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Safety While Swimming in a Sea of Energy

Humans have always existed in an environment full of energy transmissions. For most of our history, this energy has been amorphous, coming from sources such as cosmic radiation and lightning. Since the introduction of electrical devices (eg, telegraph, light bulb, radio), humans have been exposed to increasing amounts of electromagnetic energy. Today, the variety of devices and their respective energy transmissions seem endless, yet modern life would not exist without these products. However, since the beginning of the electronic age, there have been concerns about the health consequences of exposure to electromagnetic energy. One of the first to report such concerns was Benjamin Franklin, when he experimented with a kite and lightning.

In this issue of *Mayo Clinic Proceedings*, 3 articles bring the issue of exposure to electrical transmissions and patient safety to the forefront. Tri et al[1] report on their investigation of possible cell telephone interference with medical equipment in a hospital setting. Gimbel and Cox[2] provide a report of 2 patients with implantable cardioverter defibrillators (ICD) who had adverse interactions with electromagnetic scanning devices in their community. Finally, Austin et al[3] report on a person whose consumer electronic device interfered with an electrocardiogram (ECG) and led to an initial misdiagnosis of atrial flutter. What is most interesting is that Tri's data (which identified no interference) conflict with those of Gimbel and Austin despite the fact that the in-hospital setting would seem more likely to produce an electrically hostile environment. Despite this apparent contradiction, the core message of these 3 reports may be the same (see subsequent discussion).

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The current investigation by Tri et al[1] is a follow-up to their previous 2005 in vitro report.[4] In their earlier research, the authors discovered that cell telephones produced interference in 44% of the tested devices, although the incidence of clinically important interference was only 1.2%. Older analog cell telephones that emit a relatively high-energy signal produced the most interference. Cell telephones had to be placed fairly close to the tested device (ie, <33 in) to produce any interference. Cell telephones were less likely to cause interference in newer medical technology. The authors concluded in 2005 that technologic advances had improved the resistance of medical devices to interference from cell telephones, but that the type and number of electronic designs were anticipated to steadily change, necessitating ongoing testing.

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Tri et al heeded their own advice and tested newer technology, using a study design more relevant to daily patient care. Specifically, in the current 2007 report, they investigated cell telephone and wireless handheld device (Blackberry, Research In Motion, Waterloo, Ontario) interference of medical equipment while the equipment was being used on hospitalized patients, including those in intensive care units. The tested medical equipment was both diagnostic and therapeutic (eg, physiologic monitors, infusion pumps, mechanical ventilators). The authors performed 300 tests of cell telephone interference and 40 tests of wireless handheld device interference. They found no interference with any of the tested medical technology. The authors concluded that institutions should consider revising hospital policies that restrict cell telephones.

In contrast, Gimbel and Cox reported on 2 patients having ICD devices that were triggered by electronic article surveillance (EAS) systems (ie, electronic devices placed at store exits to detect stolen merchandise). In both cases, the patient had relatively close contact with an EAS

device at a retail store exit. In one case, when the patient collapsed after being shocked, an employee propped the patient against the EAS pedestal, thereby triggering further shocks. In both cases, the patients had ICDs from the same manufacturer. Austin et al reported on a similar but less dramatic electrical interference event. A healthy volunteer had an ECG recorded as part of an extra-hospital drug study. The ECG was read as atrial flutter with an atrial rate of 333/min. It was discovered that the volunteer had a portable compact disk (CD) player (Walkman, Sony Corp, Tokyo, Japan) close to the right-arm lead of the ECG. When the CD player was turned off, the ECG recording returned to normal sinus rhythm.

How should we translate this evidence into clinical practice? The reported data appear to show that devices that emit electromagnetic energy produce little risk in the hospital setting, whereas there is a potential for serious risk in the community based, in part, on the many thousands of people with implantable devices. We could respond by triggering a public health emergency, similar to what occurred a generation ago in response to publication of several articles that discussed electrical shock hazards in hospitalized patients.[5-7] This generated something of a panic and caused hospitals to embark on expensive retrofits to decrease shock hazards. Twenty years later, it appears that these concerns were overblown but, nevertheless, improved equipment and facility designs and decreased electroshock hazards.[8] It would be prudent not to repeat the mistakes of the past by overreacting to such reports on electromagnetic interference (EMI).

