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## Evaluation of the Efficacy of Surgical Treatment of Patients with Chronic Critical Ischemia of Lower Extremities at the Stage of Trophic Complications

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**RELEVANCE** Chronic critical ischemia of the lower extremities (CCILE) in the stage of trophic complications is the final stage of diseases of the arteries of the lower extremities, leading to disability of patients and having a poor prognosis in terms of preservation of the lower extremities and mortality.

**AIM OF STUDY** Objective assessment of the efficacy of lower limb revascularization in trophic disorders.

**MATERIAL AND METHODS** The analysis of treatment of 52 patients with stage IV CCILE (according to the classification of R. Fontaine and A.V. Pokrovsky) was carried out. Of these, 42 patients underwent three-phase scintigraphy combined with X-ray computed angiography on a hybrid apparatus. After the operation, this study was conducted in 37 patients.

**RESULTS** Out of 52 patients, surgery for revascularization of the lower extremities was performed in 37 patients, 15 were not operated on. Out of 37 operated patients, improvement of blood circulation occurred in 32 (86.5%). Circulatory decompensation was observed in 5 patients (9.7%). Among non-operated patients, improvement of blood circulation occurred in 9 patients (17.3%), no effect or decompensation — in 5 (9.7%). Subjective improvement in the condition and decrease in the degree of ischemia corresponded to the improvement of microcirculation according to the data of three-phase scintigraphy.

**CONCLUSION** 1. Revascularization of the lower extremities in patients with trophic disorders is an effective method of treating this pathology. Therefore, all patients with chronic ischemia threatening limb loss should be considered as candidates for revascularization.

2. If the leg arteries or short occlusive or stenotic lesions of the main arteries are affected, such patients should be discussed together with specialists in endovascular surgery for endovascular treatment or joint intervention.

3. Hybrid radiation method (three-phase scintigraphy and single-photon emission computed tomography, combined with X-ray computed angiography) is an objective method that reflects the state of peripheral circulation and microcirculation, and allows you to objectively assess the effectiveness of the treatment.

**Keywords:** trophic complications, chronic critical ischemia of the lower extremities, chronic ischemia threatening the loss of the lower extremity, three-phase scintigraphy of the lower extremities, single-photon emission computed tomography, revascularization of the lower extremities

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CCILE, chronic critical ischemia of lower extremities  
CITLL, chronic ischemia threatening the limb loss  
CRA, coefficient of relative accumulation  
DUS, Doppler ultrasound  
RPH, radiopharmaceutical  
SPECT–CT, single-photon emission computed tomography combined with X-ray computed angiography  
SPECT, single photon emission computed tomography  
USDS, ultrasound duplex scanning

## INTRODUCTION

Occlusive diseases of the main and peripheral arteries make up the overwhelming majority of diseases of atherosclerotic genesis [1]. Chronic critical ischemia of lower extremities (CCILE) is an end-stage disease of the lower limb arteries. Currently, the term “chronic ischemia threatening limb loss” (CITLL) is widely used to denote chronic ischemia complicated by trophic ulcers, necrosis of the fingers and/or feet, or infection [2]. This stage of ischemia is a serious disease that inevitably leads to the disability of patients and has a poor prognosis.

About 90% of all amputations are performed for the progression of CITLL. According to foreign literature, up to 40% of CITLL patients, if not undergoing revascularization, suffer a limb loss in the first 6 months, and during the first year this figure rises to 90% [3]. Mortality without surgery during the first six months in such patients can reach 20%. However, after amputation of the lower limb at the hip level during the first year, the survival rate is 48–62%; in the next two years, up to 50–70% of patients die [4].

The question of activating the patients who have undergone lower limb amputation is also acutely raised: only 30% of patients use a prosthesis after amputation at the thigh level, while after amputation at the level of the lower leg, 69.4% of patients use the prosthesis [5, 6].

The opinion that it is technically difficult in CITLL to perform arterial reconstructive operations, and the results are short-lived, is still widespread today.

