Clinical Utility and Safety of a Protocol for Noncardiac and Cardiac Magnetic Resonance Imaging of Patients With Permanent Pacemakers and Implantable-Cardioverter Defibrillators at 1.5 Tesla

Saman Nazarian, MD, Ariel Roguin, MD, PhD, Menekhem M. Zviman, PhD, Albert C. Lardo, PhD, Timm L. Dickfeld, MD, PhD, Hugh Calkins, MD, Robert G. Weiss, MD, Ronald D. Berger, MD, PhD, David A. Bluemke, MD, PhD, and Henry R. Halperin, MD, MA

Abstract

Background—Magnetic resonance imaging (MRI) is an important diagnostic modality currently unavailable for millions of patients because of the presence of implantable cardiac devices. We sought to evaluate the diagnostic utility and safety of noncardiac and cardiac MRI at 1.5T using a protocol that incorporates device selection and programming and limits the estimated specific absorption rate of MRI sequences.

Methods and Results—Patients with no imaging alternative and with devices shown to be MRI safe by in vitro phantom and in vivo animal testing were enrolled. Of 55 patients who underwent 68 MRI studies, 31 had a pacemaker, and 24 had an implantable defibrillator. Pacing mode was changed to “asynchronous” for pacemaker-dependent patients and to “demand” for others. Magnet response and tachyarrhythmia functions were disabled. Blood pressure, ECG, oximetry, and symptoms were monitored. Efforts were made to limit the system-estimated whole-body average specific absorption rate to 2.0 W/kg (successful in >99% of sequences) while maintaining the diagnostic capability of MRI. No episodes of inappropriate inhibition or activation of pacing were observed. There were no significant differences between baseline and immediate or long-term (median 99 days after MRI) sensing amplitudes, lead impedances, or pacing thresholds. Diagnostic questions were answered in 100% of nonthoracic and 93% of thoracic studies. Clinical findings included diagnosis of vascular abnormalities (9 patients), diagnosis or staging of malignancy (9 patients), and assessment of cardiac viability (13 patients).

Conclusions—Given appropriate precautions, noncardiac and cardiac MRI can potentially be safely performed in patients with selected implantable pacemaker and defibrillator systems.

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Correspondence to Saman Nazarian, MD, Division of Cardiology, Johns Hopkins Hospital, Carnegie 568, 600 N Wolfe St, Baltimore, MD 21287, snazari1@jhmi.edu.
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Disclosures
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Keywords
magnetic resonance imaging; pacemakers; defibrillators; implantable

Magnetic resonance imaging (MRI) is now the modality of choice for the diagnosis of many musculoskeletal, central nervous system, and cardiovascular disorders. More than 2,000,000 patients in the United States had a permanent pacemaker as of the year 2002, and an additional 3,000,000 patients met criteria for implantable cardioverter defibrillator (ICD) implantation as of 2003. Because of the advancing age of the population and expanding indications for pacing and prophylaxis of ventricular arrhythmia, the number of patients with implantable cardiac devices will likely continue to increase. It is estimated that 50% to 75% of this increasing population of patients with implantable cardiac devices will need an MRI at some point after implantation. The presence of a permanent pacemaker or ICD, however, is currently considered a contraindication to MRI, and device manufacturers warn against MRI procedures for patients with such devices.

Traditional concerns about MRI of patients with implantable cardiac devices include possible movement of the device, programming changes, and induced lead currents that lead to heating and cardiac stimulation. Strong electromagnetic fields may also cause asynchronous pacing, activate tachyarrhythmia therapies, or inhibit a demand pacemaker. Despite these concerns, previous case series have reported the safety of MRI in the setting of pacemakers. A recent important case series has also reported neurological MRI in the setting of selected ICD systems. Despite overall safety, short-term changes in battery voltage, lead thresholds, and programming have been noted. Importantly, the literature on MRI of pacemaker-dependent patients, cardiac MRI in the setting of implantable devices, and the diagnostic utility of MRI in device recipients is limited.

The objective of the present study was to assess the immediate and long-term safety of a protocol for noncardiac and cardiac MRI of patients with a permanent pacemaker or ICD and the diagnostic yield of MRI in this setting. The protocol included (1) device selection based on previous in vitro and in vivo testing, (2) device programming to minimize inappropriate activation or inhibition of bradyarrhythmia/tachyarrhythmia therapies, and (3) limitation of the estimated whole-body averaged specific absorption rate (SAR) of MRI sequences.

