MR. Implant: Rapid Evidence-Based Determination of Implant Safety Status

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THE PROBLEM

Radiologists must make safety decisions when performing MRIs for patients with medical and cosmetic devices or embedded foreign bodies [1]. Although many sources of safety information are available online (eg, [2]), MRI may be delayed or canceled, especially after hours, when staffing is limited and the on-duty radiologist is unsure of a device's MRI safety status. Potential reasons impeding a rapid, accurate, and confident decision on safety may include problems with availability and accessibility of definitive information sources or the time required to locate and interpret sources of information, such as institutional policy documents, websites, and manufacturer documentation. These sources may list technical requirements the radiologist is uncomfortable distilling into a clinical determination, especially under time pressure. This common scenario presents an opportunity to improve patient care and safety.

MRI safety is integrated into the ACGME's Diagnostic Radiology Milestone Project [3], and a brief tutorial is available for trainees to familiarize themselves with MRI safety [4]. Comprehensive MRI safety training for medical students [5] and curricula for radiology residents [6] have also been proposed, utilizing live lectures and online modules. These approaches emphasize training and, by their nature, provide only an overview of safety principles. They review MRI compatibility of some types of implants and typically refer learners to reference sources, such as manufacturer specifications, to ultimately apply the knowledge in practice.

MRIsafety.com [7,8] is an excellent and widely utilized resource that provides information regarding MRI safety statuses of thousands of medical devices and implants. The website provides an extensive searchable list of many categories of devices, implants, and foreign bodies. Based on medical literature, manufacturer recommendations, and independent testing, devices are classified as MR Safe, MR Conditional, and MR Unsafe.

Information provided regarding MR Conditional devices and implants listed on MRIsafety.com includes detailed specifications of the specific conditions relevant to each subtype. MRIsafety.com is also generalized such that the resource could be applied in the United States and internationally. By its nature, however, the website can only provide specifications and parameters. It cannot give absolute recommendations for institution-specific practice. Thus, practitioners must determine the clinical meaning of the MR Conditional status in their particular setting. Radiologists who are not familiar with or comfortable interpreting the technical specifications may be unable to timely adjudicate a safety question at the point of care. For example, certain MR Conditional subtypes specify maximum values for parameters, such as spatial gradient of the static magnetic field. In an institution where all MR scanners have maximum spatial gradients less than the limit, this condition is never a practical consideration. However, radiologists are unlikely to know the scanner specifications or even understand the meaning of the spatial gradient parameter. An additional potential impediment to clinical use is that the Safety Information Article for each device may contain multiple paragraphs detailing background information, which is not explicitly necessary for clinical decision making. This may deter a radiologist, particularly when working after hours without ready access to advanced technical expertise, such as an MR physicist, and under time pressure due to the time and expertise required to adequately assimilate and apply the information to the immediate clinical scenario.

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Several potential resources are on the horizon but are not yet widely available, such as scanner-based software for the assessment of implants offered by MR scanner vendors. "Kanal's MagnetVision" is a mobile app currently offered on the iTunes App Store. It is "specifically designed as an adjunct teaching tool" and "provides an orderly and standardized approach to the assessment of potential risks associated with MR imaging of a patient in/on whom there may be a foreign body/implant/device." [9] It is not clear, however, that these approaches provide a platform for distributing institution-specific policy with regard to devices, and these novel approaches to providing MR safety information have not, to our knowledge, been published in the medical literature.

The goal of our study was to create, based on existing institutional policy and procedure, a source of definitive safety determinations for commonly encountered devices that can be easily accessible to radiologists at the point of care, thereby enhancing patient safety, department efficiency, and resident education.

OUR APPROACH

This study was conducted at an academic tertiary care medical center encompassing three acute care hospitals and multiple outpatient sites. An accredited diagnostic radiology residency program, enrolling a total of 36 residents, is based at the institution.

Based on the ACR White Paper on MR Safety [10], manufacturer-specific recommendations, literature review, institutional policy and procedure documents, and local experts, an Intranet-based library of implantable devices and foreign bodies was compiled, which we named "MR. Implant." For each device, a summary page was created to succinctly convey its MR safety status and, where appropriate, outline steps for determining MR compatibility (Fig. 1). The American Society for Testing and Materials symbols [11] were used to designate device safety. MR. Implant is a searchable tool with multiple hyperlinked cross-referenced indices to facilitate accessibility.

