JACC: CARDIOVASCULAR IMAGING VOL. 5, NO. 6, 2012

ISSN 1936-878X/$36.00
PUBLISHED BY ELSEVIER INC. http://dx.doi.org/10.1016/j.jcmg.2011.11.023

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BUSINESS AND ADVOCACY

Cardiac Imaging Modalities With Ionizing Radiation

The Role of Informed Consent

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Informed consent ideally results in patient autonomy and rational health care decisions. Frequently, patients face complex medical decisions that require a delicate balancing of anticipated benefits and potential risks, which is the concept of informed consent. This balancing process requires an understanding of available medical evidence and alternative medical options, and input from experienced physicians. The informed consent doctrine places a positive obligation on physicians to partner with patients as they try to make the best decision for their specific medical situation. The high prevalence and mortality related to heart disease in our society has led to increased cardiac imaging with modalities that use ionizing radiation. This paper reviews how physicians can meet the ideals of informed consent when considering cardiac imaging with ionizing radiation, given the limited evidence for risks and benefits. The goal is an informed patient making rational choices based on available medical information.

The United States currently does not have national guidelines for informing patients about potential risks of exposure to diagnostic medical radiation. Conversely, the European Union has codified into law that one who refers a patient for a radiological examination must provide "sufficient medical data" to justify the study (1–3). U.S. physicians have a fiduciary duty to obtain informed consent from patients before performing any procedure or assume the risk of medical negligence. Legally, "a fiduciary is someone who has undertaken to act for and on the behalf of another in a particular matter or circumstances that gives rise to a relationship of trust and confidence" (4). Furthermore, for a patient's consent to be valid under law, the patient must be given sufficient information to understand the risks and benefits to make a fully informed decision (5).

The evolving medical literature, U.S. Food and Drug Administration (FDA) news releases about reduction of unnecessary radiation, and House of Representatives initiatives to regulate medical radiation have focused the attention of the public, the media, and health care providers on the controversy surrounding the risk of malignancies related to medical imaging with ionizing radiation (6–10). The debate on whether it is necessary to inform patients of these potential risks prior to performing imaging with ionizing radiation is a corollary to this controversy (11). This corollary has become a focal concern for physicians, risk managers, and insurers given a recent ruling by the Wisconsin Court of Appeals, recently affirmed by the Wisconsin Supreme Court, in *Jandre v. Physi-*

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Manuscript received June 27, 2011; revised manuscript received November 10, 2011, accepted November 21, 2011.

cians Insurance Company of Wisconsin (12). The debate is "heated" because of the uncertainty and complexity surrounding the underlying issues, and the many possible unintended consequences on patient outcomes and physicians' workloads. In this paper, we discuss why physicians ordering tests that use ionizing radiation have a fiduciary responsibility to their patients to provide available medical risk/benefit data and alternative approaches to treatment, and obtain informed consent. This fiduciary responsibility has ethical and legal underpinnings. On the basis of these concepts, we outline a logical and linear approach to informed consent before cardiac imaging with ionizing radiation.

Use of Medical Imaging and Informed Consent

Utilization of medical imaging has grown exponentially in recent years (13,14). For example, the volume of nuclear myocardial perfusion imaging (MPI) has increased from <3 million procedures in the United States in 1990 to 9.3 million in 2002 (15). This increased medical radiation burden has raised public health concerns about possible malignancy rate increases in the future, and led to an FDA initiative (9,10) and a discussion in Congress of new legislation to regulate medical radiation (10). Recent studies revealed repeat testing with nuclear MPI to be common and, in many patients, associated with high cumulative doses of radiation (6,16,17). Some studies suggested that the use of computed tomography (CT) and nuclear MPI may be associated with 1.5% to 2.0% of all future cancers (18,19), and serial testing with ionizing radiation is associated with a noticeable increase of projected cancer risk in patients with acute myocardial infarction (20).

