



# Oklahoma Heart Institute

VOLUME 6 | NUMBER 3 | FALL 2011

## **Novel Tools in the Management of Atrial Fibrillation: Cryoballoon Ablation**

By Gregory A. Cogert, MD, FACC

## **Cardiac CTA or Stress Test for Chest Pain: The Promise Trial**

By Roger Des Prez, MD, FACC

## **Carotid Artery Revascularization 2011 Guideline Update: Expanding the Role of Carotid Artery Stenting**

By Raj H. Chandwaney, MD, FACC, FACAI, FSVM

## **Treatment of Cheyne-Stokes Breathing with Adaptive Servo Ventilation in Patients with Congestive Heart Failure**

By Kevin L. Lewis, MD, FAASM

Oklahoma Heart Institute Sleep Care

## **Sweet Endings**

Heart Healthy Pumpkin Pecan Cookies





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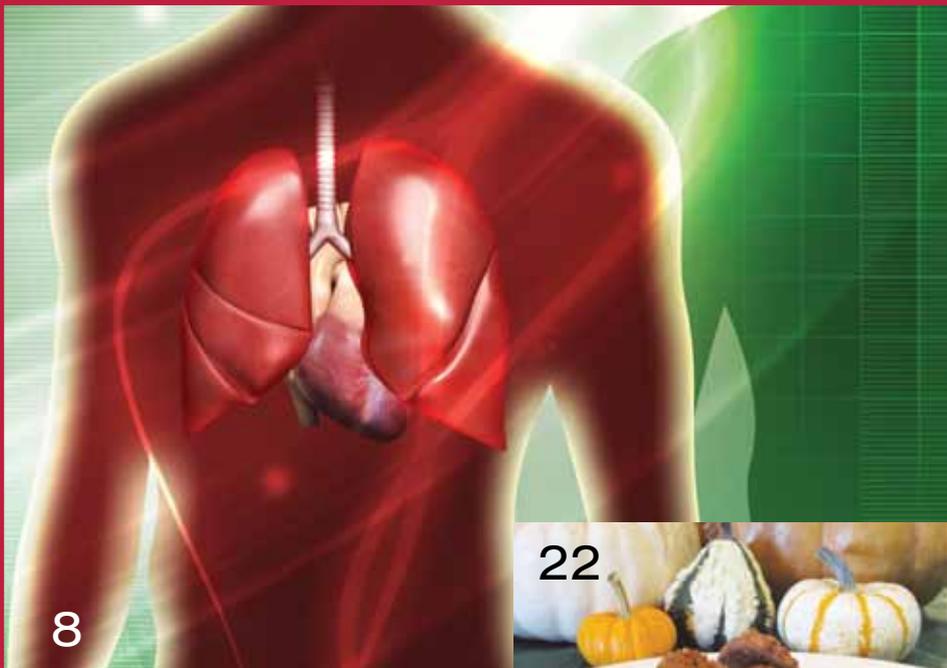
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is mailed directly to referring physicians  
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*"It's a New Day"  
Christopher Westfall, artist*

# to our readers



**Thanks to major** innovations and advancements in technology, the field of cardiology has continued to dramatically expand. New technology allows cardiologists to effectively treat patients with serious problems with more effective treatment strategies, and in some cases, with less invasive procedures. In this issue of Oklahoma Heart Institute Magazine, four examples will highlight improvements in technology which allow for better diagnostic and treatment options for patients with significant cardiovascular disease.

Dr. Roger Des Prez, who is an expert in cardiac CT angiography, will discuss the PROMISE trial, which attempts to clarify the optimal role for cardiac CT angiography versus nuclear stress testing in the evaluation of patients with possible significant coronary artery disease.

Dr. Raj Chandwaney, an interventional cardiologist at Oklahoma Heart, will discuss carotid artery revascularization guidelines and the expanding role of carotid artery stenting. Carotid artery stenting allows patients to have their carotid artery stenoses treated without having to have surgery.

Dr. Kevin Lewis, a pulmonologist and sleep specialist, will discuss treatment of Cheyne-Stokes breathing with adaptive servo ventilation in patients with congestive heart failure. Heart failure patients with Cheyne-Stokes breathing have a significantly worse prognosis, so accurate diagnosis and treatments are important in these patients. Physicians and patients need to be aware of this problem since therapy is now available.

Finally, Dr. Gregory Cogert, an electrophysiologist at Oklahoma Heart Institute, will discuss cryoballoon ablation for atrial fibrillation. This new technology allows for safer and shorter procedures in the treatment of a very common rhythm problem, atrial fibrillation.

These articles call attention to newer diagnostic and treatment strategies that are now possible thanks to recent advances in technology. Each of these procedures is available at Oklahoma Heart Institute.

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

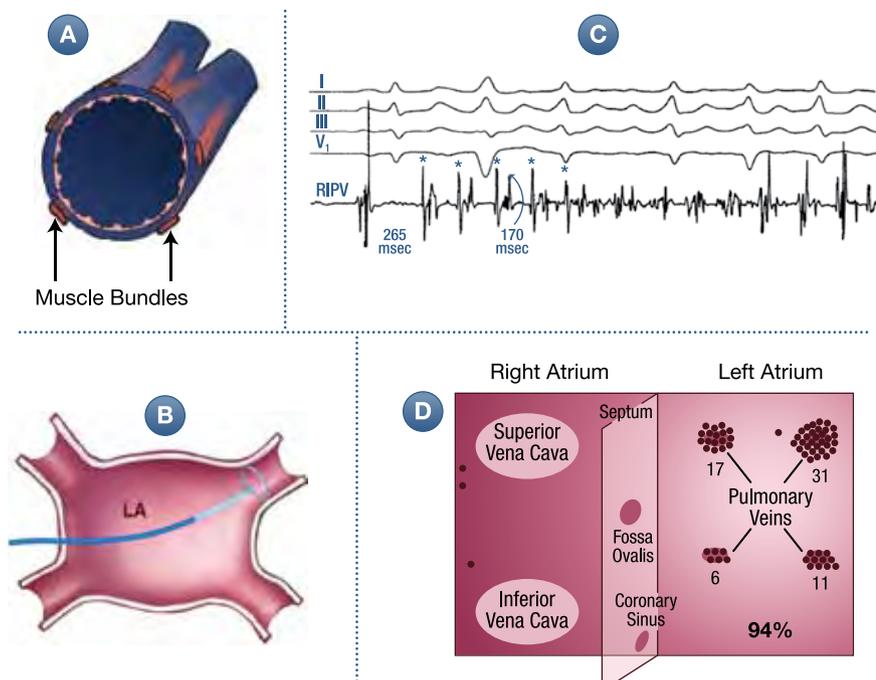
*Wayne Leimbach*

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

# Novel Tools in the Management of Atrial Fibrillation: Cryoballoon Ablation

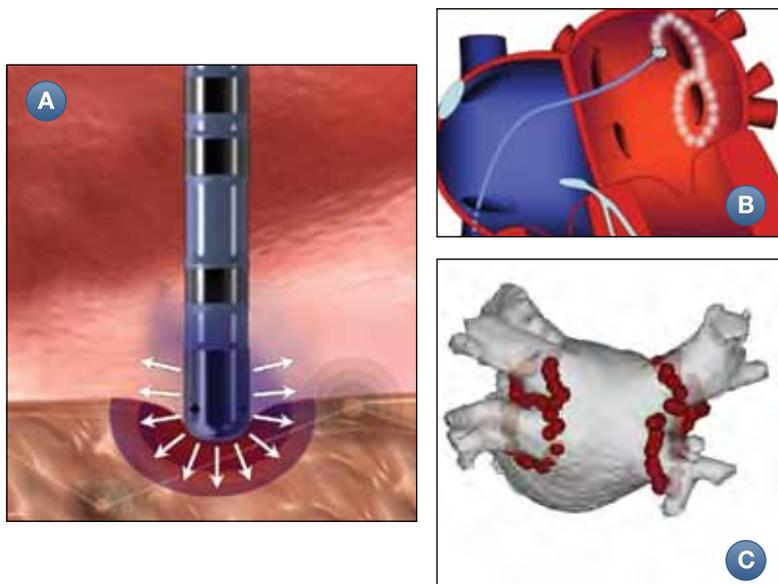
By Gregory A. Cogert, MD, FACC

**Figure 1**  
**Pulmonary Veins Trigger Atrial Fibrillation**



**Figure 2**

## Point-by-Point Radiofrequency Circumferential Pulmonary Vein Isolation



Atrial fibrillation (AF) is the most common heart rhythm problem affecting adults in America. Currently, over 4 million people carry the diagnosis of AF with many more yet to be diagnosed. There is an increasing incidence with age, and it is estimated that 25% of adults over 40 will develop AF during their lifetime. AF can result in a dramatic reduction in quality of life, physical condition, mental health and social functioning, as well as cause congestive heart failure, stroke, dementia, and death. Fortunately, successful ablation of AF has proved in multiple research trials to normalize the above quality of life measures and reduce the incidence of congestive heart failure, stroke, dementia, and death.

Ablation of AF is based on the groundbreaking work published in 1998 by Dr. Michel Haissaguerre<sup>1</sup>. In his publication, Dr. Haissaguerre described that 94% of the triggers of AF are located in the pulmonary veins (Figure 1). These veins, found in the back of the left atrium, bring oxygenated blood from the lungs to the heart. Within the vein tissue are muscle bundles capable of rapid electrical activity that causes AF. When the muscle within these veins is exposed to the stress of hypertension, increased age, obstructive sleep apnea, obesity, and certain adrenergic and hormonal changes, the result is rapid electrical activity and AF. The electrical isolation of these veins from within the heart is the cornerstone of AF ablation therapy. Prompted by research trials of over 7000 patients undergoing ablation, the Heart Rhythm Society, in conjunction with the American College of Cardiology and American Heart Association, recently published the 2011 focused update on the management of patients with AF making ablation a class I recommendation for the first line treatment of many patients with AF.

The safety and effectiveness of AF ablation limited the widespread acceptance of this technology early in its development. The biggest limitation of the procedure is the difficulty to create a durable circumferential ablation lesion to isolate each pulmonary vein (Figure 2). The ablation catheter delivers a radiofrequency “burn” lesion at a single point. The ablating physician must connect each lesion in a circular

*Continued on p. 6*

Continued from p. 5

manner to isolate the pulmonary veins. This process is technically challenging, with procedure duration often lasting over 5 hours. Also, a rare, but life threatening, complication has been reported in patients undergoing radiofrequency ablation resulting from burning the back of the left atrium adjacent to the esophagus called an atrial-esophageal fistula.

