Guidant's Woes Make Patients Leery of ICDs

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

BY JOYCE FRIEDEN
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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," said Dr. Stephen C. Hammill, 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."

In May, the Food and Drug Administration began investigating reports that Guidant failed to notify physicians for several years that one of its devices had short-circuited in some patients.

In 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."

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 buy Guidant 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.

While all this is going on 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," Dr. William Maisel, director of the pacemaker and ICD service at Beth Israel Deaconess Medical Center, Boston, said at a meeting sponsored by the Heart Rhythm Society that was held in cooperation with the FDA.

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."

And indeed, in mid-November, Guidant issued a 153-page report listing 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 report "looks like a fire hose of information," Mr. Gunderson said. "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.

For Heart Implant Patients, Feelings Of Depression, Anxiety Will Ease

BY MITCHEL L. ZOLER
Philadelphia Bureau

STOCKHOLM — Patients who get implanted cardioverter defibrillators may feel depressed and anxious at first, but with time usually feel better emotionally, according to results from a study of 70 patients who were followed for 4 years after implantation.

"You can tell patients that they may first feel distressed, but over time they will eventually adjust to having a device in place," Diane L. Carroll, R.N., Ph.D., said at a poster presentation at the annual congress of the European Society of Cardiology. "This is the first study to look at patients with ICDs [implanted cardioverter defibrillators] for more than 2 years."

'You can tell patients that they may first feel distressed, but over time they will eventually adjust.'

DR. CARROLL

Among the 70 ICD patients who were followed, 80% received the device because they had coronary artery disease and 20% because they had a genetic disease. Their average New York Heart Association class was 2.5, and their average left ventricular ejection fraction was 36%. During the 4 years of follow-up, 10 patients died, and another 19 were lost to follow-up or withdrew from the study.

During the 4 years after getting an ICD, their mean mental health composite summary scores improved significantly, even though their physical health composite summary scores continued to decline. The mental health score improvements included reductions in levels of anger, confusion, fatigue, depression, and anxiety, said Dr. Carroll, a clinical nurse-specialist in Patient Care Services at Massachusetts General Hospital in Boston. Patients also had increased vigor scores with time.

The findings highlighted the opportunity to quickly engage these patients in a cardiac rehabilitation program when they receive their ICD, Dr. Carroll said in an interview. New studies should assess the effect of strength training and activity progression on ICD patients in a supervised environment.

Although 19 of the original 70 patients were alive but declined to participate with follow-up, Dr. Carroll was doubtful that they dropped out because of psychological distress. All 19 were contacted; in general, they didn't participate in the follow-up because they felt good and didn't think that they had the time, she said. ■

Automated Home Monitoring Found To Improve Heart Failure Outcomes

BY DAMIAN McNAMARA
Miami Bureau

BOCA RATON, FLA. — Automated home monitoring improved short-term outcomes for patients with heart failure, compared with standard disease management alone, in a multicenter, randomized study, Dr. Andrew R. Weintraub reported at the annual meeting of the Heart Failure Society of America.

Previously, the benefit of disease management for heart failure patients was shown, but the studies were nonrandomized, single-center, or assessed nonspecialized teams. Then the prospective, randomized Specialized Primary and Networked Care in Heart Failure (SPAN-CHF) study demonstrated significant hospitalization reductions from heart failure and cardiovascular disease, as well as a shorter length of stay with disease management (Circulation 2004;110:1450-5), said Dr. Weintraub, director of the Coronary Care Unit at the Tufts–New England Medical Center, Boston.

Dr. Weintraub and his associates randomized 93 patients to a control group of disease management and another 95 to an intervention group with home monitoring.

The control patients received the same disease management as in the SPAN-CHF study, which included an initial nurse home visit, weekly or biweekly telephone monitoring, and the availability of a nurse manager 24 hours a day via pager. Intervention patients received the same services, but also weighed themselves on an interactive scale, measured their blood pressure, and took their pulse daily using an automated home monitor (Philips Medical Systems, Bothell, Wash.). Intervention patients answered health status and compliance questions daily via text messaging (Health Hero Network, Mountain View, Calif.).

The investigators enrolled patients within 2 weeks of discharge after their first episode of heart failure. All had a measurement of left ventricular function within 6 months (mean 30%). There was a high incidence of ACE inhibitor, angiotensin receptor blocker, and β-blocker use. Patient demographics were similar. Both groups had a wide range in baseline ejection fractions, said Dr. Weintraub.

"We detected a trend in reduction with intervention of heart failure hospitalized days, cardiac hospitalized days, and all-cause hospitalized days," said Dr. Weintraub, who received research support from GlaxoSmithKline Inc., Agilent Technologies/Philips Medical Systems, and the Health Hero Network.

The number of hospitalizations for heart failure more than 90 days in the intervention group was a mean 0.5, compared with 1.8 for the control group. Hospitalizations for all cardiac causes were 0.8 in the intervention group, compared with 2.2 in the control group. There were no significant differences between groups in all-cause hospitalizations.

There were no differences in hospitalization rates according to gender, age, left ventricular ejection fraction, New York Heart Association classification, or hypertension. However, "our patients with diabetes at baseline were significantly more likely to be hospitalized for heart failure," he added (odds ratio 4.3). ■