Safety of Implantable Pacemakers and Cardioverter Defibrillators in the MRI Environment

a report by
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Introduction

Last year, as many as 200,000 patients were denied magnetic resonance imaging (MRI) due to the presence of a pacemaker or implantable cardioverter defibrillator (ICD). Some industry data suggests that half of all patients with a pacemaker or ICD will require an MRI over the service life of that device.[1] Currently, in the absence of a compelling clinical need, a pacemaker (or ICD) is a contraindication for an MRI.[2,3] As such, device patients are rarely referred to radiologists for MR procedures.

MRI is one of the most powerful and widely employed diagnostic tools available to physicians.[4] Creating remarkable images of soft tissues and rendering anatomic structures in three dimensions not limited by bony anatomy,[5] MR procedure volume has more than doubled in the last decade and the rate of MRI use increase is accelerating.[6] MRI is expected to play an increasingly important role in cardiac diagnostic imaging.

For unrelated but equally compelling reasons ICD procedure volume has increased as dramatically. For over 40 years, pacemakers have been the treatment of choice for patients with symptomatic bradycardia. Steady advances in technology have resulted in innovations such as multichamber pacing and rate response as well as the introduction of advanced diagnostics tools and automaticity to help clinicians manage patients with many different rhythm disorders including:

- complete heart block;
- sinus node disease;
- atrial fibrillation;
- neurocardioinhibitory syncopy; and
- chronotropic incompetence.

More recently, many clinical studies attest to the effectiveness of ICDs for both primary and secondary prevention of sudden cardiac death in patients with heart disease and/or heart failure.[7–10] Cardiac resynchronisation therapy (CRT), which implements the most advanced multi-chamber pacing algorithms, is an important new treatment for patients with advanced systolic heart failure. In Western Europe and the US, there are approximately 400,000 patients newly diagnosed with heart failure annually and the population of heart failure patients, for which CRT pacing may be appropriate, may expand greatly.

Given the rapid expansion of technology in the fields of both MRI and device arrhythmia management, there is increasing interest in the issue of implantable device safety in the MR

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1. *Medtronic data on File.*
2. *www.radiology.upmc.edu/MRsafety/ Accessed 10 March 2005.*
3. *Pinski S L, Trohman R G, "Interference in implanted cardiac devices",* Pacing Clin. Electrophysiol. *(2002), 25: pp. 1,496–1,509.*
4. *Kaiser C P, "Soaring MRI use draws scrutiny. Diagnostic Imaging Online", 4 Jan 2002. CMP United Business Media: A CMP Healthcare Media Web Site. http://www.diagnosticimaging.com/dinews/2002010401.html. Accessed 19 Oct 2004.*
5. *Duru F, et al., "Pacing in magnetic resonance imaging environment: Clinical and technical considerations on compatibility",* Eur. Heart J. *(2001), 22: pp. 113–124.*
6. *IMV Medical Information Division, MRI Census Database Market, 2002/2003.*
7. *Moss A J, et al., "Improved Survival with an Implanted Defibrillator in Patients with Coronary Disease at High Risk for Ventricular Arrhythmia",* N. Engl. J. Med. *(1996), 335: pp. 1,933–1,940.*
8. *Buxton A E, et al., "A Randomized Study of the Prevention of Sudden Death in Patients with Coronary Artery Disease",* N. Engl. J. Med. *(1999), 341: pp. 1,882–1,890.*
9. *Moss A F, et al., "Prophylactic Implantation of a Defibrillator in Patients with Myocardial Infarction and Reduced Ejection Fraction",* N. Engl. J. Med. *(2002), 346: pp. 877–883.*
10. *Moss A J, Presented before ACC 51st Annual Scientific Sessions, Late Breaking Clinical Trials, 19 March 2002.*

environment. The current state of affairs significantly limits the performance of MRI on device patients. With a better understanding of the hazards of performing MRI on device patients as well as the development of MRI safe devices, we may soon enter an era where the power of MRI is used to assist in the appropriate choice of device programming and lead placement. Patients may soon be imaged not in spite of their having pacemakers and ICDs, but because they have pacemakers and ICDs.

