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E Kanal and F G Shellock

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The Value of Published Data on MR Compatibility of Metallic Implants and Devices

Emanuel Kanal and Frank G. Shellock

Since the advent of magnetic resonance (MR) imaging, there have been numerous studies of MR compatibility of various metallic implants, materials, and devices (1–15). A well-publicized case of unilateral blindness as a result of ocular trauma from an unsuspected metallic fragment in the eye of one patient (16) helped focus attention on this issue (1). There have been attempts to compile a centralized literature reference of the compatibility of these devices (6–8). Relying too heavily on these data may result in catastrophic events, whereas ignoring the published body of data may prove inefficient or dangerous. Determining why these data exist and what their actual limitations may be are the major objectives of this report.

Discussion

After a recent death from exposure of a patient with a ferromagnetic intracranial aneurysm clip to an MR system (17–18), the United States Food and Drug Administration (FDA) has stated that “. . . published studies cannot be relied upon to establish the safety of any particular clip design” (19). The statement of the FDA results in part from the fact that manufacturers of devices may alter the composition and/or material make-up of these devices without being required to notify the FDA, the surgeon, the radiologist, or the patient regarding such a change. Manufacturers do not need to notify the FDA as long as, *according to the manufacturer itself*, the proposed modification will not “. . . significantly affect safety or effectiveness of the device” (20). The exact wording from the FDA guidelines is as follows:

The manufacturer is responsible for determining if a proposed device change or modification warrants submission of a 510(k). It is not FDA's intent that a

510(k) must be submitted for every change in design, material, chemical composition, energy source, or manufacturing process, but only where such changes could significantly affect safety or effectiveness of the device. FDA believes that the manufacturer is best qualified to make this determination, which should be based on the exercise of good judgement, adequate supporting data, and sufficient documentation (20).

It is possible to interpret the statement regarding the potential to affect the device's safety or effectiveness vis-a-vis the stated purpose and function of the device itself, and not its potential interactions, for example, with an external magnetic field. In other words, there is no requirement at the present time that implant device manufacturers provide any statements whatsoever regarding the MR compatibility of their devices. They are not required to describe the magnetic-attractive properties of their devices nor their functional sensitivity to external magnetic fields. This guideline is presently being reexamined by appropriate bodies within the FDA (19).

Manufacturers may modify the composition of any given device, such as an aneurysm clip, if in their judgment they feel that the alteration is warranted and does not significantly affect the safety or effectiveness of that particular clip. There are currently no quality control guidelines in place that *mandate* that individual batches of manufactured implant devices be tested for possible interactions with externally applied magnetic fields (oral communication, Robert Phillips of the Office of Device Evaluation, Center for Devices and Radiological Health, FDA, May 19, 1993). Thus devices from different manufacturing runs, or batches, may differ in their reactions to magnetic fields.

Therefore, the data published in all of these peer-reviewed articles—and in those from the

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From the Department of Radiology (E.K.), University of Pittsburgh and the Pittsburgh NMR Institute; and the Department of Radiological Sciences (F.G.S.), University of California Los Angeles School of Medicine, and Tower Imaging.

Address reprint requests to Emanuel Kanal, MD, The Pittsburgh NMR Institute, 3260 Fifth Ave, Pittsburgh, PA 15213.

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manufacturers themselves—are simply “snapshots” of data as they were at that time and for those particular devices tested (18). The FDA is presently investigating what role, if any, it may play in requiring a statement describing interactions between externally applied magnetic fields and a device that is to be implanted into a patient (19) (oral communication, Robert Phillips, May 19, 1993).

Of what use are these lists and articles? If the data cannot be relied on, how might one determine whether such exposure will subject a patient to significant risk from a “projectile effect”?

Recommendations

Several guidelines should be developed to address this issue. Because we cannot apparently rely on present product labeling even if it claims MR compatibility (oral communication, Robert Munzener, PhD, Branch Chief for Neurological Devices, FDA, Office of Device Evaluation, August 1993), we strongly recommend that the FDA standardize such product labeling. The FDA should mandate a labeling requirement that the manufacturers of such devices state the ferromagnetic properties and sensitivities of their devices. Until that time, one must assume that there is a potential for any device to be affected by magnetic fields. Therefore, all such devices must be regarded as posing safety concerns in interactions with the static magnetic field of the MR system. The advisability of permitting a patient with such a device into the MR suite must be investigated in every case.

