Randomized clinical trials have clearly shown that the implanted cardiac defibrillator (ICD) saves lives1–3 and that cardiac resynchronization therapy (CRT) and combined ICD and CRT devices reduce both heart failure and mortality.4–6 However, during long-term follow-up of patients with these implanted devices, only a minority will use appropriate ICD therapy for life-threatening ventricular tachyarrhythmic events. For example, in the Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II), only 35% of the patients in the ICD arm received appropriate ICD therapy (shock or antitachycardia pacing) during 3-year follow-up.7 The challenge facing the medical profession is how to better identify and select patients who will benefit from implanted ICD or combined ICD and CRT devices so as to achieve greater therapeutic efficacy without losing patients. During recent years, several noninvasive and invasive electrophysiological tests have been evaluated, including signal-averaged ECG, heart rate variability, heart rate turbulence, T-wave alternans, and programmed electrophysiological testing, but the risk-stratification results from these tests have not been very encouraging. Recently, Goldenberg et al demonstrated that the ICD:conventional therapy hazard ratio in patients with advanced renal disease (blood urea nitrogen >50 mg/dL) and in good-risk patients without adverse clinical factors such as heart failure, atrial fibrillation, older age, and wide QRS complex, renal dysfunction was close to 1.0 in 35% of the ICD-treated patients, with no evident benefit from the ICD.8 The remaining 65% of the at-risk ICD-treated patients received considerably enhanced benefit from the ICD, with a 50% or greater reduction in mortality. These findings are encouraging, but we should be able to do better.

A thoughtful and innovative approach for analyzing risk-benefit considerations for patients treated with the ICD is presented in the article by Koller et al9 in the current issue of Circulation. In the introduction, the authors point out the obvious: patients who die before the first appropriate ICD therapy (shock or antitachycardia pacing) during 3-year follow-up.7 The challenge facing the medical profession is how to better identify and select patients who will benefit from implanted ICD or combined ICD and CRT devices so as to achieve greater therapeutic efficacy without losing patients. During recent years, several noninvasive and invasive electrophysiological tests have been evaluated, including signal-averaged ECG, heart rate variability, heart rate turbulence, T-wave alternans, and programmed electrophysiological testing, but the risk-stratification results from these tests have not been very encouraging. Recently, Goldenberg et al demonstrated that the ICD:conventional therapy hazard ratio in patients with advanced renal disease (blood urea nitrogen >50 mg/dL) and in good-risk patients without adverse clinical factors such as heart failure, atrial fibrillation, older age, and wide QRS complex, renal dysfunction was close to 1.0 in 35% of the ICD-treated patients, with no evident benefit from the ICD.8 The remaining 65% of the at-risk ICD-treated patients received considerably enhanced benefit from the ICD, with a 50% or greater reduction in mortality. These findings are encouraging, but we should be able to do better.

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association.

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time-dependent risk factors such as interim heart failure during follow-up are the major risk factors for appropriate device therapy.\(^1\)\(^2\) The failure of Koller et al to include interim (postenrollment) time-dependent covariates such as heart failure, coronary events, and interim drug changes and usage in the risk analysis weakens the interpretation of the findings. Programming of ICD and combined ICD and CRT devices was not standardized or uniform, and information is not provided about the specifics of antitachycardia pacing and shock detection therapy zones used. The rate at which the ventricular back-up pacing was set would be important to know because ventricular pacing can affect heart failure. Also, the authors fail to provide any information about the frequency of inappropriate ICD therapy. Because postmortem device interrogation was not routinely performed, it may be that some of the deaths without documented prior ICD therapy may have been a failure of the device to terminate the first fatal ventricular fibrillation episodes.

Many advances have taken place in device technology and in clinical electrophysiological practice since patient enrollment began in the Koller registry in 1994. Nevertheless, the competing-risk approach used in the study opens a new chapter in the application of risk stratification to implanted electrotherapeutic devices. The authors are to be commended for focusing on ways to save lives.

**Disclosures**

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**References**


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