CLINICAL STUDY

Use of the Gore Tigris Vascular Stent in Advanced Femoropopliteal Peripheral Arterial Disease

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ABSTRACT

Purpose: To prospectively evaluate the safety and efficacy of using the Tigris vascular stent (Gore, Flagstaff, Arizona) alone or in combination with the Viabahn stent (Gore) for revascularizing femoropopliteal Trans-Atlantic Intersociety Consensus (TASC) type B–D lesions with varying degrees of calcification.

Materials and Methods: Patients with Rutherford stage $\geq$ 3 and TASC type $\geq$ B were included in the study. From January 2015 to April 2017, 31 segments in 31 patients (21 men, ovarall mean age 73.3 $\pm$ 9.2 years) were treated. The breakdown by TASC type and Rutherford stage were TASC B (n = 12), C (n = 6), and D (n = 13), and Rutherford 3 (n = 28) and 4 (n = 3). The lesions were located in the common femoral artery (n = 1), superficial femoral artery (SFA; n = 20), distal SFA to P1 (n = 3), popliteal P1 (n = 1), popliteal P1–3 (n = 3), popliteal P2–3 (n = 2), and 1 femoropopliteal bypass. There were 18 occlusions (58.1%) and 13 stenoses (41.9%). The mean diseased segment length was 15.5 $\pm$ 9.9 cm with 80.6% of moderate/severe calcification. The follow-up consisted of color Doppler ultrasound and clinical assessment at 1, 3, 6, 9, 12, and 15 months.

Results: Technical success was 100%. There were no periprocedural or postprocedural complications. The mean stented lesion length was 17.2 $\pm$ 10.5 cm with a mean follow-up of 13.1 $\pm$ 6.9 months. Primary patency rates at 6, 9, 12, and 15 months were, respectively, 100% (24/31 patients), 90.5% (21/31 patients), 88.9% (20/31 patients), and 80% (15/31 patients). The median postprocedural Rutherford stage was 1. Three occlusions occurred at 7, 9, and 14 months, leading to a target lesion revascularization of 9.7% and a secondary patency of 100% at 15 months. Logistic analysis results demonstrated that lesion length (P = .003) was associated with reocclusion. Amputation-free survival at 15 months was 100%. Intrastent restenosis was observed in four cases (12.9%) but none were associated with worsening of symptoms. No stent fractures were observed.

Conclusions: The Tigris stent used alone or in combination with a Viabahn stent for femoropopliteal TASC B–D lesions demonstrated acceptable 12-month primary patency with a low reintervention rate.

ABBREVIATIONS

PA = popliteal artery, PTA = percutaneous transluminal angioplasty, SFA = superficial femoral artery, TASC = Trans-Atlantic Intersociety Consensus

The femoropopliteal segment represents a challenging location for revascularization owing to the unique biomechanical forces (flexion, elongation, compression, torsion, shortening, kinking) to which it is exposed (1,2). Despite Trans-Atlantic Intersociety Consensus (TASC) II guidelines (3) that identify angioplasty as the preferred treatment for symptomatic femoropopliteal lesions, and stenting only as a last-resort procedure, recent technology development has created stent platforms that could provide enough flexibility and conformability to overcome the aforementioned forces combined with the known patency advantages of stenting over percutaneous transluminal angioplasty (PTA) (4). Different endovascular stents have evolved, including bare-metal stent, drug-eluting stent, interwoven nitinol stent, covered stent graft, and hybrid heparin bonded nitinol stent, but no clear superiority of one device over another has been demonstrated (5–13).

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The recently Food and Drug Administration–approved Tigris stent (Gore, Flagstaff, Arizona), which uses a dual-component structure made from a single-wire nitinol stent with biocompatible fluoropolymer interconnections for heparin bonding, may offer an advantage in treating femoropopliteal disease. The few published experiences with this stent are mostly limited to lesions that are short and moderately calcified in patients with Rutherford stages of <4 (14–17). The device performance when applied to more complex and diseased vasculature, such as TASC type C–D patients or in the presence of severely calcified vasculature, have not yet been investigated.

The purpose of the present study was to examine the safety and efficacy of using the Tigris stent alone or in combination with a Viabahn endoprosthesis (Gore) in treating patients with TASC B–D femoropopliteal occlusions and stenoses, some of which were severely calcified.

