

Ethical considerations in CT angiography

Samuel Wann · Andy L. Nassef · Justin Jeffrey · Joseph V. Messer ·
Norbert M. Wilke · Andre J. Duerinckx · James C. Blankenship ·
Michael K. Rosenberg · Donald H. Dembo

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Abstract The rapid development and clinical deployment of CT angiography raises several important issues, including assurance of professional competence and technical quality, self-referral, the relative role of radiologists and cardiologists, appropriateness and proper indications, the detection and disposition of unexpected or incidental findings and the concern for the rapidly increasing costs of health care and imaging. These questions are properly addressed within the framework of medical ethics, including principles of beneficence, autonomy and justice.

Keywords Computed tomography angiography · Cardiovascular CT · Coronary angiography · Medical ethics

At the beginning of the 21st century, the editors of the New England Journal of Medicine deemed body imaging, including imaging of the heart and vascular system, one of the most important developments in medicine during the previous millennium [1]. The pace of development of cardiac imaging has continued to increase almost logarithmically since Wilhelm Konrad Roentgen discovered X-rays in 1895, and Sir Godfrey

S. Wann (✉) · D. H. Dembo
Wisconsin Heart Hospital, 10000 Bluemound Road,
Milwaukee 53226 WI, USA
e-mail: samuelwann@whvc.org

S. Wann
University of Wisconsin, Madison, WI, USA

S. Wann
Medical College of Wisconsin, Milwaukee, WI, USA

A. L. Nassef · J. C. Blankenship
Department of Cardiology, Geisinger Medical Center,
Danville, PA, USA

J. Jeffrey
Department of Philosophy and Parr Center for Ethics,
University of North Carolina at Chapel Hill, Chapel
Hill, NC, USA

J. V. Messer
Rush University Medical Center, Chicago, IL, USA

N. M. Wilke
Section of Cardiovascular MR/CT, University of
Florida – Jacksonville, Jacksonville, FL, USA

A. J. Duerinckx
Forsyth Radiological Associates, Lewisville, NC,
USA

M. K. Rosenberg
WPS Insurance Company – Medicare Part B,
Southfield, MI, USA

D. H. Dembo
Johns Hopkins Cardiology at Timonium, Easton, MD,
USA

Hounsfield and Alan Cormack invented computed tomography (CT) in 1972 [2]. All received Nobel Prizes for their work. Little wonder then that cardiologists and radiologists are excited about the most recent developments in multi-detector CT which provide the superior temporal and spatial resolution needed to non-invasively image the coronary arteries and other cardiovascular structures. They are eager to add CT to their already powerful diagnostic imaging armamentarium, which includes echocardiography, nuclear cardiology, cardiovascular magnetic resonance and intra-arterial angiography.

Phenomenal technologic advances, including those in medical imaging, are causing profound changes in the environment of medical practice, and bring with them new ethical challenges. Physicians' expectations and those of society are high, and have led to instability in the fundamental organization of the medical profession as economic, political and social realities continue to encroach on our professional autonomy. In this milieu, responsible cardiologists and radiologists and all physicians must remain true to their ethical and moral obligations to their patients and to society.

The scope and power of CT magnifies conflicts present in the use of other imaging modalities, and in other areas of medicine, and poses several specific ethical challenges. These issues should be addressed openly and widely within the profession, seeking cooperation and thoughtful resolution in order to avoid weakening our professional foundations of self-determination and self-policing, and reducing the trust we are granted by our patients and the public [3, 4].

Ethical concerns related to CT angiography can be discussed within a framework of the common ethical principles of beneficence, autonomy and justice [5]. These principles, which may conflict with one another, are embraced by both radiologists and cardiologists [6, 7]. Beneficence requires physicians to always act in the best interests of their patients, not for the primary benefit of the physician or others. The principle of autonomy guides physicians to respect a patient's right to self-determination and to honor their wishes in choosing a particular course of action. The principle of justice guides physicians to

provide patients with the care to which they are entitled, insuring that all patients are treated equitably and that medical resources are distributed fairly.

