Endovascular interventions for long occlusive disease of the superficial femoral artery in critical limb ischemia

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Background
The real challenges for the treatment of femoropopliteal disease are long and chronic total occlusions. These lesions continue to represent a major challenge for currently available endovascular approaches. The aim of this study was to evaluate the outcomes of an endovascular intervention for Transatlantic Intersociety Consensus (TASC)-II C and D femoropopliteal disease.

Patients and methods
Sixty-four patients, including 16 patients with TASC-C and 48 patients with TASC-D lesions, underwent an endovascular intervention for femoropopliteal lesions between January 2014 and December 2014. Patients' demographics and preprocedure and postprocedure ankle brachial indices were analyzed. The outcomes of our study were primary patency, periprocedural complications, and limb salvage.

Results
Our cohort included 41 (64%) men and 23 (36%) women. Twenty-one (33%) patients had rest pain and 43 (67%) patients presented with tissue loss. All patients underwent initial balloon angioplasty of occluded arterial segments, with a technical success achieved in 58 (91%) patients. Nitinol stents were used in 15 (26%) patients. Eight (14%) patients developed periprocedural complications. Primary patency rates were 96.6, 89.7, 80.9, and 62.1% at 1, 3, 6, and 12 months, respectively. Univariate analysis of sex, risk factors, Rutherford staging, and TASC-II lesion could not find any statistically significant effect on the 1-year primary patency rate in the current study.

Conclusion
Our experience showed the benefficial results of an endovascular intervention for TASC-II C and D lesions with good acceptable early-term and medium-term patency and limb salvage rates.

Keywords:
endovascular, long occlusive disease, superficial femoral artery

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Introduction

Peripheral lower limb ischemia is a condition that is prevalent worldwide and that is likely to increase with age. The increased prevalence of diabetes mellitus and hypertension in the population is considered to an important risk factor for the spread of peripheral arterial disease (PAD) [1]. The lower limb is the most common site of PAD. Because of the unique slow flow and high-resistance environment, the superficial femoral artery (SFA), extending to the proximal popliteal artery segment, is the most affected area. Femoropopliteal occlusive disease is still considered to be the Achilles heel of the vascular specialist [2].

Bypass surgery is known to be a definitive treatment [3]. Transatlantic Intersociety Consensus (TASC)-II recommends traditional surgical therapy for long femoropopliteal type C and D lesions. However, the main problems of surgery are increased morbidity and rehospitalization rates, being ~50% [4]. In addition, patients with more complex, long occlusive lesions often develop significant comorbidities, placing them at a high risk for traditional open surgical bypass [3,5,6].

Recent advances in endovascular techniques have led to the widespread application of endovascular repair for more severe femoropopliteal lesions [3,7]. Even though lesions are more distal and longer, the technical success does not seem to be altered [8–10]. Multiple studies have reported technical success rates of more than 90% for TASC-II C and D lesions [6,11,12].

The chronic nature of PAD and the high restenosis rate in many patients with femoropopliteal lesions necessitate repeat interventions, which are an essential part of the long-term treatment. The concept of more options for the future should be considered, favoring the policy of

nonstent-based treatment modalities in an attempt to limit the problem of in-stent restenosis treatment [13].

Primary stenting for longer femoropopliteal lesions is still controversial. In particular, the use of conventional nitinol stents did not yield convincing patency rates, and stent fractures have been most prevalent in long stented segments. However, some authors reported that the use of primary stenting to treat femoropopliteal occlusive lesions has shown the most promising outcomes. This is because of the appearance of newer generations of longer nitinol self-expanding stents owing to their resistance to compression and fracture in this tortuous physical environment [14,15].

Aim

The aim of this study was to evaluate the outcomes of endovascular therapy for the treatment of TASC-II C and D femoropopliteal lesions.

Patients and methods

Following approval by the Institutional Review Board, we carried out a prospective study of a series of 64 patients between January 2014 and December 2014.

