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Cardiac Pacemakers and Implantable Cardioverter Defibrillators: *In Vitro* Magnetic Resonance Imaging Evaluation at 1.5-Tesla

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ABSTRACT

Rationale and Objectives: **To evaluate the effect of Magnetic Resonance Imaging (MRI) performed at 1.5-Tesla on current generation pacemakers and ICDs to identify safe parameters for MRI examinations.** ***Methods:*** **Pacemakers (Identity ADx XL DR+ 5386 and Identity ADx DR + 5380 generators; 1688T/52-cm atrial and ventricular leads) and ICDs (Atlas + V-243, Epic + V-236, and Epic + HF V-350 generators; Riata 1581/65-cm and QuickSite 1056K/75-cm leads; St. Jude Medical, Sylmar, California, USA) were evaluated for magnetic field interactions. MRI-related heating was assessed using various levels of RF power (SARs) and conditions that included scans on different body regions. Functional aspects of the devices were evaluated immediately before and after MRI procedures utilizing nine different pulse sequences. Induced currents were measured using a custom built system.** ***Results:*** **Magnetic field interactions will not create a hazard for these pacemakers and ICDs. All scans of the "head" and "lumbar" regions resulted in temperature changes $\leq$0.5°C at SARs ranging from 2.0 to 3.0-W/kg. For the "chest" area, temperature increases ranged from 0.4°C to 3.6°C at an SAR of 2.0-W/kg. No memory corruption, hardware changes, or changes in device parameters were seen. Magnetic field gradients have a low likelihood of inducing currents that would stimulate the heart.** ***Conclusions:*** **No hazardous magnetic field interactions or physiologically significant heating occurred for certain conditions. There was no permanent effect on device function. By following specific conditions, these pacemakers and ICDs may be safe for patients scanned at 1.5-Tesla.**

Keywords: Magnetic Resonance Imaging, Safety, Implants, Cardiac Pacemaker, Implantable Cardioverter Defibrillator, Specific Absorption Rate.
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INTRODUCTION

Cardiac pacemakers and implantable cardioverter defibrillators (ICDs) are generally contraindicated devices for magnetic resonance imaging (MRI) (1–3). However, the latest generation devices have features that include decreased ferromagnetic components, more sophisticated circuitry, and improved electromagnetic interference rejection capabilities, which may make these cardiac devices less problematic for MRI (1, 2, 4–8). Recent investigations conducted using *in vitro* techniques, laboratory animals, and patients demonstrated that certain "modern-day" (for the purpose of this discussion, defined as being manufactured in year 2000 or later) pacemakers and ICDs are not adversely affected by MRI, especially if procedures are performed under highly specific conditions (5–16). Therefore, these studies add to the body of knowledge that MRI can be safe under well-controlled conditions, but more studies are warranted.

For an electronically-activated implant, it is necessary to conduct a comprehensive evaluation of possible MRI-related risks

to identify criteria that minimize patient injury and device damage (2, 7, 8, 17–22). *In vitro* testing is typically used to develop guidelines for implants, defining the particular MRI and device (e.g., reprogramming) conditions that must be followed to promote safety (2, 7, 8, 17–25). Interestingly, the Food and Drug Administration has approved labeling that allows patients with certain electronically-activated implants that have components similar to pacemakers and ICDs (e.g., neurostimulation systems used for deep brain stimulation, vagus nerve stimulation, and spinal cord stimulation) to undergo MRI, as long as specific guidelines are followed (2, 18, 19).

The strategy that is applied to determine MRI safety for electronically-activated implants on a model-by-model basis involves an assessment of magnetic field interactions, MRI-related heating, and functional changes (2, 7, 8, 17–25). For certain implants, induced currents may create problems. However, several investigators have reported that this is not a substantial concern for modern-day pacemakers and ICDs (4–7, 9–16). Therefore, in consideration of the above, the goal of this investigation was to perform a comprehensive *in vitro* evaluation of several current generation pacemakers and ICDs to define the impact of the MRI on these devices and to determine parameters that may allow patients with these particular devices to safely undergo MRI at 1.5-Tesla. To date, these cardiac devices, which represent "latest models" and commonly used pacemakers and ICDs, have not been assessed for safety relative to the MRI environment.

MATERIALS AND METHODS

Pacemakers and ICDs

Two different cardiac pacemakers were studied. The Identity ADx XL DR+ 5386 and Identity ADx DR+ 5380 with two model 1688T/52 cm leads, one connected to the right atrial (RA) and the other to the right ventricular (RV) port (St. Jude Medical, Sylmar, California, USA). Three different ICDs underwent evaluation. The Atlas+ V-243 and Epic+ V-236 with a Model 1688T/52 cm lead and a Riata 1581/65 cm high voltage lead in the RA and RV port. The third ICD was an Epic+ HF V-350 with a Model 1688/52 cm lead, QuickSite 1056K/75 cm lead and Riata 1581/65-cm high voltage lead in the RA, LV, and right ventricular (RV) ports. The ICD devices represent current generation high and standard output dual chamber systems and standard output biventricular/tri-chamber systems from the same manufacturer (St. Jude Medical). The generators connected to the leads were positioned in a phantom to simulate an anatomically correct orientation (see below).

Magnetic field interactions

Translational attraction and torque were determined for each device (i.e., generators and leads) in association with exposure to a shielded, short-bore, 1.5-Tesla MR system (Magnetom, Sonata, Siemens Medical Solutions, Malvern, Pennsylvania, USA) (22).

Translational attraction

Translational attraction was measured using the deflection angle technique, as previously described (8, 21–24, 26). Measurements of the deflection angles for each device were obtained at the position in the 1.5-Tesla MR system that produced the greatest magnetically induced deflection (22). The highest spatial gradient occurs at an off-axis position that is 85 cm from isocenter for the 1.5-Tesla MR system. The magnetic spatial gradient at this position is 2.5-Tesla/meter (22). The deflection angle for the device from the vertical direction to the nearest 1 degree was measured 3 times and a mean value was calculated.

