Saint-Petersburg State Pediatric Medical University

Manuscript

KUCHAY
Arshed Ahmad

REVASCULARISATION OF THE EXTENDED OCCLUSION OF THE SUPERFICIAL FEMORAL ARTERY IN COMBINATION WITH THE LESIONS OF THE CRURAL ARTERIES IN LOWER EXTREMITIES

Scientific specialty 3.1.15. Cardiovascular surgery

Dissertation for the degree of Candidate of Medical Sciences

Translation from Russian

Scientific advisor:
Doctor of Medical Sciences, professor
LIPIN Alexander Nikolaevich

Saint Petersburg - 2024

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INTROUCTION

Relevance of the research topic

Hemodynamically significant lesions of the superficial femoral artery (SFA) are recorded in more than half of patients with chronic limb threatening ischemia (CLTI) [119, 138, 139]. Such lesions are often represented by extended occlusion of SFA, which significantly reduces blood flow in the lower limbs and leads to severe ischemia. In a significant proportion of patients, these changes are combined with severe steno-occlusive lesions of tibial arteries, which further aggravates the perfusion of the distal limb and increases the risk of necrotic changes [19, 22, 145-148].

It is known that the extended occlusion of SFA, combined with widespread changes in outflow pathways, negatively affects the long-term results of endovascular correction of this arterial segment [75, 34, 57, 6, 140-144]. In this regard, autovenous bypass remains the preferred method of revascularization in «long» occlusions of SFA and multi-level lesions of the infrainguinal segment [1, 138, 139]. However, as the data of large studies have shown, the risk of early complications, including bypass thrombosis and limb amputation, increases when bypassing to the tibial arteries (compared to femoral-popliteal bypass) [86, 18].

Endovascular correction of steno-occlusive lesions at the level of the tibial segment demonstrates high rates of limb preservation in the long-term period, but its patency is much inferior to that achieved by bypass surgery [99, 153].

This combination of advantages and disadvantages of the open and endovascular reconstruction methods with multi-level lesions of the infrainguinal segment forms the preconditions for the application of hybrid revascularization of the extremity [141, 143, 144, 148]. This combined approach makes it possible to effectively use the strengths of both methods: surgical intervention ensures long-term passability, and endovascular correction – minimally invasive blood flow recovery at additional levels.

The study goal

To improve the results of the lower limb revascularization in extended occlusion of SFA in combination with outflow artery lesions.

The research objectives

1. To identify the frequency of prolonged occlusion of SFA in combination with severe tibial arteries lesions in patients with CLTI.

2. To determine the indications for performing hybrid operations in CLTI.

3. To develop an algorithm for planning hybrid surgical interventions in patients with CLTI.

4. To determine the efficacy and safety of a hybrid approach to the revascularization of the lower extremity in extended SFA occlusion combined with outflow artery lesions.

Scientific novelty

We analyzed the results of 80 hybrid surgical interventions in patients of both genders suffering from obliterating atherosclerosis of lower limb arteries in the critical ischemia stage. The performance and safety indicators were evaluated in the following time frames: 1, 3, 6, 12 and 24 months.

The effectiveness of hybrid surgical interventions was shown in patients suffering with obliterative atherosclerosis of lower limb arteries in the critical ischemia stage.

Practical significance of the study

Based on the conducted studies, personalization of the approach in the selection of a specific method of hybrid operative interventions in patients suffering with obliterative atherosclerosis of lower limb arteries in the critical ischemia stage was introduced into clinical practice. The results of the study showed high clinical efficiency of the performed hybrid surgical reconstruction.

Author's personal contribution

The author personally collected the material for the study; analyzed the medical documentation, including case histories, surgical protocols, anesthesiology charts; studied the immediate and long-term results of treatment; formed a unified electronic database on the basis of the obtained data; performed statistical processing of the material; analyzed and scientifically interpreted the obtained results. He directly participated in the treatment of patients, including at the stage of performing hybrid surgical interventions on the arteries of the lower limbs and treatment of postoperative complications.

Implementation of research results in practice

The basic provisions and practical recommendations of the dissertation are implemented in the therapeutic and treatment process of the city limb salvage center, St. Petersburg State Budgetary Institution "City Hospital No. 14". (St. Petersburg, Kosinovo str., 19/9).

The results of the research are used in the educational process at the department of Surgery, Cardiovascular surgery St. Petersburg State Pediatric University (St. Petersburg, Litovskaya St., 2) and the Department of Cardiovascular Surgery, Department and Clinic of Naval Surgery, S.M. Kirov Military Medical Academy (St. Petersburg, Akademika Lebedeva St., 6).

Work approbation

The main materials and provisions of the study were reported and discussed at the following conferences: EuroSciCon 4th Edition of world congress & exhibition on vascular surgery. (28-29 march 2019. Rome, Italy); at the V anniversary scientific and practical conference: limb salvage - multidisciplinary approach. LISMA 2019 - Limb Salvage Multidisciplinary Approach. (April 4-5, 2019, St. Petersburg); at the XXXV International Conference "Introduction of high technologies in vascular surgery and phlebology." (June 21-23, 2019, St.

Petersburg); at the XXXVI International Conference "Horizons of Modern Angiology, Vascular Surgery and Phlebology." (June 17-19, 2021, Kazan); at the XXXVII International Conference "Horizons of Modern Angiology, Vascular Surgery and Phlebology" with an extended section "Rehabilitation of Vascular Patients after Surgical Interventions". (May 20-22, 2022, Kislovodsk); at the XV Conference of Pathophysiologists of the Urals. All-Russian conference (October 13-14, 2022, Ekaterinburg); at Health - the basis of human potential: problems and ways of their solution. (November 23-26, 2022, St. Petersburg); at Fundamental Science and Clinical Medicine – Human being and his Health. (April 22, 2023, St. Petersburg); at XXXVIII Conference of the Russian Society of Angiologists and Vascular Surgeons and V Conference on Vascular Pathology of the Russian Scientific Society of Specialists in Endovascular Diagnostics and Treatment. <<International Conference on Vascular and Endovascular Surgery. (June 23-25, 2023, Moscow); at Russian Scientific Conference <<The role of clinical anatomy in the practice of surgeon's work>>, dedicated to the 115th anniversary of the birth of Professor E.M. Margorin and the 90th anniversary of the Department of Operative Surgery and Topographic Anatomy named after Professor F.I. Valker. (November 24, 2023, St. Petersburg).

Ethics committee approval

Decision of the Ethical Committee of the St. Petersburg State Pediatric Medical University Protocol No. 2/10 of February 10, 2020.

Publications

The main content of the dissertation research is sufficiently presented in the 24 scientific works of the applicant, including 12 articles in journals recommended by the Higher Attestation Commission of the Russian Federation.

1. Kuchay, A. A. Advantages of the hybrid revascularization technique in the treatment of extended occlusions of the superficial femoral artery and multilevel lesions of the lower extremity arteries/ A.A. Kuchay, A. N.

Lipin, P. S. Kurianov // Regional hemodynamics and microcirculation. – 2024. Vol.23. №.2. – pp. 60–66. Doi: 10.24884/1682-6655-2024-23-2-60-66

2. Kuchay, A.A. Conception of "distal hybrid" for extended occlusions of the superficial femoral artery with severe lesions of outflow in critical limb ischemia/_ A.A. Kuchay, A.N. Lipin [et al.] // Angiology and Vascular Surgery. Journal of Academician A.V. Pokrovsky // - 2022. Vol. 28. № S1. pp. 157-161
3. Kuchay, A.A. Hybrid approach in treatment of extended occlusions of arteries of the lower limbs in CLI / A.A. Kuchay, A.N. Lipin [et al.] // Angiology and Vascular Surgery. Journal of Academician A.V. Pokrovsky // - 2019. Vol. 25. № S2. pp. 260-264
4. Kuchay, A.A. Treatment of multi-level arterial lesions of lower limb arteries in CLI / A.A. Kuchay, A.N. Lipin [et al.] // Angiology and Vascular Surgery. Journal of Academician A.V. Pokrovsky // 2021. Vol. 27. № S2. pp. 410-412
5. Kuchay, A.A. Hybrid approach to extended occlusions of SFA in CLI / A.A. Kuchay, A.N. Lipin [et al.] // Angiology and Vascular Surgery. Journal of Academician A.V. Pokrovsky // 2022. Vol. 28. № S1. pp. 161-163
6. Kuchay, A.A. Revascularization of patients with multilevel artery lesions of the lower limbs / A.A. Kuchay, A.N. Lipin [et al.] // Angiology and Vascular Surgery. Journal of Academician A.V. Pokrovsky // 2023. Vol. 29. № S2. pp. 176-177
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11. Borisov, A.G. Alternative conduit from the contralateral of lower limb in infrainguinal reconstructions: assessment of risk factors for complications / A.G. Borisov, K.A. Atmadzas, N.N. Gruzdev, A.A. Kuchay [et al.] // International Journal of Interventional Cardioangiology. 2024. № S1-1. - pp. 98.
12. Borisov, A.G. Autovenous bypass from the deep femoral artery as preservation of antegrade puncture option while performing distal hybrid reconstruction in the treatment of chronic limb threatening ischemia // A.G. Borisov, A.V. Atmadzas, K.A. Atmadzas [et al] // International Journal of Interventional Cardioangiology. 2024. № S1-1. pp. 98-99.
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23. Kuchay, A.A. Advantages of the hybrid surgery technique in the treatment of multilevel lesions of the lower limb arteries / A.A. Kuchay, A.N. Lipin, N.R. Karelina [et al.] // Forcipe. - 2023. - VOL. 6, NO. S3. - pp. 44.
24. Kuchay, A.A. The concept of distal hybrid in pathogenetically justified surgical treatment of atherosclerosis / A.A. Kuchay, G.S. Kulikov, A.E. Korovin, A.N. Lipin // Health - the basis of human potential: problems and ways of their solution. - 2022. - Vol. 17, № 2. - pp. 653-659.

Main scientific results

1. Formation and study of the concept of distal hybrid intervention for extended occlusion of SFA combined with tibial artery lesions in CLTI [138, pp. 20-31, 56, 57]; [139, pp. 19-29, 56, 57]; [146, pp. 19-29, 56]; [147, pp. 19-29]; [148, pp. 19-29]; [153, pp. 14]; [155, pp. 17, 19] (author's personal contribution is at least 80%).

2. Study of mortality and shunt failure rates, 1-year primary patency of shunts and 1-year amputation-free survival with hybrid interventions compared with femoral-tibial bypass (FTB) [138, pp. 20-31, 56, 57]; [139, pp. 19-29, 56, 57]; [142, pp. 21]; [146, pp. 19-29, 56]; [147, pp. 19-29]; [148, pp. 19-29]; [153, pp. 14] (author's personal contribution at least 80%).

3. Evaluating the effectiveness of hybrid surgical interventions [68, pp. 14]; [69, pp. 14, 29, 57]; [138, pp. 20-31, 56, 57]; [139, pp. 19-29, 56, 57]; [144, pp. 21, 24]; [145, pp. 21]; [146, pp. 19-29, 56]; [147, pp. 19-29] (author's personal contribution at least 80%).

4. Study of the method of hybrid approach selection in the treatment of extended occlusions of lower limb arteries [138, pp. 20-31, 56, 57]; [139, pp. 19-29, 56, 57]; [140, pp. 21, 29]; [141, pp. 20-31, 56, 57]; [142, pp. 21]; [143, pp. 21]; [146, pp. 19-29, 56]; [147, pp. 19-29]; [148, pp. 19-29]; [150, pp. 14, 20]; [152, pp. 14, 16]; [153, pp. 14]; [154, pp. 17, 59]; [155, pp. 17, 19]; [156, pp. 17]; [157, pp. 17] (author's personal contribution not less than 80%).

5. Study of comparative retrospective analysis of the results of hybrid interventions and femoral-tibial bypass for extended multilevel lesions of the infrainguinal arterial segment [127, pp. 33]; [128, pp. 33]; [138, pp. 20-31, 56, 57]; [139, pp. 19-29, 56, 57]; [148, pp. 19-29] (author's personal contribution at least 80%).

6. Study of the advantage of hybrid revascularization technique [127, pp. 33]; [128, pp. 33]; [138, pp. 20-31, 56, 57]; [139, pp. 19-29, 56, 57]; [146, pp. 19-29, 56]; [147, pp. 19-29]; [148, pp. 19-29]; [149, pp. 16]; [151, pp. 14] (author's personal contribution at least 80%).

7. Study of the implementation of access through the lateral branch of the conduit [127, pp. 33]; [128, pp. 33]; [138, pp. 20-31, 56, 57]; [139, pp. 19-29, 56, 57]; [146, pp. 19-29, 56]; [147, pp. 19-29]; [148, pp. 19-29] (author's personal contribution at least 80%).

Provisions to be defended

1. The most effective approach to complete rehabilitation of patients with extended occlusion of SFA combined with outflow pathway lesions in CLTI is a hybrid method of revascularization combining open arterial reconstruction with endovascular manipulations. High efficiency of the method is determined by the multimodal approach with cumulation of advantages of open and endovascular methods.

2. The elaborated algorithms for planning hybrid surgical interventions reliably improve the immediate results of lower limb revascularization in extended occlusion of SFA combined with outflow artery lesions in CLTI and save the limb in the early and distant postoperative period.

