

Randomized trial of pacemaker and lead system for safe scanning at 1.5 Tesla

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BACKGROUND Magnetic resonance imaging (MRI) of pacemakers is a relative contraindication because of the risks to the patient from potentially hazardous interactions between the MRI and the pacemaker system. Chest scans (ie, cardiac magnetic resonance scans) are of particular importance and higher risk. The previously Food and Drug Administration-approved magnetic resonance conditional system includes positioning restrictions, limiting the powerful utility of MRI.

OBJECTIVE To confirm the safety and effectiveness of a pacemaker system designed for safe whole body MRI without MRI scan positioning restrictions.

METHODS Primary eligibility criteria included standard dual-chamber pacing indications. Patients (n = 263) were randomized in a 2:1 ratio to undergo 16 chest and head scans at 1.5 T between 9 and 12 weeks postimplant (n = 177) or to not undergo MRI (n = 86) post-implant. Evaluation of the pacemaker system occurred immediately before, during (monitoring), and after MRI, 1-week post-MRI, and 1-month post-MRI, and similarly for controls. Primary end points measured the MRI-related complication-free rate for safety and compared pacing capture threshold between MRI and control subjects for effectiveness.

RESULTS There were no MRI-related complications during or after MRI in subjects undergoing MRI (n = 148). Differences in pacing capture threshold values from pre-MRI to 1-month post-MRI were minimal and similar between the MRI and control groups.

CONCLUSIONS This randomized trial demonstrates that the Advisa MRI pulse generator and CapSureFix MRI 5086MRI lead system is safe and effective in the 1.5 T MRI environment without positioning restrictions for MRI scans or limitations of body parts scanned.

KEYWORDS Advisa MRI; CapSureFix MRI; Chest scan; EnRhythm MRI; Magnetic resonance imaging; Pacemaker; Revo MRI; Safety; SureScan; 5086MRI

ABBREVIATIONS AEAC = adverse events adjudication committee; MR = magnetic resonance; MRI = magnetic resonance imaging; PCT = pacing capture threshold; RF = radiofrequency; SAR = specific absorption rate

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Introduction

Safe, unrestricted whole body imaging, particularly of the thoracic region, is a critical unmet need for patients with pacemakers

Before the Food and Drug Administration approval of the Medtronic Revo MRI system, all pacemakers had a label

warning against magnetic resonance imaging (MRI) scanning. The Revo MRI system has positioning restrictions for MRI scans around the chest region; the position of the isocenter of the radiofrequency (RF) transmitter coil must be above the C1 vertebra or below T12. This may pose a challenge to readily image thoracic structures optimally without degrading the resolution of the image.

Cardiac magnetic resonance (CMR) defines cardiac masses,¹ detects ischemia,² helps manage heart failure,³ defines coronary flow reserve,⁴ optimizes placement of cardiac resynchronization therapy leads,⁵ and helps guide RF ablation therapy through the integration of MRI into clinical mapping systems.⁶ CMR is being integrated whole-sale into ablation/imaging suites.⁷

The Advisa MRI System Study was funded by Medtronic. The following persons are consultants to Medtronic: David Bello, David L. Hayes, Emanuel Kanal, J. Rod Gimbel, Juerg Schwitter, and Torsten Sommer. The following persons are employed by Medtronic: Yanping Chang and Sarah Willey. **Address reprint requests and correspondence:** Dr J. Rod Gimbel, Cardiology Associates of East Tennessee, 9330 Park West Blvd Ste 202, Knoxville, TN 37923-4310. E-mail address: gimbeljr@ix.netcom.com.

Complex chronic cardiovascular disease requires safe, repeatable imaging defining a broad spectrum of cardiovascular pathologies coexisting within the same patient (with pacemaker). Without the development of pacing systems capable of easily and safely undergoing chest scans without positioning restrictions, many patients with cardiovascular diseases who would benefit most from MR scanning would be excluded.

