

# The Journal of: Modern Cardiovascular Medicine

by Westside Regional Medical Center

V2N2

Cox Maze for Atrial Fibrillation

## Modifying the Maze for Optimal Treatment of Atrial Fibrillation

A variation of the Cox Maze procedure at Westside Regional Medical Center offers patients with atrial fibrillation (AF) an alternative to medical management and increases the probability of curing arrhythmia.



Treatment goals for patients with AF include restoring sinus rhythm, controlling heart rate, and preventing blood clots to minimize the risk of stroke. Medical management is the initial step and may include antiarrhythmic drugs, rate control medications, or a combination of the two with warfarin. However, when medical therapy proves

ineffective, or if a patient presents with clotting or stroke, surgical intervention should be considered.

### A Surgical Solution

Patients with medically resistant AF, particularly paroxysmal (intermittent) AF, are increasingly referred to electrophysiologists for percutaneous isolation of the pulmonary veins that trigger arrhythmia.

“In experienced hands, this catheter-based approach works for intermittent AF patients in about 70 percent of cases,” says Harold G. Roberts Jr., M.D., F.A.C.S., cardiac surgeon at Westside Regional Medical Center. “However, at least 30 percent fail, and the treatment doesn’t work well at all for patients with continual AF.”

The Cox Maze, which was considered experimental two decades ago, is now accepted as a mainstream interventional procedure for arrhythmia. The traditional

Maze corrects AF with a series of cuts and sutures within the atrium, but Dr. Roberts offers a variation he refers to as the robotic, endoscopic Cox CryoMaze at Westside Regional.

### Performing the Procedure

Using the robotic da Vinci® S HD Surgical System, Dr. Roberts performs a Cox Maze using cryoablation and closes the left atrial appendage, a primary source for the formation of stroke-inducing clots. Although long-term results are not available for this relatively new version of the procedure, nationally, almost 90 percent of patients who undergo the CryoMaze with closure of the left atrial appendage are cured of AF.

Dr. Roberts reports that 100 percent of patients who have undergone this surgery with robotic assistance at Westside Regional have experienced complete relief of symptoms and are able to discontinue the use of warfarin. Because the largest incision made using the robotic method is only about two-thirds of an inch long, recovery also has been faster for patients.

“I’ve had patients stay as little as two days with no need for blood products, and infection and complication rates have been very low,” Dr. Roberts says. “This modification of the CryoMaze is ideal—especially for younger patients who do not wish to be relegated to a lifetime of warfarin and cardiac medication use.”

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# Treatment Evolution

Updated guidelines for patients with unstable angina (UA)/non-ST-elevation myocardial infarction (NSTEMI) emphasize the importance of risk scores in assessment and treatment.

**Guidelines for the treatment** of patients with UA/NSTEMI created in 2002 by the American College of Cardiology and the American Heart Association were updated in 2007. The guidelines panel—comprised of experts in emergency medicine, family medicine, general internal medicine, interventional cardiology, general and critical care cardiology, and thoracic surgery—reviewed published data from 2002 to 2007 to form recommendations in this latest update.

## Assessing Risk

One major change is the emphasis on risk scores as a part of routine assessment throughout the hospital stay and periodically after discharge. Patients with UA/NSTEMI were delineated into high-, intermediate-, and low-risk categories.

The 2002 guidelines urged invasive techniques for all who presented with UA/NSTEMI. Now, findings show stabilized patients or those considered low-risk see greater benefit from conservative management, including noninvasive stress tests, echocardiograms, and radionuclide angiograms. Clinical studies support the continued use of invasive management techniques for high-risk UA/NSTEMI patients, favoring intervention at shorter intervals than previously recommended.

## Secondary Prevention

Per the 2007 recommendations, statin therapy should be initiated for all patients with definite UA/NSTEMI. Low-density lipoprotein (LDL) cholesterol should be managed at levels well below 100 mg/dL, targeting levels less than 70 mg/dL. The goal for blood pressure is below 140/90 mmHg

for patients unless chronic kidney disease or diabetes is present. The target in these cases should be lower than 130/80 mmHg.

