# Real-world safety of magnetic resonance imaging after His bundle pacemaker implantation

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## Introduction

The Medtronic SureScan 3830 (Medtronic, Minneapolis, MN) pacing lead is increasingly being utilized for applications in conduction system pacing, including His bundle pacing, left bundle branch (LBB) area or left conduction system (LCS) pacing, and left ventricular (LV) septal pacing. The 3830 lead is a 4.1F (1.4 mm) lumenless braided core pacing lead that is typically delivered using a fixed-curve or steerable guiding sheath.[1,2] Multiple studies have demonstrated safety of thoracic and nonthoracic magnetic resonance imaging (MRI) in patients with traditional pacing or defibrillator leads that are larger (>5.6F), but similar reports are not available for the 3830 lead.[3,4] Although it is conditionally approved for patients undergoing MRI, the real-world safety and performance of the 3830 remain uncertain.

Particularly given the need for precise placement at the His bundle region or at the LCS, there is concern that MRI may be associated with risk of micro-dislodgement and subsequent rise in pacing threshold. Furthermore, given the lead's smaller diameter, there is a theoretical risk of greater tissue heating at the lead tip, which may have unanticipated effects at this location. We report a case of a patient who underwent cardiac MRI with a 3830 lead in place and maintained stable thresholds and also describe the real-world outcomes after MRI in a series of 11 patients.

## Case report

A 66-year-old man with a past medical history of nonischemic cardiomyopathy with an ejection fraction of 30% secondary to viral myocarditis presented to clinic following multiple shocks from his implantable cardioverter-defibrillator (ICD). Three months prior to this, the patient had undergone implantation of a cardiac resynchronization therapy device for LBB block and heart failure using a Medtronic 3830 lead placed in the LV port. Of note, traditional biventricular pacing with a coronary sinus lead was attempted but was unsuccessful owing to unfavorable coronary sinus anatomy. At the time of his clinic visit, interrogation of his device revealed 100% biventricular pacing with 3 episodes of sustained monomorphic ventricular tachycardia (VT). The first episode terminated spontaneously, while the following 2 episodes were appropriately treated with 36 J shocks following failed antitachycardia pacing.

The patient had already been maintained on medical therapy with amiodarone and mexiletine. Given ongoing VT refractory to medical therapy, the decision was made to pursue VT ablation. Cardiac positron emission tomography and MRI were ordered as part of preprocedural planning. At the time of cardiac MRI, the patient's device was set to DOO, antitachycardia pacing was disabled, and he underwent a modified 1.5 Tesla steady-state free precession MRI protocol.[5] MRI occurred 112 days after device implantation. The patient's 3830 lead parameters remained comparable pre- and immediately post-MRI: absolute ventricular capture threshold remained comparable (1.5 V at 1 ms pre-MRI vs 1.75 V at 1 ms post-MRI), corrective His threshold was unchanged (2.25 V at 1 ms pre- and post-MRI), and impedance declined slightly (304 ohms pre-MRI vs 266 ohms post-MRI with the lead programmed in the His-to–right ventricle [RV] coil configuration). The patient's right atrial (RA) and backup RV lead parameters were otherwise stable, and the device maintained 100% biventricular pacing throughout the MRI. No device-related complications were noted, and the device was reprogrammed to its original settings (ie, DDD) after MRI. MRI showed mid-myocardial late gadolinium enhancement in the basal inferior and inferolateral wall and a severely dilated RV. The 3830 lead was noted in the His position (Figure 1). Cardiac positron emission tomography showed no evidence of active inflammation (Figure 2). Transthoracic echocardiography showed a stable ejection fraction of 29% with global LV dysfunction and a flattened septum consistent with RV volume overload. The patient's VT was attributed to scarring from prior myocarditis and he was referred for VT

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## KEY TEACHING POINTS

- Magnetic resonance imaging (MRI), including cardiac MRI, appears safe in patients with the Medtronic 3830 lead (Medtronic, Minneapolis, MN). No electrical reset or acute arrhythmias were noted in this cohort.
- In this series, stable sensing, capture thresholds, and impedance were noted before and immediately after MRI.
- There was a nonsignificant trend toward reduced R-wave sensing at the His bundle location at 1 year, although numbers were small, and this finding should be verified in larger prospective studies.

ablation. The patient was taken to the electrophysiology lab and mapping of VT revealed a large clockwise macroreentrant circuit around the RV free wall with inferior breakout at the annulus. Extensive epicardial and endocardial ablation was performed until VT was no longer inducible. The patient tolerated the procedure well, and amiodarone and mexiletine were subsequently discontinued.

