

## ANALYSIS OF REPEAT LOWER LIMB REVASCULARISATION FAILURES IN PATIENTS WITH CHRONIC LIMB ISCHAEMIA

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### Abstract

**Introduction.** The natural course of the disease in intermittent claudication and critical limb ischaemia differs significantly, which is an important factor in choosing a treatment strategy.

**Aim.** To analyse the clinical outcomes of unsuccessful primary and repeat revascularisation in patients with chronic limb ischaemia following reocclusion of the reconstructed arterial segment, and to evaluate the outcomes of lower limb amputations.

**Materials and methods.** A retrospective analysis was performed of the treatment outcomes of 119 patients with occlusive-stenotic lesions of the lower limb arteries who underwent open and endovascular interventions for revascularisation in chronic limb ischaemia over a 2-year period. In 103 (86.5%) patients, reocclusion of the reconstructed segment developed in the postoperative period, which necessitated repeated revascularisation or amputation. Two groups were formed: the first consisted of 17 patients after primary revascularisation who underwent amputation due to the absence of ischaemia regression; the second consisted of 31 patients after repeated revascularisation who, despite the intervention, developed progressive ischaemia requiring amputation. An analysis was performed of the timing and level of amputations, the frequency of complications, and the influence of concomitant pathology.

**Results.** In the group of patients who underwent repeat revascularisation, amputations were more often performed at a later date: more than 1 year in 29% of cases compared to 5.8% in the group of primary interventions. The main causes of limb loss after repeat reconstructions were shunt thrombosis, vascular prosthesis infection, false aneurysms, and bleeding. High amputations at the hip level prevailed (59.3%). Diabetes mellitus and cerebrovascular disease were associated with a higher risk of limb loss, but no statistically significant differences between the groups in the frequency of these conditions were found.

**Conclusions.** Repeated revascularisation in cases of arterial reocclusion in patients with chronic limb ischaemia allows amputation to be postponed in some patients and prolongs limb preservation, but is accompanied by a high risk of severe vascular complications, necessitating major amputations. Optimisation of patient selection and choice of revascularisation tactics are key to improving treatment outcomes and limb preservation.

**Keywords:** chronic limb ischaemia, peripheral artery disease, repeat revascularisation, reocclusion, lower limb amputation, critical limb ischaemia, open vascular reconstruction, endovascular interventions

### INTRODUCTION

Peripheral artery disease (PAD), which manifests itself as chronic atherosclerotic occlusive lesions of the lower extremities, remains one of the most pressing problems in modern medicine, affecting more than 230 million people worldwide [1, 2]. The clinical symptoms of PAD can range from mild intermittent claudication to critical limb ischaemia

(CLI) [3]. CLI is the most serious form of this disease and manifests itself as pain in the limbs at rest or tissue necrosis, with the development of ulcers or gangrene, and is observed in about 11% of patients with PAD [4-6].

The natural course of the disease in intermittent claudication and critical limb ischaemia (CLI) differs significantly, which is an important factor in choosing

a treatment strategy. Untreated CLI is associated with a high risk of mortality and the need for major amputations, mainly due to severe ischaemic cardiovascular complications and the risk of developing renal failure. Peripheral artery disease, chronic kidney disease and diabetes mellitus are significant predictors of amputation and mortality. Intermittent claudication usually has a better prognosis, with an annual risk of major amputations of less than 1% [7]. At the same time, for PAD, this figure reaches about 22% and applies to both overall mortality and amputations [8].

According to current clinical guidelines, patients with severe intermittent claudication that does not respond to conservative treatment, as well as most individuals with CLI, are recommended to undergo revascularisation to preserve the limb and improve quality of life [7-10]. The 2024 guidelines from the ESC and ACC/AHA emphasise the importance of an individualised approach to the choice of revascularisation strategy (open or endovascular), taking into account the anatomy of the lesion and the patient's comorbidities.

However, there is a pool of patients who have undergone primary revascularisation but, due to certain factors in the postoperative period, develop complications that cause thrombosis of the reconstructed segment and lead to the risk of amputation as an end-stage complication of CLI.

Given the generally accepted recognition of indications for revascularisation in CLI in modern medical practice, finding an answer to the question of the need for repeat revascularisation in patients at risk of amputation becomes an extremely important task. Current studies indicate that the choice of the optimal revascularisation strategy has a significant impact on the frequency of clinical failures and limb preservation [11, 12].

