In April 2005, the US Food and Drug Administration (FDA) commented on the current research regarding the use of magnetic resonance imaging (MRI) on patients with a pacemaker or implantable cardioverter-defibrillator (ICD). Pacemaker and ICD labeling currently cautions physicians against the use of MRI, and MRI manufacturers contraindicate MRI for pacemaker and ICD patients. As discussed in our previous editorial, several studies have demonstrated the potential for MRI to be performed in pacemaker or ICD patients without serious clinical consequence. Studies presented by Sommer et al6 and Nazarian et al6 in this issue of Circulation offer further promising evidence in this regard. As with the previous studies, however, the authors acknowledge a multitude of limitations that prevent broad applicability of the results. Furthermore, one of these studies was not entirely free from concerning outcomes with the potential for serious clinical events. We view these results as consistent with our previous message that, on a case-by-case basis, the diagnostic benefit from MRI outweighs the presumed risks for some pacemaker and ICD patients. However, the FDA remains firm in its belief that those risks have not yet been characterized and mitigated sufficiently to justify the routine use of MRI in those populations. The FDA continues to believe that a more thorough evaluation of concerns related to heating, arrhythmogenesis, and proper device function during and after MRI, as well as validated MR protocols, should be available before approval for labeling that endorses the use of MRI for pacemaker or ICD patients is obtained.

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association.

The views and opinions expressed are those of the authors and do not necessarily reflect those of the US Food and Drug Administration or the US Department of Health and Human Services. From the Division of Cardiovascular Devices, Center for Devices and Radiological Health, Food and Drug Administration, Rockville, Md. Correspondence to Mitchell J. Shein, MS, FDA Expert, Cardiac Pacing, Division of Cardiovascular Devices, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, MD 20850. E-mail mitchell.shein@fda.hhs.gov (Circulation. 2006;114:1232-1233.) © 2006 American Heart Association, Inc.

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Food and Drug Administration Perspective

Magnetic Resonance Imaging of Pacemaker and Implantable Cardioverter-Defibrillator Patients

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Articles pp 1277 and 1285

The studies presented by Sommer et al and Nazarian et al in this issue involved a total of 113 pacemaker and 24 ICD patients who underwent 183 MR exams for an urgent or MR-specific clinical need. The Sommer et al study was limited to patients with a pacemaker from a single manufacturer; the Nazarian et al study enrolled only patients whose pacemaker or ICD model had already been evaluated through in vitro and in vivo testing by the authors. Each study was restricted to a single MR system manufacturer and model. Meaningful exclusion criteria included pacemaker dependency and the need for a thoracic MR scan for the Sommer et al study and the presence of an epicardial, nonfixated, or abandoned lead for the Nazarian et al study. It is important to note that the MR scanning parameters allowed for clinically relevant scans that were moderately rigorous in terms of specific absorption rate. Both studies demonstrated the encouraging result of no observed adverse clinical events. Furthermore, Nazarian et al comment that the MR examination resulted in a clinical diagnosis in nearly all subjects.

Although the ability to arrive at clinical diagnoses is a positive note, other outcomes, particularly from the Sommer et al study, have implications that are of concern. Seven of the 115 MR exams in the Sommer et al study resulted in pacemaker reset and a reversion to the factory VVI settings, and in 21 of the 47 devices evaluated, the reed switch did not close to activate the magnet mode for the device. Although not exhibited in this study, these 2 malfunctions in combination could have serious consequences, particularly for a pacemaker-dependent patient, because MR-induced interference could be sensed by the pacemaker, resulting in inhibition of therapy. This observation is consistent with other studies that have demonstrated that MRI may adversely affect the function or programmability of certain ICDs or pacemakers. To date, published studies have not thoroughly explored the extent to which the risk for device malfunction is dependent on scan parameters, MR system, and patient and device position within the MR system or the device design.

Results of the Sommer et al study also indicate the presence of tissue damage as assessed by small but statistically significant changes in mean pacing threshold and lead impedance across patients, and clinically meaningful changes in pacing threshold and troponin I for some individual patients. The Nazarian et al study did not demonstrate any statistically significant changes in the means for sensing amplitude, lead impedance, or pacing threshold. Of note, Nazarian et al did not present data regarding individual patient outcomes. The Sommer et al results are consistent with previous studies that indicate that the potential for MR-induced thermal injury in pacemaker and ICD patients exists and that methods for consistently avoiding such heating have not been validated. In the study conducted by Martin et al, for example, 9.4% of the leads studied exhibited a “significant” change in pacing threshold; most of these changes were threshold increases, likely indicating thermal...
injury. Of particular concern is the potential cumulative effect for patients who undergo several MRI procedures. It is encouraging to note that neither study presented in this issue reports observed arrhythmia induction from MRI. However, as acknowledged by Sommer et al., the potential for such events exists. This is consistent with the FDA’s perspective that, although arrhythmia induction in pacemaker or ICD patients from MRI is likely a rare event, the consequences could be catastrophic. This is of particular concern for ICD patients who may be more susceptible to arrhythmias and would likely have their ICD disabled during the MRI procedure. Both studies presented in this issue followed rigorous patient monitoring protocols to avoid such an event. However, the FDA remains concerned that the extent to which arrhythmogenic risk is dependent on scan parameters, MR system, patient and device position, and device design has not been adequately characterized. Furthermore, protocols such as those presented in this issue, while worthy of consideration, have not been sufficiently validated to support routine clinical use.

Given the range of available MR systems and scan conditions, pacemaker and ICD systems and leads, and the range of potential patient conditions, the authors of both studies presented in this issue acknowledge the limitations that prevent extending these encouraging results to recommendations for routine use of MRI in pacemaker and ICD patients. Of note, given the potential risks that an MR procedure presents, both studies were limited to patients with a substantial clinical need for MRI. The FDA concurs with the authors that, for some patients, the risks presented by MRI under specific, characterized scanning and monitoring conditions may be acceptable given the diagnostic benefit of this powerful imaging modality.

The FDA continues to believe that extending MRI use to the general pacemaker and ICD patient population through removal or modification of device warnings and contraindications will require thorough characterization of the array of safety concerns related to heating, arrhythmogenesis, and proper device function and validation of the measures taken to mitigate these concerns. Although many of these concerns are best addressed through bench and animal studies, prospectively designed and adequately powered clinical trials will likely be necessary to confirm the results from preclinical testing. The FDA is committed to working with pacemaker and ICD manufacturers to pursue these studies to seek labeling modifications for their devices.

Disclosures

None.

References


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