In response to these limitations, in December, 2010 the FDA approved the first circumferential ablation delivery system (Arctic Front, Cryocath, Medtronic). This technology offers multiple improvements upon the previous radiofrequency point ablation technique. The balloon technology delivers a continuous circular lesion around the ostium of the vein with a single application of cryoablation (Figure 3). This simplified approach to pulmonary vein isolation results in a significant reduction in procedure duration and X-ray radiation exposure to the patient and physician. Another advantage of the cryoballoon technology is that cryoballoon freezes and sticks to the beating heart, delivering ablation energy to the desired area throughout cardiac contraction. Also, unlike radiofrequency ablation, tissue exposed to cryoablation maintains its natural architecture, eliminating the risk of a catastrophic atrial-esophageal fistula.

The cryoballoon technology has been extensively studied in Europe. Over 10,000 cases have been performed in over 200 centers. Success rates and safety have been comparable or superior to radiofrequency ablation in all reported studies. Based on the initial European experience, the pivotal Sustained Treatment of Paroxysmal Atrial Fibrillation (STOP-AF) trial was performed in the US and Canada. This trial randomized 245 patients to Cryoballoon AF ablation or medical therapy. The results were presented at the American College of Cardiology May 2010 and were overwhelmingly in favor of cryoballoon ablation (Figure 4). At 1 year, 70% of cryoballoon treated patients were free of AF compared with just 7% in the medication group. Importantly, there is a steep learning curve with this technology. In centers performing over 12 procedures, success rates were significantly higher at 90% (Figure 5). Perhaps the most exciting results from the STOP-AF trial are found in the quality of life data (Figure 6). Patients undergoing cryoablation experienced remarkable improvements in their quality of life symptoms including palpitations, fatigue, shortness of breath, and dizziness.

Since adopting the cryoballoon technology

Figure 3  
Cryoballoon Ablation

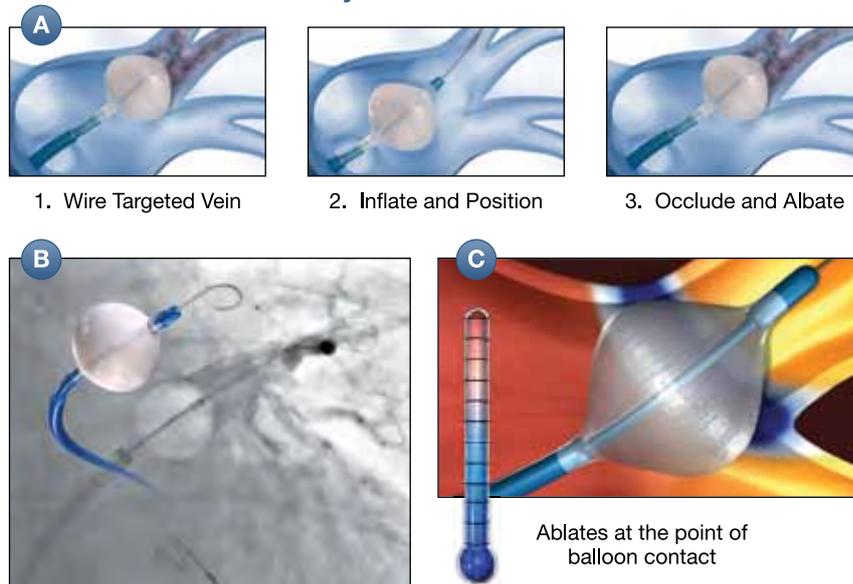
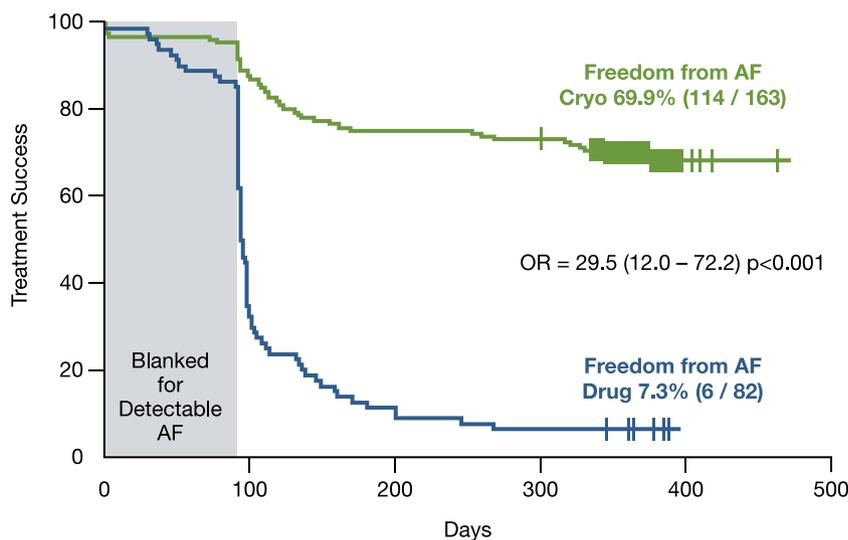


Figure 4  
STOP-AF Results

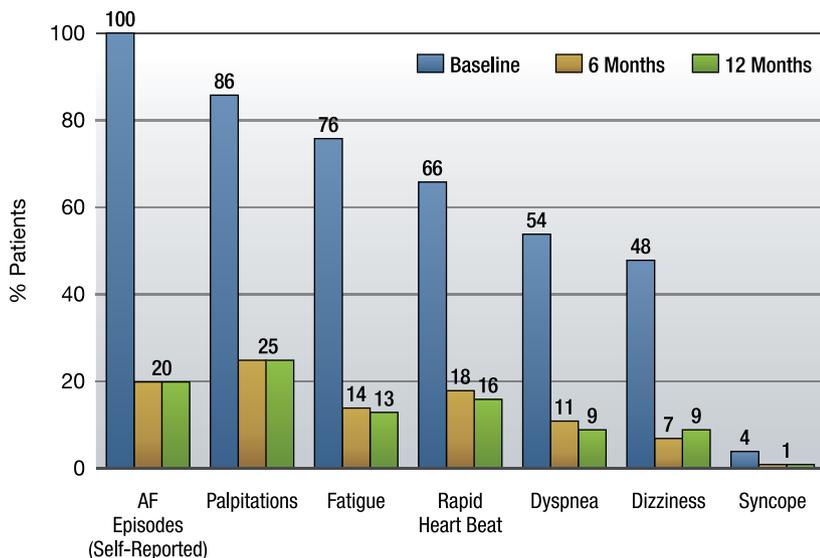


in May 2011, the Oklahoma Heart Institute physicians have performed 33 AF cryoablation procedures (through August 2011). Although early in our experience, we currently have an acute procedural success rate of 100%. We have experienced no complications related to these procedures. During short-term follow-up, success rates for paroxysmal AF are currently over 90%. As expected, procedure duration and X-ray exposure times continue to improve and are superior to the previous point

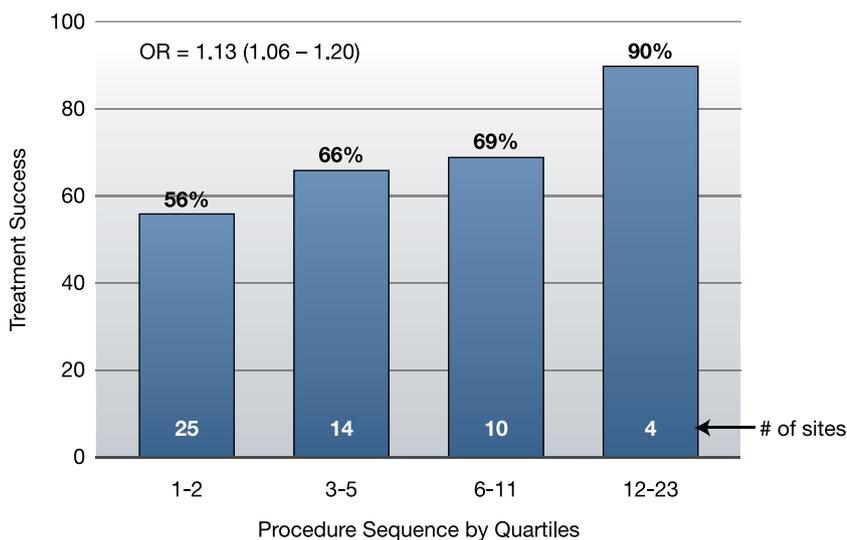
to point radiofrequency ablation technology.

In summary, AF is the most common heart rhythm problem in America. It can lead to a decreased quality of life as well as congestive heart failure, stroke, dementia, and death. AF is triggered by abnormal electrical activity in the pulmonary veins that can be eliminated by pulmonary vein isolation. Ablation of AF is superior to medical therapy and has recently received a class 1 recommendation for the first line treatment of AF. Cryoballoon abla-

**Figure 6**  
**STOP-AF: Cryo-Balloon Patients**



**Figure 5**  
**Cryo-Balloon Procedure Experience Impacts Treatment Success**



tion was approved by the FDA in December of 2010 and represents the first approved circumferential ablation technology for pulmonary vein isolation. This second generation technology for AF ablation offers multiple advances to facilitate procedure safety and effectiveness. Both in the nationally presented STOP-AF trial and in the Oklahoma Heart Institute experience, this technology has proven valuable in successfully treating patients with AF.

*Gregory A. Cogert is a cardiologist who specializes in electrophysiology, including catheter ablation of arrhythmia, as well as the implantation and management of cardiac pacemakers, defibrillators, and cardiac resynchronization devices.*



AF is the most common heart rhythm problem in America . . . Cryoballoon ablation was approved by the FDA in December of 2010 and represents the first approved circumferential ablation technology for pulmonary vein isolation.

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2. 2011 ACCF/AHA/HRS focused update on the management of patients with atrial fibrillation, *Heart Rhythm* 2011;8(1): 157-76

#### FIGURES

Figure 1. A. Cross section of a pulmonary vein with electrically active muscle bundles (green arrows). B. Cross section of left atrium with 4 pulmonary veins present. The mapping catheter (blue) measures electrical activity in each vein. C. Recording of electrical activity in a pulmonary vein triggering AF. D. Distribution of AF triggers with 94% arising from the pulmonary veins.

