

Diagnostics and Treatment of Patients with Chronic Limb Ischemia (Single-Center Experience)

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ABSTRACT

BACKGROUND: The success of treating the patients with chronic ischemia of the lower limbs consists of a number of components, such as the full-scale diagnostics; the re-vascularisation volume, the therapeutic means (including the use of modern developments in angiogenesis); the engagement of specialists from the adjacent fields. **AIM:** the improvement of treatment results in patients with chronic ischemia in the lower limbs and developing an optimal treatment and diagnostic algorithm for this group of patients.

METHODS: The analysis included the treatment results of 218 patients with chronic ischemia of the lower limbs (136 males, 82 females; the mean age was 67 ± 6 years), of which 144 patients were operated, 74 were treated conservatively. Diagnostics and examination methods: ultrasound angioscanning, single-photon emission computed tomography combined with three-phase scintigraphy and computed tomography, consulting by a neurologist and a cardiologist, electroneuromyography by prescription from the neurologist and additional examinations by prescription from the cardiologist. The follow-up was implemented as the control out-patient examinations or upon the repeated hospitalization. The follow-up period was 6 months.

RESULTS: The distribution of patients by the degree of ischemia as per the classification by A.V. Pokrovsky was the following: IIA — 57 (26.1%), IIB — 31 (14.2%), III — 42 (19.2%), IV — 88 (40.5%) patients. The number of open-access surgeries conducted was 56 (25.7%), with 64 endovascular (29.4%) and 24 hybrid ones (11.0%); conservative therapy was administered to 40 patients (18.3%), conservative therapy accompanied by additional administrations of plasma-free auto-platelet lysate — 34 (15.6%). In the group of operated patients, there were no significant differences depending on the method of surgical treatment at the early post-surgery period and after 6 months of follow-up ($p > 0.05$). Among the patients receiving conservative therapy, the best results at the follow-up of 6 months were reported in patients, in which the standard therapy was accompanied by stimulation of angiogenesis with auto-platelet factors ($p < 0.05$). The presence of ischemic neuropathy was investigated in 98 patients. Neuropathy was detected in 69 cases using the method of electroneuromyography. After prescribing the neurotropic therapy, resolving of neuropathic pain was reported in 52 (75.4%) patients. **CONCLUSION:** The multi-disciplinary approach developed by us for the diagnostics and treatment of patients with chronic ischemia of the lower limbs, allows for improving the treatment results, while the extended spectrum of diagnostic methods allows for evaluating the risk factors, for determining the optimal treatment tactics and for objectively evaluating the dynamic changes of the patient status.

Keywords: chronic ischemia of the lower limbs; plasma-free lysate of autologous platelets; three-phase scintigraphy; ischemic neuropathy; re-vascularisation.

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BACKGROUND

Chronic ischemia of the lower limbs is a socially significant disease of the XXI century. According to the data from the World Health Organization, the impairments of the arteries in the lower limbs take the third place within the structure of atherosclerotic diseases, which is 3% of the whole population worldwide [1]. Upon the progression of chronic ischemia in the lower limbs, critical ischemia in the lower limbs develops, which,

in turn, in the absence of providing medical aid at the period of 6 months, can lead to amputations in 40% of cases and shows 20% mortality [2].

In the absence of indications for surgical re-vascularisation or the absence of the possibilities of its conduction, the actual issue is developing new methods of therapeutic means, primarily the use of therapeutic angiogenesis. The methods of angiogenesis were a subject of multiple research

Диагностика и лечение пациентов с хронической ишемией нижних конечностей (опыт одного центра)