Inclusion criteria

Symptomatic patients (Rutherford 4–6), patients with de novo atheromatous femoropopliteal disease, patients with TASC-II C and D femoropopliteal lesion, and patients with patent distal popliteal artery with at least one infragenicular runoff were included.

Exclusion criteria

Patients with asymptomatic lesions, nonatheromatous disease, acute ischemia or arterial thrombosis, aneurysm, or lesion near an aneurysm were excluded.

Procedure

After proper counseling and obtaining a written informed consent, all patients underwent a preoperative ankle brachial indices (ABI) measurement and duplex ultrasound (DUS) examination to visualize the extent and morphology of the femoropopliteal lesion. Computed tomography angiography was also performed to determine the TASC stage of the lesion and to evaluate the distal runoff vessels. Before intervention, each patient was administered clopidogrel (300 mg as the loading dose). The patients were treated under local anesthesia associated with sedation. The access to the lesions was achieved by retrograde femoral puncture and crossover. A 6 Fr 45-cm long introducer sheath (Cordis Corporation, Warren, New Jersey, USA) was used.

Once the introducer was positioned, a heparin bolus of 5000 U was injected by intravenous route. An initial diagnostic angiogram was performed following access.

Lesions were crossed either endoluminally or subintimally using a 0.035-inch stiff wire Glidewire (Terumo Medical Corporation, Somerset, UK) or AquaLiner (AngioDynamics, Queensbury, NY, USA). The wires were supported using a 4 Fr or a 5 Fr hydrophilic-coated diagnostic catheter (Cordis Corporation, Miami, Florida, USA). In the subintimal approach, a plane of dissection was created by a loop formed by a stiff hydrophilic guide. The true lumen re-entry was indicated by a subtle release of wire resistance near the distal portion of arterial occlusion and was confirmed by the injection of a small quantity of product of contrast through the lumen of the catheter.

After crossing the occlusions, all patients initially underwent balloon angioplasty with long-length (5 mm/6 mm×10 cm/20 cm) balloons. Balloon diameter was selected on the basis of the angiographic measurements of the nondiseased artery proximal and distal to the lesion. In the event of severe calcifications, a predilatation using a 3-mm diameter balloon was carried out.

Lesions with residual stenosis greater than 30%, recoil, or flow-limiting dissections were subsequently treated with stent placement. The stents used for this study were 6 mm in diameter. The length of the available stents ranged from 120 to 200 mm. Nitinol stents used were Protégé Everflex (ev3 Inc., Plymouth, UK) and Luminexx (Bard Inc., Murray Hill, New Jersey, USA). After implantation, the stents were routinely remodeled with a balloon to ensure an optimal extension and apposition. The balloon diameter was 1 mm less than the diameter of the implanted stent to reduce the medial damage and the length of the remodeling balloon did not exceed that of the stent.

Postoperative angiography was performed to assess the technical result of the procedure. The closing of the point of puncture was performed by manual compression.

Postoperatively, a treatment by dual antiplatelet agents (aspirin 75 mg/day and clopidogrel 75 mg/day) was prescribed for 3 months. Afterwards, only aspirin was maintained.

Follow-up

Postoperative follow-up was performed before discharge and at 1, 3, 6, and 12 months. Follow-up visits included an office visit with a physician and

noninvasive studies including ABI and complete DUS examinations of the treated limb.

Statistical analysis

All data were analyzed using the statistical package for the social sciences (SPSS, version 18; SPSS Inc., Chicago, IL, USA) software.

Descriptive statistics were used, with continuous variables expressed as mean±SD, categorical data expressed as percentages, and univariate analysis carried out using the χ^2-test for categorical variables. The primary patency rate was determined using a Kaplan–Meier life table analysis. A value of P less than 0.05 was considered significant for all analyses.

Results

Between January 2014 and December 2014, 64 patients, including 41 (64%) men and 23 (36%) women, ranging in age from 48 to 83 years (mean: 63.1±6.3 years) were enrolled in the current series.