Figure 2. A. Radiofrequency ablation catheter creates a point lesion. B. Point-by-point circumferential pulmonary vein isolation. C. Reconstructed CT scan of the posterior left atrium with point ablation (red dots) around pulmonary veins to achieve electrical isolation.

Figure 3. A. Cryoballoon ablation procedure with wire selecting pulmonary vein branch, inflating balloon, confirming vein occlusion, and performing ablation. B. Xray of cryoballoon occluding pulmonary vein prior to ablation with superimposed schematic of cryoballoon (blue). C. Cryoballoon creates circumferential ablation at the pulmonary vein ostium.

Figure 4. Efficacy results of the STOP-AF trial. Cryoablation is far superior to medical therapy in eliminating AF.

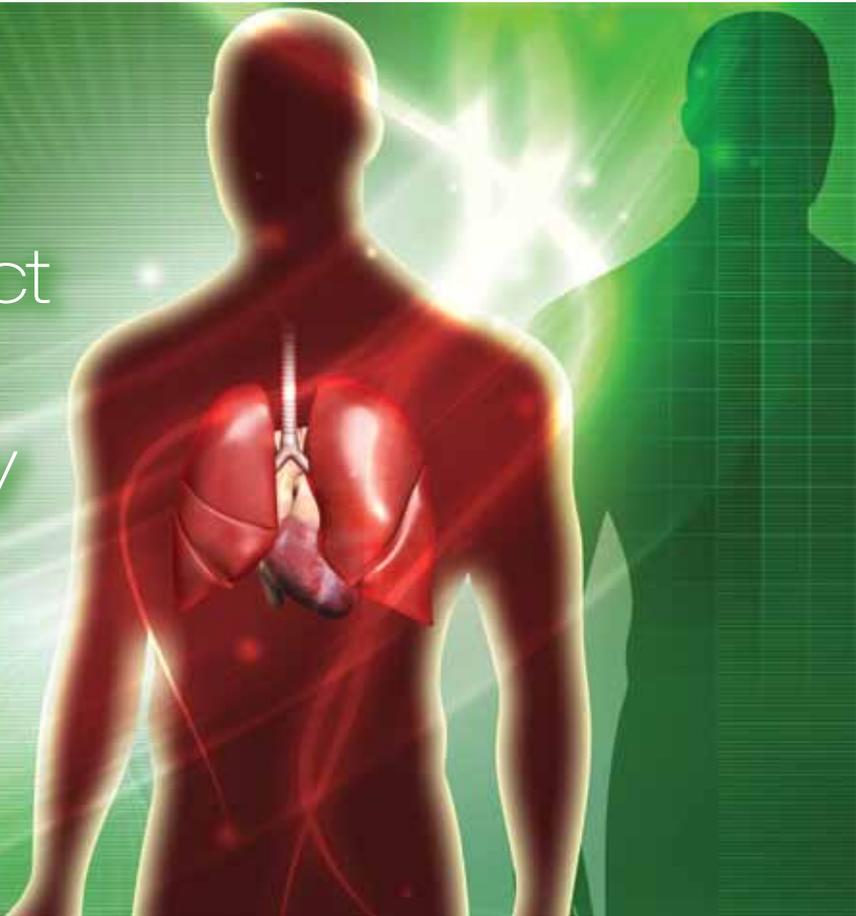
Figure 5. Cryoballoon procedure volume and experience improve success rates. STOP-AF Centers performing over 12 procedures enjoyed a 90% success rate.

Figure 6. Symptomatic improvement following cryoablation of AF. Results from the STOP-AF trial show durable improvements in quality of life following cryoablation.

# Cardiac CTA or Stress Test for Chest Pain: The Promise Trial

By Roger Des Prez, MD, FACC

Cardiac CTA  
provides direct  
visualization  
of the severity  
of coronary  
plaque and  
stenoses



When a patient reports the new onset of chest discomfort suggesting coronary disease, physicians often order a stress test. These tests stress the heart by exercise or by pharmacologic means, then assess the presence or absence of myocardial ischemia, by nuclear imaging, echo, or ECG criteria. The severity of the measured ischemia signifies the severity and clinical significance of the coronary stenoses. Cardiac CTA (computed tomography angiography) has recently become available as another technique to evaluate for possible coronary disease. Cardiac CTA provides direct visualization of the severity of coronary plaque and stenoses (Figure 1). CTA cannot (reliably) detect ischemia.

So, physicians now have a choice between two fundamentally different non-invasive approaches to evaluating a patient for coronary disease: an anatomic evaluation with CTA, or a physiologic evaluation with a stress test.

## WELL-ESTABLISHED STANDARD OF STRESS TESTING

The clinical importance of detecting and measuring myocardial ischemia by stress testing is established. Patients with no or minimal ischemia on a nuclear stress test have a less than 1% chance of a coronary event in the following year. The degree of ischemia predicts coronary prognosis and can help guide thera-

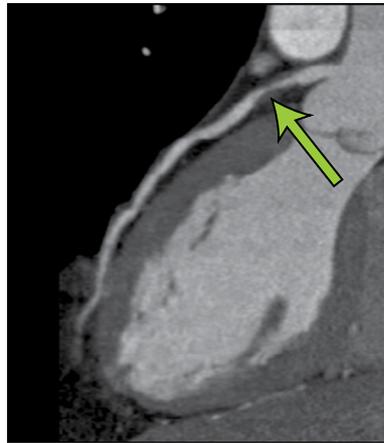
peutic choices. Patients with a moderate or greater degree of ischemia are likely to do better if treated with revascularization, whereas those with a lesser degree of ischemia are likely to do better with medical therapy (Figure 2).

## LIMITATIONS OF STRESS TESTS

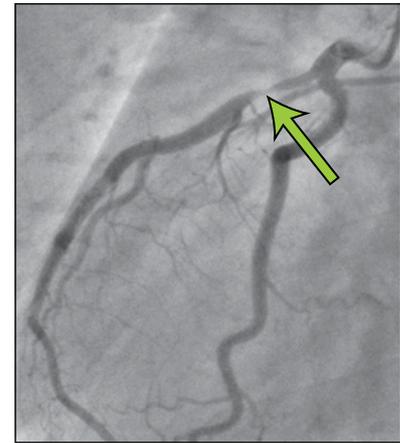
Stress tests, however, have limitations. The ECG may be abnormal at baseline, making interpretation of the stress ECG more difficult. Imaging may be complicated by artifacts, potentially causing false positive or negative studies. Stress may be suboptimal, reducing the sensitivity of the test. This may be particularly problematic for pharmacologic stress

**Figure 1**  
**Cardiac CT Angiography Compared With Invasive Cardiac Catheterization**

tests, since we cannot reliably gauge the degree of stress caused by the most commonly used pharmacologic stress agents. For these and other reasons, even the best nuclear labs can fail to recognize important coronary disease. In one study, nuclear stress testing missed left main significant and/or 3-vessel disease in 10-15% of cases. Recent data suggests that, in real world use, inaccuracies of stress testing, in particular false positives, may be higher than previously appreciated. A recent NEJM article described a database of 398,978 patients from 663 major U.S. hospitals who had elective cardiac catheterization for chest pain. Most of these patients had a stress test before their cardiac cath, and in a majority the stress test was a false positive, with a positive cardiac catheterization defined as one with a stenosis of over 50%. (Figure 3). Even when symptoms were typical and the stress test was positive, only approximately half of the cardiac catheterizations demonstrated significant disease.



Cardiac CTA showing a severe proximal left anterior descending stenosis



Stenosis confirmed by cardiac catheterization

Images courtesy of S. Achenbach

### CARDIAC CT OFFERS AN ALTERNATIVE ANATOMIC APPROACH

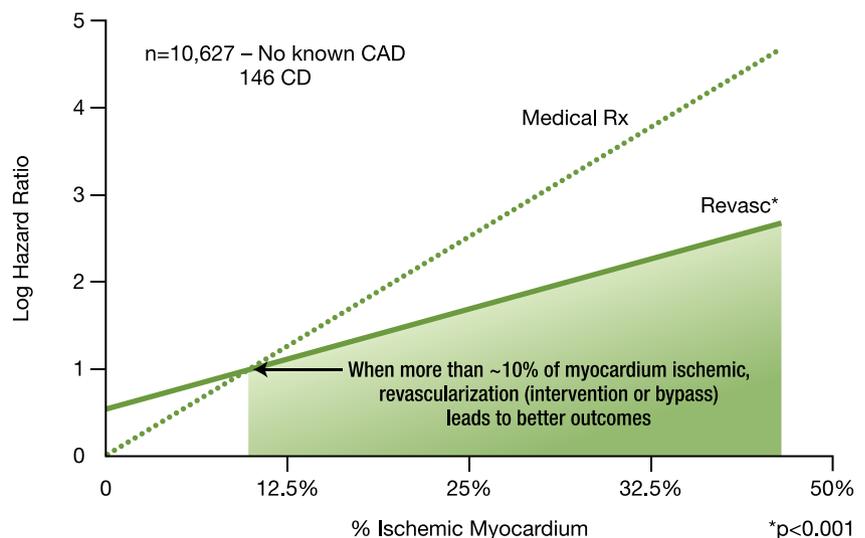
Cardiac CT angiography has developed to the point where it can offer excellent non-invasive images of coronaries (Figure 1). Meta-analyses and multicenter prospective trials find that the overall accuracy of cardiac CT to detect significant stenoses is over 90%. It has also been demonstrated that the amount of coronary disease detected by CT has prognostic power similar to that of nuclear stress testing (Figure 4).

### LIMITATIONS OF CT

Cardiac CT also, however, has limitations. CT can be thought of as a camera with a fair shutter speed or temporal resolution, so motion, including cardiac motion, will blur the images. It is essential that a patient cooperate, not move and hold his breath on request. Imaging is best when a patient's heart rate is slower (optimal under 60) and regular without ectopy. Extensive calcium in the coronaries makes accurate interpretation of the degree of stenoses difficult at best. Contrast can be mis-timed, which will cause poor coronary images. Cardiac CT angiography uses intravenous contrast, and so is relatively contraindicated in patients with renal insufficiency or a dye allergy.

