

©Borgis

\*Piotr Słowiński, Andrzej Eberhardt, Jan Wawszczak, Grzegorz Madycki, Walerian Staszkiwicz

## Pathophysiology, diagnosis and treatment of patients with critical limb ischaemia, based on the results of surgical treatment

### Patofizjologia, diagnostyka oraz leczenie chorych z krytycznym niedokrwieniem kończyn dolnych w oparciu o własne wyniki leczenia zabiegowego

Department of Vascular Surgery and Angiology, Centre of Postgraduate Medical Education, Bielany Hospital, Warsaw  
Head of Department: Professor Walerian Staszkiwicz, MD, PhD

#### Keywords

peripheral artery disease, critical limb ischaemia, atherosclerosis

#### Słowa kluczowe

choroba tętnic obwodowych, krytyczne niedokrwienie kończyn dolnych, miażdżyca tętnic

#### Conflict of interest Konflikt interesów

None

Brak konfliktu interesów

#### Address/adres:

\*Piotr Słowiński  
Department of Vascular Surgery and Angiology  
Centre of Postgraduate Medical Education  
Bielany Hospital  
ul. Cegłowska 80, 01-809 Warszawa  
tel. +48 (22) 569-02-85  
sloviski.p@wp.pl

#### Summary

**Introduction.** Critical limb ischaemia is a form of peripheral artery disease where patients experience typical chronic ischaemic pain at rest or ischaemic ulcers. Prompt CLI diagnosis is essential, as the condition means high risk of limb loss, fatal and non-fatal cardiovascular events, myocardial infarction, and stroke.

**Aim.** The aim of the study was to compare the results of surgical and endovascular treatment in patients with critical limb ischaemia.

**Material and methods.** The study included 120 patients with symptoms of critical limb ischaemia admitted into and treated at our department in 2010-2012, and then covered by a 3-year follow-up. Following necessary vascular diagnosis and assessment of their general condition, patients were determined eligible for surgical treatment: surgery or endovascular treatment. During the follow-up period, the patency of the prosthesis/vessels and the number of salvaged limbs in given treatment groups were compared.

**Results.** The majority of patients were found eligible for surgical treatment, either endovascular management or surgery. In 26 patients both methods were combined in one procedure known as "hybrid procedure". Both early and late patient outcomes were superior for surgical (71.4% patency after 3 years) and hybrid (74.4%) intervention as compared to endovascular therapy (58.2%). Comparing the rate of amputations, in the entire follow-up period the outcomes of surgical treatment were comparable regardless of the method used.

**Conclusions.** Vascular intervention in CLI patients is an effective method, allowing to prevent limb amputation. It is our recommendation that such patients should be treated in highly specialized vascular surgery centres, and the choice of the method of management should always be made individually, taking into account both the severity of atherosclerotic lesions and the patient's overall condition, with the main goal of treatment being the reduction of amputation and mortality rates in the high-risk group of CLI patients.

#### Streszczenie

**Wstęp.** Krytyczne niedokrwienie kończyn dolnych jest postacią choroby tętnic obwodowych, opisującą pacjentów z typowym przewlekłym bólem niedokrwieniowym występującym u pacjentów w czasie spoczynku lub pacjentów z niedokrwieniowymi zmianami skórnymi. Bardzo ważne jest szybkie zdiagnozowanie CLI, ponieważ oznacza ono wysokie ryzyko utraty kończyny oraz wystąpienia śmiertelnych i niezakończonych zgonem epizodów naczyniowych, zawału serca oraz udaru mózgu.

**Cel pracy.** Celem pracy było porównanie wyników leczenia chirurgicznego i wewnątrz-naczyniowego u chorych z krytycznym niedokrwieniem kończyn dolnych.

**Materiał i metody.** Badaniem objęto 120 chorych z objawami krytycznego niedokrwienia kończyn dolnych, których przyjęto i leczono w naszej klinice w latach 2010-2012, a następnie poddano 3-letniej obserwacji. Po niezbędnej diagnostyce naczyniowej i ocenie stanu ogólnego chorych kwalifikowano do leczenia zabiegowego: chirurgicznego lub wewnątrz-naczyniowego. W czasie obserwacji porównywano drożność protezy/naczynia oraz ilość uratowanych kończyn.

