Multiple clinical trials have shown that a properly functioning implantable cardioverter-defibrillator (ICD) is capable of interrupting sudden death caused by ventricular tachyarrhythmias. Unfortunately, ICDs are complex medical devices, and they do not always perform as expected. For example, only 5% of ICD batteries last >7 years, and most dual-chamber ICD models must be replaced for battery depletion every 3 to 5 years.1 Normal battery depletion, however, is reliably predicted by routine follow-up methods before an ICD fails. In contrast, electronic malfunctions are unpredictable and may not be detected by standard follow-up techniques before an ICD is unable to deliver effective therapy. Thus, sudden cardiac arrest or death may be the first and only sign that an ICD has failed.2

Recently, we reported the death of a 21-year-old patient who received a Prizm 2 DR model 1861 ICD pulse generator (Guidant, Inc) in 2001 to prevent sudden cardiac death resulting from hypertrophic cardiomyopathy.3 In March 2005, this young man experienced a witnessed arrest and could not be resuscitated. His ICD was returned to Guidant, which found that the device had failed during the delivery of a shock. The cause of failure was massive electronic damage caused by electrical overstress that occurred when a short circuit developed between a high-voltage wire and a tube used to test the housing during manufacturing (see the Figure).

At the time of our patient’s death, Guidant had knowledge of 25 similar Prizm 2 DR model 1861 failures in patients, 3 of whom had required rescue defibrillation. Indeed, Guidant had first observed this mode of failure 3 years earlier, in February 2002, when 2 returned Prizm 2 DR pulse generators exhibited the same short circuiting that caused our patient’s device to fail. Guidant was sufficiently concerned about these failures that manufacturing changes were made in April and November of 2002, which allegedly prevented short circuiting. Nevertheless, Guidant chose not to inform patients or physicians about these failures or the manufacturing changes designed to prevent them. Moreover, Guidant continued to sell pulse generators that were built before the 2002 manufacturing changes. Unknowingly, therefore, we and other physicians implanted Prizm 2 DR ICDs in 2002 and 2003 that Guidant knew were prone to sudden unexpected failure.4

In May 2005, after the death of our patient, we recommended during meetings with Guidant officials that the company promptly communicate the detailed nature of this flaw to physicians and patients. That communication, it was noted, should also emphasize that no test or monitoring technique could predict if or when a suspect Prizm 2 DR device may fail. This recommendation was based on the view that physicians and patients should have all critical information so that they can decide whether prophylactic ICD replacement was prudent. Guidant’s responsibility, in our opinion, was to disclose these vital data completely and expeditiously.

However, Guidant believed that such a communication was inadvisable and unnecessary. The company maintained that because the observed failure rate was very low, physicians could unnecessarily expose patients to the risks of device replacement surgery, including infection. Guidant’s statistical argument ignored the basic tenet that patients have a fundamental right to be fully informed when they are exposed to the risk of death no matter how low that risk may be perceived. Furthermore, by withholding vital information, Guidant had in effect assumed the primary role of managing high-risk patients, a responsibility that belongs to physicians. The prognosis of our young, otherwise healthy patient for a long, productive life was favorable if sudden death could have been prevented.5 Certainly, this was the rationale for implanting his Prizm 2 DR in 2001. If we had known that the Prizm 2 DR was prone to sudden failure as a result of short circuiting or another mechanism, his device would have been replaced promptly.

Because Guidant declined to inform patients and their physicians, we regarded it as our moral and ethical obligation to disclose the problem to the medical community and the public.6–8 On May 23, 2005, the day before the New York Times reported these events, Guidant sent a letter to physicians describing the Prizm 2 DR flaw and suggested the failures were random events; Guidant recommended that physicians continue normal monitoring.7

On June 17, 2005, after alerting the Food and Drug Administration (FDA), Guidant recalled 26 000 Prizm 2 DR devices manufactured before April 2002.4 Simultaneously, Guidant issued 3 additional recalls affecting >50 000 of its cardiac resynchronization ICDs.8–10 One of these recalls was prompted by 15 Contak Renewal and Contak Renewal 2 ICD failures that were also caused by short circuiting that Guidant had known about for at least a year. Similar to its management of the Prizm 2 DR situation, Guidant had implemented manufacturing changes in August 2004 and did not disclose the problem until a patient died when a Contak Renewal...
Lesson 1: The FDA’s Postmarket ICD Device Surveillance System Is Broken

According to the FDA, the purpose of postmarket surveillance is to improve the safety and effectiveness of devices by identifying serious low-frequency events like those involving the Prizm 2 DR. The present experience suggests that the FDA is currently unable to satisfy its legal responsibility to monitor the safety of market released medical devices like the Prizm 2 DR.

Guidant reported 2 adverse events to the FDA in 2004 that described the same Prizm 2 DR defect that caused our patient’s device to fail and further indicated that the company had made manufacturing changes to prevent it. The first report was received by the FDA >1 year before to the death of our patient. The second report was received by the FDA in August 2004 after a patient received an ineffective shock; the second report was explicit: “Analysis confirmed an electrical short between two components, specifically the feedthrough wire and backfill tube. It was concluded that the shorted condition involving the header of feed-thru wires resulted in the clinical observations. Although the occurrence of this failure has been very low, Guidant implemented manufacturing enhancements in April and November 2002 to correct this issue.”

The FDA, therefore, was in possession of important information about the safety of the Prizm 2 DR many months before the death of our patient and, to the best of our knowledge, took no action. The explanation for the FDA’s inaction is unknown, but it may be that the agency was not prepared for the upsurge in ICD technology and the extraordinary growth in the number of ICD implantations that has occurred during the past 5 years.

