

Initiative 32

You may have heard about a new statewide initiative called “32” that is getting off the ground. The initiative’s name refers to the sobering fact that **every day in North Carolina, there are “32” deaths from sudden cardiac arrest.** This translates into 980 North Carolinians a month and 11,765 a year (1). In the United States, sudden cardiac death is the leading cause of death, with an estimated 300,000 deaths each year.

I’m sure you agree that these are alarming numbers for our state. They are even more alarming when we consider that SCD is largely preventable. I feel strongly that the issue is not that North Carolina simply has more patients at risk (our prevalence is above the national average), but that there is more that we can do as far as screening patients and recommending appropriate therapy.

As my professional colleagues, **I would like to enlist your help in increasing awareness of the seriousness of SCD in our state — and in promoting solutions to help reduce deaths.** In particular, I feel that implantable cardioverter defibrillator (ICD) therapy is a life-saving technology that the North Carolina cardiology community has not embraced to its full potential.

Device therapy is a recognized standard of care for appropriately selected patients. In my electrophysiology practice, I have seen numerous patients who have benefited from an ICD — and survived an episode of sudden cardiac arrest.

In this letter, I’d like to summarize some background information about ICD therapy. **My hope is that you will take this opportunity to become acquainted with ICD therapy. Help us improve quality of care by implementing screening guidelines and ensuring that at-risk patients are appropriately evaluated.**

Some facts about SCD and ICD therapy

- Recent scientific research shows that a reduced EF (usually less than 35%) is the single most important risk factor for sudden cardiac death.
- Only one person in 20 usually survives an episode of sudden cardiac arrest. The other 19 die before reaching the hospital (2).
- In contrast, with an ICD, 19 out of 20 people will survive. ICD’s have been shown to effectively terminate the vast majority of lethal arrhythmias(3).
- According to the Heart Rhythm Society, ICDs are 99 percent effective in stopping life-threatening arrhythmias and are the most successful therapy to treat ventricular fibrillation, the major cause of sudden cardiac arrest (4).
- However, only 35 percent of patients who could be helped by an ICD have one. ICDs continuously monitor the heart rhythm, automatically function as pacemakers for heart rates that are too slow, and deliver life-saving shocks if a dangerously fast heart rhythm is detected.
- Between 70 and 89 percent of sudden cardiac deaths occur in men, and the annual incidence is three to four times higher in men than in women. However, this disparity decreases with advancing age.

- People who've had a heart attack have a sudden death rate that's four to six times that of the general population (2).

Notable Research Studies on the Efficacy of ICD Therapy

Several research studies have shown the benefits of an ICD for appropriately evaluated patients:

- **The Multicenter Automatic Defibrillator Implantation Trial (MADIT II)** showed that ICDs provide a significant survival benefit for patients with prior MI and EF \leq 30 %.

The results included a 31% relative reduction in all-cause mortality over average 20-month follow-up and 5.6% absolute reduction in all-cause mortality over average 20-month follow-up. **Indication:** Every patient with prior MI and low EF should be considered for ICD therapy (5).

MADIT II showed that mortality risk in contemporary post-MI patients with EF \leq 30% tends to increase as a function of time from last MI. Even up to 15 years following MI, the survival benefit from the ICD remains substantial. Aggressive use of prophylactic ICDs in the late phase of MI associated with an EF \leq 30% appears warranted (6).

- **The Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT)** concluded that in NYHA class II or III patients with EF \leq 35% on optimal medical therapy, ICD therapy significantly decreased the relative risk of death by 23% (vs. placebo). Amiodarone had no beneficial effect on survival (vs. placebo), despite the use of appropriate dosage and reasonable compliance rates. **Indication:** Every NYHA class II/III patient with low EF should be considered for ICD therapy (7).

ACC/AHA Guidelines

In short, the American Heart Association and the American College of Cardiology's latest guidelines give the highest recommendation that implantable defibrillators can help those who have heart failure or have suffered a heart attack survive an episode of sudden cardiac arrest. Here is a brief overview of the various clinical guidelines:

- **ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities:** In May 2008, the American College of Cardiology (ACC), American Heart Association (AHA) and the Heart Rhythm Society (HRS) jointly released updated cardiac device-based therapy guidelines. The ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities are the first guidelines that combine indications for all cardiac implantable electronic devices.

In announcing the guidelines, leaders stressed that these guidelines are unique in that they emphasize not just taking care of rhythm problems or heart failure, but global cardiovascular needs of patients. The term "optimized medical therapy" used throughout the guidelines refers to treatment beyond devices, such as drug therapies, that may reduce the need for devices.