Risks associated with MRI of patients with pacemakers

MRI of pacing systems not labeled MR conditional remains a cause of concern. Complications appear to occur at a frequency of <10%,⁸ and while some are rare⁹ and clinically benign without a permanent impact, others are serious¹⁰ and potentially life-threatening.¹¹ Underreporting of the ill effects of off-label scanning is probably common. In addition, when an adverse outcome occurs, litigation may follow,¹² further shrouding the details of the event.

Patient deaths during inadvertent scans or when patients were insufficiently monitored have been documented.^{13–15} Despite an infrequent occurrence, the seemingly occasional random occurrence of life-threatening asystole¹¹ or ventricular fibrillation¹⁵ may not provide satisfactory comfort for the device patient or physician contemplating MRI if technology exists that anticipates and addresses the risks involved in scanning patients with pacemakers. Within this context, the Advisa MRI pacemaker and CapSureFix 5086MRI lead system was developed to provide a safe, reliable access to MRI at 1.5 T without anatomical positioning restrictions.

Methods

Pacemaker system

Before the introduction of the Advisa MRI system for human use, preclinical testing involving bench and animal investigations as well as computer modeling was conducted to understand the effects of MRI on pacing systems.¹⁶ Multiple system design modifications were required to ameliorate the adverse interactions seen in these investigations: (1) the leads were modified to reduce RF heating, (2) internal circuitry was designed to reduce the potential for inappropriate cardiac stimulation, (3) the amount of ferromagnetic materials was limited, (4) a robust front-end protection network and hybrid filtering was implemented to prevent disruption of the internal power supply and mitigate the effects of MRI energy coupling to the telemetry coil, (5) the reed switch was replaced with a Hall sensor (disengaged during the MRI SureScan mode) helping to provide predictable pacing during MRI, and (6) a dedicated programming care pathway was implemented to facilitate execution of a pre-MRI checklist and selection of tailored pacing settings appropriate for the patient during MRI. These modifications combine to effectively address the risks of MRI scanning in patients with pacemakers.

Trial design and patient selection

This was a prospective randomized controlled, nonblinded, multicenter trial (ClinicalTrials.gov Identifier NCT01110915). The Declaration of Helsinki was followed, as well as laws and regulations of participating countries. The institutional review board approval and patient informed consent were obtained. Enrollment required class I or II dual-chamber pacemaker indications¹⁷ and pectoral implant. Patients agreed to undergo a protocol-required MRI without intravenous sedation, had no implanted non-MRI compatible devices or materials, had no other implantable-active medical devices, and had no abandoned leads. Assuming the actual atrial or ventricular pacing capture threshold (PCT) success rates were 96% in both the MRI and control groups, sample sizes of approximately 133 MRI and 67 control subjects would achieve 90% power to detect a 10% noninferiority margin difference by using the 1-sided Farrington and Manning method. The overall sample size was increased to 270 subjects to account for up to 25% attrition from enrollment to 1-month post-MRI to ensure 200 subjects would have primary end point data.

Randomization

After successful device implant, randomization took place in a 2:1 ratio to undergo (MRI group) or to not undergo (control group) an MRI scan 9–12 weeks after implant. Statisticians created randomization schedules stratified by center by using randomized block methods. The center-specific randomization schedule was transferred in sequence to labels in individually sealed envelopes, which were then opened in order.

Data collection and analysis

Follow-up occurred 2 months postimplant, 9–12 weeks postimplant, 1-week post-MRI/control, 1-month post-MRI/control, 6 months postimplant, and then every 6 months until study closure. The 9–12-week visit consisted of an evaluation immediately before MRI (pre-MRI evaluation), during MRI, and immediately after MRI (post-MRI evaluation), as well as at corresponding time points for the control group. During these evaluations, PCT at a pulse width of 0.5 ms, sensed electrocardiogram amplitude, and lead impedance were collected. Adverse events and technical observations were evaluated at all visits, including before and after the MRI scan. Pacemaker stored data, rhythm strips during PCT testing, and case report forms were collected.