MR. Implant was implemented using the Python-based static site generator Pelican [12], which generates HTML automatically from Markdown-formatted text files [13]. The summary page for each device is separately maintained as its own text file. For devices with more complicated criteria for conditional status, flowcharts are automatically generated from text using the Mermaid JavaScript library. All source files for the website are currently stored in a secure online git repository [14], and the generated HTML files are hosted on the secure institutional Intranet.

Two unique multiple-choice tests were created to test radiology residents' knowledge before and after launching MR. Implant (Fig. 2). One-half of the residents completed version 1 and the other half completed version 2. Each test contained 20 MR safety screening scenarios that residents might face on call. Residents were asked to make a safety determination by responding to true-or-false or multiple-choice answer options. Correct answers were based upon the device summary pages included in the MR. Implant library and were created by the same team who produced MR. Implant. The tests were administered after an unrelated regularly scheduled mandatory didactic lecture. Thirty minutes were allotted for the test, with unrestricted access to any print or online resource. Residents were not aware of MR. Implant at the first testing session (it was released subsequently), and so could not use the site during the first session.

For each question, participants were asked to indicate how confident they were with their safety determination using a Likert-type scale (range: 1 [not confident, would need to ask an expert or postpone MRI to the next day] to 5 [completely confident]). A questionnaire followed each test, asking residents to agree or disagree to statements such as "I have adequate access to sufficient resources to independently make MRI safety determinations;" "The resources I use are accessible and user friendly;" and "The resources I use are sufficiently comprehensive." Students were asked to identify sites and sources they found useful.

After the release of MR. Implant, the same residents were tested again, each completing the alternate version of the test. Residents had not been aware that a second testing session would occur, and they were not aware that the tests were based on MR. Implant. They were again informed that they could access any online resource. The percentage of questions correctly answered as well as average confidence levels were compared between the two tests using Student's paired *t*-test.

