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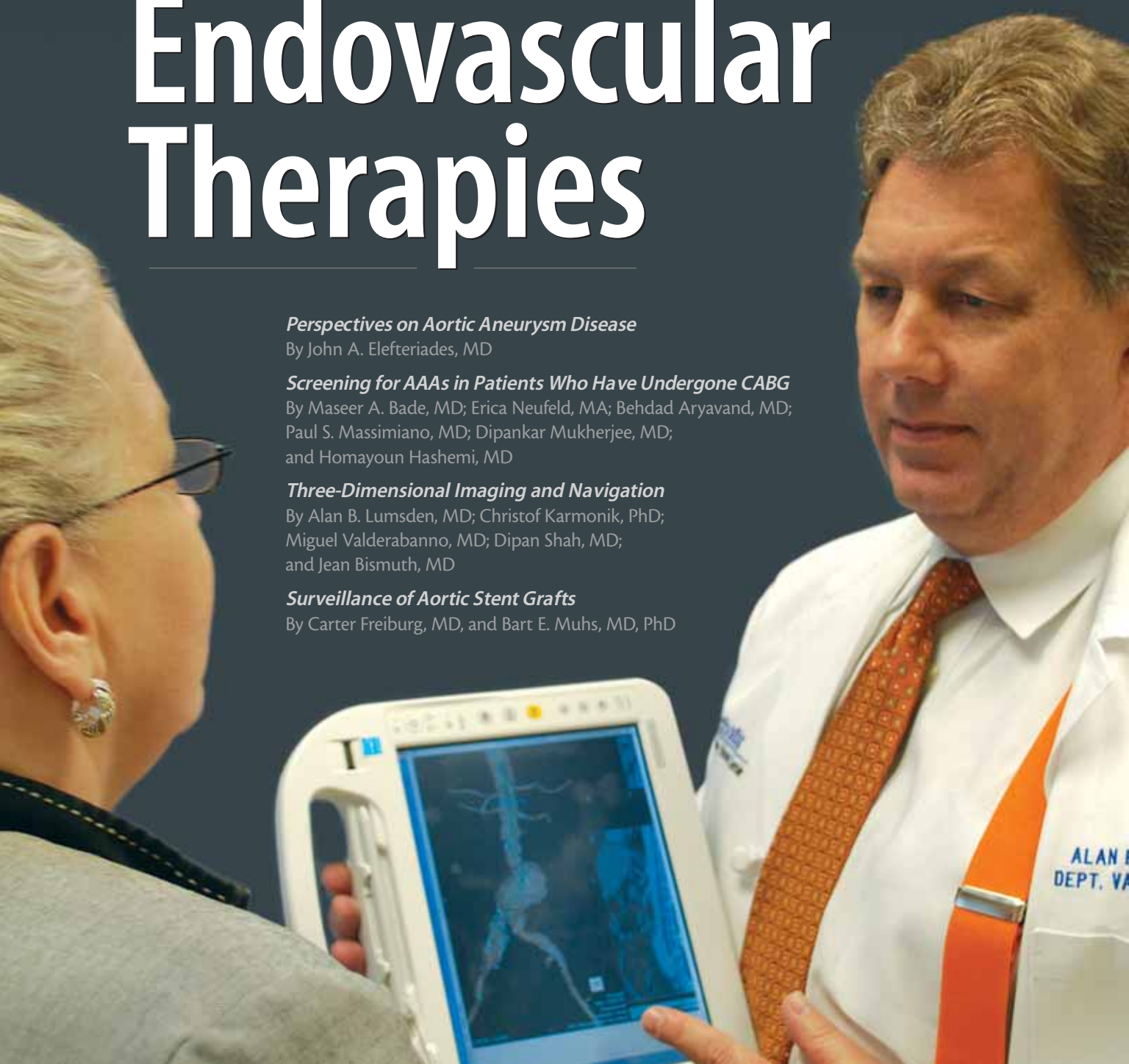

Perspectives on Aortic Aneurysm Disease

An overview of how aortic aneurysm disease is viewed today and some advice on improving awareness, detection, and follow-up.

BY JOHN A. ELEFTERIADES, MD

As health care professionals, we play a critical role in educating patients about aortic disease, recommending life-saving screening, and advising the best treatment options. Throughout this supplement, you will review concepts and best practices on how to improve disease awareness, diagnosis, treatment, and follow-up.

This last decade has seen a tremendous amount of change in the aortic aneurysm space. Aneurysm ruptures and related deaths are down from higher levels in 2000.[1] Treatment modalities have advanced and are now providing multiple options for treating abdominal aortic (AAA) and thoracic aortic (TAA) aneurysms (Figure 1).[2] Imaging technologies are better than ever, and patients, with increased access to the Internet, are becoming more aware of aneurysm disease. However, we have a long way to go; it is estimated that annually we treat only 20% of the aneurysm patients appropriate for intervention.[2] Improved disease awareness and diagnosis hold the potential to save many lives.

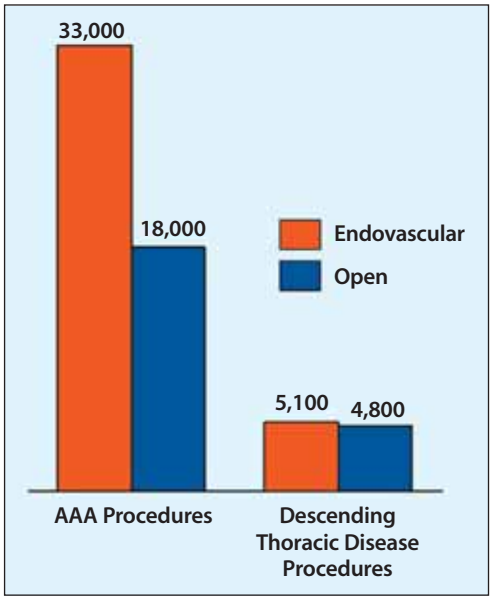

Figure 1. 2008 United States usage of endovascular and open therapies for abdominal and descending thoracic aortic disease.[2]

INCIDENCE, PREVALENCE, IMPACT

Aortic aneurysms are common. Aneurysmal disease is more common than generally appreciated. In fact, recent statistics indicate that AAA is the third leading cause of sudden death in men over age 60.[3] Research has shown that 95% of AAAs can be successfully treated if detected before rupture, yet an astonishing 1 million people are living today with undiagnosed AAAs.[4] Only 10% to 25% of patients survive a ruptured aneurysm.[5] In fact, aneurysms cause more deaths than the more widely publicized HIV disease. The figures for aneurysm-related death almost certainly represent underestimates of the impact of aortic diseases due to misclassification of ruptured aneurysms as myocardial infarction and incorrect coding in large databases. Experts have suggested that 30,000 to even 60,000 deaths per year in the United States represent a reasonable estimate.[6,7]

