The New World of Peripheral Vascular Disease — Percutaneous Treatment of Popliteal Aneurysm Disease

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Case Study
A 78-year-old man presented to his primary care physician with “fullness” behind knee. He had a history of prior endovascular AAA repair, coronary artery disease, and atrial fibrillation. He is a nonsmoker. On exam he had a 3+ popliteal pulse and 2+ PT and DP pulses bilaterally. Of note, the right great toe exhibited patchy discoloration consistent with distal embolism. Duplex ultrasound revealed a 2.3 cm popliteal aneurysm with mural thrombus and a patent flow channel. Patient was taken for angiographic evaluation and possible stent graft treatment. The images illustrate the aneurysm (left) prior to and after (right) placement of a covered stent graft into the popliteal artery. The patient did well and was discharged the following day.

Over the last 15 years, a paradigm shift has occurred in the treatment of lower-extremity atherosclerotic occlusive disease and aortic aneurysmal disease. This shift has been away from traditional open surgical techniques and toward minimally invasive endovascular treatment.

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The New World of Peripheral Vascular Disease – Percutaneous Treatment of Popliteal Aneurysm Disease

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The stimulus for this shift has been the decreased morbidity associated with minimally invasive endovascular techniques and the rapid recovery of patients and concomitant return to full functional status. This paradigm shift has now expanded to encompass the treatment of popliteal aneurysm disease.

Popliteal artery aneurysms (PAA) are the most common peripheral artery aneurysm, and have an estimated incidence of 0.1 percent in the United States. They are nearly exclusively found in males, have a tendency for bilaterality, and may be associated with aneurysmal disease in other vascular beds. Patients with popliteal aneurysms should be screened for contralateral PAA as well as aneurysms in the femoral arteries and infrarenal aorta. Up to half of all patients are symptomatic at the time of diagnosis. Symptoms are primarily ischemic, both from chronic embolism and from thrombosis. Symptoms range from claudication to limb-threatening ischemia. Less frequent symptoms include compression from large aneurysms that may affect the local nerves and veins resulting in limb pain and/or deep venous thrombosis with swelling. Popliteal aneurysms rarely present with rupture, but when they do this presentation often results in limb amputation.

The natural history of untreated PAA has been reported, and nearly all patients eventually develop symptoms and require revascularization. The longer intervention is delayed, the greater the likelihood of distal ischemic complications from the aneurysm. Distal embolization and loss of tibial outflow vessels has been reported to effect patency of revascularization. Consequent to the association with significant risk of limb-threatening complications, repair is advocated in asymptomatic patients at a diameter greater than 2 cm and for those less than 1.2 cm if there is mural thrombus seen within the aneurysm, either on duplex ultrasound or CT scan.

Saphenous vein bypass has long been considered to be the gold standard treatment for PAA. A literature review revealed the five-year primary patency of vein bypass repair of PAA to range from 77 to 100 percent. This procedure can be performed from either a posterior or medial approach, and is associated with significant morbidity related to lower-extremity incisions, wounds, and edema. Wound complication rates range from 8 percent to greater than 30 percent in reported series, and result in prolonged patient convalescence and slow return to functional status.

With the advancement of endovascular techniques, there has been increasing interest in the application of these technologies in the treatment of PAA. The first reported endovascular repair of PAA was in 1994. Early results were poor, with a high rate of graft thrombosis during short term follow-up of only 14 months. These results were likely related to the fact that at that time there were no stent grafts designed specifically for the highly mobile (flexion/extension) forces exhibited in the popliteal artery. However, since that time specific devices have been designed for this application and numerous reports have demonstrated comparable short- and mid-term patency of endovascular and open surgical repair.

Endovascular repair has been associated with significant benefits attendant to percutaneous interventions, including decreased morbidity and mortality, faster recovery, shorter hospital length of stay, and the avoidance of general anesthesia. However, debate continues as to the durability of stent graft repair of popliteal artery aneurysm disease.

At UPMC, we have reported on the largest series of popliteal artery aneurysm treatment in the world. Since 2004, we have identified 186 limbs treated for PAA disease on both an elective and emergent basis. 110 patients were treated with open surgical techniques, while 76 were treated with minimally invasive endovascular techniques. These patients were identified by retrospective chart review and their outcomes were assessed by review of both inpatient and outpatient records, as well as duplex data. The mean follow-up was five years.