Compliance of the dissertation to the academic profession

The dissertation work corresponds to the scientific specialty 3.1.15 - «Cardiovascular surgery», in particular, paragraph 7 «Surgical, including endovascular, treatment of heart diseases, arterial, venous and lymphatic systems» and paragraph 8 «Prevention, diagnosis and treatment of complications of surgical, including endovascular, methods of treatment of heart diseases, arterial, venous and lymphatic systems».

Structure and scope of the dissertation

The dissertation is presented in 86 pages of the typewritten text, consists of an introduction, 4 chapters, conclusion, conclusions, practical recommendations and list of literature, which includes 165 sources, including 44 domestic and 121 foreign. The dissertation is illustrated with 4 tables, 8 figures.

1. MODERN METHODS OF THE REVASCULARIZATION OF THE LOWER LIMBS IN CHRONIC LIMB THREATENING ISCHEMIA (LITERATURE REVIEW)

According to the international estimates of peripheral artery disease (PAD) suffer more than 200 million people worldwide with an estimated annual incidence of between 220 and 3500 cases per million people [63, 70, 117]. This condition is rarely seen in young people, but its prevalence increases significantly with age: more than 10% of people over 65 years old suffer from PAD, and among people over 80 years old the figure reaches 29.4% [9, 15, 53, 117]. These rates are expected to increase as increasing life expectancy and declining fertility rates lead to an aging world population [53, 107, 117]. Chronic limb threatening ischemia (CLTI), also known as critical lower limb ischemia (CLI), affects about 10% of patients with PAD and can be considered the most severe form of it, associated with a reduced quality of life and a decreased quality of life. It is considered the most severe form, associated with reduced quality of life, a high risk of amputation and cardiovascular events, including death [48, 60, 63, 68, 69, 70, 82]. Current approaches to the definition and staging of CLTI have been developed to more accurately reflect the wide range of diseases encountered in modern clinical practice [30, 53]. For this reason, the term "CLTI" seems to be preferable to "CLI", as the latter refers exclusively to critical perfusion disorders, whereas the new term covers the entire range of ischemic disorders, allowing for a more flexible approach to patient assessment and treatment [30, 152]. CLTI is a clinical syndrome defined as the presence of PAD combined with pain at rest, gangrene or ulceration of the lower limb that does not heal for more than 2 weeks [30, 150 - 153]. Patients with CLTI are at risk for two significant outcomes. First, reduced blood flow to the lower extremity increases the incidence of amputation without adequate vascular reconstructive therapy. Second, the presence of CLTI indicates a systemic atherosclerotic burden [63, 87, 88, 90].

1.1 General and private epidemiology of chronic limb threatening ischemia

According to recent reports, the annual incidence of CLTI in Europe and the United States ranges from 50 to 100 new cases per 100,000 people (0.05 to 0.1%) [2, 70, 93]. Among US adults aged ≥40 years, the prevalence of CLTI is estimated to range from 0.3% to 2.0%, with a mean estimate of 1.28% [42]. According to the data of the national health insurance program in the USA for persons 65 years and older (Medicare), the prevalence of CLTI ranges from 0.23 to 0.32%, and the incidence ranges from 0.20 to 0.26% [85, 86, 89]. Thus, O. Baser et al. (2013) estimated the incidence of CLTI for the period from January 2007 to December 2008 at 200 cases per 100,000 persons per year in the U.S. population aged ≥65 years based on Medicare data. The prevalence and incidence of CLTI were 0.23 and 0.20%, respectively [14]. Similar to the prevalence, the incidence increased dramatically among patients aged 65 to 69 years (0.13 %) to 85 years and older (0.31 %) [14]. At the same time, M. Kwong et al. (2023) determined the estimated annual incidence and estimated 2-year prevalence for the period from January 1, 2017 to December 31, 2018 according to Medicare data to be 0.33 and 0.74 %, respectively [70, 91]. On the other hand, the Oxford Vascular Study evaluating the incidence of CLTI in Oxfordshire (UK) revealed 22 cases per 100,000 people per year in age groups < 65 years with a sharp increase among the elderly: 67 cases in the age group 65-74 years, 168 cases in the age group 75-84 years, and 171 cases in the age group ≥ 85 years [100]. In Russia, no randomized studies have been conducted, but according to some authors, the incidence of CLTI is registered from 100 to 120 cases per 100,000 people [130-133, 149, 152].

Although patients with CLTI represents only about 10% of the total number of patients with PAD, their mortality rate remains high. Within the first 6 months after diagnosis, the mortality rate can be as high as 20%, and within 5 and 10 years it can be approximately 50% and 70%, respectively [4, 93, 108].

In the BASIL (Bypass versus Angioplasty in Severe Ischaemia of the Leg) study, 1- and 3-year amputation-free survival rates were 70 and 55%, respectively, in the overall group of participants with CLTI, with mortality rates of approximately 20% at one year [4, 21, 22, 23]. According to the Italian CLIMATE (Chronic Limb-threatening Ischemia Mortality At short-medium Term and Sex) registry, including 2399 patients treated for CLTI between January 1 and December 31, 2019, an overall mortality rate of 3.1% at 30 days and 13.5% at 1 year was recorded [82].

In addition, patients with CLTI have been found to have a higher rate of hospitalization and a higher risk of amputation than patients with milder forms of PAD [52]. Thus, the development of CLTI is associated with a 200-fold increased risk of amputation and a 3-fold increased risk of mortality, emphasizing the paramount importance of preventing deterioration of the condition [8]. Excess mortality in patients with CLTI may be associated with systemic cardiovascular disease (CVD), including coronary heart disease (CHD) and cerebrovascular disease [114]. In addition, CLTI is associated with peripheral complications such as gangrene, infectious disease, and a high risk of lower limb amputation estimated in 10-40% of patients after 6 months, especially in high-risk patients [2, 93], and up to 95% of patients may lose a limb after 1 year [122]. By 2050, the number of patients undergoing amputation is expected to more than double from 1.6 to 3.6 million people [74].

According to the Intercommunity Consensus on the Management of Peripheral Arterial Disease (TASC II), CLTI is defined by the presence of chronic rest pain and/or ischemic skin lesions, ulcers, or gangrene [93]. CLTI is also confirmed by imaging and/or laboratory tests. The term should only be used in patients with chronic ischemic rest pain when symptoms have been present for more than 2 weeks and should be differentiated from acute ischemia [93, 124]. Usually, impaired peripheral perfusion implies a chronic course that may last months or years depending on age, predisposing and cardiovascular risk factors such as smoking, diabetes, hypertension, dyslipidemia, chronic kidney disease, hypercoagulability states and hyperhomocysteinemia [109, 114]. Other risk factors include obesity, physical inactivity, older age and family history of CVD.

1.2 Pathogenesis of chronic limb threatening ischemia

The basis of CLTI pathogenesis is progressive damage to the arterial bed of such a degree of severity that the compensatory mechanisms (hemodynamic and metabolic) are unable to prevent fall-induced perfusion pressure inhibition and circulatory hypoxia of tissues of distal extremity sections [124, 154, 157)]. Such pathophysiological shifts can be caused by an extensive obliterating process in the arterial channel of the limb, usually having the character of diffuse or multi-level lesions. Despite the fact that the steno-occlusion process in the main arteries is the fundamental link of pathogenesis, the fall of perfusion pressure triggers a cascade of local microcirculation disorders that are involved in the formation of the pathological circle [124, 154-157].

The CLTI is usually the result of a multisegmental PAD with impaired blood flow in peripheral tissues. In some cases, the simultaneous presence of a cardiac discharge disorder may worsen peripheral perfusion in patients with CLTI. Decreased oxygenation and nutrition of peripheral tissues can lead to pain or numbness at rest. In addition, patients with CLTI may experience intermittent claudication, which is a cramping pain in the leg, arising during physical activity and decreasing in rest [114].

The diagnosis of CLTI should be confirmed by the results of the determination of blood pressure (BP) of the tibial, ankle and brachial index (ABI), finger systolic pressure or percutaneous oxygen pressure (TcPO2) [85]. CLTI is considered in the case of ischemic pain at rest at an ankle pressure of less than 50mm Hg. or a finger pressure of less than 30mm Hg. as well as in patients with ulcers or gangrene at the ankle pressure equal to or less than 70 mm Hg. or with a finger systolic pressure equal to or less than 50 mm Hg. [124].

If necessary, these data can be supplemented by magnetic resonance imaging (MRI), computed tomography (CT) and aortoarthrography [85, 137].

Among patients with CLTI, a subgroup of asymptomatic patients should also be considered. These are usually sedentary or diabetic (DM) patients with peripheral neuropathy with reduced pain perception. Neuropathy can mask the clinical pattern of critical ischemia [46]. In these patients, CLTI is determined in the case of long-term persistent ulcers against the background of occlusive artery disease.

Occlusive atherosclerotic alterations or changes in lower limb arteries in patients with CLTI are mostly multi-level and are typically found in the femoral segment and tibial arteries [27, 101, 138, 139, 155]. Such patients are the most difficult group to treat due to the lack of adequate outflow routes. Hemodynamically significant lesions of the superficial femoral artery (SFA) are reported in more than half of patients with CLTI [119, 138, 139, 146, 147], often represented by extended occlusion of SFA and in a significant proportion of patients combine with severe steno-occlusive alterations of tibial arteries [19, 22]. In addition, in patients with ischemic limb necrosis, long occlusion of the femoral-popliteal segment is often accompanied by severe damage to the drainage channels, with occlusion rates of all three tibial arteries reaching 40% [18, 94]. Occlusive atherosclerotic lesion of SFA and tibial arteries of different severity have 32-61% of patients [130, 138, 146-148].

1.2.1 Anatomical features of the superficial femoral artery

The femoral artery is a large vessel carrying oxygenated blood to the lower limb structures and partially to the anterior abdominal wall [110]. The femoral artery is of clinical importance as it is a frequent site of complications of PAD [44].

The superficial femoral artery (SFA), traditionally grouped together with the popliteal artery as the femoral-popliteal segment, is the most frequent localization of peripheral arterial lesions and accounts for about 70% [102]. Despite relatively low mortality, SFA lesions are accompanied by high morbidity and require a significant level of technical difficulty for repair. Prompt diagnosis and timely treatment are key factors for a successful outcome, along with the main objectives of minimizing ischemia time, restoring limb perfusion, ensuring limb salvage, and starting rehabilitation as early as possible [102, 150].

Atherosclerotic disease of SFA is considered to have a high risk of diffuse spread, frequent calcification, large number of plaques, and high rate of progression to complete occlusion of SFA [64, 138, 146, 147]. In addition, the popliteal-femoral segment is subjected to significant flexion, bending, and compression forces. Consequently, unique anatomical features, along with unfavorable atherosclerotic plaques characteristic of this region, contribute significantly to the management of peripheral arterial lesions. In addition to the differences in anatomy and manifestation of pathology in the SFA region, there are also many unique features in presentation and diagnosis. These, in combination with downstream blood supply areas at risk, can manifest with pain on exertion, at rest, and/or non-healing ulcers extending anywhere from the thigh to the foot region.

In cases when the SFA is chronically occluded, extensive collaterals may be present between the deep femoral artery (DFA) and, because of this, distal blood flow is more robust. Thus, the tactics of lower limb revascularization in CLTI caused by extended occlusion of SFA is determined by the degree, localization and intensity of stenosis and calcification [5].

1.3 Treatment methods for chronic limb threatening ischemia

To date, the treatment of CLTI remains one of the serious problems in modern vascular surgery, as there remains a high risk of lower limb amputation and high mortality of patients after it [135, 42]. According to the National

Guidelines for the Diagnosis and Treatment of Lower Extremity Arterial Disease (2019), revascularization is recommended whenever possible to preserve the limb [124].

Effective revascularization is the cornerstone for limb preservation in patients with CLTI [124]. Revascularizations reduce the incidence of amputations and are economically justified. The surgical treatments for patients with CLTI are direct revascularization techniques: endovascular revascularization, open surgery, and hybrid reconstruction [30-32, 79, 98, 116, 138-148].

The European Society of Vascular and Endovascular Surgeons (ESVES) has developed the concept of an integrated stepwise PLAN (Patient risk estimation, Limb staging, Anatomic pattern of disease) approach for objective justification of revascularization. This approach includes three key components: patient risk assessment, limb staging, and anatomic pattern of disease (and coduite accessibility) [124]. The components of each of these three dimensions are respectively: the VQI (Vascular Quality Initiative) prediction model to determine the overall risk to the patient [118], the WIfI Society for Vascular Surgery classification system based on the assessment of wound, ischemia and infection [26], and the Global Limb Anatomic Staging System (GLASS) to identify different anatomical patterns of disease and associated chances of revascularization success [121].

The PLAN concept, aimed at supporting clinical decision making, justifying revascularization, and conducting research on evidence-based revascularization (Figure 1), represents a significant step forward.