Aortic aneurysms are increasing in frequency. Above and beyond the fact that aneurysmal disease is common, there is also accumulating evidence that aortic aneurysms are increasing in frequency. At first, it was believed that the apparent increase in frequency was an artifact of increasing use of three-dimensional imaging techniques such as echocardiography, computed tomography (CT) scanning, and magnetic resonance imaging. The concept that aortic disease is truly increasing in incidence is based on evidence from geographic regions with stable populations with little out- or in-migration, as studied in Minnesota and Sweden.[8,9] Analysis in these regions suggests a true, bona fide increase in the incidence of aortic disease. This is seen clearly in Figure 2. We do not know the reasons for this apparent dramatic increase in this disease over evolutionarily short intervals of decades.

Aortic aneurysms are underrecognized. This situation cries out for biomarkers of this disease. Ninety-five percent of aneurysm patients have no symptoms. Thus, aneurysm patients, unlike those with other diseases, must take no solace from their having no symptoms. They must recognize that the first symptom is often death or a severely life-threatening complication such as rupture or dissection.

Because aortic aneurysms constitute a virulent, potentially lethal disease, and a predominantly silent disease, this combination of circumstances cries out for discovery of biomarkers—blood tests that can detect aneurysms in the gen-

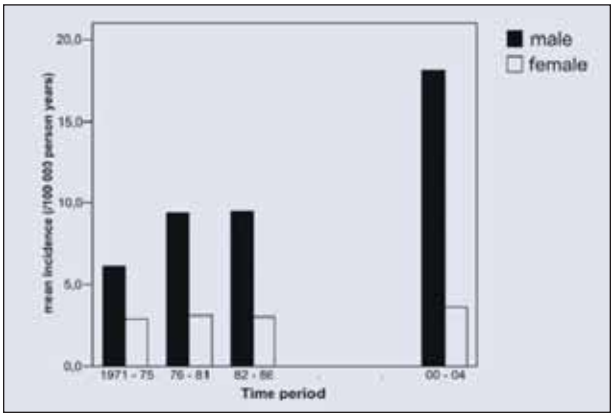

Figure 2. Note increased incidence of ruptured abdominal aortic aneurysms in total population of Malmo, Sweden, between 1971 and 2004.[8,9]

eral population, monitor the progress of an aneurysm, and predict complications in patients known to be afflicted. We have recently reviewed the nascent field of biomarkers in aortic diseases. Potential biomarkers linked to the emerging understanding of the pathophysiology of this disease are summarized in Table 1.

IMPROVED DETECTION

We need to improve our intervention criteria, moving beyond morphology (size) alone to other types of parameters (mechanical, biological). Symptoms and size have been the cornerstone aneurysm intervention criteria for decades. At our institution, we are looking at direct measurement of aortic distensibility and wall stress (by echo) as potential intervention criteria. It may be that wall stress predicts rupture or dissection even better than aortic size.[10] Other institutions report potentially important findings on positron emission tomography (PET) scan, which can detect intramural inflammation in the aortic wall, a suspected sign of pathologic activity; PET activity may inform our surgical decision making in the future.[11,12] Also, we are hopeful that our RNA Signature test, which directly reflects inflammatory, lytic, and apopotic pathways (among others) in the aorta, may contribute to predicting impending rupture or dissection (see *Advancing Screening* sidebar).

Because aneurysmal disease is asymptomatic, better population screening by radiographic means is essential. For the thoracic aorta, there is powerful evidence of a familial pattern to transmission of aneurysm and dissection.[13-15] Thus, we strongly recommend screening of all first-order relatives of patients with known aneurysms. We screen with echo for younger individuals and echo plus CT scan for patients of middle age or higher. Also, it is becoming abundantly clear that athletes with unrecognized ascending aortic aneurysms are prone to exercise-related aortic dissection, which is usually fatal.[16,17] The Olympic Committee now requires a cardiac echo for all athletes competing in the games. We recommend that all high school or college athletes be screened by echo for ascending aortic aneurysms to prevent tragic deaths of these talented, dedicated young people.

TABLE 1. POTENTIAL BIOMARKERS IN AORTIC DISEASES FOR DIAGNOSIS AND/OR MONITORING

Indicators of Ongoing Thrombosis
- D-dimer
- Plasmin
- Fibrinogen

Matrix Metalloproteinases (MMPs)

Inflammatory Markers
- Cytokines
- CD4+CD28- T cells
- C-reactive protein (CRP)

Markers of Collagen Turnover
- Elastin peptide (EP)

Other
- Endothelin
- Hepatocyte growth factor
- Homocysteine

Genetic Markers
- "RNA Signature"

The abdominal aorta is easily and accurately interrogated by echo techniques. It has been demonstrated that if a single abdominal aortic echo is negative for aneurysm at 65 years or beyond, the patient will not die from a ruptured aortic aneurysm.[18] This provides a unique opportunity for population screening (see *Advancing Detection* sidebar).

In our zeal to treat the interesting disease of thoracic or aortic aneurysm or dissection—and to help the afflicted patients—we are best served to keep basic principles regarding incidence and treatment guidelines closely in mind. Advances in biology and imaging, along with funding

ADVANCING SCREENING

The SAAAVE Act (Screening Abdominal Aortic Aneurysms Very Efficiently) permits one abdominal aortic echo examination in male individuals who reach Medicare age. This promises to save many lives, as scientific evidence indicates that having no aneurysm at age 65 implies that the patient will not die of ruptured aortic aneurysm during his lifetime. This Congressional Act makes a giant forward step toward preventing death from AAA.

The shortcoming of the SAAAVE Act is that it requires that the aortic echo be performed within 1 year of Medicare enrollment. We urge Congress to eliminate this restrictive time requirement, so that more of the Medicare population can benefit from even this single screening test.

for screening tests, promise to produce better future detection of these diseases as well as more informed surgical or interventional decision making.

