CAROTID STENTING • INFRAINGUINAL PAD • AAA REPAIR

Supplement to

Endovascular TODAY

June 2005

BEST OF

Highlights from the most innovative meeting in endovascular therapy.

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INFRAPOPLITEAL INTERVENTION • AV DIALYSIS ACCESS GRAFTS

VIVA

The philosophy behind VIVA, and what to expect at this year's meeting.

The field of vascular medicine and intervention is rapidly evolving. It is difficult even for experts to remain current on all of the new data, emerging technologies, reimbursement issues, and outcomes data. In addition, further challenges surround the educational components of participants with various skill and knowledge levels among the specialties involved in the management of patients with vascular disease.

ADDRESSING TODAY'S EMERGING EDUCATIONAL MEETING NEEDS

The challenge of educating physicians who have varying degrees of knowledge and expertise while incorporating the power of today's most advanced communications technology is what formed the foundation for Vascular InterVentional Advances (VIVA).

Against the backdrop of Las Vegas, Nevada, a city classically ignored by major cardiovascular meetings, but possessing some of the finest hotels, restaurants, and meeting facilities in the US, VIVA brings together the major thought leaders and educators from all disciplines: vascular surgery, cardiology, vascular medicine, and radiology. The goal is to provide the highest-quality educational program in vascular medicine and intervention using a unique computer platform, live case demonstrations, and thoughtful discussion about current issues facing patients with vascular disease.

The first 2 years were designed predominantly for physicians interested in entering the field of vascular medicine and intervention.

VIVA 2005

The third meeting, scheduled for September 27-30, 2005, at the Mandalay Bay Resort and Casino in Las Vegas, is entering a new phase of development. The agenda highlights expansion of the knowledge of physicians to current and future developments in the diagnosis and management of vascular disease. As the field evolves, so will VIVA. This fall, in-depth analysis of carotid intervention, advances in aortic aneurysm endograft therapy, and a novel review of current complications associated with peripheral intervention are just a few of the highlights. In addition, for the first time, the VIVA faculty will offer its own unique style of education to provide the necessary information required to proceed with cerebral angiography as a pre-session to VIVA 2005 on Monday, September 26.

ENHANCED INTERACTION

Attendees will have the unique opportunity to ask virtually any question they desire while avoiding potential embarrassment. Using the VIVA intranet, all attendees will have a computer at their seat. Any question can be instantly sent via the intranet to one of the faculty, who will reply in "real time" to the questioner.

The intranet provides a continuous opportunity to view any presentation delivered by faculty at any time. A rich literature library can be referenced throughout the meeting. When live cases are projected, audience members can view them on their own computer screens. In addition, once the case is terminated on the main screen, attendees will have the opportunity to "peer into" the angiography suite on their individual screens.

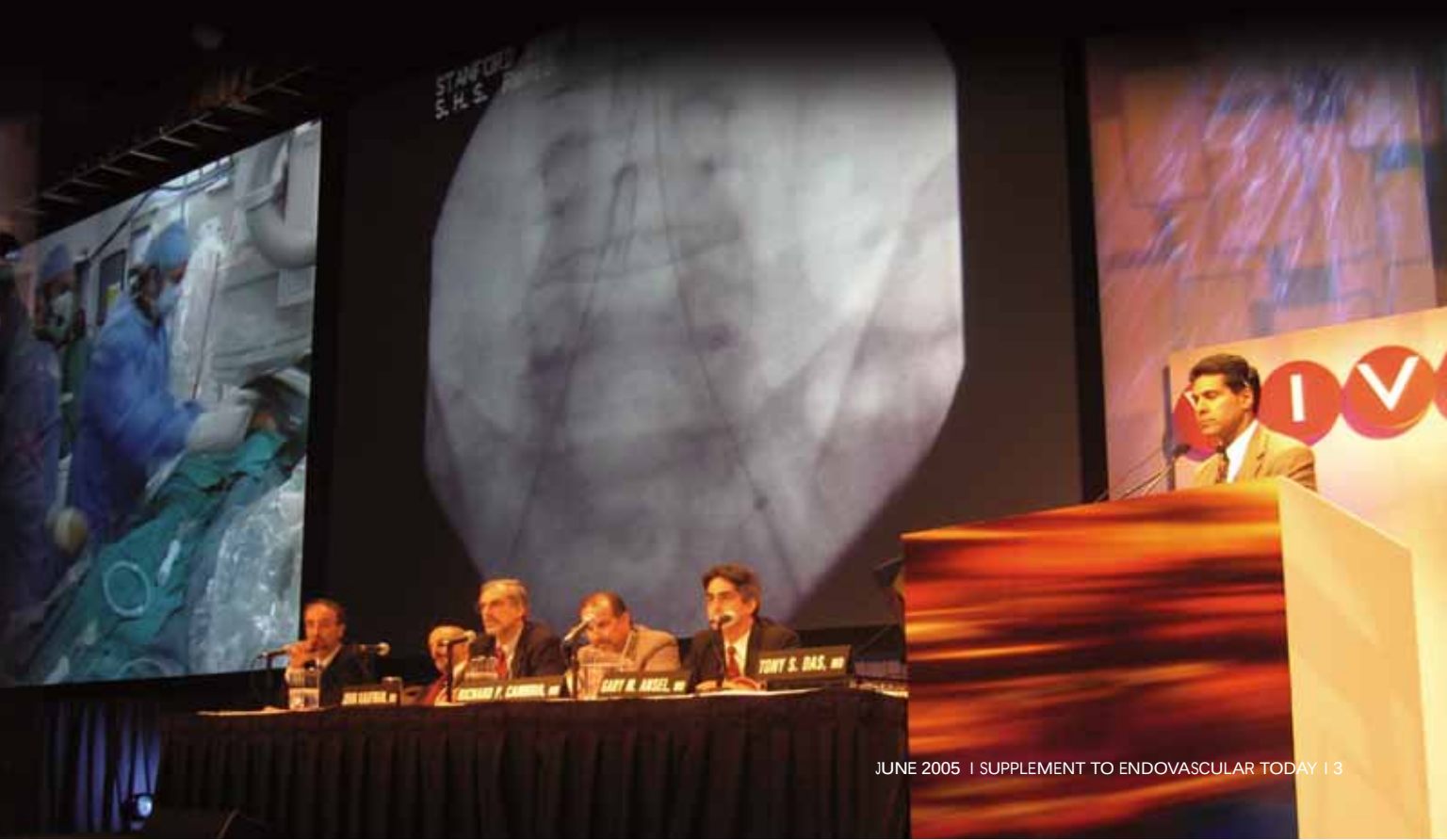
The power of "laptop learning" becomes exquisitely clear soon after you log on to the VIVA intranet.

One final advantage of VIVA…the faculty is instructed to remain at the meeting for the entire 4 days. Informal conversations, review of cases presented by attendees to faculty, and advice on adopting novel technologies occur frequently at VIVA.

This supplement will give you an idea of the quality of the presentations at VIVA. However, without attending the meeting, you cannot possibly experience the entire look and feel of the most technologically advanced, fully dedicated vascular therapy educational experience available. We look forward to welcoming you to VIVA 2005!

Michael R. Jaff, DO
VIVA Faculty

VIVA 2005 DAILY AGENDA	
Tuesday, September 27	Hot Topics, Hot Trials: Overview of the latest trials and therapies in carotid, aneurysmal, venous, and peripheral arterial disease; In-depth analysis of carotid artery therapy
Wednesday, September 28	Aneurysmal Disease and Renal/Mesenteric Intervention: Detailed coverage of the devices, trials, and therapies in aneurysmal, renal, and mesenteric disease
Thursday, September 29	Chronic Total Occlusions in PAD: Techniques and treatment options
Friday, September 30	Complications Symposium: Experts discuss how they handle their most difficult cases, and how to avoid them



BEST OF VIVA 04

VASCULAR INTERVENTIONAL ADVANCES
THE NATIONAL EDUCATION COURSE FOR PERIPHERAL VASCULAR INTERVENTIONS

MANDALAY BAY RESORT
LAS VEGAS, OCTOBER 19-22, 2004

CONTENTS

Produced under an educational grant from Boston Scientific Corporation

The Case for Carotid Stenting

Clinical equipoise and beyond.

PRESENTED BY WILLIAM A. GRAY, MD

Carotid endarterectomy (CEA) for stroke prevention has long been the standard of care for patients with extracranial carotid artery bifurcation disease. The NASCET trial[1] clearly established it as a treatment of choice for symptomatic patients, with a 17% absolute reduction in stroke and death after 2 years compared to medical therapy. The subsequent ACAS study established CEA for treatment of asymptomatic carotid lesions, albeit with a somewhat less profound reduction in stroke and death than was seen in the symptomatic cohort.[2]

STEP ONE: CLINICAL EQUIPOISE

Although clearly beneficial, CEA in patients with significant comorbidities is associated with an excess risk of stroke and death in hospital.[3] To create a more homogenous population for study so as not to confound subsequent analysis, patients with significant medical or surgical comorbidities have typically been excluded from studies comparing CEA to medical management, and the data we have on these patients are almost exclusively gleaned from real-world CEA registries, but without input from randomized trials.

Carotid artery stenting (CAS) has been around for just over a decade, and although single-center registry experience suggested competitive safety and efficacy outcomes compared to CEA, prior to commencing randomized clinical trials of CAS, it was necessary to establish it in a position of clinical equipoise with CEA. Clinical equipoise, a concept described by Benjamin Freedman, MD, in a 1987 *New England Journal of Medicine* article,[4] exists when "a state of genuine uncertainty on the part of the clinical investigator [and in the opinion of experts] regarding the comparative therapeutic merits of each arm in a trial." Clinical equipoise is a cornerstone of randomized research. If it becomes clear that one therapy or treatment is superior to the other, the investigators must stop the trial and offer that treatment to all participants. Only in the face of reasonable uncertainty can an ethical comparison of alternative treatments be conducted.

