

## EDITORIAL COMMENT

## Can Patients With Implantable Pacemakers Safely Undergo Magnetic Resonance Imaging?\*

J. Rod Gimbel, MD, FACC,†  
Emanuel Kanal, MD, FACR‡  
Knoxville, Tennessee; and  
Pittsburgh, Pennsylvania

The controversy over whether pacemaker patients should be allowed in the magnetic resonance imaging (MRI) suite is not new (1). With nearly 250 device patients reportedly having undergone safe magnetic resonance (MR) scanning, some investigators suggest selected pacemaker patients might safely undergo MRI (2–5). Nevertheless, many authorities such as Pinski and Trohman (6), flatly state that MR scanning of device patients is a “prima facie” contraindication with experts like Pennel adding that such scanning is done only on a “wing and a prayer” (7).

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Within the context of this controversy, the study by Martin et al. (8) appears in this issue of the *Journal*. Notably, among the investigators is Shellock, an advocate of MR safety who also quite recently stated that “the presence of a cardiac pacemaker is considered a strict contraindication for undergoing an MR procedure” (9). The researchers performed a variety of MR examinations using a 1.5-Tesla (T) magnet on 54 consecutive non-pacemaker-dependent patients having a variety of pulse generators in a mix of atrial and ventricular configurations. No patient experienced a severe adverse event immediately or during the short-term follow-up. By design, the investigators excluded implantable cardioverter-defibrillators (ICDs) from MR scanning. The safety of scanning patients who, like Vice President Dick Cheney, have an ICD has only recently received attention (10–12).

Safety issues of scanning patients with implanted devices, including the risk of death, have been enumerated (1,6,13). The findings by Martin et al. (8) are consistent with previous reports (2–5) of deliberate MRI of pacemaker patients, with the MRI proceeding in a largely uneventful fashion. Martin et al. (8) conclude that, if medically necessary, MRI may proceed irrespective of the imaging site, during electrocardiographic (ECG) monitoring, and with

minimal reprogramming of the device with an “acceptable safety profile.”

Should restrictions prohibiting MRI in device patients be significantly modified? Indeed, may we one day use the power of MR to perform scans not merely in spite of the presence of a device, but because the patient has a device, harnessing the power of MR to better understand issues such as pacing mechanics and what occurs during defibrillation?

Despite the encouraging results, we are concerned about the broad conclusions and recommendations presented. During MRI, Martin et al. (8) recorded a variety of phenomena, all of which have been reported and reviewed (13). Understandably, the investigators concede that “the effects of MRI-related heating were not directly measured.” Ethical and practical concerns have precluded such measurements in humans.

Evaluating pacing thresholds prior to MRI and “immediately upon exiting the MR system” may not detect problems that occur subsequently. In the Martin et al. (8) study, the lack of intermediate and long-term follow-up of the post-MRI pacing thresholds is of concern in all patients, but particularly in those who demonstrated a rise in thresholds post-MRI. Previous scanning at 1.5-T reported unchanged thresholds following MRI (4,5). Concerns are underscored by reports of marked elevations in thresholds after MRI imaging of ICD systems (10,12). Given such concerns (14), evaluation of the pacing system beyond “immediately upon exiting the MR system” remains an important need.

The results presented in Table 2 of the Martin et al. (8) paper regarding specific absorption rate measurements and the evaluation of “MR examinations grouped above and below the diaphragm” on the basis of “ease of statistical analysis” raise additional questions. Although the renal arteries are “below the diaphragm,” imaging them may deposit more radiofrequency (RF) power over the thoracic device than a brain scan. In this study, many scans where power deposition is greatest (fast-spin echo) occurred during extremity or brain scans, where direct power deposition on the device and leads would be far less. Additionally, the actual rise times and strengths of the gradients used, and what RF power was actually deposited on the PG system, are entirely unknown and may be negligible (such as with many extremity examinations). Thus, although conveniently tidy, conclusions based on the method of analysis presented are problematic. Our understanding of these complex phenomena, including heating from resonant RF circuitry behavior, is incomplete and needs further investigation before clinical acceptance of the safety of these procedures.

Both the monitoring and the supervision of patients during MRI also raise issues. Previous reviews (6,13,14) and prior studies of MRI (2,4,6) in device patients all included the use of pulse oximetry in addition to ECG monitoring. Martin et al. (8) acknowledge that during MRI “electro-

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From the †Parkwest Hospital, Knoxville, Tennessee; and ‡Magnetic Resonance Services, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania.

magnetically induced noise was encountered occasionally on telemetry." During MRI, the intense electromagnetic interference may render reliable assessment of the ECG quite difficult and often impossible. The difficulty interpreting artifacts is well known (15) and is seen in patients with insertable loop recorders undergoing MRI (16). The utility of pulse oximetry provides additional safety, and it is strongly recommended.