**Wyniki.** Większość chorych została zakwalifikowana do leczenia zabiegowego, wewnątrz-naczyniowego lub chirurgicznego. U 26 chorych połączono obie metody leczenia podczas jednego zabiegu zwanego „operacją hybrydową”. Zarówno wczesne, jak i późne wyniki co do drożności naczynia/protezy po zabiegach są lepsze w przypadku leczenia chirurgicznego (71,4% drożności po 3 latach) i „hybrydowego” (74,3%) w porównaniu

z leczeniem wewnątrznacyniowym (58,2%). Porównując wskaźnik amputacji, możemy stwierdzić, że w całym okresie obserwacji wyniki leczenia zabiegowego są porównywalne niezależnie od użytej metody.

**Wnioski.** Leczenie zabiegowe chorych z CLI jest metodą skuteczną, pozwalającą na uratowanie kończyny przed amputacją. Sugerujemy, że chorzy ci powinni być leczeni w wyspospecjalistycznych ośrodkach chirurgii naczyniowej, a kwalifikacja co do sposobu postępowania powinna być zawsze indywidualna i uwzględniać zarówno stopień zaawansowania zmian miażdżycowych, jak i ogólną kondycję zdrowotną chorego, a najważniejszym celem leczenia powinno być zmniejszenie odsetka amputacji i zgonów w grupie wysokiego ryzyka, jaką są chorzy z CLI.

## INTRODUCTION

Critical limb ischaemia is a form of peripheral artery disease affecting patients with typical chronic ischaemic pain at rest or with ischaemic ulcers or gangrene. CLI should only be used to describe patients with chronic ischaemia, defined as symptoms lasting for a period longer than 2 weeks. CLI is a term that describes patients with the most advanced form of chronic peripheral arterial disease (PAD) (1, 2). Even though acute limb ischaemia may be caused by occlusion of a large vessel, the majority of CLI cases are due to progressing atherosclerosis. Sometimes, CLI may be the result of Buerger's disease or other inflammatory vascular disease.

Prompt CLI diagnosis is crucial, as the condition is equivalent with a high risk of limb loss and occurrence of either fatal or non-fatal cardiovascular events, myocardial infarction, and ischaemic brain stroke. The prognosis in CLI patients is far worse than in patients with intermittent claudication. Observation studies on CLI patients who are not eligible for revascularization suggest that one year from the onset of CLI approximately only half of them will have survived without a major amputation, and some will still sustain rest pain, gangrene or ulcers (3). Approximately 25% of the patients will have died, and in 25% a major amputation will have been necessary. The prognosis in these patients is largely similar to prognosis in some neoplastic conditions. CLI diagnosis means very poor prognosis in terms of patient survival and limb salvage (4, 5). The patients require instant modification of risk factors for the progression of cardiovascular diseases. They should also receive anti-platelet therapy. For many CLI patients palliative care is necessary, an important factor when considering revascularization or amputation (1).

### Epidemiology and natural history

Based on reliable results from large prospective clinical studies on the occurrence of CLI, its incidence has been determined at 220 cases per 1 million citizens, thus accounting for 1% of all PAD patients. In this patient group, the risk for cardiovascular diseases is significantly increased. In PAD patients the risk for cardiac ischaemia or heart failure-related mortality is 3-6 times higher than in the rest of the population (1, 6, 7).

### Pathophysiology

Chronic CLI is most commonly caused by atherosclerosis of peripheral arteries associated with old age, hyper-

tension, hypercholesterolemia. Separately or combined, these risk factors contribute to aggravation of PAD symptoms from intermittent claudication to CLI. Other causes of CLI include arterial embolism formed by atherosclerotic plaques, vascular inflammation, popliteal artery entrapment, and injuries. CLI is a condition characterized by severely deteriorated blood flow in the limb, resulting in nutrient deficiency in the relevant tissues. Atherosclerosis in the lower limb is typically located in the distal end of the femoral superficial artery and in the region where it descends into the popliteal artery (8, 9). As atherosclerosis progresses, the lesions are propagated in the proximal direction with simultaneously occurring stenosis and occlusions of the arteries of the calf and subsequently the external iliac artery and the common iliac artery. Ischaemic symptoms depend not only on the length of the involved arterial region and the location, but also on the formation of collateral circulation. In CLI patients the patency of the arteries is substantially impaired, with common concomitant multilevel stenoses or occlusions. The presence of multilevel lesions in the arteries combined with functional and structural changes in microcirculation results in diminished tissue perfusion that may lead to ulceration and necrotic lesions. On the level of microcirculation, epithelial damage and dysfunction occur, facilitating CLI progression by excessive decrease of vascular perfusion and propagation of conditions destabilizing atherosclerotic plaques and increasing embolic response to plaque rupture. Inflammation and thrombosis result in progressing tissue damage, increased capillary permeability and oedema (1, 4, 10).

