Clinical Decisions Based on Cost-Effectiveness as Well as Efficacy

Physicians Debate Role of Imaging Modalities in Coronary Artery Disease

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Physicians who specialize in seven noninvasive imaging modalities examined their role in clinical decision-making for coronary artery disease (CAD) during a symposium held September 9–10 in Washington, DC. Sponsored by The Society of Nuclear Medicine and the American College of Nuclear Physicians (ACNP), the meeting also covered cost reimbursement policies and the methodology of clinical decision analysis.

Ischemic heart disease was responsible for 566,900 deaths in the United States in 1980, at a total annual cost of $56 billion, said H. William Strauss, MD, director of nuclear medicine at Massachusetts General Hospital in Boston. He noted three objectives in the detection of CAD: (1) to restore the patient to health, (2) to prevent infarction, and (3) to make an accurate prognosis.

Clinical decision analysis needs to be addressed now because members of the medical community are questioning the fundamental philosophy that more health care is equated with good health care, said Dr. Strauss, co-chairman of the symposium program committee. "The new concept, which is now raging in the literature, is that more care may be of no demonstrated value," he explained.

According to Ismael G. Mena, director of nuclear medicine at the Harbor-UCLA Medical Center in Los Angeles and cochairman of the symposium program committee, clinical decision-making in CAD is an important topic to address because "the explosion of new noninvasive technologies can easily lead to duplication of diagnostic efforts that in many cases are difficult to justify economically. The goal of this meeting should be to reduce the number of procedures performed in a specific patient maximizing the data from a single test."

"In the area of cost containment," explained Dr. Mena, "the use of noninvasive procedures in the emergency department of our hospitals should provide identification of patients suspected of myocardial infarction, but with low likelihood of disease, who could be monitored on medical acute wards rather than in the coronary care unit, resulting in considerable cost savings."

Cost-effectiveness

According to Dr. Mena, "The role of nuclear medicine in evaluating coronary artery disease is unsurpassed in its cost-effectiveness and relevance of results."

In addition to the efficacy of various diagnostic tests, clinical decisions today also depend on economic factors, such as the cost of procedures and reimbursement policies of third-party payers.

Representing the Blue Cross/Blue Shield Association, David Tennenbaum noted that in the past, third-party payers reimbursed for new technologies almost immediately after they were introduced. "With the pressure today to contain insurance premiums, however, Blue Cross/Blue Shield does a more critical analysis of new technologies," he said, which delays their wide-spread use in the health care system.

Literature lacks data

"There is no lack of information in refereed journals on the capacity of noninvasive diagnostic procedures to image the heart and assess cellular metabolism. What is lacking, which causes us some difficulty, is information regarding the implications of that capacity and its effect on patient management," said Mr. Tennenbaum.

Jane Sisk, PhD, of the congressional Office of Technology Assessment (OTA), described the use of a cost-effectiveness technique for evaluating medical technologies. She gave nu-

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clear magnetic resonance (NMR) as an example of a sophisticated new technology which the medical field is accepting "before evaluating its efficacy and appropriate role relative to alternative technologies."

Cost-effective analysis is intended to evaluate the efficient use of limited resources in the health care system. "It compares the difference in health benefits and medical expenditures, and the cost-effectiveness ratio represents the net cost per unit of net effectiveness," said Dr. Sisk.

Budgetary motives in Congress

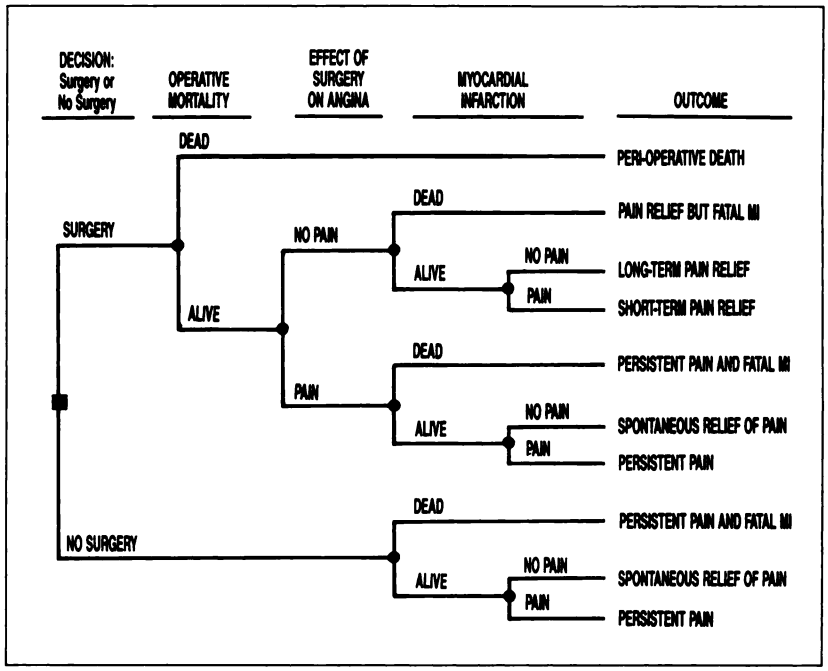
Donald W. Moran, a former executive associate director at the Office of Budget and Management (OMB), cautioned against trying to address major health care issues at a time when "Congress is making policy based solely on cost.

