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The Trouble With Aneurysms

An aneurysm is a progressive weakening and ballooning of a blood vessel. Aneurysms commonly affect the abdominal and thoracic aortas and, if undiagnosed and untreated, can lead to rupture and death. Approximately 17% of the U.S. population is currently over the age of 60, putting them at greatest risk of developing an aneurysm. It is estimated that more than 1.5 million Americans already have an aortic aneurysm, of which only 20% have been diagnosed and a mere 3% are receiving treatment.

There are many reasons for our inability to detect aneurysms, the most important being a fundamental lack of awareness and education about the risk factors that predispose patients to develop this deadly problem.

The vascular specialty is relatively new in the history of medicine, being only 50 years young. In the past decade, there has been an increasing effort toward providing education and developing patient awareness about vascular issues throughout the United States, and we are excited to be a part of this campaign. In the same 10 years, aneurysm research has led to significant advances in innovative and minimally invasive endovascular means of treating these life-threatening conditions and improving patient outcomes. We are grateful for the opportunity to present this comprehensive issue of V-Aware focusing on the risk factors, diagnosis, and treatment of aneurysms.

The expert contributors here include Dr. Sean P. Roddy discussing the impact of the SAAAVE Act, a bill signed by President George W. Bush in 2006, on finding aneurysms and saving lives. This article is followed by Dr. Carlo A. Dall’Olmo explaining the findings of the landmark EPICS I study, which underscored the value of screening for abdominal aortic aneurysms in patients with heart disease who had undergone a prior heart bypass.

Most vascular diseases including aneurysms share risk factors with coronary artery disease, and Dr. Lance E. Sullenberger describes the importance of cardiac evaluation in aneurysm patients. Next, I had the privilege to discuss endovascular methods of treating abdominal and thoracic aortic aneurysms; these techniques have clearly revolutionized our ability to treat aneurysms. Of course, no review of aortic aneurysms would be complete without a comprehensive overview of the surgical treatment option; Dr. R. Clement Darling III presents The Vascular Group’s experience of performing more than 4,000 surgical aortic reconstructions.

All patients that undergo aneurysm repair, whether endovascular or surgical, require anesthesia, and Dr. Michael Sandison outlines the different types of anesthesia care appropriate for aneurysm patients. We have the privilege of sharing the heartwarming story of a retired professor of physics turned “Santa Claus,” who presented emergently with thoracic and abdominal aortic aneurysm/dissection, underwent repair, and continues to delight children at Christmas.

Aortic aneurysm patients are certainly at risk of developing aneurysms in other parts of the body. Dr. Philip S. K. Paty goes over the diagnosis and treatment options for aneurysms in the lower extremities; and Bernadette V. Barnum, RPA-C, and Dr. Alan S. Boulos provide a detailed discussion on brain aneurysms. Finally, this comprehensive issue on aneurysms is balanced with Dr. Peter D. Cospito’s advice on healthy living for patients with cardiovascular disease, registered nurse Deborah Hill talks about the importance of aneurysm research and clinical studies available in the northeast United States, and health news reporter Benita Zahn offers her unique view on making vascular health a priority. I hope you enjoy this issue of V-Aware, and as always we welcome your comments and suggestions. Please write to us at info@vaware.org.

Warmest regards,

Manish Mehta, MD, MPH
President and CEO of the Center for Vascular Awareness, Inc., in Albany, NY
FINDING ANEURYSMS and Saving Lives

Sean P. Roddy, MD

Abdominal aortic aneurysms (often referred to as AAAs) are expansions of the main artery that resides directly behind the stomach and intestines.

The outer wall of this artery can weaken, resulting in progressive stretching and enlargement over time. Left unrepaired with increasing tension in the artery wall, the AAA may burst leading to serious blood loss and death. More than 15,000 Americans die annually from ruptured AAAs. Surgical repair of these aneurysms can prevent rupture with a reasonably low risk of complications.

Ultrasound screening to detect AAAs has been the focus of the Society for Vascular Surgery for many years. In general, screening programs must always consider how often the disease is identified in society, the cost of the screening, and any possible harm that might affect patients as a result of the screening test. Additionally, the financial burden and risk to the patient must be evaluated, both in cases where the disease process is never identified as well as if the disease is diagnosed and properly treated.

More than 15,000 Americans die annually from ruptured AAAs.

PAYING FOR SCREENING

Adding any kind of screening benefits for Medicare beneficiaries requires an Act of Congress. Examples of current screening initiatives covered by Medicare include glaucoma, prostate cancer, colorectal cancer, and mammography for breast cancer. Private carriers develop their own guidelines regarding the screening tests they will pay for.

In 2004, the Society for Vascular Surgery, in cooperation with other professional organizations and industry partners, established the National Aneurysm Alliance. During this same time period, the United States Preventive Services Task Force recommended that men between the ages of 65 and 74 who have smoked at some point in their lives be screened for AAAs. After an extensive lobbying effort, Congress finally passed the Screen for Abdominal Aortic Aneurysms Very Efficiently (SAAAVE) Act in 2005. President George W. Bush signed the bill on February 8, 2006, and it went into effect in 2007.

SAAAVE provides a Medicare screening benefit limited to men who have smoked more than 100 cigarettes or men and women with a family history of AAA. The ultrasound can only be requested by the patient’s physician after completion of a “Welcome to Medicare” physical. The Center for Medicare and Medicaid Services (CMS) even created a new billing code to refer to the screening test.

Several private carriers have also created policies regarding AAA screening coverage. For example, Cigna Healthcare published guidelines in February 2007 that allow for one screening per lifetime in any man between the age of 65 and 75 who has smoked at some point in his life.
SAAAVE took effect on January 1, 2007 and fewer than 10,000 people were screened for AAA that year. This has been a great disappointment to vascular surgeons nationally. Recently, H.R. 1213 was introduced as a bipartisan bill sponsored by Rep. Gene Green (D-Texas) and Rep. John Shimkus (R-Illinois).

This bill aims to unlink the AAA screening benefit from the “Welcome to Medicare” physical exam and expand the one-time screening to all 65- to 75-year-old Medicare beneficiaries who are at risk. Each AAA that is identified may defuse a silent “time bomb” in an unsuspecting patient. A simple ultrasound test may be all that is needed to find an aneurysm and save a life.

Contact your congressional representatives today and ask them to co-sponsor H.R. 1213 and extend AAA screening to more people, including more women.
Physical examination is a vital component of aortic aneurysm diagnosis.
We found that both men and women who have undergone coronary artery bypass grafting have a higher prevalence of AAAs than the population at large.

The prevalence of coronary artery disease (CAD) in patients with abdominal aortic aneurysms (AAA) has been extensively documented. Now studies are demonstrating the importance of also reversing directions and screening CAD patients for AAA.

A COMMON CAUSE
AAA, peripheral arterial disease (PAD), and CVD are serious manifestations of peripheral vascular disease (PVD). These diseases share many of the same risk factors with coronary artery disease (CAD), along with a common cause in atherosclerosis, a primarily systemic inflammatory process. Patients with AAs, for example, are thoroughly evaluated for the presence of CAD, but in patients with CAD, coexisting manifestations of PVD (including AAA) may be overlooked. Considering the possibly global nature of vascular disease for any individual with symptomatic atherosclerosis, we have undertaken studies to support our belief that all CAD patients should be routinely screened for AAAs and other vascular diseases.

The occurrence of AAA in the general population has been well assessed in large-population-based studies, which have reported AAA in 3.6% to 7.6% in men and in 1% in women. The incidence of AAA has also been found to increase with patient age and to be especially associated with smoking: The risk of AAA is 7.6 times greater for current smokers than for nonsmokers and 3 times greater for former smokers than never smokers.