CONCLUSION

With the articles in this supplement from some of the leading specialists around the country, we hope to share with you research and tools that will help enhance identification and treatment of aneurysm patients. I have shared with you in this short section just a fraction of the exciting epidemiologic and biological work being done at our Aortic Center at Yale. In the remainder of this volume, you will find extremely exciting and innovative concepts and tools being used to identify and treat affected patients, to train surgeons and interventionists, and to leverage technology to enhance treatment and follow-up. I urge you to read through this supplement and to consider how implementing these ideas and tools into your practice may enhance patient care. ■

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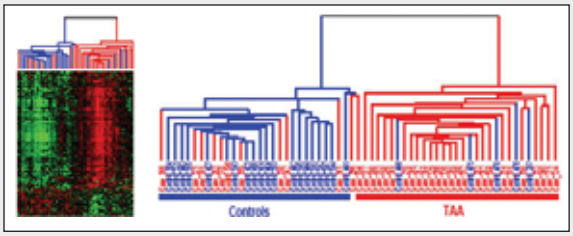
ADVANCING DETECTION

RNA Signature test. Our group has undertaken intensive efforts aimed toward identifying the specific genetic aberrations that underlie these family transmissions of aortic disease in the hope of developing a widely sensitive genetic screening test for thoracic aortic aneurysms. We studied 30,000 RNA expression patterns in the blood of patients with thoracic aortic aneurysms and compared them with control patients. We found that a 41-SNP panel could discriminate quite well between patients with and without aneurysms—from a blood test alone (Sidebar Figure 1).[1] Our gene chip test has an accuracy of 82% (for comparison, the widely used PSA test for prostate cancer has an overall accuracy of about 40%). Our validation studies of this RNA Signature test are nearing completion. It is hoped that this or other biomarkers based on the pathophysiology of aneurysm development may soon permit screening of the general population for this lethal, asymptomatic, and elusive disease.



Sidebar Figure 1. Hierarchical clustering analysis of RNA expression in aneurysms and controls. If all red (thoracic aortic aneurysm) and all green (control) bars in right diagram had grouped together, the blood test would have been 100% accurate. Overall accuracy was approximately 80%.

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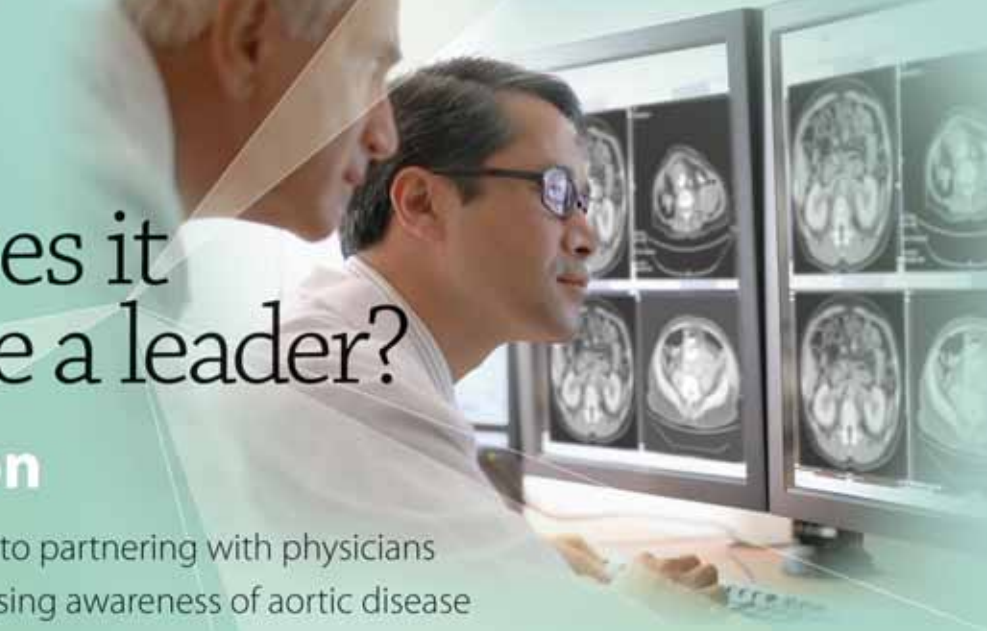

What does it take to be a leader?

Collaboration

Medtronic is committed to partnering with physicians to lead the way in increasing awareness of aortic disease

Did you know?

67% of abdominal aortic aneurysms over 5 cm go undiagnosed*

Over 90% of abdominal aortic aneurysms diagnosed are incidental findings**

Medtronic offers leading, value-added therapy development solutions such as:

Patient Awareness
- SAAAVE Act
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- National Media
- Patient Education

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- Studies on Co-morbidities

Implanting Physician Tools
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- StentGraftTracker
- MyMedPages.com
- Fellows Programs

Medtronic offers dedicated support through its Therapy Development Specialists

- Medtronic Therapy Development Specialists are dedicated to increasing awareness and treatment of aortic disease
- Therapy Development Specialists work with different stakeholders (implanters, referrers, hospital administration) to help ensure patient access to endovascular therapies

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*Internal Medtronic Market Data, Verispan National Patient Profile Data
**Ann Intern Med. 2009;151:21-27.

Screening for AAAs in Patients Who Have Undergone CABG

The experience at Inova Fairfax with disease identification in high-risk patients.

BY MASEER A. BADE, MD; ERICA NEUFELD, MA; BEHDAD ARYAVAND, MD; PAUL S. MASSIMIANO, MD; DIPANKAR MUKHERJEE, MD; AND HOMAYOUN HASHEMI, MD

Due to the lethal nature of abdominal aortic aneurysm (AAA) disease, a widespread interest in screening programs has developed. Abdominal ultrasound provides a rapid, painless, and inexpensive way to screen for AAAs, with a sensitivity and specificity approximating 99%.[1] Randomized, population-based screening protocols have demonstrated that ultrasound identification of AAAs facilitates elective surgical repair, thereby reducing mortality rates.[2] The United States Preventive Services Task Force (USPSTF) has identified a 43% relative risk reduction from AAA-related deaths with screening.[3] Furthermore, cost-effectiveness of screening programs has been established by four randomized controlled trials that demonstrated a 50% reduction in AAA-related deaths in screened patients.[4-7]

Unfortunately, screening programs have not become widespread due to logistical limitations, the relatively low incidence of AAAs in the general population, and a low yield of AAAs requiring surgical therapy. Therefore, certain subgroups with a higher prevalence of AAAs should be targeted in order for the screening to be not only cost-effective but also to result in elective surgical therapy that ultimately prevents AAA rupture and preserves life.

