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Carotid Angioplasty and Stenting Using Novel Cerebral Protection Technology of Flow Reversal and Direct Carotid Access

Rabih A. Chaer, MD
Professor of Surgery, UPMC Division of Vascular Surgery
Chief of Vascular Surgery, UPMC Presbyterian

Stroke continues to be a major public health concern, with more than 750,000 strokes occurring per year in the United States, making it the third most common cause of death and the leading neurologic cause of long-term disability. The majority of strokes are ischemic in nature, and up to 20 percent of ischemic strokes are a result of carotid artery atherosclerotic disease. Treatment of carotid artery stenosis is aimed at preventing ischemic events caused by embolization of components of atherosclerotic plaque, and less commonly, by hemodynamic compromise secondary to progression to occlusion of a previously narrowed but patent internal carotid artery.

Management of carotid occlusive disease continues to evolve and best practices currently include medical therapy with antiplatelet and lipid lowering therapy, as well as carotid revascularization in selected patients.

Carotid endarterectomy (CEA), first introduced in the 1950s, was established as the gold standard for treatment of carotid stenosis by several landmark trials in the 1990s. More recently, carotid

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Drug-Eluting Balloons in Peripheral Angioplasty

Eric Hager, MD
Assistant Professor of Surgery, UPMC Division of Vascular Surgery

Case Report

A 75 year old patient presented to the office with gangrenous changes in his right great toe. He had significant coronary artery disease with a recent myocardial infarction and was relatively debilitated. His noninvasive testing suggested superficial artery occlusive disease with an ankle brachial index that suggested severe arterial insufficiency. He was brought to the angiography suite for revascularization as he was stratified as high surgical risk for bypass surgery.

His angiogram (Figure 1) showed a flush occlusion of the superficial femoral artery at its origin with reconstitution in the distal thigh and preserved below knee vessels. The flush occlusion was not able to be crossed with a wire from above and we accessed the vessel in a retrograde manner through the dorsalis pedis artery in the foot. We were able to successfully cross the occluded femoral artery from below. We did not elect to place a stent due to the proximity of the profunda femoris artery and the fear we would partially cover this critical artery. Instead we performed a primary balloon angioplasty using a drug-eluting balloon (DEB). The completion angiogram showed brisk runoff through the superficial femoral artery (Figure 2) and preserved runoff into the foot with palpable pulses. The gangrenous toe was amputated and over the following month healed without difficulty. Several duplex exams over the next year revealed a widely patent superficial femoral artery without evidence of restenosis.

Overview

Lower extremity peripheral arterial disease is a common diagnosis seen in approximately 30 percent of patients over the age of 50 who smoke or have diabetes[1]. The treatment of PAD has evolved with new technologies and most practitioners are utilizing endovascular techniques as a first line therapy for occlusive disease. The anatomic location of the arterial occlusion typically dictates the modality used during treatment. Despite proven efficacy and safety, restensosis rates remain high in patients treated with angioplasty alone[2]. In patients with long lesions, restenosis rates have been shown to be has high as 70 percent in the infrapopliteal arteries leading to high reintervention rates. Stents are typically placed either primarily or as a bailout to balloon angioplasty (i.e., flow limiting dissection, poor initial response to angioplasty). Stent implantation is not without risk as the metal is subject to fatigue and, with continuous stress, can lead to fracture and occlusion. In addition, there are certain anatomic areas where stent placement may become problematic due to flexion of a joint or proximity to the origin of a main arterial branch. Because of the long-term problems associated with stents, many practitioners avoid stenting when possible. Drug-eluting balloons have recently become widely available in the United States and are being used with increased frequency.

Drug-eluting balloons utilize paclitaxel-coated delivery balloons to deliver the chemotherapeutic agent directly to the arterial wall which has been shown to inhibit neointimal hyperplasia and reduce restenosis rates[3]. Theoretically this allows for the expanded use of balloon angioplasty and reduces the frequency of stent placement. The technique for deployment of the balloon is slightly different than traditional angioplasty balloons. In order to maximize the drug uptake in the target artery, most interventionists advocate aggressive predilation with a traditional balloon. The DEB is then advanced through the sheath rapidly to minimize the drug loss in transit. Once in position, the balloon is insufflated for a three minute duration which will allow maximal contact and uptake.

There have been several studies that compare DEB to traditional angioplasty in femoral-popliteal disease[4,5] which show a statistically significant improvement in restenosis rates at 12 months in patients

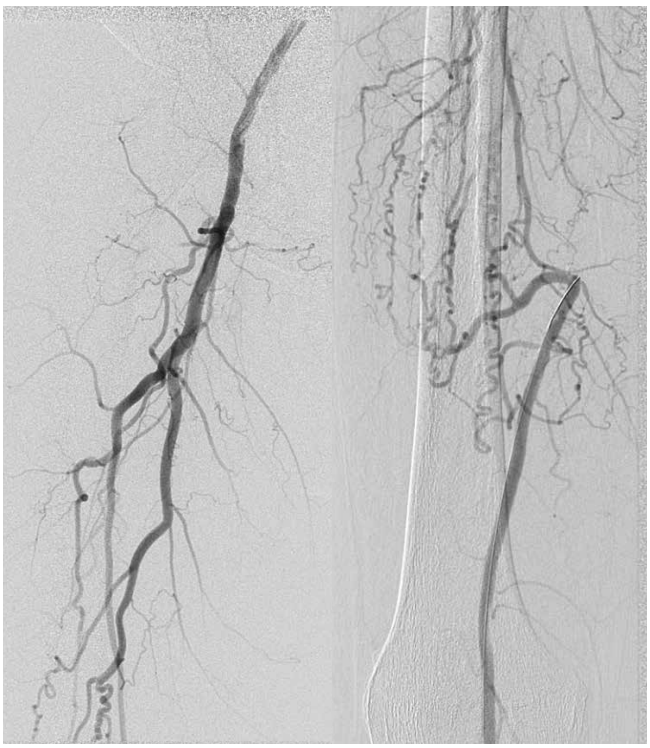

Figure 1:
Angiogram showing flush occlusion of the superficial femoral artery with reconstitution in the mid thigh.

treated with a DEB (Figure 3)[6]. In 2012, Fanelli and colleagues randomized 50 patients with 122 lesions (96 stenosis and 26 occlusions) to either a DEB arm or conventional angioplasty balloon (AB). The purpose was to study the response to multilevel disease. They found a significant (P<.05) improvement in binary restenosis rates as well as amputation rates with DEB compared to AB[5] . In a recent meta-analysis by Cassese et al., comparison between DEB angioplasty versus PTA alone for femoral-popliteal disease demonstrated significant reduction in angiographic restenosis at 10.3 months (18.7 percent vs. 45.5 percent; or, 0.26; P<.00001)[7]. Overall the improvement in binary restenosis rates with DEB has led to a decline in the number of interventions for restenosis. Although drug eluting balloons are more costly to use, their increased utilization has been shown to decrease overall cost due to the reduction in the number of reinterventions. A recent cost analysis of patients treated with a DEB versus traditional balloon showed an estimated 24-month Medicare cost to be $10,214 versus $13,114 respectively[8].