Due to the difficulty of using the deflection angle method for the ICD generators (Atlas+ V-243, Epic+ V-236, and Epic+ HF V-350) (which contained larger amounts of materials with high magnetic susceptibility compared to the pacemaker generators), translational attraction was assessed for these devices using a digital force gauge (Model 475040, Extech Instruments, Waltham, Massachusettes, USA) (7, 25). The displacement force was calculated by vector techniques to subtract the weight of the generator (F_g) from the total measured force (F_t), using the following equation:

$$F_m = ((F_t)^2 - (F_g)^2)^{1/2}, \quad [1]$$

according to Baker et al. (25).

Torque

Torque was quantitatively determined for each pacemaker and ICD in three different orientations using an adaptation of the procedure described by Baker et al. (25) and the ASTM standard (27) (Note: The leads exhibited a deflection angles that ranged from 0 to 1degree. Therefore, it was deemed unnecessary to measure torque for these devices). Peak forces were measured at the center of the MR system using a turntable/pulley system and a digital force gauge (Model 475040, Extech Instruments) (25). Peak force values, measured in Newtons, were recorded in the three orthogonal axes for each implant and converted to peak torque by multiplying the peak force by the radius of the pulley. Torque ratios (T_m/T_g) were then calculated by dividing the peak torque in the magnet (T_m) by the torque induced by gravity (T_g), with the latter taken as the product of the generator's weight and the longest length in each orientation.

MRI-related heating

MRI system

MRI was performed using a 1.5-Tesla/64-MHz MR system (Magnetom, Sonata, Maestro Class, Software Numaris 4, version A21B, N4VA21B; Siemens Medical Solutions). The body radiofrequency (RF) coil was used to send (transmit) and receive RF energy.

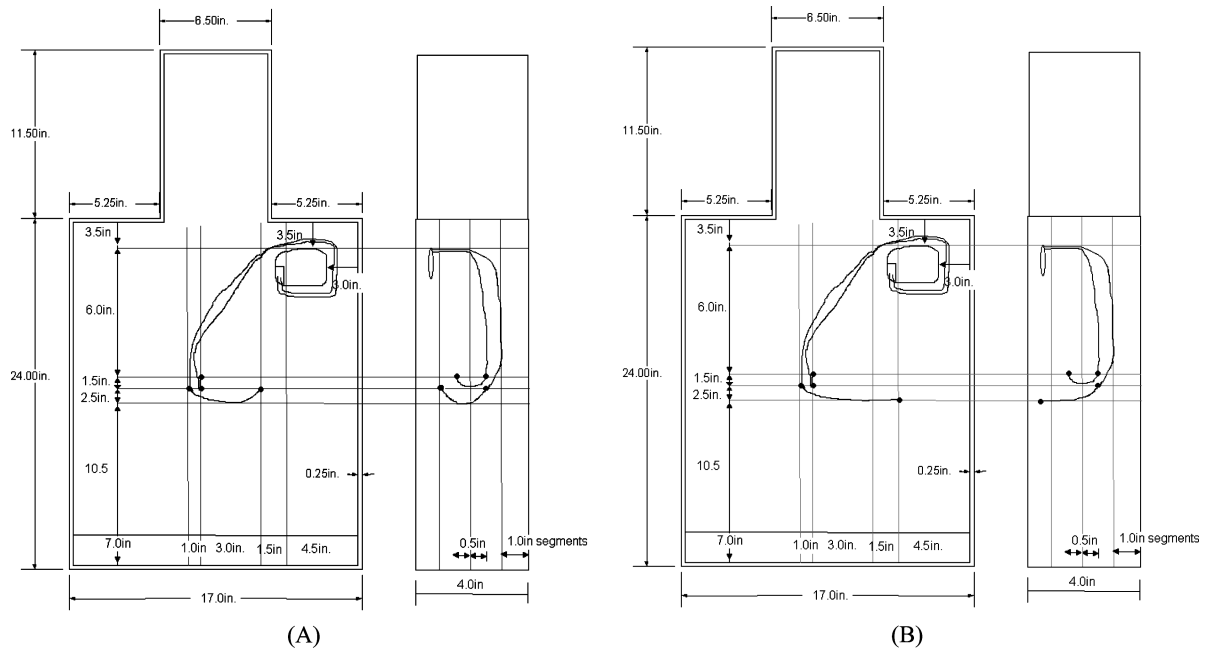

Figure 1. MRI-related heating for pacemakers and ICDs: Diagram showing positions for right atrial appendage and right ventricular outflow tract lead positions. B. Diagram showing positions for right atrial appendage and right ventricular apex lead positions. Effective lead lengths Atrial: Pacer: 32 cm, ICD: 30.5 cm; Ventricular: Pacer: 42 cm, ICD: 39.4 cm; The atrial lead was coiled one full turn under the generator and draped over device. The ventricular lead was coiled one full turn under the generator and draped over device for the ICD. For the pacemaker, the ventricular lead was not coiled under the can. The effective lead length is defined as the length of the lead from the tip to the point where the lead exits the generator.

Phantom and experimental set-up

A phantom designed to approximate the proportions of the head and torso of a human subject (i.e., 50 kg subject size) was used for the experiments, as previously described (8, 19–21, 23, 24). The phantom was filled to a depth of 11 cm with a gelling agent (hydroxyetheyl-cellulose, HEC) in an aqueous solution (91.48% H2O) with 0.12% NaCl to create a dielectric constant of 80 and a conductivity of 0.8 S/m at 64-MHz (8, 19–21, 23, 24, 28). Each pacemaker and ICD was positioned in a typical thorax position (i.e., based on an evaluation of dimensions of typical lead positions using chest radiographs). Figures 1 and 2 show the experimental set-ups used for this investigation.