The guidelines also recommend a thorough risk assessment and quality of life discussion with patients and their families and provide a clear discussion of who should not get devices. According to HRS, the three major changes to the new 2008 guidelines are:

- The elevation of primary prevention of sudden cardiac arrest in patients with an ischemic cardiomyopathy from a level IIa to a level I
 - The clarification of the ejection fraction for implantation at 35 percent, and
 - The focus on optimized medical therapy for patients
- **ACC/AHA/ESC 2006 Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death:** Developed in Collaboration with the Heart Rhythm Society and the European Heart Rhythm Association. This document updates and combines the previously published recommendations into one source approved by the major cardiology organizations in the United States and Europe. The streamlined document assists in locating recommendations on the evaluation and treatment of patients who have or may be at risk for ventricular arrhythmias.
 - **The ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult:** The risk of sudden cardiac death is an underlying problem for many heart failure patients. Heart failure patients are six to nine times more likely to die of sudden cardiac death (2). These guidelines address device therapy recommendations for heart failure patients.
 - **The Centers for Medicare and Medicaid Services (CMS) guidelines:** In 2005, CMS announced its expanded ICD coverage decision for primary prevention ICD therapy. Immediately, coverage for primary prevention was expanded to include many people who had not first had a heart attack, arrhythmias or proven risk of arrhythmias.

Implantable Cardioverter Defibrillator Indications at a Glance

ICDs are intended to provide ventricular anti-tachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

- Prior MI **and** EF \leq 30%
- Ischemic or non-ischemic dilated cardiomyopathy, EF \leq 35%, NYHA class II or III
- Prior MI **and** EF \leq 35% **and** documented, non-sustained VT **and** inducible VT at EP testing
- Recurrent, poorly tolerated, sustained VT
- Survival of at least one episode of cardiac arrest (manifested by loss of consciousness) due to VT

Cardiac Resynchronization Therapy Defibrillator (CRT-D) Indications at a Glance

A CRT device is used to treat dyssynchrony of the heart's ventricles. A CRT-D also provides ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

- Moderate to severe heart failure (NYHA class III or IV)
- LVEF \leq 35%
- QRS width \geq 120 ms
- Remains symptomatic despite stable, optimal heart failure drug therapy

Cost-effectiveness and Reliability Issues

- From a cost perspective, studies show that in appropriately selected patients, ICDs compare favorably, in terms of cost-effectiveness, with other therapeutic interventions. (8)

- Reports in recent years have put the spotlight on device therapy and reliability issues. The U.S. Food and Drug Administration most recent advisories were prompted by data indicating that some ICD models have a design flaw that can potentially cause them to malfunction.

In ICDs, device malfunction may prevent generation of the electrical pulse necessary to correct a ventricular arrhythmia. This may be caused by an electrical malfunction of the lead wire or its insulation. Other, nonlife-threatening pulse generator malfunctions can occur and may require that the device be replaced. These types of malfunctions are very rare, occurring in only about 2 percent of cases.

- **Although a device malfunction may mean the ICD does not provide life-saving therapy as designed, there is no record of the device itself causing death for any patients.**
- **Most device malfunctions are not harmful to the patient.** Device problems often are related to the software and can be fixed by reprogramming. Although sometimes the device does need to be removed and replaced, in the vast majority of patients, this is not the best answer, as the risks associated with device removal can be greater than the risks of device malfunction.
- **According to an HRS industry analysis, defibrillators experience no confirmed malfunctions in greater than 99 percent of cases.** (9). The industry’s leading manufacturers actively report information about device reliability and malfunctions with physicians, regulatory bodies and the public.

Patient Education

- Many physicians have expressed concern about the time required to adequately explain device therapy and possible risks to patients. There are many resources available to assist in the discussion of device therapy with patients. With the right resources and the information provided in this overview, the initial discussion preceding a referral to an EP can be accomplished in about a 10 to 15-minute conversation.
- The most critical message is that implanted cardiac devices help tens of thousands of people enjoy full, active lives and are the most effective technology for stopping life-threatening arrhythmias. The statistics about sudden cardiac arrest survival rates that I’ve included on page 2 of this overview are also powerful testaments to the success of this technology.
- Device manufacturers and organizations such as the Sudden Cardiac Arrest Association (www.suddencardiacarrest.org), the Heart Rhythm Society (www.hrspatients.org) and the American Heart Association (www.americanheart.org) offer a variety of helpful resources for patients.
- In addition, the Cleveland Clinic has authored an article for patients titled, “Implantable Heart Rhythm Devices: Safe, Effective Treatment” that provides a good overview of device therapy and also addresses reliability issues. A PDF of this article is attached.

I hope the information provided here has provided you with some additional insights about the value of ICDs in treating sudden cardiac arrest. Thank you in advance for your commitment to ensuring the highest quality care for our family members, neighbors, colleagues and friends in North Carolina who are at risk for death from such an episode. If I can be of a resource to you in any way, please do not hesitate to contact me.

Best regards,

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*Malfunction rates may be understated because not all devices are explanted and returned for analysis.

Advanced Technology at NHRMC Heart Center Saves Maryann

Implantable defibrillator staves off cardiac arrest, increases quality of life

Maryann Robison sits on a floral, cream-colored sofa in her elegant Wilmington home.