At a 2-month follow-up, the 3830 lead parameters (3 months after MRI) were slightly increased: absolute capture threshold was 2.0 V at 1 ms (rise by 0.25 V since prior MRI), corrective His threshold was 2.5 V at 1 ms (rise by 0.25 V before MRI), and impedance was 304 ohms. RA and RV lead parameters remained stable and the device continued to maintain 100% biventricular pacing. Interrogation at that time also revealed multiple ICD shocks and VT storm. The patient's amiodarone was resumed and he was referred for repeat VT ablation. The patient tolerated the procedure well with no complications. Amiodarone was subsequently discontinued. He presented for follow-up 6 months later with no new complaints and no further ICD therapies. Device interrogation at 6-month follow-up (10 months from MRI) again revealed stable 3830 lead parameters. Absolute pacing threshold was now similar to initial testing immediately post-MRI (1.75 V at 1 ms), corrective His threshold was 2.0 V at 1 ms, and impedance was 323 ohms. RA and RV lead parameters remained stable with 100% biventricular pacing. He had no further VT. The patient was instructed to follow up in 1 year. At 22 months post-MRI, the patient continued to demonstrate corrective pacing (Figure 3).

To supplement the observations of safe MRI in this case, we conducted a retrospective analysis of all patients at our center undergoing MRI with a 3830 lead in place. A total of 11 patients were identified (8 pacemakers, 3 cardiac resynchronization therapy systems with defibrillator). All patients underwent MRI with a 1.5 Tesla magnet a median of 272 days after lead implantation. Mean age was 71.5 ± 14.9 years. Three patients (27%) were female. Three patients (27%) had cardiac MRI, while 8 (73%) had nonthoracic MRI. Ten patients (91%) were utilizing the 3830 lead for attempted

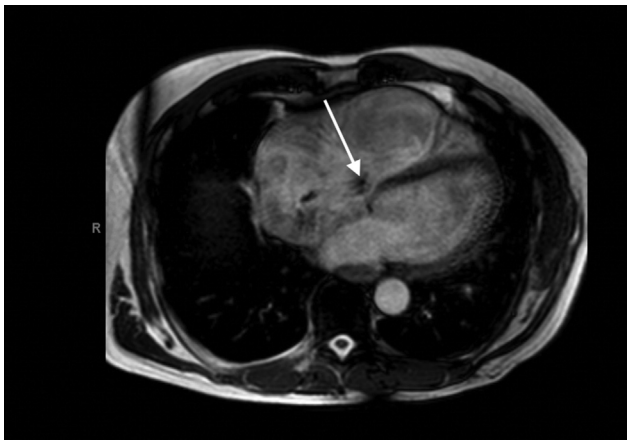


**Figure 1** Magnetic resonance imaging demonstrating basal inferior and inferolateral late gadolinium enhancement and a severely dilated right ventricle. The Medtronic 3830 lead (Medtronic, Minneapolis, MN) is visible at the His position (*arrow*).

His bundle pacing, and 1 patient (9%) had the lead deployed for left conduction system pacing. At the time of device implant, nonselective capture was present in 8 patients (73%), selective capture in 2 patients (18%), and proximal LCS (or LBB area) pacing in 1 patient (9%). At the time of MRI, 5 patients (45%) had unipolar 3830 lead configurations (ie, His tip–to–RV coil or His tip–to-can), and 6 (55%) had bipolar (ie, His tip–to–His ring) configuration. In 1 patient,