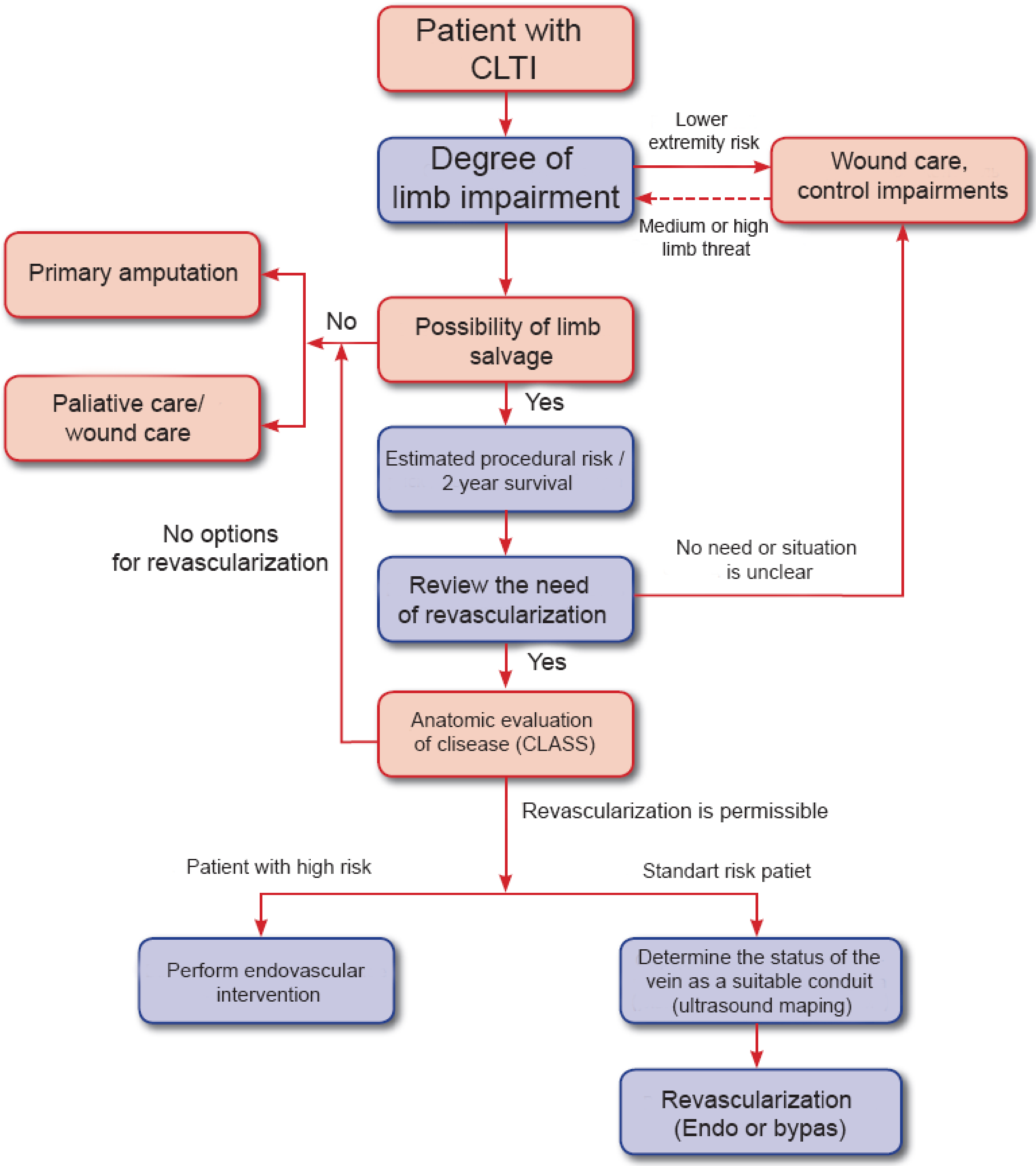

Figure 1 - The PLAN concept for clinical decision making for CLTI; infrainguinal lesion. Algorithm for selecting the preferred revascularization strategy in standard-risk patients with an available conduit based on the assessment of limb lesion extent and anatomical complexity [124].

However, despite the existing recommendations and concepts, there are still issues that need to be discussed on a case-by-case basis. For example, angiosurgeons and endovascular surgeons should jointly consider all possible revascularization options for each patient. The choice between surgery and endovascular therapy as the primary treatment modality can vary considerably among specialists and depends on many factors. These include the nature of the arterial lesion in the patient, surgical risks, the availability of an autogenous venous bypass conduit, the patient's own preferences, as well as the physician's qualifications, professional skills, and personal preferences in choosing the treatment method [43, 79].

1.3.1 Endovascular and surgical treatment

1.3.1.1 Endovascular approach

Endovascular surgery remains a young direction and is increasingly used in the treatment of obliterating diseases of the lower extremity arteries [180, 135]. The introduction of the new generation of stents and drug-coated balloons, devices for atherectomy and venous arterialization has led to a steady increase in the success rate of endovascular interventions, given their advantages, providing better short-term results with less use of resources [80]. The most common endovascular procedures for lower limb arterial pathology, which allow blood flow to be restored through the vessels without an open operation, are balloon angioplasty and stenting of lower limb arteries. Endovascular revascularization of lower limb arteries is a continuously developing area and is therefore increasingly used in many patients as a less invasive treatment of lower limb arterial diseases, providing comparable direct and immediate results compared to conventional or traditional surgical treatment [126]. Technological improvements in the equipment used for endovascular revascularization have expanded the possibilities of treating complex lesions previously treated with exclusively open surgical procedure [112]. According to the published data, the frequency of endovascular interventions in patients with peripheral artery occlusion in the lower limbs in the Russian Federation for 2012 was from 21.3 to 25.6% [125].

There is increasing evidence of high efficacy of endovascular revascularization treatment in patients with CLTI. The main advantages of endovascular methods over the open ones are considered their minimally invasiveness, the ability to perform under local anesthesia, use in patients with severe concomitant pathology, reduction of patient stay in hospital and lower use of resources [30-32, 80, 116, 134, 144, 158]. Also, the advantage of the endovascular technique of revascularization is the possibility of its repeated execution and reduction of the frequency of postoperative complications [21, 22, 23].

However, endovascular treatment with CLTI has a number of drawbacks. According to the BASIL study, the incidence of technical or early clinical failures in endovascular interventions reaches 27% [21], and the incidence of stent-related complications, according to various data, varies from 1.6 to 20% [77, 135]. The main complications are considered: stent displacement; migration or embolization of stent; acute stent thrombosis; risk of developing infectious disease; arterial spasm associated with intervention; formation of hematoma, false aneurysm or arteriovenous fistula; Intimate dissection; vascular perforation; lateral branch occlusion; allergic reaction to contrast; development of transient renal failure caused by contrast [112, 158].

The most common complication in the long-term post-surgical period of endovascular intervention is restenosis of the reconstruction zone, which develops in 18-40% of cases and can lead to the development of thrombosis and increase the risk of limb loss up to 20-25% [83, 90, 120, 136, 163]. The development mechanism of restenosis is very complex, in some cases, drug-coated stents can induce local inflammation and even lead to late thromboses due to hypersensitivity reactions. There is also an increased risk of high amputation after 6 months in patients performing endovascular interventions compared to the group performing direct surgery [80].

Currently there are recommendations to perform endovascular operations on the lower limb arteries, which are regulated by TASC II [79]. In case of ineffectiveness of endovascular treatment open revascularization is considered [105]. As the frequency of endovascular operations increases, the frequency of complications increases, both in the near and in the distant post-operative periods, requiring repeated surgical interventions, the technique of which can be significantly more traumatic.

1.3.1.2 Surgical approach

The leading role in the common atherosclerotic lesion of the lower limb arteries, occupy various methods of open surgery. The most widely used methods of artery reconstruction are bypass surgery and prosthetics (using autologous or synthetic prostheses), as well as various methods of endarterectomy from affected arterial segments [78, 130-133]. All these procedures are aimed at restoring the permeability of arteries, improving blood supply to the lower extremities and preventing the development of complications.

One of the features of the open surgical methods of treatment of CLTI is the low tolerance of tissues of the ischemic limb to surgical trauma, and as a consequence, a high risk of early postoperative complications and a long rehabilitation period [161]. The main advantages of an open surgical operation are considered to be: a longer patency or permeability of bypass and a high percentage of technical success; no exposure to X-ray radiation and the possibility of performing a hybrid operation [135, 138, 146-148]. According to the data of the completed BASIL study, open reconstructive surgeries in the treatment of CLTI patients have an advantage over endovascular interventions in terms of limb preservation for more than 2 years [21-23]. However, it should be noted that open reconstructive surgeries in already developed CLTI are technically difficult, and in 30-40% of patients with distal lesions are practically impossible. It should also be noted that most patients often have severe concomitant pathology, accompanied by an increased risk of anesthesia and surgery, which limits the use of open surgery. In addition, there is often no suitable autovenous material, and the use of a synthetic prosthesis is associated with risk of infection and a shorter permeability of the bypass. Also, open reconstructive surgeries require a long execution time and the need for regional or general anesthesia [135].

When analyzing the data from multiple randomized controlled trials, the Society of Vascular Surgery (SVS) presented the results of open revascularizations in critical ischemia: total perioperative mortality was 2,7%, myocardial infarction fatality rate - 6.2%, bypass thrombosis in early postoperative period - about 5%, estimated amputation rate - 2%, limb preservation within 1 year - 88%, amputation - free survival - more than 75% [29, 31, 32].

It is worth noting that over the past two decades, open reconstructive surgeries have become more secure. In the United States, mortality after surgical bypass surgery decreased from 7% to 4% from the 1980's until the mid-1990's. From 1998 to 2003, mortality in open and combined procedures stabilized at 3-4% [105]. Data from the National Inpatient Survey comparing the outcomes in 1998 and 2007 show's a significant decrease in the frequency of complications in all categories.

1.3.1.3 Comparison of endovascular and surgical approaches

A. Farber et al. (2022) conducted the international randomized BEST-CLI (Best Endovascular versus Best Surgical Therapy in Patients with CLTI) trial to determine whether endovascular revascularization is superior to surgical revascularization in patients with CLTI caused by infrainguinal peripheral artery lesions who were deemed suitable candidates for both approaches. As part of the study, patients were included in one of two parallel cohort trials according to pre-randomization duplex ultrasonography of the right and left great saphenous veins. Patients in whom a single segment of the great saphenous vein was available for use in surgery were included in cohort 1. Those requiring an alternative bypass were included in cohort 2. The primary outcome assessed was the composite of serious adverse limb events, including amputation above the ankle or significant reintervention (new bypass, graft revision, thrombectomy, or thrombolysis), and death from any cause. In cohort 1, after a median follow-up of 2.7 years, the primary initial event occurred in 302 of 709 patients (42.6%) in the surgical group and in 408 of 711 patients (57.4%) in the endovascular group (hazard ratio (HR) 0.68; 95% confidence interval (CI) 0.59-0.79; $P < 0.001$). In cohort 2, the primary initial event occurred in 83 of 194 patients (42.8%) in the surgical group and in 95 of 199 patients (47.7%) in the endovascular group (HR 0.79; 95% CI 0.58 to 1.06; P = 0.12) after a median follow-up of 1.6 years. The incidence of adverse events was similar in the two groups in the two cohorts. The study authors concluded that in patients with CLTI, surgical revascularization was associated with a lower risk of serious adverse limb events or death (by 32%) compared with an endovascular strategy, provided a single segment of the great saphenous vein suitable for use as a conduit was available (cohort 1). In cohort 2 of 396 patients who did not have an optimal single-segment great saphenous vein for bypass, outcomes were similar between treatment groups with no significant differences between surgical and endovascular approaches [43].

In contrast, in the randomized controlled BASIL-1 (Bypass vs Angioplastic in Severe Ischemia of the Leg) trial, which compared endovascular treatment and bypass surgery in 452 patients, the investigators found no significant difference between the groups in terms of amputation-free survival and overall survival. However, for approximately 70% of patients who survived 2 years or more, the HR for overall survival (0.65; P = 0.009) and amputation-free survival rates (0.85; P = 0.108) were better among those who initially received bypass surgery [4].

In contrast, in the BASIL-2 (Bypass vs Angioplasty for Severe Ischaemia of the Leg) study, after a median follow-up period of 40 (interquartile range: 20.9-60.6) months, serious amputation or death occurred in 108 of 172 (63%) and 92 of 173 (53%) patients who underwent venous bypass or endovascular treatment, respectively (HR 1.35; 95% CI 1.02 to 1.80; P = .037). Thus, it was concluded that in patients with CLTI who required a subcutaneous (with/without additional more proximal infrainguinal) revascularization procedure to restore limb perfusion, the vein first bypass strategy resulted in a 35% increased relative risk of major amputation or death from any cause compared with the best revascularization strategy with first endovascular therapy. The better endovascular treatment strategy of first revascularization was associated with better amputation-free survival, which was largely due to fewer deaths in the better endovascular treatment group [20].

Thus, the conflicting results of the mentioned studies should be interpreted with caution, considering the potential limitations of each study as well as other factors that may affect the results, such as differences in methods, patient sampling, and clinical settings. In addition, these circumstances reinforce the need to use hybrid surgeries that combine the advantages of open and endovascular techniques, allowing treatment to be tailored to individual patient characteristics and the complex structure of vascular lesions.

1.3.2 Hybrid method

For many years open surgery was considered as the «golden standard» for the treatment of patients with the clinical presentation of CLTI. With the advent of endovascular surgery, these two methods were constantly opposed to each other [69, 74, 138-140, 146-148]. There is still debate about whether to use a surgical or endovascular approach, given the lack of current comparative data and mixed results from observational studies [60, 80]. It is important to note that both approaches have their advantages and disadvantages in this regard, in recent times there are more and more frequent reports about the desire to find the best strategies to improve the effectiveness of surgical treatment for patients, suffering from CLTI, which led in practice to the merger of open and endovascular reconstructions [39, 56, 96, 162].