In the early years of CAS, before there was dedicated equipment, patients at higher than normal risk for surgical intervention were, for obvious ethical reasons, primarily the patients entered into studies because the new therapies were untested and an established alternative therapy existed. Only when early reports of CAS showed acceptable rates of stroke and death at 30 days could we reasonably consider randomly assigning patients to either CEA or CAS and realistically deter-

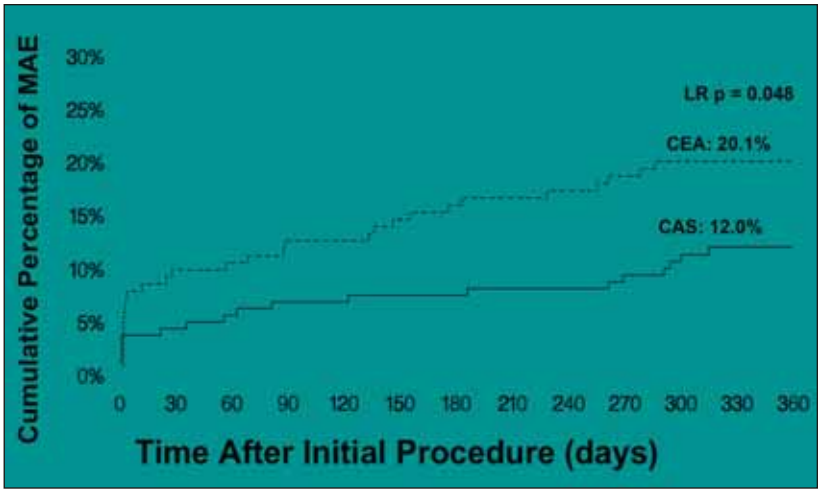


Figure 1. SAPPHIRE trial: 1-year primary endpoint of death, stroke, or MI at 30 days plus ipsilateral stroke or death from 31 days to 1 year.

	ARCHeR 1 N = 158	ARCHeR 2 N = 278
Fatal strokes	0	0
Non-fatal major strokes	0	1
Minor strokes	1	3

Figure 2. Incidence of major and minor stroke in ARCHeR 1 and 2.

mine if this new treatment were worth advancing. The Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) trial was designed and conducted to do just that.

STEP TWO: SUCCESS IN HIGH-RISK PATIENTS

The SAPPHIRE trial was a prospective randomized trial comparing CAS using the self-expanding, nitinol Precise stent (Cordis Corporation, a Johnson & Johnson company, Miami, FL) and the AngioGuard embolic protection filter (Cordis) to CEA in high-risk surgical patients.[5] Eligible patients had coexisting conditions that increased their surgical risk and either a symptomatic carotid artery stenosis of at least 50% luminal diameter or an asymptomatic stenosis of at least 80%.

Because clinical equipoise did not exist for the randomization of low– or normal-risk surgical patients to interventional treatment, the SAPPHIRE trial enrolled only patients deemed at increased surgical risk—patients in whom outcomes after CEA were less optimal. In fact, the SAPPHIRE trial was the only randomized trial to ever include procedures performed in high-risk surgical patients, a void that certainly left room for a comparison to the nascent CAS.

By looking at the standard metrics of procedural safety, stroke prevention, and durability, along with cost and patient preference, a clear argument can be made based on the SAPPHIRE data, along with supporting registry data from ARCHeR and other trials, for the superiority of CAS with distal protection over CEA in high-risk patients with extracranial bifurcation carotid disease.

Procedural Safety

At 30 days, major adverse event rates trended lower for CAS compared to CEA, but were not significantly different (4.8% vs 9.8%, respectively; *P*=.09). In fact, complication rates in the CAS trials and registries subsequent to SAPPHIRE have consistently trended lower, representing perhaps the effects of operator experience, protocol differences, patient selection, or differences in equipment.

Efficacy

The goal of treatment for carotid artery disease is stroke prevention. Looking at the primary endpoint of the SAPPHIRE trial—death, stroke, or MI at 30 days plus ipsilateral stroke or death from 31 days to 1 year—we see that compared to CEA, CAS in high-risk patients is certainly not an inferior therapy and actually approaches statistical superiority (*P*=.004 for noninferiority and *P*=.053 for superiority) (Figure 1). Because SAPPHIRE was designed as a noninferiority trial, the trial was considered successful.

What happens to stroke protection going out 365

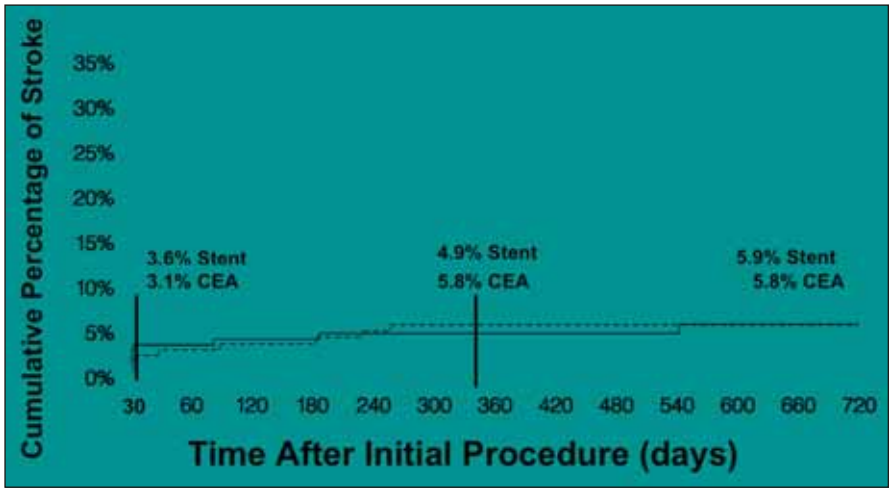


Figure 3. SAPPHIRE trial: all strokes to 30 days and ipsilateral stroke from 31 to 720 days.

Symptomatic			
Study	Patients	Stenosis	Stroke & Death
NASCET	328	>70%	5.8%
CREST	163	≥50%	5.5%
Asymptomatic			
Study	Patients	Stenosis	Stroke & Death
ACAS	721	>60%	2.2%
CREST	321	≥70%	2.8%

Figure 4. CREST: lead-in phase results.

days? In the two ARCHeR registries, fatal strokes did not occur, nonfatal major strokes occurred once in roughly 450 patients, and there were minor strokes in four patients (Figure 2). It is important to note that these patients comprised a relatively sick cohort with multiple comorbidities, and the extent to which these strokes were related to carotid disease is unclear.

In the SAPPHIRE trial, if one examines the actual risk of stroke alone to 2 years in both treatment arms, the statistics of CEA and those of CAS are quite similar, demonstrating that stroke prevention, at least to 2 years, is as good after CAS as after CEA (Figure 3).

Durability

In SAPPHIRE, CAS restenosis rates were quite low, and compared to CEA, although not statistically significant, trended toward superiority. The target lesion revascularization rate at 1 year was 0.6%. Similarly, in ARCHeR, the target lesion revascularization rate was 2.6% at 1 year, and still only about 3% at 2 years; the durability of these results is quite remarkable for a stenting procedure.

The ARCHeR data compare favorably to both contemporary data from SAPPHIRE (3.6% rate of target lesion revascularization in the CEA arm) and historical data from the ACAS trial, in which revascularization rates after CEA ranged from 5% to 10% in a careful analysis by Moore et al of the ACAS data set.

Cost

Working under the assumption that stroke prevention and durability are independent of surgical risk, as are cost and patient preference, we published an article[6] looking at our own results of approximately 270 patients. We did not randomize the patients, but we evaluated using a contemporary control, to CEA or CAS. This work was done in the mid-to-late 1990s, so our data do not include embolic protection. However, the direct costs for CAS were about 40% of those of CEA, and the average length of stay after CAS was approximately 1.4 days compared to 3 days for CEA.

There are a few caveats to these data: approximately 75% of CEA patients go home before 3 days, but for that last 25% who experience complications, average hospital stays are driven up. Also, the current average stay after CEA is probably somewhat lower, at 2 days instead of 3. When we include the cost of embolic protection devices, which were not available at the time of this analysis, the cost differential largely disappears. More recent prospective data from the SAPPHIRE trial confirm rough equivalence of the two therapies at 1 year, with a slight cost edge to CEA.

Trial (n)	Fatal Stroke	Disabling or Major Stroke	Combined
SAPPHIRE (567)	XX	XX	2.1%
ARCHeR 1, 2, 3 (581)	0.5%	1.0%	1.5%
SECuRITY (305)	0.7%	1.6%	2.3%
NASCET I (659)	0.3%	1.5%	1.8%
NASCET II (858)	0.8%	1.2%	2.0%

Figure 5. Thirty-day outcomes of high-risk trials versus normal-risk historical controls.

Patient Preference

Most patients increasingly prefer a nonsurgical intervention when possible, and this preference should not be minimized. Although strictly speaking not quantifiable, little or no SAPPHIRE enrollment took place in the final 6 months of the trial once other, nonrandomized registries began enrolling patients.

STEP THREE: CAS FOR EVERYONE?

Although clinical equipoise was achieved relatively quickly in high-risk surgical patients, what about those at low or normal risk? What about the asymptomatic patient? Has clinical equipoise been established in the asymptomatic patient? Given some of the safety data generated in these high-risk trials, it appears adequately uncertain as to the relative safety and efficacy between the surgical and endovascular cohorts in this population.

Specifically, asymptomatic patient trials are justified based on evidence collected from previous trials and registries: in NASCET (comparing CEA to standard medical care), the stroke and death rate was 5.8%, very similar to the 5.5% seen in symptomatic stented patients in the lead-in phase of the Carotid Revascularization Endarterectomy versus Stent Trial (CREST) (Figure 4). In the asymptomatic patient cohort of CREST, when compared to ACAS (CEA in asymptomatic patients), there is a comparable incidence of stroke and death at 30 days (2.2% and 2.8%). In addition, if the averaged, combined major stroke and death rates among the US carotid stent with embolic protection trials is compared to NASCET I and II, the rates are similar. The major adverse outcomes are then quite comparable to the low-risk CEA trials (Figure 5).

As a result, there are several asymptomatic, normal-risk patient trials ongoing or planned in CAS. CREST randomized its first patient in December 2000. Eligible patients are normal-risk surgical individuals who have experienced a transient ischemic attack, amaurosis fugax, or nondisabling stroke within the previous 6 months and have ipsilateral carotid artery stenosis of 50% by angiography or 70% by ultrasound. Patients with significant medical or surgical comorbidities are excluded. A second arm of this NIH/NINDS-sponsored effort, enrolling asymptomatic normal-risk patients, recently began.