THE VALUE OF SCREENING
The timing of treatment for AAA is based in large part on aneurysm size; those that are greater than 5 cm at maximum diameter represent a greatly increased risk of rupture (if not treated). The prognosis is poor when AAs—often undiagnosed—rupture, however, screening and detection by non-invasive ultrasound imaging have been shown to greatly reduce the rate of death directly related to AAA. For example, one randomized single-center mass screening trial among elderly patients, without regard to risk, found that over 10 years, screening reduced emergency operations for AAAs by 68% and death due to AAAs by 73%.

The value of such screening has been recognized to some extent in the United States by the recently implemented Screening Abdominal Aortic Aneurysms Very Efficiently (SAAAVE) Act of 2005, which allows a one-time ultrasound screening benefit to check for AAAs in Medicare patients who are designated at risk based on being male with a history of smoking or (for women as well as men) having a family history of AAA. (An amendment to the SAAAVE Act that is currently before Congress would unlink the one-time screening from having to take place at the Welcome to Medicare Physical Exam, which is available only during the first year of Medicare eligibility, but the issue of expanding the definition of at risk has not been addressed.)

THE AAA/CAD/CABG LINK
That the coexistent occurrence of AAA for patients with CAD who undergo coronary artery bypass grafting (CABG) may be far greater than that in the general population has been suggested by a small handful of studies, including one in which 40 unsuspected AAAs were detected in 395 male patients aged 60 years or older who were hospitalized for CABG and who accepted optional abdominal imaging—a rate of 10.1%.

We have extended the terms of that study, and have as a result broadened the appeal for greater AAA screening (beyond the qualifications in the SAAAVE Act) by assessing the prevalence of AAA in women as well as men who had previously undergone CABG. Including patients 60 years of age and older without regard to whether they had been previously diagnosed with or treated for AAA allowed us not only to estimate the prevalence of AAA in the elderly CABG population but also to potentially offer further demonstration of the value of screening.
Between September 2004 and July 2005, registered vascular technologists at our facility screened a total of 752 self-enrolled patients with a history of CABG, basing diagnosis of AAAs on duplex ultrasound determination of an infrarenal aortic diameter \( \geq 30 \) mm, with the probe perpendicular to the axis of the aorta.

In the 517 men screened, we found a total of 47 AAAs (for a rate of 9.0%), 31 (66%) of which had not been previously detected, and 16 (34%) of which were either being followed by a physician or had been surgically treated. In the 235 women screened, we found a total of 12 AAAs (for a rate of 5.1%), 6 (50%) of which had not been previously detected.

In our analysis of the ultrasound findings, we categorized the AAAs—separately for the men and for the women—by size, patient age, smoking history, and by diabetes and hypertension status. The maximum AAA diameter was 3.0 to 3.9 cm in 30 of the men and six of the women, 4.0 to 4.9 cm in 11 of the men and four of the women, and 5.0 cm or greater in six of the men and two of the women. For the men, the prevalence of AAAs increased with age, to a rate of 10.5% for those aged 75 to 79 years and a rate of 13.7% for those 80 years of age and older. The number of women was too small to indicate any such trend. Our analysis confirmed that smoking is the single most preventable risk factor for AAA. Among the men screened, the prevalence of AAAs increased from only 2.3% in the 126 who had never smoked to 10.3% in the 348 former smokers and 18.6% in the 43 current smokers. Likewise, among the women screened, the prevalence of AAA increased from only 1.6% in the 118 who had never smoked to 6.9% in the 101 former smokers and 18.7% in the 16 current smokers.

Our findings did not suggest a relationship between diabetes and the number of AAAs in the previous CABG patients. There were no AAAs detected in any of the small number of patients with type I diabetes, and for both men and women the prevalence of AAA was greater for nondiabetics than for type II diabetics. Unlike the previous study of AAA in patients who were hospitalized for CABG, in which hypertension was found to be a significant risk factor, our analysis could demonstrate no such association, at least for the men who were screened. However, the possibility that hypertension may be an important risk factor for AAA among women with CAD is at least suggested by the fact that only one AAA was detected in the small number (37 out of 235 total) of screened women with normal blood pressure.

PROVIDING OPTIMAL CARE

We found that both men and women who have undergone CABG have a higher prevalence of AAAs than the population at large—9.0% in our study versus 4% in the general population of men and 5.1% in our study versus 1% in the general population of women. The importance of screening for this population is underscored by the fact that 66% of the AAA we detected in men and 50% of the AAA in women had been previously unsuspected. Our study was unique in its inclusion of women, and our findings for the women screened support the amending of the SAAAVE Act definition of at risk to include all men and women who have undergone or are about to undergo CABG. Our findings, considered along with those of previous evaluations of AAA prevalence in CABG patients, support the contention that deleterious consequences may be avoided by routine screening for AAA in these patients before surgery.

THE EPICS 1 STUDY

Between September 2004 and July 2005, registered vascular technologists at our facility screened a total of 752 self-enrolled patients with a history of CABG, basing diagnosis of AAAs on duplex ultrasound determination of an infrarenal aortic diameter \( \geq 30 \) mm, with the probe perpendicular to the axis of the aorta.
The discovery of an aortic aneurysm is an important opportunity.

Abdominal aortic aneurysms (AAAs) are abnormal enlargements of the aorta, the largest blood vessel in the body, and are a common medical problem, affecting 2% to 4% of the U.S. population. Aneurysms develop when the lining of the aorta becomes damaged, most commonly from high blood pressure, diabetes, high cholesterol, or smoking. An enlargement of the aorta is a dangerous condition that may eventually need surgical correction.

It is important to recognize that the same diseases that damage the aorta are likely to damage the coronary arteries, the smaller blood vessels that supply the heart muscle with blood. Damage to these smaller blood vessels can eventually lead to the formation of plaque, thickened areas of the blood vessel walls that have become rich in cholesterol (a type of fat). Blockage of these arteries due to plaque is referred to as coronary artery disease (CAD). Damaged and obstructed coronary arteries can lead to chest pain (angina), heart attack, abnormal heart rhythms, or even death.

(ARTICLE CONTINUES ON NEXT PAGE)
As a cardiologist, when I see a patient with an aortic aneurysm I have three major concerns:

**Preoperative evaluation**
Many patients with AAAs will need operative repair of their aneurysms, either through open surgery or a newer, “nonsurgical” procedure performed through an artery in the groin area. Open surgery is considered a high-risk procedure, the nonsurgical procedure less so. For either repair, however, it is important that the cardiologist relay to the patient, the anesthesiologist, and the surgeon, the risk of heart attack or death from the stress the procedure will place on the patient’s heart. Many factors help determine this risk, but the main ones are a history of congestive heart failure, a history of heart attack or angina, an abnormal heart rhythm, and the presence and extent of ischemia (mainly obtained through stress testing). The cardiologist then assigns the patient a risk category:

- **Excessive** (surgery should be cancelled)
- **High** (more than 10% risk of heart attack, heart failure, or death from cardiovascular disease)
- **Intermediate** (a 2% to 10% risk)
- **Low** (a risk of less than 2%)

Once a patient with CAD is headed to surgery for an aneurysm, there are only two proven medical ways to reduce the chance of a heart attack during the procedure. The first treatment involves medications called **beta blockers**, which reduce the amount of oxygen the heart muscle needs. The other treatment utilizes statin medications, which help lower cholesterol and have recently been shown to prevent heart attacks if taken before and after vascular surgery. Most of the patients who take either of these drugs will receive close care in the hospital by a cardiologist as well as their vascular surgery team.