The open surgical and endovascular groups were comparable based upon clinical characteristics; however, some anatomic differences were identified. The minimally invasive cohort had better-preserved tibial vessels patency, and open repair was utilized more frequently in the setting of thrombosed PAA. This reflected our selection bias of offering minimally invasive stent graft treatment for those patients with preserved tibial run-off vessels. 75 percent of patients treated with endovascular technique were treated without the need for general anesthesia and without a surgical incision (percutaneously). Evaluation of outcomes included mortality, morbidity, hospital length of stay, reintervention rate, vessel patency, and limb salvage. There were no identified differences of mortality between the two groups; however, the morbidity rate in the open repair cohort was significantly higher than that in the minimally invasive cohort (32 percent vs. 14 percent, p=0.02). Hospital length of stay was significantly shorter in the minimally invasive group (one day vs. four days, p<0.05), and the reintervention rate during follow-up did not differ between the two cohorts. The five-year vessel patency was not statistically different at 85 percent for the open repair group and 83 percent for the minimally invasive repair group (p=0.96). Limb salvage was greater than 95 percent and did not differ between the two groups.

Popliteal artery aneurysms are the most common peripheral aneurysms and often associated with abdominal aortic aneurysm disease. Treatment strategy has now shifted away from open surgical exclusion and bypass to endovascular minimally invasive therapy with stent graft placement. The majority of patients can be treated with this technique and outcomes are comparable to open bypass, but with significantly reduced morbidity, shorter length of hospital stay, and quicker return to baseline function.
Peripheral arterial disease (PAD) is a manifestation of systemic atherosclerosis that is reported to affect 4 percent of the population over 40 and 10 to 15 percent of the population over 70. In addition to the morbidity associated with limb ischemia along its spectrum of presentations, patients with PAD are at significant risk of death. In particular, patients who present with critical limb ischemia (CLI) have a yearly mortality of 20 percent. The mainstay of treatment for patients presenting with CLI is management of systemic risk factors, wound care, and revascularization using either surgical or endovascular techniques. However, for the group of patients who are not amenable to revascularization due to comorbid or anatomic considerations, the risk of limb loss is 25 to 40 percent. Nonreconstructable PAD resulting in CLI is a challenging clinical problem that has prompted significant research on alternative therapies to improve outcomes.

Therapeutic angiogenesis is an investigational approach to treat patients who have severe PAD who do not have options for surgical or endovascular reconstruction. It is based on the premise that improving capillary density in skeletal muscle will improve perfusion, and prevent the sequelae of tissue ischemia. There is data to support such a hypothesis. Muscle biopsies from patients with claudication demonstrate that increases in capillary density precede functional recovery after a regimen of supervised exercise. Eradication of tumor vascularity using anti-angiogenic agents such as Avastin® has emerged as an important treatment adjunct in cancer. Unfortunately, to date, attempts to promote angiogenesis in the setting of limb ischemia have seen less clinical success than its antagonism has seen in tumors. Over the past 20 years, various reagents and delivery methods have been tested. The field has progressed from single-agent delivery of growth factors to gene therapy, and recently to the administration of autologous tissue repair cells harvested from the iliac crest. While many reports on therapeutic angiogenesis in the literature are single-center experiences, a few agents and delivery mechanisms have been rigorously tested in multicenter, double-blinded, randomized, controlled trials. These will be reviewed in the following report.

Given its contemporaneous identification as a growth factor for tumor vessels, vascular endothelial growth factor (VEGF) was a logical choice to test for its efficacy in promoting angiogenesis in ischemic limbs.

In 1996, Dr. Jeffrey Isner and colleagues administered a plasmid encoding VEGF via angioplasty balloon to the popliteal artery, demonstrating the development of proliferative endothelium distally on the leg in the form of angioma. The patient also developed edema, consistent with VEGF’s known role in increasing vascular permeability.