1 Competence and technical quality—professional autonomy and external regulation

Complex and overlapping structures have been created over the last 100 years to fulfill our responsibility to deliver safe and effective care, including the use of CT. Recognizing their responsibility to protect the public from unqualified practitioners, the American College of Radiology [8], the American Heart Association and the American College of Cardiology [9] have published detailed statements on the requirements for physicians to achieve competence in cardiovascular CT. These guidelines, formed by respected experts in the field and based on limited existing evidence in a new and rapidly expanding field, are being implemented by hospital medical staff organizations and others who issue credentials to physicians to use CT angiography equipment and to report findings on these images. The American College of Radiology also accredits CT imaging programs. The American Registry of Radiological Technology certifies radiology technologists who operate CT machines. The Joint Commission for Accreditation of Health Care Organizations and others accredit institutions providing CT angiograms. The National Association of Electronic Manufacturers Association guides its industry members in manufacturing, safety and ethical standards. The Federal Food and Drug Administration regulates the manufacture and sale of CT machines and monitors the safety of these devices. State laws govern access to diagnostic X-ray equipment.

Ethical practitioners comply with the rules, regulations and recommendations of these regulatory and advisory bodies. The principle of beneficence dictates that an imaging procedure should only be performed (a) by a properly qualified physician who can safely supervise and accurately interpret the examination, (b) using protocols that maximize diagnostic yield, but

minimize patient risk and limit exposure to potentially harmful ionizing radiation, (c) for the primary benefit of the patient, not for the benefit of the physician or others, (d) for appropriate indications and in the context of the individual patient's overall condition and needs for medical diagnostics and therapeutic decision making.

Compliance with these rules and regulations can be time consuming and expensive, adding to the cost of care and decreasing its availability. Regulatory bureaucracy tends to self-perpetuate and self-expand and may not always be well focused on the desired goal of protecting patients and assuring quality care. Excess regulation can limit patients' access to needed care, and reduce their autonomy. Restrictions such as state issued "certificate of need" permits may be created primarily to limit expenditures by limiting patients' opportunities to receive care, or to protect the economic interests of certain groups of physicians or hospitals, regardless of safety or efficacy of the care delivered. In these circumstances, ethical principles conflict with one another. The principle of justice supports equal access to care by all patients and directs that resources be allocated primarily based on patient need, rather than patient choice or the needs of individual physicians, physicians' offices, hospitals and other health care institutions, governmental bodies or insurance companies.

Regardless of how and where service is provided, cardiologists and radiologists need to work together to insure that professional guidelines are realistic and not unduly restrictive, and that legislation and regulations protect rather than harm patients [10].

2 Self-referral

Self-referral is a controversial, highly charged and complex subject which is particularly relevant to the current development of CT angiography. While radiologists generally image patients only on the request of other physicians, cardiologists often image their own patients (self-referral), leading to concern about conflict of interest and the potential for abuse by those who might place

personal financial gain before the best interests of the patient [11–16]. Radiologists believe that they bring not only focus and the benefits of highly specialized training to CT angiography, but that they are also more objective in its application, since they do not order examinations on individual patients and are thus free of self-referral bias. When reporting imaging results, radiologists often suggest additional imaging procedures and clearly have influence on the ordering of studies which bring them additional revenue. Radiologists also have a financial disincentive for refusing to perform imaging procedures ordered by other physicians.

The American College of Radiology Code of Ethics states "The practice of physicians referring patients to health care facilities in which they have a financial interest is not in the best interest of patients. Self-referral may improperly influence the professional judgments of those physicians referring patients to such facilities [6]." The American College of Radiology takes a clear position that ethical physicians should not refer patients for imaging to facilities in which they have an ownership interest. Radiologists believe they themselves can avoid conflict of interest, even if they own an imaging facility, by segregating the imaging procedure from ongoing direct care of patients and the ordering of imaging procedures.