**Risk factors**
As mentioned previously, the diseases that lead to aneurysms also lead to CAD. Thus, controlling your risk factors is essential to the prevention of heart disease as well as the prevention of AAA or careful management for existing AAA. Blood pressure should be controlled with medications to a level below 140/90. Your level of low-density lipoprotein (LDL or so-called bad) cholesterol should be reduced to less than 100 mg/dL (even better is less than 70 mg/dL) using statin medications. Diabetes should be controlled to a hemoglobin A1C level of less than 7.0%. Most importantly, all smoking should be stopped. Controlling your risk factors is of the utmost importance: It makes no sense to fix surgically the end result of a problem such as an aneurysm or CAD without addressing the source of the damage.

**Extent of disease**
Nearly all patients with aortic aneurysms have some degree of CAD. The cardiologist must determine whether the degree of CAD is severe enough to limit blood flow to the heart muscle either at rest or with stress. This lack of blood flow is known as **ischemia** and it can sometimes, but not always, be associated with chest pain or shortness of breath. That’s why a careful history is so critical to the cardiac evaluation of a patient with an aortic aneurysm. When the information gathered from a patient’s history does not suffice, however, it is important to use another means of looking for ischemia or CAD. This is best achieved through stress testing, which allows pictures of the heart to be taken before and after stress. The coronary arteries can also be seen through a CT scan. In some cases, invasive coronary catheterization may even be necessary.

The discovery of an aortic aneurysm is an important opportunity. At that time, the cardiologist can address an individual patient’s overall cardiac health and also institute a treatment plan that will benefit the patient not only around the time of surgery but also for the rest of his or her life.
ENDOVASCULAR OPTIONS
for Abdominal and Thoracic Aortic Aneurysms

Manish Mehta, MD, MPH

More than 2,500 lives were lost on September 11, 2001, one of the most catastrophic days in the history of United States.

Now imagine an emergent, life-threatening condition that takes tens of thousands of American lives each year, creating devastation similar to a 9/11-like tragedy every other week. Rupture of abdominal aortic aneurysms (AAAs) and thoracic aortic aneurysms (TAAs) are potentially fatal events affecting the aorta that brings thousands of Americans to the emergency room each year. Aortic rupture has been responsible for the deaths of some famous people such as John Ritter, Lucille Ball, Albert Einstein, and King George II, to name a few.

The aorta is the main blood vessel that carries blood from the heart to the rest of the body and is similar in size to a large garden hose. It wraps around the heart and travels through the chest (where it is known as the thoracic aorta) into the lower abdomen (where it becomes the abdominal aorta). Along the way, the aorta gives rise to blood vessels that supply circulation to all parts of the body. An aneurysm is a progressive weakening and ballooning of the blood vessel wall, a condition that commonly affects the abdominal and thoracic aorta. If undiagnosed and untreated, an aneurysm can rupture resulting in catastrophic internal bleeding and death.

ENDOVASCULAR REPAIR EXPLAINED
Endovascular repair is a minimally invasive alternative to conventional open surgical repair. In these procedures, a vascular surgeon gains access to the aorta by making two small incisions in the groin area. Through that opening, the surgeon delivers treatment by navigating narrow wires and catheters within the blood vessels. Live x-ray guidance is used to identify the aneurysm as well as the normal, healthy aorta and iliac arteries above and below the aneurysm.
A device called a stent graft is then advanced through a catheter into the aneurysm from the groin. The abdominal aortic stent graft is composed of synthetic fabric supported by a metal mesh framework; it looks like a pair of pants with a waist and two legs. A thoracic aortic stent graft is tubular in shape. Both devices are designed to anchor onto sections of healthy artery above and below the aneurysm. Once fully deployed, the stent graft diverts blood flow and takes the pressure off the aneurysm, thus reducing the risk of growth and rupture.

SUCCESSFUL AND SAFE PROCEDURES
Our experience of performing approximately 2,000 endovascular abdominal and TAA repairs at the Vascular Institute for Health and Disease at Albany Medical Center happens to be one of the largest experiences in the world. We understand that a successful procedure depends on careful patient selection and planning, and having a standardized team approach improves outcomes.

Endovascular aneurysm repair can be performed under general anesthesia, spinal or epidural anesthesia, or even local anesthesia. The procedure takes approximately 1 to 2 hours to perform and is generally associated with fewer complications than the standard open surgical repair. In patients who are considered suitable candidates, endovascular aneurysm repair has a technical success rate of over 98%. Complications affecting the heart, lungs, kidneys, bowels, and other organs occur in fewer than 10% of patients, and the chance of death as a result of endovascular aneurysm repair is generally less than 1% to 2%. In addition, the risk of paraplegia is lower with endovascular TAA repair compared to open surgical repair.

Most patients recover in the hospital for a couple of days and return to their normal baseline activities in 2 to 4 weeks. After endovascular aneurysm repair, patients require lifelong follow-up by their vascular surgeon, and they must undergo routine clinical evaluation and appropriate imaging to evaluate the integrity of the stent graft and confirm aneurysm exclusion.

CHOOSING TREATMENT
Over the past decade, endovascular technology has had a substantial impact on vascular surgeons’ ability to treat patients with aortic aneurysms. In the United States, approximately 200,000 patients each year are diagnosed with AAAs. Of these, 45,000 people will receive treatment, and the majority will undergo an endovascular procedure. Preprocedure planning is critical for technical success of endovascular aneurysm repair, and the vascular surgeon will routinely evaluate the patient’s anatomy to determine whether he or she qualifies for open surgical repair or endovascular repair. Patients also undergo a careful evaluation of their risk factors with particular attention to their cardiac, pulmonary, and renal status.
POSSIBLE COMPLICATIONS
Currently available studies suggest that within 5 years after endovascular aneurysm repair, less than 15% of patients will require a secondary minimally invasive intervention, and only 1% to 2% will require conversion to open surgical repair.

However, there are several possible complications of endovascular aneurysm repair that may require secondary intervention. Endoleaks are the presence of persistent blood flow in the aneurysm sac due to inadequate stent graft seal or back-bleeding from small collateral blood vessels originating in the aortic aneurysm. Stent graft migration can occur over time and may lead to endoleaks from stent graft seal zones above and below the aneurysm. The development of other aortic and iliac aneurysms and failure of stent graft integrity may also call for additional treatment.

It is for these reasons that following endovascular aneurysm repair, patients need to stay connected to their vascular surgeon in order to undergo routine follow-up and be treated appropriately for any issues that might arise.

APPROVED DEVICES
Today, in the United States, there are five different FDA-approved abdominal aortic stent grafts and three different thoracic stent grafts. Together, these devices can accommodate up to 60% of all aortic aneurysms. At various centers of excellence, vascular surgeons are investigating several new stent grafts that would enable us to offer this minimally invasive endovascular therapy to patients who cannot be treated with currently available devices.

There are many advantages to endovascular aneurysm repair as well as open surgical repair. Vascular surgeons are the experts that treat aortic aneurysms and perform both procedures, and can best determine which treatment will benefit a patient most. If you or someone you know has an aortic aneurysm, I encourage you to consult with a vascular surgeon to better understand all of the risks and benefits of both endovascular and open aortic aneurysm repair.
In high-risk patients, the entire abdominal and thoracic aorta can form aneurysms.

**The aorta is the largest artery in the body.**

It exits the left ventricle of the heart, sends off blood vessels to both arms and the brain, and then proceeds down through the chest, where it is considered the thoracic aorta. Once the aorta extends below the diaphragm it becomes the abdominal aorta and sends off blood vessels to the bowels (celiac and superior mesenteric artery) and both kidneys (the right and left renal arteries).

