New Guidelines Cover Heart Rhythm Devices

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SAN FRANCISCO — New guidelines from three major heart-specialty organizations on the use of implantable devices for heart rhythm abnormalities emphasize talking with patients about their needs and desires, and stress optimizing medical therapy.

"For the first time, we have addressed human needs and not just numbers," such as ejection fractions, when considering implanting pacemakers, defibrillators, or cardiac resynchronization therapy (CRT) devices, Dr. Andrew E. Epstein said at a press conference at the annual meeting of the Hearth Rhythm Society (HRS). "We really need to talk to patients, be at the bedside, find out what they want, and see that their issues are addressed," he said.

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This has been implied in previous guidelines but never made as explicit as in the new guidelines issued jointly by the American College of Cardiology (ACC), the American Heart Association (AHA), and the HRS, said Dr. Epstein, chair of the joint task force that produced the new guidelines and professor of medicine at the University of Alabama at Birmingham.

"Especially with devices, the issue of recalls and safety advisories has interfered with the trust of the public with physicians. I think we have a credibility issue," he said.

In addition to guidance on talking with patients before implanting devices, the guidelines for the first time also provide guidance on talking with patients about end-of-life care and when to turn off the devices.

The ACC/AHA/HRS "2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities" updates the 2002 joint guidelines by the ACC and AHA, and, more than ever, emphasizes the need for optimal medical therapy before the implantation of a cardiac device is considered.

"We're trying to emphasize that a global approach to patients is what saves lives," Dr. Epstein said.

Optimal medical therapy may improve a patient's ejection fraction and quality of life after a heart attack to the point where an implantable device is not indicated.

The guidelines are the first to cover all cardiac implantable devices.

Data from recent studies and advances in device technology influenced some key changes in recommendations.

For example, evidence from MADIT II (the second Multicenter Automatic Defibrillator Implantation Trial) elevated the recommendation—that implantable cardiac defibrillators (ICDs) be used for primary prevention of sudden cardiac arrest in patients who have ischemic cardiomyopathy due to prior MI, have a left ventricular ejection fraction of less than 30%, and are New York Heart Association functional class I—from a class IIa recommendation ("it is reasonable") to a class I recommendation (it "should be performed/administered").

"We can very strongly tell physicians that primary prevention of sudden cardiac arrest is very important," Dr. Epstein said.

Some studies published in recent years have made the issue of which ejection fraction should be the cutoff for initiating the consideration of implantable devices "very murky," he added.

The new guidelines clarify that patients who have an ejection fraction of 35% or less should be considered for device implantation.

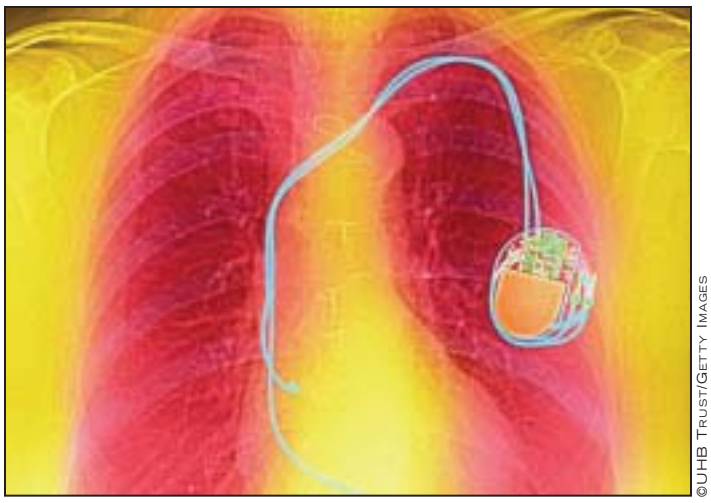
The section on the use of CRTs to manage heart failure has been expanded greatly, thanks to an abundance of recent trial data.

The guidelines primarily are evidence based, will be reviewed annually, and will evolve as technology advances.

"Indications for ICDs, CRT devices, and combined ICDs and CRT devices are [continually changing] and can be expected to change further as new trials are reported," Dr. Epstein said.

In addition to addressing cardiac arrhythmias, heart failure, congenital heart disease, and sudden cardiac arrest as indications for device-based therapy, the new guidelines for the first time also address treatment for genetic disorders, including catecholaminergic polymorphic ventricular tachycardia, Brugada syndrome, arrhythmogenic right ventricular cardiomyopathy, and short QT syndrome.

The full text of the guidelines is posted on each group's Web site (www.acc.org, my.americanheart.org, and www.hrsonline.org). An executive summary and abbreviated recommendations have been published in the Journal of the American College of Cardiology and the journal Circulation, in the June 2008 issue of Heart Rhythm, and in the electronic versions of those issues. ■



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The guidelines emphasize the need for optimal medical therapy before considering the implantation of a cardiac device, such as the pacemaker shown in the x-ray at left.