Tibial Trial Endpoints: Are We Evaluating Appropriate Outcomes?

By P. Michael Grossman, MD

Clinical trials designed to evaluate next-generation treatment strategies for tibial artery disease need to evolve. In an aging population with multiple comorbid conditions, the prevalence and complexity of peripheral arterial disease (PAD) is increasing. Lower extremity PAD of the tibial arteries is often associated with critical limb ischemia, tissue loss, and a high risk for amputation. This below-the-knee PAD is extremely challenging to treat with either surgical or percutaneous revascularization techniques. Therefore, many clinical trials have been or will be designed to evaluate devices or therapies that target these small and diffusely diseased vessels. These trials have been modeled based on iliac artery, superficial femoral artery, or coronary artery disease trials. Given the complexity of the vascular disease and extensive comorbid conditions of patients with severe symptomatic below-the-knee PAD, we must ask ourselves if we are evaluating appropriate outcomes in these studies.

The purpose of clinical medical device trials is to establish the safety and effectiveness of the medical device and to gather data to bring that device to market. These studies compare the new therapy to traditional approved treatment strategies such as plain old balloon angioplasty or bare-metal stents. These trials often exclude more complex or diffuse disease or critically ill patients. The challenges of tibial artery disease are that traditional treatment strategies, such as angioplasty and stenting, are associated (Tibial Trial Endpoints, Continued on page 4).

Renal Artery Denervation for Treatment-Resistant Hypertension: Emerging Controversies and Technical Evolution

By Krishna J. Rocha-Singh, MD, FACC, FAHA, FSCAI, FSVM

Renal denervation (RDN), a new therapeutic option to address severe treatment-resistant hypertension (TRH), targets the autonomic nervous system at the level of the renal artery and has generated considerable attention from the physician, medical device, investor, and payer communities. However, as 3-year follow-up data from the original Avidan-Medtronic Symplicity HTN I and II trial cohorts are reported, the initial enthusiasm has given way to the emergence of important questions and controversies regarding trial design and definitions. Concern regarding the (RDN for TRH, Continued on page 6)
When Is Open Surgical Reconstruction Preferable for Common and Profunda Femoral Lesions?

By David H. Deaton, MD

Over the last 15 years, there has been a major shift in the practice of catheter-based interventions for lower extremity arterial disease. Before this period, a patient under the care of a vascular surgeon would undergo diagnostic arteriography and potentially an intervention. The vast majority of these catheter-based interventions were performed by interventional radiologists who did not have a primary clinical practice, but performed procedures at the behest of treating physicians. This paradigm was radically altered by the entrance of vascular surgeons and interventional cardiologists into the arena of catheter-based interventions for lower extremity arterial disease.

The benefits of an open or endovascular approach to a particular vascular lesion can be evaluated from a variety of perspectives: acute outcome, recovery and periprocedural morbidity, durability of outcome, implications for future interventions (ie, “burning bridges”), need for patient compliance and follow-up, etc. The benefits of an endovascular procedure over an open reconstruction are easy to document and appreciate for coronary, aortic, renal, and mesenteric lesions. Intervention with open exposure for each of these requires a major anatomic exposure and often other high-mobility surgical maneuvers (eg, carotid, pulmonary bypass, aortic clamping, renal and mesenteric ischemia). The lower extremity represents a less forbidding scenario for open surgical reconstruction, but, generally speaking, an endovascular approach is usually chosen first for superficial femoral arteries (SFA) and some tibial disease, particularly if the clinical situation does not involve severe limb threat and does not involve multilevel diffuse disease.

The lower extremity arterial vasculature is unique in a number of ways. It is highly collateralized so that limb-threatening ischemia results only after multiple sources of blood flow have been occluded or severely compromised. The lower extremity arterial supply involves long vessels that are often diffusely diseased. They are encased in musculofascial compartments across multiple joints that impart significant torsional, compression, and stretch forces across their length. Reconstructive procedures, open or endovascular, must be cognizant of these features if they are to have a meaningful result for the patient suffering from lower extremity arterial ischemia.

Open lower extremity bypass generally provides excellent results but at the expense of long incisions to harvest autogenous conduit and deep exposures of the popliteal and tibial vessels. All of these elements of open reconstruction can result in significant recovery and post-procedural morbidity. When successful though, open reconstruction usually provides a redundant amount of blood flow sufficient for relief of claudication or wound healing and can be durable for many years. Endovascular procedures can be done under local anesthetic and sedation with almost no significant recovery or acute morbidity issues. Endovascular procedures would entirely supplant open reconstruction but suffer as a result of the length of the lesions involved and the significant alteration of arterial physiology that implanted devices impose on normal lower extremity arteries, both of which result in less-than-desired durability. As long as an endovascular approach does not preclude or impair the possibility for a future open and definitive reconstruction, they still remain the usual primary option.

The common femoral artery (CFA), like the carotid leading to the brain, represents a very unique and critical aspect of lower extremity arterial anatomy. Because of its location and anatomy, the approach to lesions in the CFA is often significantly different than for other lower extremity vascular lesions. First, it is in a very surgically accessible location for both open and endovascular procedures. It is the gateway or access point for the vast majority of all endovascular procedures done anywhere in the body. From an open standpoint, it is easily exposed and reconstructed under local anesthesia. The CFA bifurcates into the SFA and the deep femoral (or profunda). The profunda is often referred to as “the lifeline” of the lower extremity as its compromise or occlusion has profound repercussions for limb salvage. For all of these reasons, CFA reconstruction is typically done with an open technique that allows complete removal of all of the plaque in the CFA, proximal profunda, and SFA. Furthermore, the lumen is generally further enhanced by reconstruction with patch angioplasty to create a vessel significantly larger than even healthy individuals. The durability of this repair is excellent and preserves the CFA for both future endovascular intervention as the point of access or as the inflow for more distal bypass grafts that are often inevitable if the patient does not succumb to cerebral or cardiac complications of atherosclerosis. The benefits of endovascular reconstruction are minimal at this location as a result of the ease and success of open reconstruction, not to mention the fact that it overlies a joint space (ie, significantly increased bending, torsion) and involves a critical bifurcation not easily treated with current endovascular technology. While there are occasions when endovascular therapy is advantageous at the level of the CFA, it will continue to be a mainstay for open reconstruction for the foreseeable future.