Temperature recording system and placement of thermometry probes

Temperature recordings were obtained using a Model 3100 Fluoroptic Thermometry System with Model SFF probes (Luxtron, Santa Clara, California, USA)(8, 19–21, 23, 24). The sensor portions of the thermometry probes were positioned to record sites that would generate the greatest, MRI-related heating, based on previously reports (8, 15, 17, 19–21, 23, 24) and pilot experiments conducted by our group. For the pacemakers and ICDs, fluoroptic thermometry probes were attached to record representative temperatures during heating experiments as

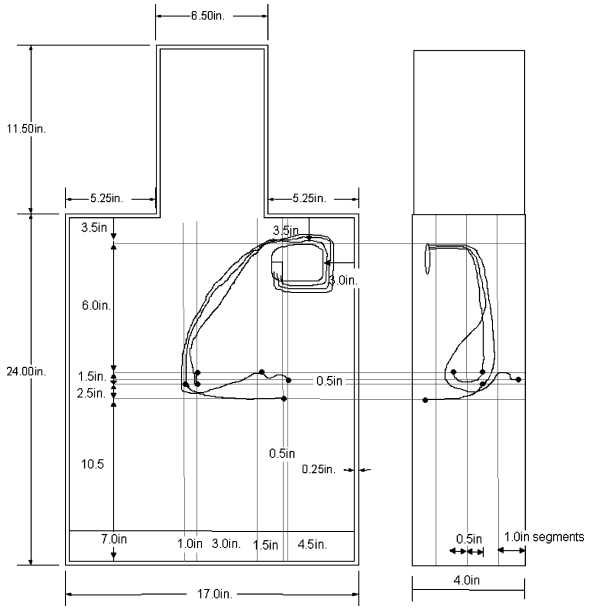

Figure 2. Diagram showing positions for right atrial, RV, and LV leads. Effective lead lengths Atrial: 30.5 cm; Right Ventricular: 39.4 cm; Left Ventricular: 40.6 cm. The atrial and ventricular leads were coiled one full turn under the generator and draped over the device. The effective lead length is defined as the length of the lead from the tip to the point where the lead exits the generator.

Table 1. Summary of experimental conditions for the MRI-related heating experiments conducted on the pacemakers

					Thermometry probe positions			
Exp. #	Device	Lead positions	SAR	Scan area	1	2	3	4
(1)	Identity ADx XL DR+ 5386	RVOT	1.0 W/kg	vent. elect. tip	V-tip	A-tip	Generator	Ref.
(2)	Identity ADx XL DR+ 5386	RVOT	2.0 W/kg	vent. elect. tip	V-tip	A-tip	Generator	Ref.
(3)	Identity ADx XL DR+ 5386	RVOT	2.9 W/kg	Head	V-tip	A-tip	Generator	Ref.
(4)	Identity ADx XL DR+ 5386	RVOT	2.9 W/kg	lumbarspine	V-tip	A-tip	Generator	Ref.
(5)	Identity ADx XL DR+ 5386	RVA	2.0 W/kg	vent. elect. tip	V-tip	A-tip	V-ring	Ref.
(6)	Identity ADx XL DR+ 5386	RVA	3.0 W/kg	Head	V-tip	A-tip	V-ring	Ref.
(7)	Identity ADx XL DR+ 5386	RVA	2.9 W/kg	Lumbarspine	V-tip	A-tip	V-ring	Ref.
(8)	Identity ADx DR+ 5380	RVA	2.0 W/kg	vent. elect. tip	V-tip	A-tip	Generator	Ref.
(9)	Identity ADx DR+ 5380	RVA	2.9 W/kg	Head	V-tip	A-tip	Generator	Ref.

RVOT right ventricular outflow tract; RVA = right ventricular apex; LV = left ventricle; vent. elect. tip = thorax region; V-tip = right ventricular electrode tip; A-tip = atrial electrode tip; V-ring = ventricular lead ring electrode; Ref. = Reference site; SAR = whole body averaged specific absorption rate.

indicated in Tables 1 and 2. The sensor portions of the probes were inserted into the helix (i.e., corkscrew) of the tip of the atrial or ventricular lead, at the edge of the ring electrode, at the distal portion of the shocking coil, or in contact with the edge of the generator. In some cases, a thermometry probe was placed in a remote position from the device (i.e., 1 cm from the edge of the bottom portion of the phantom) to record a reference temperature. The thermometry probes were visually inspected immediately before and after each experiment to ensure that they were properly positioned.

MRI protocols and conditions

MRI was performed on the phantom with the device using various conditions that included changing the landmarking position (i.e., the center position or anatomic region for MRI) along with different whole-body-averaged specific absorption rates (SAR)(8, 19, 20). Because the anatomic site for the MRI procedure in relation to the position of the device impacts heating (8, 19, 20), different "landmarks" (i.e., the center position designating an anatomic region or scan area for the MRI imaging procedure) were evaluated and included the tip of the ventricular electrode (i.e., the thorax, to generate the greatest heating), the "lumbar spine" region of the phantom (5 cm from the bottom of the phantom), and the "head" portion of the phantom (14.5 cm from the top of the phantom) (8). Similar to other studies, the scanner used in this investigation reported the whole-body-averaged SARs based on the pulse sequence parameters (8, 19–21, 23, 24). Parameters were altered within a given range to achieve different whole body averaged SARs. The parameters were, as follows: pulse sequence, TrueFisp; imaging plane, axial; echo time 1.1 to 1.6 msec; repetition time, 39 to 821 ms;