Hazards to Patient Safety

All major device manufacturers continue to caution clinicians regarding routine MR scanning of their devices[11–13] and no implantable pacemaker or ICD has received regulatory approval for use in the MR environment.[14] Hazards to patients with implanted devices undergoing an MRI are a result of the static and gradient magnetic fields and the radio-frequency (RF) energy produced during the MRI, as well as effects produced from a combination of the above. The following outlines some of the hazards involved with pacemakers.

Static Magnetic Field

- Mechanical forces, e.g. torque and/or device dislodgement.
- Unpredictable reed switch operation.

Gradient Magnetic Field

- Inappropriate pacing leading to arrhythmia.
- Oversensing leading to failure to pace.
- Undersensing leading to inappropriate pacing.

Combined Field Effects

- Vibration of the generator.
- Alteration of device function or operation.
- Electrical reset of the pacemaker.

Effects of RF Energy

- Heating of the tissue adjacent to the lead tip resulting in failure to capture and/or sense.
- Arrhythmia induction.

In addition, several variables exist with an MRI that also affect the magnitude of the patient's risks, including:

- the strength of the RF field;
- patient, device and device lead position within the MRI;
- duration of the MR scan;
- target anatomy;
- lead length and design;
- imaging sequence; and
- device design.

Clinical Controversy

Device manufacturers routinely urge clinicians to exercise caution regarding decisions to scan patients with implanted pacemakers and ICDs. Clinicians, however, may order an MRI when the clinical need is so compelling that they feel the potential benefit to the patient outweighs the potential risks of undergoing MRI.

Also, given the large numbers of patients with implanted devices and the proliferation of MRI scanning, it is unfortunate, but inevitable, that some patients are scanned accidentally. To date, over 300 device patients have reported to have been scanned in the medical literature with mixed outcomes.

Because of the importance of both MRI and implantable rhythm devices, clinicians have become acutely interested in studying device–MRI safety.[15,16] Recently, the results of two of these studies (Rougin et al. and Martin et al.) have been published and discussed in both peer-reviewed and the non-medical press.

While these studies are important, they also have limitations, and the results should be placed in context with patient safety emphasised. Notably, the discussions of these studies in the non-medical press, lacking the context and insight of peer review, may have led clinicians, patients and institutions into a false sense of security when approaching the issue of device–MRI safety. Indeed, in flagrant disregard to the caveats that the authors of these studies provide regarding the performance of routine MRI on device patients, routine MRI scanning of patients with devices is apparently already taking place.[17]

11. *Medtronic, Inc. http://www.medtronic.com Accessed 10 March 2005.*
12. *Guidant Corporation. http://www.guidant.com Accessed 10 March 2005.*
13. *St. Jude Medical. http://www.sjm.com Accessed 10 March 2005.*
14. *U.S. Food and Drug Administration Center for Devices and Radiological Health. MDR Database: MDR-405200 and MDR-234698. http://fda.gov.cdrh/odo/primerf6.html Accessed 5 Jan 2005.*
15. *Vahlhaus C, et al., "Interference with Cardiac Pacemakers by Magnetic Resonance Imaging: Are There Irreversible Changes at 0.5 Tesla?",* PACE, *V24 Pt 1; April 2001: pp. 10,504–0418.*
16. *Luechinger R, et al., "Force and Torque Effects of a 1.5-Tesla MRI Scanner on Cardiac Pacemakers and ICDs",* PACE, *V 24 N2; February 2001: pp. 10504–0418.*

Discussion of Recent Clinical Studies

Roguin et al.[18] tested multiple pacemaker and ICD models in a 1.5-Tesla (T) MR scanner. The study included nine different pacemaker models and 17 different ICD models in a single scanner.

The authors conclude that "pacemakers appear to be MRI safe", and, in reference to the ICDs tested, "all other newer devices seem to be safe", but acknowledge that their findings and conclusions can only be applied to the devices and clinical situations tested and cannot be automatically extrapolated to human subjects.

Importantly, close reading of the study results reveals a wide variability in response to MR interactions with devices from different manufacturers and from different years. With regard to its routine performance, Roquin's data in particular highlights several concerns when performing MRI on device patients, including:

- one subject animal that had pacing capture failure for 12 hours post-MRI;
- a lead sustaining a marked temperature increase (imbedded deeply in gel to simulate tissue);
- three (33%) pacemakers experiencing an electrical reset; and
- nine (53%) ICD models with post-scan interrogation problems or battery changes.