The Asymptomatic Carotid Trial (ACT I), sponsored by Abbott Vascular Devices (Abbott Park, IL), enrolled its first patient in March 2005. This trial will enroll patients at normal surgical risk with asymptomatic carotid lesions greater than 80% severity as determined by ultrasound in patients undergoing CEA and by angiography in patients undergoing CAS. The trial will employ the Mednova Emboshield and the Xact carotid stent (Abbott Vascular Devices). In addition to comparing clinical impacts, ACT I will assess the economic and quality-of-life factors associated with CAS and CEA.

The TACIT study is currently in the planning stages and is designed to randomize asymptomatic normal-risk patients into one of three treatment arms: medical, surgical, and CAS.

SUMMARY

Although it is still a relatively new technology, CAS is already becoming a preferable treatment strategy for the care of patients with extracranial carotid disease and high-risk surgical features. The technique is safe, and the long-term outcomes are excellent and durable in the trial setting, when performed by expert, high-volume operators. One significant challenge the future holds is to ensure the transfer of that experience into noninvestigational settings.

For normal-risk or asymptomatic patients who constitute 70% to 75% of the CEAs done in this country, the data are not yet complete, and CAS should be performed only in the trial setting at this time. If the trial shows reasonable equivalence between the two, then there will likely to continue to be a significant shift from CEA to CAS in the next several years. ■

William A. Gray, MD, is from the Columbia University, Cardiovascular Research Foundation, New York, New York. He has disclosed that he is a paid consultant to Abbott Vascular Devices and Cordis.

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Produced under an educational grant from Edwards Lifesciences LLC

Endovascular Therapy for Infrainguinal PAD

What are the challenges faced by today's endovascular specialists?

PRESENTED BY KENNETH ROSENFIELD, MD

Endovascular therapy for infrainguinal peripheral artery disease (PAD) presents unique challenges. There are anatomical and pathophysiological idiosyncrasies of the circulation below the groin, and endovascular interventions in these locations tend to be less durable than those performed in the iliac arteries. Indications for revascularization also differ, as does the threshold of symptoms at which we might decide to intervene. Numerous technical questions have yet to be definitively answered. However, this is an area that retains a great deal of promise.

IDENTIFYING THE CHALLENGES

When compared to balloon angioplasty and stenting of the iliac circulation, infrainguinal intervention almost always produces suboptimal results. Ideally, we would like to see focal, treatable stenoses in the superficial femoral artery (SFA), which we can readily recanalize using several means (Figure 1A). Unfortunately, the usual scenario is very different, frequently involving diffuse disease (Figure 1B,C), calcification, total occlusion (Figure 1D), or even restenosis inside a stent (Figure 1E), all of which are less amenable to recanalization.

Patency rates after femoropopliteal percutaneous transluminal angioplasty vary between quite good and rather dismal. In one study, 3-year patency rates ranged from a high of 78% in a best-case scenario (femoropopliteal stenosis with good two- or three-vessel runoff) down to 25% in a worst-case scenario (femoropopliteal occlusion with no patent calf vessels).[1]

The SFA/popliteal arterial segment has been called "the worst vessel in the body" for a number of reasons, including the high-resistance/low-flow system in this location and the presence of torsional forces that constantly twist, bend, and

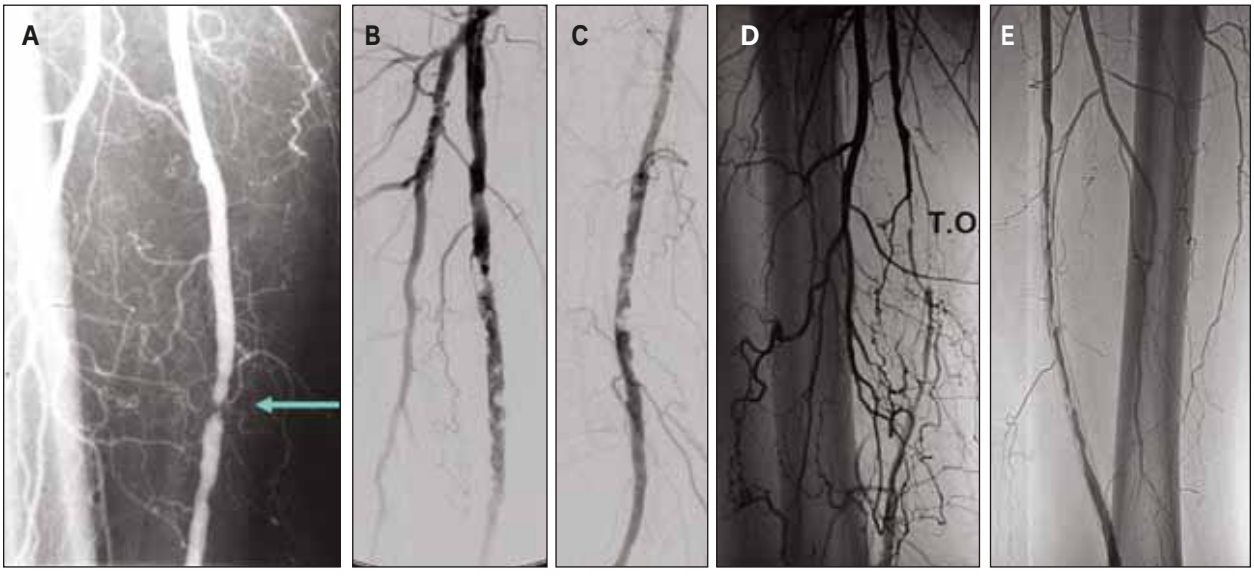

Figure 1. Easily treated stenosis in the SFA (A). Diffuse disease in the SFA (B,C). Total occlusion of the SFA (D). Restenosis inside a stent in the SFA (E).

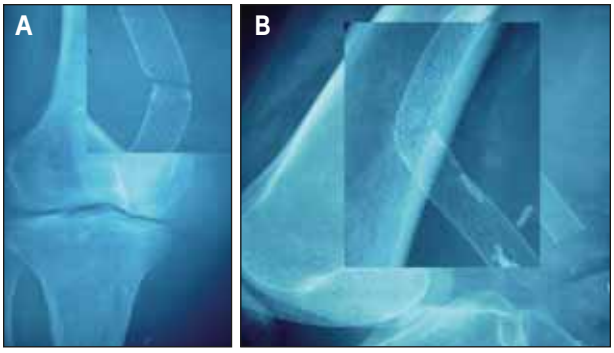

Figure 2. An example of stent fracture.

stretch the vessel in ways no other vessel in the body must tolerate. The plaque burden also tends to be heavy in this area: diffuse disease and heavy calcification are more the rule than the exception, especially at the adductor hiatus. Occlusion is common, perhaps partly because the profunda femoris artery forms a natural collateral, and runoff vessels are often extensively diseased.

Stent fracture is an important issue that is unique to this circulation and has caused FDA concern (Figure 2). This vascular bed is a challenge for the vascular specialist because it is difficult to maintain patency after either endovascular or surgical revascularization.

In addition, one of the unique challenges in this population is simply keeping these patients alive. In one study of infrainguinal surgical revascularization in 3,005 limbs, the 5-year survival rate was only 54%.[2] The surgical mortality rate was 2% to 5%, hemorrhage occurred in 2%, graft thrombosis occurred in 2% to 7%, and wound infection occurred in 8% to 19%.

We know we can achieve reasonable results in these patients, even with balloon angioplasty alone, but the problem is durability. For example, one study of femoropopliteal angioplasties in patients with PAD found a 2-year patency rate of less than 50% (Figure 3).[3] Although this study was conducted in 1987, the numbers are borne out by the TransAtlantic Inter-Society Consensus (TASC) Working Group review published in 2000, which summarized results of balloon angioplasty with and without stenting for various segments.[2] Primary patency rates at 1, 3, and 5 years were substantially lower in SFA/popliteal arteries than in iliac arteries (Figure 4).

Figure 3. Results of femoropopliteal angioplasties in PAD patients (Reprinted with permission from Johnston et al. Ann Surg. 1987;206:403-413).

On the basis of these results, the TASC document outlined recommendations for managing the four types of infrainguinal lesions. TASC A lesions (a single stenosis or occlusion <3 cm) can be treated endovascularly, as can most TASC B lesions (a single stenosis or occlusion 3 cm to 10 cm; multiple lesions, each <3 cm; or single or multiple lesions in the absence of continuous runoff to improve inflow for distal surgical bypass). However, we should think twice before using endovascular techniques in TASC C (a single stenosis or occlusion >5 cm) or TASC D (complete common femoral artery or long SFA occlusions; or complete and proximal trifurcation occlusions) lesions.[2]

TESTING THE TOOLS OF THE TRADE

Our toolbox for dealing with infrainguinal lesions has expanded greatly in recent years. We have hydrophilic and "coronary" guidewires (which enable us to cross nearly any occlusion), self-expanding stents, thrombolytic therapy, lasers, cryoplasty, percutaneous bypass, and atherectomy. If a patient has a bad result with balloon angioplasty alone, we can use stents; if stents fail, we can perform a bypass.

An early study of stent deployment using primarily self-expanding Wallstents (Boston Scientific Corporation, Natick, MA) in SFA and popliteal occlusions found fairly aggressive restenosis.[4] Patency rates were 87% at 6 months (74% primary, 6% primary assisted, and 7% secondary), 79% at 1 year (47% primary, 19% primary assisted, and 13% secondary), and 63% at 4 years (25% primary and 38% secondary).

