Guidant's Woes Make Patients Leery of ICDs

The device manufacturer has been at the center of controversy about disclosure of ICD malfunctions.

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While Guidant Corp., the troubled maker of implantable cardioverter defibrillators, struggles to repair its reputation and salvage its acquisition by Johnson & Johnson, physicians are finding it increasingly difficult to convince patients of the benefits of ICDs.

"It is more common now for a patient to say that they are concerned about whether or not they should have an ICD implanted because of problems they have read about, so I'm having to spend more time explaining the very small risk of the device compared to the huge benefit," commented Stephen C. Hammill, M.D., director of heart rhythm services at the Mayo Clinic, Rochester, Minn.

"That's a longer discussion now. My concern is that it's deterred people from even pursuing it with the doctor," Dr. Hammill added.

Lately, Guidant has been at the center of the controversy surrounding the safety of ICDs. In May, the Food and Drug Administration began investigating reports that the company failed to notify physicians for several years that one of its devices had short-circuited in some patients.

In early November, New York State Attorney General Eliot Spitzer filed suit against the company in federal court, alleging: "In April and November 2002, Guidant made manufacturing changes to the Prizm 1861 defibrillator intended to remedy the systemic defect and prevent the short-circuiting and resulting catastrophic failure of the device. Despite making these design changes, Guidant continued to sell Prizm 1861 defibrillators that had been manufactured before April 2002. Guidant did not disclose to physicians and patients that these devices contained a serious design flaw that had been corrected in later devices."

A few days later, Johnson & Johnson, which had agreed to buy Guidant in a deal valued at more than $25 billion, announced that it was reconsidering the deal. Guidant sued Johnson & Johnson in federal court to force it to complete the buyout. However, Guidant also noted in its 10-Q filing to the Securities and Exchange Commission the same day that the SEC was investigating the company "related to certain of [Guidant's] product disclosures and trading in Guidant stock."

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In the same 10-Q report, Guidant also announced that it had received three requests for information from the attorneys general of Arizona, Illinois, and Oregon relating to whether the company violated any state laws in connection with its ICDs, and that 31 other states and the District of Columbia "are cooperating in these [requests]."

The company also is under scrutiny from the U.S. attorney's office in Boston "concerning marketing practices for pacemakers, ICDs, leads, and related products," according to the filing.

Eventually, Johnson & Johnson agreed to purchase Guidant Corp. at a reduced price, lowering the value of the deal to $19 billion.

"We are delighted that our companies have reached an according," Johnson & Johnson CEO William C. Weldon said in a statement. "Our agreement demonstrates that we remain committed to the goal of together building an extraordinary cardiovascular business that can deliver better medical options sooner to millions of patients."

Meanwhile, as these events transpire at Guidant, device makers and physicians alike are trying to figure out exactly what level of postmarket reporting is needed for problems with ICDs.

"If people want notification about [every] model that has a malfunction, you're going to be hearing about essentially every model of every device," commented William Maisel, M.D., director of the pacemaker and ICD service at Beth Israel Deaconess Medical Center, Boston, at a meeting sponsored by the Heart Rhythm Society that was held in cooperation with the FDA.

"These things happen, and to draw the line and expect to hear about every single malfunction by notification or letter, you'd be very, very busy," Dr. Maisel explained.

These disclosure issues will become more prominent as medical device companies' sales volumes increase, said Thomas Gunderson, senior research analyst at Piper Jaffray & Co., a Minneapolis-based investment banking firm. "You can't have a '1-in-10,000' problem until you start selling 10,000 products. In the old days, these companies didn't. Now they do, and they're going to have to provide more data."

This is especially important in the type of market that device companies now find themselves in, he added. "What you don't want to do in a tight oligopoly with large margins is lose consumer confidence," Mr. Gunderson said.

And indeed, during mid-November, Guidant issued a 153-page report that listed data on the outcomes for all of its devices.

The company noted that the report was being published "in response to the medical community's call for more detailed description of device performance and access to product performance information. … We understand that lives depend on our products, and that we must seize every opportunity for continuous quality improvement."

"The detail in this report is meant to provide an open window into this process," the publication continues.

The Guidant report "looks like a fire hose of information," Mr. Gunderson commented. "It will be difficult to complain that physicians, patients, Wall Street, and the media are not being provided enough data." ■

The Guidant report is available online at www.guidant.com/physician/ppr.

