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# Balloon angioplasty and stenting of lower extremity arteries in patients with critical limb ischemia

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## Abstract
Lower extremity peripheral vascular disease is a typical, rapidly progressive, and disabling condition. In most patients, limb ischemia is detected at late stages of the disease. As a result, they are at high risk of limb loss, which makes a complete conventional treatment ineffective. In this situation, balloon angioplasty and stenting of lower extremity arteries are considered the optimal modern method of treating patients with critical limb ischemia. This study aims to evaluate the effectiveness of endovascular techniques to improve revascularization during the treatment of critical lower extremity ischemia. The research involved a comprehensive examination and endovascular treatment of 170 patients with occlusive-stenotic lesions of the lower extremity arteries. The patients were operated for critical ischemia between January 2016 and December 2022, and the effectiveness of the measures taken was analyzed. It was found that the pathology under the study requires timely diagnosis and identification of the severity of limb ischemia and circulatory disorders, with the subsequent preparation of an appropriate treatment plan. The authors discussed the main problems accompanying balloon angioplasty and stenting of the lower extremity arteries in patients with critical limb ischemia. Also, the experience of developed countries in the optimization and improvement of the studied technique was studied. It has been proven that the diagnosis of lower extremity vascular disease is related to specific difficulties. However, it can be made on an outpatient basis by analyzing medical examination data and simple laboratory methods. The authors also examined the feasibility and prospects of balloon angioplasty and stenting of the lower extremity arteries in patients with critical limb ischemia. The re-search findings have a practical value for improving the treatment of patients with occlusive and stenotic lesions of the lower extremities, as well as for improving the effec-tiveness of balloon angioplasty and stenting.

**KEYWORDS**
endovascular treatment, angioplasty, stent, occlusive-stenotic lesions, critical lower extremity ischemia, endovascular devices

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## 1. INTRODUCTION

Endovascular intervention in patients with obliterating atherosclerosis of the ankle and foot almost always restores blood flow in one (or two) tibial arteries. It prevents inevitable limb amputations and reduces mortality. Compared to balloon angioplasty, the use of special self-expanding stents for the

popliteal artery allows for better long-term results and reduces the number of repeated occlusions.

Ukrainian and foreign scientists are actively studying the issues of angioplasty and stenting as progressive modern treatment methods. Some studies of modern scholars are devoted to the research of endovascular treatment specifics [1], as well as angioplasty of the tibial arteries [2]. Most Ukrainian scientists study the specifics of the endovascular treatment process of lower extremity ischemia based on their own experience [3]. When considering the peculiarities of treating patients with occlusive and stenotic arterial diseases, some authors see the endovascular method as the optimal combination of traditional reliability and innovative approach [4].

The scholars emphasize that the potential for the development of interventional cardiology is fully revealed only by using the functionality of angioplasty and stenting [5]. The most comprehensive studies of the recent period include the papers by Chekhlov M.V. and Stoliarchuk Ye.A. [6]. These authors present the concept of innovative approaches to endovascular treatment. Some issues of optimizing the treatment process in terms of personalization were considered by several scholars [7]. Many scientists in the modern Ukrainian scientific community have made a significant contribution to the general methodology of forming the concept of treating occlusive stenotic lesions [8,9].

Despite the scientific value of specialized scientific papers, there are still several issues that need to be solved. The problems related to the development of personalized algorithms for the successful implementation of modern endovascular treatment options still need to be better understood and require further scientific research and practical validation.

This study aimed to determine the effectiveness of endovascular techniques in the revascularization of the lower extremities using balloon angioplasty and stents in case of critical ischemia.

## 2. LITERATURE REVIEW

The scientific and methodological background of the studied issues was laid by those researchers whose scientific research is focused on the practical testing of endovascular techniques in the revascularization of the lower extremities using balloon angioplasty and stents. In particular, scientists have taken the following steps:

- Thoroughly analyzed the algorithm of optimal endovascular therapy [10,11].
- Highlighted the conceptual differences between balloon angioplasty and its conventional traditional variant [12,13,14].
- Determined the functionality of point stenting devices in the treatment of diseases of the peripheral arteries of the lower extremities [15].