The case presented here involved a debilitated patient who was deemed unfit for surgical bypass. He suffered from a flush occlusion of the superficial femoral artery and stenting would have partially covered the profunda femoris artery which may have resulted in significant long term morbidity should restenosis occur. We successfully treated this occlusion with a drug-eluting balloon and he has healed his wound with no evidence of restenosis after a year of surveillance.

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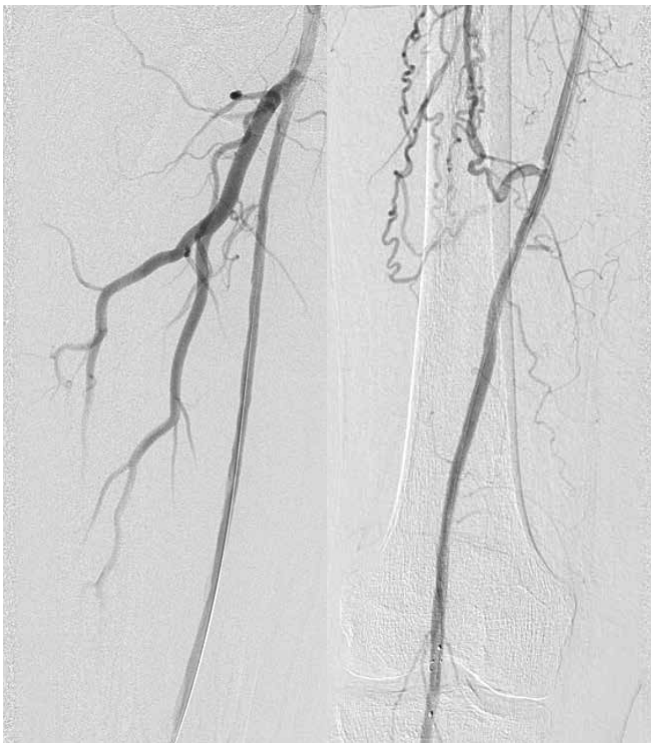

Figure 2:
Completion angiogram showing recanalized superficial femoral artery after DEB angioplasty.

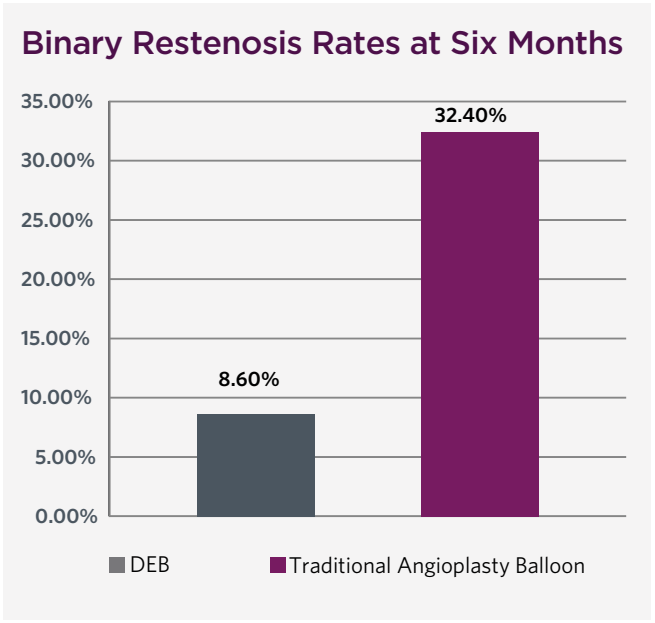

Figure 3:
Kaplan-Meier survival of target lesion revascularization comparing DEB to uncoated balloon angioplasty. Adapted from: Werk M., et al. Paclitaxel-Coated Balloons Restenosis After Femoro-Popliteal Angioplasty: Evidence from the Randomized PACIFIER Trial. Circ Cardiovasc Interv 212;5:831-840.

Improved Outcomes for Vascular Surgery Patients on Statins

Mohammad H. Eslami, MD, MPH
Professor of Surgery, UPMC Division of Vascular Surgery

Elevated total serum cholesterol and low density lipoprotein (LDL) cholesterol are independent risk factors for the development of peripheral arterial disease (PAD) while high density lipoprotein (HDL-C) cholesterol is protective. In a study of subjects enrolled in the Physician Health Study, the total cholesterol: HDL-C ratio and C-reactive protein were the strongest independent predictors of the development of PAD. Since then, there have been many other studies that showed that a significant reduction in the total cholesterol will improve survival among patients with PAD. Contemporary studies have acknowledged the well-established benefit of cholesterol reduction but the recent focus is on the use of the class of agents with the most robust benefit: -3-hydroxy-3-methyl-glutaryl-coenzyyme A, also known as the statins. In a study of more than 20,000 high-risk patients, the administration of 40 mg/day of simvastatin decreased cardiovascular morbidities and mortality among patients with PAD by 25 percent over a five year period. Other cardioprotective medications have shown significant protection from cardiac morbidity and mortality among PAD patients but statins had the highest protective effect. The effects of statins may be beyond the cardioprotective and lipid-reducing effects of these medications (Figure 1). Multiple studies on patients with claudication, for example, have shown significant beneficial effects of statins on the quality and quantity (pain-free distance) of walking. Potential mechanisms of statins that may be associated with improved leg function include decreased atheromatous burden, improved angiogenesis, decreased inflammation, and improved endothelial function[1].

The use of statins has been shown to lead to a four-fold decrease in mortality after vascular procedures. The most common fatal complication after peripheral vascular procedures is related to myocardial infarction (MI). The exact pathophysiology of this is unknown but fatal MI is probably

