RadioGraphics

# Reconsideration of Pacemakers and MR Imaging[1]

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The presence of an implanted pacemaker is widely regarded as an absolute contraindication to magnetic resonance (MR) imaging; however, this viewpoint is based largely on safety concerns in the 1982–1996 period. Since 1996, changes in pacemaker electronics including decreased ferromagnetic content, increased sophistication of the circuitry, and onboard computer capabilities suggest that the absolute contraindication of MR imaging for pacemaker patients should be reconsidered. In addition, there are now data from prospective trials of 232 patients with demand pacemakers who underwent MR imaging at 0.5–1.5 T. Although a variety of pacemaker parameters were evaluated before, during, immediately after, and 3 months after MR imaging, no significant pacemaker changes were identified. No patients reported abnormal sensations such as pacemaker movement or irregular heartbeats even at direct questioning. These results suggest that peripheral locations such as the brain and knee may be considered for MR imaging. Thus, pacemaker patients should be assessed individually for their suitability for MR imaging, which may be performed safely under defined conditions.

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**Abbreviations:** ECG = electrocardiogram, EMI = electromagnetic interference

**Index terms:** Heart, MR, 51.1214, 51.43, 51.456 • Heart, pacemakers, 51.43, 51.456 • Magnetic resonance (MR), safety, 51.1214, 51.43, 51.456 Magnetic resonance (MR), utilization, 51.1214, 51.43, 51.456

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See the commentary by Steiner following this article.

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## Introduction

A search for "pacemaker + MRI" on the Web-based search engine Google produced over 5000 hits, and a check of the first 100 hits showed that a majority were radiology sites in Europe and North America stating that pacemakers are an absolute contraindication for magnetic resonance (MR) imaging. The potentially lethal outcome from the interaction of MR-generated electromagnetic interference (EMI) on pacemakers provides the medical basis for this view (1–3), as well as safety and liability concerns. This orientation has spread through the medical and nonmedical communities (4–6). However, more than 2.4 million Americans and a similar number of Europeans have pacemakers. Should these people continue to be denied access to the powerful diagnostic search that MR imaging provides?

Current opinion was captured in a survey from the Cleveland Clinic (7) that asked academic radiologists and cardiologists whether they would image a pacemaker patient, and 78 (41%) out of the 192 surveys were returned. Responses from radiologists suggested 97% would not do so, whereas 34% of cardiologists said they would under the right circumstances. In light of these findings, one is tempted to speculate that a knowledge void exists between these two medical communities and that a new framework for information exchange is required.

The biophysical implications of technical advances in pacemaker engineering challenge any absolute preclusion of demand pacemakers in the MR imaging setting. Herein, we will review recent studies of patients with demand pacemakers and critically review the literature on the potential hazards of pacemaker patients in the MR imaging environment. The reader is invited to reflect on the evidence and consider two questions: Would you image a pacemaker patient at your MR facility? If not, what additional evidence might allow you to consider imaging such patients?

## Innovations in Pacemakers

A major force driving the technological changes in pacemakers has been the increased risk of exposure to EMI in everyday life. The possibility of EMI may arise in a number of circumstances, and the clinical impact of EMI has been reviewed in the cardiology literature (8,9). In modern society, EMI is a ubiquitous environmental contaminant. Potential sources of EMI outside the hospital include electronic antitheft surveillance devices, airport security devices, cellular telephones, microwaves, high-tension power lines, electric motors, electrical welding units, degaussing coils, and high-voltage generators. Hospitals themselves contribute to EMI "contamination" with many EMI-producing instruments: electrocautery devices, radiation therapy sources, extracorporeal shock wave lithotripsy, electrical defibrillation, electrical shock wave therapy, transcutaneous electrical nerve stimulation, peripheral nerve conduction stimulation tests, and some dental devices.

As a result of these concerns over EMI, a number of changes have occurred in pacemaker design, construction, and control (10). There has been a shift away from the use of ferromagnetic materials by decreasing the ferromagnetic content and substituting other metals such as titanium in as many parts of the power supply as possible. The electronic components of the pulse generator, noise protection, and programming circuits have also seen major changes. Programming options have expanded significantly, as has the communications technology used to effect programming changes. The external device that communicates with the pacemaker contains special fail-safe recognition software to eliminate incidental errors.

