Magnetic resonance imaging-conditional devices: Luxury or real clinical need?

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Abstract Although the risk of MRI scanning on patients with conventional devices is lower than initially thought, the patient’s safety can only be guaranteed when using MRI-conditional devices. The most important modifications in MRI-conditional devices include a) Reduction in ferromagnetic components to reduce magnetic attraction and susceptibility artifacts; b) Replacement of the reed switch by a Hall sensor in order to avoid unpredictable reed switch behavior; c) Lead coil design to minimize lead heating and electrical current induction; d) Filter circuitry to prevent damage to the internal power supply; and e) Dedicated pacemaker programming to prevent inappropriate pacemaker inhibition and competing rhythms. Although many companies claim to have MRI-conditional devices, adoption in clinical practice is limited because a) Not all companies have MRI-conditional devices approved for both 1.5 and 3T; b) Not all companies offer the option of unlimited MRI scanning (without an exclusion zone in the thorax); c) Certain companies allow only a 30-min MRI scanning and only in afebrile patients; and d) Despite having MRI-conditional pacemakers, certain companies do not have MRI-conditional defibrillators and CRT systems. It is clear that this new technology opens the door for MRI to a growing number of patients; however, the widespread adoption of MRI-conditional devices will depend on real-life issues, such as cost, clinical indications for such a device and the permanent education of health care professionals.

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1. Introduction

Magnetic resonance imaging (MRI) is a technique capable of providing high-quality images of the whole human body. MRI can provide images of excellent spatial resolution together with functional and tissue characterization information without the use of ionizing radiation and iodinated contrast agents. For these reasons, MRI is the imaging modality of choice in a wide spectrum of diseases, not only for diagnosis but also for staging and follow-up of affected patients, including those with involvement of the neurological, musculoskeletal, oncological, and cardiovascular systems. This has led to a recent rapid increase of the number of MRI scans performed. In the USA, the number of scans increased from 7.7 million in 1993 to 22 million in 2002 [1] and it was estimated that 60 million scans will be performed worldwide each year [2] with a continuous increase due to the combination of an aging world population and the expanding applications and increasing availability of MRI scanners.

In parallel with the increase of MRI scans, the number of patients with implantable cardiac devices, including pacemakers, cardioverter defibrillators, and cardiac resynchronization therapy, has also increased. Between 1993 and 2009, the number of implanted pacemakers increased by more than 50% in the U.S. [3,4] The combined increase of these two phenomena has led to a 50–75% probability of a patient requiring an MRI scan over the lifetime of the device, [5] which will in most cases not occur due to safety concerns. [6–9] The introduction of MRI-conditional devices overcomes this limitation and allows MRI scanning in patients with implantable cardiac devices, thus providing clinicians access to a wealth of additional diagnostic information in this patient group.

In this review, our aim is to discuss the potential hazards of conventional pacemakers in MRI scanners, provide updated information about the characteristics of MRI-conditional devices and discuss future directions in the field.

2. MRI in patients with conventional devices

According to the literature, there have been at least 17 MRI-associated deaths among patients with conventional pacemakers, [10] but the number is likely underestimated because there are several patients with a cardiac device who have died after MRI scans that have never been reported in the medical literature, but they gained publicity due to general pressure and/or the legal system. [11] However, a causal relationship between MRI scans and death in patients with conventional devices has not been established, and most deaths occurred in elderly patients with older pacemaker models undergoing MRI without appropriate programming or physician supervision. [10,12]

In practice, there are many patients with conventional devices that underwent an uneventful MRI (non-thoracic) scan. A recent review of 15 studies including 1,419 MRI non-thoracic scans reported no serious complications, although 65% of cases were performed in MRI-conditional devices. [12] Additionally, 49% of examinations were not followed by any change in device function after the scan. [12] A multicenter registry of clinically indicated non-thoracic MRI at 1.5 T for patients with non-MRI-conditional devices implanted after 2001 is underway and will provide more details regarding the risks of MRI scanning in these patients. [13]

3. MRI-conditional devices: When and how?

To avoid the hazardous events taking place during the MRI scanning of patients with traditional devices, pacemaker manufacturers have introduced significant modifications. [14] The most important modifications in MRI-conditional devices include

- Reduction in ferromagnetic components to reduce magnetic attraction and susceptibility artifacts.
- Replacement of reed switches by a Hall sensor in order to avoid unpredictable reed switch behavior.
- Lead coil design to minimize lead heating and electrical current induction.
- Filter circuitry to prevent damage to internal power supply.
- Dedicated pacemaker programming to prevent inappropriate pacemaker inhibition and competing rhythms.