Methods
Patient Selection

The protocol was reviewed and approved by the Johns Hopkins Institutional Review Board. Candidates referred from a variety of inpatient and outpatient services at Johns Hopkins Hospital with a clinical indication for MRI, no acceptable imaging alternative (due to superiority of MRI or contraindication to the alternative imaging modality), and an implantable cardiac device were considered. Patients were enrolled in the study if the permanent pacemaker or ICD was found to be safe by previous in vitro phantom and in vivo animal testing. Patients with device implantation <6 weeks before MRI and those with nontransvenous epicardial leads, no fixation (such as superior vena cava coil), or abandoned leads were excluded. No restrictions were imposed on different transvenous lead models. All patients gave written informed consent after demonstrating an understanding of potential risks, which included irreversible damage to the device, thermal injury, and device malfunction leading to arrhythmia. A total of 68 MRI examinations were performed from February 2003 to September 2005 in 55 patients, 31 (56%) of whom had a permanent pacemaker and 24 (44%) of whom had an ICD. Of 55 total patients, 7 (13%) had a...
biventricular pacing system. Twelve patients (22%) were pacemaker dependent and underwent 15 different MRI examinations. A radiologist (a fellowship-trained expert with >10 years’ experience in MRI) and cardiac electrophysiologist were present during all scans. The experimental protocol has been summarized in Figure 1. Pacemaker and ICD models, lead models and lengths, regions imaged, MRI parameters, and estimated whole-body averaged SAR of sequences are listed in the online-only Data Supplement.

Device Interrogation and Programming

All devices were interrogated before and immediately after MRI. Long-term device interrogation was performed at routine follow-up in electrophysiology device clinic. Device parameters including battery voltage, lead capture thresholds, lead impedances, and sensing signal amplitudes were recorded at each interrogation. Pacemaker dependence was assessed before MRI by transient programming of the device to ventricular-inhibited pacing at a backup rate of 30 ppm with continuous ECG telemetry and blood pressure monitoring. Pacing mode was programmed to asynchronous for patients without a hemodynamically stable escape rhythm. In patients without hemodynamic pacemaker dependence, either the ventricular- or dual-chamber–inhibited pacing mode was used. Magnet response, rate response, premature ventricular contraction response, noise response, ventricular sense response, conducted atrial fibrillation response, and tachyarrhythmia functions (monitoring, antitachycardia pacing, and defibrillation) were disabled. After completion of MRI, device and lead parameters were reinterrogated, and pacing and tachyarrhythmia functions were reprogrammed to original settings. Shortly after MRI, 2 patients (4%) underwent device upgrade to a biventricular pacing system for worsening heart failure, and 2 patients (4%) underwent device explantation after exclusion of right ventricular dysplasia. Before discharge from their index admission, 4 patients (7%) died, all of pacemaker-unrelated causes (hemorrhagic pancreatitis, septic shock, respiratory arrest, and decompensated heart failure). Of the remaining 47 patients, 29 (62%) underwent chronic device interrogation with a median time to follow-up of 99 days (interquartile range 49 to 203 days).

Magnetic Resonance Imaging

Imaging was performed with a 1.5T (Signa CV/i, General Electric Healthcare Technologies, Waukesha, Wis) scanner. Continuous ECG telemetry, pulse oximetry, and symptoms were monitored. Noninvasive blood pressure measurements were obtained every 3 minutes. MRI was performed according to institutional protocol for the region of interest. All selected devices were previously tested under worst-case scenario MRI conditions (SAR up to 3.5 W/kg). To allow an adequate safety margin, efforts were made to limit the estimated whole-body averaged SAR to 2.0 W/kg. In sequences with high SAR, adjustments were made by increasing repetition time or field of view and/or reducing flip angle or the acquisition bandwidth to limit SAR while maintaining the diagnostic capability of MRI, as validated by a radiologist in attendance. With this protocol, >99% of all sequences were performed with SAR <2.0. Two time-of-flight sequences had minimal excess SAR at 2.06 and 2.11 W/kg, respectively, and a fast spin echo sequence was performed with an estimated SAR of 2.50 W/kg.