An aneurysm is a weakness or ballooning of the arterial wall leading to an increase to twice the diameter of its original size. Left untreated, aneurysms of the thoracic and abdominal aorta will continue to grow until they burst. This fatal event can be prevented by early diagnosis and appropriate treatment.

The aorta is the most common artery in the body to form aneurysms, and 95% of all aneurysms occur in the infrarenal aorta (below the level of the kidneys). The thoracic aorta is the second most likely location for an aneurysm to occur.

**DETECTION**

More than three-quarters of aortic aneurysms are picked up serendipitously, when a patient is undergoing other tests such as an ultrasound for kidney or gallstones, or a chest CAT scan examining the lungs or investigating back pain. Abdominal aortic aneurysms (AAAs) can also be picked up by a vigorous abdominal exam, but aneurysms can be difficult to palpate in much of the American population who may be heavy or obese. An ultrasound by an accredited vascular lab can easily pick up AAAs, and a CAT scan can be used to diagnose aneurysms of the thoracic aorta.

Up to 20% of patients with an aneurysm will have a first-degree relative who also has, or has had, an aneurysm. Patients with a family history are at higher risk for aneurysm formation and should be screened more rigorously after reaching the age of 50.

Because the aorta lies right next to the backbone, the most common sign of rapid enlargement or early rupture is back or abdominal pain. If rupture occurs, it is universally fatal. Even with treatment, the risk of death and complications ranges from 1% to 5% to over 50%, so it is important that patients are screened early. Individuals who are found to have only a small aneurysm can then be followed closely. Others may require treatment.

Once a thoracic or aortic aneurysm is identified and evaluated by a CAT scan or duplex ultrasound, a decision can be made regarding the best form of therapy. Intervention is indicated if an abdominal aneurysm has a diameter greater than 5 cm or shows growth of more than .5 cm over a 6-month period. Thoracic aneurysms require treatment when they measure 5.5 to 6.0 cm in diameter or similarly rapid growth. Smaller aneurysms should be followed closely by non-invasive means.
Benefits of Open Surgery

Abdominal surgical repair
If patients are anatomically unsuitable for minimally invasive, endovascular aneurysm repair, they should be evaluated for open (surgical) aortic reconstruction. In the infra- or pararenal aorta, there are two common approaches used for repair of the aneurysm. The retroperitoneal approach, through an incision made in the side of the patient’s body, has been pioneered by The Vascular Group in Albany, NY, and has significant technical benefits for the surgeons and an earlier return to normal daily activities for patients. We have performed more than 4,000 aortic reconstructions in this way and have found that patients usually stay in the hospital about 1 week and are fully recovered after 4 to 6 weeks.

The retroperitoneal approach utilizes an incision on the left side of the abdomen; the aorta is clamped above and below the aneurysm, and a plastic tube, usually made of Gore-Tex or Dacron is directly inserted and sewn in using a permanent suture. Occasionally, we also have to make a small incision on the right side of the patient’s body; this allows us to approach one of the blood vessels going to the leg, in order to fully remove all aneurysmal disease.

One of the benefits of open aortic reconstruction for AAA is that it is a definitive procedure and the need for additional procedures is minimal. We have had excellent results over the last 30 years using this procedure, even in high-risk and elderly patients.

Thoracic surgical repair
Repair of thoracic aneurysm entails making an incision in the patient’s chest, and sometimes also the abdomen, in order to clamp the aorta above and below the aneurysm and replace the diseased segment with a plastic tube of Gore-Tex or Dacron. This procedure is a little more strenuous for the patient than surgical AAA repair, as the blood supply to the bowels, kidney, and spinal cord has to be interrupted during the operation. However, these procedures are performed with excellent results in high-volume centers.

Early Detection is Vital
It is vitally important that aneurysmal disease of the thoracic and abdominal aorta be diagnosed as early as possible. Early diagnosis and intervention by board-certified vascular surgeons working as a team in high-volume centers can repair the aneurysm and return patients to their normal state of health.
ANESTHESIA CARE
of the Aneurysm Patient

Michael Sandison, MD

Repair of abdominal aortic aneurysms (AAAs) or thoracic aortic aneurysms (TAAs) presents a formidable challenge to the anesthesiologist and the rest of the medical team.

These challenges increase when the aneurysm to be repaired is located closer to the heart because of the effect surgery has on circulation. In addition, many patients are elderly and have significant medical problems, such as hypertension, diabetes, atherosclerosis, coronary artery disease (CAD), stroke, peripheral arterial disease, and chronic obstructive pulmonary disease, often related to many years of smoking tobacco. Some patients may have aneurysms related to trauma or infection.

PREOPERATIVE CARE
Aortic aneurysms can rupture, requiring emergency surgery with a high risk of death or complications. Once an aneurysm reaches around 5 cm in diameter, it is far safer to repair it electively as a planned procedure in consultation with cardiologists and pulmonary specialists. These consultants can determine the severity of any associated medical conditions and treat them with medicines (such as statin drugs, beta blockers, antiarrhythmics, antihypertensives, bronchodilators, and insulin) to optimize the patient’s condition prior to surgery. It is also important for the physicians to consider the condition of the heart muscle, as the ventricles may have been damaged by repeated heart attacks related to CAD.

ANESTHESIA OPTIONS
If an open surgical repair of the aneurysm is planned, the patient will require general anesthesia. A combination of intravenous and inhaled medications will be administered to induce and maintain unconsciousness, combined with drugs to limit pain, recall, and anxiety, and to produce muscle relaxation of the belly or chest. During general anesthesia, a breathing tube is placed in the patient’s windpipe, and a ventilator ensures adequate breathing.

Minimally invasive endovascular aortic aneurysm repair (EVAR) or thoracic aortic aneurysm repair (TEVAR) require no belly incision and may be performed under general anesthesia, spinal anesthesia using local anesthetics and analgesics to induce immobility and lack of sensation from the waist down, or local infiltration anesthesia. During spinal or infiltration anesthesia, the patient is usually also given sedation and is asleep. Patient participation is sometimes required during the procedure, so they may remember being asked to hold their breath during the operation.

Minimally invasive endovascular aortic repair (EVAR) requires no belly incision and may be performed under general anesthesia.
In the operating room, the anesthesia team prepares the patient for the procedure.

**MONITORING THE CIRCULATION**

During surgery, intravenous lines must be inserted to enable the anesthesia team to replace fluids and blood that the patient may lose. A transfusion may be required, so blood and blood products must be cross-matched and available. In addition, blood warming and cell salvage equipment must be ready for use. During the procedure, any shed blood is collected, anticoagulated, centrifuged, washed, and returned to the patient.

Wrist (radial) or elbow (brachial) arterial catheters are placed to carefully monitor blood pressure, which rises sharply when the aorta is cross-clamped during open surgery. This rise in blood pressure is followed by a sharp drop when the clamp is removed and circulation is restored to the legs and abdomen. A central line is usually placed in the patient’s neck or under the collarbone for the delivery of powerful drugs that can constrict or open the arterial circulation and to monitor blood pressure in the venous circulation. This may include a catheter in the pulmonary artery if a clamp above the renal arteries is considered necessary.

For TAA repairs, an ultrasound probe called a transesophageal echo (TEE) might be used to provide a two-dimensional image of the heart and enables the anesthesiologist to monitor the performance of the heart against the resistance created by the high thoracic aortic clamp. TEE also gives the team the ability to watch cardiac filling, pump function, and ventricular wall motion, which may be impaired by CAD and the high stress imposed on the heart by open surgery. A spinal catheter may also be placed to improve the blood supply to the spinal cord.