Table 2. Summary of experimental conditions for the MRI-related heating experiments conducted on the ICDs

					Thermometry probe positions			
Exp. #	Device	Lead positions	SAR	Scan area	1	2	3	4
(1)	Atlas + V-243	RVOT	2.0 W/kg	vent. elect. tip	V-tip	Shock	Generator	Ref.
(2)	Atlas + V-243	RVA	2.0 W/kg	vent. elect. tip	V-tip	Shock	Generator	Ref.
(3)	Atlas + V-243	RVA	3.0 W/kg	Head	V-tip	Shock	Generator	Ref.
(4)	Epic + V-236	RVA	3.0 W/kg	Head	V-tip	Shock2	Generator	Ref.
(5)	Epic + V-236	RVA	2.0 W/kg	vent. elect. tip	V-tip	Shock2	Generator	Ref.
(6)	Epic + HF V-350	RVA/LV	2.9 W/kg	Lumbar spine	V-tip	LV-tip	Generator	Ref.
(7)	Epic + HF V-350	RVA/LV	2.0 W/kg	vent. elect. tip	V-tip	LV-tip	Generator	Ref.
(8)	Epic + HF V-350	RVA/LV	2.9 W/kg	Head	V-tip	LV-tip	Generator	A-tip

RVOT = right ventricular outflow tract; RVA = right ventricular apex; LV = left ventricle; vent. elect. tip = thorax region; V-tip = right ventricular electrode tip; LV-tip = left ventricular electrode tip; A-tip = atrial electrode tip; Shock = Distal RV shocking coil; Shock2 = Distal SVC shocking coil; Ref. = Reference site; SAR = whole body averaged specific absorption rate.

Table 3. Pulse sequences used for the functional assessment experiments for the pacemakers and ICDs

Condition No.	#1	#2	#3	#4	#5	#6	#7	#8	#9
Pulse Sequence	T1-SE	T2-SE	T1-FSE	T2-FSE	GRE	TrueFISP	High SAR T1-SE (2.2 W/kg)	High SAR T2-FSE (3.6 W/kg)	EPI
TR (msec.)	500	2,000	500	6,100	87	4	300	4,000	8
TE (msec.)	20	80	21	118	3.4	2	21	123	2
Flip Angle	90	90	90	180	15°	15	180	180	15
Field of View	40 cm	40 cm	40 cm	40	40 cm	40 cm	40 cm	40 cm	40 cm
Matrix Size	256 × 256	128 × 64	256 × 128	256 × 128	256 × 256	256 × 256	256 × 256	256 × 256	256 × 256
Section Thickness	20 mm	20 mm	20 mm	20 mm	20 mm	20 mm	20 mm	20 mm	20 mm
Intersection gap	1 mm	1 mm	1 mm	1 mm	1 mm	1 mm	1 mm	1 mm	1 mm
Imaging Plane	Axial	Axial	Axial	Axial	Axial	Axial	Axial	Axial	Axial
Number of slices	15	15	15	15	15	15	15	15	15
Imaging time	4:20	2:00	4:00	5:00	4:00	4:00	4:00	4:00	5:00
Whole body SAR	2.9	0.7	2.1	1.4	0.1	0.1	2.2	3.6	0.1

T1-SE = T1-weighted spin echo; T1-FSE = T1-weighted fast spin echo; T2-FSE = T2-weighted fast spin echo; GRE = gradient echo; TR = repetition time; TE = echo time; N/A = not applicable; High SAR = high whole body averaged specific absorption rate of RF power; EPI = echo planar imaging; all with bandwidth of 980 Hz/pixel.

field of view, 400 mm; matrix size, 256 × 256; section thickness, 10 mm (for the head landmark location) to 20 mm (for the thorax and lumbar spine landmark locations); inter-slice gap, 0 mm; number of averages, 7 to 32; bandwidth, 977 to 980 Hz per pixel; flip angle, 50 to 82 degrees. MRI was performed continuously for 15 minutes to 16 minutes. This basic strategy used to assess MRI-related heating for the pacemakers and ICDs is similar to that utilized in studies performed on other devices (8, 19–21, 23, 24).

Experimental protocol

The fluoroptic thermometry system was calibrated, and the probes were positioned. The phantom was filled with the gelled-saline solution and allowed to equilibrate to the environmental temperature. For each experiment, the room temperature and temperature of the bore of the MRI system were at a constant level. After recording baseline temperatures (2 minutes), MRI was performed for 15 minutes with temperatures recorded at 10 s intervals. Post-MRI temperatures were recorded for 2 minutes at 10 s intervals.

Function

An *in vitro* experiment was performed to determine if exposing the pacemakers and ICDs to MRI at 1.5 Tesla/64 MHz altered the function of these devices, following a similar methodology reported by Roguin et al. (7) and Shellock et al. (8). MRI conditions involved the use of the transmit/receive body RF coil and 9 different pulse sequences applied in a continuous manner and selected to represent typical techniques for clinical procedures as well as "extreme" imaging parameters (Table 3). Each device underwent a comprehensive evaluation of all critical functional parameters according to manufacturer-derived specifications before and after exposure to MRI. For example, every major functional block, such as pacing, shocking, sensing, memory, telemetry, magnet detection, activity sensor, device leakage, filtering, and measured data, was tested. The devices were programmed to a dual chamber asynchronous pacing mode (dual chamber pace, independent sense, and independent response, DOO, which is dual chamber asynchronous pacing mode) or a clinically typical pacing mode (dual chamber pace, dual chamber sense, and dual chamber response, DDD, which is dual chamber pacing and sensing mode). Defibrillation therapy was turned off in the ICDs. The devices were configured so that every magnet activation was recorded by the devices' diagnostic counters. The devices were programmed to the most sensitive bipolar sensitivity settings on the atrial and ventricular channels if in DDD mode. The sensors were also programmed to "passive" in order to determine if the sensor would be activated during the scanning. All other parameters were programmed to nominal settings. After the series of pulse sequences, the device memory was downloaded, measured data read, and all diagnostics cleared and printed. Table 4 outlines the specific programmed parameters for each device. Each device was positioned in a gelled-saline-filled phantom, similar to that used for the evaluation performed to assess MRI-related heating. The landmark location used for MRI corresponded to scanning the thorax, thus creating an extreme condition. Multiple transverse plane section locations were used for imaging to expose the generator and leads to the MRI conditions. At the conclusion of MRI, functional testing was repeated and compared to the results obtained before MRI.