There are multiple publications in scientific journals on the research topic. The studies of modern scientists address the following aspects:

- Endovascular treatment of stable aneurysms with primary stenting [16].
- The basic conceptual principles of adequate vascular preparation during intervention on the arteries of the lower extremities [17].
- Current need for active implementation of stenting and balloon angioplasty for diseases of the peripheral arteries of the lower extremities [18].

Among the scientific research results on the current topic, it is necessary to highlight the works that fundamentally substantiate the feasibility of combined stenting and deep profundoplasty in patients with lower extremity arterial disease [19]. At the same time, some scientists emphasize the difficulty of implementing some aspects of stenting [20].

Consequently, despite the significance of the scientific and practical achievements of experts in this field, there is an urgent need to develop scientific research in the aspects of the outlined issues to ensure a stable trend of positive dynamics of endovascular treatment by means of balloon angioplasty and stents in critical ischemia cases.

## 3. MATERIALS AND METHODS

The study involved 170 patients between January 2016 and December 2022. All patients had occlusive and stenotic lesions of the lower extremities. They underwent surgery using endovascular techniques to restore revascularization of the lower extremities. The study included patients with obliterating atherosclerosis and lower extremity ischemia of stages III and IV.

The study analyzed the effectiveness of individual methods of endovascular revascularization. In particular, angioplasty and stenting were analyzed separately.

## 4. RESULTS

Critical lower extremity ischemia (CLEI) is the culminating stage of peripheral arterial occlusive disease. At this stage, occlusive and stenotic lesions of the main arteries of the lower extremities cause a significant decrease in distal perfusion pressure. It leads to an imbalance between the supply and demand of tissues for oxygen to maintain the viability of the limb at rest [2,15]. It should be noted that in the case of CLEI, the level of blood supply

to the extremities' tissues decreases to such an extent that it does not allow for maintaining the integrity of the skin, as well as wound healing without revascularization. At the same time, the variability of local or systemic treatment is not effective.

Most patients suffering from CLEI have concomitant illnesses with varying severity, such as coronary heart disease, hypertension, diabetes mellitus, and kidney disease. As a result, it is necessary to strive to reduce surgical trauma by using hybrid and mostly minimally invasive technologies. Usually, there is no time for surgical correction of myocardial ischemia. It has also been found that diabetes mellitus is a factor that reduces the effectiveness of arterial reconstructions in case of extremity ischemia [1,5].

Patients with CLEI have severe lesions of the distal parts of the limbs. This always leads to long-term temporary or permanent disability, a significant decrease in their life quality, a change of profession, and, in some cases, even death [6,8].

Endovascular revascularization (EVR) methods for the treatment of symptomatic peripheral arterial disease can significantly reduce limb pain in patients with claudication and the incidence of forced limb amputation in cases of chronic ischemia. They include such methods as simple balloon angioplasty or drug-eluting balloon angioplasty, as well as bare metal and drug-eluting stents [14]. Rapid technological progress creates innovative opportunities for the technique development. As a result, endovascular treatment methods have become the preferred options for most patients with claudication and CLEI, even with long-lasting, more severe lesions [11]. First of all, it is relevant for patients with diabetes mellitus (DM). The synergy of balloon angioplasty and stenting allows to consolidate the success of dilatation by avoiding elastic recoil and dissection of the arterial wall [7].

Revascularization of the lower extremities is recommended in the presence of specific clinical symptoms and an appropriate morphological image [17]. At the same time, CLEI is positioned as the most crucial evidence for surgical intervention.

The popliteal artery segment, located at the level of the knee joint cleft, is a critical zone where angioplasty and stenting often fail and depend on the chosen instruments. Severe deformity of the popliteal segment rarely causes balloon-eluting stents to be used during movement. At the same time, self-expanding stents have more stable radial stiffness.