## AIM

The aim was to evaluate the results of lower limb amputations in patients with chronic limb ischaemia after primary and repeat revascularisation in cases of reocclusion of the reconstructed arterial segment.

## MATERIALS AND METHODS

The study was conducted at the vascular surgery department of the Kyiv Regional Clinical Hospital in Kyiv. Over a two-year observation period, 120 patients with occlusive-stenotic lesions of the lower limb arteries were included in the study. All patients underwent surgical revascularisation of the arteries of the lower extremities due to chronic limb ischaemia (CLI). In 103 patients (86% of cases included in this study), there were complications in the postoperative period that led to reocclusion of the reconstructed arterial segment and required repeat surgery. In 17 patients (14%), no repeat surgery was performed to restore blood flow in the arteries of the lower extremities.

The study also included patients who came to the medical facility during the study period with a history of primary reconstructive surgery for occlusive-stenotic lesions of the arteries of the lower extremities.

Primary intervention in 92 (77.3%) cases was performed using open surgery, and in 27 (22.7%) cases, radiovascular dilatation (RVD) was performed. Repeat surgery was performed using open surgery in 70 (68%) cases and using XDD in 33 (32%) cases. Among the patients, there were 20 (17%) women and 99 (83%) men, ranging in age from 38 to 87 years.

Endovascular interventions were performed according to recommendations (ESVS 2024) [3]. The study included patients with occlusive-stenotic lesions of the arterial segment of the lower extremities, including patients with diabetes mellitus and cerebrovascular disease (CVD). Given the age category of patients and the prevalence of the disease, ischaemic heart disease (IHD) and hypertension (HT) were not identified as concomitant pathologies.

All patients underwent typical surgical procedures for limb amputation according to the stage of the process, localisation and severity of the lesion.

During thigh amputation, skin-fascial flaps were excised with two semicircular incisions in the upper or middle third of the thigh. The vessels on the thigh were identified, transected, sutured, and ligated. The femur was sawed, the bone debris was processed to smooth the edges, and the N. ischiadicus was transected higher to draw it into the soft tissues, after alcohol-procaine blockade and plastic repair. After haemostasis, a stump was formed and the postoperative wound was sutured layer by layer.

During amputation of the lower leg, skin-fascial flaps were excised with two semicircular incisions in the upper or middle third of the lower leg. The vessels of the lower leg were isolated, transected, sutured and ligated. The tibia and fibula were divided, and the the bone ends were filed to smooth the edges. After haemostasis, a stump was formed, and the postoperative wound was sutured layer by layer.

Interventions at the foot level were characterised by the fact that necrosectomy was performed within the tissues with preserved blood flow once a clear demarcation line had formed. Two semi-circular incisions were made to remove skin and fascial flaps, and the bones of the foot were sawn with a Gigli saw. After haemostasis, a stump was formed and the postoperative wound was sutured layer by layer.

Considering the severity of complications, patients in our study were divided into two groups:

The first group consisted of 17 patients with occlusive-stenotic limb lesions who underwent primary limb revascularisation and lower limb amputation due to the absence of limb ischaemia regression.

The second group consisted of 31 patients with occlusive-stenotic limb lesions who underwent repeated

limb revascularisation and lower limb amputation due to the absence of limb ischaemia regression.

The second group of patients was divided into two homogeneous subgroups according to the method of repeated revascularisation. Subgroup A (27 observations): patients who underwent open surgery; subgroup B (4 observations): patients who underwent endovascular interventions. Table 1 shows the general characteristics of patients in both groups.

The analysis revealed no statistically significant differences between the groups for most baseline indicators. However, in terms of the prevalence of cerebrovascular disease (CVD), the differences were statistically significant ( $p < 0.001$ ), with CVD in group 2A undergoing open surgery occurring in 11.1% of cases, in group 2B undergoing CTA in 0% of cases, and deviations were observed in group 2A – 22% and in group 2B – 0% ( $p > 0.05$  for all indicators except the frequency of CVD and complications) (Table 1).