MRI

The MRI scans were performed with 1.5 T systems from 3 commercially available MRI manufacturers (General Electric, Philips, and Siemens). MRI sequences were chosen to represent clinically relevant scans that were similar between scanners. Sixteen MRI head and chest scan sequences were performed. The scan protocol included MR scans with maximized RF energy deposition up to specific absorption rate (SAR) levels of 2 W/kg body and scans with maximized gradient slew rates. The body coil served as the RF transmit

coil. Static magnetic field exposure was approximately 60 minutes with cumulative actual MRI scan times of approximately 30 minutes (gradient and RF field exposure). Pulse oximetry, verbal communication, and either electrocardiography or noninvasive blood pressure measurements provided monitoring information.

Statistical analysis

The study had 2 primary objectives. An α -level of .025 was used for each analysis.

The primary safety objective was to demonstrate that the MRI-related complication-free rate in the month following MRI was $>90\%$. A 1-sided, 1-proportion binomial exact test was used, and the corresponding 1-sided 97.5% lower confidence bound was calculated.

The primary effectiveness objective was to demonstrate the noninferiority of the MRI group compared to the control group with regard to the proportion of patients who experienced a change in atrial or ventricular PCT ≤ 0.5 V at 0.5 ms pulse width from before the MRI/control visit to the

1-month after the visit. The noninferiority margin was 10%. A Farrington-Manning test of 2 independent proportions was performed, and the 1-sided P value was used to evaluate the test. Atrial and ventricular end points were evaluated separately.

Data imputation methodology was prespecified in the protocol. If a PCT measurement before the MRI/control visit was unavailable or invalid, a valid 2-month PCT value was used. For the post-MRI/control PCT value, the 1-month post MRI PCT was used. If that did not exist or was not valid, the first available follow-up value from (in order) 1-week post-MRI, 6 months postimplant, or 12 months postimplant was used.

Prespecified analysis exclusions were listed in the protocol. To assess the robustness of the analysis to missing/excluded data, a tipping point analysis was performed on the basis of all randomized patients. A tipping point analysis replaces the missing data with values so that the resulting P value is equal to (or greater than but close to) a prespecified significance level.¹⁸ Tipping point analyses were carried out separately for atrial and ventricular end points.