Statistical Analysis

Continuous variables are summarized as mean and SEM, and discrete variables are summarized as absolute numbers and percentages. Immediate and long-term lead parameters were compared with the paired Student t test. Analyses were performed with SAS statistical software (version 9.1, SAS Institute Inc, Cary, NC). All tests were 2 tailed, and P<0.05 was considered significant.
The authors had full access to the data and take full responsibility for its integrity. All authors have read and agree to the manuscript as written.

Results

Safety and Device Function

No symptoms consistent with device movement, torque, or heating were reported during MRI examinations. No inappropriate inhibition of pacing was observed during MRI. In permanent pacemakers without magnet-mode programming capability (10 devices [18%]: 2 Medtronic In-Sync 8040, 1 Medtronic E2DSRO1, 3 Medtronic EnPulse E2DRO1, 3 Medtronic Kappa 701, and 1 Medtronic Kappa-DR 901), reed switch activation by the static magnetic field of MRI led to transient asynchronous pacing at the device-specific magnet rate (85 ppm), which ceased on patient positioning in the magnet bore. No unexpected or rapid activation of pacing was observed during MRI, however.

All devices were functioning appropriately after MRI, and no changes in device programming were observed. Comparison of device interrogation results obtained before and immediately after MRI revealed no significant individual or mean changes in battery voltage, lead thresholds, lead impedances, or sensing signal amplitudes (Table). Comparison of device interrogation results obtained before MRI and at long-term follow-up revealed no significant individual or mean changes in battery voltage, lead thresholds, lead impedances, or sensing signal amplitudes (Table). There was a trend toward reduced battery voltage after long-term follow-up, but this likely reflects normal battery depletion over the follow-up period. Individual examination of immediate and long-term device parameters in the 3 patients who underwent high SAR sequences revealed no significant changes compared with baseline values. Repeat MRI examination was performed in 11 patients without adverse effects.

Image Quality and Diagnostic Yield

Image quality was not affected when the pacemaker or ICD was located outside the field of view. Diagnostic questions were answered in all 39 (100%) of the nonthoracic sequences. Thoracic images were obtained in 29 MRI examinations (43%). Bright and dark artifacts with spatial distortion of surrounding anatomy were present on thoracic images and extended to a maximal radius of 12 cm from the device generator. Artifacts were most pronounced on inversion-prepared gradient echo and steady-state free-precession cine sequences (Figure 2). Of 29 thoracic sequences performed, 2 (7%) were incomplete owing to back pain (unrelated to the implanted device) and claustrophobia. Images of sufficient quality to answer diagnostic questions were obtained in 25 (93%) of the remaining 27 thoracic sequences (Figure 3).

During the course of the present study, MRI helped identify renal artery stenosis or other vascular abnormalities in 9 patients and aided in the planning of cardiac revascularization or ventricular reconstruction in 13 patients. Perhaps most importantly, MRI was instrumental in the diagnosis and treatment of malignancy in 9 patients. MRI also identified an acute cerebrovascular accident in 1 patient after a normal computed tomography examination (Figure 4).

Discussion

Because of its superior spatial and tissue contrast resolution, multiplanar imaging capability, and lack of ionizing radiation, MRI is an invaluable clinical tool and has become the imaging modality of choice in many clinical situations. Unfortunately, MRI is currently unavailable for an increasing proportion of patients owing to the presence of permanent
pacemaker and ICD systems. The results of the present study show that noncardiac and cardiac MRI can be performed safely in such patients using a protocol that incorporates device selection based on previous in vitro and in vivo testing, device programming to minimize inappropriate activation or inhibition of bradyarrhythmia/tachyarrhythmia therapies, and limitation of the estimated whole-body averaged SAR of MRI sequences.

