Computer software monitoring detects implantable cardioverter-defibrillator malfunctions sooner

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A software monitoring program that tracks implantable cardioverter-defibrillator (ICD) function could detect problems with the devices earlier than current monitoring processes, according to new research in *Circulation: Cardiovascular Quality and Outcomes*, an American Heart Association journal.

ICDs monitor heart rhythms and deliver electric shocks to restore normal rhythm when life-threatening, irregular heartbeats occur. But the surgically implanted devices can malfunction, particularly in the leads, or wires, that connect them to the heart, causing injury or death. Device manufacturers track repeated malfunctions and issue recalls if they're widespread. However, often by the time of the recall, thousands of the devices have been implanted in patients worldwide.

"Current monitoring approaches aimed at reducing harm from malfunctioning medical devices rely largely on voluntary reporting of adverse events by manufacturers, possibly leading to missed warning signs and delayed responses to the problems, such as late recalls," said Robert G. Hauser, M.D., lead study author and senior consulting cardiologist at the Minneapolis Heart Institute at Abbott Northwestern Hospital in Minneapolis, Minn. "We looked at whether using an automated software program to monitor large databases of ICD patients might help us detect potential device-related problems earlier."

Hauser and colleagues used a commercially available software surveillance program to compare data from about 1,000 patients with recalled leads to about 1,600 patients implanted with ICD leads still on the market. Patients in both databases had their ICDs implanted between 2001 and 2008.

Using the surveillance software, researchers simulated what occurred years earlier. The software detected problems with the recalled leads at least a year before the company had recalled them.

"The software works," Hauser said. "Looking at ICD patients implanted years ago, we showed that the automated program detects medical device problems faster than current approaches. Pinpointing the malfunction a year earlier in this case could have spared thousands of patients the health risks, costs and inconvenience of receiving a device prone to failure."

Monitoring newly approved devices could help identify potential problems before the ICDs are introduced on a large scale, he said.

The next step, according to Hauser, is to apply the software to large populations of newly implanted ICD patients, in order to reduce gaps in warning sign detection and action.

Provided by American Heart Association