Clinical Outcomes after Endovascular Treatment Failure in Patients with Femoropopliteal Occlusive Disease

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Background: To analyze the clinical impact derived from endovascular treatment failure on patients with femoropopliteal occlusive disease (FPOD) regarding their preoperative clinical stage.
Methods: Retrospective review for primary endovascular procedures for FPOD from 2008 to 2013. Primary end point included clinical deterioration defined as acute limb ischemia (ALI) or clinical worsening by, at least, one Rutherford's classification category, related to procedure's failure (restenosis >70% or occlusion).
Results: Ninety procedures were analyzed in 85 patients, 87.8% operated due to critical limb ischemia. The lesion treated was classified as Trans-Atlantic Inter-Society Consensus (TASC)-A/B in 76.7%, with a mean length of 98.5 ± 54 mm. Covered stent graft (SG) was used in 31.1% of the cases. Median follow-up was 14.5 months and treatment failure occurred in 33.3% of cases ($n = 30$, 9 restenosis and 21 occlusions). Clinical worsening was assessed in 40% of treatment failures and 6 of 21 (28.6%) presented as ALI. Twenty-two major adverse limb events (MALEs) were recorded and 8 major amputations. Regarding the type of stent, more occlusions were recorded on patients treated with SG compared with bare metal stent (39.3% vs. 16%; $P = 0.02$). However, no differences were found between groups regarding clinical worsening attributable to treatment failure (HR, 1.33; CI 95%, 0.5–3.5; $P = 0.5$). On multivariate analysis, TASC-C/D lesions (HR, 5.5; CI 95%, 2.3–13.3; $P < 0.001$) and female sex (HR, 4.9; CI 95%, 1.9–12.5; $P = 0.001$) behaved as significant predictors for failure and dual-antiplatelet therapy as a protective factor (HR, 0.3; CI 95%, 0.3–0.13; $P = 0.03$). No predictors were obtained regarding clinical worsening and occurrence of MALEs in our series.
Conclusions: Patients with failure of endovascular procedures on FPOD appeared with clinical worsening in a no negligible number of cases in our sample regarding their preoperative clinical situation. Thus, we believe that endovascular treatment should be carefully deliberated.

INTRODUCTION

The treatment of chronic limb ischemia due to femoropopliteal occlusive disease (FPOD) has experienced a rapid change from conventional open surgery to today's fastly expanding endovascular procedures, which have become the first-line treatment in many institutions. The popularity of percutaneous intervention methods is related mainly to a lower morbidity and quicker recovery,[1] and this has led to a 3-fold increase in this type of intervention over the past decade.[2] Despite such

Conflict of Interest: None.

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advantages, there is still an incomplete understanding of the risk factors for and clinical consequences of early or midterm treatment failure.

This study was designed to define the clinical outcomes derived from failure of the endovascular procedures used to treat FPOD at our center and to identify those factors related to this failure.

METHODS

This is a retrospective, single-center review. The patients reviewed were those consecutively treated over the period January 2008—December 2013 for FPOD because of a lesion of the superficial femoral artery (SFA) and/or proximal popliteal artery by either the implant of a self-expandable bare metal stent (BMS) or a covered stent graft (SG). Covered SG was generally preferred for complex lesions (occlusions and long lesions). In some cases, the use of either type of device depended on surgeon's preference.

Patients with Rutherford stage 3—5 were included in the analysis. Patients were excluded if they had been treated for acute limb ischemia (ALI), undergone percutaneous transluminal angioplasty or received a balloon-expandable stent.

Once our protocol was read and approved by the Ethics Committee of our hospital, medical records were used to compile data on patient demographics, comorbidities, indication for intervention, and anatomic characteristics of the lesion. Preinterventional angiography was used to classify lesions according to Trans-Atlantic Inter-Society Consensus (TASC)-II classification system[3] and define runoff. Poor distal runoff was defined as the presence of one or no tibial vessels distal to the site of intervention.

Intraoperative data included the implanted device type and intraoperative complications. The SG used was: Hemobahn (in the first patients of the series) and Viabahn (W.L. Gore, Flagstaff, AZ). The BMS used was: SMART (Cordis Bridgewater, NJ), Tigris (W.L. Gore, Flagstaff, AZ), Biotronik Pulsar-18 and Pulsar-35 (Biotronik SE & Co. KG, Berlin, Germany), Superflex (OptiMed, Ettlingen, Germany), and Protégé Everflex (eV3 Endovascular, Plymouth, MN, USA).

After intervention, patients received either dual-antiplatelet therapy: acetylsalicylic acid (100 mg/24 hr) and clopidogrel (75 mg/24 hr) for 6 weeks with clopidogrel alone maintained indefinitely thereafter or antithrombotics and single-antiplatelet regimen if they were on antithrombotics before surgery.

Complications were recorded for the early (<30 days) postoperative period and during the course of follow-up. Follow-up visits consisted on clinical, hemodynamic, and ultrasonographic surveillance at 3, 6, and 12 months, and yearly thereafter. Restenosis was described as significant (>70%) when peak systolic velocity in the area of maximum stenosis was greater than 300 cm/sec (ratio 3:1) by duplex ultrasound.

Primary end point under study was clinical worsening compared with the preinterventional clinical stage attributable to endovascular treatment failure. Clinical worsening was defined as the presence of ALI or clinical deterioration by, at least, one Rutherford's classification category. Treatment failure was considered when >70% restenosis or occlusion occurred. The composite outcome end point major adverse limb events (MALEs) included the need for major amputation, bypass, or thrombolysis (open thrombectomy or fibrinolysis treatment),[4] and it was analyzed as a secondary end point.

Statistical analysis was performed using SPSS 20.0. Qualitative data were expressed as absolute values and percentages. Quantitative data were expressed as mean ± standard deviation or mean and interquartile range. Statistical analysis used chi-squared test and Fisher's exact test for frequencies, Student's *t*-test for means. Survival analysis was performed for all time-to-event data. Univariate analysis was performed using Breslow's test. Cox's proportional hazards model was used in the multivariate analysis on those variables with a significant impact on survival after using Breslow's test. A P value < 0.05 was considered statistically significant.

RESULTS

Over the 6-year study period, 90 percutaneous endovascular interventions were performed in 85 patients.

Mean age was 70.6 ± 10 years old with 77.8% men proportion. Seventy-nine patients (87.8%) were intervened for critical limb ischemia (CLI): 27 (30%) due to rest pain and 52 (57.8%) with minor trophic lesions. Demographic characteristics of the cohort are provided in Table I.

Most lesions treated were classified as TASC-A/B (76.7%) with a mean length of 98.5 ± 54 mm, mostly seen at the level of Hunter's canal or proximal popliteal artery. In over half of the cases, poor distal outflow was observed in the preinterventional angiography (Table II).

There were no intraoperative complications. An SG was placed in 28 of 90 (31.1%) procedures,