Such combinations of technically different interventions are referred to as hybrid surgeries. Hybrid surgery ensures the success of treatment in conditions where the use of only one of the methods of revascularization fails to achieve the proper effect and also significantly expands the possibilities of surgical treatment. In the case of multilevel lesions of lower limb arteries, combined operations consisting in the simultaneous use of open arterial reconstructive operations with endovascular procedures (stenting, balloon angioplasty, etc.) were more often performed. [105, 161, 165]. Data on the combined use of open and endovascular surgery in patients with CLTI were first published in 1973 by J.M. Porter. He reported a balloon angioplasty of the iliac artery with simultaneous femoral - femoral crossover bypass [97].

Hybrid surgery is used, as a rule, for patients at high surgical risk, with severe concomitant pathology in multilevel atherosclerotic lesions, but it should be borne in mind that in the presence of stage IV limb ischemia, DM and chronic renal failure, may adversely affect the long-term patency of the reconstruction zones.

Hybrid surgery should be performed in X-ray or specially equipped hybrid operating rooms, where conditions are provided for simultaneous performance of endovascular and open intervention with subsequent angiographic control [129, 165]. The endovascular and open stage of the procedure can be performed simultaneously or sequentially [105]. However, in most cases, the open stage is initially performed, followed by the endovascular stage. In this order, control angiography of the area of vascular reconstruction is possible [165].

Hybrid revascularization is a rather promising and young direction in the treatment of CLTI and according to different sources from 5 to 21% of operations on arterial vessels of the lower extremities in foreign clinics [33, 34]. The results of hybrid surgery are comparable to staged operative and percutaneous revascularization in multilevel arterial occlusive disease, although large-scale systematic studies have not been conducted [55]. Hybrid procedures allow patients at high risk of complete conventional surgical reconstruction to undergo long-term revascularization with a less extensive operative procedure, shorter operative duration, and reduced overall surgical risk with improved immediate and long-term outcomes [165, 138]. For patients with CLTI, limb preservation rates after hybrid revascularization range from 80 to 100% [105, 161]. The technical success of hybrid interventions in the treatment of patients with CLTI is 90-100 % [161], clinical improvement is 92-98 %. However, the long-term results are different from one author to another. Some report that the long-term results of such operations are comparable to those of endovascular and open reconstructions [38]. Others, on the contrary, claim that in the long-term period there is a large amount of thrombosis of the reconstruction zones [159, 164].

There is an opinion that when combining endovascular and open techniques in one patient, the risk of restenosis and occlusions of reconstruction in the long-term postoperative period is much higher than after standard open surgery [160].

Nevertheless, the popularity of hybrid interventions continues to grow, as they allow simultaneous use of the advantages of both techniques, which becomes especially relevant in complex multilevel arterial lesions. The increasing number of such surgeries demonstrates the need for a comprehensive approach to revascularization, especially in patients with a high risk of complications.

1.4 Methods of lower limb revascularization in chronic limb threatening ischemia caused by extended occlusion of the superficial femoral artery

The traditional method of lower limb revascularization in CLTI caused by extended occlusion of the SFA with a passable popliteal artery (PopA) and severe lesions of the tibial arteries is femoral-tibial bypass (FTB). There is also a hybrid approach to the treatment of such lesions, which consists in performing femoral-popliteal bypass (FPB) followed by endovascular reconstruction of the arteries below the knee joint fissure. This approach combines the well-established advantages of open vascular surgery with those of less invasive endovascular interventions, providing a reliable and safe solution that can be adapted to individual disease characteristics.

According to their long-term results, endovascular interventions in extended occlusions of SFA with severe outflow tract lesions are inferior to autovenous infrainguinal bypass [6, 34, 57, 75], which remains the preferred method of correction of multilevel lesions of the infrainguinal segment with involvement of a significant part of the SFA length [1]. In some cases, the presence of occlusive changes in the tibial arteries in such patients requires the surgeon to form a lower anastomosis with a more distal part of the vascular bed, which, according to large studies, is associated with a higher incidence of early complications, such as bypass thrombosis and high limb amputation [18, 86]. A widespread approach to the treatment of occlusive lesions of the tibial arteries is balloon angioplasty, which, although is inferior to bypass interventions in terms of long - term patency, according to some data is as effective for limb preservation [99].

Another potential advantage of endovascular treatment of infrapopliteal lesions is the possibility of accurate intraoperative assessment of blood supply features of the affected area of the foot in order to perform direct (angiosomal) revascularization [10], which, according to some data, improves the long-term efficacy of reconstructive interventions in CLTI [7, 58].

The complementary advantages of open and endovascular techniques in multilevel lesions of the infrainguinal arterial segment create prerequisites for the introduction of a hybrid approach to limb revascularization in such patients [33, 123, 127, 128]. In this case, to correct the occlusive lesion of the SFA, bypass intervention is performed, and endovascular intervention is performed to restore patency of outflow pathways at the level of the popliteal-plantar segment.

Endovascular correction of the aorto-iliac segment can be combined with various variants of distal channel correction, including cross femoral-femoral, femoral-popliteal bypass; endarterectomy from the femoral artery in combination with femoral-popliteal bypass (above or below the level of the knee joint fissure); cross femoral-popliteal bypass in combination with contralateral femoral-popliteal bypass (above or below the level of the knee joint fissure); femoral-distal bypass [130-133].

Open interventions such as endarterectomy, cross femoral-femoral and femoral-popliteal bypass are considered typical methods after endovascular correction of the aorto-iliac segment. It should be noted that cross femoral-femoral bypass has lower rates of 5-year secondary patency as compared to anatomic bypass [84].

At present, recommendations for hybrid operations in peripheral arterial diseases and description of clinical cases remain underdeveloped. The choice of treatment tactics continues to be largely determined by the experience of the vascular surgeon and his or her ability to apply both open and endovascular approaches. This lack of standardization emphasizes the need for clearer clinical guidelines for the optimal choice of treatment method depending on the individual characteristics of the patient and the nature of the vascular lesion.

2. MATERIALS AND METHODS

2.1 Research design

This single-center retrospective cohort study was conducted in accordance with the principles of the Declaration of Helsinki, registered and approved by the Ethical Committee of the St. Petersburg State Pediatric Medical University, protocol No. 2/10 of February 10, 2020. The work was carried out on the basis of St. Petersburg state budgetary health care institution, "City Hospital No. 14" "City limb salvage center".

Patients with obliterative atherosclerosis of lower limb vessels (OALLV) and CLTI who underwent open or hybrid reconstructive interventions on lower extremity arteries from January 2017 to March 2024 were included in the study. Exclusion criteria were:

(I) rest pain in the absence of trophic changes (chronic arterial insufficiency of grade 3 according to A.V. Pokrovsky);
(II) hemodynamically significant changes in the aorto-iliac segment or common femoral artery on the affected side;
(III) patients who underwent bypass to the popliteal artery without subsequent endovascular correction of outflow tracts;
(IV) patients who underwent any other open reconstructive intervention other than infrainguinal bypass (e.g., endarterectomy or thrombectomy);
(V) hybrid interventions in which femoral-tibial bypass was performed during the open reconstruction phase.

Thus, the inclusion/exclusion criteria were aimed at forming two groups of patients: (I) patients who underwent femoral-popliteal bypass with endovascular outflow tract correction and (II) patients who underwent femoral-tibial bypass.

The decision to perform surgical intervention was based on the presence of clinical signs of CLTI, instrumental data confirming the presence of occlusive changes in the infrainguinal segment, factors increasing the risk of perioperative complications, unchanged saphenous vein of sufficient diameter (for use as a conduit), and the patient's informed consent. The indications for one or another type of intervention (hybrid or open) were determined based on the general principles of lower limb revascularization, relevant to Russian and international recommendations. Patients with extended occlusion of the SFA (> 20 cm) and a functioning popliteal artery (PopA) underwent FPB with subsequent endovascular correction of outflow tracts. Patients with simultaneous occlusions of both SFA and PopA underwent FTB. Patients with short (< 20 cm) SFA lesions, as well as steno-occlusive PopA lesions not extending to the PopA trifurcation and to the distal segment of the SFA, were operated endovascularly and were not included in this study.

2.2 Patient groups and study parameters

The study included 2 groups of patients: patients who underwent distal hybrid interventions (DHI) and patients who underwent FTB. In the DHI group the first stage of treatment was FPB followed by endovascular correction of outflow tracts (main arteries of the popliteal - tibial segment).

Initial demographic, clinical parameters, preoperative angiography data were evaluated in both groups. The immediate (30-day mortality, postoperative complications, bypass thrombosis, postoperative bed days) and long-term (overall survival, limb preservation, primary bypass patency, freedom from repeated revascularizations, and healing rate of trophic defects after 12 months) results of interventions in the DHI and FTB groups were also considered. Due to the retrospective design of the study, the healing rate of trophic defects was evaluated only after 12 months and only for those patients whose status information was available at that time.

2.3 Pre-operative examination

Preoperative examination included an examination by a vascular surgeon and the required minimum of laboratory tests. The depth of trophic changes and the course of the wound process after necrectomy on the affected limb were evaluated, respectively, at admission and at discharge from the hospital. Methods of visualization of the limb arteries in patients in both groups included triplex scanning and direct subtraction angiography (DSA). Routine measurement of ankle/finger pressure and ankle/brachial index was not performed due to the fact that a large proportion of patients had significant calcification of the tibial arteries, gangrene or the condition after amputation of the 1st toe, and often there were no passable segments of the main arteries at the ankle level.

2.4 Bypass interventions

All open bypass interventions were performed under spinal anesthesia. Antiaggregant therapy before surgery included acetylsalicylic acid (ASA) at a dose of 100 mg/day. The great saphenous vein (GSV), which was isolated from separate incisions and irrigated with heparinized saline solution, was used as a conduit. The inflow and outflow arteries were isolated. Immediately before arterial clamping, heparin at a dose of 5000 IU was administered intravenously. In the DHI group the proximal anastomosis was formed with the common (CFA) or deep femoral artery (DFA). The distal anastomosis was created at the level of P1 or P3 segment of the PopA. In the FTB group, the proximal anastomosis was formed with the CFA, DFA, SFA or PopA, the distal one - with one of the tibial arteries (unstenosed, preferably anterior or posterior tibial). The autovenous conduit was implanted in a reversed or non-reversed position (in the latter case, a valvulotome was used). The choice of sites for anastomoses as well as the decision to reverse the bypass was made by the operating surgeon. After the vascular clamps were removed, the bypass function was manually monitored; in doubtful cases intraoperative triplex scanning was used. After hemostasis was achieved, the wounds were sutured layer by layer. On the first day after the operation the patients received low molecular weight heparin in a prophylactic dose (1 IU/kg once) to prevent venous thromboembolic complications. Further anticoagulant therapy was performed only in patients with chronic atrial fibrillation. Triplex scanning was performed in all patients on the 1st day after bypass to control the patency and function of the shunt.

2.5 Endovascular interventions

Endovascular interventions in the DHI group were performed after FPB, either on the same day, immediately after wound closure (simultaneous DHI), or several days later (two-stage DHI) (Fig. 2).

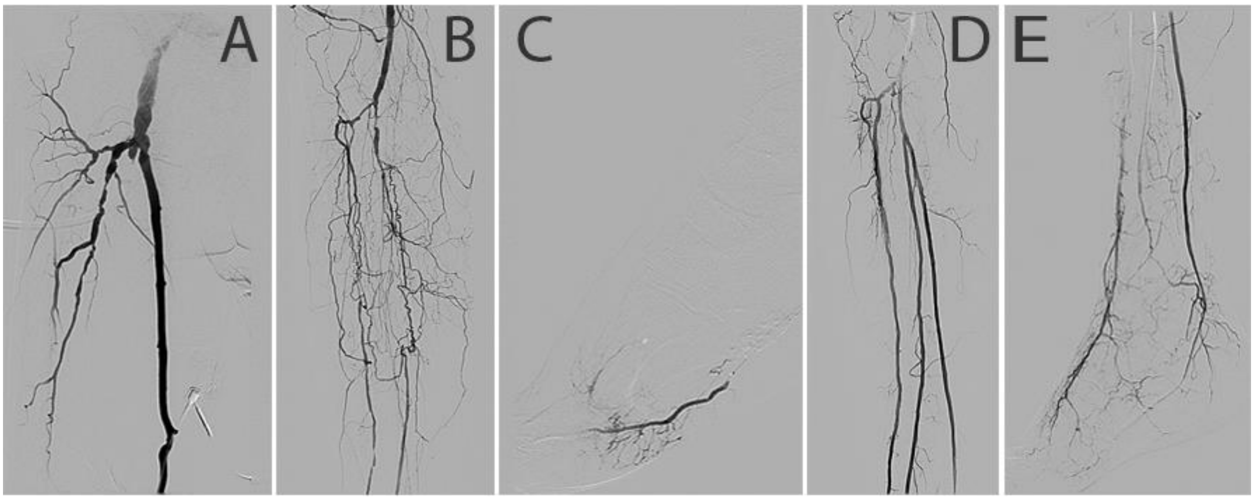

Figure 2: Example of simultaneous distal hybrid intervention performed in a 64-year-old patient with CLTI and profound trophic changes in the lateral plantar artery basin. (A) 6F introducer placed antegradely through the lateral branch of a functioning FPB; (B) selective direct angiography of the arteries of the popliteal-tibial segment performed through the introducer: occlusion of all three tibial arteries; (C) recanalization step of the posterior tibial artery: injection of contrast agent into the lateral plantar artery through the lumen of the balloon catheter; (D) final outcome of the endovascular intervention: all three tibial arteries are functional; (E) direct angiosomal revascularization of the foot.

