



Oklahoma Heart Institute

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CLEARING THE CONFUSION ABOUT CORONARY STENTING

By Wayne N. Leimbach, Jr., MD, FACC,
FSCAI, FCCP, FAHA

WHEN TO ORDER - AND WHAT TO DO WITH - A CARDIAC CT CALCIUM SCORE

By Roger D. Des Prez, MD, FACC

ABDOMINAL AORTIC ANEURYSMS: DETECTION, MANAGEMENT AND REPAIR

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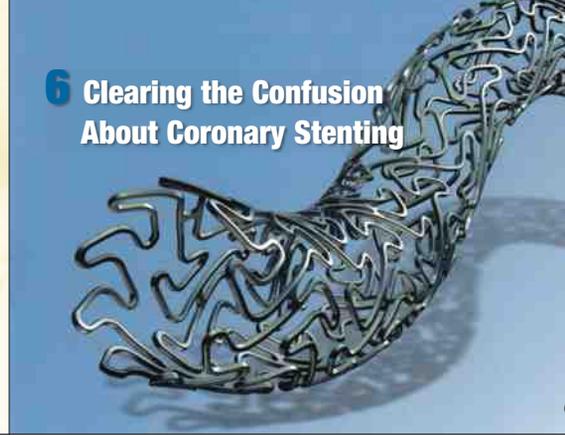
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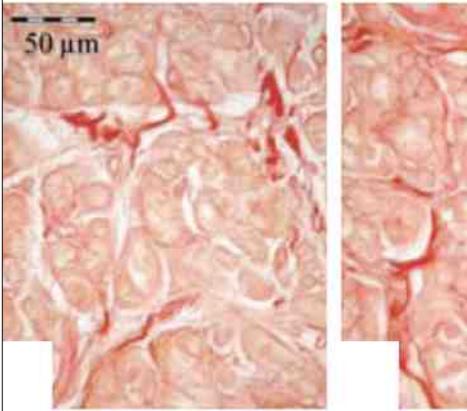
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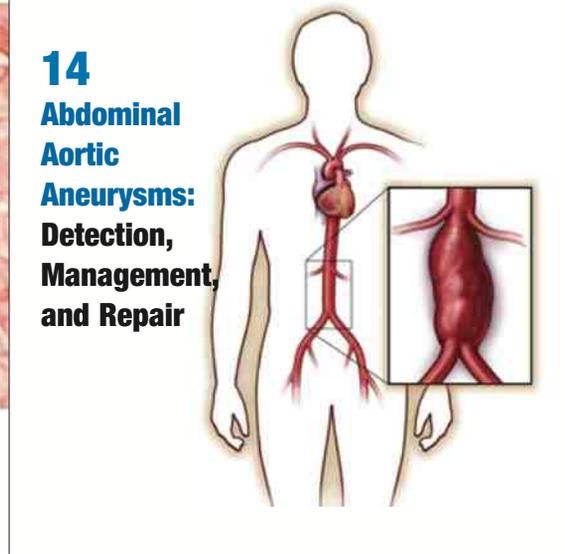
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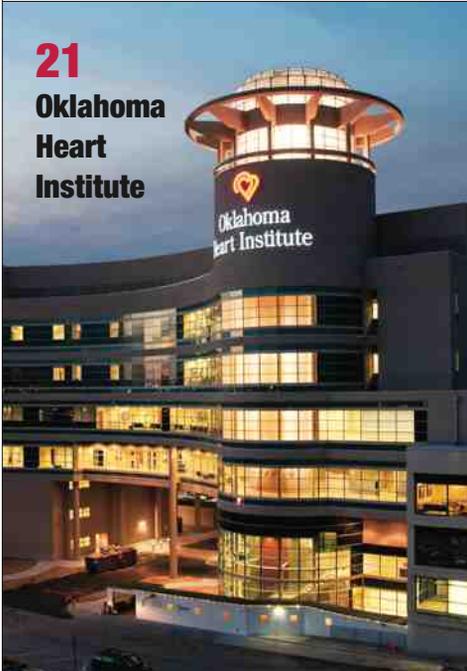
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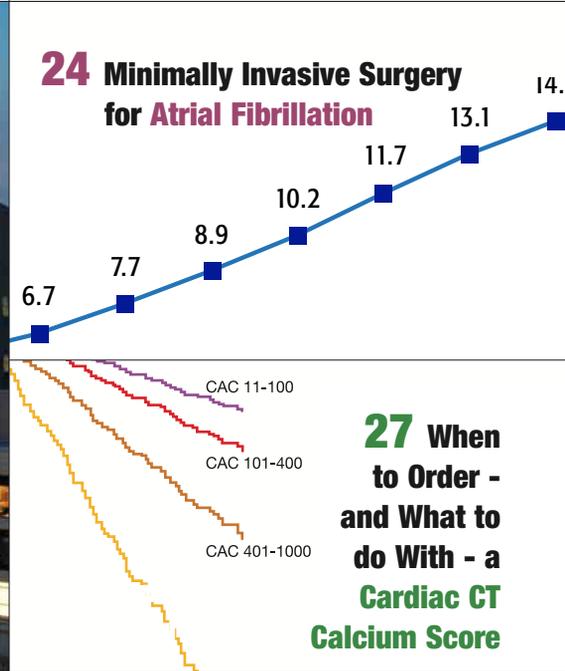
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To Our Readers



OPTIONS FOR DIAGNOSING AND TREATING CARDIOVASCULAR DISEASE continues to grow at a rapid pace. Understanding how the newer options fit into current diagnosis and treatment algorithms is important to physicians when discussing risk and benefit considerations.

Dr. Robert Smith discusses current guidelines on screening for abdominal aortic aneurysms (AAA) and describes standard surgical options versus newer noninvasive percutaneous endograft options.

Cardiac CT is one of the newest noninvasive imaging technologies to help better identify people at risk of a myocardial infarction. Dr. Roger Des Prez, director of Cardiac CT at Oklahoma Heart Institute, discusses when to order and what to do with a cardiac CT calcium score.

For those patients with significant coronary artery disease, stenting has become an effective therapy for angina relief. The article “Clearing the Confusion About Coronary Stenting” helps physicians understand the recent controversy about the safety and efficacy of coronary stenting and role of drug-eluting stents.

In the area of dysrhythmia management, major advances have been made in the treatment of atrial fibrillation. Drs. Sandler and Spann highlight the newest atrial fibrillation techniques which eliminate this common dysrhythmia. For the patient with paroxysmal atrial fibrillation, cath lab based catheter ablation is very effective. For more difficult cases, minimally invasive surgical procedures produce excellent results. Many physicians and patients don't realize these procedures are now routinely available. Finally, the cover of this issue introduces you to our beautiful new, state of the art Oklahoma Heart Institute hospital.

We hope you enjoy these articles and welcome any comments or suggestions in regards to the magazine content.

Sincerely,

A handwritten signature in black ink, appearing to read "Wayne N. Leimbach Jr." The signature is fluid and cursive.

Wayne N. Leimbach Jr., MD,
Editor, Oklahoma Heart Institute Magazine



CLEARING THE CONFUSION About Coronary Stenting

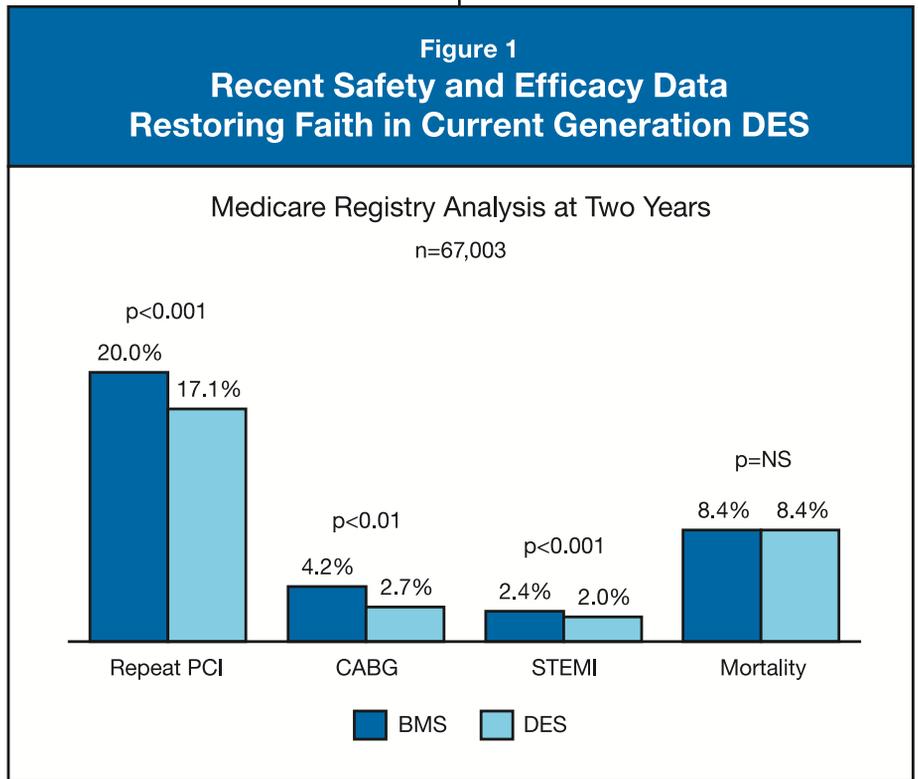
THE NUMBER OF coronary artery stent procedures performed in the U. S. declined from 2007 to 2008 because of four major areas of controversy. The stenting dispute, centered on efficacy and safety, was widely publicized. Many physicians and patients received confusing messages, leaving them reluctant or unable to navigate the clinical algorithms for the management of coronary artery disease and angina.

The four major areas of controversy were:

1. Efficacy of stenting over medical therapy in elective cases, which was sparked by the COURAGE Trial.
2. Concern about late stent thrombosis in drug-eluting stents.
3. Uncertainty about the duration of dual anti-platelet therapy to prevent late stent thrombosis.
4. Whether multi-vessel stenting and left main stenting is as effective as more invasive bypass graft surgery.

EFFICACY OF CORONARY STENTING AND THE MANAGEMENT OF STABLE ANGINA

The COURAGE Trial results were presented in 2007 (NEJM 2007; 356:1503-16). This trial compared optimal medical therapy with optimal medical therapy plus immediate coronary stenting in patients with stable coronary artery disease. The study found no significant difference in the primary outcome of death or MI at 4.6 years of follow up.



Drug-eluting stents have been shown to reduce the risk of restenosis in stented coronary arteries by more than 70 percent.

The message many physicians got from the study was that it was safe and good practice to first test optimal medical therapy in patients with stable angina and then refer patients for stenting

only if medical therapy did not work.

