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Treatment of TASC C and D Femoropoliteal Lesions with Paclitaxel eluting Stents: 12 month Results of the STELLA-PTX Registry

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WHAT THIS PAPER ADDS

In the present study the safety and the efficacy of paclitaxel-eluting stents for Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease (TASC) C/D femoropopliteal lesions have been prospectively assessed. It was found that critical limb ischemia (CLI) and TASC D lesions had poorer outcomes than claudicants and TASC C lesions.

Objective: The aim was to evaluate the safety and the efficacy of primary stenting with paclitaxel eluting stents for TASC C and D femoropopliteal lesions.

Methods: Patients with TASC C/D de novo femoropopliteal lesions were treated by implanting paclitaxel eluting stents. Patients were included in a single center registry and prospectively followed by clinical and ultrasound evaluation. X-ray of the stented zone was systematically performed 12 months after implantation. The primary endpoint was primary sustained clinical improvement after 12 months.

Results: A total of 45 patients (48 limbs) suffering from claudication (25 limbs) or CLI (23 limbs) were enrolled. Lesions were either TASC C (28 limbs) or TASC D (20 limbs). The mean length of the treated segment was 252 ± 90 mm. The mean number of stents was 2.9 ± 1 (2–5). Mean follow up was 12.7 months. No patient was lost to follow up. At 1 year post procedure, primary and secondary sustained clinical improvements were 56.3 ± 7.4% and 80.1 ± 5.9% respectively. Freedom from target lesion and target extremity revascularization were 63.6% and 90.1%, respectively. Primary and secondary patency rates were 52.5% and 79.6%. One year primary sustained clinical improvement rates for TASC C/D were 63.3 ± 9.2% and 45.6 ± 11.7%, respectively ($p = .34$). One year primary sustained clinical improvement rates for claudication/CLI patients were 68 ± 9.3% and 41.6 ± 11.1%, respectively ($p = .13$). The incidence of in stent re-stenosis and in stent thrombosis were 25% and 14%, respectively. The incidence of stent fracture was 12.5% on a limb basis and 9% on a per stent basis.

Conclusions: The paclitaxel eluting stent did not achieve its goal in terms of prevention of in stent re-stenosis for TASC C/D femoropopliteal lesions. It requires frequent re-interventions during the first year to maintain satisfactory clinical results.

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INTRODUCTION

Indications for endovascular treatment of femoropopliteal lesions have been steadily increasing over the past decade. Recent studies have shown that even the most challenging lesions are successfully treated, with technical success rates up to 95%.[1] An increasing number of tools are continuously enriching the armamentarium of endovascular specialists, and require regular updates to the available evidence. Previous studies have established the superiority of bare and paclitaxel eluting stents (PES) over plain balloon angioplasty (POBA) for the Trans-Atlantic Inter-Society Consensus Document II on Management of Peripheral Arterial Disease (TASC) A/B femoropopliteal lesions.[2–4] However, treatment of more challenging femoropopliteal lesions such as TASC C/D is still unresolved. Implantation of the latest generation of nitinol stents for femoropopliteal long lesions has given promising results.[5,6] However, in stent re-stenosis remains a major concern after femoropopliteal stent implantation, with in stent re-stenosis occurring in up to 37%.[4] In this perspective, PES

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represents an interesting technology for the treatment of long femoropopliteal lesions.[7,8] Herein, the 1 year outcomes of a single center prospective registry assessing the safety and the efficacy of PES in the treatment of TASC C/D femoropopliteal lesions are reported.

METHODS

Study design

STEnting Long de L'Artère fémorale superficielle par Zilver-PTX (STELLA-PTX) is a single center, prospective registry in which patients presenting with femoropopliteal TASC C/D de novo lesions were included between March 2011 and April 2012. Endovascular treatment by primary stenting was considered as a first line treatment. This registry was established as a pilot study to determine the safety and the feasibility of drug eluting stents for TASC C/D femoropopliteal lesions. As a result, no size calculations were made prior to the start of the study, but all the patients treated over a 1 year period were included. Inclusion and exclusion criteria are summarized in the Supplementary data. Patients had either one or two limbs treated in this study. The protocol was approved by the local ethics committee and all patients gave their informed consent.

