

Arterial Pedal Arch Revascularization Impact on the Clinical Results in Critical Lower Limb Ischemia

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Abstract

Background: There are still many unresolved problems that reduce frequency of clinical and technical success of angioplasty of lower limb arteries. One of such problems is impact of the arterial pedal arch revascularization on the clinical result of angioplasty in patients with IV class critical lower limb ischemia according to Pokrovsky-Fontaine classification. **Material and methods:** The results of treatment of 98 patients with peripheral arterial disease (PAD), complicated by critical lower limb ischemia of IV class according to Pokrovsky-Fontaine classification were analyzed in the early postoperative period and 1 year later after the completed angioplasty. Patients were divided into two comparable groups: the first group-the patients with the arterial pedal arch revascularization, the second group – the patients whom it had been impossible to revascularize the arterial arch. **Results:** “Good result” in patients of the first group in the early postoperative period and one year later was 23.1% and 22.7% respectively. In the patients of the second group-9.2% and 5.6%. The both group patients avoided amputations in the early postoperative period, but one year later 53.3% of the second group patients with the “unsatisfactory result” underwent amputation. **Conclusions:** According to the results, the arterial pedal arch revascularization influences on the clinical results and decreases the quantity of amputations in patients with purulent-necrotic changes in the lower limb.

Keywords: *Critical low limb ischemia; Arterial pedal arch; Revascularization; Transluminal balloon angioplasty.*

Introduction

Peripheral artery disease (PAD) of the lower limbs, as well as ischemic heart and cerebrovascular diseases are the manifestations of atherosclerosis [1]. PAD has been neglected for a long period, but nowadays it is of a special attention as an important cause of disability, cardiovascular morbidity and even mortality [2].

The term “critical limb ischemia” (CLI) is used to determine the state in which the arterial disease has resulted in foot pain even at rest or in the skin destruction (ulcer, gangrene and sepsis) [3]. If not revascularized, patients with CLI are at risk for limb loss and for potentially fatal complications, so the best result in the patient treatment is achieved when the diagnosis and appropriate treatment for CLI are in due time without any delay [4]. CLI is a consequence of various diseases, namely: atherosclerosis, nonspecific aortoarteritis, obliterating endarteritis, diabetic macroangiopathy, postembolic occlusions,

and some congenital diseases such as hypoplasia of the abdominal aorta and external iliac arteries [5]. Age, smoking and diabetes mellitus are the most important risk factors of the development of CLI [4, 3]. Diabetic PAD patients are approximately 10 times more likely to need a major amputation than nondiabetic PAD ones [4].

Smoking seems to have an additive effect and, in any case, for those who are heavy smokers, major amputation is more frequent among PAD, independently from the presence of diabetes [1]. Patients with CLI are restricted in physical activity and may get depressed [6]. Every third patient with peripheral arterial disease of the lower limb reaches critical limb ischemia after 7-8 years of the initial symptoms appearing [7]. This state occurs in 30-35% of patients during the first 12 months, 15-20% of patients die, 20% of patients undergo amputation of the limbs and only in 55-60% patients it is possible to save the limb [8].

The clinical manifestations of the disease of the lower extremities arteries are very diverse, ranging from asymptomatic ones to critical ischemia and gangrene of the lower extremities [9]. According to various sources, due to the presence of critical lower limb ischemia about 200 amputations per 1,000,000 people are performed each year, and patients with diabetes have a history of about 3,900 amputations [5].

A diagnosis of CLI can be made on the basis of each patient's history and physical examination, but further diagnostic studies are usually needed for clinical decision to make [8, 3]. As far as CLI classification is concerned, the Rutherford categorization has classically defined CLI as rest pain (class IV), tissue loss (class V), and/or gangrene (class VI) [10].

Alternatively, Pokrovsky - Fontaine classification defines rest pain as class III and tissue loss or gangrene as class IV [9]. None of these classifications includes wound size, perfusion assessment, or infection [8]. Nowadays many researches are carrying out to find a personalized classification system that would provide a basis for development of an optimal revascularization strategy in clinical practice [10].

The aim of medical therapy as a great therapeutic assistant is to prevent myocardial infarction, stroke, and death, and help to accelerate wound healing, prevent amputation, and improve quality of life [11, 3]. However, the role of medical therapy to improve limb outcomes, quality of life, and patency and to reduce reintervention and recurrent CLI is less clear [12]. Retrospective studies have shown a reduction in repeat revascularization and amputation rates among patients with CLI who have been treated with guideline-recommended therapies [13].