MATERIAL AND METHODS

Study Design

This prospective, single-center, nonrandomized study was approved by the local Institutional Review Board and included all patients who underwent a femoropopliteal recanalization procedure with the use of a Tigris vascular stent or with a combination of the Tigris vascular stent and a Viabahn endoprosthesis (for longer lesions) from January 2015 to April 2017 in our center. All patients signed written informed consents for both the recanalization procedure and study participation.

Inclusion criteria were:

1. Symptomatic peripheral arterial disease (Rutherford stage ≥3).
2. Femoropopliteal TASC B–D de novo lesions, diagnosed on the basis of second-line imaging (computerized tomographic [CT] angiography).
3. Patient age >18 years.
4. Patient life expectancy >1 year.
5. Exclusion criteria were:
6. Known hypersensitivity to stent components.
7. Known sensitivity to heparin or a previous incidence of heparin-induced thrombocytopenia.
8. Hypercoagulation disorders.
9. Contraindication to dual antiplatelet therapy or anticoagulants.

A previous bypass procedure was not a contraindication for enrollment.

Device Detail

The Tigris stent is a self-expanding stent made of a helically wound nitinol wire interconnected by an expanded polytetrafluorethylene (ePTFE) structure. Its surface is coated with a covalently bonded heparin. The stent is available in 5–8-mm diameters and in 30–100-mm lengths. The Viabahn endoprosthesis is a self-expanding endoprosthesis consisting of an ePTFE lining with an external nitinol support extending along its entire length. Its surface, like the Tigris stent, is completely coated with a covalently bonded heparin.

Procedure

All patients were evaluated with the use of CT angiography before the recanalization procedure.

All procedures were performed by an interventional radiologist team (P.L., M.C., G.G., with 10, 15, and 20 years of experience, respectively), in an angiosuite under local anesthetic (1% lidocaine) with continuous monitoring of vital signs (ECG, SpO_2, arterial pressure) performed by an anesthesiology team. Intravenous analgesia (fentanyl; Pfizer Italia, Milan, Italy) was used in all patients.

All patients received a loading dose of 300 mg clopidogrel (Bb Farma, Samarate, Italy) and 75 mg aspirin (Bayer, Leverkusen, Germany) orally before the intervention unless they were already receiving dual-antiplatelet treatment.

A contralateral percutaneous approach to the target limb of the femoropopliteal revascularization procedure was used whenever possible. When this was not possible (because of tortuous anatomy or heavily calcified common femoral artery) surgical cut-down of the omolateral groin was preferred to perform surgical vessel reconstruction in the case of disease at the level of the access. All procedures with contralateral percutaneous access used a 7-F 45-cm Destination introducer sheath (Terumo, Tokyo, Japan) with a 0.035” Advantage (Terumo). In cases of ipsilateral access, a 7-F 11-cm sheath (Boston Scientific, Galway, Ireland) was used. In all cases, detailed angiography assessment was performed of the vascular target segment and the distal run-off. Intravenous heparin (5,000 UI) was provided after the angiography and before angioplasty or stent deployment. An activated clotting time of more than 200 seconds was maintained during the procedure with the use of regular measurements and supplementary heparin administration as necessary.

In cases of intraluminal crossing, a 0.035” Advantage Stiff or Standard hydrophilic wire (Terumo) was used to traverse stenoses and occlusions. Subintimal recanalization procedures were performed with the use of a Trailblazer 0.035″ support catheter (Ev3, Plymouth, Minnesota) and the previously mentioned 0.035″ wires. In those cases where distal reentry in the true lumen failed, an Outback (Cordis, Miami Lakes, Florida) or Off-Road (Boston Scientific) reentry catheter was used.

All stenoses and occlusions were first treated with the use of balloon angioplasty (various manufacturers). Indications for stent deployment in stenotic lesions were for a residual stenosis after prolonged dilation (>50%), elastic recoil, or flow-limiting dissection. Stents were used for chronic occlusion in all cases. Predilation was performed in all cases with a balloon diameter 1 mm smaller than the nominal stent diameter. Sizing of both angioplasty balloon diameter and the diameter and length of the stents was performed on the