Arch Iran Med. March 2018;21(3):118-121

http www.aimjournal.ir

ARCHIVES OF IRANIAN MEDICINE

Open Access

Original Article

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

Pasternak J. Janko, MD[1*]; Budakov B. Nebojsa, MD[1]; Petres V. Andrej, MD[2]

[1]Department of Vascular Surgery, Clinical Centre of Vojvodina, University of Novi Sad, Faculty of Medicine, Novi Sad, Serbia
[2]Department of Radiology, Clinical Centre of Vojvodina, University of Novi Sad, Faculty of Medicine, Novi Sad, Serbia

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 occurance 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 (clinicaly 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

Cite this article as: Janko PJ, Nebojsa BB, Andrej PV. Endovascular procedures in treatment of infrapopliteal arterial occlusive disease: single center experience with 69 infrapopliteal procedures. Arch Iran Med. 2018;21(3):118–121.

Received: August 20, 2016, Accepted: November 29, 2017, ePublished: March 1, 2018

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 orded 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 polivascular 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

*Corresponding Author: Pasternak J. Janko, MD; General and Vascular Surgeon, Chair of Department of Surgery, Faculty of Medicine, University of Novi Sad, Novi Sad, Hajduk Veljka 1, 21000, Novi Sad, Serbia. Tel: +38-1648059798, Fax: +38-121421545, Email: janko.pasternak@mf.uns.ac.rs.

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[7]. These comorbidities decrease the efficiency and functional patency of revascularazation 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 .[8]

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.[9] 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.[10]

This study aimed to determe 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 caracteristics: 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 leasions;
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 was 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 Ankele 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.

Discusion

It is necessary to take active attitude with patients experiencing CLI. A large percentage of patients with chronic critical ischemia without revascularization experience amputation. A retrospective analysis that included 69 patients with critical ischemia showed that without revascularization, only 5% of them salvaged limb during the period of one year.[7]

The most important issue is the initial decision whether to attempt limb salvage or proceed with major amputation. Although many surgeons regard amputation as a personal failure, for some patients primary amputation may be the best approach in specific subsets. Taylor et al recently reported that in a group of patients with CLI who were unsuitable for open surgery, PTA was not better than primary amputation.[10] Ambulation and independent living lasted only 12 and 3 months, respectively, with higher mortality rate in PTA group. For patients with extensive foot lesions, severe comordibities or very unfavorable anatomy, primary amputation is often the best option. This indicates the importance of studies in order to follow-up functional status and quality of life of those patients.

When deciding on the type of treatment, we should take into account the stage of disease, the extension of arterial lesions, the current restrictions on patients everyday activities, comorbid conditions, previous revascularization interventions and predictive maintenance and achievable functional status.[7]

Opinions on the role of endovascular treatment for infrapopliteal disease are divided. There is not enough evidence to recommend its application in patients with claudication. It is recommended that for patients with CLI, infrapopliteal occlusive disease and numerous comorbid conditions who are not suitable for open treatment, endovascular treatment should be considereed to avoid ablative treatment.[11] The greatest clinical significance is withdrawal of symptoms, limb preservation and patient survival.

In this study, limb preservation was achieved in 88.4% of cases, which as an early result is similar to the published data.[12-14] This includes six patients who underwent minor amputation which healed. Bosiers et al had even better limb salvage rate of nearly 97%.[14] The primary weakness of our study is the relatively short follow-up and impossibility to perform evaluation of ambulation and living status.

Only 8 cases of secondary major amputation of 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.[12] Nowadays, endovascular treatment is the primary method of choice in treatment of critical ischemia of the lower limbs in infrapoplitealne occlusive disease.[11-18]

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.[19] Most studies emphasize the complementarity of the treatment modalities rather than rivalry.[20,21]

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 ballons), different types of stents (BMS - bare metal stents, DES-drug eluting stents, bioabsorptive), atherectomies, laser assisted aterectomies, and kryoplasty.[22] A group of authors indicated the superiority of DEB in relation to PTA, because DEB markedly reduces the restenosis rate.[23] Stent application and kryoplasties in treatment of popliteal artery lesions also showed satisfactory results.[24,25] 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.