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АННОТАЦИЯ

Обоснование. Успех лечения больных с хронической ишемией нижних конечностей складывается из ряда составляющих, таких как полноценная диагностика; объём реваскуляризации, терапевтических мер (в том числе применение современных разработок в области ангиогенеза); привлечение смежных специалистов. **Цель исследования** — улучшение результатов лечения пациентов с хронической ишемией нижних конечностей и разработка оптимального лечебно-диагностического алгоритма для данной группы пациентов. **Методы.** Проанализированы результаты лечения 218 пациентов с хронической ишемией нижних конечностей (136 мужчин, 82 женщины; средний возраст 67 ± 6 лет), из них 144 пациента прооперированы, 74 — пролечены консервативно. Методы диагностики и обследования: ультразвуковое ангиосканирование, однофотонная эмиссионная компьютерная томография, совмещённая с трёхфазной сцинтиграфией и компьютерной томографией, консультирование неврологом и кардиологом, электронейромиография по назначению невролога и дополнительные обследования по назначению кардиолога. Динамику оценивали на контрольных амбулаторных осмотрах либо при повторной госпитализации. Срок наблюдения — 6 месяцев. **Результаты.** Распределение пациентов по степеням ишемии по А.В. Покровскому было следующим: IIA — 57 (26,1%), IIB — 31 (14,2%), III — 42 (19,2%), IV — 88 (40,5%). Открытых хирургических операций выполнено 56 (25,7%), эндоваскулярных — 64 (29,4%), гибридных — 24 (11,0%); консервативное лечение получили 40 (18,3%), консервативное лечение, дополненное введением бесплазменного лизата аутотромбоцитов, — 34 (15,6%). В группе прооперированных больных значимых различий в зависимости от метода хирургического лечения в раннем послеоперационном периоде и спустя 6 месяцев наблюдения не было ($p > 0,05$). Среди больных, получавших консервативную терапию, лучшие результаты через 6 месяцев наблюдения отмечены у пациентов, которым стандартная терапия была дополнена стимуляцией ангиогенеза аутотромбоцитарными факторами ($p < 0,05$). На предмет ишемической нейропатии обследовано 98 пациентов. Нейропатия методом электронейромиографии выявлена в 69 случаях. После назначения нейротропной терапии купирование нейропатических болей отмечено у 52 (75,4%) пациентов. **Заключение.** Разработанный нами мультидисциплинарный подход к диагностике и лечению пациентов с хронической ишемией нижних конечностей позволяет улучшить результаты лечения, а расширенный спектр диагностических методов помогает определить факторы риска, выбрать оптимальную лечебную тактику и объективно оценить динамику состояния пациентов.

Ключевые слова: хроническая ишемия нижних конечностей; бесплазменный лизат аутологических тромбоцитов; трёхфазная сцинтиграфия; ишемическая нейропатия; реваскуляризация.

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works, with proving its efficiency in the patients with intermittent claudication and in groups of patients with minor trophic lesions [3–5]. But, even when saving the limb or when decreasing the degree of ischemia, the quality of life in a patient can be significantly decreased due to peripheral neuropathy. In case of chronic ischemia in the lower limbs, the peripheral nerves experience certain morphological reorganizations. Upon performing the reconstruction and morphological

remodeling of soft tissues, the process may affect the peripheral nerve with the development of compression-ischemic neuropathy [6, 7].

Upon the modern view on the problem, it becomes evident that the success of treating patients with chronic ischemia of the lower limbs includes several components: a complex set of modern diagnostic methods; re-vascularisation of the limb, the extent of which is evaluated by a group of specialists; the

extension of therapeutic means (including the use of developments in angiogenesis); the involvement of specialists from adjacent fields.

The research work presents an experience of treating the patients with chronic ischemia of the lower limbs according to the developed algorithm.

Research aim — improvement of treatment results in the patients with chronic ischemia of the lower limbs and developing an optimal treatment and diagnostic algorithm for this group of patients.

METHODS

Research design

Retrospective single-center observational.

Conformity Criteria

Inclusion criteria: chronic ischemia of the lower limbs; atherosclerotic origin of the disease; age from 45 to 90 years old.

Exclusion criteria: severe heart failure; acute myocardial infarction dated less than one month without the re-vascularisation of the myocardium; acute impairment of cerebral circulation dated less than one month; thromboangiitis; oncology diseases with low survival prognosis.

