Using Floating Atrial Electrodes to Combat the Rising Tide of Inappropriate Defibrillator Therapies

Alexandru B. Chicos, MD; Bradley P. Knight, MD

Despite various implantable defibrillator algorithms and strategies used to improve discrimination between potentially life-threatening ventricular arrhythmias (ventricular tachycardia/ventricular fibrillation [VT/VF]) and more benign supraventricular tachycardias (SVTs), this remains a problem. In addition to significant discomfort and impairment of quality of life, there is some suggestion that shocks may increase mortality.1 Recording atrial intracardiac electrograms during arrhythmic episodes would be expected to improve our ability to discriminate tachycardias and thus reduce the number of inappropriate shocks. It may also lead to the diagnosis of otherwise unsuspected atrial arrhythmias that may require specific therapy, such as anticoagulation therapy for patients with atrial flutter or atrial fibrillation (AF).

The evidence available so far, however, does not clearly demonstrate that atrial electrograms reduce inappropriate shocks.2–7 Although some studies performed in patients with a dual-chamber device have shown a reduction in inappropriate detection, inappropriate shocks also were avoided in the single-chamber detection arm by using antitachycardia pacing.8 In addition, placement of an atrial lead is associated with a risk of lead dislodgement (≈4.5%) and increased procedural and fluoroscopy times compared to a single-chamber defibrillator. Thus, there currently is no strong evidence to support the addition of an atrial lead for the sole purpose of SVT discrimination and reducing implantable cardioverter-defibrillator (ICD) shocks.8

Using a single-pass VDD defibrillator lead holds the promise of offering atrial electrograms without the additional risks and procedural time related to implantation of a separate atrial lead. Similar lead designs with integrated atrial electrodes have been used in VDD pacemakers.9

In a study published by Sticherling et al in this issue of Circulation: Arrhythmia and Electrophysiology, the ADRIA (Study to Verify Proper Detection of Supraventricular Tachyarrhythmia With Single-Lead Dual-Chamber Implantable Cardioverter-Defibrillators) study, the authors investigated the use of a right ventricular ICD lead with built-in right atrial bipolar electrodes, at 15 or 17 cm from the lead tip and with interelectrode distance of 15, designed to float in the atrium. Noncontact atrial electrograms are recorded and preamplified (four times amplitude gain) in a separate atrial channel included in the dedicated generator. This A+ICD system has been shown previously to be safe and operational.10–14 Two generations of leads were used in the study: initially, the Biotronik Kainox A+ and then the Biotronik Kentrox A+, a newer design with a smaller-tip electrode area. The leads are silicone insulated, passive fixation, and single coil with a tip area of 6.0 mm² and 1.8 mm², respectively. A total of 124 patients received the A+ICD lead and were compared with 125 patients who received a standard dual-chamber system (DR-ICD). Analyzed outcomes included the sensitivity and specificity for detection of VT/VF as well as the procedural times.

Current ICD algorithms for arrhythmia discrimination include criteria related to rate, onset, stability, and morphology discrimination. The SMART tachycardia discrimination algorithm used in the Sticherling et al study10 is proprietary and has been previously validated.15 The SMART algorithm uses criteria related to rate, onset, and stability. Morphology discrimination is not used. In the present study, the VT detection rate was set very low at 130 to 140 beats/minute. The authors state that this rate was chosen in order to facilitate detection of “as many SVT episodes as possible in order to compare the efficacy of the SMART detection enhancement algorithm between the 2 groups.”10

As expected, procedural times were shorter for the A+ICD group (67 versus 79 minutes; P=0.003). Aside from shorter implant times, the VDD lead avoided the complication of atrial lead dislodgement, which occurred in 4% of patients in the DR-ICD arm, similar to reported rates. The ventricular pacing thresholds were similar in the 2 groups (1.2±1.0 V/0.5 ms versus 0.8±0.6 V/0.5 ms), and defibrillation thresholds were adequate (2 patients had high defibrillation thresholds in the A+ arm and 1 in the DR arm).

