

Innovations in Cardiovascular Care



I HOPE YOU ENJOYED the first edition of *The Sanger Report*, in which the current clinical research, heart failure and acute myocardial infarction (Code STEMI) programs at Sanger Heart & Vascular

Institute (SHVI) were highlighted.

In this issue, several other innovative programs are discussed. Rohit Mehta, MD, from our electrophysiology and rhythm management group, reports on Initiative 32. The number 32 refers to the fact that every day in North Carolina, there are 32 deaths from sudden cardiac arrest. This translates into 980 North Carolinian deaths a month or 11,765 a year. These are alarming numbers. They are even more alarming when we consider that sudden cardiac death is largely preventable. Device therapies are a recognized standard of care for appropriately selected patients. Dr. Mehta provides some background information regarding implantable cardioverter defibrillator (ICD) therapy. Our hope is that you will become acquainted with ICD therapy and help us improve the quality of care for at-risk patients by implementing screening guidelines and insuring that these patients are appropriately evaluated.

Additionally, the treatment of atherosclerotic renal artery stenosis (ARAS) is discussed. ARAS is a relatively under-recognized condition that can be associated with refractory hypertension and progressive renal dysfunction. Michael Rinaldi, MD, a member of our cardiac intervention and peripheral vascular medicine departments,

offers information about the ASTRAL trial, which compared the efficacy of renal artery stenting to medical management. The current literature is summarized and recommendations are made regarding the treatment of patients who have ARAS.

Kevin Lobdell, MD, director of quality and associate program director, recounts the process improvement program initiated at SHVI in 2004. He explains how our efforts to extubate patients less than six hours after surgery were associated with reduced cardiac morbidity and mortality. This quality improvement program has reduced the risk of patient mortality by 40 percent while also reducing the risk of major complications. These process improvement programs have been initiated at both Carolinas Medical Center (CMC) and CMC-Mercy. Our cardiothoracic surgical program and its physicians are available at both hospitals—we now have one program with two locations in Charlotte.

We hope you will enjoy this edition of *The Sanger Report* as much as the first. Look for future editions that will highlight our pediatric and congenital heart program, as well as our cardiothoracic surgery and peripheral vascular surgery departments.

Sincerely,

Paul G. Colavita, MD, FACC
President
Sanger Heart & Vascular Institute

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PATIENT SUPPORT PROGRAMS

- ▶ Heart of a Woman Support Group
www.heartofawoman.org
- ▶ ICD (Implantable Cardioverter Defibrillator) Support Groups
www.sangerheart.org/support.php
- ▶ Levine Children's Hospital's Cardiac Kids
www.levinecardiackids.com
- ▶ Dare to C.A.R.E. Carolinas
www.daretocarecarolinas.org



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Quality Improvement Program

REDUCING MORTALITY AND MORBIDITY WHILE INCREASING THE RATE OF EARLY EXTUBATION

Kevin Lobdell, MD

Director of Quality and Associate Program Director, Sanger Heart & Vascular Institute