CLINICAL CAPSULES

Calcification and CHD in Young Men

CT evidence of coronary artery calcification strongly predicts premature coronary heart disease in young, healthy, physically active men, said Allen J. Taylor, M.D., of Walter Reed Army Medical Center, Washington, and his associates.

The researchers are conducting the ongoing Prospective Army Coronary Calcium project to assess the value coronary artery calcium in predicting coronary risk, beyond the predictive value of conventional risk assessment. This interim report on the data after a mean of 3 years of follow-up involved 1,983 healthy, asymptomatic Army personnel aged 40-50 years. More than 80% were white males, and all had presented for routine physical exams between 1998 and 2003.

Coronary artery calcification was identified in 22.4% of the subjects, and acute CHD events have occurred in nine men to date, at a mean age of 46 years. The presence of calcification raised the risk for CHD events by a factor of 12, after the data had been adjusted to control for subjects' Framingham risk scores, the investigators said (J. Am. Coll. Cardiol. 2005;46:807-14).

The findings "challenge the notion that plaque burden assessments should not be applied to younger populations at lower absolute CHD risk," they noted. Further studies including women and ethnic minorities are needed to extend the findings to the general population, they added.

Coffee and Hypertension in Women

Coffee drinking doesn't appear to raise the risk of hypertension in women, reported Wolfgang C. Winkelmayer, M.D., and his associates at Brigham and Women's Hospital and Harvard Medical School, Boston.

Published studies have involved men only and have focused on acute changes in blood pressure. Caffeine's hypertensive effects are known to attenuate over time, they said (JAMA 2005;294:2330-5).

They studied caffeine intake and hypertension in two cohort studies: Nurses' Health Studies I comprised 61,091 normotensive nurses who were 30-55 years old when enrolled in 1976; Nurses' Health Studies II comprised a separate group of 94,503 nurses who were aged 25-42 years when enrolled in 1989. During a 12-year follow-up (NHS I, 1990-2002; NHS II, 1991-2003), 19,541 and 13,536 subjects, respectively, reported being diagnosed as having high blood pressure. Neither group showed a relationship between the development of hypertension and overall caffeine intake, intake of caffeinated coffee, or intake of decaffeinated coffee.

The results for caffeinated tea were termed "inconclusive." There was no link between tea drinking and hypertension in the NHS I cohort, but a moderate rise in hypertension was seen with increasing tea consumption in the NHS II cohort.

There was a highly significant association between drinking regular or sugar-free caffeinated colas and developing hypertension in both cohorts. "We speculate that it is not caffeine but perhaps some other compound contained in soda-type soft drinks that may be responsible for the increased risk in hypertension," they said.

Operator Volume Still Matters in PCI

Low procedure volume continues to put patients at greater risk for major adverse cardiovascular events in the era of PCI.

In a study of 18,504 consecutive PCIs performed by 165 operators at 14 Michigan hospitals in 2002, patients of low-volume operators had significantly higher rates of adverse cardiovascular events than patients of high-volume operators, according to Mauro Moscucci, M.D., of the University of Michigan Medical Center, Ann Arbor, and his associates (J. Am. Coll. Cardiol. 2005;46:625-32).

"Technological advancements have not yet completely offset the influence of procedural volume in determining proficiency of contemporary PCIs," they said.

The researchers noted one encouraging change in recent years: Operator volume no longer appears to influence the rate of in-hospital mortality in PCI patients.

Retinopathy Flags Kidney Disease Risk

Retinal microvascular abnormalities may signal impending renal decline in the elderly, reported Matthew S. Edwards, M.D., of Wake Forest University, Winston-Salem, N.C., and his associates.

They assessed the link between these two conditions using data from the Cardiovascular Health Study, a longitudinal multicenter trial involving subjects aged 65 and older. In a subset of 1,394 subjects, a finding of retinal exudates and hemorrhages strongly correlated with declining renal function over the next 4 years, independent of the presence of diabetes or hypertension (Am. J. Kidney Dis. 2005;46:214-24).

Such retinopathy may be an early sign of diffuse, end-organ microvascular damage that will eventually involve the kidneys, and may affect other organs as well. "By extension, these findings potentially could identify individuals in need of aggressive treatment with agents designed to minimize microvascular complications, such as ACE inhibitors," the researchers noted.

—Mary Ann Moon

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