Another study found a high incidence of restenosis and reocclusion in long-segment SFA lesions treated with stents: at 1 year, primary patency rates were 22% and secondary patency rates were 46% (Figure 5).[5] However, in that study, clinical benefit was maintained in 56% of the patients, indicating that even if restenosis or reocclusion occurs, some clinical benefit persists. This may be because the profunda femoris col-

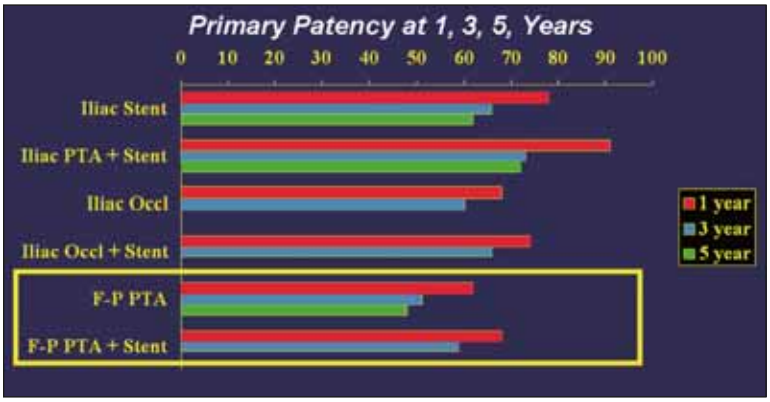

Figure 4. Primary patency rates after endovascular intervention in iliac and femoropopliteal arteries (Reprinted with permission from TASC. J Vasc Surg. 2000;31:S1-296).

lateral has become more developed over time, or it may be because even with 50% or 70% restenosis, there is still flow. Either way, it brings up the question of whether the binary restenosis rate is the appropriate yardstick for outcomes in infrainguinal disease. It is not unusual to have a focal site of >50% angiographic restenosis after opening a long-segment stenosis or occlusion, but the patient's symptoms may not recur. This may represent a different paradigm for looking at restenosis in these arteries compared to the coronary arteries, for example.

A randomized trial of the IntraCoil self-expanding, nitinol stent (ev3, Inc., Plymouth, MN) also found high rates of binary restenosis—rates that were at least as high as those seen in balloon angioplasty patients (41.2% vs 33.7%; *P*=.30). Again, however, in both the stent group and the angioplasty group, the reintervention rate was much less than the binary restenosis rate. At 270 days, 85.7% of the stent group and 83.9% of the angioplasty group were target lesion revascularization (TLR)-free, and 81.1% of the stent group and 83.1% of the angioplasty group were target vessel revascularization (TVR)-free (*P*=NS for both comparisons).

Another consequence of the IntraCoil stent trial was the suggestion that stents may actually be a little safer than balloon angioplasty alone. Rates of any major complication to 30 days (a composite of major adverse cardiac events plus abrupt closure, renal failure, major bleeding, and amputation) were 1.5% in the stent group and 8.4% in the angioplasty group (*P*=.01). This risk is high enough that we may choose to use a stent as opposed to balloon angioplasty alone, and brings up the question of whether we should perhaps primarily stent some of these lesions, particularly total occlusions and longer lesions.

BLASTER was a randomized, prospective, multicenter trial looking at nitinol stenting of long SFA lesions or total occlusions, and we had the privilege of participating in this trial. The mean age of these patients was 69 years, 47% were diabetic, 48% had a total occlusion, and the mean lesion length was 119 mm. The technical success rate was 100%, and I believe this suggests for the first time, that if you eliminate the gradients and use the new self-expanding nitinol stents to their best ability, you can achieve pretty good results in these patients. The restenosis rate in this trial was 17% at 9 months, and it also showed, interestingly, that if you survey these patients closely and reintervene when they develop focal in-stent restenosis, you can achieve as high as a 98% primary-assisted patency rate, with comparable improvements in clinical status. At 9 months, TLR was 14%, mean ankle-brachial index (ABI) improvement was 0.18, mean change in Rutherford category was 1.6, and 88% of the patients improved by at least one Rutherford category.

This also means that the TASC Working Group document may be outdated with respect to its recommendations for femoropopliteal stenting: "Femoropopliteal stenting as a primary approach to the interventional treatment… is not indicated. Stents may have a limited role in salvage of

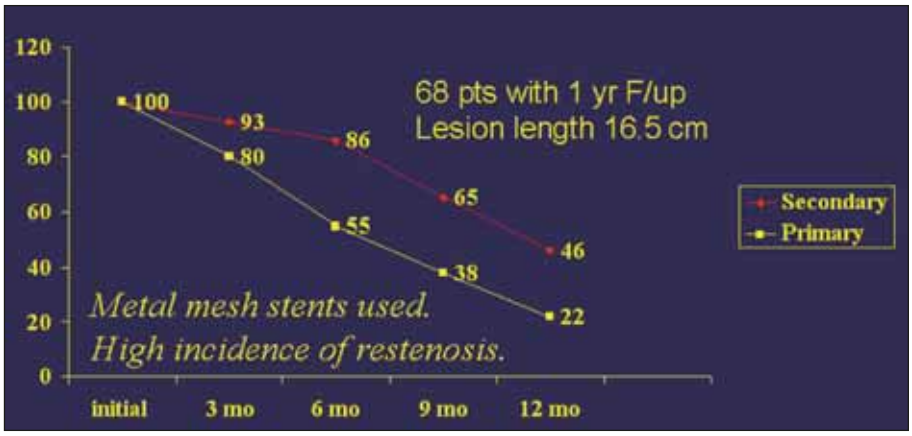

Figure 5. Outcomes after stenting of long-segment SFA lesions (Reprinted with permission from Gray et al. J Vasc Surg. 1997;25:74-83).

acute PTA failures."[2] Recent data with nitinol stents suggest very favorable outcomes, but it remains a challenge to determine the most appropriate patients to treat.

Initial results from the SIROCCO trial, the first trial to use a drug-eluting stent in the SFA, also showed some promise, but we need to know much more about the drugs and the stents involved. Over the next 4 or 5 years, I think we will see some drug-eluting stents that will benefit the patients and give more durability to our results.

CHOOSING APPROPRIATE PATIENTS

Deciding in which patients we should intervene is often a challenge. Issues to consider include the patient's level of symptoms, especially if disabling or lifestyle-limiting claudication or if critical limb ischemia is present. Consider the complexity and risk level of the intervention and whether it will allow you to carry out a surgical bailout later, if necessary. Look at the patient's comorbid conditions and the alternative treatments that are available; then compare the benefits (eg, the chance of acute success and long-term durability, the relative patient benefit compared to other therapies, the consequences of no treatment) with the risks (eg, the acute risk and negative consequences of a potential complication, the chance of late failure, and the cost).

TECHNICAL CHALLENGES

The technical challenges of the procedure itself can be numerous, beginning with the selection and achievement of access. Should an antegrade ipsilateral or a retrograde contralateral puncture be used? Using an antegrade puncture means that you have in-line access, better control of guidewires and catheters, and probably a somewhat easier time crossing total occlusions because force is applied directly. A wider selection of equipment is available, and a smaller sheath size can be used. However, the antegrade puncture requires an entry angle much closer to the horizontal, which can present problems in heavy patients due to the distance between the skin puncture and the arterial puncture. In addition, flow may be compromised during the procedure. The retrograde contralateral puncture is technically easier with a lower risk of bleeding and access to the origin of the SFA. It avoids compression of the instrumented vessel and allows an iliac intervention to be done during the same procedure. However, access to angulated bifurcation lesions is difficult with a retrograde puncture, and there is a risk of injury to the iliac arteries.

Choosing the appropriate tools and techniques can also be difficult, especially because so many options are available. Which guidewire should you use? Which support catheter? Do you cross a total occlusion through lysis or direct recanalization? Which technique do you use to open the vessel—balloon angioplasty, a stent, atherectomy, a laser, or cryotherapy? These are difficult questions, but remember that there is no single best way to do this.

Other considerations include when to stent and when to stop. At what point are you no longer helping the patient? How do you treat the runoff vessels? Do you need to treat them below the knee? Do you need to eliminate the gradient in the SFA? We do not yet know the answers to these questions.

Using these devices in heavily calcified and plaque-laden vessels can be problematic, but the most common technical challenge is the total occlusion. There is much controversy over when and how to treat total occlusions, including questions about maximum length, gradient elimination, choice of stent, and treatment of runoff vessels. Should you use one of the new devices, such as the Frontrunner catheter (LuMend, Inc., Redwood City, CA) or the Safecross catheter (IntraLuminal Therapeutics, Inc., Carlsbad, CA)? If you end up in a subintimal channel, how do you get back in? Should you use plaque excision? Is debulking important? Is there a role for cutting balloon angioplasty? We are still accumulating the data needed to answer all these questions.

The final technical challenge is how to follow up your patients. Options include duplex ultrasound, ABI, postexercise ABI, and evaluating patient symptoms. At what point should you reintervene? This has not been well studied, and we still have a long way to go.

CONCLUSION

Based on the improved results and the lower level of risk we have seen, there is now a new treatment paradigm for infrainguinal disease. It is appropriate to use endovascular therapy for claudication treatment, limb salvage, and wound healing. With rare exceptions, we can use a percutaneous approach first, as long as we do not preclude later surgery. Challenges remain in terms of durability and long-term restenosis, but I believe we will overcome them. ■

Kenneth Rosenfield, MD, is from the Massachusetts General Hospital, Boston, Massachusetts. He has disclosed that he is a paid consultant to Boston Scientific and Cordis.

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Produced under an educational grant from Cook Incorporated

Endovascular AAA Repair

A thorough understanding of the anatomic considerations is essential for a successful outcome.

PRESENTED BY LUIS A. SANCHEZ, MD

Endovascular aneurysm repair (EVAR) was developed as a less-invasive alternative to open surgery for patients with abdominal aortic aneurysms (AAAs). Recent trials have reported lower operative mortality rates after EVAR than after surgical repair.[1] However, as many as 20% to 50% of AAA patients have anatomy that is not suitable for endovascular repair. Preplanning and patient selection are essential for good short-term and long-term results and crucial to the successful widespread adoption of EVAR.

Certain basic anatomic considerations must be understood before choosing the device or procedure to use in the endovascular treatment of patients with AAAs. There are four AAA endografts on the market at this time, and they each fit different anatomical features and accommodate patients uniquely. A thorough understanding of these devices is necessary before a good clinical decision can be made about which device will fit a particular patient. Poor device adaptation and patient selection lead to poor results and significant complications, something we have unfortunately seen over and over again as we have tried to accommodate some of these devices in patients who may not be suitable anatomic candidates for EVAR.

When assessing the anatomy of an EVAR candidate, several factors need to be considered. These include the quality of iliofemoral access, the proximal attachment site (infrarenal neck), the anatomy of the aneurysm itself, the anatomy of the distal aorta, and the distal attachment site, which is most commonly in the iliac arteries, but can be more distal, depending on the patient's pelvic anatomy.

