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EDITORIAL COMMENT

Sustaining and Disruptive Innovation in Clinical Electrophysiology

The Subcutaneous Implantable Cardioverter-Defibrillator in the Young*

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Use of an implantable cardioverter-defibrillator (ICD) to prevent sudden cardiac death in humans was first described in 1980 by Mirowski et al. (1). Thus began the current era of sudden cardiac death prevention, in which ICDs are the favored treatment for at-risk patients. Since 1980, ICDs have evolved and improved significantly and are now used to help patients from infancy to old age.

However, despite widespread acceptance, ICDs are not perfect. Today our patients remain at risk for significant complications from these devices: inappropriate shocks, infection, venous occlusion, cardiac or vessel perforation, device failure, extraction, and other events (2). Young patients are more susceptible to complications due to multiple factors. One of the biggest problems for this population is a higher rate of endocardial high-voltage lead failure. The increased frequency of lead failure in youth has been attributed to greater tensile stress from somatic growth and higher levels of vigorous physical activity. Another factor contributing to lead failure in young patients is physical size: children are small. This has led to our preference for leads with thin diameters in little children, so that ICDs can be implanted. Finally, we gravitated to use of thin leads for youth of all ages in order to mitigate risk for short- and long-term venous occlusion. Unfortunately, thin high-voltage leads have, to date, turned out to be more prone to fracture (3).

Another ICD complication that occurs at increased rates in youth are inappropriate shocks from T-wave oversensing, supraventricular tachycardia, and "out of the box" noncustomized detection algorithms. The arrhythmia indications for ICDs in youth differ from those in adults; young patients rarely receive an ICD due to sequelae from atherosclerotic coronary artery disease. Youth most likely have inherited arrhythmia syndromes or congenital heart disease. The different morphology and rates of ventricular tachycardias in combination with youthful, fast sinus and AV node conduction contribute to the high rate of inappropriate shocks (2). Young patients also may have more unnecessary shocks for well-tolerated, relatively slow ventricular tachycardia if detection parameters and are not customized but are programmed using algorithms designed for typical adults with ICDs.

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The newest commercial iteration of the ICD, the subcutaneous-ICD (S-ICD) (4), diminishes risks for lead failure, venous occlusion, and endocarditis, and therefore has been widely adopted for use in young patients. Although at first glance the S-ICD appears to be a disruptive innovation, one can argue it is a sustaining innovation built on the foundation of epicardial nontransvenous ICD implantation in youth (5). The article by Bettin et al. (6) in this issue of *JACC: Clinical Electrophysiology* elucidates some of the successes and limitations of the new S-ICD when used for teens and young adults. This retrospective review

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includes 31 patients from 1 large electrophysiology program in Germany. The authors compare outcomes for patients with the S-ICD to age-matched controls with endocardial ICD systems. Due to the limited body of knowledge about outcomes for young patients with the S-ICD, this article is of significant interest to electrophysiologists, including those specializing in pediatrics and congenital heart disease.

Although this clinical study is susceptible to the well-described flaws of both retrospective and single-center designs, the length of follow-up and the number of subjects give us more information than prior reports about the use of S-ICDs in young patients. Another strength of this report is the case-control design including patients with endocardial ICDs with comparable age, sex, size, cardiac disease, and indications for treatment. The study by Bettin et al. (6) shows the S-ICD is safe and feasible for patients in the second and third decades of life, and there were no cases of failed life-saving treatment. Unfortunately, the report also shows that, despite the reduction in high-voltage lead failures, young patients with S-ICD remain at risk for inappropriate shocks, with rates similar to those of endocardial ICD systems (2,7).

Reasons for inappropriate shocks for patients with S-ICD in the study by Bettin et al. (6) include the usual suspects: T-wave oversensing, supraventricular tachycardia, and electrical artifact, similar to those in control patients with endocardial leads. Several of the inappropriate shocks for patients with S-ICD occurred during exercise or change in position. These reasons for inappropriate shocks are encouraging because they relate to elements of the S-ICD that represent truly disruptive innovation: use of surface electrocardiograms for arrhythmia detection in an implantable device. Because this mechanism for arrhythmia detection is a novel, early generation technology, there is potential to reduce inappropriate shocks by honing S-ICD sensing algorithms or by changing clinical screening practices before implantation. Indeed, the rate of inappropriate shocks with endocardial ICDs has decreased significantly with the recent refinement of electrogram detection algorithms that help discriminate true life-threatening arrhythmia from noise, T-wave oversensing, and supraventricular tachycardia; and there is no reason to assume we cannot achieve similar results by honing electrocardiographic detection algorithms in the S-ICD (7,8).

Furthermore, if electrocardiographic screening before S-ICD implantation were to be performed with exercise in addition to standing, sitting, and squatting plus supine positions, it may be possible to prevent inappropriate shocks. There is anecdotal evidence in the pediatric and congenital electrophysiology community that using exercise and positional electrocardiograms to qualify and disqualify youth for the S-ICD has been successful.

The report by Bettin et al. (6) is indeed a small, retrospective, single-center study, yet it is a relatively large study from a pediatric and congenital perspective. Of 147 S-ICD implantations performed at this large European electrophysiology center, only 21% (31 of 147 implantations) were performed in patients younger than 27 years of age and only 9% (13 of 147 implantations) in teens younger than 20 years of age. Generally, ICD implantations are relatively infrequent in youth, and <5% of current enrollees in the American College of Cardiology National Cardiovascular Data Registry ICD registry are patients younger than 18 years of age. These statistics, juxtaposed with a well-described difference in cardiac diagnoses and reasons for and rates of complications, indicate a need for a multicenter registry dedicated to ICDs in the young. With this dedicated registry, data from multiple centers would allow heart rhythm specialists to achieve numbers affording the statistical power required to quantify the true risks and benefits of the S-ICD and endocardial systems in youth. In addition, analysis of collective data and practice variation could identify effective strategies that shift the risk-benefit ratio for ICDs in young patients. Finally, such a multicenter registry could spur future sustaining and disruptive innovation in ICD therapy by broadcasting novel approaches to those interested in optimal treatment of arrhythmia in young patients.

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