Behind her on the wall, ink sketches of Charleston's historic downtown dwellings bathe in morning's light. French Huguenots, wrought iron and sand between her toes – they're all part of her Low Country heritage, she explains.

It's a storied ancestral past to be sure, but in recent years it's the future that's mostly occupied Robison's mind, a future that's had her hanging on every heartbeat.

That's because more than once Robison's heart has stopped beating altogether, the result of a heart condition called cardiomyopathy. It's a condition where the heart fails to adequately supply blood to the rest of the body, sometimes producing irregular heart rhythms that can lead to cardiac arrest.

Each time, of course, Robison has returned to the land of the living thanks to New Hanover Regional Medical Center Heart Center and a life-saving technology called an Implantable Cardioverter Defibrillator, or ICD, a small, battery-operated, surgically implanted device that corrects irregular heart rhythms, staving off cardiac arrest.

June 1991

"That's when I experienced my first symptoms," she says. "I was at the mall in Myrtle Beach, and I got so dizzy I had to lean up against the wall. I thought it was because I hadn't eaten."

It wasn't an empty stomach, however, causing Robison's dizziness and, eventually, severe shortness of breath. Over the next few weeks, Robison's condition worsened until she was admitted to NHRMC's Cardiac Intensive Care Unit in late August for two weeks.

"I was so weak I couldn't brush my teeth," she says. "At that point they diagnosed me with cardiomyopathy, told me I might only have two to three years to live, and recommended a heart transplant. But I told them, 'No way – 'came into this world with this heart, going out of this world with this heart!'"

August 1991 to February 2004

Having decided against a heart transplant and with grim news of her life expectancy, Robison committed over the next 13 years to a rigorous regimen of robust medications and dietary restrictions: low sodium, no alcohol, no caffeine and limited fluid intake. "Not a lot of fun," she says.

While the regimen helped improve her condition and regulate the cardiomyopathy, Robison still suffered episodes of cardiac arrest, each one requiring extensive hospitalization.

And then what was probably the biggest blow: “This whole time I wasn’t allowed to drive,” says Robison, whose life’s work in homebuilding often took her on the road. “You can’t begin to believe how something so simple could impact who and what you are.”

February 2004 to the Present

In 2004, however, a physician with a machine the size of a human palm would impact her far more than anything she’d experienced yet.

“When I met Maryann in 2004, all medical therapies to improve her heart condition had been exhausted, but her will to survive was strong,” says Maryann’s cardiologist, Dr. Henry Patel, of NHRMC’s Heart Center. “We decided to surgically implant a defibrillator.”

Defibrillation, or the delivery of electrical energy to the heart, returns the heart to its normal rhythm when the heart experiences irregular rhythms. In Maryann’s case, the ICD, while capable of delivering a shock, actually has two ways of correcting her fast, irregular heartbeats before they give way to cardiac arrest.

“Let’s say you’re walking and you break into a fast run,” Dr. Patel says. “There are two ways for me to stop you: block you from the front or sneak up behind you and push you, so you stumble.”

Dr. Patel says Robison’s ICD first attempts a “push and stumble” mode to correct the irregular heartbeats; if that fails, an electric shock follows. “In both cases we’re shaking up the irregular rhythm to bring about a normal rhythm,” says Dr. Patel.

“Within two months of the implant, I felt stronger,” says Robison, “and I kept getting stronger.” Robison says her ICD activates mostly at night when she sleeps. Awake, she says, the activation is brief and painless: “Your body jerks when it goes off, but it’s not as bad as you think, and people need to understand that. It’s a small price to pay for something that keeps you alive.”

“Since the implantation, each time Maryann’s gone into cardiac arrest, the ICD has successfully, repeatedly and reliably brought her back to life,” says Dr. Patel.

And it also brought back something else equally as important: Her independence: “The implant continues to allow me to function at a higher level, to be who I am, the real me,” she says, “and that has made all the difference.”

Ask the Expert: Dr. Henry Patel, Cardiologist

What Is Sudden Cardiac Arrest?

Sudden cardiac arrest is a condition where the heart stops beating because the electrical activity that's normally organized in the heart becomes disorganized. When this occurs, blood stops flowing to the brain and other vital organs. If not treated in minutes, a person can die.

Initiative 32: A Statewide Initiative to Combat SCA

Every day 32 North Carolinians die from Sudden Cardiac Arrest, or SCA. This translates into 980 North Carolinians a month and 11,765 a year. But this disease is largely preventable. Through education through such organizations as the Sudden Cardiac Arrest Association and with life-saving technology like the Implantable Cardioverter Defibrillator, or ICD, more lives are being saved.

Did You Know?

- Only one person in 20 usually survives an episode of sudden cardiac arrest. The other 19 die before reaching the hospital.
- In contrast, with an ICD, 19 out of 20 people will survive. ICD's have been shown to effectively terminate the vast majority of lethal arrhythmias, or irregular heartbeats

Source: NC Chapter of the American College of Cardiology