Endovascular Procedures in Treatment of Infrapopliteal Arterial Occlusive Disease: Single Center Experience With 69 Infrapopliteal Procedures

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Abstract

Background: Peripheral arterial occlusive disease (PAD) includes acute and chronic disorders of the blood supply as a result of obstruction of blood flow in the arteries of the limb. Treatment of PAD can be conservative, surgical and endovascular. Percutaneous transluminal angioplasty with or without stenting has become a recognized method, which is increasingly used in treatment of arterial occlusive disease. This study aimed to determine early results of endovascular treatment of critical limb ischemia (CLI) patients with infrapopliteal lesions.

Methods: The study included 69 patients (46 men; mean age 65 years, range 38–84) with CLI (class 4 to 6 according to Rutherford). The primary study endpoints were absence of major amputation of the target limb at 6 months and occurrence of local and systemic complications specifically related to use of endovascular treatment.

Results: Major amputation was avoided in 61 patients. Through 6 months, 6 patients underwent additional revascularization. One local complication (clinically significant dissection of popliteal artery) occurred, and it was resolved by stent implantation. There were no cases of systemic complications and death during the follow-up period. Rates of major amputation were 12.3% for diabetics versus 8.3% for non-diabetics.

Conclusion: Our data showed that endovascular treatment of infrapopliteal disease is an effective and safe treatment in patients experiencing CLI, provides high limb preservation and low complication rates. Study outcomes support endovascular treatment as a primary option for patients experiencing CLI due to below the knee (BTK) occlusive disease.

Keywords: Angioplasty, Balloon, Endovascular procedures, Peripheral arterial disease, Tibial arteries

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Introduction

Peripheral arterial occlusive disease (PAD) includes acute and chronic disorders of the blood supply as a result of obstruction of blood flow in the arteries of the limb. The basic pathoanatomical substrate is atherosclerosis, which is also responsible for coronary, cerebrovascular, mesenteric and renal artery occlusive disease. The prevalence of PAD in the general population is between 12% and 14%.1

The risk factors are the same as those for other massive non-infectious diseases, but there are three factors which are especially connected with high incidence of PAD. Smoking, chronic renal failure (CRF) and diabetes strongly initiate the process of atherosclerosis and lead to the most serious forms of PAD. Diabetes and CRF lead primarily to the development of infrainguinal and infrapopliteal arterial lesions. Severe infrapopliteal lesions significantly decrease the possibility of revascularization.2

Critical limb ischemia (CLI) is characterized by “rest pain” or trophic ulcers in the limb, caused by reduction of distal tissue perfusion below the level of the basal needs. According to Rutherford classification of chronic ischemia of the lower extremity, there are six classes: classes 1 to 3 for different degrees of claudications, class 4 for “rest pain” and classes 5 and 6 for minor and major tissue loss.3

The course of disease is significantly different with intermittent claudications and CLI. Patients with chronic critical ischemia usually require revascularization in order to salvage the limb. Natural disease often leads to a high percentage of major amputations.3

Chronic critical ischemia of the lower extremity leads to amputation and death in high numbers. CLI is a sign of advanced polyvascular disease, poorly controlled chronic diseases, metabolic disorders and some other serious health disorders and conditions.4 The percentage of major amputations in patients with CLI in several large studies varied from 14.3% to 46.4%.5,6

Based on the involvement of the vascular system, there are three main types of arterial obstruction: in-flow

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lesions, out-flow lesions and both simultaneously. In-flow segment represents aorto-biiliacal, whereas the out-flow system is infrainguinal part of vascular system. The occurrence of chronic critical ischemia is usually caused by the combined failure.

Selection of patients for revascularization is the most important stage in the treatment algorithm. Patients with occlusive disease of infrapopliteal segment and chronic critical ischemia are extremely burdened with multiple, clinically significant comorbidities. Typically, these patients, in addition to diabetes and chronic renal insufficiency, manifest significant atherosclerotic changes in cerebrovascular and cardiovascular systems. These comorbidities decrease the efficiency and functional patency of revascularization techniques and increase perioperative and periprocedural mortality and morbidity. Thus, primary amputation should be considered for some patients who have no ability to walk and have CLI.

For a long time, bypass procedures represented the only revascularization technique in patients with CLI. In recent years, endovascular methods are more often used in treatment of PAD and CLI. Percutaneous transluminal angioplasty with or without stenting has become a recognized method, which is increasingly used in treatment of arterial occlusive disease. Endovascular procedures have shown satisfactory results in treating the signs and symptoms of PAD, comparable to results of open treatment, while showing significantly lower rates of morbidity and mortality. Thus, patients with multiple comorbidities and those without an adequate saphenous vein graft are candidates for endovascular treatment. Most studies have shown that endovascular procedures at the infrainguinal level can be done with minimal perioperative risk. Today, in many Western countries, endovascular treatment has become the method of choice in treatment of PAD. In Germany, 53.5% of patients with critical ischemia of the lower limbs are treated endovascularly.

This study aimed to determine the early results of endovascular treatment of CLI patients with infrapopliteal lesions.

