

Worldwide Randomized Clinical Trial to Evaluate New Pacemaker System Designed for Use During Magnetic Resonance Imaging

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Pacemaker patients are excluded from magnetic resonance imaging (MRI) due to potential electromagnetic interference that could result in under/oversensing, thermogenic damage, device malfunction, or life-threatening cardiac arrhythmias. A new pacemaker and lead system designed to minimize lead tip heating and provide a programmable MRI pacing mode was tested in a worldwide randomized clinical trial. The pacemaker system has obtained CE mark but is investigational in the United States.

After successful implant of pacemaker and leads (EnRhythm MRI system, Medtronic), patients were randomized to MRI or no MRI (control). At 9-12 weeks post-implant, MRI patients received 14 clinically relevant head and lumbar scan sequences performed on 1.5 Tesla machines maximizing gradient slew rate and/or transmitted power up to specific absorption rate of 2 W/kg, and control patients waited 1 hour with no MRI. All patients were evaluated before, 1 week and 1 month after MRI scan/control visit.

A total of 464 patients were implanted at 41 centers in the US, Europe, Canada, and Middle East; 244 MRI scan visits occurred and 444 patients were followed 1 month after MRI scan/control visit. No MRI-related complications or MRI-attributed sustained ventricular arrhythmias, asystole episodes, or pacemaker malfunctions occurred. The system-related complication-free rate was 91.7% ($p < 0.001$). After 1 month post-MRI/control visit, capture thresholds, sensing amplitudes, and lead impedance were stable and similar between MRI and control patients. Pacing capture threshold increases were ≤ 0.5 V except in 1 control ventricular lead. Sensing amplitude decreases $> 50\%$, or to < 1.5 mV in atrial lead or < 5.0 mV in ventricular lead, occurred for atrial leads in 5.3% of MRI patients vs. 7.2% of control patients, and for ventricular leads in 3.0% of MRI patients vs. 5.1% of control patients.

There was no evidence of clinical (bradycardia or tachycardia), subclinical (pacemaker performance) or technical (pacemaker or lead damage) adverse events observed in patients receiving an MRI. In the MRI environment under specific guidelines, the new pacemaker system facilitates access to this important diagnostic imaging technique.

		Pre-MRI/control visit to 1 month post-MRI/control visit Mean \pm SD Change
Atrial pacing capture threshold	MRI	-0.01 \pm 0.23
	Control	-0.04 \pm 0.64
Ventricular pacing capture threshold	MRI	0 \pm 0.21
	Control	0.04 \pm 0.39
Atrial sensing	MRI	0 \pm 0.7
	Control	-0.1 \pm 0.8
Ventricular sensing	MRI	-0.1 \pm 1.9
	Control	-0.1 \pm 1.7
atrial impedance	MRI	-0.6 \pm 61.8
	Control	7.3 \pm 50.4
Ventricular impedance	MRI	-9.0 \pm 48.5
	Control	-5.7 \pm 51.8