Reflecting data gathered over the last five years, the use of angiotensin converting enzyme (ACE) inhibitors, or angiotensin receptor blockers if patients are ACEI intolerant, is emphasized along with a drug category—aldosterone receptor blockage—for patients with heart failure. However, the position on high-dose antioxidant therapy, including beta carotene, vitamins E and C, and folic acid, has reversed, as clinical trials have shown no benefit and, in some cases, suggest increased potential for harm.

## Five Key Points

The guidelines published online August 6, 2007, in *The Journal of the American College of Cardiology and Circulation* merit further study. Because the options for therapy have changed considerably in the last five years, the new guidelines document may be considered a rewrite.

The following are five key changes in the new guidelines:

- Long-term antiplatelet therapy should be more aggressive, using clopidogrel up to one year with medical therapy and bare-metal stent placement, as well as up to one year after drug-eluting stent placement.
- Cardiologists and primary care physicians should place a greater emphasis on smoking cessation.
- Lipid and blood pressure control should be more intense.
- Hormone therapy should be discontinued in postmenopausal women who experience UA/NSTEMI.
- The use of nonsteroidal anti-inflammatory drugs other than aspirin should cease in patients with acute coronary syndrome.

# Cardiovascular Outcomes Data and Steps Toward Transparency

Reliable data about the costs and quality of medical services must be made available for consumers to make informed choices about their healthcare.

To accomplish disclosure or transparency—the federally mandated initiative to provide broad-scale quality and cost comparisons for medical services—the healthcare industry must develop standardized performance measures and database management systems capable of the required analyses. The order of complexity of modern cardiovascular care and other medical specialties calls for scrupulous examination of clinical factors and data-entry practices capable of skewing the input information and the resulting reports.

## Data In, Data Out

Cardiovascular-related outcomes depend on data from multiple sources, including interventional cardiology, peripheral vascular intervention, electrophysiology, and cardiac surgery. Performance measurements incorporate patient demographics and follow-up as well. The Society of Thoracic Surgeons and the American College of Cardiology have developed separate systems for harvesting data in their respective specialties, each of which must be incorporated in implementation.

The validity of electronic health records as a means of measuring quality care for coronary artery disease was the subject of a study published in 2006 in the *Archives of Internal Medicine* (166:2272–2277). After electronic results were compiled for the research, a review of free-text notes indicated widespread misclassification of data in the electronic records, revealing significant limitations in the use of the currently operating automated systems.

This study cautioned that an electronic system for broad-scope quality assessment of clinical outcomes must first resolve such issues as how to overrule an incorrectly entered diagnosis, how to configure the system to easily standardize data from sources outside the facility, how to reliably capture the reason for a patient's exclusion from treatment, and how to retrieve for analysis all of the factors a physician takes into account when managing a patient's disease.

## Quality of Care

Some clinicians have questioned the effect of national performance measurement on patient care. An essay in

*Annals of Family Medicine* (5:159–163) published in 2007 articulates these concerns by illustrating how patient needs might be underserved in various scenarios: if the tracking of measurements with limited clinical benefit is mandated; if assessments give equal weight to benefits of unequal magnitude by failing to establish value-based priorities; and if physicians conclude they must manage their schedules on the basis of measurable activities.

Such cautions will aid in the design of the transparency-initiative infrastructure, as can adding patient-satisfaction input to technical measurements of care and safety, if assessments take into account that not all aspects of care are evident to patients.

## The Shape of Healthcare to Come

The mandate for accountability—along with the evolution of pay-for-performance as an aspect of providing cost-effective, quality medical services—makes data transparency inevitable. On the National Conference of State Legislatures website ([www.ncsl.org](http://www.ncsl.org)), a chart summarizes signed laws and proposed legislation on healthcare disclosure by state. By December 2007, 15 months after the issuance of the executive order, more than 60 such actions were underway in more than 30 states, and some had already reached the stage of introducing pilot programs and pre-implementation plans.

