Environmental Causes of Breast Cancer and Radiation From Medical Imaging

Findings From the Institute of Medicine Report

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Susan G. Komen for the Cure asked the Institute of Medicine (IOM) to perform a comprehensive review of environmental causes and risk factors for breast cancer. Interestingly, none of the consumer products (ie, bisphenol A, phthalates), industrial chemicals (ie, benzene, ethylene oxide), or pesticides (ie, DDT/DDE) considered could be conclusively linked to an increased risk of breast cancer, although the IOM acknowledged that the available evidence was insufficient to draw firm conclusions for many of these exposures, calling for more research in these areas. The IOM found sufficient evidence to conclude that the 2 environmental factors most strongly associated with breast cancer were exposure to ionizing radiation and to combined postmenopausal hormone therapy. The IOM’s conclusion of a causal relation between radiation exposure and cancer is consistent with a large and varied literature showing that exposure to radiation in the same range as used for computed tomography will increase the risk of cancer. It is the responsibility of individual health care providers who order medical imaging to understand and weigh the risk of any medical procedures against the expected benefit.

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Susan G. Komen for the Cure, the largest grassroots network of breast cancer survivors and activists in the United States, asked the Institute of Medicine (IOM) to perform a comprehensive and evidence-based review of environmental causes and risk factors for breast cancer, with a focus on identifying evidence-based actions that women can take to reduce their risk.1 Environmental exposures were defined broadly to include all factors not genetically inherited, and the IOM committee appointed to write this report included academicians and chairs from departments of environmental health, toxicology, cancer epidemiology, preventive medicine, and biostatistics in addition to advocates for patients with breast cancer. Committee members conducted their own reviews of the peer-reviewed epidemiological and basic science literature, commissioned several papers specifically for their report, and drew on evidence-based reviews already completed by organizations such as the Agency for Research on Cancer and the World Cancer Research Fund International. The publication Breast Cancer and the Environment: A Life Course Approach was released online in December 2011.1

IOM’s CONCLUSIONS

Interestingly, none of the consumer products (ie, bisphenol A, phthalates), industrial chemicals (ie, benzene, ethylene oxide), or pesticides (ie, DDT/DDE) con-
considered could be conclusively linked to an increased risk of breast cancer, although the IOM acknowledged that the available evidence was insufficient to draw firm conclusions for many of these exposures, calling for more research in these areas. The IOM found sufficient evidence to conclude that the 2 environmental factors most strongly associated with breast cancer were exposure to ionizing radiation and to combined postmenopausal hormone therapy. Since the Women’s Health Initiative reported that combined estrogen and progestin hormone therapy increases a woman’s risk of breast cancer, there has been a steep decline in hormone therapy use, followed by small decline in breast cancer incidence. Thus, the most significant conclusion of the IOM report is that to reduce her risk of breast cancer, a woman should avoid inappropriate radiation exposure. In particular, because the radiation doses delivered by computed tomographic (CT) imaging are high, women should reduce any unnecessary exposure to CT. The IOM also concluded that several lifestyle factors may modestly reduce a woman’s risk of breast cancer, such as limiting alcohol consumption, maintaining a healthy body weight, and reducing active smoking, all of which have health benefits beyond lowering a risk woman’s risk of breast cancer.

The IOM’s conclusion of a causal relation between radiation exposure and cancer is consistent with a large and varied literature showing that exposure to radiation in the same range as used for CT will increase the risk of cancer. Many national and international organizations such as the National Council on Radiation Protection (NCRP), the International Council on Radiation Protection (ICRP), and the International Atomic Energy Agency (IAEA) were established in part to promote radiation protection, given its carcinogenic properties. What is surprising is the IOM’s focus on the avoidance of medical imaging as one of the most important and concrete steps that women can take to reduce their risk of breast cancer, reflecting the growing awareness that CT is overused and that a reduction in unnecessary use would lead to health improvement. Furthermore, the IOM highlighted that excess radiation exposure is aggravated by the large variation in CT doses for the same imaging test conducted among different institutions, as well as dosing errors by inadequately trained or supervised technologists and poorly designed equipment. A reduction in variation in doses across patients and institutions and elimination of overdosing errors would greatly improve the safety of CT and reduce its potential for causing cancer. The IOM estimated that 2800 future breast cancers would result from 1 year of medical radiation exposure among the entire US female population, with two-thirds of those cases resulting from CT radiation exposures. While these represent a small proportion of all breast cancers, they are important because they can potentially be reduced.

CT OVERUSE

The use of CT has increased nearly 5-fold over the last 2 decades. Currently, 75 million CT scans are performed annually in the United States, around half in women, reflecting the large number of individuals who are exposed to this source of radiation. Thought leaders in radiology are often quoted as estimating that 30% or more of advanced imaging tests may be unnecessary, and while there are few scientific data to precisely estimate the amount of overuse, many radiologists believe the proportion may be even higher.

