Consider Deactivating ICD Near End of Life

BY SHERRY BOSCHERT
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SAN FRANCISCO — One reason that few implantable cardioverter defibrillators get shut off to prevent a painful, unnecessary shock near the end of a patient's life is that physicians disagree about who should begin the deactivation discussion, Dr. Amy S. Kelley said.

In addition, some physicians prefer further aggressive medical treatments and postpone discussing deactivation of implantable cardioverter defibrillators (ICDs), according to a survey mailed to 4,876 physicians and completed by 558. Inadequate knowledge about or awareness of ICDs also contributed to physicians' lack of attention to the issue, Dr. Kelley reported in a poster presentation at the annual meeting of the Gerontological Society of America.

"People at the bedside caring for a dying patient—internists and palliative care physicians—may not be familiar with how the ICD works, and the fact that they are very easy to deactivate," said Dr. Kelley of the University of California, Los Angeles. "Even if it's functioning as a pacemaker, the shut-off function is entirely separate and could be deactivated in a moment's time at the bedside with a magnet and an electrophysiologist or even a nurse."

The 96 general internists, 106 cardiologists, 163 geriatricians, and 193 electrophysiologists surveyed were asked if they would discuss ICD deactivation, advance directives, and do not resuscitate (DNR) orders with terminally ill patients described in five vignettes. (See box.) The survey also solicited comments, and investigators analyzed 310 comments provided by 177 physicians to identify recurrent themes.

Of the 177 who commented, 6% said they had never thought about deactivating an ICD, 2% were unaware of the separate pacer and defibrillator functions, and 1% declared a lack of knowledge about defibrillators, reported Dr. Kelley and her associates. Overall, 21% of the commenters expressed a preference for further medical treatments (including medications, devices, and procedures) over ICD deactivation.

Of the 177, 13% accepted primary responsibility for initiating discussions about deactivating pacemakers, 10% said another specialist should start the discussion, and 7% said the patient or family should bring it up first.

"As a geriatrician and a primary care provider, if I'm ready to discuss other end-of-life topics with a patient or with the family, this would be on my list of things to discuss," Dr. Kelley said. "I want them to know they have the option to possibly pass quietly from arrhythmia versus the possibility of being shocked."

Data from a previous retrospective study that surveyed next of kin after a patient's death suggest that fewer than a fourth of ICDs get deactivated near the end of life, and then only after the patient suffered a painful shock from the device, she said.

Informed consent for ICD implantation should include information about deactivation options, 77% of physicians in the current survey agreed. A majority (58%) said that guidance from experts regarding management of patients with ICDs would be helpful. There are no guidelines for managing the deactivation of ICDs.

The study has been accepted for publication in the American Journal of Geriatric Cardiology, Dr. Kelley said.

In two of the patient vignettes, physicians who said they had no religious affiliation were more likely to discuss ICD deactivation with patients. ■

Most Physicians Willing to Talk

In the following scenarios, the percentages indicate how many of 558 surveyed physicians would discuss ICD deactivation, advance directives, or DNR orders with patients.

► A man with severe chronic obstructive pulmonary disease who reports a poor quality of life:
ICD deactivation: 56%
Advance directives: 88%
DNR: 82%

► A man with advanced dementia who is agitated by medical tests:
ICD deactivation: 71%
Advance directives: 84%
DNR: 84%

► A woman with stage IV ovarian cancer who requests palliative care:
ICD deactivation: 79%
Advance directives: 94%
DNR: 93%

► A man with end-stage renal failure who declines dialysis:
ICD deactivation: 76%
Advance directives: 90%
DNR: 90%

► A woman with a massive stroke whose family requests ventilator withdrawal:
ICD deactivation: 83%
Advance directives: 80%
DNR: 83%

Medtronic Defibrillator Lead Recall Underway

BY ELIZABETH MECHCATIE
Senior Writer

Medtronic Inc.'s decision to voluntarily recall all Sprint Fidelis defibrillator leads was announced "because of the potential for lead fractures," but recommended against replacing leads with no apparent problems.

The company identified five deaths "in which a Sprint Fidelis lead fracture may have been a possible or likely contributing factor," Medtronic said in a statement announcing the recall. The clinical signs of lead fractures can include audible alerts, inappropriate shocks, and/or loss of output.

The leads are used with defibrillators, including implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds). Patients with Medtronic pacemakers are not affected. About 268,000 of these leads (models 6930, 6931, 6948, and 6949) have been implanted worldwide, the company said.

Medtronic has data showing that at 30 months, the viability of the Sprint Fidelis lead is lower than that of the company's Sprint Quattro lead (97.7% vs. 99.1%), which is not statistically different. However, "if the current lead fracture rates become constant," the difference will become significant over time, the statement said.

The Medtronic statement explains that the company, its independent panel of physicians, and Dr. Bruce Lindsay, professor of medicine and director of cardiac electrophysiology at Washington University, St. Louis, who is also president of the Heart Rhythm Society, "do not recommend that patients seek prophylactic replacement of Sprint Fidelis leads, as the risks of removal or insertion of another lead exceed the small risk to patients of a lead fracture."

The letter to physicians points out that lead extraction carries risks "that should be considered in patient management," and that published literature "suggests major complications (death or surgical intervention) from lead extraction range from 1.4% [to] 7.3%. As always, with confirmed lead failure, the risk of extraction should be weighed against the risk of adding an additional lead."

In a statement issued by the Food and Drug Administration, Dr. Daniel Schultz, director of the FDA's Center for Devices and Radiological Health, said that based on the agency's initial review of reported adverse events, some deaths and major complications have occurred after the leads have fractured.

Although this can be frightening to patients, Dr. Schultz added that "patients can be assured that the likelihood of fracture is very low."

The currently available adverse event data for the leads indicate that fractures have occurred in less than 1% of the approximately 268,000 leads implanted, but whether the rate will increase or remain constant over the life of the leads is unknown, the FDA statement said.

The day after the Medtronic announcement, Sen. Chuck Grassley (R-Iowa) sent a letter to the FDA and Medtronic requesting more information about the recalled leads. And in another letter to the FDA, the public advocacy group, Public Citizen's Health Research Group, requested that the agency conduct an investigation into why the FDA did not compel Medtronic to recall the Sprint Fidelis defibrillator leads earlier this year, when the FDA was aware of "the rapidly mounting number of injury reports" associated with these leads, according to the letter.

The FDA statement says that Medtronic first notified physicians about the lead fracture rate and about the proper method of implantation of the leads in March, and that the decision to suspend marketing of the leads was prompted by "additional data on adverse events" that had accumulated since that time. ■

Medtronic has posted information for physicians and patients at www.medtronic.com/fidelis.