The benefits of disclosure extend beyond helping consumers make good decisions about their healthcare. The benchmarking that results will provide hospitals with the opportunity and motivation to enact continuous quality improvement programs. In his essay “Consumer-Directed Health Care” in *The New England Journal of Medicine* (Vol. 355, No. 17, October 26, 2006), M. Gregg Bloche, M.D., J.D., points out some concomitant challenges for physicians and hospitals: how to respond to the prospect of multiple levels of care; and how to fulfill the Hippocratic oath to meet needs of patients regardless of their personal financial constraints at a time of escalating healthcare costs.

# Advancements in Coronary Care

Intravascular ultrasound (IVUS) provides real-time views of the interior of the coronary arteries via a catheter that serves as a camera. A recent upgrade to the system now brings more enhancements, including even better image quality, to enhance patient safety and improve outcomes.



Since 2005, Westside Regional Medical Center has used IVUS technology to broaden the spectrum of techniques used to study coronary arteries. As only the third hospital in South Florida to implement IVUS, Westside Regional offers patients advanced technology to enhance safety and care. A combination of cardiac catheterization and ultrasound, IVUS is an invasive procedure that enables physicians to view the interior of the coronary arteries.

IVUS is typically performed during angioplasty and uses echocardiography to display an inside-out, cross-sectional view of the artery walls in real time via a catheter that acts as a camera.

“While angiograms are still useful in cardiovascular care, IVUS takes the technology to the next level,” says Vijay Vakharia, M.D., cardiologist on staff at Westside Regional. “It provides valuable information so we can make better decisions and provide more accurate care for the patient.”

Unlike angiography, which shows only the lumen of the artery, this image displays the distinct layers of the artery, including the adventitia, media, intima, and lumen using Boston Scientific Galaxy2™ technology. Westside Regional will soon be adding Boston Scientific’s iLab® Ultrasound Imaging System to further enhance the resulting images.

With IVUS, the catheter is able to detect where a normal artery wall is interrupted by plaques of fat or cholesterol that may ultimately lead to atherosclerosis. In addition to determining the exact amount of plaque present in an artery, the procedure can also reveal the amount of blood that travels into the vessel. This new

vantage point provides physicians with a tool that surpasses angiography and multi-slice CT scans in terms of the depth of information provided.

IVUS offers several advantages over traditional imaging techniques. The procedure can help determine the specific blood vessels involved in aortic dissection, where a stent should be applied, and the degree to which angioplasty and stenting procedures are effective. It also has been helpful in revealing information about how stents become clogged as well as improper expansion of stents that led to restenosis. This knowledge enables physicians to ensure that stents operate correctly, further enhancing patient safety and improving the accuracy of the procedure.

“The IVUS technology gives us an entirely new avenue of providing optimal care for patients,” says Frederick Chaleff, M.D., cardiologist on staff at Westside Regional. “When questionable issues are encountered with an existing stent or a decision must be made with regard to deploying a stent in a patient with de novo lesions, IVUS is an excellent tool to assess intracoronary disease.”

In March 2008, Westside Regional will upgrade IVUS with the iLab® Ultrasound Imaging System, a technology that improves on the image quality and further enhances interpretation by utilizing color to delineate vessel and lumen borders and better identify soft plaque. The iLab software also enables the physician to graphically compare the actual stent size with the length and diameter of the blocked vessel prior to placement.

# Improving Door-to-Balloon Time

ST-segment elevation myocardial infarctions (STEMI) strike nearly half a million Americans each year. Advanced protocol is in place at Westside Regional Medical Center to expediently treat patients presenting STEMI symptoms and limit damage to the heart.

With STEMI patients, restoring blood flow to the heart quickly is imperative. The longer blood flow to the heart muscle is restricted, the more likely damage to the muscle will occur. Performing percutaneous coronary intervention by using a balloon to reopen a narrowed blood vessel is considered to be the most effective method of reperfusion.