Research facilities

The research included patients treated at the Vascular Surgery Department of the State Budgetary Healthcare Institution “Sklifosovsky Institute for Emergency Medicine of the Healthcare Department of Moscow City” (SBHI Sklifosovsky IEM, HDM) during the period from 2022 until 2024.

Medical Procedure Description

The diagnostic algorithm included the following diagnostics methods:

- ultrasound angioscanning with measuring the ankle-brachial index: the “first line” examination method, allowing for visualizing the arterial circulation system of the lower limbs, for evaluating the blood circulation parameters and the type of plaques;
- the hybrid method (three-phase scintigraphy — single-photon emission computed tomography, combined with computed angiography, or SPECT/CT-angiography): the method allows for visualizing the arterial circulation system in the lower limbs and shows the objective data on the status of microcirculation. The three-phase scintigraphy with osteotropic radiopharmaceutical Tc^{99m} -Pirfotech, unlike the transcutaneous oxymetry, provides

a possibility of localizing the zones of depleted microcirculation and its extent. Upon the dynamic examination, one can observe the changes in the distribution of the radiopharmaceutical, which objectively reflects the improvement/aggravation of blood supply in the tissues [8];

- general methods of examination, such as electrocardiography, echocardiography, chest cavity X-ray, as well as ultrasound angioscanning of the brachiocephalic arteries, coronary angiography according to indications from the cardiologist — for the evaluation of risk factors in patients;
- electroneuromyography of peripheral nerves was used according to the prescription by the neurologist for the purpose of verifying the lesions of peripheral nerves with a background of impaired blood supply in the lower limbs;
- consulting by the specialists: the patients were obligatory assessed by the cardiologist and by the neurologist (the cardiologist detects and corrects the cardiac risk factors; the examination and medical supervision by the neurologist is necessary for detecting the neuropathies and prescribing medicines for their correction).

On an aggregate basis of the examinations conducted during the combined assessment with the radio-endovascular surgery specialists, a tactics of in-patient treatment was defined. It is worth noting that all the patients with chronic grade IIA ischemia in the lower limbs, as well as with chronic grade IIB ischemia of the lower limbs, in which, with a background of therapy, the degree of ischemia was decreasing, according to the recommendations [9], were not considered as candidates for surgery, also, the patients with higher degree of ischemia were considered inoperable in case of unsatisfactory status of the distal arterial circulation system or in cases of severe concomitant diseases. As for the other patients, a decision was drawn up on the extent and the type of surgical intervention: open-access reconstruction, endovascular intervention or hybrid surgery.

For the purpose of therapeutic angiogenesis, a medicinal product based on the autplatelet pro-angiogenic factors was developed — a plasma-free lysate of autologous platelets. The application of this medicine in inoperable patients has shown satisfactory results [9, 10].

Research findings

Main research outcomes: decreased degree of ischemia, preserving the limb.

Table 1

Clinical-demographic characterization of patients

Parameter	Patients, n (%)
Gender:	
• males	136 (62.4)
• females	82 (37.6)
Age, years	67±6
Ischemic heart disease	180 (82.6)
Hypertensive disease	192 (88.1)
Chronic kidney disease, compensation	58 (26.6)
Obesity	126 (57.8)
Chronic cardiac failure, compensation	92 (42.2)
Smoking	126 (57.8)
Degree of ischemia acc. to the Fountain-Pokrovsky:	
• IIA	57 (26.1)
• IIB	31 (14.2)
• III	42 (19.3)
• IV	88 (40.4)

Additional criterion for operated patients: passability of the reconstructed area after a certain follow-up period; healing of wounds in cases of open-access interventions; local wound-related complications.

Additional criterion for all the patients: improvement in the distribution of the radiopharmaceutical according to the data from three-phase scintigraphy; decreased intensity of neuropathic pain.

Methods of registration of outcomes

The control procedures were arranged during the control out-patient examinations or upon the repeated hospitalization in 3 and in 6 months after treatment with implementing the whole diagnostic algorithm.