Figure 1. An occlusion of the CFA, profunda femoris, and SFA that required bypass from the iliac artery.

Figure 2. Large bulky plaque easily removed via endarterectomy from the femoral artery.

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with extremely high restenosis rates and that the disease itself is often very diffuse and associated with tissue loss or infection of the treated limb. In addition, these patients have multiple medical problems including diabetes, neuropathy, renal insufficiency, and wound healing, and patency of the treated vessel out 12 months. However, tibial disease management trials are focused on novel drug or cellular treatments or devices that combine mechanical revascularization and drug delivery (eg, drug-eluting balloons). Expanded data collection related to procedural complications is certainly needed. In addition, major complications including death and amputation should be collected at discharge, 30 days, 6 months, 1 year, and annually to 5 years. Data related to devices should also be collected, including stent fracture rates and restenosis rates, out to 3 years. The issue of positive remodeling related to drug-eluting and possibly bioabsorbable polymer technology requires long-term follow-up as well.

Efficacy measures should also be expanded, with standardization of definitions including device success, technical success, and clinical or procedural success, as outlined by Diehm et al in 2007. Clinical endpoints such as freedom from major amputation or reintervention should be collected out to 3 years, as should primary, assisted primary, and secondary patency. Wound healing data should also be collected. Clinical data at baseline and follow-up should be gathered, including ankle-brachial index, Rutherford clinical category, change in Rutherford category over time, vessels, avoiding the need for amputations for individuals with critical limb ischemia.

The vascular center is part of UC Davis Health System, whose mission is to improve lives by providing excellent patient care, conducting groundbreaking research, fostering innovative, interprofessional education, and creating dynamic, productive community partnerships. The academic health system includes one of the country’s best medical schools, a 619-bed acute-care teaching hospital, a 1,000-member physicians’ practice group, and the Betty Irene Moore School of Nursing. Together, they make UC Davis a hub of innovation that is transforming health for all.
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RDN for Treatment-Resistant Hypertension

(Continued from page 1) appropriate severe TRH patient selection has arisen; specifically, which elements of a pharmacotherapeutic regime constitute suboptimal/failed antihypertensive therapy in TRH and which is (and pressure assessment methodology [office blood pressure vs 24-hour ambulatory blood pressure monitoring [ABPM]]) and values show how closely to a severe target most likely to respond to RDN. Finally, RDN trialists are focusing their attention on the arbitrary identification of “non-responders” (defined as a systolic blood pressure [BP] response ≤ 10 mmHg at 6 months after RDN); the importance of reporting the exact BP values that define the “nonresponse” designation; the potential explanations for “nonresponse” (Figure 1); and if, when, and how these patients should be retreated.

CLINICAL INVESTIGATIONS IN SNS MODULATION FOR TRH: EVOLVING CONTROVERSIES

The contribution of sympathetic nervous system (SNS) hyperactivity to the progression of TRH has been extensively investigated in numerous animal and human models. The SNS is involved in renal water and sodium retention, modulating renal artery blood flow, and cerebral and peripheral vascular effects. Renal sympathetic efferent nerve activity is involved in renal water and sodium retention, modulating renal artery blood flow, and cerebral and peripheral vascular effects. Renal sympathetic efferent nerves affect central nervous system sympathetic tone, so the ablation of renal efferent and/or afferent nerves are obvious targets in TRH patients. However, RDN does not abolish the need for antihypertensive medications, and recent studies suggest the RDN response rates may be as low as approximately 60%, a response rate substantially lower than the 84% rate initially reported. These observations justify the need to evaluate other technologies denervation targets (eg, the carotid body [CB]). Systolic BP is a surrogate for hypertensin and is a de facto study endpoint in previous and ongoing RDN trials. However, BP is both variable and dynam-
It’s not whether a patient has severe calcium that counts; **IT’S WHERE THE CALCIUM LIES.** Only about 10% of severe calcium lies in the intima where you can actually treat it. Over 75% of PAD patients have calcium within the medial layer of the vessel, where it does not impede blood flow and is impossible to safely reach with mechanical treatments. Spectranetics’ laser atherectomy vaporizes the soft lesions that compose the vast majority of lesion types – including restenosis and thrombus – while it reduces the risk of distal embolization.

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**ATLAS Award: A Teacher, Leader, and Scholar**

The **VIVA ATLAS Award** is a distinction bestowed upon an extraordinary individual who has made good on the triple threat—leadership, mentorship, and scholarship—that has profoundly affected the care of patients with vascular disease. VIVA is proud to recognize **Jerry Goldstone, MD**, as the recipient of this year’s prestigious award.

After medical school training at the University of Oregon, surgery residency at UC San Francisco, and vascular medicine fellowship at the Brigham, he was on the faculty at UCSF, University of Arizona, and Case Western Reserve University. Dr. Goldstone was Chief of Vascular Surgery at both UCSF and Case Western, and in each place he demonstrated a noteworthy commitment to teaching our field and establishing a real learning environment. He also participated in some of the earliest society consensus documents at a time when multidisciplinary collaboration was not accepted.

He has contributed to the education of dozens of vascular fellows, hundreds of residents of various specialties and thousands of medical students. Aside from the many books and scientific publications he has authored, his invited lectures and visiting professorships show that he has influenced people all over the world. Dr. Goldstone is known as a contributor of good will, enthusiasm, and hard work in helping to develop the vascular field. He has been selfless with his energies in the promotion of others. It is an honor to bestow the 2013 ATLAS Award to Dr. Jerry Goldstone, a role model for all of us, as a teacher, leader, and scholar of the vascular field.

