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COMMENTARY

Primary prevention programming for defibrillators: need for a device clinic-based intervention

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The advent ofprophylactic or primary prevention implantation of implantable cardioverter-defibrillator (ICD) devices for patients with advanced cardiomyopathy has significant expanded indications for ICD implants, based on several randomized controlled trials that demonstrated a survival benefit, notably the Multicenter Automatic Defibrillator Implantation Trial II (MADIT II) and the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) trials [1]. Subsequent recognition of the adverse effects of ICD shocks led to the increased use of anti-tachycardia pacing (ATP) in lieu of defibrillation therapy, based on randomized controlled data from the PainFREE Rx II trial [2]. Furthermore, to prevent adverse effects of excessive or inappropriate ICD therapies for ventricular and non-ventricular arrhythmias, strategic programming (detection and treatment of only fast, sustained ventricular tachycardia with initial ATP, followed by high-output ICD shock) was evaluated in the Primary Prevention Parameters Evaluation (PREPARE) study [3]. The favorable findings from this observational study eventually led to the design of the Multicenter Automatic Defibrillator Implantation Trial–Reduce Inappropriate Therapy (MADIT-RIT) study [4] and other studies to minimize inappropriate ICD therapies and mortality [5]. Based on this evidence, the Heart Rhythm Society (HRS) and other electrophysiology (EP) societies strongly recommend appropriate primary prevention programming that is manufacturer specific [6]. Despite this recommendation, uptake in the EP community and device clinics appears to be low.

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In this issue of the *Journal of Interventional Cardiac Electrophysiology*, Teerawongsakul and colleagues report an observational analysis of two high-volume academic electrophysiology centers in the USA, using data from their device clinics between 2014 and 2016 [7]. The authors found that in one center, 47% of initial programming in primary prevention patients was appropriate and guideline concordant, while the other center only had 1% of patients with guideline concordant ICD programming. The analysis excluded patients with inherited arrhythmogenic cardiomyopathies, subcutaneous ICDs, and patients with less than 3 months of follow-up. The primary endpoint of first-ICD therapy (ATP or ICD shock) was unsurprisingly lower in the center with higher guideline concordant programming (1.9 per 100 person-years vs. 2.5 per 100 person-years; adjusted hazard ratio of 0.37, 0.21–0.64). This primary endpoint was primarily driven by a reduction in ATP therapy, and as such, ICD shocks and associated mortality were no different among the centers.

The overall message is sobering. Guideline concordance for primary programming (even at academic centers) is moderate at best, and nearly absent (~1%) in the worst-case scenario. The finding that ICD therapy would be lower when primary prevention programming is appropriately programmed is expected, given that it is a real-world confirmation of prior randomized controlled studies. The more important message from this paper is that electrophysiologists and EP centers are not doing enough to ensure that patients benefit from primary prevention programming. Does this suggest that implanting electrophysiologists were worried about underdiagnosis and missed therapies for ventricular tachyarrhythmias? Given the retrospective nature of the study, it is difficult to speculate on decision-making at the time of implant or in device clinic follow-up. However, it appears more likely that better guideline concordance noted at one of the centers was a corollary of the device manufacturer chosen (more Medtronic ICDs were implanted at the higher concordance center, and the nominal, out-of-the-box setting is optimized for primary prevention with Medtronic devices). This suggests that implanting physicians may not be actively choosing optimal programming at the time of ICD implantation.

What strategies are most likely to improve guideline concordant programming across the spectrum of EP centers? This clearly should be high priority issue within the EP community, as this is a relatively low-effort intervention that is directly linked to better patient outcomes [8, 9]. An obvious solution would be for the major device manufacturers to have their specified primary prevention programming as the out-of-the-box nominal setting. This would immediately improve compliance across a wide variety of EP laboratory settings, since three-quarters of ICD implants in the USA are for primary prevention [10]. While this type of intervention demands less of the implanting electrophysiologists and would have a system-wide effect, it would need motivation and action at the policy level of each device manufacturer.

Another option is for the HRS and other EP societies to mandate/guide all major device manufacturers to train their clinical specialists in primary prevention programming at the index implant. By having clinical specialists use this programming as the default strategy, unless otherwise directed by the implanting electrophysiologist, compliance with guidelines should significantly improve. The resultant conversations regarding primary prevention programming in the EP lab would also have downstream effects in educating and raising awareness among trainees and EP lab staff.

Finally, a more immediate and comprehensive solution at the institution or practice level would be to make primary prevention programming a key quality improvement metric for the EP device clinic. There is a significant opportunity to have the device clinic medical directors, managers, and device clinic nurses to champion this cause. The first step would be to ensure consensus among all implanting electrophysiologists within a practice and then to incorporate an institutional policy to verify primary prevention programming at the first device clinic visit following an ICD implant. This would complement efforts in the EP laboratory to program appropriately at the index implant, but confirmation and documentation of primary prevention programming can be delegated to the device clinic. At our institution, we have initiated this 2-step practice. The aim is always to program appropriately at implant, but the device clinic is given the onus to verify and change programming for manufacturer-specific primary prevention programming. We believe this model should work for most EP practices and represents a no-cost quality improvement initiative to achieve better patient outcomes.

Declarations

Conflict of interest Dr A.R. Atreya has received honoraria or consultancy fees from Abbott, Connected Care, and Abiomed. Dr. J.P. Mounsey has received honoraria or consultancy fees from Medtronic and Boston Scientific.

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