Safety of Magnetic Resonance Imaging in Patients With Implanted Cardiac Prostheses and Metallic Cardiovascular Electronic Devices

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Magnetic resonance imaging (MRI) in patients with implanted cardiac prostheses and metallic cardiovascular electronic devices is sometimes a risky procedure. Thus MRI in these patients should be performed when it is the only examination able to help with the diagnosis. Moreover the diagnostic benefit must outweigh the risks. Coronary artery stents, prosthetic cardiac valves, metal sternal sutures, mediastinal vascular clips, and epicardial pacing wires are not contraindications for MRI, in contrast to pacemakers and implantable cardioverter-defibrillators. Appropriate patient selection and precautions ensure MRI safety. However it is commonly accepted that although hundreds of patients with pacemakers or implantable cardioverter-defibrillators have undergone safe MRI scanning, it is not a safe procedure. Currently, heating of the pacemaker lead is the major problem undermining MRI safety. According to the US Food and Drug Administration (FDA), there are currently neither “MRI-safe” nor “MRI-compatible” pacemakers and implantable cardioverter-defibrillators. In this article we review the international literature in regard to safety during MRI of patients with implanted cardiac prostheses and metallic cardiovascular electronic devices.

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Magnetic resonance imaging (MRI) is a priceless diagnostic tool used for many diseases and conditions [1–3]. MRI is based on the structure and abundance of water in the different human tissues. It represents the absorption and emission of electromagnetic energy by atomic nuclei in a magnetic field after excitation by a radiofrequency pulse [4–6]. It is an advantageous diagnostic procedure in that it is not at all invasive because there is no exposure to ionizing radiation or potentially nephrotoxic iodinated contrast agents [1–3, 7]. Three-dimensional visualization of anatomic structures and its superiority in soft tissue contrast are additional advantages [8]. Thus MRI is now considered the gold standard for imaging the brain, spinal cord, musculoskeletal system, head and neck, and complex congenital heart malformations [6]. It also appears to be appropriate for estimating myocardial structure, wall motion, perfusion, and viability. As a result, an important increase in the number of MRI scans performed annually has been observed [6, 9–11]. However, the number of MRI scans in patients with cardiovascular implantable electronic devices—mostly pacemakers and cardioverter-defibrillators—has simultaneously increased [7]. Today millions of patients have implanted cardiac devices. Nevertheless, for many years MRI was not allowed for these patients because of the potential interference of MRI machines with their devices, putting the devices or even their own safety in danger [12]. At least 200,000 patients with cardiac devices are estimated to have been denied an MRI scan in 2004 [13]. According to the American College of Cardiology Foundation/American Heart Association “ACCF/AHA 2007 Clinical Competence Statement on Vascular Imaging With Computed Tomography and Magnetic Resonance,” metallic implants such as mechanical heart valves, coronary stents, and sternal sutures are compatible with MRI because they are not ferromagnetic, although there will be local image artifacts. In contrast, pacemakers and implanted cardioverter-defibrillators are considered a contraindication to MRI [14], although several case series of patients with pacemakers have shown that these patients can successfully undergo MRI at 1.5 T [15–17]. Patients who already have either a pacemaker or implantable cardioverter-defibrillator often need an MRI scan. After implantation of the device, each patient is estimated to have a 50% to 75% possibility of requiring an MRI scan some time in his or her life [18, 19].

Possible Interactions With Materials

Three types of electromagnetic fields are used for the generation of an MRI: a constant static magnetic field, a rapidly changing magnetic gradient field, and a strong radiofrequency field [12]. The most commonly used static magnetic field strength for clinical MRI scanning is 1.5 to
3 T [20]. Higher static magnetic fields lead to greater forces on ferromagnetic materials [21]. Gradient magnetic fields constitute spatial variations in magnetic field strength indicating the localization of the signals in the body. Electrical currents in electrically conductive devices and excitation of peripheral nerves can be induced by these changing magnetic fields [20]. The radiofrequency field can cause tissue heating. In addition certain metallic devices, such as pacemaker leads, can act as an antenna and may concentrate radiofrequency energy, resulting in dramatic local heating [20]. The specific absorption rate, expressed in watts/kilogram, describes the absorption of radiofrequency energy, which increases with the square of magnetic field strength [21]. Heating effect depends on the dimensions of the leads (length and shape), on their position in the body, and on their insulation. The heating effect is greater at the tip, where the greatest alterations in the electrical field take place [22]. Magnetic fields are able to provoke either traction forces proportionally to the mass of the device, causing shifting movements of the ferromagnetic object, or torsion forces, resulting in rotational movements that tend to align the device in the direction of the magnetic field [22]. Finally, it should be kept in mind that because these objects produce their own static magnetic field [7], image artifacts or distortions are generated in the area of the implanted device at the expense of the quality and reliability of the images [22]. This phenomenon seems to occur in the direct vicinity of the device [8], being more intense at a 10- to 15-cm distance from it [22]. Nevertheless, the risk becomes negligible, except when the area under examination is the thoracic cavity [22]. Therefore, pacemakers and implantable cardioverter-defibrillators will have no impact on imaging of more distant organs, such as knees, lower spine, liver, or brain [7].