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**Vascular Career Advancement Award**

In recognition of domestic and international physicians who show promise as potential leaders in the vascular field, **VIVA and LINC (Leipzig Interventional Course)** collaborated to present the first annual **Vascular Career Advancement Award** yesterday to Drs. Martin Werner and Mehdi Shishehbor. VIVA and LINC searched for physicians who have been in practice for 10 years or less in the fields of vascular medicine, angiography, vascular surgery, interventional radiology, or interventional cardiology, and are dedicated to improving the care and outcomes of patients with vascular disease. The two award recipients were recognized yesterday as special guests and were invited as faculty to both VIVA and the upcoming LINC meeting in January 2014 in Leipzig, Germany.
The VIVA Face-Off and International Forum

By Manish Mehta, MD

The VIVA Face-Off is back by popular demand today after its debut in 2012 in honor of our 10th anniversary. This unique format was developed as an interesting, fun, and fast-moving way to further engage attendees and enhance their VIVA experience. Approximately 50 vascular surgeons and interventionists from across the globe will participate in a lightning round competition series and will “face-off” with VIVA faculty by presenting original research or interesting cases with a focus on complex procedures, complication management, advanced and novel techniques, and/or new technology. Presenters will be judged by VIVA faculty on clarity, interest, value, originality, and the depth/scope of their presentation. The top 10 highest scoring physicians will present in the International Forum tomorrow, with the winner presenting in the VIVA General Session on Friday morning. The top three US fellows will win the new iPad, and the top international winner will be awarded a two-week hands-on vascular and endovascular training at the Albany Vascular International Academy, The Institute for Vascular Health & Disease at Albany Medical Center in New York.

The International Forum takes place tomorrow, concurrent with the main meeting. With attendees representing over 55 countries, we started this symposium several years ago to provide the opportunity for international key opinion leaders to share their global experiences with VIVA attendees in an intimate setting. The world’s leading international vascular experts will discuss regional variations in the diagnosis and treatment of vascular pathologies, including medical, endovascular, and surgical therapies, some of which are only performed outside of the United States. This year’s program will also include collaborative sessions with CICIE and ICI, and an opportunity for our top 10 Face-Off physicians to present their research/cases. Join us to expand your knowledge of vascular practices worldwide.

El Camino Hospital

Located in the heart of Silicon Valley, El Camino Hospital is an acute-care, 443-bed, nonprofit, locally governed organization focused on improving the health and wellbeing of the community with a “high tech and high touch” approach to comprehensive care, focusing on the needs of individuals and their families.

In addition to its centers of excellence, including the only Women’s Hospital in Northern California, the hospital is a hub for clinical innovation. The

Vincent Gaudiani, MD, a senior cardiothoracic surgeon and medical staff member and James Joyce, DO, interventional cardiologist at El Camino Hospital at El Camino Hospital.

Tej Singh, MD, Clinical Director of Vascular Surgery and Christopher Zarins, MD, Medical Director, Vascular Surgery.

Norma Melchor Heart & Vascular Institute, in collaboration with the internationally renowned Fogarty Institute for Innovation, is one of a handful of hospitals participating in the CoreValve and SurTAVI trials to investigate a minimally invasive treatment option for patients with severe aortic stenosis. Moreover, El Camino Hospital physicians were instrumental in the launch of VIVA more than 10 years ago, and every year during the conference, they perform highly complex cases via satellite from the hospital's state-of-the-art facilities in order to advance knowledge and showcase the latest techniques and advances in vascular care.

Chad Ramamohan, MD, Medical Director, Chest Pain Center and Cardiac Cath Lab and Frederick St. Goar, MD, FACC, cardiologist and Director of the Fogarty Institute for Innovation Board of Directors.

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VIVA Board Review Course

By John A. Kaufman, MD, MS

This year’s Comprehensive Review Course On Vascular And Endovascular Medicine, in conjunction with the Society of Vascular Medicine (SVM), is an expansion and update of the successful Vascular and Endovascular Board Review Course. Now in its fourth year, the course was extended to 2 full days in order to provide a comprehensive overview of vascular medicine and intervention.

The VIVA–SVM collaboration has been integral to this course since the beginning. Education in vascular disorders is a major component of the missions of both organizations. The VIVA meeting brings together a multidisciplinary group of dedicated teachers and clinicians and the SVM is a multidisciplinary professional society. This alignment of culture and mission creates a unique opportunity for collaboration.

The course is designed to serve as both a refresher for the practicing clinician and a review for those intending to sit for certification examinations. The faculty is comprised of people who are both experts in the field and excellent teachers. The topic list is extensive, ranging from vasculitis to thoracic aortic endografts, and includes venous diseases, clinical and imaging evaluation, medical therapy of arterial and venous disorders, and postintervention follow-up. It is a very full 2 days.

Many attendees plan to take a vascular medicine, vascular surgery, or interventional radiology certifying examination. As such, the attendees will have an opportunity to complete two multiple-choice sample examinations covering vascular medicine and interventions. As is characteristic of VIVA, each test question will then be dissected in an interactive format that will allow attendees to grill the faculty, rather than vice-versa. The questions in these examinations are unique to this course and are educational tools to help the learner direct her/his study.

There are also two companion books for those who would like additional study and reading materials. The Vascular and Endovascular Medicine Study Guide, edited by Drs. Weinberg, Hawkins, and Jaff is a 10-year compilation of questions and content from the VIVA meetings. There are over 250 questions with complete answers and imaging. The Comprehensive Review In Vascular and Endovascular Medicine textbook, edited by Drs. Slovut, Dean, Jaff, and Schneider, provides a multimodality, evidence-based, and practical approach to the diagnosis and treatment of vascular diseases. Case studies and self-test questions are also included. Both books can be ordered through the VIVA website (http://vivapvd.com/misc/ReviewBooks.aspx).

Whether a new graduate or seasoned clinician, the Comprehensive Review Course On Vascular And Endovascular Medicine and the companion books provide an excellent overview of the field. VIVA and the SVM have worked together for 4 years to organize this uniquely multidisciplinary suite of educational opportunities. Each year it has grown in attendance and content. The course was held before the VIVA meeting, from Saturday afternoon to Monday at noon. This allows a minimum of time away from work, but also the ability to complete the review course in its entirety without missing any parts of the VIVA meeting. If you missed it this year, plan ahead for 2014!
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Late-Breaking Trials

Highlights from yesterday’s trial presentations.

