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Clinical Research

SHORT-TERM OUTCOMES OF ENDOVASCULAR INTERVENTION OF INFRAINGUINAL ARTERIES IN PATIENTS WITH CRITICAL LIMB ISCHEMIA

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Abstract

Main treatment goal of critical limb ischemia is arterial revascularization and limb salvage. In present study short term outcomes of endovascular treatment of infrainguinal lesions were evaluated in 28 patients (28 limbs) with critical limb ischemia treated from July 2013 to December 2014. The study included 24 men (85.7%) and 4 women whose mean age was 64.8±8.75 years. TASC II (Trans Atlantic Inter Society Consensus II) C or D type lesions were represented in 85.7% of patients. From conducted 28 interventions 11 (39.3%) were hybrid, including open endarterectomy from common femoral artery with or without profundoplasty. Balloon angioplasty was enough for achieving technical success in 4 cases (1 4.3%). Overall 32 stents were implanted in 24 (85.7%) patients. In 19 cases (67.9%) balloon angioplasty of infrapopliteal arteries was performed to establish at least 1 vessel runoff to the foot. Positive outcomes were achieved in 27 patients (96.4%). The mean ankle-brachial index increased from 0.39±0.19 before intervention to 0.8±0.21 after revascularization. During 3-18 months follow-up (mean – 5.4 months) clinically driven target lesion revascularization was necessary in 4 cases (14.3%), 3 of these patients had in-stent thrombosis, and one had in-stent restenosis. There were 7 minor and one major amputation (limb salvage rate was 96.4%). One patient died in 7 months after procedure due to oncological disease.

Conducted study demonstrates that endovascular treatment of patients with critical limb ischemia is safe and viable, even in cases of complex TASC II C/D lesions of the femoropopliteal segment with acceptable short-term (≈ 6 months) patency and limb salvage rates.

Keywords: *critical limb ischemia, endovascular treatment, infrainguinal arteries, limb salvage.*

Introduction

Critical limb ischemia represents the most severe clinical manifestation of peripheral arterial disease, defined as the presence of chronic ischemic rest pain, ulcers, or gangrene for more than 2 weeks, attributable to objectively proven arterial occlusive disease [*Norgen L et al., 2007*]. Patients with critical limb ischemia have a poor prognosis, with a high mortality rate (19-54% at 1 year), and high amputation rate (≥25% at 6 months after failure of primary revascularization) [*Critical limb ischemia, 1995; Bailey C et al., 2003; Arain S, White C, 2008*]. The dominant pathology underlying critical limb ischemia is atherosclerosis, distributed at multiple levels involving femoropopliteal and below-the-knee arteries. The attainment of limb salvage in limb ischemia relies on restoration of stight in-line flow within at least one of the tibial arteries to meet the increased metabolic demands of wound healing under the conditions of tissue ischemia.

According to the TransAtlantic Inter-Society Consensus (TASC-II) guidelines (2007) for the management of peripheral artery disease, endovascular therapy is the preferred treatment for TASC A/B lesions; surgical bypass is recommended for

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patients with TASC-C/D lesions [*Norgen L et al., 2007*]. Recent advances in endovascular technology and low rates of procedure-related morbidity and mortality has made endovascular treatment of critical limb ischemia more attractive in recent years. The aim of present study was to evaluate short term outcomes of endovascular treatment of infrainguinal lesions in patients with critical limb ischemia, with the primary end point – limb salvage during follow-up period (3-18 months).