Endovascular interventions in the lower limb arteries demonstrate high efficacy in most patients with CLEI. At the same time, they are accompanied by a small percentage of complications and the lowest mortality rate. Angioplasty of the lower limb arteries is a widespread procedure. Moreover, its results in limb salvage are quite impressive. Thanks to modern special stents for the lower limb arteries, the success of stenting in this area is increasing significantly [8].

In the course of this study, patients were divided into two groups according to the final method of lumen restoration. The first group included patients who underwent endovascular treatment with balloon angioplasty ("BA" group). The second group included patients who underwent dilatation with stenting ("S" group). The "BA" group consisted of 102 (60%) patients, and the "S" group – 68 (40%) patients. All patients in the studied groups were between 44 and 83 years old, and the average age was 65.4 years. There were 68 patients over 70 years old (40.0%). Among the surgically treated patients, there were 92 (54.1%) men and 78 (45.8%) women (Table 1).

**Table 1.** Classification of patients by age and gender

| Gender | "BA" Group | "S" Group | Total |
|---|---|---|---|
| **Men** | 58 (56.9%) | 34 (50.0 %) | 92 (54.1%) |
| **Women** | 44 (43.1%) | 34 (50.0 %) | 78 (45.8%) |

Source: the authors

Illness duration ranged from a few weeks to more than a year. Almost half of the patients, namely 86 (50.5%), approached a healthcare facility between one and six months after the illness onset. However, the number of patients suffering from symptoms for over a year is comparable to the first indicator but much higher – 60 (35.29%). It raises the question of why so many patients have sought help from a vascular surgeon more than a year after the onset of symptoms. The smallest number of patients (24 – 14.1%) sought medical care within one month after the first disease symptoms appeared.

A clinical examination of patients with lower extremity arterial disease revealed the presence of concomitant illnesses and risk factors for atherosclerosis progression. They play an essential role in determining indications for surgery and analyzing postoperative complications [11]. In most patients, we found non-diabetic complications (Table 2).

The diagnosis of coronary heart disease was made based on the clinical history, anamnesis, impartial tests, as well as laboratory and instrumental methods of examination. Hypertension was diagnosed based on the clinical picture and anamnesis. Gastric and duodenal diseases were detected by gastrointestinal endoscopy.

As can be seen from the abovementioned data, 114 (67.1%) patients were diagnosed with coronary heart disease, and 110 (64.7%) with ar-

terial hypertension (Figure 1). Furthermore, 37.6% of patients had a history of diabetes mellitus of the second type. In patients of the "S" group, this percentage is comparable to the similar one observed in the "BA" group. Almost one-third of all patients were diagnosed with gastrointestinal diseases. This percentage was nearly the same in both groups – from 36.2% to 35.3%. A history of kidney and urinary tract diseases was also found in 23.5% of all patients.

**Table 2.** Concomitant illnesses

| Concomitant illnesses | Number of cases | | | | | |
|---|---|---|---|---|---|---|
| | "BA" Group (n=102) | | "S" Group (n=68) | | Total (n=170) | |
| | Abs. | % | Abs. | % | Abs. | % |
| **Ischemic heart disease** | 71 | 70.2 | 43 | 63.2 | 114 | 67.1 |
| **Hypertensive disease** | 62 | 60.8 | 48 | 70.5 | 110 | 64.7 |
| **Diabetes mellitus** | 39 | 38.2 | 25 | 36,7 | 64 | 37.6 |
| **Gastrointestinal tract disorders** | 37 | 36.2 | 24 | 35.3 | 61 | 35.9 |
| **Kidney disease** | 21 | 20.6 | 19 | 28.0 | 40 | 23.5 |
| **Nicotine addiction** | 43 | 42.2 | 15 | 22.1 | 58 | 34.1 |