Zilver PTX Randomized Trial of Paclitaxel-Eluting Stents for Femoropopliteal Artery Disease: 4-Year Results

Presenter: Gary M. Ansel, MD

The Zilver PTX multinational, prospective, randomized trial compared the safety and effectiveness of the Zilver PTX drug-eluting stent to balloon angioplasty (PTA) and bare-metal stenting (BMS) in the superficial femoral artery (SFA). Patients with de novo or restenotic SFA lesions were randomized to Zilver PTX stent placement or PTA. PTA patients experiencing acute failure (eg, a 30% residual stenosis) underwent secondary randomization to provisional stenting with Zilver BMS or Zilver PTX. Follow-up included event-free survival and primary patency by duplex ultrasound core laboratory analysis (peak systolic velocity ratio < 2.0).

As previously reported, 479 patients were enrolled in the United States, Japan, and Germany. The 12-month primary endpoints were met and showed no inferior event-free survival and superior patency for the Zilver PTX group compared to the PTA control group. The randomized comparison of provisional stenting with Zilver PTX versus Zilver BMS also showed significant benefit of the paclitaxel coating. Currently, 4-year follow-up data are available for > 75% of eligible patients. The 4-year freedom from target lesion revascularization rate is significantly higher for the Zilver PTX group compared to the standard care group, which includes optional PTA and provisional BMS (83.2% vs 69.4%, P < .01, log-rank). Regarding effectiveness, the 4-year patency rate for the Zilver PTX group is superior to the standard care group (67.6% vs 45.5%, P < .01, log-rank). Provisional stenting with Zilver PTX versus Zilver BMS continues to demonstrate significant benefit of the paclitaxel coating through 4 years, with patency rates of 75% and 57.9%, respectively (P = .04, log-rank).

The 4-year results of this randomized, multicenter trial support the sustained safety and effectiveness of the Zilver PTX drug-eluting stent.

12-Month Data From the MIMICS Study of the BioMimics 3D Stent

Presenter: Professor Thomas Zeller, MD

BioMimics is a randomized, controlled trial comparing safety and efficacy of BioMimics 3D stent (Veeva Medical Ltd, Horsham, West Sussex, United Kingdom) and control nitinol stents in subjects undergoing femoropopliteal intervention. The 3D helical geometry of the BioMimics 3D stent closely mimics natural vascular curvature and is designed to promote swirling blood flow and increase wall shear stress, which is patency-protective. The BioMimics 3D stent is also designed to enhance biomechanical performance of the stented segment, reducing the risk of vessel kinking and trauma during knee bending.

After a 10-subject phase I lead-in, MIMICS enrolled 76 subjects with 2:1 phase II randomization. Fifty patients received the BioMimics 3D stent and 26 patients received a control stent (LifeStent [Bard Peripheral Vascular, Tempe, AZ]) in 24 of 26 patients. The 12-month Kaplan-Meier estimate of freedom from clinically driven target lesion revascularization was 91% for BioMimics 3D, compared to 92% for control (day 365; P = .87). The 12-month Kaplan-Meier estimates of freedom from loss of primary patency were 80.6% and 72.0% for BioMimics 3D and control, respectively (day 365; P = .436). No stent fractures were detected by core lab in BioMimics 3D or control in 12-month x-rays. No loss of stent patency was observed in any subject where stent curvature was measured > 0.02 mm-1. Biplanar x-ray imaging and computational fluid dynamic modeling showed a 55% increase in swirling flow (P = .017) and an 18% increase in wall shear stress (P = .054) for BioMimics 3D compared to control. Interim 24-month data show that 76% of BioMimics 3D subjects gained a peak systolic velocity ratio improvement between 12 and 24 months, which is 83% more than the control (P = .007).

Principal Investigator for MIMICS, Professor Thomas Zeller, Universitäts-Herzzentrum, Freiburg-Bad Krozingen, Germany, said, “Data on the BioMimics 3D stent demonstrate the promotion of swirling flow and increased wall shear stress, together with 12-month and emerging 24-month patency data, point to the merits of this innovative approach to stent design for femoropopliteal use.”

Health-Related QOL Outcomes 3 Years After SFA Stenting: Results From the STROLL Trial

Presenter: David Safley, MD

Data from a quality-of-life (QOL) subanalysis of the STROLL trial, which assessed the safety and efficacy of the S.M.A.R.T. nitinol self-expandable stent system (Cordis Corporation, Fremont, CA), showed that patients with peripheral artery disease (PAD) in the superficial femoral artery (SFA) treated with the S.M.A.R.T. stent experienced clinically meaningful improvements in QOL, such as social function, walking distance, and speed, which were maintained for at least 3 years. The S.M.A.R.T. stent is used in the treatment of patients with obstructive SFA disease.

At 1-month follow-up, there was significant improvement on the Peripheral Artery Questionnaire (PAQ) impairment summary scale (mean change, 31.4 points, P < .001 vs baseline; minimum clinically important difference, 8 points) as well as most other disease-specific and generic scales. Significant improvement on the PAQ summary scale and other scales were sustained through 3-year follow-up (mean change, 28 points, P < .001). All 250 patients enrolled in the multicenter trial had Rutherford Class 2-4 symptoms, an ankle-brachial index < 0.8, and were treated with standard PTA with placement of one or more S.M.A.R.T. stents. QOL was assessed on all patients at baseline and to 36 months follow-up using the Short Form 12 and EQ-5D (for generic health status), the PAQ, and Walking Impairment Questionnaire for PAD-specific health status. The mean age for the study was 68 years and 47% of patients had diabetes mellitus. Mean lesion length was 77±35 mm and 24% were total occlusions. Baseline health status was substantially impaired for generic and disease-specific measures.
Late-Breaking Trials
Highlights from yesterday’s trial presentations.

Three-Year Clinical Follow-Up From the DURABILITY II Study
Presenter: Krishna Rocha-Singh, MD

DURABILITY II was a prospective, multicenter, nonrandomized study to evaluate the safety and efficacy of a single EverFlex self-expanding nitinol stent (Covidien, Mansfield, MA) in patients with Rutherford class 2-4 claudication and femoropopliteal atherosclerotic lesions up to 20 cm in length. Compared to VIVA Physician’s percutaneous transluminal angioplasty (PTA) objective performance criteria (OPC) for safety and efficacy.