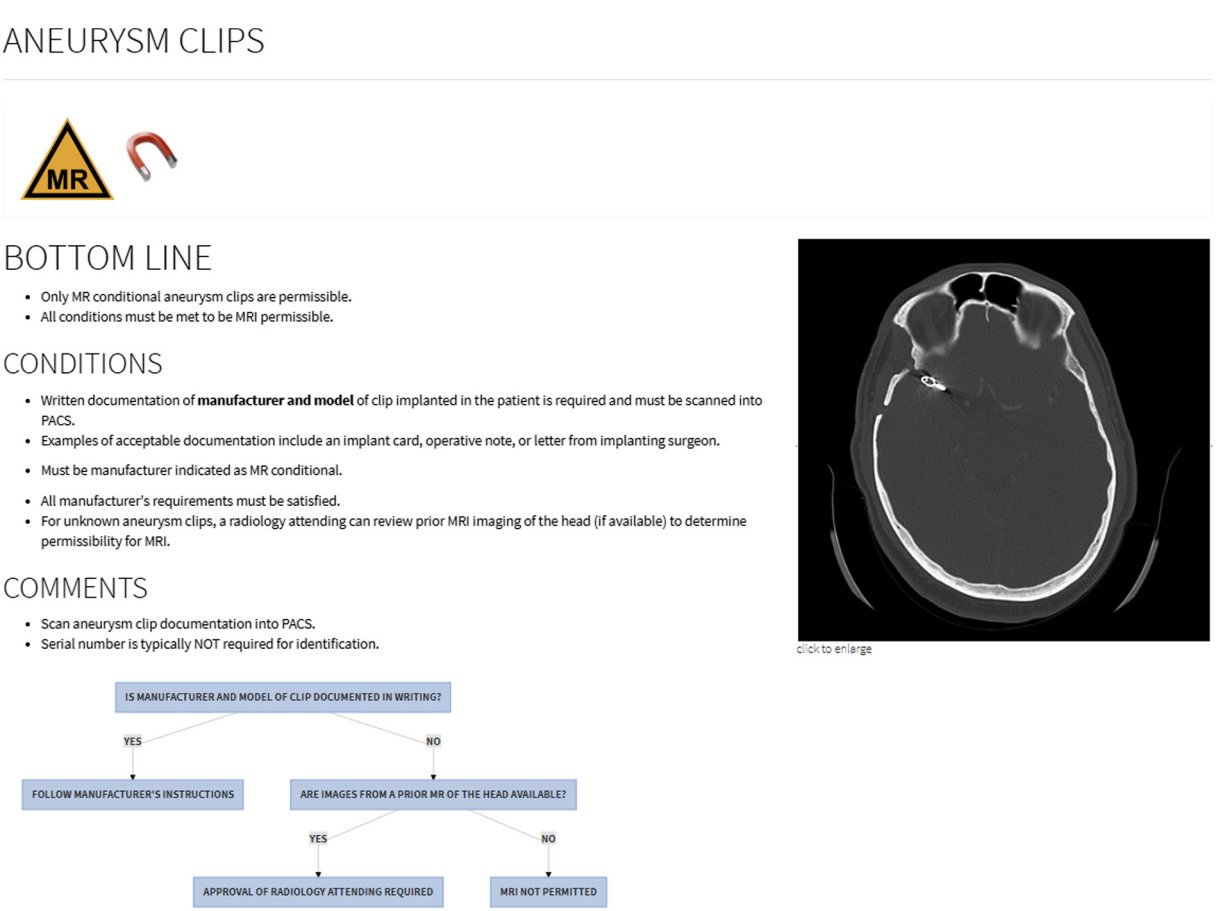

Fig 1. Screenshot from MR. Implant detailing steps to determine safety of aneurysm clips for use in MRI.

OUTCOMES

MR. Implant currently includes 53 categories of devices, with cross-referenced entries for alternate names for the same device. Devices are subdivided into eight classes (Fig. 3), with several entries from each class cross-referenced under additional related classes. For example, "Prior eye injury with metal or history of metal working" was categorized as both "Ophthalmologic" and "Foreign Body," and many cardiovascular devices were also categorized under "Vascular" (Table 1). MR. Implant is accessible from any web-enabled device connected to the hospital Intranet, either directly or via virtual private network. Many device pages utilize flowcharts to clearly depict steps in determining device safety (Fig. 1) and incorporate example medical images, such as radiographs, to aid in identification of devices, implants, and foreign bodies.

Fifteen residents in postgraduate years 2 to 5 (median 3) completed tests both before and after the release of MR. Implant. The interval between tests was 1 year. After the release of MR. Implant, we found a significant increase in both percentage of correct determinations and reported confidence. Accuracy ($p < .01$) increased from a mean of 54.7% (median 55; SD 9.3) to mean 71.7% (median 75; SD 18.0). Confidence ($p < .001$) increased from a mean of 2.8 (median 3; SD 0.7) to mean 3.7 (median 3.7; SD 0.7).

Seventy percent of residents reported using MRIsafety.com at the first testing session, with 40% identifying the hospital's MRI safety policy and 50% Google as also helpful. Fifty percent of residents identified MR. Implant as useful in completing the second test, with the remaining residents continuing the use of MRIsafety.com or indicating no resources were used. After the second quiz, residents more commonly agreed to questionnaire statements indicating that they had adequate access to resources that were sufficiently comprehensive, accessible, and user friendly.

Safety screening is an essential prerequisite to MR imaging [10]. Radiologist approval is often required to determine whether MRI can proceed safely in patients with certain implantable devices or foreign bodies. Although referring clinicians may raise potential safety concerns before a patient's arrival for their scan,

Resident: _____
Level of training: R1 R2 R3 R4
Age: _____ **Gender:**_____
Date: _____

Please circle your answers:

3. A patient had a brain aneurysm clipped three weeks ago and presents for a brain MRI. She does not have any documentation of the type of clip implanted. She may proceed with MRI:

a. Only if she has had a prior brain MR performed without incident since placement of the clip.

b. Only if attending approval has been obtained.

c. Only if she remembers being told the aneurysm clip is safe for MRI.

d. Only if she has had a prior brain MR performed after placement of the clip AND a radiology attending has reviewed the images and determined the clip is NOT ferromagnetic.