AAA is a disease predominantly affecting men, has an increased incidence with increasing age, and has a three- to fivefold increased prevalence in smokers.[3,8] In fact, smokers > 60 years of age have a 4% incidence of AAAs.[9,10] In addition, a number of investigators have identified an increased prevalence of AAAs in patients with coronary artery disease, peripheral vascular disease, and carotid artery stenosis.[11-15] The landmark Epics I study has demonstrated that patients who have undergone coronary artery bypass grafting (CABG) have a higher prevalence of AAAs compared to the overall population. In male patients with CABG, AAA incidence was 9%, versus 4% for the general population. In women with CABG, the prevalence of AAAs was 5.1%, versus 1% for the general population. The study found that male gender, increased age, and smoking were independent risk factors for AAAs. Finally, the study recommended that AAA screening should be performed in all patients needing to undergo CABG.[16] Based on these recommendations, our practice, Cardiac, Vascular, & Thoracic Surgery Associates, P.C., decided to retrospectively screen our CABG patients for the presence of AAAs.

SCREENING RATIONALE AT OUR PRACTICE

Our practice is located in Northern Virginia and consists of 17 cardiac, vascular, thoracic, pediatric cardiac, and heart-lung transplant surgeons. We have been in practice since 1977 and provide services to six hospitals in the greater Washington, DC, metropolitan area. We have performed more than 30,000 cardiac operations during the last 30 years. With an extensive CABG surgery patient base, we believe that our practice provides a fertile ground for AAA screening. We share with you the AAA screening program we have devised, in the hopes that it may serve as a template for the development of similar screening programs nationwide (see *Advancing Awareness* sidebar).

PATIENT SELECTION

We partnered with Inova Fairfax Hospital and Medtronic Corporation to screen patients for AAAs and carotid occlusive disease. Inova Fairfax Hospital provided the venue and ultrasonographers for the screenings, and Medtronic Vascular (Santa Rosa, CA) provided an educational grant for funding.

Using the hospital's database of previous patients upon whom we performed CABG, an informational letter was mailed to 350 patients randomly selected who met the criteria of undergoing CABG between 2007 and 2008, who were at least 60 (men) or 65 (women) years of age, also possessing one of the following risk factors for AAAs: history of smoking or history of hypertension, or family history of AAAs.

The letter explained the relationship between CABG and AAAs, invited patients with the appropriate risk factors to sign up for a free screening, and was signed by the

Vascular Surgery Section Chief. Within 3 days of mailing, both the spring and fall screenings were filled.

Of the 350 patients invited, approximately 100 called the customer service number, and operators ensured they were appropriate candidates for screening. Of those 100 patients, 80 signed up for the March and September screenings. After registering, patients received a confirmation letter that included the date and time of the Saturday screenings, directions, and parking information. In total, 66 patients were screened.

SCREENING DAY LOGISTICS

Two Saturday screenings in March and September were held in the Inova Heart and Vascular Institute. The location was easily accessible from the hospital parking garage. Complimentary parking was provided.

At the screening, a receptionist registered patients and directed them from the waiting room to the screening area. Registration included basic medical history information as well as contact information for the patient's primary care physician (PCP). In the spring screening, two rooms, each with an ultrasonographer, were used to perform aortic duplexes to screen for AAAs. Patients were screened at 30-minute intervals. For the fall event, the screening time was reduced to 15 minutes. In addition to aortic duplexes, carotid duplexes to screen for carotid occlusive disease were performed. The staff present to conduct the screening included a receptionist, two ultrasound technicians, and one doctor. Before the event, a member of the hospital's marketing team, the marketing director of our office, the vascular surgeon, the cardiothoracic surgeon (responsible for the CABG patient list), and a therapy development specialist from Medtronic worked on logistics leading to the event.

After the duplex examinations, patients met with a board-certified vascular surgeon to receive both verbal and written results. A protocol had been established that patients with AAAs < 5 cm would be advised to follow up with their PCPs. For AAAs > 5 cm, the PCPs would be called and an immediate treatment plan instituted.

Two days after the screening, letters were mailed to patients' PCPs. This letter served two purposes. First, it informed the PCP of the patient's results. Second, it served to educate the PCP of the link between CABG and AAAs. We have found that this is an excellent way to establish new relationships with future referring physicians.

COSTS

The screenings in 2009 were made possible by a $5,000 educational grant from Medtronic Vascular (Santa Rosa, CA). The cost of screenings equated to $62.50 per person, which included paying the ultrasonographers and receptionist, the cost of disposable supplies, and providing refreshments for the patients.

RESULTS

Nine percent of those screened were found to have disease. Of the 66 patients screened, 4.5% (three patients) were found to have aneurysms (AAAs > 3 cm), and 4.5% (three patients) were found to have carotid occlusive disease (> 50% stenosis). Although no patients required immediate intervention, all will be followed and monitored to evaluate for aneurysm growth or occlusive disease progression. Because our sample size was small, future screenings will serve to increase the power of our study and will allow us to calculate a more accurate incidence of AAA disease in CABG patients.

ADVANCING AWARENESS

Industry and medical societies have come together to support a multifaceted, public service campaign designed to increase awareness and understanding among patients, referring physicians, legislators, and policy makers about the seriousness of abdominal aortic aneurysms (AAAs) and increase screening among at-risk individuals.

The goal of the campaign is to help save lives by increasing awareness about AAA screening.

The campaign offers a variety of programs and resources to help individuals, local communities, and health care professionals take action. Activities include:

- Regional education and screening events to drive awareness of AAAs in select local communities nationwide;
- An interactive Web portal where individuals can learn more about AAAs, campaign initiatives, and make a personal pledge to get screened;
- Educational materials and resources on AAA screening for health care professionals, patients, and their loved ones;
- Public service announcements on the importance of AAA screenings;
- Events with health care advocates and policy influencers to identify current challenges in AAA care and advocate for meaningful change.

The campaign is sponsored by Medtronic Vascular (Santa Rosa, CA) and supported by an alliance of concerned physician societies that have come together to provide information about AAAs and improve the number of at-risk individuals that are screened. Members include the Society for Vascular Ultrasound, the Society for Vascular Surgery, and the American College of Preventive Medicine.

LESSONS LEARNED

We learned some valuable lessons from the screenings that will be helpful in planning future events. First, patients should be booked to 10% overcapacity. Invariably, some patients will fail to show up, and therefore, overbooking will serve to fill the "no-show" gaps. Second, telephone calls 48 hours before the event, reminding the patient of the screening, are generally more successful than mailing a second letter. Finally, patients can be screened at less than 30-minute intervals. Booking patients at 15-minute intervals may be a practice we adopt in the future. This decrease in screening time will likely result in a decrease in the present $62.50 per capita screening cost. In addition to screening for AAAs and carotid disease, we plan to expand the screening to include blood pressure and ankle-brachial indices to assess for peripheral vascular disease.