Cardiac CT is extremely sensitive to detect disease. Its best use may be to exclude

**Figure 2**  
**Risk of Cardiac Death and Inducible Ischemia**  
**Ischemia Predicts Benefit from Revascularization**



Hachamovitch Circulation 2003;107:2900-2907 and J Nucl Cardiol 2007;13:768-778

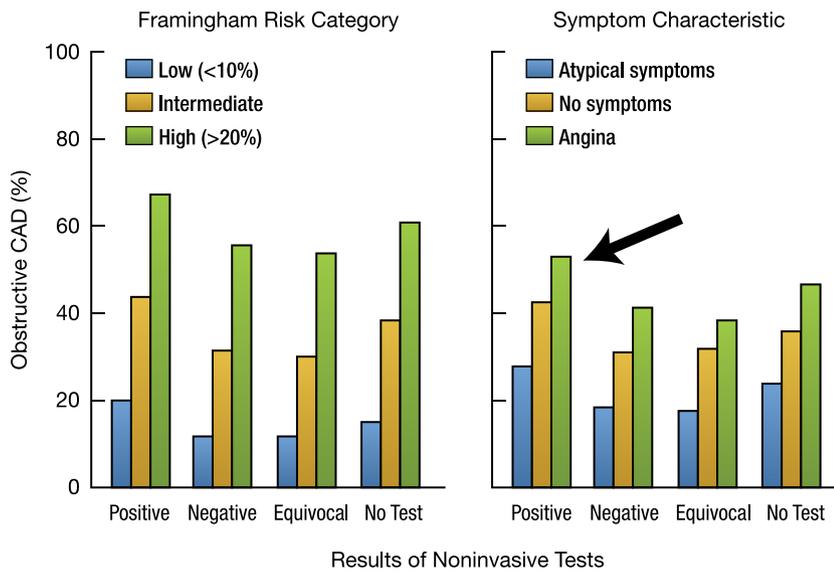
disease. However, in general use its sensitivity may paradoxically be a problem. CT tends to visually overestimate the severity of disease. Further, some referring physicians may be uncomfortable with the finding of moderate coronary disease. CT, therefore, may at times lead to downstream testing and even interventional therapies.

### THE PROMISE TRIAL

The PROMISE (PROspective Multicenter Imaging Study for the Evaluation of Chest Pain) trial is an NIH multicenter trial comparing cardiac CTA with stress testing as the initial test for the initial diagnosis of coronary disease in stable outpatients with new or worsening chest discomfort. Men must be over age 55, or over age 45 with at least one risk factor,

*Continued on p. 10*

**Figure 3**  
**Patients With Obstructive Coronary Artery Disease, According to Noninvasive Test Results**



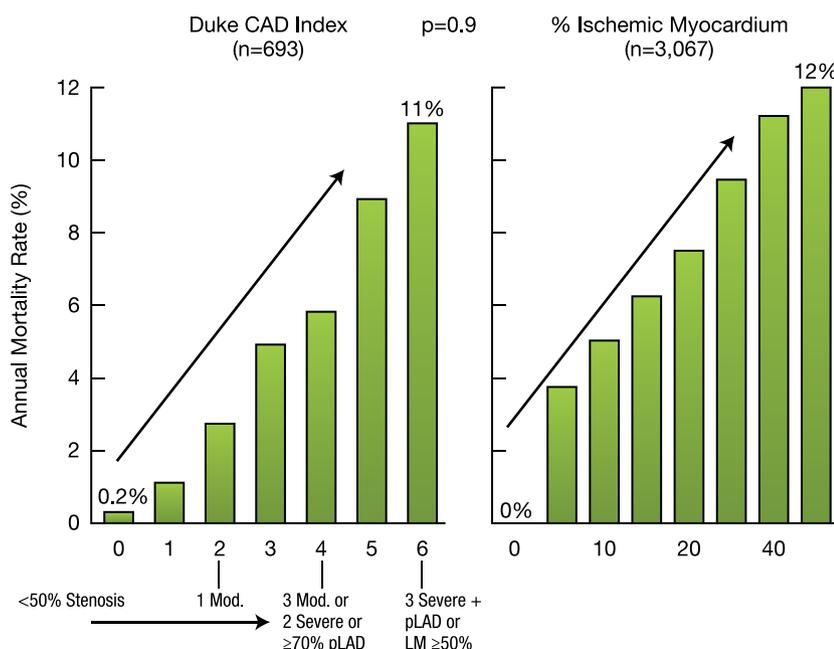
Results are presented according to the level of the Framingham Risk Category (low, intermediate, or high) and Symptom Characteristic (no symptoms, atypical symptoms, or angina). CAD denotes coronary artery disease.

Note that only a minority of patients had significant obstructive disease (stenosis over 50%).

Even in patients with typical symptoms and a positive stress test (see arrow), only approximately half of patients had significant obstructive disease (stenosis >50%) at cardiac cath.

Patel MR et al, N Engl J Med 2010; 362:886-895

**Figure 4**  
**Outcomes According to CTA vs. Nuclear Stress Testing**  
**Annual Mortality by CTA CAD vs. % Ischemic Myocardium by SPECT**



Shaw J Cardiovasc CT 2008;2(1):93:100

Continued from p. 9

such as hypertension, hyperlipidemia, diabetes, or tobacco use. Women must be over age 65, or over age 50 with at least one established risk factor.

Excluded are patients with prior myocardial infarction, revascularization (bypass or percutaneous intervention), known coronary stenosis of ≥ 50%, and patients who have had a test for coronary disease within the past year. Also excluded are patients with significant valvular, congenital, or a cardiomyopathic disease (EF ≤ 40%), patients with renal insufficiency (cr ≥ 1.5), a dye allergy, and patients with a contraindication to beta blockers.

Eligible patients are randomized to a stress test of the physician's choosing — nuclear, echo, or a simple routine treadmill ECG — or a cardiac CTA. Results of these tests are reported to the referring physician. All clinical decisions and decisions to do further testing, including cardiac catheterization, are left to the referring physician. Endpoints of the study include the clinical outcomes of death, MI, CVA, and revascularization. The study will correlate the results of any cardiac catheterization with the initial testing. It will measure quality of life endpoints, track major complications of cardiovascular procedures and assess for economic endpoints such as the cost of further “downstream” testing after the initial test. At least two years of follow-up is planned. ❤️

This study plans to enroll 10,000 patients from over 100 sites. Oklahoma Heart Institute is participating.

To refer a patient, please call Oklahoma Heart (918-592-0999) and ask for the research nurse (or call research at 918-939-8894).

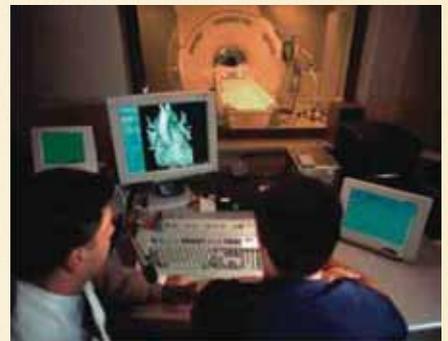
Roger D. Des Prez is a noninvasive cardiologist with subspecialty expertise in echocardiography, nuclear cardiology and cardiac computed tomography.

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## Oklahoma Heart Institute



## Services of Oklahoma Heart Institute

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- Coronary Angioplasty
- Multivessel Angioplasty and Stenting
- Atherectomy
- Rotablator Atherectomy
- Thrombolytic Therapy
- Coronary Stents
- Carotid Stenting
- Fractional Flow Reserve
- Intravascular Ultrasound
- Myocardial Biopsy
- Pericardiocentesis
- Peripheral Angioplasty
- Peripheral Stents
- Percutaneous ASD Closures
- Percutaneous PFO Closures
- Impella Circulatory Support
- Therapeutic Hypothermia for Cardiac Arrest Patients
- Venous Ablation

### Noninvasive Cardiology

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- CT Heart Scan
- Cardiac and Vascular Screening Services
- Nuclear Cardiology

- Echo and Doppler Studies
- Nuclear and Echocardiographic Exercise and Pharmacological Stress Testing
- Retinal Imaging
- Thyroid Ultrasound
- Transesophageal Echocardiography, Arterial Venous Peripheral Vascular Imaging and Doppler Studies
- Peripheral Arterial Doppler and Duplex Imaging
- Cardiovascular Magnetic Resonance Imaging
- External Counterpulsation (ECP) Therapy
- Transcranial Doppler
- Aquapheresis Therapy

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- Electrophysiology Studies
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- Pacemaker and Lead Extraction
- Pacemaker Programming
- Pacemaker Monitoring and Clinic
- Implantable Cardioverter Defibrillator (ICD) Replacement
- ICD and Hardware Removal
- ICD Programming
- ICD Monitoring and Clinic
- Holter Monitoring and Interpretation

- 30 Day Cardiac Event Monitors
- Implantation and Interpretation of Long-Term Heart Monitors
- Signal Averaged EKGs and Interpretation
- Head Up Tilt Testing and Interpretation
- Direct Current Cardioversion
- Antiarrhythmic Drug Loading and Monitoring

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- Advanced Center for Atrial Fibrillation
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- Hypertension Clinic
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- Lipid and Wellness Clinic
- Heart Failure Clinic
- Same Day Appointment Clinic
- Pre-Operative Clinic
- Center for the Treatment of Venous Disease
- Sleep Care

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# THE DOCTORS OF OKLAHOMA HEART INSTITUTE

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



Dr. Leimbach is a specialist in interventional cardiology, including cardiac catheterization, coronary angioplasty, percutaneous closure of PFOs & ASDs and related interventional procedures such as stents, atherectomy, laser, intravascular ultrasound imaging and direct PTCA for acute myocardial infarction. He is Chief of Cardiology at Oklahoma Heart Institute Hospital, where he is also Director of the Cardiac and Interventional Laboratories. Dr. Leimbach is Co-Founder 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.