Our cohort included 40 (63%) patients with diabetes mellitus. Thirty-seven (58%) patients were smokers and 23 (36%) patients had hypertension. Hypercholesterolemia was found in 29 (45%) patients. Twenty-one (33%) patients had rest pain (Rutherford 4) and 43 (67%) patients presented with tissue loss (Rutherford 5–6). According to computed tomography angiography, 16 (25%) patients had TASC-C and 48 (75%) patients had TASC-D femoropopliteal lesions. Patient demographics and clinical presentation are shown in Table 1.

All cases underwent initial balloon angioplasty of occluded arterial segments, with technical success achieved in 58 (91%) patients (Fig. 1). Stenting was deemed necessary in 15 (26%) patients, including a single stent in nine (16%) cases and two stents in six (10%) cases (Fig. 2).

No periprocedural mortality was reported. Postprocedural complications were observed in eight (14%) patients. Thrombosis of the recanalized arterial segment led to complications in four (7%) cases and was managed successfully with thrombectomy. Three (5%) patients developed a femoral pseudoaneurysm and were treated with surgical repair. However, femoral access hematoma occured in one (2%) case and was treated conservatively.

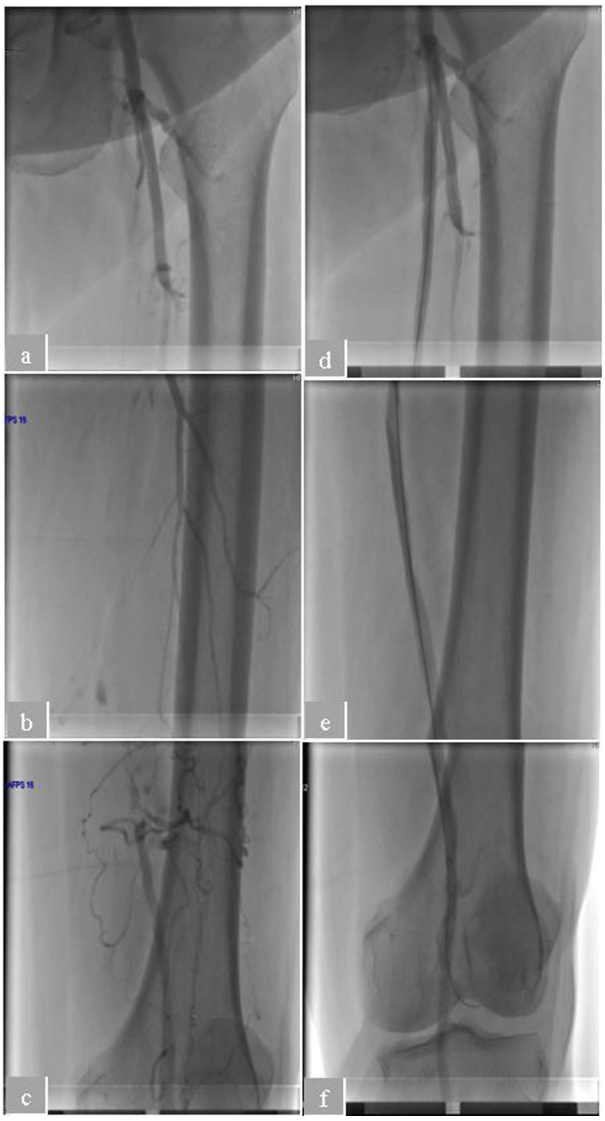
All patients in the current series were followed up using a clinical examnation and DUS, with primary patency rates of 96.6, 89.7, 80.9, and 62.1% at 1, 3, 6, and

Table 1 Patient demographics and clinical presentation

Variables	*N* (%)
Sex	
Male	41 (64)
Female	23 (36)
Risk factors	
Diabetes mellitus	40 (63)
Smoking	37 (58)
Hypertension	23 (36)
Hypercholesterolemia	29 (45)
Rutherford classification	
Stage 4	21 (33)
Stage 5	14 (22)
Stage 6	29 (45)
TASC-II	
Type C	16 (25)
Type D	48 (75)