The study enrolled 287 patients (mean age, 68 years; 66% male) at 44 centers in the United States and Europe. The mean lesion length, as adjudicated by an independent core laboratory, was 8.9 cm and included 48.1% occluded arteries with 43.2% severely calcified lesions. A single stent was implanted in 95% of subjects, and 5% received multiple stents. Subjects were followed yearly for 3 years with independent ultrasound core lab–adjudicated duplex ultrasound to determine stent patency, radiograms of the stented extremity in flexion, and extension to assess stent fractures and ankle-brachial indices.

The duplex Doppler-assessed patency (peak systolic velocity ratio < 2.0) rate at 3 years was 60%; freedom from loss of primary patency was significantly higher for lesions ≤8 cm compared to lesions > 8 cm (71% vs 50.5%; P = .0001). No difference in patency was observed between single-stent and multistent recipients.

The 3-year freedom from target lesion revascularization (TLR) was 70%. When stratified by lesions ≤8 cm or > 8 cm, the freedom from TLR was statistically significant (80% vs 61%, respectively; P = .0003). The 3-year stent fracture rate was 0.9%.

To the investigators’ knowledge, this is the first report of combined 3-year assessment duplex Doppler defined primary stent patency, clinically driven TLR, and stent fracture rates in long, complex femoropopliteal lesions in Rutherford class 2-4 claudicants. These data demonstrate that implanta-

ESPRIT I Clinical Trial Update
Presenter: Johannes Lammer, MD

The ESPRIT I trial evaluated the safety and performance of the Esprit BVS bioresorbable vascular scaffold system (Abbott Vascular, Santa Clara, CA) in subjects with symptomatic claudication from occlusive vascular disease of the superficial femoral artery (SFA) or common or external iliac arteries. The trial is a prospective, single-arm, open-label, multicenter clinical investigation in which 35 subjects received the study device at seven European centers. Subjects receive clinical and hemodynamic follow-up at 1, 6, and 12 months and at 2 and 3 years, and angiographic follow-up at 12 months. One subject withdrew consent for follow-up, so follow-up is ongoing with 34 subjects.

Subjects were predominantly male (77.1%), with a high incidence of dyslipidemia (85.7%), hypertension (71.4%), and tobacco use (82.9%). Lesions treated were predominantly located in the SFA (88.6%), and lesion length averaged 35.5 mm. Total occlusions occurred in 22.9% of cases; in those cases, the occlusion length averaged 30.6 mm. Acute success was 100%; in all cases, investigators were able to use the device without difficulty.

Preprocedure in-segment percent diameter stenosis was 80%. Excellent acute angiographic results were achieved, with postprocedure in-segment percent diameter stenosis averaging 13.1%. This was consistent with the postprocedure duplex peak systolic velocity ratio (PSVR) of 1.27. The duplex assessments at 1 month and 6 months continued to show widely patent arteries, with observed PSVR of 1.26 and 1.35, respectively.

In summary, angiography and duplex ultrasound showed widely patent arteries after treatment with Esprit BVS, sustained to 6 months with a restenosis rate of 0% on duplex. The imaging results show no indication of acute or delayed scaffold recoil. Follow-up is ongoing, with angiography and duplex ultrasound scheduled at 12 months.

Primary Safety and Efficacy Results of the Re-ROUTE Trial
Presenter: Koen Keirse, MD

The Re-ROUTE clinical study was a prospective, single-arm, multicenter study conducted at 12 centers in Europe and Canada. This postmarket study was designed to provide additional clinical data regarding the safety and technical success of the OffRoad re-entry catheter system (Boston Scientific Corporation, Natick, MA) for subintimal recanalization of chronic total occlusions (CTOs) in the femoropopliteal arteries. To be eligible for the study, patients were required to have claudication or critical limb ischemia (Rutherford 2-5) and a de novo or reoccluded CTO lesion in a native femoropopliteal artery. Target lesion length ≥1 cm and ≤30 cm and a minimum reference vessel diameter of 4 mm were required. A total of 92 patients (mean age, 70.3 ± 10.6 years; 70% male; mean lesion length, 175.1 ± 85.4 mm) were enrolled. The primary 30-day safety endpoint, the composite rate of device-related major adverse events (eg, death, perforation requiring intervention, clinically significant peripheral embolism, and major amputation of the treated lower limb) was 3.3% (3/90). All three events were clinically significant peripheral emboli. The event rate was lower than the prespecified acceptable threshold. Effectiveness was based on device technical success, defined as placement of a guidewire in the true lumen distal to a CTO. The site-reported technical success rate was 84.8% (78/92), which exceeded the prespecified performance goal. The Re-ROUTE results demonstrate that the OffRoad system is a safe and effective treatment option for recanalization of femoropopliteal CTOs.
Late-Breaking Trials

Highlights from yesterday’s trial presentations.

EndoAnchor Fixation and Sealing of Aortic Endografts: Global Real-World Experience From the First 250 Patients

Presenter: James D. Joye, DO

The Aneurysm Treatment using the Heli-FX Aortic Securement System Global Registry (ANCHOR) trial was designed to assess the safety and efficacy of the EndoAnchor (Aptus Endosystems, Inc., Sunnyvale, CA) to augment proximal fixation and sealing in primary EVAR (primaries) or therapeutically for type Ia endoleaks/migration after a prior EVAR (revisions).

Thirty-six US and 18 European centers enrolled 258 subjects over 18 months through August 16, 2013. Among 257 subjects with complete data, 194 were primaries and 63 were revisions. Primary endpoint was successful EndoAnchor deployment without type Ia endoleak/migration. Conical neck was defined as > 10% diameter increase over 10-mm length.

Proximal necks averaged 18 mm length and 24 mm diameter; 43% were conical, 28% had neck length ≤ 10 mm. The average number of EndoAnchors implanted in primaries was 5, and 6 in revisions. The most common indications for EndoAnchor use in primaries were concern for late migration/type Ia endoleak (90%) and acute type Ia treatment (13%). All acute type Ia endoleaks were successfully resolved. Most common indications in revisions were type Ia endoleaks (76%) or migration with type Ia endoleak (45%). Procedural success was achieved in 99.5% of primaries and 91% of revisions.