That is *not* what the study demonstrated. First, all patients screened already had their coronary anatomy defined by cardiac angiography.

Second, more than 30,000 patients with angiograms were screened, but less than 3,000 patients were chosen to be randomized. Therefore, the study included a very select group of stable patients. Patients with higher risk anatomy were excluded. Third, about 30 percent of the medically treated patients had to cross over to stenting, with the majority doing so in the first year. These stented patients were still considered to be in the medically treated group. Furthermore, angina resolution was significantly better in the stent group versus the medical therapy group. Finally, the nuclear stress test sub-study showed a significantly greater reduction in ischemia in the stent group (33 percent versus 19 percent, $P = 0.0004$), especially in patients with moderate to severe pre-treatment ischemia (78 percent versus 52 percent stent versus medical therapy, $P = 0.0007$). Patients with ischemia reduction experienced a lower risk of death or MI ($P = 0.037$).

Recently, the results of the COURAGE Trial have been challenged by a published meta-analysis of 17 randomized trials of percutaneous coronary intervention (PCI)-based strategy in patients with stable coronary artery disease (JACC 2008: 52; 894-904). This analysis did show a 20 percent reduction in the odds ratio of all cause of death for patients treated with percutaneous coronary intervention versus medical therapy. These findings are more consistent with multiple longitudinal studies in patients with known or suspected coronary artery disease, where detection of ischemia predicts a significantly higher overall mortality or cardiac mortality rate.

The message from these trials is that in selected patients with stable coronary artery disease, where the anatomy has already been defined by angiography, stable stenoses may not need urgent PCI, especially for the smaller vessels supplying small areas of myocardium. In

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such patients, the option of a trial of medical therapy does not seem to place the patient at increased short-term risk. However, patients with symptomatic angina or with large ischemic areas of myocardium do better with stenting to relieve the ischemia.

LATE-STENT THROMBOSIS IN DRUG-ELUTING STENTS

The availability of drug-eluting stents allows cardiologists to successfully treat more difficult and complex coronary stenoses due to their significantly lower restenosis rates. However, the concern over

late-stent thrombosis in patients receiving drug-eluting stents (DES) caused physicians to back away from treating more complex stenoses with drug-eluting stents.

Drug-eluting stents have been shown to reduce the risk of restenosis in stented coronary arteries by more than 70 percent. Because of this, by 15 months after FDA approval, almost 90 percent of stents placed in the United States were drug-eluting stents. The use of drug-eluting stents fell to about 60 percent of all stents placed after the issue of late stent thrombosis arose. The concern was due to reported heart attacks and deaths due to late-stent thrombosis. In order to address the safety issues concerning drug-eluting stents versus bare-metal stents, an observational study was performed where 38,917 Medicare patients receiving a bare-metal stent were compared to 28,086 Medicare patients receiving a drug-eluting stent (JAMA 2008: 299 (24); 2868-2876) (Figure 1). Patient outcomes were analyzed at two years. The study found a significant reduction in repeat PCI procedures for drug-eluting stents and a small, but significant decrease in ST segment elevation myocardial infarction for drug-eluting stent patients. Most importantly, there was no increase in mortality at two years for drug-eluting stent patients as compared to bare-metal stent patients (Figure 2). Therefore, this very large Medicare registry-based study failed to show a significant overall risk to using drug-eluting stents. Since the results of this study were published, drug-eluting stent usage has begun to increase.

UNCERTAINTY REGARDING THE DURATION OF DUAL ANTIPLATELET DRUGS (ASPIRIN PLUS CLOPIDOGREL)

Along with the issue of late-stent thrombosis, came the question of how long patients need to be on dual antiplatelet therapy for drug-eluting stents.

For both bare-metal stents and drug-eluting stents, dual antiplatelet therapy is recommended until the stent struts are covered by an

Figure 2
Unadjusted Cumulative Hazard of Death or ST-Elevation Myocardial Infarction for Patients Undergoing Coronary Stenting in the Bare-Metal Stent vs. Drug-Eluting Stent Eras

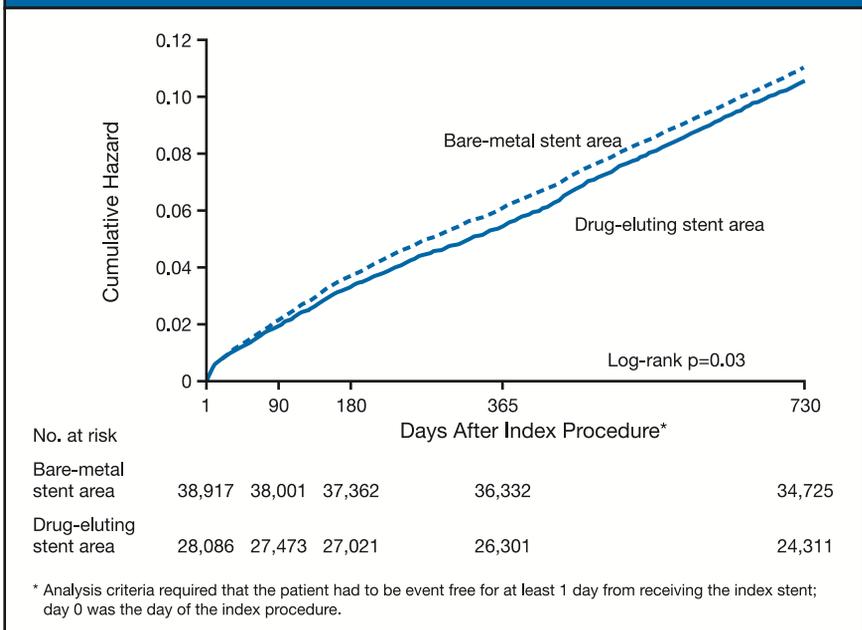
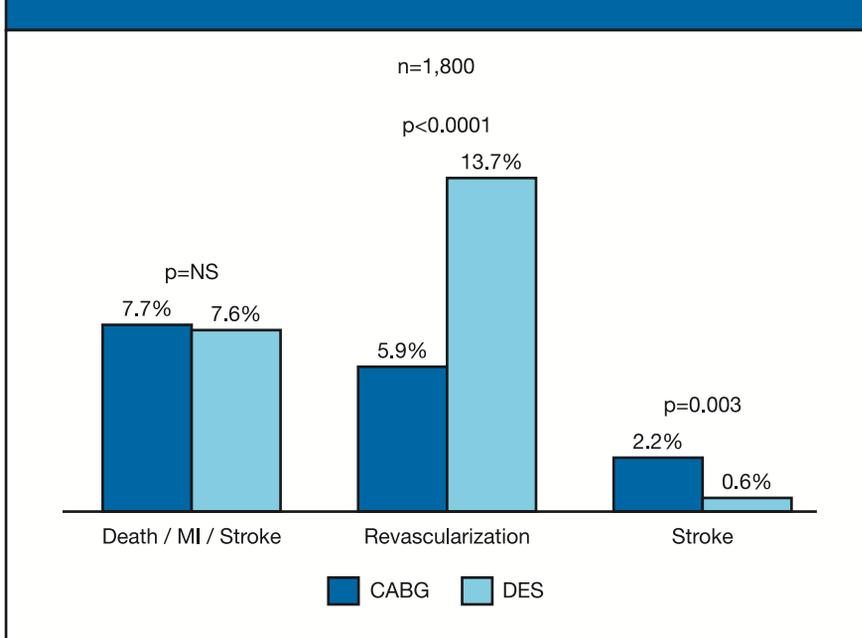


Figure 3
SYNTAX Trial at One Year



endothelial lining. Until the stent struts are fully covered, platelet aggregation and thrombosis can occur. Usually for bare-metal stents, the struts are covered within one month. For drug-eluting stents, most stents are fully covered within three to six months. However, there have been rare but well documented cases of late-stent thrombosis due to uncovered stent struts for up to one year. For this reason, dual antiplatelet therapy is recommended for a full year for all patients receiving drug-eluting stents.

Although very rare, there have also been cases of late-stent thrombosis developing out past one year for patients with drug-eluting stents. Because of this, recommendations are that stented vessels which could produce mortality if occluded, should be considered for dual antiplatelet therapy for two years or longer. Such stented vessels include the stented unprotected left main, a proximal LAD, or a proximal/ostial dominant right coronary artery.

The problem with the requirement for prolonged antiplatelet therapy is the issue of what to do when the patient develops a significant bleeding problem or needs surgery, or when there are medication compliance issues.

Because of the risk of late stent thrombosis when antiplatelet therapy is stopped, elective surgery should be delayed for one year from the placement of a drug-eluting stent.

If a surgical procedure is absolutely necessary and antiplatelet therapy must be stopped, then a cardiology consultation should be considered since other management options may be available to reduce the risk for the patient.

It should be noted that the much higher restenosis rate with bare-metal stents is not without serious risk to the patient. Some of these patients present with heart attacks and death. Therefore, the risk of restenosis with bare-metal stents must be weighed against the risk of late-stent thrombosis for drug-eluting stents. This relative risk versus



Figure 4
Coronary Stent

benefit needs to be addressed for each patient and for each stenosis that needs to be treated.

THE DEBATE OVER MULTI-VESSEL STENTING VERSUS BYPASS GRAFT SURGERY

The SYNTAX Trial randomized 1,800 patients to bypass graft surgery or multi-vessel stenting with drug-eluting stents. The study showed no significant differences in the outcome of death or myocardial infarction. The study did show lower revascularization rates for bypass surgery compared to stenting. However, stroke rates were significantly lower for the stented group compared to the bypass graft surgery group.

The real message of the SYNTAX Trial is that patients now have options as to how their significant multi-vessel coronary artery disease can be treated. Clearly there are advantages and disadvantages to both bypass graft surgery and multi-vessel stenting.

A more detailed discussion of the SYNTAX Trial can be found in the *Oklahoma Heart Institute Magazine* winter 2008 issue (Figure 3).

In conclusion, the indications and usage of coronary stents are still not fully defined. There are still some lingering doubts among doctors and patients about percutaneous coronary interventional procedures versus medical therapies versus surgical therapies for coronary artery disease. The newer published studies illus-

trate the effectiveness of percutaneous stent procedures at relieving symptoms, and suggest long-term reductions in MI and death rates. Drug-eluting stent usage is once again rising, and the overall number of stent procedures performed in the United States has been forecasted to grow by nine percent over the next three years. This growth may increase even faster as the next generation of stents comes to market.

It should be remembered that the controversy regarding angioplasty and stenting is related to patients with stable coronary artery disease. The guidelines still recommend that emergency angioplasty and stenting be performed on patients presenting with ST segment elevation myocardial infarctions (STEMI) and acute coronary syndromes. At this time, there is no significant controversy regarding stenting in the acute coronary syndrome patient.