Statistical analysis

The statistical analysis of data was carried out using the STATISTICA software version 10.0. The following nonparametric methods were used: χ^2 -test, Mann-Whitney test and McNemar's test. The statistically significant differences were considered the ones with $p < 0.05$.

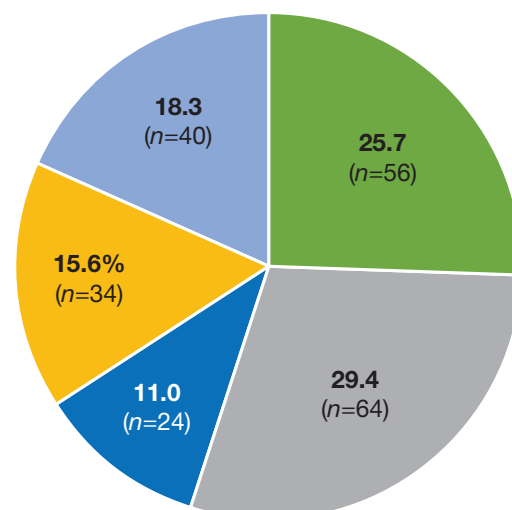
RESULTS**Research sample (participants)**

A total of 218 patients with chronic ischemia of the lower limbs were treated, of which 136 were males and 82 were females, the mean age of which was 67±6 years (Table 1). Surgical interventions were performed in 144 patients, conservative therapy was used in 74. The research included patients with chronic ischemia of the lower limbs of atherosclerotic origin with grades IIB–IV according to the classification by A.V. Pokrovsky.

Main research outcomes

In general, based on the results of combined examination and discussions on the treatment concept for the patients, three groups of surgical interventions can be isolated: open-access reconstruction, endovascular interventions and hybrid surgeries. The extent and the type of interventions were determined by the type and the level of lesions in the arteries along with the spreading of the impairment. The types of surgical interventions and the methods for therapeutic correction are provided in Fig. 1 and in Tables 2 and 3 — the results of surgical and conservative therapy used in patients, respectively.

Upon the paired comparison of the surgical groups, we did not reveal any significant differences ($p > 0.05$, Mann-Whitney U-test). Taking into consideration the small rate of amputations and mortality, these



- Open-access surgical reconstructions
- Endovascular interventions
- Hybrid surgeries
- Conservative treatment with plasma-free auto-platelet lysate
- Conservative treatment

Fig. 1. The methods of treating patients with chronic ischemia of the lower limbs, %.

parameters were not statistically evaluated. Thus, a conclusion can be made that it is justified to choose the surgical tactics depending on the type, the location and the spreading degree of the atherosclerotic lesions in the arteries of the lower limbs.

Table 2

Results of surgical treatment arranged for the patients, $n=144$

Parameter	Surgical interventions, n (%)		
	Open-access surgery $n=56$	Endovascular $n=64$	Hybrid $n=24$
Improvement at the early time period	52 (92.8)	60 (93.8)	23 (95.8)
Passability of re-constructed areas at the 6 months' time point	48 (85.7)	53 (82.8)	20 (83.3)
Re-thromboses	8 (14.3)	11 (17.2)	4 (16.7)
Repeated surgeries	5 (8.9)	7 (10.9)	2 (8.3)
Amputations	1 (1.8)	1 (1.6)	-
Mortality	1 (1.8)	1 (1.6)	-

Table 3

Results of conservative therapy arranged for the patients, $n=74$

Parameter	Conservative $n=40$	Conservative + PFAPL $n=34$
Decreased ischemia degree within 6 months	28 (70.0)	28 (82.4)
Surgeries within 6 months due to developing indications	12 (30.0)	6 (17.7)
Amputations	2 (5)	1 (2.9)
Mortality	1 (2.5)	-

Note. PFAPL — plasma-free auto-platelet lysate.

When evaluating the results of conservative therapy, after 3 and 6 months of follow-up, we have observed better results for all the parameters in a group of patients, in which standard therapy was accompanied by stimulation of angiogenesis with autoplalelet factors ($p < 0.05$, Mann-Whitney U-test).

