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Malfunctions in implantable cardiac devices: Putting the risk in perspective

Physicians must place these device malfunctions in perspective for their patients

IN THE FIRST 6 months of 2005, several implantable cardioverter-defibrillators (ICDs) from the three largest manufacturers were the subject of safety alert notifications initiated by the manufacturer and the US Food and Drug Administration (FDA). More recently, the devices were the subject of an article in the *New York Times* that claimed that the manufacturers had withheld information about known malfunctions, that these malfunctions had the potential to cause complete device failure, and that device failure could result in sudden cardiac death.[1]

In response, the manufacturers issued several communications informing physicians of some severe but infrequent and some less severe but more frequent problems.[2–6]

The alert and recall notifications, and especially the articles in the news media, have created much anxiety. They have also exposed the misperception that ICDs are perfect, never malfunction, and always successfully deliver therapy. However, now we have to consider that some patients will overreact and feel that ICDs are actually more dangerous than beneficial. The truth is certainly between these extremes.

The challenge for us as physicians is to be sensitive to the emotional distress that the alerts and recalls have on patients, for whom receiving an ICD is already an unsettling experience. At the same time, we need to put the risks into perspective and use the controversies surrounding these devices to improve communication between manufacturers, physicians, regulators, and patients.

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DESPITE IMPERFECTIONS, ICDs SAVE LIVES

Pacemakers and defibrillators have several components: a computer microprocessor, a battery, and leads that all work together to detect cardiac activity and deliver stimulating energy. The computer portion has become increasingly complex, often combining diagnostic programs, hundreds of programmable options, and combined pacing, defibrillating, and heart failure therapy.

Failures occur, just as in any mechanical device. The battery is expected to drain over time, and the leads are subject to mechanical forces that sometimes wear out the wire and insulation. Less well recognized are software and hardware malfunctions and failures. Device failures and safety alerts have always been an issue and will continue to occur. Maisel and colleagues[7] reported that the number of device failures and safety alerts increased during the 1990s. In addition, even if a device were perfect, it must be implanted properly, programmed properly, and implanted in an appropriate patient to function effectively.

However, thanks to very high manufacturing and design standards, the failure rate is very low, and despite the imperfections, these devices have been proven to save lives and have performed very well over time. This is

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quite a feat, considering the complexity of these devices and the rapid changes in technology. Compared with medications such as amiodarone that are indicated for similar medical problems, these devices have efficacy and malfunction (complication) rates that are much better.[8,9]

Still, we must be vigilant and attempt to intervene when malfunctions prevent us from delivering appropriate therapy.

FDA IS THE WATCHDOG

A congressionally mandated regulatory process is in place to identify safety and malfunction issues. The FDA monitors the safety and effectiveness of all medical devices in the United States, certifying manufacturing facilities and processes and the evaluation and appropriate labeling for use of technologies as they are developed. Each pacemaker and ICD model is certified on the basis of data obtained in monitored and carefully designed clinical trials.

Even with such close monitoring, the premarket evaluation cannot be expected to detect infrequent problems. Therefore, Congress has also mandated that medical devices undergo postmarket surveillance. Physicians, hospitals, and manufacturers are required to report any device malfunction to the FDA. These reports are contained in the Manufacturer and User Facility Device Experience (MAUDE) database, which is publicly available (**http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm**). Device manufacturers have a long history of diligently reporting every failure of which they are aware.

A recall does not mean that all devices must be removed and sent back

Unfortunately, physicians, who have the best access to the patients and are the ones best positioned to actually observe potential problems, have historically been the weakest link in the chain of reporting. This system certainly could be improved to allow us to detect trends earlier.

EACH RECALL IS DIFFERENT

When a trend is noted in device malfunctions, the FDA may analyze the data and issue a recall. Often, the manufacturer discovers a problem first and voluntarily initiates a safety alert or recall.

"Recall" is a technical term, defined by the FDA. It does not mean that all recalled devices need to be removed and sent back to the manufacturer. It is an alert that a device has a potential problem. Different levels of recall exist, depending on the potential of the malfunction to be life-threatening. Each recall is different, characterized by frequency, potential consequence to a patient, and choices.

The physician's response to a recall should be to weigh the risks and benefits based on scientific evidence and to discuss the issue with the patients at risk. The impact on the patient and his or her family often depends on how the physician communicates the situation and choices. Ideally, the medical community develops consensus and makes uniform recommendations based on the available evidence.