Wayne N. Leimbach Jr., MD is an Oklahoma Heart Institute interventional cardiologist specializing in cardiac catheterization, coronary angioplasty, percutaneous closure of PFO and ASDs and related interventional procedures such as stents, atherectomy, laser, intravascular ultrasound imaging and direct PTCA for acute myocardial infarction.

Ablation for Atrial Fibrillation: Ready for Prime Time

Catheter ablation for atrial fibrillation (AF) was introduced in the late 1990s by a group of electrophysiologists in Bordeaux, France. Initially, the procedure was relegated as a research endeavor with significant risk and marginal success.

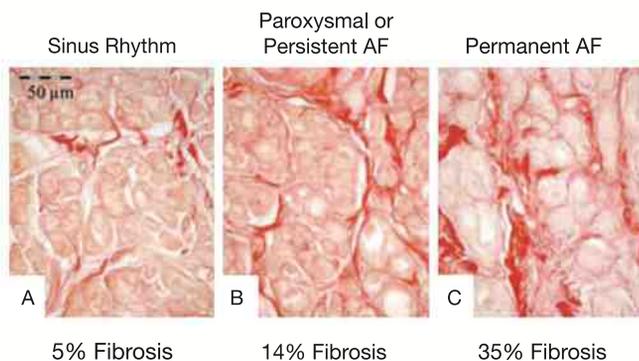
a variety of factors. First, patients may be classified as having *paroxysmal AF* if their episodes terminate spontaneously within a week. If episodes require electrical cardioversion, the patients are said to have *persistent AF*. Lastly, patients who have sustained atrial fibrillation for over a year are described as having *long-standing persistent AF* or *permanent AF*. It has been shown that the longer a heart stays in atrial fibrillation, the more cardiac cells

lation than those with normal hearts. Furthermore, cure of atrial fibrillation may be more difficult to achieve.

Conceptually, atrial fibrillation ablation is aimed at the two components of atrial fibrillation: the *triggers* that initiate AF and the substrate that *sustains* AF.

The major discovery of the Bordeaux group was that the vast majority of triggers of *paroxysmal AF* in patients *without structural heart disease* were localized to the

Figure 1
Atrial Remodeling



These slides taken from heart post-autopsy demonstrate that scarring (or fibrosis), shown in red, increases as patients remain in AF for longer periods of time. This phenomenon makes the ability to eliminate AF a daunting task. Gramley F et al, J Cardiovasc Electrophysiol 2007;18:1076

“Before, just going out and walking would make me very short of breath and lightheaded... I haven’t had any trouble since my ablation. I can really do anything I want to.”

-RM, OKLAHOMA HEART INSTITUTE PATIENT

Since that time, the procedure has undergone numerous iterations, and has become a viable option for many patients suffering from the symptoms of AF.

In order to better understand the chances of curing AF, it is important to differentiate patients based on

atrial fibrillation a daunting task.

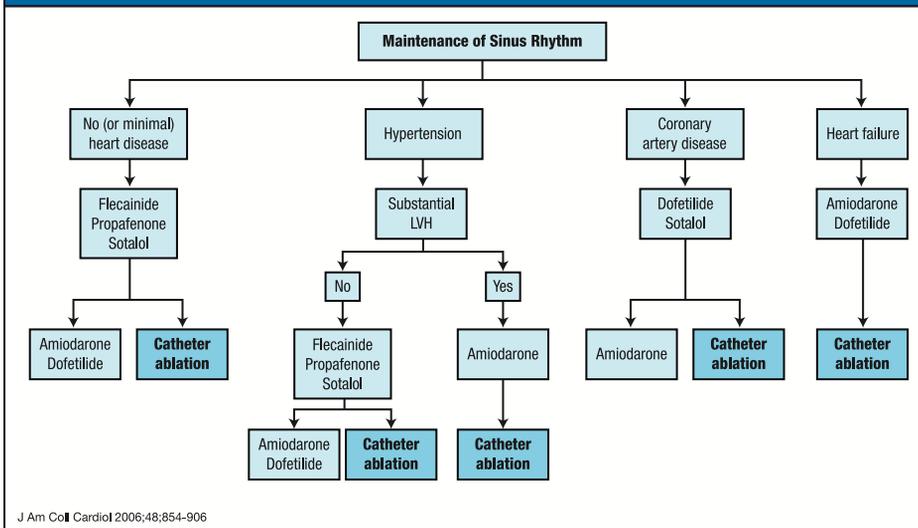
Another factor used to differentiate patients with atrial fibrillation is the presence of structural heart disease. That is to say, patients with congestive heart failure or poorly controlled hypertension have a higher risk of developing atrial fibril-

are replaced by scar tissue (Figure 1). This remodeling process can make elimination of

pulmonary veins. This allowed the investigators to target these veins in order to prevent initiation of AF.

When targeting the individual triggers, recurrence rates were high. This is because the true culprit trigger may not fire under anesthesia and because non-culprit veins at the time of the procedure often become triggers in the future. The procedure was long and required ablating within the veins. We now know this may lead to narrowing of the vein (pulmonary vein stenosis).

Figure 2
ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Atrial Fibrillation



preventing AF. Patients with structural heart disease and/or persistent AF have demonstrated that their triggers are often located within the body of the atria. The scarred atrium also serves as an excellent substrate for maintenance of AF wavelets. Furthermore, there has been a growing literature on the effects of the autonomic nervous system on initiation and maintenance of AF in diseased hearts.

In these patients, results of pulmonary vein isolation alone have been sobering. Clearly, other techniques must be applied. These techniques include making linear lesions (mimicking the scars of a surgical Maze) and targeting areas of nervous innervation. Early results of applying these additional techniques in patients with structural heart disease and persistent atrial fibrillation are more favorable.

OUR RESULTS

Over the past two years, we have performed 103 AF catheter ablation procedures on patients who have previously failed anti-arrhythmic agents or have requested ablation as a first-line treatment. The success rate for our patients with paroxysmal AF is 85 percent, with most

“My heart would go in and out of rhythm for about eight hours – I just couldn’t do anything because I was so weak... Since my ablation, it’s been a completely different life. Now, I can do anything I want to. The old man can go after it!”

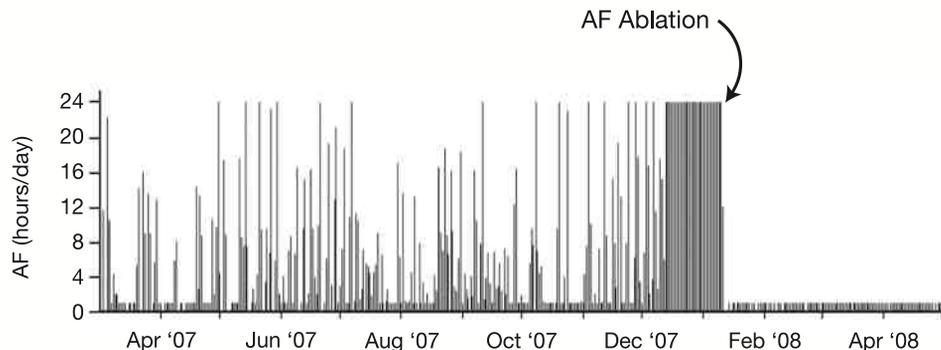
-JJ, OKLAHOMA HEART INSTITUTE PATIENT

Over the next decade, the technique has evolved to empirically isolate all four pulmonary veins by ablating outside the venous os. Numerous groups around the world have confirmed that this procedure can result in cure rates of over 80 percent in patients with paroxysmal AF.

Based on these favorable results, the AHA/ACC/ESC incorporated AF ablation into the 2006 guidelines for management of patients with AF (Figure 2). Specifically, the guidelines state that patients with symptomatic AF who have failed an anti-arrhythmic agent should be considered for catheter ablation. Furthermore, “in some patients, especially young persons with very symptomatic AF who need sinus rhythm, radiofrequency ablation may be preferred over years of drug therapy.”

Unfortunately, the pulmonary veins are not the whole story for

Figure 3
Pacemaker Interrogation in a Patient with Atrial Fibrillation



Note the frequent paroxysms of atrial fibrillation which evolved into persistent atrial fibrillation in mid-December despite anti-arrhythmic medications. Following AF ablation in mid-January, the patient has had no sustained AF. He remains AF-free one year later.

“I went from one medication to another. It seemed that they would help, but nothing ever stopped it. As time went on, it got worse and worse.... Anything I want to do at this point I can do. It’s the difference between night and day from the way I was.”

-VI, OKLAHOMA HEART INSTITUTE PATIENT

patients experiencing complete elimination of atrial fibrillation as documented by continuous home telemetry monitoring looking for asymptomatic atrial fibrillation. Repeat ablation was performed in four patients in whom electrical reconnection of the pulmonary veins was confirmed.

Some of these patients have had pacemaker implantations, which record the dramatic changes after ablation (Figure 3).

As expected, patients with persistent atrial fibrillation carry a lower success rate (60 percent) and a higher need for repeat ablation (30 percent). Most patients in this group underwent

simple pulmonary vein isolation only. Newer techniques are now being applied to improve these results.

Importantly, complication rates have been extremely low. We have experienced no deaths or strokes. There have been no patients with pericardial tamponade or symptomatic pulmonary vein stenosis.

ADVANCED CENTER FOR ATRIAL FIBRILLATION

At our Advanced Center for Atrial Fibrillation, we work closely with cardiovascular surgeons to tailor appropriate therapy for each individual patient. We believe that catheter-based ablation is the therapy of choice for patients with paroxysmal atrial fibrillation failing medical therapy.

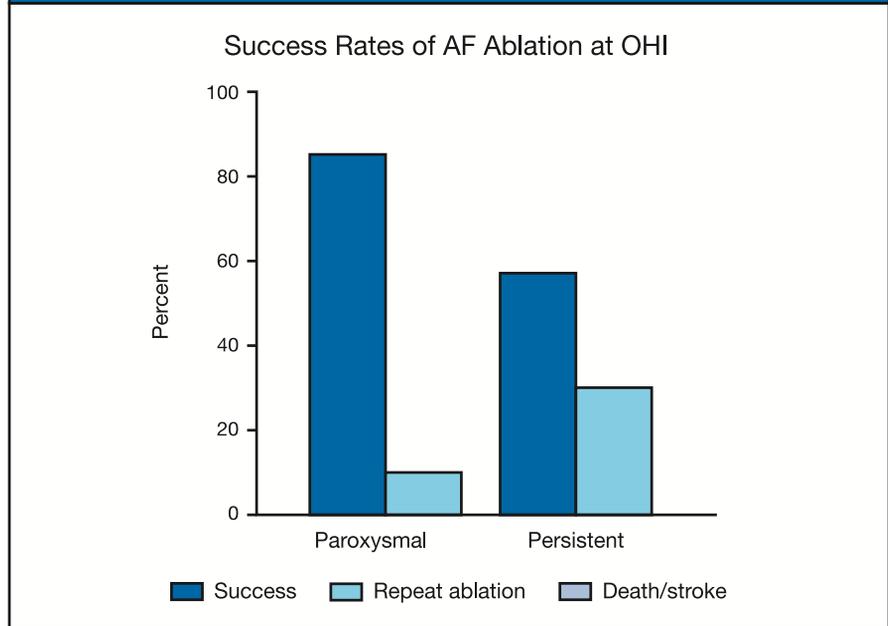
Patients with persistent atrial fibrillation are offered rate control, catheter-based ablation or surgical ablation.