Material and methods

Present study included 28 patients, who were operated during the period from July 2013 to December 2014 and followed-up to March 2015. Inclusion criteria were: presence of critical limb ischemia (Rutherford classification 4-6), atherosclerotic etiology of the disease. Exclusion criteria were the following: CLI attributable to acute arterial occlusion or nonatherosclerotic disease, treatment of isolated suprainguinal lesions. All patients were offered an endovascular intervention as the first option and gave written informed consent before undergoing the procedure. Baseline physical examinations with a focus on manifestations of lower limb ischemia included the ankle-brachial index measurement, duplex ultrasound and MSCT angiography. All procedures were performed in a hybrid endovascular operating room under monitored anesthetic care or under local anesthesia. TASC II classification was used to categorize morphologic arterial lesions. An ipsilateral antegrade approach was used in all cases. Arterial access was achieved through inserting 5-6 *F* sheaths over a 0.035-inch guidewire. In cases of significant atherosclerotic involvement of common femoral artery, open endarterectomy with or without profundoplasty was performed prior to endovascular procedure (hybrid approach). Interventions were performed following arteriography of femoropopliteal and infrapopliteal runoff vessels. Stenoses were traversed intraluminally. Occlusions were crossed using a combination of guidewires and catheters. Both intraluminal and subintimal revascularization techniques were utilized depending on lesion characteristics. All lesions were pre-dilated, and balloon size was determined by data obtained from MSCT-angiography and visual estimation. Control arteriography was performed after balloon angioplasty in order to determine patency of the arteries after dilatation. At this point, a decision was made to terminate the procedure or deploy self-expanding stents (Fig. 1, 2).

Stents were placed in cases of flow-limiting dissections, presence of residual stenosis >30% or elastic recoil. A variety of stent-types was used and included Supera (Abbott Vascular, USA), E-njoy (Jotec, Germany), Smart Control (Cordis Corp., USA), Epic (Boston Scientific Corp., USA). Infrapopliteal lesions were treated with balloon angioplasty without stenting to establish straight-line flow through at least 1 vessel runoff to the foot. Long low-profile balloons (60-150 *mm*) were used to treat the lesions, which were commonly extensive and diffuse. Post intervention arteriograms were obtained to confirm patency. Hemostasis was achieved using manual compression or by wound closure in case of hybrid approach. Intraprocedural 2500-7500 *U* of heparin was used. Dual antiplatelet therapy with clopidogrel and aspirin was administered for at least 8 weeks after the procedure, with further lifelong aspirin therapy. Follow-up was conducted in 1, 3, 6, 12 months and every 6 months thereafter and was consisted of interval history, physical exam and ankle-brachial index measurement. Patients, who experienced recurrent symptoms and demonstrated decrease in ankle-brachial indices of more than 0.15, underwent duplex ultrasound and, if necessary, subsequent MSCT-angiography to reveal possible re-stenosis or re-occlusion.

Results

The analysis included 24 men (85.7%) and 4 women, whose mean age was 64.8±8.75 years. The baseline clinical characteristics of these 28 patients are shown in Table 1. Cardiovascular risk factors were highly prevalent, including coronary artery disease in 82.1% patients, diabetes in 67.9%, and 75% of patients were current smokers.

Procedural characteristics and immediate results: Procedural characteristics and types of lesions are summarized in Table 2. From conducted 28 interventions 11 (39.3%) were hybrid, including open endarterectomy from common femoral artery with or without profundoplasty. Balloon angioplasty was enough for achieving technical success in 4 cases (14.3%). Overall 32 stents were

