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VIEWPOINT AND COMMENTARY

Computed Tomographic Angiography

More Than Just a Pretty Picture?

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There is increased interest in and use of cardiac computed tomographic and magnetic resonance imaging as the technology continues to improve. We have many small single-center trials on the diagnostic accuracy of these techniques, but no studies that show a patient benefit from testing. The American College of Cardiology has recently tackled the "appropriateness challenge" for imaging tests, including computed tomographic and magnetic resonance imaging. The importance of outcomes data and risks of continuing our investment in computed tomography without outcomes data on benefits for patient care are discussed in this paper. (J Am Coll Cardiol 2007;49:1827–9) © 2007 by the American College of Cardiology Foundation

With headlines such as "How New Heart-Scanning Technology Could Save Your Life" on a recent *Time* magazine cover (1), and spirited marketing by scanner manufacturers and the clinics that use them, it is no wonder that the volume of cardiac imaging tests is increasing at an exponential rate. As Oprah Winfrey has shown on national television (2), computed tomographic (CT) imaging can take beautiful pictures, and even create 3-dimensional reconstructions of the heart. In light of the explosive growth of CT, it is appropriate to ask whether these pictures lead to better patient care and outcomes. In this case, despite the assertion of *Time* that this "new test can prevent heart attacks," there are no data showing that a CT scan (or any test for that matter) can prevent a heart attack (3).

From 1993 to 2002, the number of cardiac imaging tests increased 26% per year (4). In the same time period, Medicare spending for imaging services paid under the physician fee schedule grew over 60%, from $5.7 to $9.3 billion. The volume of CT scans of parts of the body other than the head increased 82% from 1999 to 2003 per Medicare beneficiary (5). This staggering increase in imaging costs also has attracted a lot of attention, especially from those who pay for health care. What value are we getting for these expenditures? It is important to know whether these increased expenditures for imaging tests lead to incremental diagnostic or prognostic information or to improved patient outcomes.

The increase in cardiac imaging has led to a call for evidence-based guidance on appropriate use. The American College of Cardiology (ACC), in furtherance of its mission to advocate optimal patient care through the development and application of clinical practice guidelines, has taken on this "appropriateness challenge," as described in an October 2005 article by Patel et al. (6). In introducing its appropriateness initiative, former ACC President Michael Wolk explained that, ideally, criteria for appropriateness should encompass "cost effective" and "benefit versus risk" analysis of available care alternatives, and should be simple, reliable, valid, and transparent (7). Patel et al. (6) agree that Appropriateness Criteria (AC) preferably should be based on high-quality research comparing benefits and risks for common clinical scenarios, but they also recognize that "in the absence of ideal evidence," judgments still must be made.

In deriving its recommendations, the ACC used a method for evaluating appropriateness based on work by RAND, which pioneered "appropriate" methodology in the 1990s when it convened expert panels to define appropriateness of use of coronary angiography (CA) (8) and coronary artery bypass grafts (9). Using a similar approach, the ACC, when necessary, uses expert opinion in lieu of evidence of benefit when formulating AC. In February of 2006, with the expanding use of CT and magnetic resonance (MR) potentially outpacing data showing its clinical benefit, a committee of the ACC evaluated computed tomography angiography (CTA) under its AC.

Most importantly, we must understand how the data obtained from CTA will change patient management and/or lead to better outcomes. There are claims, for example, that CTA will act as a gatekeeper and reduce invasive angiography rates. However, as of yet, there are no data to support this hypothesis. The new AC applied to CTA found that use of cardiac CT/MR for structure and function and for diagnosis in symptomatic patients at intermediate risk for coronary artery disease is appropriate, but repeat testing and general screening uses were viewed

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Abbreviations and Acronyms

AC = Appropriateness Criteria

ACC = American College of Cardiology

CA = coronary angiography

CT = computed tomography

CTA = computed tomography angiography

MR = magnetic resonance

less favorably (10). Moreover, because symptomatic patients with coronary artery disease probably will be referred to CA for possible stent placement, it does not seem likely that CTA will reduce the number of coronary angiographies.

A major concern is that CTA instead will be used in asymptomatic, low-risk patients, as suggested by the *Time* cover story and Oprah Winfrey's show. Before CTA, this population generally would not have been (directly) referred for CA. However, after a CTA, the portion of this group with positive findings, whether true-positive or false-positive, very likely will be referred for angiography. For true-positive results, patients will get a percutaneous coronary intervention or coronary artery bypass graft, and for false-positive results, patients will undergo unnecessary invasive testing. However, there currently are no data showing benefits of revascularization for asymptomatic patients. Indeed, percutaneous coronary intervention's major benefit has been symptom relief, which obviously is not relevant for asymptomatic patients. Moreover, percutaneous coronary intervention has not been shown to prevent myocardial infarction or to decrease mortality. Similarly, there have been no studies showing the benefit of coronary artery bypass grafting for asymptomatic patients.

