Outcomes at a single center after subintimal arterial flossing with antegrade-retrograde intervention for critical limb ischemia

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ABSTRACT

Objective: The subintimal arterial flossing with antegrade-retrograde intervention technique has been used to overcome antegrade recanalization failures for peripheral lower limb arterial occlusive disease. There are few outcomes published for this technique and we sought to evaluate outcomes at our institution over a 7-year period.

Methods: A retrospective review was performed of all subintimal arterial flossing with antegrade-retrograde intervention procedures of infrainguinal occlusive disease from 2009 to 2016. Retrograde and antegrade accesses were combined when occlusions could not be crossed from the antegrade direction. Baseline patient characteristics, procedures, procedure time, fluoroscopy time, contrast used, and radiation dose were collected. Posterior tibial waveforms, ankle-brachial index, limb salvage, vessel patency, and the presence of symptoms were assessed at follow-up.

Results: Treatment was performed in 52 limbs in 52 patients (35 men and 17 women; mean age, 77.62 ± 11.61 years) with critical limb ischemia and no appropriate venous conduit for surgical bypass. Among the cohort, 63.5% were diabetics, 98% had hypertension, 53.8% had a prior myocardial infarction, and 36.5% end-stage renal disease. The average Rutherford Category before the intervention was 5.08 ± 1.01. Retrograde pedal access was most commonly obtained in the anterior tibial artery/dorsalis pedis (55.7%), followed by the posterior tibial artery (40.3%). The technical success rate was 63.5% (33/52); adjunctive stenting was needed in 19 (36.5%) to optimize results. Preprocedural ankle-brachial index score was 0.54 ± 0.25, which improved after the procedure to an ankle-brachial index score of 0.77 ± 0.25. The primary patency rates at 3 and 6 months were 65% and 60%, respectively. The limb salvage rate at a mean follow-up of 5.4 months was 78.8%. There were 5 complications; 4 were hematomas managed conservatively and 1 was a major retroperitoneal bleed resulting in patient death.

Conclusions: Retrograde pedal access is a viable revascularization technique for achieving limb salvage in patients with critical limb ischemia with acceptable patency for limb-threatening ischemia. This technique expands revascularization options after failed conventional endovascular antegrade approaches. (J Vasc Surg 2017;■:1-7.)

Endovascular techniques are common practice in treating patients with chronic critical limb ischemia. Since subintimal recanalization was initially described by Bolia et al, treatment of long superficial femoral artery[1] and tibial artery occlusions[2] are common. Many interventionalists have been successful in treating patients using subintimal angioplasty via an antegrade approach as demonstrated in a metaanalysis done by Bown et al.[3] It demonstrated a technical success rate of 86% with a limb salvage rate of 89%. However, the technical success of the procedure is still restricted by the failure in some cases to cross the lesion and reenter the true lumen.

Since being described by Spinosa et al[4] in 2005, the subintimal arterial flossing with antegrade-retrograde intervention (SAFARI) technique has been used to overcome antegrade recanalization failures. Retrograde access is obtained and a guidewire is passed cephalad from the popliteal artery, posterior tibial artery, or dorsalis pedis artery, until it reaches the subintimal space created from the antegrade approach. Since this initial study, there has been limited published studies on the outcomes of the SAFARI technique.[5-9] Given this relative paucity of studies, we retrospectively evaluated patients who had undergone the SAFARI procedure at our institution to assess outcomes and factors that my influence them.

METHODS

Patients. All patients provided informed consent before any intervention. Institutional ethics board approval was obtained for this study. A retrospective study of SAFARI procedures from January 2009 to June 2016 was carried

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out. The hospital electronic patient database, along with the Vascular Quality Initiative, a vascular surgery database, was retrospectively accessed and patients were included if they had undergone SAFARI procedures within the last 7 years. All patients were treated by an interventional radiologist and/or a vascular surgeon experienced in subintimal recanalization and endovascular interventions as the primary operator with trainees providing assistance during the procedures. Patients were selected to undergo the SAFARI procedure if the antegrade attempt failed, the patients were not candidates for surgical intervention, and there was an available artery for retrograde access.