Safety Protocol

There is now increasing evidence that MRI can be performed safely in patients with a permanent pacemaker. Given reports of device malfunction with use of particular models and our own and other investigators' hesitation about lack of individualized device programming before MRI, we sought to standardize and add to various methodologies used for MRI to develop and test a uniform protocol for safe imaging of patients with implanted devices. The protocol begins by candidate selection with a list of device generators previously tested under worst-case scenarios (imaging over the region containing the generator, and SAR 3.5 W/kg) for MRI conditions. Identification and exclusion of (generally older) device generators prone to electromagnetic interference, through previous in vitro phantom and in vivo animal testing, is an essential cornerstone of the safety protocol. Despite the low risk for lead and generator movement, conservative measures are suggested to identify and exclude patients with leads that are more prone to movement, such as patients with <6 weeks' time since device implant. The protocol also precludes device leads that are prone to heating owing to lack of cooling by blood flow, in the case of nontransvenous epicardial leads, or lack of being connected to a generator, in the case of abandoned leads. Given previous findings during in vitro and in vivo studies, no restrictions were placed on different transvenous lead models or conformations such as lead loops in the device pocket. To reduce the risk of inappropriate inhibition of pacing due to detection of radiofrequency pulses, the protocol specifies device programming to an asynchronous, dedicated pacing mode in pacemaker-dependent patients. Also, given the lack of asynchronous pacing programming capability and transient loss of pacing capture after worst-case scenario (SAR 3.5 W/kg for 3 hours) in vivo testing of 1 of 15 animals implanted with an ICD, the protocol excludes pacemaker-dependent patients with ICD systems. To avoid inappropriate activation of pacing due to tracking of radiofrequency pulses, the protocol specifies device programming to a nontracking ventricular- or dual-chamber–inhibited pacing mode. The steps to deactivate rate response, premature ventricular contraction response, ventricular sense response, and conducted atrial fibrillation response ensure that sensing of vibrations or radiofrequency pulses does not lead to unwarranted pacing. Although asynchronous pacing for short time periods is typically well tolerated, we believed it best to reduce the already minimal chance of inducing arrhythmia or causing ativoventricular dyssynchrony by minimizing asynchronous pacing in patients without pacemaker dependence through deactivation of the magnet mode when possible. The protocol incorporates the deactivation of tachyarrhythmia monitoring to avoid battery drainage that results from recording of multiple radiofrequency pulse sequences as arrhythmic episodes. Reed switch activation in ICD systems disables tachyarrhythmia therapies. As demonstrated in the present study, however, reed switch function in the periphery versus the bore of the magnet is unpredictable, and deactivation of therapies is necessary to avoid unwarranted antiarrhythmic pacing or shocks. Finally, to reduce the risk of thermal injury and changes in lead threshold and impedance, attempts were made to limit the estimated whole-body averaged SAR to <2.0 W/kg. Previous studies have reported safety at different maximal estimated SAR levels. The value of 2.0 W/kg was used in the present study to allow an adequate safety margin below the worst-case scenario conditions previously tested in our in vitro phantom and in vivo animal studies. Blood pressure, ECG, pulse oximetry, and symptoms were monitored, and a radiologist and cardiac electrophysiologist were present.
during all scans. With this protocol (Figure 1), all MRI examinations were performed without adverse events.

**ECG Telemetry**

Aside from 10 transient episodes of expected reed switch activation in devices with no magnet-mode programming capability, no MRI-pacing interactions were observed. Reed switch activation of pacing is a part of normal device function typically used to assess battery voltage–related asynchronous rates, and its transient activation has minimal to no clinical consequences. Specifically, induction of tachyarrhythmias during asynchronous pacing is extremely rare, and this mode of pacing is generally considered safe. However, owing to concerns about the potential for induction of ventricular fibrillation during asynchronous pacing in patients with a spontaneous rhythm, the use of continuous ECG telemetry and the availability of resuscitation personnel and equipment are imperative. Importantly, several pacemaker-dependent patients were imaged without any evidence of device inhibition. The present study complements the findings of a previous study of head and neck MRI in pacemaker-dependent patients by reporting safe musculoskeletal, brain, thoracic and abdominal MRI in pacemaker-dependent patients with generators from all 3 major manufacturers. It is vital, however, to emphasize the need for appropriate programming of the device to an asynchronous mode and the availability of pacing backup for such patients. One of the feared complications of MRI is the potential for rapid pacing. The lack of any rapid pacing observations in the present study and in the study by Martin et al is consistent with the assumption that the frequency of induced lead voltages from the radiofrequency field is too high, the amplitude too low, and/or the pulse width too short for direct cardiac stimulation.