ILIOFEMORAL ACCESS

When assessing iliofemoral access, we need to take into account the tortuosity of these vessels, their calcification, degree of stenotic disease, and their size. Because each of the stent grafts has a different introducer system, you may need to choose the size most appropriate for both the main trunk of the device and its contralateral portion. It is also important to know which guidewire will best get you from your femoral or other access to the site of the stent graft's implantation because the delivery systems are relatively bulky devices (Figure 1).

Issues involving iliofemoral access can usually be resolved in the majority of patients being considered for EVAR. Currently, tortuosity is not a major problem because there are a variety of stiff guidewires available that can navigate tortuous anatomy. Focal stenoses can usually be overcome, but when you encounter the combination of some of these

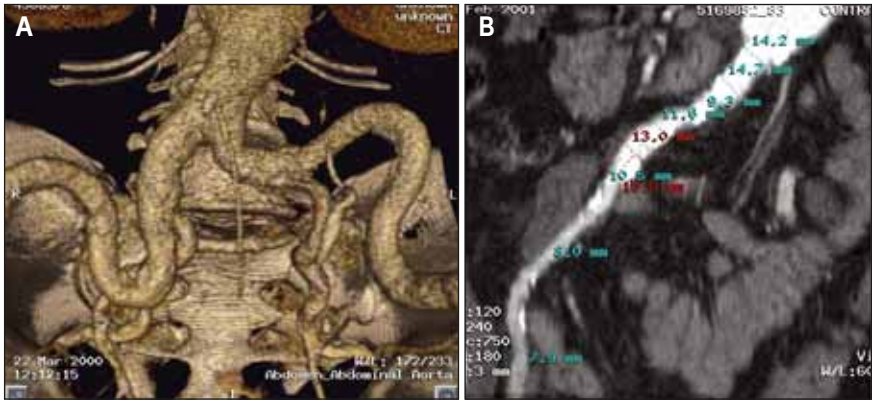

Figure 1. When assessing iliofemoral access, it is important to take into account the tortuosity of these vessels, their calcification, stenotic disease, and size.

problems (calcified vessels, relatively small vessels, and tortuous vessels), which are much more common in elderly women, it should raise a warning flag that there may be problems associated with access during the endovascular intervention in this patient.

If the anatomy of the pelvis is difficult and you still think the patient can be best treated in an endovascular fashion, retroperitoneal access, even with a conduit and a reconstruction, is sometimes a better option (Figure 2). Rupture of the iliac vessel can be an unpleasant and life-threatening complication and the last thing you want is to turn an elective procedure into an emergent one.

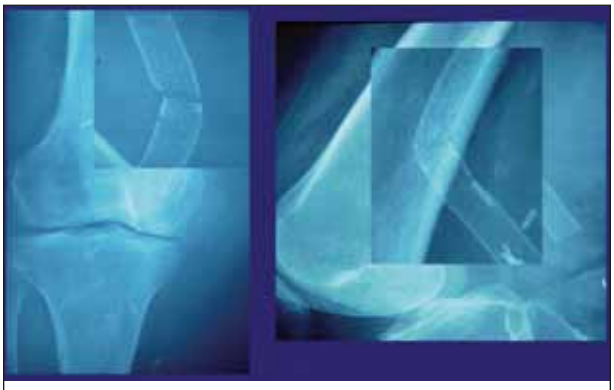

Figure 2. Difficult pelvic anatomy can sometimes be best treated by retroperitoneal access.

PROXIMAL ATTACHMENT SITE (INFRARENAL NECK)

If you have chosen the wrong patient for EVAR, the infrarenal neck is where failure is most likely to occur. Improper device placement or poor device selection will not easily accommodate suboptimal infrarenal neck anatomy. Know the diameter and length of the infrarenal aortic neck, and oversize the device by approximately 10% to 15%. Necks that are 15 mm in length in a portion that is reasonably healthy are preferred. If the neck is shorter, you run a greater risk of reconstruction failure and the need for further endovascular or open interventions.

Patients with long infrarenal necks appear to be perfect candidates for these devices, but it must be kept in mind how the devices are constructed. Two of the four stent graft devices currently available have relatively short bodies from which two large limbs extend. In a relatively long and narrowed neck, those two limbs may not fit inside that narrow distal neck and may lead to limb failure. It is better to choose a device with a longer body to create a longer seal zone and move the bifurcation of the device lower and closer to the native aortic bifurcation.

It is also important to know whether there is a significant amount of thrombus, plaque, or calcification in the infrarenal neck. None of these is an absolute contraindication for endovascular repair, but they will make a difference when deciding how to place the device, where to expect a good seal, and what adjunctive measures you may need to take to ensure the best possible result and avoid a type 1 endoleak or migration of the device.

Renal pathology is also a consideration, especially now that renal artery interventions have become commonplace. If your patient has significant renal artery stenosis, when working very close to the renal arteries or even placing a transrenal device, you run the risk of partially or totally covering a renal artery. You should consider renal artery angioplasty and stenting before placing your AAA endograft, but you need to be very accurate in your stent placement to allow accurate and safe placement of the endovascular graft.

Too much angulation of the infrarenal neck can be problematic and is a contraindication for EVAR. By its nature, the larger the AAA is, the more anterior angulation the proximal neck usually has. It is easy to underestimate the length of the infrarenal neck when evaluated purely by cross-sections, which is why three-dimensional reconstructions are needed. If you evaluate your patients with angiography, try to obtain a lateral view to get a better sense of anterior angulation. Patients ideally should have angulations of less than 45º, with 60º being the cut-off at which most investigators believe that the risk of endovascular repair failure is high.

The device must be accurately placed just below the renal artery. To do this, you need to change the angle of your image intensifier to see the renal arteries and the length of the infrarenal aortic neck. To ensure a good result, you want to be close to the renal arteries. If you do not adjust your image intensifier appropriately, you may lose the ability to see a portion of the neck, and when you think you're deploying the device very close to the renal arteries, in fact, you may be a centimeter or more farther away from the renal arteries, setting up the patient for poor long-term graft durability, an increased risk of migration, poor apposition of the device, type 1 endoleak, and the need for further intervention. In general, craniocaudal angulation of 15º is reasonable as a starting point, but many patients will require further angulation to be perfectly perpendicular to the aortic neck. Devices that allow slow, controlled deployment permit readjustment of the device and the image intensifier during deployment depending on the specific location of the renal arteries.

Many potential EVAR patients have one or two suboptimal factors related to their infrarenal neck, but a patient with multiple issues, especially if the neck is somewhat short and angled, diseased and somewhat irregular, is not a good candidate for EVAR. In the future, as newer devices such as grafts with transrenal configurations, fenestrated devices, and branched devices become available, we will then be able to treat patients with more complex proximal neck anatomy.

AAA ANATOMY

If there are large patent branches coming out of the aneurysm (eg, a large accessory renal artery or inferior mesenteric artery), which the graft itself is not going to seal, consider embolization to try to prevent some of the type 2 leaks or persistent outflow from even a type 1 endoleak that may occur in that situation.

Aneurysm length might also be an issue. The bodies of most of the modular devices currently available are approximately 7 cm to the bifurcated portion of the device. If the aneurysmal segment is shorter than 7 cm, it will not accommodate a bifurcated device. An aorto-uni-iliac graft reconstruction or a shorter bifurcated graft would be needed for an endovascular repair.

Aortic stenosis in the middle of the aneurysm, or what we refer to as a bilobed aneurysm, can be challenging, and you will need to set yourself up so that the gate or the contralateral limb of the device opens in the widest portion so cannulation is easier. Otherwise, you might be forced to convert to an aorto-uni-iliac reconstruction or fail to complete your procedure because you cannot enter the contralateral gate. A longer device, such as the Zenith, may work in some of these situations, or your best choice may be to defer EVAR and opt for surgical repair.

DISTAL AORTA

If the aortic bifurcation is challenging (Figure 3A,B), narrowed (Figure 3C), or calcified, a scenario more often encountered in female patients, EVAR may not be your best option. I look for a minimum diameter of approximately 18 mm to be able to accommodate two limbs on those patients. There are a few techniques to consider when trying to accommodate a bifurcated device: (1) maintain access to the aneurysm sac at all times with a sheath, and (2) do not jail yourself out of the aneurysm from the contralateral side. The majority of patients can accommodate a bifurcated device, but if you do not think the anatomy is suitable, aorto-uni-iliac reconstructions are a good option.

If there are already stents in the common iliacs or in the bifurcation of the aorta, these are much more difficult to traverse with the large sheaths required for an endograft device. If the patient has a stenosis distal to the AAA, avoid treating it until after you treat the aneurysm. Besides the obvious issue of metal against metal, it is technically much more difficult to place and seal your stent graft appropriately if the iliac arteries have been stented in the past.

DISTAL ATTACHMENT SITE (ILIAC ARTERIES)

Ideally, there should be a landing zone of at least 2.5 cm for the distal attachment, whether in the common or external iliac arteries. The devices available can accommodate iliac artery diameters up to 21 mm. Most people will consider diameters up to 25 mm ectatic, not truly aneurysmal, but in the event that your common iliac artery is aneurysmal or greater than 21 mm in diameter, it is reasonable to consider occlusion of one of the hypogastric arteries in order to seal the stent graft in one of the external iliac arteries. Try to avoid occluding both hypogastric arteries, which incurs a risk of buttock claudication and other potential pelvic ischemic complications.