**TEAMWORK AND COMMUNICATION**

The anesthesia and surgical teams must communicate and cooperate to deal with the effects of blood loss, associated clotting abnormalities, heart failure, and disturbances in heart rhythm, coronary supply and demand, kidney function, and spinal cord circulation (perfusion). The teams must ensure adequate one-lung ventilation during certain procedures and restoration of lung volume and lung function afterward. The teams will also control pain in the recovery room and monitor the patient’s recovery from sedatives and muscle relaxants. Patients having open TAA (and some AAA) repairs will require postoperative ventilation in an intensive care unit.

Effective teamwork and communication between the patient, consultants, surgeons, and the anesthesia team are vital aspects of the successful care of patients undergoing these high-risk, complex, and ultimately rewarding procedures.
A PATIENT'S STORY: John

John had never been screened for an aneurysm before he wound up in the emergency room.

On May 22, 1995, John Corelli was awakened at 4 a.m. by a strange feeling in his body. His breathing was labored, and he had pain between his shoulder blades. John’s friend Brenda became so concerned that she drove him directly to the hospital emergency room.

There, an ultrasound of his chest showed a thoraco-abdominal aortic dissection, a tear in a layer of the body’s largest blood vessel—a condition that could have killed him.

John remained in the hospital for 2 weeks. “I remember during the first few days of my hospitalization, all of the medical staff appeared to walk on eggshells around me,” he said. “They all had that grim, serious look on their faces.”

John’s elevated blood pressure was slowly gotten under control with medication. Upon being discharged home he was told to follow up with his doctors, and he did just that. Over the next 12 years, the size of John’s aneurysm was monitored by regular computed tomographic angiogram (CTA) scans.
LIVING A FULL LIFE
John, a retired physics professor at Rensselaer Polytechnic Institute in Troy, NY, went on to live his life and did not let health concerns slow him down. “I didn’t worry about the aneurysm,” he said. “My family and friends took my condition more seriously than I did.” A colleague told him, “John, you shook hands with your maker.”

In spite of others’ worries, John went to the beach and body surfed, visited Indonesia, and walked the islands of the Pacific. He continued to volunteer with his local fire department and even started a new job as a shopping mall Santa, making good use of his authentic white beard and love of children. Despite his regular scans, John recalls thinking about the aneurysm in only a “fleeting way.”

PLAYING SANTA FIRST
By October 2007, the size of the aneurysm in John’s chest had grown to a diameter of 7.5 cm, requiring treatment. He met with a vascular surgeon and was given the option to undergo a procedure called thoracic endovascular aneurysm repair, or TEVAR. This alternative to open surgery uses a small incision in the groin to place a flexible tube called an endograft inside the damaged section of the aorta. The endograft takes pressure off of the aneurysm and essentially becomes a new pathway for blood to flow through. John agreed but chose to postpone treatment until after the Christmas season. When asked why he wanted to wait, he said, “I wasn’t that worried. I knew I was being taken care of. I had good diagnostic care and great medical follow-up. My vascular surgeon explained it all in complete detail. He drew out the procedure on a piece of paper that I still have. I just needed to be Santa first.”

In January 2008, John finally underwent the TEVAR procedure, which was a success. In September 2008, John required another procedure, an endovascular aortoiliac aneurysm repair, which also went very well.

THE NEED TO SCREEN
John has many of the risk factors that contribute to vascular disease including diabetes, high cholesterol, high blood pressure, and he is overweight. Unfortunately, he had never been screened for an aneurysm before he wound up in the emergency room.

He now takes medication that has lowered his blood pressure, cholesterol, and sugar levels, and he has lost some weight. His only brother is healthy, but knows that he should be checked for aneurysms since he is over age 50. John’s two children are nearing their 50th birthdays and are also aware that they should be screened for aneurysms. Currently, John says he “feels great” and continues to look forward to each November and December, “Santa’s busy time.”

- by Sharon Cillis, RN

KEEPING HIS FAITH
John has a strong religious faith and has read about the Catholic saint from Italy, Padre Pio. When the saint visited the sick, people would say that they smelled roses. John vividly recalls waking up from surgery and smelling roses. The scent was also in the recovery room. He asked the nurses if they detected roses. They did not.

A few weeks ago, he again caught a whiff of rose. He thought to himself, “What does that mean?” Nothing has come of it yet.
LOWER EXTREMITY ANEURYSMS:
Diagnosis and Treatment

Philip S. K. Paty, MD

Lower extremity peripheral artery aneurysms occur uncommonly, however, they can bring a risk of limb loss and are often a marker for aneurysms elsewhere in the body.

After abdominal aortic aneurysms, most aneurysms occur in the peripheral arteries of the lower extremities, specifically in the femoral and popliteal arteries. These aneurysms are rare, occurring in less than 8 per 100,000 person-years in some studies. They happen up to five times more often in men than in women.

With a diagnosis of a lower extremity aneurysm comes an increased likelihood that there is an aneurysm in the same artery of the opposite leg or in other arteries such as the iliac arteries and the aorta. The presence of a lower extremity aneurysm in a patient should prompt the physician to look for other associated aneurysms.

As opposed to aortic aneurysms, which usually rupture, lower extremity aneurysms are more prone to become completely clotted off (thrombosed) or to shower clots (embolize) downstream. These complications can cause an acute loss of the nutritive blood supply to the limb (ischemia). If left untreated, ischemia may lead to loss of the leg; this is why symptomatic or large peripheral artery aneurysms should be treated.

FEMORAL ANEURYSMS
Most aneurysms of the common femoral artery are asymptomatic. If they do cause symptoms, it is usually due to compression of the femoral vein, which can cause leg swelling or pain from nerve compression. Occasionally, these aneurysms can thrombose or embolize leading to severe leg ischemia. This presentation is more common in patients with aneurysms of the femoral artery branches, especially the deep femoral artery. This risk may be due to the artery's deeper location in the muscular part of the thigh as well as the larger size of the aneurysm when detected. This is also true of aneurysms of the other branch of the common femoral artery, the superficial femoral artery. As with most aneurysms, the chance of complications increases with the size of the aneurysm; problems are more prevalent in aneurysms that measure more than 2.5 to 3 cm in diameter.

A diagnosis can be made by physical examination, but this method can miss up to 50% of these aneurysms. The best screening test at this time is duplex ultrasonography. This allows the vascular specialist not only to accurately measure the size of the aneurysm but also to determine the amount of thrombus or clot that may be present. Other diagnostic tests include CT angiogram and MRI.

Treatment
Treatment is based upon symptoms as well as the size of the aneurysm. In patients who are asymptomatic and in good health, 2-cm aneurysms may be repaired, especially if there is a large amount of thrombus in the aneurysm itself. In general, most asymptomatic femoral aneurysms are not repaired unless they measure greater than 2.5 to 3 cm. These indications are modified if
the patient has symptoms. The optimal treatment involves surgical bypass or replacement of the diseased artery. This is done either with a vein bypass using a harvested section of a patient’s own vein or replacement with a synthetic graft. As the normal femoral artery diameter is about 0.75 to 1 cm, a synthetic graft usually works well.

POPLITEAL ANEURYSMS

Popliteal aneurysms account for 70% of peripheral artery aneurysms. The normal diameter of the popliteal artery is about 0.9 cm. The critical diameter for considering a popliteal artery an aneurysm is 1.5 cm. However, most vascular surgeons usually do not repair such aneurysms unless they are greater than 2 cm in diameter.

The diagnostic workup is similar to that of femoral aneurysms. Since physical examination alone is also apt to miss many of these aneurysms, diagnosis is usually done with duplex scan. Other diagnostic modalities include CT angiogram and MRI, however, a duplex scan is less expensive, easier to obtain, and provides additional information, such as the amount of thrombus in the aneurysm and the open flow (patency) within the popliteal artery branches. For planning subsequent repair of the aneurysm, conventional angiograms or CT angiograms are best.