A simultaneous approach was used when trophic changes on the affected limb were deep and rapidly progressive. Two-stage intervention was performed in patients with superficial and non-progressive necrotic changes. The time interval between FPB and endovascular correction of outflow tracts was 2-10 days. Before surgery, all patients received daily ASC at a dose of 100 mg/day. In simultaneous DHI patients received a loading dose of clopidogrel (300 mg) immediately after completion of the open stage of reconstruction in order to reduce possible blood loss during bypass surgery. In two-stage DHI, a loading dose of clopidogrel was administered immediately before the second (endovascular) stage of intervention. The antegrade femoral, contralateral femoral or lateral branch of the autovenous bypass was used as intravascular access.

The choice of access was made by the operating surgeon. Most often the 6F introducer was used. Before recanalization of the affected arterial segment the patient was injected intravenously with unfractionated heparin in the dose of 5000 IU. Recanalization of occlusive lesions in the popliteal segment was performed using a 0.035-inch diameter hydrophilic guide, and in the tibial segment - using a 0.014-inch diameter hydrophilic guide. After the guidewire exit into the true lumen distal to the occlusion, a balloon catheter was inserted into the lesion area along the guidewire (in some cases short balloon inflation was required to facilitate antegrade catheter advancement), then balloon angioplasty was performed at nominal pressure, the duration of angioplasty was 90 seconds after complete balloon deployment. If after the first balloon inflation the angiographic result was unsatisfactory (residual stenosis > 30% or hemodynamically significant dissection), a second inflation was performed at a pressure 2 atm higher than the nominal pressure for a duration of 120 sec. If residual stenosis/dissection persisted after that, a self-expandable stent without drug-coating (in the popliteal segment) or a balloon-expandable stent covered with paclitaxel (in the tibial segment) was implanted in the angioplasty zone.

The angioplasty strategy at the level of the tibial segment was to restore patency of as many tibial arteries as possible, giving preference to the artery supplying the affected angiosome. The choice of the balloon catheter diameter as well as the choice of the stent was made by the operating surgeon. No devices for intravascular atherectomy, thrombectomy, true lumen exit, and anti-embolic filters were used during the intervention. Triplex scanning was performed in all patients on the next day after the procedure in order to control the patency of the limb arteries in the area of intervention.

Duration of antiaggregant therapy (clopidogrel 75 mg/day + ASC 100 mg/day) after the operation was 6 months. Further the patients continued to take ASC at a dose of 100 mg/day.

2.6 Local treatment of trophic changes

All patients on admission were prescribed antibacterial therapy with broad-spectrum drugs followed by switching to narrower-spectrum drugs according to the results of wound discharge culture.

Antibacterial therapy was continued for 2 weeks or until the signs of active infection disappeared (if it was faster). Primary minor amputation/necrectomy for necrotic changes on the foot was performed either before revascularization (in the presence of significant inflammation) or a few days after it. After revascularization, patients underwent daily dressings with antiseptics, with mechanical necrectomy if necessary, until the wound (ulcer) defect on the foot was completely cleared of dead tissues. In isolated cases, vacuum therapy and closure of extensive wound/ulcer defects with a free perforated skin graft were used.

After discharge from the hospital, the patients continued to be treated by a surgeon in the outpatient clinic at the place of residence until the trophic defect was completely healed.

2.7 Follow-up and repeated interventions in the long-term post-operative period

Overall survival and limb preservation were assessed by telephone contact with the patients; data on repeat interventions were verified using an in-hospital database (most of the repeat interventions in the patients studied were performed in the same center).

The primary patency of the bypass was assessed by triplex scanning after 12 months. Due to the insufficiently high diagnostic significance of ultrasound examination to assess the state of the lumen of the tibial arteries, their patency in the long-term period was not evaluated. The indication for repeat revascularization was considered to be the recurrence of CLTI symptoms, including rest pain and/or necrotic changes on the lower limb with restenosis/occlusion of the limb arteries or bypass confirmed by instrumental methods. If the condition of the limb did not allow its preservation, patients underwent primary high amputation.

2.8 Main outcomes and investigated parameters

Chronic limb threatening ischemia with ischemic trophic changes was defined as a clinical syndrome including rest pain and necrosis of the limb tissues in the presence of steno-occlusive changes of the femoral-popliteal segment (lesion of more proximal segments was an exclusion criterion) confirmed by triplex scanning and direct contrast angiography. Routine ankle/toe pressure measurements were not performed (see paragraph 2.3). Trophic changes were classified as deep if tissue necrosis extended to bony structures, joints, muscles, or tendons of the foot. In other cases, trophic changes were classified as superficial.

The technical success of the intervention was defined as the absence of stenosis of 50% or more (in diameter) throughout the entire reconstruction zone. Overall survival was estimated as the inverse of the cumulative probability of death from any cause during the follow-up period. Limb preservation was estimated as the inverse of the accumulated probability of high amputation (amputation above the level of the ankle joint) during the follow-up period. Primary patency of the bypass - as an inverse indicator to the accumulated probability of bypass occlusion or formation of a significant stenosis somewhere along its length, determined by peak systolic velocity > 250 cm/s on the basis of triplex scanning data. Freedom from repeated revascularizations was defined as the inverse of the cumulative probability of repeated revascularization of the same arterial segment during the follow-up period.

When defining the affected angiosome of the foot we used the scheme of angiosomes published by Attinger C.E. et al. (2006) [10]: three angiosomes in the zone of blood supply of the posterior tibial artery (PTA); two angiosomes in the zone of blood supply of the peroneal artery; one angiosome in the zone of blood supply of the dorsalis pedis artery (DPA). Direct (angiosome) foot revascularization was defined as complete restoration of patency of the main artery supplying the affected angiosome. Revascularization of the affected angiosome through the plantar arterial arch (e.g., revascularization of the angiosome of the dorsum of the foot through the arterial arch from the lateral plantar artery, or revascularization of the toes through the plantar arch from the DPA) was also classified as direct.

2.9 Statistical analysis

Statistical analysis of the obtained data was performed using SPSS software (version 26; IBM) with the R extension (version 3.5.3; the R Foundation for Statistical Computing). When comparing groups, appropriate methods of descriptive statistics were used for each type of variable: number and percentage of observations for qualitative and ordinal variables; mean and standard deviation for quantitative (continuous) variables with normal distribution; median and interval for quantitative variables with non-normal distribution. The Shapiro-Wilk criterion was used to assess the normality of the distribution of quantitative variables.

Fisher's exact test was used to compare qualitative variables. Student's criterion for independent samples was used to compare quantitative variables with normal distribution. The Mann-Whitney criterion was used to assess the reliability of differences between variables with non-normal distribution.

The accumulated probability of reaching the end point was compared by the Kaplan-Meier method using the log-rank criterion to assess the level of statistical significance.

For all statistical criteria, a significance level of less than 0.05 was considered statistically significant.

3. RESULTS

Depending on the method of treatment, all patients were categorized into 2 groups: (I), a group of patients who underwent DHI, which included 80 patients (mean age 69.5±7.9 years) who underwent 80 interventions of this type; (II), a comparison group included 70 patients (mean age 69±11.2 years) who underwent 70 FTB. The groups were comparable in their baseline demographic and clinical characteristics (Figure 3, Table 1).

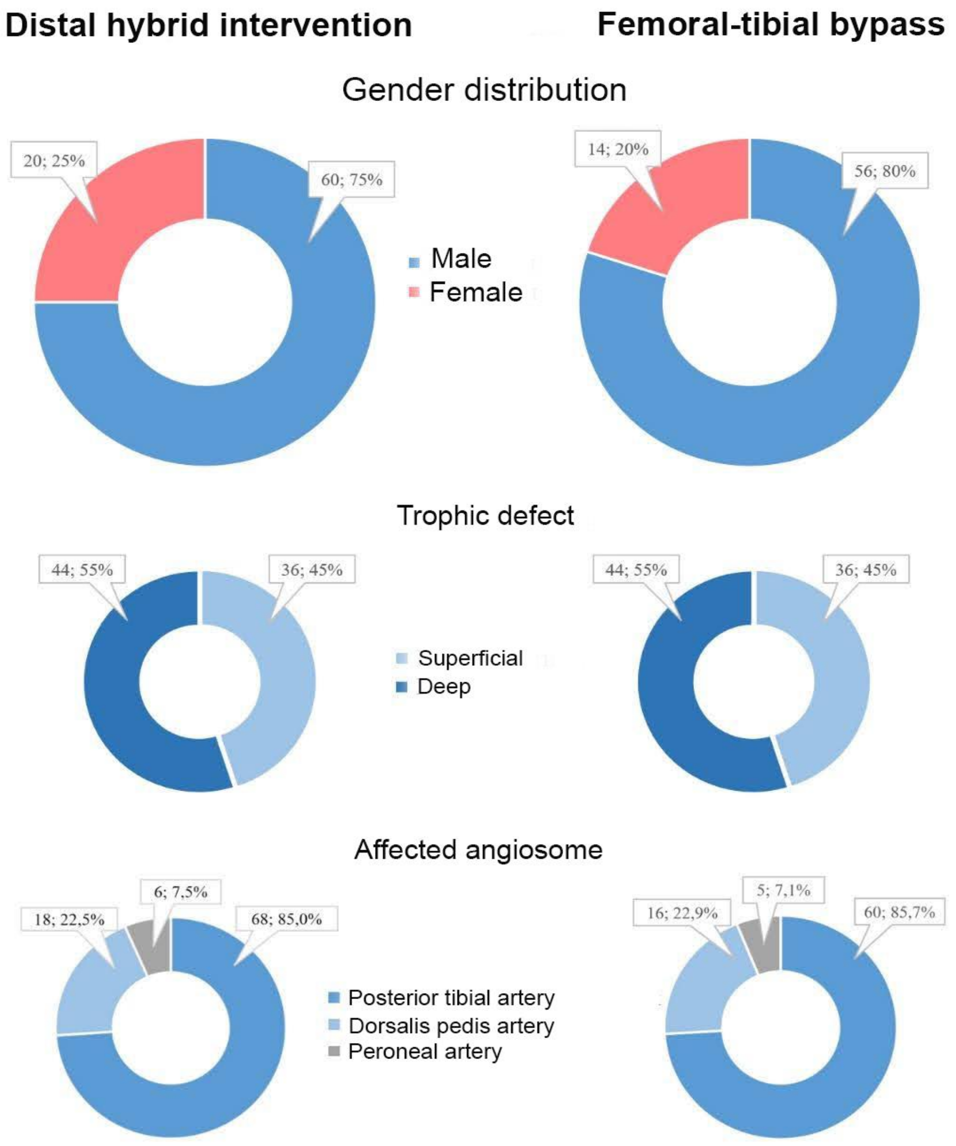

Figure 3 - Baseline demographic and clinical characteristics of patients.

Table 1: Baseline demographic and clinical characteristics of patients.

Indicator	DHI (n = 80)	FTB (n = 70)	P
Age, years	69.5 ± 7.9	69 ± 11.2	0.059
Male	60 (75.0)	56 (80.0)	0.783
Arterial hypertension	74 (92.5)	66 (94.3)	1.000
Hyperlipidemia	44 (55.0)	40 (57.1)	1.000
IHD	76 (95.0)	66 (94.3)	1.000
AMI in anamnesis	30 (37.5)	18 (25.7)	0.632
DM	38 (47.5)	20 (28.6)	0.104
Smoking	44 (55.0)	40 (57.1)	1.000
CKD	8 (10)	5 (10.8)	1.000
ACD in anamnesis	14 (17.5)	10 (14.2)	0.762
Trophic defect			
Superficial	36 (45)	38 (54.3)	0.491
Deep	44 (55)	32 (45.7)	
Affected Angiosome			
PTA	68 (85.0)	60 (85.7)	1.000
DPA	18 (22.5)	16 (22.9)	1.000
Peroneal artery	6 (7.5)	5 (7.1)	1.000

Note: DHI = distal hybrid intervention; FTB = femoral - tibial bypass; IHD = ischemic heart disease; AMI = acute myocardial infarction; DM = diabetes mellitus; CKD = chronic kidney disease; PTA = posterior tibial artery; DPA = dorsalis pedis artery.

The characteristics and frequency of concomitant diseases were, in our opinion, common for this category of patients. It is important to note that in a significant proportion of cases trophic changes in the tissues of the affected limb were deep and were mainly represented by necrosis of the toes, often spreading to the metatarsal area.

According to the preoperative angiography data (Table 2), in the DHI group the majority of patients had extended occlusion of SFA in combination with shuntable PopA and occlusion of 3 arteries of the lower extremity (65,0%), some patients had occlusion of 3 segments of PopA with passable 1,2 segments (22,5%), in a small number of cases - passable PopA and stenosis of peroneal artery as the only outflow pathway (12,5%). The proximal anastomosis was most often formed with the CFA and the distal one with the P1 segment of the PopA. About a half of hybrid interventions were two-stage.

Table 2. Preoperative angiography results and surgical features in the DHI group.