AF ablation is no longer an experimental procedure with poor success rates – it is ready for Prime Time. Together with our surgeons, we strive to eliminate AF in all patients who continue to have severe symptoms despite aggressive medical therapy.



David A. Sandler, MD is an Oklahoma Heart Institute electrophysiologist who specializes in electrophysiology, complex ablation and atrial fibrillation management.

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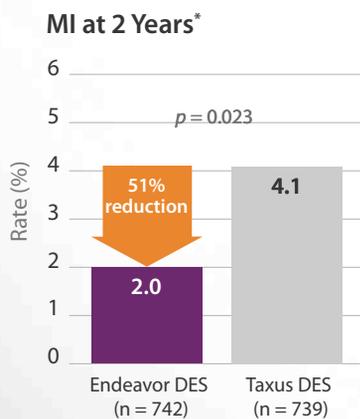
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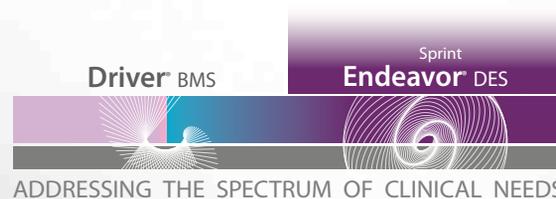
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* E IV data, Leon, TCT 2008. Endeavor TLR at 2 years = 5.9%; Taxus TLR = 4.6% ($p = 0.295$).

Abdominal Aortic Aneurysms: Detection, Management, and Repair

An abdominal aortic aneurysm (AAA) is caused by a localized weakening of the wall of the aorta – the largest blood vessel in the body – causing it to dilate and expand beyond its normal circumference (Figure 1). Although the normal diameter of the abdominal aorta is two to three cm, abdominal aortic aneurysms may cause the vessel to swell to more than twice the normal size, thereby increasing the risk of rupture of the aorta, which in turn may cause rapid internal exsanguination. About 90 percent of these aneurysms occur in the segment of the aorta that courses through the mid and lower abdomen, below the level of the kidneys.

Traditionally, these aneurysms have been treated with open surgical repair in order to reduce the risk of rupture and thereby prolong the life of the affected patient. When the diameter of an abdominal aortic aneurysm reaches 5.5cm or greater, the risk of rupture of the aneurysm is a greater risk to the patient than the risk of surgical repair in most cases.

A number of risk factors for abdominal aortic aneurysms exist, though the absence of risk factors does not guarantee against the development of an aneurysm. Risk factors for the development of abdominal aortic aneurysm include hypertension, advancing age, family history, male gender and tobacco

use. One study found the prevalence of AAAs measuring 2.9 to 4.9cm in diameter ranges from 1.3 percent for men aged 45-54 years up to 12.5 percent for men 74 to 85 years of age. Comparable prevalence figures for women are 0 percent and 5.2 percent respectively.¹

The American College of Cardiology recommends screening for AAA in certain high-risk populations. Men of 60 years of age or older who are either the siblings or offspring of patients with AAAs should undergo physical examination and ultrasound screening for detection of abdominal aortic aneurysms. Men who are aged 65 to 75 years who have ever

Indications

The Endeavor[®] Sprint Zotarolimus-Eluting Coronary Stent Delivery System is indicated for improving coronary luminal diameter in patients with ischemic heart disease due to de novo lesions of length ≤ 27 mm in native coronary arteries with reference vessel diameters of ≥ 2.5 mm to ≤ 3.5 mm.

Contraindications

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Coronary artery stenting is contraindicated for use in:

- Patients with a known hypersensitivity or allergies to aspirin, heparin, clopidogrel or ticlopidine
- Patients who cannot receive recommended antiplatelet and/or anticoagulation therapy
- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.

Warnings

- Please ensure that the inner package has not been opened or damaged, as this indicates the sterile barrier has been breached
- The use of this product carries the risks associated with coronary artery stenting, including subacute thrombosis, vascular complications, and/or bleeding events
- This product should not be used in patients who are not likely to comply with the recommended antiplatelet therapy

Precautions

- Only physicians who have received adequate training should perform implantation of the stent
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed
- Subsequent stent blockage may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized stents is not well characterized
- Risks and benefits of the stent should be assessed for patients with history of severe reaction to contrast agents
- Do not expose or wipe the product with organic solvents such as alcohol or detergents
- Stent thrombosis is a low-frequency event that current drug-eluting stent (DES) clinical trials are not adequately powered to fully characterize. Stent thrombosis is frequently associated with myocardial infarction (MI) or death. Data from the ENDEAVOR randomized clinical trials have been prospectively evaluated and adjudicated using both the protocol definition of stent thrombosis and the definition developed by the Academic Research Consortium (ARC), and demonstrate specific patterns of stent thrombosis that vary depending on the definition used. In the ENDEAVOR clinical trials analyzed to date, the differences in the incidence of stent thrombosis observed with the Endeavor stent compared to bare metal stents have not been associated with an increased risk of cardiac death, MI, or all-cause mortality. Additional data from longer-term follow-up in the ENDEAVOR randomized clinical trials and analyses of DES-related stent thrombosis are expected and should be considered in making treatment decisions as data become available
- When DES are used outside the specified Indications for Use, patient outcomes may differ from the results observed in the pivotal clinical trials
- Compared to use within the specified Indications for Use, the use of DES in patients and lesions outside of the labeled indications, including more tortuous anatomy, may have an increased risk of adverse events, including stent thrombosis, stent embolization, MI, or death.

The safety and effectiveness of the Endeavor stent have not yet been established in the following patient populations:

- Women who are pregnant or lactating
- Men intending to father children
- Pediatric patients
- Patients with vessel thrombus at the lesion site
- Patients with coronary artery reference vessel diameters < 2.5 mm or > 3.5 mm
- Patients with coronary artery lesions longer than 27 mm or requiring more than one Endeavor stent
- Patients with lesions located in saphenous vein grafts, in the unprotected left main coronary artery, ostial lesions, or lesions located at a bifurcation
- Patients with diffuse disease or poor flow distal to the identified lesions
- Patients with multivessel disease
- Patients with tortuous vessels in the region of the obstruction or

proximal to the lesion- Patients with a recent acute myocardial infarction where there is evidence of thrombus or poor flow
- Patients for longer than 48 months of follow-up
- Patients with in-stent restenosis
- Patients with moderate or severe calcification in the lesion or a chronic total occlusion
- Patients with prior brachytherapy of the target lesion or the use of brachytherapy to treat in-stent restenosis in an Endeavor stent.

The safety and effectiveness of the Endeavor stent have not been established in the cerebral, carotid, or peripheral vasculature.

Potential Adverse Events

Other risks associated with using this device are those associated with percutaneous coronary diagnostic (including angiography and IVUS) and treatment procedures. These risks may include, but are not limited to:

- Abrupt vessel closure
- Access site pain, hematoma or hemorrhage
- Allergic reaction (to contrast, antiplatelet therapy, stent material, or drug and polymer coating)
- Aneurysm, pseudoaneurysm, or arteriovenous fistula (AVF)
- Arrhythmias
- Balloon rupture
- Cardiac tamponade
- Coronary artery occlusion, perforation, rupture, or dissection
- Coronary artery spasm
- Death
- Embolism (air, tissue, device, or thrombus)
- Emergency surgery: peripheral vascular or coronary bypass
- Failure to deliver the stent
- Hemorrhage requiring transfusion
- Hypotension/hypertension
- Incomplete stent apposition
- Infection or fever
- Late or very late thrombosis
- Myocardial infarction (MI)
- Myocardial ischemia
- Peripheral ischemia/peripheral nerve injury
- Renal failure
- Restenosis of the stented artery
- Rupture of native or bypass graft
- Shock/pulmonary edema
- Stent deformation, collapse, or fracture
- Stent migration
- Stent misplacement
- Stroke/transient ischemic attack
- Thrombosis (acute and subacute)
- Unstable angina
- Ventricular fibrillation.

Adverse Events Related to Zotarolimus

Patients' exposure to zotarolimus is directly related to the total amount of stent length implanted. The actual side effects/complications that may be associated with the use of zotarolimus are not fully known. The adverse events that have been associated with the intravenous injection of zotarolimus in humans include:

- Anemia
- Application site reaction
- Diarrhea
- Dry skin
- Headache
- Hematuria
- Infection
- Injection site reaction
- Pain (abdominal, arthralgia, injection site)
- Rash.

Please reference appropriate product Instructions for Use for more information regarding indications, warnings, precautions and potential adverse events.