The presence of distal stenoses increases the frequency of amputations and the risk of chronic CLI (11).

### Diagnostic methods

The diagnostics in CLI patients must be prompt, as adequate therapy timing affects treatment success. It should entail both imaging of the vascular system to determine the character and the severity of atherosclerotic lesions, and necessary diagnostics of concomitant diseases. Evaluation of the cardiovascular system, diabetes and renal function are key, hence imaging examinations (cardiac echo, chest radiograph), and necessary consultations by various specialists (cardiologist, nephrologist, diabetologist, neurologist) (2, 12).

The clinical picture is not sufficient for CLI diagnosis which requires also confirmation of atherosclerosis of peripheral arteries as the main cause of rest pain, ul-

ceration or limb gangrene. For this purpose ankle-brachial index (ABI) or toe-brachial index (TBI) calculation is required, along with measurement of intracutaneous oxygen partial pressure, and relevant imaging tests. Atherosclerosis may be demonstrated by US (colour duplex, Doppler), angiography, CTA, and MRA (13-15).

At present, instead of classic angiography or to limit the extent of this test in patients with limb ischaemia, US, CTA or MRA are increasingly often utilized. In most cases, owing to an earlier duplex Doppler evaluation, both the location and the severity of atherosclerotic lesions are known, with only their morphology remaining unknown. In practice, imaging frequently begins with an ultrasound test, as it is non-invasive, allows to determine the character of the lesions, may be done quickly, and facilitates faster introduction of treatment. Based on an US scan, it is oftentimes possible to plan adequate therapy, particularly in patients who have counter-indications for imaging tests with contrast agents (renal insufficiency, allergic response). Even though this technique is the most useful for evaluating lesions located in the superficial femoral artery, it has been also shown to detect lesions in arteries in the calves, feet, as well as the aortoiliac region (7, 14-16).

If the revascularization procedure is to be performed in a CLI patient, CTA is indicated. As it utilizes a contrast agent, it is an invasive test, associated with an additional risk of complications upon its administration. The exam is especially important in the case of multi-level lesions in the region of the femoral artery and arteries in the calf, responsible for CLI. It also important to note that the patient after receiving the contrast during a diagnostic procedure, may within a short period of time be treated with endovascular therapy also utilizing radiocontrast, which may additionally contribute to the occurrence of post-contrast renal insufficiency (17).

### Management

The main objectives of CLI management include: reduction of ischaemic pain, treatment of neuroischaemic ulcerations, preventing amputation, improvement of the patient's overall functioning, quality of life, and survival time. The primary aim of the therapy, therefore, is to extend the patient's survival time without having to perform an amputation. For the majority of patients, revascularization at a specialized centre is the most desirable. Other components of CLI management include pain control, limiting infection in the ischaemic limb, preventing atherosclerosis progression, and optimizing the functioning of the circulatory and respiratory system. For some CLI patients with severe comorbidities or a very limited chance for successful revascularization, amputation may be the appropriate method of treatment. Patients with CLI, just like patients with PAD, require efficient control of risk factors for atherosclerosis (14, 15, 18, 19).

### Conservative treatment

Some of the patients with CLI symptoms may not eligible for surgical or endovascular revascularization

due to severe concomitant diseases or the severity and extent of atherosclerotic lesions, precluding successful revascularization. In the course of conservative therapy of such patients, it is essential to identify all the comorbidities (especially cardiovascular diseases and diabetes), and institute adequate treatment (8, 14-17).

### SURGICAL TREATMENT: REVASCULARIZATION OR PRIMARY AMPUTATION?

The best method of preserving a limb in CLI patients without counter-indications is revascularization with surgical or endovascular means. According to a large meta-analysis, in CLI patients who had a vascular graft planted below the inguinal ligament, within 5 years' time 63% primary patency and 71% secondary patency of the graft was achieved, and in 78% patients the limb was salvaged. However, such results were achieved in centres specializing in CLI management (18).

