HEART OF THE MATTER

What the ICD Registry Tells Us

Implantable cardioverter defibrillators have been rapidly incorporated into the standard therapy for patients with left ventricular failure in the United States where nearly 10,000s ICDs are implanted each month.

BY SIDNEY GOLDSTEIN, M.D.

Now data sources are beginning to give us a glimpse of who these patients are and of the risks associated with ICD implantation. The first report of the National ICD Registry provides the cardiology community with rich and robust information regarding the demographics of the patients receiving ICDs and the medical environment in which they are being implanted. As such, it provides an opportunity to enlarge our knowledge about these ICD recipients and this special therapy. The registry also provides a model for future investigations using the Medicare database to evaluate various cardiac therapies.

Registries will become increasingly important as we proceed with gene and device therapies where our understanding of the long-term safety and efficacy will be required and where the usual clinical trial construct cannot provide the necessary information.

Since April 2006, the National ICD registry has collected data from more than 100,000 implants, most in Medicare patients as mandated by the Centers for Medicare and Medicaid Services, and an additional 30% from non–Medicare insured patients. Fortunately, the inclusion of privately insured patients provides information about patients aged younger than 65 years.

Most of the patients (79.2%) in the registry received the device for primary prevention using current class IIA guidelines advising implantation of the ICD in patients with a left ventricular ejection fraction of less than 30% at least 1 month after an acute myocardial infarction or 3 months after coronary bypass surgery. The remaining patients were implanted for secondary prevention, presumably having experienced previous life-threatening events. Very few adverse events were associated with implantation. The development of a pocket hematoma, the most frequent adverse effect, occurred in 1.3% of the implantations. Interestingly, slightly more that one-third of the patients had biventricular pacemakers implanted with the device.

Cardiologists, and particularly electrophysiologists, were the main players. Sixty percent of the devices were implanted by cardiologists who had undergone electrophysiology training; most had passed the board examination for that specialty. About 10% had completed surgical or thoracic residencies, and they implanted 2.7% of the devices. And 15% of the physicians, who placed 6.2% of the devices, had no training in implantation.

Additional information about the use of ICDs emerges from a recent examination of the Medicare database. In that analysis of ICD implantation for both primary and secondary prevention, there is striking disparity in the implantation by sex and race. In both the primary prevention and secondary prevention groups, there was more than a threefold increase in the implantation of ICDs in men compared with women. There was a similar disparity between white and black patients. Of particular interest, mortality data adjusted for a variety of comorbidities indicated no difference in benefit accrued to patients receiving the ICD for primary prevention. In contrast, those patients receiving the ICD for secondary prevention experienced a 35% decrease in mortality compared with the nonrecipients (JAMA 2007;298:1517-24).

The variations in the use of defibrillators based on race and sex are just examples of how a number of contemporary cardiovascular technologies are not equally applied. These disparities cannot be fully explained by insurance coverage differences but probably relate to differences in clinical factors as well as a number of sociologic differences.

We will learn more about the risks of implantation in the future, but unfortunately we will not gain any further precise information about the relative mortality and morbidity benefit of these devices other than what we received from the MADIT II and SCD-HeFT trials. That evaluation will depend upon the development of other methods for the treatment and prevention of sudden cardiac death. ■

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.*

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