Editorial Comment

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

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Key words: Heart failure, defibrillator, sudden death

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

misunderstanding the therapy from media reports of recalls (eg, of the Fidelis lead), or out of fear of pain from defibrillation from another's experience.[13] In such cases, it is imperative for physicians to educate patients about the truth of ICD therapy and dispel any misconceptions.[13] Modern devices, such as subcutaneous ICDs (which do not require implantation of transvenous leads), evolving leadless device technology, improved algorithms for detection of ventricular arrhythmias to reduce the rate of inappropriate shocks, and research into painless defibrillation may also help improve patient perception of ICDs.

The starkest finding is that the plurality of patients did not receive ICDs due to lack of discussion by the physician. This is a critical issue and either reflects lack of provider education or other barriers that need to be identified. Discussion of ICDs, given its clear potential life-saving benefit in patients with irreversible cardiomyopathy, should be considered as much a performance measure as use of ACE/ARB or beta-blockers. Thus, better research into why physicians do not have the discussion with patients is necessary.

Yet another reason for ICD underutilization may be the imprecise nature of current guidelines when it comes to assessing appropriateness of implantation in patients with varying comorbidities. While the appropriate use criteria (AUC) do allocate an entire section of their document to assessing comorbidities and how they impact appropriateness of implantation, the majority of the indications are listed in the middle range of "M," suggesting that it is still unclear as to whether the patient should be implanted or not. [7,9] This leaves the ultimate decision up to the physician and patient, and given that patients can be influenced by outside factors (i.e. media), it is not surprising that the ICD implantation rate is low. However, this issue can be seen the other way - namely that perhaps more data is needed to better inform clinicians about which sub-populations reflect patients in whom ICD should not be considered - whether due to age, renal failure, or other comorbidities.

Future Innovations

Other more proactive ways to prevent underutilization of ICD in the future involve significant changes in the way ICD care is delivered. Creation of simpler, inexpensive and novel devices along with integrated preventative ablative therapies and pharmacologic treatments for heart failure are stepping stones for achieving this revolutionized form of SCD care. With increasing technological advances and the growing prevalence of percutaneously delivered devices since its introduction by Sosa et al., [14] epicardial devices that have the potential to deliver painless defibrillation to patients are being generated. [15] If these devices are successful, then their use may help in decreasing the fear of defibrillation for patients and encourage ICD implantation.

While the use of beta blockers, ARBs, and ACE inhibitors are still implemented unanimously in patients with heart failure, they have shown varying success. Newer agents with angiotensin-neprilysin inhibition are showing even more promise in managing HF. [16] The PARADIGM-HF trial laid out a novel approach to heart-failure therapy consisting of angiotensin-receptor blockade and neprilysin inhibition with LCZ696 (consisting of both sacubitril and valsartan). [17] Their findings showed that cardiovascular mortality fell by nearly 20% and overall mortality decreased by 16% compared with enalapril. [16] Neprilysin, an endopeptidase that metabolizes peptides, when inhibited is thought to lead to the degradation of vasoactive peptides, including natriuretic peptides that vasodilate vessels and lead to sodium excretion, thereby reducing the load on the heart in patients with HF. [16]

Conclusion

Ultimately, a better understanding of current guidelines coupled with novel ICD devices and pharmacological regimen may be a solution to reducing the rate of ICD under-utilization.

Disclosures

Dr. Asirvatham receives no significant honoraria and is a consultant with Abiomed, Atricure, Biosense Webster, Biotronik, Boston Scientific, Medtronic, Spectranetics, St. Jude, Sanofi-Aventis, Wolters Kluwer, Elsevier.

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