

Original Article

Outcomes after implantation of superflexible nitinol stents in the superficial femoral artery

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ABSTRACT

Background: Endovascular interventions in the superficial femoral artery for the treatment of peripheral arterial occlusive disease have increased over the last decades. The first- and second-generation stents in the superficial femoral artery have failed to demonstrate improved patency of the treated vessel due to high fracture rates. The aim of this study was to evaluate the clinical, short-term outcomes of using third-generation superflexible nitinol stents in the treatment of atherosclerotic lesions in the superficial femoral artery.

Methods: This was a retrospective study carried out in a single center, from June 2013 to May 2014. A total of 27 patients underwent angioplasty with third-generation, superflexible nitinol stents in atherosclerotic lesions of the superficial femoral artery.

Results: The mean age was 68 ± 12 years, 55.6% were females, and 74.1% were diabetics. Patients were classified as TASC B and C in 77.7% of cases. Technical success was 100%. There was an increase in the ankle-brachial index from 0.35 ± 0.1 before the intervention to 0.75 ± 0.2 at hospital discharge. The mean follow-up of patients was 6.7 ± 2.3 months. The primary patency rate was 96.3%. The limb salvage rate was 100%. There were no stent fractures documented by X-rays.

Conclusions: Angioplasty with third-generation superflexible nitinol stent placement was shown to be effective in the treatment of atherosclerotic lesions of the superficial femoral artery.

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Resultados do uso de stents de nitinol superflexíveis na artéria femoral superficial

RESUMO

Introdução: As intervenções endovasculares na artéria femoral superficial para o tratamento da doença arterial oclusiva periférica têm crescido nas últimas décadas. A primeira e a segunda geração de stents na artéria femoral superficial falharam em demonstrar a melhora da perviedade do vaso tratado, devido às altas taxas de fratura. O objetivo deste estudo foi avaliar os desfechos clínicos no curto prazo com o uso de stents de nitinol superflexíveis de terceira geração no tratamento de lesões ateroscleróticas na artéria femoral superficial.

Métodos: Trata-se de um estudo retrospectivo, realizado em único centro, no período de junho de 2013 a maio de 2014. Um total de 27 pacientes foi submetido à angioplastia com stents de nitinol superflexíveis de terceira geração em lesões ateroscleróticas da artéria femoral superficial.

Resultados: A média de idades foi de 68 ± 12 anos, 55,6% eram do sexo feminino e 74,1%, diabéticos. Os pacientes foram classificados em TASC B e C em 77,7% dos casos. O sucesso técnico foi de 100%. Houve aumento do índice tornozelo-braquial de $0,35 \pm 0,1$ pré-intervenção para $0,75 \pm 0,2$ na alta hospitalar. O seguimento médio dos pacientes foi de $6,7 \pm 2,3$ meses. A taxa de patência primária foi de 96,3%. A taxa de salvamento de membro foi de 100%. Não ocorreram fraturas de stent documentadas por raios X.

Conclusões: A angioplastia com uso de stent de nitinol superflexível de terceira geração demonstrou ser efetiva no tratamento das lesões ateroscleróticas da artéria femoral superficial.

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Introduction

Endovascular interventions for the treatment of peripheral arterial occlusive disease (PAOD) have grown exponentially over the past few decades.¹ Around 40% of these procedures are performed in the femoral segment.² However, despite the large number, these interventions still remain a challenge for the interventionists due to the biomechanical forces exerted by the muscle compartments on the vessel wall, promoting metal fatigue and stent fracture, in addition to restenosis.³

The first- and second-generation stents in the superficial femoral artery failed to demonstrate improved patency of the treated vessel when compared to conventional surgery, as even with the second-generation nitinol stents, fracture rates reach up to 20%.^{3,4}

This study aimed to evaluate the short-term clinical outcomes of using superflexible third-generation nitinol stents in the treatment of atherosclerotic lesions in the superficial femoral artery.

Methods

Type of study and population

This was a retrospective, longitudinal, observational study carried out at a referral center for cardiovascular diseases from June 2013 to May 2014. The study included patients of both genders, with limiting intermittent claudication, pain at rest, or ulceration in the affected limb, with lesions limited to the superficial femoral arteries and with at least one leg artery left for distal run-off. Patients who had a history of severe allergy to iodinated contrast, significant atherosclerotic disease in aortoiliac territories, and with creatinine clearance < 30 mL/kg/minute were excluded from the procedure.

Preoperative arteriography was used to classify lesions according to: (1) the Trans-Atlantic Inter-Society Consensus II (TASC- II) A, B, C, and D criteria⁵ (Table 1); (2) the type of lesion (stenosis, occlusion, dissection, or restenosis); and (3) the location of the lesion in relation to the superficial femoral artery segments (Fig. 1).