Reduction in the distance between the pacemaker electrodes reduces the antenna effects of the leads, minimizing stray-field effects. In a bipolar or two-lead system, the anode and cathode are in the myocardial area to be paced and sensed, respectively. Unipolar or single-lead systems consist of the power pack as the anode and a single electrode at the distal tip of the lead in the myocardium as the cathode, so a return pathway occurs through body tissue. Increased spacing between the anode and cathode in a unipolar system may result in a greater susceptibility to EMI and potential interference from the myopotentials of the body (8).

The potential for EMI in the leads has been reduced by adopting a materials standard that includes the use of a nickel, cobalt, chromium, and molybdenum alloy known as MP35N that is less magnetically susceptible. Other developments under consideration for leads include copper, a modified pacing catheter, and fiber-optic materials among others (10).

For our purposes, we consider two groups of pacemaker patients. Those who are pacemaker dependent rely on the pacemaker all the time to maintain heart rhythm and are hemodynamically unstable without a functioning pacemaker. Patients who are pacemaker dependent may present a greater experimental risk and must still await a

**Table 1**
**Reports of Nonlethal Outcomes after MR Imaging of Pacemaker Patients**

| Type of Study | Year | Authors | No. of Cases* | Field Strength (T) | Outcome |
|---|---|---|---|---|---|
| Case report | 1989 | Alagona et al | 1/1 | 1.5 | Normal pacemaker function |
| Case report | 1993 | Inbar et al | 1/1 | 1.5 | Normal pacemaker function |
| Case report | 1998 | Garcia-Bolao et al | 1/2 | 1.0 | Asynchronous pacing |
| Case report | 1998 | Fontaine et al | 1/1 | 1.5 | Rapid ventricular pacing |
| Retrospective | 1996 | Gimbel et al | 5/5 | 0.35–1.5 | Normal pacemaker function, asynchronous pacing, artifact |
| Retrospective | 1996 | Gimbel et al | 20/20† | 0.35–1.5 | Normal pacemaker function, asynchronous pacing, artifact |
| Prospective | 1998 | Sommer et al | 18/18‡ | 0.5 | No significant changes |
| Prospective | 2000 | Sommer et al | 44/51‡ | 0.5 | No significant changes |
| Prospective | 2001 | Vahlhaus et al | 32/34‡ | 0.5 | Asynchronous pacing, no irreversible changes |
| Prospective | 2001 | Sommer et al | . . .§/80‡ | 0.5 | Asynchronous pacing, no significant changes |
| Prospective | 2001 | Coman et al | 24/24 | 1.5 | Pacing inhibition, no significant changes |
| Prospective | 2002 | Sommer et al | 51/77 | 1.5 | No significant changes |
| Prospective | 2002 | Sommer et al | . . .§/90‖ | 1.5 | No significant changes |
| Prospective | 2003 | Coman et al | 62/62# | 1.5 | No significant changes |

*Values are number of patients/number of examinations.
†Includes the five cases reported earlier.
‡The total of 80 examinations includes some cases reported earlier.
§Number of patients not clear.
‖Includes 55 patients and 71 examinations reported earlier.
#Includes the 24 cases reported earlier.

larger body of evidence before they can be considered for MR imaging. On the other hand, patients with demand pacemakers have an intrinsic heartbeat but develop aberrancies from time to time. The pacemaker senses the irregularity and starts to pace at a preprogrammed rate until it senses a return of the patient's basic rhythm. Only patients with demand pacemakers can be considered for MR imaging at this time. In our community hospital, about 80% of pacemaker patients have a demand pacemaker (Dr R. Bauer, cardiologist; personal communication, April 2004); in a teaching hospital in Toronto, the estimated ratio is about 70% (Dr I. Mangot, cardiologist, St Michael's Hospital; personal communication, June 2004). The ratios will vary considerably depending on the hospital setting and patient profile. In settings where there is a large number of arrhythmia patients and atrioventricular node ablation is carried out, the number of patients with permanent pacemakers will be increased.

