Medical Imaging: The Challenges of Radiation Risk Assessment

According to the International Atomic Energy Agency (IAEA), "The use of ionizing radiation is one of the greatest medical discoveries of the last 120 years. Its use has vastly improved our understanding of the body's processes and functions and our ability to diagnose and to cure diseases." Ionizing radiation has undoubtedly been good for medical advancement and for patients' quality of life around the world. But some believe that ionizing radiation also carries a risk and that deliberate exposure of an individual is justified only when there is a potential direct benefit. This benefit-versus-risk balance is the main reason IAEA is promoting a new AAA (awareness, appropriateness, audit) approach to radiation protection and safety. The purpose of this approach is to encourage medical practitioners, nuclear regulators, and medical facilities to "significantly reduce the number of radiological procedures done each year and ensure that those procedures that are carried out are in the patients' best interests." To promote its AAA approach, the IAEA Radiation Safety and Monitoring Section held an event on September 23 during the IAEA's 58th General Conference. There Lodewijk Van Bladel, MD (a senior radiological protection expert at the Federaal Agentschap voor Nucleaire Controle; Brussels, Belgium), and Jim Malone, PhD (Professor of Medical Physics at Trinity College; Dublin, Ireland), gave presentations on the history, importance, and benefits of using the AAA approach to improve patient radiation protection (www.iaea.org/newscenter/news/2014/aaa.html). More than 40 regulators from around the world, responsible for managing radiation safety in their countries, were in attendance.

The IAEA AAA basics include: (1) Awareness: the physician or radiologist must understand the potential risks associated with exposing patients to various radiation doses, be able to evaluate whether each patient's condition and potential knowledge and benefits gained from any procedure are worth possible risks, and be able to communicate potential risks and benefits to the patient. (2) Appropriateness: each procedure using ionizing radiation should be suitable for the illness the patient is believed to have. (3) Audits: the quality and consistency with which the principles of awareness and appropriateness are used in the clinical setting should be assessed. Outcomes from such audits should be integrated into the hospital/clinic operating life. According to Van Bladel, financial concerns are often important in determining how many radiological procedures are requested. He encouraged regulators present at the meeting to join forces with other stakeholders in government, medicine, and education to address this problem. Malone noted that although progress has been made, with several European countries and medical and radiological professional societies adopting the AAA approach, much remains to be done. The likely outcome of this approach and this meeting will be to encourage the medical profession to adopt the AAA approach to significantly reduce the number of radiological imaging procedures performed each year and justify every medical imaging exposure.

Concern about risks involved with radiological imaging and, more recently, radionuclide imaging are already being addressed in the ongoing Image Wisely and Image Gently campaigns (*1,2*). A key question for the imaging community is whether risks associated with today's typical radiological imaging procedures are so high—or even so well understood—that enhanced radiation protection and regulatory intervention by the IAEA are justified. Answers to this key question can be informed by a fact-based historical review of what is known and not known about excess cancer risk associated with low-dose/dose-rate radiation exposure.

The use of radiological and nuclear medicine imaging procedures has increased dramatically over the past 20–30 years, along with considerable evidence of effectiveness in contributing to reductions in morbidity and accompanying increases in average longevity. At the same time, cumulative public radiation exposure has increased (most notably as a result of increased CT imaging), along with concerns that this increased radiation dose may be associated with (as yet undefined) radiation-induced cancer risk.

Radiogenic cancer risks associated with low-dose/dose-rate exposures are theoretical and based on extrapolation of modeled effects documented mainly from data obtained from atomic bomb survivors exposed to single high doses of radiation. The basic assumption most often applied is that of the linear no-threshold (LNT) model, which holds that no radiation dose is without carcinogenic risk. This model addresses only the radiogenic risk, with no reference to potential benefits (*3*). Moreover, it ignores the significantly higher risks associated with *not* undergoing medical imaging, including increased burdens of disease with delayed/no diagnoses and/or increased rates of invasive procedures (such as exploratory surgeries) (*4*). The LNT model and the philosophy behind it are more concerned with the extremely small number of very long-term and only theoretically predicted cancer deaths attributed to radiation exposure than the much larger numbers of actual deaths that are certain to occur without imaging.

Cancer risks associated with radiation from a CT scan are generally understood to be quite small but not zero. Provided that the scan is clinically justified, the diagnostic benefit is believed to far outweigh risk (*5*). The AAA policies adopted by the IAEA and the optimization and justification policies of the International Commission on Radiological Protection (ICRP) have as a common purpose the minimization of radiation-induced cancer risks (*6*). These policies are premised on the assumption that such risks are real and substantial (*7*). Risk estimates based on the LNT model presume the accuracy of its predictions, an assumption not uniformly supported by either contemporary or historical data. It is of course important to minimize radiological imaging studies that are not clinically warranted, as should be the case for any medical procedure.

Atomic bomb survivor data are the most frequently cited source for current widespread cancer concerns about low-dose/dose-rate radiation exposure. However, a 2012 update reported from Ozasa et al. (*8*) suggests that new dose-response data for cancer mortality at low doses are more consistent with a linear-quadratic dose-response model because a significant upward curvature is exhibited (i.e., these data no longer support the LNT model and the excess relative risk is likely lower than that predicted using LNT-based estimates). It is important to note that no model is currently capable of accurately establishing the level of associated risk at doses $<$100 mSv (*9*). Two recently published epidemiologic studies report increased cancer risks associated with pediatric CT imaging (*10,11*). Significant concerns were raised in a 2013 United Nations Scientific Committee on the Effects of Atomic Reaction report, identifying key questions about these risk estimates (*12*). Cancers included in the study may have been caused by the medical conditions for which the imaging was performed and may have had nothing to do with radiation exposure (reverse causation). Moreover, individual dosimetry was not performed in these studies, with resulting high levels of uncertainty about the assigned radiation doses.

We believe that the use of the LNT model should end. It has been shown to be incorrect, epidemiologic studies have failed to conclusively demonstrate excess cancer risk at low doses, and LNT is not conservative. It is important to note that ICRP Publication 103 (*13*) stressed that, because of uncertainties surrounding the risks of health effects at low doses, the LNT hypothesis should not be used to calculate the hypothetical number of cancers that might be associated with small radiation doses received by large numbers of people. It follows that such LNT-derived estimates are not valid for individual risk assessment. Any approach touting the "known" cancer risks to an individual from low-dose/dose-rate radiation exposure as delivered from a radiological imaging procedure should be vigorously challenged, because it serves to alarm and frighten rather than educate. With the poor quality of dosimetry information in general, assignment of a specific radiation dose to a given patient (which may not even be a good surrogate for risk) is susceptible to much uncertainty. The excess carcinogenic risk assumed to be associated with this dose is also not accurately known, so physicians cannot therefore accurately communicate potential risks to patients.

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