Currently, there is a debate over the strategy for surgical treatment, comparing endovascular procedure and surgical bypass procedure with or without thromboendarterectomy. According to the TASC II guidelines for the management of PAD, open surgery is the method of choice in patients with D lesions (2). For the remaining groups, endovascular treatment is preferable or considered possible. It is nonetheless worth noting that the document was created in 2007, with new techniques of endovascular treatment of atherosclerotic lesions in lower limbs both in the region below and above the inguinal ligament having since then been developed, and old ones improved (8, 19). The supporters of open surgery particularly point out the largely superior results of long-term graft patency and the good clinical outcome, while the supporters of endovascular therapy highlight the higher perioperative mortality of open surgery with a similar outcome in terms of limb salvage (20-22).

The success of surgical management, be it endovascular procedure or open surgery, largely relies on good blood inflow and outflow into patent arteries below the intervention site. In CLI patients this relationship is especially clear, yet difficult to obtain (9). Considering that in this group of patients multilevel lesions are at stake, adequate procedure planning is key. It is crucial that the chosen procedure facilitates improved flow on all the levels of the limb's vascular system. Prior to endovascular treatment of the superficial femoral artery, patients should be evaluated for the severity of the lesions present in the arteries of the calf. In some cases it is necessary, following removal of occlusion within the femoral artery, to perform angioplasty of the arteries of the calf, aimed at obtaining satisfactory patency of at least two arteries. Restoring patency of the arteries of the calf frequently seems essential to prevent leg amputation (21,23).

### AIM

The aim of the study was the comparison of the outcomes of open surgery and endovascular management in CLI patients.

## MATERIAL AND METHODS

The study covered 120 patients with CLI symptoms, admitted into and treated at the Department of Vascular Surgery of the Centre for Medical Postgraduate Education in 2010-2012, who were subsequently followed up for 3 years. The study included all the patients admitted into our department at that time, whereas the final analysis covers only the followed-up patients. Patients with acute limb ischaemia were not enrolled for the study.

The majority of patients with CLI symptoms were admitted either on an emergency basis or referred as urgent by the Vascular Outpatient Centre. As a priority, the patients underwent prompt necessary vascular diagnostics and overall health evaluation to assess the perioperative risk and to facilitate optimal preoperative management. The key elements were considered to be evaluation of current circulatory function (insufficiency, hypertension), renal function, and blood glucose level. Necessary accessory investigations were also performed on an emergency basis, including echocardiography, ECG, and chest radiography, and the patients were consulted by other specialists, such as the cardiologist, diabetologist, or neurologist, as required.

The evaluation of the cardiovascular system comprised US and invasive imaging (CTA, MRA). The US scan included lower limb arteries but also carotid arteries. Even though a thorough US assessment of the entire lower limb’s vascular system is feasible, in our study US modality most frequently served as the starting point, facilitating confirmation of the clinical diagnosis of ischaemia due to arterial stenosis or occlusion. In isolated cases, the diagnostics relied solely on the US scan, primarily in the patients with counter-indications for invasive tests, such as allergy to the contrast agent or renal insufficiency, or when the unambiguous result of the US scan did not call for any further details. Invasive examinations such as CTA or, less frequently, MRA were also performed as emergency tests, typically on the day of the admission.

Admitting patients with CLI symptoms on the emergency basis, and the prompt vascular diagnostics and evaluation of overall patient’s condition allowed to get the majority of patients ready for the surgical intervention within 1-2 days from the date of their respective admission. The decision on how to proceed included the following available options: conservative management, palliative management (chemical sympathectomy), or surgical management, such as amputation and endovascular or surgical revascularization.

## RESULTS

The final analysis covered 120 patients treated for CLI symptoms at our clinic. The patients were found to commonly reveal multiple risk factors for atherosclerosis. The most common ones were many-year history of smoking, arterial hypertension, cholesterol metabolism disorders, old age, and diabetes (tab. 1).

**Tab. 1.** Characteristics of the studied group

Characteristics of the studied group	Studied group (N = 120)
Sex	
female	54 (45%)
male	66 (55%)
Age	
(min, max)	(45, 88)
mean (SD)	67 (9.4)
Age > 67	66 (55%)
Smoking	80 (67%)
Overweight	46 (38%)
Hypertension	64 (38%)
Diabetes	46 (38%)
Renal insufficiency	34 (28%)
Myocardial infarction	82 (68%)
Total cholesterol	
(min, max)	(156, 330)
mean (SD)	211.2 (39.2)
Total cholesterol > 200	60 (50%)
LDL	
(min, max)	(78, 258)
mean (SD)	158.9 (50.1)
LDL > 135	72 (60%)
HDL	
(min, max)	(30, 74)
mean (SD)	45 (8.5)
TG	
(min, max)	(78, 330)
mean (SD)	167.0 (60.1)

The majority of patients were admitted for treatment on an emergency basis, hence the waiting time for imaging diagnostics and preoperative patient management time were relatively short (3 days on average). The large majority of the patients were found eligible for the surgical therapy, either endovascular procedure or open surgery. In 26 patients the two methods were combined in one procedure known as “hybrid surgery” (tab. 2).