Radiologists (and MRI personnel) may be uncomfortable, unwilling, or simply unable to evaluate complex, artifact-laden, intermittently paced rhythms during scanning. Because serious dysrhythmias may occur during MRI, it would seem advisable that a cardiologist be present in the MR suite during the entire scan and not merely "available" or on call if needed. From a medical-legal perspective, it may not be hard to make a case that a more pleasant outcome might have resulted had an "expert" been there to immediately manage the complications when scanning this controversial patient group. The medical-legal implications of scanning device patients are emphasized by Pinski and Trohman (6).

The reprogramming (or lack thereof) of the patient's pacemaker prior to scanning in the Martin et al. (8) study gives us pause. The investigators explicitly chose no device reprogramming initially; in the end, they recommend only minimal reprogramming prior to MR. They dismiss as benign "magnet mode" asynchronous pacing while in the MRI suite, stating that this takes place "numerous times (during) transtelephonic pacemaker interrogation occurring without incident on a daily basis." Shellock (17) (independently) and Goldschlager et al. (1) concur.

But is asynchronous pacing (13) always benign? A healthier outpatient population undergoing pacemaker checks is unlike sicker, hospitalized patients, who may not tolerate prolonged asynchronous pacing (14). We agree "that the risk of developing ventricular fibrillation during asynchronous pacing is extremely low." However, as with our comments regarding monitoring and supervision, the goal is to make scanning of patients as safe as possible, and every effort should be made to do so. We recommend the "magnet mode" feature be programmed to "off," thus avoiding prolonged asynchronous pacing.

We believe that the researchers do not emphasize enough the pacing features that appear in today's devices and the implication for their own findings. "Over-sensing of electromagnetic noise" leading to non-physiologic pacing was noted, yet only minimal pre-MRI reprogramming is recommended. Further, we believe that features such as ventricular rate regularization (Guidant Corp., St. Paul, Minnesota), dynamic overdrive pacing (St. Jude Inc., Sylmar, California), and pacing algorithms in the Medtronic AT-500 (Minneapolis, Minnesota) should also be disabled. The report of "vibration" by a patient suggests that the "rate-response" feature should be turned off to avoid non-physiologic rapid pacing. In a non-pacemaker-dependent patient, it is our opinion that the device should be pro-

grammed in the "OOO mode or to deliver subthreshold pulses" (6), understanding that this will not necessarily preclude rapid cardiac pacing. Similar recommendations are made for MRI of patients with neurostimulators (effectively repurposed cardiac pacemakers) by Rezaei et al. (18) and Shellock himself (19), and we assume that a similar argument is valid here.

Finally, failing to identify an adverse event is not equivalent to demonstrating safety—especially when only a limited number of patients are studied. The investigators state: "Of note is that a recent study has identified safe criteria for a neurostimulation system (which is a pacing device for the brain with bilateral leads and dual implantable pulse generators) at 1.5-T." However, recent reports describe serious thermal injuries from MRI of implanted leads (20,21). More extensive experience may result in a similar situation with cardiac devices.

Current pacemakers are neither "MRI safe" nor "MRI compatible" by the Food and Drug Administration's strict definition (19). We believe strongly that device manufacturers must design their implantables as MR-compatible "from the ground up" rather than depend on a series of intrepid patients and physicians engaged in post-manufacturing experiments. Patients and the implanting community should expect nothing less than devices that are MR-safe by design, not by chance.

So, is a paradigm shift occurring? Clearly, the answer is yes. In controversial matters, shifts often occur at a glacial pace, and where patient safety is concerned, this is quite appropriate. In principle, we agree that non-pacemaker-dependent patients can be scanned with an appropriate risk-benefit ratio when appropriate care takes place before, during, and after MRI. But in practice, we are unconvinced that it matters not what type of scan is performed, nor are we persuaded that the investigators (8) have presented the safest way to scan device patients. Differences we highlight are small, yet they should be viewed within the context of the handful of device patients who died while undergoing MRI. Further, we do not believe that this controversy is settled simply because a handful of device patients have safely undergone MRI. The additional measures suggested above will make MRI of device patients safer still. At the present time, if MRI procedures are performed in patients with pacemakers because of an overriding medical need, they should be approached thoughtfully and with great caution.

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**Reprint requests and correspondence:** Dr. J. Rod Gimbel, 9330 Parkwest Boulevard, Suite 202, Knoxville, Tennessee 37923. E-mail: gimbeljr@ix.netcom.com.

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