EDITORIAL

Myths, Magical Thinking, and MRI

J. ROD GIMBEL, M.D.
From the Parkwest Hospital–Cardiology, Knoxville, Tennessee

In this issue of *PACE*, Goldsher et al. describe the safe scanning of a patient requiring a cranial magnetic resonance imaging (MRI) shortly (hours) after implantation of a pacemaker.[1] Why publish another case report of a patient with a pacemaker undergoing MRI? At once, this case report provides insight into a number of important issues; namely, the evolutionary and difficult process of "expert"-driven guidelines as well as the need for clinicians to "step outside the boundaries" of what these guidelines suggest is advisable. Finally, at the very least, this case report reminds us again of the urgent need to develop pacemakers (and implantable cardioverter-defibrillators) that are fully MRI safe and compatible. And while this case report is important insofar as it shows (again) that pacemaker-dependent patients can be safely scanned, it also helps dispel the myth that newly implanted pacemaker patients need to wait for an extended length of time prior to MRI to allow lead and pulse generator encapsulation. Despite this, the safe MRI of the patient described by Goldsher et al. should not further the magical thinking of those who believe that "modern" devices are MRI safe.

Recent publications in both the medical literature and the lay press have called attention to the intellectual pedigree of medical guidelines, noting that there are "plenty of guidelines, but where's the evidence,"[2] and that their creation is often "idiosyncratic and error prone."[2] The recent European position paper on "MRI imaging in individuals with cardiovascular implantable electronic devices" recommends "devices must have been in place preferably for at least 4–8 weeks prior to MR imaging."[3] This position is echoed by a recent publication from an experienced center outlining "how to perform MRI on cardiac device patients."[4] No doubt, these recommendations are largely based on the perceived need for the system to encapsulate, preventing movement of the system and perhaps dislodgement of the lead when exposed to the powerful forces of the MRI's static magnetic field.

Address for reprints: J. Rod Gimbel, M.D., Parkwest Hospital–Cardiology, 9330 Parkwest Boulevard, Suite 202, Knoxville, Tennessee 37919. Fax: 865-539-5073; e-mail: gimbeljr@ix.netcom.com

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But really now, how much additional risk accrues to the patient when MRI is performed immediately after implantation of their device? In an excellent review of the safety of performing MRI on cardiac device patients, Luechinger et al. note that there is little if any ferromagnetic material in recently manufactured cardiac rhythm devices and that as far as the leads are concerned they are made of an "alloy nickel, cobalt, chromium, molybdenum" that "is non-ferromagnetic; therefore, there is no concern that such leads will dislodge."[5] Given the data that have been reviewed by Luechinger et al. and presented elsewhere,[6] future guidelines and position statements on device MRI interaction should be modified to dispel this "waiting period" as a myth "entirely unfounded."[6] Even immediately after implant, modern cardiac rhythm systems simply do not have enough ferromagnetic material to pose a risk of dislodgement when exposed to the strong static magnetic fields present in the MRI suite.

The patient scanned by Goldsher et al. was pacemaker dependent, and recent important advisory statements from experts[3,4,7] suggest that many pacemaker-dependent patients might not undergo MRI. The foundation for this recommendation is largely based on the outcome of a single incompletely understood event that took place during the scanning of a dog implanted with an ICD at high specific absorbtion rate and using protocols that are not used in clinical practice.[4,8] If so, the data supporting restrictions on device-dependent patients undergoing MRI are scant. As previously noted, there is nothing about pacemaker-dependent patients that would make them more likely to have noncapture than non-pacemaker-dependent patients.[9] Future advisory statements might more clearly place the limited data supporting their recommendations regarding MRI of pacemaker-dependent patients in perspective. Guidelines, position papers, advisory statements aside, Goldsher et al. should be commended for the courage to provide safe and needed care, pushing the frontier beyond that traditionally recommended by such expert panels. Ultimately, MRI will become too important to the practice of electrophysiology to prevent device-dependent patients (or any device patient for that matter) from entering the MRI suite.[10]

While "modern" devices have less ferromagnetic material in them and may be less susceptible

to the powerful electromagnetic interference that they are exposed to during MRI, careful readers will not overextend the conclusions presented in this case report as yet another example of "modern pacemaker and cardioverter/defibrillator systems can be MRI safe."[8] The careful wording and multiple caveats that are included in virtually all manuscripts published on the scanning of device patients seem sometimes to have been lost, and this thinking is perfectly illustrated when we see titles such as "Yes, Doctor, It Can be Done: MRIs Made Safe for People with Defibrillators and Pacemakers."[11] While this may be illustrative of the "pitfalls of health care journalism,"[12] one wonders if the lay press is solely alone in its responsibility for this misunderstanding. Device industry inquiries into physician opinions regarding the safety of device-MRI interaction suggest that over half of all physicians believe that at least some of the hardware they implant is MRI safe.