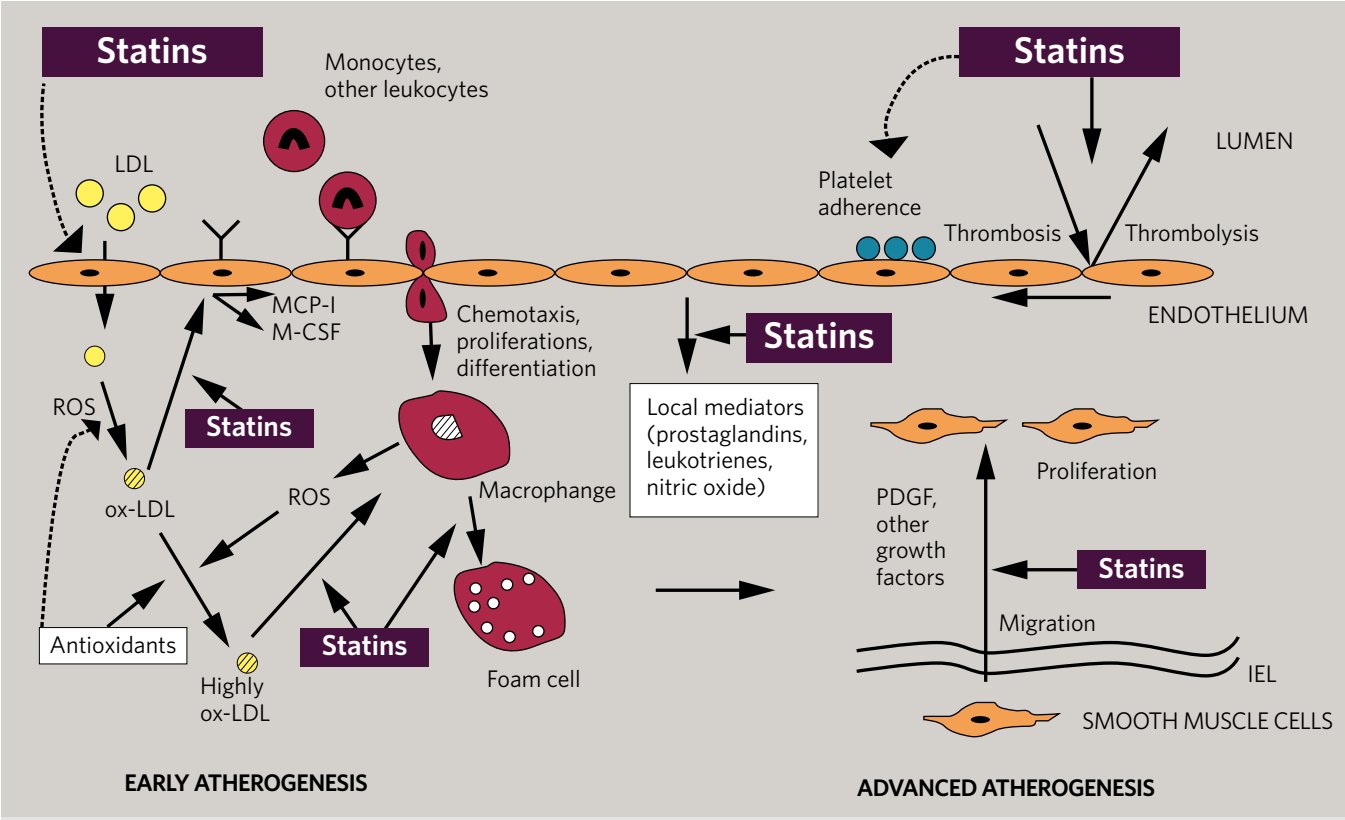

Figure 1:
Multiple effects of statins on cardiovascular components [Adapted from Stancu C, Sima A. Statins: Mechanism of action and effects. J Cell Mol Med 2001;5:378-87.].

related to coronary plaque rupture, which leads to thrombus formation and subsequent coronary artery occlusion. Statin use has been shown to be associated with a reduced risk of major adverse cardiovascular events including myocardial infarction, stroke, and death at five years after bypass for chronic limb ischemia (CLI).

The effects of statins on stroke prevention have been somewhat difficult to decipher. It has been suggested that a "U-shaped" relationship exists between blood lipid levels and stroke with high stroke rates at both very low and very high lipid profiles. Despite discrepancies regarding the causative relationship of dyslipidemia in stroke, some interventional trials with statins, mainly in high-risk patients with cardiovascular disease, do show a significant decrease in the stroke rate and relative risk reductions of stroke ranging from 20 to 30 percent. Several possible mechanisms implicated in the benefit of statins in stroke prevention have been the retardation of plaque progression and the stabilization and reduction of coronary events. The benefits of statin use on limb outcomes are less certain as no effect was seen on one-year limb outcomes after bypass for CLI, but other studies have shown improvement. The periprocedural use of statin therapy was associated with reduced risk of major amputation and death, and improved patency was seen after percutaneous intervention in CLI.

The benefits of statin use come at a very reasonable cost. It is estimated that daily cost of 40 mg simvastatin is about $1. Among patients with a cardiovascular history, maintenance on statins reduced the estimated U.S. costs of hospitalization due to new vascular events by 20 percent leading to significant cost saving with significant cost per life year gained among these patients.

Given the significant body of evidence, the American Heart Association (AHA) and the American College of Cardiology (ACC) have developed careful guidelines for statin therapy. These guidelines recommend use of statins with any individual with atherosclerotic cardiovascular disease (ASCVD), individuals with primary elevations of LDL-C ≥ 190 mg/dL, individuals between 40-75 years of age with diabetes and LDL-C 70-189 mg/dL without clinical ASCVD, and even among individuals without ASCVD or diabetes who are 40-75 years of age and have LDL-C 70-189 mg/dL, who have an estimated 10-year ASCVD risk of ≥ 7.5 percent.* Provided that patients can tolerate statin therapy and there are no contraindications to therapy, high-intensity therapy is recommended for patients younger than 75 with clinical ASCVD whereas moderate- intensity therapy is recommended for patients older than 75 years of age or those with statin intolerance ASCVD. AHA/ACC guidelines define high-intensity statin therapy as daily use of atrovastatin 40-80 mg or rosuvastatin 20-40 mg. These guidelines define moderate intensity statin therapy as daily use of 20-40 mg simvastatin or 10-20 mg of atorvastatin. Initiation of statin therapy requires careful evaluation of laboratory tests (fasting lipid panels as well as blood CK and ALT levels) and careful exclusion of secondary causes of hyperlipidemia which include patient's diet, drugs (e.g. estrogens, diuretics, amiodarone, beta-blockers), diseases (e.g. biliary disease, renal failure, and nephrotic syndrome), and metabolic disorders (e.g. hypothyroidism, diabetes). The AHA and ACC recommend close monitoring of the patients who are started on statin therapy. This requires a second lipid panel at four to 12 weeks after the initiation of statin therapy and subsequent follow up panels every three to 12 months. Treatment is considered successful if LDL-C reduction of ≥ 50 percent from baseline or 30 to 50 percent from the baseline is observed for high-intensity and moderate intensity regimens, respectively. The most current recommendations have shifted focus from an LDL-C of less than 100 mg/dl in those with clinical ACSVD—including PAD—to assuring the use of moderate- to high-intensity statin therapy in these patients.