"We might all sit back for six to 18 months and fashion an internally coherent solution so that by the time Congress is out of its budgetary binge and ready to do health policy again, we might have some health policies worth considering," said Mr. Moran.

According to Enrique Carter, MD, director of the Office of Health Technology Assessment (OHTA), "Never before has there been a greater need for cooperation and collaboration on the part of health care providers, government, third-party reimbursers, and manufacturers in establishing determinations concerning the safety and clinical effectiveness of emerging medical technologies." The OHTA evaluates medical procedures for the Health Care Financing Administration (HCFA), which controls Medicare and Medicaid reimbursement.

Methodology of decision-making

Several physicians outlined variations and enhancements of Bayesian methodology. Michael L. Goris, MD, PhD, professor of radiology in the nuclear medicine division at Stanford University Medical Center in California, said that Bayes's theorem is useful if one knows its limitations and the interdependency of some CAD symptoms, said Dr. Goris.



An example of a decision-making tree for CAD. The decision between surgical and medical therapy is denoted by a square node. The circular nodes denote chance occurrences. **(Reprinted with permission from Pauker SG: Coronary artery surgery: The use of decision analysis. *Ann Intern Med* 85:8-18, 1976)**

Referring to the emphasis on diagnosis instead of on determining accurate probabilities of the effects of various treatment procedures based on diagnostic test results, Dr. Goris said, "We're defining people as having CAD when, in fact, we have defined almost nothing. We spend millions of dollars and we still don't know the value of coronary bypass surgery."

"Many aspects of clinical decision analysis seem to classify people the way 19th-century scientists classified bugs, a sort of taxonomy of patients. When physicians place a patient in some category that can be named properly, they think they have made a diagnosis. What we should be doing is an inclusive evaluation of existing CAD data so that we can learn something about survival rates and effects of therapy, and the name of the disease doesn't matter at all," said Dr. Goris.

Aids in cost reduction

F. Tim deDombal, MA, MD, FRCS, reader in clinical information science at the University of Leeds in England, presented step-by-step guidelines for developing a decision support system.

A decision support system can aid in cost reduction. "Simplistically, we can stop admitting patients unnecessarily to the intensive-care unit," said Dr. deDombal.

Ironically, the sophisticated statistical analysis reaffirms the value of traditional medical practices such as taking detailed histories, he added, because of the importance of assigning accurate probabilities to patients early in the clinical strategy.

Finally, these analytical systems can form the basis for standard clinical trials to ensure that the risks of two study populations are standardized, said Dr. deDombal.

Barbara J. McNeil, MD, PhD, professor of radiology at Harvard University, gave an overview of the various parameters of cost-effectiveness. Physicians need to determine diagnostic probabilities for each branch of the clinical decision-making tree, and then introduce cost factors.

Identifying trade-offs

"We have to indicate the trade-off in dollars that we are willing to spend to achieve that particular trade-off in health benefits," said Dr. McNeil, who is also a member of the Prospective Payment Assessment Commission (ProPAC), an advisory body to the congressional Office of Technology Assessment.

The second day of the symposium covered the efficacy and cost-effectiveness of seven noninvasive cardiac imaging modalities: thallium planar imaging, thallium single-photon emission computed tomography (SPECT), ventriculography, positron emission computed tomography (PET), nuclear magnetic resonance (NMR), cine x-ray computed tomography (CT), and echocardiography.

Thallium-201 planar imaging

Daniel S. Berman, MD, director of nuclear cardiology at Cedars Sinai Medical Center in Los Angeles, presented data on thallium-201 stress redistribution imaging. Over the past 10 years more than 1 million planar thallium scans have been performed on cardiac patients, said Dr. Berman, rendering a substantial clinical database. Stress-redistribution thallium-201 scintigraphy for CAD detection has a sensitivity of 85 percent and a specificity of 90 percent, said Dr. Berman, and the test is best used for patients with an intermediate likelihood of CAD.

The number of segments that show a thallium-201 perfusion defect can also indicate the extent of CAD. In addition, explained Dr. Berman, quantitative thallium-201 scintigraphy has significantly improved standard planar imaging by detecting abnormal zones that manifest washout abnormality without initial perfusion defect. "The severity of stenoses can also be gauged by thallium-201 imaging. This capacity to assess extent and severity of CAD has led to reports of profound prognostic potential of thallium-201 imaging," said Dr. Berman. For prognostic purposes, the thallium scan is best utilized in patients with an intermediate likelihood of subsequent cardiac event.

"A variety of other clinical applications, such as assessments of myocardial viability, the hemodynamic significance of known coronary lesions, and the efficacy of therapeutic interventions, lend themselves to evaluation by stress-redistribution thallium-201 scintigraphy," he added.

Thallium myocardial tomography

William Ashburn, MD, chief of nuclear medicine at the University of California San Diego School of Medicine, described the advantages of SPECT imaging for thallium studies. "If the only purpose of the study is to diagnose CAD, planar imaging is sufficient. But in identifying individual territories which are potentially suitable for revascularization versus zones of nonreperfusable myocardium, planar imaging does not stand up to SPECT," he said.