Cardiologists, on the other hand, believe it is advantageous to their patients to incorporate advanced imaging techniques, including CT angiography, into their practices in the same fashion that they have used electrocardiography, cardiac fluoroscopy, cardiac catheterization, nuclear imaging and echocardiography to care for their patients. Imaging has become an integral part of cardiology practice, taking its place along side the history and physical examination.

Aware that potential conflicts of interest are inherent in many aspects of medicine, not just imaging, Dr. William Parmley, a former President of the American College of Cardiology, made a seminal observation concerning self-referral: "At issue is the question of intent; if the intent (of self-referral) is to provide excellent medical care, the practice is laudable. If the intent is to subjugate medical decision-making, then the practice is

unethical [17].” Self-referral and conflicts of interest are inherent in many areas of medicine other than imaging, including both the surgical and cognitive specialties. Conflicts of interest are not in themselves unethical.

Cardiologists believe that close integration of imaging into the context of direct patient interaction provides great value. While personal familiarity with the patient and his or her medical history and physical examination, knowledge of ancillary laboratory findings, the responsibility for making clinical decisions and a continuing relationship with the patient may create conflicts of interest, that same comprehensive contact can also be used to better serve the patient [18–20].

Several approaches have been suggested as means to reduce concerns about inappropriate self-referral, including (a) use of evidence-based guidelines, (b) physician and laboratory credentialing, (c) periodic case conferences, (d) oversight/review processes, (e) consultation with other providers, (f) full disclosure/transparency and discussion with patients regarding alternatives, including an option for a second opinion.

Independent of the ownership of the equipment used to perform CT, cardiologists and radiologists alike benefit financially when they supervise and interpret CT angiograms. When more studies are interpreted, greater direct or indirect financial benefit generally accrues to the individual supervising and interpreting the study, or to his or her practice organization or institution. As discussed above, it is unethical for a cardiologist to refer a patient to himself for CT angiography to profit from his ownership of the CT equipment. It is also unethical for a cardiologist or radiologist to charge a fee for supervising and interpreting a CT angiogram (with no ownership of equipment) performed on a patient referred by an independent physician, if that patient will not benefit from the procedure. It is the responsibility of the physician who supervises and interprets the CT angiogram to assist and educate referring physicians, and to screen all patients referred to insure that the examination is being performed for appropriate indications.

Conflicts of interest and self-referral are pervasive issues in modern medicine, not limited to the simple example of a physician owning imaging

equipment in his or her own office. A recent study of for-profit enterprise in health care by the Institute for Medicine of the National Academy of Sciences [21], found that the organizational structure of health care in not-for-profit as well as for-profit institutions has become exceedingly complex. Exclusive contracts, steering of referrals from employed primary care physicians, payments for management services, economic credentialing, managed care incentives, pre-certification, gain sharing arrangements with hospitals, and income sharing in group practice and integrated health care settings can be used to motivate physicians to order or not to order imaging procedures, without personal ownership of imaging facilities or overt self-referral. Some of these incentives are proper and desirable, while others do not serve patients’ best interests.

It is safe to predict that conflicts of interest will be of continuing concern to all physicians as medical practice and the health care enterprise continue to evolve.

3 Proper indications

One might think that many of these potential conflicts of interest could easily be resolved if CT angiography were always performed only for proven appropriate indications. Unfortunately, there are many degrees of appropriateness. The kind of prospective, randomized, double-blinded, controlled trials which bring the greatest scientific rigor to medical practice are applicable only to a fraction of the decisions that are made on a continuing basis in clinical medicine. Evidence of imaging efficacy and impact on patient outcome may be more difficult to collect than data supporting the use of a new pharmaceutical or device, but research to more precisely refine the role of CT angiography is ongoing. Hard data are being sought to support clinical decisions. Appropriateness is an evolving concept.

As evidence defining the clinical utility of CT angiography accumulates, the American College of Cardiology [22, 23] and the American College of Radiology [8] continue to develop up to date, formal standards, guidelines, appropriateness criteria, and performance measures for the use of

CT angiography in clinical practice. This is an extremely valuable contribution and an essential function of our professional organizations.