To ensure quality STEMI treatment in the most expedient manner possible, Westside Regional Medical Center follows the D2B protocol emphasized by the American College of Cardiology. Protocol implementations include:

- Emergency Department physician activation of the catheterization lab through a “blast page”
- Employment of the catheterization lab team within 20 to 30 minutes of page
- Prompt data feedback in the form of peer review of each fall out
- Strong senior management commitment and a team-based approach

“Heart attacks are caused by interrupted blood flow to the cardiac muscle, and for a patient having a heart attack, ‘time is muscle,’” says Robert Singal, M.D., F.A.C.C., Director of Westside Regional Cardiac Catheterization Lab. “The ultimate outcome of a heart attack is in large part determined by how quickly a patient is seen and treated from the initial onset of symptoms.”

An increased emphasis has been placed in recent years on reducing “door-to-balloon” times, which refers to the interval between a patient’s arrival at the

hospital and commencement of treatment to restore blood flow to the heart muscle. The American College of Cardiology and the American Heart Association recommend that treatment begin within 90 minutes of first medical contact with the patient.

While a high correlation exists between door-to-balloon time and patient survival of the STEMI, fewer than 40 percent of hospitals within the United States meet recommended guidelines for treatment. Patients who do not receive treatment within the 90-minute “golden hour” tend to have reduced cardiac pumping function and more scarring.

## Above the Standard

Through a comprehensive hospital initiative regarding STEMI treatment, Westside Regional maintains a door-to-balloon time performance far exceeding the national recommendation.

“Hospital-wide, the entire team is committed to ensuring patients get to the catheterization lab in the shortest time possible,” says Debra Brindley, Chief Nursing Officer at Westside Regional. “Our door-to-balloon average is less than 60 minutes. In the third quarter of 2007, our results were even better, with an average of 57 minutes.”

Westside Regional’s efficiency in treating patients presenting with STEMI symptoms can be attributed to having a specific protocol in place.

“We have protocols in place for patients presenting with chest pain, which allow for rapid diagnosis and treatment, saving valuable time in the first crucial moments of presentation,” says Dr. Singal. “The Westside Regional emergency physicians, their staffs, and the cardiac catheterization lab staff are among the best-trained in the nation. We consistently go beyond the current national recommendations for the treatment of heart attacks.”

# Women and Cardiovascular Health

Gender differences exist in heart failure (HF) patients with impaired left ventricular ejection fraction (LVEF). Early percutaneous coronary intervention (PCI) is called for to improve long-term outcomes in women with non-ST-elevation acute coronary artery syndromes (NSTACS).

Significant progress has been made toward increasing awareness of the risks posed by coronary artery disease (CAD), which remains the leading cause of morbidity and mortality in this country. Yet the advances in cardiovascular medicine that have led to dramatic declines in fatality rates for men with CAD have not been equaled in female populations. In actuality, recent data analysis by the Centers for Disease Control and Prevention in conjunction with Britain's University of Liverpool identified a statistically significant increase in CAD fatality rates in U.S. women in the 35 to 44 age group, in contrast to relatively stable rates for men in that age group. Also significantly, this age group had been considered less at risk than the 45-and-older cohort that includes higher-risk postmenopausal women. Theorized to be associated with the upward trend in obesity and other lifestyle-linked risk factors in younger populations, this finding broadens the population of women projected to meet the algorithms in the new "non-male" paradigm for patients presenting with CAD.

## Women and Heart Disease

Women have tended to be underrepresented in cardiovascular clinical trials. For that reason, the Beta-Blocker Evaluation of Survival Trial (BEST), published in *The Journal of the American College of Cardiology* (Vol. 42, No. 12, 2003), puts a high emphasis on including women in clinical findings. This landmark study—stratified by ethnicity, gender, etiology, and LVEF—utilized patients suffering from class III or class IV heart failure (HF) as defined by the New York Heart Association (NYHA). The large number of women enrolled in the study (593 of the total 2,708) and the methodology selected by the research team provided an opportunity to delineate gender

differences in the presence of ischemic etiology, defined as documented CAD or prior myocardial infarction (MI).

