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Recent innovations in the development of magnetic resonance imaging conditional pacemakers and implantable cardioverter-defibrillators

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Abstract

The first generation of magnetic resonance conditional pacemakers and implantable cardioverter-defibrillators has finally arrived in clinical practice after many years of development. These devices have been optimized to properly function within magnetic fields of 1.5 T and ensure safe operation in controlled environments. Further progress is needed to develop a new generation of magnetic resonance imaging (MRI) conditional devices that can operate in higher powered MRI machines (3 T) which produce clearer images. (Cardiol J 2012; 19, 1: 98–104)

Key words: magnetic resonance imaging, MRI safety, implantable cardioverter-defibrillator, pacemaker

Introduction

Recently, the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) approved the first magnetic resonance imaging (MRI) conditional pacemakers and implantable cardioverter-defibrillators (ICD) designed for use in the MRI environment under specific conditions [1, 2].

As MRI use increases, so does the number of patients benefiting from pacemakers and ICDs. This has resulted in an escalating number of patients who require magnetic resonance (MR) diagnostic imaging. Approximately 40% of Europeans and 50–75% of Americans of the more than 1.5 million patients with implanted cardiac devices may have indications for MRI during the lifetime of their device (Figs. 1, 2) [3, 4].

Until recently, the presence of pacemakers and ICDs was considered a contraindication to MR imaging due to a variety of safety concerns related to potential adverse effects on the device from the strong magnetic and radiofrequency (RF) forces generated during the scan [5, 6]. These included the possibility of erratic and inappropriate device functioning during (or after) the scan, over-sensing that can cause high rate pacing or thermal damage to the device, and induced voltages on leads that can cause over- and under-sensing [7]. Moreover, it was feared that the combined effects would cause component failures, mechanical vibration, and device damage [8–10]. Another reported problem was an apparent wide variability in response to MRI with devices of different brands and ages, although there was some evidence to suggest that newer devices containing better protective circuitry may be safer in the setting of MRI. There also was a variability of effect depending upon the type and duration of the MRI scan [7].

Serious injury, and even death, have been reported in patients with non conditional pacemakers and ICDs who have undergone MRI scans [11]. Such events are rare and most reported to date have occurred during emergency scans in patients who were not properly prepared or monitored (Fig. 3).

MRIC technology

Patients implanted with pacemakers may require radiological imaging with MRI for related and unrelated reasons, such as rotator cuff tears, so the

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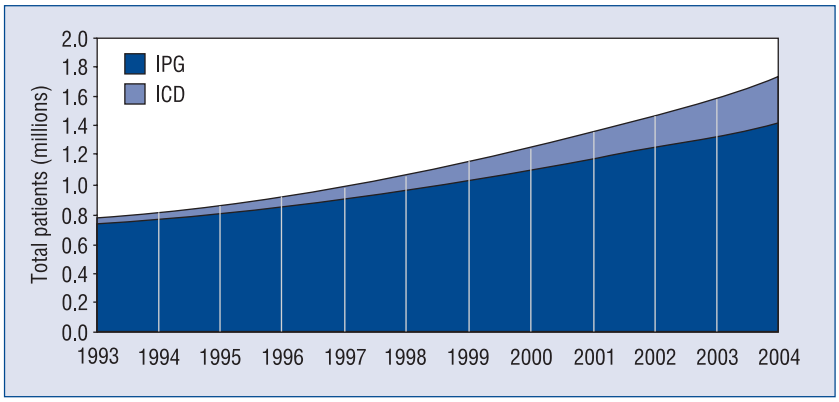

Figure 1. Pacemaker and cardioverter-defibrillator (ICD) implants — prevalence of implantable pulse generators (IPG) and ICDs implanted in the US, 1993–2004 [4].