MRI-related induced currents

Induced currents within the lead conductor wire were measured to evaluate if gradient magnetic fields used during MRI induce currents and to determine if RF currents were rectified and could potentially cause pacing. Additionally, the pacing output timing was monitored. This testing was accomplished using a custom built induced current measurement system. The induced current measurement system was designed to measure induced, rectified MRI-related RF current due to non-linearities at the electrode-to-tissue and lead-to-pulse generator interfaces. The system incorporates a series of low pass filters that

Table 4. Programming parameters used for the evaluation of function for the pacemakers and ICDs

Device	Mode	Parameter settings
5386 Identity ADx XL DR+ Pacemaker	DDD	Atrial Sensitivity = 0.1 mV; Ventricular Sensitivity = 0.5 mV; Magnet Response = Battery Test; Sensor = Passive, Sensor Threshold = 5, Sensor Slope = 8; Stored EGM Triggers = Magnet Trigger; PVC (2 beats); High Ventricular Rate (125 bpm w/5 cycles); High Atrial Rate (125 bpm w/5 cycles)
5380 Identity ADx DR+ Pacemaker	DOO	Stored EGM Trigger = Magnet Trigger (*pre-store a magnet trigger); Magnet Response = Battery Test
Atlas + V-243 ICD	DOO	Stored EGM channels on (magnet trigger automatically on); Magnet Mode = Normal
Epic V-236 ICD	DOO	Stored EGM channels on (magnet trigger automatically on); Magnet Mode = Normal
Epic + HF-350 ICD	DDD	Atrial Sensitivity = 0.2 mV; Ventricular Sensitivity = 0.2 mV; All other ASC settings nominal; Sensor = Passive, Sensor Threshold = 5, Sensor Slope = 8; Stored EGM Triggers = Magnet Trigger (automatically on), AMS Entry/Exit; Magnet Mode = Normal

measure positive and negative currents within the lead conductor connected to the tip of the lead. Each filter modules is a 7 pole low pass filter that sharply attenuates frequencies above 10 MHz. This system linearly converts current induced in the lead that is below 50 kHz to a light analog. The light is passed through a fiber optic cable and is then linearly converted to voltage. The fiber optic cable was routed from the test system outside of the MR system room, where the rest of the equipment was located to prevent influence from the electromagnetic fields used for MRI. The voltage signal was recorded during the scans using the National Instruments DAQPad 6020E (Austin, Texas, USA) data acquisition system interfaced with VI Logger Software (Austin, Texas, USA). Voltage measurements were converted into current using equations defined for the test system.

The Model 5380 pulse generator (St. Jude Medical) attached to a 1688T/58 cm modified lead with the induced current system was placed in the gelled-saline filled phantom with the ventricular lead positioned to simulate a right ventricular apex position. While the pacing system was brought into the MR system room and positioned, the data acquisition system obtained recordings. Different pulse sequences were run normally with gradients and RF on (i.e., using parameter similar to those shown in Table 3). The same sequences were then repeated with the RF turned off to determine the effects of the gradients, alone.

RESULTS

Magnetic field interactions

The results of the assessment of force and torque for each device are summarized in Table 5. In general, magnetic field interactions will not create a hazard for these pacemakers and ICDs (i.e., the generators and leads).

MRI-related heating

The results of the tests performed to assess MRI-related heating for the pacemakers and ICDs are summarized in Tables 6 and 7. For the pacemakers, the highest temperature changes ranged from 0.2 to 1.0°C and primarily depended on the scan area, with the highest temperature changes observed for the landmark at the ventricular electrode tip area (range 0.7 to 1.0°C) when scanning the thorax area of the phantom. The lowest temperature changes were seen for the head and lumbar spine areas of the phantom (range, 0.2 to 0.4°C) (Table 6). For the ICDs, the highest temperature changes ranged from 0.3 to 3.6°C (Fig. 3) and again depended on the scan area, with the highest temperature changes observed for the landmark at the right ventricular electrode tip area (range 0.9 to 3.6°C) associated with scanning the thorax area. The lowest temperature changes were seen for the

Table 5. Magnetic field interactions for the pacemaker and ICD generators

Device	Mass (grams)	Displacement Force (Newtons) Maximum	Torque due to Gravity (N*m) Maximum	T (mass/T (gravity)
Identity ADx XL DR+ 5386	23.6	0.049	0.012	0.274
Identity ADx DR+ 5380	17.9	0.053	0.008	0.494
Atlas+ V-243	77.7	1.422	0.050	0.689
Epic+ V-236	71.3	1.192	0.044	0.783
Epic+ HF V-350	74.2	1.359	0.052	0.687

For the pacemaker generators, the force of attraction due to the static magnetic field was calculated as the product of the force due to gravity, or weight of the device, and the tangent of the measured deflection angle, q [i.e., $F_m = F_g \times \tan q$]. The translational attraction of the ICD generators exceeded the capability of the deflection angle measurement technique. Thus, F_m was calculated by measuring the total force F_t using a digital force gauge (see Materials and Methods) and removing the force or weight of the device due to gravity [$Fm = ((F_t)^2 - (F_g)^2)^{1/2}$, according to Baker et al. (25).