By contrast, there may be a lack of awareness among health care providers and patients regarding the probability of potential risks of ionizing radiation and the concepts of radiation protection. The courts have declared a "prudent-person standard," in which any risk from an investigation or treatment must be communicated if a reasonable person would want to know that information to determine whether to proceed (21–25). The medical literature suggests the informed consent process is sporadic, at best, at ensuring patients are informed about the risks and benefits of diagnostic ionizing radiation. Although most academic medical centers have guidelines about obtaining informed consent before CT, only a minority of these institutions follow through with providing information on potential radiation risks and alternative approaches to patients (2). Most physicians do not know whether patients at their institutions are informed about potential cancer risk from ionizing radiation, but do believe that informing them about it is important (2,26). However, most physicians, independent of their experience level, cannot provide reasonable estimates for the radiation doses associated with proposed diagnostic testing (27). A recent study found that more than 90% of patients were not informed of any radiation risk prior to CT (27). The prevailing opinion in medicine and law emphasizes the need to inform patients about the potential risks of ionizing radiation while obtaining informed consent, and the need to implement pragmatic strategies to achieve that goal (25,28).

Risks and Benefits of Cardiac Imaging With Ionizing Radiation

Discussing risks and benefits of cardiac imaging with patients is difficult because of the lack of solid evidence that would suggest disease-management strategies guided by cardiac imaging more often lead to better patient outcomes than empirical medical strategies. Additionally, there is a lack of direct evidence for harm from low-dose diagnostic medical radiation (29). Examples for radiation dose estimates for contemporary cardiac imaging tests are presented in Table 1 (30–44). It is important to recognize that most cardiac imaging studies across the United States are probably done on equipment that is not capable of the latest, most effective dose-sparing techniques.

Benefits of imaging. Imaging generally has not been held to the same standard of rigorous evaluation as have other aspects of medical care (45). Prospective, randomized clinical trials that compare the outcomes of management strategies with and without imaging (46,47) are difficult to design and, hence, rare. In symptomatic patients, there is a risk of failing to diagnose a cardiac condition and, thus, improving quality of life or longevity by not performing an imaging study to avoid radiation exposure. As a corollary to the potential benefits of imaging, patients must be made aware of this important risk of avoiding diagnostic imaging that uses ionizing radiation.

Risks of ionizing radiation. At the radiation doses typically used in diagnostic medical imaging, the risks of morbidity and mortality due to malignancy that often carry over into the lay press are derived from epidemiological models largely based on extrapolations from survivors of the atomic bomb explosions in Japan in 1945 (48). To optimally protect the best interests of patients, current radiation protection concepts are based on the so-called "linear no-threshold" model, which postulates that any level of ionizing radiation, however low, can cause a malignancy, and that the risk of malignancy increases linearly with radiation dose (49). Controversies about the precise magnitude of risk for malignancy related to low-dose ionizing radiation notwithstanding, these projected risks are generally greater for younger than older patients, and greater for women than men.

Doctrine of Medical Informed Consent

How can we translate this background information effectively into a meaningful practice of obtaining informed con-

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Table 1. Ionizing Radiation in Cardiac Imaging

Examination	Representative Effective Dose Value (mSv)	Range of Reported Effective Dose Values (mSv)	Administered Activity (MBq)
Chest x-ray posteroanterior and lateral	0.1	0.05–0.24	N/A
Diagnostic invasive coronary angiogram	7	2–16	N/A
Coronary CT angiogram			
64-slice multidetector, retrospective gating	12	9–19	N/A
64-slice multidetector, reduced tube voltage (100 kVp)	6	3–8	N/A
64-slice multidetector, prospective triggering	3	2–4	N/A
Dual-source high pitch	<1	<1	N/A
264 or 320 multidetector row CT	4	2–8	N/A
Nuclear medicine studies			
Myocardial perfusion			
Sestamibi (1-day) stress/rest	12	N/A	1,480
Tetrofosmin (1-day) stress/rest	10	N/A	1,480
Thallium stress/redistribution	29	N/A	130
Rubidium-82 rest/stress	10	N/A	2,960
Myocardial viability			
PET F-18 FDG	14	N/A	740
Thallium stress/reinjection	41	N/A	185