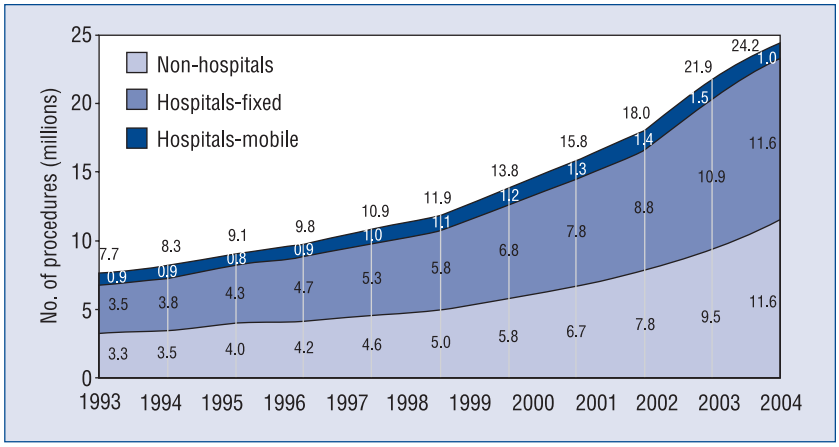

Figure 2. Magnetic resonance imaging (MRI) procedures — total US MRI procedure volume, hospital and non-hospital sites, 1993–2003.

		Field		
		B_0	G_x G_y G_z	B_1
Potential hazard	Force, Torque	√		
	Cardiac arrhythmia		√	√
	Pacemaker component damage	√	√	√
	Intereference with pacemaker function		√	
	Electrical reset	√	√	√
	Lead tip heating			√

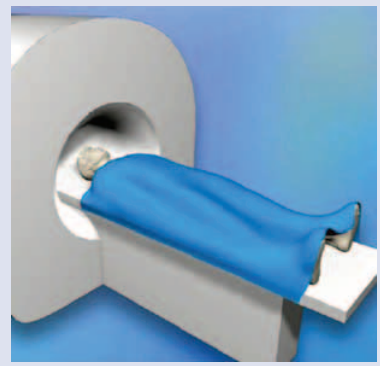

Figure 3. Potential hazard areas for non-conditional implantable cardiac devices in magnetic resonance environment: B_0 — static magnetic field; G_x, G_y and G_z — gravity forces; B_1 — radiofrequency signals.

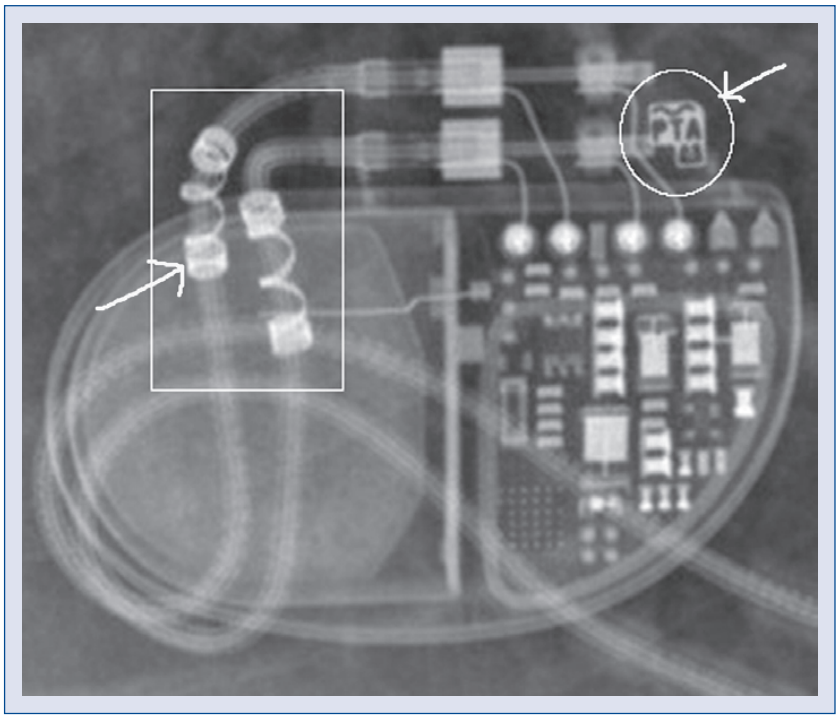

Figure 4. Right arrow indicates radiopaque emblem of a magnetic resonance-conditional pacemaker. Left arrow indicates appropriate electrodes or 'leads' with magnetic resonance-conditional wavy radiopaque markers [18, 19].

recent development of MRI-compatible cardiac implants should be a major help in managing these patients. The development of magnetic resonance imaging conditional (MRIC) devices is a logical progression of the implantable technology. MRIC refers to the idea that to be used safely in an MRI machine, a set of specific conditions has to be met regarding the nature and settings of the magnet [12]. The effects of the MR environment and MR procedures on the functional and operational aspects of cardiac pacemakers and ICDs may vary depending on several factors, including the type of device, how the device is programmed, the static magnetic field strength of the MR system, and the imaging conditions used for the procedure (i.e. the anatomical region imaged, the type of transmit RF coil used, the pulse sequence, the amount of RF energy used, etc.). New MRIC pacemakers and ICDs have been optimized to function within magnetic fields of 1.5 T (Tesla) [13, 14]. 'Tesla' is a measure of the strength of a magnetic field.