Participants were divided into two groups: one given the beta blocker bucindolol and the other a placebo. The study aimed to identify: 1) all-cause mortality; 2) cardiovascular mortality; 3) all-cause and HF hospitalization; 4) the combination of death and heart transplantation; and 5) LVEF at 3 and 12 months. The bucindolol had no impact on the overall crude mortality rate of patients, and the women showed a slightly lower mortality rate of 27 percent versus the mortality rate in men of 33 percent.

Baseline characteristics included age differences (the women studied tended to be older than their male counterparts). More women in the study were African-American. More women had a higher right ventricular ejection fraction (RVEF). The women in the study tended toward higher heart rates but lower blood pressure. Women with late menopause were found to have lower LVEF, a factor not found in women with earlier menopause. In women, univariates included a history of diabetes and systolic high blood pressure, while ethnicity, treatment, and QRS duration were not found to be univariate factors.

Results showed significant differences between survival rates for men and women with CAD, and inverse trends were linked to etiology. Men in the ischemic group and women in the nonischemic group showed higher survival trends.

The BEST study researchers acknowledged limitations of the study size and other factors not measured such as gender-related differences in socioeconomic status and use of beta-blockers. Nonetheless, the identification of major baseline and prognostic-indicator differences between men and women with CAD highlighted the need to change

study criteria and design as well as enroll more women in trials for HF.

Recent years have seen an increase in gender-specific cardiovascular research, which has generated a larger body of evidence of the efficacy of contemporary imaging approaches and interventions in women with CAD. Another landmark study, the Women's Ischemia Syndrome Evaluation (WISE), sponsored by the National Institutes of Health and National Heart, Lung, and Blood Institute and published in *The Journal of the American College of Cardiology* in 2006, identified gender-based pathophysiology in atherosclerotic plaque deposition, metabolic alterations, vascular wall, and functional expression on worsening outcomes.

### Benefits of PCI for Women with CAD

In response to earlier research indicating that women had less to gain than men from early invasive treatment for CAD, researchers from Germany, Switzerland, and Cleveland, Ohio, set out to investigate whether a strategy of early revascularization with coronary stenting might prove equally effective in men and women. Their resulting study, published in *The Journal of the American College of Cardiology* (Vol. 40, No. 2, 2002), followed 1,446 patients (1,033 male and 413 female) admitted for NSTACS who received very aggressive (within 24 hours) revascularization of the culprit lesion. Angiography followed by coronary stenting was performed immediately on patients with persistent chest pain and within 24 hours of admission on patients asymptomatic while on medical therapy. Stenting extended to patients with three-vessel disease if the target lesion could be accessed. Patients needing revascularization who were not good candidates for PCI were scheduled for coronary artery bypass grafting (CABG). Participants were evaluated six months after admission. Follow-up surveys were sent roughly five years after the study ended to determine long-term outcomes.

Baseline characteristics differed on the basis of gender. The women were older and had fewer occurrences of a prior MI or CABG. More women had hypertension, while more men were smokers. For all patients, more than half received PCI and stenting followed 80 percent of the time. The PCI:CABG ratio for men was 4:1 and for women was 5:1.

The results indicated a significantly lower risk of death or MI for women (7 percent) than for men (10.5 percent) undergoing this treatment. In contrast to the Fragmin and fast Revascularization during InStability in Coronary Artery Disease (FRISC) II study, female gender reduced risk of death or MI by nearly 50 percent in multivariate analysis of PCI-based early revascularization. These findings are consistent with those of TACTICS—Thrombolysis In Myocardial Infarction (TIMI) and other research.

Researchers concluded that women benefit more than men from early PCI response to NSTACS, possibly due to their forming fewer coronary collaterals than men, therefore allowing them to benefit from rapid correction of the epicardial obstruction.

### The Impact of a Low-Risk Lifestyle

Coronary artery disease (CAD) remains the leading cause of death in the United States. While beneficial, pharmacological solutions designed to lower blood lipid levels and hypertension, as well as advanced treatments for myocardial infarction (MI), are expensive and often cause side effects in contrast to diet and lifestyle factors under patient control that can positively impact CAD.