**Tab. 2.** Characteristics of the course of management in the studied group

Diagnostics and treatment in the studied group	Studied group (N = 120)
Admission	
emergency	86 (72%)
scheduled	34 (28%)
Diagnostics	
US only	16 (13%)
CTA/MRA	18 (15%)
US + CTA/MRA	96 (80%)
Waiting time for the decision on the management method	
(min, max)	(0, 14)
mean (SD)	3.1 (9.6)
Treatment	
conservative	17 (14%)
intervention	103 (86%)
surgery	32 (27%)
endovascular	38 (32%)
hybrid	26 (22%)
primary amputation	7 (6%)

When comparing the surgical treatment outcomes, it should be noted that both early and late outcomes in respect of vessel/prosthesis patency following the treatment are superior for surgical treatment (71.4% patency at 3 years) and “hybrid” (74.3%) as compared to endovascular treatment (58.2%). Yet, when comparing the crucial aspect from the patient’s perspective, i.e. the amputation rate, the outcomes throughout the follow-up period are comparable regardless of the management method adopted (tab. 3).

**Tab. 3.** Outcomes of surgical treatment

Outcomes	At 1 month	At 1 year	At 3 years
Vessel/draft patency			
endovascular	77.4%	66.3%	58.2%
surgery	98.3%	80.2%	71.4%
hybrid	93.6%	82.3%	74.3%
No amputation			
endovascular	94.4%	87.1%	82.5%
surgery	96.3%	87.3%	82.1%
hybrid	95.8%	84.3%	79.6%

In the group of patients not found eligible for surgical treatment, 9 primary amputations (53% of the patients receiving conservative treatment) were performed, whereas in the 3-year follow-up period, amputations in 6 more patients were necessary.

## DISCUSSION

According to the current guidelines on the surgical management of patients with lower limb atherosclerosis, in the case of stenoses and shorter occlusions endovascular management is recommended or favoured, whereas for longer occlusions of the superficial femoral artery (TASC II C and D lesions) surgical treatment is recommended or favoured (femoral-popliteal graft). TASC II document, published in 2007, is largely based on studies no longer up-to-date and not taking into account the current progress both in the endovascular procedures and the materials used for balloons, stents and stent-grafts (I). Since that time, the number of endovascular interventions in the femoral-popliteal region has increased dramatically, and according to the current literature of the subject so has the number of endovascular interventions in this region performed to treat longer occlusions (7, 24-26).

The stents now used in the femoral-popliteal region are self-expanding open-cell design ones made of nitinol (nickel titanium alloy). Owing to their construction and characteristics, they are best suited to the conditions inside the superficial femoral and popliteal arteries. As the only ones of the arteries of the lower limb, these arteries are exposed to a considerable deal of flexing, twisting and expanding (II). Despite the fact that in such conditions it is self-expanding stents that are the most preferable, practitioners avoid placing them in the popliteal fossa. The effectiveness of self-expanding stents in the femoral-popliteal region has been proven in numerous clinical studies (12-16, 20-24).

The results of endovascular treatment in the femoral-popliteal region, especially for longer occlusions, are comparable with the surgical outcomes. The femoral-popliteal graft in such patients is the treatment of choice or the recommended treatment (26, 27).

When applying this method of treatment, it must be remembered that numerous clinical studies confirm a significant difference in the draft patency time depending on the type of material used for the prosthesis (28, 29). A meta-analysis comprising 75 clinical trials suggests that a femoral-popliteal bypass made from the great saphenous vein remains patent significantly longer than a PTFE bypass. Additionally, this difference is even more pronounced to the vein bypass’s advantage in patients treated for CLI symptoms.