The devices are now smaller, made with less ferrous materials and improved electromagnetic interference protection [15]. Critical improvements over older, non MRIC devices include:

1. Elimination of movement of the pulse generator (can) or lead(s).
2. Preservation of the temporary or permanent function of the device.
3. Elimination of inappropriate sensing, triggering, or activation of the device in 1.5 T fields.
4. Elimination of heating of the leads.
5. Elimination of induced currents in the leads.

MRIC device safety

Non-clinical and clinical testing has demonstrated that the approved pacing systems are safe for use in the MRI environment when used according to the instructions provided by the manufacturer [16, 17]. Comprehensive labeling information must be reviewed and adhered to in order to ensure patient safety prior to an MRI scan, which includes, but is not limited to, MRIC for use [20–22].

A pre-MRI X-ray allows for visual confirmation of electrode placement and integrity, implantable pulse generator position, and MR-conditional radiopaque markers, as shown in Figure 4.

As an example, we review a typical set of MRIC for the SureScan pacing system [4, 23]:

1. Cylindrical bore magnet, clinical MRI systems with a static magnetic field of 1.5 T must be used.
2. Gradient systems with a maximum gradient slew rate performance per axis of less than or equal to 200 T/m/s must be used.
3. Whole body averaged specific absorption rate (SAR) as reported by the MRI equipment must be

less than or equal to 2.0 W/kg; head SAR as reported by the MRI equipment must be < 3.2 W/kg.

4. Patients and their implanted systems must be screened for the following contraindications:
   a. Patients with previously implanted (active or abandoned) medical devices, leads, lead extenders, or lead adaptors are contraindicated for an MRI scan.
   b. Patients with broken or intermittent leads are contraindicated for an MRI scan.
   c. Patients with a SureScan pacing system that has been implanted for less than six weeks are contraindicated for an MRI scan.
   d. Patients with a SureScan pacing system implanted in sites other than the left and right pectoral region are contraindicated for an MRI scan.
   e. Patients who do not have a complete SureScan pacing system, which includes a SureScan device and both atrial and ventricular SureScan leads, are contraindicated for an MRI scan.
   f. Patients with pacing capture threshold values of > 2.0 V at a pulse width of 0.4 ms are contraindicated for an MRI scan. Note: Patients experiencing atrial fibrillation may be scanned if all other pre-MRI scan requirements are satisfied.
   g. Patients whose device will be programmed to an asynchronous pacing mode when MRI SureScan is on, and who have diaphragmatic stimulation at a pacing output of 5.0 V and at a pulse width of 1.0 ms, are contraindicated for an MRI scan.
   h. Patients with a lead impedance value of < 200 Ω or > 1,500 Ω are contraindicated for an MRI scan.
   i. A patient with an implanted SureScan pacing system must not be positioned on his or her side within the MRI bore. This position, called the lateral decubitus position, is contraindicated for all MRI scans.
   j. The use of local transmit-only coils or local transmit and receive coils placed directly over the pacing system has not been studied, and such use is contraindicated.
5. Continuous patient monitoring must be provided:
   a. Preparation for patient rescue. External defibrillator must be available during the MRI scan.
   b. Patient monitoring. During the MRI scan, the patient's hemodynamic function must be continuously monitored using at least one of the following monitoring systems:
      i. electrocardiography
      ii. pulse oximetry
      iii. non-invasive blood pressure measurement.

   Note: If the patient's hemodynamic function is compromised during the MRI scan, discontinue the MRI scan and take the proper measures to restore the patient's hemodynamic function.
6. The patient must be positioned according to the contraindications:
   a. A patient with an implanted SureScan pacing system must not be positioned on his or her side within the MRI bore. This position, called the lateral decubitus position, is contraindicated for all MRI scans.
   b. The use of local transmit-only coils or local transmit and receive coils placed directly over the pacing system has not been studied, and such use is contraindicated.
7. There are no patient positioning restrictions relative to the MRI isocenter landmark when using the body coil.
8. There are no patient positioning restrictions relative to the use of any receive-only coils.
9. The implanted system must consist solely of a SureScan device and SureScan leads. Any other combination may put the patient at risk during MRI scans.