Coronary Stents
Some stents are made of alloys including stainless steel, carbon, or gold, whereas others are composed of cobalt or tantalum [23]. All but two nonferromagnetic models are weakly ferromagnetic. The forces caused by the magnetic field on the implanted stent are proportional to its length and mass, but they seem to be insufficient to provoke any shifting [22, 23]. As far as the heating effect produced by the radiofrequency field is concerned, no temperature alterations in stents have been observed [24]. Finally, distortion of the images is possible only close to the prosthesis [22]. According to several ex vivo studies, coronary artery stents appear to be absolutely safe in terms of magnetic field interactions and heating [25, 26]. Although the manufacturers and cardiologists’ associations suggest waiting 4 to 8 weeks after implantation before performing an MRI in such patients [27], a recent study carried out at the Mayo Clinic on 111 patients with coronary stents proved safety of the MRI, even only days after the implantation. No differences were observed in terms of all-cause deaths, myocardial infarction, and revascularization in the 30 days after MRI examination between patients who had undergone MRI soon after stent implantation and those who had waited the recommended time [28]. Porto and colleagues [29] showed the safety of MRI in the immediate period after implantation (1 to 3 days). Neither acute thrombosis nor adverse cardiovascular events (target vessel restenosis or non–target vessel revascularization) at 9-month clinical follow-up were documented. Other clinical trials also showed that MRI at 1.5 T can be performed within 1 to 14 days after stent implantation without any adverse clinical cardiac outcomes [30, 31]. More recent ex vivo studies, demonstrated that MRI at 3 T is also safe without risk for stent migration [32, 33]. Therefore MRI at 3 T or less appears absolutely safe for patients with coronary stents any time after the implantation of the stent, even in the immediate period after implantation [32, 34].

Heart Valve Prostheses
 Metals, polymers, and carbons are used in prosthetic cardiac valves. Titanium, alloys of cobalt and chromium, and alloys of nickel, molybdenum, and tungsten, as well as aluminium and vanadium are the metals used because of both biocompatibility and high-grade mechanical resistance. Polytetrafluoroethylene (Teflon; DuPont, Wilmington, DE), polyethylene terephthalate (Dacron; DuPont) and polycetal resins such as Delrin (DuPont) constitute the polymer materials used, whereas the carbon materials include pyrolytic carbon [22]. An external magnetic field at 3 T produce forces even smaller than those generated by the beating heart, so there is negligible risk if a patient with a mechanical heart valve undergoes MRI [35]. Moreover, no case of movement of the mobile parts of valves caused by a magnetic field greater than 1.5 T (which might render them permanently open or closed) [36], has ever been reported [22]. The heating effect also is not a hazard [37], as heat from the area involved is taken up by the continuous blood flow to the heart during the examination [22]. Finally, image interpretation is rarely influenced by the artifacts provoked by mechanical valves [38]. In Hartnell and colleagues’ study [38], 25 patients with mechanical cardiac valves who underwent MRI examinations at 1 or 1.5 T sustained no cardiac adverse events, such as arrhythmia or worsening cardiac function, related to MRI. There also appears to be no risk to prosthetic valves, according to Randall and associates [39]. No significant heating effects in sternal wires or other postoperative metal material were documented. Consequently, prosthetic heart valves, as well as metal sternal sutures and mediastinal clips, should not be considered contraindications for an MRI at 3 T or less any time after implantation [34, 38, 40].