Material and Methods
This prospective study covered the period from 2014 to 2015 at the Department of Vascular Surgery Clinical Center of Vojvodina. The study included 69 patients who were hospitalized at our clinic after ambulatory diagnosed CLI because of infrapopliteal disease and were treated endovascularly. All patients were classified as class 4 to 6 according to Rutherford. The following parameters were included:

1) General characteristics: gender, age;
2) Class of chronic CLI according to Rutherford;
3) Type of procedure: PTA alone, or PTA followed by stent placement;
4) Localization of treated segment: one of three crural arteries, third segment of popliteal artery and treating superficial femoral artery stenosis together with infrapopliteal lesions;
5) Need for additional revascularization: endovascular or open technique;
6) Periprocedural complications;
7) Data on co-morbidities were obtained: diabetes mellitus /DM/ and chronic renal failure /CRF/.

The treatment outcome was monitored for 6 months after the procedure and the following outcomes were indicated as possible in that period:

1) preserved extremity (no amputation, toe, Ray and transmetatarsal amputation)
2) amputation (below-knee and above-knee amputation)

Electronic database of Department of Vascular and Transplantation Surgery of The Clinical Center of Vojvodina in Novi Sad was used for data collection.

Results
The male to female ratio was 46:23. Mean age was 65, the youngest and the oldest being 38 and 84 years old, respectively. More patients (57) had tissue loss at the time of undergoing a procedure, and only 12 had “rest pain”.

Only 7 patients received stent placement followed by balloon angioplasty. In one case, two stents were placed to treat arterial dissection as the only complication accompanying this group of patients.

Only infrapopliteal arteries were treated in more than half of the cases (37/69). Endovascular procedure include terminal segment of popliteal artery in 20 and superficial femoral artery stenosis were treated simultaneously with below the knee (BTK) segments in 12 patients.

Additional revascularization was used in 6 patients: four of them endovascularly again and two of them with open treatment.

Most patients (59) had diabetes mellitus and 6 of them had signs of chronic renal failure.

Limb preservation was achieved in 61 patients. Six patients underwent toe, Ray and transmetatarsal amputation which healed. All patients who experienced major limb amputation were diagnosed with diabetes. We performed Ankle Brachial Index and duplex scan examination after 1, 3 and 6 months following PTA, and noticed, in seven cases, some plaque recoil (hemodynamically significant), 2 after 1 month and 5 after 3 months, but without any clinical significance on wound healing.

Discussion
It is necessary to take active attitude with patients
A group of authors indicated the endovascularly (1.4%). There were no cases of systemic treatment. Another endovascular intervention, while 2 required open revascularization occurred in 6 patients, 4 of whom had secondary limbs were recorded (11.6%), one at above the knee level. All those patients had diabetes. Secondary revascularization occurred in 6 patients, 4 of whom had another endovascular intervention, while 2 required open treatment.

One local complication occurred and was resolved endovascularly (1.4%). There were no cases of systemic complications and death during the follow-up period. This establishes infrapopliteal endovascular procedure as a low risk procedure.

A large number of studies have dealt with critical ischemia associated with proximal stenosis, while data on the endovascular treatment of infrapopliteal occlusive disease were limited primarily because of the low patency rates and frequent technical failures. In the last decade, due to advances in technology and gaining clinical experience, the results are numerous and notable. Nowadays, endovascular treatment is the primary method of choice in treatment of critical ischemia of the lower limbs in infrapopliteal occlusive disease.

Certain studies have shown equal results of endovascular and open treatment of infrapopliteal segments. Open surgery proved to be superior only in the treatment of TASC D lesions. Most studies emphasize the complementarity of the treatment modalities rather than rivalry.

With the development of modern technology, endovascular methods are becoming more numerous, diverse and applicable to a larger number of patients. Nowadays, in addition to traditional balloon angioplasty, more modern devices are used: balloon dilators (DEB - drug eluting balloons), different types of stents (BMS - bare metal stents, DES-drug eluting stents, bioabsorptive), atherectomies, laser assisted aterectomies, and kryoplasty. A group of authors indicated the superiority of DEB in relation to PTA, because DEB markedly reduces the restenosis rate. Stent application and kryoplasties in treatment of popliteal artery lesions also showed satisfactory results. However, despite the encouraging initial results of the new endovascular procedures, classic balloon angioplasty remains the method of choice in treatment due to lack of randomized trials.

In conclusion, endovascular treatment of infrapopliteal disease in patients experiencing CLI is a low risk procedure with limb preservation rates comparable to open treatment. The main advantage of this procedure is that it can be done in patients with significant comorbidity.

Authors’ Contribution
PJJ contributed to study conception and design and interpretation of data. PVA contributed to study conception and design and critical revision. All authors revised subsequent drafts of the paper. PJJ and BBN did review and final approval of manuscript.

Conflict of Interest Disclosures
The authors declare that there are not any potential financial and non-financial conflicts of interest.

Ethical Statement
We obtained approval of the Ethics Committee in our institute as well as informed consent of all participants in this study.

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