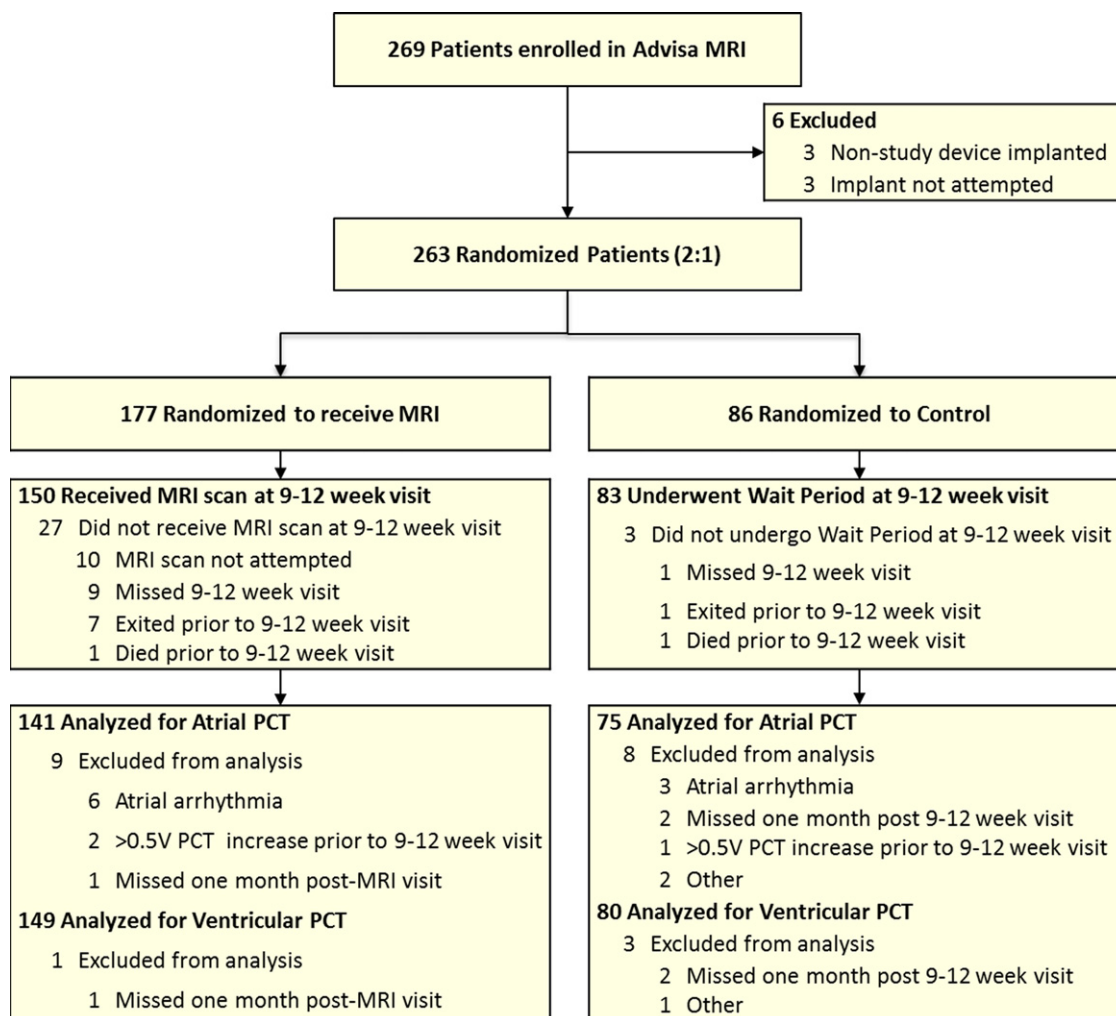


Figure 1 CONSORT¹⁹ diagram: pacing capture threshold population analysis. MRI = magnetic resonance imaging; PCT = pacing capture threshold.

The pacing system-related complication-free rate through the 1-month post-MRI visit was compared to a value of 80% by using Kaplan-Meier method with a 95% lower confidence bound. Events between studies were compared by using the Fisher exact test.

Adverse event classification

Adverse events were collected throughout the trial. The adverse events adjudication committee (AEAC) reviewed all events, providing adjudication of the relationship between adverse events and the implant procedure, MR procedure, and the pacing system. On occasion, adverse events were classified as having an unknown relationship. All adverse events were classified as either a complication or an observation. Complications included events resulting in death, involving termination of significant device function, or required invasive intervention; an observation was any adverse event that was not a complication.

The accreditations for all MR scanners were reviewed. The scan sequences, duration, and SAR values for all subjects were reviewed by at least 3 members of the scan advisory board.

Results

Trial population sample size

Distribution of patient enrollments, randomization group, and inclusion and exclusion of data is presented in [Figure 1](#). Mean follow-up was 7.1 ± 4.1 months (range 0–18.8 months) for the 269 subjects enrolled between June 2010 and October 2011. Evaluation of the Advisa MRI system included 1903.1 months of the device implant in 263 successfully implanted subjects. Patient characteristics of the patients with pacemakers are shown in [Table 1](#).

Safety

A total of 150 subjects underwent an MRI scan, and 148 of these were followed through the 1-month post-MRI visit or later follow-up and were included in the analysis. One subject missed the 1-month post-MRI visit and 1 died before the 1-month post-MRI visit. Neither subject experienced an MRI-related complication.

There were no MRI-related complications among the 148 patients included in the analysis. This is 100% success (1-sided lower 97.5% confidence bound 97.5%). The primary safety objective was met ($P < .0001$).