Table 1

General Characteristics of Patients in Both Groups

Indicator	Type of operation		Level of significance of differences between groups, p	
	Open surgical interventions (n=27)	Endovascular interventions (n=4)		
Age, years	62,5,7±5,8	61,3±4,8	0,875	
Gender	F	7 (25,9%)	3 (75%)	0,316
Chronic limb ischaemia Wifl	II	7 (25,9%)	2 (50%)	0,512
	III	20 (74,1%)	2 (50%)	
	IV	0	0	
Diabetes	A	11(41%)	2 (50%)	0,235
Cerebrovascular diseases	Yes	3 (11,1%)	0	4,055
	No	24 (88,9%)	0	
trophic changes	Yes	27 (100%)	4 (100%)	1,146
	No	0	0	
Complications	Yes	6 (22%)	0	2,064
	No	21(78%)	4 (100%)	

To determine the degree of clinical severity of ischemic limb damage, the Wifl classification was used. Patients who underwent PEA: category 2-2 (50%), category 3-2 (50%). In open surgery, there were 7 patients (25.9%) in category 2 and 20 (74.1%) in category 3.

When planning surgical intervention, patients underwent an examination algorithm that included: physical and laboratory tests, ultrasound Doppler imaging (UDI) using Toshiba Medical Systems Aplio 500, Toshiba Medical Systems Aplio 400, and BK Medical Holding Co. Inc. Pro Focus 2202, taking into account blood flow velocity, usually using a linear transducer with a variable ultrasound frequency of 9-15 MHz; computed tomography (CT) or contrast-enhanced angiography (CEA) Siemens Artis Zee and Philips Alura Xper FD20. After the examination, the location, prevalence and severity of ischaemic damage to the limb were determined.

Exclusion criteria: patients with multi-level arterial damage, popliteal artery aneurysm, and non-atherosclerotic peripheral arterial disease.

## RESULTS

In 4 (3.8%) patients who underwent repeat surgery to restore blood flow in the arteries of the limb in the early postoperative period, limb amputation was performed due to complications: (erosive bleeding – 1, lymphorrhea – 1, prosthesis infection – 1, false aneurysm and shunt thrombosis – 1). In 1 patient (1%) who underwent repeat

surgery to restore blood flow in the arteries of the limb in the long-term postoperative period, a false aneurysm developed, which caused shunt thrombosis, leading to amputation of the limb. Another patient (1%) developed erosive bleeding 2 years after repeat surgery, which also led to amputation. By gender, complications occurred in 6 men (100%) and in no women (0%).

The results obtained in patients who underwent endovascular dilatation and open surgery for occlusive-stenotic lesions of the limb arteries with CVD are shown in Table 2.

Only in 1 case (0.97%) after repeated revascularisation, necrotomy of the distal parts of the foot was performed, and the supporting function of the foot was preserved during the first year of observation. However, due to infection (phlegmon) of the foot, amputation of the lower limb at the level of the shin was performed after a year.

In another 1 (0.97%) case, after repeated surgical revascularisation, the weight-bearing function of the foot was preserved and distal resection of the foot according to Chopart was performed. However, due to the progression of the atherosclerotic process and complications of diabetic angiopathy, after 1 year of observation, amputation of the lower limb at the level of the middle third of the thigh was performed.

Within the above-mentioned groups of patients and levels of amputation, patients with diabetes mellitus and cerebrovascular disease among concomitant diseases were identified (Table 3).

Table 2

## Results of Different Types of Surgical Interventions

Indicator	Type of operation		Level of significance of differences between groups, p
	Repeat surgical interventions, (n=31)	Primary surgical interventions, (n=17)	
Up to 1 month	4 (12,9%)	8 (47,1%)	1,410
Up to 1 year	18 (58,1%)	8 (47,1%)	0,520
More than 1 year	9 (29%)	1 (5,8%)	0,835
Level of amputation			
Foot	7 (25,9%)	2 (50%)	0,617
Lower leg	4 (14,8%)	1 (25%)	0,219
Thigh	16 (59,3%)	1 (25%)	0,060

Table 3

## Distribution of Patients with Concomitant Diseases by Level of Amputation

Level of amputation	First group					Second group				
	DM	CVD	MI	Other concomitant conditions	DM +	DM	CVD	MI	Other concomitant conditions	DM +
Foot	2			3	1	2		1	3	2
Lower leg	2			3		2		1	1	1
Thigh	1			4	1	6		1	11	

In the first group, diabetes mellitus was detected in 5 (29.4%) patients, whereas in the second group, diabetes mellitus was diagnosed in 10 (32.3%) patients ( $t = 0.115$ ), which is not a statistically significant difference. Patients with diabetes mellitus who had a history of acute cerebrovascular accident (CVA) or myocardial infarction (MI) were detected in 2 (11.8%) cases in the first observation group, whereas in the second observation group, there were 3 (9.7%) such patients ( $t = 0.073$ ), which was also not statistically significant. Patients who had other concomitant diseases, such as chronic kidney disease, hypertension, and others, accounted for 10 (58.8%) cases in the first observation group and 15 (48.3%) cases in the second observation group, which ( $t = 0.519$ ) is not statistically significant and shows the statistical homogeneity of the study groups.