The mode of pacemaker operation is described by three letters: the first represents the chamber paced, the second the chamber sensed, and the third the response to the sensing. A pacemaker in VVI mode paces the ventricle, senses the ventricle, and responds by inhibiting the next pacemaker beat, whereas a setting of VOO paces the ventricle and turns off the sensing and inhibiting functions. Inactivation may be programmed on some pacemakers (OOO mode). Asynchronous pacing refers to pacing that bypasses the pacemaker sensing system, producing a fixed rate; such settings include AOO, VOO, or DOO, depending on the pacemaker manufacturer. Synchronous operation refers to a pacemaker that operates in demand mode (DDD).

## Data on Nonlethal Outcomes for Pacemaker Patients Undergoing MR Imaging

### Case and Anecdotal Reports

Table 1 summarizes the reports on nonlethal outcomes for pacemaker patients in the MR imaging environment. Before 1997, the reports relate mostly individual cases (11–14). The retrospective studies by Gimbel et al (7,15) mark the first departure from the individual case reports. One interesting aspect of their second study is the fact that in 11 of the 20 cases that they reported, the MR unit staff were unaware of the presence of a pacemaker; the cases were gathered as anecdotes

**Table 2**
**Proposed Protocol for MR Imaging of Patients with Demand Pacemakers**

| |
|---|
| Obtain institutional approval |
| Establish a risk-benefit ratio for the patient |
| Establish whether the patient is pacemaker dependent (exclude) or has a demand pacemaker (can be considered for study) |
| Obtain informed consent |
| Pretest pacemaker functions outside the MR imaging suite |
| Have an attending cardiologist decide about preprogramming of the pacemaker |
| Have the cardiologist in attendance for the study |
| Hook the patient up to monitoring equipment (blood pressure, pulse rate, oxygen saturation, ECG, and breathing motion, if possible) |
| Ensure that the monitoring equipment is functioning |
| Consider having an attendant beside the MR imaging unit or two-way communication at all times |
| Begin imaging; check the monitoring devices continually, and speak with the patient after each sequence to check for voiced concerns |
| If functions remain stable, continue imaging |
| After the study, check all pacemaker parameters outside the MR imaging suite again |
| Document all monitoring data and consider sharing these data |

from other practitioners. We speculate that other patients with pacemakers may have been unwittingly imaged and that there may be a large untapped data pool available in these incidents. A Web-based research project on this subject at *www.mripacemaker.ca* has been initiated in order to gather anecdotal data from colleagues around the world.

A major change after 1997 is the publication of data from carefully controlled prospective trials of pacemaker patients and MR imaging, which accounts for 232 (91%) of the 256 examinations in Table 1. This may be related to the changes in pacemaker technology as well as the need for more scientific rigor.

## Bonn Prospective Trials

The German group has imaged a total of 80 pacemaker patients at 0.5 T and another 90 patients at 1.5 T (16–18) (Torsten Sommer, MD, personal communication, August 2002). The patients were all receiving demand pacing in everyday life, and the benefits of the MR imaging study were thought to outweigh the potential risks to the patient. Institutional approval and informed consent were obtained. One additional step taken in the Bonn studies was to program all the pacemakers to asynchronous mode (setting the pacemaker to a fixed pacing rate) prior to MR imaging. In addition, the electrocardiogram (ECG), oxygen saturation, blood pressure, and breathing rate were all monitored, an observer was beside the patient in the MR suite to check on any voiced complaints, and a cardiologist with pacemaker expertise was present during the examination. Pacemaker parameters were all carefully checked before entry into the suite, again once the patient was in the imaging unit, and after MR imaging. All these steps provide an excellent model for studying pacemaker patients with MR imaging and are elaborated on in Table 2.