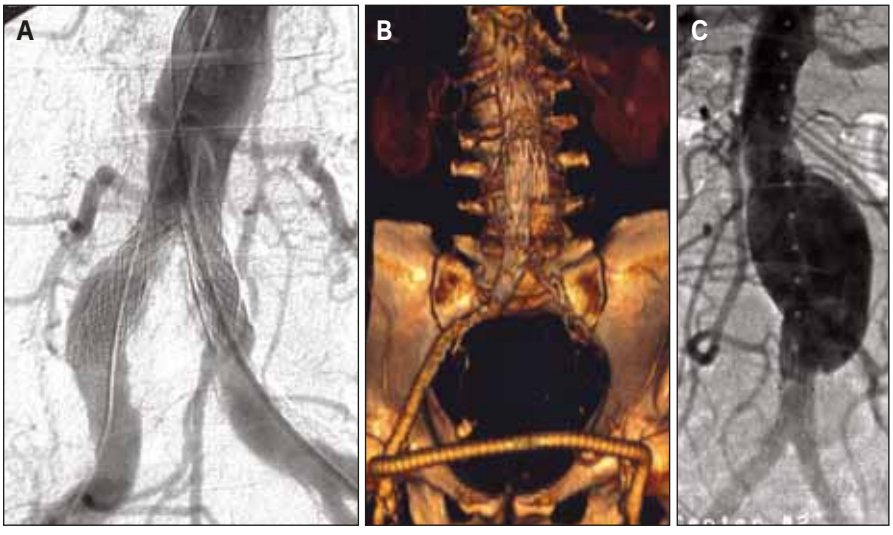

Figure 3. The aortic bifurcation presents a unique set of challenges.

If you encounter bilateral common iliac artery aneurysms and you want to maintain patency of at least one hypogastric artery, there are a variety of options. One is a small retroperitoneal access with a

TABLE 1. ENDOVASCULAR AAA REPAIR: ANATOMICAL CONSIDERATIONS

	DEVICE CHARACTERISTICS			
	AneuRx	Excluder	Zenith	PowerLink
Aortic Neck				
Diameter	17-25 mm	18-25 mm	18-28 mm	18-26 mm
Length	15 mm	15 mm	15 mm	15 mm
Neck Angulation				
Neck-AAA	<45°	<45°	<60°	<60°
Suprarenal-Neck	N/A	N/A	<45°	N/A
AAA Length	>70 mm	>70 mm	>74 mm	>90 mm
Iliac Diameter	10-15 mm	8-18 mm	8-21 mm	8-18 mm
Introducer				
Main Device	21 F (OD)	18 F (ID)	18-20 F (ID)	21 F (OD)
Contralateral	16 F (OD)	12 F (ID)	14-16 F (ID)	10.5 F (OD)

short bypass to salvage one of the internal iliac arteries. An endovascular external iliac artery–internal iliac artery bypass is another possibility, and it is probably the most commonly employed one in combination with an aorto-uni-iliac endovascular reconstruction. If one system is completely occluded on one side, aorto-uni-iliac devices are readily available. People have even recanalized short common iliac artery occlusions and have been able to accommodate a bifurcated device. In the near future, branched components will allow reconstructions that maintain hypogastric artery patency.

PATIENT SELECTION GUIDELINES

At least initially, patient selection guidelines are similar for all the available prostheses. Because there is considerable variation among devices in terms of size, trackability, and flexibility of the introducer systems, it is important to be very familiar with the devices and their differences. Table 1 shows a basic comparison of the four available devices. As far as aortic neck diameter is concerned, the Zenith device (Cook Incorporated, Bloomington, IN) goes larger than any of the others, up to 28 cm. For neck angulation, the Zenith is the only endograft with a suprarenal component. And, if you look at the introducer systems, the main component of each system is fairly similar, from the 18-F Excluder sheath (W. L. Gore & Associates, Flagstaff, AZ) (inside diameter) to the 21-F AneuRx (Medtronic, Inc., Santa Rosa, CA) (outside diameter). As far as the contralateral limb is concerned, the Excluder has the lowest profile, which is its biggest advantage.

CONCLUSION

EVAR is a great procedure when performed appropriately and with good preplanning. You need to be very familiar with appropriate patient selection because your outcomes will depend heavily on it. Do not underestimate the value of a thorough understanding of the parameters of the different endograft devices and the different technique options for accurate deployment and to navigate through tough situations. If you place the device from the renal arteries to the hypogastrics, have good seal zones, and if you have chosen the patient well, your likelihood of achieving good short- and long-term results is excellent. ■

Luis A. Sanchez, MD, is from the Washington University School of Medicine, St. Louis, Missouri. He has disclosed that he is a paid consultant to Medtronic AVE.

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Produced under an educational grant from Boston Scientific Corporation

Endovascular Techniques of Infrapopliteal Intervention

Ready for prime time!

PRESENTED BY JAMES D. JOYE, DO

Nearly 1 million patients suffer annually from critical limb ischemia. Awareness of interventional treatment options for limb salvage and access to skilled interventionists are severely limited. The result of this professional and public lack of understanding of interventional treatment options is that despite advancements in infrapopliteal intervention, there are still nearly 200,000 major amputations (below or above the knee) performed annually. Even more disturbing than the loss of function and quality of life is that 30% of these patients will die within 2 years of their amputation. The numbers of minor amputations done annually are even greater, and these numbers show few signs of subsiding.

General medical understanding of endovascular treatments for infrapopliteal athero-occlusive disease is quite limited; we have spent much time embracing new treatments for heart attack and stroke, yet not much time working on limb ischemia. Worse yet, public awareness of the range of options that exist between simply having podiatric foot care and having an amputation is low. Partially contributing to this is the fact that most of us, except for some of the more recently trained interventionists, were trained in an overly conservative mode of vascular medicine in which there is a presumption that angioplasty for limb salvage is too risky and yields poor results. The result is that highly invasive bypass surgeries and amputations are delayed, and we are left with a substantial number of patients who become too sick too late in the game for us to actually help.

The primary goal in any endovascular procedure for limb salvage is obviously to protect the patient from major amputation, which requires restoring continuous in-line pulsatile flow to the foot. This does not mean we have to open up every tibioperoneal vessel; a single vessel will often suffice. A palpable pulse in the foot at the conclusion of the intervention (sometimes you have to wait until the day after) is a good indication that wound healing and elimination of rest pain will follow. Obviously, expert wound care is crucial, so a multidisciplinary approach to this is important—keep the podiatrists in the loop. Also, repeat intervention and close surveillance are needed, so these patients need to be motivated and loyal.

CROSSING THE LESION

The first critical step in performing any kind of salvage intervention is crossing the lesion. Certainly, some of the newer hydrophilic guidewires have made a big impact on our ability to do that. These wires are often actually small wire systems (.014 inch to .018 inch), and those of us who have experience in the coronary world have been able to take some of the advanced hydrophilic technology below the knee, where it works quite well.

Laser catheters have been a mainstay for a number of years, and some data support their use in infrapopliteal intervention. There are also .014-inch, .018-inch, and .035-inch support catheters that are long enough to advance to the infrapopliteal region and give support to guidewire approaches. And certainly, the more you become involved in these types of interventions, the more you have to consider alternative access approaches, whether they are antegrade, retrograde popliteal, or even pedal.

Figure 1. Retrograde pedal puncture using a micropuncture kit.

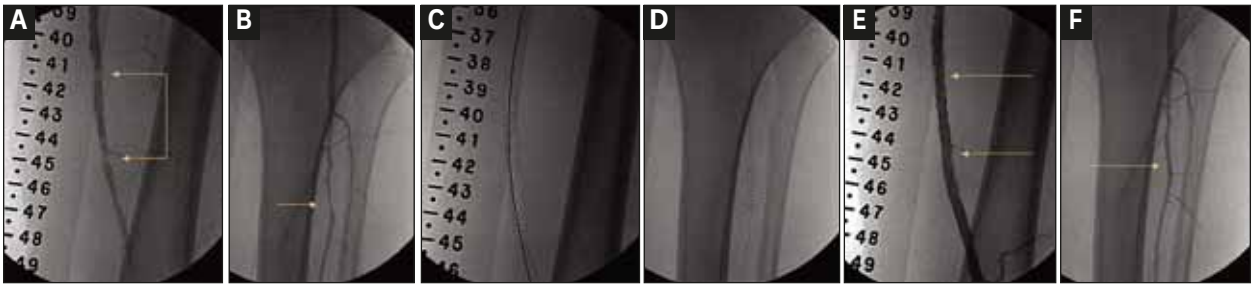

Figure 2. Baseline angiography in a 76-year-old man with multiple risk factors, including tandem, calcified femoropopliteal stenoses, diffuse adductor canal disease (A, arrows), occluded anterior and posterior tibial arteries, and critical peroneal stenosis (B, arrow). This patient was treated with stand-alone cryoplasty (C,D) with excellent angiographic results showing all targets optimally treated (E,F, arrows), and rest pain resolved with pulses restored.

THE NATURE OF THE LESION

Typically, patients with critical limb ischemia present with multilevel lesions, severe disease, or occlusion of all tibioperoneal vessels. The exception to this rule is the diabetic patient who has a relatively spared femoropopliteal segment but occlusion or stenosis of all three trifurcation vessels. These chronically occluded vessels are often deceptive looking because they differ significantly from iliac and femoropopliteal occlusions. Whereas femoropopliteal occlusions are typically a series of very dense, fibrotic, calcified caps with intervening cores of large atheromatous burden, chronically occluded tibioperoneal arteries are often functionally occluded due to a series of tandem subtotal stenoses that appear to be long-segment occlusions, whereby the path of least resistance for blood flow is through collateral channels. Because of this phenomenon, it is often very surprising to see how easily a hydrophilic wire will pass through what appears to be a long segment of disease in a tibioperoneal vessel.

WIRE TECHNIQUES

In contrast to femoropopliteal occlusions, most below-the-knee lesions can be crossed with a .014-inch hydrophilic wire (PT Graphix, Boston Scientific Corporation, Natick, MA) with backup support from a low-profile exchange catheter (Quick Cross support catheter, Spectranetics Corporation, Colorado Springs, CO). The ideal approach in these patients is to go contralateral because if a groin complication occurs, flow will not be obstructed to a freshly dilated segment. Often, my preference is to use either a 90-cm Pinnacle Destination (Terumo Medical Corporation, Somerset, NJ) or a Shuttle sheath (Cook Incorporated, Bloomington, IN) advanced to the popliteal level. Through that sheath, you then have a very good support system and direct visualization with injection of contrast through a syringe.

In rare cases, a retrograde access from the foot is needed in conjunction with snare techniques (Figure 1). This retrograde pedal puncture is a procedure that Gary Ansel, MD, really brought to the forefront. Retrograde pedal puncture is useful in cases in which you simply cannot pass your wire through an occlusion from the popliteal position, but you do have distal reconstitution of a pedal vessel. With a micropuncture kit, sometimes under fluoroscopic guidance and sometimes with ultrasound, you enter at the level of the foot and angle retrograde. Often, the wire will cross a tibioperoneal lesion going retrograde that could not be crossed antegrade. The wire can then be snared and brought to the proximal access site, where it is reversed and used to complete the procedure.