Magnetic Resonance Imaging in Patients With Implantable Devices
 Ferromagnetic materials, complex electrical systems, and pacemaker leads implanted into the myocardial tissue constitute pacemakers and implantable cardioverter-defibrillators. Electromagnetic forces produced by MRI can induce several adverse events in patients with implantable devices, including shifting of the device, dam-
Pacemakers

Reports from the 1980s to the mid-1990s [41, 43, 44, 47–49] showed an adverse impact of MRI on pacemakers. However most of them concerned earlier generation pacemakers that are currently not in use. Studies from the mid-1990s to today [45, 50–52] have found no functional complications in most pacemakers after an MRI examination. It has been observed that during MRI, the stimulation frequency may be raised to the maximum programmed rate. Although this increase will be symptomatic, it is not life-threatening [22, 53, 54]. However, deactivating the device before performing MRI is advisable to make the procedure safer [22]. With regard to the heating effect on catheters and electrodes potentially resulting in thermal injury of the surrounding tissue, a recent study reported temperature increases of more than 20°C when the catheters were close to the area of the image, but increases of 4°C to 5°C when they were more than 30 cm away (MRI of the brain, abdomen, pelvis, lumbar spine, and lower extremities) [55]. However, although several reports [50, 51, 55] proved an in vitro temperature increase ranging from 7°C to 63.1°C, Roguin and coworkers [50] in an animal study of MRI fields [22, 45, 50]. Finally, no thermal injury was reported [17]. Wollmann and colleagues [64], Roguin and associates [65], Gimbel and colleagues [61] and Nazarian and coworkers [17] reported that they had their patients with implantable cardioverter-defibrillator safely scanned with MRI. Buendía and associates [66] proved the safety of MRI in 33 patients: 5 patients with implantable cardioverter-defibrillator performed after cardioverter-defibrillator implantation. Overall, implantable devices tested in vitro and in animals in the MRI environment were associated with no significant complications in terms of device function, tissue damage, or pacing threshold alteration [45, 50, 58, 59]. Moreover, relative safety of MRI at 0.5 to 3.0 T was documented in recent prospective human studies of almost 500 patients [15–17, 60–63]. There have been only a few cases of minor pacing threshold alterations, the need for device reprogramming, and battery depletion [12]. Wollmann and colleagues [64], Roguin and associates [65], Gimbel and colleagues [61] and Nazarian and coworkers [17] reported that they had their patients with implantable cardioverter-defibrillators safely scanned with MRI. Buendía and associates [66] proved the safety of MRI in 33 patients: 5 patients with implantable cardioverter-defibrillators and 28 with pacemakers, 4 of whom were pacemaker dependent. There was no irreversible device malfunction or any clinical events or significant threshold changes. No significant irreversible complications were found by Halshtok and coworkers [67], who

Cardioverter-Defibrillators

Despite being significantly smaller and lighter than in the past (forces on older implantable cardioverter-defibrillators were 1 to 5.9 N), new-generation implantable cardioverter-defibrillators are associated with 10 times higher magnetic forces than pacemakers (0.5 to 1.1 N versus 0.05 to 0.12 N, respectively) [7, 50, 52]. However patients will not feel forces less than 2 N [50]. Deflection and rotation of the ferromagnetic materials of defibrillators may take place because of the static magnetic field generated by MRI, as they are still relatively large [57]. Additionally, in the environment of a static magnetic field, the implantable cardioverter-defibrillator transformer will be rendered unable to charge the capacitor, potentially leading to a permanently inactive device, as happens after repeated unsuccessful attempts to charge the capacitor. Consequently, although there is no evidence to support this theory, there seems to be a risk that implantable cardioverter-defibrillators will be incapable of delivering therapy. That is the reason that deactivation of therapy delivery before MRI is imperative. However, there is still the risk of an electrical reset, which may induce its reactivation [7]. The MRI radiofrequency field may be misinterpreted by implantable cardioverter-defibrillator devices as ventricular tachyarrhythmia, resulting in inappropriate antitachycardia pacing, cardioversion, or defibrillation. Moreover, ventricular tachycardia or fibrillation may escape detection by implantable cardioverter-defibrillators because of magnetic fields [22, 45, 50]. Finally, no thermal injury was reported by Roguin and associates [50] in an animal study of MRI performed after cardioverter-defibrillator implantation. Overall, implantable devices tested in vitro and in animals in the MRI environment were associated with no significant complications in terms of device function, tissue damage, or pacing threshold alteration [45, 50, 58, 59]. Moreover, relative safety of MRI at 0.5 to 3.0 T was documented in recent prospective human studies of almost 500 patients [15–17, 60–63]. There have been only a few cases of minor pacing threshold alterations, the need for device reprogramming, and battery depletion [12].
studied 34 MRI scans performed at 1.5 T in 18 patients with 11 pacemakers and 7 implantable cardioverter-defibrillators (1 patient underwent 11 scans). All but 1 MRI scan was diagnostic. The nondiagnostic scan was a cardiac MRI scan performed in an 11-year-old boy with hypertrophic cardiomyopathy. The same result concerning safety was proved by Roguin and Goldsher [12], who performed 49 MRI scans in more than 40 patients with both types of implantable devices. Therefore patients with cardiac implantable devices can safely have an MRI scan at 1.5 T. However, MRI in these patients must be performed under strict conditions and only if there is an absolute indication [12, 67].