Well established review processes, including modifications of the Delphi technique and expert opinion as well as published data and guidelines are being used to quantitatively assess the benefits and risks associated with the emerging technologies such as CT angiography. The resulting “appropriateness criteria” are expected to be useful for clinicians, health care facilities and third-party payers committed to delivering high quality, effective cardiovascular care. Insurance companies are already making coverage decisions for this expensive technology based on limited scientific data [24].

Physicians practice an inexact science, with few absolutes. To function effectively, practitioners must make a series of choices based on imperfect data, often designed to achieve indistinct outcomes, a far different milieu than that of most clinical trials. It is not inherently unethical to perform CT angiography in the absence of solid evidence of its benefit so long as thoughtful boundaries are set and parameters designed to seek maximum patient benefit are followed. These steps might include (a) identification of patient subsets in which current practice guidelines are limited, but in which CT angiography is of logical benefit, (b) correlation of risk/benefit for individual patients compared to currently accepted patient diagnostic strategies, and (c) ongoing review of the results of different cardiac imaging strategies within one’s own group or practice community, including oversight and consultation with other providers [15]. Proper indications for the use of CT angiography will continue to evolve as the technology is applied in the clinical setting. Ethical practitioners will stay abreast of these refinements and modify their practices accordingly.

4 Incidental findings

The multi-slice CT technology used to produce angiographic images generates a volumetric data set which can also be processed to produce high resolution images of non-vascular structures.

Although the field of view for CT angiography is typically limited to focus on the body part containing the vascular structure of interest, data is also obligatorily acquired from contiguous non-vascular structures through which the X-ray beam passes through the body.

CT angiography thus routinely produces literally 1000’s of high definition images that may contain a myriad of unsuspected but potentially important non-vascular abnormalities. How to process, interpret, report and act on incidental findings uncovered during the course of performing CT angiography remains controversial. When addressing this controversy in the context of medical ethics, the principles of beneficence, autonomy and justice may conflict. Clear benefit may accrue to patients when certain unexpected abnormalities are detected and dealt with, but in other cases the detection of an unexpected abnormality may not lead to an improved outcome, and can cause anxiety or physical harm from unanticipated evaluation and treatment. The patient may lose autonomy, pressured by fear to engage in further diagnostic and therapeutic procedures of uncertain value. Physicians too may act from fear rather than objective analysis when the possibility of cancer or another hidden condition is even raised. Just distribution of medical services may thus be impeded when resources are diverted to detection and follow up of abnormalities which were not suspected or sought.

Abnormal findings in the lungs pose a particularly difficult dilemma. Lung cancer shares many common risk factors with cardiovascular disease, and is second only to cardiovascular disease as a cause of death in the patient population usually undergoing CT angiography. Small lung nodules of indeterminate but potentially malignant etiology can be readily identified on CT examinations performed primarily to detect coronary disease [25]. However, the utility of CT in detecting lung cancer at a point early enough in its natural history to prolong life or relieve suffering remains unproven, even in trials whose primary purpose was to screen high risk populations for lung cancer, not to detect heart disease [26–30]. The inter- and intra-observer variability in detecting these small nodules is high [31]. The use of CT to

screen for lung nodules, similar to the use of mammography for detecting breast nodules, may be time consuming and requires special expertise and dedication. Computer assisted diagnostic algorithms are being developed to aid in analysis of these images and to improve this potentially important application of CT.

Follow up of an unexpected lung nodule often entails repeated CT examinations that would not have otherwise been performed, and even invasive diagnostic procedures including bronchoscopy, lung biopsy and lung resection, all of which entail significant risks of morbidity and mortality. Because of these potential risks and uncertain benefit, neither the U.S. Preventive Health Task Force nor the American College of Radiology have yet endorsed widespread use of CT as a screening test for lung cancer [32–34].