The evaluation of the degree of artery patency following a given course of treatment is very important, yet the its efficiency in terms of limb salvaging is even more so. According to our results, the percentage of salvaged limbs is higher than the percentage of patent arteries following a given type of procedure. This is consistent with observations by other authors. This is likely linked to the fact that when the blood supply is restored to the calf even temporarily, it aids the development of collateral circulation in this area, thus allowing longer limb survival (30-32).

The results we obtained are comparable with the results achieved by other vascular surgery centres. They are, however, superior to those achieved on a global scale in patients treated for CLI, and published in the TASC II document. This refers both to the vessel/prosthesis patency following revascularization procedures, and limb survival and patient mortality rates throughout the entire follow-up period (33). This is primarily due to treatment at a specialized vascular surgery centre and the comprehensive approach taken to the multiple diseases affecting this group of patients.

## CONCLUSIONS

Surgical management in CLI patients is an effective method, allowing to prevent limb amputation. However, the positive outcome is largely influenced by prompt institution of comprehensive therapy of concomitant diseases followed by immediate revascularization. When comparing the results of surgical and endovascular therapies, it can be seen that the larger artery/graft patency rate following surgical removal of stenosis or vascular bypasses does not translate into a larger percentage of limbs salvaged. Based on the available literature and our study results, it appears that endovascular management compared with open surgery or with a “hybrid” combination of the above are characterized by similar outcomes at 3 years from the onset of the therapy. At present, no current detailed guidelines on the surgical management of LCI patients exist, hence our recommendation that such patients should be treated in highly specialized centres of vascular surgery, and the decision

concerning the course of management should always be individually made, based on the severity of atherosclerotic lesions and the overall patient's

condition. The main objective of treatment should always be reducing amputation and mortality rates in the high-risk group of CLI patients.

