## SFA Angioplasty Versus Femoropopliteal Bypass

What can we realistically expect?

BY HEATHER Y. WOLFORD, MD; SCOTT M. SUROWIEC, MD; AND MARK G. DAVIES, MD, PHD

he initial treatment for patients with symptomatic lower-extremity atherosclerotic occlusive disease is aggressive risk-factor modification, including antiplatelet therapy, an LDLcholesterol goal less than 100 mg/dL, and exercise programs. 1 In spite of these medical interventions, many patients remain severely symptomatic and seek additional remedies to improve their quality of life.<sup>2</sup> Traditionally, patients proceeded to femoropopliteal bypasses when their symptoms warranted treatment. Much has been written on the indications, timing, and conduit choice of these bypasses. They remain a viable and durable option for many patients, but are associated with inherent perioperative morbidity and mortality rates, mandatory inpatient stays, and variable periods out of work. In this new and evolving environment, treatment paradigms are changing, and endoluminal therapy is emerging as first-line therapy in many centers. In this article, we review our recent findings with both open and endoluminal superficial femoral artery (SFA) therapies in the global management of occlusive SFA disease.

## UNIVERSITY OF ROCHESTER EXPERIENCE

We recently reported the University of Rochester's experience with SFA interventions between 1986 and 2004.<sup>3</sup> As part of a retrospective review, we identified 329 patients who underwent endoluminal intervention of the SFA and 666 patients who underwent femoral

"Early failure of an endoluminal intervention did not result in increased morbidity or mortality and did not compromise subsequent open surgical bypass."

above-knee or below-knee bypass (350 with prosthetic [PTFE or Dacron] and 316 with a venous conduit). The indication for therapy was claudication in two thirds of patients and critical limb ischemia in the remainder. The demographics varied slightly between the two groups. The bypass patients were on average 10 years older than the endoluminal patients and had a 10% higher incidence of tissue loss. Femoropopliteal bypasses were most commonly placed to treat TASC C and D lesions, whereas patients undergoing endoluminal therapy had primarily TASC A and B lesions.

Technical success was 93% in the endoluminal group with a 10% morbidity rate, mostly due to access-related issues. Primary patency rates for endoluminal therapy at 1 and 6 years were 75% and 50%, respectively. Limb salvage for endoluminal therapy at 1 and 2 years was 84% and 70%, respectively. Compared with the open bypass group, the patency of TASC C and D lesions treated endoluminally was statistically worse than that for open femoropopliteal bypass with either vein or prosthetic.<sup>3</sup> Early failure of an endoluminal intervention did not

result in increased morbidity or mortality and did not compromise subsequent open surgical bypass.<sup>4</sup>

The use of SFA angioplasty with or without stenting is expanding, with an increasingly aggressive management strategy for all TASC lesions. It is widely accepted that TASC A and TASC B lesions can be treated endoluminally. The role of endovascular therapy for TASC C and D remains controversial, and many would advocate that these patients should be considered for surgical intervention. A review of all published trials of percutaneous angioplasty (PTA) with or without stenting in the femoropopliteal arteries shows median patencies (anatomic success rates) of 71%, 59%, and 53% at 1, 3, and 5 years respectively.<sup>5</sup> Lesion types were not routinely reported, but most studies contained only type A, B, and C lesions. Four randomized studies comparing PTA alone versus PTA plus stent placement in the SFA have all failed to demonstrate a benefit to stenting in terms of long-term patency and symptom relief.<sup>6-9</sup> Our own recent data support this conclusion.<sup>3</sup>

Stent use should be confined, at present, to flow-limiting dissections or inadequate results from balloon angioplasty alone. In our study, advanced levels of disease led to poorer results with the currently available endoluminal technology.3 Multiple factors adversely affect patency of PTA in the SFA, including presenting symptoms (claudication vs critical ischemia), type of lesion (stenosis vs occlusion), length of lesion <10 cm and >10 cm), and distal runoff. Factors associated with early failure (<30 days) include the presence of TASC D lesions and tissue loss.<sup>4</sup> Interestingly, early failure of endoluminal therapy for SFA disease is not associated with significant morbidity and mortality. Options for surgical bypass are not compromised, and the amputation level in patients with significant tissue loss is not altered. In our series on early failure of SFA interventions, 8% of patients were able to undergo a second successful SFA endoluminal intervention using the retrograde popliteal approach, and 49% of patients eventually underwent an ipsilateral femoropopliteal bypass.<sup>4</sup> In contrast to these findings with early failure, Boeckler et al showed that in patients who suffer a late failure of endoluminal SFA interventions (mean, 6 months after intervention), open surgical options were more limited, and outcomes were poorer with a higher incidence of complications and major amputations.<sup>10</sup>

Although anatomic patency and hemodynamic success are important, the primary reason to perform an intervention is symptom relief, and it can be argued that the best barometer should be long-term clinical success (ie, relief of symptoms). In our own series, freedom from recurrent symptoms was seen in 87%, 72%,

and 62% of the patients at 1, 4, and 6 years, respectively. Clinical failures appear only partially related to anatomic patency of the treated area. Other factors such as progression of disease in the inflow vessels and in the outflow tract are also implicated. Fifty percent of these lesions are amenable to additional percutaneous intervention. The findings that clinical success appears to be higher than anatomic success have been reported by others. 11,12 Similarly, we have found that retained clinical success (lack of amputation) was significantly higher than patency with our open bypass group.