Source: the authors

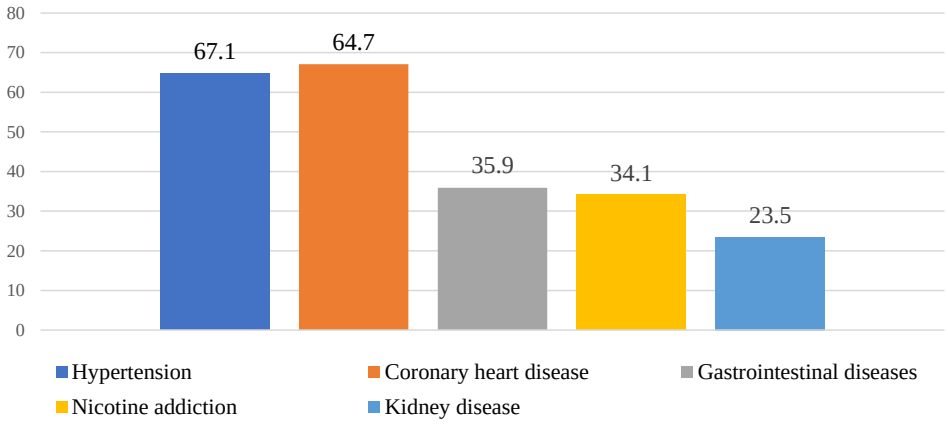


**Figure 1.** The frequency of concomitant illnesses
Source: authors' elaboration

Diabetes mellitus was diagnosed based on glycemic levels. Thus, 64 patients were diagnosed as having diabetes mellitus of the second type. All patients with diabetes mellitus had complications, such as diabetic foot syndrome of mixed (neuroischemic) form. According to the Wanger classification, patients with DFS had different degrees depending on the extent of the Ulcerative lesion.

Atherosclerosis was the etiologic factor of occlusive and stenotic lesions in all patients.

The criteria for CLEI include the presence of pain at rest requiring pain relief for more than two weeks and/or the presence of trophic ulcers or gangrene of the feet formed on the background of chronic arterial insufficiency of the lower extremities [4,10].

Patients with obstructive atherosclerosis of the lower extremities and stages III and IV ischemia were selected for the study. In all patients, the severity of critical ischemia was determined by the

modified Fontain clinical classification proposed by the Second European Consensus Document on chronic critical leg ischemia, where critical limb ischemia corresponds to the III and IV stages of ischemia. Consequently, the patients enrolled in the study included Stage III of ischemia – 55 (32.4%) and Stage IV – 115 (67.6%). The data are shown in Figure 2 and Table 3. In most cases necrotic changes in the toes were detected in patients of both groups.

