Magnetic Resonance Imaging in Patients With Implantable Cardioverter-Defibrillators and Pacemakers*

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The number of patients who benefit from cardiovascular implantable electronic devices (CIEDs), which include pacemakers, biventricular pacing devices, and implantable cardioverter–defibrillators (ICDs), is increasing. This trend is likely to continue because of the growing proportion of the elderly individuals in the population, new indications for heart failure therapy, innovative device features, and expanded medical coverage.

Compared with other imaging modalities, magnetic resonance imaging (MRI) has many advantages that include its unparalleled ability to discriminate between different soft tissues and its nonradiation nature. The number of magnetic resonance (MR) scans that are performed worldwide is also increasing. Although there is no data, it is estimated that at least 50% of patients with a CIED will probably need to undergo MRI over the lifetime of their device as a result of the combination of these growing phenomena (1). Thus, in coming years, we will more frequently meet patients with a CIED who are referred for an MRI. The American Heart Association and the European Society of Cardiology issued statements on this topic with a detailed strategy for performing MRI in these individuals (2,3).

Three types of electromagnetic fields are used to generate an MRI: a constant static magnetic field, a rapidly changing magnetic gradient field, and a strong radiofrequency field that is “pulsed” into the body. CIEDs contain ferromagnetic components, complex electrical systems, and leads that are implanted into the myocardial tissue. As a result, several potentially hazardous events can occur: movement of the device, programming changes, asynchronous pacing, activation of tachyarrhythmia therapies, inhibition of pacing output, and induced lead currents that could lead to cardiac stimulation. In addition, heating of the lead tip can result in tissue damage and changes in thresholds. This may potentially cause loss of lead function. The likelihood that such an event will occur when performing MRI in patients with CIEDs has led to concerns.

Indeed, pacemaker and ICD labeling currently cautions against the use of MRI, and MRI manufacturers contraindicate MRI for individuals with a pacemaker or an ICD (1–3). During the late 1980s, the death of 10 patients with pacemakers has been attributed to MR procedures. However, these cases were poorly documented and occurred in the setting of an MR examination that was not supervised or monitored by a physician. Most of the previous studies that recommended against MRI in patients with CIEDs were based on in vitro and animal data from the 1980s, when older pacemaker and lead technologies were used.

Advances in device technology were the driving forces to study the interactions between MRI and pacemaker and ICD systems in seminal ex vivo and animal studies. The results of these studies demonstrated that the devices in use today may be more resistant to changes in function during an MR examination (4). Several groups have measured the effect of MRI on lead temperature in vivo, and reported only minor stimulation threshold changes without any obvious signs that heat-induced damage occurred (2,4).

In recent years, there have been several prospective human trials on the relative safety of MR examination at 0.5– to 3.0-T field strength. Data on 430 patients who underwent clinically driven MRI are now available (2,5–7). No deaths have been reported in physician-supervised MR studies in which the patients were carefully monitored, although the authors of these reports documented a few cases of minor changes in pacing threshold, the need for device reprogramming, and possibly battery depletion.

A device may be either MR-safe, which means that it has or causes no known hazards in all MR environments, or MR-conditional, which means that the device has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Current pacemakers and ICDs are neither MR-safe nor MR-conditional. However, a pacing system (Medtronic EnRhythm–MRI SureScan, Minneapolis, Minnesota) was developed and tested specifically for safe use in MRI. Recently, an international clinical study to test the safety and efficacy of this prospective newly designed dual-chamber pacemaker and modified pacing leads completed enrollment. The interim analysis was encouraging (8). Accordingly, this device has a European CE-mark, and is the first MR-conditional pacemaker. It is now available commercially in Europe, and is currently under clinical evaluation in the U.S.

ICDs have more complex technology than pacemakers and have larger capacitors and batteries. As a result, the magnetic forces are greater, and they are theoretically more prone to
electromagnetic and mechanical interference when a patient with an ICD undergoes MRI. Yet, ICDs and pacemakers share similar components and software algorithm protection, and, thus, to some extent, their responses to interference during MR scanning may be expected to be similar. Laboratory testing found that modern ICD systems may undergo extensive MR scanning without harm, while older ICDs were damaged irreversibly (4).

In this issue of the Journal, Naehle et al. (9) report their experience with MR scanning of 18 non–pacemaker-dependent ICD patients with a clinical need for MRI. All examinations, which included all body parts, were completed safely. ICDs could be interrogated and reprogrammed normally after MRI. There were no increases in serum troponin-I levels, thereby confirming that no clinically relevant thermal changes developed during MRI. There were no increases in serum troponin-I levels, thereby confirming that no clinically relevant thermal injury occurred at the ICD lead tips. There were no significant changes in pacing parameters. The mean battery voltage decreased from pre-MRI 3.86 ± 1.48 V, to post-MRI 3.83 ± 1.48 V but was 3.90 ± 1.52 V at follow-up. None of the patients reported any torque or heating sensations, or other unusual symptoms during MRI. The ICD was programmed to a monitor-only mode, although this may lead to battery depletion because of false detection of electromagnetic noise as ventricular fibrillation has occurred in 2 cases. The ICD should have been programmed to “detection off” (2,3). No unexpected changes in heart rate or rhythm occurred. The authors conclude that MRI of nonpacemaker-dependent ICD patients can be performed with an acceptable risk-benefit ratio under controlled conditions by taking both MR- and device-related precautions.

The results of this study contribute to our existing knowledge on MRI in patients with ICDs and confirm the results of previous reports (2). Gimbel et al. (10) reported their experience on 7 ICD patients who underwent 8 MRI scans at 1.5-T. No changes in pacing, sensing, impedances, charge times, and battery status could be demonstrated in all devices after MRI, and none of the patients experienced any discomfort during MRI. Nazarian et al. (7) reported their findings on the largest reported series of patients with ICDs who underwent MRI. They scanned 24 patients with ICDs, and reported that all were scanned safely. In our institution, we have scanned 8 patients with ICDs in recent years, and all examinations were uneventful.

We must exercise caution, however, given the wide range of available MRI systems, MRI scanning conditions, patient positions, pacemaker and ICD systems, and leads when extending these results to recommendations for routine use of MRI in these patients. The fact that several hundreds of patients with CIEDs underwent uneventful MRI does not allow us to conclude that MRI in this population is indeed safe. All published studies were performed at centers with expertise in MRI and electrophysiology, and were limited to patients with a true clinical need for MRI. The number of patients who experienced adverse events during and/or after MRI is unknown because it has not been reported.

The diagnostic need for an MR study has to be evaluated individually. Based on current data, it should be done only when there is a true necessity and in the absence of an alternative imaging modality, and the diagnostic benefit from MRI must outweigh the presumed risks (2,3). Faris and Shein (1) from the Food and Drug Administration state, “for some patients, the risks presented by MRI under specific, characterized scanning and monitoring conditions may be acceptable given the diagnostic benefit of this powerful imaging modality.”

The risks of MR scanning should be discussed with the patient, and written informed consent must be obtained before MR scanning. The MR study should be performed at centers with expertise in MRI and electrophysiology. The MR scan should be optimally planned in order to minimize time and energy. A physician who is knowledgeable in device therapy and programming should be present during the MR scan. Thoughtful pre-MR reprogramming, careful patient monitoring during MR scanning, and thorough follow-up after MR scanning must be performed. Full resuscitation facilities should be available should any adverse event occur during MR scanning.

MRI may be considered after careful evaluation in selected patients with a CIED, and should only be done when clinically indicated. This may have major implications on current imaging practice (2,3).

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