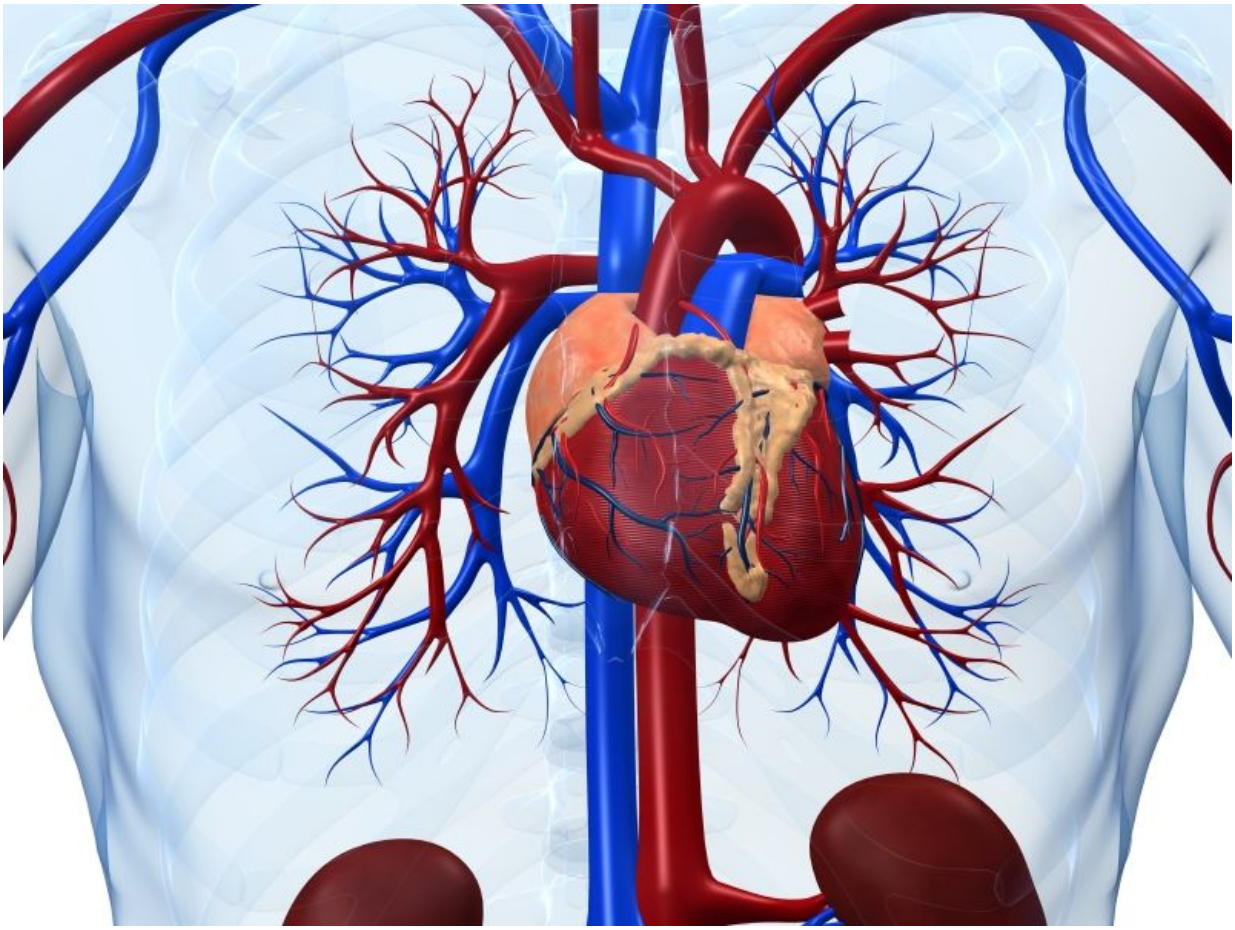
Postmarketing adverse events low for CardioMEMS HF system

September 19 2017



(HealthDay)—Postmarketing adverse events related to the CardioMEMS

HF System are infrequent, but can be serious, according to a research letter published online Sept. 18 in *JAMA Cardiology*.

Muthiah Vaduganathan, M.D., M.P.H., from the Brigham and Women's Hospital Heart & Vascular Center in Boston, and colleagues used data from the publicly available Manufacturer and User Facility Device Experience database to identify CardioMEMS HF System-related adverse events within three years of U.S. Food and Drug Administration approval.

The researchers found that there were more than 5,500 total CardioMEMS HF System implants in the United States in the first three years after FDA approval. During this period, 155 reports (2.8 percent) described 177 unique adverse events. There was a median of 42 days between the date of event and date the FDA received a report; 36 reports came within one week of the event. Overall, 94.8 percent of the reports were mandatorily reported by the manufacturer/user facility. Overall adverse events accrued gradually; reports of pulmonary artery (PA) injury/hemoptysis and deaths were clustered early after device introduction. There were 28 reports of PA injury/hemoptysis (0.5 percent), including 14 intensive care unit stays, seven intubations, and six deaths. Twenty-two deaths were included in the reports.

"Future partnerships between regulators, industry sponsors, and academia may help better triage available resources toward improving patient selection, operator experience, or device technology to optimize device use in clinical practice," the authors write.

Several authors disclosed financial ties to pharmaceutical and medical device companies, including St. Jude Medical (now Abbott, which markets the CardioMEMS System).

More information: Abstract/Full Text