In addition, a 3-month follow-up was performed in 51 patients studied at 0.5 T (17). When the 0.5-T equipment was replaced with a 1.5-T unit, the same approach was implemented. Thus far, 90 pacemaker patients have undergone brain studies, and a preliminary report on 51 patients and 71 examinations has been produced (Torsten Sommer, MD, personal communication, August 2002). An important part of their work has also been the extensive and detailed in vitro testing of various models of pacemakers and leads (16).

## Oklahoma Prospective Trials

The Oklahoma Heart Institute studies on a 1.5-T system (19–21) (Edward T. Martin, MD, personal communication, August 2002) instituted monitoring similar to the European study but did not perform any pacemaker preprogramming. In other words, the pacemaker was left to function the way it might in everyday life outside the MR suite. A second difference was that consecutive patients requiring MR imaging for any indication were accepted, although again informed consent and institutional approval were obtained.

The group has now reported on a total of 62 patients with a preliminary poster at the International Society for Magnetic Resonance in Medicine meeting (20) and recently with a very detailed article (21). They found no damage to

**Table 3**
**Theoretical Concerns about Pacemakers in an MR Imaging Environment**

| |
|---|
| Static magnetic field |
| Closure of the reed switch |
| Pacemaker displacement |
| ECG changes |
| Radiofrequency field |
| Heating of the leads |
| Alterations in the pacing rate |
| Pacemaker reprogramming or resetting |
| Damage to the electronic components |
| Time-varying magnetic gradient field |
| Induction voltage |
| Heating |
| Closure of the reed switch |
| Damage to the electronic components |
| Image artifacts |

pacemaker circuits, no episode of loss of capture, and no changes in lead impedances. They encountered some pacing threshold changes in the 48 atrial and 59 ventricular leads, but only two of the 107 leads required an output programming change. Two patients experienced transient symptoms, but no studies were terminated as a result. They concluded that inhibition of the pacing pulse or resetting the pacemaker to asynchronous mode was not necessary. Also, 29 of the pacemakers predated 1996 with the oldest from 1986.

## Critical Review of the Literature

Human experimental MR systems became available in 1977, and concerns about the biologic effects were raised as early as 1982. The initial framework proposed by Mathur–De Vre (22) was based on the three types of magnetic fields in an MR imaging unit. The static field is on all the time in superconducting systems and is the strength of the field as expressed in tesla. The radiofrequency fields are the varying fields generated by the excitation pulses in all sequences. Time-varying fields refer to the gradients used to allow section selection in the x, y, and z planes. A summary of the potential hazards identified by Mathur–De Vre (22) and others is outlined in Table 3.

### Activation of the Reed Switch

Pacemakers have a built-in magnetically activated reed switch. When this switch is activated or closed, a preset pacing rate is established. In order to check pacemaker function, a magnet may be applied to the pacemaker to activate the reed switch. Thus, it is no surprise that the MR environment may also activate the reed switch. Activation was initially thought to occur at field strengths of 1 mT (10 gauss), and this formed the basis for recommending that pacemaker patients remain outside the 5-gauss line (3).

Movement through the static field may activate or close the reed switch, but the effects are not uniform and are dependent on the orientation of the reed switch to the magnetic field (17,23,24). Once the patient is in position, the imaging magnetic fields may activate the reed switch; however, the conditions under which this effect comes into play are poorly understood. This has led some to advocate programming the pacemaker to the "magnet off" mode and using a fixed pacing rate for the MR experiment to avoid the possible influence of the reed switch turning on and off. Vahlhaus et al (18) reported imaging patients in the asynchronous mode for a mean duration of 99.5 minutes (range, ±29.6 minutes) without adverse effects on the patient or pacemaker.

Experimental work on reed switch closure (25) with 0.5-, 1.5-, and 3.0-T systems has been performed. When the reed switch is parallel to the magnetic field and gradually moved through the magnet, it is closed or activated at 1.0 mT ± 0.2 and as it is moved away from the isocenter it is opened or inactivated at 0.7 mT ± 0.2. These data suggest a much lower limit than was previously thought. Thus, in very low strength magnetic fields, the reed switch may be closed or activated. In magnetic fields greater than 200 mT, the reed switch was open in 50% of the tested orientations, and this occurred irrespective of the magnetic field strength. The reed switch then does not necessarily remain closed or activated in the magnetic bore. The Oklahoma group noted five patients with non–magnet-mode response, confirming that the reed switch may behave variably during MR imaging (21).