Revascularization is of great importance in of therapy for CLI and has a Class I recommendation by all professional guidelines, because without revascularization up to 40% of patients with CLI will require lower limb amputation in 1 year [11]. Furthermore, after an index amputation, a significant number of patients will require contralateral amputation (5.7% and 11.5% in 1 and 5 years, respectively), have recurrent ulcers on the ipsilateral leg, or die [8].

Revascularization for patients with CLI is performing with endovascular or surgical methods, or the combination of both (hybrid procedure) [9]. One of the methods to treat critical ischemia was and still is the reconstructive surgery on the arteries of the lower extremities [8].

Active surgical tactics in the treatment of critical lower limb ischemia with the use of combined methods of blood flow restoration have led to the possibility to save the limb in the near postoperative period in 85.8% of patients, regarding the long-term results, the limb can be saved in 67.9% of cases, in 15.3% of patients, amputations are limited to a small volume, therefore, it remains possible to save the limb support function [14]. IIB-IV ischemia according to Pokrovsky-Fontaine classification is a prescription to transluminal balloon angioplasty [9]. This method of treatment is more suitable for shot arterial stenosis [9].

Clinical success with angioplasty on arteries below the inguinal ligament can reach 87%, long-term patency-60-70% [8]. Some authors indicate that the frequency of limb preservation during critical ischemia within one year after the use of endovascular treatment reaches 93.5% [15]. The use of endovascular interventions for patients with critical ischemia is of great importance today [16]. The increased number of critical limb ischemia operations dictates the conducting of new scientific researches to develop the optimal treatment strategy for such a category of patients [1].

Currently, the percutaneous transluminal balloon angioplasty technique successfully competes with classical surgical techniques in the treatment of vascular diseases [9]. In recent years, the use of endovascular techniques has increased dramatically due to its low invasiveness and reduced patient stay in hospital compared with bypass operations [16].

However, despite the large number of advantages of percutaneous transluminal balloon angioplasty in critical limb ischemia, there are still many unresolved problems that reduce frequency of clinical and technical success of angioplasty [17]. One of such problems is impact of the arterial pedal arch revascularization on the clinical result [18].

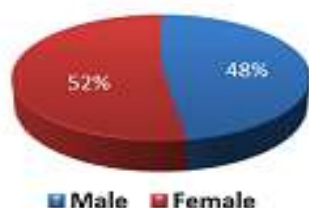
The aims of this study were to assess the clinical results of the arterial pedal arch revascularization of the patients with critical lower limb ischemia of IV class according to Pokrovsky-Fontaine classification and to compare the results of treatment of such patients after angioplasty with/without the arterial pedal arch revascularization.

Materials and Methods

The results of treatment of 98 patients with peripheral arterial disease (PAD), complicated by critical lower limb ischemia of IV class according to Pokrovsky-Fontaine classification were analyzed in the early postoperative period and 1 year later after the completed angioplasty of lower limb arteries. Patients had been treating from

2010 to 2018 years in the vascular surgery department of the clinic of the Federal State Budget Educational Institution of Higher Medical Education of Rostov State Medical University, Rostov-on-Don, Russia. Patients were divided into two, comparable by sex, age, concomitant pathology, groups depending on the volume of surgery intervention performed. The first group included 44 patients with restoration of blood flow, both direct and through the fibular artery, along the arterial arch of the foot. The second group included 54 patients who underwent angioplasty of the lower limb arteries; however, it was not possible to revascularize the arterial arch of the foot. The ratio of male and female patients in the first group was 47.7% (21 patients) and 52.3% (23) respectively, in the second group- 53.7% (29) and 46.3% (25) (Figure 1).

Distribution of patients to sex in the 1st group



Distribution of patients to sex in the 2nd group

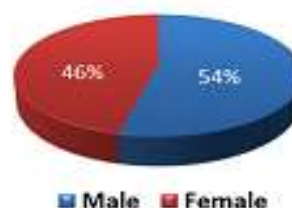


Figure 1: Distribution of patients to sex

Analysis of the distribution of patients with critical ischemia by age showed that in the first group, the average age of patients was

64.6 ± 7.4 years. While in the second group, the average age was 63.3 ± 9.7 years (Table 1).

Table 1: Distribution of patients to age

Index	1 st group	2 nd group	P
Patient age	64.6 ± 7.4	63.3 ± 9.7	0.915

All patients had

concomitant diseases given in the Table 2.

