

EDITORIAL COMMENT

Experience Counts

Better Patient Outcomes With Higher Device Volumes*

Anne B. Curtis, MD, FACC
Tampa, Florida

With the recently expanded coverage guidelines by the Centers for Medicare and Medicaid Services for implantable cardioverter-defibrillators (ICDs), there is now a much larger pool of patients potentially eligible for implantation of prophylactic ICDs. It would be unusual to find an electrophysiologist, or a cardiologist for that matter, who is not already running a busy practice. However, there has been no outcry among board-certified or -eligible electrophysiologists that they are not prepared to handle the increased volume of patients who could benefit from prophylactic ICDs. In fact, given that the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) used single-chamber ICDs (1), the implant duration for the typical case is not so long that the average experienced clinician would not be able to add additional volume in their electrophysiology laboratories to handle this load. Nevertheless, there are cardiologists who have not completed specialty training in electrophysiology who either implant ICDs or plan to do so in the near future. Why is this happening, and should they be doing it?

See page 1536

In some areas, cardiologists in practice may be located remotely from an electrophysiology center. If so, then the ability to implant ICDs without necessitating that the patient travel a great distance to have the procedure performed may be an advantage to the patient and the patient's family. Although this situation has been touted as a good reason to train non-electrophysiologists to implant ICDs, frankly, it is uncommon that patients in this country find themselves in such a circumstance. It is actually more common that patients who could have access to a trained electrophysiologist for implantation of an ICD are instead offered the procedure by a cardiologist without such advanced subspecialty training. Under what circumstances would a non-electrophysiologist be competent to implant ICDs to obtain optimal patient outcomes?

There are several important aspects to competency in device implantation. First and foremost is expertise in implantation techniques and management of difficult cases

and complications. Such training is an integral part of a fellowship in clinical cardiac electrophysiology. However, there are physicians who have completed cardiology fellowships who are trained in pacemaker implantations and who currently have high-volume practices in pacemaker implantation and follow-up. For such physicians, the technical skills required to implant an ICD lead are not very different from those required for a pacemaker implantation. However, there is a great deal of additional knowledge that is necessary that is unique to ICD implantations, such as the use of conscious sedation for device testing, testing of defibrillation thresholds, and proper programming and follow-up. Such knowledge can be attained by a cardiologist experienced in pacemaker implantations, if one has the dedication and interest to pursue that knowledge. This was the rationale behind the recently published Heart Rhythm Society (HRS) clinical competency statement on implantation of ICDs and cardiac resynchronization devices (2), which was also endorsed by the American College of Cardiology Foundation. In addition, the Centers for Medicare and Medicaid Services in their decision memorandum on ICDs earlier this year supported the concept that adequate training is necessary for physicians who implant ICDs. Key components of the clinical competency statement included a sufficiently high-volume pacemaker practice by the operator currently, in addition to didactic training, proctoring, and successful completion of NASPEXAM, an examination of knowledge in pacing and defibrillation. It should be noted that only experienced pacemaker implanters should ever consider expanding their practices to include prophylactic ICD implantations because of the difficulties of obtaining the technical skills required for device implantation in general outside of a training program.

Why is it necessary to have an adequate amount of pacemaker implantations before considering ICD implantation? From a limited number of studies, it is apparent that pacemaker complications become much more common among physicians who implant fewer than 12 pacemakers per year (3–8). In addition, it has been shown that physicians who implant more than 30 pacemakers per year are more likely to use advanced programming features in devices and to require less support from industry (7). Because proper programming and troubleshooting are important aspects of optimal device function, an adequate volume of implantation experience is critical to achieving the goals of optimizing device function and minimizing the need to rely on industry. Hence, the HRS guidelines state that a minimum of 100 pacemaker implantations over the preceding three years would be considered necessary to proceed with additional training to allow prophylactic ICD implantation.

Until now, there have not been any data available on ICD implantation volumes and outcomes. In the study published in this issue of the *Journal* by Al-Khatib et al. (9), the

*Editorials published in the *Journal of the American College of Cardiology* reflect the views of the authors and do not necessarily represent the views of *JACC* or the American College of Cardiology.