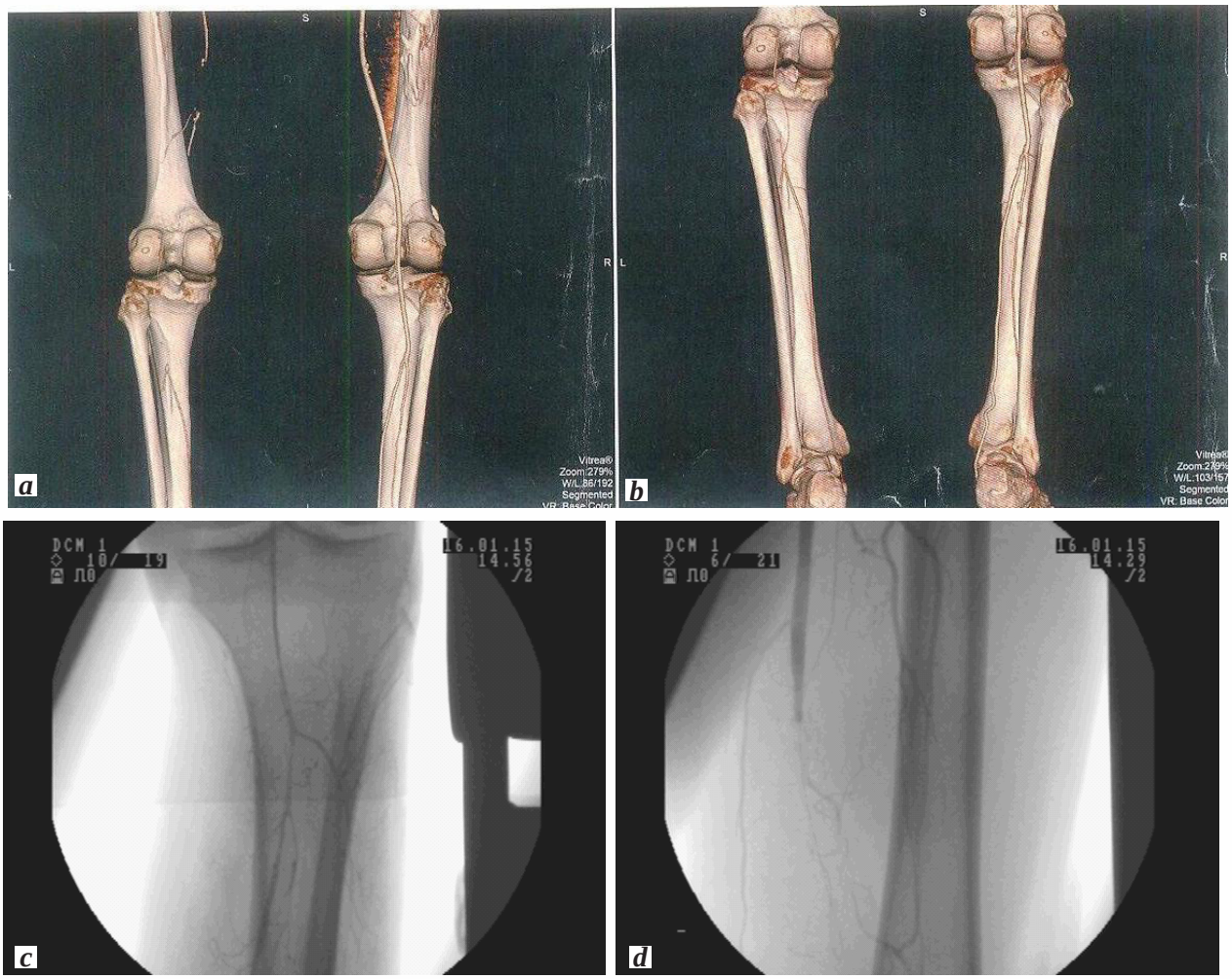

Figure 1. *Occlusion of the distal part of* ***(a), (d)*** *superficial femoral artery and* ***(b), (c)*** *popliteal artery.*

implanted in 24 (85.7%) patients. In 19 cases (67.9%) balloon angioplasty of infrapopliteal arteries was performed to establish at least 1 vessel runoff to the foot. Technical success, which was defined as the ability to obtain in-line arterial flow into the foot with less than 30% residual stenosis, without flow limiting dissections and elastic recoil was achieved in 27 patients (96.4%). The only technical failure was due to the inability to completely cross the lesion with a guidewire. In 1 case retrograde open access through the posterior tibial artery was performed to facilitate procedural success. The mean ankle-brachial index increased from 0.39±0.19 before intervention to 0.8±0.21 after revascularization.

Follow-up: Mean follow-up was 5.4 months (3-18 months). Complications were observed in 2 patients (7.1%) in the immediate postoperative period. One major complication was retroperitoneal bleeding, which was managed surgically, without the need of blood transfusion. Second complication was lymphorrhea from groin incision after hybrid intervention, which was managed conservatively. Clinically driven target lesion revascularization was necessary in 4 cases (14.3%), 3 of these patients had in-stent thrombosis (2 of them due to interrupted antiplatelet therapy, 1 – poor runoff), and one had in-stent restenosis. Two patients with in-stent thrombosis underwent surgical thrombectomy with Fogarty catheter. Third patient underwent femoropopliteal bypass surgery. The case of in-stent restenosis was successfully treated by conventional balloon angioplasty. During the follow-up only the patient with failed intervention underwent a major amputation (limb salvage rate was 96.4%). There were 7 minor amputations in