CT angiography performed as a diagnostic test for cardiovascular disease may thus have the unintended consequence of identifying a lung nodule of uncertain etiology, or other non-vascular pathology, for which limited data exist to guide further diagnostic or therapeutic interventions which offer clear benefit to patients. Radiologists and cardiologists may differ in their approaches to these non-vascular findings. Based on a combination of perspective, habit, training, professional ethics and legal considerations [35], radiologists strive to report in detail all abnormalities present on any given image, make recommendations for further diagnostic imaging procedures which might be considered, often serial lung CT scans, and return continuing responsibility for dealing with abnormal findings to the referring physician.

Cardiologists, on the other hand, focus on the original intent of the diagnostic CT angiogram, and may lack the expertise to detect subtle non-vascular abnormalities, or the clinical interest in pursuing diseases outside the cardiovascular system. This can deprive patients of the benefit of detecting important unexpected non-vascular abnormalities on a CT angiogram which the patient may wish to know about, and which may provide benefit to the patient. Recognizing their overlapping skill sets, some cardiologists and radiologists interpret CT angiograms as a team, deferring to one another various aspects of

interpreting a single CT volume acquisition. Recently published training guidelines from the American College of Cardiology, the American Society of Nuclear Cardiology, the Society of Cardiovascular Angiography and interventions, the Society of Atherosclerosis Imaging and Prevention, and the Society of Cardiovascular Computed Tomography endorse education and training of all individuals interpreting CT angiograms in the recognition of incidental non-vascular abnormalities [36].

Further experience and careful thought is needed to clarify the manner in which CT angiograms are analyzed for non-vascular abnormalities. There is precedence for other imaging modalities including ultrasound, nuclear cardiology, cardiovascular magnetic resonance and cardiac catheterization to look for and report only major and fairly obvious abnormalities unrelated to the vascular system. For instance, we do not expect diagnostic information about the thyroid on a report of a carotid ultrasound, or detailed information about the lungs on images obtained at cardiac catheterization. We have a long tradition of targeting imaging procedures based on the results of existing clinical data rather than broadly casting an imaging net to screen for unsuspected, or unimportant, abnormalities.

It seems clear that cardiologists, radiologists and other physicians must work together to deliver maximal benefits and avoid untoward outcomes in patients undergoing CT angiography. More experience and further research is needed to clarify the patients' best interests in detecting, reporting and dealing with incidental, non-vascular findings on coronary CT angiograms. These incidental findings cannot simply be ignored. Principle V of the AMA Code of Ethics is apropos: "A physician shall continue to study, apply and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patient, colleagues and the public, obtain consultation, and use the talents of other health professionals when indicated [37]."

Defensive medicine and fear of malpractice lawsuits undoubtedly fuels the ordering of many diagnostic tests and has changed the behavior of both cardiologists and radiologists [38]. The ethical principle of beneficence provides

important guidance to physicians as they consider recommends for serial CT examinations with the attendant exposure to significant doses of ionizing radiation for marginal non-cardiac findings. This principle requires that all imaging studies, including follow-up examinations, should be obtained only if to help the patient, not to protect the physician or the institution. The ethical principle of justice requires that limited resources not be wasted.

4.1 Advertising

Physician advertising is legal under the Federal Trade Commission Act and is ethically permissible so long as the material is not misleading and communicates key issues in a truthful and comprehensible manner [39]. Advertising by hospitals, clinics, and free-standing imaging centers as well as by individual physicians and physician practices has become pervasive. Concern has been raised about the impact of direct-to-the-consumer advertising on utilization of specific services, often those which are most profitable, the appropriateness of care given, and issues of self-referral [7].

Advertising for imaging services including CT angiography is largely unregulated. To best avoid ethical lapses, advertising should be purely informational in nature. Hyperbolic promotion of CT angiography should be avoided. The availability of alternative imaging options should be acknowledged and the need for professional input into selection of the best approach for each individual patient should be stressed. Advertising should not be directed at attracting customers primarily for the economic benefit of the advertiser, rather than to legitimately promote a health benefit for the consumer. The overall impact of advertising on health care deserves more attention to assure a proper balance is achieved between patients' autonomy and the desire for justice, and with that, society's need to conserve resources so that appropriate medical care is available to all.

