Magnetic Resonance Imaging in Cochlear Implant Recipients
Pros and Cons
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The article by Kim et al\(^1\) brings to light a larger topic—namely, how does one “prove” safety, either in general or specifically within the magnetic resonance imaging (MRI) environment? For example, in the case of cochlear implants, several studies have documented the "safety" of MRI exposure by numerous patients with various cochlear implants. Why, then, did the patients in the study by Kim et al experience adverse events or pain, even to the point of terminating the examination?

It is important to recognize that it is a mathematical impossibility to prove something to be safe, per se. All that can be done is to document that when specifically tested, some stimulus, agent, process, or other influencing factor was found to not be associated with any recognized adverse events to a specifically tested threshold of detectability or statistical significance. For example, if 100 patients were studied following exposure to a specific drug, one might claim that following 100 exposures, the incidence of hives or other recognized cutaneous allergic reactions was 0. Clearly this is not the same as proving safety—it merely documents that in their experience, the recorded incidence of a specifically studied adverse event was 0. This might provide a statistical window of confidence to safety, but it is far from proving that this agent is, per se, safe. For example, it is entirely possible that the 101st patient exposed might experience a severe anaphylactic reaction from exposure to that same drug. Additionally, it may be that allergic reactions were not observed, but perhaps the patient did experience a severe but clinically asymptomatic hypokalemia or thrombocytopenia—adverse events that may not have been anticipated, specifically prospectively studied, or clinically recognized in the study cohort. Not having observed that which one did not study is exceedingly common and must be considered before broadly painting the tested hypothesis itself as entirely safe.

Furthermore, many studies purport to document safety merely by exposing a finite number of patients to a specific stimulus, environment, or situation and failing to observe—or recognize—any adverse reactions. The current literature is replete with such cases: for example, MRI exposure and patients with cardiac pacemakers. What remains unrecognized, however, is that failing to identify an adverse reaction or event is not the same as proving safety. Yet a single publication documenting a life-threatening adverse event on a single patient with a cardiac pacemaker exposed to MRI successfully disproves the entire inappropriately broad safety claim. As has been previously noted, "...failing to identify an adverse event is not equivalent to demonstrating safety—especially when only a limited number of patients are studied."\(^2\) This solid principle is the basis of the US Food and Drug Administration's rejection of the “we saw no problems” methodology and for their having required far more rigorous science before they would approve the first truly MRI conditionally safe cardiac pacemaker.\(^3\)

Finally, while MRI scanners operating at magnetic fields of 1.5 T to 3.0 T raise concerns of potential translational and rotational forces, as detailed by Kim et al,\(^1\) scanners operating at higher magnetic fields, such as 7.0 T, carry additional dangers. At those frequencies and wavelengths, we would have to revisit safety issues related to potential significant heating of the tip of the cochlear implant wires and leads as well. Another issue relatively specific to MRI is that in the dynamic environment of resonant circuitry—what is safe, or conditionally acceptable, safe, at one magnetic field may not be safe at another.

Kim et al\(^1\) have reinforced a strong lesson for us all, that what may be considered safe by some may well be unsafe or unacceptable to others. Their reminder to consider not just what may be considered safe by some may well be unsafe or unacceptable to others. Their reminder to consider not just mere safety but also morbidity and acceptability to the patient, is refreshing indeed. This should be added to our list of considerations prior to determining any risk-benefit assessment and patient scan recommendations regarding exposure of patients with implants to MRI environments.

REFERENCES

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