4. Patient selection for MRI-conditional devices

From a clinical point of view, opting for MRI-conditional devices seems rational in patients who have no other contraindications for MRI. However, the adoption of this technology was slower than expected, and in many countries conventional devices still represent the majority of implantable devices. This is mainly due to the higher cost of MRI-conditional devices, the lack of clear guidelines regarding their use and the absence of long-term follow-up on safety and durability; usually, final patient selection is based on selective implantation in patients who are more likely to require MRI scanning in the future. Patients with a history of malignancy, neural/myoskeletal/autoimmune diseases and those who have contraindications for computed tomography (CT) or to iodinated contrast agents, are also included in this category. Although there are some reasonable patient factors requiring the use of MRI-conditional devices, [15,16] prediction of the need for such devices is carried out on an individual basis.

Taking the increasing life expectancy of our population and the rapid improvement of our therapeutic options in various diseases under consideration, it seems rational that every patient deserves to have access to highly diagnostic modalities, such as MRI. There was no difference in terms of efficiency between the currently used devices and the newly proposed MRI conditional devices, except that the latter have the additional advantage of being compatible with a magnetic field environment, albeit at a higher cost. However, if we promote the wider adoption of such devices, the difference in cost will decrease, as is the case in countries such as Switzerland, where non-MRI conditional devices are not in use anymore. Finally, we should always keep in mind that patients with MRI conditional devices
require a detailed electrophysiological assessment before and after an MRI scan and the cardiologist or radiologist performing the MRI should follow all instructions for use given by each company carefully.

5. MRI-conditional devices: “Safe by design”

The term “MRI-conditional” is used for devices that have no known hazards in a specific MRI environment under specific device and MRI scanner conditions. As their name suggests, scanning patients with “MRI-conditional” devices is safe only if a number of conditions related to the MRI scanner, and the MRI-conditional pacemaker (generator and leads) and patient’s characteristics are present.

Although many companies claim to have MRI-conditional devices, adoption in clinical practice is limited because:

a) Not all companies have MRI-conditional devices approved for both 1.5 and 3T.

b) Not all companies offer the option of unlimited MRI scanning (without exclusion zone in thorax).

c) Some companies allow only a 30-min MRI scanning and only in afebrile patients.

d) Despite having MRI-conditional pacemakers, some companies do not have MRI-conditional defibrillators and CRT systems.

All the aforementioned limitations, together with the patient’s needs and the cost-benefit ratio, should be carefully evaluated by clinicians in charge of device implantation while also taking ethical and legal aspects related to this decision under consideration.

6. Medtronic® MRI-conditional pacemakers

Medtronic (Minneapolis, MN, USA) was the first company to introduce an MRI-conditional pacemaker in 2008 (named EnRhythm™ in Europe, Revo MRI™ in the USA). A second generation of MRI-conditional pacemakers (Ensura MRI™ and Advisa MRI™) was introduced in 2011, overcoming some of the limitations of the first models. These limitations include an upper rate limit of 150 beats per minute and the inability to be used in unipolar mode (sometimes useful for dealing with sensing or threshold problems). All these dual chamber devices were approved for whole-body scans and included arrhythmia detection and software designed to minimize ventricular pacing. Medtronic provides MRI-conditional leads with active and passive fixation. The active fixation lead 5086 is based on the older 5076 CapSureFix Novus™ with a two-filar inner coil designed to reduce lead tip heating. Recently, the 5076 lead received a CE marking for backwards MRI compatibility, meaning that patients with older pacemaker systems using this lead can be upgraded to MRI-conditional systems with a simple box change. The passive fixation 5.3F isodiametric lead (CapSure Sense™) also received a CE marking for backwards MRI compatibility.

The first prospective, randomized, multicenter study assessing the efficacy and safety of an MRI-conditional pacemaker in the MRI environment was published by Wilkoff et al in 2011. In this study, 664 patients implanted with the Medtronic Revo SureScan pacemaker were randomized to undergo (n=258) or not undergo (n=206) a non-medically indicated brain and lumbar MRI in the 9–12 weeks post-implantation. MRI scan restrictions were similar to those used in protocols for conventional pacemakers, i.e., the exclusion of thoracic scanning, a static magnetic field strength limited to 1.5 T, a maximum specific absorption rate of 2 W/kg, and a maximum gradient slew rate of 200 mT/m per second. There were no complications (primary safety endpoint) and no MRI-attributed pacemaker sensing or threshold changes (primary efficacy endpoint) in patients who underwent scans. These included subjects with and without pacemaker dependency using the asynchronous mode (n=158) and no pacing with a continuous intrinsic rhythm during scanning (n=67).