PROSPECTIVE SCREENING

In 2010, our goal is to hold four screening events yearly in order to screen a total of 200 patients for AAAs and carotid occlusive disease. Our goals are twofold: first, we want to identify the true incidence of AAA and carotid occlusive disease in CABG patients. The second goal is to surgically treat indicated patients, resulting in prevention of AAA rupture and ischemic strokes. ■

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Three-Dimensional Imaging and Navigation

Three-dimensional CT reconstruction should be included throughout endovascular procedures, enabling better procedure planning and increasing patient satisfaction.

BY ALAN B. LUMSDEN, MD; CHRISTOF KARMONIK, PHD; MIGUEL VALDERABANNO, MD; DIPAN SHAH, MD; AND JEAN BISMUTH, MD

We live and work in a three-dimensional (3D) world but have learned to plan and perform endovascular procedures with two-dimensional (2D) systems. Further, we have learned to perform those procedures very well, to the point that some may question whether developing a 3D operating environment is worth the effort. However, 3D imaging can assist case planning and conduct in two modes: preoperative case planning and intraoperative performance of the case. For preoperative planning, 3D computed tomography (CT) reconstruction has been extensively validated:[1] centerline length measurements, evaluating complex aortic necks and iliac tortuosity (Figure 1),[2] measuring inner and outer diameters of the aortic arch, understanding complex anatomy in congenital aortic anomalies,[3] and planning carotid stenting.[4] This has now reached the realm of necessity: we expect and need to be able to view a 3D reconstructed image. It is in response to these demands that 3D Recon, a service from Medtronic Vascular (Santa Rosa, CA) in partnership with Vital Images (Minnetonka, MN), has evolved and provides 3D reconstruction viewing even if this is not available locally to all its customers. To enable 3D Recon from a remote location, the availability of DICOM (Digital Imaging and Communications in Medicine) image transfer becomes important. This too is available through Medtronic's CTeXpress (also in partnership with Vital Images), a service that allows for not only transfer of images but also the ability to utilize these 2D axial images to reconstruct in 3D remotely.

3D Recon provides additional important capabilities: remote viewing and consultation with referring physicians, diameter and centerline measurements, and electronic reports. Physicians can upload CT images to a Web site, where the axial data are converted to 3D using the 3D Recon service. The 3D reconstruction allows for aneurysm measurement that can be used for accurate sizing during endograft placement. Reliable image viewing is consistently accessible. Images can be viewed online before patient arrival in the clinic, resolving the constant irritation of lost discs or incompatible viewers. Frequently, CT scans must be repeated because the patient and images are not present at the same time. This increases radiation exposure for the patient and greatly increases cost. The presence of a 3D image enables better communication with the patient about the nature of the aneurysm and the planned procedure, increasing patient understanding and satisfaction. Similarly, although experienced interventionists have learned to use 2D axial images, 3D images make it easier for referring physicians to understand and further discuss a completed procedure with a patient, as well as explain the necessity for longitudinal follow-up.

Although 3D Recon does provide immediate added value, an additional and perhaps even greater role for 3D reconstruction is its use as a tool to facilitate endoluminal navigation and to understand complex flow patterns within areas of pathology. The following sections will explore these potential benefits. We believe that the

Figure 1. Three-dimensional reconstruction with centerline of an abdominal aortic aneurysm.

Figure 2. Virtual 3D rendering of the left atrium and virtual robotic catheter (Sensei System, Hansen Medical, Mountain View, CA) used for ablation of pulmonary vein orifices.

future of endovascular intervention will involve use of 3D images to facilitate navigation.

CENTERLINE NAVIGATION

Currently, we talk about navigating a catheter through a vascular bed. However, navigating a catheter consists of a series of interactions between the vascular wall and the catheter. We have remarkably little catheter control: advancement and rotation. Literally, we bump a specially shaped catheter off the vessel wall to move the tip through tortuous anatomy or to enter a vessel orifice. It is the catheter-wall interaction that generates complications: embolization, occlusion, and dissection. With current 2D imaging and manual catheter manipulation, it is impossible to avoid wall contact, and this premise has not substantially changed for decades. However, centerline navigation—the same centerline currently created in 3D Recon—fundamentally alters the way we work inside the vascular system and could prevent damaging wall interaction. The concept of centerline navigation may also be thought of as "off-the-wall" navigation—deliberately trying to minimize catheter-wall interaction until a therapeutic intervention is delivered. Centerlines have traditionally been used to improve accuracy in CT measurements for endografting; let's now think of this as a navigation strategy. The tools to permit centerline navigation all exist; the challenge is in making them work in harmony. Three-dimensional imaging is the imaging core for such a strategy. Fusion technology and robotic navigation in a 3D environment are not pipe dreams but currently exist and are used daily in electrophysiology in an environment that arguably is much more complex than an aorta (Figure 2).

FLUORO CT SCANNING

As we replace older angiography suites, the new systems add powerful imaging modalities, namely fluoro CT or

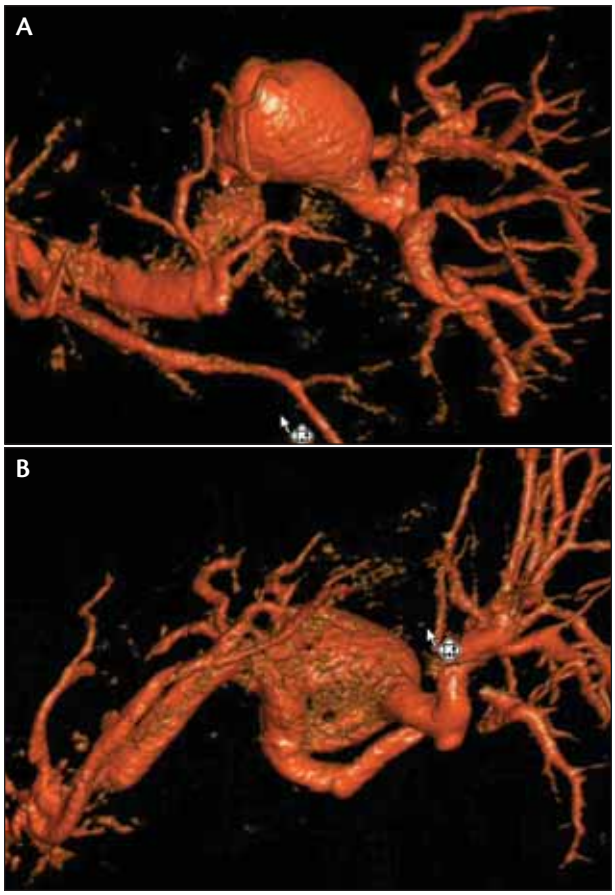

Figure 3. DynaCT (Siemens Healthcare, Malvern, PA) reconstruction of a complex splenic artery aneurysm (A). Rotation of the 3D reconstruction revealed that there are in fact two major branches arising from the aneurysm, significantly altering the therapeutic approach (B).