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

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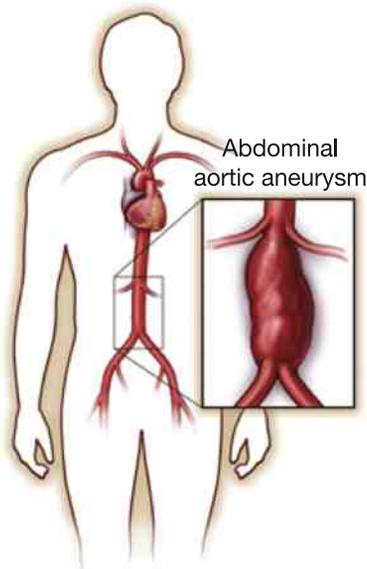
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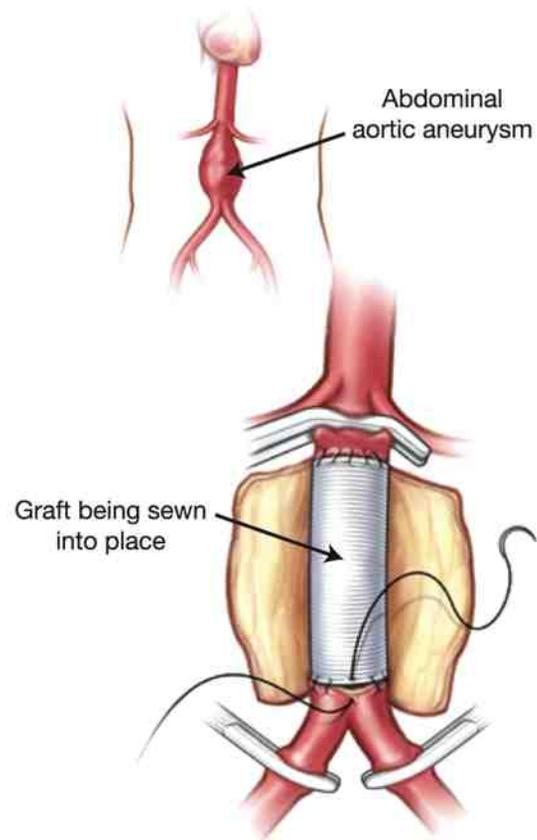


Figure 1
Abdominal Aortic Aneurysm



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Figure 2
Open Surgical Repair of Abdominal Aortic Aneurysm



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Risk factors for the development of abdominal aortic aneurysm include hypertension, advancing age, family history, male gender and tobacco use.

smoked should undergo a physical examination and 1-time ultrasound screening for detection of AAA². Because of the decreased prevalence of the disease in women, there are currently no formal recommendations that women undergo screening evaluations for AAA, other than routine physical examination.

Patients with non-surgical AAA or family history of AAA should be advised to stop smoking and be offered smoking cessation interventions, including behavior modification, nicotine replacement, or certain pharmacologic therapies. In patients with non-surgical AAA, blood pressure and fasting serum lipid values should be monitored and controlled as recommended for patients with atherosclerotic heart disease.²

Surveillance of AAAs that do not meet surgical criteria should also be performed. For an AAA that is less than 4.0cm. in diameter, it is reasonable to perform annual surveillance with abdominal ultrasonography or MRA in order to monitor the rate of progression of the aneurysm. Aneurysms measuring 4.0 to 4.9cm should initially be monitored every six months, though your caregiver may choose to decrease surveillance to once per year after an appropriately slow progression of aneurysmal expansion has been documented. Most providers will refer their patients to a vascular surgeon once a threshold of five cm in diameter has been met. If left untreated, AAAs may rupture, resulting in very poor survival for affected patients. Of patients

that survive AAA rupture long enough to make it to the hospital, up to 70 percent of them will not survive long enough to be discharged from the hospital³. Conversely, with appropriate management, elective AAA repair in most centers will be fairly uncomplicated in approximately 93 percent of patients,^{4,5,6,7} though it is important for patients to understand that it remains a major surgery with significant risk. A surgeon with expertise in the field must determine an individual's expected surgical risk on a case-by-case basis. Present practice guidelines dictate that eligible patients with AAA measuring 5.5cm or larger should undergo repair to eliminate the risk of rupture. It is reasonable to proceed with elective repair in most cases once the AAA diameter has reached 5.0cm. However, repair of an asymptomatic AAA less than 5.0cm in diameter is not recommended, as

the risk of the repair likely outweighs the risk to the patient from the aneurysm itself at diameters less than 5.0cm.

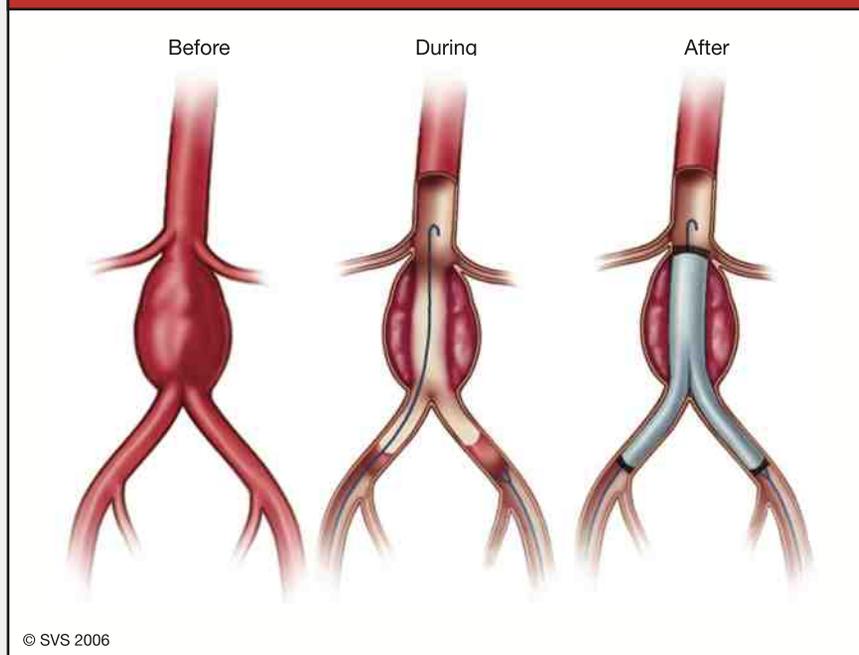
The mainstay of AAA repair for many years has been open surgical repair, during which an incision is made in the abdomen, exposing the affected segment of the aorta. The aneurysmal segment is then removed and replaced with a synthetic surgical graft (Figure 2). This is a major vascular surgical procedure. Recent years have seen the introduction of a less invasive type of repair for AAA. Endovascular AAA repair is a procedure where an incision is made in one or both groins and a covered cylindrical sleeve is passed through the arteries and across the affected segment of the aorta. This sleeve may be anchored using tiny hooks that position

protocols. These surveillance scans are performed to verify that the stent-graft has not migrated from its original position and that it is functioning properly. Though endovascular repair poses less risk to the patient than open surgical repair, sufficient long-term outcomes data regarding the performance of these stent-graft devices over many years are not yet available. As such, the American College of Cardiology gives its highest recommendation to open surgical repair of AAAs in patients who are good or average surgical candidates. Endovascular repair of AAAs, however, is reasonable in patients who are at high risk of complications from open surgeries because of cardiopulmonary or other associated diseases.² While the American College of Cardiology does not stipulate



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Figure 3
Abdominal Aortic Aneurysm Before, During and After Endovascular Stent-Graft Placement

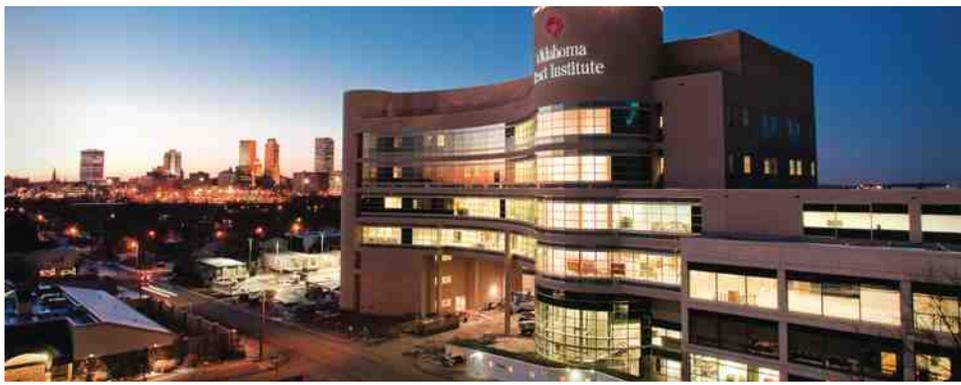


it in place, fully covering the aneurysmal segment of the vessel, thereby reducing the risk of aortic rupture and its associated consequences (Figure 3). There are a host of anatomic considerations that must be made by the treating surgeon to determine which aneurysms can be effectively treated using this method. If endovascular repair is performed, annual surveillance of the implanted sleeve (called a stent-graft) may be performed using specialized CT scan

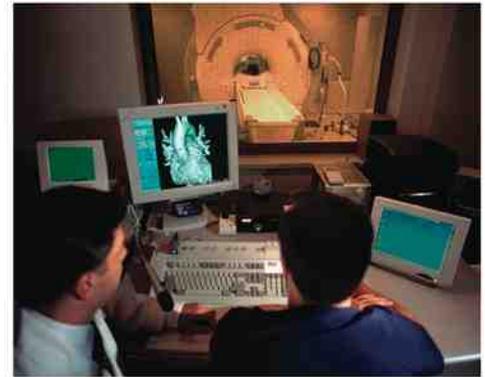
directly against endovascular repair of AAAs in patients at low or average surgical risk, it does not yet offer enthusiastic support for the practice. However, given the lower risk of endovascular AAA repair and mostly favorable short-term data, it remains possible that the current practice guidelines may turn in greater favor of endovascular repair when more information about the long-term performance of these devices becomes available.

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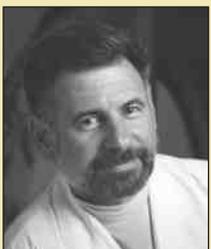


PTCA for acute myocardial infarction. He is Chief of Cardiology at Hillcrest Medical Center, where he is also Director of the Cardiac and Interventional Laboratories at Hillcrest Medical Center. Dr. Leimbach is Co-Director of the Lipid and Wellness Clinic at Oklahoma Heart Institute. He is Director of the James D. Harvey Center for Cardiovascular Research at Hillcrest Medical Center, as well as Director of the Oklahoma Heart Research and Education Foundation. He also serves as Clinical Associate Professor of Medicine at the University of Oklahoma College of Medicine – Tulsa. Dr. Leimbach completed a Clinical Cardiology Fellowship and a Research Fellowship at the University of Iowa Hospitals and Clinics. He also completed his Internal Medicine Internship and Residency programs at Iowa, where he was selected Chief Resident in Medicine. He received his medical degree from Northwestern University in Chicago and his Bachelor of Science degree from the University of Michigan.

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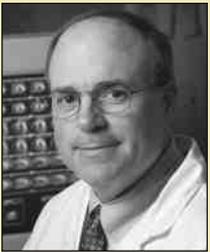


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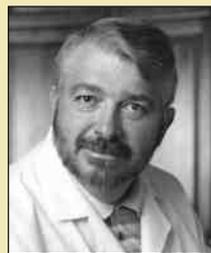
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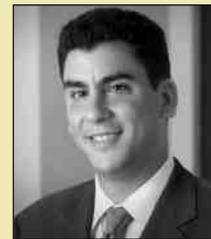


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Board certified in Internal Medicine and Cardiovascular Disease

Eugene J. Ichinose, MD

Dr. Ichinose specializes in interventional cardiology including cardiac catheterization, coronary angioplasty and related interventional procedures such as coronary stents, atherectomy, intravascular ultrasound and peripheral vascular interventional procedures. He earned his Bachelor of Science degree from Texas



Christian University in Fort Worth, TX and his medical degree from Louisiana State University in New Orleans. He then completed his Internal Medicine residency, general cardiology and interventional cardiology fellowships at the University of Massachusetts Memorial Health Care Center in Worcester, MA.