QUALITY IMPROVEMENT IS A

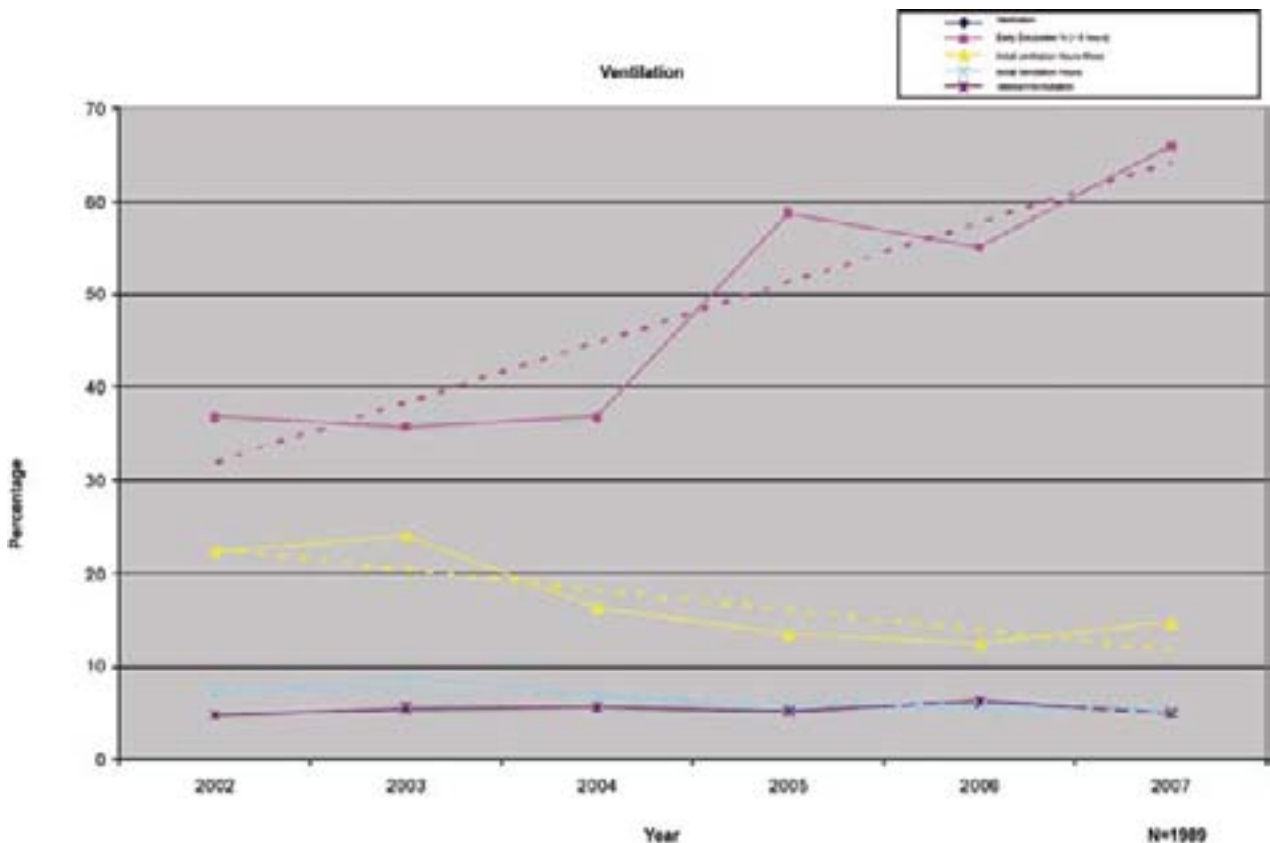
pragmatic science with a detailed history in manufacturing. Vital components of quality include efficiency, efficacy, effectiveness, optimality, acceptability, legitimacy and equity. A quality cycle includes data acquisition, pattern analysis, interpretation, prioritization, change in action and repetition with further data acquisition on subsequent performances. The quality improvement program (QIP) at Sanger Heart & Vascular Institute began in 2004 to improve cardiac surgery outcomes. Stimuli for change included increasing acuity, aging patient populations and declining procedure volumes, as well

as pay-for-quality and value-based competition.

A UNIFYING FACTOR

Early tracheal extubation (less than six hours) in the cardiovascular intensive care unit (ICU) was utilized as a multidisciplinary driver for the QIP.¹ Our team believed that early extubation could unify the efforts of a complex system and serve as a key performance indicator, since factors contributing to successful early extubation span the preoperative, intraoperative and post-operative periods, as well as the disciplines (surgery, anesthesia, critical care, nursing, respiratory therapy, administration, etc.). We envisioned early extubation to be a

leading indicator of early and late outcomes. Supportive educational efforts included principles of change, trust, competing values, crew resource management, evidence-based medicine and quality improvement. We used metrics and guidelines from the National Quality Forum and Society of Thoracic Surgeons' National STS Database to create our QIP. Evidence-based management protocols and guidelines included communication tools (standardized hand-off and goal sheets), sedation monitoring, respiratory protocols for early extubation and best pulmonary practices bundles, computerized euglycemia management, blood management and infection-control programs.²



Our early extubation efforts have resulted in a marked increase in the rates of early extubation in our coronary artery bypass, valve and coronary artery bypass+valve patients.

