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ENDOVASCULAR TREATMENT OF SUPERFICIAL FEMORAL AND PROXIMAL POPLITEAL ARTERIES LESIONS

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Abstract: *Mechanical stress due to flexion-extension in the femoropopliteal space may cause stent failure via stent fracture and thrombosis. Wire-Interwoven self-expanding Nitinol Stents design partially mimics the reticular structure of native vessels, emphasizing radial strength, flexibility and kink resistance; these stent features can offer more chances for short and long term patency. We have evaluated 5 patients with peripheral artery disease with significant superficial femoral artery or proximal popliteal artery lesions. All patients underwent endovascular therapy with Wire-Interwoven self-expanding Nitinol Stents, with primary focus on stent patency at follow-up visits (1, 6, 12 months). The endovascular initial success was achieved in all 5 patients. Stent patency at 1-year follow-up was achieved in 3 patients (60%). 2 patients (40%) had stent thrombosis within 30 days after procedure secondary to arterial dissection at distal stent extremity and self-withdrawal dual antiplatelet therapy; subsequently target lesion revascularization with endovascular therapy and ilio-femoral bypass was performed.*

INTRODUCTION

Femoropopliteal lesions represent an important cause for disabling claudication and chronic limb ischemia in patients with peripheral artery disease.(1) Endovascular therapies play an increasingly important role in lower limb artery disease, while surgery remains the primary focus in selected cases.

The endovascular therapy success is limited by the increased biomechanical stress occurring on the normal anatomical pathway of femoropopliteal arteries through the hip and knee joints and through the muscular adductor canal in the thigh.(1)

Treatment strategies are well defined for aortoiliac vessels, yet the initial success and durability of endovascular therapy in the femoropopliteal artery is limited by the diffuse nature of the disease, presence of calcification, heavy plaque burden, and high prevalence of total occlusion. Furthermore, dynamic forces (compression, torsion, bending, lengthening and shortening) found within the femoropopliteal artery impose stress on any endoprosthesis, potentially causing kinking, compression, fracture and accelerated restenosis.(2)

Mechanical stress due to flexion-extension in the femoropopliteal space may cause stent failure via stent fracture and thrombosis. Wire-Interwoven self-expanding Nitinol Stents design partially mimics the reticular structure of native vessels, emphasizing radial strength, flexibility and kink resistance.(2)

AIM

The purpose of our analysis was to evaluate femoropopliteal wire-interwoven self-expanding nitinol stent patency at 1, 6 and 12 months post revascularization and absence of target lesion revascularization (TLR) or surgical treatment with any amputation of the lower limb**.**

MATERIALS AND METHODS

We have evaluated 5 patients with stage IIB and III Leriche-Fontaine lower extremity artery disease.

All patients underwent clinical examination, ankle-brachial index (ABI) measurement, duplex ultrasound and peripheral angiography with invasive ABI measurement prior to endovascular therapy with wire-interwoven self-expanding nitinol stent.

Follow-up evaluation at 1, 6 and 12 months post revascularization included Leriche-Fontaine category evaluation, ABI measurement, Duplex ultrasonography and X-ray examination.

The primary features evaluated at follow-up visits were: target lesion revascularization (TLR) or surgical treatment with any amputation of the lower limb during the first 30 days after stent implantation, stent patency at 12 months defined as no restenosis (diameter stenosis >50% evaluated by duplex ultrasonography using a peak systolic velocity ratio >2.0 as parameter) and absence of TLR.

RESULTS

Patients mean (±SD) age was 60.40 (±7.66) years; 60% were males. The patient's demographic characteristics and co-morbidities are summarized in table no 1.

All patients had an ABI lower than 0.9 (0.42±0.08).

Two patients (40%) had significant lesion/occlusion in proximal superficial artery (SFA) and the other three patients (60%) were found with significant lesion/occlusion in proximal popliteal artery, with lesion length ranging for 60 mm to 140 mm.

The baseline clinical and angiographic characteristics of femoropopliteal lesions are summarized in table no. 2.

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Table no. 1. Demographic characteristics and co-morbidities of the patients

Characteristics	N=5 Patients
Age, years	60.40±7.66
Sex, male	60% (3/5)
BMI	26.52±4.74
Hypertension	60% (3/5)
Dyslipidemia	100% (5/5)
Diabetes mellitus	20%(1/5)
Renal insufficiency	0% (0/5)
Coronary artery disease	40% (2/5)
Carotid disease	60% (3/5)
Cigarette smoking	
Current	80%(4/5)
Former	0%(0/5)
Nonsmoker	20% (1/5)
Leriche Fontaine Category	
IIB	80% (4/5)
III	20% (1/5)
IV	0% (0/5)

Variable reporting: mean±SD for continuous variables, % - proportion for categorical variables.