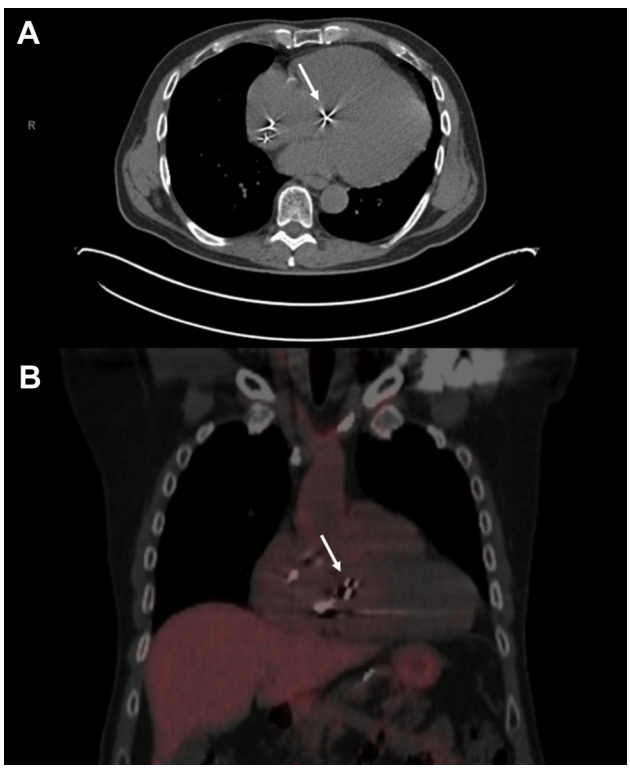


**Figure 2** Computed tomography scan images obtained during cardiac positron emission tomography. **A:** Axial image. **B:** Coronal image. The Medtronic 3830 lead (Medtronic, Minneapolis, MN) is displayed at the His position in both views (*arrows*).

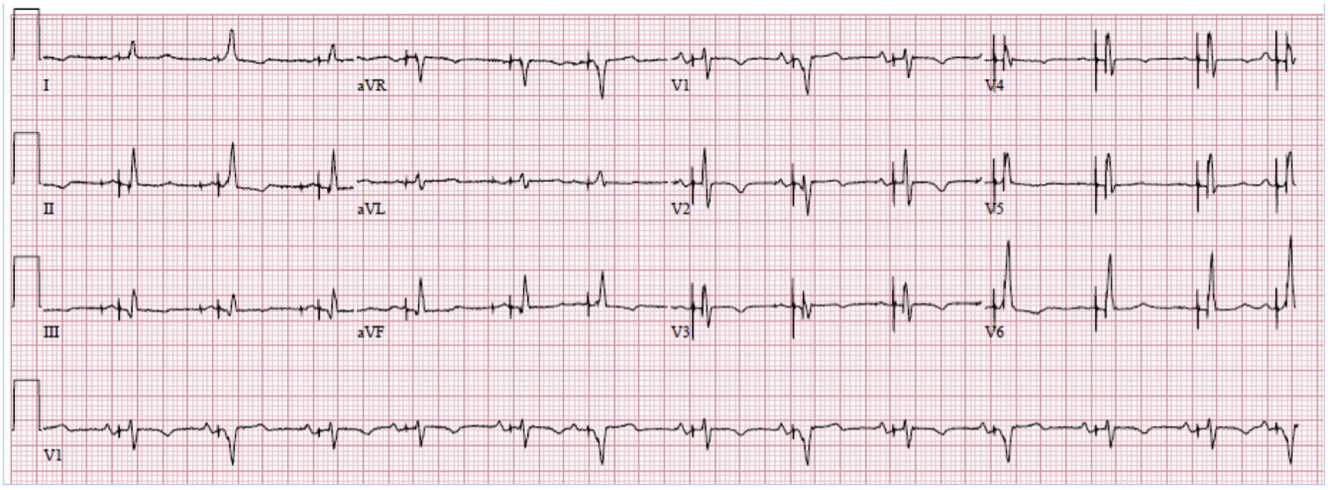


**Figure 3** Electrocardiogram obtained 22 months post–magnetic resonance imaging demonstrating continued corrective His pacing. Alternating QRS morphology is consistent with varying selective and nonselective capture at the programmed output.

capture thresholds were not available pre- or post-MRI owing to His lead micro-dislodgement that had been noted even prior to the study.

Sensing parameters and thresholds were assessed manually before and after MRI. Average lead parameters remained comparable pre-MRI and immediately post-MRI (Table 1). No MRI-related device complications were noted, including electrical reset or acute atrial or ventricular arrhythmias. Seven patients (64%) had repeat device interrogation a median of 382 days post-MRI and absolute ventricular capture thresholds, corrective His capture thresholds, and impedance remained comparable (Table 2). In patients for whom R-wave sensing data were available, however, a decrease in sensed R waves was noted at follow-up that neared significance when compared to initial assessment prior to MRI (Table 2).

## Discussion

The primary findings of the present case and series are as follows: (1) Patients with 3830 leads did not experience significant lead or device complications at the time of MRI, such as significant rise in pacing threshold, loss of corrective His pacing, or induction of atrial or ventricular arrhythmia. (2) The 3830 lead parameters (absolute threshold, corrective His pacing threshold, and pacing impedance) demonstrated minimal change after MRI and continued to remain stable in up to median 13 months of follow-up across patients.