EndoAnchors were associated with excellent early results when high-risk anatomy was encountered in initial EVAR procedures. EndoAnchors were successful in repairing most proximal neck problems in EVAR revisions. Definitive results await longer-term follow-up data.

Two-Year Outcomes From the Ovation Pivotal Study

Presenter: Manish Mehta, MD

The objective of the TriVascular (Santa Rosa, CA) Ovation pivotal study is to evaluate the safety and effectiveness outcomes of the ultra-low profile, 14-F outer diameter (OD) Ovation abdominal stent graft system for endovascular repair of abdominal aortic aneurysms (AAA). This prospective trial enrolled 161 patients from 36 sites in the United States, Germany, and Chile between November 2009 and May 2011.

The TriVascular Ovation abdominal stent graft system is tri-modular, consisting of two iliac limbs and a 14-F OD aortic body, the smallest profile of any currently commercially available stent graft. Ovation is designed to accommodate a broader range of anatomy by addressing the two most available stent grafts. Ovation is designed to accommodate the two most available stent grafts. The ability of the Ovation stent graft to treat a broad range of aortoiliac anatomies may help to address the two most available stent grafts.

All TriVascular Ovation study patients were treated under a common protocol. A Clinical Events Committee adjudicated adverse events and an independent imaging core laboratory analyzed imaging. The main inclusion criteria included proximal aortic neck length ≥ 7 mm, inner wall diameter between 16 and 30 mm, and iliac inner wall diameter between 8 and 20 mm in the distal sealing area.

Despite relatively broad inclusion criteria, results of the study were positive. Technical success was achieved in 100% of cases. Mean procedure time was 110 minutes, median procedural blood loss was 150 cc, and median hospital stay was 1 day. No AAA rupture or conversion to open surgery was reported. The imaging core laboratory reported no type I or III endoleak or migration. A further anatomically challenging subgroup analysis indicated that 39% (63/161) of the treated patients had aortic neck length of < 10 mm, access vessel of < 6 mm, or both. Remarkably, no differences in clinical or imaging outcomes were noted in patients with or without challenging aortic anatomy.

The 2-year outcomes with the Ovation stent graft are promising with excellent demonstrated safety and effectiveness in patients with AAA. These results were similarly impressive in patients with challenging anatomical characteristics who would be ineligible for treatment with other approved stent grafts. The ability of the Ovation stent graft to treat a broad range of aortoiliac aneurysms may help to expand the patient population eligible for EVAR.

VIVA 13 badges must be worn to all VIVA sessions and events, including VIVA After Hours at Club XS on Wednesday evening (ID required).

Guests may attend VIVA After Hours for $100. Tickets MUST be purchased at Registration Desk 2 prior to 5:45 PM on Wednesday.

Recording or videotaping any session is strictly prohibited.

This year, VIVA is providing complimentary Wi-Fi Internet access throughout the convention space. Simply connect to the VIVA13 network and enter the password VIVA2013. Note: This does not extend to the pool area, casino, or hotel rooms.

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If you plan to attend a Satellite Session (refer to your on-site registration booklet or signage for the schedule), a meal is usually provided. The box lunches in the exhibit pavilion are for those attendees NOT attending a satellite session.

Refer to your on-site registration booklet (pages 3-4) for information and instructions about obtaining CME/CE credits.

LOST AND FOUND: Items can be submitted and retrieved at the VIVA Registration Desk.

Content from the meeting (including updated presentations) can be found online at http://viva13.vivapvd.com after November 15th.

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Peripheral arterial disease (PAD) is an epidemic that affects an ever-growing number of patients worldwide. Critical limb ischemia (CLI) represents the terminal stage of PAD. Within 1 year of clinical diagnosis, 30% of patients will undergo a major amputation, and 25% to 30% will be deceased. Despite advances in medical therapies, the number of patients with CLI continues to increase. The preprocedural stage should encompass a thorough physical examination followed by detailed noninvasive imaging of the tibiopedal vessels and selective diagnostic angiography of the target limb.

**Physical Examination**

Physical examination should focus on mapping of pulses by palpation and documentation of radial, brachial, femoral, popliteal, dorsalis pedis, and posterior tibial pulses, as well as results of the Allen’s test. If pedal pulses are not identified, then bedside Doppler evaluation is performed. The assessment is completed with identification of the presence or absence of ulcerations, their location, base, border, and size. Pictures are taken in four standard views (dorsal, plantar, medial, and lateral) and archived in the patient’s chart. With this information at hand, the ischemic cutaneous angiosome is established.

**Noninvasive Imaging and Physiologic Evaluation**

**Ankle-Brachial Index**

In patients with severe PAD/CLI, the ankle-brachial index (ABI) can be unreliable, as this may appear normal secondary to the increased pressure required to obliterate the calcified tibial vessels, resulting in false elevation of the pedal component of the ABI. In these patients, the measurement of TBI (toe-brachial index) and Doppler waveforms is more likely to be of benefit.

Recently, the traditional concept of the ABI has been challenged and it has been proposed that measuring the lowest ABI instead of the higher in each limb may be of more value.

**Duplex Ultrasound**

The duplex ultrasound (DUS) examination of the infrapopliteal vessels allows identification of chronic total occlusions (CTOs), points of reconstitution, “hibernating” segments, and potential areas for retrograde tibiopedal and digital access. Among patients with CLI, it is not rare to find distal areas where calcium completely obliterates the arterial lumen. These are segments that are nearly impossible to access or cross with the currently available endovascular tools; therefore, we have coined the term “white stop sign” to designate them. Once we have this information available, we define the noninvasive angiosome (Figures 1 and 2).

**Diagnostic Selective Angiography**

The tip of the catheter is placed as close as possible to the target vessel. Then, intra-arterial vasodilators are administered, followed by angiography with delayed imaging to identify collaterals and all possible sites for tibial, pedal, and even digital access. This information is used to build the angiographic angiosome. This strategy will allow us to identify the vessel(s) that will benefit from endovascular intervention, as well as which will be the best target(s) for arterial puncture.