Table adapted from Mark et al. (30) and Raff (31), with permission from Elsevier. Data include a survey of the literature since 2008 (30–44).
CT = computed tomography; FDG = fluorodeoxyglucose; N/A = not applicable; PET = positron emission tomography.

sent? The legal foundation for the doctrine of medical informed consent is 2-fold: 1) to establish and promote patient autonomy; and 2) to promote informed rational decisions. The courts hold that it is reasonable to require physicians to inform, educate, and partner with patients because patients are generally unable to translate the details of medical science into making educated decisions about testing or treatment by themselves (50). This educational process should inform the patient sufficiently to allow a rational decision that reasonably reflects the possibilities of positive or negative consequences.

Elements of informed consent. The doctrine of medical informed consent states that before a patient elects to proceed with a treatment that carries risks, there must be a balanced discussion of the treatment strategy, including potential risks and anticipated benefits (51). Risk can be defined as exposure to a chance of injury or loss (14). This definition contains 2 distinct components: 1) chance related to uncertain events—those that are unpredictable in any single case, but for which a probability that an event will occur in any 1 case can be estimated through statistical pooling of large databases; and 2) injury or loss, including any consequences by which the patient sustains a disability.

All physicians have a mandatory obligation to understand the medical informed consent process. Understanding the process allows for the exchange of ideas in medical practice that will yield informed, high-utility decisions while limiting the potential for negligence cases filed for lack of informed consent. Cardiac imaging with ionizing radiation has anticipated benefits and potential risks that a patient must understand to make an informed choice about whether to undergo such testing. This risk/benefit analysis is particularly important for certain subsets of patients for whom the risk may exceed the benefit.

Medical informed consent is ethically, morally, and legally mandated by the fiduciary responsibilities of the patient–physician relationship. Negligence "per se" (an automatic finding of negligence) occurs when an actor's violation of a statute or regulation causes the kind of harm the statute was intended to prevent (21,22). Physicians have a moral responsibility to identify the best treatments for each patient on the basis of available medical evidence, and to discuss with patients the anticipated benefits and potential risks. This exchange of information and ideas is the foundation of the patient–physician partnership and promotes informed decision-making in the most complex medical situations. This approach reflects physicians' ethical and moral responsibilities in patient care, and there is no easy way out.

What level of disclosure is sufficient? Historically, the "professional standard" asserted it was a physician's duty to disclose what a reasonably prudent physician with the same background, training, and experience would have disclosed to a patient in the same or similar circumstances (21–25,50,51). That standard has evolved, and now a physician must disclose "what a reasonable person in the patient's position would want to know to make an intelligent decision with respect to the choices of treatment or diagnosis" (50,51). The courts stress that "full" disclosure is neither required, nor at-

tainable, and acknowledge that: 1) the burden of identifying minimal consequences of extremely improbable risks imposes too great a burden on the physician; and 2) the patient's choice of treatment would be impaired by a litany of potential consequences. However, even though the courts have pronounced that "full" disclosure is not required (21,24), they generally have not defined how much information less than "full" disclosure will satisfy informed consent requirements (21,24). Therefore, there are no explicit directions on how to achieve the disclosure standard to which physicians must adhere to avoid liability with certainty.

Courts have attempted to provide guidance for physicians by suggesting that their duty to disclose risk increases as the magnitude of risk increases. However, the courts uniformly fail to explicitly identify the scale by which probability and severity of risks are to be measured (21–25,50,51). Serious risks (death, paralysis, loss of cognition, loss of limb, and inducement of cancer) should always be disclosed, even if the probability of occurrence is negligible. Further, less serious risks always should be disclosed if the probability of occurrence is high. Courts do not place emphasis solely on severity, but recognize probability as an important component of risk (50,51).