The reasons for overuse of CT are many and include the ease of conducting this examination and the clear diagnostic images made possible through advances in technology. Intense marketing focusing on profit leads to the rapid purchase of machines prior to completely understanding how this technology should be used to improve health outcomes has created excess capacity, complicated by few evidence-based guidelines for its use. Strong financial incentives, reflected by the growing ownership of CT scanners by nonradiologists for use in their private medical offices, strong patient demand (in part resulting from direct-to-consumer advertisements that do not mention untoward effects), and medical malpractice concerns leading to defensive test ordering have all further contributed to high excess use. Thus, while CT is clearly indicated and valuable in many cases—for example, for patients with acute appendicitis and pulmonary embolism—CT is frequently used in the absence of evidence. The threshold for using CT for imaging has dropped dramatically, and thus it is not surprising that the IOM suggested curtailting unnecessary radiation exposure from medical imaging to reduce cancer risks.

Outside the medical world, such as the nuclear power industry, the military, or homeland security, radiation use must be carefully justified. The concern for limiting radiation exposures in occupational and industrial settings where the person exposed does not receive direct benefit from that exposure should be the same for medical use. We can learn from Europe, where very clear justification for CT is required. The referral guidelines for imaging published by the European Commission state in view of the potential high doses, CT should only be carried out after proper clinical justification by an experienced radiologist. Examinations on children require a higher level of justification, since such patients are at greater risk from radiation. Justification in the United States for medical imaging that delivers radiation was present in the earlier years of its use, but ironically, as the doses of radiation used in medical imaging have increased with the wider use of CT, and the development of higher-dose CT scanning protocols, the requirement for justification for its use has declined. Recently, and surprisingly, its known harms have even been trivialized by some in contrast to the large literature that has clearly documented the potential for radiation doses in the same range as used in CT for causing cancer.
WEIGHING THE RISKS OF CT

To reduce inappropriate medical imaging, individual patients, health care providers, and patient advocacy organizations all have a role to play, and the IOM highlights steps that can be taken to limit unnecessary exposures. Individual patients and their families should expect that their health care providers will discuss both the expected health benefits and potential harms of any imaging test that has been ordered—particularly if the test involves exposure to radiation—and patients should directly question any health care provider who does not provide a complete picture. This picture should be appropriate for the clinical context—the likely benefit, the potential risk if imaging is not performed, as well as the radiation the test is likely to deliver. A useful rule of thumb is that patients should ask if a test is likely to alter their clinical management or add confidence to their clinician’s diagnosis, which would not be possible without the test.

It is the responsibility of individual health care providers who order medical imaging to understand and weigh the risk of any medical procedures against the expected benefit. New imaging technologies are delivering vastly larger radiation doses than conventional x-rays. For example, a chest CT may deliver a dose 100- to 500-fold higher than a conventional chest radiograph (conventional x-ray). With radiographs, the radiation dose is relatively small, so decisions about whether to order radiographs can be made based on less careful weighing of these risks. New imaging and complex scanning protocols developed for CT generate much larger doses, in the range where increased rates of cancer can be measured and where the doses have gotten so high that accidents such as hair loss or radiation burns can result. Many ordering physicians are insufficiently informed about radiation doses and the cancer risks attributable to medical images, and yet this information is crucial to weigh risks and benefits and provide appropriate justification for the use of CT and other high-dose imaging studies to patients and families. Brook recently hypothesized that showing clinicians the cost of a medical test every time they ordered one for their patient might lead to the more judicious and cost-effective use of medical care. Similarly, if clinicians were provided with detailed information about the expected radiation exposure of a procedure, as well as about a patient’s cumulative exposure to medical radiation at the time a test is ordered, they might choose the tests more judiciously. Current electronic medical records and test ordering platforms can be adopted to include this information, as well as information on the likely benefit of any imaging examination, and this would help to fulfill the Centers for Medicare and Medicaid Services (CMS) requirements for meaningful use of these information systems. There is a pressing need for educational information for the broad medical community (ie, not just medical physicists) to enhance understanding of the doses of radiation involved in diagnostic imaging tests and the health risks associated with those doses.

A CALL FOR OUTCOMES RESEARCH FOR IMAGING

Outcomes research for imaging is sorely needed. Health care advocates, such as the National Partnership for Patients, should lobby for research that quantifies the risks and benefits of medical imaging, given how important advanced imaging is to medical care. Currently, the National Institute of Biomedical Imaging (the National Institutes of Health institute tasked with medical imaging related research) has spent the majority of its research dollars on the development of new imaging modalities rather than on quantifying the risks and benefits of existing imaging technology. Lastly, Congress and the CMS, as well as other payers, have already enacted payment reforms targeted to reducing the expenditures on imaging and to removing some of the financial incentives that have led to the rapid rise in imaging. These measures have slowed the growth rate of imaging over the last few years. The recently released White House health care budget specifically calls for an additional $820 million dollar reduction in payments for imaging and introduces prior authorization to further reduce utilization, although these specific recommendations may not be incorporated into the final approved budget. Since prior authorization adds costs, complexities, and time delays into the medical care process, it is in the self-interest of both payers and health care providers to develop alternative approaches to improving the appropriateness of imaging orders. There are some promising initiatives in that regard, including the implementation of clinical decision support in the electronic medical record of several large health systems.