Table 6. Summary of MRI-related heating test results for the pacemakers

Exp. #	Device	Lead position	SAR	Scan area	Highest Temp. change	Site of highest Temp. change
(1)	Identity ADx XL DR+ 5386	RVOT	1.0 W/kg	vent. elect. tip	0.7°C	vent. elec. tip
(2)	Identity ADx XL DR+ 5386	RVOT	2.0 W/kg	vent. elect. tip	0.9°C	vent. elect. tip
(3)	Identity ADx XL DR+ 5386	RVOT	2.9 W/kg	Head	0.2°C	vent. elect. tip
(4)	Identity ADx XL DR+ 5386	RVOT	2.9 W/kg	Lumbar spine	0.4°C	vent. elect. tip
(5)	Identity ADx XL DR+ 5386	RVA	2.0 W/kg	vent. elect. tip	1.0°C	vent. elect. tip
(6)	Identity ADx XL DR+ 5386	RVA	3.0 W/kg	Head	0.4°C	vent. elect. tip
(7)	Identity ADx XL DR+ 5386	RVA	2.9 W/kg	Lumbar	0.2°C	atrial elect. tip
(8)	Identity ADx DR+ 5380	RVA	2.0 W/kg	vent. elect. tip	1.0°C	vent. elect. tip
(9)	Identity ADx DR+ 5380	RVA	2.9 W/kg	Head	0.4°C	vent. elect. tip

RVOT = right ventricular outflow tract; RVA = right ventricular apex; LV = left ventricle; vent. elect. tip = (thorax region); V-tip = right ventricular electrode tip; A-tip = atrial electrode tip; V-ring = ventricular lead ring electrode; Ref. = Reference site; SAR = whole body averaged specific absorption rate.

head and lumbar spine areas of the phantom (range, 0.3 to 0.4°C) (Table 7).

Function

The results of the tests conducted to assess the function of the pacemakers and ICDs indicated that MRI performed at 1.5 Tesla using the transmit/receive body RF coil did not alter the programmed settings or functioning of these devices in a permanent manner. No memory corruption, hardware changes, changes in battery voltage, change to reset mode, changes to the magnet detect sensors (GMR), or alterations in device parameters were seen. None of the devices were found in "reset mode" after MRI. The magnet mode was triggered intermittently. Oversensing was observed at the most sensitive device settings when programmed to DDD during some of the MRI scans with totally normal function at all other times. Device function was unaffected in DOO. The pacemakers and ICDs were undamaged and remained fully operational.

MRI-related induced currents

The induced current was calculated for each scan sequence by measuring the largest peak-to-peak voltage deflection during the recording (excluding the pacing pulses). Next, the voltage measurements were converted into current using the calibration that was established for the measurement system. When the RF was turned off (gradients remained on), the induced currents ranged from 7–38 μA with pulse widths ranging from 0.02–0.46 ms. When the same pulse sequence was run with both RF and gradient fields on, the induced currents ranged from 13–413 μA, with pulse widths ranging from 0.2–1.14 msec. During

Table 7. Summary of MRI-related heating test results for the ICDs

Exp. #	Device	Lead position	SAR	Scan area	Highest Temp. change	Site of highest Temp. change
(1)	Atlas+ V-243	RVOT	2.0 W/kg	vent. elect. tip	3.6°C	vent. elect. tip
(2)	Atlas+ V-243	RVA	2.0 W/kg	vent. elect. tip	0.9°C	vent. elect. tip
(3)	Atlas+ V-243	RVA	3.0 W/kg	Head	0.3°C	vent. elect. tip
(4)	Epic+ V-236	RVA	3.0 W/kg	Head	0.4°C	vent. elect. tip
(5)	Epic+ V-236	RVA	2.0 W/kg	vent. elect. tip	0.8°C	Generator
(6)	Epic+ HF V-350	RVA/LV	2.9 W/kg	Lumbar spine	0.4°C	LV-tip
(7)	Epic+ HF V-350	RVA/LV	2.0 W/kg	vent. elect. tip	1.0°C	Generator
(8)	Epic+ HF V-350	RVA/LV	2.9 W/kg	Head	0.5°C	LV-tip

RVOT = right ventricular outflow tract; RVA = right ventricular apex; LV = left ventricle; vent. elect. tip = (thorax region); V-tip = right ventricular electrode tip; LV-tip = left ventricular electrode tip; A-tip = atrial electrode tip; Shock = Distal RV shocking coil; Shock2 = Distal SVC shocking coil; Ref. = Reference site; SAR = whole body averaged specific absorption rate.

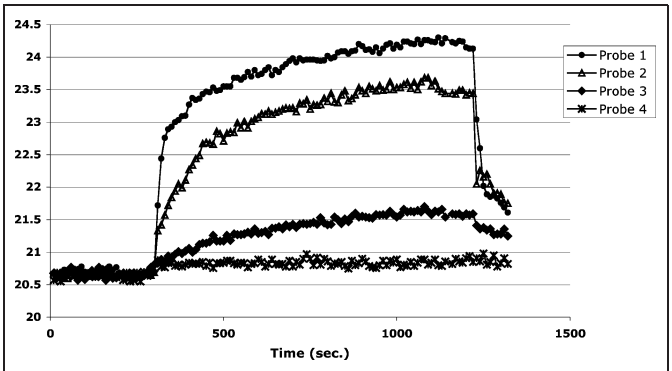

Figure 3. Example of MRI-related heating for the ICD, Atlas+ V-243 generator with Model 1688T/52-cm leads in the RA and RV ports. The highest temperature change was 3.6°C measured at the tip of the ventricular electrode (landmark position, ventricular lead; whole body averaged SAR, 2.0-W/kg).

some pulse sequences, there was no discernable pulse width. In the scans with RF on, the largest peak-to-peak deflection represented the RF pulse as determined by analysis of the pulse sequence repetition time (TR) parameter. All scans were analyzed to determine if pacing pulses were delivered at the programmed rate for every beat. There was no evidence of missed pacing pulses or pacing interval extension. Table 8 reports the measurements for each scan.