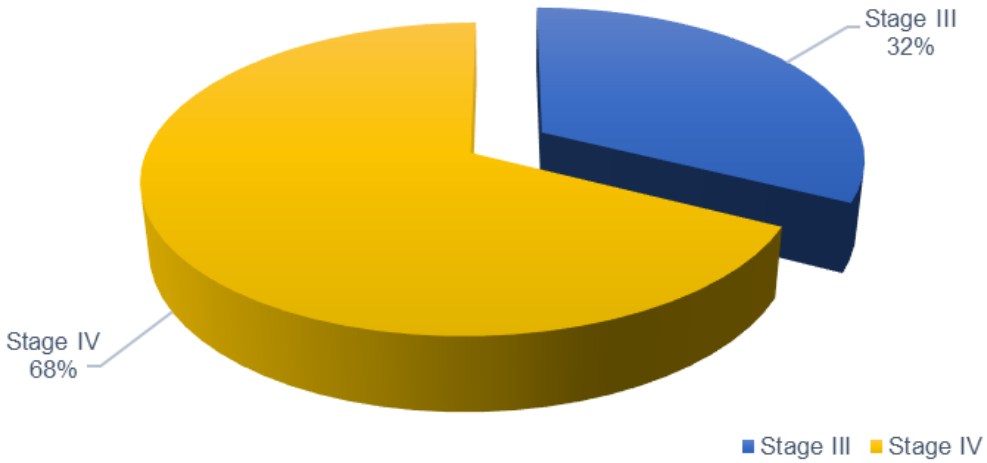


**Figure 2.** Classification of patients by ischemia stage
Source: authors' elaboration

**Table 3.** Groups of patients by ischemia stage and the method of endovascular intervention

| Group | Ischemia stage, n (%) | |
|---|---|---|
| | III | IV |
| **«BA», n=102** | 37 (36.3%) | 65 (63.7%) |
| **«S», n=68** | 18 (26.5%) | 50 (73.5%) |
| **Total, n=170** | 55 (32.4%) | 115 (67.6%) |

Source: the authors

Therefore, there were no significant differences between the clinical groups in terms of age, disease duration, ischemia stage, and concomitant illnesses. Thus, the groups can be considered identical and comparable.

The examination of patients followed a specific algorithm:

- careful anamnesis collection;
- physical examination;
- laboratory diagnostics;
- instrumental methods.

The final examination stage included a pre-operative angiographic study performed on all 170 patients. This method finally allowed us to determine the localization, extent, and nature of arterial lesions.

During the angiographic examination of the iliofemoral and tibial segments of the lower extremity arteries of occlusive-stenotic lesions, a classification was performed by the stenosis level of the vessel lumen and the corresponding expression as a percentage of its diameter. The following groups were distinguished:

- diffuse lesions without hemodynamically significant stenoses, stenoses from 40 to 60%;
- stenoses from 60 to 99%;
- more than 90% – occlusions.

In addition, we took into account the course of the artery, the presence or absence of vascular wall calcification, assessed blood flow in the bifurcation zones of the arterial bed, the degree of development of small branches and collaterals, and the contrast of the foot arteries [17,20].

The study included patients with lesions of the lower leg arteries. The examination revealed 365 lesions in the arteries of the lower leg and foot, as well as 125 lesions of the popliteal artery in combination with lesions of the tibial segment arteries. Multifocal longitudinal lesions are typical for patients with DM with a concomitant diabetic foot syndrome.

Overall, a total of 479 lesions were detected in the popliteal zone, including stenoses – 224 (46.7%), occlusions – 233 (48.7%), and segmental occlusion with severe stenosis – 22 (4.6%). The pattern and localization of arterial lesions are seen in Table 4.

Therefore, balloon angioplasty as an independent method followed by stent implantation was performed on limbs with mostly multifocal atherosclerotic lesions, ulcerative-necrotic foot defects, and severe concomitant pathology. This made open reconstructive interventions impossible and identified attempts at isolated drug therapy as ineffective.

The indications for balloon angioplasty were stenoses, multiple short occlusions, and long occlusions of the popliteal and lower limb arteries.

Indications for stent implantation in the restored lumen of the lower extremity arteries were as follows:

- Residual arterial stenosis after balloon angioplasty >30% of the lumen.
- Dissection of the arterial intima that obstructs the blood flow.
- Displacement of atheromatous plaque to the arterial mouth.

**Table 4.** The pattern and localization of arterial lesions

| Type of arterial lesion | Popliteal segment | | | | |
|---|---|---|---|---|---|
| | PA | TPT | ATA | PTA | FA |
| **Stenosis** | 45 | 41 | 55 | 26 | 57 |
| **Occlusion** | 47 | 42 | 50 | 55 | 39 |
| **Segmental occlusion and severe stenosis** | 11 | 3 | 3 | 2 | 2 |
| **Total** | 103 | 86 | 108 | 83 | 98 |

Source: the authors

Our treatment tactics depended on the nature of local tissue lesions and the state of blood circulation in the lower extremities. Moreover, they were aimed at preserving the supporting function of the limb. Before surgery, during, and after the intervention, all patients received a complex drug therapy to improve blood's rheological qualities and correct concomitant illnesses.