However, one may reasonably ask whether activation of the reed switch is of any clinical import? In the instances where the patient is undergoing acute myocardial infarction, is markedly hypoxemic, or has a major electrolyte imbalance, reed switch activation is a potential concern (26). The reed switch is set to pace at 80–100 beats per minute, and under the specified clinical conditions ventricular fibrillation may theoretically develop. Otherwise, there need be little concern about the reed switch in practical terms (19,21, 27). In addition, thus far there have been no reports of damage to the reed switch.

## Pacemaker Displacement

All ferromagnetic materials may be subject to magnetic force or magnetic torque effect with possible resultant displacement. Magnetic force increases with increased distance from the magnetic isocenter if there are changing magnetic fields. The concern is considerably decreased for newer pacemakers, where the measured magnetic force at 1.5 T on 32 newer pacemaker models at the entrance of the clinical imaging unit was less than the gravitational force (28,29). This finding reflects the much reduced ferromagnetic components in newer pacemakers.

On the other hand, magnetic torque effect is minimal in the sweet spot of the magnet and tends to align ferromagnetic material parallel to the magnetic field. Usually, the patient lies parallel to the main magnetic field and the orientation of the pacemaker is usually parallel to the main magnetic field, so the magnetic torque effect is minimal.

Concerns regarding pacemaker displacement were raised as early as 1984, and this concern was likely valid with the ferromagnetic content of that era (30). In view of these concerns, it was suggested that a pressure dressing be applied to the pacemaker to prevent deflection. However, this precaution is probably redundant for modern devices, as no significant evidence for pacemaker displacement has surfaced in the German or Oklahoma prospective trials. Gimbel et al (15) reported one case of discomfort in the pacemaker pocket.

## ECG Changes

A cautionary note remains for cardiac monitoring, as T-wave elevation may occur at field strengths as low as 0.1 T and increases linearly with increasing field strength (23). This may potentially be a problem when gating is employed. However, the pacemaker senses on waves corresponding to the P and R waves of the ECG, and no significant effect on these waves has thus far been shown. Electromagnetically induced noise may occur during telemetry and can resemble an arrhythmia. The Oklahoma group (21) encountered varied and transient ECG changes, but none resulted in cessation of the study.

## Heating

The prominent concerns about heat deposition in MR imaging have led to the development of guidelines on whole-body exposure expressed as the specific absorption rate (SAR) in units of watts per kilogram. However, the concern in pacemaker patients is not with the total-body SAR but with possible local heating effects at the lead tip–myocardial interface. Theoretical concerns about heating in the leads have postulated the possibility of sufficient heating to result in myocardial destruction with a range of outcomes from scarring to muscle penetration or even perforation.

A number of in vitro experiments have been conducted that demonstrate radiofrequency heating in the pacemaker lead tip, and one example of a particular model will suffice. Luechinger et al (31) studied 10 leads of various types in different positions during turbospin sequences with a 1.5-T system in a water bath. They recorded temperature increases greater than 10°C in eight leads and greater than 20°C in five leads. On one occasion, a rise of 69°C was obtained. It should be borne in mind that these types of experiments are mostly conducted in saline baths, and a major limitation of these studies is the variety of heat dissipation methods that are present in vivo.