DynaCT capabilities (Figure 3). These systems add a CT scanner to our hybrid suite, which we never had before. We believe that this will not only have an important role in cardiovascular disease but will also revolutionize general and thoracic surgery by providing en suite CT: CT-guided biopsies, drainage of collections, or optimizing access port locations. Imaging companies have developed new combined angiography/CT suites, which use flat-panel detector (FD) technology for improved resolution angiography that is also able to produce improved cone-beam volume CT images. The system permits 3D rotational digital subtraction angiography (DSA) or cone-beam volume CT interchangeably with the same FD C-arm so that patients do not have to be transferred to a separate unit in order to obtain both imaging modalities. Real-time feedback of endovascular procedures is possible for both DSA and CT. One of the most striking features of this technology is its simplicity, which allows for efficient and fluid endovascular procedures.

When comparing DynaCT to a 16-slice multidetector CT scanner (Somatom Sensation 16, Siemens Healthcare),

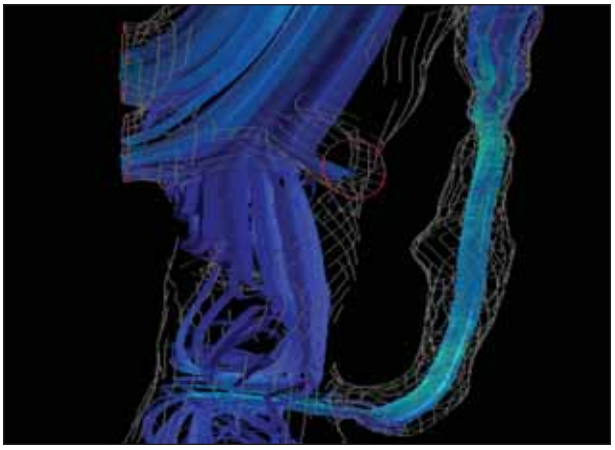

Figure 4. Three-dimensional computational fluid dynamic reconstruction of a distal re-entry point of a type B dissection. Re-entry is occurring distal to the celiac and superior mesenteric arteries (red circle).

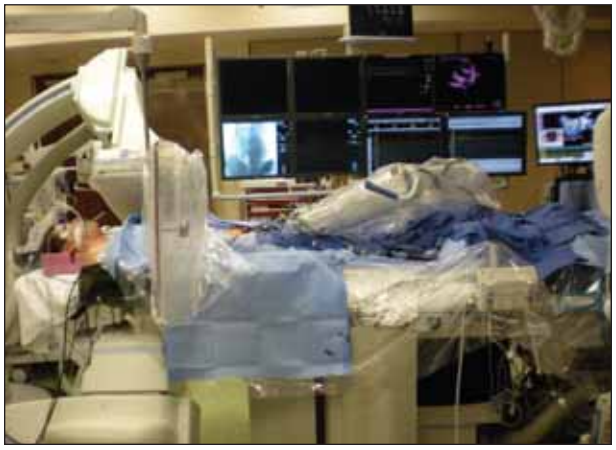

Figure 5. A robotic arm controls catheter movement inside the patient.

Irie et al found that DynaCT was able to scan a wider area in a shorter period of time while delivering superior quality coronal and sagittal reconstruction images.[5] DynaCT allows a contrast resolution of 10 HU (Hounsfield units) as well as a slice thickness and in-plane resolution of < 1 mm.[6] It is also ideal if the system is able to boast better coverage, which can be a clear advantage when treating an obese patient but can also serve to decrease exposure times.

One of the concerns with this cone-beam technology is the amount of radiation exposure to the surgeon/interventionist and patient. It was found that the total radiation dose is 236 mGy for FD-based DynaCT, while the dose for 3D DSA using the same system is about 50 mGy.[5] Other investigators revealed that the dose of radiation for a conventional head CT was similar to that of DynaCT, namely 60 mGy.[7,8]

One of the areas where DynaCT has the potential to garner the most advantages is as a navigational tool. As devices become more refined and are able to challenge more complex anatomy, DynaCT will be able to assist obtaining the 3D imaging necessary to situate and guide the instrument to its target. This can be a particularly attractive feature when one starts discussing potential applications for flexible robotics.

REGISTRATION OF AXIAL IMAGING WITH ANGIOGRAPHY

The fusion of axial imaging and angiography in the interventional suite will soon enable endovascular navigation in 3D-like perspective. Coregistration of multimodality imaging in the angiographic suite overcomes some of the weakness of each separate modality and accentuates the strengths of both. Angiography provides 2D luminal contour detail but does not provide extraluminal tissue information. Combination technology that aligns 2D angiography with 3D images allows for better visualization of vessel tortuosity and the relationship of the lumen to surrounding structures. Because the vessels are 3D structures, visualizing them in 3D during procedures is more intuitive.

Specialized software now allows for coregistration of the angiographic images with the reconstructed axial images. Initially, most applications for fused multimodality imaging were used for cardiac or intracranial interventions.[9-11] In the future, multimodality imaging and processing will likely evolve to become standard tools of vascular specialists.

Multimodality image fusion can be achieved in different ways. One option for coregistration of fluoroscopy and axial imaging is real-time magnetic resonance imaging (MRI) or CT in the interventional suite. However, this currently requires specialized endovascular equipment and poses safety concerns for the treating clinicians. New angiography systems enable CT-like reconstruction of images using rotational angiography (Philips Allura Xper FD20/10 [Philips Healthcare, Andover, MA] and the Siemens zeego). Another option is aligning the diagnostic axial images with fluoroscopic images via externally placed fiducial markers or internal anatomic landmarks. This emerging technique combines reconstructed 3D axial CT or MR images with the 2D imaging in the angiography suite. In one example of bringing fusion imaging into the angiography suite, Gutierrez and colleagues performed both cardiac and peripheral vascular interventions using MRI coregistered to fluoroscopy.[10] They placed external fiducial markers on patients before a baseline electrocardiography-gated MRI. The patients were subsequently moved to the angiographic table with the external markers still in place. Several baseline x-rays were acquired, and special software fused the MR and the fluoroscopic data using the markers to align the images. Although the authors found problems coregistering external markers on loose skin and abdominal fat, MRI road mapping proved feasible. Future systems under investigation may include such internal markers as bones.