References

1. Shammas NW. Epidemiology, classification, and modifiable risk

factors of peripheral arterial disease. Vasc Health Risk Manag. 2007;3(2):229-234.
2. Jaff MR, White CJ, Hiatt WR, Fowkes GR, Dormandy J, Razavi M, et al. An update on methods for revascularization and expansion of the TASC lesion classification to include below-the-knee arteries: A supplement to the inter-society consensus for the management of peripheral arterial disease (TASC II): The TASC steering committee. Catheter Cardiovasc Interv. 2015;86(4):611-625. doi: 10.1002/ccd.26122.
3. Varu VN, Hogg ME, Kibbe MR. Critical limb ischemia. J Vasc Surg. 2010;51(1):230-241. doi: 10.1016/j.jvs.2009.08.073.
4. Manojlovic V, Popovic V, Nikolic D, Milosevic D, Pasternak J, Kacanski M. Analysis of associated diseases in patients with acute critical lower limb ischemia. Med Pregl. 2013;66(1-2):41-45.
5. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). J Vasc Surg. 2007;45 Suppl S:S5-67. doi: 10.1016/j.jvs.2006.12.037.
6. Teraa M, Conte MS, Moll FL, Verhaar MC. Critical Limb Ischemia: Current Trends and Future Directions. J Am Heart Assoc. 2016;5(2). doi: 10.1161/jaha.115.002938.
7. Komai H, Obitsu Y, Shigematsu H. Diabetes and old age could affect long-term patency of paramalleolar distal bypass for peripheral arterial disease in Japanese patients. Circ J. 2011;75(10):2460-2464.
8. Saqib NU, Domenick N, Cho JS, Marone L, Leers S, Makaroun MS, et al. Predictors and outcomes of restenosis following tibial artery endovascular interventions for critical limb ischemia. J Vasc Surg. 2013;57(3):692-699. doi: 10.1016/j.jvs.2012.08.115.
9. Meyer A, Lang W, Borowski M, Torsello G, Bisdas T. In-hospital outcomes in patients with critical limb ischemia and end-stage renal disease after revascularization. J Vasc Surg. 2016;63(4):966-973. doi: 10.1016/j.jvs.2015.10.009.
10. Taylor SM, Kalbaugh CA, Blackhurst DW, Kellicut DC, Langan EM 3rd, Youkey JR. A comparison of percutaneous transluminal angioplasty versus amputation for critical limb ischemia in patients unsuitable for open surgery. J Vasc Surg. 2007;45(2):304-310. doi: 10.1016/j.jvs.2006.09.038.
11. Rana MA, Gloviczki P. Endovascular interventions for infrapopliteal arterial disease: an update. Semin Vasc Surg. 2012;25(1):29-34. doi: 10.1053/j.semvascsurg.2012.03.003.
12. Sacks D, Marinelli DL, Martin LG, Spies JB. Reporting standards for clinical evaluation of new peripheral arterial revascularization devices. J Vasc Interv Radiol. 2003;14(9 Pt 2):S395-404.
13. Bosiers M, Deloose K, Cagiannos C, Verbist J, Peeters P. Use of the AngioSculpt scoring balloon for infrapopliteal lesions in patients with critical limb ischemia: 1-year outcome. Vascular. 2009;17(1):29-35. doi: 10.2310/6670.2009.00001.
14. Bosiers M, Hart JP, Deloose K, Verbist J, Peeters P. Endovascular therapy as the primary approach for limb salvage in patients with critical limb ischemia: experience with 443 infrapopliteal procedures. Vascular. 2006;14(2):63-69. doi: 10.2310/6670.2006.00014.
15. van Overhagen H, Spiliopoulos S, Tsetis D. Below-the-knee interventions. Cardiovasc Intervent Radiol. 2013;36(2):302-311. doi: 10.1007/s00270-013-0550-1.
16. Gray BH, Diaz-Sandoval LJ, Dieter RS, Jaff MR, White CJ. SCAI expert consensus statement for infrapopliteal arterial intervention appropriate use. Catheter Cardiovasc Interv. 2014;84(4):539-545. doi: 10.1002/ccd.25395.
17. Lumsden AB, Davies MG, Peden EK. Medical and endovascular management of critical limb ischemia. J Endovasc Ther. 2009;16(2 Suppl 2):Ii31-62. doi: 10.1583/08-2657.1.
18. Casella IB, Brochado-Neto FC, Sandri Gde A, Kalaf MJ, Godoy MR, Costa VS, et al. Outcome analysis of infrapopliteal percutaneous transluminal angioplasty and bypass graft surgery with nonreversed saphenous vein for individuals with critical limb ischemia. Vasc Endovascular Surg. 2010;44(8):625-632. doi: 10.1177/1538574410373663.
19. Schamp KB, Meerwaldt R, Reijnen MM, Geelkerken RH, Zeebregts CJ. The ongoing battle between infrapopliteal angioplasty and bypass surgery for critical limb ischemia. Ann Vasc Surg. 2012;26(8):1145-1153. doi: 10.1016/j.avsg.2012.02.006.
20. Spillerova K, Biancari F, Leppaniemi A, Alback A, Soderstrom M, Venermo M. Differential impact of bypass surgery and angioplasty on angiosome-targeted infrapopliteal revascularization. Eur J Vasc Endovasc Surg. 2015;49(4):412-419. doi: 10.1016/j.ejvs.2014.12.023.
21. Attinger CE, Evans KK, Bulan E, Blume P, Cooper P. Angiosomes of the foot and ankle and clinical implications for limb salvage: reconstruction, incisions, and revascularization. Plast Reconstr Surg. 2006;117(7 Suppl):261s-293s. doi: 10.1097/01.prs.0000222582.84385.54.
22. Liistro F, Porto I, Angioli P, et al. Drug-eluting balloon in peripheral intervention for below the knee angioplasty evaluation (DEBATE-BTK): a randomized trial in diabetic patients with critical limb ischemia. Circulation. 2013;128(6):615-621. doi: 10.1161/circulationaha.113.001811.
23. Karnabatidis D, Katsanos K, Siablis D. Infrapopliteal stents: overview and unresolved issues. J Endovasc Ther. 2009;16 Suppl 1:I153-162. doi: 10.1583/08-2593.1.
24. Bosiers M, Lioupis C, Deloose K, Verbist J, Peeters P. Two-year outcome after Xpert stent implantation for treating below the knee lesions in critical limb ischemia. Vascular. 2009;17(1):1-8. doi: 10.2310/6670.2009.00002.
25. Das TS, McNamara T, Gray B, Sedillo GJ, Turley BR, Kollmeyer K, et al. Primary cryoplasty therapy provides durable support for limb salvage in critical limb ischemia patients with infrapopliteal lesions: 12-month follow-up results from the BTK Chill Trial. J Endovasc Ther. 2009;16(2 Suppl 2):Ii19-30. doi: 10.1583/08-2652.1.