Endovascular procedures

Endovascular procedures have already been described.[6] Briefly, the self expandable paclitaxel eluting stent (Zilver PTX, Cook Medical, Bloomington, IN, USA) was the only stent implanted (5—7 mm diameter). The maximum available length of the stent was 120 mm. Lesions were treated with as few stents as possible. Stent diameter was chosen to be the size of the vessel diameter, and remodeling of the stent was achieved through the use of a balloon 1 mm smaller than the stent. When several stents were necessary, there was a 1 cm overlap between stent edges. Concomitant procedures were performed according to the surgeon's preference. Groin closure was usually accomplished by manual compression and, for day case procedures, an arterial closure device was used (Angioseal, St Jude Medical, Boulogne-Billancort, France).

A prophylactic dose of low molecular weight heparin was given during hospitalization to prevent venous thromboembolic events. Post-operatively, patients were prescribed aspirin (75—160 mg/day) and clopidogrel (75 mg/day) for 6 months followed by clopidogrel alone.[9] When patients were already taking oral anticoagulants, aspirin was the only antiplatelet agent added.

Follow up

Patients were prospectively followed up on an outpatient basis. Major adverse clinical events (MACE) and treatment observations were intentionally sought. Follow up included medical examination, ankle brachial index (ABI) measurements and duplex scan at 1, 3, 6, 9, 12, and 18 months, and annually thereafter. Stent fractures were assessed by biplanar X-rays at 12 months with two different projections separated by at least 45° using the highest available magnification.

Endpoints and definitions

The primary endpoint was primary sustained clinical improvement at 12 months.

Secondary endpoints were secondary sustained clinical improvement, primary and secondary patency, technical success, minor and major complications, MACE, limb salvage, target lesion revascularization (TLR), target extremity revascularization (TER), in stent re-stenosis (ISR), in stent thrombosis, and stent fracture. Detailed definitions of outcomes are as follows.[10]

Primary sustained clinical improvement was defined as a sustained upward shift of the $\geq$1 category of the Rutherford classification for claudicants and by wound healing and resolution of rest pain for patients with critical limb ischemia (CLI), without the need for repeated TLR in surviving patients. Secondary sustained clinical improvement was defined as a sustained upward shift of $\geq$1 category of the Rutherford classification for claudicants and by wound healing and resolution of rest pain for patients with CLI, including the need for repeated TLR in surviving patients. Primary patency was defined as patency without any percutaneous or surgical re-intervention in the treated segment or in the adjacent areas. Technical success was defined as achievement of a final residual diameter stenosis of $<$30% on the procedural completion angiogram. Minor complications are those following the procedure (within the first month) and not requiring further treatment and not extending hospital stay. Major complications refer to complications occurring during the first month following the procedure and requiring re-intervention or delay (more than 24 hours) in patient discharge. Major cardiovascular events included all deaths, major amputation, procedure related serious adverse events, and device failure or malfunction. Target lesion revascularization expresses the frequency of the need for repeated procedures (endovascular or surgical) due to a problem arising from the lesion (+1 cm proximally and distally to include edge phenomena) in surviving patients with preserved limb. Target extremity revascularization expresses the frequency of the need for repeated procedures (endovascular or surgical) due to a problem arising remotely from the lesion initially treated in surviving patients with a preserved limb. In stent re-stenosis was assessed by duplex ultrasound and was defined by re-stenosis of more than 50% and by a peak systolic velocity index greater than 2.4 at the target lesion. The diagnosis of stent thrombosis was considered when a complete occlusion was seen on duplex scan without any previous sign of re-stenosis. The occurrence of stent fracture was determined by biplanar radiography at 12 months. Stent fractures were classified according to the Jaff et al.[11] classification.

Statistical analysis

Statistical analysis results were reported prospectively on an intention to treat basis and analyzed. Continuous variables