Small wireless pacemaker is safe, effective in early testing

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A new small, wireless self-contained pacemaker appears safe and feasible for use in patients, according to a small study in the American Heart Association journal *Circulation*.

Although traditional pacemakers pose minimal risk, patients are still vulnerable to some short- or long-term complications, said Vivek Y. Reddy, M.D., lead author of the study and director of the Cardiac Arrhythmia Service at Mount Sinai Hospital in New York City.

Those complications can stem from the pulse generator implanted under the skin of the chest, where infections or skin breakdown can occur, and particularly from the leads, or wires, that run from the generator through a vein to the heart. Leads can break, dislodge or contribute to a vein blockage.

However, the new pacemaker has no leads—its pulse generator lies within the unit in the heart – and is placed without the need for surgery.

At 6 millimeters in diameter and about 42 millimeters long, the wireless device is smaller than a triple-A battery. It's faster and easier to implant than traditional pacemakers, Reddy said, and it's programmed and monitored similarly.

"While a much larger study is required to prove this, one may expect the leadless pacemaker to be associated with less chance of infection and lead-related problems such as lead fracture," Reddy said. "Overall, the self-contained pacemaker is a paradigm shift in cardiac pacing."

The study, called LEADLESS, was conducted in 33 Caucasian patients, average age 77, two-thirds men, at two hospitals in Prague and one in Amsterdam. The self-contained pacemaker was successfully implanted in 32 patients, or 97 percent. Ninety-four percent were free of complications through the three-month study period, the researchers reported.

The new device is a self-modulating pacer guided into place using a catheter inserted in the femoral vein and is affixed to the heart in the right ventricle, the same place a standard lead would be located. The device is for patients who require single-chamber pacing, or roughly 20 percent to 30 percent of U.S. and European patients who need pacemakers. Patients who need dual-chamber pacing would still require traditional pacemakers, according to Reddy.

Among the study's 33 patients, one suffered complications during the procedure and underwent emergency surgery but later died after suffering a stroke.

After three months, the new pacemakers were functioning well, the researchers found. They are continuing to track the patients and expect to report longer-term outcomes later this year. Meanwhile, a much larger study at multiple U.S. locations that will include longer-term follow-up is under way, Reddy said.

Provided by American Heart Association