Follow-up studies of VEGF therapy during this time were largely single-center experiences showing some benefits in patient with Buergers disease and claudication. In 2003, the results of a double-blinded, placebo-controlled, randomized trial evaluating the efficacy of VEGF-121 adenovirus delivery to the ischemic limbs of claudicants were published (the RAVE study). A total of 105 patients were enrolled. Study drug or control solution was injected into the ischemic limb in 20 locations and patients were evaluated at 12 and 26 weeks. Despite the promising results of smaller studies, this well-designed study confirmed no difference between placebo and VEGF therapy on ankle brachial index (ABI), peak walking time (PWT), or quality of life.

Two other important growth factors were also tested for their efficacy in improving angiogenesis in limb ischemia. One is fibroblast growth factor (FGF), which has been delivered in a recombinant protein form and as DNA. The other is hepatocyte growth factor (HGF) which is known to cause upregulation of VEGF. The TRAFFIC study, reported in 2002, evaluated the benefit of intra-arterial administration of basic fibroblast growth factor (bFGF) in patients with intermittent claudication (IC).

The initial results appeared promising: 190 patients were enrolled, and 174 completed the study. bFGF improved peak walking time over placebo (1.77 minutes vs. 0.6 minutes, respectively), suggesting a possible benefit. However, similar success was not achieved when bFGF was administered for coronary artery disease, in part due to unfavorable pharmacokinetics. The enthusiasm for bFGF therapy in protein form waned, but its delivery as DNA was still investigated. In TALISMAN, a Phase II study to evaluate safety and efficacy, patients were randomized to receive NV1FGF, a plasmid containing FGF DNA, or injections of a control solution into the ischemic limb. NV1FGF was found to improve amputation-free survival over a one year period despite no difference in wound healing at 25 weeks. In another disappointing confirmatory trial, TAMARIS, a Phase III study to evaluate the benefit of NV1FGF, there was no difference in the one-year amputation and death in patients who received plasmid or placebo.

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Cutting Edge Therapy: Therapeutic Angiogenesis for Critical Limb Ischemia (Continued from Page 3)

Hepatocyte growth factor (HGF) is another agent that has been tested in a Phase II trial for patients with CLI (rest pain, ulcer, or gangrene). The results were published in Circulation in 2008. Administration of HGF–encoding plasmid was found to be safe and resulted in improved TcPO2, a surrogate for tissue perfusion. There was no difference in wound healing and amputation rates, although the authors report that the study was not powered to test those parameters. Of the growth factors that have been rigorously tested, HGF appears to have the most promise.

Recently, there has been a strong interest in the administration of autologous tissue repair cells harvested from the patient’s own bone marrow. The benefits include the avoidance of off-target angiogenesis that can occur with growth factors, although none of the randomized trials described above reported increased rates of tumor growth or retinopathy in the growth factor-treated patients. Another benefit of cell-based therapies is that they likely target many functions, as opposed to single-agent treatments. The downside associated with cell-based therapies is that the process of harvesting the cells in clinical trials requires anesthesia. The results of RESTORE-CLI, a multicenter, double-blinded, placebo-controlled, randomized trial to assess the benefit of TRCs in critical limb ischemia, were reported in 2011. Interim analysis demonstrated a prolonged time to treatment failure, defined as amputation, death, or doubling of wound size, in the TRC treated patients compared to controls. As a result, the study was stopped and the sponsoring company, Aastrom, is in the process of designing Phase III studies. The treatment requires bone marrow aspiration, enrichment of the proliferative fractions of the harvested cells, and administration of that enriched fraction directly into ischemic tissue. Treatment with TRCs appears promising, even if the process is arduous.

In summary, treatment of patients with critical limb ischemia who are not candidates for revascularization remains a challenging problem. While therapeutic angiogenesis appears theoretically possible, the results to date have not been overwhelmingly positive. Nonetheless, new therapies hold great promise to help this difficult group of patients.

Immediate-Access Dialysis Grafts

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The National Kidney Foundation expert panel supports the arteriovenous fistula (AVF) as the access of choice, followed by an arteriovenous graft (AVG) as a second option, acknowledging poor mid- and long-term outcomes and multiple associated re-interventions. While this initiative has been challenged for certain subgroups of patients (for example, elderly, life expectancy less than two years), there is no controversy on the need to limit central venous catheters (CVC), given their high rate of complications, most notably infection and central venous stenosis, suboptimal flow, and higher associated mortality.