In the conducted studies, patients had a combination of lesions of the lower limb and foot arteries with lesions of the popliteal segment arteries. For this reason, an antegrade access was used in the vast majority of cases. It is more efficient as it provides the highest control and passage during manipulations with the guide wire and catheter.

Besides, when choosing the access method, we considered that most patients had diabetes mellitus with impaired renal function. In the case of ipsilateral antegrade access, the use of a long introducer reaching the popliteal artery allows for performing high-quality angiography with minimal contrast agent consumption. This is important for the given category of patients [19].

The balloon angioplasty was preferred in isolated PA lesions. Stent implantation was performed in cases of unsatisfactory BA results that could not be corrected by repeated dilatation. However, repeated PA deformations during limb flexion are accompanied by a large external load on the implanted stent, which can lead to its breakage. Stent breakage, in turn, is accompanied by an increased risk of re-occlusion of the stented PA. Therefore, there were certain requirements for choosing a stent for implantation in the PA. The stent had to have a design that made it flexible and resistant to fracture. A significant advantage of self-expanding nitinol stents is their flexibility. Self-expanding stents adapt better to the shape of the vessel compared to balloon stents. However, they tend to shrink by 6-20% depending on the vessel diameter in which they are placed. This is a disadvantage, especially when the stent must be held firmly in a strictly defined position.

We used 0.014" or 0.018" guidewires to pass through the lesions of the tibial arteries. Low-profile balloon catheters with a diameter of 1.5 to 3.5 mm and a length of up to 200 mm were used for dilatation. Long catheters were required since most patients had prolonged lesions in the distal arterial segments.

The indications for stenting the affected arteries of the lower limb segment were similar to those of the femoropopliteal segment. Stenting of the lower limb and foot arteries was performed for short lesions that can be treated with limited-length short coronary balloon stents or modern stents designed for the lower limb arteries. Balloon-eluting stents have a high radial stability, which allows to maintain the patency of the affected vessel even with severe stenosis, a slight reduction in length during opening, the possibility of additional expansion of the stent in case of its incomplete opening using larger diameter balloons, and greater implantation accuracy [16].

The disadvantage of such stents is their limited length, which is determined by the balloon.

Due to the fact that most patients with CLEI had multi-level combined lesions of the popliteal and lower limb arteries, such patients mainly underwent endovascular correction of all lesions during a single surgical intervention.

Among the 170 patients in our study, 69 (41%) underwent balloon angioplasty followed by stenting. At the same time, 5 (3%) patients had 2 stents implanted during one surgical intervention. Multifocal arterial lesions in the "S" group required additional dilatation by balloon angioplasty. In case of prolonged or multi-stage occlusions, arterial stenting was supplemented with balloon dilatation of the area above/below the stent. In total, 98 additional cases of balloon angioplasty were performed in the "S" group.

101 (59%) patients underwent balloon angioplasty to dilate the affected arteries. Additional balloon dilation was performed in cases of insufficient angiographic results (residual stenosis >30%).

As a result of the practical study, it was found that the immediate result, which can be assessed immediately after the surgery, indicates the appearance of a marked pulsation of the posterior tibial or dorsal artery of the foot. Elimination of critical ischemia in the surgically treated limb and healing of the foot wound were considered indicators of successful revascularization. It allowed for avoiding high amputation and preserving the supporting function of the limb.

The angiographic success of the surgery includes the restoration of arterial lumen in the intervened artery. Most wounds and foot ulcers disappear within 10-60 days.

The immediate technical (angiographic) success was considered to be the final stenosis with an index of less than 30%. Successful recanalization of the guide wire with subsequent balloon dilatation and stenting led to good angiographic results in 93.5% of cases (159 of 170 patients). The reason for angiographic failure included prolonged chronic occlusion, which prevented the guide wire from passing through.

The results of endovascular interventions in patients with diabetic CLEI with femoral artery lesions are shown in Figures 3 and 4.