Multidisciplinary ICU rounds were a part of the QIP and included a nurse, a charge nurse, a nurse practitioner, a respiratory therapist, a pharmacist, a cardiac intensivist and the cardiothoracic surgeons and residents.³

PROMISING RESULTS

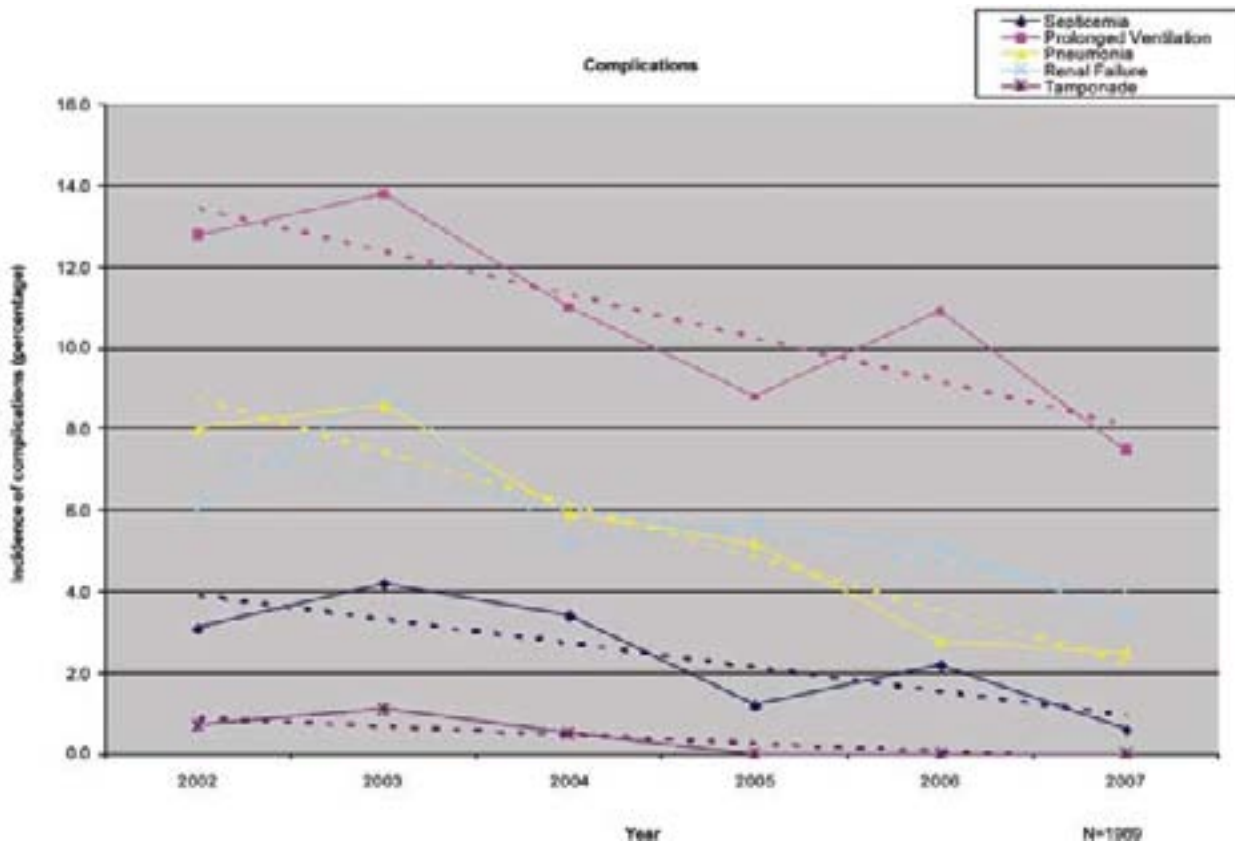
Our early extubation efforts have resulted in a marked increase in the rates of early extubation in our coronary artery bypass, valve and coronary artery bypass+valve patients. In fact, while the national average is about 35 percent, we have consistently extubated more than 65 percent of these patients in less than six hours (and for a number of months

have exceeded 80 percent) in the last few years. We've determined that early extubation correlates with improved outcomes through lower rates of pneumonia, sepsis, reintubation and ICU readmission.^{1,4} We have also correlated our improvement in early extubation with shorter ICU and hospital lengths of stay. Our QIP has reduced the risk of mortality by 40 percent while also reducing the risk of major complications.^{5,6}

In summary, we have used clinical teamwork, resources and analytic capabilities to improve patient care and operational efficiencies through our QIP. We're committed to providing excellence in patient care and improving continuously. ■

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It's Time for Some Common Sense in the Treatment of Renal Artery Stenosis

Michael J. Rinaldi, MD, FACC, FSCAI

Medical Director, Clinical Research, Sanger Heart & Vascular Institute

Q: IS ATHEROSCLEROTIC RENAL ARTERY STENOSIS A REAL PROBLEM?