Patients with CLI have multilevel disease with relative frequency, and if selective angiography is not performed, the contrast washout severely compromises the quality of the infrapopliteal imaging and vessels are inadequately labeled as occluded.

Many decisions to perform major amputations have been and are made based on the inability to identify patent outflow vessels during selective angiography. At our institution, we overlap the information obtained with the DUS imaging and the angiogram to plan our access and revascularization strategy. This combined approach is especially helpful in patients who undergo selective angiography and do not show evidence of tibiopedal outflow during delayed imaging with digital subtraction angiography, as the tibiopedal DUS imaging will allow mapping of hibernating tibiopedal outflow vessels.

At this point, we superimpose the cutaneous, noninvasive, and angiographic angiosomes and proceed with the planning of the revascularization, which starts with access selection. For common femoral artery (CFA) access (either retrograde or antegrade), as well as popliteal, radial, and brachial access, we generally use the Site-Rite Vision ultrasound system (Bard Peripheral Vascular, Inc., Tempe, AZ) due to its smaller size and ease of maneuverability. The system employs a variable 5- to 10-MHz linear array transducer that can image up to 6 cm in depth. For tibiopedal and digital access, we use the 15-MHz iU22 xMatrix (Philips Healthcare, Andover, MA), as it offers higher spatial resolution at shallower depths. In our lab, we use ultrasound guidance and micro-puncture kit in 100% of the cases, regardless of the access site.
Arterial Access

ACCESS SITES

Contralateral Retrograde CFA Access

The main advantage of the contralateral retrograde CFA approach is the familiarity of most operators with this technique. The main disadvantages are: (1) tortuous bifurcations, requiring expertise used to advance devices when attempting to cross a below-the-knee chronic CTO, and (2) most of the available peripheral interventional devices are not long enough to reach lesions located at or beyond the distal tibial arteries from the contralateral approach.

Ipsilateral Antegrade CFA Access

Advantages of this technique include the coaxial force vector that can be applied to the interventional tools, which allow for more pushability and torqueability of the devices, ultimately increasing the likelihood of success. It also allows for treatment of distal infra-popliteal lesions and provides the ability to treat potential complications (distal emboli). This technique is helpful and can be used in patients with unfavorable aortic bifurcations: aortobiliomeral bypass, endovascular aneurysm repair, tight bifurcations, tortuous bifurcations, reconstructed aortic carinas, and contralateral iliac occlusion.

The main disadvantage of this approach is the increased rate of complications from the access site. In obese patients, the pannus should be systematically retracted to expose the groin. Subsequently, we use fluoro-guided puncture echogenic-tip needle and a microsheath. Once access is confirmed angiographically, the microsheath is exchanged for a regular-sized sheath. At the end of the case, it should be considered in patients with hostile groins or ipsilateral severe CFA disease. This approach allows for easier crossing of the distal CTO cap and in complex limb salvage procedures. It provides the ability to perform “dual drilling” (when combined with either ipsilateral antegrade or contralateral retrograde CFA access) by simultaneously spinning the wires from both approaches in the CTO cap, increasing the likelihood of CTO crossing. When this approach is utilized, it is of paramount importance to try to use just a 4-F sheath, and administer a high dose of heparin (70 to 80 units/kg) and peri- odic intra-arterial vasodilators (in our lab, we administer 200 µg of nitroglycerin every 15 minutes).

Radial/Brachial Access

This approach can be utilized to treat renal, mesenteric, iliac, common femoral, and proximal to mid-SFAs. The main limitations of this strategy are the limited length of the current interventional devices. The main advantages are related to the ability to avoid hostile groins and unfavorable bifurcations.

SUMMARY

As to which of these represents the best approach, this is a question without an answer, as the best approach will vary depending on the individual patient. As of 2013, the best recommendation is to become familiar and proficient with each one of these approaches, as well as with the equipment that should be used with each of them. As our field continues to evolve, newer and better iterations of the currently available tools will become available, which will demand our continuous and relentless commitment to remain abreast of new developments, with our sight centered in evidence-based strategies that provide the best outcomes for our patients. ■

Retrograde Tibiopedal Access

Retrograde tibiopedal access is indicated in patients who require below-the-knee, popliteal, and even distal SFA interventions when the antegrade approach has failed. This also should be considered in patients with hostile groins or ipsilateral severe CFA disease. This approach allows for easier crossing of the distal CTO cap and in complex limb salvage procedures. It provides the ability to perform “dual drilling” (when combined with either ipsilateral antegrade or contralateral retrograde CFA access) by simultaneously spinning the wires from both approaches in the CTO cap, increasing the likelihood of CTO crossing. When this approach is utilized, it is of paramount importance to try to use just a 4-F sheath, and administer a high dose of heparin (70 to 80 units/kg) and peri-dic intra-arterial vasodilators (in our lab, we administer 200 µg of nitroglycerin every 15 minutes).

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Retrograde Popliteal Access

This approach is useful in patients with flush SFA occlusions without stump, hostile groins, severe disease of the ipsilateral CFA, or unfavorable aortic bifurcations.

For more state-of-the-art access tips, attend “Navigating Access Safely” from 5:06 PM to 5:27 PM in the General Session.

SEE IT LIVE

WHAT IS ONE THING YOU’VE LEARNED FROM DOCTORS FROM OTHER COUNTRIES THAT HAS INFLUENCED YOUR PRACTICE?

D. Christopher Metzger, MD
Interventional Cardiology
Wellmont CVA Heart Institute
Kingsport, Tennessee

I have learned invaluable procedural innovative techniques from our international interventional colleagues. For example, in watching Drs. Dierk Schienert and Andrej Schmidt perform cases, I witnessed direct access to an occluded stent through the thigh when the stent could not be entered from above, as well as using a re-entry device from above to puncture a balloon from below to recanalize very difficult CTOs. These techniques and procedural approaches of high-volume, talented operators have been used effectively in my lab and others, and have proven to be invaluable additions to our procedural armamentarium.