Despite the development of vascular and endovascular surgery in recent decades, the total number of reconstructive operations on the arteries of the lower extremities remains relatively small. Thus, in 2018, 13,473 surgeries for CCILE were performed, which practically does not differ from the data of 5 years ago making 13,457. The conventional amputation rate in 2018 was 7.4% [7].

According to a number of studies, revascularization allows limb salvage in 94.4% of patients at a follow-up period of 1 year, while the phenomena of critical ischemia can be controlled in 87.8% of patients [8]. A number of statistical studies have shown a clear negative correlation between the number of vascular reconstructions and the frequency of amputations in the population [9]. Therefore, we can confidently say that the optimal solution to the CITLL problem is timely revascularization. To prove this tactic and justify an increase in the number of reconstructive operations, an objective assessment of the effectiveness of surgical treatment is required. The existing radiation techniques for assessing the state of microcirculation and tissue viability allow us to solve this problem.

## MATERIAL AND METHODS

We analyzed the treatment of 52 patients with CCILE stage IV (up to R.Fontaine and A.V. Pokrovsky classification), who were managed in the Department of Vascular Surgery of the N.V. Sklifosovsky Research Institute for Emergency Medicine in 2018–2019. All patients had trophic impairments on the lower leg or foot (Fig. 1).



Fig. 1. Examples of trophic disorders in patients with chronic ischemia threatening the loss of a limb: A — necrosis of part of the foot in a patient with femoral artery occlusion; B — trophic ulcer of the leg in a patient with occlusion of the popliteal artery and arteries of the leg

Most of these patients 39 (75.0%) had superficial ulcers the feet or legs or with necrotic signs in one toe. Eight patients (15.4%) were diagnosed with necrosis of 3 or more toes, 2 (3.8%) had deep necrosis of the heel region. There were also 3 patients (5.8%) with sluggish healing wounds on the amputation stump or with suppuration of postoperative wounds of the amputation stump, who had been transferred from the purulent surgery departments of other Moscow hospitals (Fig. 2).

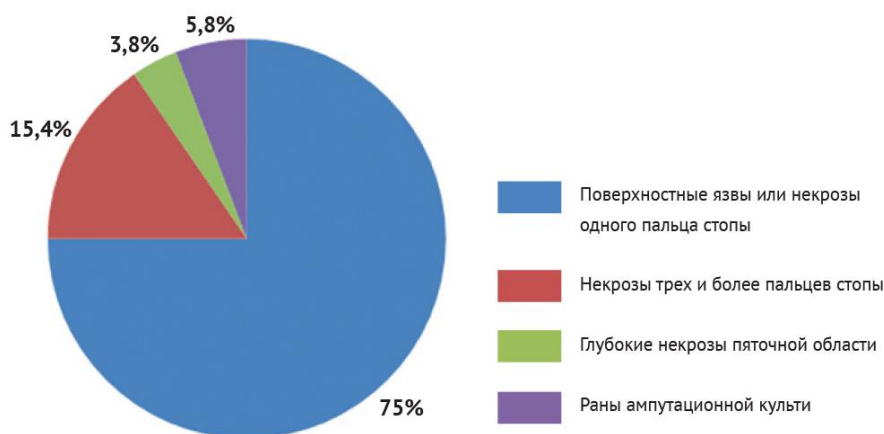


Fig. 2. Distribution of patients according to the location of trophic disorders

superficial ulcers or necrotic signs in one toe  
necrosis of 3 or more toes  
deep necrosis of the heel region  
wounds on the amputation

There were 40 men (76.9%), and 12 (23.1%) women; 14 patients (26.9%) had type 2 diabetes mellitus. The average age of the patients was 64.6 years.