There were 1894 tachycardia episodes in the A+ group and 1316 in the DR group included in the analysis. The sensitivity for detection of VT/VF was 100% in each group. However, the specificity was only 61.8% in the A+ group and 66.2% in the DR group (P=0.22); this was lower than previously found for the same detection algorithm. Based on an analysis of a sample of 492 episodes, the authors attributed the low specificity to 3 main factors: premature ventricular contractions, which were more likely to trigger the sudden onset criterion at the lower heart rates monitored in this study, and atrial oversensing and undersensing, which occurred in 36% of A+ patients (versus 11% in the DR group). Poor
atrial sensing in the A+ group included both atrial undersensing of the noncontact atrial signal and oversensing of far-field ventricular activity, leading to tachycardia misclassification. It is worth mentioning, however, that the low detection rates used in the Sticherling et al study have the potential to lead to higher calculated specificities by virtue of their mathematical definition: true negatives/(true negatives + false positives). With inclusion of events at lower heart rates, more SVT than VT episodes are likely to be included in the analysis (because SVT generally is more likely than VT to occur at low rates), thus generating more true-negative events and resulting in a higher calculated value for the fraction that defines specificity. When the authors analyzed a small sample of 321 events in 21 patients with a cutoff value of ≥140 beats/minute, they calculated a higher specificity of 86%, similar to prior studies. The authors assume that the specificity of the detection algorithm would be better and in line with previous studies if higher rates for VT detection were set on the basis of this sample analysis, but it would be preferable to see the analysis of all the actual data.

This being considered, the difference in discrimination abilities between the 2 groups was not statistically significant. Importantly, though, the authors acknowledge that the null hypothesis of A+ICD noninferiority in terms of specificity could not be rejected; thus, noninferiority of detection specificity is not proven by this study.

But what is the impact of detection accuracy in terms of inappropriate shocks delivered? This measure would be a true one of the clinical usefulness of the noncontact atrial electrograms for discrimination. The authors report that of the 1126 false-positive episodes in the VT or VF zone, 41 resulted in shocks. Thirty-four of these shocks occurred in 7 patients in the A+ group, and 12 shocks occurred in 7 patients in the DR group. Numbers of misclassified SVT events (false-positives) and inappropriate shocks thus were higher in the A+ICD group.

The authors remark that another benefit of recording atrial electrograms is detection of AF or atrial flutter that was not previously known to be present, which may occur in ~13% of patients. We are not told how many of the patients in this study derived this benefit. One wonders, also, how many of the AF episodes could be diagnosed without having atrial electrograms available, on the basis of the analysis of ventricular electrograms during ventricular high-rate episodes using ventricular rate stability and electrogram morphology identical to that during sinus rhythm.

So what should we conclude? First, this novel ICD lead, single-coil design with an atrial bipolar records noncontact atrial electrograms, which are then filtered and amplified before being used in the detection algorithm. This study confirms that the lead is safe to use and, compared with a standard dual-chamber system, saves procedural and fluoroscopy time, is associated with fewer lead dislodgements, and has similar ventricular pacing and defibrillation thresholds. With this detection algorithm, there is no loss in sensitivity in detecting VT/VF when compared with standard dual-chamber systems. Although ventricular arrhythmia detection specificity also appears to be similar, there was a significant increase in atrial undersensing and oversensing events when using noncontact recordings. With the algorithm and detection settings that were used in this study, there was a large number of SVT episodes misclassified as VT. Few of these episodes resulted in inappropriate shocks, but more were noted in the A+ICD group than in the DR-ICD group (although in the same number of patients), and it is not clear whether this difference was statistically significant. In any case, the use of atrial electrograms in automated detection algorithms to discriminate VT/VF is not demonstrated to be clearly helpful in reducing inappropriate shocks compared to dual-chamber systems. The results of an additional trial are pending. This is not to say that atrial electrograms cannot be useful, because they certainly can help when making a diagnosis, particularly when reviewed by expert readers. So, we agree with the authors’ conclusion that this system “provides an attractive alternative to an additional atrial lead if one wishes to obtain an atrial electrogram in ICD patients.”

Disclosures

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