Despite these guidelines, only one third of patients with PAD are taking statins, based on recent data from the National Health and Nutrition Examination Study. The Society for Vascular Surgery (SVS) has adopted a very aggressive posture towards statin therapy to improve these numbers and survival of PAD patients. In 2011, for example, SVS launched the Vascular Quality Initiative (VQI), which was built on foundations created by the Vascular Study Group of New England to improve the quality of care for patients who undergo vascular interventions. As of 2016, there are 377 centers and 2,929 physicians who participate in this initiative. It is interesting to note that vascular surgeons compose only 41 percent of participating physicians in VQI. One of the most important quality initiatives undertaken by VQI is called "optimizing discharge medications," in which the percentage of patients discharged on statins and antiplatelet medications are reported to the participating physician or center. It has been observed that participation in the VQI is associated with improved medication use and improved survival. UPMC is a participating center in the VQI and its physicians, appreciating the significant importance of statin use in patients with vascular disease, consistently reach the goal of discharging more than 90 percent of their patients on statins.

*10-year risk prediction can be calculated using the Pooled Cohort Equations for ASCVD risk prediction.

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Further Reading Suggestions

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Suction Thrombectomy for Iliocaval or Atrial Thrombus, Pulmonary Embolism, and Septic Vegetations

Rabih A. Chaer, MD
Professor of Surgery, UPMC Division of Vascular Surgery
Chief of Vascular Surgery, UPMC Presbyterian

Efthymios D. Avgerinos, MD
Assistant Professor of Surgery, UPMC Division of Vascular Surgery

Catheter-directed pharmacologic and mechanical techniques for treating venous thrombus and recanalizing large thrombosed veins or pulmonary arteries have been increasingly used over the past decade with successful outcomes. However, when the thrombus is large, subacute, or chronic, it is challenging, if at all feasible, to achieve good clinical outcomes; in addition, lytic therapy is associated with bleeding risks, particularly in patients with contraindications (e.g. recent surgery or stroke, advanced malignancy, etc.), which limit the safety and effectiveness of standard catheter-directed techniques. The AngioVac® System (AngioDynamics, Inc. Latham, N.Y.) has emerged as an intravascular aspiration tool indicated for removal of large thrombus burden within the iliac, caval, atrial, ventricular, and pulmonary arterial tree. The technology rapidly evolved to include removal of any intravascular material including tumors and septic vegetations. This article reviews this novel technology and its applications.

The AngioVac Aspiration Thrombectomy Device

The AngioVac System is manufactured by Vortex Medical for AngioDynamics, and is approved by the U.S. Food and Drug Administration (FDA) "to remove fresh, soft thrombi or emboli during extracorporeal bypass for up to six hours."

The AngioVac device consists of a large-bore 22-F suction cannula with a balloon-actuated, expandable, funnel-shaped tip that opens up to 48-F. This tip serves as the suction end of a veno-venous non-oxygenating bypass circuit that filters removed blood and returns it through a pump to the venous system via a separate 18-F reinfusion cannula (extracorporeal bypass) (Figure 1).

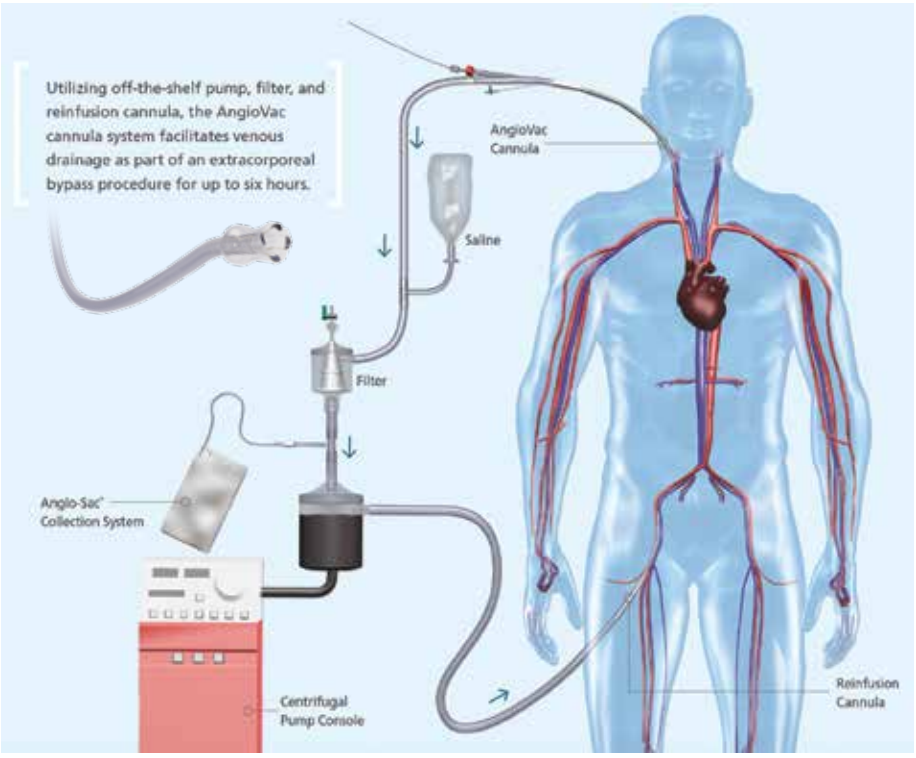


Figure 1:
The AngioVac System. Utilizing an off-the-shelf pump, filter, and reinfusion cannula, the AngioVac cannula facilitates venous drainage as part of an extracorporeal bypass procedure for up to six hours.

With the patient under general anesthesia, the AngioVac suction cannula is percutaneously introduced through the femoral or jugular vein over a stiff wire and advanced to the area of interest under direct fluoroscopic and, when appropriate, transesophageal echocardiographic guidance. Additional femoral or jugular vein access is obtained for positioning the reinfusion catheter.

Blood is suctioned from the patient via the AngioVac cannula, circulated through the pump generating flow rates of up to four liters per minute (2,500-4,000 RPM), then returned directly to the patient via the reinfusion catheter. The AngioVac cannula is placed in apposition to the intravascular debris or clot and then repeatedly advanced and withdrawn. Progress is actively monitored by transesophageal echo and usually sudden en bloc disappearance of large filling defects is witnessed. Hemodynamic status is monitored closely by the anesthesiologist. The aspirant is collected in a filter trap.

Iliac and Caval Thrombus

Inferior vena cava (VC) thrombosis is a common finding in patients with proximal iliofemoral deep vein thrombosis (DVT), estimated to occur in 22 percent of cases, mainly as a result of thrombus propagation. Caval thrombosis may otherwise occur in situ due to a congenital anomaly or external compression, or due to the traditional DVT risk factors (e.g. malignancy, hypercoagulable disorders). Quite frequently though, caval thrombosis occurs due to an indwelling IVC filter with a reported incidence among last decade's filter generation of five to 30 percent. Catheter-associated thrombus in the inferior or superior VC is also seen in hospitalized patients and it sometimes trails into the right atrium (see next section). Acute caval thrombus puts the patient at a higher risk for clinically significant pulmonary embolism (PE). Not infrequently, the thrombus may be infected and a source of sepsis requiring immediate removal.