▶ **A:** Atherosclerotic renal artery stenosis (ARAS) is relatively common, with a prevalence of up to 7 percent in some populations. The presence of ARAS doubles the risk of cardiovascular events at five years. ARAS has been associated with refractory hypertension, progressive renal dysfunction and acute pulmonary edema. Yet, despite the associations, causality has been difficult to prove.

Q: DOES TREATMENT OF ARAS IMPROVE OUTCOMES?

▶ **A:** Medical therapy with aggressive risk factor modification, especially with statins, clearly improves outcomes. Despite classic teaching, ACE inhibitors can benefit patients with ARAS if monitored closely. The benefits of revascularization with stenting remain controversial.

Anecdotal evidence for benefit in hypertension abounds. Numerous registries of renal artery stenting show substantial benefits for both hypertension and renal function in patients with chronic kidney disease. The 208-patient ASPIRE 2 registry demonstrated a 19 mm Hg reduction in systolic blood pressure at two years. Unfortunately, only half of the patients

treated showed a significant response.

The evidence for stabilization of renal function is less encouraging. While early studies suggested benefit, these registries lacked a control arm. It has been shown that stenting can lead to plaque microembolization and renal injury. A more contemporary and sobering study looking at renal artery stenting in patients with chronic kidney disease (CKD) using state-of-the-art techniques showed worsening of glomerular filtration rate at one month in virtually all patients.

Q: ARE THERE ANY RANDOMIZED TRIALS OF RENAL ARTERY STENTING TO GUIDE US?

▶ **A:** The ASTRAL trial results, published in 2009, have further thrown the field into turmoil. This study randomized 806 patients with ARAS and hypertension or CKD to best medical therapy with or without stenting. At three years, there was no difference in either hypertension control or renal function.

Q: IS THE ASTRAL TRIAL THE FINAL WORD ON RENAL ARTERY STENTING?

▶ **A:** No. The trial had serious methodological flaws, which limit its applicability. First, 40 percent of patients had less than 70 percent stenosis and therefore non-critical disease. Second, only visual estimates of stenosis were used, and visual estimates routinely overestimate severity. Third, and most important, the study design only allowed randomization if there was "uncertainty that the patient would definitely have a clinical benefit." Patients most likely to benefit were excluded. What this study really showed was that patients with ARAS and weak indications for

intervention don't benefit from therapy.

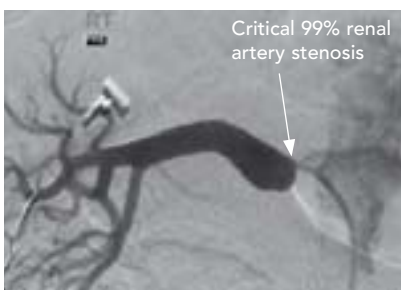
We now can only wait for the results of the NIH-sponsored CORAL trial, which will likely become available in 2013.

Q: WHAT IS THE ROLE OF RENAL ARTERY STENTING IN 2010?

▶ **A:** Clearly, there are patients who may benefit from renal artery stenting. Results from the ASTRAL trial helped to temper the exuberance of the stenting zealots. Screening for ARAS should be reserved for patients with recent worsening of hypertension refractory to aggressive medical therapy (four drugs). For progressive CKD, treatment should be limited to critical disease in a sole remaining kidney or to bilateral disease. Even these indications are less than certain. Patients with recurrent unexplained pulmonary edema are likely worth screening.