All patients underwent Doppler ultrasound (DUS) as a primary diagnosis of arterial lesions of the lower extremities. A hybrid study: three-phase scintigraphy with osteotropic radiopharmaceutical (RPH)  $^{99m}\text{Tc}$ -pirfotech, supplemented by single-photon emission computed tomography (SPECT) combined with X-ray computed angiography (CT-AG) of the lower extremities on a hybrid device Discovery of 670 NM / CT was performed in 42 patients. The hybrid technique (SPECT/CT-AG) made it possible both to assess tissue viability and to determine the prevalence of aseptic necrosis foci, and also to visualize the arterial bed in order to determine the possibility of revascularization and the extent of the suggested surgery. After surgical treatment, this investigation was conducted in 37 patients. All patients underwent ultrasound duplex scanning (USDS) for detection of stenotic lesions of the brachiocephalic arteries.

## RESULTS

According to the localization of lesions of the main arteries, the patients were distributed as follows: occlusion of the terminal aorta in 4 (7.7%), occlusion of the iliac artery in 9 (17.3%), occlusion of the femoral artery in 11 (21.2%), occlusion of the popliteal artery in 12 (23.1%), the lower leg arterial lesion in 16 (30.1%) (Fig. 3).



Fig. 3. Distribution of patients according to the location of vascular lesions

occlusion of the terminal aorta  
occlusion of the iliac artery  
occlusion of the femoral artery  
occlusion of the popliteal artery  
the lower leg arterial lesion

Among 52 patients, 37 (71.2%) were operated on. According to the localization of lesions of the main arteries, they were distributed as follows: 4 patients (10.7%) with occlusion of the terminal aorta, 9 (24.3%) with occlusion of the iliac artery, 10 (27.2%) with occlusion of the superficial femoral artery, 7 (18.9%) with occlusion of the popliteal artery, 7 (18.9%) with the lower leg arterial lesion.

Of these, 6 patients (16.2%) underwent aorto-femoral bifurcation prosthetics, 6 (16.2%) underwent ilio-femoral prosthetics, 7 (18.9%) underwent femoral-popliteal prosthetics, 3 patients (8.1 %) had endarterectomy from the femoral artery, and 3 (8.1%) had endarterectomy from the popliteal artery. Stenting and/or angioplasty of peripheral arteries after joint examination with specialists in endovascular surgery were performed in 9 patients (24.3%), hybrid operations were made in 3 (8.1%) (Fig. 4). In connection with the presence of hemodynamically significant pathology of the carotid

arteries, 5 patients (9.6%) underwent carotid endarterectomy as the first stage. Four patients (7.7%) were diagnosed with coronary pathology, in connection with which stenting of the coronary arteries was performed.



Fig. 4. Distribution of patients according to performed operations

- аорто-бедренное бифуркационное протезирование
- илио-бедренное протезирование
- бедренно-подколенное протезирование
- эндартерэктомия из бедренной артерии
- эндартерэктомия из подколенной артерии
- Стентирование и/или ангиопластика периферических артерий
- гибридные операции

As a result of the surgical treatment, blood circulation improved in 32 (86.5%) of 37 patients. There was a subjective improvement in well-being, relief of pain at rest, limitation of the necrosis zone, epithelialization of trophic ulcers. Circulatory decompensation was observed in 5 (9.7%). These patients developed postoperative retrombosis with ischemia progression of.

Surgical treatment was not performed in 15 patients (28.8%) due to the absence of a distal arterial bed (according to USDS and SPECT/CT-AG data). This category of patients underwent a course of rheological, angiotropic, vasodilating therapy, physiotherapy course, hyperbaric oxygenation; and the cell technologies were used. As a result of therapy, blood circulation improved in 9 patients (60.0%), no effect or decompensation was noted in 6 (40.0%).

In total, 6 patients (11.5%) were transferred to the Department of Purulent Surgery for primary amputation of the lower limb.