Several techniques have been developed over the past 20 years to treat symptomatic iliocaval thrombosis, the most popular one being pharmacomechanical thrombectomy. In patients with large thrombus burden, particularly when subacute or with a chronic component, and/or contraindications to thrombolytic therapy, the AngioVac device is an alternative that can be safer and more efficient.

The two largest series to date reported their AngioVac experience with 11/15 and 10/16 cases involving the inferior VC. Both series demonstrated a 100 percent success rate with no major complications.

There are also reports that what was thought to be thrombus proved to be intravascular neoplastic tissue. Removal with the AngioVac allows filtered specimens to be sent to pathology, something that traditional smaller thrombectomy devices do not.

Atrial Thrombus and Pulmonary Embolism

Thrombi-in-transit represent a right heart thrombus that is traveling from the venous system to the lung. While rare it can be life threatening, particularly when mobile (Type A) and when associated with PE. The optimal therapy for thrombi-in-transit remains controversial. Open thrombectomy is recommended when associated with massive PE, but the management is controversial when the thrombus is associated with submassive PE or it is an echocardiographic finding in an otherwise asymptomatic patient. Systemic thrombolytics can cause hemorrhage or fragmentation and dislodgment of the thrombus; catheter directed thrombolysis requires crossing wires through the right heart and may also result in dislodgment of thrombotic material and further hemodynamic instability; and open thrombectomy may be too high risk for a patient with multiple comorbidities. Vacuum thrombectomy using the AngioVac suction cannula is an attractive modality, allowing complete en bloc removal of the right atrial thrombus and potentially avoiding a high-risk surgical procedure. Once the main bulk of the thrombus is removed and there are PE signs of right heart strain with or without hemodynamic instability, catheter-directed thrombolysis can be used.

More than 20 cases have been reported in the literature and the technical success rate is roughly 90 percent, with failures reported when the mass is tightly attached on the atrial wall or when the vacuum needs to be navigated through the tricuspid valve.

For patients with PE and right ventricular strain, predominately for those with hemodynamic instability and some selected ones without, intervention with thrombolysis or embolectomy is indicated to prevent death. When the risk of bleeding (e.g., recent surgery or recent stroke) precludes the use of thrombolytics, or the patient is deemed as high surgical risk catheter-based embolectomy prevails as the most acceptable treatment option.

Few reports are published on pulmonary artery thrombus aspiration using the AngioVac System and the results are mixed. Excluding some successful case reports, the two largest series reported a technical success of 33 percent (1/3) and 40 percent (2/5) with major complications and high mortality. The limited tractability of the rigid cannula and the associated complications have raised concerns for its use in the pulmonary arteries, but it still can be a reasonable alternative for these high-risk patients, when open surgery is not an option.

Vegetations

Infection of leads or vegetation formation is one of the major adverse effects after insertion of a cardiovascular implantable electronic device (CIED). Complete device and lead removal is recommended for all patients with definite CIED infection involving lead endocarditis. Management of patients with a large lead vegetation (>2 cm) is still in debate. Open thoracotomy is generally reserved for refractory and unstable patients who failed standard percutaneous techniques. Alongside, standard endovascular techniques have been associated with a 34 to 55 percent risk of septic pulmonary embolism.

The use of the AngioVac System to debulk large lead vegetations has been recently reported with successful outcomes in three patients. The same concept has been also applied for tricuspid valve vegetations in septic/unstable patients, as a bridge therapy until they are optimized for valve replacement. Use of the AngioVac cannula can significantly reduce the incidence of septic pulmonary embolism at the time of lead removal, due to its large diameter tip and high aspiration force. It can be used safely and effectively as an adjunctive measure to percutaneous lead removal.

Complications

Potential complications, including arrhythmia, embolization of clot or tumor fragments with subsequent cardiorespiratory compromise or failure, damage to intracardiac structures (namely the tricuspid valve) with the potential for acute valvular insufficiency, and right atrial wall rupture have been reported. Such complications, if not lethal, will necessitate acute cardiac surgery.

Bleeding or hematoma is otherwise the most common complication. It will typically be related to the access site. More commonly, a significant drop in hematocrit will be seen without evidence of overt hemorrhage, attributed to the volume retained in the circuit.

UPMC Experience and Case Report

At UPMC, the AngioVac System has been used seven times over the past two years with optimal results and no periprocedural mortality: five cavoatrial thrombi, one pulmonary embolus and one septic lead vegetation. We herein present a case of septic cavoatrial thrombus aspiration.

(Continued on page 11)

The Era of Branched Aortic Endografts for the Treatment of Aortic Arch and Thoracoabdominal Aneurysms is Here

Michael J. Singh, MD FACS RPVI
Chief of Vascular Surgery, UPMC Shadyside
Associate Professor of Surgery, UPMC
Division of Vascular Surgery
Co-Director, Aortic Center

Raymond E. Eid, MD
Assistant Professor of Surgery,
UPMC Division of Vascular Surgery

Over the last 20 years, endovascular therapy has revolutionized the way various abdominal and thoracic aortic pathologies have been managed. Short- and mid-term data have shown the benefit of utilizing less invasive endovascular technology for elective aortic aneurysms as well as acute aortic emergencies (i.e., rupture, dissection, intramural hematoma, trauma and penetrating aortic ulceration).

Up to 80 percent of abdominal aortic aneurysms and most descending thoracic aneurysms can now be readily treated with conventional aortic endografts when no major branch arteries are involved. This has certainly been the case since the introduction of fenestrated endografts that have been offered to our patients at UPMC since 2005 to deal with aneurysms close to the renal arteries before their final FDA approval two years ago. Endovascular technology however remains limited in cases of thoracoabdominal aneurysms as well as proximal aortic arch aneurysms.

The indications for treatment of complex aneurysms are not always clear because of the morbidity associated with conventional open surgical management. A wide variety of recommendations, including societal consensus documents, primarily recommend assessing the likelihood of aortic rupture compared to operative risk of the individual patient. As a general guideline, degenerative aneurysms > 60 mm in diameter and aneurysms associated with chronic dissections or connective tissue disorders > 55 mm in diameter should be repaired if existing comorbidities are not a prohibitive risk. In the latter case, the presence of dissection or connective tissue disorder portend to aneurysm rupture at smaller diameters. Despite major advances in surgical technique, medical optimization, and post-operative critical care, conventional open surgical repair is fraught with significant morbidity and mortality even at centers of excellence.