CONCLUSIONS

Renal artery stenting still has a place in clinical management of patients who have ARAS. I recommend screening patients, but only if treatment may be beneficial. Duplex ultrasound is the best screening tool as it is inexpensive and without risk. Variability in quality often limits its use to higher volume centers. Sanger Heart & Vascular Institute's accredited vascular laboratory has a rigorous quality improvement program in place that provides useful data. CT and MR angiography are limited and expose patients with already tenuous renal function to the risk of complications associated with contrast administration. Who should treat this disease? As with all invasive procedures, high-volume operators and institutions generally have the best outcomes. ■





Initiative 32

PREVENTING SUDDEN CARDIAC DEATH IN OUR COMMUNITY

Rohit Mehta, MD, FACC
Cardiac Electrophysiologist



EVERY DAY IN NORTH CAROLINA, 32 people die of sudden cardiac death (SCD). Nationally, 325,000 people each year suffer the same fate, with 95 percent of these patients dying prior to receiving medical care. This amounts to one person every two minutes.

While the majority of patients with sudden cardiac death die in the setting of normal heart function, prospective identification of high-risk features is paramount to the prevention of this lethal occurrence. The single most identifiable high-risk feature is the presence of cardiomyopathy—either ischemic or non-ischemic—with a left ventricular ejection fraction of less than 35 percent. Hence the development of Initiative 32.

MORTALITY DATA

Data from the Multicenter Automatic Defibrillator Implantation Trial (MADIT I, II and MADIT CRT) corroborate the concept of SCD prevention. As a **Class I** indication under the **American College of Cardiology's national guidelines**, implantable cardioverter defibrillator (ICD) therapy is the standard of care in patients receiving optimal medical therapy (maximally tolerated doses of beta-blockers and angiotensin inhibitors), with under-

lying **ischemic cardiomyopathy** and a left ventricular ejection fraction of less than 30 percent, with no clinical symptoms of congestive heart failure (CHF).¹

In patients who have **non-ischemic cardiomyopathy**, the presence of co-existent heart failure, New York Heart Association (NYHA) Classes II or III, suggests a high-risk feature. In patients on optimal medical therapy, the presence of CHF highlights patients who would benefit substantially from ICD implantation.¹ Patients who have systolic CHF with an underlying conduction system disease in the form of a left bundle branch block benefit from cardiac resynchronization therapy with the additional placement of a left ventricular lead through the coronary sinus, and as a result of left ventricular pacing. Biventricular pacing in this capacity has been shown to reduce mortality, improve symptoms and reduce hospitalization from CHF, independent of the presence or absence of a defibrillator component to the device.^{1,2}

Nationally, significant disparities exist within candidate populations, and data from the American Heart Association's Get With The Guidelines program suggest that only 75 percent of all African-American men who are candidates receive

this life-prolonging therapy.³ Fifty percent of all eligible women, independent of race, receive ICDs.³ Across all demographic patterns, only 30 percent of all eligible patients are referred to appropriate heart rhythm specialists for a discussion about ICD therapy.³

PREVENTION

The core concept behind ICD therapy for CHF revolves around risk stratification for SCD. Other high-risk subsets include patients with hypertrophic cardiomyopathy, long-QT syndromes (both congenital and acquired) and many other familial SCD syndromes. Out-of-hospital cardiac arrest or SCD is often the first manifestation of these disorders. In this setting, counseling and screening of all immediate family members becomes imperative as a preventive strategy.

SCD remains a therapeutic challenge, which is best handled in a preventive fashion. While not every patient is a candidate, every eligible patient deserves a conversation regarding the appropriateness of this therapy in the context of his or her life. After all, we often don't get a second chance to prevent sudden death. ■

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► **SCD remains a therapeutic challenge, which is best handled in a preventive fashion. While not every patient is a candidate, every eligible patient deserves a conversation regarding the appropriateness of this therapy in the context of his or her life. After all, we often don't get a second chance to prevent sudden death.**