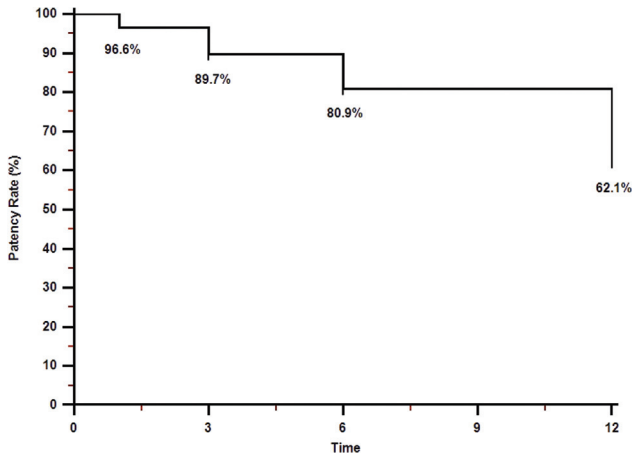
TASC, Transatlantic Intersociety Consensus.

Figure 1



(a–c) Angiography shows total superfacial femoral atery occlusion. (d–f) End result after balloon angioplasty.

Figure 2



Kaplan–Meier life table analysis of the primary patency rates in the current study.

12 months, respectively (Fig. 3). The 1-year limb salvage rate achieved in 48 patients was 83%.

A univariate analysis of sex, risk factors, Rutherford staging, and TASC-II lesion did not find any statistically significant effect on the 1-year primary patency rate in the current study (Table 2).

Discussion

TASC-II recommendations advocate traditional surgical therapy for the treatment of complex lesions of femoropopliteal segments [4]. However, advances in endovascular techniques including the utilization of the subintimal technique and advances in technology, specifically, the development of re-entry devices and more flexible nitinol stents, have significantly enabled the treatment of even the most complex occlusive lesion with minimally invasive techniques and yielded favorable outcomes [6,16].

The treatment of TASC-II C and D lesions relies on particular techniques as well as equipment to optimize technical success. In particular, these lesions, by definition, are often quite long, which may require the use of stiff wires to optimize the ability to push across these lesions. In addition to crossing ability, TASC-II C and D lesions are more complex in that re-entry may be difficult secondary to calcification or because of a suboptimal anatomic location [17].

Our overall technical success, selectively utilizing the aforementioned techniques, was 91%. Almost similar results were reported by Rabellino *et al.* [18], who reviewed 234 limbs, 52% of which were TASC-II D lesions and the initial technical success rate was 97%. This is not dissimilar from other studies that have examined combined outcomes of endovascular treatment of TASC-II C and D lesions. Setacci *et al.* [19] reviewed 145 patients with TASC-II C and D lesions who were treated with subintimal angioplasty and selective use of a re-entry device and reported a technical success rate of 83.5%.

Given the long length of these lesions or their popliteal location, such patency rates are not unexpected. However, it should be noted that the majority of these restenoses can be treated using endovascular techniques. Furthermore, a large number of the limbs that go on to occlusion can be salvaged through an endovascular approach. Close surveillance using frequent noninvasive testing including both arterial DUS and ABI measurement in combination with a clinical assessment appears to be useful in maintaining the patency of these lesions [12].

