Centers for Medicare and Medicaid Services' Decision to Reconsider Coverage Indications for ICDs

Where to Now?

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Several well-designed and -conducted randomized clinical trials (RCTs) have proven the survival benefit of implantable cardioverter defibrillators (ICDs).[1] This benefit has been demonstrated in patients who survive a cardiac arrest attributable to a ventricular tachyarrhythmia or have sustained ventricular tachycardia not attributable to a transient or a reversible cause.[1] The survival benefit of ICDs has also been shown in patients with significant systolic dysfunction (left ventricular ejection fraction [LVEF] ≤35%) attributable to ischemic or nonischemic cardiomyopathy.[1] The compelling evidence on the benefits of ICDs led the Centers for Medicare and Medicaid Services (CMS) to cover secondary and primary prevention ICDs in Medicare beneficiaries. However, for primary prevention ICDs, CMS provides coverage with evidence development that requires clinicians to enter data on primary prevention ICD implants in Medicare beneficiaries into the National Cardiovascular Data Registry (NCDR) ICD Registry.

In their Coverage with Evidence Development Decision Memorandum for ICDs (CAG-00157R3) issued in 2005, CMS stated that they had determined that the evidence is adequate to conclude that an ICD is reasonable and necessary for patients with ischemic cardiomyopathy and nonischemic dilated cardiomyopathy >9 months (>3 months if patient data are entered into a registry), New York Heart Association class II and III heart failure, and measured LVEF≤35% (as long as they do not have any of the exclusionary criteria such as a limited life expectancy <1 year). These criteria are aligned with recommendations in professional guidelines on primary prevention ICDs in patients with ischemic or nonischemic cardiomyopathy.[1] Specifically, the 2012 American College of Cardiology/American Heart Association/Heart Rhythm Society guidelines designate the ICD as a class I indication in patients with ischemic or nonischemic cardiomyopathy, an LVEF≤35%, and New York Heart Association class II or III.[1] On May 30, 2017, CMS announced that they are reopening their national coverage analysis to reconsider coverage indications for ICDs. So, how does the evidence on ICDs today compare with the evidence that prevailed when CMS issued their 2005 memorandum?

In comparison with 2005, the available evidence today is even more supportive of the role of primary prevention ICDs in patients with ischemic or nonischemic cardiomyopathy. The findings of RCTs on ICDs have been supported by data from numerous research projects that have been completed using the NCDR ICD Registry, which CMS had hoped would answer many important clinical and health policy questions. One study used patient-level data to compare the characteristics and outcomes of patients in the pivotal MADIT II study (Multicenter Automatic Defibrillator Implantation Trial-II) and the SCD-HeFT study (Sudden Cardiac Death in Heart Failure Trial) with those of patients in the NCDR ICD Registry. It showed that patients with a primary prevention ICD in the registry had survival similar to patients who received an ICD in these 2 RCTs and better survival than patients who received medical therapy only.[2] These findings support

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the continued use of primary prevention ICDs in clinical practice in patients with an LVEF≤35% attributable to ischemic or nonischemic cardiomyopathy. Another study examined the survival of Medicare beneficiaries with an LVEF of 30% to 35% according to whether or not they receive a prophylactic ICD. Survival at 3 years was better in patients who received a prophylactic ICD than comparable patients with no ICD.[3] These findings support guideline recommendations to implant ICDs in eligible patients with an LVEF≤35%. In other analyses, a survival benefit was observed in association with the use of primary prevention ICDs among women, racial minorities, and patients with multiple comorbidities; therefore, those findings support the continued use of primary prevention ICDs in these groups of patients. These studies along with many other studies from the NCDR ICD Registry have largely answered the questions that CMS had intended the NCDR ICD Registry to address. The results are clearly concordant with those of the pivotal RCTs and support the continued use of primary prevention ICDs in patients with an LVEF≤35% attributable to ischemic or nonischemic cardiomyopathy.

As for ICDs in older patients, many of these NCDR ICD Registry analyses were limited to Medicare beneficiaries. Other analyses on this important topic have been published. One such analysis combined data on primary prevention ICDs in 3530 patients from 5 RCTs. In unadjusted analyses, patients with an ICD were less likely to die than patients with no ICD in all age groups with a hazard ratio (HR), 0.48; 95% posterior credible interval, 0.33 to 0.69 among patients <55 years; HR, 0.69; 95% posterior credible interval, 0.53 to 0.90 among patients 55 to 64 years; HR, 0.67; 95% posterior credible interval, 0.53 to 0.85 among patients 65 to 74 years; and HR, 0.54; 95% posterior credible interval, 0.37 to 0.78 among patients >75 years. After adjustment, the survival benefit of ICDs appeared to persist even in patients >75 years; however, the analysis was limited by the relatively small sample size in patients >75 years.[4]

Another important area relates to the role of the ICD in patients with nonischemic cardiomyopathy. As mentioned previously, the SCD-HeFT demonstrated the survival benefit of ICDs in patients with nonischemic cardiomyopathy.[1] However, this evidence was recently challenged by the findings of the DANISH trial (Danish Study to Assess the Efficacy of ICDs in Patients with Non-ischemic Systolic Heart Failure on Mortality).[5] Although the results of the DANISH trial may have created doubts regarding the role of primary prevention ICDs in patients with nonischemic cardiomyopathy, the trial's findings do not refute the survival benefit of primary prevention ICDs in patients with nonischemic cardiomyopathy. Although the main purpose of the DANISH trial was to determine whether primary prevention ICDs improve the survival of patients with nonischemic cardiomyopathy, 58% of patients in the ICD and the medical therapy arms received a cardiac resynchronization therapy device. Therefore, the results of the DANISH trial should not be extrapolated to patients who do not qualify for a cardiac resynchronization therapy device. The DANISH trial has been the only ICD trial to date to require an elevated NT-proBNP (N-terminal pro-B-type natriuretic peptide) level as an inclusion criterion, and the median level of NT-proBNP of enrolled patients was high. This criterion likely led to the inclusion of patients who are more likely to succumb to nonsudden cardiac death.[5]

A few meta-analyses of primary prevention ICDs in patients with nonischemic cardiomyopathy have been recently published. One analysis combined data from 4 RCTs and included only patients not receiving cardiac resynchronization therapy in the DANISH trial. Of 1874 patients, 937 were treated with medical therapy and an ICD, and 937 received medical therapy only. This analysis showed that ICDs reduced all-cause mortality by 25% (HR, 0.75; 95% confidence interval, 0.61–0.93; *P*=0.008; *P* value for heterogeneity=0.873).[5]

In summary, there is strong and robust evidence of the efficacy and effectiveness of secondary and primary prevention ICDs in many patient populations, including patients ≥65 years. This evidence supports the continued use of these life-saving devices in all patients who are currently indicated for an ICD. As CMS officials deliberate about potential changes to the coverage indications for ICDs in Medicare beneficiaries, it is hoped that the powerful evidence supporting ICD efficacy and effectiveness in different patient groups will again result in a decision that will help save many lives.

DISCLOSURES

Dr Gillis receives research funding from Medtronic Inc for participation in a device surveillance registry. Dr Curtis receives honoraria for speaking for Medtronic Inc and Abbott, participates in research studies with Medtronic Inc. and Abbott, and is a member of a medical advisory board for Abbott. Dr Al-Khatib reports no conflict.

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FOOTNOTES

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