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EDITORIAL COMMENT

The Subcutaneous Implantable Cardioverter-Defibrillator

When Less Is More*

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Led by a tremendous effort by Mirowski et al. (1), the implantable cardioverter-defibrillator (ICD) was first successfully implanted in humans 35 years ago via an epicardial approach at the Johns Hopkins Hospital (Baltimore, Maryland). Subsequently, the development of transvenous leads and smaller generators as well as the results of clinical trials led to an explosion in the use of ICDs for primary and secondary prevention of sudden cardiac death. More than 1 million patients have undergone implantation over the last 3 decades (2). However, despite the widespread adoption of ICDs, the transvenous implantable cardioverter-defibrillator (T-ICD) has recognized limitations, including the difficulty of implanting leads in patients with vascular access issues, the vulnerability of leads to structural damage over time, which necessitates additional leads and/or lead extraction (a particular concern in younger patients), and the risk of systemic infection.

SEE PAGE 1605

In an attempt to address these issues, the subcutaneous implantable cardioverter-defibrillator (S-ICD) was introduced in 2010 (3). Following Food and Drug Administration approval in 2012, the S-ICD has been steadily gaining in popularity, because it allows implantation of a system without the need for endocardial leads. The study by Burke et al. (4), in this issue of the *Journal*, provides a large-scale evaluation of the safety and efficacy of the S-ICD over a longer term follow-up of 2 years, by combining the 2 largest prospective studies of the S-ICD, IDE (S-ICD System IDE Clinical Investigation) and EFFORTLESS (Boston Scientific Post Market S-ICD Registry) (5,6). By pooling these studies, Burke et al. (4) evaluated a large database with 882 patients who received S-ICDs who were followed for 651 ± 345 days (1,571.5 patient-years), which allowed an analysis of a larger cohort over a longer duration of time. The results of this analysis lent further support for the use of the S-ICD in appropriate patients. The success of shock therapy after up to 5 shocks for ventricular tachyarrhythmias was 98.2%, and the estimated 3-year inappropriate shock rate was 13.1%. The estimated all-cause mortality was 4.7% at 3 years with a total of 26 deaths, which was 2.9% of patients who underwent implantation, with only 1 known arrhythmic death (0.1%) due to Loeffler's syndrome. Device-related complications occurred in 11.1% of patients at 3 years, but there was no S-ICD-related endocarditis or bacteremia.

The S-ICD is certainly an attractive system to avoid endocardial complications in the long run. However, the lack of endocardial leads has certain specific implications. First, the system does not provide pacing, except for up to 30 s of post-shock ventricular pacing. For this reason, the study methods excluded patients who had episodes of ventricular tachycardia (VT) of <170 beats/min that could potentially be terminated by anti-tachycardia pacing (ATP). Therefore, the index arrhythmia for the secondary prevention patients in this study was predominantly ventricular fibrillation (VF) or polymorphic ventricular tachycardia (PVT). Although the efficacy of the S-ICD for VT at <170 beats/min was higher compared with PVT/VF (first and second shock conversion rates of 91.7% and 100% for monomorphic VT vs. 88.2% and 96.1% for PVT/VF, respectively), the known high efficacy of ATP

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for VT (7) indicates that transvenous systems that allow for painless ATP are preferable in patients with a history of monomorphic VT. The S-ICD would also not be appropriate in the occasional patient whose arrhythmia might be suppressed by overdrive pacing.

The second broad category of patients for whom the S-ICD would not be appropriate includes patients who require pacing for bradycardia, atrioventricular block, or cardiac resynchronization therapy. Such patients should receive a de novo system with the appropriate number and types of transvenous leads. For patients with pre-existing endocardial pacemakers, it is possible to implant an S-ICD system as well, although additional screening processes are necessary to avoid unfavorable device interactions. For patients with existing pacemakers who require an ICD upgrade, the risk and benefit of lead extraction and endocardial lead implantation versus the use of an S-ICD system need to be carefully evaluated. Fortunately, by using the inclusion and/or exclusion criteria in these 2 studies, the future need for system revision to allow transvenous pacing was quite low (0.4%). Future generations of the S-ICD system may incorporate pacing features that accommodate these pacing requirements by using Blue Tooth and leadless pacing technology.

A major cause of morbidity in patients with ICDs is inappropriate shocks. The rate of inappropriate shocks in this study was 13.5%, which is similar to the rate of 11.5% reported in a substudy of MADIT II (Multicenter Automatic Defibrillator Implantation Trial II) (8). However, inappropriate shocks have been reduced in more recent studies to <5% in T-ICD systems with the use of newer algorithms for programming that incorporate longer detection times and/or higher rate cutoffs (9). The S-ICD features 2 possible tachyarrhythmia detection zones: 1) a "shock-only" zone, in which detection and therapy are based on rate only; and 2) an additional "conditional zone," in which a morphology analysis algorithm is applied in addition to rate. Burke et al. (4) pointed out that the relatively high inappropriate shock rate reported in this study was driven by the early experience in the IDE study. With the increased use of programming of 2 zones of therapy over time in these 2 studies (from 51% in the first quartile of enrolled patients to 95% in the last quartile), the rate of inappropriate shocks was reduced from 20.5% to 11.7% at 3 years. Although this rate was still higher than that achieved in MADIT-RIT (Multicenter Automatic Defibrillator Implantation Trial-Reduce Inappropriate Therapy) (9), we do not have information on the rate cutoffs and detection times programmed in the S-ICD studies, which were left up to the discretion of the investigators. It is possible that attention to these programming variables could have led to a further reduction in inappropriate shocks.

Although there was no bacteremia or endocarditis, infection was a leading complication of S-ICD implantation, with 1.7% of patients requiring extraction due to infection. Compared with an earlier study (10), in which there was a 5% risk of infection, this is a significant improvement. Better training in operative preparation and technique, as well as aggressive management of skin infection, appear to have lowered the risk of infection that could necessitate device removal.

ICDs are meant to save lives, ideally with a low rate of complications, including inappropriate shocks. We want any patient to need an ICD rarely, but when it is needed, we want it to work quickly and effectively. We have learned that programming to minimize shocks is just as effective as previous approaches to programming, while lessening the chances that a patient will receive unnecessary shocks. We now know that removing the transvenous lead from the ICD system can be done safely and effectively, and yields a potentially life-saving, but less invasive, system that is appropriate for many patients. Overall, ICD systems have become simpler with respect to implantation techniques and location, while remaining technologically sophisticated. As the poet Robert Browning once wrote (Andrea del Sarto, 1855):

> *Yet do much less, so much less, Someone says,*
> *(I know his name, no matter) - so much less!*
> *Well, less is more, Lucrezia.*
>
> —Robert Browning (11)

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