The data from peer-reviewed published lists and tested devices permit us rapid access to information at least regarding that snapshot in time when a particular device was tested. If we can determine that a patient has a particular brand, type, and model implant, the manufacturer of this device could be contacted, and further information might be exchanged (preferably in a written format) regarding the manufacturing history of the device in question. One would inquire about any deviations in the manufacturing process of that device (since the date of the published data) that might affect its magnetic-attractive properties. Does the manufacturer have any data that demonstrate magnetic field compatibility for the static magnetic field strength of the MR system to which you expect to expose this patient? Is this available for random sampling of these devices from various batches, or was it a one-time test of one or

several specific devices? Positive findings of paramagnetic or ferromagnetic* properties of these devices are more useful (in excluding the patient from the study) than are negative or unclear histories. Knowing the component metallic make-up of the device also may assist the radiologist in determining what, if any, magnetic field distortion artifacts may result from imaging the region of the device with the anticipated scan parameters and protocols selected.

Our own sites' evaluation of MR safety of patients with implanted devices has changed several times. We initially scanned no patients with intracranial aneurysm clips of any kind. We subsequently agreed to scan them if it could be reliably verified that the clip was of a type that had been previously tested and reported on and found not to be attracted by the magnetic fields of the strengths tested. We now recommend the following guideline for assessment of aneurysm clips that have not yet been implanted:

All intracranial aneurysm clips should be tested in an MR imager bay for magnetic-attractive properties before they are brought into the neurosurgical suite. For example, all intracranial aneurysm clips, as they arrive at our institution(s), would be removed from their packaging, placed flat on a freshly cleaned and dried sheet of plate glass, and placed within the bore of the MR system. (Our neurosurgeons [E.K.] do not permit individually sterilized/packaged aneurysm clips into the operating room, because they want rapid access to multiple types of clips on a single tray.) If there is no sign of aneurysm clip motion, either rotational or translational even with tapping/drumming the fingers on the undersurface of the glass, the person performing this testing would record the results, and the clips would then be resterilized for possible surgical implantation.

This information (ie, the clips having been so tested and found to be not attracted by the MR system's magnetic field) would then find its way into the surgical report or permanent record of the patient. Only with such documentation would patients with intracranial aneurysm clips be permit-

* Paramagnetic objects are those that have the potential to align along the direction of an externally applied magnetic field. Ferromagnetic objects are a subtype of paramagnetic (which may retain their magnetic internal alignment even after removing the externally applied magnetic field). With greater-strength magnetic fields being used and investigated, even paramagnetic (and not ferromagnetic) objects may pose potential risks at these very high field strengths. We have thus used the more broad category of paramagnetic herein to include potential problems that may arise with this category of devices in general.

ted into an MR suite (of similar or lower static field strength than that tested) without the need for further investigation. It should be understood that such a practice is far from foolproof; the effects of magnetic fields are nonlinear, and what we find at the field strength of an unshielded MR system does not guarantee what effects might be present at higher strengths or at sites where magnetic shielding may be in place. For now, however, it is the only test that we have for such screening information, and, imperfect as it may be, until a consensus is reached on how to assess magnetic properties, it is the mechanism that we recommend.

A similar policy should be applied to any metallic device (to be implanted in an anatomically sensitive location) that is amenable to MR magnet testing before implantation. It is crucial that the results of such testing become an integral part of the written record of that patient, and that the person responsible for overseeing such testing be identified therein. It is only in such a manner that one can be somewhat certain that the metallic device does not pose a projectile-effect risk to the patient.

It is only in such a manner that true informed consent might be obtained from the patient. Precluding a patient from ever undergoing an MR examination as a consequence of the implantation of such a device should be part of the information on which informed consent is obtained and provided. It should be incumbent on the manufacturers of all implantable devices to include a statement regarding the effects of magnetic fields on their device as a part of the device's approved labeling. It then should be incumbent on both the manufacturer of the device and the physician implanting it to inform the patient of any possible MR restrictions that may result from its implantation to obtain the necessary truly informed consent. Such a practice would significantly assist the MR industry by ensuring the safety of the patients who undergo such examinations.

These suggestions are being considered by the FDA (19) but are not presently FDA guidelines or even recommendations. Until such changes in product labeling are effected, it is incumbent on all radiologists to ensure the safety of patients undergoing MR examinations. Awareness of the advantages—and limitations—of published testing results and compiled literature lists will enable us to apply them wisely in screening patients for entry into the MR environment.

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