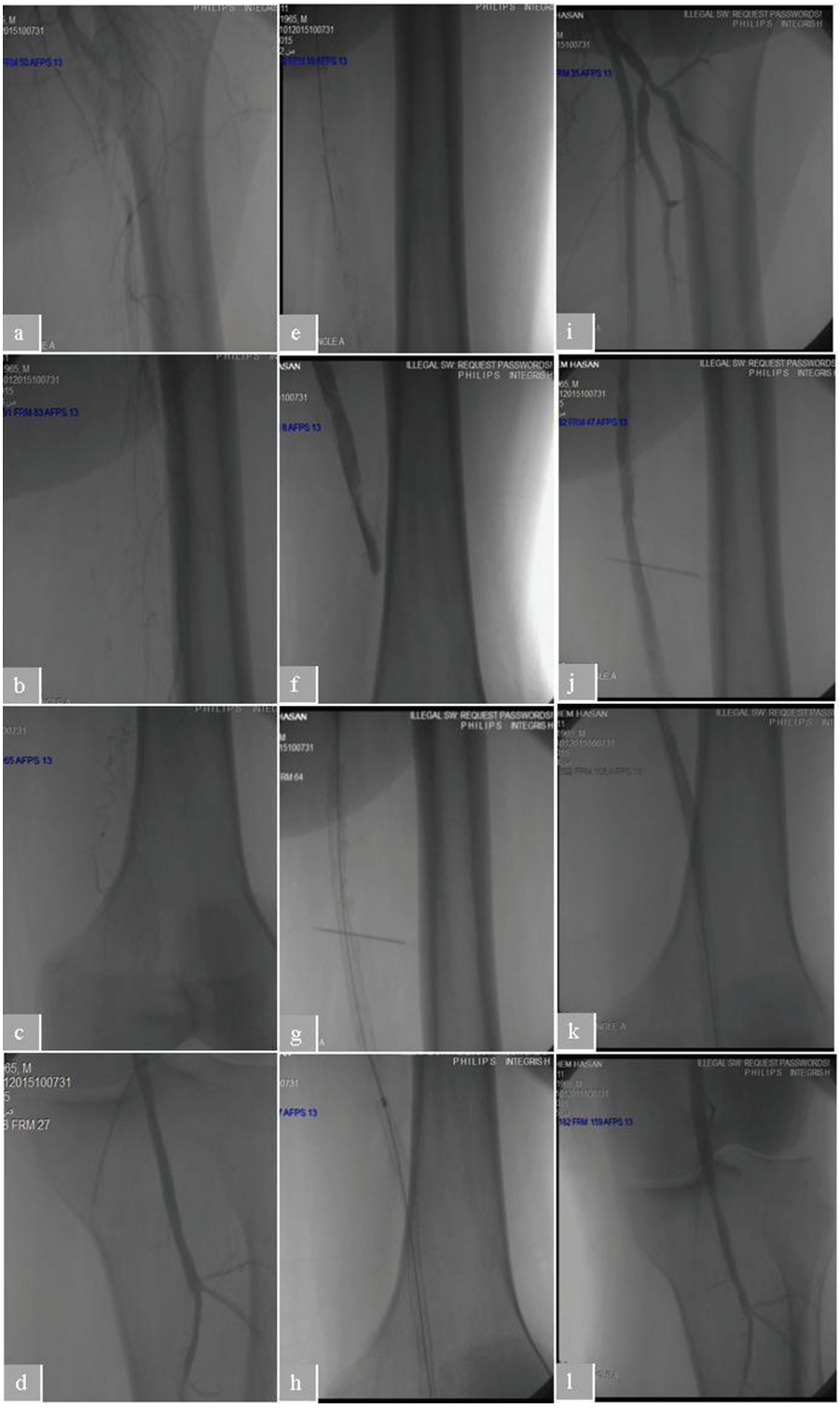
The primary patency rate at the 1-year follow-up in this study was 62.1%. Davaine et al. [7], in their study, examined 62 limbs with TASC-II C and D femoropopliteal lesions and reported that the primary rate at 12 months was 66%. Guo *et al.* [17] also reported a comparable outcome, with primary and assisted primary rates at 12 months of 63 and 77%, respectively.

The preferential use of primary stenting versus selective stenting during endovascular treatment for longer lesions (TASC-II C and D lesions) is still controversial. Surowiec *et al.* [20] have shown that there was no difference in the outcomes (patency or limb salvage) between patients in whom primary stenting was used compared with those in whom selective stenting was used. However, a previous meta-analysis suggested that primary stenting can be used as a first-line endovascular treatment for femoropopliteal long lesions [21].