"patency may not be the best measure for therapy, but rather retained clinical benefit and avoidance of procedural morbidity and mortality."

A recent decision and cost-effectiveness analysis of revascularization procedures for femoropopliteal disease analyzed six treatment strategies: (1) no treatment, (2) initial PTA with no further revascularization, (3) initial PTA with subsequent PTA, (4) initial PTA with subsequent bypass surgery, (5) bypass surgery followed by no therapy, and (6) bypass surgery followed by graft revision. The results showed that for a 65-year-old man with disabling claudication and a femoropopliteal stenosis or occlusion, an initial PTA strategy increased quality-adjusted life years by 2 to 13 months and resulted in decreased lifetime expenditures as compared with bypass surgery. Analysis suggested that when the 5-year patency of endoluminal intervention exceeds 30%, endoluminal intervention is the preferred initial invasive strategy in patients with disabling claudication and femoropopliteal stenosis or occlusion.<sup>13</sup> In our own series, when we break down by lesion type, the results of SFA endoluminal intervention for TASC A and TASC B lesions achieve this 5-year patency rate, but those for TASC C and D do not.3

## CONCLUSION

In summary, TASC A and B lesions can be safely and effectively treated with endoluminal intervention.

TASC C and D lesions do not fare well long-term compared to femoropopliteal bypass. Early failure of endoluminal therapy does not appear to compromise future bypass options or outcomes. However, late intrinsic failure appears associated with poorer open bypass success and great risk for major amputation. Clinical outcomes (symptom relief, limb salvage) tend to exceed patency results. It is not uncommon for the

patient with a failed SFA intervention to remain symptom-free. Therefore, patency may not be the best measure for therapy, but rather retained clinical benefit and avoidance of procedural morbidity and mortality. As endoluminal therapy continues to increase in prevalence, the benefits and the limitations of such interventions in the SFA will likely be more fully realized. Comparisons to open surgical options need to continue to help define each therapy's role in treating the patient with occlusive SFA disease.

Heather Y. Wolford, MD, is a vascular fellow at the Center for Vascular Disease, University of Rochester, in Rochester, New York. She has disclosed that she has no financial interest in any product or company mentioned

Scott M. Surowiec, MD, is a vascular fellow at the Center for Vascular Disease, University of Rochester, in Rochester, New York. He has disclosed that he has no financial interest in any product or company mentioned herein.

Mark G. Davies, MD, PhD, is Associate Professor and Director of Endovascular Therapy at the Center for Vascular Disease, University of Rochester, in Rochester, New York. He has disclosed that he is a paid consultant to SimSuite, Genentech, and Boston Scientific, Dr. Davies may be reached at (585) 275-8090;

mark\_davies@urmc.rochester.edu.

- 1. Grundy SM, Cleeman JI, Merz NB, et al. Implications of recent clinical trials for national cholesterol education program adult treatment panel III guidelines. Circulation. 2004;110:227-239.
- 2. Breek JC, Hamming JF, DeVries J. The impact of walking impairment, cardiovascular risk factors, and co-morbidity on quality of life in patients with intermittent claudication. J Vasc Surg. 2002;36:94-99.
- 3. Surowiec SM, Davies MG, Lee D, et al. Percutaneous angioplasty and stenting of the superficial femoral artery. J Vasc Surg. 2005;41:269-278.
- 4. Galaria II, Surowiec SM, Rhodes JM, et al. Implications of early failure of superficial femoral artery endoluminal interventions. Ann Vasc Surg. In press.
- 5. Davies MG, Waldman DL, Pearson TA. Comprehensive endovascular therapy for femoropopliteal arterial atherosclerotic occlusive disease. J Am Coll Surg. In press.
- 6. Becquemin JP, Allaire E, Qvarfordt P, et al. Surgical transluminal iliac angioplasty with selective stenting: long term results assessed by means of duplex scanning. J Vasc Surg. 1999-29-422-429
- 7. Ceina M. Schoder M. Lammer J. PTA versus stent in femoro-popliteal obstruction. Radiologie. 1999;39:144-150.
- 8. Vroegindeweii D. Vos LD. Buth J. Bosch HC. Balloon angioplasty combined with primary stenting versus balloon angioplasty alone in femoro-popliteal obstructions: a comparative randomized study. Cardiovasc Intervent Radiol. 1997;20:420-425.
- 9. Zdanowski Z, Albrechtsson U, Lundin A, et al. Percutaneous transluminal angioplasty with or without stenting for femoro-popliteal occlusions? A randomized controlled study. Int Angiol. 1999:18:251-255.
- 10. Boeckler D, Blaurock P, Mannsman U, et al. Early surgical outcomes after failed primary stenting for lower limb occlusive disease. J Endovasc Ther. 2005;12:13-21.
- 11. Karch LA, Mattos MA, Henretta JP, et al. Clinical failure after percutaneous transluminal angioplasty of the SFA and popliteal arteries. J Vasc Surg. 2000;31:880-887.
- 12. Vroegindewij D, Tielbeck AV, Buth J, et al. Recanalization of femoro-popliteal occlusive lesions: a comparison of long term clinical color duplex ultrasound and arteriographic follow-up. J Vasc Interv Radiol. 1995;6:331-337.
- 13. Hunink MGM, Wong JB, Donaldson MC, et al. Revascularization for femoro-popliteal disease: a decision and cost effectiveness analysis. JAMA. 1995;274:165-171.