While there were no MRI-related complications, the AEAC classified 5 events as MRI-procedure-related observations. Subjects reported implant site paresthesia ($n = 2$) and implant site warmth ($n = 1$), which required no actions and the MRI scanning continued. Two subjects had their MRI scans stopped early owing to a hot flush ($n = 1$) and implant site pain ($n = 1$). Diagnostic tests and procedures were unremarkable for all 5 subjects.

Three deaths occurred: 2 in the MRI group and 1 in the control group. None were related to the Advisa MRI system, implant procedure, or MRI procedure as

Table 1 Baseline demographic and clinical characteristics

Characteristic	MRI group (n = 177)	Control group (n = 86)
Age (y)	68.1 \pm 12.8	68.7 \pm 10.8
Sex: Male	109 (61.6%)	54 (62.8%)
Race		
White or Caucasian	147 (83.1%)	75 (87.2%)
Asian	4 (2.3%)	2 (2.3%)
Black or African American	3 (1.7%)	0 (0.0%)
Hispanic or Latino	2 (1.1%)	0 (0.0%)
American Indian or Alaska Native	1 (0.6%)	0 (0.0%)
Not available	20 (11.3%)	9 (10.5%)
Primary indication for implant		
AV block	51 (28.8%)	35 (40.7%)
Sinus node dysfunction	95 (53.7%)	41 (47.7%)
Other	31 (17.5%)	10 (11.6%)
Atrial arrhythmias	119 (67.2%)	57 (66.3%)
Ventricular arrhythmias*	23 (13.0%)	8 (9.3%)
AV junctional arrhythmias and blocks	108 (61.0%)	50 (58.1%)
Cardiovascular surgery history		
Ablation	9 (5.1%)	5 (5.8%)
Coronary artery bypass graft	15 (8.5%)	5 (5.8%)
Coronary artery intervention	23 (13.0%)	7 (8.1%)
Valve surgery	16 (9.0%)	5 (5.8%)
Cardiovascular history		
Cardiomyopathy	30 (16.9%)	8 (9.3%)
Myocardial infarction	17 (9.6%)	9 (10.5%)
Syncope	70 (39.5%)	35 (40.7%)
Valve dysfunction	38 (21.5%)	21 (24.4%)

Values are represented as mean \pm SD or as n (%).

AV = atrioventricular.

*Ventricular arrhythmia includes long Q/T syndrome, premature ventricular complexes, nonsustained ventricular tachycardia, ectopic ventricular beats, slow ventricular rhythm, polytop ventricular extrasystoles, ventricular extra systoles, torsades de pointes, and severe left diastolic dysfunction.

adjudicated by the AEAC. Of the 2 MRI group deaths, 1 subject died of sudden cardiac death 21 days post-MRI and the other died 26 days postimplant without having an MRI scan.

The proportion of subjects free of pacing system-related complications through 4 months postimplant was 92.3% with a 1-sided lower 95% confidence bound of 89.1%. Twenty-five pacing system-related complications were reported from 20 subjects. System-related complications with an occurrence greater than 1 included lead dislodgement, pericardial effusion, and cardiac perforation ([Table 2](#)). The percentages of patients with these events were not statistically different from those seen in the EnRhythm MRI study.²⁰

Effectiveness

No patients saw an increase of >0.5 V in their atrial PCT, and so the success rate for atrial PCT was 100% (141 of 141) in the MRI group and 100% (75 of 75) in the control group ([Figure 2](#)). With both rates at 100%, a P value could not be calculated.

The success rate for ventricular PCT was 98.0% (146 of 149) in the MRI group and 97.5% (78 of 80) in the control group ([Figure 3](#)). The 95% confidence interval for the

Table 2 System-related complications occurring more than once in both the Advisa MRI and the EnRhythm MRI studies through 4 months postimplant

Events	EnRhythm MRI (n = 467)		Advisa MRI (n = 266)		P
	No. of events	No. of subjects	No. of events	No. of subjects	
Lead dislodgement	17	17 (3.6%)	14	11 (4.1%)	.84
Cardiac perforation	2	2 (0.4%)	3	3 (1.1%)	.36
Pericardial effusion	3	3 (0.6%)	2	2 (0.8%)	1.00

difference was -5.0% to 5.9% . The *P* value of the statistical test evaluating whether the MRI group is noninferior to the control group with a 10% margin was $<.0001$.