STEPS TOWARD REDUCING RADIATION EXPOSURE

The first step toward lowering exposures to unnecessary radiation is to reduce unnecessary testing. A second, and equally important, strategy for reducing inappropriate exposures to radiation from medical radiation is to lower the doses delivered for each imaging examination. This can be done through the development of greater oversight of CT. Patient demands for improvement can help speed such oversight. Patients should ask their physicians about the radiation doses involved in their examinations, and request a record of the doses to which they are exposed. The National Quality Forum recently adopted a quality measure focused on CT radiation dose that calls for facilities who conduct CT to record their doses. Consumers and physicians should ask the facilities they belong to adopt this measure and to publically report dose information. This would rapidly improve a facility's knowledge of the doses they use, as well as motivate them to do whatever they can to lower and standardize radiation dose. Furthermore, this would allow patients and health care providers to use this information in their decision-making regarding where to go for imaging.
The US Food and Drug Administration (FDA) created a road map for reducing and standardizing the doses patients are exposed to when they undergo CT; they called for the creation of benchmarks (standard dosing levels), recording doses in the medical record and creating evidence-based guidelines for imaging.\(^3^5\) However, they have not moved these efforts forward, instead asking medical societies and professional groups to take the lead. Unfortunately, there has been little progress in these areas since the FDA initially made these recommendations in early 2010. Radiology professional organizations could take the lead in creating concrete dose benchmarks, working closely with the FDA to do so, as this could result in a marked reduction in the variation in radiation doses observed for CT. Legislators could get involved as well, as was done toward the standardizing of doses used in mammography through the Mammography Quality Standards Act (MQSA); this successful effort can be a model for how legislation can optimize use of radiation in medical imaging.\(^3^6\) At a minimum, the US Congress should pass the CARE Bill (HR 2104, The Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy)\(^3^7\) that is currently under consideration. It would improve the training of those who order and conduct imaging examinations. California has recently enacted legislation that goes into effect in July 2012 (SB 1237) requiring the dose used for CT examinations be recorded in every patient’s medical record and further requires inadvertent CT radiation overdoses to be immediately reported to the state.\(^3^8\) This will inform patients and referring health care providers about dose and will further encourage facilities to begin assessing and reducing the doses they are delivering to their patients. The California legislation provides a template for consideration of national legislation.

Lastly, while manufacturers are developing and marketing devices that can create diagnostic images using considerably lower doses of radiation, it may take decades for these devices to replace those currently in operation. Thus, the manufacturers should work closely with all facilities who use their equipment to provide existing software upgrades to immediately reduce the doses to which patients are exposed. Currently, the costs of these software upgrades are marketed at prices outside the reach of many facilities that conduct CT. Furthermore, as the IOM suggested, manufacturers could adopt uniform design standards—as has been successfully done in other areas of medicine (such as anesthesia) and outside of medicine (such as the airline industry)—that would make it easier for technologists to move between different manufacturers and machines to improve safety. For example, the different manufacturers have developed different techniques to modulate the tube current for patients of different sizes to reduce the doses patients receive. GE has defined a measure known as the noise index, and the higher values in the noise index result in lower dose. Siemens has defined reference milliampereseconds (mAs)—higher values in the effective mAs resulting in higher dose. Thus, if a technologist has a small patient and would like to reduce the dose, they need to turn the noise index up on a GE machine, whereas they need to turn the effective mAs down on a Siemens’s machine—seemingly opposite directions to lower the dose.

CONCLUSIONS

Computed tomography is a highly valuable tool, but unnecessary use may lead to a small but real increase in a patients’ risk of cancer, and patients should be appropriately involved in the decision to undergo imaging.\(^3^9\) Many imaging enthusiasts believe patients cannot be told about the radiation exposure associated with medical imaging, believing they will make poor choices and refuse indicated imaging.\(^4^0\) This fear has not been substantiated. When given balanced information about both risks and benefits, patients usually have made informed and appropriate decisions regarding medical imaging for themselves or their families. For example, in one study of caregivers informed of the radiation risk associated with a diagnostic CT for their child, they preferred the lower-risk option of observation if the physician believed it would be equally effective and chose in favor of CT if it was preferred and recommended by their physician.\(^4^2\)

Now we need to develop the evidence needed by both physicians and patients so they can take advantage of this tool in the situations when it will be most important to do so.

The IOM conclusion is that current evidence-based options for women to reduce their risk of breast cancer are limited. Most of the known risks factors for breast cancer, such as the age of menarche or family history, cannot be controlled. Avoiding and reducing exposure to medical radiation is one of the primary evidence-based actions that could reduce breast cancer risk, and the medical community should do everything in our power to reduce unnecessary exposures as quickly as possible.

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