

# 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 Heart Rhythm Society (HRS).

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“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. 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 glob-

al 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.



*In the treatment of painful Diabetic Peripheral Neuropathy (DPN) and Postherpetic Neuralgia (PHN),*

# W e l c o m e

**Selected safety information:** LYRICA is indicated for the management of Fibromyalgia, neuropathic pain associated with Diabetic Peripheral Neuropathy, Postherpetic Neuralgia, and as adjunctive therapy for adults with Partial Onset Seizures.

LYRICA is contraindicated in patients with known hypersensitivity to pregabalin or any of its other components.

There have been postmarketing reports of angioedema in patients during initial and chronic treatment with LYRICA. Specific symptoms included swelling of the face, mouth (tongue, lips, and gums), and neck (throat and larynx). There were reports of life-threatening angioedema with respiratory compromise requiring emergency treatment. LYRICA should be discontinued immediately in patients with these symptoms.

There have been postmarketing reports of hypersensitivity in patients shortly after initiation of treatment with LYRICA. Adverse reactions included skin redness, blisters, hives, rash, dyspnea, and wheezing. LYRICA should be discontinued immediately in patients with these symptoms.

In controlled studies, a higher proportion of patients treated with LYRICA reported blurred vision (7%) than did patients treated with placebo (2%), which resolved in a majority of cases with continued dosing. More frequent assessment should be considered for patients who are already routinely monitored for ocular conditions.

Patients with a history of drug or alcohol abuse may have a higher chance of misuse or abuse of LYRICA.

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

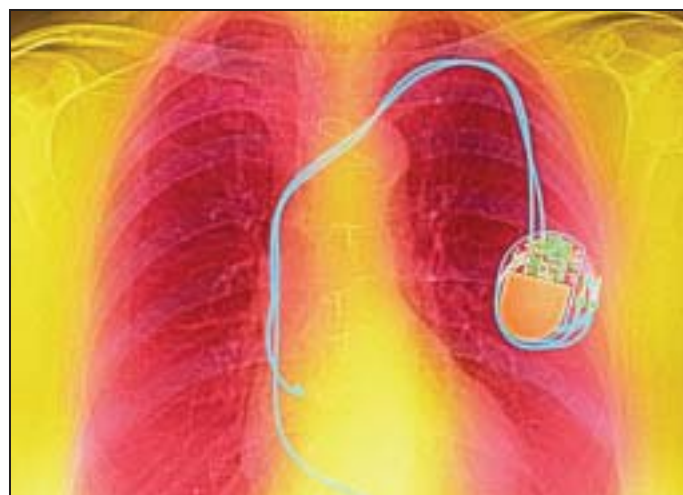
The guidelines primarily are evidence based, will be reviewed annually, and will evolve as technology advances.

"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. ■

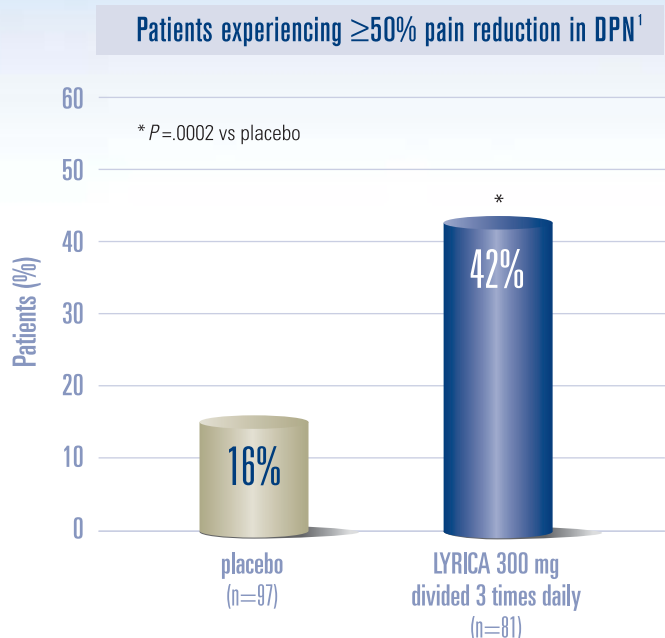


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The guidelines emphasize the need for optimal medical therapy before considering the implantation of a cardiac device, such as the pacemaker shown in the x-ray at left.

*t o c a l m*

**LYRICA provides powerful pain relief in DPN and PHN**



• LYRICA also demonstrated significant pain reduction in 3 pivotal PHN studies<sup>3</sup>

Adapted from Lesser et al. *Neurology*. 2004.<sup>2</sup>  
 Results from a 5-week, double-blind, placebo-controlled, multicenter study of 337 patients with moderate-to-severe pain of DPN. Randomized patients received LYRICA 25 mg, 100 mg, 200 mg, or placebo, all given 3 times daily. The primary efficacy parameter was end point least-squares mean pain score on a numeric scale ranging from 0 (no pain) to 10 (worst possible pain) taken from patient diaries. For this responder rate analysis, patients who did not complete the study were assigned a 0% improvement, known as baseline observation carried forward (BOCF) analysis.

**Selected safety information:** The most common adverse reactions occurring during Fibromyalgia and/or other controlled clinical trials for patients taking LYRICA vs those taking a placebo were dizziness, somnolence, dry mouth, edema, blurred vision, weight gain, constipation, euphoric mood, balance disorder, increased appetite, and thinking abnormal (primarily difficulty with concentration/attention).

**References:** 1. Data on file. Pfizer Inc, New York, NY. 2. Lesser H, Sharma U, LaMoreaux L, Poole RM. Pregabalin relieves symptoms of painful diabetic neuropathy: a randomized controlled trial. *Neurology*. 2004;63:2104-2110. 3. Prescribing Information for LYRICA® (pregabalin) capsules ©. Pfizer Inc, New York, NY.

[www.pfizerpro.com/lyrica](http://www.pfizerpro.com/lyrica)

Please see adjacent brief summary of prescribing information.

