The Superficial Femoral Artery Conundrum

So Close, Yet So Far Away!*  

Thomas T. Tsai, MD, MSc†‡§
Denver, Colorado

The endovascular treatment of the superficial femoral artery (SFA) remains one of the biggest conundrums for interventionalists in everyday clinical practice. Whereas we have grown accustomed to excellent endovascular outcomes in the coronary, carotid, renal, and iliac arteries, the femoropopliteal (FP) artery continues to be our “Achilles heel,” exhibiting relatively poor primary patency rates, from 77% to 86.1% at 1 year in prospective clinical trials, with much poorer rates in the real world (1,2). Many reasons have been implicated, including the SFA’s location deep in the thigh, which undergoes constant conformational changes (e.g., extension/contraction, torsion, compression, and flexion), its unique anatomic complexities (e.g., increased incidence of chronic total occlusions [CTO], diffuse disease, and dense calcifications), and common flow perturbations both upstream and downstream (e.g., inflow disease and poor tibial runoff). Although the effectiveness (patency) of these procedures continues to be a challenge, the safety is superb, with a 30-day freedom from composite death, target limb amputation, and reintervention of >99% and same-day discharge for most patients (3,4). As in other arterial beds, this safety advantage of endovascular procedures over open surgery has led to a shift toward a less invasive approach to treating symptomatic SFA disease, with an increase in the use of peripheral vascular intervention procedures by more than 1,000% in the last 2 decades (5,6).

With this explosion of endovascular procedures, consensus recommendations have developed around the anatomic distribution, number, and nature of lesions (stenosis, occlusion), and published outcomes to guide treatment decisions (7,8). The revised Trans-Atlantic Inter-Society Consensus Classification (TASC) II document recommends endovascular therapy for type A and B lesions, and recommends surgery for type D lesions. Patients with type C lesions who are not good risk candidates for surgery may also benefit from an endovascular approach. Since 2000, the classification schemes in the femoropopliteal (FP) region have been modified to reflect the technological advances in endovascular equipment such that type D lesions only include CTO of the SFA >20 cm, involving the popliteal artery, or CTO of the popliteal artery including the proximal trifurcation vessels (8).

In this issue of JACC: Interventions, Iida et al. (9) studied 2,400 limbs from 1,889 consecutive patients who underwent successful endovascular therapy (EVT) for de novo FP lesions. This study was a subanalysis of the REAL-FP (Retrospective Multicenter Analysis for Femoropopliteal Stenting) registry, a nonrandomized multicenter registry representing 13 institutions in Japan. Using this retrospective registry, the investigators contributed 3 main findings to the existing literature.

1. In a large cohort using relatively contemporary techniques and devices, primary patency was 80% in the TASC II A to C group versus 69% in the TASC II D group at 1 year, 62% versus 48% at 3 years, and 49% versus 34% at 5 years, consistently demonstrating reasonable rates of primary patency in the TASC II A to C group up to 5 years.

2. Common restenosis determinants for TASC II A to C and D lesions included: 1) diabetes mellitus; 2) no stent usage; 3) CTO; and 4) poor below-the-knee runoff.

3. There may be a differential effect of the variables female sex and renal insufficiency on restenosis in TASC II A to C versus D lesions.

Beyond the specific findings, the study by Iida et al. (9) represents a growing trend of research in peripheral arterial disease to capture procedural and patient-level data, either retrospectively or prospectively. In this case, a large retrospective registry of 13 institutions in Japan compiled their data to focus on FP stenting in 3,471 limbs in 2,759 consecutive patients. Because of the large cohort size and number of follow-up events, multivariable modeling determined that diabetes, no stent use, CTO, and below-the-knee runoff were shared risk predictors for restenosis consistent between TASC II A to C and D lesions. Furthermore, interaction terms can be added to the models to ascertain whether certain variables have a differential impact on different strata. In this study, chronic kidney disease and female sex predicted restenosis in only the TASC II A to C and D lesions, respectively. Concretely, these data reiterate what can be expected when FP lesions are treated with EVT and reconfirm which variables are associated with the loss of primary patency.

*Editorials published in JACC: Cardiovascular Interventions reflect the views of the authors and do not necessarily represent the views of JACC: Cardiovascular Interventions or the American College of Cardiology.

From the Institute for Health Research, Kaiser Permanente Colorado, Denver, Colorado; Division of Cardiology, University of Colorado Denver, Denver, Colorado; and Interventional Cardiology, Colorado Permanente Medical Group, Denver, Colorado. Dr. Tsai has reported that he has no relationships relevant to the contents of this paper to disclose.
Although this study and studies like these (single-arm observational studies) continue to provide data on the technical outcomes of one end of the spectrum of treatment (EVT), true comparative effectiveness studies focused on the merits of one treatment versus another are lacking, and limited attention is being paid to patient-centered health status measures and patient preference, which are the cornerstones of treatment selection. Moving forward, there is a strong need to refocus our agenda in peripheral artery disease (PAD) research to best serve our patients. Comparative effectiveness research defined by the Institute of Medicine as “the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care” is in its infancy in PAD research (10). Prospective registries need to incorporate the clinical spectrum of PAD treatment to include exercise programs, pharmacological therapies, EVT, and open surgery with consistent definitions and outcome metrics to compare the safety and effectiveness of different treatment options. The Institute of Medicine also envisioned a more patient-centered healthcare system focused on patients’ functional status and health-related quality of life (defined as the patient’s perceived physical, emotional, and social well-being and function). Treatment of claudication is entirely focused on improving health status rather than survival or limb preservation. How should we weigh the tradeoffs of repeat revascularization with EVT compared with the increased periprocedural complications and recovery time of open surgical bypass? How shall we counsel patients with regard to exercise programs, pharmacological therapy, and invasive treatment? What bearing does primary and secondary patency have on a patient’s functional status and quality of life? Disease-specific questionnaires like the Peripheral Artery Questionnaire and the Walking Impairment Questionnaire are just a few of the validated tools in assessing functional status and quality of life in patients with lower extremity claudication (11). Large national prospective registries like the recently launched NCDR (National Cardiovascular Data Registry), the PVI (Peripheral Vascular Intervention) registry, and the Society for Vascular Surgery’s VQI (Vascular Quality Initiative) registry need to incorporate functional assessment and quality-of-life measures to their efforts to allow meaningful comparisons of different treatment beyond technical success and periprocedural complications. Lastly, the PAD community must encourage our industry partners, funding agencies, and academic affiliates to design meaningful randomized controlled trials comparing emerging technologies such as drug-eluting balloons to bare-metal self-expanding stents as opposed to balloon angioplasty with provisional stenting. The current focus of most trials is for device approval as opposed to device superiority, which has led to the concept of the “Wild Wild West” in EVT. Unless we address the gaps in our research portfolio in the care of patients with claudication, we will continue to be close, yet so far away.

Reprint requests and correspondence: Dr. Thomas T. Tsai, Institute for Health Research, Kaiser Permanente Colorado, 10065 East Harvard Avenue, Suite 300, Denver, Colorado, 80231. E-mail: thomas.tsai@coloradooutcomes.org.

REFERENCES


Key Words: restenosis • stenting • superficial femoral artery.