An attempt to overcome some of the shortcomings of the saline bath model was performed in vitro at 0.5 T in an isolated pig heart with eight single-chamber and 13 dual-chamber pacemaker models and 44 leads, both unipolar and bipolar (17). At an SAR of 0.6 W/kg, the electrode tip–specific maximum temperature in the isocenter of the field was a mean of 1.79°C, with a highest recorded level of 8.9°C. When the SAR was increased to 1.3 W/kg, the mean temperature recorded at the isocenter was 4.68°C; however, one out of 44 leads demonstrated a maximum of 23.5°C. The mean temperature increases in all cases were considerably less near the edge of the body coil, with many recordings of no temperature increase and a maximum reading of 4.45°C. If one may extrapolate from these data, heating effects may not really be significant for imaging body regions with a dedicated coil outside the chest in pacemaker patients. In vivo confirmation of the latter point is now available in the latest data from the Bonn group (Torsten Sommer, MD, personal communication, August 2002). At experimental SAR levels of 3.9 W/kg and 1.2 W/kg, mean temperature elevations of 0.4°C and 0.2°C and maximum temperatures of 3.5°C and 0.9°C, respectively, were recorded at the pacemaker lead tip during MR imaging of the brain by using in vivo measurements.

It is indeed one of the limitations of the "safety reports" that they were for the most part performed with dedicated peripheral coils. In the initial series from Bonn, only five of the 18 patients underwent chest or abdominal studies at 0.5 T, and all the latest patients studied at 1.5 T

underwent brain imaging. The data from Oklahoma (21) included 15 out of 63 patients with a chest or abdominal study, and the numbers for the Bonn group are seven out of 51 (17). Thus, more research is likely needed on pacemaker patients undergoing chest or abdominal studies with respect to local heating effects.

Sommer et al (16) found that 90% heat dissipation from the lead tip occurred over 5 minutes and thus instituted an intersequence delay of 5 minutes. Other strategies to avoid heating that they have suggested include limiting the duration of sequences, avoiding sequences where there is very rapid gradient switching (eg, gradient-recalled echo), using the lowest slew rate, and using equipment of lower magnetic field strength.

One possible outcome of heating damage is myocardial scarring. Manifestations of such a scar might be a raised pacing threshold, failure to capture, or development of an arrhythmia. In the two available Bonn prospective trials where an initial poststudy evaluation and a 3-month follow-up evaluation of pacemaker function were completed, no significant changes in these parameters were found at 0.5 T, and the 3-month follow-up in Oklahoma at 1.5 T showed similar results.

### Alterations in Pacing Rate, Pacemaker Reprogramming, Inappropriate Inhibition or Triggering, and Changed Battery Life

The literature on alterations in the pacing rate, pacemaker reprogramming, inappropriate inhibition or triggering, and changed battery life seems to divide into two groups: before and after 1997. Perhaps this is a function of changes in pacemaker design, or it may reflect differences in attitude. Work done in the period 1983–1997 raised significant concerns about pacemaker patients in the MR imaging suite. It must be borne in mind that in the early days of MR imaging, the effects of MR on pacemakers were unknown and investigators raised safety issues that were essentially being overlooked. In 1983, Pavlicek et al (32) raised theoretical concerns about a number of EMI effects on pacemakers such as inadvertent reprogramming, damage to the electronics, and inappropriate inhibition or triggering. They investigated six different pacemakers at field strengths ranging from 0.15 T to 0.35 T and 0.5 T in vitro. They defined an acceptable limit for controlling access to the MR imaging suite as 10 gauss and also raised the key issue that pacemaker output be tested particularly with respect to the time-varying magnetic fields.

In 1986, Erlebacher et al (33) reported on four different pacemakers set in DDD mode tested in a saline phantom on a 0.5-T system. They noted that during the pulse sequences the function of three of the pacemakers was inhibited, and one pacemaker showed ventricular backup pacing at high radiofrequency pulse repetition rates. Lauck et al (34) examined several dual-chamber and single-chamber pacemakers with unipolar and bipolar leads at 0.5 T. Their major finding of concern was again related to the pulse sequences as opposed to the static and gradient fields. They noted an inhibitory effect on single-lead pacemaker function and a triggering of dual-lead pacemakers. Thus, they recommended that pacemakers be programmed before imaging to avoid these potential effects.