More recently, the second-generation Medtronic Advisa MRI™ SureScan Pacemaker and CapSureFix MRI SureScan lead were studied in a clinical trial, where 263 patients were randomized in a 2:1 ratio to undergo 16 chest and head scans at 1.5 T between 9 and 12 weeks after pacemaker implantation or not to undergo MRI. There were no MRI-related complications during or after MRI in the scanned patients. This device has subsequently received a CE marking in Europe and was also approved by the FDA without positioning restrictions for MRI scans or limitations of body parts scanned, overcoming previous limitations in chest imaging.

7. St. Jude Medical® MRI-conditional pacemakers

The Accent MRI™ conditional pacemaker, available in single and dual chamber versions, was introduced in the European market in 2011 and is currently awaiting FDA approval. In Europe, this device is approved for full body scans (no zone restrictions) at 1.5 T when used in combination with Tendril™ MRI leads. St Jude (St Paul, MN, USA) also introduced a hand-held MRI Activator™ that allows quick enabling and disabling of pre-approved MRI settings to facilitate the MRI scanning workflow (these can be pre-programmed at any follow-up visit).

The Accent MRI-conditional pacemaker features full bradyarrhythmia therapy and is also compatible with the St Jude Merlin™ home monitoring system. The Tendril™ MRI lead has a coaxial design and 6.6 F body (requiring an 8F introducer). It is based on standard Tendril™ lead inner and outer coils with additional silicone inner tubing and Optim™ insulation, including a second filter to prevent tissue heating and unintended cardiac stimulation. A soft silicone tip was also introduced to reduce the chances of cardiac perforation.

8. Boston Scientific® MRI-conditional pacemakers

The Ingenio™ and Advantio™ Boston Scientific (Natick, MA, USA) MRI pacemakers are available in single and dual chambers with CE approval. The devices are based on the Ingenio conventional pacemaker and are compatible with the Latitude™ remote monitoring system. They include a
programmable MRI timer designed to return pacemaker settings back to normal after the scan. FINELINE™ II 5.1F active fixation leads received backwards MRI-conditional approval. A multicenter, non-randomized single-arm study (INFINITE MRI) to collect data on the Boston Scientific MRI-conditional pacing system (consisting of an Ingenio MRI or Advantio MRI pacemaker with FINELINE™ II Sterox or FINELINE™ II Sterox EZ leads) is currently running.

9. Biotronik® MRI-conditional pacemakers

The Evia™ and Estella™ MRI-conditional pacemakers, available in single and dual chamber models, are approved in Europe for MRI scanning at 1.5 T with the limitation that they usually preclude thoracic and upper abdominal imaging, but not head or lower extremity scans. Biotronik (Berlin, Germany) recommends limiting the scan duration to 30 minutes and the total device lifetime scan time to 10 hours. Both devices are compatible with a remote monitoring system.

A prospective feasibility pilot study assessing 30 patients with the Biotronik Evia SR-T and DR-T pacemaker with Safio™ 553/650 screw-in leads showed encouraging results. All patients underwent MRI scans of the head and lumbar spine and were evaluated before, immediately after, and at one and 3 months post-MRI. There were no MRI-related adverse events, and no significant differences in lead parameters were identified. These findings await confirmation from a multicenter, randomized clinical trial designed to evaluate the one-month rate of adverse events with the Biotronik ProMRI™ Entovis™ MRI-conditional pacing system, which has finished the recruitment phase (n=245) and is expected to reach completion in early 2014. A trial extension to evaluate the safety of this device without exclusion zones has already received FDA approval.

10. Sorin Group (Milano, Italy) MRI-conditional pacemaker

The KORA 100 MRI-conditional pacemaker is available in Europe in single and dual chamber models. This device, built on the REPLY™ pacemaker platform, includes a filter between the lead and device electronics and received a CE mark approval for MRI scanning at 1.5 T with chest exclusion. The KORA 100 was designed for implantation with MRI-conditional BEFLEX™ leads. Sorin (Milan, Italy) developed an “auto MRI mode” that automatically switches to asynchronous pacing in the presence of a strong magnetic field, thus limiting the time in asynchronous mode to the MRI scan duration.

11. Current situation in Greece

MRI-conditional devices have recently attracted the interest of electrophysiologists and heart failure cardiologists due to the increasing use of implantable devices and valves. However, it seems that the expansion of this new market will eventually occur in Greece, despite the financial crisis, at least for young patients with known heart failure or middle-age patients with a known disease that will potentially require MRI follow-up.

12. Conclusions

Although the risk of MRI scanning in patients with conventional devices is lower than initially thought, the patient's safety can only be ensured using MRI-conditional devices, which are especially elaborated to minimize the interactions between the device system and the MRI environment.

Currently available devices differ from each other in several points, including conditions of use and the robustness of clinical trials. This new technology opens the door for MRI to a growing number of patients; however, the widespread adoption of MRI-conditional devices will be dependent on real-life issues such as cost, clinical indications for implanting an MRI-conditional device and the permanent education of health care professionals.

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