ADVANCING SIMULATION

The apprenticeship model, with its "see one, do one, teach one" philosophy, has been the standard approach for physician training. However, the landscape of surgical training has been changing: there are an increasing number of procedures to learn, fewer patient hours available for resident and student teaching, and more technical procedures. In this context, surgical simulation is becoming an increasingly important part of physician training. More and more programs are investing in surgical simulation centers of excellence, ultimately to improve patient outcomes and care.

In the endovascular space, Medtronic Vascular (Santa Rosa, CA) has invested in developing a simulation program for thoracic aortic aneurysms in partnership with Medical Simulation Corporation (MSC) (Denver, CO). Physicians have the opportunity to practice device deployments in a realistic simulation environment with a variety of case scenarios and tough, real-world challenges and complications. The cases were developed with highly experienced implanters of thoracic stent grafts and MSC's haptic resistance technology so that the simulator mimics the feel of an actual stent graft implantation. These simulators are used extensively in physician education courses and recently traveled to 70 cities across the United States for further physician training (Sidebar Figure 1).

"Simulation is about preparation, practice, and performance," said Dr. Carlos Donayre, a vascular surgeon at Harbor-UCLA Medical Center in Torrance, California. "The simulators prepare physicians to become IFU-compliant in an interactive way; we are able to reiterate key points in the IFU and point out important features of the stent graft. Simulation also allows physicians to gain practice so that if complications do arise, they can work through them in a simulated environment with haptics that provide them with immediate and realistic feedback. Both preparation and practice lead to improved performance and better outcomes for patients."

Sidebar Figure 1. Endovascular simulator.

Once the CT or MRI images are coregistered with the angiographic images, a real-time working overlay or road mapping can be projected for the treating clinician. New software to perform the coregistration with CT and MR is now becoming commercially available, but the quality of the fusion images remains unclear. One unsolved problem is the vessel deformity caused by stiff intraluminal wires, catheters, and devices. The deformity of the vessel causes a mismatch between the preoperative imaging and the live angiogram. However, as this exciting technique evolves, more precise and integrated images will become available.

DYNAMIC MRA

Although the resolution of 3D CT scans is optimal, MRI has the added advantage of being capable of providing additional physiologic data. We use dynamic 3D MR reconstruction in all patients with aortic dissections, often with computational fluid dynamics overlay (Figure 4). Although computational simulations in general and of blood flow in human arteries in particular have been the topic of research in the last decades,[11,12] only recently with the introduction of advanced clinical imaging techniques and progressed computing power has it been possible to tailor these simulations toward the conditions found in a particular individual.[13-16] Initially, computational fluid dynamics (CFD) simulations were restricted to 2D models and idealized geometries. Solutions even for these simplified geometries could only be obtained after many hours or even days. Continuous technical advances, however, have now made it possible to convert information from images acquired during a routine clinical exam into 3D complex mathematical meshes consisting of hundreds of thousands of small-volume elements for transient simulation of the hemodynamics in artery segments of the human vasculature either in health or in disease.[17] The results of these simulations provide access to hemodynamic parameters that are currently not reliably measurable with clinical imaging methods. Arguably one of the most important of these parameters is the wall shear stress (WSS) that the flowing blood is exerting onto the arterial wall. Wall shear is an important determinant of dissection. Other parameters include dynamic pressures (dynP) and recirculation patterns; the latter may facilitate the adhesion of material onto the artery wall and promote the creation of atherosclerotic lesions, for example, in the bulb of the carotid bifurcation.

Hemodynamics may play an important role in type B aortic dissection (TB-AD). A recent flow study of a chronic TB-AD demonstrated a direct dependence of systolic and diastolic pressures in the true and false lumen on TB-AD morphology, emphasizing the need for a better understanding of hemodynamic forces in TB-AD.[18,19] Toward this goal, we employed CFD simulations to investigate the feasibility of quantifying changes in hemodynamic parameters before and after thoracic

endovascular aortic repair (TEVAR) of a type B aortic dissection.[20,21]

3D IN THE MODERN ANGIOGRAPHIC OPERATING ROOM

Fusion of preoperative images with live angiography or simultaneous 3D imaging allows for the delineation of the vessel lumen centerline during interventions. Especially in vessels with atherosclerosis or thrombus, manipulation of endoluminal devices invariably leads to dislodgement of plaque debris and clot. The catheter or device dragging along the vessel wall could also cause injury such as dissection or perforation. Although the clinical significance is unknown, catheter manipulation in the atherosclerotic aortic arch is associated with embolic signals on brain ultrasound.[22]

Using computer-generated projections of the luminal centerline, could wires, catheters, and devices one day be steered away from the vessel wall? One current system uses a special ferromagnetic-tipped wire to navigate through blood vessels using magnets on either side of the patient. By altering the direction and strength of the magnets, the wire tip can navigate through tortuous vessels and tight stenoses while minimizing vessel wall contact (Axiom Artis dBC [Siemens] and Niobe Magnetic Navigation system [Stereotaxis, Inc., St. Louis, MO]). In addition, new catheter control systems remove the clinician from standing next to the radiation source or the magnet (Sensei Robotic Catheter Control System). Instead, the clinician is seated at a workstation with a controller, and a robotic arm takes the place of the clinician's hand next to the fluoroscopy unit (Figure 5). In addition to reducing radiation doses from decreased fluoroscopy time, this could result in fewer complications due to catheter and wire vessel wall injury (see *Advancing Simulation* sidebar).

CONCLUSION

CT scanning plays a central role in the diagnosis, treatment, and follow-up of patients with abdominal aortic aneurysms. CTeXpress facilitates the electronic exchange of the 2D images and provides an online image repository. Furthermore, with 3D Recon, this 2D image database permits postprocessing of the images to provide 3D rendering, diameter and length measurements, the key tools necessary for planning endograft placement. We believe 3D reconstruction will increasingly be used to guide endovascular procedures. ■

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Surveillance of Aortic Stent Grafts

With the proper patient follow-up regimen, new imaging modalities are optimizing the current standard of care for EVAR surveillance.