Table no. 2. Baseline clinical and angiographic characteristics of femoropopliteal lesions

Characteristics	N=5 Patients
Claudicant (m)	106±75.36 (minimum 0m, maximum 200m)
ABI	0.42±0.08
Critical limb ischemia	20% (1/4)
Vessel location	
SFA	40% (2/5)
Popliteal artery - proximal	60% (3/5)
Therapeutic vascular approach	
Anterograde – common femoral artery	40% (2/5)
Retrograde – popliteal artery	20% (1/5)
– posterior tibial artery	40% (2/5)
Lesion length (mm)	80±34.64 (minimum 60mm, maximum 140mm)
Lesion severity	
Occlusion	60% (3/5)
Severe stenosis (>75%)	40% (2/5)
Calcification	
Mild	40% (2/5)
Moderate	40% (2/5)
Severe	20% (1/5)

Variable reporting: mean±SD for continuous variables, % - proportion for categorical variables.

Table no. 3. Primary features evaluated at follow-up visits

Characteristics	N=5 Patients
TLR within 30 days after stent implantation	40% (2/5)
DES endovascular therapy	20% (1/5)
Ilio-femural bypass	20% (1/5)
Amputation within 30 days after stent implantation	0% (0/5)
Primary patency at 6, 12 months after stent implantation	60% (3/5)
Amputation at 6, 12 months after stent implantation	0% (0/5)

Endovascular therapy with wire-interwoven self-expanding nitinol stent was performed (40% through anterograde approach – figure 1, 60% through retrograde approach – figure no. 2) with initial success in all 5 patients, with symptoms relief and invasively measured ABI increase above 0.9 (1.08±0.10). Primary patency at 12 months (table no. 3) was achieved in 3 patients. 2 patients had stent thrombosis within 2, respectively 5 days after procedure secondary to arterial dissection at the distal stent extremity (in maximum baseline lesion length - 140mm) and respectively to self-withdrawal dual antiplatelet therapy (in minimum baseline lesion length - 60mm); in the first patient endovascular therapy with drug eluting stent (DES) with overlapping was performed without residual stenosis and 12-month patency preserved; the second patient was referred for ilio-femoral bypass with good outcome at 12-month evaluation. No stent fracture was observed on X-ray examination.

Figure no. 1. Moderately calcified popliteal artery with occlusion in the middle segment (digital subtraction angiography– anterograde femoral artery approach) (A) treated with a 5.0×180 mm Wire-Interwoven Nitinol stent with no significant residual stenosis (B)

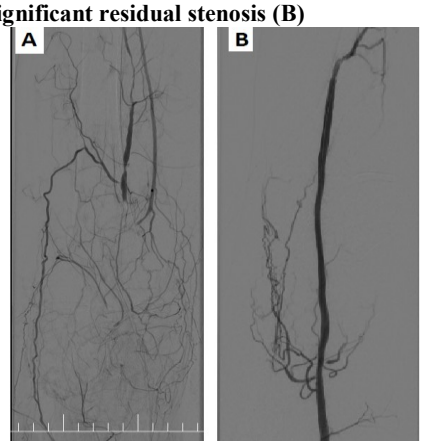
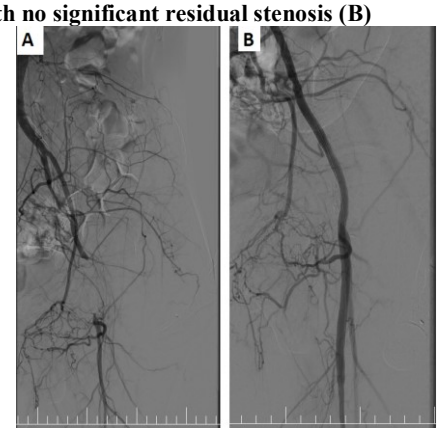


Figure no. 2. Mild calcified superficial femoral artery with occlusion in the middle segment (digital subtraction angiography– retrograde posterior tibial artery approach) (A) treated with a 5.0×150 mm Wire-Interwoven Nitinol stent with no significant residual stenosis (B)



DISCUSSIONS

This case series of 5 symptomatic patients with PAD treated prospectively with Wire-Interwoven Nitinol stent shows relatively good outcomes of these patients (60% primary patency at 12 months), with symptom relief, improvement in Leriche-Fontaine class, ABI and life quality.