Treatment

Asymptomatic popliteal aneurysms greater than 2 cm in diameter should be repaired, as aneurysms of this diameter or larger have a higher incidence of acute lower extremity ischemia with limb loss. The standard treatment involves surgery with bypass using the patient’s own vein. Alternatively, a synthetic graft can be used, but these do not tend to stay open for as long as the bypasses with natural veins.

For the high-risk patient with multiple medical problems, another option is to use an endoluminal bypass, which introduces a stent into the artery through a small incision in the skin (percutaneously). The problem with this approach is the risk of stent graft fracture due to its location across the knee joint.

In patients with an acutely threatened leg due to thrombosis of a popliteal aneurysm, clot-dissolving or thrombolytic drugs may be used to dissolve the thrombus before revascularization or bypass. This procedure may take time to dissolve the thrombus, so it is not used for situations in which time is of the essence.

Surgery, for now

Lower extremity peripheral artery aneurysms occur uncommonly, however, they can bring a risk of limb loss and are often a marker for aneurysms elsewhere in the body. Duplex scan is the best diagnostic modality, and the risk of limb loss is often predicted by the diameter of the aneurysm. Although there are minimally invasive means of treating these aneurysms on the horizon, currently the most reliable way to achieve the best results and prevent limb loss involves surgical reconstruction with bypass.
Every year, roughly 7 in 100,000 Americans suffer a subarachnoid hemorrhage caused by the rupture of a cerebral aneurysm.

This is a serious condition that carries a 65% mortality rate depending on the statistical source. The diagnosis and treatment of a cerebral aneurysm will differ in patients who have or have not suffered a subarachnoid hemorrhage. This article briefly considers both scenarios.

Cerebral aneurysms form on arteries within the brain. Most of them occur at the base of the brain on the Circle of Willis, a system of arteries that supply blood to the brain and is similar to a traffic circle. The main arteries that enter the brain communicate here and send off branches to supply all parts of the brain with blood. Aneurysms of the brain occur because the brain utilizes nearly one-third of all blood pumped by the heart, yet the vessels of the brain are very thin-walled in order to fit within the enclosed space of the skull.

Aneurysms may form where the arterial wall divides into several branches. One example includes the anterior communicating artery. Aneurysms may also form at places where the arterial wall is under constant pressure from blood flow, such as at the basilar tip. Cerebral aneurysms can also occur as the result of trauma or infection, although these are less common. The location, size, and shape of the aneurysm are important factors in developing the treatment plan.

**RISKS AND DIAGNOSIS**

Smoking has been documented as an important risk factor for forming cerebral aneurysms. High blood pressure (hypertension) that is not monitored and controlled by medication also presents a risk. A patient who has previously suffered a subarachnoid hemorrhage is at risk to develop another cerebral aneurysm. There are familial risks factors as well, including a history of a sibling who has suffered a subarachnoid hemorrhage secondary to a cerebral aneurysm, or a family member with polycystic kidney disease or one of the rare connective tissue disorders such as Marfan syndrome and Ehlers-Danlos syndrome.

The diagnosis of a cerebral aneurysm may be made when a patient undergoes an examination for an unrelated problem such as dizziness or trauma. A computed tomography (CT) scan or magnetic resonance imaging (MRI) may reveal suspicion.
Aneurysms may form where the arterial wall divides into several branches. Further workup with a CT angiography (CTA) or MR angiography (MRA) may reveal incidental cerebral aneurysm. The patient will then be referred to a neurosurgeon who specializes in the management of cerebral aneurysms. A diagnostic cerebral angiogram will clearly demonstrate all of the arteries in the brain as well as the aneurysm. This diagnostic tool is considered the gold standard in the management of the patient with a cerebral aneurysm. From this test, the neurosurgeon will be able to determine the size, location, shape, and relationship of the aneurysm to other arteries near the aneurysm. This information is essential in making a treatment plan.

The diagnosis of cerebral aneurysm can be a frightening event for a patient.

TREATMENT PLANS

The goal of treatment is to isolate the aneurysm from the normal circulation in the brain without affecting the nearby arteries. Stopping blood flow within the aneurysm will significantly reduce, if not eliminate, the risk of rupture. Depending on the information obtained from the diagnostic angiogram, the patient’s age, and general health, the neurosurgeon may propose one of the following treatment plans.

Craniotomy
This procedure involves delicate surgery in the operating room. Surgery to apply a clip that will block blood flow to the aneurysm may require a lengthy hospital stay and post-op recovery period before returning the patient to his or her normal routine. The patient’s age and general health, as well as accessibility of the aneurysm, are important considerations in this procedure.

Arterial bypass
This may be a staged procedure requiring two surgeries on different days. Arterial bypass may be the only option for treating a giant cerebral aneurysm (greater than 2.5 cm in size) and may be performed with or without clipping of the aneurysm.

Coil embolization
This minimally invasive endovascular treatment is performed in the angiography suite within the radiology department. Coil embolization may be done with or without the insertion of a stent. The procedure does require general anesthesia but may necessitate a shorter hospital stay than open surgery. The patient may be able to resume normal activity without restrictions within 3 months. Again, the patient’s age and general health, as well as the size and shape of the aneurysm, are important considerations in this procedure.

Observation
The neurosurgeon will discuss risk factors for rupture based on the aneurysm’s size and location. Observation on a regular basis with MRA or CTA may be the patient’s best option considering the risk of rupture, the patient’s age, and general health. Aneurysm size plays an important role as well. Several studies have confirmed that the risk of bleeding from an aneurysm is directly related to its size. Therefore, very small aneurysms are highly unlikely to rupture and do not need treatment.

(article continues on next page)
A CRITICAL MATTER

The patient who presents at the emergency room with a subarachnoid hemorrhage secondary to a ruptured cerebral aneurysm is critically ill. If the patient is awake, he or she may describe having the “worst headache of my life.” A CT scan of the brain may reveal a subarachnoid hemorrhage. To determine if that is indeed the case, the patient may need to undergo a lumbar puncture. The patient may then require a diagnostic cerebral angiogram to treat the aneurysm with embolization or to plan a craniotomy as the patient’s best option.

This patient is at risk to rebleed or rupture again, or to develop related problems such as hydrocephalus or life-threatening vasospasm. Treatment options will be limited by the patient’s critical condition. It is sometimes difficult for loved ones to understand that treating an aneurysm in this situation will not change the damage that may have already been done to the brain by the initial hemorrhage.

The diagnosis of cerebral aneurysm can be a frightening event for a patient. The workup and management of the patient with a cerebral aneurysm should be supportive and realistic. The best outcome requires a motivated patient and treatment by a neurosurgeon with expertise in all of the modalities of aneurysm management at a hospital with advanced critical-care abilities.

Even after successful treatment, we know that these patients have a higher likelihood of developing new cerebral aneurysms. The patient will need careful follow-up with diagnostic imaging and blood pressure monitoring for years after diagnosis and treatment. This is necessary to identify new aneurysms as early as possible in order to reduce the risk of rupture.
Healthy Living
for People With Cardiovascular Disease

Peter D. Cospito, MD

Regardless of whether you are focused on primary or secondary prevention, there are many steps you can take to improve your cardiovascular health.

Cardiovascular disease (CVD) refers to a group of diagnoses that have hardening of the arteries (arteriosclerosis) as their common underlying pathology. CVD is the leading cause of death in the United States and most other developed countries, accounting for more than 900,000 deaths annually in the United States alone. As our population ages, the prevalence and impact of CVD will continue to increase. It is estimated that by the year 2050, the incidence of CVD in the U.S. population will have doubled compared to levels from the year 2000.