Board certified in Internal Medicine, Cardiovascular Disease, Interventional Cardiology and Nuclear Cardiology

Cristin M. Bruns, MD

Dr. Bruns is a specialist in endocrinology, diabetes and metabolism at Oklahoma Heart Institute, with expertise in diabetes, thyroid disease (including thyroid cancer) and polycystic ovary syndrome. She completed her Internal Medicine Internship and Residency and Endocrinology Fellowship at the



University of Wisconsin Hospital and Clinics in Madison, WI. Dr. Bruns earned her medical degree from Saint Louis University School of Medicine in St. Louis, MO and her Bachelor of Arts and Bachelor of Science degrees in biology from Truman State University in Kirksville, MO. Prior to joining Oklahoma Heart Institute, Dr. Bruns worked as a clinical endocrinologist at the Dean Clinic in Madison, Wisconsin.

Board certified in Internal Medicine, Endocrinology, Diabetes and Metabolism



Oklahoma Heart Institute

By Elaine Burkhardt

All New. All Heart.

When a spectacular new \$65 million heart hospital is built with the latest technology for diagnosing and treating heart disease, it is an asset to the city where it is located, its residents and to the physicians who practice in the region and have access to such a mighty facility for their patients.

So it is with the new Oklahoma Heart Institute, our brand new heart hospital, which opened March 11 in Tulsa on the campus of Hillcrest Medical Center. It is the region's most comprehensive heart hospital, with 104 beds on six floors and more than 183,000 square feet of space. And, it is nothing short of spectacular.

"Many years of planning and preparation have gone into this

heart hospital, and we are thrilled to see our vision for a world-class cardiovascular hospital come to life," said Steve Dobbs, chief executive officer of Hillcrest Medical Center. "We set out to build a facility that would provide patients from throughout the region with access to nationally recognized physicians and surgeons as well as the latest treatments and the most advanced technology. With the opening of this extraordinary hospital, we have achieved all of this and more."

Oklahoma Heart Institute is, quite simply, so high tech there is almost no heart problem that cannot be solved or managed here. And many heart problems can be prevented.

With statistics that certainly warrant this kind of powerful resource to combat it, heart disease contin-

ues to be America's No. 1 killer of men and women. While it is preventable, treatable and even reversible, heart disease remains a threat to all of us. But, the new OHI lessens the odds of cardiovascular disease getting the upper hand on the patients who are treated here.

A powerful presence inside and out, the workings of this hospital are in the hands of the highly trained, highly skilled Oklahoma Heart Institute specialists. They come here from the finest medical training centers nationwide. Many of them are recognized authorities in their fields. Together, they form a winning team and are a fearsome foe of this deadly disease.

"We are proud to present our referring physicians with Oklahoma Heart Institute's new spectacular



Oh What a Night ! Cutting the ribbon to open the all new Oklahoma Heart Institute

PHOTO BELOW: Left to right: Joe Kelly, KRMG Radio; Sandra Alexander, Chairman of the Board - Hillcrest Medical Center; Robert Sonnenschein, MD, Director of Peripheral Vascular Ultrasound Imaging - OHI; Steve Dobbs, Chief Executive Officer - Hillcrest Medical Center; Wayne N. Leimbach, Jr, MD, Chief of Cardiology and Director of Cardiac & Interventional Laboratories - OHI; David Vandewater, President & CEO - Ardent Health System; Kathy Taylor, Mayor, City of Tulsa; Earl Denning, President & CEO, Oklahoma Division - Ardent Health System; Robert E. Lynch, MD Interventional Cardiologist - OHI; Brad Hoyt, MD, President of Medical Staff - Hillcrest Medical Center



hospital,” says Wayne N. Leimbach, Jr., MD, president of OHI. “In this freestanding facility, there is state of the art technology, beautiful comfortable hotel like rooms and expanded capacity to accommodate all referrals,” he explains. “On top of that, OHI is staffed by seasoned nurses and technicians, as well as our cardiac and vascular specialists whose credentials are unsurpassed by others in the area.”

Powerful. Impressive.

OHI provides a full range of cardiovascular services including a comprehensive Cardiovascular Diagnostic Center, Cardiovascular Interventional and Electrophysiology Laboratories, Pre- and Post-Cardiac Cath Lab Procedure Beds, a Cardiovascular Intensive Care Unit, Cardiac Telemetry Beds, a Heart Failure CARE Center and an Education Center. The hospital also offers seven Centers of

Excellence, which are highly specialized programs dedicated to the treatment of common cardiovascular conditions ranging from diabetes and hypertension to more complex conditions such as heart failure, atrial fibrillation and non-surgical closure of holes in the heart.

All OHI patients will benefit from state-of-the-art technology and medical equipment including brand new catheter labs with the latest imaging

techniques available nowhere else in the city. Images that are not visible with current equipment are visible on OHI's equipment. 3d mapping allows for 3d reconstruction of the heart, and GPS guidance provides less invasive and safer procedures. The GPS offers greater accuracy in guidance of the catheters, which increases efficacy and results in higher success rates.

An MRI magnet with the very latest in magnetic resonance imaging technology allows for diagnostic procedures with zero risk to the patient. "We are at the forefront of cardiac MRI and publish in this area. Our patients will benefit from the highest level of expertise. Our new MRI magnet provides images that allow us to see the beating heart and blood vessels in great detail. There is zero radiation so the procedure is totally safe for the patient," says Leimbach. Another impressive piece of equipment, which is coming to the hospital, is the newest generation multi-slice CT scanner, which

emits only a fraction of the radiation levels of current scanners. These scanners enable doctors to see the coronaries without catheterizations.

The Heart Failure Clinic is staffed with expert physicians who have reduced hospital re-admittance rates by 60 percent and reduced the patient return rate from every two months to over a year. "Heart failure is the number one hospital discharge diagnosis in people over 65," says Leimbach. "Our heart failure clinic will offer daily and weekly treatments for heart failure patients without requiring them to be admitted to the hospital, which is good news for patients."

OHI offers an optimal patient care setting as well. All patient rooms are private and have flat panel HDTVs and wireless Internet. Each is decorated in tranquil colors with comfortable home-like furnishings and pleasing artwork. The result is a beautiful, soothing, healing environment geared towards total comfort for OHI's patients.

Now, referral physicians do not need to send patients to places like Houston or to the Mayo Clinic for treatment. "We have everything here that patients need. This is beneficial to patients because they can avoid the stress of travel, says Leimbach." "Additionally," he says, "we are engaged in research and clinical trials here. Over the past 20 years, we have done over a hundred clinical trials and carefully select each one. We reject any that would present a foreseeable risk to the patient. The benefit of clinical trials is that it makes treatment and medications available to patients that would normally not be available for five to ten years; this can save lives."

For all of our referral physicians, we invite you to tour the new Oklahoma Heart Institute at your convenience. For more information call 918.592.0999 or visit www.oklahomaheart.com.

Elaine Burkhardt is a writer, editor and producer with Newsgroup Communications, a marketing firm in Tulsa, Okla.

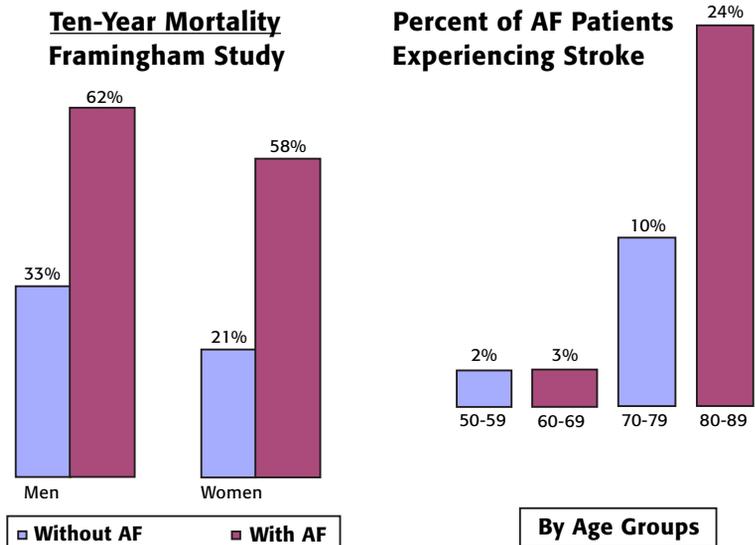


Minimally Invasive Surgery for ATRIAL FIBRILLATION

Atrial fibrillation is a common disease, which has substantial implications for both individual and public health. It is a leading cause of stroke, an independent predictor of mortality and has a substantial adverse effect on quality of life in many patients. Traditionally, there have been few options to correct atrial fibrillation. Rhythm control by medications and cardioversion are not highly successful. So, for many years, the mainstay of treatment for atrial fibrillation has been rate control and anticoagulation. We now have very good options to eradicate atrial fibrillation and return many patients to normal lifestyles.

The impact of atrial fibrillation can be expressed in a number of ways. Stroke rate is an important outcome (Figures 1 and 2). Mortality is another important measure (Figure 1). The overall burden on the healthcare system is another (Figure 3). Annual cost of healthcare for inpatient Afib treatment was \$6.65 billion in 2005. Also, admissions for Afib have almost tripled in the last 15 years. With regard to stroke, the incidence remains higher in Afib populations even when treated appropriately with anticoagulation. The choice of anticoagulation can be made using a number of parameters, but the easiest to utilize is the CHADS score (Figure 4). However, even when Coumadin is utilized appropriately, the stroke risk is only reduced by 70 percent. It is paramount that Coumadin be used when indicated, because no other form of anticoagulation has been shown to be as effective as Coumadin, but it does not solve the problem of stroke completely.