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

## Robert C. Sonnenschein, MD, FACC, ASE, RVT



Dr. Sonnenschein specializes in echocardiography and noninvasive peripheral vascular imaging. He is past Director of Peripheral Vascular Ultrasound Imaging at Hillcrest Medical Center and Oklahoma Heart Institute and serves as Clinical Associate Professor of Medicine at the University of Oklahoma College of Medicine – Tulsa. He completed his Cardiology Fellowship at the State University of New York Upstate Medical Center in Syracuse, where he also completed his Internal Medicine Internship and Residency programs. Dr. Sonnenschein received his medical degree from Rush Medical College in Chicago and his Bachelor of Arts degree from the University of Pennsylvania.

*Board certified in Internal Medicine, Cardiovascular Disease, and Adult Echocardiography Registered Vascular Technologist*

## Robert E. Lynch, MD, FACC



Dr. Lynch is a specialist trained in noninvasive and invasive cardiology with a special interest in the prevention of cardiovascular disease. He is former Chief of Cardiology at Hillcrest Medical Center, where he also has served as Chief of Medicine and President of the medical staff. Dr. Lynch is former Co-Director of the Lipid and Wellness Clinic at Oklahoma Heart Institute

and Director of the Executive Health Program. Dr. Lynch is also a Clinical Assistant Professor at the University of Oklahoma College of Medicine – Tulsa. He completed his Cardiology Fellowship, as well as his Internal Medicine Internship and Residency, at the University of Oklahoma Health Sciences Center. Dr. Lynch received his medical degree from the University of Oklahoma School of Medicine and his Bachelor of Science degree from the University of Tulsa. Before establishing his practice in Tulsa, he served as Chief of Medicine at the U.S. Army Hospital, Bangkok, Thailand.

*Board certified in Internal Medicine and Cardiovascular Disease*

## James J. Nemeec, MD, FACC



Dr. Nemeec is a specialist in echocardiography, stress echocardiography and nuclear cardiology. He serves as Director of Nuclear Cardiology for Oklahoma Heart Institute. Dr. Nemeec has served as Assistant Professor of Internal

Medicine, Division of Cardiology, at Creighton University and as Assistant Professor, Department of Radiology, also at Creighton University. He completed his Clinical Cardiology Fellowship at the Cleveland Clinic Foundation and his Internal Medicine Internship and Residency at Creighton University. Dr. Nemeec also completed a year of training in pathology at the University of Missouri, Columbia, MO. He received his medical degree from Creighton University, where he also received his Bachelor of Arts degree.

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*Board certified in Internal Medicine and Cardiovascular Disease*

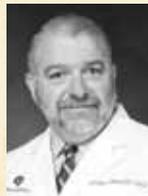
## Roger D. Des Prez, MD, FACC



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Dr. Lewis completed Fellowship training in Sleep Care, Pulmonary, and Critical Care at the University of Missouri Hospitals and Clinics in Columbia and the University of Kentucky Medical Center in Lexington. He completed his Internal Medicine Residency programs at the University of Nebraska Medical Center in Omaha and the Oklahoma University College of Medicine in Tulsa. Dr. Lewis earned his medical degree from the University of Texas Health Science Center in San Antonio.

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Dr. Muhammad is a subspecialist in interventional cardiology with expertise in cardiac catheterization, coronary intervention (including angioplasty, stent placement, atherectomy, intravascular ultrasound), peripheral vascular intervention (including carotid intervention) as well as

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Dr. Muhammad completed his Interventional Cardiology Fellowship at the Cleveland Clinic in Cleveland, Ohio, which included an additional year of dedicated training in peripheral vascular and structural cardiac intervention. His Clinical Cardiology Fellowship was also conducted at the Cleveland Clinic. Dr. Muhammad completed his Internal Medicine Internship and Residency at Yale University in New Haven, Connecticut, where he was selected and served as Chief Resident. He earned his medical degree from the University of Massachusetts Medical School in Worcester, Massachusetts. Dr. Muhammad earned his Bachelor of Science degree in computer science from the University of Massachusetts in Amherst, Massachusetts.

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Dr. Lim is an interventional and noninvasive cardiologist with subspecialty expertise in cardiac catheterization, angioplasty, stents and atherectomy, as well as echocardiography, nuclear cardiology and coronary angiography. He completed his Interventional Cardiology Fellowship

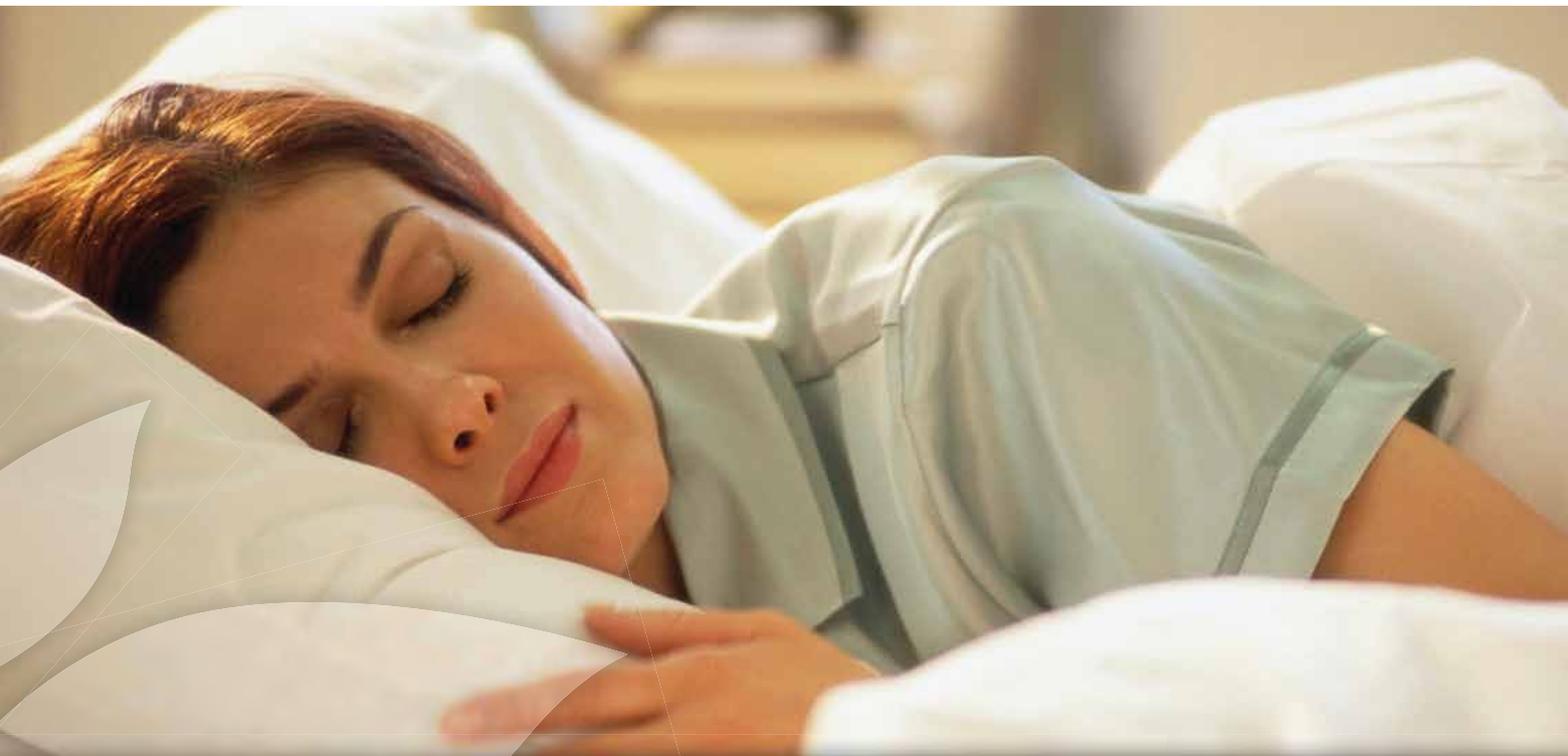
at the University of Medicine and Dentistry of New Jersey/Robert Wood Johnson Medical School in New Brunswick, NJ. His Clinical Cardiology Fellowship was conducted at the Albert Einstein College of Medicine in the Bronx, NY.

Dr. Lim completed his Internal Medicine Internship and Residency at Loma Linda University in Loma Linda, CA. He earned his medical degree from the Stony Brook School of Medicine in Stony Brook, NY. Dr. Lim received his Bachelor of Science degree in physics at New York University in New York, NY.

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## Oklahoma Heart Institute Sleep Care *of Hillcrest Medical Center*



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  - 300+ thread count sheets
- A continental breakfast in the morning

# Carotid Artery Revascularization 2011 Guideline Update:

## Expanding the Role of Carotid Artery Stenting

By Raj H. Chandwaney, MD, FACC, FSCAI, FSVM

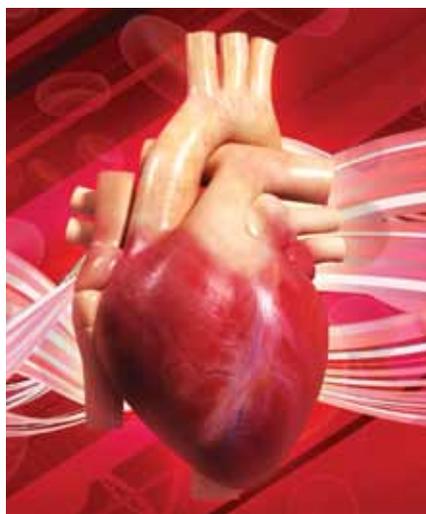
A 2011 guideline update on the management of patients with extracranial carotid artery disease was recently published.<sup>1</sup> The updated guidelines are based on the compilation of several randomized studies examining methods of revascularization in patients with extracranial carotid artery stenoses. This guideline statement is unique because it represents a true multidisciplinary consensus across several specialties in medicine. The document is endorsed by multiple professional societies including the American Heart Association, American College of Cardiology, American Stroke Association, American Association of Neuroscience Nurses, American Association of Neurological Surgeons, American College of Radiology, American Society of Neuroradiology, Congress of Neurological Surgeons, Society of Atherosclerosis Imaging and Prevention, Society of Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of Neuro-Interventional Surgery, Society for Vascular Medicine, and Society for Vascular Surgery.

### BACKGROUND

Stroke is an important cause of morbidity and mortality in the United States.<sup>2</sup> When considered separately from other cardiovascular diseases, stroke is ranked as the third most common cause of death in the country (heart disease ranks first; cancer ranks second). Stroke accounted for approximately 1 of every 17 deaths occurring in the United States in 2005. For patients who survive stroke, it can cause devastating disabilities.

