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T-Wave Test for Patients Facing Defibrillator Recall

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"A Hard Choice for Heart Patients[1]" (Personal Journal, Oct. 12) provides an excellent discussion of failure rates for implantable cardiac defibrillators and operative risks faced by patients and their physicians when a defibrillator is recalled. A third important issue is how likely is a patient to have a life-threatening sustained arrhythmia that would benefit from ICD therapy?

An FDA recall doesn't mandate replacement of all affected ICDs because most won't fail. Deciding whether to replace an ICD is especially difficult when the patient received an ICD without having had a life-threatening rhythm disturbance, but was judged to be at high risk for one. The current method for selecting patients for ICD prophylaxis depends primarily on the presence of reduced heart pumping function, and a large and growing proportion of all ICD implants are prophylactic. But at the time patients with prophylactic ICD face a recall, fewer than 10% will have had a sustained, life-threatening rhythm disturbance.

Recently a relatively inexpensive, non-invasive test, microvolt T-wave alternans, has been shown highly capable of predicting which patients with heart impairment are unlikely to have life-threatening sustained arrhythmias, and the test can be helpful with the replacement decision. A normal test favors the decision not to replace an ICD; conversely, an abnormal test favors the decision to replace it. But T-wave alternans testing hasn't been formally tested in the setting of ICD recalls.

During an ICD recall, the likelihood of future ICD failure, probability of operative complications and patient factors should be factored into the decision to replace an ICD.

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A Hard Choice for Heart Patients

After Defibrillator Recalls, People Weigh Risk of Surgery Against Risk of Malfunction

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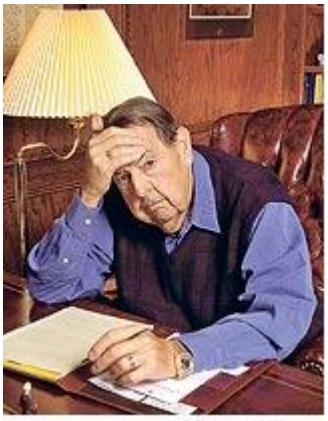
When Albert Klaben Sr. learned this year that the defibrillator implanted in his chest bore a tiny chance of malfunctioning, he opted to have it replaced. A Florida cardiologist, he says, told him that replacement would bring "peace of mind."

But with the procedure came life-threatening complications. In device replacement, patients generally are sedated because a new defibrillator must be tested by sending an electrical jolt to the heart. Mr. Klaben almost died, possibly from the sedation. "They tried to bring me out of it, but I couldn't breathe," recalls Mr. Klaben, a 73-year-old Ohioan who had to be treated in the coronary intensive-care unit before recovering.

Mr. Klaben's experience underscores a quandary that many heart patients face, in the wake of announcements this year that certain pacemakers and defibrillators face a small risk of malfunction. Should they do nothing, and risk having their devices fail, or should they have replacement surgery, which carries undeniable risks of its own?



Michael Williams

Tough Choices: Albert Klaben Sr. (left) opted for early replacement of his Medtronic defibrillator.

Nearly 200,000 heart patients depend on the devices affected by this year's announcements. Defibrillators use powerful electrical jolts to slow down dangerously fast heartbeats. Pacemakers use small electrical impulses to speed up slow ones. The prospect of one malfunctioning is a frightening one, so it is little wonder that many patients are opting for replacement. Guidant Corp., the maker of several defibrillators and pacemakers that were recalled, won't say how many have been replaced. But Medtronic Inc. says more than 18,000 of its defibrillators have been removed since it announced in February that some devices could face early battery depletion. Mr. Klaben's was among them.

Replacement is hardly free of danger, however. Besides the risks associated with any surgery, including infection, bleeding and possible reactions to anesthesia, there are certain unique dangers with the removal and replacement of a device whose "lead" wire runs directly to the heart. The risks associated with either alternative -- surgical removal or leaving the device in place -- are very low. But

weighing the dangers can be an agonizing exercise.

Certainly, there are patients for whom the risks of malfunction exceed the risks of replacement. People who have survived previous episodes of sudden cardiac arrest, for instance, are at a higher risk of sudden death and probably can't afford the possibility that their defibrillator might not fire off when needed. People who are "pacemaker-dependent" literally can't survive without a working pacemaker, and are strong candidates for replacement.

Age of battery can also be a factor favoring replacement. Defibrillators and pacemakers must be replaced every five to seven years anyway because of battery depletion. For patients near the end of their devices' natural battery life, replacing it now simply bumps up a procedure they would have to undergo soon anyway. But for others, early replacement will mean an additional procedure, with all its attendant risks.