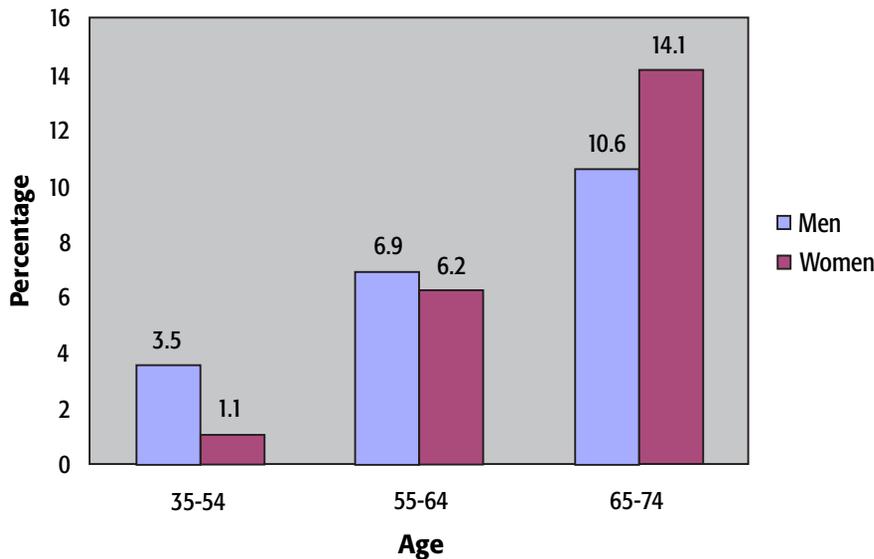
**Figure 1
Morality and Stroke in AF**



The mortality data has been a strong impetus in the development of strategies to eradicate atrial fibrillation. We currently do not

have enough data to prove mortality reduction with Afib eradication, but studies are underway. Quality of life improvement is no longer in

Figure 2
Prevalence of Atrial Fibrillation by Age and Sex in Patients with the First Ischemic Stroke



atrial lesions of the standard open maze. This allows 90 percent success in treatment of persistent Afib, even long-term persistent. Most paroxysmal patients are treated in the EP lab with a catheter-based approach, with excellent success.

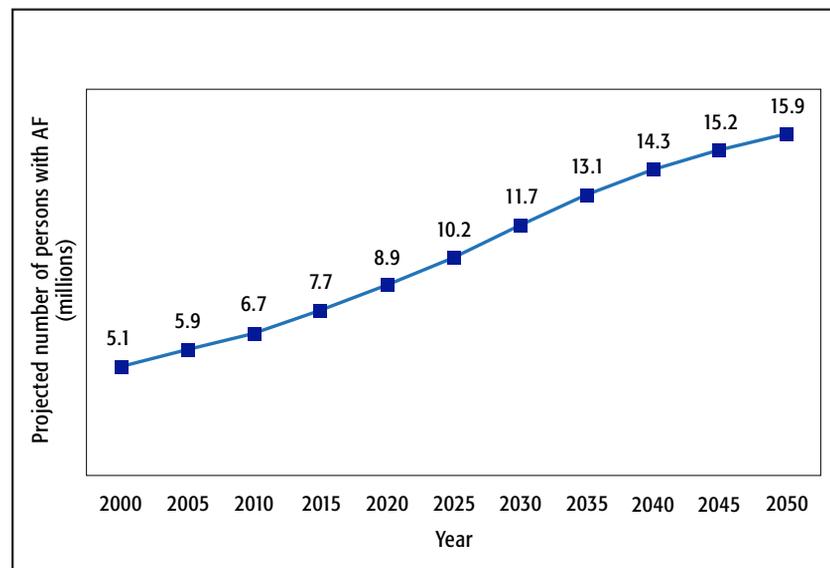
Our results are 90 percent success at restoring sinus rhythm at one year with the minimally invasive, totally thoracoscopic approach. Our results agree with recently presented data, in which 90 percent of patients were free from Afib at 11 months. It should be noted that some of these patients require cardioversion (typically one to three times) and some even require an additional EP lab procedure (usually for right atrial flutter), but the end result is reliable restoration of sinus rhythm. The majority of these patients also come off anti-

question. This group of patients improves symptomatically more than any other group of patients I see when we are able to eradicate their Afib.

The procedure we offer is surgical ablation of atrial fibrillation. This can be done as a concomitant procedure with cardiac surgery, or as a stand-alone minimally invasive procedure. The success of either of these is in excess of 90 percent in restoring normal rhythm. The minimally invasive procedure is performed using thoracoscopy bilaterally. There are three to four 5mm ports and one 10mm port on each side. Patients are generally in the hospital three or four days, and back to work in a couple of weeks. We offer this procedure to patients with persistent Afib who have failed drug therapy and cardioversion. The original "mini-Maze" as described by Wolf (1) was pulmonary vein isolation, and was better for paroxysmal. Edgerton (2) and Longoria (3) have added extended lesions to make our current procedure essentially all of the left

Figure 3
AF Much More Common than Previously Thought -- the Mayo Clinic Study --

- Doubles previous estimates
- Number may triple by 2050



Miyasaka, Y., et al. *Circulation* 2006;114:119-125. Projected number of persons with AF in the U.S. between 2000 and 2050, assuming a continued increase in incidence rate as evident from 1980 to 2000.

Figure 4 CHADS SCORE

- **C** - congestive heart failure - 1
 - **H** - hypertension - 1
 - **A** - age over 75 - 1
 - **D** - Diabetes - 1
 - **S** - Stroke or TIA - 2
- **Score 2 or more - Coumadin**
 - **Score 0 - ASA**
 - **Score 1 - either**

our healthcare system. We now have procedures that were simply not available even two or three years ago. The success of these minimally invasive approaches has been established, and we are now ready for broader application to a larger population. To have a patient evaluated in the Center for the Advanced Treatment of Atrial Fibrillation, simply call 918-579-AFIB.



James C. Spann, MD is a cardiac thoracic surgeon with CVT Surgery in Tulsa. Dr. Spann is the chairman of the Cardiovascular Surgery Division at Hillcrest Medical Center, Tulsa.

The majority of these patients also come off anti-arrhythmics and even Coumadin. Also, the quality of life improvement is tremendous.

arrhythmics and even Coumadin. Also, the quality of life improvement is tremendous.

The patients are evaluated in our comprehensive Afib clinic, where both an EP cardiologist and a cardiovascular surgeon are present, to give patients the most appropriate care. Every possible treatment is available from rate or rhythm control with drugs, to EP lab catheter-based ablation, to minimally invasive surgery, to complete maze as an open procedure. We are not aware of any other program in the country where all of this is present in one clinic. If the patient appears to be an appropriate candidate for minimally invasive surgery, then the workup includes cardiac catheterization and echocardiography, to rule out structural abnormalities, which might necessitate a concomitant approach. After

surgery, close follow-up is of paramount importance. In order to achieve long-term success, aggressive restoration of sinus rhythm is an absolute necessity. Careful monitoring of rhythm is also paramount. This cannot be accomplished by EKG or even Holter monitoring alone, but must include a month-long Cardionet type monitor which will catch any brief episodes of Afib that might be missed by other methods. This is particularly important when considering discontinuation of Coumadin. Some patients already have permanent pacemakers in place, so that monitoring is much simpler with pacemaker interrogation as the only monitoring required.

CONCLUSION

Atrial fibrillation causes extensive morbidity and mortality, as well as a substantial burden on

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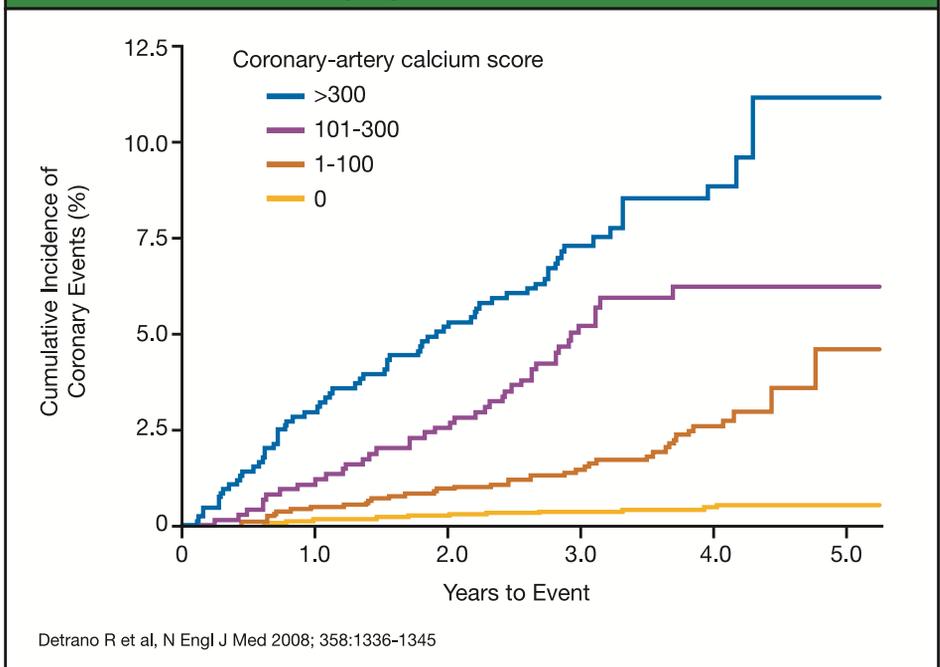
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When To Order - and what to do with - a **CARDIAC CT CALCIUM SCORE**

There are two types of cardiac CT scans: CT Angiograms (CTAs) and calcium scores. CTAs are contrasted images similar to cardiac cath images, obtained non-invasively. CTAs are best used in patients with chest pain to look for significant coronary disease. Calcium scans are non-contrast cardiac CTs that detect and measure the calcified plaque in the coronaries. Calcium scores are best used for asymptomatic patients without known coronary disease to help assess their risk for future heart attacks.

Calcium scanning is based on the observation, first noted in autopsy studies, that the amount of calcified coronary plaque directly and consistently predicts the amount of total plaque – including non-calcified plaque – in the coronaries.ⁱ The likelihood of significant coronary disease and of subsequent infarction or cardiac death for any one individual is determined largely by the total amount of plaque in the coronaries. Hence calcium scores - which reflect this overall amount of plaque in an individual's coronaries - are good predictors of coronary events. A criticism of previous calcium scoring studies was that the populations were self-selected and so were not reflective of a general population. A recent multi-center study in which patients were recruited from populations between the ages of 45 and 85 without clinical

Figure 1
Calcium Score Groups Predict the Incidence of Subsequent Coronary Events in Initially Asymptomatic Patients



cardiovascular disease (not self-selected) confirmed that calcium scoring predicts cardiac risk well, including in multiple ethnic populations.ⁱⁱ This study demonstrates that calcium scores are best used to define broad risk categories with increasing scores reflecting increasing risk (Figure 1).

Calcium scoring is attractive because of the limitations in our current approach to screening for occult coronary disease, primarily with Framingham and other risk scores. Some have observed that these risk scores overestimate

risk in the low risk patients and underestimate risk in the higher risk patients.ⁱⁱⁱ Others note that these risk scores fail to predict at least 25 percent of patients who will develop coronary disease.^{iv} Some patients will have an unexpected fatal heart attack with no preceding symptoms, and with never having been identified as at risk for coronary disease. Further, in at least two community-based studies of sudden cardiac death, the majority of patients had normal ejection fractions.^{vi vii} Calcium scoring may help over-

come the limitations of population based risk assessments by basing risk assessment on measuring the manifestations of disease in an individual's coronaries.