To support the decision to use an AVG, there is a wide variety of products in the market, most commonly based on expanded polytetrafluoroethylene (ePTFE). While PTFE is available in various configurations, including cuffs or hoods at the venous outflow, graft tapering, external wraps and heparin bonding, there is no hard evidence to indicate any advantage of one over the other in improving patency or the longevity of the access. Since all traditional AV grafts require an in-situ maturation for two to four weeks before being accessed, patients also need a CVC until the graft can be used. The concept of an immediate-access AVG is intriguing because reducing the time to catheter removal or avoiding catheters altogether could have a positive impact. Also, as our dialysis population lives longer, patients may come to have very limited access options. Some have only one patent outflow vein, and so do not have the option of a catheter while a new access matures. The impact of immediate-use grafts could result in a reduction in infections, improving mortality and morbidity, and possibly reducing the incidence of central vein stenosis.

The first reports about early cannulation grafts were published in the 1980s but entered clinical practice over the past decade, the most popular one being the Vectra® trilayer graft (C.R. Bard Inc., Murray Hill, N.J.), made of a proprietary blend of segmented polyetherurethanea and a siloxane containing a surface-modifying additive. Early reports showed that, beyond early cannulation, this graft conferred no additional benefit compared to standard ePTFE grafts. A later study comparing the Vectra graft to transposed brachio-basilic vein (BBV) autogenous access showed that aggressive graft surveillance and endovascular treatment methods resulted in equivalent long-term secondary patency rates (Vectra 83 percent and BBV 87 percent at 18 months), but at the cost of more frequent secondary interventions and a potential higher risk of graft infection for Vectra patients.
The Flixene™ vascular graft (Atrium Medical Corporation, Hudson, NH) is a trilaminate ePTFE vascular graft that has been in the U.S. market since 2006 and can be accessed within 72 hours after implantation. Current literature supports its equivalent (if not better) secondary patency compared to standard PTFE graft, ranging from 73 to 77 percent at 12 months and 51 to 55 percent at 18 months, without a higher risk of infection. A comparative study with BBV autogenous access showed equivalent patency (Flixene 55 percent and BBV 51 percent at 18 months), but as with the VECTRA graft, at the cost of frequent reinterventions.

The most recent entry in the field is the Gore® Acuseal vascular graft (W.L. Gore & Associates Inc., Flagstaff, Ariz.). This is a trilayer ePTFE graft composed of an inner layer of ePTFE bonded with heparin. It can be accessed within 24 hours. A prospective, nonrandomized, multicenter U.S. clinical trial was completed last year and demonstrated a six-month secondary patency of 84 percent, comparable to that of other AVG historical controls. Two small recent series reported a six-month secondary patency of 93 percent and 59 percent with no graft infections.

From a technical perspective, compared to standard AVGs, immediate-access grafts merit some comments regarding tunneling, anastomosing, and puncturing. Because they are thicker, a slightly larger tunneling tip (for example, 8 mm for a 6 mm graft) needs to be used. Sewing of these grafts to the vessels, though not mechanically different, must incorporate all three graft layers. Typically, the suture line bleeding is minimal. Suggested guidelines for accessing immediate-access grafts include prepping the cannulation site, having the nurse wear sterile gloves, and using a 17-gauge dialysis needle for the first three sessions within the first two weeks of implantation, whichever comes first. The literature suggests using lower flows, up to 250 mL/min, as opposed to high flows of up to 400 mL/min, which can be used after the graft has fully matured.

In conclusion, the use of immediate-access grafts has the potential to shift the paradigm of catheter usage. This may be done by either early access of the graft after implantation and removal of the present catheter within 24 hours, with catheter avoidance by cannulizing the graft immediately after placement, or by using a sole venous outflow. The expectations for mid- and long-term patency, reintervention, and complication rates should not be different from those for standard PTFE grafts. Continued experience with these grafts allows for more aggressive and creative approaches, such as incorporation of a HeRO® graft, in complex patients with extensive venous occlusion. They are undoubtedly an additional instrument in our armamentarium.

