CLINICAL STUDY

Treatment of Superficial Femoral Artery Restenosis

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ABSTRACT

Purpose: To determine the predictors of restenosis, major adverse limb events (MALEs), postoperative death (POD), and all-cause mortality after repeat endovascular treatment of superficial femoral artery (SFA) restenosis.

Materials and Methods: This was a retrospective review of 440 patients with 518 SFA lesions who were treated between January 2002 and October 2011. Ninety-six limbs were treated for restenosis with bare metal stents (BMSs) or percutaneous transluminal angioplasty (PTA), of which 28 limbs developed another restenosis requiring a third procedure. The interaction measured in this study was between the second and third intervention. Predictors of SFA patency, MALEs, POD, and all-cause mortality after SFA restenosis treatment were identified.

Results: Patients who were treated with BMSs (n = 51) had similar rates of restenosis compared with patients who were treated with PTA (n = 45) (hazard ratio [HR] 1.40; 95% confidence interval [CI] 0.68–2.90; $P = .37$). Patients in the BMS group who took statins had a significantly lower risk of restenosis than patients who did not take statins (HR 0.13; 95% CI 0.04–0.41; $P < .001$). Stage 4–5 chronic kidney disease (CKD) (n = 12) was associated with a significantly higher risk of MALE + POD (HR 6.17; 95% CI 1.45–26.18; $P = .014$) and all-cause mortality (HR 2.83; 95% CI 1.27–6.33; $P = .01$). Clopidogrel was protective against all-cause mortality (HR 0.41; 95% CI 0.20–0.80; $P = .01$).

Conclusions: Patients in the BMS group who took statins at the time of intervention had a significantly lower risk of developing restenosis. Stage 4–5 CKD was a risk factor for MALE + POD and all-cause mortality, while clopidogrel decreased all-cause mortality risk.

ABBREVIATIONS

BMS = bare metal stent, CKD = chronic kidney disease, MALE = major adverse limb event, POD = postoperative death, PTA = percutaneous transluminal angioplasty, SFA = superficial femoral artery

INTRODUCTION

Peripheral artery disease (PAD) is an underrecognized manifestation of systemic atherosclerotic disease (1). The management of PAD is often difficult and requires a multidisciplinary approach. In the femoral arteries, potential treatments include medical therapy, endovascular revascularization, and surgical bypass (2,3). Recently, endovascular intervention was shown to be an effective alternative to surgical bypass for patients with lifestyle-limiting claudication, critical limb ischemia (CLI), and acute limb ischemia for whom medical therapy was not successful (2,4). However, the long-term primary femoropopliteal patency after endovascular treatment remains low with rates around 25% (5,6).

A major challenge with endovascular treatment is restenosis. Limited data exist on risk factors for recurrent restenosis that require target lesion revascularization (TLR) after repeat endovascular revascularization in the femoropopliteal segment (7–9). The aim of this study was to evaluate the predictors of restenosis, major adverse limb events (MALEs), postoperative death (POD), and all-cause mortality after repeat endovascular treatment of femoropopliteal disease restenosis.

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MATERIALS AND METHODS

Institutional review board approval was obtained for this single-center retrospective, longitudinal follow-up study.

Patient Selection

A total of 440 patients with 518 lower extremities treated for claudication (n = 251) or CLI (n = 267) between January 2002 and October 2011 were identified. Baseline patient characteristics are noted in Table 1. Medical records were reviewed for clinical history of superficial femoral artery (SFA) patency, antiplatelet medications, statin medications, renal function, and Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease (TASC) II lesion classification. Of the 518 treated limbs, 109 underwent endovascular treatment for restenosis. Thirteen of these 109 limbs were treated with endovascular laser, drug-eluting stents, or stent grafts and were excluded because of limited sample size and data per intervention. The final cohort consisted of 96 limbs.

Of these 96 limbs, 28 developed restenosis requiring a third procedure. Diagnosis of recurrent restenosis was made with duplex ultrasound (11/28), computed tomography angiography (CTA) (11/28), or conventional angiography (6/28). Ultrasound studies were performed using a 9.0-MHz phased array transducer (GE Logiq E9; GE Healthcare, Wauwatosa, Wisconsin). Criteria for restenosis included a peak systolic velocity ratio $\geq$ 2.5 or luminal stenosis exceeding 50% on CTA or catheter angiography (10). Catheter angiography was used only when there was a high clinical suspicion for acute limb ischemia.

Table 1. Baseline Patient Characteristics

Characteristic	Value
Age at second procedure, y, mean (standard deviation)	74.3 (9.9)
Sex, n (%)	
Men	44 (45.8)
Women	52 (54.2)
Claudication, n (%)	47 (49)
Critical limb ischemia, n (%)	49 (51)
Procedure, n (%)	
Angioplasty	51 (53)
Stent	45 (47)
TASC II classification, n (%)	
Type A/B	71 (74)
Type C/D	25 (26)
KDOQI CKD stage, n (%)	
Stage 1–3B	84 (87)
Stage 4–5	12 (13)
Plavix, n (%)*	
Yes	55 (59)
No	39 (41)
Aspirin, n (%)*	
Yes	74 (79)
No	20 (21)
Statin, n (%)*	
Yes	62 (66)
No	32 (34)

CKD = chronic kidney disease; TASC = Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease.
*Two patients had incomplete medication records and were excluded.

Endovascular Treatment

The 96 SFA restenoses were treated with either self-expanding bare-metal stents (BMSs) or percutaneous transluminal angioplasty (PTA). The following stents were used: Absolute and Herculink (Abbott Vascular, Santa Clara, California), Conformexx and Luminexx (Bard Peripheral Vascular, Inc., Tempe, Arizona), PROTÉGÉ (Medtronic, Plymouth, Minnesota), S.M.A.R.T. and Precise (Cordis Corporation, Bridgewater, New Jersey), Racer (Medtronic, Inc, Minneapolis, Minnesota), and Zilver (Cook, Inc., Bloomington, Indiana).

Patient follow-up was determined by the referring physician and generally included a routine acquisition of ankle-brachial index, transcutaneous oxygen pressure measurement, and duplex ultrasound with CTA, and catheter angiography being less commonly acquired. Follow-up was advised at 1, 3, 6, and 12 months and then yearly. Additional follow-up examinations and imaging were performed as needed to determine the patency of the treated arteries.

Definitions

Duration of arterial patency was defined as the time between the first restenosis treatment (second intervention) and the second restenosis treatment (third intervention). Glomerular filtration rate was calculated based on serum creatinine levels before the initial procedure and patient demographic information using the Modification of Diet in Renal Disease equation (11). Patients were stratified into stages of renal disease based on the Kidney Disease: Improving Global Outcomes CKD Work Group classification (12). Superficial femoral artery stenosis and occlusion were defined according to the TASC II classification (13). Technical treatment success was defined by <30% residual stenosis by visual estimate on the final angiogram. MALEs were defined as above-ankle amputation or major repeat revascularization of the target limb, which included thrombectomy, thrombolysis, or major surgical intervention. POD was defined as mortality within 30 days of endovascular intervention.

Measured Outcomes

The primary outcome was the need for reintervention for recurrent restenosis (second restenosis procedure, third overall procedure). Secondary outcomes related to the cause for TLR, MALE, MALE + POD, all-cause mortality, comorbidities, and concurrent medical therapy.