WHO MIGHT BENEFIT FROM CALCIUM SCANS

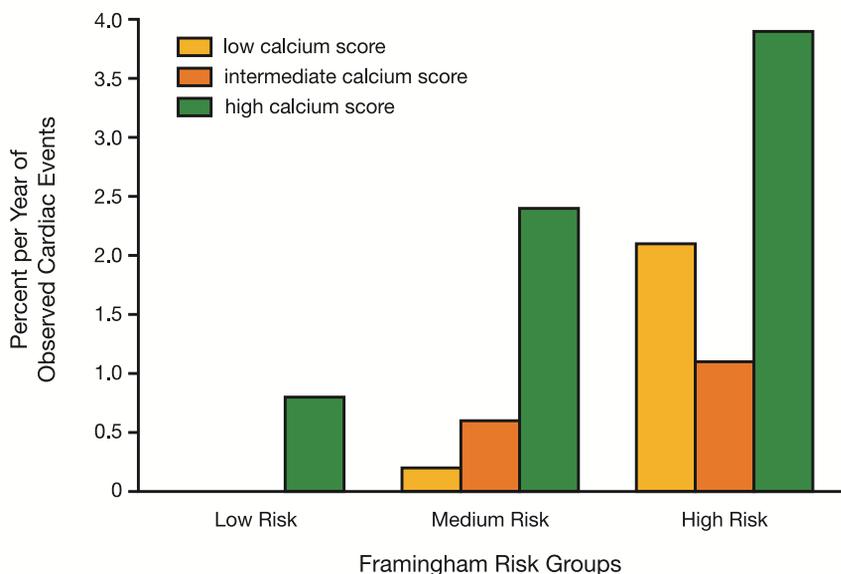
1) Coronary calcium scoring is **best used for an asymptomatic person**, with risk factors that indicate **an intermediate risk of coronary disease**, to help more precisely define that individual's

Other groups who may benefit include:

2) **Women.** Women with coronary disease more often than men have atypical, if any, symptoms. Risk scores, including Framingham, tend to underestimate cardiac risk in women. Calcium scoring appears to be a more sensitive and probably more accurate assessment of coronary risk in women.^{viii} Hence, in some women - particu-

available indicates that smokers^{ix} and diabetics with low calcium scores have cardiac risks that approach or equal the risk in the general age matched population (Figures 3 and 4). Even in the elderly, low calcium scores indicate low cardiac risk. Hence, low calcium scores may allow less testing and some reduction in medications in some elderly patients.^x In one study, calcium scor-

**Figure 2
Calcium Score Further Predicts Risk
Within Framingham Risk Groups**



Calcium scores are a better independent predictor of an individual's cardiac risk than other risk factors and are better yet used in combination with Framingham scores.

risk for future cardiac events. Calcium scores are a better independent predictor of an individual's cardiac risk than other risk factors and are better yet used in combination with Framingham scores (Figure 2). Calcium scoring, therefore, may help guide the aggressiveness of lipid and other risk reduction therapies by more precisely defining an individual's risk of future coronary events. In addition, if patients know their cardiac risk they may be better able to gauge the importance of their symptoms.

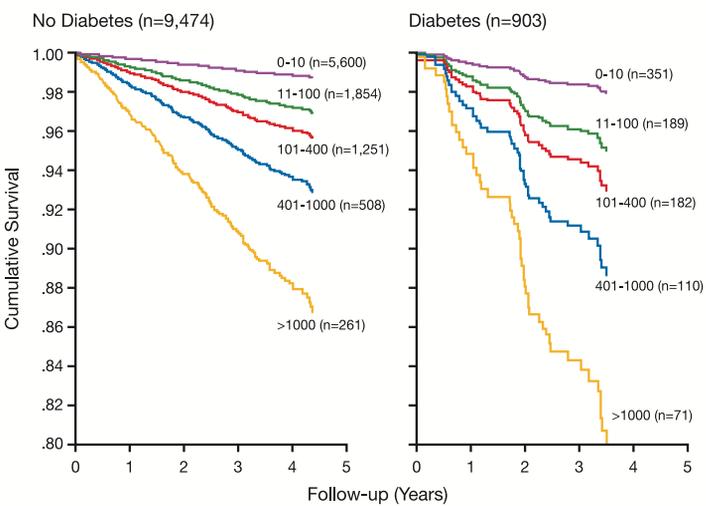
larly those with some risks and a family history - calcium scoring may help select a group who would benefit from more aggressive risk factor modification. Calcium scores that indicate increased risk may help women and their physicians pay more attention to potentially concerning atypical symptoms.

3) **Some high risk groups including smokers, diabetics and the elderly.** In each of these high-risk populations, calcium scoring can help refine risk. For instance, information

ing was used to decide which diabetics would benefit from stress testing.^{xi}

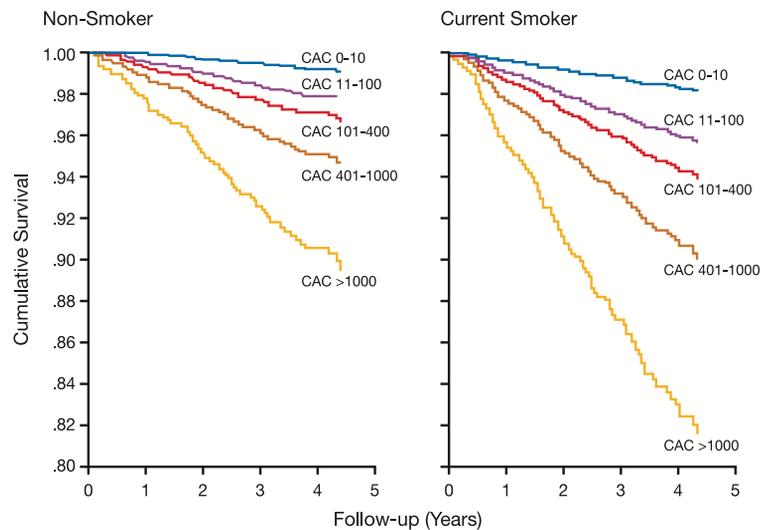
4) Some selected **low risk patients including young patients.** Men under age 45 and women under age 55 are at low risk for coronary events. However, sudden cardiac death can occur in this group and is increasing in frequency, usually without preceding typical symptoms. Calcium scoring selectively applied in this group can help evaluate risk and direct risk reduction therapy.^{xii}

Figure 3
Cox Proportional Hazards Survival (n = 10,377) by Electron Beam Tomography Coronary Calcium Measurements in Subjects With and Without Diabetes Mellitus (chi-square = 204, p<0.0001)



Raggi P et al, J Am Coll Cardiol 2004; 43:1663-1669

Figure 4
Prognostic Value of Coronary Artery Calcium Scoring in Asymptomatic Smokers and Non-Smokers



Shaw LJ et al, European Heart Journal (2006) 27, 968-975

5) In selected low risk **symptomatic patients**, calcium scoring is best used in patients without symptoms. However, a recent consensus document on the use of calcium scoring suggests that calcium scoring may be an acceptable alternative to stress testing in some patients, particularly patients with atypical symptoms.^{xiii} In this setting, a score of zero is probably most useful, indicating a low risk, similar to, or lower than, the low risk of a normal stress test.

HOW TO INTERPRET CALCIUM SCORES

In interpreting calcium scores, one should recognize that the reproducibility of any one score is limited. In some series, the variation between repeat studies has been as high as 30 percent. Hence, calcium scores generally are interpreted as designating risk groups (see above Figures 1 and 2). Variations between scores and changes in serial scores should be interpreted with caution. There are no agreed upon standards about what score should lead to what action. However, certain thresholds of calcium scoring warrant mention.

- 1) A **Zero score** indicates a very low risk of coronary disease, in the asymptomatic person, with a risk of coronary events in the next two to five years of less than 1 percent. In patients with atypical symptoms, a zero score also generally indicates a low risk. In some populations of symptomatic patients, however, the risk of coronary events with a score of zero may be high as eight percent per year.^{xiv}
- 2) Most experts view a **score of over 300 to 400 as equivalent to known coronary disease**, with at least a moderate chance that a person with this score would have a clinically significant coronary stenosis. What to do with this level of score is controversial. Some experts suggest that such a patient could benefit from stress testing, even in the absence of symptoms.^{xv} Other experts, however, believe that no further testing should be done at any level, unless there are symptoms.^{xvi} The knowledge that a person has a high score may make that person and his or her physician more vigilant for symptoms, including atypical symptoms that might suggest

ischemia.

- 3) A score **over 1,000 indicates an especially high risk**. In one study 98 asymptomatic patients with a score of over 1,000 were followed without further testing or specific intervention. In this group approximately one third (36 percent) suffered myocardial infarctions or death within 28 months of the initial calcium score.^{xvii} There is no consensus as to what action should be taken in a person with such a score. However, most would do a careful clinical assessment and consider at least a stress test.

HOW TO USE CALCIUM SCORES

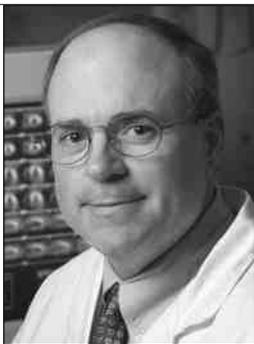
In general, calcium scores should be used as another piece of data - similar to the data from lab, or from a stress test - integrated with other clinical information to assess a patient's cardiac risk. As such calcium scores can help evaluate risk, which in turn helps guide therapy. Combined with other clinical data, calcium scores can also help clinicians decide who needs further testing.

Calcium scoring can also help enhance compliance with recommended lipid therapy. Often

patients (and sometimes physicians) are not convinced as to how aggressive to be with therapy when this therapy is based on population based risk factor assessment. A recent study found that sharing calcium-scoring information with patients substantially enhanced compliance with lipid therapy, especially in the patients defined as higher risk by calcium score.^{xviii}

In patients with known coronary disease, calcium scoring usually does not add information and so should generally not be used.

In summary, calcium scoring is most useful in people without symptoms or known heart disease, and with an intermediate risk of coronary disease, to help stratify risk and guide the intensity of risk reduction therapy. It may help enhance compliance with lipid and other therapies. Finally, calcium scoring may judiciously be used in patients with atypical symptoms as an alternative to stress testing.



Roger D. Des Prez, MD is a noninvasive cardiologist with specialty expertise in echocardiography, nuclear cardiology and cardiac computed tomography.

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THAT REASON DOES NOT KNOW...”

Blaise Pascal

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