Case Report
The patient was a 53-year-old diabetic male with end-stage renal disease on dialysis for more than 10 years. He was obese and a bilateral amputee with known antiphospholipid syndrome and ulcerative colitis. He had peritoneal dialysis in the past that was eventually abandoned following repeated episodes of peritonitis. He had several prior accesses in his bilateral upper extremities and stents at his superior vena cava (SVC), eventually leading to bilateral chronic subclavian and internal jugular vein occlusions as well as SVC occlusion. (Figures 1a, 1b). He also had multiple lower-extremity DVTs, and in association with several groin tunneled dialysis catheters he had inferior vena cava occlusion. He had been dialyzing through a left-groin CDC (tip placed in a patent left renal vein) for the past few months until it stopped working, and following several failed attempts to replace it he was transferred to UPMC Presbyterian hospital. He received a transhepatic CDC that worked for a few days and soon failed, leaving him with no further options for dialysis. Palliative care was involved. After performing a venogram and confirming patency of his right brachial and axillary veins (Figures 1c, 1d), we decided to place an immediate cannulation right forearm loop brachio-brachial graft. At the end of the procedure, he had a pulsatile thrill over his medial arm. He received dialysis 16 hours later uneventfully and was discharged on Coumadin® and aspirin. It was a life-saving procedure. Over a 12-month course, his graft thrombosed and was thrombectomized successfully three times, all three either because he had to discontinue his Coumadin for another procedure or because the INR was not appropriately monitored and dropped below 2. (Figure 2). Further thrombectomies were abandoned because a new transhepatic CDC was eventually placed, and this has been functioning well so far.
Advances in Management of Carotid Artery Stenosis

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Ischemic stroke related to extracranial carotid disease accounts for up to one-third of all strokes. Risk factors for carotid occlusive disease include all of the known risk factors for systemic atherosclerosis: smoking, hypertension, hypercholesterolemia, and diabetes. Most patients will undergo duplex ultrasonography of their carotid arteries when a bruit is heard on physical examination (sensitivity and specificity of bruit on physical exam is only in the 60 percent range for representing a significant carotid stenosis) or when they possess two or more risk factors, as outlined above, or if they have known coronary or peripheral arterial disease. Patients who present with hemispheric symptoms, such as expressive aphasia, monocular blindness (amaurosis), or contralateral extremity numbness, weakness, or paresthesias need to be immediately evaluated for stroke with appropriate imaging, including noncontrasted head CT. If other causes of stroke are ruled out, and duplex demonstrates a significant extracranial internal carotid stenosis, then treatment is tailored based on the patient and individual risk factors.

Medical management of carotid disease, whether symptomatic or asymptomatic, is the key to long-term success to avoid progression and/or recurrence following intervention. The cornerstones of medical management of carotid stenosis include aggressive attempts at smoking cessation, statin therapy with a target low-density lipoprotein level to lower than 100mg/dL (lower than 70mg/dL if the patient has known coronary artery disease (CAD) or peripheral artery disease (PAD)), and glycemic and blood pressure control. Patients are placed on anti-platelet treatment with aspirin as well. Clopidogrel is added to patients who have had recent symptoms and dual antiplatelet therapy is often applied in these patients who typically have concomitant coronary disease.

Surgical treatment of symptomatic carotid stenosis along with medical therapy has been shown to be more effective than medical management alone. This was demonstrated in patients with lesions ranging in the 70 percent to 99 percent range in randomized controlled trials performed in a few decades ago in both Europe and North America (European Carotid Surgery Trial and North American Symptomatic Carotid Endarterectomy Trial). In the category of patients with hemispheric transient ischemic attack (TIA) or stroke, treatment should occur within the first two weeks of symptom onset, unless the patient has a large infarct or significant residual deficit.

