Magnetic Resonance Imaging and Implantable Cardiac Electronic Devices: It's Not What We Can Do, It's What We Should Do

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Magnetic resonance imaging is an invaluable medical diagnostic tool used for many common diseases and conditions. Currently, millions of patients around the world have implanted cardiac devices, namely, pacemakers or implantable cardioverter defibrillators. However, for many years these patients were prohibited from having MRI scans because their device may interact with MRI machines, potentially affecting the device or compromising patient safety.

One of the chief advantages of MRI it that it has no ionizing radiation. In order to generate an MR image three types of electromagnetic fields are used: a constant static magnetic field, a rapidly changing magnetic gradient field, and a strong radiofrequency field. Pacemakers and ICDs 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 [1-3]. In addition, heating of the lead tip can result in tissue damage as well as changes in thresholds, with the potential loss of lead function.

According to estimates, at least half of all patients worldwide with implanted cardiac devices are expected to need an MRI scan during the lifetime of their devices [3]. This is certainly a burning question that the medical community will face more frequently in the coming years.

In the 1980s, severe adverse events occurred as a result of unknowingly scanning individuals with pacemakers [4,5]. With advances in technology and better electromagnetic interference protection, several devices were tested in vitro and in animals in the MR environment and were found safe [6-9]. No significant device malfunction occurred. More importantly, no tissue damage or change in threshold was observed, reinforcing the key role of heat dissipation by blood flow inside the heart. In parallel, in recent years, several prospective human trials reported the relative safety of MR examination at 0.5–3.0 Tesla field strength. Data on almost 500 patients who underwent clinically driven MRI are now available [10-16]. No deaths have been reported in physician-supervised MR studies in which the patients were carefully monitored. In only a few cases have there been reports of minor changes in pacing threshold, the need for device reprogramming, and possibly battery depletion.

In this issue of *IMAJ*, Halshtok et al. [17] add to the cumulative published data. They present their single-center experience with uneventful MRI scanning in 18 patients (11 pacemakers and 7 ICDs) and a total of 34 scans (1 patient underwent 11 scans). They conclude that MRI scanning in the presence of cardiac implantable devices is safe and feasible, although not recommended for routine scans. Our group has performed safe MRI scanning in more than 40 patients (49 MRIs) with both pacemakers and ICDs and we concur with Halshtok that in patients with cardiac implant devices, when clinically indicated, MRI may be performed under strict conditions.

There is a wide range of available MRI systems, MRI scanning conditions, patient positions, pacemaker and ICD systems, and leads. Consequently, it is not possible to test all the combinations and prove the safety of a particular system. Thus, extending these results to recommendations for routine use of MRI in these patients should be done with caution. The fact that hundreds of patients with pacemakers or ICDs underwent uneventful MRI does not allow us to conclude that MRI in this population is indeed safe. Just crossing a highway blindfolded ten times without getting hit by a car does not make it safe. The true number of patients who experienced adverse events during and/or after MRI is unknown because it has not been reported. All published studies were performed at centers with expertise in MRI and device monitoring and were limited to patients with a true clinical need for MRI.

Another implanted cardiac device used to monitor arrhythmia is the loop recorder, a small subcutaneously implanted programmable device that

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ICD = implantable cardioverter defibrillators

contains two surface electrodes. This device has no lead wires and has received approval from the U.S. Food and Drug administration for MRI. Clinical MR studies of patients with these loop recorders did not demonstrate any subjective symptoms experienced by patients, adverse clinical events, or damage to the devices. Of note, interrogation of the devices after MR revealed tachyarrhythmias and bradyarrhythmias recorded during the examinations that were believed to be artifacts [18]. Patients with a loop recorder (Reveal Plus ILR, Medtronic) can undergo MR examination any time after implantation, provided there is no reason to believe the device is not well implanted. Because of the theoretical risk of electromagnetic fields adversely affecting data stored by the device, all stored data should be downloaded before scanning.

A device may be either MR safe, which means that it 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 [1]. The loop recorder is MRI conditional, but current pacemakers and ICDs are neither.

Yet, there is some encouraging news. A pacing system (the Medtronic EnRhythm-MRI SureScan) was designed, tested and approved for use with MRI under specified scanning conditions [19]. An international clinical trial to test the safety and efficacy of this prospectively newly designed dual-chamber pacemaker and modified pacing leads has recently completed enrollment. The interim analysis was encouraging [20]. Accordingly, this device, the first MR conditional pacemaker, received the European CE mark. This system is now commercially available in several European countries and in Israel, and is currently under clinical evaluation in the United States.

So what should we do with the patient with a pacemaker or ICD who needs a brain or spine or knee MRI now? Our patients have devices that were implanted in the past and were not designed, tested or approved for use with MRI.

The current consensus is that MRI should be done only when there is a true need, and only MRI and no other imaging modality can help with the diagnosis. The diagnostic benefit from MRI must outweigh the presumed risks [1,2]. Faris and Shein from the FDA [3] 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."

Position papers with guidelines were issued in Europe and North America with detailed background, possible hazards, available laboratory and human clinical data, and recommendations [1,2]. 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 to minimize time and energy. A physician who is knowledgeable in device therapy and programming should preferably 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 in case of an adverse event.

In summary, it is not what we *can* do, it's what we *should* do. MR imaging in patients with pacemakers or ICDs can be performed, but it is an off-label procedure requiring sound justification and safety precautions. It should be performed only when clinically indicated and only in selected centers with the proper expertise, resources and experience. Individuals with a pacemaker or ICD can now benefit from the advantages of this imaging modality.

FDA = Food and Drug Administration

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