Limitations of the MRIC devices

The MRIC systems have some significant limitations, which include the following:

1. The MRIC pacemakers are for new heart patients only. Patients who already have a pacemaker cannot get the new models unless they undergo the risky procedure of having their old pacemaker completely removed. Usually, when the time comes to replace the battery in a pacemaker (about 5–7 years), the metal case containing the battery and circuitry is detached from the leads, and a new model device is hooked up to the leads. But doctors generally consider it too risky to remove the old leads from the heart for fear of tearing the heart or the veins through which the leads are inserted into the heart. Part of the design of the MRIC pacemakers involves their new leads, and only these can be used with new devices [24].
2. Patients must have a new pacemaker implanted for six weeks before receiving an MRI.
3. The MRIC pacemaker requires a certain position of the patient inside the MRI tube so as to avoid most chest scans. This is to prevent overheating the metal tips of the leads that are attached to

Table 1. Availability of approved magnetic resonance imaging conditional devices.

Device	Type	Availability date	Region
EnRhythm MRI SureScan (Medtronic, Inc.)	Pacemaker	2008	Europe
Accent MRI (St. Jude Medical Inc.)	Pacemaker	2010	Europe
ProMRI (Biotronik)	Pacemaker	2010	Europe
Ensura MRI SureScan (Medtronic, Inc.)	Pacemaker	2010	Europe
Advisa DR MRI SureScan (Medtronic, Inc.)	Pacemaker	2010	Europe
Revo MRI SureScan Pacemaker System (Medtronic, Inc.)	Pacemaker	2011	USA
Lumax 740 series Device (Biotronik)	ICD	2011	Europe

the heart. So, heart scans are forbidden with this first generation model (En Rhythm, Revo) [4].

4. MRIC will not work for all types of MRI scans and in all MRI scanners. In addition to the chest scan exclusion, there is a restriction on how much RF energy can be deposited into the body by the scanner. MRI scanners have two operating modes for most clinical applications. 'Normal operating mode' is how the scanner is normally programmed and that mode restricts the scanner to lower-energy scans (less than 2 W/kg). This is sufficient energy for most clinical MRI scans.

However, for some patients and for certain scans, more power is needed. In these cases, the MRI scanner is placed in 'First level control' mode, which allows for greater energy deposition (up to 4 W/kg). Patients implanted with the Revo MRI pacemaker are not allowed to have these higher energy scans. MRIs for these patients are also restricted to only allow use of 1.5 T MRI systems. Medtronic's second generation MRIC Ensura MRI™ SureScan™ Pacing System (June 2010) and Advisa DR MRI™ SureScan™ pacemaker (March 2010) have no restrictions on chest scans [4].

The technical specification and functions of the MRIC pacemakers listed in Table 1 are available on the manufacturers' websites [4, 25, 26] and will not be discussed here.

First MRIC ICD device

In general, exposure to an MR system or to an MR procedure has similar effects on an ICD as those previously discussed for a cardiac pacemaker, since the devices share the same basic components. However, there are several unique aspects of ICDs that impact the possible safe performance of MR procedures in patients with these devices. Therefore, MRI has been generally contraindicated for patients with implanted traditional ICDs. All ICDs have also metallic electrodes placed in the myocardium; therefore MRI scanning is not advisable with older, non conditional devices due to the inherent risks related to the presence of these conductive materials. Although sophisticated scanning algorithms are proposed for traditional ICDs, their safety remains uncertain.

In November 2011, Biotronik announced the world's first MRIC ICD device that directly addressed the safety issues of ICDs in the MR environment [26].

MRIC ICD — Lumax 740 series device

Lumax 740 series implantable defibrillators have received European clearance that has confirmed them to be MR-compatible when proper precautions are taken. The series is designed to work in tandem with Biotronik's Home Monitoring technology that can wirelessly transmit critical diagnostic data from the implant to the patient's physician or monitoring center. Biotronik has reported that following the approval, initial implantations of the devices were performed.