While prior data suggest a low incidence of MRI-related complications even in legacy pacemakers and ICDs with traditional leads, there are theoretical concerns that the 3830 lead may be associated with higher risk during MRI owing to its small size and lower dispersive area, leading to greater risk for tissue heating at the lead tip and greater risk of subsequent local myocardial injury or micro-dislodgement.[6] In the present case and associated series, no significant adverse events were noted at the time of MRI for patients with 3830 leads. Overall pacing parameters, including absolute pacing threshold, corrective His pacing thresholds, and impedance, were comparable at baseline, immediately post-MRI, and in short-term follow-up (median 13 months). These results are consistent with one prior report showing no adverse outcomes immediately post-MRI in 10 patients with permanent His bundle devices,[7] and extend those observations to patients undergoing cardiac MRI. There was a trend toward reduction in sensed R waves in this series, which contrasts with other long-term reports of chronic sensing in His bundle pacemakers.[8] It is uncertain if this was due to possible fibrosis from lead tip heating or progression of underlying His-Purkinje conduction disease. Given relatively few patients with longer-term follow-up, the ability to make inferences remains limited. In a single patient in whom micro-dislodgement and loss of myocardial capture was noted prior to scheduling MRI, there was minimal change in sensing and impedance immediately pre- and post-study (0.5 mV and 38 ohms, respectively).

In the MagnaSafe Registry analysis, induction of atrial fibrillation or atrial flutter was noted in 6 of 1500 patients (0.4%) and no ventricular arrhythmias were noted.[4] In patients receiving the 3830 lead for His bundle pacing, depending on final lead tip location (either atrial or subvalvular), there is a theoretical risk of induction of either atrial or ventricular arrhythmias. No MRI-associated arrhythmias were noted in this study, although given the small sample size, findings cannot be generalized.

Importantly, the majority of the patients in the present study underwent nonthoracic MRI. There may be increased risk for MRI-associated complication in patients undergoing thoracic imaging owing to greater magnetic field strength acting on the leads. The 3 patients undergoing cardiac MRI in the present case review did not demonstrate differences compared to nonthoracic MRI patients.

**Table 1** Medtronic 3830 lead (Medtronic, Minneapolis, MN) parameters pre– and immediately post–magnetic resonance imaging

| | MRI type | Time from implantation (days) | 3830 lead location and device type | Time of interrogation (pre-/post-MRI) | R-wave sensing (mV) | Absolute pacing threshold (V) | Corrective His threshold | Pulse width (ms) | Impedance (ohms) |
|---|---|---|---|---|---|---|---|---|---|
| Patient 1[†] | Nonthoracic | 126 | His in LV port, CRT-D | Pre | —— | 0.5 | 0.75 | 0.8 | 304 |
| | | | | Post | —— | 0.5 | 0.75 | 0.8 | 304 |
| Patient 2 | Nonthoracic | 107 | RV His, PPM | Pre | 6.1 | 0.5 | 0.5 | 1.0 | 342 |
| | | | | Post | 6.1 | 0.5 | 0.5 | 1.0 | 342 |
| Patient 3[†] | Nonthoracic | 157 | His in LV port, CRT-D | Pre | —— | 4.25 | 5.0 | 1.0 | 285 |
| | | | | Post | —— | 4.25 | 5.25 | 1.0 | 285 |
| Patient 4 | Nonthoracic | 103 | LCS, PPM | Pre | 9.5 | 0.75 | —— | 0.4 | 475 |
| | | | | Post | 9.6 | 0.75 | —— | 0.4 | 475 |
| Patient 5 | Cardiac | 272 | RV His, PPM | Pre | 7.65 | 0.75 | —— | 0.4 | 571 |
| | | | | Post | 7.75 | 0.75 | —— | 0.4 | 570 |
| Patient 6 | Nonthoracic | 852 | RV His, PPM | Pre | 12.1 | 0.75 | 0.75 | 0.4 | 361 |
| | | | | Post | 12.1 | 0.75 | 0.75 | 0.4 | 342 |
| Patient 7 | Nonthoracic | 839 | His in RV port, CRT-P | Pre | 13.8 | 0.75 | 0.75 | 0.4 | 542 |
| | | | | Post | 13.8 | 0.75 | 0.75 | 0.4 | 551 |
| Patient 8 | Nonthoracic | 468 | RV His, PPM | Pre | 5.6 | 2.0 | 2.0 | 0.4 | 456 |
| | | | | Post | 5.9 | 1.75 | 1.75 | 0.6 | 456 |
| Patient 9[‡] | Cardiac | 737 | RV His, PPM | Pre | —— | 1.0 | 1.0 | 0.4 | 323 |
| | | | | Post | —— | 1.0 | 1.0 | 0.4 | 399 |
| Patient 10 | Nonthoracic | 642 | RV His, PPM | Pre | 1.6 | —— | —— | —— | 456 |
| | | | | Post | 1.1 | —— | —— | —— | 494 |
| Patient 11[†] | Cardiac | 112 | His in LV port, CRT-D | Pre | —— | 1.5 | 2.25 | 1.1 | 304 |
| | | | | Post | —— | 1.75 | 2.25 | 1.1 | 266 |
| Mean (N = 11) | | | | Pre | 8.1 | 1.3 | 1.6 | 0.6 | 402 |
| | | | | Post | 8.1 | 1.3 | 1.6 | 0.7 | 408 |
| Standard deviation | | | | Pre | 4.1 | 1.2 | 1.5 | 0.3 | 102 |
| | | | | Post | 4.3 | 1.1 | 1.6 | 0.3 | 108 |
| *P* value (paired t test) | | | | | 1 | 1 | 1 | 0.34 | 0.52 |