Medicolegal Implications of Informed Consent

A recent Wisconsin Court of Appeals decision reinforces the argument for broad application of the informed consent requirements and deserves review (12). The court analyzed this case based on Wisconsin Statute, Wis. Stat. section 448.30, which, in part, provides that "any physician who treats a patient shall inform the patient about the availability of all alternative, viable medical modes of treatment and about the benefits of these treatments."

In *Jandre v. Physicians Insurance Company of Wisconsin*, the patient was brought to the emergency department (ED) with complaints of sudden-onset drooling, slurred speech, left facial droop, dizziness, balance issues, and leg weakness. The ED physician noted left-sided facial weakness and mildly slurred speech. The physician's differential diagnosis included stroke and Bell's palsy. The final diagnosis was Bell's palsy after physical examination revealed absence of carotid bruits (which could have implied ischemic stroke) and a CT scan of the head showed no findings suggestive of hemorrhagic stroke. The patient was discharged and instructed to follow-up with his family physician. Eleven days after the ED visit, the patient suffered a stroke. Carotid ultrasound performed at that time revealed 95% stenosis of the right internal carotid artery.

A jury trial exonerated the physician on a count of medical negligence for misdiagnosis. However, the jury ruled, and the Wisconsin Court of Appeals and Wisconsin Supreme Court affirmed, that the physician violated the Wisconsin informed consent statute, and awarded a $1.8 million judgment to the patient. The Appeals Court affirmed that the ED physician's failure to inform the patient that his symptoms also were consistent with stroke, and that carotid ultrasound was available to aid in diagnostic evaluation, violated the informed consent law. Of note, the court in its judgment did not mention embolic stroke as yet another differential diagnosis for which testing was not performed. The court reaffirmed that the standard of informed consent is objective, and is defined by what a reasonable person would want to know to make an intelligent decision about testing and treatment. The court specifically noted that, because a stroke can severely incapacitate or kill, a reasonable person would want to know of a test to address the possibility of stroke to explain his or her symptoms, and to evaluate the physician's diagnosis and recommended treatment for Bell's palsy.

In Wisconsin, the state's Supreme Court decision extends the reach of the informed consent doctrine to a very broad dimension. This case could have broad implications for the diagnostic approach to patients, including disclosure of potential carcinogenicity of diagnostic medical radiation or, conversely, the possibility of failing to diagnose a dangerous condition by foregoing a radiological examination because of radiation concerns. The *Jandre* case suggests that physicians shoulder broad legal responsibility to obtain informed consent, not only for the procedure or treatment they are recommending, but also for other strategies and options for diagnosis and treatment. As fiduciary, the physician performing or supervising the procedure is legally responsible to inform the patient of the risks, benefits, and viable alternatives to obtain the best medical care.

Too Much Effort for Too Little Gain?

Because it is currently not possible to define a threshold dose of ionizing radiation or level of radiation-related cancer risk that absolutely would require informed consent, prudent physicians will obtain informed consent for all procedures that use ionizing radiation. The typical physician counterarguments that the informed consent process is too time-consuming and requires too many resources in busy medical practices, or that the risk of ionizing radiation is uncertain and detailed discussions would only confuse patients, would never endure a legal analysis, and are unlikely to prevail in a court of law.

The argument that there is no case law regarding ionizing radiation and cancer only reflects the fact that most claims are settled out of court or are tried but not appealed, meaning there is no recorded, precedential decision. The absence of case law does not imply that legal risk does not exist. The *Jandre* court found that Wis. Stat. sec. 448.30 requires a physician to inform a patient of all alternative viable modes of treatment—including diagnosis—that a reasonable person in the patient's position would want to know to make an

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intelligent decision with respect to treatment or diagnosis. A reasonable person would want to know the potential risk of cancer from the use of ionizing radiation no matter how negligible the risk, especially when alternative modes of diagnosis are available that do not carry such risk.

