Recall of pacemaker in November 2015 was delayed unnecessarily

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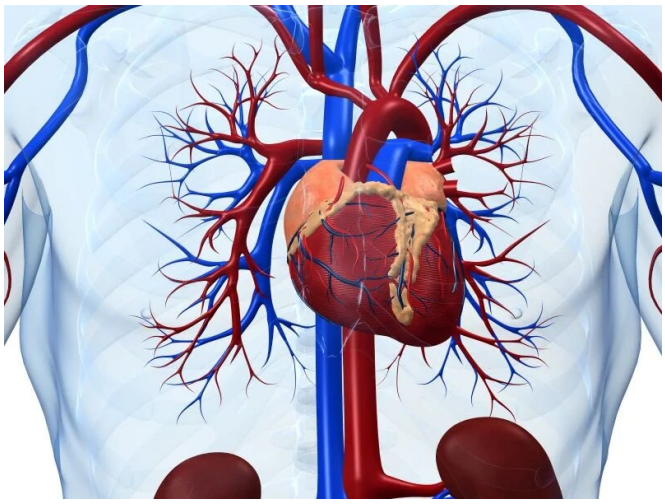

(HealthDay)—Recall of a cardiac resynchronization therapy pacemaker, which occurred in November 2015, was delayed unnecessarily, according to a report published online Dec. 20 in *JAMA Internal Medicine*.

Jay Sengupta, M.D., from the Minneapolis Heart Institute Foundation, and colleagues conducted a retrospective case series involving 90 patients who were implanted with a cardiac resynchronization therapy pacemaker from May 2003 to January 2011.

The researchers found that five of the patients observed during 2015 experienced syncope when their pacemakers stopped pacing due to battery or wire connection defects before the recall. Battery failures prior to the recall were associated with serious adverse events, including one death, one cardiac arrest, five syncopal attacks, and six heart failure exacerbations; in addition, there were three pre-recall syncope events due to wire connection defects. For 19 months before issuing the recall, the manufacturer and U.S. Food and Drug Administration were aware of the battery and wire connection defects; the wire connection problem was not listed in the advisory, and physicians were not informed about the loss of pacing that could result from interrogating the pacemaker. The recall was classified as class II rather than class I by the FDA.

"The heart failure pacemaker recall was unnecessarily delayed and did not include all the critical information needed for patient management," the authors write. "These findings should prompt reforms in how the medical device industry and the FDA conduct medical device surveillance and manage future recalls."

Two authors disclosed financial ties to the medical device industry.

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