Matthew Johnson, MD
Interventional Radiology
Indiana University Health
Indianapolis, Indiana

So many things that we take for granted, such as fluoroscopy, IV fluids, prep solutions, and even towels, are often unavailable in Kenya, where I have worked as part of the AMPATH (Academic Model for the Prevention and Treatment of HIV-AIDS) program. We used sterile gloves on donated ultrasound probes, alcohol and paper towels for sterility, and donated needles and catheters to perform nephrostomies and biliary drain placements. We used the same portable ultrasound to evaluate hearts and baby heads. We photographed x-rays, so there’d be a record that they exist when the patients took them home. It’s possible to do a lot with very little. I’ve learned that—and to respect those who do it every day.

Jason Lee, MD
Vascular Surgery
Stanford University Medical Center
Stanford, California

International collaboration has been extremely important in learning about advanced endovascular techniques, particularly as it relates to complex aortic repair. The availability of fenestrated and branched devices worldwide and the generosity of numerous international experts to train and expose United States surgeons to the technology was extremely valuable to me to gain early access and knowledge about these procedures. When we finally were able to perform the procedures in the United States, I greatly appreciated the teaching from our international colleagues, and my patients were able to greatly benefit from these advanced techniques.

Thomas Zeller, MD
Vascular Medicine
Universitaets-Herzzentrum Freiburg-Bad Krozingen
Bad Krozingen, Germany

Even though I started using retrograde tibial access techniques in 1999, I was very impressed with using collateral vessel access techniques for retrograde recanalizations, such as the plantar loop technique and using metatarsal arteries for retrograde puncture. Step by step, I established these techniques in my lab. Just recently at the Amputation Prevention (AMP) congress in Chicago, I learned a lot about using ultrasound to guide tibial interventions. Every time I am a guest in another cath lab, I find something new to add to my own interventional toolbox.
The Future of the Practicing Physician and Supply Chain Management

By Sean P. Lyden, MD

My guess is that many physicians still don’t understand how products end up on the shelves of their operating rooms and catheterization labs. For decades, most physicians have not cared how much devices cost as long as we had access to the new technology and devices needed to treat our patients with vascular diseases. I am here to say, those days are numbered.

I have a unique role outside of my job as a practicing vascular surgeon. Since 2010, I have been the Medical Director for Supply Chain Management for the Cleveland Clinic Health System. I have been tasked with engaging physicians to work with administration to lower our cost basis for everything we use both clinically and non-clinically. Why did I take on this role? I had spent the previous 5 years working on cost reduction for vascular surgery at the Cleveland Clinic. As an employed physician in a physician-owned and run health system, I felt that physicians—not administrators—should make decisions regarding what devices were best for patients to achieve the best outcomes. I viewed the money we spent on devices as my money and pushed others to use fiscal responsibility in device choices.

The growth of outpatient catheterization labs has pushed many physicians who care for vascular disease to become more knowledgeable in device choices, costs, and negotiations as their own money was put at stake. The financial viability of those endeavors, many times, rested on the balance of device costs and reimbursement for the procedures. Similarly, as hospitals have seen declining reimbursement, the need for physician input to these decisions if they do not become involved now.

I believe only caregivers can decide what offers the best chance of a good outcome. As physicians, we often are not aware of the costs of what we use. We must begin to take cost of devices in to account when we choose what we will use to treat our patients. When outcomes are disparate either in the short or long term, the better device should be chosen. When two devices are equivalent in regard to outcomes, we must begin to choose the less expensive option. We will need to increasingly work with administration and industry to lower the cost basis of the procedures we perform. We have undertaken a cost-visibility campaign at the Cleveland Clinic for vascular products and have found that this influences physicians’ choices and highlighted potential price differences between products such as balloon-expandable stents (Figure 1). We have asked physicians to choose wisely, and, if choosing a more expensive item, to make sure the added cost provides patient benefit. We have also seen that this creates pressure on the vendors to reduce pricing when disparities exist.

The future of health care will require physicians to become more involved with administrators to understand supply chain spending. As hospital budgets are squeezed tighter due to declining reimbursement, we will undoubtedly be pushed to limit our choices and vendors for many clinical areas. The need for physician input to these decisions will be critical to maintain the best choices for our patients.

Figure 1. Part of Cleveland Clinic’s cost-visibility campaign. Image courtesy of Clinical Supply Chain Management, Cleveland Clinic Foundation.

The Center of Vascular Medicine at the Park Hospital Leipzig

The Center of Vascular Medicine at the Park Hospital Leipzig combines the departments of angiology, cardiology, and vascular surgery. The center has a strong focus on minimally invasive vascular therapies; as such, it is one of the leading centers in the world in the field of peripheral vascular interventions with highly experienced clinicians and staff. The Center of Vascular Medicine runs under the leadership of Prof. Dirk Scheinert, MD, who is associated with Andreas Schmidt, MD; Sven Bräunlich, MD; Matthias Ulrich, MD; and other vascular specialists.

More than 4,000 patients are treated annually with the newest technologies in the three catheter labs. Interventions in challenging below-the-knee, carotid, renal, or aortic abdominal aneurysm/descending thoracic aorta cases are performed with the latest techniques and devices. One of our recent focal points is renal denervation for treatment of patients with therapy-refractory hypertension.

In order to contribute to an advancement of international treatment options, our center is highly committed to clinical research. Therefore, we are participating in several physician- and industry-initiated clinical trials.

One of our key objectives is continuous medical education in the field of vascular interventions. Since the first edition in 2005, the Center of Vascular Medicine at the Park Hospital Leipzig is primarily involved in the Leipzig Interventional Course (LINC), which is held in Leipzig on an annual basis and attracts more than 4,000 attendees from around the globe. At any time, physicians from all over the world are welcome to visit our facility for education in the newest developments in the field of interventional treatments.
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Potential Adverse Events: Potential adverse events which may be associated with the use of a stent in the SFA and proximal popliteal arteries include, but are not limited to: Allergic reaction, Amputation, Arterial dissection/perforation, Bleeding disorders (including GI, lymphatic), Infection (local or systemic including bacteremia or septicemia), Pseudoaneurysm, Restenosis, Stent/Vessel Thrombosis, Surgical or endovascular intervention. See the Instructions for Use provided with the product for a complete list of warnings, precaution, adverse events and device information.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.

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