Martin et al.[19] studied 54 patients who underwent a total of 62 MRI examinations at 1.5-T; 107 leads and 61 pacemakers were evaluated. The protocol required device interrogations pre-and post-MRI. No adverse events were noted and the authors conclude, "...safety was demonstrated in this series of patients."[19]

Despite their conclusions, areas for concern were apparent. For example, pacing thresholds changed in 40 (37%) of the leads, and 10 (9.4%) leads underwent a 'significant' change in thresholds.

In addition, no long-term follow-up of the patients who underwent an MR scan was reported in this study. This is especially a concern for those who demonstrated a significant change in pacing thresholds because the possibility of a latent response to thermogenic tissue damage may eventually compromise patient safety.

Placing the Controversy in Context

In an editorial published April 2004, Drs Gimbel and Kanal[20] highlighted several key safety issues in the debate on the performance of MRI on patients with implantable pacemakers. As they note:

- "...failing to identify an adverse event is not equivalent to demonstrating safety – especially when only a limited number of patients are studied."
- "Current pacemakers are neither safe nor MRI-compatible by the Food and Drug Administration's [FDA] strict definition."
- "Patients and the implanting community should expect nothing less than devices that are MR-safe by design, not by chance."[20]

Underscoring the potential risks, Roguin et al. declare "...routine imaging of (pacemaker) patients by MRI centers would not be appropriate"[21] and placing their own work in context, Martin et al., point out that "...it should be noted that the findings described herein are highly specific to the MR system, the software version running the scanner, MRI conditions, and types of pacemakers and lead systems present in the patients."

Future Developments

Recent Eucomed discussions[22] between industry and the medical community indicate that the issues are complex but not insurmountable. MRI manufacturers warn that the differences in their designs and operation prevent extrapolating test results from one manufacturer to all brands of MRI scanners of the same Tesla strength. Significant variation exists among the design and operation of pacemakers and ICDs from various manufacturers.

17. *http://www.herzschrittmacherpatient.de/englisch_kurz.htm. Accessed March 10, 2005.*
18. *Roguin A, et al., "Modern pacemaker and implantable cardioverter/defibrillator systems can be magnetic resonance imaging safe",* Circulation *(2004), 110: pp. 475–482.*
19. *Martin E, et al., "Magnetic resonance imaging and cardiac pacemaker safety at 1.5-Tesla",* J. Am. Coll. Cardiol. *(2004), 43: pp. 1,315–1,324.*
20. *Gimbel J R, Kanal E, "Can Patients with Implantable Pacemakers Safely Undergo Magnetic Resonance Imaging?",* J. Am. Coll. Cardiol. *(2004), 43: pp. 1,325–1,327.*
21. *Roguin A, et al., "Modern pacemaker and implantable cardioverter/defibrillator systems can be magnetic resonance imaging safe",* Circulation *(2004), 110: pp. 475–482.*
22. *Eucomed meeting February, 2005. Brussels, Belgium.*

One device manufacturer has reported that it is currently investigating and actively testing several modifications to pacing systems (devices and leads) with the goal of releasing a complete system that is designed for safe use and compatibility with MRI. They have indicated[23] that the first of these devices can be expected in Europe in the near future, with the ultimate goal being a complete product line designed and tested to be safe during MRI scanning.

Advice to Clinicians

Clinicians should be aware that information on this subject is limited and that only a few investigators have reported the outcome of MRI on a handful of patients. All clinicians should clearly understand that no manufacturers currently label their devices as 'MRI safe' or 'MRI compatible'.

Recognising these limitations, clinicians must balance the clinical need while minimising patient risk. Without question, the safest strategy is to utilise an alternative imaging modality (for example, CT scan) if possible and every effort should be made to avoid MRI. If, in the physician's judgment, the clinical need outweighs the risk, the patient should be monitored closely, utilising two independent modalities (electrocardiogram (EKG) and pulse oximetry) during the MRI. Consider also:

- extensive reprogramming of the device prior to the MRI;
- increasing the pacing outputs during the scan;
- interrogate, test and reprogramme the device post-scan; and
- intensify the patient follow-up in the months following the scan.

Physicians who choose to perform MRI on their patients should understand that taking care to follow all of the above recommendations does not in any way prevent a serious adverse outcome from occurring, including death. n

23. Medtronic Report to Financial Analysts, February 2004.