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Editorial Comment

Over, Under, or Just Right? How do we interpret ICD utilization in the modern era?

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Over 5 million individuals are afflicted with heart failure in the United States per year. [1] Current guidelines based on the MADIT- I and II, MUSTT and SCDHeFT trials recommend the use of pharmacologic as well as implantable cardioverter defibrillator (ICD) therapy as Class I indications for the prevention of sudden cardiac death (SCD) in a subgroup of patients (depending on their ejection fraction, NYHA class, and a variety of other parameters). [2-7] However, despite these guidelines, the use of ICDs has been reported as suboptimal in prior publications as well as in the article by Pillarisetti, et al in this issue of the *Journal*. [8]

Pillarisetti, et al present the current state of ICD use in their single center experience, noting profound underutilization of ICDs as a prophylactic treatment for sudden cardiac death. [8] They subsequently went on to carefully examine the reasons behind ICD underuse. In their retrospective study, they found that though pharmacologic treatment of SCD with a beta-blocker, angiotensin cardioverter enzyme inhibitory/angiotensin receptor blocker (ACE/ARB), diuretics and aldosterone antagonists (AA) was nearly perfect, the implementation of ICDs for treatment of patients who met ICD Class I indications was only 1/3 of the expected rate. [2]

Over- or under-utilization?

Prior to delving into the data, it is important to put into perspective the last several years in electrophysiology which have proven complicated for many ICD implanters. After Al-Khatib, et al suggested a high rate of inappropriate ICD implantation in the United Stated, investigations by the Department of Justice into the practice patterns of implanting centers became more common. [9-11] However, one clear limitation of that seminal publication was precisely how "appropriateness" was defined - namely by criteria advanced by Medicare/insurers rather than strictly abiding by guidelines. The issue at hand is that, while all legislation to identify appropriate versus inappropriate is well-meaning, the number of different guidelines to which physicians must refer is extensive and can prove to be near

impossible for the average, busy clinician to navigate through. Nowadays, there are consensus guidelines, appropriate use criteria, Medicare reimbursement guidelines, criteria put forth by the Department of Justice, and assessment tools by the National Cardiovascular Data Registry that may inform the clinician about ICD appropriateness. These varied resources do not perfectly overlap. Furthermore, while in the guidelines statements that something should be done (i.e. a Class I indication) or should not be done (i.e. a Class III indication) are present, an ICD implant for an indication not specifically mentioned in those guidelines does not necessarily mean that an ICD in such a patient is inappropriate.

This difficulty in clinical decision making is highlighted best by the appropriate use criteria, in which a large number of considerations based on comorbidities and other less clear-cut cases not specifically mentioned in the guidelines were adjudicated to fall within the realm of "may be appropriate" - suggesting a lack of evidence for or against.[7] Thus, despite a wealth of data and ongoing research into which patient populations would best meet criteria for an ICD implant, for many patients, decision-making is still quite murky.

How do we determine underutilization?

The patient population probably best understood in terms of primary prevention indications for ICDs is that of patients with heart failure due to reduced ejection fraction (i.e. <35%). Putting the article by Pillarisetti, et al in context requires a close review of who did not receive an ICD and why.[8] Amongst patients who did not receive ICD implants in their study, there are cohorts of patients who should perhaps never have qualified. For example, 20.4% (those who had improvement in their EF and those who died within one year of diagnosis or who were expected to have a low one year survival) should not have received an ICD according to current guidelines and appropriate use criteria. One can debate the fact that the currently accepted timeline to wait for EF improvement after instituting guideline directed medical therapy is 3 months. However, that time cut-off was based on an arbitrary time period used in SCD-HeFT and not based on any systematic data of the amount of time necessary to see EF recovery. In fact, recently published data suggests that perhaps 3 months is not long enough to wait for EF recovery given that nearly 1/3 of patients implanted with a primary prevention ICD may demonstrate sufficient EF recovery at the time of generator change (i.e. years after diagnosis) to no longer qualify.[12] In addition, expected survival of less than 1 year is considered a contraindication to ICD therapy and, while retrospective, those patients who did die within one year likely reflected a group of patients who should never have been considered for ICD implantation.

While the authors also postulate possible reasons patients refused an ICD, the number of patients refusing is in keeping with prior published studies (22.6%) and should not be considered underutilization since it reflects a patient's right to refuse, though we agree it is important to understand better why these patients refuse. Furthermore, there were several other reasons that cannot be considered "underutilization" as it seems from the reasons offered that the patients were, in fact, not eligible for an ICD (lack of patient followup which is a class III indication for ICD implantation, active infection such as osteomyelitis, comorbidities precluding implant, etc) which would account for another 19.4% of those not implanted. Thus, if it is assumed all patients who received ICDs were appropriate, a total of 39% of eligible patients did not receive ICDs, largely due to lack of physician discussion with the patient rather than the much higher number quoted.

Why is utilization not at expected levels?

There are several reasons for the noted discrepancies in ICD utilization. As Pillarisetti, et al point out, [8] one reason may be that patient education and reinforcement of the necessity of ICD treatment is lacking. Many patients may have chosen not to pursue an ICD due to