

Heart Device Guidelines Stress Medical Therapy

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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). “We



Before pacemaker implantation, the guidelines stress talking to patients.

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 global approach to patients is what saves lives,” Dr. Epstein said.

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. “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 frac-

tion should be the cutoff for initiating the consideration of implantable devices “very murky,” he added. The new guidelines clarify that patients with 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 ventricu-

lar 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; <http://my.americanheart.org>; and www.hrsonline.org). An executive summary and abbreviated recommendations were published in the May 27 issues of the Journal of the American College of Cardiology and the journal *Circulation*, and in the June issue of *Heart Rhythm*. ■

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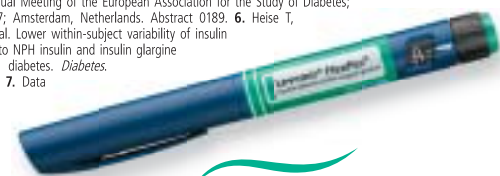
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References: 1. Meneghini LF, Rosenberg KH, Koenen C, Meriläinen MJ, Lüddecke H-J. Insulin detemir improves glycaemic control with less hypoglycaemia and no weight gain in patients with type 2 diabetes who were insulin naive or treated with NPH or insulin glargine: clinical practice experience from a German subgroup of the PREDICTIVE study. *Diabetes Obes Metab*. 2007;9(3):418-427. 2. Hermansen K, Davies M, Derezinski T, Ravn GM, Clauson P, Home P, for the Levemir Treat-to-Target Study Group. A 26-week, randomized, parallel, treat-to-target trial comparing insulin detemir with NPH insulin as add-on therapy to oral glucose-lowering drugs in insulin-naïve people with type 2 diabetes. *Diabetes Care*. 2006;29(6):1269-1274. 3. Klein O, Lyngé J, Endahl L, Damholt B, Nosek L, Heise T. Albumin-bound basal insulin analogues (insulin detemir and N344): comparable time-action profiles but less variability than insulin glargine in type 2 diabetes. *Diabetes Obes Metab*. 2007;9(3):290-299. 4. Philis-Tsimikas A, Charpentier G, Clauson P, Ravn GM, Roberts VL, Thorsteinnsson B. Comparison of once-daily insulin detemir with NPH insulin added to a regimen of oral antidiabetic drugs in poorly controlled type 2 diabetes. *Clin Ther*. 2006;28(10):1569-1581. 5. Danne T, Endahl L, Haahr H, et al. Lower within-subject variability in pharmacokinetic profiles of insulin detemir in comparison to insulin glargine in children and adolescents with type 1 diabetes. Presented at: 43rd Annual Meeting of the European Association for the Study of Diabetes; September 17-21, 2007; Amsterdam, Netherlands. Abstract 0189. 6. Heise T, Nosek L, Rönn BB, et al. Lower within-subject variability of insulin detemir in comparison to NPH insulin and insulin glargine in people with type 1 diabetes. *Diabetes*. 2004;53(6):1614-1620. 7. Data on file. NDA21-536. Novo Nordisk Inc, Princeton, NJ.



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