Each year, approximately 795,000 Americans experience a stroke. Approximately 610,000 are initial attacks; and 185,000 are recurrent attacks. On average, every 40 seconds, someone in the United States suffers a stroke. Locally, stroke is a much more disturbing problem than it is nationally. Recent statistics rank the state of Oklahoma's stroke death rate to be the forty-ninth worst in the country.<sup>2</sup>

Of all strokes, 87% are ischemic in etiology, and 13% are hemorrhagic in etiology.<sup>2</sup> Carotid artery disease is an important cause of ischemic stroke. The majority of ischemic strokes (59%) that occur in patients aged 45 to 70 years old are attributed to large artery atherosclerosis.<sup>3</sup>



### LANDMARK CLINICAL TRIALS

The updated 2011 guidelines on the management of patients with extracranial carotid artery disease are inspired by several randomized studies examining the role of carotid artery revascularization.<sup>1</sup> Landmark clinical trials that have examined the role of carotid artery revascularization include the North American Symptomatic Carotid Endarterectomy Trial (NASCET),<sup>4</sup> the Asymptomatic Carotid Atherosclerosis Study (ACAS),<sup>5</sup> the Asymptomatic Carotid Surgery Trial (ACST),<sup>6</sup> the Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy trial (SAPPHIRE)<sup>7</sup> and the Carotid Revascularization Endarterectomy versus Stent Trial (CREST).<sup>8</sup> These landmark clinical trials are briefly summarized here to familiarize the reader with their important findings.

NASCET<sup>4</sup> was a multi-center, randomized, controlled trial of 2226 patients at 106 centers. The inclusion criteria included hemispheric or retinal transient ischemic attack or a nondisabling stroke within 120 days of entry. Patients were divided into two predetermined categories based on the severity of carotid stenosis: 30-69% and 70-99%. Patients were then randomly assigned to receive carotid endarterectomy or medical care alone. All patients received optimal medical care, including antiplatelet therapy. The risk of ipsilateral stroke was reduced significantly ( $p=0.045$ ) in patients with carotid stenosis of 50-69% who

received carotid endarterectomy. Patients with stenosis of 70-99% showed the most significant reduction ( $p < 0.001$ ) in the rate of ipsilateral stroke while patients with stenosis of  $<50\%$  did not show a significantly lower rate of ipsilateral stroke. NASCET validates the use of carotid endarterectomy in patients with symptomatic carotid artery disease to reduce the risk of stroke.

ACAS<sup>5</sup> was a prospective, randomized, multicenter trial of 1662 patients at 39 centers. The inclusion criteria included asymptomatic carotid artery stenosis of 60% or greater reduction in diameter. Daily aspirin administration and medical risk factor management was required for all patients. Carotid endarterectomy was performed for patients randomized to receive surgery. Aggregate risk for ipsilateral stroke and any perioperative stroke or death was found to be 5.1% for surgical patients and 11.0% for patients treated medically.

ACST<sup>6</sup> was an international, multi-center, prospective, randomized trial involving 3120 patients. Inclusion criteria included patients with unilateral or bilateral carotid stenosis considered appropriate for surgery who have experienced no ipsilateral transient ischemic attack, amaurosis fugax, or stroke within the past 6 months, and who have no history of ipsilateral disabling stroke or severe contralateral stroke. Eligible patients were randomized to receive either best medical therapy or best medical therapy combined with carotid endarterectomy. Comparing all patients randomized to immediate carotid endarterectomy versus all patients randomized to deferral (combining the perioperative events and non-perioperative strokes), the net 5 year stroke risks were 6.4% vs 11.8% for all strokes (net gain 5.4% [3.0-7.8],  $p < 0.0001$ ) and 3.5% vs 6.1% for fatal or disabling strokes (net gain 2.5% [0.8-4.3],  $p < 0.004$ ) and 2.1% vs 4.2% for only fatal strokes (net gain 2.1% [0.6-3.6],  $p=0.006$ ).

ACAS and ACST validate the use of carotid endarterectomy in patients with significant asymptomatic carotid artery disease to reduce their risk of stroke.

SAPPHIRE<sup>7</sup> was a multicenter trial, which randomized 334 high risk patients to receive either carotid endarterectomy or the protec-

tive stenting procedure. The inclusion criteria included patients with symptomatic carotid-artery disease with  $\geq 50\%$  stenosis and patients with asymptomatic carotid-artery disease with  $\geq 80\%$ , determined by color duplex ultrasonography. All patients were required to have at least one co-existing condition that potentially increased the risk posed by carotid endarterectomy (e.g., severe cardiac or pulmonary disease; age  $> 80$ , etc), but were judged potentially suitable for either endarterectomy or stenting. Treatment with aspirin at a dose of 81 or 325 mg per day was begun at least 72 hours before stenting or endarterectomy and was continued indefinitely in both study groups. Both groups received intraprocedural heparin to maintain a therapeutic activated partial-thromboplastin time of 250 to 300 seconds. Patients undergoing stenting received clopidogrel (75 mg per day) starting 24 hours before the procedure and continuing for two to four weeks thereafter. Patients undergoing endarterectomy did not receive clopidogrel. The primary end point (cumulative incidence of a major cardiovascular event at one year: a composite of death, stroke or myocardial infarction within 30 days of intervention or ipsilateral stroke between 31 days and 1 year) occurred in 20 patients randomly assigned to undergo carotid-artery stenting with an emboli-protection device (cumulative incidence, 12.2%) and in 32 patients randomly assigned to undergo carotid endarterectomy (cumulative incidence, 20.1%, absolute difference, 7.9%; 95 percent confidence interval, 16.4 to 0.7 %;  $P=0.004$  for noninferiority, and

$P=0.053$  for superiority). SAPHIRE validates the use of carotid artery stenting instead of carotid endarterectomy in patients who have significant carotid artery disease but are at increased risk for carotid endarterectomy surgery.

CREST<sup>8</sup> was a prospective, randomized, parallel, two-arm, multi-center clinical trial with blinded endpoint evaluation involving 2522 patients. The inclusion criteria included patients who have experienced a transient ischemic attack, amaurosis fugax, or non-disabling stroke within the past 180 days, and who have an ipsilateral carotid stenosis  $\geq 50\%$  by angiography or  $\geq 70\%$  by ultrasound or  $\geq 70\%$  by CTA or MRA are eligible for this study. Asymptomatic patients who have carotid stenosis  $\geq 60\%$  by angiography or  $\geq 70\%$  by ultrasound or  $\geq 80\%$  by CTA or MRA were eligible for this study. (Subjects with symptoms beyond 180 days are considered asymptomatic). Eligible patients were randomized to undergo either carotid artery stenting or carotid artery endarterectomy. All patients received aspirin antiplatelet therapy, treatment for hypertension, and management of other stroke risk factors. The primary composite end point was stroke, myocardial infarction, or death from any cause during the periprocedural period or any ipsilateral stroke within 4 years after randomization. For 2502 patients over a median follow-up period of 2.5 years, there was no significant difference in the estimated 4-year rates of the primary end point between the stenting group and the endarterectomy group (7.2% and 6.8%, respec-

tively; hazard ratio with stenting, 1.11; 95% confidence interval, 0.81 to 1.51;  $P=0.51$ ). See Figure 1. An interesting observation in the CREST trial is that younger patients actually did best with carotid artery stenting (see Figure 2). CREST validates the expanded role of carotid artery stenting as an option to carotid endarterectomy in both symptomatic and asymptomatic patients with carotid artery disease who are not necessarily considered high risk for carotid surgery. Younger patients under the age of 70 may actually fare better with carotid artery stenting.

### INTRODUCTION TO THE CAROTID ARTERY STENTING TECHNIQUE

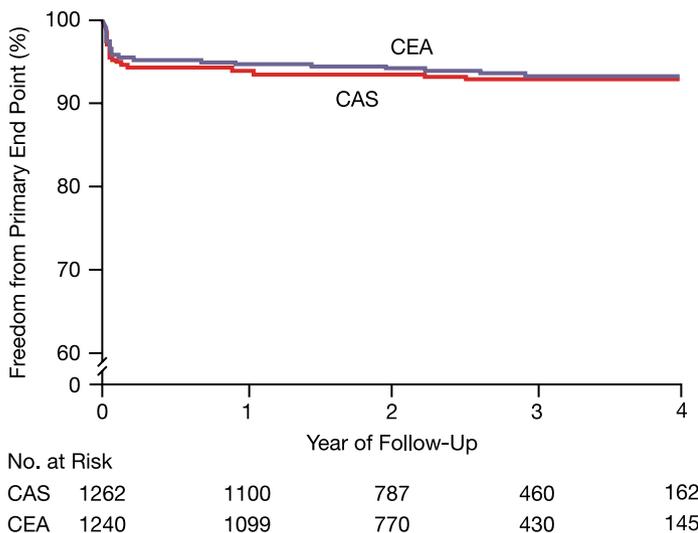
Physicians at the Oklahoma Heart Institute have many years of experience with the technique of carotid artery stenting. By participating in some of the early multicenter registries studying the role of carotid artery stenting in both symptomatic and asymptomatic patients considered high risk for carotid endarterectomy, Oklahoma Heart Institute has contributed to the scientific body of knowledge that exists in this rapidly advancing field of medicine.

The carotid artery stent procedure requires that a small tube be placed in the femoral artery. The size of the tube is the same as the tube that is used during most cardiac catheterizations. Using x-ray guidance the tube is carefully advanced up through the aorta into the carotid artery of interest. Angiograms are per-

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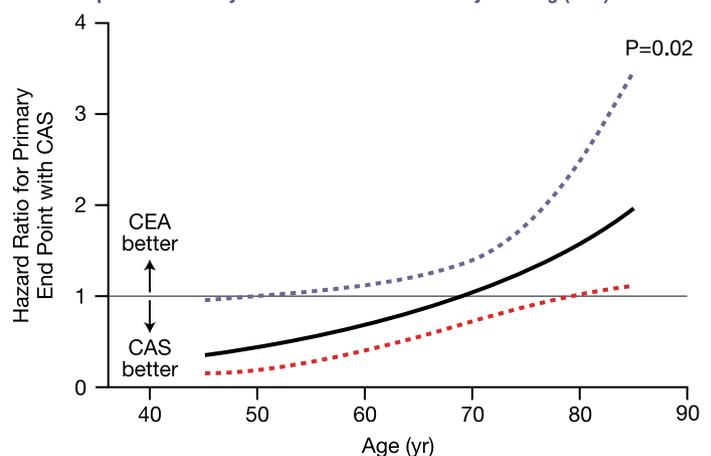
**Figure 1**  
**CREST Trial Results**

There was no significant difference in the primary endpoint of this large randomized study sponsored by the National Institute of Health that compared carotid artery stenting to carotid artery endarterectomy.