PHARMACOLOGIC CONSIDERATIONS

There are a variety of agents available for use as pretreatment thrombolysis, and some newer agents that are being developed. Aggressive periprocedural anticoagulation with abciximab or bivalirudin should be considered in certain situations, either in addition to or instead of conventional heparin. And, of course, lifelong aspirin or clopidogrel therapy for these individuals offers benefits beyond the wounds and beyond the endovascular result. It is well documented that patients with PAD have the greatest risk reduction of stroke and myocardial infarction when maintained on dual antiplatelet therapy.

ENDOVASCULAR OPTIONS

Angioplasty

We have at least reasonable data to support angioplasty for limb salvage. Dorros et al published a 5-year follow-up study wherein they treated 270 of 284 critically ischemic limbs using just tibioperoneal angioplasty.[1] They had a limb salvage rate of 91%, supporting the idea that you can open the artery even with plain old balloon angioplasty, attain

flow to the foot, and, if you follow the patient closely, the outcomes are quite favorable. In this group of patients, only 8% required surgical bypass during the follow-up period, and only 9% required significant amputation. Admittedly, this was in a single-center experience with a very aggressive endovascular specialist, but it shows what is achievable.

Cutting Balloon

The cutting balloon is another tool that has been found to be quite useful below the knee for its ability to (like angioplasty) improve luminal dimension while simultaneously limiting the need for stents. Ansel et al successfully treated 73 patients with critical limb ischemia using the cutting balloon.[2] In this 2004 study, adjunct stenting was minimized to 20%. No patients required surgical bypass, and the limb salvage rate at 1 year was 89.5%. Balloon-based technologies can work below the knee and should be considered.

Cryoplasty

Moran and some investigators at my institution recently presented data on 26 lesions treated in 20 patients with critical limb ischemia, examining the feasibility of using cryoplasty below the knee.[3] We performed adjunct laser atherectomy in 20% of patients, mostly in patients with more diffuse lesions. No stents were used in this group. At 6-month follow-up, 95% of the patients were free from major amputation. One patient did go on to below-the-knee amputation, and another required femorotibial bypass. Again, we see balloon-based technology that is able to yield good results for limb salvage. Figure 2 shows an example of how cryoplasty might be used as a stand-alone treatment.

Atherectomy

There have been some promising data regarding atherectomy for infrapopliteal intervention, although they are still preliminary. The LACI trial was a large, multicenter, prospective trial looking at laser-assisted angioplasty for treating critical limb ischemia. In the LACI trial, there was a 93% limb salvage rate at 6 months, arguably in a group of patients with more complex lesions than in some of the other studies, and a lot of multisegment disease that required femoropopliteal treatment in addition to treatment below the knee. Despite this, only 2% of the patients required surgical bypass, and only 4% had a decrease in Rutherford class. Continuous in-line flow was established in 89% of the limbs treated.

Stenting

What about stenting below the knee? In older data reported by Motarjeme et al, which did not use the newest-generation stents, procedural success was greater than 90%, with a 1-year limb salvage rate >80%, despite a vessel patency rate <30%. I suspect we can achieve higher limb salvage rates using newer technologies, but, again, we see that by using endovascular approaches to this problem, we can gain pulsatile flow and salvage limbs.

We see cases, and I'm sure this is true at other centers, in which a patient is recanalized and there is a natural tendency from a cardiologist's perspective to implant a coronary stent to maintain vessel patency. I think there is definitely a need for some discussion about which vascular targets below the knee are potentially compressible by external forces, and whether existing coronary technology is appropriate for this area. Tibioperoneal vessels are small in diameter and have an aggressive neointimal process that occurs with stenting. Because of this, and because we have not really developed good stents specifically designed for the tibioperoneal region, I would consider stents best utilized below the knee as a bailout strategy only. Hopefully, in the near future, we will have an easily deployable self-expanding stent for below the knee to use adjunctly in those cases in which we cannot achieve good results. I certainly think drug-eluting stents are promising, but we aren't there yet, so we should avoid blindly throwing them into the tibioperoneal vasculature until we know more.

CONCLUSION

With progressive and aggressive treatment strategies, infrapopliteal disease can be treated endovascularly, resulting in limb salvage in a high percentage of cases. Reducing the number of major and minor amputations currently performed is a goal we should all embrace. We now have several good techniques and technologies available that allow us to tailor the therapy for the clinical circumstances and anatomic considerations. The keys to success are early referral, aggressive treatment, close surveillance, and multispecialty collaboration. ■

James D. Joye, DO, is from the El Camino Hospital, and The Cardiovascular Institute, Mountain View, California. He has disclosed that he is an owner or shareholder of Cryovascular Systems, Inc.

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Management of Failed Arteriovenous Dialysis Access Grafts

Percutaneous approaches for an increasingly prevalent problem.

PRESENTED BY ALAIN T. DROOZ, MD

There are more than 300,000 chronic dialysis patients in the US alone, at an estimated annual cost for hemodialysis of about $18 billion, or more than $65,000 per patient. Estimates are that these numbers will likely double in the next 10 years. Only approximately 1% of the Medicare population is on chronic hemodialysis, but unfortunately, this population accounts for approximately 9% of Medicare costs, so it clearly represents a very expensive chronic disease.

One of the major challenges in this population is dialysis access failure. The scope of the problem of dialysis access should not be underestimated: the average hemodialysis patient has two dialysis-related hospital visits per year, mostly related to access failure. Access failure is the most frequent diagnosis-related group in patients with end-stage renal disease (ESRD).[1]

Percutaneous management of hemodialysis access grafts and fistulas has emerged as a complementary treatment alternative to surgical thrombectomy and revision. It is important to understand the etiology of arteriovenous access failure and the various approaches to revascularization.

PREVALENCE OF ESRD IN THE US

The United States Renal Data System (USRDS) is a national data system that collects, analyzes, and distributes information about ESRD in the US. The USRDS initiated a program in 1972 to track the incidence of ESRD. The numbers have grown quickly, and there are currently about 380,000 patients in this program (Figure 1).

There is an epidemic of diabetes and hypertension in the US. The NHANES 3 study estimated that there are between 6 million and 20 million patients in the US with early chronic kidney disease, so this issue is going to continue to haunt us in the generations to come. According to work by Xue et al,[2] the forecasted numbers of patients with ESRD in 2010 are quite sobering: 129,200 new patients, 651,330 long-term ESRD patients, 520,240 dialysis patients, 178,806 patients with functioning transplants, and 95,550 patients on transplant waiting lists. Medicare expenditures are projected to increase to $28.3 ± 1.7 billion by 2010.

WHY DIALYSIS ACCESS FAILS

Chang et al recently published an intriguing article looking at proliferative indices in 10 primary and 20 post-PTA restenotic Brescia-Cimino fistulas, comparing their results to historical data in the coronary and peripheral circulation and in hemodialysis grafts (Table

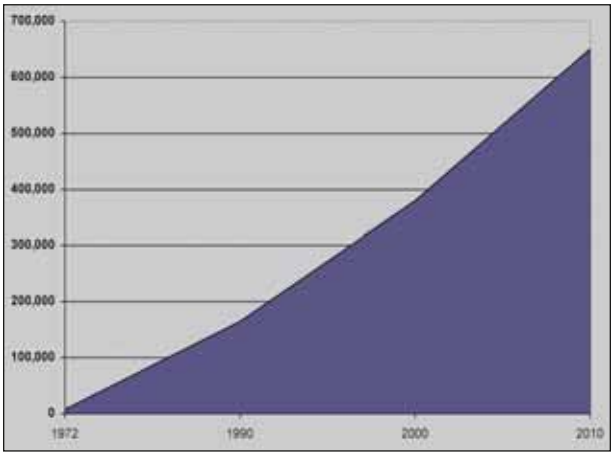

Figure 1. United States End-Stage Renal Disease Program estimates of the incidence of ESRD in the US.

TABLE 1. WHY DIALYSIS ACCESS FAILS

Proliferative indices in primary and restenotic Brescia-Cimino fistulas, compared to historical data in the coronaries, peripheral circulation, and hemodialysis grafts

Restenosis After PTA: 36%-62% at 6 Months

Proliferative Indices (PCNA Activity)
- Primary coronary stenosis: 0%-7.2%
- Restenosis (PTCA, peripheral, HD graft): 18%-24%
- BC fistula primary restenosis: 15%-19%
- BC fistula secondary restenosis: 39%-48%

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1).[3] They found that there was a statistically significant increase in proliferative cell activity in restenotic fistulas compared to primary stenotic fistulas (intima, *P*<.001; media, *P*=.001), both of which showed more activity than primary coronary stenoses. Also, proliferative indices of patients with diabetes in the restenotic group were significantly higher than those of patients without diabetes (intima, *P*=.028; media, *P*=.002). The degree of the proliferative index's evaluation correlated strongly with a shorter interval to restenosis.

Although it would be nice to see a comparison of Brescia-Cimino fistulas with prosthetic grafts directly, I think that these data really suggest that antiproliferative approaches are the future solution for the dialysis access population.

GRAFT MONITORING AND SURVEILLANCE

Most of us do some degree of subjective access graft monitoring, which might include assessing the loss of a palpable thrill within a dialysis graft, noting increased bleeding after dialysis, decreased pulsation, etc. Objective surveillance, however, of a dialysis graft is crucial and has been shown effective in decreasing the incidence of thrombosis and prolonging access life. One method to consider is static venous pressure measurement, in which the pump is turned off and a venous pressure measurement is obtained and normalized to the mean arterial pressure. Static venous pressure measurement is good for detecting downstream stenoses and works for venous anastomotic lesions, but it does not work for intragraft or arterial anastomotic stenoses. Intra-access blood flow measurement is another objective means of graft surveillance and is performed with the Transonic Flow-QC Hemodialysis Monitor (HD01/HD01Plus, Transonic Systems Inc, Ithaca, NY), in which the flow is actually reversed in the graft. A small bolus of saline is injected at the efferent limb and detected by a flow meter at the arterial end.