The Many Forms of CVD

Coronary heart disease (CHD) is the most common manifestation of CVD. On one end of the CHD spectrum, patients may have no symptoms, classic effort-related chest pain (angina), acute coronary syndrome with rest angina, heart attack, or congestive heart failure (CHF). On the other end of the spectrum, in up to 15% of patients the initial manifestation of CHD is sudden cardiac death. Chest pain, chest pressure, or indigestion associated with shortness of breath, sweating, or nausea should always be treated as an emergency.

Cerebrovascular disease is a form of CVD that may manifest clinically as a stroke or a transient ischemic attack (TIA or “mini-stroke”).

Peripheral arterial disease (PAD) refers to arteriosclerosis involving the legs. A very small percentage of patients will present with critical limb ischemia (rest pain or nonhealing ulcers in the legs or feet). The vast majority of patients with PAD see their doctor because of claudication, a sort of “angina in the legs” brought on by physical activity. More than 80% of patients, however, either have no symptoms or have very atypical leg pain complaints. The unpredictable nature of PAD symptoms, as well as a lack of awareness among both patients and healthcare providers, has resulted in it being a greatly underdiagnosed and undertreated condition. Leg pain with walking should not be ignored or assumed to be due to age or arthritis.

Arteriosclerosis of the chest (thoracic) or abdominal aorta may present as aortas (weakening of the arterial wall leading to potential rupture).
RISK FACTORS
Whether a patient has CHD, cerebrovascular disease, PAD, or an aneurysm, the underlying problem is the same: arteriosclerosis. As such, risk factors for the varied forms of CVD are also exactly the same and include high blood pressure (hypertension), tobacco use, obesity, physical inactivity, diabetes, abnormal lipid panel, poor kidney function, age greater than 55 years for men and 65 years for women, and a family history of premature CHD (onset at less than 55 years of age for men and less than 65 years for women).

THE POWER OF THERAPEUTIC LIFESTYLE CHANGES
The phrase primary prevention refers to modifying risk factors to prevent or delay the onset of CVD. Primary prevention aims to keep an individual from becoming a cardiovascular disease patient in the first place. In patients with already-established CVD, secondary prevention efforts are aimed at optimizing care to reduce recurrent cardiovascular events and decrease cardiac mortality.

Risk factor modification with drug therapies as well as therapeutic lifestyle changes (TLC) can further decrease the risk of complications and death. Regardless of whether you are focused on primary or secondary prevention, there are many TLC steps you can take to improve your cardiovascular health.

A SHARED RESPONSIBILITY
Patients have the responsibility of taking ownership in their cardiovascular disease management, making appropriate therapeutic lifestyle changes, and being compliant with taking medications. Healthcare providers have the responsibility to stay current in the therapeutic options available in order to educate patients and their families about optimal disease management. Tremendous strides have been made in the care of CVD, and progress continues. Aggressive primary and secondary prevention strategies including lifestyle changes and medical therapy have resulted in a dramatic decline in age-specific death rates from CVD.

PRIMARY PREVENTION

Quit tobacco
Smoking cessation is perhaps the most powerful of healthy lifestyle changes. Tobacco use ranks highest on the list of preventable causes of death worldwide. For example, people who smoke 20 cigarettes per day have a risk of heart attack that is six times that of a nonsmoker. Smoking cessation begins to lower CVD risk within a matter of months of quitting. In just 3 to 5 years, the CVD risk in a former smoker decreases to that of a nonsmoker.

Healthcare providers and patients are equal partners in managing cardiovascular disease.
Boost your nutrition
An ideal diet is rich in fruits and vegetables, whole grains, fiber, and fish (especially oily fish, at least twice per week). Food should be prepared with little or no salt. Minimize beverages and foods with added sugar. Saturated fat should make up less than 7% and trans fat less than 1% of total calories. Cholesterol intake should be less than 300 mg per day.

Be more active
Physical inactivity has been linked to higher mortality rates. Exercise should include a combination of aerobic activity such as walking, jogging, cycling, and swimming, supplemented by strength training with weights or bands 2 days per week. A basic goal is to exercise 30 to 60 minutes, 5 days per week with an optimal goal of 30 to 60 minutes, 7 days per week.

Drug therapy
Regarding primary prevention, randomized trials have shown a clear benefit from drug therapy to lower blood pressure. Lowering cholesterol, specifically with statin drugs, has also been proven effective in the primary prevention of CVD. In those who have already been diagnosed with CVD, multiple studies suggest a benefit from maintaining an LDL cholesterol level of less than 70 mg/dl. For people with CVD as well as diabetes, tight blood sugar control can help to prevent complications such as diabetes-related kidney disease.

The effect of blood sugar on CVA and heart attack are less clear. Taking aspirin at a dose of 81 mg daily or 100 mg every other day in women with risk factors over 65 years of age is recommended for primary prevention. For men at intermediate risk, the recommendation is 75 to 162 mg of aspirin daily.
Together, physicians and other experts work to develop new devices and to build on existing technology for the treatment of aneurysms.

Many people are familiar with research studies that test medications, such as drugs to treat cancer and AIDS. In this technologically driven age, each year many new medical devices are also developed with the help of FDA-mandated clinical research studies. There are many ongoing, national studies evaluating devices including stent grafts (also known as endografts), to assess their efficacy in treating complex aortic aneurysms by minimally invasive means. The research studies described here are taking place at locations within the upstate New York area.

OVERCOMING LIMITATIONS

Today if you are diagnosed with an abdominal aortic aneurysm (AAA) or a thoracic aortic aneurysm (TAA), there are several treatment options available, including standard surgical repair or minimally invasive endovascular repair using a stent graft. Currently there are several FDA-approved stent grafts available for treatment of both AAAs and TAAs. Although advances in vascular health have come a long way with minimally invasive procedures, there remain some limitations.

To overcome the limits of currently available devices, physicians collaborate with the FDA and the medical device industry. Together, physicians and other experts work to develop new devices and to build on existing technology for the treatment of aneurysms.

STEPS TO APPROVAL

The process of clinical research studies that can lead to the FDA approval of stent grafts is rigorous. The steps include initial testing that must meet certain benchmarks established by the FDA. Based on initial data, the FDA may then approve a clinical research study to be conducted at a few hospitals that are considered “centers of excellence.” At these hospitals, a research team of doctors, nurses, and scientists must obtain approval from an institutional review board before they can go on to conduct the study. Subsequently, these devices are implanted in patients following standardized protocols, and all data is collected and evaluated.

The integrity of these devices is tested for years before the FDA grants approval and these devices become available for routine use.

In addition to the research team, it takes many people and departments to run a successful study. This kind of research requires cooperation and help from staff in the operating room, nursing units, special care units, physician offices, medical records, vascular labs, radiology, CAT scanners, cardiology offices, primary care offices, and even the shipping department, which must receive the devices before a case can begin. Conducting a research study following good clinical practice is truly a comprehensive collaborative effort.
AAA STUDIES

The studies listed here focus on the development of devices intended to improve treatment for AAAs. They are being carried out at sites in upstate New York.

PYTHAGORAS
Lombard Medical Technologies
This study offers the Aorfix stent graft and is enrolling 160 patients nationwide at 39 hospitals. The device tolerates extreme bending (angulation) within the AAA, which is a limitation with currently available stent grafts.

UNITE
LeMaitre Vascular Inc.
A special one-piece device is being examined at 16 sites in the United States and will enroll 90 patients. This single-piece stent graft facilitates ease of use and can accommodate complex aortic anatomy.

NELLIX
Endovascular Fillable Sac Anchoring Prosthesis
Designed to treat all infrarenal AAAs and aortoiliac aneurysms, this study will also include an expanded patient population with adverse neck anatomies. The study will start in late 2009.