Fixing the postmarket surveillance system must be a high priority for the FDA and Congress. The public should have full access to all of the FDA’s medical device safety and efficacy data. This should include manufacturers’ annual reports that may contain failure data and manufacturing changes, which the FDA is presently withholding from public scrutiny presumably because they may reveal a company’s trade secrets. For government to keep such vital product safety information from patients or physicians for any reason should be unlawful.

A physician or patient should be able to learn quickly from the FDA if a particular ICD or other critical medical device has exhibited quality issues that may affect the performance of a product. Moreover, the FDA’s postmarket surveillance system should alert physicians and user facilities when manufacturers report the type of life-threatening failure modes exemplified by the Prizm 2 DR and the Contak Renewal and Contak Renewal 2 ICDs. Currently, the public’s only source of postmarket product performance data are the FDA’s Manufacturers and User Facility Device Experience (MAUDE) database. However, MAUDE is not designed to be a routine surveillance tool for physicians or a useful source of information for patients. Moreover, the MAUDE database may not be a reliable source of information; eg, it contained only 10 of the 28 Prizm 2 DR failures at the time these devices were recalled.

Lesson 2: Physicians Do Not Have the Data Necessary to Assess Device Problems and to Make Rational Clinical Judgments

Although it is important to identify ICD problems, it is critical to know their frequency and failure rates over time. Unfortunately, the medical community has become totally dependent on the ICD industry to supply failure rate data, but manufacturers can provide only crude estimates based on their unit sales and returned products. In its recent Prizm 2 DR recall letter, Guidant based its recommendations on 26,000 devices built before April 2002 and 28 failed devices that were returned for analysis. This approach unavoidably underestimates the actual number of failures because devices often are not returned to the manufacturer after death or replacement. Consequently, the actual failure rates for the Prizm 2 DR and other recalled ICDs are unknown.

Without precise failure rate data, physicians and patients cannot make prudent management decisions. In the aftermath of the Prizm 2 DR and Contak Renewal recalls, physicians and patients have had to choose between prophylactic replacement or continued follow-up. Because accurate failure rate data are unavailable for these devices, management decisions are being made according to the perceived rather than the actual risk of catastrophic ICD failure. Caught in this conundrum, and wishing to avoid surgical complications, eg, infection, and to “do no harm,” physicians may be hesitant to replace these devices. For ICD patients at high risk for sudden cardiac arrest, however, the low likelihood of a treatable
infection is acceptable when the alternative is sudden death should the device malfunction.

Because precise failure rate data are needed, a reformed postmarket surveillance system must include government-mandated prospective follow-up studies of market-released devices. These studies should be sufficiently powered to detect low-frequency device failures and to provide accurate estimates of ICD longevity.

Lesson 3: Quality Standards for ICDs and Guidelines for Managing Device Recalls Are Needed

So far, >130 000 ICDs have been recalled or subject to safety alerts in 2005. ICDs should conform to the highest quality standards for clinical performance. Yet, remarkably, such standards do not exist. Standards are needed as the foundation for quality improvement and for assessing the clinical reliability of ICDs. They can also define the boundaries for product safety and longevity. Knowledge that a manufacturer has met or exceeded accepted quality measures would help patients and physicians select devices for implantation. Furthermore, manufacturers would strengthen their design and quality processes if they were held accountable for all of the healthcare costs associated with inferior products.

Additionally, no universally accepted definitions exist for such critical device events as “random component failure.” Guidant has stated that short circuiting in the Prizm 2 DR was due to a rare random component failure and implied that such failures occurred despite industry’s best efforts to mitigate them.7 To suggest that the death of our patient or the death of the Contak Renewal patient was not due to a specific, avoidable failure mode is misleading and incorrect.

Despite the volume of recalls and advisories and the number of patients affected by them, the appropriate clinical strategies for managing ICD recalls and advisories are uncertain. A recent survey suggested that experienced physicians differ significantly in their approach to ICD recalls.16 The factor that most strongly influenced a physician’s decision to replace a suspect device was the manufacturer’s estimated risk of sudden device failure. In our judgment, the death of our patient or the death of the Contak Renewal patient was not due to a specific, avoidable failure mode is misleading and incorrect.

Given the large number of patients who have or will receive ICDs and the inevitability of future device problems, the Heart Rhythm Society, whose declared mission is to improve the care of patients affected by them, the appropriate clinical strategies for managing ICD recalls and advisories are uncertain. A recent survey suggested that experienced physicians differ significantly in their approach to ICD recalls.16 The factor that most strongly influenced a physician’s decision to replace a suspect device was the manufacturer’s estimated risk of sudden device failure. In our judgment, the patient’s underlying heart disease and prognosis should be the deciding factors favoring prophylactic device replacement. For example, the ICD may be truly life-saving for patients with genetic heart diseases because, for many of them, the only risk of cardiovascular death is ventricular fibrillation.

Conclusions

These unfortunate events underscore the importance of a fundamental principle, namely that patients and their physicians are entitled to full disclosure of product information that may affect an individual’s health or safety. This principle is broadly applicable to the healthcare industry, including the manufacturers of medical devices and drugs, and to regulatory agencies such as the FDA. Successful application of this principle requires that a completely open, transparent relationship exist between patients, manufacturers, the FDA, and the medical community.

Although ICDs are highly effective and generally dependable, the recent Prizm 2 DR model 1861 experience and the recalls of 2005 demand that ICD quality and reliability improve. The Heart Rhythm Society should lead the development of quality standards for ICDs and guidelines for managing device recalls and safety alerts. Congress and the FDA must develop and apply an effective postmarket surveillance system that improves the safety of medical devices for all patients. Finally, a major goal of these reforms is to reassure patients that ICD therapy is reliable and effectively regulated.

Disclosure

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References


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