



Study shows reduced complications from leadless pacemakers



A Cleveland Clinic-led study on the safety and effectiveness of leadless pacemakers has yielded encouraging results. Patients receiving leadless pacemakers experience overall fewer short-term and mid-term complications than those receiving traditional transvenous pacemakers, according to the multicentre study published in the journal *Heart Rhythm*.

Approximately one million pacemakers are implanted annually, providing electrical stimulation to regulate a patient's heartbeat. Conventional pacemakers are surgically placed under the skin of a patient's chest, with wires, or leads, stretching from the shoulder vein and attaching to the heart. These wires and the surgical implantation are the most common source of complications, occurring in up to 12 percent of device recipients, according to previous research.

Leadless pacemakers, by contrast, do not need wires. The small self-contained devices – about 10 percent of the size of a traditional pacemaker – are placed directly into the heart using a catheter passed through the femoral vein in the leg. As shown in the new study, leadless pacemakers reduced complications up to 18 months and eliminated pocket and lead-related problems.

“While this research shows benefit for leadless pacing, we must keep in mind that the field is still too young to compare the long-term results of this technology, the implications of which will not be fully understood for at least another decade,” said lead author Daniel Cantillon, MD, research director for Cardiac Electrophysiology and Pacing at Cleveland Clinic. Leadless pacemakers were introduced in 2014, and the first leadless pacemaker was approved by the FDA in 2016.

Dr. Cantillon and colleagues compared short- and mid-term complications between 718 patients receiving the Nanostim leadless pacemaker and 1,436 patients with conventional (transvenous) pacemakers. Leadless pacemaker patient data was taken from the LEADLESS II trial, while transvenous patient data were obtained from Truven Health MarketScan claims databases for patients implanted with single-chamber pacemakers.

At one month, the researchers found that patients receiving one type of leadless pacemaker (Nanostim) overall had fewer complications (5.8 percent vs. 9.4 percent). Leadless pacemakers completely eliminated lead and pocket complications, including infection. By comparison, complications among traditional pacemaker recipients included lead complications (3.62 percent), pocket complications (0.42 percent) and infection (1.74 percent). There were no significant differences between the groups in regard to rates of vascular complications, electrode dislodgement and generator complications.

However, the researchers noted that those receiving leadless pacemakers had an increased risk of developing pericardial effusion – bleeding between the heart and the sac that surrounds the heart (1.53 percent vs. 0.35 percent). These complications were uncommon but serious, and sometimes required surgery.

Beyond one month and up to 18 months of follow-up, leadless patients continued to experience overall fewer complications than transvenous patients (0.56 percent vs. 4.94 percent). In the conventional pacemaker group, there were a number of complications wholly absent from the leadless group, including lead-related complications, electrode dislodgement, infection and pocket complications.

Source: [Cleveland Clinic](#)

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