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## Toward More Optimal Use of Primary Prevention Implantable Cardioverter-Defibrillators

### How Do We Get There?

Sana M. Al-Khatib, MD, MHS

The implantable cardioverter-defibrillator (ICD) has been shown in several randomized clinical trials to improve the survival of patients with systolic heart failure (HF).<sup>1-4</sup> As a result, practice guidelines designate ICD therapy as a class I indication in many patients with HF.<sup>5-7</sup> Notwithstanding the evidence from randomized clinical trials and practice guidelines, several studies have demonstrated significant underutilization of primary prevention ICDs in many HF patients who are potentially eligible for this therapy.<sup>8,9</sup> Some of these studies also described racial and sex-based disparities in the use of this device.<sup>8-10</sup> In one investigation of a national HF registry, the majority of patients with a history of myocardial infarction and a left ventricular ejection fraction (LVEF)  $\leq 35\%$  did not receive an ICD, and black patients were significantly less likely than their white counterparts to receive one.<sup>8</sup> In another study that used Medicare Claims data, women were 3 times less likely than men to receive an ICD for a primary prevention indication.<sup>10</sup> In a third study of ICD use among patients with HF and an LVEF  $\leq 30\%$  in the American Heart Association's (AHA) Get With the Guidelines-Heart Failure (GWTG-HF) program, only a third of these patients had an ICD in place or an ICD planned after discharge.<sup>9</sup> Importantly, this analysis showed major race- and sex-based disparities.<sup>9</sup>

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#### Articles see p 146 and 152

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To appreciate the gravity of these findings, two facts must be emphasized. First, sudden cardiac death is the leading cause of death in the United States.<sup>11,12</sup> Second, the ICD is the most effective therapy currently available to prevent sudden cardiac death.<sup>13</sup> Thus, underutilization of ICD therapy and racial and sex-based disparities in its use constitute major public health problems that must be addressed. To address these issues, the medical community should determine why this life-saving therapy is being underused and why women and racial minorities are significantly less likely than their counterparts to receive this therapy.

Several potential barriers to the optimal use of ICD therapy have been reported.<sup>14</sup> These barriers exist at the patient and health care provider levels. Patients may refuse this therapy

because of their inability to grasp their risk of sudden death with and without an ICD, their alarm over the implantation procedure and the potential negative impact that the ICD may have on their quality of life, their fear of ICDs fueled by several previous device and lead recalls, and their disbelief in the benefits of ICD therapy, especially in the absence of symptoms. Furthermore, personal and cultural values probably influence patients' decisions regarding an ICD.<sup>14</sup>

What about health care providers? Are they withholding ICD therapy from their patients knowingly? In many cases, this is unlikely to be true because one of the reasons that health care providers are underusing this therapy is difficulty identifying patients in their practice who may benefit from an ICD. This difficulty is largely driven by the limited use of tools that can help health care providers identify potentially eligible patients as well as the absence of clinical decision support, an electronic medical record, and multidisciplinary disease management programs in most clinical practices.<sup>14</sup> Other factors that may play a role are health care providers' unawareness of ICD practice guidelines or their inability to interpret some aspects of the guidelines that are admittedly vague. For example, what constitutes optimal medical therapy? What is the best approach to making a judgment regarding a patient's functional status and quality of life? Other reasons for why providers may not recommend an ICD when indicated are concerns over the safety and reliability of ICDs and leads, skepticism about the applicability of clinical trial results to patients seen in routine clinical practice, discontent with the high rate of inappropriate ICD shocks, trepidations about the cost and cost-effectiveness of ICD therapy, the perceived need for more optimal risk stratification for sudden cardiac death, and physicians' biases and personal beliefs.<sup>14</sup>

Thus, the key question at hand is: How can we improve quality of care related to ICDs? Education is pivotal. Patients must be educated about their risk of sudden cardiac death and the role of ICD therapy in reducing this risk. They need to know that the lack of symptoms does not protect them from sudden cardiac death. Equally important is to educate patients about the potential complications of the implantation procedure, the risk of shocks (both appropriate and inappropriate) and their potential negative effect on quality of life, and the risk of device and/or lead failure. If expected, these potential adverse events will be better accepted by patients. Likewise, educating health care providers about the guidelines, the benefits and risks of ICD implantation, and the risk of shocks and device and/or lead failure is essential. Certain aspects of the guidelines must be clarified to help physicians improve their performance.

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In addition to education, it is important to implement web-based registries that offer opportunities for quality improvement by measuring and benchmarking quality of care and meaningful outcomes. This approach has been tested in HF patients through the Organized Program To Initiate life-saving treatment In hospitalizED patients with Heart Failure (OPTIMIZE-HF).<sup>15</sup> This program, which has developed into the AHA-GWTG database for HF, tracks and benchmarks performance measures, collects data on imperative outcomes, and helps hospitals improve patient care by providing them with standardized orders, educational materials for patients and health care providers, and critical pathways for health care delivery.<sup>15</sup> Participation in OPTIMIZE-HF has been associated with an increase in the use of evidence-based therapies for HF and improved adherence to practice guidelines.<sup>16</sup>

Other quality improvement initiatives have been shown to improve quality of care. One such initiative is the Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting (IMPROVE-HF) program.<sup>17</sup> One study examined the effect of this program on 7 HF-related quality measures including the use of an ICD in potentially eligible patients. A total of 15 177 patients (4383 women) were included in this analysis. At baseline, the rate of ICD use was low in both sexes but significantly lower in women than men (40.7% versus 52.2%). After 24 months of participation in IMPROVE-HF, the rate of ICD use increased significantly both for women (increased from 40.7% to 75.6%) and men (increased from 52.2% to 80.4%). Notably, the absolute magnitude of improvement in ICD use was significantly higher in women than in men ( $P < 0.01$ ).<sup>18</sup> To improve adherence to guidelines, IMPROVE-HF provides sites with evidence-based algorithms and practice pocket cards, clinical trials and current guideline information, toolkits, workshop materials, and customized patient assessment and management forms to help with the identification of at-risk patients.<sup>17,18</sup> This highlights the value of a multifaceted approach to improving adherence to guidelines and reducing disparities.

