

Advanced Imaging Digest

Magnetic resonance imaging in patients with leadless pacemakers

First introduced in the 1970's and approved by the U.S. Food and Drug Administration in 2016, the leadless pacemaker is a novel alternative to standard transvenous pacemakers. The leadless pacemaker consists of a capsule-like device containing a generator and electrode system that is implanted into the right ventricular septum via a percutaneously inserted femoral venous catheter and anchored via self-expanding nitinol tines or a screw-in helix mechanism. Insertion requires no chest incision or subcutaneous pocket because vascular access is obtained through the femoral vein in the leg versus the subclavian vein in the chest, avoiding the risk of injury to the lung.

Magnetic resonance imaging (MRI) and leadless pacemaker compatibility

For decades, it was considered a contraindication and unsafe for patients with a pacemaker to receive an MRI because of the risk of life-threatening interference with the device. However, increased MRI adoption and demand are driving the need for device patients to have safe access to MRI.

Medtronic and Abbott have developed commercially available leadless pacemakers, Micra Transcatheter Pacing System and Nanostim Leadless Pacemaker, respectively. Both devices are MRI-compatible, meaning they are not damaged or displaced by the magnetic fields encountered in MRI imaging systems. On average, leadless pacemakers have seven percent the volume of standard pacemakers, roughly the size and shape of a large vitamin capsule. Comparable to a standard transvenous pacemaker, the battery of a leadless pacemaker typically lasts 4.7 to 15 years.

	Micra Transcatheter Pacing System (Medtronic)	Nanostim Leadless Pacemaker (Abbott)
Length	41.4 mm	25.9 mm
Volume	1 cm ³	0.8 cm ³
Weight	2 g	2g
Battery longevity	9.8 years (2.5 V @ 0.4 ms) 14.7 years (1.5 V @ 0.24 ms)	4.7 years (2.5 V @ 0.4 ms) 10 years (1.5 V @ 0.24 ms)

At battery end-of-life, the devices can be deactivated and new leadless pacemakers or standard transvenous pacemakers may be implanted. Leadless pacemakers are not typically removed as they become endothelialized in the myocardium, although extraction techniques are available if required.

Advantages of leadless pacemakers

The main advantage of leadless pacemakers is elimination of some of the adverse events encountered with conventional transvenous pacemakers. A recent meta-analysis comparing standard transvenous pacing systems with pooled data on Micra and Nanostim identified a 51% lower risk of complications using the Micra system versus transvenous pacing over the first year after implantation. (Data on the Nanostim device is inadequate.)

Of patients who receive a standard transvenous pacemaker, six to eight percent experience short-term complications, and 16% experience long-term complications (at three years). Early complications include hematoma and infection in the subcutaneous pocket, lead dislodgement, septicemia, pneumothorax, and venous thrombosis and occlusion. Long-term complications include lead fracture and insulation failure, lead-related infective endocarditis, tricuspid regurgitation, infection involving the pulse generator and skin erosion over the pulse generator. Complications involving leadless pacemakers totaled three percent and include femoral vascular trauma in 0.9% and cardiac perforation with subsequent pericardial effusion and cardiac tamponade in up to 1.5%. Although device dislodgement is a potential concern, it is rarely reported.

Advantages of MRI and leadless pacemaker compatibility

Leadless pacemakers have significantly improved the relationship between pacemakers and MRI, with the main advantage being the absence of leads and their small size. Micra and Nanostim leadless pacemakers allow patients to undergo body scans in 1.5-, and 1.5- and 3-tesla MRI machines, respectively. Additionally, many of the adverse events that patients may experience with standard transvenous pacemakers are rare, nonexistent and/or clinically insignificant. (Data on the Nanostim device is inadequate.)

Conclusion

Leadless pacemakers

Leadless pacemakers are not appropriate for all patients requiring pacing, as they are not capable of pacing or electrical sensing in the atria. They are most suitable for patients with permanent atrial fibrillation and high-grade atrioventricular (AV) block resulting in bradycardia in whom only ventricular pacing is indicated, patients with poor vascular access and elderly patients with complete AV block

who have limited physical activity. The device is not appropriate for patients who require active pacing in both chambers. Medtronic has recently introduced a leadless pacemaker that uses an accelerometer to detect atrial mechanical contractions and synchronize ventricular activation to atrial activity. Although it does not pace the atrium, it can restore AV synchrony in patients with competent sinus node function and high-grade AV block.

MRI in patients with leadless pacemakers

Due to their small size and absence of lead, leadless pacemakers significantly reduce risks long associated with standard transvenous pacemakers, including device heating, unintended cardiac stimulation, force, torque, vibration and device malfunction. With the appropriate precautions and protocols, and experienced personnel, patients with leadless pacemakers can safely undergo MRI scans in both 1.5- and 3-T MRI scanners.

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Dr. Fleck, a board-certified cardiologist and electrophysiologist with over 35 years of experience, joined Magellan in 2019. He earned a MD degree from Loyola University Chicago Stritch School of Medicine and completed his internal medicine training at Naval Medical Center San Diego. Dr. Fleck also completed training in cardiovascular disease at Naval Medical Center San Diego and clinical cardiac electrophysiology at the University of California San Diego.



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