The examination purposed to reveal the presence of post-ischemic and compression-ischemic neuropathies was carried out in 98 patients: signs of impaired conductivity were reported in 69 (70.4%) patients, of which 40 were operated and 29 were receiving conservative therapy, including the one with using the auto-platelet lysate. Ischemic peripheral neuropathy was diagnosed in 50 patients, mixed-type form — in 19. All the patients had received prescriptions of neurotrophics from the neurologist at the out-patient phase. According to the questionnaires, the pain syndrome regressed in 52 (75.4%) patients.

Based on the satisfactory treatment results, we have developed a treatment-diagnostic algorithm for patients with chronic ischemia of the lower limbs (Fig. 2).

DISCUSSION

This article demonstrates the experience of treating the patients with chronic ischemia of the lower limbs with an extension of the range of diagnostic

procedures and with the multidisciplinary approach. A wide spectrum of patients is presented in terms of the degrees of ischemia, but it is worth noting that 40.5% were the patients with chronic ischemia of the lower limbs stage IV according to the classification by A.V. Pokrovsky. This segment was the exact source of lethal outcomes and amputations, nevertheless, even in patients with critical ischemia we managed to achieve the general relatively low rates of unfavorable outcomes.

For achieving better results, for timely detection of risk factors and for improving the quality of life for the patients, we actively involve the specialists from the adjacent fields — cardiologists and neurologists.

Three-phase scintigraphy has proven itself as an irreplaceable objective method showing the status of the ischemic tissues and the dynamic changes of their status with a background of therapy [8], while performing this examinations using the hybrid-mode equipment (SPECT/CT-AG) allows for shortening the duration of the examination.

The principally new method of treating the inoperable patients or patients with intermittent claudication is the type of therapeutic angiogenesis — the use of plasma-free lysate of autologous platelets, allowing for improving the results of conservative therapy.