Characteristics	No. of patients (%)
Preoperative angiography	
DFA occlusion	6 (7.5)
Occlusion of P3 segment in PopA	18 (22.5)
Functioning and non-stenosis of PopA (in presence of)	
Occlusion of 3 main arteries in lower leg	52 (65.0)
Stenosis of PA as the only outflow artery	10 (12.5)
Features of operations	
Proximal anastomosis	
CFA	76 (95.0)
DFA	4 (5.0)
Distal anastomosis	
P1 PopA	76 (95.0)
P3 PopA	4 (5.0)
Shunt from unreversed GSV	62 (77.5)
Reversed GSV shunt	18 (22.5)

Continuation of table 2

Staging	
Simultaneous DHI	44 (55.0)
Two stage DHI	36 (45.0)
Endovascular access	
Contralateral femoral	38(47.5)
Lateral branch shunt	36 (45.0)
Antegrade femoral	6 (7.5)
BAP of PopA + 1-2 tibial arteries	18 (22.5)
BAP 1 tibial artery	30 (37.5)
BAP 2 tibial arteries	30 (37.5)
BAP 3 tibial arteries	2 (2.5)
Stent implantation*	6 (7.5)
Direct angiosomal revascularization	72 (90.0)

Note: DHI = distal hybrid intervention; DFA = Deep femoral artery; PA = peroneal artery; PopA = popliteal artery; CFA = common femoral artery; GSV = great saphenous vein; BAP = balloon angioplasty

* Stent was implanted in PopA in 4 patients, and in tibial artery in 2 patients.

During endovascular outflow tract correction, access through the lateral branch of the shunt was most often used in simultaneous operations. If the hybrid procedure was performed in two stages, the contralateral femoral access was used in most cases. The need for stent implantation was quite rare, immediate angiographic success was 100%, direct (angiosomal) revascularization was achieved in 90.0% of cases.

In patients in the FTB group, preoperative angiography most often revealed occlusion of the SFA and/or PopA (Table 3). Hybrid intervention was always started with an autovenous femoral-popliteal bypass. In approximately 2/3 of cases, a proximal anastomosis was formed with the CFA or SFA. The distal anastomosis was located at the level of the upper or middle third of the tibia, the rate of direct foot revascularization was 69.2% - significantly lower than in the DHI group (p = 0.006).

Table 3: Preoperative angiography results and surgical features in the FTB group.

Characteristics	No. of patients. (%)
DFA occlusion	4 (5.7)
SFA lesion	44 (62.9)
SFA Occlusion	70 (100.0)
PopA lesion	52 (74.3)
PopA Occlusion	70 (100.0)
Proximal anastomosis	
CFA	40 (57.1)
SFA	18 (25.7)
DFA	8 (11.4)
PopA (P1)	4 (5.7)
Distal anastomosis	
ATA/PTA	40 (57.1)
PA	30 (42.9)
Level of distal anastomosis	
Upper third of tibia	16 (22.9)
Middle third of tibia	46 (65.7)
Lower third of tibia	8 (11.4)
Reversed GSV shunt	22 (31.4)
Non reversed GSV shunt	48 (68.6)
Direct angiosomal revascularization	44 (62.9)

Note: FTB = femoral-tibial bypass; DFA = deep femoral artery; SFA = superficial femoral artery; PopA = popliteal artery; CFA = common femoral artery; PTA = posterior tibial artery; ATA = anterior tibial artery; PA = peroneal artery; GSV = great saphenous vein.

The indication for simultaneous intervention was considered to be deep and widespread necrosis of foot tissues, signs of "moistening" necrosis, inflammatory changes in blood analysis (leukocytosis, left shift of leukocytic formula) and/or fever.

There were no significant differences in the frequency of using an autovenous shunt in a non-reversed position between the DHI and FTB groups: this figure was 77.5% and 68.6%, respectively (p = 0.439).

The DHI and FTB groups did not differ in terms of immediate outcomes and early complications (Table 4), including the incidence of early shunt thrombosis and postoperative bed days.

Table 4: Immediate (30-day) results and complications in patients after DHI and FTB

Indicator	DHI (n = 80)	FTB (n = 70)	P
Mortality	2 (2.5)	4 (5.7)	0.596
High limb amputation	2 (2.5)	2 (2.9)	1.000
Bypass thrombosis	2 (2.5)	10 (14.3)	0.092
Tibial artery thrombosis after BAP	2 (2.5)	N/A	–
Complications in the endovascular access area	2 (2.5)	N/A	–
Post - operative bed days	23 (1-68)	17 (1-67)	0.165

Note: DHI = distal hybrid intervention; FTB = femoral-tibial bypass.

The only case of early thrombosis in the DHI group developed one week after the simultaneous hybrid intervention, which required high limb amputation. In two-stage reconstruction, despite severe lesions of the tibial arteries in all patients, there were no cases of early thrombosis of the infrainguinal shunt between the open and endovascular stages. Two patient’s (2.5%) had thrombosis of the tibial artery after balloon angioplasty with stenting. At the same time the bypass continued to function, the phenomena of critical ischemia were controlled. In this group of hybrid interventions only two (2.5%) early high amputation at the level of the upper third of the thigh was performed.

Ten (n = 10) cases of early bypass thrombosis were registered in the FTB group: successful endovascular thrombectomy was performed in 4 patients, repeated bypass surgery - 2, high limb amputation - 2, drug therapy - 2. All cases of early bypass thrombosis were reported in 1-7 days after open intervention. After 12 months (Figure 4), the DHI and FTB groups had comparable rates of overall survival (87.1 and 82.5%; p = 0.704), limb preservation (73.7 and 74.9%; p = 0.755), freedom from repeat revascularizations (96.0 and 82.0%; p = 0.162), and trophic defect healing rates (88.2 and 80.0%; p = 0.645), respectively. Primary patency was significantly higher in patients after DHI (80.8 %) compared to patients who underwent FTB (53.2 %), p = 0.041.

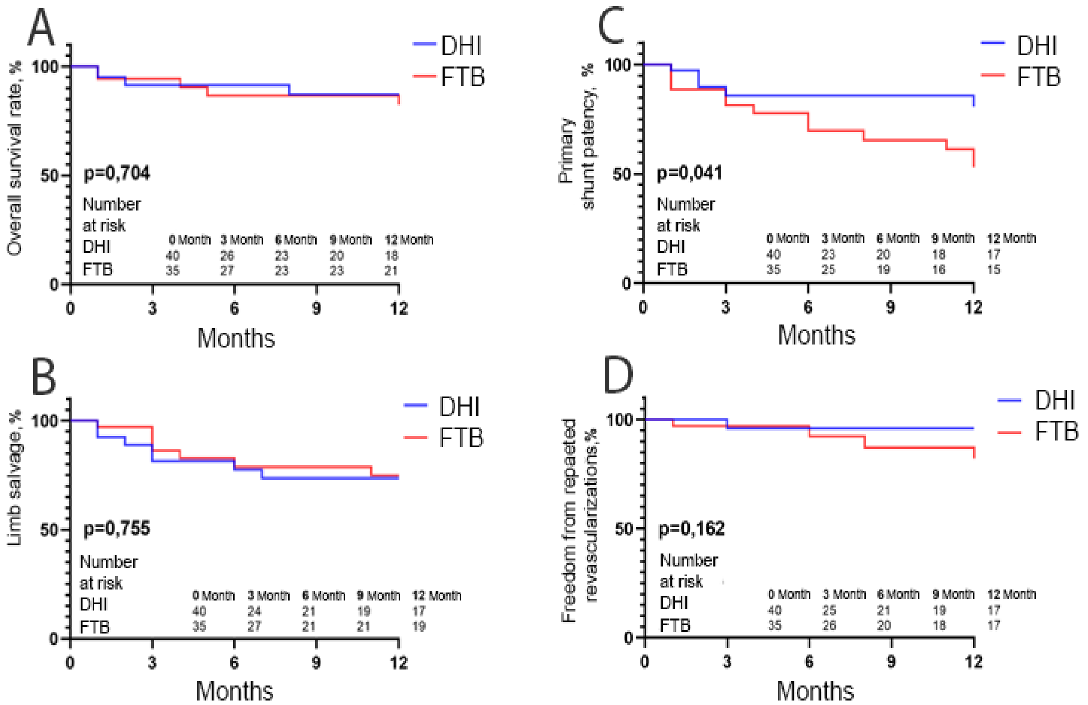

Figure 4: Overall survival (A), limb preservation (B), primary shunt patency (C), and freedom from repeat revascularization (D) at 12 months in the DHI and FTB groups. DHI, distal hybrid interventions; FTB, femoral-tibial bypass.

The proportion of tibial amputations among all high amputations performed during the follow-up period was 50.0% (8 of 16) and 28.6% (4 of 14) in the DHI and FTB groups, respectively ($p = 0.608$).

Amputation-free survival, primary patency of the shunt, and primary patency of the outflow arteries after BAP/stenting after 1 year were 82.1% (95% CI 66.8-97.4); 77.7% (95% CI 61.7-93.7); and 31.8% (95% CI 22.5-41.1), respectively. After 2 years, 75% (95% CI 66.3-83.7); 58% (95% CI 48.1-67.9); 25% (95% CI 16.3-33.7), respectively.

In the comparison group (femoral-tibial bypass), early mortality, incidence of early shunt thrombosis, amputation-free survival, and primary shunt patency after 1 year were 4.3% (95% CI 0-8.3); 13% (95% CI 6.1-19.9); 69.6% (95% CI 56.1-83.1); and 57.1% (95% CI 42.9-71.3), respectively. Thus, there were statistically non-significant differences in favor of the hybrid approach in all measures (Figure 5).

Example of a distal hybrid intervention performed in patient A., a 64-year-old male with CLTI (Rutherford grade 6). Results of preoperative angiography (Figure 6), Course of one-stage hybrid intervention with insertion of an intraducer through the lateral branch of the bypass anastomosis, selective angiography of the outflow vessels, successful recanalization of the posterior tibial artery and final outcome (Figure 7), Angiography results after 1.5 years showed occlusion of the deep femoral artery and functioning shunt, passable popliteal segment, reocclusion of the outflow vessels, collateral filling of the distal vessels of the tibia and healed foot with no evidence of CLTI (Figure 8).

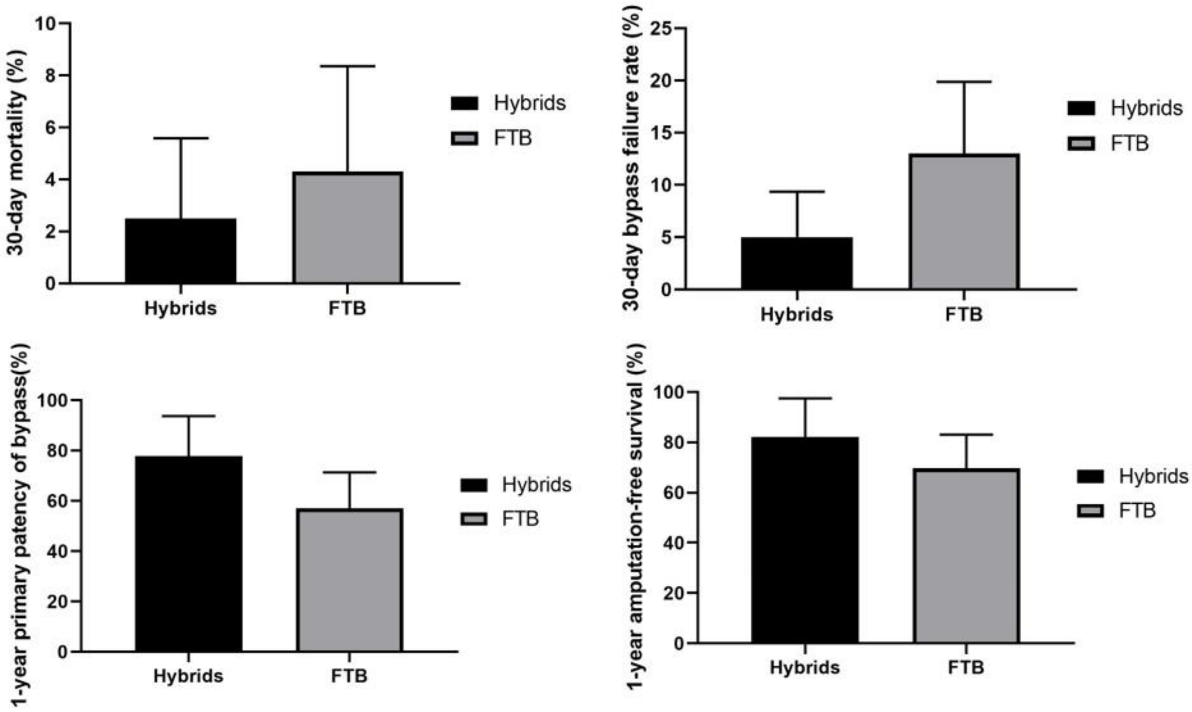

Figure 5 - 30-day mortality and rates of shunt failure, 1-year primary shunt patency, and 1-year amputation-free survival for hybrid interventions compared with femoral-tibial bypass (FTB).