In the operated patients (in addition to subjective improvement of blood circulation and objective physical data), the efficacy of surgical treatment was assessed using three-phase scintigraphy and SPECT/CT-AG. This method made it possible to visualize the restored patency of the great arteries in the area of the performed reconstruction or angioplasty/stenting and to assess the dynamics of improving microcirculation. When comparing the results of three-phase scintigraphy, the following changes were noted: a visual improvement in microcirculation, which manifests itself in a diffuse increase in the accumulation of a radiopharmaceutical (RPH) in muscle tissue, a decrease in the number or size of zones without RPH accumulation (zones of no blood supply), as well as a decrease or complete disappearance of foci of RPH hyperfixation with an increase in accumulation in the bone phase, which corresponded to a decrease or disappearance of aseptic necrosis foci. These changes were typical for all patients with a favourable outcome of surgery (Fig. 5 and 6).

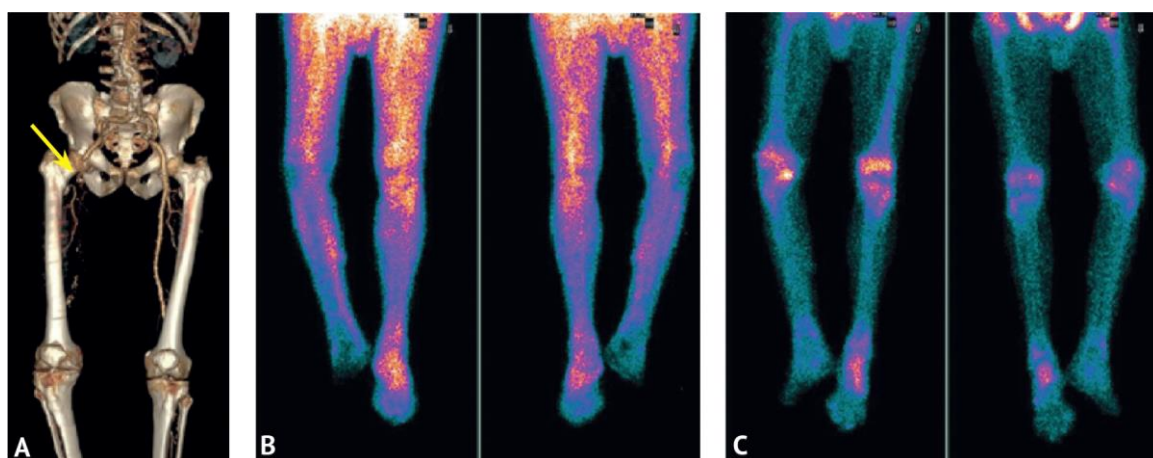


Fig. 5. A 75-year-old patient L., before surgery: A — occlusion of the right common femoral artery (indicated by an arrow); B — tissue phase: in the area of the foot there is a pronounced violation of the inclusion of the indicator, the coefficient of relative accumulation (CRA) 0.35; C — bone phase: CRA 0.57, the area of the fingers is not determined