Proponents of CTA argue that the latest scanners now provide more detail and sharper images than ever. More information, however, even if accurate and more precise, is not necessarily better. The real value of any diagnostic procedure derives not from its ability to give more information, but from whether it suggests a better course of treatment than the physician would have recommended anyway. As for CTA, many studies support to some extent the technology's accuracy and precision, but do not yet show that CT leads to improvement in patient care over better-studied noninvasive diagnostic techniques.

The current data on CTA generally involve comparisons with CA as the reference standard. Such data on diagnostic accuracy are a necessary first step for any new imaging test. The data on all CTA studies were summarized in the spring of 2006 by the Duke Evidence-Based Practice Center for use by the Medicare Coverage Advisory Commission (11). The investigators note that there were only 4 studies of coronary CTA with 16-slice CT that prospectively enrolled more than 100 patients, all single-center studies. There were 6 studies of CTA using 64-slice CT, all single-center studies and with fewer than 100 patients. In their data summary on CTA, the Duke investigators note that the analysis by coronary segment showed sensitivity estimates between 30% and 99% and specificity estimates between 91% and 98%. The patient level analysis reports sensitivities from 85% to 100% and specificities between 49% and 98%. However, these studies excluded inevaluable segments and patients with poor quality images from analysis, which inflated accuracy estimates. In some of the studies, patients were prescreened to be sure they could hold their breath for 20 to 25 s before enrollment.

The largest and first multicenter study of multislice CT to date was published in July 2006, after the Duke summary was written. The 11-site, 238-patient study found a high percentage of inevaluable scans and false-positive results. Of 1,629 nonstented segments evaluated, 427 were inevaluable, and there were 96 false-positive results (12). After censoring all inevaluable segments as positive, the sensitivity for detecting more than 70% luminal stenoses was 94%, specificity 67%, positive predictive value 6%, and negative predictive value 99% in this study.

Although CTA is noninvasive compared with CA, it is not without risks. The estimated radiation dose for a 16-slice CT scan is between 4 and 16.3 mSv depending on whether electrocardiographic pulsing is used and on the gender of the patient (radiation doses are higher in women) (13). For 64-slice CT scans, the radiation dose is higher, between 4.8 and 21.4 mSv. Comparatively, for CA the radiation dose is 5.6 mSv (14). There is a risk of nephrotoxicity from the contrast agent used, and one must consider that often it is necessary to administer intravenous beta-blockade at the time of the study, because the heart rate should be <60 beats/min for imaging. Finally, there is the thorny issue of incidental findings. Such incidental findings, estimated to occur in 5% to 50% of studies, may or may not be important, but can take a toll on patients.

Unquestionably, imaging tests such as CT and MR provide pictures that generally are accurate and, some would say, beautiful. As physicians, however, our goal is to help people feel better and to live longer, and information is helpful only to the extent that it furthers this goal. Although physicians may disagree about the extent of our responsibility (and ability) to control health care expenses—a subject for another debate—we can at least distinguish between procedures that provide useful additive information and those that do not.

We now need to put this additional information into the wider context of outcomes. Key questions to be asked and answered before adopting widespread use of CTA (or any new technology) include: 1) What is the incremental value of the information from this new test compared with existing standard assessments (such as office evaluation and risk factor assessment or stress imaging)? 2) What incremental information is offered by this new test? 3) How will the incremental information lead to a change in treatment? and finally, 4) Will the change in treatment, based on this test, lead to better patient outcomes? Until we answer yes to the last question, studies of diagnostic accuracy must be regarded as important first contributions to our understanding of a new technology, but not sufficient to change clinical care or guidelines.

The ACC has taken a leadership position in this new environment. The ACC is working hard on steps to ensure quality imaging (15). The new Appropriateness Initiative currently is addressing the optimal use of imaging tests in cardiology. However, at the 2006 ACC Convocation, Steve Nissen advised cardiologists to temper their enthusiasm for emerging technologies such as imaging with judgment: "New imaging modalities give us a clearer picture of the heart and vascular system than ever before," Dr. Nissen said. "But what may be useful and beneficial is still evolving. Our infatuation with technology can be wonderful, but it is costly and must be used appropriately." It is important that cardiologists remain in the forefront not only of acquiring new information, but also of understanding how to use it to improve patient care. Otherwise, we are just paying extra for pretty pictures, without getting patient benefit.

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