Remote Monitoring of ICDs Safe, Effective

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NEW ORLEANS — Daily remote monitoring of patients with an implantable cardioverter defibrillator led to a substantial reduction in scheduled office visits with no change in the rate of adverse events, compared with patients monitored by scheduled office visits every 3 months, in a randomized trial with about 1,300 evaluable patients.

As might be expected, remote monitoring with automatic data transmission and electronic flagging of unusual electrical patterns detected in patients also led to faster identification of arrhythmias, compared with standard, scheduled in-office monitoring, Dr. Niraj Varma reported at the annual scientific sessions of the American Heart Association.

"This was a test of the real-world situation," with about 85% of the patients in the study monitored at community hospitals; the other 15% were monitored at academic centers, said Dr. Varma, a cardiac electrophysiologist at the Cleveland Clinic. The study was done at 105 centers in North America.

The home monitoring system tested is made by Biotronik and is built into the company's implantable cardioverter defibrillators (ICDs). The fully automatic system, which is already on the U.S. market, requires no action by patients to transmit monitoring data. Data are accessed and transmitted by a data collection device that sits by the patient's bed and is usually programmed to retrieve a day's worth of monitoring data at about 2 a.m. and then transmit it to a central monitoring station at the patient's hospital.

The Lumos-T Safely Reduces Routine Office Device Follow-Up (TRUST) study was sponsored by Biotronik. Dr. Varma is a consultant to Biotronik and to other cardiac device manufacturers.

All patients in the study received an ICD with remote-monitoring capability. The 972 patients randomized to remote monitoring also received a bedside transmitter, and were scheduled for in-office monitoring at 3 and 15 months after implantation. The 471 patients randomized to the control group did not transmit monitoring data, and were scheduled for the same two monitoring visits as well as additional office visits at 6, 9, and 12 months after ICD placement. The average age of the patients was about 63 years, about 72% were men, and about 73% received their ICD for arrhythmia prophylaxis. Their average left ventricular ejection fraction was 29%.

During the first year following placement, compliance with scheduled office visits fell steadily in the 414 control patients, with follow-up data from 91% for the 3-month visit to 65% for the 12-month visit. This pattern of gradually falling compliance with scheduled monitoring is typical of patients who receive an ICD for prophylaxis, Dr. Varma said in an interview. Compliance with the schedule for automated data transmission and analysis ranged from 90% to 84% during the first year in the 898 patients who had follow-up in the remote-monitoring group. Although data transmission was automatic and required no action by patients, in 10%-16% of cases the transmitted data were not reviewed on a timely basis at the hospital and were therefore counted as a noncompliant episode.

During the first year of follow-up, the remote-monitoring patients had an average of 1.3 scheduled office visits and an average of 0.7 nonscheduled visits, for a total average of 2 office visits per year. The control patients averaged 3 scheduled office visits and an additional average of 0.5 unscheduled office visits, for a total average of 3.5 office visits. Remote monitoring therefore resulted in an average cut of 1.5 office visits per patient per year, or a 43% reduction that was statistically significant for the study's primary outcome.

The primary safety measure was the combined incidence of death, stroke, or need for surgical intervention during the year of follow-up. This end point occurred in 9% of the remote-monitoring patients and also in 9% of the control patients, showing that "remote monitoring is safe for ICD surveillance," Dr. Varma said.

An additional analysis looked at the average time elapsed between the onset of an arrhythmia and its detection by a physician. In the remote-monitoring group, the delay ranged from 11 days for ventricular fibrillation episodes to 25 days for atrial fibrillation. In the control group, the delay interval ranged from 42 days for supraventricular tachycardias to 47 days for ventricular tachycardias and atrial fibrillations. For all types of arrhythmias, remote monitoring led to significantly quicker identification.

One concern about remote monitoring is dealing with the huge amount of data transmitted every day. "There are logistical concerns about having the infrastructure to deal with the immense amounts of data," commented Dr. Gordon F. Tomaselli, professor of medicine and codirector of the Cardiovascular Clinical Research Center at Johns Hopkins University in Baltimore. ■