**Figure 2**  
**CREST Trial Results**

Retrospective analysis of this large randomized study sponsored by the National Institute of Health that compared carotid artery stenting to carotid artery endarterectomy (CEA) reveals that younger patients actually do better with carotid artery stenting (CAS).



Continued from p. 17

formed by injecting contrast dye through the tube to quantitate the degree of narrowing in the carotid artery. Figure 3 is an example of a carotid angiogram performed in a patient

treated by physicians at Oklahoma Heart Institute for a severe carotid artery stenosis with a carotid artery stent. After performing the angiogram, a thin wire is carefully advanced through the blockage in the carotid artery

Figure 3

### Baseline Carotid Angiogram Revealing Critical Carotid Artery Stenosis in a Patient Referred for Carotid Stenting at the Oklahoma Heart Institute.

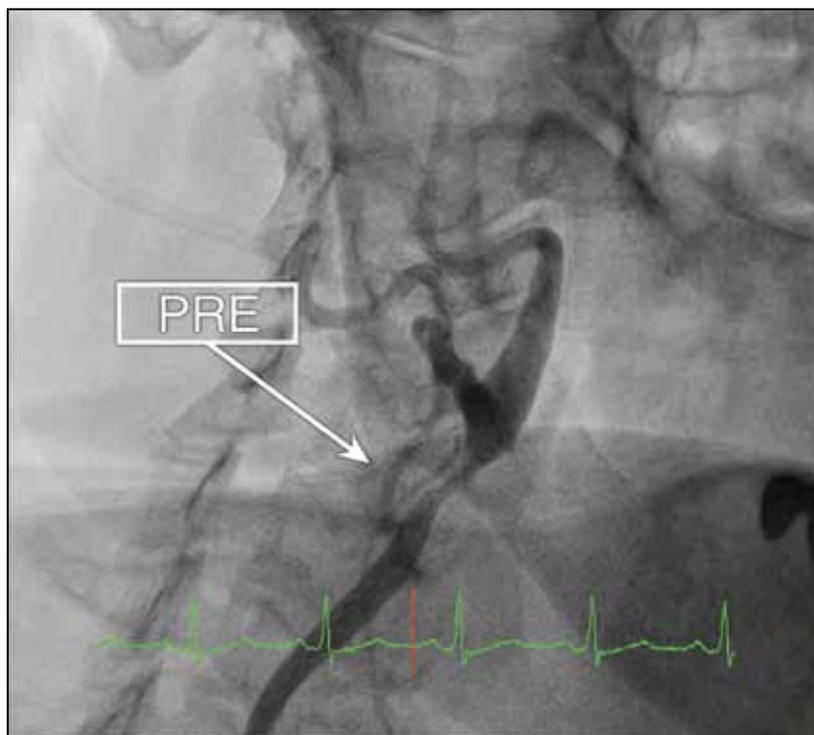


Figure 4

### Final Carotid Angiogram of the Same Carotid Artery After the Patient Was Successfully Treated With a Carotid Stent at the Oklahoma Heart Institute.



and ultimately placed several centimeters above the blockage. The wire is used as a railroad track to take different pieces of equipment in and out of the vessel. Next, a small filter can be deployed past the blockage near the tip of the wire. This filter is called a distal protection device. It is designed to catch any plaque that might break off from the blockage before it travels up to the brain and causes a stroke. After deploying the distal protection device, a balloon tipped catheter is advanced over the wire and inflated to stretch open the blockage in the carotid artery. Then, a mesh tube called a stent is deployed across the blockage to create a scaffold which helps to keep the carotid artery open. After deploying the stent, it is usually fully expanded by inflating a balloon inside of it again. Final angiograms are performed after the distal protection device and the wire are retrieved. Figure 4 demonstrates the final angiogram in the same patient treated with a carotid stent by physicians at the Oklahoma Heart Institute.

### SUMMARY OF THE NEW GUIDELINE RECOMMENDATIONS

Based on the compiled scientific evidence the following recommendations for selection of patients for carotid revascularization have been proposed in the 2011 update on the management of patients with extracranial carotid artery disease.<sup>1</sup> Like other published guidelines, the document states Class I recommendations should be performed, Class IIA recommendations are reasonable to perform, Class IIB recommendations may be reasonable to perform, and Class III recommendations are not beneficial and potentially harmful. The new guidelines for carotid artery revascularization are summarized below and shown in Table 1.

#### Class I

- Symptomatic patients should undergo carotid endarterectomy (CEA) if they are documented to have significant ipsilateral internal carotid artery stenosis (70% by doppler, 50% by angiography) and the anticipated rate of perioperative stroke or mortality is less than 6%.
- Carotid artery stenting (CAS) is indicated as an alternative to CEA for symptomatic patients with significant ipsilateral internal carotid artery stenosis and the anticipated rate of periprocedural stroke or mortality is less than 6%.

#### Class IIA

- It is reasonable to perform CEA in asymptomatic patients who have more than 70% stenosis of the internal carotid artery if the risk of perioperative stroke, MI, and death is low.
- It is reasonable to choose CEA over CAS when revascularization is indicated in older patients, particularly when arterial pathoanatomy is unfavorable for endovascular intervention.
- It is reasonable to choose CAS over CEA when revascularization is indicated in patients with neck anatomy unfavorable for arterial surgery.

Table 1

## Summary of the 2011 Recommendations for Selection of Patients for Carotid Artery Revascularization

<b>Class I</b>	<ul style="list-style-type: none"> <li>Symptomatic patients should undergo carotid endarterectomy (CEA) if they are documented to have significant ipsilateral internal carotid artery stenosis (70% by doppler, 50% by angiography) and the anticipated rate of perioperative stroke or mortality is less than 6%.</li> <li>Carotid artery stenting (CAS) is indicated as an alternative to CEA for symptomatic patients with significant ipsilateral internal carotid artery stenosis and the anticipated rate of periprocedural stroke or mortality is less than 6%.</li> </ul>
<b>Class IIa</b>	<ul style="list-style-type: none"> <li>It is reasonable to perform CEA in asymptomatic patients who have more than 70% stenosis of the internal carotid artery if the risk of perioperative stroke, MI, and death is low.</li> <li>It is reasonable to choose CEA over CAS when revascularization is indicated in older patients, particularly when arterial pathoanatomy is unfavorable for endovascular intervention.</li> <li>It is reasonable to choose CAS over CEA when revascularization is indicated in patients with neck anatomy unfavorable for arterial surgery.</li> </ul>
<b>Class IIb</b>	<ul style="list-style-type: none"> <li>Prophylactic CAS may be considered in selected patients with significant asymptomatic carotid artery stenosis.</li> <li>In symptomatic or asymptomatic patients at high risk of complications for carotid revascularization by either CEA or CAS because of comorbidities, the effectiveness of revascularization versus medical therapy alone is not well established.</li> </ul>
<b>Class III (no benefit)</b>	<ul style="list-style-type: none"> <li>Carotid revascularization by either CEA or CAS is not recommended when atherosclerosis narrows the lumen by less than 50%.</li> <li>Carotid revascularization is not recommended for patients with chronic total occlusions of the targeted carotid artery.</li> <li>Carotid revascularization is not recommended for patients with severe disability caused by cerebral infarction that precludes preservation of useful function.</li> </ul>

### Class IIb

- Prophylactic CAS may be considered in selected patients with significant asymptomatic carotid artery stenosis.
- In symptomatic or asymptomatic patients at high risk of complications for carotid revascularization by either CEA or CAS because of comorbidities, the effectiveness of revascularization versus medical therapy alone is not well established.

### Class III (No Benefit)

- Carotid revascularization by either CEA or CAS is not recommended when atherosclerosis narrows the lumen by less than 50%.
- Carotid revascularization is not recommended for patients with chronic total occlusions of the targeted carotid artery.
- Carotid revascularization is not recommended for patients with severe disability caused by cerebral infarction that precludes preservation of useful function.

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### CONCLUSIONS

Stroke is an important cause of morbidity and mortality. Carotid artery disease is a common cause of ischemic stroke. Carotid endarterectomy surgery has been scientifically proven to reduce the risk of stroke in both symptomatic and asymptomatic patients with significant carotid artery disease. Additionally, years of real-world experience with carotid endarterectomy surgery have established carotid artery revascularization as the standard of care to be offered to patients with significant carotid artery stenosis. More recent studies confirm that carotid artery stenting is a viable, less invasive option to be considered as an alternative to carotid endarterectomy surgery. The recently published 2011 guidelines on the management of patients with extracranial carotid artery disease support broadening the use of carotid artery stenting to treat patients with carotid artery disease and reduce their risk of stroke.