One important approach to improving quality of care is through the use of performance measures that are central to public reporting and pay-for-performance programs. In 2010, many HF performance measures were proposed. Among these measures is ICD counseling in eligible patients. This performance measure, along with other future ICD-related performance measures, may help improve adherence to guidelines and reduce disparities. To accomplish this latter goal, these performance measures should be reported by race, ethnicity, sex, and age.

Another intervention that could help health care providers increase their appropriate use of ICDs is by improving the identification of eligible patients primarily by using validated screening tools. Furthermore, increasing resources to facilitate access to care, improving the safety and reliability of ICDs and ICD leads, decreasing the rate of inappropriate ICD shocks, and developing better sudden cardiac death risk stratification tools are likely to be effective at optimizing the use of primary prevention ICDs. Equally important is gaining a better understanding of how personal and cultural values influence patients' and health care providers' decisions regarding an ICD.

This issue of *Circulation: Cardiovascular Quality and Outcomes* includes two reports on the use of primary prevention ICDs.<sup>19,20</sup> The first article, by Allen LaPointe et al,<sup>19</sup> reports the results of a detailed chart review performed at the authors' institution to identify patients hospitalized with HF and depressed LVEF between January 1, 2007, and August 30, 2007, who were truly eligible for a primary prevention ICD. Within this population, the authors determined the rate of ICD nonuse up to 1 year after HF hospitalization and reasons for nonuse. They also attempted to examine patient characteristics associated with the lack of ICD use. Of the 542 patients found to be potentially eligible for an ICD, 224 (41%) did not have one. Notably, women and older patients were significantly less likely to have an ICD. After detailed chart review, the authors found that of the 224 patients with no ICD, 117 (52%) were not eligible for the device, based on improvement in the LVEF, limited life expectancy, or severe HF symptoms. Importantly, 38 (17%) patients refused an ICD. As such, only 69 (13%) patients who were eligible for an ICD failed to receive one. Examining variables independently associated with ICD nonuse in these 69 patients revealed the following 3 factors: absence of ventricular arrhythmias, hospitalization in a noncardiology service, and lack of health insurance. The authors concluded that the true rate of ICD underuse may be appreciably lower than what was previously reported and that after accounting for ICD eligibility, sex, and age disparities in ICD use were no longer present.<sup>19</sup>

The authors should be commended for taking on this onerous task. Detailed review of hundreds of charts requires substantial resources. Their research is important because administrative and other national registries have limited clinical information and may not capture vital information, such as contraindications to a particular therapy, patient refusals of recommended interventions, and long-term follow-up. The study by Allen LaPointe et al<sup>19</sup> has a few limitations that must be kept in mind when interpreting its findings. This study was conducted at one of the premier institutions in this country. As such, its results may portray a best-case scenario. In addition and as acknowledged by the authors, the number of patients in each group was relatively small. This may have deprived the authors of achieving adequate statistical power to show significant associations. This limitation may have especially affected their analysis of factors that are independently associated with nonuse of ICDs in the 69 patients who were truly eligible for one. Notwithstanding these limitations, this study by Allen LaPointe is a good addition to the literature because it highlights the importance of verifying findings derived from registries through chart reviews. It is hoped that this research will encourage other investigators to validate the findings of this study in other practices and other patient populations.<sup>19</sup>

The second report, by Gravelin et al,<sup>20</sup> investigated the effect of implementing a screening tool on the appropriate identification of patients who may benefit from an ICD and whether this tool would prompt referral to an electrophysiologist for ICD implantation. The screening tool was included in the medical records of patients seen in 2 outpatient cardiology offices, and it queried the patient's LVEF and whether the patient was referred to an electrophysiologist. The number of appropriate referrals to an electrophysiologist was compared with the number of such

referrals made before implementation of the screening tool. The screening tool resulted in a significantly higher referral rate (80% versus 33% at site 1 and 100% versus 60% at site 2). Notably, of all patients offered to be referred to an electrophysiologist, only 41% accepted.<sup>20</sup>

The authors should be acclaimed for performing this important study. Indisputably, there is an urgent need for tools that can help health care providers identify patients in their practice at risk for sudden cardiac death. To be worthwhile, these tools must be clear and easy to implement. They also must be pilot-tested in various types of practices and validated before dissemination. With the advent of electronic medical record, the implementation of such tools will undoubtedly be more plausible. Thus, for now, and as acknowledged by Gavelin et al, their results must be viewed as hypothesis-generating because their tool still must be tested and validated in other practices while minimizing the possibility of observation bias. Finally, given that the majority of patients who were identified for ICD therapy refused referral to an electrophysiologist, this study highlights the need to better understand how personal and cultural beliefs and how the quality of ICD counseling influence patients' decisions about an ICD.<sup>20</sup>

That two studies in this issue of the journal have tackled the use of primary prevention ICDs is quite encouraging. Indeed, this may be a reflection that the medical community is striving to better understand the problem of ICD underuse and is ready to implement tools and programs that could enhance the use of this life-saving therapy in patients who could benefit from it. More devoted efforts in this arena will probably result in more optimal use of primary prevention ICDs in the near future.

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