A brief device description from the manufacturer's announcement:

The new Lumax 740 series is part of Biotronik's technologically advanced tachycardia product portfolio, which includes three ICDs, one CRT-D device and 16 leads. The Linoxsmart ICD leads have been proven over time to be of the highest quality and reliability, and are now further enhanced with ProMRI® compatibility. Besides featuring ProMRI® technology, the devices also stand out in the industry by providing longevity of up to 11 years.

Additionally, the intracardiac impedance measure is being used to investigate changes in left ventricular volume as a parameter that could potentially be taken for optimizing cardiac resynchronization therapy (CRT) and predicting worsening heart failure. This data is transmitted from the patient's device to the physician continuously and automatically using Biotronik Home Monitoring®,

the industry's only remote patient management system that is FDA and EMA approved for the early detection of clinically relevant events.

Regulatory status of MRIC

Medtronic is the first supplier to gain FDA approval for the MR-conditional device. Medtronic's Revo MRI™ SureScanR Pacing System (Model#: RVDR01) received FDA approval on 8 February, 2011. Medtronic's Ensura MRI™ SureScan™ Pacing System (June 2010) and Advisa DR MRI™ SureScan™ pacemaker (March 2010) have been approved for use outside the United States [4]. Both devices have labeling with no restrictions on chest scans. St. Jude Medical Inc. Accent MRI MR-conditional pacemaker 25 has also been approved for use outside the United States. Biotronik's Lumax 740 ICD is available in Europe [26].

Clinical research summary

There are several ongoing clinical trials centered on MRIC devices [27, 28]:

The MagnaSafe Registry

- Device: ALL
- Company: ALL
- Dr. R.J. Russo (United States) (Principal Investigator) (Scripps Clinic/Green)
- N = 1,500 patients
- Status: Enrolling (since April 2009)
- Multi-center, observational registry

This investigator-initiated study is designed to determine the risks of performing MRI for patients with pacemakers and ICDs. The goal is to provide physicians with the risk-assessment data needed to determine the use of MRI as a diagnostic tool when no alternative diagnostic imaging technology is appropriate.

Advisa MRI Study

- Device: Advisa DR MRI™ Pacing System
- Company: Medtronic
- Medtronic Advisa MRI Lead (United States) (Principal Investigator)
- N = 270 patients
- Status: Enrolling (since June 2010)
- Allocated, randomized, multi-center U.S. trial

This clinical study is designed to confirm the safety and effectiveness of the Advisa DR MRI pacing system in the clinical MRI environment. The device will be studied with MRI scans up to 2 W/kg SAR without positioning restrictions. Enrollment was scheduled to be completed by October 2011.

Accent MRI Study

- Device: Accent MRI™ Pacemaker System
- Company: St. Jude Medical
- St. Jude Lead (United States) (Principal Investigator)
- N = 60 patients
- Status: Enrolling (since January 2011)
- Prospective, observational, single-center study.

This Accent MRI study is designed to evaluate the performance of the implanted Accent MRI™ pacing system in a clinical setting and optionally in the MRI environment. The pacer will include the Tendril MRI™ lead as well as the MRI Activator™. The study goal is to prove the safety and efficacy of the system. Enrollment is scheduled for completion by January 2012.

Clinically indicated magnetic resonance imaging in patients with cardiac devices

- Device: Revo MRI pacing system
- Company: Medtronic
- Dr. H.R. Halperin (United States) (Principal Investigator) (Johns Hopkins University) (UHC)
- N = 1,000 patients
- Status: Enrolling (since May 2010)
- Prospective, observational, single-center study.

This prospective cohort study is designed to use an established MRI device safety protocol to decrease the risk of clinically indicated MR imaging in patients who have implantable cardiac devices.

Conclusions

MRIC technology for implantable cardiac devices has arrived. It has the potential to change clinical practice and significantly increase hospital costs. At the present time it is limited to 1.5 T scanners for safety reasons. Right now, the issue is that MRIC devices are designed only for 1.5 T powered MRI systems and the trend is to move to higher powered MRI machines (3 T), which produce clearer images in less time and for which the present devices are not indicated [27]. In the foreseeable future, all pacemakers and ICDs should be MRI-compatible and we believe they will be. So it seems to have been a good start for MRIC technology, but there is plenty of technical development still to go.

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Conflict of interest: none declared

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