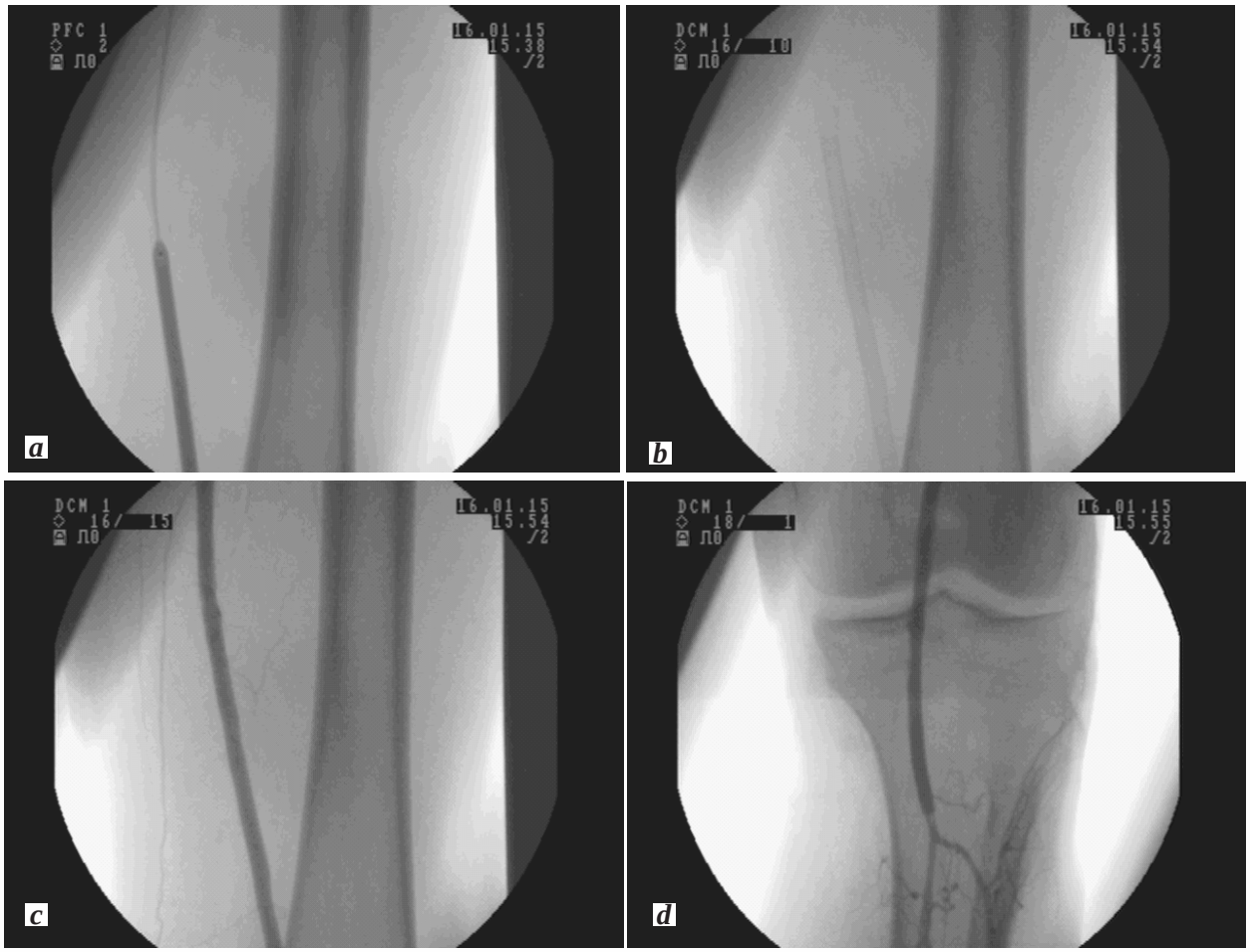

Figure 2. *(a) Balloon dilatation of the lesion, (b) implantation of 2 self-expanding Supera stents (4x60 mm and 5x80 mm). Final angiographic result with restoration of magistral blood flow in (c) superficial femoral artery and (d) popliteal artery.*

patients with Rutherford classification V and VI (3 – transmetatarsal, 4 – digit amputations). There were no perioperative deaths. One patient died in 7 months after procedure due to oncological disease.