## BIBLIOGRAPHY

- Hernando FJS, Conejero AM: Periferal arterial disease: pathophysiology, diagnosis and treatment. *Rev Esp Cardiol* 2007; 60: 969-982.
- Norgren L, Hiatt WR, Dormandy JA: Inter society consensus for the management of periferal arterial disease (TASC II). *Eur J Vasc Endovasc Surg* 2007; 33: S5-S75.
- Creager MA, Dzau VJ, Loscalzo J: Choroby naczyń. Wydawnictwo Czelej, Lublin 2008: 286.
- Diotati JG, Dakak N, Gilligan DM et al.: Effect of atherosclerosis on endothelium-dependent inhibition of platelet activation in humans. *Circulation* 1998; 98: 17.
- Tegos TJ, Kalodiki E, Sabetai MM et al.: The Genesis of atherosclerosis and risk factors: a review. *Angiology* 2001; 52: 89.
- Capek P, McLean GK, Berkowitz HD: Femoropopliteal angioplasty. Factors influencing long-term success. *Circulation* 1991; 83: 170-180.
- Dormandy JA, Rutherford B: Management of peripheral arterial disease (PAD). TASC Working Group. *TransAtlantic Inter-Society Consensus (TASC)*. *J Vasc Surg* 2000; 31: S1-296.
- Sabeti S, Schillinger M, Amighi J et al.: Primary patency of femoropopliteal arteries treated with nitinol versus stainless steel self-expanding stents: propensity score-adjusted analysis. *Radiology* 2004; 232: 516-521.
- Kawamura Y, Ishii H, Aoyama T et al.: Nitinol stenting improves primary patency of the superficial femoral artery after percutaneous transluminal angioplasty in hemodialysis patients: a propensity-matched analysis. *J Vasc Surg* 2009; 50: 1057-1062.
- Henry M, Henry I, Klonaris C et al.: Clinical experience with the OptiMed sinus stent in the peripheral arteries. *J Endovasc Ther* 2003; 10: 772-779.
- Vogel Tr, Shindelman LE, Nackman GB et al.: Efficacious use of nitinol stents in the femoral and popliteal arteries. *J Vasc Surg* 2003; 38: 1178-1184.
- Mewissen MW: Self-expanding nitinol stents in the femoropopliteal segment: technique and midterm results. *Tech Vasc Interv radiol* 2004; 7: 2-5.
- Laird Jr, Katzen BT, Scheinert D et al.: Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery: twelve-month results from the RESILIENT randomized trial. *Circ Cardiovasc Interv* 2010; 3: 267-276.
- Han DK, Shah Tr, Ellozy Sh et al.: The success of endovascular therapy for all TransAtlantic Society Consensus graded femoropopliteal lesions. *Ann Vasc Surg* 2011; 25: 15-24.
- Taneja M, Tay Kh, Dewan A et al.: Bare nitinol stent enabled recanalization of long-segment, chronic total occlusion of superficial femoral and adjacent proximal popliteal artery in diabetic patients presenting with critical limb ischaemia. *Cardiovasc Revasc Med* 2010; 11: 232-235.
- Lepántalo M, Laurila K, Roth WD et al.: Scandinavian Thrupass Study Group, PTFE bypass or thrupass for superficial femoral artery occlusion? A randomised controlled trial. *Eur J Vasc Endovasc Surg* 2009; 37: 578-584.
- Bauermeister G: Endovascular stent-grafting in the treatment of superficial femoral artery occlusive disease. *J Endovasc Ther* 2001; 8: 315-320.
- Kedora J, Hohmann S, Garrett W et al.: Randomized comparison of percutaneous Viabahn stent grafts vs prosthetic femoralpopliteal bypass in the treatment of superficial femoral arterial occlusive disease. *J Vasc Surg* 2007; 45: 10-16.
- Alimi YS, Hakam Z, Hartung O et al.: Efficacy of Viabahn in the treatment of severe superficial femoral artery lesions: which factors influence long-term patency? *Eur J Vasc Endovasc Surg* 2008; 35: 346-352.
- Farrar N, Srivastava A, Pershad A: One-year outcomes for recanalization of long superficial femoral artery chronic total occlusions with the Viabahn stent graft. *J Invasive Cardiol* 2009; 21: 278-281.
- McQuade K, Gable D, Hohman S et al.: Randomized comparison of ePTFE/nitinol self-expanding stent graft vs prosthetic femoral-popliteal bypass in the treatment of superficial femoral artery occlusive disease. *J Vasc Surg* 2009; 49: 109-116.
- Lammer J, Bosiers M, Zeller T et al.: First clinical trial of nitinol self-expanding everolimus-eluting stent implantation for peripheral arterial occlusive disease. *J Vasc Surg* 2011; 54: 394-401.
- Werk M, Langner S, Reinkensmeier B et al.: Inhibition of restenosis in femoropopliteal arteries: paclitaxel-coated versus uncoated balloon: femoral paclitaxel randomized pilot trial. *Circulation* 2008; 118: 1358-1365.
- Tepe G, Zeller T, Albrecht T et al.: Local delivery of paclitaxel to inhibit restenosis during angioplasty of the leg. *N Engl J Med* 2008; 358: 689-699.
- Wolf GL, Wilson SE, Cross AP et al.: Surgery or balloon angioplasty for peripheral vascular disease: a randomized clinical trial. *J Vasc Interv Radiol* 1993; 4: 639-648.
- Holm J, Arvidsson B, Jivegard L et al.: Chronic lower limb ischaemia: a prospective randomized controlled study comparing the 1-year results of vascular surgery and percutaneous transluminal angioplasty. *Eur J Vasc Endovasc Surg* 1991; 5: 517-522.
- Karch LA, Mattos MA, Henretta JP et al.: Clinical failure after percutaneous transluminal angioplasty of the superficial femoral and popliteal arteries. *J Vasc Surg* 2000; 31: 880-888.
- Johnston KW: Femoral and popliteal arteries: reanalysis of results of balloon angioplasty. *Radiology* 1992; 183: 767-771.
- Samson RH, Sprayregen S, Veith FJ et al.: Management of angioplasty complications, unsuccessful procedures and early and late failures. *Ann Surg* 1984; 199: 234-240.
- Parsons RE, Suggs WD, Lee JJ et al.: Percutaneous transluminal angioplasty for the treatment of limb threatening ischaemia: do the results justify an attempt before bypass grafting? *J Vasc Surg* 1998; 28: 1066-1071.
- Hunink MG, Donaldson MC, Meyerovitz MF et al.: Risks and benefits of femoropopliteal percutaneous balloon angioplasty. *J Vasc Surg* 1993; 17: 183-194.
- Becquemain JP, Cavillon A, Haiduc F: Surgical transluminal femoropopliteal angioplasty: multivariate analysis of outcome. *J Vasc Surg* 1994; 19: 495-502.
- Murray RR Jr, Hewes RC, White RI Jr et al.: Long-segment ( $\geq 10$  cm) femoropopliteal stenoses: is angioplasty a boon or a bust? *Radiology* 1987; 162: 473-476.

received/otrzymano: 11.10.2016  
accepted/zaakceptowano: 02.11.2016