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MRI Conditional Pacemakers

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Introduction

Conventionally, magnetic resonance [MR] imaging is an absolute contraindication for those with an implanted pacemaker [1]. This represents a significant clinical problem as several studies have shown approximately 75% of patients with pacemakers will have an indication for an MRI scan. Patients over the age of 65 are twice as likely to require an MRI and 80% of pacemaker patients are over the age of 65. MR imaging is an important source of information for neurological disorders and several soft tissue abnormalities. Hence denying this important diagnostic modality for those with an implanted pacemaker and other cardiac implantable electronic devices [CIED] is a tremendous clinical problem both because of concerns about MRI signals interfering with the function of the pacemaker and the pacemaker in turn interfering with the MR images.

There are a number of potential effects of MRI signals on cardiac pacemakers and leads. MRI signals can interfere with the function of the pacemaker and the leads as a result of the static magnetic field, the gradient magnetic field, the modulated radiofrequency field and the combined field effects. A lot of research has gone into the development of pacemakers and other CIEDs, which are compatible with MR imaging.

Potential harmful effects of MR imaging on pacemakers

Strong magnetic fields ranging from 1.5 to 3 Tesla, used in current MR imaging could affect the implanted cardiac pacemaker in various ways. Ferromagnetic material in the implanted device will experience mechanical forces when placed in strong magnetic fields, which could lead to displacement of a newly implanted device. Older generation pacemakers with a magnetic reed switch will revert to asynchronous mode of pacing when the reed switch is activated by the magnetic field. Asynchronous pacing without sensing the inherent cardiac rhythm can potentially lead to life threatening ventricular arrhythmias including ventricular fibrillation and the gradient magnetic field may cause inhibition of pacing or undersensing. Fluctuating magnetic field in the MR environment can induce currents in the pacemaker leads, which in turn can cause heating at the lead tissue

interface. Induced currents can also interfere with the functioning of the pacemaker circuitry and cause temporary or permanent malfunction of the device [2].

Protocol for MR scanning in patients with conventional pacemakers

In patients who are not pacemaker dependent, when there is a documented serious condition which would benefit from MR imaging and if the same information cannot be obtained by another modality of imaging, MR imaging may be considered with a certain protocol. The protocol should be approved by the attending radiologist and the cardiologist. The study should be scheduled in regular working hours so that maximum support from all faculty are available. MR Field strengths of 1.5 Tesla or lesser would be preferable, though it might have some compromise on the scan speed and quality of images. The device must have been implanted at least 4 weeks prior to the MR scan so that the chance of device movement in the magnetic field is limited. The pacemaker should be programmed to off mode or very low outputs during MR scanning. Full device interrogation should be done prior, immediately after and 3 months after the MR scan to confirm good device function. The patient should be monitored at the MR console by an ACLS (Advanced Cardiac Life Support) certified physician. Pacemaker programmer and crashcart with external defibrillator-pacemaker should be available. In case defibrillation is required, patient should be immediately shifted out of the MR room as it is not feasible to defibrillate in the MR environment [2].

The total number of patients reported to undergo MRI with CIED remains limited. No single protocol has been used consistently. Patients with PM and ICDs have been reported to have undergone MR successfully. The vast majority of patients having undergone MRI were not pacemaker dependent but some patients who are pacemaker dependent have undergone MR scanning. Non-thoracic and thoracic MR have been successfully performed.

MRI conditional pacemakers

In recent years pacemaker technology has been evolving more and more to make pacemakers which are compatible with MR imaging. MRI conditional pacemakers are those devices for which no known hazards occur when MR imaging is performed with a pre specified protocol which includes device programming, patient monitoring during imaging, and using special imaging protocol. Less of ferromagnetic material and lead design to reduce the chance heating are some of the technological aspects of MRI conditional pacemakers. The magnetic read switch is replaced by a Hall Effect sensor in these devices so that interference due to MR signal is minimized. Most of these devices have an easily programmable MRI mode. The internal circuitry and power supply is well shielded to reduce electromagnetic interference from the MR signal [3].



Figure 1: ASTM Standard F2503 for Making Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. From top to bottom the symbols for MR safe, MR unsafe and MR conditionally safe.

MRI protocols and procedures to reduce chance of interaction

Useful MRI procedures are using lower static gradient field strengths, maximizing the distance between the pacemaker and the scanner and limiting the radiofrequency power used by the scanner. In general, MRI scanning is not recommended until the device must have been in place preferably for at least 4-8 weeks prior to imaging.

Important studies on MRI conditional pacemakers

One of the first studies to be published was by Forleo and associates, who reported on 107 patients who had either MRI conditional system or conventional dual chamber pacemaker implanted [4]. Though the procedural time and fluoroscopic times were higher with MRI conditional pacemakers, there was no difference in pacemaker lead performance.

Another important study was from Wilkoff and colleagues [5] involving 464 MRI conditional pacemakers (EnRhythm MRI pulse generator and CapSureFix 5086 MRI leads from Medtronic Inc., Minneapolis, MN) between 2007 and 2009. MRI evaluation was done in a randomized pattern between study and control groups at 9-12 weeks. 211 patients underwent MRI and the follow up period was 11.2 \pm 5.2 months. Scanning range was above C1 vertebra and below T12 vertebra as per protocol. Dedicated MRI mode was programmed in the pacemakers. No MRI related complications were observed in the study group. Following the study, the device was approved by United States Food and Drug Administration (US FDA) in 2011, renamed as RevoMRISureScan system. A newer generation device named Advisa DR MRI SureScan is available currently both in and outside the United States.

Other manufacturers also have MRI conditional systems - Accent MRI pacemaker with Tendril MRI leads from St. Jude Medical Inc, EviaPro MRI Pacing Systems and Solia and Safio pacing leads from Biotronik, Berlin, Germany and Vitalio MRI pacemaker with Ingevity leads from Boston Scientific.

Potential concerns on MRI conditional pacemakers

It is yet to be seen whether the MRI conditional pacemaker leads function quite well in the long term as the studies were of short duration. Another important concern is the higher cost of MRI conditional pacemakers, making it difficult to choose when there are economic constraints. When the time comes for a lead extraction in future, it is not known whether the MRI conditional leads will be riskier to extract given their higher diameters at present. These concerns may very well be addressed in future by technological developments.

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