While all devices "can" be scanned, the question, of course, is "what happens when you scan them?" In an act of magical thinking, some have conveniently substituted the word "can" with "are" in the title of one of the oft-quoted publications "modern pacemaker and cardioverter/defibrillator systems can be MRI safe."[8] At this time, perhaps 800 events describing MRI of device patients have been reported; hardly a tsunami of data on which to provide the terra firma of sound recommendations. Nor is the number so large as to provide the expectation that following the experts recommendations will lead to safe scanning of device patients. All investigators in the field have a healthy respect for what might happen during MRI. This commentator was reminded of this recently when a prolonged asystolic event took place during the onset of MRI scanning of a "modern" pacemaker patient. The scan was aborted with a stable rhythm returning, and no permanent harm took place. Currently, no devices are FDA approved for safe scanning, "modern" or otherwise.

Nevertheless, the future looks bright for the possibility that US implanters might soon have access to a pacemaker that is labeled "MRI conditional" for MRI scanning.[13] On release of these devices, a great deal of education will need to be done as to what is "safe" and what is not with a wide variety of "unsafe" legacy hardware remaining in the patients considered for MRI.

Myths and magical thinking will not be an allowed luxury in providing safe comprehensive care for device patients considered for MRI; what is needed are implantable rhythm devices that are unconditionally MRI safe and that require a minimum of expert supervision to perform a scan. There is neither the will nor the expert manpower to personally supervise all the device patients who might need an MRI in the future. While we await the development of such hardware to implant, we are left with small incremental advances like the case report by Goldsher et al. that help expand our horizons as to what is possible for device patients by directly addressing a myth without engaging in magical thinking.

References

1. Goldsher D, Jahshan S, Roguin A. Successful cervical MR scan in a patient several hours after pacemaker implantation. Pacing Clin Electrophysiol 2009; 32:1355–1356.
2. Sanghavi D. Plenty of guidelines, but where's the evidence? The New York Times, published December 8, 2008; Accessed December 9, 2008, at http://www.nytimes.com/2008/12/09/health/views/09essa.html.
3. Roguin A, Schwitter J, Vahlhaus C, Lombardi M, Brugada J, Vardas P, Auricchio A, et al. ESC position paper—Magnetic resonance imaging in individuals with pacemakers or implantable cardioverter defibrillator systems. Europace 2008; 10:336–346.
4. Nazarian S, Halperin HR. How to perform magnetic resonance imaging on patients with implantable cardiac arrhythmia devices. Heart Rhythm 2009; 6:138–143.
5. Luechinger R, Duru F, Candinas R, Boesiger P. Safety considerations for magnetic resonance imaging of pacemaker and ICD patients. Herzschr Elektrophys 2004; 15:73–81.
6. Irnich W, Irnich B, Bartsch C, Stertmann WA, Gufler H, Weiler G. Do we need pacemakers resistant to magnetic resonance imaging? Europace 2005; 7:353–365.
7. Levine GN, Gomes AS, Arai AE, Bluemke DA, Flamm SD, Kanal E, Manning WJ, et al. Safety of magnetic resonance imaging in patients with cardiovascular devices: An American Heart Association scientific statement from the Committee on Diagnostic and Interventional Cardiac Catheterization, Council on Clinical Cardiology, and the Council on Cardiovascular Radiology and Intervention: Endorsed by the American College of Cardiology Foundation, the North American Society for Cardiac Imaging, and the Society for Cardiovascular Magnetic Resonance. Circulation 2007; 116:2878–2891.
8. Roguin A, Zviman MM, Meininger GR, Rodrigues ER, Dickfeld TM, Bluemke DA, Lardo A, et al. Modern pacemaker and implantable cardioverter/defibrillator systems can be magnetic resonance imaging safe: In vitro and in vivo assessment of safety and function at 1.5 T. Circulation 2004; 110:475–482.
9. Gimbel JR. The AHA scientific statement of MRI in patients with devices: Neat, but incomplete. Unwise and unsupported. Pacing Clin Electrophysiol 2008; 31:649–651.
10. Nazarian S, Bluemke DA, Halperin HR. Applications of cardiac magnetic resonance imaging in electrophysiology. Circ Arrhythmia Electrophysiol 2009; 2:63–71.
11. Yes, Doctor, It Can be Done: MRIs Made Safe for People with Defibrillators and Pacemakers. Newswire. Accessed April 7, 2009, at http://www.newswise.com/p/articles/view/523575/.
12. Dentzer S. Communicating medical news—pitfalls of health care journalism. N Engl J Med 2009; 360:1–3.
13. Mitka M. Researchers seek MRI-safe pacemakers. JAMA 2009; 301:476.