Aortic arch aneurysms usually require a median sternotomy with circulatory arrest and deep hypothermia to repair, as cerebral perfusion must be temporarily stopped. Mortality and stroke rates of these procedures are significant. Thoracoabdominal aneurysms require a large incision extending from the chest to the lower abdomen. Current nationwide data has shown that, depending on the extent of aortic involvement, mortality can be as high as 23 percent and the paraplegia rate as high as 17 percent with many strokes and a high incidence of renal failure. Because of the magnitude of these procedures, many patients with these types of extensive aneurysms are considered poor surgical candidates and not offered surgical treatment at all. In select situations,

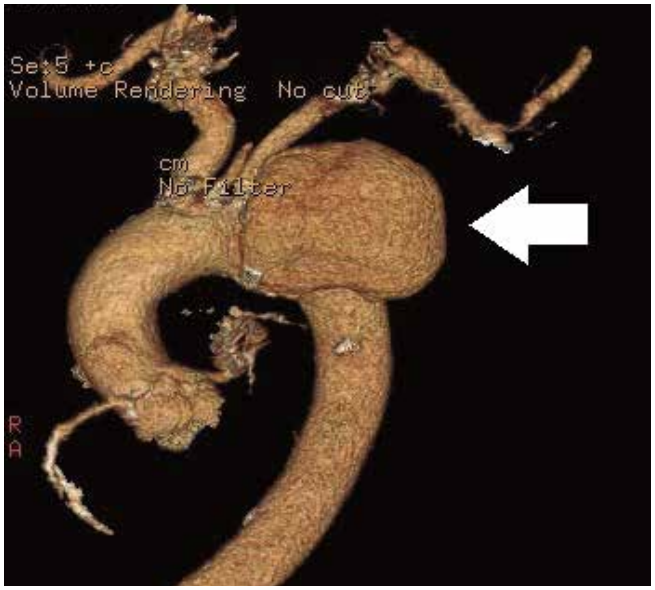


Figure 1:
Preoperative CT angiogram, white arrow points to 7.3 x 3.3 cm aortic arch aneurysm.

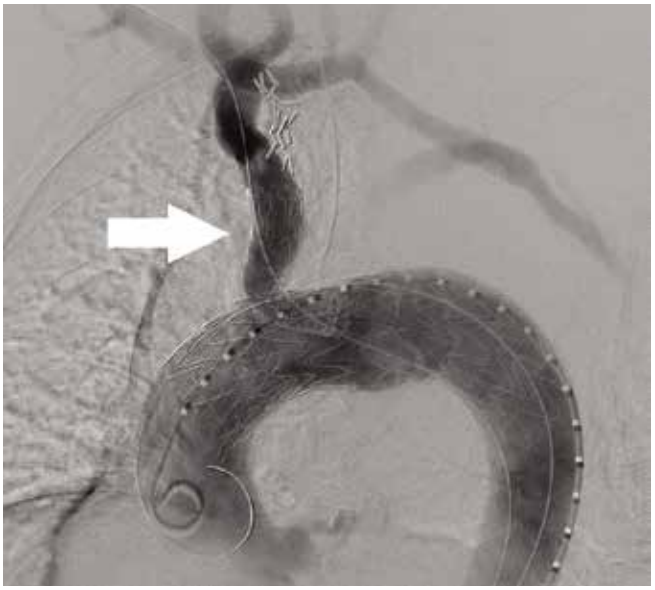


Figure 2:
Completion angiogram of GORE® TAG® Thoracic Aortic Single Branch Endoprothesis; white arrow points to the innominate branch stent, metal clips are from prior thyroidectomy procedure.

extensive aortic debranching operations are combined with a hybrid endovascular approach to lower the overall morbidity and mortality.

Endovascular therapy of complex aortic aneurysms has gained widespread acceptance for many of the previously recognized reasons. Fenestrated endografts are finally available in the United States, while multibranched endografts have yet to be approved. Branched endografts, which utilize side branches to maintain perfusion of essential arteries involved in the aneurysmal segment, represent the next frontier in managing these difficult cases. Experience with branched endografts continues to accumulate outside the United States, where these devices are readily available and in a few sites in the United States with investigator sponsored IDEs. Multiple clinical series and systematic reviews have shown that multibranch endografts are feasible, applicable, and have a high degree of technical success with lower associated morbidity and mortality compared to open surgical repair. Inherent branch endograft challenges include complex spatial geometry of the branch vessels, inadequate endograft conformability in angulated vessels and maintaining cerebral perfusion during the operative repair.

Several new research programs are finally now available in the United States to offer this technology to our patients with complex aortic aneurysms. The UPMC Division of Vascular Surgery has recently implanted six branched thoracic/thoracoabdominal aortic endografts successfully for complex aortic aneurysms involving the aortic arch and thoracoabdominal aorta as part of three investigational studies in these areas.

Two of these studies were feasibility trials for arch aneurysms using a single branch device, and UPMC was one of only eight major academic institutions in the United States chosen to participate. The single branch device perfuses the most proximal great vessel (i.e., the innominate or left carotid artery) involved with the aneurysm, while the remainder of the great vessels are revascularized with various bypass procedures. UPMC was the first institution in the United States to deploy an aortic arch branch device in the innominate artery and the second institution in the United States to deploy a device in the subclavian artery. The third study is an early feasibility evaluation of a four branch endograft system to treat thoracoabdominal aortic aneurysms. UPMC is one of only five national institutions to participate in this study, which is led by Michel Makaroun, MD, chief of the UPMC Division of Vascular Surgery and co-director of UPMC Heart and Vascular Institute. Early data from all three studies is very favorable and has shown better outcomes compared to open procedures.

All devices involved in the three mentioned studies are intended to be off-the-shelf devices. Although the delivery systems of the various devices are somewhat large, all six procedures were performed percutaneously from the femoral artery. The technique of implantation is somewhat similar to that used for infrarenal AAA endovascular repair (EVAR). The addition of arterial access via the brachial or subclavian artery facilitates advancement and placement of the bridging stents.

Case Report

The patient is an 83-year-old female who was transferred to UPMC Shadyside with abrupt onset of sharp non-radiating mid-sternal chest pain. A standard cardiac workup was preformed and found to be unremarkable. A CT angiogram of the chest (Figure 1) showed a large 7.3 x 3.3 cm false aneurysm of the aortic arch. The patient's past medical history was extensive and included chronic pulmonary disease, hypothyroidism, hypertension, coronary artery disease, dyslipidemia, gout, right total knee replacement, bladder suspension, total thyroidectomy, dysphagia, dysphonia, reflux, and cholecystectomy. The UPMC Cardiac Surgery team discussed open surgical repair with the patient and family but determined she was too high a surgical risk. In May 2016, the patient underwent an aortic arch debranching procedure via bilateral cervical and left supraclavicular incisions. An 8 mm Dacron graft was anastomosed from the right common carotid to the left common carotid and the left subclavian arteries. Two weeks later, the patient underwent endovascular repair of the aortic arch aneurysm with a 37 mm x 15 cm GORE® TAG ® Thoracic Aortic Single Branch Endoprothesis (GORE Medical, Flagstaff, Ariz.), a 20 mm x 6 cm innominate branch stent, and embolization of the proximal left subclavian artery. The main aortic device and branch stent were both inserted percutaneously through the right femoral artery. Completion aortogram (Figure 2) showed successful repair of the aneurysm, patency of all branch vessels, and no endoleak. The patient tolerated the procedure and was appropriately discharged to a rehabilitation facility within one week. Follow-up imaging at 30 days (Figure 3) showed successful exclusion of the aneurysm, decreased size of the aortic sac, absence of an endoleak, and widely patent aortic branch vessels.