Hayes et al (30) tested eight pacemakers from two different manufacturers, but this time used an anesthetized 20-kg mongrel dog as the experimental model in a 1.5-T system. Seven of the eight pacemakers tested showed a drop in arterial pressure, which the authors attributed to rapid cardiac stimulation. They concluded that pacemaker patients should not be imaged in high-field-strength systems. They mentioned difficulties monitoring the ECG. Thus, their criterion for cardiac stimulation was based on intraarterial hemodynamic monitoring. They did not comment on the location of anesthetic administration or the hemodynamic output equipment, so it remains a possibility that the results obtained may reflect EMI effects on the equipment rather than a change in the pacemaker function. They noted that seven out of eight pulse generators paced rapidly when exposed to high radiofrequency signal. Achenbach et al (35) used a phantom model and studied 25 leads in isolation or attached to 11 pacemakers. They found no pacemaker malfunctions if the pacemakers were preprogrammed in asynchronous pacing mode, whereas in other modes inhibition and rapid pacing did occur.

Fontaine et al (14) reported a case of rapid cardiac pacing that was directly related to radiofrequency pulsing and postulated two explanations. One was that the lead acts as an antenna for radiofrequency energy that interacts, creating harmonics that drive the pacemaker's output circuit. Alternatively, they suggested induced currents between the MR system and pacing lead could account for the finding.

Shellock et al (36) completed an in vitro experiment in a dedicated extremity 0.2-T system, confirming the possible safe conduct of MR for leads positioned distant from the sweet spot of the magnet. No reprogramming changes, operational problems, or functional problems arose with the pacemaker in this setting.

There are three in vivo case reports of the safe performance of MR imaging in pacemaker patients in the period 1989–1998 (12–14). The work of Gimbel et al (15) in 1996 showed normal pacemaker function in four patients and only a momentary 2-second pause at the end of one of the pulse sequences in a fifth patient, who was the only pacemaker-dependent patient. A subsequent survey by the Cleveland group (7) found one case of rapid pacing, and hence the examination was stopped. No adverse effects on the patient or pacemaker were noted. The prospective work of Sommer et al (16) in 1998 on 14 pacemaker models in vitro and 18 pacemaker patients in vivo showed neither stimulatory nor inhibitory effects at 0.5 T, and similar findings were obtained as they added further patients. They incorporated the cautions of Hayes et al (30) and Achenbach et al (35) into the study design and preprogrammed all pacemakers before the examination.

However, the prospective in vivo work of Coman et al (19) in 2001 on a 1.5-T system without preprogramming the pacemaker showed no episodes of loss of capture, programming change, pacing rate alteration, or voiced symptoms. One device did show pacing inhibition during the examination. They also studied 44 leads; while none showed a change in impedance, 10 leads did undergo a minor threshold change to the next lower value.

Pacemaker reprogramming is highly unlikely with the newer pacemakers, which require both a specific pattern of programming sequences and communication back from the pacemaker to the programmer before programming changes take effect. Indeed, no reprogramming changes have been noted in the prospective reports published thus far.

Telemetry frequencies used to monitor pacemaker function remotely are in the range of 32–175 kHz, which is significantly different from the radiofrequency and gradient fields used in MR imaging (11). Finally, battery life was not shortened in the Oklahoma study (21) nor in the Bonn study (18), although a brief drop in voltage after MR imaging was reported by the Bonn group.

### Induction Voltage

Lauck et al (34) found that there were induced voltage increases during the pulse sequences. They specifically noted that these were not sufficient to affect the pacemaker. However, their concern was that the induced voltage was sufficient to mimic an intracardiac signal. In the situation where the reed switch was inactivated, they postulated that this might lead to sensing of the signal and hence explain the inhibitory or stimulation pulsing that they noted. The possibility that the induced voltage may influence sensing remains and is thought to be a greater concern in unipolar than bipolar lead systems. Despite these earlier concerns, the major prospective in vivo trials have not produced supportive evidence to suggest that this is a significant practical concern (21).

### Damage to the Electronic Components

Electronic damage is a theoretical possibility that has not yet been reported. Many studies, even with older pacemakers, have made note of the fact that pacemaker damage was not found in vitro. The Bonn prospective in vivo studies (17) found minimal changes in pulse generator function at the time of MR imaging in some patients and no significant changes in the 51 patients who also underwent a 3-month post–MR imaging pacemaker checkup. The Oklahoma study (20) included 47 patients with 3-month follow-up and also found no apparent damage.