In terms of lower limb amputation timing in the first observation group, amputation was performed in 8 (47.1%) cases within the first month of observation, in 8 (47.1%) cases within the first year, and in 1 (5.8%) case after more than 1 year following endovascular dilatation (see Table 2).

In the second observation group, amputation was performed within the first month in 4 (12.9%) cases, within the first year in 18 (58.1%) cases, and more than one year in 9 (29%) cases, respectively. Taking into account the time of limb preservation in the second group from the first visit to amputation within 1 month, there were 2 (6.4%) patients, within 1 year 10 (32.3%) patients, and more than 1 year 19 (61.3%) patients.

The period between the first surgical intervention and repeated revascularisation of the lower limb due to reocclusion of the arteries in patients in the second

observation group was: up to 1 month of observation – 9 (29%) patients, up to 1 year – 10 (32.3%) patients, and more than 1 year – 12 (38.7%) patients, respectively.

## DISCUSSION

The results of the present study indicate that the absence of regression of limb ischaemia after primary revascularisation should not automatically be interpreted as evidence of futility of further limb-salvage attempts. In the group of patients who underwent repeat revascularisation, amputation was more often shifted to later follow-up intervals, suggesting that restoration of arterial inflow even after reocclusion may prolong the period of tissue viability and provide additional time for a more controlled surgical decision-making process. Such an interpretation is consistent with current concepts, according to which chronic limb-threatening ischaemia represents the most severe clinical manifestation of peripheral artery disease, whereas revascularisation remains the principal strategy for limb preservation in this category of patients [13, 14].

At the same time, the substantial proportion of major amputations observed in the study should be interpreted in the context of the advanced structural severity of arterial disease in these patients. Severe calcification reduces arterial compliance, limits adequate balloon expansion, increases the probability of residual stenosis and flow-limiting dissection, and adversely affects long-term patency. Published data demonstrate that marked calcification and poor infrapopliteal runoff are associated with less favourable endovascular outcomes, while severe femoropopliteal calcification in patients with tissue

loss is linked to worse limb-related results. Therefore, reocclusion after reconstruction in such patients is likely to reflect not only technical failure of the procedure, but also the biological aggressiveness and anatomical complexity of the underlying atherosclerotic process [15, 16].

Another clinically relevant aspect is that the benefit of repeat revascularisation should not be assessed solely through the binary endpoint of limb preservation. Even when major amputation ultimately remains unavoidable, postponement of limb loss may still be clinically meaningful, as it creates additional opportunities for infection control, clearer demarcation of non-viable tissue, optimisation of the patient's general condition, selection of a lower amputation level, and preparation for subsequent rehabilitation. This consideration is particularly important because peripheral artery disease itself is associated with marked deterioration in patient-reported health status, while utility values are even lower in patients who undergo amputation. Accordingly, treatment effectiveness in this population should be interpreted not only in terms of technical patency or repeat intervention rates, but also through its influence on functional recovery and quality of life [17].

## CONCLUSIONS

Chronic limb ischaemia is the most serious form of peripheral artery disease and is associated with a high risk of mortality and the need for major amputations.

Most patients who undergo limb amputation due to the absence of ischaemia regression have a history of primary or repeat revascularisation.

Complications in the early and late postoperative periods after repeat revascularisation (such as aneurysm, shunt thrombosis, prosthesis infection, bleeding) are the main causes leading to further amputation.

Patients with diabetes mellitus and other comorbidities (e.g., cerebrovascular disease) account for a significant proportion of individuals undergoing amputation, although no statistical difference between the primary and repeat revascularisation groups has been found for these indicators.

The timing of amputation varies considerably: in the repeat revascularisation group, follow-up amputations (more than 1 year of follow-up) are more common, indicating a temporary prolongation of limb preservation.

*Prospects for further research* include analysing lower limb preservation in patients with reocclusion of occlusive-stenotic lesions of the lower limb arteries, surgical treatment tactics, and diagnostic algorithms, which can help to obtain additional information and identify clinically important aspects of patients, thereby improving the quality of life and limb preservation in patients with obliterating atherosclerosis of the lower extremities.