Table 2: The rate of concomitant pathologies

Concomitant pathology	1 st group N=44	2 nd group N=54
Diabetes mellitus of type II	45.5% (20)	51.8% (28)
Arterial hypertension	63.6% (28)	33.3% (18)
Ischemic heart diseases	36.4% (16)	25.9% (14)
Post-infarction cardiosclerosis	2.3% (1)	7.4% (4)
Obese	22.7% (10)	18.5% (10)
COPD	2.3% (1)	0% (0)
PUD	0% (0)	3.7% (2)
Chronic gastroduodenitis	0% (0)	1.8% (1)
Pancreatitis	0% (0)	1.8% (1)
Osteochondrosis	2.3% (1)	0% (0)
Diabetic nephropathy	2.3% (1)	3.7% (2)

Concomitant pathology	1 st group N=44	2 nd group N=54
Chronic pyelonephritis	4.5% (2)	0% (0)
Bronchial asthma	2.3% (1)	0% (0)
Aortic stenosis	0% (0)	1.8% (1)
Diffuse goiter	0% (0)	1.8% (1)
Thyroid cancer	0% (0)	1.8% (1)
Hypothyroidism	4.5% (2)	1.8% (1)
Post-thrombophlebitic syndrome	2.3% (1)	0% (0)

Analysis of concomitant pathology showed that in 48.98% (48 patients), critical ischemia is combined with diabetes mellitus of type II: 45.5% (20 patients) in the first group and 51.8% (28) in the second. Arterial hypertension was diagnosed in 46 (46.9%) patients: in the first group - 28 (63.6%) patients, in the second group - 18 (33.3%). 30 (30.6%) patients had ischemic heart diseases, of which 5 (5.1%) had post-infarction cardiosclerosis. 20 (20.4%) patients are obese.

Concomitant diseases such as chronic obstructive pulmonary disease (COPD), peptic ulcer disease (PUD), chronic gastroduodenitis, pancreatitis, osteochondrosis, diabetic nephropathy, chronic pyelonephritis, bronchial asthma, aortic stenosis, diffuse goiter, thyroid cancer, hypothyroidism, post-thrombophlebitic syndrome have also been found.

But, it should be underlined that atherosclerosis was the main etiological factor in the onset of the disease. Before the operation, all patients underwent a comprehensive examination, which included general clinical, laboratory and instrumental methods of research as well as ultrasound duplex examination of the arteries of the lower extremities with the determination of the peak linear blood flow velocity in the arteries of the lower leg, and transcutaneous oximetry at two standard points. The complex evaluation of all the results confirmed the diagnosis of "Critical limb ischemia of IV class according to Pokrovsky-Fontaine".

After standard preoperative preparation, consisting of the appointment of a double dose of antiplatelet agents, percutaneous transluminal balloon angioplasty of the arteries of the lower limb was done to all the patients; and besides, in patients of the first group it was also managed to restore the blood flow through the arterial pedal arch. Slow and continuous balloon inflation in transluminal balloon angioplasty was carried out up to its full opening with the help of "Invatec" balloon catheters (diameter 1.5-4.0

mm, length 80-210 mm). As a basis for assessing the results of reconstructive intervention, we selected IV class ischemia evaluation criteria developed by A.V. Pokrovsky:

- "Good result"-no pain at rest; the healing of ulcers;
- "Satisfactory result"-no pain at rest, but pain during physical activity; lack of dynamics in the healing of ulcers that increases the hospital stay term;
- "Unsatisfactory result"-absence of positive dynamics after the angioplasty performed; progression of necrotic ulceration.

According to the Pearson χ^2 test, χ^2 Emp is equal to or greater than the critical value, the differences between the distributions are statistically significant ($p < 0.05$).

In the postoperative period the efficiency of transluminal balloon angioplasty was evaluated in:

- Dynamics of the clinical manifestations of ischemia;
- Number of amputations performed, necrectomy;
- Angiographic control.

Results

The results were evaluated in the early postoperative period and 1 year later after the completed angioplasty. In the early postoperative period 88.6% of the first group patients (39 patients) had the arterial pedal arch completely opened, 11.4% (5 patients) had arterial pedal arch filled only through the fibular artery.

Among patients with a fully opened pedal arch, "good result" was observed in 23.1%, (9 patients) "satisfactory result" - 51.3% (20 patients), "unsatisfactory result" - 25.6% (10 patients). Among patients with filling the pedal arch only through the fibular artery, "good result was not observed, "satisfactory

result” - 40% (2 patients), “unsatisfactory result” - 60% (3 patients). In the early postoperative period, among 54 patients whom it was impossible to restore arterial pedal arch blood, “good result” was observed in 9.2%, “satisfactory result” - 31.5%,

“unsatisfactory result” - 59.3%. The mentioned data were clinically confirmed by peripheral angiography. Long-term results of treatment 1 year later were also evaluated (Figure 2).