From the Division of Cardiology, University of South Florida, Tampa, Florida.

relationship between ICD implantation volumes and patient outcomes was examined in a Medicare population. Using Medicare files, physician volume categories were divided into quartiles. Although 90-day mortality did not differ in the four groups, there was a significantly higher rate of mechanical complications as well as device infections among patients who had devices implanted by physicians in the lowest-volume quartile.

There are several implications of the present study that should be noted. First, the volume examined was for Medicare patients only. Because Medicare often accounts for around 50% of a cardiologist's volume of patients, the total volume of ICD implantations by the physicians reported in this study could be approximately double what is reported. If so, then implanting fewer than two ICDs per month would be associated with a higher complication rate. Second, infection is a serious issue among ICD recipients. With a higher rate of mechanical complications, there may be a potential need for repeat operations, which are associated with a higher infection rate than initial procedures. This fact, coupled with the higher infection rate overall for low-volume implantation group, indicates that some patients who have their implantations performed by those with less experience will be exposed to the risks of lead extraction, which has a finite mortality risk associated with it, as well as a risk of other serious complications, beyond the 90-day window examined in this study.

Although programming was not specifically examined in the Al-Khatib et al. (9) study, it is probable that physicians with low-volume implantation rates would be less likely to customize programming for an individual patient, a situation similar to what has been found previously for pacemaker programming (7). This may not be a significant problem in patients who have ICDs implanted solely for prophylactic reasons, in whom simple, high-rate cutoffs for shock therapy for ventricular tachyarrhythmias and low-rate, backup pacing are appropriate. However, for any patient who has received therapy from an ICD, whether appropriate or inappropriate, expertise is necessary to adjust

pharmacologic therapy and fine-tune device therapy for optimal patient outcomes as well as quality of life. Such outcomes are most likely to be achieved by specialists who have devoted the time to proper training and education in this area. Although there are cardiologists and surgeons who have attained the knowledge and expertise to achieve good outcomes with ICDs, clinical cardiac electrophysiologists have devoted their careers to arrhythmia management and by definition have the expertise required in this area. Whatever the physician's background in this area, it is clear that experience counts, and it counts for a lot.

Reprint requests and correspondence: Dr. Anne B. Curtis, Division of Cardiology, University of South Florida, 12901 Bruce B. Downs Boulevard, MDC 87, Tampa, Florida 33612. E-mail: acurtis@hsc.usf.edu.

REFERENCES

1. Bardy GH, Lee KL, Mark DB, et al., for the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) Investigators. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *N Engl J Med* 2005;352:225-37.
2. Curtis AB, Ellenbogen KA, Hammill SC, et al. Clinical competency statement: training pathways for implantation of cardioverter defibrillators and cardiac resynchronization devices. *Heart Rhythm* 2004;1:371-5.
3. Parsonnet V, Bernstein AD, Galasso D. Cardiac pacing practices in the United States in 1985. *Am J Cardiol* 1988;62:71-7.
4. Tobin K, Stewart J, Westveer D, Frumin H. Acute complications of permanent pacemaker implantation: their financial implication and relation to volume and operator experience. *Am J Cardiol* 2000;85:774-6.
5. Moller M, Arnsbo P, Asklund M, et al. Quality assessment of pacemaker implantations in Denmark. *Europace* 2002;4:107-12.
6. Parsonnet V, Bernstein AD, Lindsay B. Pacemaker implantation complication rate: an analysis of some contributing factors. *J Am Coll Cardiol* 1989;13:917-21.
7. Parsonnet V, Crawford CC, Bernstein AD. The 1981 United States survey of cardiac pacing practices. *J Am Coll Cardiol* 1984;3:1321-2.
8. Bernstein AD, Parsonnet V. Survey of cardiac pacing and implanted defibrillator practice patterns in the United States in 1997. *Pacing Clin Electrophysiol* 2001;24:842-55.
9. Al-Khatib SM, Lucas FL, Jollis JG, Malenka DJ, Wennberg DE. The relation between patients' outcomes and the volume of cardioverter-defibrillator implantation procedures performed by physicians treating Medicare beneficiaries. *J Am Coll Cardiol* 2005;46:1536-40.