Heart of the Matter

The Age of Device Therapy

BY SIDNEY GOLDSTEIN, M.D.

The recently published Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities do not recommend any major changes in the use of these new technologies, but do represent a watershed moment in cardiac therapy. The guidelines clearly emphasize the important role that these new devices play in cardiology therapeutics.

Implantable pacemakers are now recommended widely for the treatment of sinus bradycardia and sinus node dysfunction in proven and even suspected symptomatic bradycardia. In acquired atrioventricular block, pacemaker therapy remains the mainstay for the prevention of syncope and the treatment of cardiac failure. The technologic hurdles to achieve safe and effective pacing in a variety of clinical situations have in a large part been overcome. A new study, PACE-MI (Pacemaker and β-Blocker Therapy After Myocardial Infarction), sponsored by the National Heart, Lung, and Blood Institute, is attempting to expand the envelope of pacemaker therapy by testing the benefit of a pacemaker and β-blockers in post-MI patients who have primary or drug-induced bradycardia.

Biventricular pacing has become widely accepted for the treatment of heart failure in patients with QRS intervals more than 120 msec who remain symptomatic on standard therapy with or without an ICD. The only area of controversy is the ejection fraction threshold for defibrillator implantation in patients with an ejection fraction of 35% or 40%. Previous guidelines published in 2006 by the American College of Cardiology, the American Heart Association, and the European Society of Cardiology suggested an ejection fraction of less than 40% as the threshold, but the 2008 version by the ACC/AHA/HRS has chosen an ejection fraction of less than 35% as the threshold, on the basis of the two largest defibrillator trials (MADIT and SCD-HEFT).

Not covered in the guidelines is any concern about the safety of the defibrillators in use today. The lack of candor regarding the dangers of ICD implantation is surprising, particularly in light of the frequent occurrence of inappropriate shocks in patients receiving the device. In a recent report from the MADIT II trial (J. Am. Coll. Cardiol. 2008;51:1357) 11.5% of patients received an inappropriate shock during the 2-year follow-up period, and there was a greater than twofold increase in mortality among patients experiencing an inappropriate shock. It is not clear whether these patients are at greater risk because of the nature of their disease or that increased risk results from the inappropriate shock itself. The report indicated that patients who received an inappropriate shock had an increased frequency of atrial fibrillation; they were more commonly smokers and had a decreased use of β-blockers.

There is reason to be concerned that as ICDs become more widely used for the primary prevention of ventricular fibrillation, the number of inappropriate shocks will increase and the number of appropriate shocks will decrease. It appears that the heart rhythm doctors who write the guidelines are more intent on spreading the use of ICDs than on identifying those patients who need the device the most and in whom the device is safe.

We have not seen the end of the role of device technology in cardiology. On the drawing board and in clinical trials are devices that can potentiate myocardial contractility and remodel the molecular biology of the myocardium by providing subthreshold electrical stimulation. There are also implantable devices that stimulate the vagus nerve, which may be able to modify heart rate and blood pressure, improve myocardial function, and prevent ventricular fibrillation. Carotid sinus stimulation is also under study to lower heart rate and blood pressure in patients with heart failure. And somewhat farther afield, devices are now being tested to change and modify the shape of the dilated ventricle to improve contractility and limit ventricular remodeling.

All of these efforts are exciting and will pose important challenges to clinicians as they apply them to their patients. Unlike medical therapy, it is difficult if not impossible to stop therapy and remove the device once implanted. This raises the bar for ensuring safety before implantation. ■

Dr. Goldstein, medical editor of Cardiology News, is professor of medicine at Wayne State University and division head, emeritus, of cardiovascular medicine at Henry Ford Hospital, Detroit.

Chronic Illnesses Now Biggest Killer, WHO Reports

Chronic conditions such as heart disease and stroke are now the biggest killers worldwide, signifying the shift of global disease burden away from communicable diseases, the World Health Organization said in its annual international health statistics report.

The report on the 193 WHO-member countries indicated that three diseases—ischemic heart disease, cerebrovascular disease, and chronic obstructive pulmonary disease—will constitute 34.9% of deaths worldwide by 2030, up from 27% in 2004. By comparison, the top three communicable diseases of today—lower respiratory infections, diarrheal diseases, and HIV/AIDS—will constitute 6.5% of deaths in 2030, down from 14.1% today.

"We are definitely seeing a trend towards fewer people dying of infectious diseases across the world," Dr. Ties Boerma, director of the WHO's Department of Health Statistics and Informatics, said in a written statement. "We tend to associate developing countries with infectious diseases, such as HIV/AIDS, tuberculosis, and malaria. But in more and more countries the chief causes of death are noncommunicable diseases, such as heart disease and stroke."

Among the chronic or behavior-related diseases on the increase around the world will be trachea, bronchus, and lung cancers, representing 3.4% of deaths in 2030 compared with 2.3% in 2004; diabetes, representing 3.3% of deaths in 2030 compared with 1.9% in 2004; and hypertension, representing 2.1% of deaths in 2030 compared with 1.7% in 2004, according to the WHO.

—Jonathan Gardner

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Cardiology News is an independent newspaper that provides the practicing specialist with timely and relevant news and commentary about clinical developments in the field and about the impact of health care policy on the specialty and the physician's practice.

POSTMASTER Send changes of address (with old mailing label) to Cardiology News Circulation, 60 Columbia Rd., Bldg. B, 2nd flr., Morristown, NJ 07960.

Cardiology News (ISSN 1544-8800) *is published monthly by Elsevier Inc., 60 Columbia Rd., Bldg. B, 2nd flr., Morristown, NJ 07960, 973-290-8200, fax 973-290-8250. Subscription price is $95.00 per year.*

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