In the group that underwent only balloon angioplasty, the primary patency rate after 2 years was 43%. At the same time, in the group where angioplasty was supplemented with stenting, this indicator was 59%. Secondary patency in the BA and S groups after 2 years was 52% and 87%, respectively.

The two-year limb preservation rate for the "BA" group was 61%, while for the "S" group, it was 88%. The survival rate for both groups was 82% and 90%, respectively, for "BA" and "S." Based on the obtained data, it is possible to reassess the higher rates for the "S" group, in particular:

- for primary patency in the "S" group, the rate is 16% higher than in the "BA" group;
- secondary patency in the "S" group is 35% higher than in the "BA" group;
- the rate of extremity preservation in the "S" group is 27% higher;
- the survival rate in the "S" group is 8% higher than in the "BA" group.

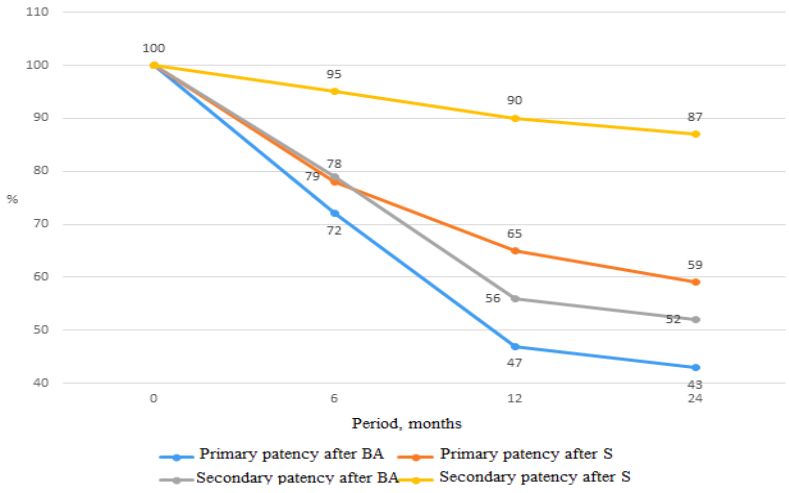


**Figure 3.** Primary and secondary patency of tibial arteries after endovascular dilatation
Source: authors' elaboration

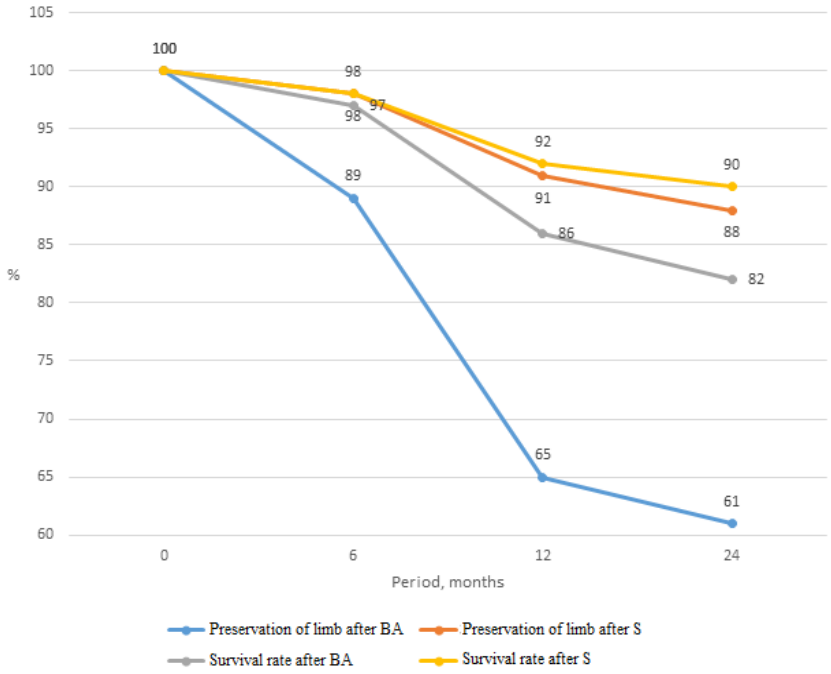


**Figure 4.** Preservation of the limb and survival of tibial arteries after endovascular dilatation
Source: authors' elaboration