CRT-D = cardiac resynchronization therapy with defibrillator; CRT-P = cardiac resynchronization therapy pacemaker; LCS = left conduction system; LV = left ventricle; MRI = magnetic resonance imaging; PPM = permanent pacemaker; RV = right ventricle.

[†]Patient with His lead in LV position and R-wave magnitude was not retrievable.

[‡]Patient was pacemaker dependent and no R waves could be sensed.

**Table 2** Medtronic 3830 lead (Medtronic, Minneapolis, MN) parameters pre–magnetic resonance imaging and at short-term follow-up (median 382 days from initial magnetic resonance imaging) for patients who underwent repeat interrogation

| | Follow-up interval (days) | Time of interrogation (pre-MRI or follow-up) | R-wave sensing (mV) | Absolute pacing threshold (V) | Corrective His threshold | Pulse width (ms) | Impedance (ohms) |
|---|---|---|---|---|---|---|---|
| Patient 1 | 181 | Pre-MRI | —— | 0.5 | 0.75 | 0.8 | 304 |
| | | Follow-up | —— | 1.0 | 1.25 | 0.8 | 247 |
| Patient 2 | 382 | Pre-MRI | 6.1 | 0.5 | 0.5 | 1.0 | 342 |
| | | Follow-up | 3.3 | 0.75 | 0.75 | 0.4 | 342 |
| Patient 3 | 524 | Pre-MRI | —— | 4.25 | 5 | 1.0 | 285 |
| | | Follow-up | —— | 3.5 | 4.25 | 1.0 | 285 |
| Patient 5 | 1129 | Pre-MRI | 7.65 | 0.75 | —— | 0.4 | 571 |
| | | Follow-up | 5.3 | 1.0 | —— | 0.4 | 532 |
| Patient 8 | 905 | Pre-MRI | 5.6 | 2.0 | 2.0 | 0.4 | 456 |
| | | Follow-up | 4.8 | 1.25 | 1.25 | 1.0 | 418 |
| Patient 10 | 22 | Pre-MRI | 1.6 | —— | —— | —— | 456 |
| | | Follow-up | 1.0 | —— | —— | —— | 513 |
| Patient 11 | 307 | Pre-MRI | —— | 1.5 | 2.25 | 1.1 | 304 |
| | | Follow-up | —— | 1.5 | 2.25 | 0.5 | 266 |
| Mean (N = 7) | | Pre-MRI | 5.2 | 1.6 | 2.1 | 0.8 | 388 |
| | | Follow-up | 3.6 | 1.5 | 2.0 | 0.7 | 372 |
| Standard deviation | | Pre-MRI | 2.6 | 1.4 | 1.8 | 0.3 | 108 |
| | | Follow-up | 1.9 | 1.0 | 1.4 | 0.3 | 118 |
| *P* value (paired *t* test) | | | 0.06 | 0.72 | 0.59 | 0.61 | 0.31 |

MRI = magnetic resonance imaging.

## Conclusion

MRI in patients with the Medtronic SureScan 3830 pacing lead at the His bundle position appears safe based on these initial observations. No significant changes in lead parameters were seen either immediately post-MRI or in short-term follow-up, although these findings will need to be verified in larger prospective studies.

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