Further Reading Suggestions:

Patel HJ, Dake MD, Bavaria JE, Singh MJ, Fillinger M, Fischbein MP, et al. Branched Endovascular Therapy of the Distal Arch Aorta: Preliminary Results of the Feasibility Multicenter Trial of Gore Thoracic Branch Endoprothesis. J Thor Surg March 2016.

Dake MD, Bavaria, JE, Singh MJ, Oderich GS, Fillinger M, Fischbein MP, et al. Management of Arch Aneurysms with Single Branch TEVAR in Zone 0: A US Feasibility Study of the Gore Thoracic Branch Endograft. J Thor Surg June 2016.

Oderich GS, Mendes B. Endovascular repair for TAAs With the t-branch multibranched Stent graft. Supp Endovasc Today Nov 2015.

Abraham CZ, Rodrigues VM. Upcoming technology for aortic arch aneurysms. Endovasc Today Nov 2015.

Figure 3:
Follow-up CT angiogram at 30 days, 3-D reconstruction of the GORE® TAG® Thoracic Aortic Single Branch Endoprothesis.

Carotid Angioplasty and Stenting Using Novel Cerebral Protection Technology of Flow Reversal and Direct Carotid Access (continued from page 1)

angioplasty and stenting (CAS) emerged as a minimally invasive alternative, and several trials ensued to determine its safety and efficacy, and the indications for its use. While CAS is relatively safer in patients with a hostile neck from previous surgery or neck irradiation, and in patients with cardiac comorbidities, the neurologic outcomes with CAS continue to be suboptimal when compared to endarterectomy. The risk of procedural stroke continues to be higher with CAS, especially in symptomatic patients and in octogenarians. This has led the enthusiasm for CAS to wane but many patients who may benefit from a less invasive approach remain.

Sources of embolization during and after CAS are multiple but it appears the aortic arch is a prime culprit. Direct carotid access with flow reversal with the ENROUTE® Transcarotid Neuroprotection System (Silk Road Medical®, Sunnyvale, Ca.) has just been approved by the FDA this year to address this concern as an alternative to the standard femoral approach with some reported benefits. The results of the IDE trial in 141 patients had a procedural success rate of 96 percent and showed a neurologic complication rate that is lower than standard stenting, approaching the outcomes of carotid endarterectomy. The stroke death rate of only 2.8 percent was certainly an improvement on other stenting trials. This improved stenting and cerebral protection technology promises to better outcomes for CAS by eliminating a major source of embolization: maneuvering the aortic arch and crossing the stenotic lesion.

In contrast to traditional CAS, the direct access procedure starts at the neck instead of the groin. Direct carotid access is intended to minimize the risk of microemboli and stroke associated with arch navigation. Control of the common carotid artery is accomplished through a small cut down above the clavicle, where an arterial access sheath is placed. Because the incision is made just above the clavicle, the risk of cranial nerve injury is minimized. A second access sheath is placed in the femoral vein. The two sheaths are connected by a flow controller to create an arteriovenous shunt to divert embolic debris away from the brain by reversing flow in the internal and external carotid arteries. Flow reversal is established at the start of the procedure, providing embolic protection before any manipulation of the carotid lesion. Additionally, direct common carotid placement of a large-diameter sheath and large-bore extracorporeal tubing generates high reverse flow rates. The high rate of flow reversal is controllable with the push of a button, allowing the operator to increase, decrease, or arrest flow at any given step, which is especially important during key procedural maneuvers at high risk for embolization. Debris is trapped in an inline filter, preventing it from entering the venous circulation.

The system is designed to simplify the introduction of stents and other interventional devices due to the straight, short path from the carotid access site (Figure 1) to the lesion (typically one to two inches). The system is compatible with all commercially available guidewires, balloons, and carotid stent delivery systems, although specialized carotid stents are under development to offer shorter shaft lengths to enhance ease of delivery.

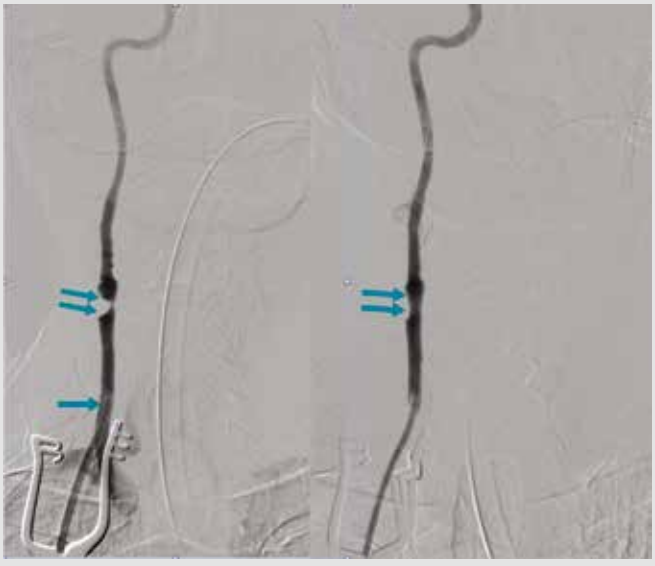
Case Report

A 75-year-old man with severe COPD, on home oxygen, presented with left hand weakness and expressive aphasia. His symptoms spontaneously recovered within 48 hours but with residual hand motor deficit. MRI and CTA imaging reveal a right hemispheric stroke and a severe right sided internal carotid stenosis. This was also confirmed with carotid duplex ultrasound.

The patient was started on dual antiplatelet therapy with aspirin and clopidogrel. His lipid profile was normal.

Carotid revascularization was indicated in the setting of a symptomatic severe carotid stenosis and good spontaneous near complete functional recovery. While CEA is the safer option in patients with a symptomatic stenosis based on current data, this patient was treated with CAS using the ENROUTE® Transcarotid Neuropresevation System (Silk Road Medical®, Sunnyvale, Ca.) given his prohibitive pulmonary risk for surgery. In the figure below, the first panel shows a severe carotid stenosis at the carotid bifurcation and into the internal carotid artery (top two arrows), and sheath in the common carotid artery (bottom arrow). The second panel shows the angiographic result after angioplasty and stenting, with a widely patent stent (arrows). The patient was discharged home after an overnight hospital stay, with a good angiographic and clinical outcome, with no residual neurologic deficit.