STAPLE-2
Aptus Endosystem Inc.
This study is being offered at 25 clinical sites and will enroll 200 patients. The company’s EndoStaple system is used to secure the endograft to the vessel wall.

TRIVASCULAR2, INC.
This company is developing new medical devices to address unmet clinical needs for AAA and TAA stent grafts. The company has developed a novel device design and is planning two new clinical trials for late 2009.

TAAR STUDIES

The following research studies are examining improvements in devices used to treat TAAAs and are available in upstate New York.

VALOR II
Medtronic AVE
Conducted in 26 hospitals in the United States, this study is evaluating a new thoracic stent graft with improvements that will accommodate a significantly higher percentage of patients with TAA.

RELAY
Bolton Medical, Inc.
This study is being offered at 30 clinical sites and will enroll 120 patients for TAA endograft using the Relay stent graft. This study will also enroll patients that receive open surgical repair.

TAG 08-03: CONFORMABLE TAG THORACIC ENDOPROSTHESIS
W. L. Gore & Associates
This study evaluates the primary treatment of aneurysm of the descending thoracic aorta. This study will begin enrollment in late 2009.

TAG 08-01
W. L. Gore & Associates
This is a study for subjects with aneurysm dissections of the thoracic aorta. The study will begin enrollment in late 2009.

TAG 06-02
W. L. Gore & Associates
This study is being conducted in 25 clinical sites and will enroll 35 patients. The researchers are testing several improvements on an existing device that should be able to accommodate a significantly higher percentage of patients with TAA.

THRIVE STUDY
Medtronic AVE
The study is being offered at 15 clinical sites and will enroll 256 patients. This is a post-marketing study collecting data on Medtronic’s already FDA-approved stent graft.

(ARTICLE CONTINUES ON NEXT PAGE)
CEREBRAL ANEURYSM STUDIES

These research studies focus on new or improved treatments for cerebral aneurysms and are available at locations in upstate New York.

EVALUATION OF PRESIDIO AND CERECYTE COILS IN LARGE AND GIANT ANEURYSMS
Micrus Endovascular Corporation
This study is available at 30 global clinical sites and will enroll 200 patients.

COMPLETE OCCLUSION OF COILABLE ANEURYSMS USING PIPELINE EMBOLIZATION DEVICE
Chestnut Medical Technologies, Inc.
Available at 10 clinical sites, this study will enroll 200 patients and utilizes a stent to close off cerebral aneurysm as a stand-alone treatment.

CEREBRAL ANEURYSM HUD STUDIES

According to the FDA, a humanitarian use device (HUD) is a “medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.” HUD studies provide innovative care to people who have rare conditions.

ENTERPRISE
CORDIS Neurovascular, Inc.
This vascular reconstruction device and delivery system is intended for treatment of intracranial wide-neck, saccular, or fusiform aneurysms.

ONYX LES
EV3 Neurovascular
The Onyx Liquid Embolic System (LES) is used to treat intracranial aneurysms.

NEUROFORM3
Boston Scientific
This microdelivery stent is intended for treatment of wide-necked cerebral aneurysms.

TAking PART

The following organizations can provide more information regarding research studies, including how to participate. The Web sites for individual device companies also often list the research studies they are offering.

CLINICALTRIALS.GOV
www.clinicaltrials.gov
888-247-2773
This Web site is a service of the U.S. National Institutes of Health and provides study status, locations, and other information.

THE CENTER FOR INFORMATION AND STUDY ON CLINICAL RESEARCH PARTICIPATION
www.ciscrp.org
888-247-2773
This independent nonprofit organization was founded for the purpose of educating the public about participation in clinical research trials.

Thank You.

Physicians and healthcare teams are always striving to offer their patients diagnosed with aneurysms the best possible treatment options. Research studies offer a way to discover new technology, create next-generation devices, improve on existing technology, and add to the ongoing discussion physicians engage in all over the world regarding the treatment of aneurysms. All people who volunteer to participate in research studies should be admired and thanked. These volunteers play a vital role in creating important new treatments and improving healthcare for all.
Becoming a partner in your own health care is at the heart of true wellness.

When I think about health priorities, I use the sign in my dental hygienist’s office as a guidepost. It reads, “You only have to floss the teeth you want to keep.”

That simple statement raises the not-so-simple question of which teeth wouldn’t I want to keep? Are my front teeth, the pearly whites the public gets to see, any more important than the molars that chew the food that nourishes me? Probably not. Well, perhaps I can do without some of the incisors. After all, I don’t eat meat and could probably manage if they went away. But those teeth give my mouth its form and help create my smile. In short, there are no teeth that are less important than others when it comes to the overall health and appearance of my mouth.

That’s the beauty of that little sign. First it gets me thinking, and next, it puts the power to protect my health right in my own hands. Too often in medicine, the patient has things done to them. Some of those things are understandable, while others are way beyond our comprehension. When a person, the patient, has a role to play, however, compliance and follow-through are improved. Becoming a partner in your own health care is at the heart of true wellness.

There is no shortage of magazine and Web articles that tell us what to eat and not eat, exhort us to exercise, and advise us to reduce stress, all in the name of heart health. Such general advice is useful to a point, but these are concepts rather than the simple steps we need to make our own vascular health a priority. It doesn’t help that every time we turn around, subtle shifts occur in those magazine messages. Are we supposed to put in three 30-minute workouts a week or 10-minute workouts, three times a day? Can we safely consume two or five eggs a week and does it matter how much beef we eat? What about a little ice cream—if I am already at risk for heart disease, will that really hurt me?

IT’S YOUR HEALTH

This brings me back to the dental question. Let’s rewrite that to consider our vascular status by asking, “Which arteries do you want to keep healthy?” Should you worry most about those feeding your brain? What about your legs? The arteries in your legs can clog, and that means peripheral arterial disease, which can sideline you. That means no tennis, golf, or any sport you like to play, not to mention the pain you may endure during a simple trip to the mall. But what about your heart? If you don’t protect the arteries that feed the heart, you run the risk of a potentially deadly heart attack. Again, that sneaky question of what to protect and what not to protect teaches us an important lesson: The cardiac and vascular system is made of integrated parts that cannot be separated. Like individual teeth that comprise the mouth, different arteries comprise the vascular system, and they each have an important role to play.

I encourage you to use the magazine you are holding in your hands right now, which is chock-full of important information, to learn about your vascular health and to take steps to improve things if necessary. Remember: It’s your life and your body.
Early Detection Equals Successful Outcomes

Over 30,000 Lives Saved

The Vascular Group PLLC is one of the largest vascular specialty practices in the world dedicated to comprehensive vascular care. Our world-class leadership, knowledge, and experience in the treatment of vascular illnesses are unmatched.

To date we have performed more than:

- 13,000 lower extremity revascularizations by endovascular and open surgical repair
- 12,000 carotid artery revascularizations for stroke prevention and treatment by surgery and stent
- 6,000 thoracic and abdominal aortic aneurysm repairs by endovascular or open surgical means
- 5,000 varicose vein procedures to improve patient quality of life

The Vascular Group has been a pioneer in vascular research and has provided comprehensive and cutting edge procedures in upstate New York over the past three decades.

For more information on the highest-quality vascular care, please contact The Vascular Group PLLC.

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The Vascular Group was founded to establish a comprehensive vascular care center consisting of board-certified vascular specialists trained in endovascular, angiographic, and surgical techniques. Our physicians distinctively combine expertise in both traditional open surgery and cutting-edge, minimally invasive catheterization techniques to manage peripheral vascular disease. We are committed to promoting vascular health and delivering the highest-quality care to our patients and our community.

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