**Device and Lead Parameters**

Previous MRI case reports and series have noted temporary drops in pacemaker/ICD battery voltage that may be due to (1) capacitance by the leads or telemetry coils as a result of a brief power interruption due to electromagnetic interference or (2) effects of the magnetic field on the power supply circuitry of the device. Of greater concern, however, are previous reports of changes in programming and lead thresholds after MRI in patients with permanent pacemaker and ICD systems. No programming changes were noted in the present study, likely because of our protocol’s avoidance of electronic platforms susceptible to electromagnetic interference through previous in vitro and in vivo testing. Pacing threshold changes have been attributed to heating at the lead-tissue interface. In the present study, no significant immediate or long-term changes in device or lead parameters were observed. The lack of any changes in device parameters in the previous study may be related to avoidance of non-transvenous epicardial leads, limitation of estimated SAR, or improved electromagnetic interference protection in the modern devices approved for entry into the study.

**Thoracic and Cardiac MRI**

Previous reports have suggested that thoracic MRI may be riskier owing to greater radiofrequency power deposition over the region containing the device. However, 6 patients with functional permanent pacemakers and 1 patient with an ICD have previously undergone uncomplicated thoracic MRI. The present study represents the largest series of patients undergoing thoracic and cardiac MRI (29 studies). No programming changes or significant changes in device or lead parameters were noted in this subset of patients.
MRI Artifacts

The presence of ferromagnetic materials can cause variations in the surrounding magnetic field that result in image distortion, signal voids or bright areas, and poor fat suppression. Such artifacts are most pronounced on inversion recovery and steady-state free-precession sequences. Importantly, artifacts on inversion recovery images show high signal intensity and can mimic areas of delayed enhancement, which would otherwise indicate myocardial fibrosis (Figure 2A). Correlation of artifactually bright areas on different pulse sequences can help avoid misidentification of artifact. The selection of imaging planes perpendicular to the plane of the device generator, shortening of the echo time, and the use of spin echo and fast spin echo sequences reduced the qualitative extent of artifact, albeit with the potential for increased SAR.

Clinical Implications

The patient population of the present study was selected to identify those who would benefit most from MRI given the risks of imaging in the setting of a permanent pacemaker or ICD. Preservation of the diagnostic capability of MRI in the setting of implantable devices, as well as its superior soft tissue resolution, led to significant benefits in clinical decision making during the present study. Extrapolation from the proportion of important diagnoses made in this sample to the large and growing population of patients with permanent pacemaker and ICD systems underscores the importance of developing a safe methodology for MRI in such patients. Given the public health importance of this issue, it is necessary that device manufacturers continue their efforts to design and test permanent pacemaker and ICD systems so that all such marketed devices are MRI compatible.

Study Limitations

Owing to strict entry criteria with an absolute clinical need for MRI and rigorous selection of safe device systems, the sample size is moderate. It is possible that with a larger sample, changes in device parameters or function not identified in the present study would be observed. Given the lack of any significant changes in sensing and pacing parameters or abnormalities on post-MRI destructive testing, the previously demonstrated 10-J safety margin after MRI, the questionable utility of routine testing, and serious associated side effects, we opted not to repeat defibrillation threshold testing in ICD patients undergoing MRI. However, of 24 patients with an ICD, 5 (21%) in the present series have had successful ICD shocks delivered for ventricular arrhythmia during long-term follow-up after MRI.

The diagnostic yield of MRI in patients in the present study was not compared with the yield of alternative modalities in a control group. Such a control group would consist of patients with implantable devices and no acceptable imaging alternative who were not undergoing MRI. A controlled comparison would not be feasible owing to the lack of an appropriate modality to compare the frequency of missed diagnoses in the 2 arms.

The estimated whole-body averaged SAR was used as a measure of energy deposition in the present study. Calculation rather than estimation of SAR would require in vivo temperature measurements and is not feasible in a clinical study. However, typical estimated SAR values are an overestimation, which thus adds to the safety margin. Furthermore, there is a high degree of linearity between estimated SAR and heating within each MRI system. The present findings should not be extrapolated to device models not yet tested for susceptibility to MRI effects, lead configurations other than standard transvenous lead systems, or other scanners such as 3T, or even equal or lower field strengths. Importantly, a recent study by Baker et al suggested that significantly different levels of
radiofrequency-induced temperature changes per unit of whole-body SAR for a neuro-
stimulation system are applied by different-generation scanners manufactured by Siemens
Medical Solutions USA, Inc. Therefore, the results of the present study should not be
applied to scanners made by different manufacturers, or even different-generation 1.5T
scanners or software platforms manufactured by General Electric Healthcare Technologies
Inc. Also of note, open-bore scanners have static magnetic field orientation in the
anteroposterior direction, which may have a higher likelihood of inducing lead currents in
leads oriented orthogonal to this axis.

