Medicare to Cover Test to Identify ICD Candidates

BY ALICIA AULT
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Medicare has ruled that microvolt T-wave alternans testing should be covered nationally, calling it an accurate screen for sudden cardiac death.

The test is used primarily to determine candidates for an implantable cardioverter defibrillator, but the Centers for Medicare and Medicaid Services did not require use of the diagnostic to select those patients.

"CMS has determined that MTWA is a useful risk stratification tool and can identify which heart patients are at negligible risk of sudden death, and who may therefore be able to avoid ICD implantation and its attendant risks," the agency wrote in its coverage decision.

The test is manufactured and sold by Cambridge Heart Inc., based in Bedford, Mass. It was originally approved by the Food and Drug Administration in 2000, but has not been widely adopted. According to the company, only 500 of the $30,000 units have been sold.

Dr. Anne B. Curtis, president of the Heart Rhythm Society, said that clinicians have not been quick to adopt MTWA testing. Although it has been shown to have a high negative predictive value, it has not given clinicians confidence that patients with normal results have a very low likelihood of having a cardiac event, Dr. Curtis said in an interview.

ICDs have been shown to improve survival in patients with an ejection fraction at or below 35%, so there is no real incentive to conduct MTWA testing in those patients, especially since so many still have not received ICDs, said Dr. Curtis, who is also chief of cardiovascular services at the University of South Florida, Tampa.

In those high-risk patients, "you clearly would want that patient to have a defibrillator—you don't need any other tests," agreed Dr. Michael J. Mirro, a trustee of the American College of Cardiology and medical director of the Parkview Research Center, Fort Wayne, Ind. "Where it is going to be of value—and why the academic electrophysiologists are waiting for more clinical data—is to see if it has more compelling positive predictive value in patients in the intermediate-risk group," Dr. Mirro said in an interview. Dr. Mirro is a shareholder in Cambridge Heart.

Both Dr. Mirro and Dr. Curtis agreed that positive data from an ongoing prospective study, the Alternans Before Cardioverter Defibrillator (ABCD) trial—in addition to wider insurance coverage—would prompt more widespread use of MTWA testing.

The diagnostic has been evaluated prospectively in patients with ischemic cardiomyopathy, nonischemic dilated cardiomyopathy, or mixed cardiomyopathy. In the 19 prospective studies reviewed by CMS, patients had an ejection fraction of 23%-71%. Patients with indeterminate test results were excluded. Overall, the positive predictive value ranged from 0% to 67%, and the negative predictive value ranged from 71% to 100%.

The Heart Rhythm Society and ACC wrote to CMS to urge against making MTWA testing a prerequisite for ICD implantation. Several manufacturers took the same position, and said that Medicare should wait for the results of the ABCD study.

That 42-center trial is being led jointly by St. Jude Medical Inc., Case Western Reserve's MetroHealth Medical Center, and Cambridge Heart. Patients with a positive MTWA test are given an ICD and then followed for a year to evaluate ventricular tachyarrhythmia and death rates. Enrolled patients have ischemic heart disease, a left ventricular ejection fraction less than or equal to 40%, and nonsustained tachycardia.

MTWA testing was previously covered by CMS local contractors and, according to David Chazanovitz, CEO of Cambridge Heart, 10 BlueCross BlueShield plans—even though an October 2005 review by the BlueCross BlueShield Association's Technology Evaluation Center said there was insufficient evidence to recommend the testing. Aetna recently agreed to cover MTWA on a national basis, said Mr. Chazanovitz in an interview.

Currently, about 1.3 million Americans have been deemed eligible for an ICD. ■

ICD Efficacy May Be Lower in Women, Metaanalysis Finds

BY BRUCE JANCIN
Denver Bureau

ATLANTA — Women may not derive a significant mortality benefit from implantable cardioverter defibrillator therapy, Nickole N. Henyan, Pharm.D., said at the annual meeting of the American College of Cardiology.

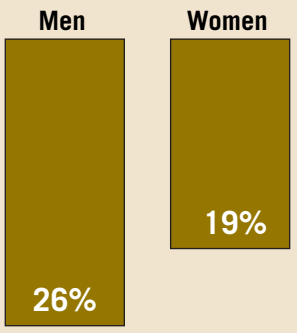
She presented a metaanalysis examining the effect of gender on all-cause mortality in the major randomized, controlled trials of implantable cardioverter defibrillator (ICD) therapy for primary prevention of arrhythmic death.