### Lethal Effects and Major Rhythm Disturbances

As commentators (7,19) have noted, the deaths attributed to MR imaging share some common features: The presence of a pacemaker was not known to personnel imaging the patient, none of these patients were monitored, and the exact cause of death was not determined.

The exact number of deaths that have occurred in the MR imaging setting is very difficult to determine. Avery (37) has reported one such case, Gimbel et al (7) report on five deaths, and the Web site of the U.S. Food and Drug Administration reported three patients up to 1996 (38), but the number has since risen to 10 (21). Whether there is overlap among these cases is unknown. It is interesting that Gimbel et al (7) found some of their cases through incident reports. In view of the threat of lawsuits, it clearly would be unusual for all such incidents to be reported in the literature. In 2000, a patient in Australia died while undergoing MR imaging, according to online newspaper reports (*The Australian*, May 2, 2000; *Herald Sun* [Melbourne], April 13, 2000). However, the patient was questioned as to whether he had a pacemaker and he evidently stated that he did not, as has been noted with some of the other deaths.

There are two important take-home messages from these incidents. The first is that all potential pacemaker patients should be actively screened. Screening methods might include visual inspec-

tion of the infraclavicular regions for patients over 50 years of age, a check with a handheld magnet (39), a check of the patient file, or chest radiography. It appears to be insufficient to just ask patients if they have a pacemaker as they might not recall this piece of medical history. The second point is that all pacemaker patients must be fully monitored, as illustrated in Table 2. If a patient is inadvertently imaged, it is prudent to have the pacemaker checked to ensure that none of the parameters have been altered significantly enough to require reprogramming.

### Imaging Artifacts

Schueler et al (40) have offered an assessment of image quality according to four criteria: geometric distortion; susceptibility-induced artifact; warping artifact; and bending, warping, or obliteration of image contours. Most artifacts from pacemakers and leads result in local image distortion, signal voids, or increased noise.

### Effects of Retained Leads

The pacemaker power pack may sometimes be removed and the leads left in place. A systematic study with regard to the safety of retained leads in patients remains to be done. However, in a dog experiment, two unipolar leads were implanted with one tip in the atrium and the other in the ventricle. Testing done without a pacemaker attached in a 1.5-T system pulsed at 200 msec did produce an ECG artifact but did not stimulate the heart, with falling blood pressure used as the criterion (30). However, the authors acknowledge that their monitoring capabilities were such that they might not have differentiated rapid atrial pacing from an antenna effect.

After cardiac surgery, two epicardial leads are left in place so an external pacemaker can be connected in the event of a developing bradycardia or heart block. The changing magnetic field strengths associated with rapidly pulsed sequences are zero at the magnet isocenter and are greatest at the physical edges of the gradient coils. Hartnell et al (41) studied 51 patients in the postoperative period, when the wires had been shortened to skin level. Their study included a variety of anatomic regions, both at and distant from the magnetic isocenter. At 1.0 T and 1.5 T, no symptoms were reported and no ECG changes were noted outside or in the MR imaging environment. Indirect supportive evidence comes from a survey of 53 neuroradiology fellowship directors with respect to practices regarding epicardial wires (42). No serious incidents or complications were reported by the respondents.

## Conclusions

There are millions of pacemaker patients now, and perhaps the time has come for the manufacturers to develop a pacemaker that is specifically designed for safety in the MR imaging environment (43).

Preliminary evidence from controlled trials suggests that patients with a demand pacemaker can be studied under carefully controlled conditions, especially in areas more distant from the chest such as the brain and the knee. Surely the time has come when individually tailored MR imaging examinations may be considered for pacemaker patients. The recent American College of Radiology update on MR safety cautiously acknowledges this possibility (44), although radiology as a discipline continues generally to exclude pacemaker patients from MR imaging. The pioneering studies from Germany and Oklahoma may be considered very successful pilot studies. Is it not time that the radiology community engaged in a large multicenter trial to settle this matter with scientific rigor?

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