Permanent and Temporary Pacing Leads
Endocardial pacemaker leads left in place after device removal potentially act as antennas, resulting in significant heating. The thermal effect may be even more intense than the one provoked by normally connected leads. However, these patients can undergo MRI with the appropriate precautions [7]. Temporary epicardial pacing wires, composed of stainless steel, are usually sutured to the epicardial surface of the right ventricle and right atrium during cardiac operations. These wires are connected to an external pacemaker to prevent atrioventricular block or bradycardia [68]. If their removal is not possible, they are cut and left in place [38]. Hence when MRI is performed, there is a risk of carrying an induced current, potentially leading to pacing complications [68]. However according to Hartnell and colleagues’ study [38], none of 51 patients with temporary epicardial pacing wires experienced arrhythmia or other cardiac dysfunction during MRI. Consequently the presence of epicardial pacing wires does not constitute a contraindication to performing MRI [38].

How To Perform Safe Magnetic Resonance Imaging in Patients With Implantable Devices
The smaller the implantable device and the fewer ferromagnetic materials it includes, the better is the protection from the external magnetic environment it has. Reconsideration of the contraindication for MRI in patients with implantable devices is taking place [18, 34]. Several reports [15, 17, 50, 60, 69] have proved safe MRI at 1.5 T in patients with pacemakers or implantable cardioverter-defibrillators within a professionally supervised environment [16, 17, 63]. However, a few surveys have examined MRI at 3 T in such patients [58, 59, 62]. Currently, new “MRI-conditioned” pacemakers are being introduced [70, 71], but most devices are still “non-MRI safe” [67]. MRI should only be performed provided that it is absolutely necessary and no other diagnostic technique can replace it [7, 22]. The risks and benefits of MRI should be balanced, and the patient’s written informed consent must be obtained before the scan [7,12]. Procedure time and energy should be minimized [12], as should the risk of radiofrequency-induced thermal injury by reducing the specific absorption rate [7, 8]. If the patient is pacemaker dependent, stimulation regardless of the interaction with magnetic fields is necessary, so AOO (atrial pacing without sensing), VOO (ventricular pacing without sensing), or BOO (atrial and ventricular pacing without sensing) are advisable asynchronous modes to which the device should be programmed. Conversely, if the patient has sufficient rhythm at rest, the pacemaker should be temporarily switched off (OOO mode) during MRI. Finally, when a patient with an implantable cardioverter-defibrillator is going to undergo MRI, interrupting the therapy before the performance of MRI is recommended [7, 22]. Whatever the conditions, maximum safety can be obtained only by close patient monitoring, meaning continuous electrocardiography and pulse oximetry during the procedure [7, 8, 22, 67]. Continuous verbal communication is also important [67]. Moreover, an expert cardiologist, an electrophysiologist, a physician with advanced cardiac life support training, full resuscitation facilities, and advanced cardiac life support equipment must be on site [7, 8, 12, 67]. The function of the device should be estimated before and directly after performance of MRI. In addition, thorough follow-up at 6 to 12 weeks is mandatory in every patient with an implantable device [7, 12]. High-risk patients, such as those with high thresholds and those who are pacemaker dependent, should be excluded from undergoing MRI [8] or special attention should be paid to them [7]. Maximum safety for patients with implantable cardiac device who undergo MRI is ensured if these guidelines are applied [7].

Conclusions
Magnetic resonance imaging in patients with implanted cardiac prostheses is sometimes a risky procedure [22]. Thus MRI in these patients should be performed only when it is the only examination able to help with the diagnosis. Moreover the diagnostic benefit must outweigh the risks [7, 19, 34]. Coronary artery stents, prosthetic cardiac valves, metal sternal sutures, mediastinal clips, and epicardial pacing wires are not contraindications for MRI, in contrast to pacemakers and implantable cardioverter-defibrillators [8]. It appears to be feasible and safe for MRI to be performed at 1.5 T [15–17, 50, 63, 67]. Appropriate patient selection and precautions ensure MRI safety [8]. However it is commonly accepted that although hundreds of patients with pacemakers or implantable cardioverter-defibrillators underwent safe MRI, it is not a safe procedure [7]. Currently, heating of the pacemaker leads is the major problem undermining MRI safety [8]. According to the FDA [19], there are currently neither “MRI-safe” nor “MRI-compatible” pacemakers and implantable cardioverter-defibrillators. Continuous monitoring—including pulse oximetry and heart rate control as well as verbal communication with the patient—along with performing MRI in a specialized center with experts and resuscitation equipment on hand, ensure maximum MRI patient safety [67].
References


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