BY CARTER FREIBURG, MD, AND BART E. MUHS, MD, PhD

With increasing application of aortic stent graft placement (EVAR) for aortic aneurysm repair comes the potential for more long-term complications. In light of health care expenditure debates, an economical yet safe protocol to monitor the patient and device after EVAR is critical. Consensus guidelines by Chaikof et al[1] recommend obtaining a computed tomographic angiogram (CTA) every 5 years for open surgical repair (OSR) of an abdominal aortic aneurysm (AAA), while EVAR requires yearly surveillance for endoleaks and device migration. During the first postoperative year, CTA—the current gold standard—at 1 month and 1 year is recommended unless an endoleak is detected. If a type II endoleak is detected, CTA at 6-month intervals is recommended. After 1 to 3 years without endoleak or aneurysm sac expansion, yearly duplex ultrasound can be considered if surveillance can be performed and interpreted by experienced staff.[1,2]

WHY DOES SURVEILLANCE MATTER?

Recent analysis from our institution of 270 ruptures after EVAR revealed that most ruptures will occur in the first 2 to 3 years after implantation. Endoleaks in which the aneurysm sac continues to fill despite EVAR were the most common cause of rupture. Only six of these endoleaks were type II endoleaks. The majority of endoleaks leading to rupture were type I and III from leaks at proximal and distal seal zones or component separation, respectively.[3] Type I and type III endoleaks require timely intervention. However, many of these dangerous endoleaks were not detected due to inadequate follow-up. Endovascular or open treatment of type II endoleaks should be considered after persistence for > 6 months.[1] Device migration was the second most common cause of rupture. The fact that failure of follow-up contributed to rupture in 43 patients underscores the necessity of a surveillance protocol.[3]

WHAT IS THE IDEAL MODALITY FOR EVAR SURVEILLANCE?

The ideal EVAR follow-up modality remains controversial. Proponents of yearly surveillance with CTA emphasize the superior reproducibility, convenience, and a clearer picture of graft integrity and morphology of the aneurysm. CTA sensitivity is 92% with specificity 90%.[4] Ultrasound follow-up regimens cite decreased cost, decreased radiation exposure, and similar rates of endoleak detection as benefits of ultrasound over CTA.[2,5] The sensitivity of color duplex for endoleaks has been reported to be 52% to 81% with a specificity of 89% to 97%, with a positive predictive value of 88% and a negative predictive value of 100%.[6,7] With yearly CTA within the first 5 years, 9.3% of patients will benefit from the detection and intervention upon endoleaks.[8] Chaer et al support that surveillance solely by ultrasound is effective in detecting endoleaks especially after the first 3 years.[2]

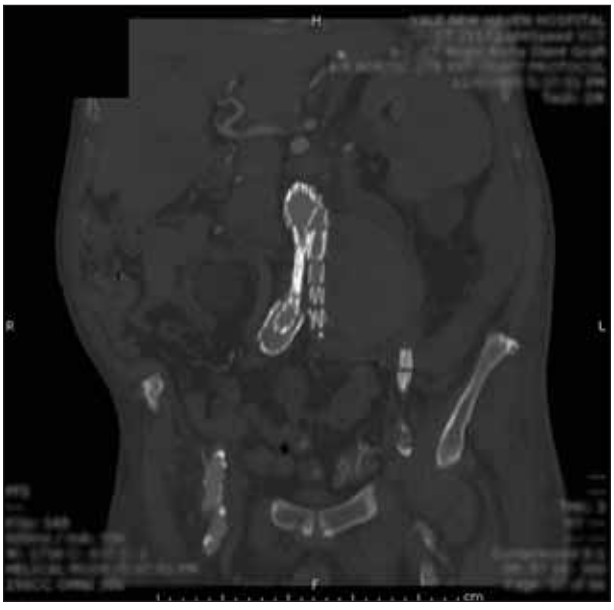

Figure 1. This patient, who underwent EVAR 4 years prior, presented with hemodynamic instability and a ruptured AAA. He had been lost to follow-up and had received inadequate postoperative imaging. The CT, shown here, demonstrated an AAA that had grown in size to nearly 9 cm from 5.5 cm 4 years before. There was active extravasation of contrast into the retroperitoneum.

Figure 2. Some companies offer surveillance software, such as the StentGraftTracker by Medtronic Vascular.

WHAT DOES THE FUTURE OF EVAR SURVEILLANCE LOOK LIKE?

Follow-up CTA at 1 month and 1 year after EVAR is likely a legacy of the US pivotal trials conducted for FDA device approval. Most clinicians have used the 1-month, 6-month, and yearly CTA follow-up surveillance regimen mandated in the trials in their routine clinical practice. There are very little data supporting this regimen, and many centers, including our own, now routinely eliminate the 1-month CTA if the procedural angiogram was pristine. Our current practice is to use both ultrasound and CTA after 3 to 6 months and then yearly for the next 3 years. Adjustments are considered in cases of expansion or large type II endoleaks. After 36 months without aneurysm expansion or endoleak, annual ultrasound is a safe mode of surveillance. Any suspicion for aneurysm expansion or graft abnormality should prompt CTA. Failure of the follow-up regimen clearly results in preventable aneurysm rupture (Figure 1). The best regimen is one that is frequent enough to detect endoleaks within the first 3 to 5 years and is individualized to the patient's habitus and reliability.

Newer imaging modalities are showing promise. Contrast-enhanced ultrasound should increase the sensitivity and specificity and enable ultrasound to continue to replace CTA as the preferred method. At Yale, all of our follow-up imaging is performed with extensive three-dimensional postprocessing and examined by both a radiologist and vascular surgeon. This collaborative approach has clearly improved our readings and allowed subtle findings to be more widely recognized and acted upon.

Ensuring that this follow-up happens is more important and less expensive than any imaging modality—yet it is underappreciated. Obviously, a patient lost to follow-up will never have an asymptomatic endoleak detected before rupture. As our group has previously published, the majority of patients who experience rupture did so after missing one or more follow-up intervals. Industry has begun to recognize this fact. Medtronic Vascular (Santa Rosa, CA) has introduced StentGraftTracker and 3D Recon (in partnership with Vital Images, Minnetonka, MN) in an effort to ensure patients treated with their devices achieve optimal surveillance (Figure 2). Whether one chooses to use a service from industry or simply create one's own system to ensure proper follow-up, surveillance cannot be overemphasized. ■

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