The metaanalysis included five randomized trials totalling 6,405 subjects, 1,575 of them women. The risk of all-cause mortality in men who received an ICD was reduced by 26% relative to controls who got the then-standard therapy. In contrast, the relative risk reduction in women with an ICD was 19%, which didn't attain statistical significance, said Dr. Henyan of the University of Connecticut School of Pharmacy, Storrs, and Hartford (Conn.) Hospital.

When the metaanalysis was redone after excluding the 1,520-patient Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) trial, on the grounds that it studied ICD therapy in combination with biventricular pacing, the gender disparity in all-cause mortality became even more pronounced. Men who got an ICD showed a highly significant 24% reduction in all-cause mortality compared with male controls, whereas women who received an ICD had only a nonsignificant 12% relative risk reduction.

"Perhaps we're overtreating women by implanting ICDs for primary prevention," Dr. Henyan said. "There are concerns of cosmetic alteration and inappropriate shocks that come with an ICD, and no patient should have to endure this unless significant life-saving benefit results."

Mortality Risk Reduction With ICDs Greater in Men



Note: Based on a metaanalysis of 6,405 subjects.
Source: Dr. Henyan

Session moderator Dr. Douglas P. Zipes was skeptical. "Those data are extremely provocative. To my knowledge, ventricular fibrillation is the same whether you're a man or a woman, and a shock should terminate it. I have no answer as to why there should be a gender difference to an ICD response, assuming patients are matched in terms of sickness and ejection fraction," said Dr. Zipes, distinguished emeritus professor of medicine at Indiana University, Indianapolis.

Dr. Henyan noted that any metaanalysis should be viewed as hypothesis-generating rather than as the final word. She said one possible explanation for the observed gender difference is that it could be an artifact resulting from the limited number of women included in the analysis. ■

Study: ICD Recalls Have Had No Significant Impact on Mortality

BY BRUCE JANCIN
Denver Bureau

ATLANTA — Ill-conceived Food and Drug Administration recalls and safety alerts involving implantable cardioverter defibrillators have created needless hysteria in a large population of patients, Dr. Mina K. Chung asserted at the annual meeting of the American College of Cardiology.

Her study of the 1,664 patients who received an ICD at the Cleveland Clinic Foundation between August 1996 and May 2004 showed that 44% of them had a device subject to an FDA class I, II, or III recall or a manufacturer's safety alert.

Overall mortality in the ICD recipients during a mean 3.9 years of follow-up was 31%. The key finding was that mortality was not significantly different in patients with or without a device warning or recall. Nor was mortality significantly increased even in patients whose ICD was subject to a class I recall, reserved for device problems deemed by the FDA to be potentially life threatening, added Dr. Chung, an electrophysiologist at the clinic.

It's important to keep a sense of perspective about ICD malfunctions, she continued, citing the case of the Medtronic Marquis ICD recall that affected 87,000 patients.

The recall was triggered by a risk of ICD malfunction estimated at 0.2%-1.5%, with the lesser figure probably being more accurate. That's a very modest risk in a generally sick patient population having close to 10% annual mortality even with an ICD in place, especially in light of the finding in the Cleveland Clinic series that ICD recalls and safety alerts had no impact on mortality. Yet a substantial number of patients requested device removal as a result of the Marquis recall.

For ICDs to have a failure rate of 1% or less is 'an incredible engineering accomplishment.'

DR. CHUNG

"All mechanical-electrical devices have some rate of failure. For this type of very sophisticated device to have a failure rate of 1% or less is an incredible engineering accomplishment. We can't expect this kind of therapy to make us immortal," the cardiologist said.

Session moderator Dr. Douglas P. Zipes hailed Dr. Chung's study as "a very important observation. "I find your data extremely reassuring, particularly in this time of hysteria over the recalls," commented Dr. Zipes, professor of medicine at Indiana University, Indianapolis, and a former ACC president.

He added that he has heard of patients who refused an ICD implantation because of a much-publicized 1% or so device failure risk—even though their risk of sudden arrhythmic death without a device was much greater.

Dr. Zipes is a consultant to Medtronic. Dr. Chung has received honoraria from Medtronic and Guidant for speaking at educational seminars. ■