The landmark nurses' study published in *The New England Journal of Medicine* (July 6, 2000) tracked 84,129 female nurses who were free of cardiovascular disease, cancer, and diabetes at baseline in 1980 for 14 years to document major coronary events and assess the effect of adherence to a low-risk lifestyle pattern. Participants considered at low risk for CAD did not smoke, had a body mass index of less than 25, drank half of an alcoholic beverage daily at most, and participated in at least 30 minutes of physical activity per day. Overall, about 3 percent of the population met these low-risk criteria. Criteria were relaxed to include 10 percent of the population, and participants who exercised at least 15 minutes daily, consumed more than 2 g of alcohol daily, and had a BMI of less than 28 also reported a relatively low risk.

During the course of the study, participants experienced 1,128 major coronary events, including 296 deaths from CAD and 932 non-fatal infarctions. Eighty-two percent of the coronary events could be attributed to lack of adherence to the low-risk pattern.

Risk factors including BMI and consumption of alcohol were evaluated on a gradient. For example, those who had once smoked but stopped were at a slightly higher risk than participants who never smoked. The alcohol consumption gradient placed those who consumed 5 g of alcohol at lower risk than those who consumed more than that amount.

Cigarette smoking was found to greatly raise risk. Smoking as few as one cigarette daily significantly raised the participants' risk of developing CAD. More than 40 percent of the coronary events in the participant group could be linked to smoking.

Although several correlations were found, each risk factor contributed significantly to outcome. Overall, the study found that, for women, adherence to a healthful diet, abstinence from smoking, and regular exercise are associated with a significantly lowered risk of developing CAD.

# Advanced Cardiac Imaging Capabilities

Westside Regional Medical Center's new magnetic resonance imaging (MRI) equipment produces advanced cardiac images.

Westside Regional installed a new GE Signa® HDx 1.5T MRI, one of the most advanced imaging technologies available, last October. The first GE 16 Channel MRI installed in Broward and Dade counties, the high definition equipment is capable of generating images with enhanced clarity and contrast for all cardiac and vascular imaging needs.

## Clear Cardiac Images

Traditional imaging modalities require a breath hold to obtain an accurate image of the heart. This can prove a challenge if the patient is weak or critically ill. The new MRI equipment at Westside Regional features GE's HD MR Echo, which produces real-time images without breath holding or electrocardiogram (ECG) gating. It combines the benefits of both MRI and echocardiography technology, resulting in images with the detail of MRI and the real-time efficiency of echocardiography.

The new MRI also features IDEAL, a program designed to optimize consistent fat suppression, especially in challenging patients. This makes one scan result in four images: fat only, water only, in-phase, and out-of-phase. Motion-correction sequences further enable the MRI to be used, even with a patient who would otherwise not be a good candidate for scanning due to medical condition or physical attributes.

## Improved Vascular Capabilities

For vascular studies, the new MRI features GE

TRICKS software that collects more than 12 times the data traditionally acquired by gathering two 3-D volumes simultaneously. This provides high-resolution detail down to the smallest vessels in the foot without the problem of inaccurate bolus timing. The equipment allows the radiologist to inject and scan with complete separation of arterial and venous phases.

Other cardiac and vascular capabilities include diagnosing intracardiac masses, valve function, wall motion studies, coronary imaging, and perfusion studies.

## Report Card

In addition to the advanced scanning capabilities, the new GE MRI also features a detailed reporting analysis program for all images. GE's Report Card quantifies MR cardiac images with in-depth reports of cardiac anatomy and pathology, including images, charts, and listings of relevant information. This unique reporting feature makes results and details readily available to physicians for diagnostic work-ups.

"This advanced MRI technology further enhances our hospital-wide cardiology program," says Evelio Alvarez, M.D., Medical Director of the Radiology Department at Westside Regional. "The MRI reduces the scan time while increasing the quality of the image, providing an excellent diagnostic tool for our physicians. It features software for 16 future channel upgrades and coils, meaning this equipment can remain on the leading edge of technology for years to come."



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