# Clinical Capsules

### Guidelines for ICD Recall Response

Physicians should soon have a better idea of how to handle recalls of their patients' implantable cardioverter defibrillators.

A 14-member task force working on guidelines for responding to ICD recalls is "on track" for getting its report out on May 1, according to a spokeswoman for the Heart Rhythm Society, which has 12 members on the task force. The American College of Cardiology and the American Heart Association each have one member representing their groups.

Members of the committee "recognize that these devices perform to a very high standard, and we recognize the challenge of how to respond to a low incidence of potentially catastrophic failures" Dr. Saxon said. She noted that doctors who choose to replace a recalled device often end up putting in a replacement that has similar odds of a catastrophic event occurring.

One factor that is very important in considering whether to recall a device is what happens over time, Dr. Saxon said. "Suppose there are four deaths out of 30,000 patients. You would want to follow this over time, because something different [from what] you first thought may be going on in 3-6 months."

The committee is consulting with several outside parties to prepare the guidelines, including device manufacturers, patient advocates, and risk communicators.

### Rx for Heart Failure–Related Apnea

A 6-day course of acetazolamide appeared to improve sleep-disordered breathing in a study of 12 men with heart failure-related central sleep apnea.

In central sleep apnea (CSA), respiration temporarily ceases because of a decline in partial pressure of carbon dioxide ($PCO_2$) below the apneic threshold. However, in a randomized, double-blind study by Dr. Shahrokh Javaheri and his associates, the diuretic and respiratory stimulant acetazolamide seemed to reduce the likelihood of $PCO_2$ crossing the apneic threshold by inducing a state of metabolic acidosis. Dr. Javaheri of the University of Cincinnati and associates evaluated acetazolamide in 12 men with stable heart failure with left ventricular systolic dysfunction and CSA (Am. J. Respir. Crit. Care Med. 2006;173:234-7).

For 6 nights, patients received either placebo or a single dose (3.5 mg/kg) of acetazolamide and 30 mEq of potassium chloride (to offset the urinary potassium loss caused by acetazolamide). The acetazolamide dosage was increased to 4.0 mg/kg on the third day. After a 2-week washout period, crossover studies were initiated.

The mean baseline frequency of central apnea was 44 episodes/hour. With acetazolamide, CSA frequency was 23 episodes/hour, compared with 49 episodes/hour when patients received placebo. Arterial oxyhemoglobin saturation also improved significantly with acetazolamide, although other sleep-related and pulmonary measurements were similar between study arms.

Patients reported significant improvements in sleep quality, daytime fatigue, and other daytime symptoms with acetazolamide. "In spite of the short duration of the study and modest reduction in period breathing, patient perception improved," the investigators noted. They hypothesized that long-term improvement in periodic breathing could, in turn, improve cardiac function.

### Acupuncture Works for Hypertension

Acupuncture proved effective and safe for the treatment of mild to moderate hypertension in a randomized, single-blind German clinical trial.

This form of therapy may appeal to patients who dislike taking medication. But it's not curative; 3 months after completion of the course of acupuncture, blood pressures were back at baseline levels, Dr. Frank A. Flachskampf reported at the annual scientific sessions of the American Heart Association.

The trial involved 160 patients aged 45-75 years who were randomized to a 6-week course of traditional Chinese acupuncture or sham acupuncture. Seventy-two patients in the acupuncture arm and 69 assigned to sham acupuncture completed the study.

Overall, 78% of study participants were taking antihypertensive medication at baseline, and their dosing remained unchanged during the trial. Mean 24-hour ambulatory blood pressure in the acupuncture group fell from 131/81 mm Hg at baseline to 125/78 at 6 weeks. Blood pressure remained unchanged in the sham-therapy group, said Dr. Flachskampf of the University of Erlangen, Germany.

Follow-up 24-hour ambulatory blood pressure monitoring conducted 3 and 6 months after completing the acupuncture showed blood pressures had returned to pretreatment levels.

Two patients in the acupuncture group dropped out of the study because they said acupuncture was too painful; they were the only subjects who reported any side effects.

**—From staff reports**