Elements of Informed Consent for Diagnostic Medical Radiation Use

The doctrine of informed consent demands that physicians carefully consider whether the benefits outweigh the risks when testing with ionizing radiation compared with alternative strategies for each individual patient. What do we share with patients about the risks and benefits of cardiac imaging to achieve informed consent based on the available medical knowledge? The projected probability and potential severity of risks should be emphasized candidly. Also, alternative strategies and their benefits, risks, and measured utility (the risks of testing and the probability of a benefit with the alternative strategy) versus the primary strategy should be considered. We propose that a physician acting as a patient's fiduciary frame the risks as follows:

1. The precise magnitude of risk for malignancy related to low-dose ionizing radiation is not, and may never be, known. However, to optimally protect the best interests of the patients, current radiation protection concepts are based on an assumption that any dose level of ionizing radiation can cause a malignancy.
2. At the radiation doses typically used in diagnostic medical imaging, the cancer risks patients may have heard about from mass media are based on extrapolations from survivors of the atomic bomb explosions in Japan in 1945 who experienced whole-body exposures to different types, different energies, and higher doses of radiation.
3. In a number of studies in which many subjects were followed for many years, there are no unequivocal, direct confirmations of increased risk for solid cancers related to low-dose radiation (<100 mSv).
4. Projected risks for malignancy from ionizing radiation are greater for younger than older patients and greater for women than men.
5. Cancer resulting from exposure to ionizing radiation would occur, if at all, only after a latency period of several years.

The benefits could be framed as follows:

1. For symptomatic patients, the potential benefits of imaging include establishing the presence of cardiovascular disease, which allows disease-specific therapy to improve quality of life, for example, through relief of angina symptoms. If imaging refutes the presence of cardiovascular disease, medical attention can be appropriately refocused on noncardiac conditions as the cause of symptoms. In some symptomatic patients, imaging may uncover medical conditions for which targeted treatment will improve survival.
2. Not performing a cardiac imaging study because of radiation dose concerns may carry the risk of missing a condition that could be remedied with the effect of improving quality of life or longevity.
3. In select asymptomatic patients, CT for coronary artery calcium screening may refine prediction of cardiovascular risk. However, for most asymptomatic, active patients, including those considered at high cardiovascular risk, there are no proven benefits of cardiac imaging.

The potential alternatives to disclose include nonimaging approaches such as electrocardiography, or imaging modalities that do not use ionizing radiation, such as echocardiography or cardiac magnetic resonance imaging. Their availability depends on local expertise and applicability on the clinical question at hand. Some of these alternatives may not be useful in any given clinical scenario.

Summary

Given the uncertainty regarding the carcinogenic potential of ionizing radiation at the doses used for noncontrast cardiac CT and nuclear cardiology, the prudent physician should use these imaging modalities only when the clinical benefits can be expected to exceed the risk, and when the patient understands that risk/benefit relationship and wishes to proceed.

From a legal perspective, the balanced discussion between the physician and the patient about the risks and benefits mandated by the medical doctrine of informed consent (a positive obligation) should lead to informed patients who make autonomous choices based on the best available medical information. In the specific case of cardiac imaging with modalities that use ionizing radiation, informed consent could reduce the rate of such procedures in young patients and women except in those where there are compelling, countervailing reasons why imaging is the best diagnostic choice, and in asymptomatic patients where improvement in quality of life or survival benefit by cardiac imaging are not defined.

The absence of case law on cancer risk related to ionizing radiation does not imply that no such risk exists, or that there is no medicolegal liability for the physician. Informed consent will reduce the risk of liability for physicians by carefully balancing risks and benefits and sharing them with their patients before proceeding with testing or treatment.

Acknowledgments

The authors gratefully acknowledge Barbara Danek, Joe Grundle, and Katie Klein for editorial preparation of the manuscript.

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Key Words: carcinogenic potential ■ doctrine of informed consent ■ epidemiology of ionizing radiation ■ fiduciary duty ■ risk/benefit ratio.