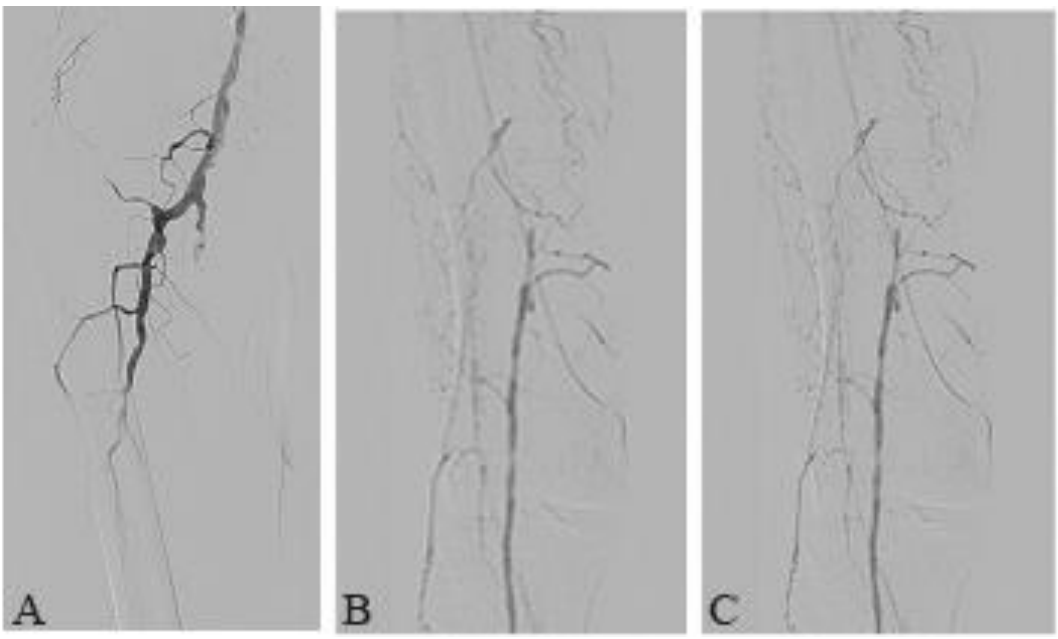

Figure 6 - Example of a distal hybrid intervention performed in patient A., a 64-year-old male patient with CLTI (Rutherford grade 6). Results of preoperative angiography: long CTO of SFA (A), unstenotized popliteal artery filled through collaterals (B), three-vessel CTO of the tibial arteries (C).

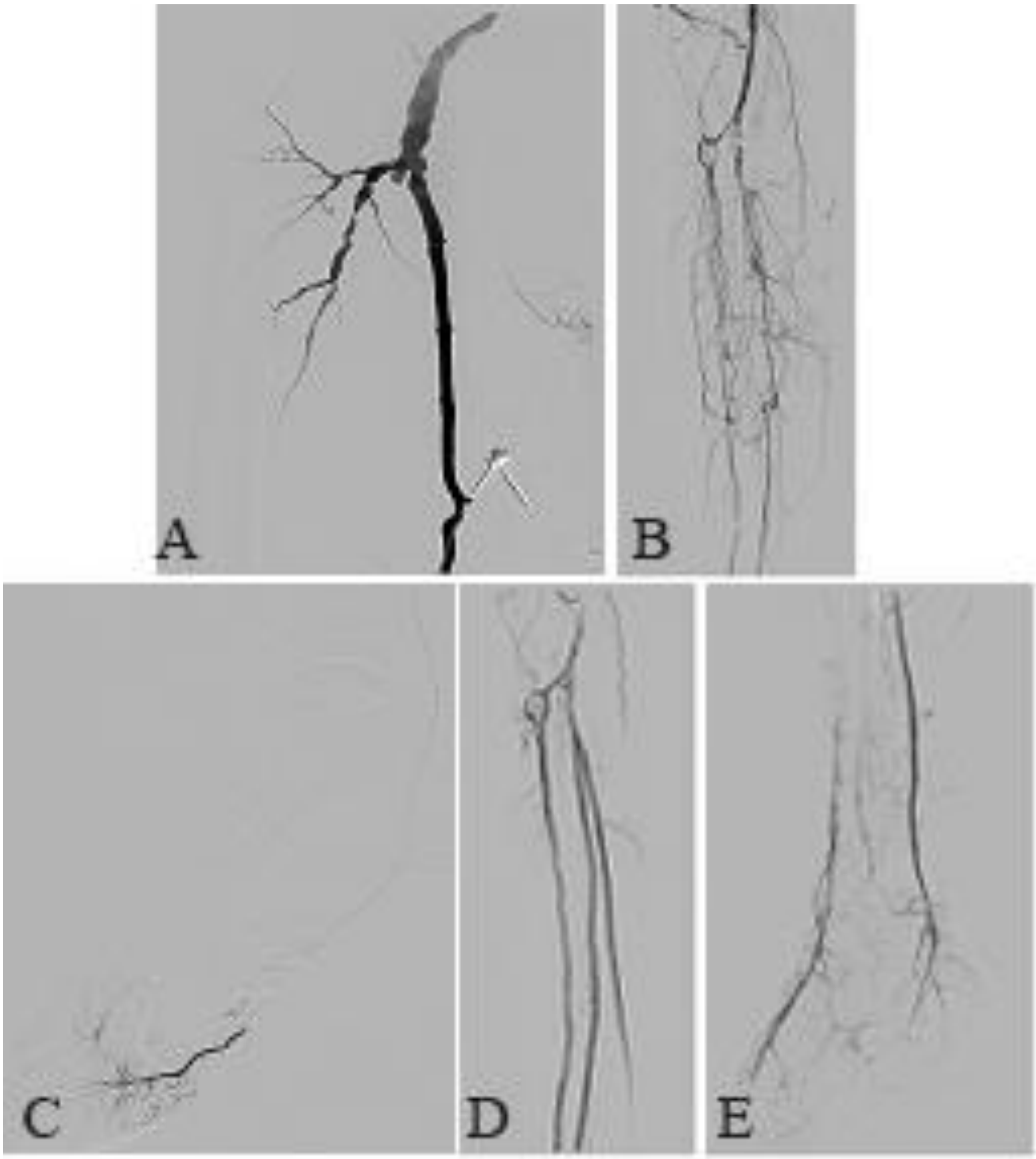

Figure 7 - Example of a distal hybrid intervention performed in patient A., a 64-year-old male with CLTI (Rutherford grade 6). Course of the one-stage hybrid intervention with introduction of the intradplease through the lateral branch of the bypass anastomosis (A); selective angiography of the diverting vessels (B); successful recanalization of the posterior tibial artery (C); final result: all three tibial arteries are passable (D), providing direct revascularization of the foot (E).

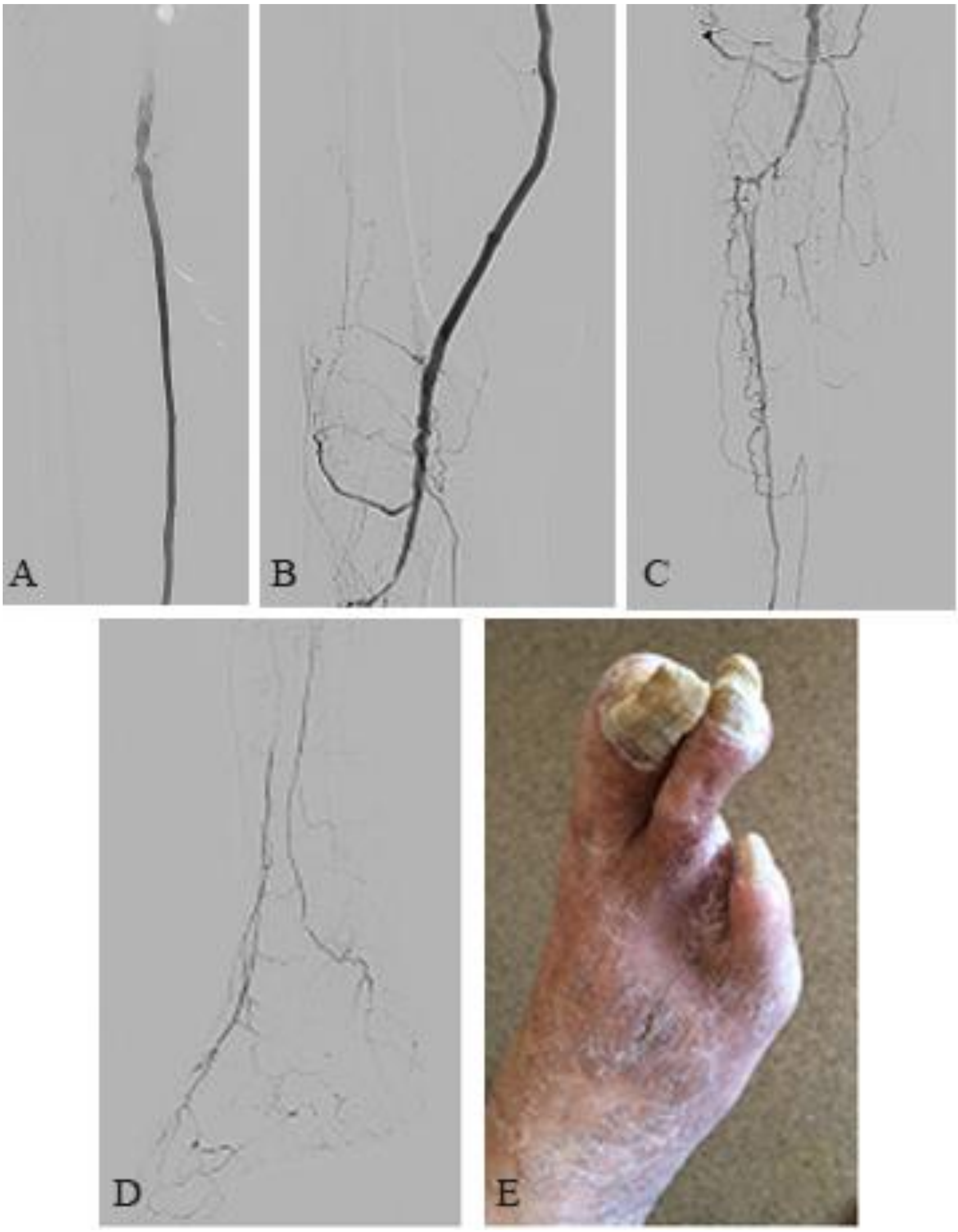

Figure 8 - An example of distal hybrid intervention performed in patient A., a 64-year-old male with CLTI (Rutherford class 6). Angiography performed 1.5 years later showed occlusion of the deep femoral artery and functioning shunt (A), open popliteal segment (B), reocclusion of the diverting vessels (C), collateral filling of the distal tibial vessels (D). View of the healed foot without evidence of CLTI (E).

4. DISCUSSION

Autovenous bypass remains the preferred method of revascularization for extended SFA occlusions in patients with CLTI [1, 30, 138, 139, 146], because the length of the lesion of the femoral-popliteal segment, poor outflow tract condition and the presence of critical ischemia significantly worsens the long-term results of angioplasty/stenting of this arterial segment [28, 51, 71, 75, 89, 95]. However, common outflow pathway changes also negatively affect the patency of the FPB [49, 50, 113], in addition, their presence prevents direct revascularization of the affected angiosomes in the distal parts of the limb.

Among a large number of variants of hybrid reconstructions in CLTI, the approach described by us is quite rare [33, 123]. The published works are characterized by a small number of observations, there are no relevant comparative studies.

In this regard, while determining the indications for hybrid operations of this type, we relied on two well-known principles confirmed by numerous studies. First, we gave preference to open revascularization (bypass) for extended (more than 20 cm) occlusions of the SFA. This is due to the relatively low patency of endovascular reconstructions (as an alternative to open interventions) in extended occlusive lesions of this segment [6, 28, 57, 75], as well as with severe changes in the arteries of the lower leg [28, 34, 57].

In the present work, we investigated the results of hybrid interventions combining the advantages of both (open and endovascular) approaches. The most interesting and debatable in this respect is the rejection of the traditional surgical treatment tactics in this situation (femoral-tibial or femoral-popliteal bypass) in favor of hybrid revascularization. In fact, the more common approach in such multilevel lesions is to restore direct arterial blood flow to the affected part of the foot by increasing the length of the conduit and without any need for endovascular correction of outflow pathways [18, 72, 86, 104]. This is evidenced by the high proportion of femoral-tibial shunts (from 12 to 40-50%) in the largest world "registries" of open infrainguinal reconstructions in CLTI [18, 69, 72, 86, 104, 138, 139].

The downside of this strategy, however, is a higher rate of early shunt thrombosis, reaching, according to some data, 19.4% [18, 40, 50], high amputations (4.7-8.3 %) [18, 72, 86], revisions of the reconstruction zones (13.3 %) [104] and consequently mortality (4.6-6.8 %) [72, 86] as compared to FPB. For us, this became one of the arguments in favor of femoral-popliteal bypass.

Indeed, in the group of distal hybrids in our study, the incidence of thrombosis and amputations in the early postoperative period was lower than the "world average". In addition, according to large observational studies (CRITISCH) [18], a small proportion of femoral-popliteal bypass operations to the first segment of the popliteal artery are indeed performed for triple vessel occlusion of the tibial arteries (12 %). At the same time, the question about the long-term results of such tactics remains unclear. On the one hand, bypassing to the proximal part of the popliteal artery is associated with higher patency rates, and hence amputation-free survival [18, 84]. On the other hand, marked changes in outflow tracts can negatively affect long-term outcomes [17, 59, 113]. Improvement of the peripheral channel state by balloon angioplasty of the lower leg arteries is expected to increase blood flow through the femoral-popliteal shunt for some period, but taking into account relatively low patency of intravascular operations on this arterial segment [99], hardly such hemodynamic effect will last long enough.