A number of randomized patients (atrial PCT: 20% MRI and 13% control subjects; ventricular PCT: 16% MRI and 7% control subjects) did not contribute data to the analysis primarily because of MRI scans not being performed for various reasons and atrial arrhythmia (Figure 1). Tipping point analyses were done to assess potential effects of the missing data. Those analyses showed that unless the missing patients had results far off the observed results (ie, 10 of 36 and 10 of 28 MRI group patients with missing data would need to see an atrial and ventricular PCT rise of >0.5 V post-MRI, respectively), the study would still meet its end points.

One subject in the MRI group experienced a change of 1.75 V from the pre-MRI visit to the 1-month post-MRI visit. A review of thresholds and recorded pulse generator data for visits pre- and post-MRI scan indicate that this subject experienced high thresholds shortly after implant, which continued to increase over time. Thresholds reported pre-MRI and immediately post-MRI examination were the same (2 V at 0.5 ms), indicating that MRI had no effect on the subjects' PCT. This subject had a system revision 185 days post-MRI for lead dislodgement. The lead dislodgment was adjudicated as not MRI procedure related.

Discussion

This prospective randomized controlled, nonblinded, multicenter trial was conducted to evaluate the safety and efficacy of a specially engineered full featured pacing system designed to undergo 1.5 T MRI of any body part and without anatomical positioning restrictions. This is the first

prospective randomized evaluation known of patients with pacemakers who were receiving MRI scans within the cardiac region. Radiology conditions are simplified by removing positioning restrictions and thus facilitate diagnostic MR scanning. The primary objectives of safety and efficacy were robustly demonstrated. There were no MRI-related complications observed in this study, supporting the view that the Advisa MRI SureScan technology effectively addresses the many and varied potential concerns that physicians consider and patients with pacemakers face when undergoing 1.5 T MRI. System-related complications associated with system use (Table 2) were within an acceptable and expected range.²¹

Comparison to off-label use of conventional unmodified pacing systems

Many adverse effects reported during off-label MRI are infrequent. Nevertheless, this may not allay the concerns of the everyday practitioner who might want to regularly scan patients with pacemakers. Strategies to facilitate off-label scanning have been proposed.²²⁻²⁴ However, without a system specifically designed and modified for safe scanning, these strategies do little or nothing to address lead heating, power on reset and its consequences, unpredictable reed switch behavior, and inhibition of device output, for example. In contrast, because of the many system modifications, the Advisa MRI system provides a safe predictable MRI experience for both the patient and the physician as confirmed in this study.

Suggestions that off-label MRI is "safe" for patients with pacemakers remain causes of concern, particularly since fewer than 2000 pacing systems have reportedly undergone

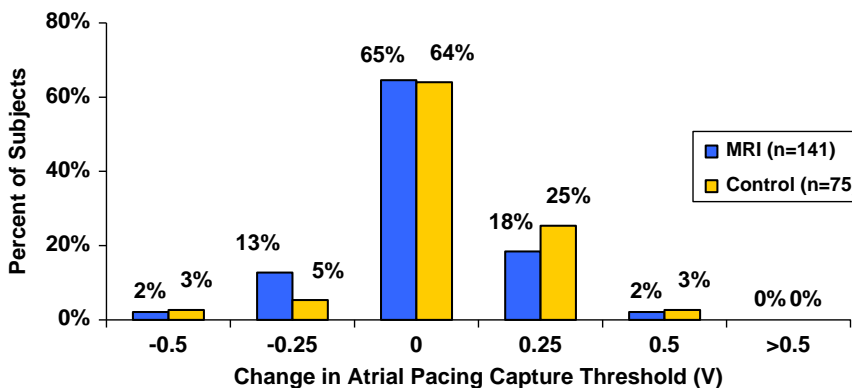


Figure 2 Atrial pacing capture threshold changes from the pre-9–12-week visit to the 4-month visit. MRI = magnetic resonance imaging.