4.2 Cost

CT angiography is an expensive procedure. Under the ethical principle of justice, physicians

should consider the impact of the cost of treating one patient on the ability to treat other patients. A physician's paramount responsibility is care of the individual patient, but we must strive to create a system in which *all* patients have access to medical care. The practice of evidence based medicine and thoughtful deployment of expensive and limited resources is part of this commitment.

CT angiography enters the arena at a time when the rate of utilization of all imaging including cardiac procedures such as echocardiography, nuclear cardiology and coronary angiography, has already expanded dramatically [40–46]. For example, the overall rate of utilization of radio-nuclide myocardial perfusion imaging in Medicare recipients increased 19.1% from 1996–1998. Much of this increase occurred in the outpatient imaging performed by cardiologists [44]. Lesser increases were seen in inpatient nuclear cardiology imaging, which is more often performed by radiologists. No data have been presented regarding the appropriateness of this increased testing by cardiologists, but we must address the perception that this dramatic increase in utilization is driven as much by economics as by patient need. The ethical principles of beneficence, justice and autonomy may conflict when applied to this issue. Patients should have the opportunity to choose to have an appropriate diagnostic test performed proficiently in the setting of their choice, by the physician of their choice. But justice requires restraint, so that appropriate services are available to all. Autonomous patients do not have a right to undergo any test they want, nor do physicians have the right or responsibility to order tests indiscriminately.

There are many conflicts of interest which directly effect further development and wide application of CT angiography, but which only indirectly involve patients and physicians. Third party payers, many of them highly profitable enterprises, and their customers, the employers who pay for much of the health care delivered in the United States, have conflicting interests to reduce costs, while continuing to provide reasonable quality of medical care [45, 46]. As the costs of medical care continue to escalate, CT angiography will be under particular scrutiny from third party payers. The level of evidence required

before providing insurance coverage will be higher than has previously been required for other procedures. Cardiologists and radiologists should work together to provide this evidence so that the highest benefit and the least cost can accrue to all our patients.

In the age of market driven health care, physicians are expected to recommend the best treatments, provide a wide range of services and improve patients' quality and quantity of life, but at the same time limit use of expensive services, increase efficiency and comply with a myriad of insurance company rules designed to reduce utilization of services and save money. In the managed care environment, physicians are given incentives *not* to provide care and may be forced to choose between the best interests of their patients and their own continued employment [47–49].

Acknowledging the conflict between the desire to provide unlimited care and the reality of finite financial resources, physicians must be intimately involved in efforts to reduce excessive testing, to properly deploy new technology and to improve the cost-effectiveness of care.

5 Conclusions

Ethical principles outline ways to act properly in a world where error, imperfect outcomes and conflicts of interest are the norm. A central theme is always to ask which approach provides the most good for the patient, what the patient's wishes are and how medical resources can be distributed fairly to society as a whole. Applying these principles of beneficence, autonomy and justice and the discipline of ethical analysis to medicine does not guarantee avoidance of error in decision-making. Nor does it eliminate conflicts of interest or nullify the inherent conflict in developing precise guidelines for the use of new technology in the absence of pre-existing, irrefutable evidence of benefit.

Physicians should participate in the evolution of CT angiography primarily as patient advocates. Cardiologists and radiologists should work together to provide the level of evidence needed to fully and properly deploy this exciting new technology to help patients. Multiple conflicts of

interest should be acknowledged and dealt with in a thoughtful and constructive manner. Government and other payers and their intermediaries should be encouraged to avoid overly simplistic solutions which detract from patients' rights and impede physicians' ability to deliver high quality care. Industry must receive proper incentives to develop better, safer equipment. The capabilities of CT angiography should not be exaggerated or applied injudiciously.

As we physicians serve all society and strive to deliver benefit to each of our autonomous patients, we should recall that respect for life, competence, compassion, politeness and non-discrimination have been among the most important elements of the ethical practice of medicine from ancient Greece and Asia until modern times [50]. These principles guide us well in the development of CT angiography.

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