While investigating this problem, we studied a number of publications devoted to infrainguinal bypass with the formation of distal anastomosis with the genicular, sural arteries, as well as with the popliteal artery in three-vessel occlusion of the lower leg arteries (so-called "isolated" popliteal artery) [13, 24, 35-37, 66, 76, 81, 103]. These are small papers, usually including a few dozen observations. In most cases, the authors used autovenous as a conduit [24, 25, 35-37], others have also used polytetrafluoroethylene (PTFE) shunts [13, 66, 103]. The frequency of early thrombosis of autovenous shunts of this type was 0-3.3 % [36, 37, 103]. Primary patency of autovenous shunts after 1 year ranged from 73 to 94% [25, 35, 76], after 3 years - 65-84.1 % [36, 37, 76, 103], and after 5 years - 72-74 % [24, 66]. Frequency of limb preservation after 3 years - 68-90 % [36, 37, 103]; after 5 years - up to 78 % [66]. Dual antiaggregant therapy, as well as prolonged anticoagulant therapy in the postoperative period was not used by any of the authors. In 3.3-6.3% of patients [36, 37, 66], despite a functioning shunt, the phenomena of CLTI did not stop, as a result of which they underwent amputation of the limb at the level of the tibia. The rate of healing of trophic changes was not evaluated in any of the listed works. Thus, even with total lesion of outflow tracts, autovenous femoral-popliteal bypass was not associated with an increased incidence of early shunt thrombosis and any noticeable drop in the indices of remote patency in comparison with the known data of large studies of open infrainguinal reconstructions [18, 72, 86, 104].

Finally, the latest international guidelines for the treatment of OALLV [47] recognize the efficacy of autovenous bypass to the "isolated" popliteal artery in the absence of other recipient vessels and (or) insufficient length of the conduit (class of recommendations I, level of evidence A). At the same time, there are no comparative studies of femoral-popliteal bypass for three-vessel occlusion of the lower leg arteries and femoral-tibial/plantar bypass. Also, in the literature we cannot find any results of quantitative assessment of blood flow through the femoral-popliteal shunt in total lesions of the main arteries of the lower leg.

Another important principle underlying the chosen method of revascularization is the desire to provide direct angiosomal revascularization of the foot [111, 154], for which patients underwent balloon angioplasty of the tibial arteries. It should be noted here that, despite the affirmative results of meta-analysis of studies devoted to the problem of angiosomal revascularization [54, 61], there is still a discussion in the literature about the need to provide direct blood supply to ischemic areas of the foot. Thus, in some studies included in the meta-analysis, no advantages of direct revascularization compared to indirect revascularization were found at all

[11, 45, 115], other authors found differences between them only in the rate of healing of trophic defects, while the frequency of limb preservation was the same [62, 106]. There were also those who found differences in amputation-free survival, but not in the rate of healing [92]. It is worth adding that the studies differed in the method of revascularization and included either exclusively bypass surgery [11, 67, 73, 92] or, on the contrary, only endovascular interventions [7, 45, 58, 106]. Finally, in selected papers, both open and endovascular reconstructions were included in the study group [45, 115]. Publications differed by the percentage of patients with deep and superficial necrosis, by the frequency of small amputations and even by the definition of angiosomal revascularization: in the works of Fossaceca R. et al. (2013) [45]; Kabra A. et al. (2013) [62]; Söderström M. et al. (2013) [106] and Lejay A. et al. (2014) [73] used the "classic" scheme of foot angiosomes [111]; in other studies, the authors equated revascularization through the plantar arch and (or) revascularization of the calcaneal region through the peroneal artery to angiosomal, i.e. direct [67, 92, 115]. Common for all studies was the fact that in patients in the indirect revascularization group, according to angiography, at least one tibial artery always functioned. In published studies of hybrid operations of the "distal" type, the peripheral channel was also represented by at least one artery in most cases [12, 123].

In our work, the majority of patients (78.8%) in the group of hybrid type 2 interventions showed occlusion of all three outflow arteries. Thus, the results of the above publications (and, in particular, of those publications in which no differences between direct and indirect revascularization were found) hardly reflect the prospects of healing of trophic defects in the patients in our study. In addition, total lesion of the tibial arteries itself is able to cause critical ischemia of the distal parts of the foot, which, in our opinion, was an additional reason for correction of outflow pathways distal to the femoral-popliteal shunt.

Finally, an important circumstance in choosing the tactics of hybrid limb revascularization in the presented group of patients was the fact that a significant proportion of them had deep trophic changes that required small amputations. If in such a situation, despite the compensation of blood flow in the limb, stump healing does not occur, there are indications for lower leg amputation. In such a case, the location of the distal anastomosis near the knee joint gap allows to save the shunt from inevitable ligation and, thus, to promote good blood supply of the amputation stump.

Undoubtedly, the above considerations require detailed verification in the framework of comparative studies. However, on the basis of the presented data we can conclude that the hybrid approach to revascularization of extended occlusions of the SFA with widespread peripheral lesions of the lower leg is an effective strategy of surgical treatment in the discussed group of patients with CLI.

According to a number of studies, even without balloon angioplasty of outflow tracts, autovenous bypass to the so-called "blind" popliteal segment (i.e.., to the non-stenosis area of PopA at complete occlusion of the distal segment of PopA or all three arteries of the lower leg), provided high enough indices of long-term patency [24, 25, 34, 76, 103], not yielding to this criterion femoral-tibial bypass [24, 34], regardless of the severe lesion of the underlying arterial segments. In the international guidelines for the treatment of OALLV [47] bypass to the "blind" popliteal segment is recommended as the method of choice in case of limited length of the conductor or in the absence of adequate recipient arteries on the tibia/foot. The concept of "distal hybrid" for extended occlusions of the SFA with widespread outflow tract damage is to ensure high (as compared to FTB) patency in the early and distant period due to the use of a shorter conduit and a larger recipient artery. At the same time, endovascular correction of outflow tracts provides a high frequency of direct angiosomal revascularization. Even in the case of reocclusion of the tibial arteries in the long term, a functioning shunt to the blind PopA maintains arterial blood flow in the distal limb at a sufficient level, preventing the recurrence of CLTI.

In the literature we can find only a few descriptions of this type of hybrid reconstruction in CLTI [33, 123]. The available studies include a very limited number of observations in the absence of any comparison group.

In this study, the differences between DHI and FTB in the incidence of early shunt thrombosis did not reach the level of statistical significance. The percentage of direct angiosomal revascularization was significantly (and naturally) higher in the DHI group, because the location of the distal anastomosis at the level of the PopA allows the surgeon to choose for balloon angioplasty the tibial artery that predominantly supplies the affected angiosome of the foot. An important finding appears to be the higher primary patency of the shunt after DHI compared with FTB. It is not clear whether this is due to the improvement of the peripheral channel, since the patency of the tibial arteries in the remote period was not evaluated. In addition, the effectiveness of direct anigosomal revascularization compared to indirect revascularization is questioned by some authors [72]. However, in the vast majority of studies of the angiosomal concept patients had at least one of the three main arteries of the lower leg, while in the present study the majority of patients in the DHI group had occlusion of all three arteries of the lower leg or occlusion of the distal part of the PopA. In addition to limb preservation, a possible advantage of angiosomal revascularization is an increase in the rate of epithelialization of the trophic defect on the foot [7, 58]. In our work, the healing rate was evaluated as the percentage of patients with healed trophic changes after 12 months. The studied groups did not differ significantly in this indicator. It is worth noting that a more sensitive method for estimating the healing rate is the determination of the accumulated probability of healing according to serial examinations of patients. Unfortunately, the study design did not allow using this approach.

One of the possible factors determining the outcome of revascularization in lesions of the lower leg arteries is the restoration of patency of several arteries of the lower leg (so-called multiple revascularization). Compared to angioplasty of a single artery of the lower leg, multiple revascularizations, according to some data, improves the long-term result of reconstructive intervention [3, 65]. Formation of a distal anastomosis at the level of PopA in the DHI group allows to perform further multiple revascularizations of outflow tracts, which was successfully performed in a significant part of patients in this group. Two interventions in the DHI group compared to one operation in the FTB group did not lead to an increase in postoperative bed days. This is probably due to the fact that the main limiting factor that determined the duration of hospitalization was the need for prolonged care of the wound defect of the foot with repeated dressings and secondary surgical treatment.

Another important consideration related to distal hybrid interventions is the possibility of performing a tibial amputation (in a situation where the patient's foot cannot be saved) without ligation of the shunt, which in this case is located entirely above the level of amputation. In patients with OALLV, the nature of blood circulation in the tibial stump affects the risk of possible reamputation of the limb at a more proximal level [16]. Thus, a functioning FPB possibly reduces the risk of such reamputation in such cases. In the present study, however, it was not possible to confirm this thesis.

Withdrawal of clopidogrel before performing simultaneous hybrid interventions did not increase the incidence of early shunt or tibial artery thrombosis.

Methodological limitations of the study include (I) the retrospective, nonrandomized design; (II) the lack of assessment of distant patency of the tibial arteries; and (III) the rate of trophic defect healing was assessed only at the end of follow-up.

5. CONCLUSION

Hybrid interventions appear to us to be reasonable in patients with extended (>20 cm) SFA occlusion combined with significant tibial arterial lesions. No lesion of the tibial arteries resulted in early thrombosis of the autovenous SFA in two-stage hybrid interventions of this type. Balloon angioplasty of the tibial arteries after femoral-popliteal bypass provided direct angiosomal revascularization of the foot in the vast majority of observations (90%). The refusal from double antiaggregant therapy at one-stage hybrid interventions was not accompanied by any appreciable increase in the incidence of early thrombosis in the PTA/stenting zone.

The use of accesses through the brachial artery and the lateral branch of the autovenous is a rather convenient and safe approach. Large comparative studies with long-term postoperative follow-up are needed to evaluate the efficacy of the hybrid approach to revascularization of such infrainguinal lesions in CLTI.

6. CONCLUSIONS

1. The frequency of extended occlusion of the superficial femoral artery (> 20 cm) with lesions of the tibial arteries in patients with CLTI was 43.5% (184 patients with CLTI were examined, of whom 80 patients had extended occlusion of SFA (> 20 cm) and lesions of the tibial arteries).

2. Distal hybrid interventions are an effective revascularization strategy in patients with extended occlusion of SFA combined with outflow tract lesions in CLTI. Compared to femoral-tibial bypass, distal hybrid interventions provided higher primary shunt patency with comparable rates of limb preservation, survival, and trophic defect healing. At the same time, despite common occlusive outflow tract changes, the risk of early shunt thrombosis was low with hybrid interventions.

3. The developed therapeutic algorithms on the tactics of hybrid surgery in patients with extended occlusion of SFA combined with the lesion of tibial arteries in CLTI reliably allow to save the limb in the early and distant postoperative period.

4. In comparison with the classical method of treatment of the extended occlusion of SFA combined with outflow tract lesions in CLTI the hybrid approach is significantly more effective, modern, reliable and safe method of treatment, and also has a high potential for complete rehabilitation of patients, providing higher primary patency of the shunt with comparable indices of limb preservation, survival and healing of the trophic defect.

PRACTICAL RECOMMENDATIONS

1. Among the patients with CLTI its appropriate and advisable to distinguish the patients with occlusion of the superficial femoral artery of more than 20 cm, combined with distinct steno-occlusive lesion of the lower leg arteries for planning a hybrid intervention.

2. While planning the hybrid surgical intervention it is advisable to separate <<open>> and endovascular stages of the operation. Simultaneous implementation of hybrid surgery is possible only in patients with a low degree of perioperative risk and in the conditions of a specially equipped <<hybrid>> operation theatre.

3. In case of simultaneous surgical intervention, it is advisable to perform the endovascular procedure through the lateral branch of the conduit. This is a convenient and safe method that provides minimal risks for the patient.

LIST OF ABBREVIATIONS AND SYMBOLS

BASIL - Bypass Versus Angioplasty in Severe Ischaemia of the Leg

GLASS	–	Global Limb Anatomic Staging System
PLAN	–	Patient risk estimation, Limb staging, ANatomic pattern of disease

TASC II - The Inter-Society Consensus on the Management of Peripheral Arterial Disease

TcPO2 - percutaneous oxygen pressure

BP - blood pressure

ASC - acetylsalicylic acid

DPA – dorsalis pedis artery

BAP - balloon angioplasty

GSV - great saphenous vein

FPB - femoral-popliteal bypass

FTB - femoral-tibial bypass

DFA - deep femoral artery

DHI - distal hybrid intervention

PTA - posterior tibial artery

PAD - peripheral artery disease

IHD - ischemic heart disease

CLI - critical limb ischemia

ABI - ankle brachial index

PA - peroneal artery

OALLV - obliterative atherosclerosis of lower limb vessels

CFA - common femoral artery

AMI - acute myocardial infarction

SFA - superficial femoral artery

ATA - anterior tibial artery

PopA - popliteal artery

DSA - direct subtraction angiography

DM - diabetes mellitus

CAI - chronic arterial insufficiency

CKD - chronic kidney disease

CLTI – chronic limb threatening ischemia

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