In the study of Chalmers *et al.* [22], the primary end point of 12-month binary restenosis was not significantly reduced by a strategy of primary stenting compared with balloon angioplasty in long SFA lesions. This is similar to the findings of the FAST study [23], but in contrast to the ABSOLUTE [24] and ASTRON [25] studies.

At our institution, balloon angioplasty-enabled recanalization is still the preferred first-line endovascular therapy because of its lower cost. In the present study, 15 (26%) patients underwent selective stenting because of a suboptimal angiographic result or a flow-limiting dissection.

Figure 3



(a–d) Transatlantic Intersociety Consensus-D superficial femoral artery (SFA) occlusion. (e, f) Subintimal recanalization with a wire loop and retained dye. (g, h) Stenting of SFA with two stents. (i–l) Final angiography after SFA stenting.

The 1-year limb salvage rate in our study was 83%. Similary, Taneja *et al*. [26] reported that the overall limb salvage rate at the 1-year follow-up was 81%.

Endovascular intervention may be performed with minimal physiologic impact on this often critically ill patient population. The reported rate of complications after endovascular interventions for lower extremity ischemia is low in TASC-II A/B cases, but is relatively higher in TASC-II C/D cases, mostly exceeding 15% [27].

Periprocedural complications were observed in eight (14%) patients, including four (75%) patients with

Table 2 Effect of sex, medical comorbities, Rutherford staging, and Transatlantic Intersociety Consensus-II lesion on the 1-year patency rate

Variables	*N* (%)			*P*-value
	Overall (*N*=58)	Patent	Occluded	
Sex				
Male	37 (64)	14 (38)	23 (62)	0.1884
Female	21 (36)	9 (43)	12 (57)	0.6625
Risk factors				
Diabetes mellitus	35 (60)	15 (43)	20 (57)	0.4990
Smoking	36 (62)	19 (53)	17 (47)	0.8676
Hypertension	20 (34)	12 (60)	8 (40)	0.5023
Hypercholesterolemia	29 (50)	11 (38)	18 (62)	0.2652
Rutherford classification				
Stage 4	19 (33)	11 (58)	8 (42)	0.6464
Stage 5	13 (22)	4 (31)	9 (69)	0.2673
Stage 6	26 (45)	10 (38)	16 (62)	0.3268
TASC-II				
Type C	14 (24)	9 (64)	5 (36)	0.4227
Type D	44 (76)	21 (48)	23 (52)	0.8802

TASC, Transatlantic Intersociety Consensus.

thrombosis of the recanalized arterial segment, three (5%) pateints with femoral pseudoaneurysm, and one (2%) patient with femoral access hematoma.

Yin *et al.* [6] reported a similar overall complication rate (12.0%) in their study; the rate of major complications was only 5.1% (embolisms, thrombosis, femoral pseudoaneurysms, rupture of SFA, and acute myocardial infarction). Importantly, most major complications could be treated successfully and immediately using an endovascular approach. Baril *et al.* [12] reported lower rates (6.3%) in endovascular interventions for 79 cases with TASC-II D femoropopliteal lesions, with only two (2.5%) intraprocedural complications.

In the current study, analysis including sex, risk factors, and Rutherford staging did not find any statistically significant effect on the 1-year primary patency rate. Baril *et al.* [12], in their series, reported that smokers were at a higher risk for restenosis and occlusion.

An endovascular intervention for TASC-II C and D lesions can be performed safely with acceptable patency and limb salvage rates. This approach should be considered especially in patients with multiple comorbidities. Restenosis is not uncommon in these complex lengthy lesions that mandate close follow-up.

The limitation of our study is the small sample size. However, it provided useful evidence and guidelines in treating patients with TASC-II C and D lesions. A randomized-controlled study comparing balloon angioplasty and stent for long segment SFA disease will be very useful.

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Conflicts of interest
There are no conflicts of interest.

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