Procedural technique. The antegrade procedure was initially attempted in all patients in a manner similar to that defined by Bolia et al,[10] with some variation in devices used including the use of reentry devices. Once reentry into the distal true lumen was unsuccessful via an antegrade approach, access to the true lumen was attempted via a retrograde approach. This was done by directly entering the ipsilateral posterior tibial, popliteal or dorsalis pedal artery with fluoroscopic or ultrasound guidance. Once retrograde entry was achieved, therapeutic anticoagulation, if not already administered with the antegrade approach, was administered using intravenous heparin; a 0.014- or a 0.018-inch guidewire was initially advanced followed by a 2.4-F support catheter. In a majority of the cases, the guidewire could be advanced into the true lumen or subintimal lumen created by the antegrade catheter and past the level of occlusion without much difficulty. After this step, the wire was engaged with a snare and pulled through the antegrade access creating a flossing-type guidewire. Once this through-and-through access was created, the occlusion was dilated/stented from the antegrade direction. When the true lumen could not be reentered from either direction, a subintimal entry technique was performed where balloons were advanced from each direction and inflated simultaneously adjacent to but not overlapping within the subintimal space.[11] This maneuver often resulted in access to the true lumen.

Once the occlusion was angioplastied and/or stented, the catheter was removed and posterior tibial, popliteal, or dorsalis pedis puncture site hemostasis was obtained with manual compression. Femoral access site hemostasis was obtained either with a femoral arterial closure device or manual compression. No additional independent procedures were performed for initial revascularization in the study population. Antiplatelet medications were not withheld before the intervention and were continued after the intervention.

Study endpoints and definitions. Every patient was assessed for age, existing comorbidities, symptoms, prescription medication, and atherosclerotic risk factors. A number of procedural variables were also collected, including vessels accessed, total procedure time and radiation dose. Primary vs primary assisted patency, limb salvage, and time to death were also examined. Primary patency was defined as patent limb segments (>50% reduction in luminal diameter determined by a peak systolic velocity ratio of ≥2.5) without recurrent stenosis or occlusion vs primary assisted patency (reintervention for stenosis or occlusion in the treated leg). Occlusion was defined as no flow in the treated vessel by ultrasound or angiography. Kaplan-Meier curves with 95% confidence intervals were generated for primary vs primary-assisted patency, patient survival, and limb salvage. Procedure time was defined as the time the patient was in the procedure room from prepping of the access site to hemostasis being obtained. A person-year analysis was performed that allows the creation of an incidence rate when individuals contributed differing amounts of time under observation. Attempts were made to follow-up all patients at different time points after the procedure with duplex ultrasound scans. The follow-up was random according the ordering vascular surgeon and did not follow any specific algorithm. Forty-two patients had follow-up duplex scans with no fixed interval with most undergoing a duplex study within a month of the intervention. All calculations were performed with SPSS v 24.0 (SPSS, Inc, Chicago, Ill).

ARTICLE HIGHLIGHTS

- **Type of Research:** retrospective single-center cohort study
- **Take Home Message:** In 52 critically ischemic limbs treated with the subintimal arterial flossing with antegrade-retrograde intervention, technical success was 63.5%, adjunctive stenting had to be done in 36.5%, and the 6-month primary patency and limb salvage rates were 60% and 78.8%, respectively.
- **Recommendation:** When a conventional antegrade endovascular approach fails, this study suggests adding a retrograde technique to revascularize limbs with critical ischemia.

RESULTS

All 52 patients (35 men, 17 women) underwent SAFARI technique over the course of this retrospective study after attempting antegrade crossing of the occlusion. A large proportion of the patient group (63.5%) had diabetes, more than one-half of patients had a previously documented myocardial infarction (53.8%), and more than one-third of patients had end-stage renal disease (36.5%). There were 26 patients (49.1%) with a previous antegrade attempt; 50.9% of patients had no previous procedure. Most lesions (88.5%) treated were classified as TransAtlantic Inter-Society Consensus for the