DISCUSSION

Pacemakers and ICDs are generally contraindicated implants for patients referred for MRI procedures due to concerns related to movement of the generator and/or leads, excessive heating of the leads, and changes in the pacing device (including temporary or permanent functional changes) inappropriate sensing or triggering of the device, and other theoretical or realistic concerns (1-3, 18). The effects of the MRI on pacemakers and ICDs vary and depend on factors including the type of device, how the device is programmed, the static magnetic field strength of the MRI system and the conditions used for the procedure (e.g., the anatomic region imaged, the type of RF coil used, and the amount of radiofrequency energy applied during imaging) (1–18, 22). Most reports concerning the deleterious effects of MRI on pacemakers and ICDs involved older generation devices and often involved a lack of intra-procedure monitoring, while current systems appear to be substantially less affected by MRI (1, 3–17). In fact, there is growing evidence from *in vitro*, laboratory, and clinical investigations, especially for pacemakers, that it may be possible to perform MRI procedures safely in carefully selected patients by following strategies designed to minimize risks (4–7, 9–16). Accordingly, similar to other electronically-activated devices, pacemakers and ICDs should be characterized with regard to the critical factors that are potentially problematic for MRI procedures, including magnetic field interactions, heating, and functional alterations.

MRI-related heating

Findings from the MRI-related heating experiments indicated that the highest temperature changes for the pacemakers and ICDs were associated with the landmark position involving the thorax area of the phantom (i.e., the tip of the right ventricular electrode) during MRI performed at a MRI system-reported whole body averaged SAR of 2.0 W/kg. Heating was reduced if the landmark position was at the level of the head (range, 0.2 to 0.5°C; whole body averaged SAR, 2.9 to 3.0 W/kg) or lumbar spine (range 0.2 to 0.4°C; whole body averaged SAR, 2.9 W/kg). As you move the phantom with the device higher (e.g., MRI of the head/brain) or lower (lumbar spine, lower extremities) in the transmit RF body coil, temperature levels are reduced, even when higher SAR levels are used (i.e., compared to MRI of the area of the ventricular tip of the lead). This is because less RF power is coupled to the lead. The MRI-related heating dependence on landmark position relative to the implanted device has been reported in several studies (8, 17, 19, 20). Notably, experiments performed in this study used a gelled-saline-filled phantom that lacked blood flow and, as such, represented worst-case scenarios with regard to MRI-related heating. *In vivo* studies performed at 1.5 Tesla by Roguin et al. (7) and Luechinger

Table 8. MRI-related induced current measurements through the tip conductor wire in a 1688/58-cm lead in the RVA position with a pacemaker model 5380 attached

Pulse sequence	SAR (W/kg)	Flip angle	Current (μA) RF and gradients	Current (μA) gradients only
T1 SE	1.8	90°	380	33
T2 SE	0.4	90°	413	31
T1 FSE	1.3	150°	407	29
T2 FSE	0.9	180°	237	7
GRE	0.0	15°	24	38
True FISP	0.1	15°	43	32
True FISP	3.8	81°	74	20
T1 SE	1.3	180°	375	32
T2 FSE	0.8	180°	83	33
EPI	0.0	15°	29	28
EPI	1.6	90°	318	33
EPI	0.2	35°	13	25

et al. (17) reported that, while substantial lead heating may be observed under *in vitro* conditions, no significant or permanent heat-induced damage was seen using pathologic and histologic techniques. Presumably, perfused cardiac tissue around the lead tip interface has a high capacity to remove heat *in vivo*, preventing excessive temperature rises and concomitant tissue damage (5, 7, 17).

Given the findings of this study and to improve the risk:benefit aspects of MRI-related heating, a conservative approach may be used by selecting MRI conditions that minimize heating. According to the MRI-related heating findings of this investigation (Tables 6 and 7), the data indicates that the lowest temperature changes occurred when imaging the head and lumbar spine areas of the phantom (i.e., 0.2 to 0.5°C) vs. the ventricular electrode tip (range 0.7 to 3.6°C). Therefore, lead heating will be minimized by either confining the examination to body parts removed from the pacemakers and ICDs (e.g., head, lumbar spine, and lower extremities) and/or by decreasing the amount of RF power used (i.e., the MRI system reported whole body averaged SAR) for the procedure (7–13). A similar strategy has been utilized to prevent MRI-induced lead heating for neurostimulation systems used for deep brain stimulation (19, 20).

Magnetic field interactions

Translational attraction and torque associated with powerful static magnetic fields may cause movement of a ferromagnetic implant, resulting in an uncomfortable sensation or injury (2, 18). However, findings from recent investigations of magnetic field interactions for pacemakers and ICDs reported that "newer" devices demonstrated relatively low magnetic field interactions compared to older devices, and pacemakers demonstrated relatively low interactions compared to ICD generators (7, 8, 22). Accordingly, magnetic field interactions are not believed to present a major safety issue for patients with current generation pacemakers and ICDs (1, 5–16).