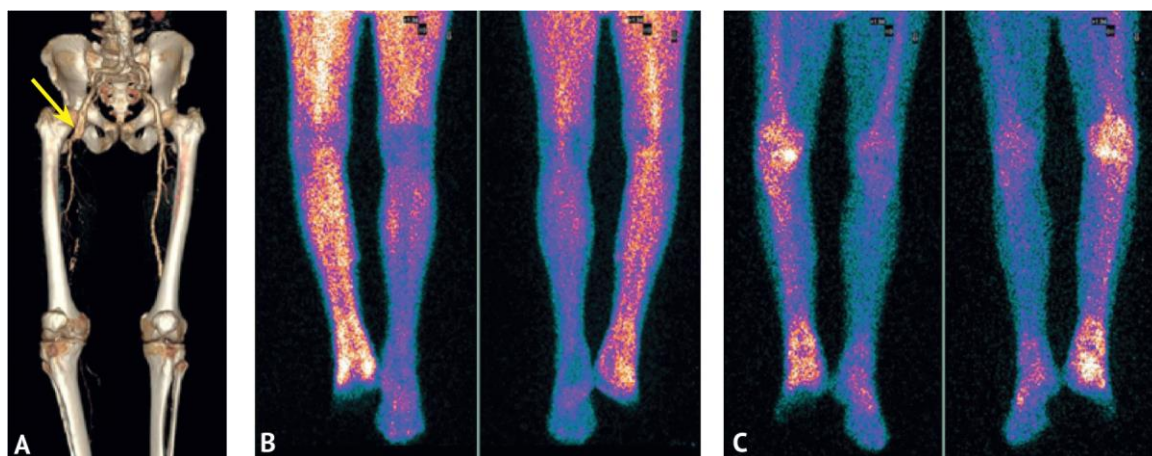


Fig. 6. The same patient 1 week after revascularization of the left lower limb (endarterectomy from the common and deep femoral arteries with profundoplasty): A — the reconstruction zone is indicated by an arrow; B — tissue phase: improvement of microcirculation while maintaining the uneven distribution of the indicator, the coefficient of relative accumulation (CRA) 2.0; C — bone phase, CRA 1.6

## DISCUSSION

Frequently, the patients with trophic disorders on the foot or lower leg are considered by general and purulent surgeons as candidates for the forthcoming amputation, and the lesions of large segments of the arterial bed in the lower extremities and, especially the arteries of the legs, are considered inoperable cases. Also, the threat of purulent-septic complications of surgical interventions in patients with trophic disorders may serve as an excuse for refusal of surgical treatment. At the same time, according to a number of authors, in case of direct revascularization in patients with CITLL, the ischemic lesion of the distal parts of the lower limb is severe but reversible [10]. In addition, the development of endovascular and hybrid technologies in some cases makes it possible to expand the range of operations and restore the patency of the lower leg arteries. Revascularization leads to more effective healing of trophic ulcers and amputation stumps.

In our study, in the group of operated patients ( $n = 37$ ), we managed to achieve positive results in 32 (86.5%). Faster healing of trophic impairments significantly improves the quality of life of the patients and reduces the cost of treating these complications. It should be noted that the best results were observed with superficial ulcers of the feet and legs, as well as with delimited necrosis of one toe. These complications most often arise as a result of atherosclerotic vascular lesions, and with the restoration of the blood flow and further local therapy, there is no need for the second stage of surgical treatment (in a department of purulent surgery) [11].

A special place is taken by a group of patients with a moderate clinical effect, in whom the compensation of blood circulation was noted in the proximal segments of the extremities. In these cases, with restoring the blood flow in the main arteries, it was possible to reduce the level of the forthcoming amputation, which would contribute to a much faster recovery of patients and allow them to get on the prostheses and become more active at an earlier date; in this connection, we also consider the treatment results in this patient group satisfactory.

When performing three-phase scintigraphy and SPECT/CT-AG in dynamics, an improvement in microcirculation in the operated limb (or in its proximal segment) and a decrease in necrosis zones were noted. This makes it possible to include a hybrid method for assessing the tissue and main blood flow of the lower extremities (three-phase scintigraphy with an osteotropic radiopharmaceutical and SPECT/CT-AG of the lower extremities) into the list of objective methods for assessing the efficacy of limb revascularization.

## CONCLUSIONS

1. Revascularization of the lower extremities in patients with trophic disorders is an effective treatment method for this pathology. Therefore, all patients with chronic ischemia threatening limb loss should be considered as candidates for revascularization.

2. For patients with lower leg arterial lesions or short occlusive or stenotic lesions of the main arteries, the issue of endovascular treatment or simultaneous interventions should be considered jointly with the specialists in X-ray endovascular surgery.

3. The hybrid radiology method (three-phase scintigraphy and single-photon emission computed tomography combined with X-ray computed angiography) is a reliable tool that displays the state of peripheral blood circulation and microcirculation, and allows an objective assessment of the treatment efficacy.

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