Discussion

The main treatment goal of critical limb ischemia is arterial revascularization and limb salvage, which can be achieved by means of bypass surgery or endovasculary. According to literature data, 40% of patients with critical limb ischemia need high amputation, and 20% die within six months after failed revascularization [*Norgen L et al., 2007*]. The TASC-II guidelines recommend traditional surgical bypass for TASC C/D lesions. Infrainguinal bypass surgery is often associated with high periprocedural morbidity, prolonged recovery and multiple reoperations [*Gashima K et al., 2004*]. Nowadays many high-volume centers have adopted endovascular therapy as the initial treatment of choice in response to acceptable short- and mid-term patency rates. Despite the fact that 85.7% of patients in presented study had extended lesions of infrainguinal arteries of C and D type, the limb salvage rate was 96.4% during follow-up. To date, several new technologies, such as nitinol stents with specific design, drug-eluting stents, covered stents and drug-coated balloons, have emerged with the aim to improve long-term patency outcomes following angioplasty of femoral and popliteal arteries [*Duda S et al., 2002; Saxon R et al., 2008; Dake M et al., 2011; Scheinert D et al., 2011; Cassese S et al., 2012*]. Supera self-expanding nitinol stents (Abbott Vascular) were used in 71.8% cases in present study, the choice of which was based on the fact, that the majority of patients were diabetics with calcified le-

Table 1.

Clinical characteristics of patients

Indicators	n (%)	mean±SD
Age, years		64.8±87.5
Male	24 (85.7)	
Female	4 (14.3)	
Smoking (risk factor)	21 (75)	
Comorbidities		
Diabetes	19 (67.9)	
Arterial hypertension	18 (64.3)	
Coronary artery disease	23 (82.1)	
Cerebrovascular disease	3 (10.7)	
Chronic renal failure (creatinine ≥ 1.5 mg/dl)	2 (7.1)	
Degree of ischemia according to Rutherford classification		
IV	13 (46.4)	
V	13 (46.4)	
VI	2 (7.1)	
Location of necrotic lesions		
Digits	7 (46.6)	
Calcaneal	3 (20)	
Multiple wounds	5 (33.3)	
Ankle-brachial index		0.39±0.19

Table 2.

Lesion and procedural characteristics

Variables	n=28 (%)
TASC II	
A	0 (0)
B	4 (14.3)
C	14 (50)
D	10 (35.7)
Location	
Common femoral artery	11 (39.3)
Superficial femoral artery	26 (92.9)
Popliteal artery	23 (82.1)
Infrapopliteal arteries	19 (67.9)
Number of vessel runoff	
0	3 (10.7)
1	10 (35.7)
2	11 (39.3)
3	4 (14.3)
Balloon angioplasty	4 (14.3)
Stenting	24 (85.7)
Number of stents	
1	16 (66.6)
2	8 (33.3)
Stent diameter *mm*	
4	1 (3.1)
5	18 (56.2)
6	12 (37.5)
7	1 (3.1)
Stent Length *mm*	111±50,2 (60-330)
Stent types	
Supera	23 (71.8)
E-njoy	4 (12.5)
Smart Control	4 (12.5)
Epic	1 (3.1)

sions predominantly located in distal superficial femoral artery and popliteal artery. The novel Supera self-expanding nitinol stent consists of woven nitinol wires braided in a tubular mesh configuration. The design configuration results in a stent that is flexible, compliant, self-expanding and has a very high radial resistive strength. These features make the stent more suitable to withstand dynamic forces such as compression, torsion, bending, shortening. In the analysis of its use in superficial femoral artery, the device has shown to have very good patency rates up to two years, as well as a complete absence of stent fractures [*Scheinert D et al., 2011*]. The main limitations of present study include relatively low number of patients and short period of mean follow-up.

Therefore, recent advances in endovascular technology made endovascular treatment of patients with critical limb ischemia safe and viable, even in cases of complex TASC II C/D lesions of the femoropopliteal segment with acceptable short-term (≈ 6 months) patency and limb salvage rates.

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