A number of heart-rhythm specialists say their assessment suggests that device replacement may pose the greater danger than leaving it in, for many patients. They note that four people are known to have died from malfunctions of defibrillators from Indianapolis-based Guidant. The recent failures of Guidant devices are occurring at rates the company has estimated at between 1 in 400 and 1 in 20,000, depending on the model.

By contrast, these heart-rhythm specialists, such as Steven L. Higgins of Scripps Memorial Hospital in La Jolla, Calif., say the chance of a serious infection from the replacement is between 1 and 3 in 100 patients, based on medical literature and their experience. Dr. Higgins is a Guidant consultant, but other heart-rhythm doctors and literature bear him out. For instance, a 2001 study from Massachusetts General Hospital says that infection historically has occurred in up to 6.7% of defibrillator implantations, and that Mass General's own experience was a 1.2% infection rate.

In replacement procedures, the device is removed from just underneath the skin in the shoulder area, and a new one is inserted and hooked up to the "lead" wire, which remains attached to the heart. It is mostly outpatient surgery, and a patient can go home within hours. But if the wound gets badly infected, that infection often spreads along the lead toward the heart. In most cases, the lead must then be pulled out in a subsequent procedure.

"Removing the lead is a riskier operation. You basically have to tear the scar tissue" that forms along the lead, says Jeffrey J. Goldberger, director of cardiac electrophysiology at Northwestern Memorial Hospital in Chicago. "Then there's a 1% risk of a tear in a vessel or in the heart." Dr. Goldberger has given paid lectures for defibrillator makers, highlighting patients' difficulty in getting truly objective advice. However, various studies confirm such an estimate. A Dutch study last year, for instance, found that major complications occurred in 6 out of 82 lead-extraction cases, including two patients who died.

For 70-year-old Edward A. Sullivan of South Bend, Ind., a routine replacement of a battery-depleted defibrillator evolved into a month in intensive care. The area around the device became infected, and the device and lead had to be pulled out. In the extraction, his blood pressure

plummeted. Then his kidneys failed, requiring dialysis. Even after leaving the hospital, the onetime Notre Dame football player was exhausted for two months before regaining his energy.

At least one prominent doctor, Douglas Zipes of Indiana University, recommends that all models of malfunctioning defibrillators be removed. "I put it in because the patient is at risk of sudden death," he says. "How can I in good conscience then not replace the device?" His appears to be a minority view among electrophysiologists, or heart-rhythm doctors.

The difficulty of balancing replacement versus device malfunction is evident from the experience of Medtronic's defibrillator notice earlier this year. The Minneapolis-based company announced that a very small number of 87,000 Marquis defibrillators -- about 1 in 10,000 -- might be subject to early battery depletion. Medtronic's conclusion was based on nine episodes of battery depletion observed in returned devices. But upon examining the 18,000 devices that have since been returned to the manufacturer, Medtronic didn't find one with a depleted battery. The company does say that since the malfunction occurs over time, some depletions may yet be found.

Medtronic executives say they were surprised by how many patients decided to have the devices removed. That experience led them to push for a national meeting on the topic of device safety. That conference took place last month in Washington, D.C., and was sponsored by the Food and Drug Administration and the Heart Rhythm Society, the medical group representing doctors who put in pacemakers and defibrillators. These doctors are urging earlier notifications of rare malfunctions, but are also concerned that earlier notices may frighten people into taking out a device that ought to stay in place.

"I am certain that many more people have been harmed than helped by our collective response" to the Medtronic battery-depletion problem, said Bruce L. Wilkoff, the Cleveland Clinic's director of cardiac pacing, in a recent commentary in the Journal of Cardiovascular Electrophysiology. Dr. Wilkoff says there have been "over a half-dozen infection cases" among his patients who had defibrillators replaced recently. Like most prominent electrophysiologists, Dr. Wilkoff is a consultant to major device companies, including Guidant and Medtronic.

Publicity about defibrillator malfunctions can also prompt patients to decide against getting a device at all -- a phenomenon that some electrophysiologists say is occurring in the wake of the recent recalls.

For patients at risk of sudden cardiac death, going without a defibrillator is a gamble, considering that more than 400,000 Americans die annually of sudden cardiac arrest, and that implanted defibrillators have been shown to save lives in various studies. One recent national defibrillator study demonstrated that the devices lowered the relative risk of death in heart-failure patients by 23%.

"These are life-saving devices," says Anne B. Curtis, chief of cardiology at the University of South Florida in Tampa and president of the Heart Rhythm Society. "The chances of having your life saved by them is far greater than the chance of one not working."