The leads evaluated in the present study showed little or no magnetic field interactions. Magnetic field interactions for the ICD generators, while higher than those for the pacemaker generators, were still within an acceptable range (i.e., at a level that would not pose a problem with regard to movement) and, as such, are not believed to present a risk to patients relative to the use of a 1.5-Tesla scanner. Importantly, for the ICDs, if there is concern about the level of magnetic field interactions, this may be mitigated by fibrous tissue which forms around implanted objects after a few weeks of implantation and is known to provide substantial counter-force (21). To date, there has been no movement or dislodgement hazard reported in association with magnetic field interactions for current generation pacemakers and ICDs for MRI procedures performed using scanners operating at field strengths ranging from 0.5- to 2.0-Tesla (5–16).

Function

The effects of electromagnetic interference (EMI) on pacemakers and ICDs depends on a variety of factors including the intensity of the electromagnetic field, the frequency, the spectrum of the signal, the position of the source of the EMI relative to the cardiac device, the configuration of the lead, the type of electrode (i.e., unipolar vs. bipolar), the programmed settings, shielding within the device, the presence of active circuit components and other considerations (1, 7, 29). Importantly, an MRI procedure applied to scan an anatomic region above (e.g., the brain) or below (e.g., lumbar spine, lower extremities, etc.) the cardiac device is believed to have a comparable or less effect on the function of these particular pacemakers and ICDs.

The magnet function of the device was activated intermittently during MRI. Due to these findings it cannot be assumed that a magnet, in this case a Giant Magneto Resistive (GMR) sensor, will behave consistently inside the MRI environment. In a pacemaker, if the magnet is triggered, asynchronous pacing at the battery indicated rate could occur if programmed to respond to a magnet. In an ICD patient, if the magnet is not activated, defibrillation therapies will be left on, and it is very likely a shock could be delivered due to over-sensing of EMI and interpretation of the signal as ventricular fibrillation.

As was shown in this study, it is possible for the device to sense EMI in the MRI environment on both channels either intermittently or continuously. The amount of over-sensing will vary depending on the MRI pulse sequence as well as the programmed atrial and ventricular sensitivity settings. Over-sensing could cause inappropriate tracking of a fast atrial rate and fast ventricular pacing or inhibition of pacing pulses resulting in relative pauses. In addition, if the device enters noise mode, asynchronous pacing could occur in one or both chambers. Therefore, depending on the clinical indication of the pacing system and patient's rhythm, the device can be programmed appropriately to reduce these risks.

MRI-related induced currents

Theoretically, currents induced at the tip of the lead during MRI could stimulate the heart at a fast enough repetition time or during a vulnerable period during the cardiac cycle resulting in atrial or ventricular fibrillation. Fast pacing at the same repetition rate as the RF pulse has been observed in older generation pacemakers (30, 31). Recent reports calculated that the worst case induced currents associated with MRI are below the heart's stimulation level (7, 13). However, the voltages can be strong enough to influence the sensing circuit (13). Other recent *in vitro* and *in vivo* studies suggested that this is not a major consideration (4–6, 9–16). However, *in vitro* testing was conducted in the present study to investigate this potential risk further.

The current threshold that will stimulate the heart is linearly related to the electrode surface area. As the electrode surface area decreases, current density increase, and current threshold decrease (32). It has been reported that in chronically implanted leads for a 10 mm^2 electrode surface area, the current threshold is approximately 1 mA (33). A conservative estimate of the current threshold needed to stimulate the heart for this analysis purposes is 750μA of induced current at a pulse width of 0.5 ms

over a 10 mm tip area. Using this approximation, the safety margin for stimulating the heart is as low as 20:1 with gradient magnetic fields, only. This is a large enough safety margin that it is assumed this would not stimulate the heart, even in a high-risk patient prone to arrhythmias.

Higher currents, up to 413 μA, were observed in the scans with RF and gradient pulses. Using the same approximation, the safety margin for stimulating the heart is as low as 1.8:1 with RF and gradients on. The higher currents were observed at each TR interval with a width similar to that of RF pulses. Therefore, it is assumed that the higher currents recorded were the result of the RF pulse. A reasonable explanation for the induced voltage within the distal lead is that the RF is conducted through a transmission line, formed by the coaxial design of the lead, into the measurement system.

Thus, the results from this testing showed that pacing function was not affected by MRI and that the magnetic field gradients have a low likelihood of producing induced currents that would stimulate the heart. Further study is needed to better characterize the affect of the RF pulse and to determine if some pulse sequences have a safer RF profile than others.

Possible limitations

The results of this study can only be applied to the pacemakers and ICDs that underwent evaluation and with regard to the MRI conditions used for this assessment. However, for every electronic device that currently has labeling approved by the Food and Drug Administration to permit MRI procedures, the information pertains to the given device, only (2, 18–21). As such, this may not be perceived as a "limitation" for this investigation, per se. If MRI is performed in a patient with one of these cardiac devices, the patient should be conscious and vital signs (e.g., heart rate, blood pressure, and oxygen saturation) and should be closely monitored throughout the examination using appropriate equipment, along with having appropriately-trained personnel present to respond and treat an induced arrhythmia, should one arise during the examination.

SUMMARY AND CONCLUSIONS

MRI-related issues were evaluated at 1.5-Tesla for several current generation pacemakers and ICDs. Magnetic field interactions for these devices will not pose a significant hazard. Lead heating will not create a substantial risk, especially if MRI is confined to the head, lumbar spine, and lower extremities and the risk is minimal even if MRI of the thorax is performed. As long as proper programming is implemented, the function of the pacemakers and ICDs tested in this study under specific conditions was unaffected by various pulse sequences likely to be utilized in the clinical setting.

As with other MRI safety guidelines for electronically-activated implants (2, 18–21), the information presented herein is specific to the generators and leads that were evaluated, the positions of the generators and leads, especially the regard to the length of the leads, and in relation to the use of a 1.5-Tesla MR system and specific MRI procedures. Different conditions may alter the safety profiles for these pacemakers and ICDs. Nevertheless, our findings have important implications for patients with these current generation cardiac devices.

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