Considering the diffuse nature of the atherosclerotic process, lesion location, presence of calcification, heavy plaque burden in lower limb arteries the therapeutic approach for endovascular therapy must be individualized. Thus, in our patients, retrograde approach through popliteal artery for superficial femoral artery and through posterior tibial artery for popliteal and superficial femoral artery was used in 60% (3/5) of patients.

Because of the important deformation with hinge point occurrence during knee and hip joints movement, the use of different endovascular therapies (PTA alone, endovascular stent grafts, self-expanding stents) have been widely studied. For example for the popliteal artery lesions, mean patency rate after PTA alone at 2 years follow-up was approximately 47%.(3,4,5)

Femoropopliteal endovascular treatment with self-expanding stents versus percutaneous angioplasty (PTA) alone was evaluated in several trials; at 12-month follow-up patients treated with self-expanding stent had a 50% reduction in restenosis comparing to those treated with PTA alone.(6,7)

Stent thrombosis in our patients was caused by mechanisms not related with stent features – technical deficiency at stent deployment in an atherosclerotic artery with subsequently arterial dissection and patient treatment noncompliance. However, patient's 12-month outcome was good due to hybrid procedures used: endovascular therapy with DES overlapping at Wire-Interwoven Nitinol stent distal extremity and ilio-femoral bypass. Importantly, there was no stent fracture observed at 12 month follow-up.

Studies have shown that higher restenosis rates are correlated with lesion length.(3,4,5) In our patients stent thrombosis was not necessarily correlated with lesion length since it occurred in minimum and respectively in maximum baseline lesion length.

Femoropopliteal stenting has an important limitation: stent fracture secondary to vessel flexion and torsion. Scheinert et al screened the patients for stent fracture by systematic X-ray scanning and found a fracture rate up to 37.2% of treated legs. Fracture rate was correlated with the length of stent used (for stented length < 8cm a fracture rate of 13% and for stented length > 16 cm a fracture rate up to 52%). In this study, the stent fracture direct consequence was a high risk of restenosis and occlusion.(5)

In this context the need for different stent platforms with reduced risk fracture emerged and thus, with more chances for short and long term patency.(1)

Nitinol has superelasticity and thermal shape memory, making nitinol stents preferred for use in flexible sites within the peripheral vasculature.(2) The Wire-Interwoven Nitinol stent is a nickel–titanium alloy stent with increased radial strength, flexibility and fracture resistance; this design gives it a special resistance suitable for the femoropopliteal artery unique stressors and is associated with higher patency rate and with lower stent fracture rates on follow-up.(1) In our case series there was no stent fracture observed at 12-month follow-up, result consistent with studies evaluating this stent type.

The SUPERB trial evaluated 264 patients with lower limb artery disease; the mean length of the superficial femoral and proximal popliteal arteries lesions (de novo or restenotic) treated was 80 mm, with a minimum of 40 mm and maximum of 140 mm. 99.6% of the patients achieved the main outcome evaluated in this study: freedom from death, absence of TLR or any amputation of the treated limb in the first 30 days post-procedure. The survival analysis showed that Wire-Interwoven Nitinol stent (SUPERA stent) had also one year follow-up good outcomes: primary patency of 86%, without TLR in 90% of patients and no stent fractures.(2)

Although the current studies regarding endovascular treatment with Wire Interwoven Nitinol stent show patient improved outcome, in order to validate the best treatment option for femoropopliteal artery lesions, there are still necessary further studies, and in particular randomized controlled studies, to compare the interwoven nitinol stents with other stents type and with PTA alone.

CONCLUSIONS

Flexibility associated with increased radial strength - in context of important femuropopliteal artery deformation - is the feature that place Wire-Interwoven self-expanding nitinol stent to be the first therapeutic option for femoropopliteal arteries endovascular therapy. Potentially lower rates of these stents primary patency may be caused by excessive elongation and stent fracture. In our cases, arterial dissection and dual antiplatelet therapy self-withdrawal caused stent thrombosis; both of these causes can be avoided with caution at stent delivery and a patient better understanding of drug treatment importance.

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