The reader should be advised that, at the time of this publication, Medicare still limits payment for carotid artery stenting only for patients who have symptomatic carotid artery disease and are declared to be high risk for carotid endarterectomy surgery. This limitation in coverage exists despite the fact that the FDA has approved carotid artery stenting for symptomatic and asymptomatic patients who are at low risk for carotid endarterectomy surgery. Representatives from many of the professional societies that have endorsed the 2011 guideline update are actively engaging in dialogues with representatives from Medicare advising them to expand the coverage for carotid artery stenting. Many experts in the field (including this author) are concerned that Medicare's slow response to expand coverage for carotid artery stenting is driven more by the current pressures to contain costs rather than weighing the merits of this innovative medical technology. Fortunately, medical directors at many private insurance companies are quickly responding to this evolving area of medicine by expanding the coverage for carotid artery stenting to a broader patient population. The physicians at Oklahoma Heart Institute will continue to closely follow this exciting area of medicine so we may offer our patients the most progressive treatment options available. ❤️

*Dr. Chandwaney is an interventional cardiologist with expertise in cardiac catheterization, coronary angioplasty and related interventional procedures such as coronary stents, atherectomy, intravascular ultrasound and peripheral vascular interventional procedures. In addition to receiving board certifications in Internal Medicine, Cardiovascular Disease, and Interventional Cardiology by the American Board of Internal Medicine, Dr. Chandwaney has also received board certification in Endovascular Medicine from the American Board of Vascular Medicine.*

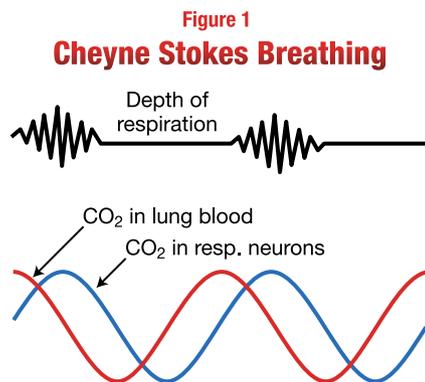


# Treatment of Cheyne-Stokes Breathing with Adaptive Servo Ventilation in Patients with Congestive Heart Failure

By Kevin L. Lewis, MD, FAASM; Oklahoma Heart Institute Sleep Care

## SLEEP DISORDERED BREATHING AND HEART FAILURE

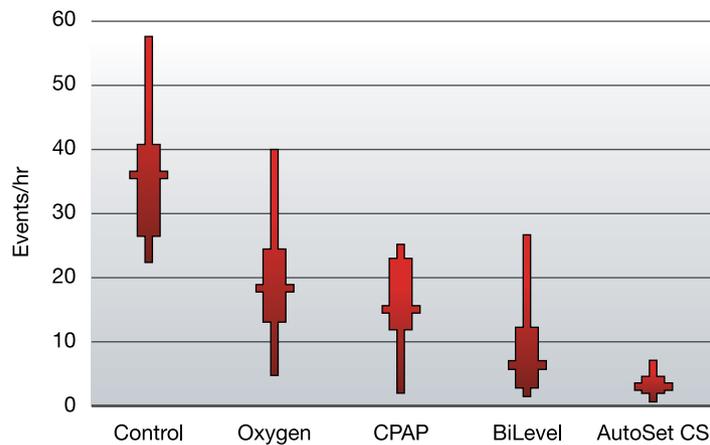
The prevalence of sleep disordered breathing (SDB) in patients with stable heart failure is much higher than that of the general population and rises even higher in patients with decompensated heart failure.<sup>1,2</sup> In fact, somewhere between 50-75% of heart failure patients meet criteria for some form of SDB. The two most common forms of SDB in heart failure are Cheyne-Stokes Breathing (CSB) and Obstructive Sleep Apnea (OSA) with both often present in the same patient. While OSA represents mechanical obstruction of the upper airway during sleep, CSB is a cyclic crescendo-decrescendo respiratory pattern with associated central apneas that are not caused by airway obstruction. The diagnosis of SDB in heart failure is made by attended overnight polysomnography in a sleep laboratory.



## CHEYNE-STOKES BREATHING

In heart failure patients, the presence of CSB is a poor prognostic indicator with worse survival rates than heart failure patients without CSB.<sup>3,4</sup> Risk factors for the development of CSB in heart failure include male gender, advanced age, atrial fibrillation, and resting hypocapnia.<sup>5</sup> The reason CSB develops in heart failure is not entirely understood, but a clue is the finding that patients with CSB have a lower resting  $PCO_2$  (less than or equal to 38mmHg).<sup>6</sup> The possible cause of this could be relative ex-

Figure 2  
Effects of Different Therapies on the Central Apnea Index of Heart Failure Patients



Teschler H, Dohring J, Wang YM, et al. AJRCCM 2001 164(4):614-19

cess ventilation due to resting dyspnea, pulmonary vascular hydrostatic changes, or attempts to improve oxygen delivery during the waking state. Once asleep, central respiratory centers take over the control of breathing where chemosensitivity to  $PCO_2$  is key. Hypothetically, recognition of the relative hypocapnia leads to the initiation of an apnea by the respiratory control center in an attempt to correct. Since circulatory time is increased by heart failure, the duration of the apnea may be prolonged before increasing  $PCO_2$  levels are detected leading to a relative hypercapnia by the time the apnea is terminated. In turn, a robust hyperpneic episode ensues and the cycle repeats itself with oscillating  $PCO_2$  levels leading to the characteristic crescendo-decrescendo breathing pattern in sleep (Figure 1).

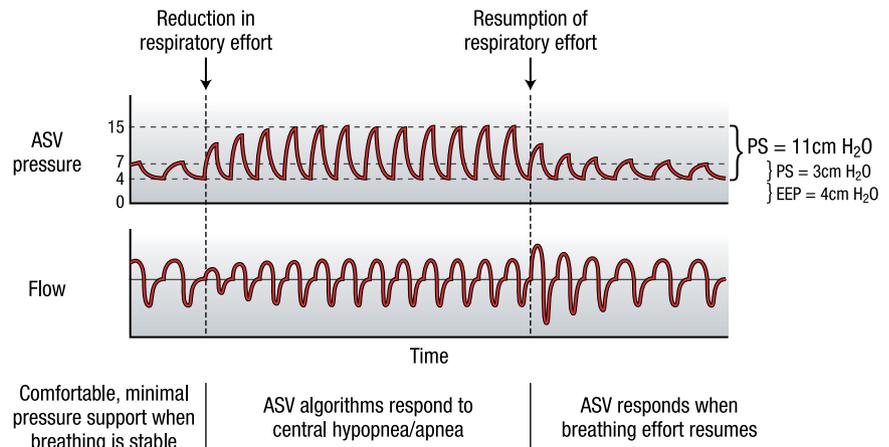
Historically, treatment of CSB has been with continuous positive airway pressure (CPAP) or continuous oxygen therapy during sleep in addition to optimal medical management of heart failure. CPAP usage for CSB has been associated with improved catecholamine levels, left ventricular ejection fraction (LVEF), oxy-hemoglobin saturation, and functional status.<sup>7</sup>

In patients where the apnea index is reduced to below 15 events per hour, there appears to be a transplant free survival benefit.<sup>8,9</sup> Thus, the degree of apnea index reduction has an impact on the degree to which outcomes can be improved in heart failure patients with CSB. To that end, the latest technology for the treatment of CSB known as Adaptive Servo Ventilation (ASV) has a superior ability to reduce the apnea index when compared to previous approaches to treatment<sup>10</sup> (Figure 2).

## ADAPTIVE SERVO VENTILATION

ASV technology provides a varying inspiratory pressure superimposed on a low level of CPAP. The level of CPAP can be adjusted to account for the presence of OSA to adequately treat patients with more complex SDB in heart failure. The additional inspiratory pressure is reciprocal to the amount of the respiratory effort, thereby improving respiratory stability in sleep with more regulated minute ventilation, which ideally leads to the elimination of the oscillatory pattern of CSB (Figure 3). Competing manufacturers have different

**Figure 3**  
**Adaptive Servo Ventilation**



algorithms for how respiratory effort is assessed and how changes in delivered pressure are triggered, but the general concept remains the same.

In addition to medical management, the use of ASV therapy to treat CSB in heart failure leads to improvements in LVEF, brain natriuretic peptide levels, C-reactive protein levels, cardiopulmonary exercise testing, and heart failure decompensation rates. These positive effects occur regardless of the severity of the baseline CSB.<sup>11-14</sup> Virtually all of the analysis for ASV in heart failure has been in systolic failure with considerations for diastolic failure patients anticipated in the near future. Information comparing ASV therapy to CPAP therapy alone is just now emerging with ASV showing superiority to CPAP in patient comfort, therapy compliance, LVEF improvement, and quality of life.<sup>15</sup> To date, large scale, well-done studies assessing the impact of ASV on hospitalization and transplant free survival are lacking.

ASV therapy is three to five times more expensive than basic CPAP therapy, so patients must be carefully selected and managed by practitioners with significant expertise in its use. Most insurance, including CMS, will cover ASV therapy under specific governing policies when central apneas are the predominant feature apparent on overnight polysomnography. The effectiveness of ASV therapy should be documented by overnight analysis in an accredited sleep laboratory with the correct expertise and technology before considering use in the home environment.

## SUMMARY

Heart failure patients have very high rates of SDB frequently in the form of CSB. The presence of CSB in heart failure portends a worse prognosis, so accurate diagnosis and treatment are important. ASV therapy is the most effective available therapy for CSB and is superior to other forms of therapy in several important indicators. The impact of ASV on survival and hospitalization remains to be clarified. Nonetheless, ASV is the treatment of choice for heart failure patients with CSB when accurately diagnosed, appropriately selected, and managed by those with adequate expertise. ❤️

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# Sweet

## ENDINGS

During the holidays, all of us eat too much sugar, which can have an adverse effect on our immune systems. This scrumptious pumpkin pecan cookie will satisfy your sweet tooth without the use of refined sugar. The bonus here is that it contains something most refined desserts do not – nutrients and fiber. So you can have your dessert and eat it too!

How sweet is that?



### Pumpkin Pecan Cookies

Makes about 30 cookies

- 2 cups pecans, toasted and cooled
- 1/2 cup rolled oats
- 1 cup whole wheat pastry flour
- 1 teaspoon baking soda
- 1/2 teaspoon sea salt
- 1 teaspoon ground cinnamon
- 1/4 teaspoon ground cloves
- 3/4 cup puréed pumpkin, or cooked fresh pumpkin
- 1 tablespoon orange zest (from 2 small oranges)
- 3/4 cup freshly squeezed orange juice (from 3 small oranges)
- 2 teaspoons vanilla extract
- 1 cup chopped, pitted dates

Preheat oven to 375 F. Put pecan and oats into a food processor. Pulse until a fine meal forms. Add flour, baking soda, salt, cinnamon, cloves and pulse to combine. Transfer to a large mixing bowl. Add remaining ingredients to the food processor. Blend until a smooth puree forms, scraping as needed. Form a well in the center of the dry ingredients. Scrape the pumpkin mixture into the well and fold all the ingredients together with a spatula. Scoop about 2 tablespoons of batter onto two parchment lined baking sheets, spacing them about 1 1/2 inches apart. Flatten slightly. Bake 20 minutes, until just browned. Cool briefly and serve or store in an airtight container.



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