Please indicate your comfort level making this decision on call:

1=NOT comfortable (would cancel exam or postpone for next day) **5=COMPLETELY comfortable (would approve right away)**

1 2 3 4 5

Fig 2. Example of MR safety scenario and question from the test administered to residents.

many concerns arise only at the time of scan and must be resolved at the point of care, often after hours. Many radiologists may be unsure about decisions regarding MR safety. A particular impediment to decision making is the relative inaccessibility of definitive, sufficiently specific, and unqualified recommendations. Information available from external sources (eg, manufacturers, medical literature, the FDA, and the Internet) often requires technical expertise to understand and implement. Moreover, it can be unclear whether qualified recommendations from an external source mirror institutional policy. Although the ACR guidelines require written safety policies to be in place, radiologists may also find these documents to be insufficiently specific and accessible. The uncertainty engendered by insufficient access to definitive information may in turn lead to delay or cancellation of MRI, which in turn adversely impacts patient care and departmental efficiency, including delayed testing of patients with devices as well as for other patients whose examinations are secondarily delayed.

We designed MR. Implant as an extension of our institutional MR safety policy to empower radiologists at the point of care with specific actionable knowledge. Institutional policies form the basis for the content of MR. Implant, which simply makes clear and definitive policy readily accessible at the point of care. We tested the impact of MR. Implant on accuracy and confidence of MR safety decision making in a group of radiology trainees. Although faculty radiologists are available at all times and provide a source of information to residents on call, it is common for residents to be the first to field questions related to safety determinations. Access to MR. Implant

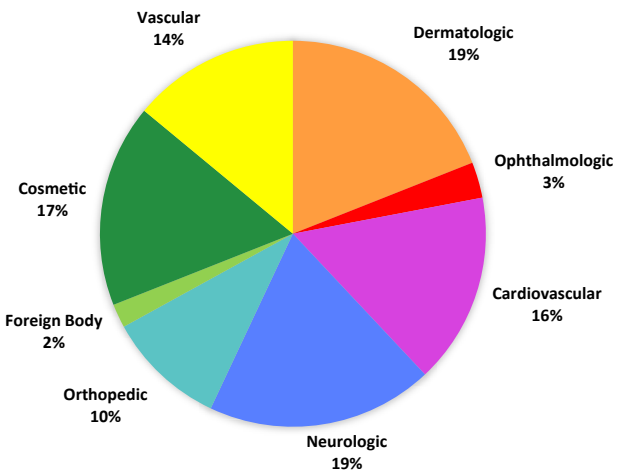

Fig 3. Pie chart demonstrating distribution of device categories included in MR. Implant.

Table 1. Example of devices from the "Cardiovascular" class included in MR. Implant

Cardiovascular	Vascular
Coronary stents	X
Bypass graft	X
Heart valves	X
Implanted cardiac event recorder	
MR conditional pacemaker	
Pacemaker/ICD/LVAD	
Retained epicardial pacer leads	
Retained pacer leads	X
Swan-Ganz catheter	X
Temporary transvenous pacer leads	X

Devices cross-referenced under the "Vascular" class indicated with an *X*.
ICD=implantable cardioverter defibrillator
LVAD=left ventricular assist device.

(which residents could utilize during the second test) improved both accuracy and confidence.

The impact of MR. Implant is dependent on the awareness of and acceptance by radiologists and staff. We note anecdotally that despite the availability of MR. Implant, not all residents who participated in our study used the tool during the second test (after the release of MR. Implant). This may in part explain why our postrelease results were not even stronger. Improved awareness and use of MR. Implant may even further enhance accuracy and confidence and, by extension, improve patient care. Future utilization of MR. Implant by technologist staff may further improve patient safety and scanning productivity. These are important areas for future longitudinal assessment.

We tested the impact of MR. Implant in a relatively small group of radiology residents at one institution. Our findings are thus not strictly generalizable to other institutions and settings, each with its own policies and protocols. A trial of MR. Implant at other institutions, both academic and community based, could assess the efficacy of this tool more widely, but this would require careful review and approval to ensure its compliance with local policies. Interinstitutional dissemination could be feasible with review, oversight, and endorsement by a national body, such as the ACR.

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