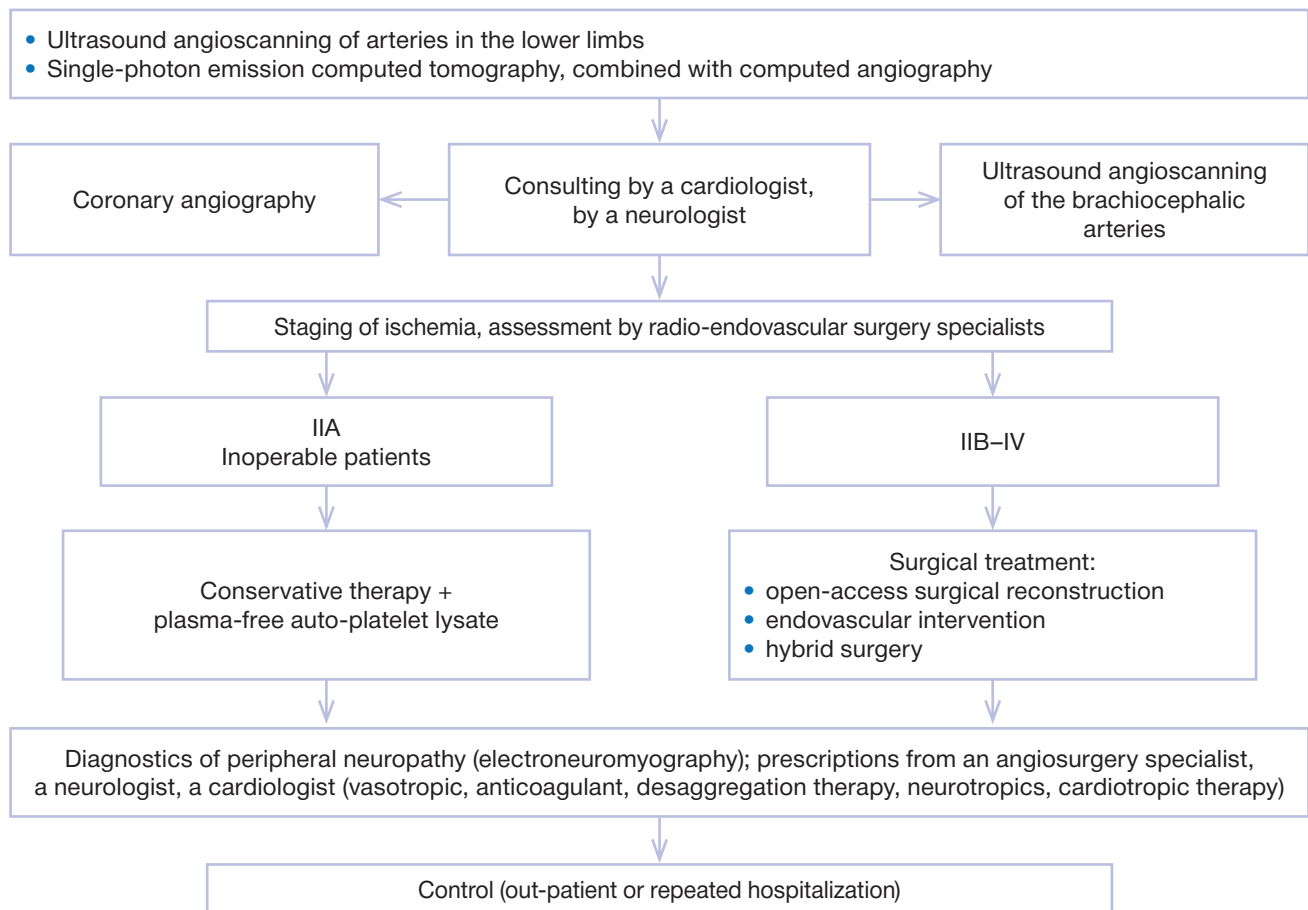


Fig. 2. Treatment-diagnostic algorithm for patients with chronic ischemia of the lower limbs.

The research included the patients with chronic ischemia of the lower limbs, meeting the inclusion criteria. Of course, the operated patients and the patients, receiving conservative therapy, represent the groups of patients that are inhomogeneous in terms of outcomes and possible complications. We did not arrange the comparison of these groups of patients between each other, for the research aim was the improvement of treatment results both in the operated and non-operated patients by selecting the optimal method for the therapy and prevention of possible complications, the most frequent of which were the early thromboses, leading to amputations, as well as the peripheral neuropathy [10].

Research limitations

The limitations of the research were the absence of separation of patients into groups by the degree of ischemia or by the level of impairment, as well as the relatively short follow-up period. The pending issue remaining is the periodicity of using the therapeutic angiogenesis, the duration of neurotropic therapy in patients with post-ischemic neuropathy and the

treatment methods for operated patients with longer (over 6 months) durations, for in this case a significant increase is expected in the rates of re-thromboses and repeated surgeries.

CONCLUSION

The multi-disciplinary approach developed by us for the diagnostics and treatment of patients with chronic ischemia of the lower limbs allows for improving the treatment results. The extended spectrum of diagnostic methods allows for evaluating the risk factors and for determining the optimal treatment tactics in patients with chronic ischemia of the lower limbs, as well as for objectively evaluating the dynamic changes of their status.

ADDITIONAL INFORMATION

Author contributions. I.P. Mikhailov, N.V. Borovkova, L.S. Kokov, L.T. Khamidova: the concept and design of the study; B.V. Kozlovskiy, V.A. Arustamyan, I.N. Ponomarev, N.E. Kudryashova, G.R. Ramazanov, E.V. Shevchenko: collection and processing of material; N.V. Borovkova, B.V. Kozlovskiy,

G.R. Ramazanov: statistical processing; B.V. Kozlovskiy, N.E. Kudryashova, I.N. Ponomarev: writing the text; I.P. Mikhailov, L.S. Kokov, L.T. Khamidova: editing. Thereby, all authors provided approval of the version to be published and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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