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Practice Guidelines

The VDD ICD lead: Friend or Foe?

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Implantable cardioverter-defibrillators (ICDs) are established therapy for primary prevention of sudden death, especially in patients with left ventricular dysfunction and heart failure. What remains unestablished is the need for an atrial lead [1]. The value propositions include the ability to provide atrial support pacing, discriminate between supraventricular and ventricular arrhythmias, and provide information about atrial high rate episodes. These have to be balanced against the procedural risks inherent to implanting the atrial lead.

When a patient requires atrial pacing support, the need for the atrial lead is self-evident. However, in the United States, an atrial lead is implanted in nearly 2/3 of patients without a pacing indication [2]. There is significant regional variation in this practice. Besides the desire to discriminate between supraventricular and ventricular arrhythmias and identify atrial high rate episodes, there is the desire to avoid having to re-operate later in the event that the patient requires pacing support due to sinus or AV node dysfunction either due to progression of underlying disease or a consequence of medications.

Implicit in the high use of an atrial lead is the assumption that the benefits exceed the harm. What exactly is the harm? Two studies clearly defined the excess risk that comes with the decision to implant the atrial lead. Using the National Cardiovascular Data Registry ICD Registry, Dewland and colleagues identified 104,049 patients who received either a single or dual chamber ICD; the latter was implanted in 62% of patients [3]. In comparison to a single chamber ICD, implantation of a dual chamber ICD was associated with an increased rate of periprocedural complications (odds ratio 1.40; 95% confidence interval: 1.28 to 1.52; $p < 0.001$) and in-hospital mortality (odds ratio 1.45; 95% confidence interval: 1.20 to 1.74; $p < 0.001$). A second study by Peterson et al. sought to understand the long-term post-implantation risks [4]. They evaluated 32,034 patients with left ventricular dysfunction who underwent ICD implantation for primary prevention of sudden death; no patient had an indication for atrial pacing or cardiac resynchronization therapy. Again, 62% of patients received a dual chamber device. The authors evaluated procedural complications within 30 days of device implant (pneumothorax requiring a chest tube; hematoma requiring a blood transfusion or surgical re-intervention; cardiac tamponade); procedural complications within 90 days of device implant (mechanical complication requiring re-operation for system, generator, and/or lead revision; device related infection; need for ICD replacement); and long-term outcome within the first year of device implant (all-cause mortality; re-hospitalization for heart failure or any reason). A complication within the first 90 days occurred significantly more commonly in patients undergoing dual chamber ICD implantation (4.76% versus 3.53% in single chamber patients; (difference −1.23%; 95% confidence interval: 1.67 to −0.79; $p < 0.001$). There was, however, no difference in 1-year likelihood of re-hospitalization for heart failure or all-cause mortality). These data suggest that the atrial lead is not necessarily a benign intervention.

To preserve the benefit of sensing atrial activity without the need to implant an additional lead, an ICD lead (Linox^{Smart} DX [Biotronik SE & Co, Berlin, Germany]) was developed, which incorporates a floating atrial dipole. The lead is coupled to a dedicated ICD generator, which amplifies and filters the signals to maximize atrial sensing and minimize far-field oversensing of ventricular signals. The lead is manufactured in 2 subtypes: a 15 and 17 cm version based on the distance between the shock coil and atrial dipole.

In this issue of the *Journal*, Marai and colleagues report on their single center prospective experience with this lead [5]. They implanted 73 patients; of these patients, 5 had history of paroxysmal atrial fibrillation and 1 had persistent atrial fibrillation. In all patients, the P wave amplitude at implant was $\geq$0.8 mV (This was chosen as the lowest level of acceptable atrial sensing since the maximal atrial sensitivity on the ICD is 0.4 mV) By 1-year post-implantation, 11% of patients had a P wave amplitude < 0.8 mV. Unfortunately, no information is provided about the baseline P wave amplitude in these patients. There was a numerical trend towards more appropriate sensing in patients implanted with the 15 cm as compared to the 17 cm ICD lead (93.5% vs. 81.5%, $p = 0.11$). Atrial fibrillation was diagnosed in 3 (4.5%) of the 67 patients without known history of AF. Only 1 inappropriate shock was observed; the underlying rhythm in this patient is not identified. However, this patient had a reduction in his P wave amplitude to 0.2 mV. From this experience, the authors state that the findings "raise concerns regarding the long-term reliability of this Linox^{Smart} DX ICD lead".

To put these data in perspective, it is helpful to review the available additional data on this lead. Several prior studies showed

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acceptable P wave amplitudes during follow-up [6–8]; however, none specifically assessed the frequency of P wave amplitudes < 0.8 mV. Finally, most recently, Thomas and colleagues reported on 150 patients without prior atrial fibrillation who were implanted with this ICD lead across 8 centers and then followed prospectively for a median of 12-months [9]. Interestingly, patients with a sensed P wave amplitude < 2 mV through the ICD were excluded. During 12 months of follow-up, the P wave amplitude dropped to <2 mV in 7% of patients and dropped to <1 mV in 3% of patients. No patient required addition of an atrial lead for atrial pacing or inadequate atrial sensing. There was, however, a 13% incidence of inappropriate detection of atrial high rate sensing, most commonly due to electromagnetic interference. No inappropriate ICD therapies were observed.

The question is how can these data inform clinical practice? To my mind, we can make the following recommendations:

1. The need for the atrial lead should be carefully evaluated. This is being implanted in 2/3 of patients without a pacing indication and is associated with a significantly higher rate of complications.
2. An ICD lead with a floating atrial dipole can sense atrial activity and facilitate detection of atrial high rate episodes and be incorporated into discrimination algorithms. All available studies with this lead show a very low rate of inappropriate ICD shocks. Importantly, the lead mitigates the risks inherent to implanting an atrial lead.
3. In some patients, atrial sensing falls over time. Using an arbitrary cutoff of 0.8 mV, this occurred in 11% of patients. Fortunately, a clinical issue was observed in only a single patient in this study.
4. Finally, long-term sensing was significantly worse with the 17 cm lead. In these patients, nearly 1/5 of patients had a P wave amplitude <0.8 mV. Since the choice of the lead is at the discretion of the operator, additional studies should attempt to identify patients who should not receive a lead with 15 cm spacing.

I congratulate the authors for adding to our understating of the performance of this novel lead. I encourage even longer-term follow-up of this cohort to determine whether the compromise in atrial sensing in a small subset of patients translates into adverse clinical outcomes (e.g., undersensing of atrial arrhythmias; inappropriate ICD shocks; need for system revision). In the interim, we will need to continue to use our experience and interpretation of the available literature to guide decision making in individual patients.

Declaration of competing interest

Consultant to Boston Scientific and Medtronic.

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