a more detailed assessment of the dynamics of changes in the size of trophic wounds, we present observation data for 7, 14 and 28 days after the applied surgical treatment (Table 3).

In the period of 3-6 months, complete healing of trophic wounds was observed in the prospective group. At the same time, in 25.53% of patients in this group complete healing was observed up to 7 days. Whereas, in patients of the retrospective group, this was observed
between 6-9 months. In addition, the rate of decrease in the area of trophic wound for the first month in the prospective group was 23.72% higher than in the retrospective group (p<0.05). We did not observe a recurrence of a trophic wound in the follow-up period up to 1 year in the prospective group.

**Table 3.** Dynamics of the average area of active trophic wound in both groups during the observation period up to 1 month (M ± m)

| Term of observation     | The average area is sm²  |
|-------------------------|-------------------------|
|                         | Prospective group (n=47) | Retrospective group (n=50) |
| Before the operation    | 13.96±0.02              | 14.21±0.02                |
| 7 days p/o period       | 12.63±0.03              | 13.95±0.05                |
| 14 days p/o period      | 11.82±0.01              | 13.37±0.04                |
| 21 days p/o period      | 10.12±0.04              | 13.04±0.02                |
| 28 days p/o period      | 9.52±0.03*              | 12.48±0.03**              |

Note: * p<0.05 - compared to the preoperative indicator, ** p<0.05 - compared to the prospective group.

When assessing the intensity of pain in the early postoperative period on a visual analog scale (Visual Analogue Scale Pain Intensity Assessment), where 0 - no pain, 1 point corresponds to the minimum pain, 10 points - the maximum possible pain), respectively, on the first day after the operation, the intensity of the pain syndrome in the prospective group was (6.10 ± 0.25) points, in the retrospective group - (6.05 ± 0.37) points (p <0.05). The dynamics of the pain syndrome is shown in Figure 1.
Figure 1. The degree of expression of pain in the dynamics of the early postoperative period, points

Rapid recovery of motor activity provided active prevention of thrombotic complications, along with the appointment of anticoagulant therapy and a significant reduction in inpatient treatment.

Discussion

The instillation of local anesthetics in surgical wounds is one of the techniques used to accelerate healing to reduce intraoperative or postoperative pain. Among the anesthetic drugs most used for this practice are amides, especially lidocaine and bupivacaine. These drugs can be administered with minimal tissue irritation or allergic reactions. But, the effects of local anesthesia on healing are not well known. In addition to absence of the technical doses not being well defined, there are even reports of deleterious effects on wound healing.

According to Dogan et al. [4], there is delay in wound healing with the use of lidocaine, and with the reduced tension strength of collagen fibers; other authors corroborate the macroscopic findings of this research, where no significant differences were observed between the healing processes.

On the other hand, the positive effects of lidocaine solution have been reported in studies by other authors. So Bahar Dernek et al. [3] report that 5-week subcutaneous lidocaine injection treatment was effective in patients with chronic venous insufficiency in the early stage who do not respond to oral medical treatment or in whom surgery is not considered.

The results obtained in the present research indicate that the doses and concentrations of lidocaine used have positive effects on skin healing even as intravenous injection.

Conclusions: Due to the use of our own developed method of surgical treatment of patients with chronic venous insufficiency in stage C6 and C6r, it was possible to significantly reduce the healing time of active trophic wounds after surgery.

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