Endovascular procedure

All procedures were performed in the Endovascular Intervention Center of Instituto Dante Pazzanese de Cardiologia. The patients received acetylsalicylic acid 100 mg and clopidogrel 75 mg daily, 3 days before the procedure. Clopidogrel was maintained for at least 30 days and acetylsalicylic acid was maintained indefinitely.

Patients were treated under local anesthesia. Antibiotic prophylaxis was performed with 1.5 g of cefuroxime at the time of anesthesia induction. The preferred approach was through the ipsilateral common femoral artery for antegrade puncture, using a 6 F Prelude® valved sheath (Merit Medical Systems, South Jordan, USA). In failing to use this access route, or when it was not possible to cross the target

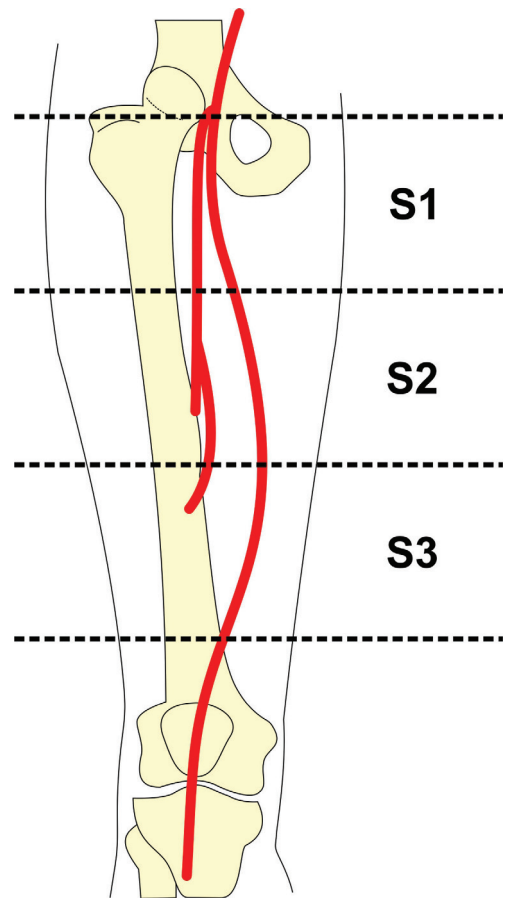


Figure 1. Segments of the superficial femoral artery. S1: proximal segment of the superficial femoral artery; S2: middle segment of the superficial femoral artery; S3: distal segment of the superficial femoral artery.

Table 1

Classification of lesions according to the Trans-Atlantic Inter-Society Consensus II (TASCII).

Classification	Criterion
A	Lesions that produce the best results and should be treated via the endovascular route
B	Lesions that produce sufficiently good results with endovascular methods, and thus these are still the preferred approach, unless surgical revascularization is required to treat other lesions in the same anatomic area
C	Lesions that exhibit superior long-term results with surgery, and thus endovascular methods should be used only in patients at high surgical risk
D	Lesions that do not produce sufficiently good results with endovascular methods to justify them as primary treatment

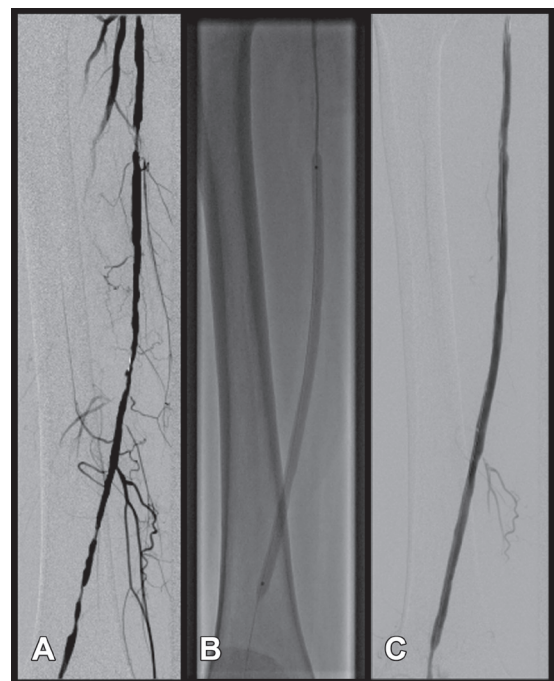


Figure 2. Angioplasty with stent placement of the superficial femoral artery. In A, lesion in the proximal, middle, and distal segments of the superficial femoral artery. In B, post-dilation with balloon angioplasty. In C, the final arteriographic outcome.

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