Figure 1



Suction Thrombectomy for Iliocaval or Atrial Thrombus, Pulmonary Embolism, and Septic Vegetations (continued from page 7)

A 39-year-old morbidly obese male presented at UPMC Presbyterian with worsening fevers and fatigue and was found to have leukocytosis and MRSA bacteremia. Two months earlier he had sleeve gastrectomy complicated by leak and septic shock with multisystem organ failure, including renal failure for which he was still dialyzing through a right internal jugular tunneled catheter.

The patient was admitted and initiated on broad spectrum antibiotics. An abdominal collection was initially thought to be the source of infection but it was subsequently ruled out as a hematoma. The dialysis catheter was also removed. Due to concerns for endocarditis, he underwent a transthoracic and then a transesophageal echocardiogram which showed a 5.5cm x 1.1cm mobile vegetation at the cavoatrial junction, thought to be the cause of his persistent bacteremia (Figure 2A). He was seen by the Division of Cardiac Surgery, which felt he was a suboptimal candidate for sternotomy and open retrieval of the vegetation. We subsequently explored the possibility of percutaneous suction thrombectomy. The patient consented and through bilateral femoral access and fluoroscopic and transesophageal echocardiographic guidance, we removed the large thrombus from the cavoatrial junction (Figure 2B and Figure 3). Subsequent blood cultures came negative. The patient was discharged 10 days later to a nursing facility and a month later returned home in good condition.

Further Reading Suggestions:

Resnick SA, O'Brien D, Strain D, et al. Single-Center Experience Using AngioVac with Extracorporeal Bypass for Mechanical Thrombectomy of Atrial and Central Vein Thrombi. J Vasc Interv Radiol 2016;27(5):723-729.

Moriarty JM, Al-Hakim R, Bansal A, et al. Removal of Caval and Right Atrial Thrombi and Masses Using the AngioVac Device: Initial Operative Experience. J Vasc Interv Radiol. 2016 in press.

Al-Hakim R, Park J, Bansal A, et al. Early Experience with AngioVac Aspiration in the Pulmonary Arteries. J Vasc Interv Radiol 2016;27(5): 730-734.

Donaldson CW, Baker JN, Narayan RL, et al. Thrombectomy using suction filtration and veno-venous bypass: single center experience with a novel device. Catheter Cardiovasc Interv 2015;86(2): E81-87.

Al Badri A, Kliger C, Weiss D, et al. Right Atrial Vacuum-Assisted Thrombectomy: Single-Center Experience. J Invasive Cardiol 2016;28(5):196-201.

Patel, N., T. Azemi, Zaeem F, et al. Vacuum assisted vegetation extraction for the management of large lead vegetations. J Card Surg 2013;28(3): 321-324.

Figure 2:
(A) Thrombus in the superior vena cava trailing in the right atrium, (B) Bilateral femoral vein access, the reinfusion cannula positioned in the left femoral vein and the AngioVac cannula ready to be introduced through the right femoral vein.

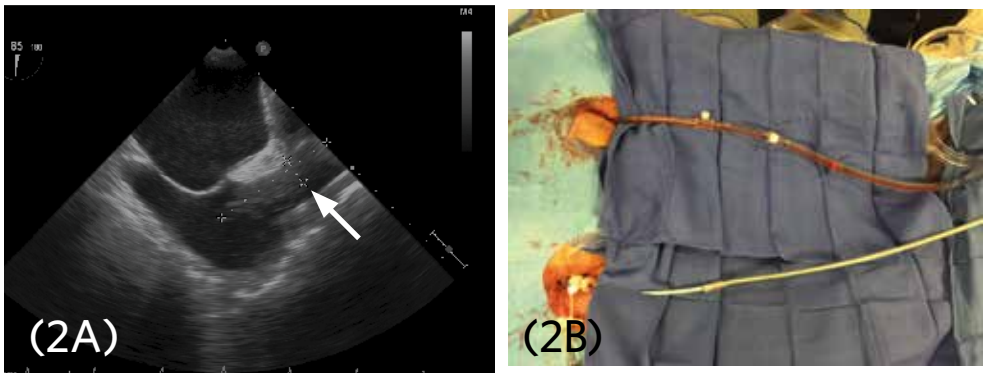
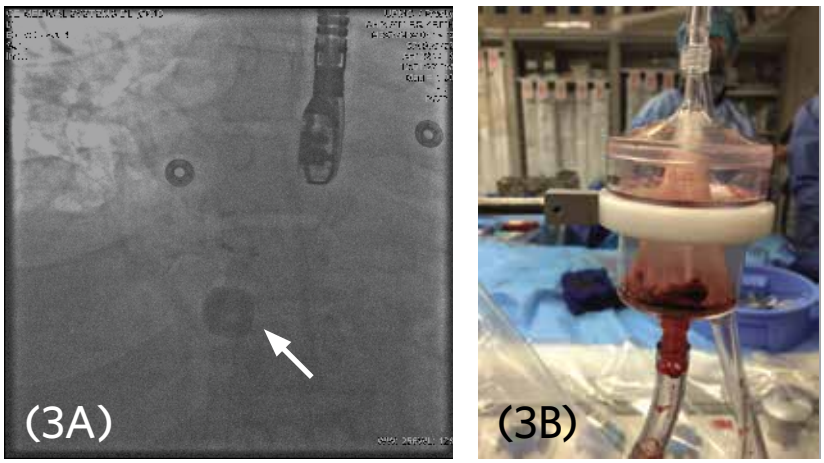


Figure 3:
(A) The AngioVac cannula tip with the balloon inflated to allow maximal expansion to 48-F in the right atrium; notice the transesophageal echocardiographic probe which gives feedback for the positioning and status of the thrombus, (B) The thrombus trapped in the filter.



UPMC
LIFE CHANGING MEDICINE
200 Lothrop St.
Pittsburgh, PA 15213-2582

FACULTY LISTING

Michel Makaroun, MD
Georges Al-Khoury, MD
Efthymios (Makis) Avgerinos, MD
Rabih Chaer, MD
Raymond Eid, MD
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Executive editor:
Michel Makaroun, MD

Assistant editor:
Mohammad Eslami, MD

Address correspondence to:

Karen Janosko
Division of Vascular Surgery
UPMC Presbyterian, Suite A-1011
200 Lothrop St.
Pittsburgh, PA 15213-2582

For additional information concerning *Vascular Rounds*, or to suggest future topics, contact Karen Janosko at janoskokm@upmc.edu or call 412-802-3333.

Division of Vascular Surgery
UPMC Heart and Vascular Institute
UPMC Presbyterian, Suite A-1011
200 Lothrop Street
Pittsburgh, PA 15213-2582

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