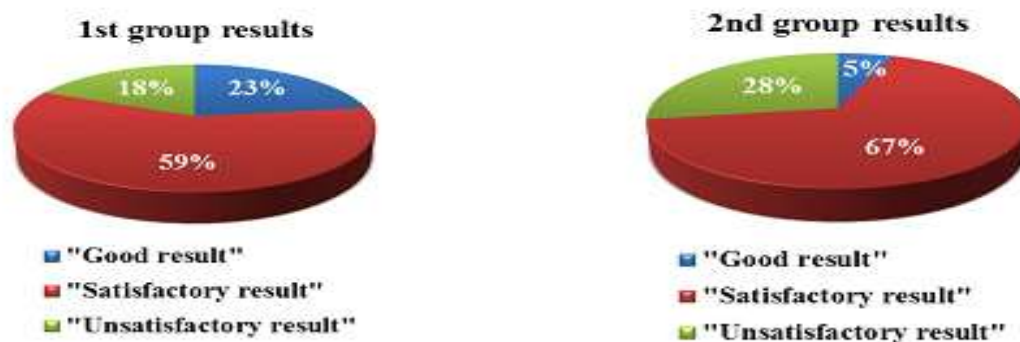


Figure 2: Results of treatment (1 year later)

In the first group:

- “good result” - 22.7% (10 patients);
- “satisfactory result” - 59.1% (26 patients);
- “Unsatisfactory result” - 18.2% (8 patients).

In the second group:

- “good result” - 5.6% (3 patients);
- “satisfactory result” - 66.7% (36 patients);
- “Unsatisfactory result” - 27.7% (15 patients).

The pedal amputation was done in the half of the patients with “unsatisfactory result”. The mentioned data was clinically confirmed by peripheral angiography.

According to the Pearson χ^2 test, χ^2 Emp is equal to or greater than the critical value, the differences between the distributions are statistically significant ($p < 0.05$).

According to the results, arterial pedal arch revascularization statistically significantly ($p < 0, 05$) influences on the clinical results and decreases the quantity of amputations in patients with purulent-necrotic changes in the limb.

Discussion

Endovascular methods are highly effective ones of critical limb ischemia of popliteal tibial arterial segment. Increases in linear blood flow velocity, significant grow of collateral channel, and reductions of clinical

symptoms are the results of treatment of patients with the help of transluminal balloon angioplasty. It is the best way in treatment for patients with CLI of the IV class according to Pokrovsky-Fontaine classification, i.e. with the ulcerative necrotic changes caused by damage of popliteal artery and/or lower limb arteries. The analysis of the results of treatment of patients showed that both in the early postoperative period and in the long term, a good result is more often achieved in patients who managed to restore blood flow along the arterial pedal arch.

However, it is worth noting that our study showed the insufficient effectiveness of the restoration of blood flow through the peroneal arteria (lack of a “good result”). “Satisfactory result” in the early postoperative period was also observed in patients with the opened arterial pedal arch, but in the late period there was no such a correlation.

“Unsatisfactory result” in the early postoperative period appeared to be the most often in the patients with the restoration of blood flow though peroneal arteria. As well as in patients whom it was impossible to restore the arterial pedal arch. In the late postoperative period we observe a greater number of “unsatisfactory results” in patients with the closed arterial pedal arch.

The analysis of arterial pedal arch showed that in the late period in the group of patients with “unsatisfactory result” who require the amputation of low extremities

there were no patients with the opened arterial pedal arch. The results received in the process of our research confirm the studies of Neville et al and Iida et al that showed the great improvement in wound healing and indicated the lower limb saving in both surgical and endovascular revascularization when during angioplasty the arterial arch was retained or opened. On the other hand, the researches of Rashid H. et al did not prove the revascularization of the arterial arch to have an impact on the healing of purulent-necrotic lesions [19, 20, 18, 3]. All this makes the researchers to carry out new randomized controlled trials.

Conclusion

Endovascular revascularization of the lower limb arteries with restoration of the arterial pedal arch is an effective technique that provides a good clinical result in patients with IV class according to Pokrovsky-Fontaine classification. The arterial pedal arch patency restoring is a significant factor

affecting the number of amputations in the early and late postoperative period. Herewith, the filling of the arterial pedal arch through one of the main arteries of the lower limb is of the great necessity because the provision of blood flow through the fibular artery does not significantly improve the clinical result.

In selecting the best revascularization option for CLI it is needed a personalized approach. It is very important to take into attention every patient data, such as age, comorbidities, life expectancy, kidney function, risk associated with anesthesia, and compliance. Besides, anatomic factors (e.g., availability of venous conduit, distal target, runoff, calcification, previous procedures) should also be noted. The choice of treatment method for CLI should be discussed with all stakeholders so that no patient should undergo a major amputation without consideration of all treatment alternatives.

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