## COMPLIANCE WITH ETHICAL REQUIREMENTS

Within the scope of the systematic review and meta-analysis, only open public data sources that had previously been published in peer-reviewed scientific journals were used. Since the study did not involve primary data collection or interference in the course of patient treatment, no separate ethical approval was required. At the same time, the authors confirm that the work complies with the ethical principles of scientific integrity, including transparency, accuracy, absence of fabrication or falsification of data, as well as correct formatting of bibliographic references in accordance with the requirements of academic ethics.

*Statement on the use of artificial intelligence.* Artificial intelligence was not used in this work to generate text, analyse data or create images. All content was prepared by the authors, who are fully responsible for its accuracy, originality and compliance with ethical standards.

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## AUTHOR CONTRIBUTIONS

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**Резюме****АНАЛІЗ НЕВДАЧ ПОВТОРНОЇ РЕВАСКУЛЯРИЗАЦІЇ НИЖНЬОЇ КІНЦІВКИ У ПАЦІЄНТІВ ІЗ ХРОНІЧНОЮ ІШЕМІЄЮ КІНЦІВКИ**Юрій М. Гупало<sup>1</sup>, Ярослав М. Аннишинець<sup>1</sup>, Андрій О. Голяченко<sup>3</sup>, Олександр А. Голяченко<sup>2</sup><sup>1</sup>Державна наукова установа «Центр інноваційних технологій охорони здоров'я» Державного управління справами, м. Київ, Україна<sup>2</sup>Національний інститут серцево-судинної хірургії імені М. М. Амосова Національної академії медичних наук України, м. Київ, Україна<sup>3</sup>Тернопільський національний медичний університет імені І. Я. Горбачевського Міністерства охорони здоров'я України, м. Тернопіль, Україна

**Вступ.** Природний перебіг захворювання при переміжній кульгавості та критичній ішемії кінцівки суттєво різниться, що є важливим фактором при виборі лікувальної стратегії.

**Мета.** Провести аналіз клінічних наслідків неуспішної первинної та повторної реvascularизації у пацієнтів із хронічною ішемією кінцівки в разі реоклюзії реконструйованого артеріального сегмента з оцінкою результатів ампутацій нижньої кінцівки.

**Матеріали та методи.** Проведено ретроспективний аналіз результатів лікування 119 пацієнтів з оклюзійно-стенотичним ураженням артерій нижніх кінцівок, яким упродовж 2 років виконували відкриті та ендovasкулярні втручання з метою реvascularизації при хронічній ішемії кінцівки. У 103 (86,5%) хворих у післяопераційному періоді розвинулась реоклюзія реконструйованого сегмента, що зумовило необхідність повторної реvascularизації або виконання ампутації. Сформовано дві групи: перша – 17 пацієнтів після первинної реvascularизації, яким ампутацію виконано через відсутність регресії ішемії; друга – 31 пацієнт після повторної реvascularизації, у яких, незважаючи на втручання, розвинулась прогресуюча ішемія з потребою в ампутації. Проведено аналіз термінів та рівнів ампутацій, частоту ускладнень і вплив супутньої патології.

**Результати.** У групі пацієнтів, яким проведено повторну реvascularизацію, ампутації частіше виконувались у віддалені терміни: понад 1 рік у 29% випадків проти 5,8% у групі первинних втручань. Основними причинами втрати кінцівки після повторних реконструкцій були тромбоз шунта, інфікування судинного протеза, хибні аневризми та кровотечі. Переважали високі ампутації на рівні стегна (59,3%). Цукровий діабет та цереброваскулярна хвороба асоціювалися з більш високим ризиком втрати кінцівки, однак статистично значущих відмінностей між групами за частотою цих станів не виявлено.

**Висновки.** Повторна реvascularизація при реоклюзії артеріального русла у пацієнтів із хронічною ішемією кінцівки дозволяє у частини хворих відтермінувати ампутацію та подовжити період збереження кінцівки, однак супроводжується високим ризиком тяжких судинних ускладнень, що зумовлюють необхідність великих ампутацій. Оптимізація відбору пацієнтів та вибору тактики повторної реvascularизації є ключовими для покращення результатів лікування та збереження кінцівки.

**Ключові слова:** хронічна ішемія кінцівки, захворювання периферичних артерій, повторна реvascularизація, реоклюзія, ампутація нижньої кінцівки, критична ішемія кінцівки, відкриті судинні реконструкції, ендovasкулярні втручання

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