Conclusions

With a protocol based on device selection and programming and limitation of estimated
whole-body averaged SAR of sequences, MRI can be performed safely in patients with
certain permanent pacemaker or ICD systems. When proper precautions are taken, MRI of
the region that contains the device is not associated with increased risk. This ability may
significantly impact clinical decision making in appropriate patients. Importantly, these
results may not apply to devices not tested for susceptibility to MRI effects or scanners other
than that used in the present study. Despite the demonstration of safety under the controlled
circumstances of this study, the reader is reminded that there are no cardiac devices that
have currently achieved industry or Food and Drug Administration clearance for MRI
compatibility, and catastrophic complications have been reported. Therefore, continuous
patient monitoring with ECG and pulse oximetry and the availability of resuscitation
personnel and equipment are warranted.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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References


Figure 1.
Safety protocol for imaging of patients with permanent pacemaker and ICD systems. Devices listed have previously undergone satisfactory in vitro phantom and in vivo animal testing.28
Figure 2.
Typical susceptibility artifacts with (A) inversion recovery prepared gradient echo and (B) steady-state free-precession sequences. In A, the region of anterolateral hyperenhancement is due to artifact compared with subendocardial hyperenhancement in the septum, which likely represents prior infarction.
Figure 3.
Cardiac MRI with minimal artifact using (A) time-of-flight sequence to demonstrate the anatomy of congenitally corrected transposition of great vessels in a patient with a permanent pacemaker and (B) steady-state free-precession sequence to assess coronary sinus patency in a patient with an implantable defibrillator.
Figure 4.
Comparison of computed tomography versus diffusion-weighted MRI images of the brain in a pacemaker-dependent patient who presented with new-onset loss of balance. Although the imaging planes are different due to computed tomography versus MRI technique, both sets of images span similar areas of the cerebellum and occipital cortex. No abnormalities were noted on computed tomography, whereas MRI readily identified infarcts involving the cerebellum and occipital cortex (arrows).
### Table

Comparison of Device Parameters After MRI With Baseline Values Before MRI

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Difference Immediately After MRI</th>
<th>$P$</th>
<th>Difference at Follow-Up (Median 99 Days After MRI)</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>P-wave amplitude, mV</td>
<td>$0.06\pm0.07$</td>
<td>0.44</td>
<td>$-0.14\pm0.27$</td>
<td>0.61</td>
</tr>
<tr>
<td>R-wave amplitude, mV</td>
<td>$-0.09\pm0.15$</td>
<td>0.58</td>
<td>$0.96\pm0.70$</td>
<td>0.19</td>
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<tr>
<td>Atrial lead impedance, $\Omega$</td>
<td>$-2.68\pm5.01$</td>
<td>0.60</td>
<td>$-6.17\pm11.53$</td>
<td>0.60</td>
</tr>
<tr>
<td>Ventricular lead impedance, $\Omega$</td>
<td>$-0.49\pm2.74$</td>
<td>0.86</td>
<td>$6.15\pm12.56$</td>
<td>0.63</td>
</tr>
<tr>
<td>Atrial capture, V</td>
<td>$0.02\pm0.02$</td>
<td>0.28</td>
<td>$-0.07\pm0.18$</td>
<td>0.69</td>
</tr>
<tr>
<td>Ventricular capture, V</td>
<td>$-0.001\pm0.013$</td>
<td>0.93</td>
<td>$-0.01\pm0.05$</td>
<td>0.85</td>
</tr>
<tr>
<td>Battery voltage, V</td>
<td>$-0.004\pm0.002$</td>
<td>0.08</td>
<td>$-0.05\pm0.02$</td>
<td>0.06</td>
</tr>
</tbody>
</table>

*Values are reported as mean difference between immediate or long-term and baseline parameter ±SEM. Student $t$ test was not performed on left ventricular lead thresholds in cardiac resynchronization therapy systems because there were not enough data points for a meaningful comparison; there were no significant changes in individual left ventricular lead thresholds after testing, however.