The Vascular and Interventional Radiology department at Indiana University started a screening program using the transonic machine (McLennan G, personal communication). As a result of regular screening, the percentage of patients in their system who present with thrombosed access has decreased from 46% to 31%. This has tremendous implications for patient safety, quality of life, institutional costs, and access durability.

Why is early detection of access failure important? The endovascular treatment of stenotic grafts is significantly more likely to result in better long-term patency—approximately 40% to 50% 6-month patency as compared to endovascular treatment of a graft thrombosis, which is only likely to be 30% to 40% patent at 3 months.

This is an important issue. Often, a patient with a dialysis graft will come in and may not be assessed for a few days. This is a mistake! It is important to attend to these patients as soon as possible. First, avoid placing a dialysis catheter, if at all possible, because it will traumatize a vein that may be necessary for dialysis access in the future, but also because a fresh clot is much easier to treat than old thrombosis.

Some grafts should not be treated. There is significant risk of septic shock when treating infected grafts. We also tend not to treat early surgical failures other than occasionally declotting them and allowing for a complete assessment of surgical anatomy. Patients who have more than two episodes of thrombosis within a 3-month period (although not an absolute contraindication) should be approached with caution. Also, any patient who comes in with fluid overload and a significantly elevated potassium level, or other manifestations of uremia, such as intractable nausea and vomiting, needs a temporary catheter and should be sent to the dialysis unit as soon as possible. Always try to postpone endovascular treatment in unstable patients.

DEVICES FOR CLEARING GRAFT THROMBOSES

There are a couple of different approaches for clearing thrombosed grafts. You can use lytics, mechanical devices, or a combination of the two. Lytics can be used

STEPWISE GRAFT TREATMENT

- Perform a dual-crossing access within the graft as close to the arterial and venous anastomoses as possible.
- Assess graft anatomy and outflow. Angiography should be used to locate the stenosis(es) that can be implicated as the anatomic etiology of access failure. Percutaneous intervention with transluminal angioplasty is the preferred treatment of central vein stenosis to restore luminal diameter.[4] A clear image of the graft's tortuosity and the central venous outflow is needed to get an idea of whether this is approachable percutaneously.
- Once the decision is made to treat, administer intravenous heparin.
- Treat the efferent limb and the venous anastomosis first.
- Mobilize the arterial plug and clear the afferent limb.
- Reassess and clear any residual thrombus.
- Treat the central venous lesions.
- Send the patient directly to dialysis or achieve hemostasis. Purse-string sutures can be used in mature grafts to achieve hemostasis. They can be removed in 20 to 30 minutes, or in approximately 45 to 60 minutes if lytics are used (Figure 2).

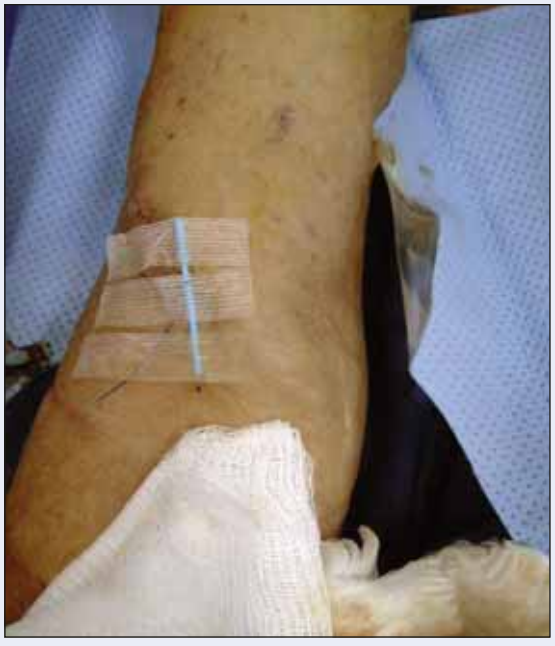

Figure 2. Use of a purse string-suture and tourniquet speeds hemostasis. Suture bites must be superficial to the graft and tightly spaced around the access point. These can usually be removed in 20 to 30 minutes for routine cases and 45 minutes to 1 hour if lytics were used.

in most patients even with a mild-to-moderate bleeding risk as long as you confine the lytics to local use and use good hemostatic technique at the termination of the procedure.

There are many mechanical thrombectomy devices on the market. Successful declotting procedures with suction thrombectomy, mechanical thrombectomy, and balloon thrombectomy have been reported. They tend to work well, but there is a potential risk of sending underfragmented clot to the lungs, particularly in patients with pulmonary hypertension or right-sided heart failure. Also, be aware of patients with unexplained strokes who may have right-to-left shunts.

PSEUDOANEURYSMS

The principle here is to bring the clot to the device or bring the device to the clot in an expanded, abnormal lumen, which is accomplished by either compressing gently on the pseudoaneurysm as your thrombectomy device is activated within it, or by using an angled guide catheter to allow the device to sweep through the pseudoaneurysm.

NATIVE FISTULAS

We do not see many native fistulas because they tend to have a bit more longevity. Fistulas are generally easy to treat if not thrombosed, but access can be difficult. The preferred access for stenotic fistulas is retrograde from the outflow vein, but antegrade brachial arterial access can be used (Figure 3) when the anatomy precludes retrograde crossing of the anastomosis. Stenotic fistulas are generally straightforward to treat. Thrombosed fistulas are very difficult to treat. We usually approach them just distal to the arterial anastomosis in retrograde fashion if there is a patent segment.

STENTING

The indications for the use of stents are persistent recoil, rapid or frequent restenoses after angioplasty, or rupture of an outflow vein after angioplasty (Figure 4). Stents are a bailout for suboptimal angioplasty, but multiple studies have shown that they do not prolong patency over PTA, and stent occlusions are much more difficult to handle. Traditionally, the results with stents in the management of hemodialysis vascular access have been poor, with a primary patency rate of about 20% per year.[5]

A recent article in the *Journal of Vascular and Interventional Radiology* suggests that the use of nitinol self-expanding stents is improving outcomes.[6] A stent

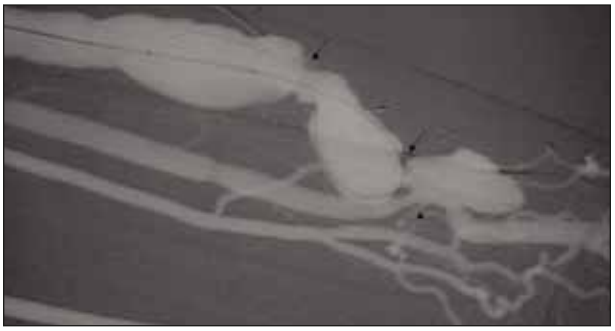

Figure 3. Fistulas are generally easy to treat if not thrombosed, but access can be difficult. Preferred access for stenotic fistulas is retrograde from the outflow vein, but antegrade brachial arterial access can be used as in this case where the anatomy precluded retrograde crossing of the anastomosis.

was placed in 15 central veins and 54 peripheral veins. One-year patency was about 20% for peripheral stenoses treated with nitinol stents and 67% for central venous lesions. The only stent-related complication occurred in a patient who had venous dissection associated with the edge of a stent placed at the elbow.

There may be a role for covered stents, although my first preference would still be a bare nitinol stent. When you are dealing with a patient who comes in repeatedly with restenoses, be sure to consider surgical options, but if the ultimate decision is to treat it percutaneously, remember there are several options, including high-pressure balloons, cutting balloons, nitinol stents, cryoplasty, and covered stents.

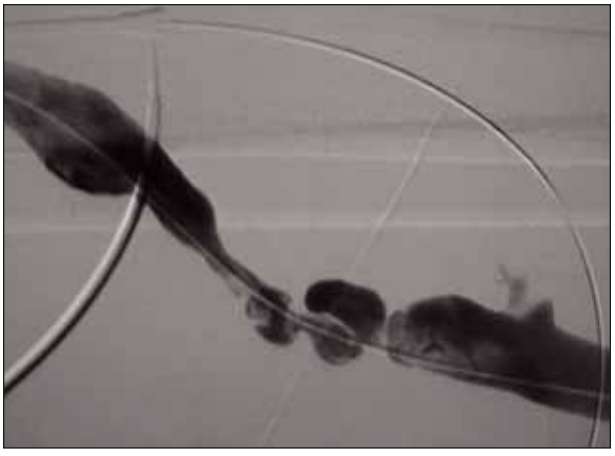

Figure 4. Resistant stenosis after angioplasty. Ensure that an appropriately sized balloon was used. If this is the case, consider a stent or surgical revision.

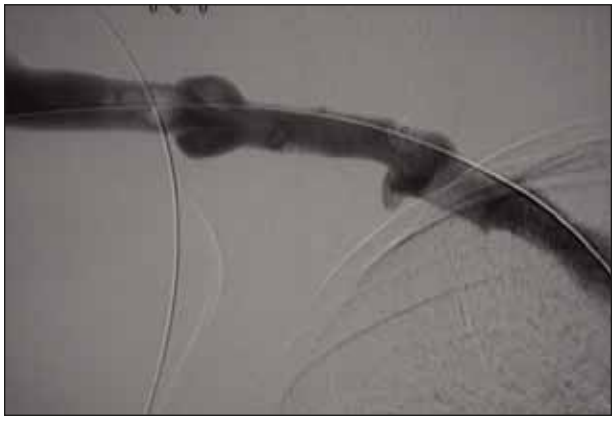

Figure 5. After the procedure, there are a couple of thrombi found sitting on a valve. These need to be addressed before the procedure is completed.

WHEN ARE YOU DONE?

A palpable thrill at the venous end of the graft is an excellent indicator of procedural success. For central venous stenoses, look for an absence of collaterals, and make sure you have cleared any residual clot (Figure 5).

Dialysis access failure is a huge and growing problem. Aggressive efforts to identify and correct the failing graft or fistula are warranted. Thorough evaluation of the access is essential, and all lesions must be treated. New devices help, but hopefully we can apply our burgeoning knowledge about antiproliferative agents to dialysis grafts as well. I believe the future here lies in inhibitors of restenosis. ■

Alain T. Drooz, MD, is from the Division of Vascular and Interventional Radiology, Inova Fairfax Hospital, Falls Church, Virginia. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein.

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