PUTTING THE RISK IN PERSPECTIVE

The physician's job is to place the scope of these device malfunctions into perspective. For instance, the Guidant Ventak Prizm 2 DR was recalled when malfunctions were discovered in 28 of 26,000 of these ICD devices.[2] There is the potential in these devices for an internal short circuit to develop that could prevent the device from delivering a shock to terminate ventricular fibrillation. In one of these cases, a young man with hypertrophic cardiomyopathy died when his Prizm 2 DR failed to work.

To put this into perspective, in the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT),[9] patients with heart failure (New York Heart Association class II or III and left ventricular ejection fraction 35% or less) were randomly assigned to receive either placebo, amiodarone, or an ICD. At 5 years, the mortality rate was 29% in the placebo group, 28% in the amiodarone group (P = .53), and 22% in the ICD group: a 23% relative risk reduction comparing ICD therapy vs placebo (P = .007).

Overall, fewer than 20% of the 1.6 million US patients with recognized indications for ICD implantation as defined by the Center for Medicare and Medicaid Services have had a device implanted. Furthermore, another

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600,000 US patients have heart failure but none of the Center's indications for ICDs; they may also be candidates for ICDs according to the SCD-HeFT trial, but almost none of them have received an ICD. Therefore, many thousands of patients are dying without defibrillators, a much larger problem than the approximately 1/1,000 failure rate of the Guidant Ventak Prizm 2 DR.

Moreover, the physician should consider the risk associated with possible interventions. If the intervention is to replace the pacemaker or ICD, the estimated risk of the surgery, including infection and sedation complications, is at least 1%.[10,11] Considering that the replacement device, like all manufactured items, would also have a small risk of failure, the risk-to-benefit ratio may not be favorable. We would assume that the risk of failure of the replacement device would be much less, but we would not know. Although well-intentioned, a recall of the Medtronic Marquis series ICDs in February 2005, due to a small rate of battery failure, resulted in more than 13,000 procedures in which the device was removed and a different device implanted. Almost certainly, more complications were caused by changing the devices than would have occurred due to the initial defect. The authors are aware of specific cases that resulted in intubation, stays in the intensive care unit, infection, extraction, and death.

ICDs are still better than antiarrhythmic drugs

NEEDED: A BETTER RISK-ASSESSMENT SYSTEM

There are several responses that we, as physicians, need to initiate and promote.

Since device recalls will continue to occur, a more formal method of risk assessment and appropriate communication should be instituted to help physicians and patients make decisions that carry the lowest risk.

We must be patient advocates and be sensitive to the emotional distress that can result from a device recall. Emotional distress is often difficult to quantify, but sometimes it is the primary reason for replacing a device. This risk needs to be evaluated in each patient, and the decisions need to be individualized.

To promote detection of device problems, every known malfunction should be reported to the MAUDE database. However, standards are needed to govern the communication of these observations to physicians and patients. Trends that may put the patient at risk should be communicated, but infrequent and minor problems that may simply call for a change in the manufacturing or programming process with minimal patient risk need not result in daily communications to physicians.

If the risk of dying in a traffic accident while driving to the clinic to get the device checked is higher than the risk of the malfunction, then perhaps the risk of malfunction should not be communicated. If the risk associated with changing the device is higher than the malfunction risk, then the device should probably not be changed unless the knowledge significantly alters the patient's life after an informed discussion. If at any time the risk to the patient surpasses these simple tests, then the community should formulate a response that considers the evidence.

The way in which the recent device recalls came to our attention demonstrates the need to improve our current system of reporting potential problems. Physicians should be diligent in reporting malfunctions, and if a patient dies with an implantable device in place, the physician should test the device, document its function in the chart, and if possible return it to the manufacturer for analysis. No current guideline or system is in place for this to occur. Early recognition and identification of trends of problems with ICDs will allow us to prevent patient deaths.

Perhaps the best outcome from the increased publicity and awareness is the dialogue that is occurring within the physician, regulatory, and manufacturing communities. The Heart Rhythm Society has published several statements and recommendations regarding the recent device recalls and will update this information as necessary. These are available on the Heart Rhythm Society Web site (**http://www.hrsonline.org**).

Device malfunctions have always occurred and will continue to occur. We must be proactive in dealing with these in a reasonable manner based on available evidence. More importantly, we must not divert our focus from delivering proven life-saving therapy to people at high risk of sudden death.

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