In those cases, treatment is usually performed four to six weeks after plateauing of symptoms and/or recovery has occurred. Another option for treating symptomatic patients is carotid stenting. This was similarly evaluated in a randomized fashion in the CREST (Carotid Revascularization Endarterectomy Versus Stenting Trial) study most recently. Current meta-analyses of the large carotid stent versus endarterectomy trials in symptomatic patients fail to clearly demonstrate any significant difference in ipsilateral stroke risk, death, or myocardial infarction. There have been higher periprocedural stroke rates identified in older (greater than age 80), females, and symptomatic patients in patients undergoing carotid stenting versus endarterectomy. Therefore, given current data, carotid stenting is typically reserved for patients with anatomically high-risk carotid lesions or recurrent lesions following prior endarterectomy, those with prior neck operations or neck radiation, or patients who are truly a prohibitive cardiac risk for endarterectomy. This is an area of treatment in evolution and is the subject of ongoing trials.

Asymptomatic patients with moderate carotid stenosis present another subgroup of patients that demand an evolving treatment paradigm. With the emergence of statin therapy and improved aggressive medical management of systemic atherosclerosis, there is renewed interest in studying optimal medical management in this group of patients. In patients with severe asymptomatic stenosis, there is good clinical evidence to suggest that with a reasonable life expectancy and low perioperative risk (less than 3 percent in total), carotid endarterectomy can provide a reasonable risk reduction. Subgroups with asymptomatic high-grade stenosis, including women and patients older than 80, should be considered carefully, given that the relative risk reduction was less in these populations than others in the original trials (Asymptomatic Carotid Atherosclerosis Surgery study).

Postintervention surveillance is critically important in both patients who undergo carotid endarterectomy or stenting. Duplex ultrasonography is used as a valuable tool to detect recurrent disease and hyperplastic lesions, especially in the first year postoperatively. Medical management to optimize blood pressure control, lipid profile, glycemic control, and smoking cessation should be an ongoing part of the overall treatment strategy in these challenging patients. Vascular surgeons have played and continue to play a critical role in the surgical and endovascular management of carotid disease. There is an interest in doing this in a collaborative manner with patients and their medical physicians, because the ultimate treatment for atherosclerosis is prevention.
Within UPMC and internationally, vascular surgeons have been actively involved in past and ongoing trials studying various treatment options for carotid disease. Because vascular surgeons are in a unique role and possess the tools to offer both open and endovascular therapy in addition to duplex surveillance, they play an increasingly important role in helping individualize patient care, especially in complex situations. Yet another area of interest is identifying features of so-called “vulnerable” carotid plaque that make it easier to predict which carotid plaque will result in TIA/stroke and which is more stable. This may help further clarify which patients would benefit most from surgical or endovascular intervention versus medical management alone.

**Case Study**

A 73-year-old, right-handed woman with a history of remote tobacco use, diabetes, hypertension, and hypercholesterolemia presented with two episodes of right arm weakness and expressive aphasia that resolved. She was placed on Plavix® in addition to the aspirin that she had been on previously, and was admitted to the hospital. It was evident on her head CT that she had had an acute stroke. She also had evidence of a hemodynamically significant stenosis at her left internal carotid artery on her carotid duplex, with just mild disease on the contralateral side. Because her duplex identified slightly aberrant anatomy, she underwent a CT angiogram of the neck and head. This demonstrated a retropharyngeal location of both internal carotid arteries and very high bifurcations of both carotids in addition to significant tortuosity. For these reasons, there was a discussion with the patient and her family regarding management options for this symptomatic carotid stenosis. In addition to her medical management with dual antiplatelet therapy and blood pressure control, she was maintained on her statin medication. Left carotid endarterectomy was discussed, but carried with it a high risk of cranial nerve injury, given the anatomically aberrant location of the carotid bifurcations. The option for a stent was discussed with the patient in light of her anatomic challenges. The risk of stroke, given the location and symptomatic nature of the plaque, was discussed extensively with the patient. However, the risk of stroke with medical management alone was higher than proceeding with endarterectomy or stent.

Therefore, she underwent cerebral angiography via a right femoral approach under local anesthesia in an effort to monitor her neurologic status throughout the course of the procedure. An embolic protection device was negotiated through the lesion and the tortuous anatomy, and a stent was deployed across the stenotic symptomatic lesion (Figure 1).

The patient did very well postoperatively and was discharged home the next day. She underwent duplex at one month postoperatively which demonstrated a widely patent stent. She remains on dual antiplatelet therapy and her statin, and will follow with us regularly for stent surveillance.
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