The studies by Tri et al can give us confidence that it is unlikely that a visitor's cell telephone or other portable device will cause harm to a hospitalized patient. However, their current study examined only 2 cell telephone and 2 wireless handheld device technologies on only 22 medical devices. While it seems reasonable to conclude that the cell telephones pose a low risk of patient harm, there are many more medical devices on the market than were tested, and wireless technology is constantly changing. Therefore, it is impossible to know with any certainty which combination of wireless device and medical equipment will pose a risk to patients. Of note, in the earlier study by Tri et al, interference occurred only when a cell telephone was placed very close to a medical device. This suggests that the potential for clinically relevant interference in the hospital is small because it would be uncommon for a visitor's portable device to be held close to a medical device.

The article by Gimbel and Cox offers a nice commentary on the results of the 2 Tri studies. The risk to patients from wireless energy transmissions is very low. Gimbel and Cox refer to 2 large studies that showed that no patient received inappropriate cardioversion triggered by an EAS system.[9,10] They then report on 2 patients whose ICDs *did* discharge inappropriately from interference from an EAS system. This is a good example of the challenges associated with understanding the clinical implications of rare events. Finally, the report by Austin et al reiterates the point that EMI is more likely to occur when the transmitting device is close to medical technology. This is consistent with the report by Gimbel and Cox[2] and the earlier study by Tri et al.[4]

Clinicians and the broader medical community should use these results and apply them to their clinical practices. Patients and families should be advised not to place electrical devices close to medical technology. Clinicians will need to share real-world examples of how failure to heed this simple rule can result in problems (as is seen with EAS systems, portable music devices, and rarely wireless products). Because both mobile and immobile electronic technology are ubiquitous in our society, those who depend on medical technology need to be aware of the small but real and unpredictable risk of such technology. In the hospital setting, the risk to patients appears to be small. It may be pointless to continue to outlaw such portable devices in hospitals simply because rules are impossible to enforce given the high proportion of the public having 1 or more devices with them much of the time. Instead, visitors and patients should be instructed to not bring their portable devices close to medical equipment. Enlisting their help is more likely to be successful than attempting a blanket ban. Medical staff must be educated on how to identify electrical interference since no matter what rules are imposed or how safe equipment design becomes, the risk will never be zero and caregivers will always provide the final safety check for patients.

The medical community must demand that manufacturers of medical technology continue to test their devices against the wide range of potential EMI that their products may face. The obligation most appropriately rests on the companies that design and fabricate our technology. If a device is found to be susceptible to EMI, purchasers and users of the device must be clearly informed of these risks. We must also insist that transmitting devices are easily identified (an issue addressed by Gimbel and Cox). Transmitters that are hidden make it impossible for patients to recognize and avoid them. Finally, there may be a role for an independent testing organization that evaluates new medical technology for susceptibility to a wide range of EMI, much like Underwriters Laboratories currently evaluates technology for compliance with safety standards.

Unfortunately, the Food and Drug Administration (FDA) provides little specific guidance regarding EMI of

medical technology. On its Web site (www.fda.gov/cdrh/emc/emc-in-hcf.html), the FDA's recommendations are more or less generic statements that medical facilities should check their equipment, identify locations where EMI could be problematic (eg, operating rooms and intensive care units), and educate staff. On the basis of the results of the 3 reports in the current issue of *Mayo Clinic Proceedings*,[1-3] it would be appropriate for the FDA to take a more explicit stand that EMI is unlikely to occur in a hospital setting and that internal regulations in health care facilities should reflect that fact. Recommendations should also reiterate that the risk is not zero and that medical personnel should remain vigilant in order to detect and mitigate the uncommon occurrence of clinically relevant EMI of medical devices.

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