## 5. DISCUSSION

Scientists in current scientific fields argue that one of the most effective means to optimize the studied area of medical practice is the development of balloon angioplasty possibilities. The latter method is more efficient than the traditional procedure prototype [21]. In the studies of modern scholars [22], attention is drawn to the fact that angioplasty and repeated stenting are equally effective and safe for treatment. According to experts, this concept should neutralize the discussion about the feasibility of using the investigated method.

Some scientific papers consider the possibility of using balloon angioplasty to treat the under-knee arteries in case of critical limb ischemia [23]. They emphasize that patients with these symptoms are mostly seen by general practitioners, which makes it difficult to provide timely and effective interventions.

Yin Y., Shi Y., Cui T., et al. [24] focus on the need to position the efficacy and safety of balloon angioplasty in dysfunctional arteriovenous fistulas and other pathologies. Such an approach will allow for qualitative positive dynamics of the transformation process of balloon angioplasty and stenting of the lower extremity arteries in patients with critical limb ischemia. At the same time, scientists Rocha-Singh K. J., Sachar R., DeRubertis B. G., et al. [25] emphasize the need for concomitant preparatory and regenerative stages of treatment.

The actualization of the feasibility of using balloon angioplasty and stenting of the lower extremity arteries in patients with critical limb ischemia, according to some scholars [26], is currently prioritized. In this context, the strategy of transforming approaches to the treatment of the studied contingent of patients has significantly expanded its scope, demonstrating the effectiveness of endovascular treatment. At the same time, other researchers [27] focus on the issues that accompany this process. When it comes to endovascular treatment, scientists [28] believe that it is necessary to implement comprehensive measures for antithrombotic therapy for lower extremity arterial diseases.

## 6. CONCLUSION

In this study, the authors were able to substantiate that endovascular interventions in patients with occlusive atherosclerotic ankle and foot segments with CLEI, in most cases, allow restoring blood flow in one (or two) of the tibial arteries. Therefore, it is possible to prevent the inevitable amputation of the limb and reduce the number of fatal cases.

The research has shown that the application of special self-expanding stents for the popliteal artery, which has a specific design for greater flexibility and resistance to breakage, has allowed better long-term results to be achieved. It has also reduced the number of re-occlusions in the artery compared to balloon angioplasty. Application of balloon-eluting stents in this area is not recommended since they are prone to bending, external compression, and deformation. Correct positioning of the stent in the proximal and distal popliteal artery determines the level of arterial patency both in the short and long term.

According to the study, stenting of the lower limb arteries is usually applied in case of unsatisfactory results of balloon angioplasty, obstructive dissection, or hemodynamically significant stenosis after repeated dilatation. The research findings showed better results in the group of patients who underwent stenting compared to those who underwent solo angioplasty. These results are most relevant in patients with clinically diagnosed diabetes mellitus of the second type. It should be emphasized that during DM, there are changes in the structure of the arterial wall, including decreased elasticity, "layering," and hyperechogenic inclusions. These changes are typical for an increase in the distribution from large-caliber arteries to small ones (tibial arteries).

During the study, it was proved that long balloon catheters are optimal for angioplasty in the lower limb arteries due to the high prevalence of atherosclerotic process and smaller vessel diameter, as well as the risk of spasms and dissection due to repeated exposure of the balloon to the arterial wall.

Based on the research outcomes, the authors identified the main directions for improving the treatment of patients with occlusive-stenotic lesions of the lower extremities, as well as improving the effectiveness of balloon angioplasty and stenting. Following the conclusions drawn from the study, the authors proposed possible priority areas for further research on this topic.

## CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

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