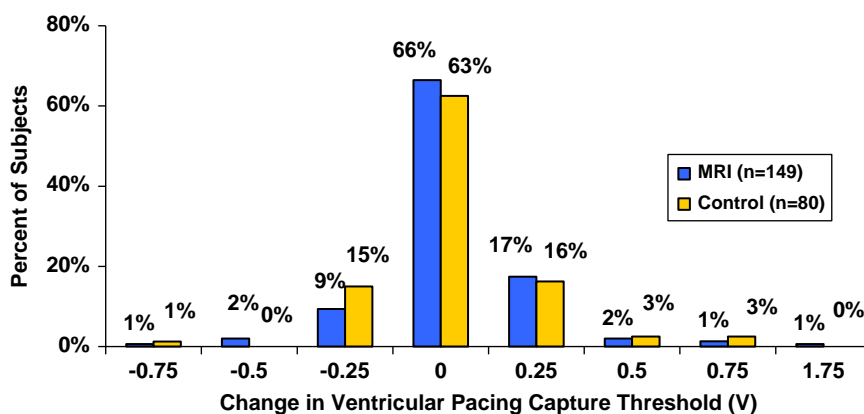


Figure 3 Ventricular pacing capture threshold changes from the pre-9–12-week visit to the 4-month visit. MRI = magnetic resonance imaging.

MRI. Why? Perhaps most importantly, previous studies involving off-label scanning are characterized by very small numbers of *specific* devices (often less than 3 and often only 1).²⁵ Different pulse generators and lead pairings are presented, making it difficult to compare “apples to apples” when evaluating the safety of off-label scanning of any *specific* device and lead system. The argument that off-label scanning of devices is potentially safe (or even that the risks are acceptably manageable)²⁶ is significantly undermined by the statistically small sample of each device and lead system presented in previous literature.²⁵ In contradistinction, the Advisa MRI trial presented *is* statistically powered to demonstrate the safety and efficacy of its prespecified end points of a *specific* single system (pulse generator and leads) undergoing 1.5 T MRI.

The off-label scanning of patients dependent on pacemakers is “strongly discouraged.”²² Patients dependent on pacemakers are most vulnerable to the effects of unexpected and unpredictable power on reset because these events may result in asystole.¹¹ Significantly, the system modifications and programming modalities available in the Advisa MRI system allow patients dependent on pacemakers to enjoy safe, reliable access to MRI.

The evaluation of the Advisa MRI system showed no evidence of PCT changes, power on reset, or unintended cardiac stimulation. Importantly, this study gives patients with Advisa MRI access to the full range of imaging capabilities that MRI can offer, including directly imaging all cardiac structures.

Limitations

Only 1.5 T MRI was evaluated. Only 1 type of pulse generator (Advisa MRI) and 1 type of lead (5086MRI) in a dual-chamber configuration was evaluated. The labeling restrictions for the Advisa MRI SureScan pacemaker system require keeping the SAR at or below 2 W/kg. From a practical perspective, other publications describing MRI of patients with device where SAR was limited to less than 2 W/kg (for safety reasons to reduce heating) failed to mention any compromise of image quality in the MR scans obtained. In fact, in multiple studies, “diagnostic quality” studies²³ are

the rule, not the exception, with investigators reporting that despite limiting SAR below 2 W/kg “all clinically relevant MRI sequences necessary for diagnosis were performed.”²⁷ In addition, pacemaker dependency was not collected, nor was information regarding the patient’s left ventricular ejection fraction.

Conclusions

This prospective randomized trial demonstrates that the Advisa MRI system is safe and effective in the 1.5 T MRI environment, providing MRI access without compromising positioning restrictions.

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