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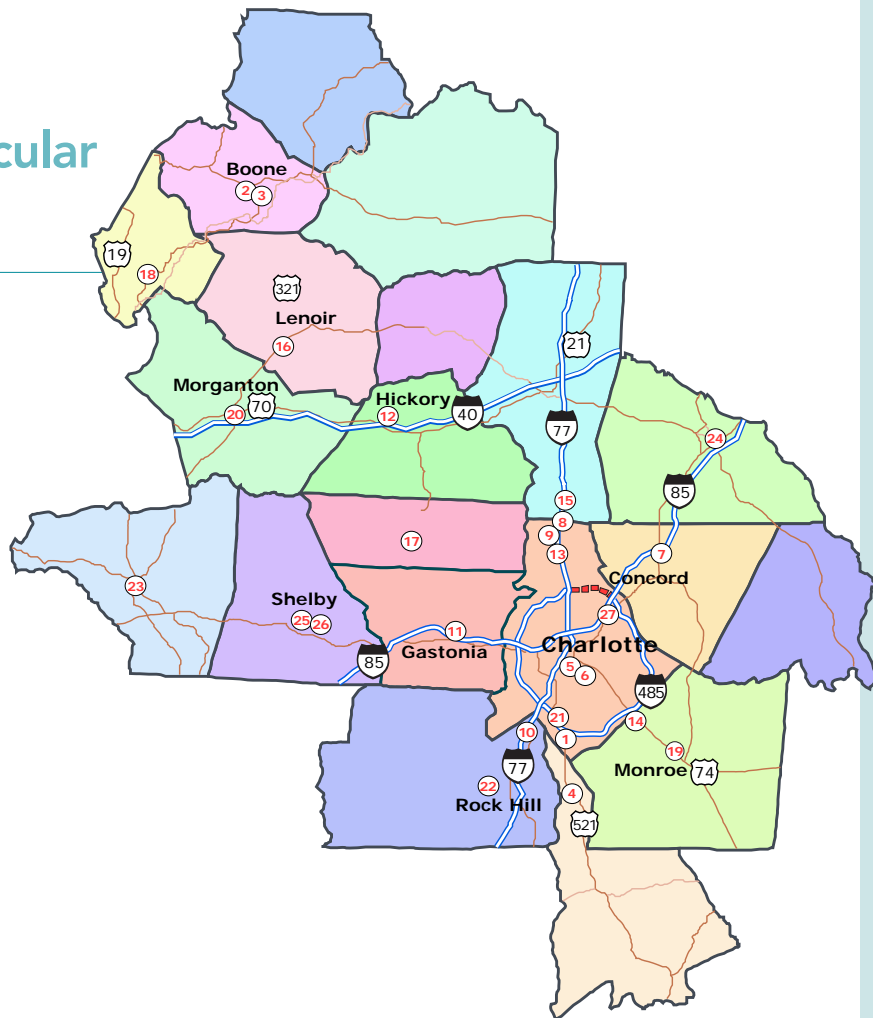
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EP and Device Therapy for Allied Professionals

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Cardiac Electrophysiologist

SANGER HEART & VASCULAR INSTITUTE (SHVI) was proud to be the site of the most well-attended and successful Heart Rhythm Society (HRS) regional CME program to date. On March 20, SHVI, in partnership with HRS, hosted a symposium dedicated to allied health professionals who are interested in the management of heart rhythm disorders.

More than 100 participants from the Southeast region and beyond (see map) attended "EP and Device Therapy for Allied Professionals: Applying Knowledge to Clinical Practice." Course director Robin Leahy, RN, BSN, CCDS, along with HRS co-directors Aileen Ferrick, ACNP-C,

FHRS, and Heather Ross, MS, ANP-BC, CEPS, CCDS, brought in a diverse array of faculty including Joe Rybicki, CRNA, MSN (Duke University); Kam Benfield, PA (Wake Forest Baptist); and Judy Walling, RN, MSN, FNP-BC (Medical University of South Carolina), as well as SHVI's own Nancy Lee, RN, BSN, CEPS, CCDS; Jennifer Houff, RN, BS, CCDS; Diane Thomas, RN, CEPS; Bob Turner, RCP, RCIS; Jill Brust, RN; Amanda Sowell, RN, BSN, CCDS; Beth Davenport, RN, BA, CCDS; Terri Cooper, RN, CCDS; and Rohit Mehta, MD, FACC.

The speakers offered a glimpse at new developments in leading-edge electrophysiology, including advancements in device therapy, arrhythmia mapping and advanced patient care. Topics ranged from the role of perioperative anesthesia in the electrophysiology laboratory and device management to the implications of remote monitoring. Additionally, the role of allied health professionals in the development and management of an atrial fibrillation program was discussed. Attendees also participated in hands-on sessions covering advanced lab techniques. ■



Diane Thomas, RN, CEPS, teaches attendees about 3-D mapping during one of the hands-on sessions.