"SPECT vastly improves the differentiation between normal and ischemic myocardium, and reduces patient imaging time from 40 to 20 minutes per session," he said. The procedure can also assess the location of damaged myocardium and the extent of remaining ischemic tissue potentially at risk for subsequent damage following infarction.

Thallium SPECT can virtually rule out significant CAD in patients with atypical symptoms and help determine the significance of moderate coronary artery lesions visualized by angiography, explained Dr. Ashburn. "Thallium myocardial tomography can also detect and localize areas of acute infarcted myocardium after bypass surgery," he added.

Ventriculography

Robert H. Jones, MD, professor of surgery and associate professor of radiology at Duke University in Durham, NC, said that the exercise ejection fraction stands out among all the noninvasive parameters in CAD as "the single most important parameter in predicting prognosis."

The exercise ejection fraction, which Dr. Jones obtains by a first-pass radionuclide study, is a fixed parameter that reflects how many muscle cells can contract and with what strength those muscle cells can contract.

The exercise ejection fraction study provides two-thirds of all the prognostic information in CAD patients who are medically treated, said Dr. Jones, and about 12 other parameters provide the remaining prognostic information.

"We're wedded to coronary anatomy as the gold standard for heart studies, since the coronary arteriogram used to be the only diagnostic test available, but I would suggest that we need to get away from it and think more in terms of physiologic parameters when we're talking about identifying patients who need intervention," said Dr. Jones, although anatomical information is still needed to determine graft location.

Role of PET

Heinrich R. Schelbert, MD, professor of radiological sciences at UCLA, noted that PET enables clinicians to look beyond blood flow and cardiac function to probe the heart's biochemistry. "With that ability, PET allows detection and characterization of metabolic abnormalities that are the origins of disease, or that mediate disease processes," he said.

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"The role of nuclear medicine in evaluating CAD is unsurpassed in cost-effectiveness."

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In ischemic heart disease, in particular, PET separates irreversibly injured myocardium from reversibly injured tissue. "This information directly impacts clinical decisions because it can help physicians predict which myocardial segments will benefit from surgical revascularization," explained Dr. Schelbert, adding that clinical decisions on bypass surgery, particularly in high-risk patients, are now being made based on PET findings in some institutions.

Currently, PET can be used to diagnose end-stage CAD. "In the future, however, PET may detect the disease much earlier and the catastrophic end result may be prevented by intervening in the disease process at the biochemical level," he added.

Nuclear magnetic resonance

According to Gerald H. Pohost, MD, director of the division of cardiovascular disease at the University of Alabama, five areas of CAD studies could potentially benefit from NMR: (1) coronary angiography, because NMR is particularly sensitive to blood flow; (2) regional blood flow distribution assessments, for which NMR could provide higher resolution studies than radionuclide methods if contrast agents that localize myocardium are developed; (3) metabolic ischemia detection, which may be possible with measurements of intracellular pH levels; (4) myocardial infarct detection; and (5) definition of infarct complications.

With respect to the last two applications, Dr. Pohost said, "The clinical usefulness of detecting infarct size is limited, but it might have an application in understanding the effect of salvage treatment on myocardium." The definition of infarct complications is done very well today with ultrasound methods, he added.

Ultrasound and CAD

"The increasing role of echocardiography, especially two-dimensional echocardiography, in managing patients with CAD, is essentially unknown to a large percentage of physicians caring for patients with CAD," said Harvey Feigenbaum, MD, director of the hemodynamic laboratory at the University of Indiana's Krannert Institute of Cardiology. Most physicians believe that the applications of echocardiography are limited to patients with valvular and congenital heart disease, added Dr. Feigenbaum.

Two-dimensional echocardiography provides multiple tomographic views of "virtually every segment of the heart, and is probably the procedure of choice for looking at regional wall motion of the left ventricle," he said.

With the recent advances in computer techniques for two-dimensional echocardiography, continuous loop images can be displayed side-by-side in split-screen or quad-screen formats. "This development has been the stimulus for the increasing use of exercise echocardiography. Wall motion abnormality is the first myocardial malfunction in ischemia, and can be detected before the patient experiences symptoms and before changes occur in the electrocardiogram," said Dr. Feigenbaum.

Echocardiography is also useful in assessing complications of myocardial infarction, he said. In addition, there are many techniques for quantifying left ventricular and diastolic functions with echocardiography, and the procedure shows potential for histologic assessment of myocardium, Dr. Feigenbaum noted.

Cine CT

With only five cine CT systems operating in the United States, the modality is not in wide use. According to Melvin L. Marcus, MD, professor of medicine at the University of Iowa Hospitals and Clinics, cine CT may be useful in the three major areas of clinical importance in the evaluation of patients with CAD: (1) cardiac structure and function, (2) patency and flow reserve in bypass grafts, and (3) regional myocardial perfusion.

"Cine CT, a new machine that shoots an x-ray beam around the patient by a magnetic field that steers the electron beam, can provide high resolution tomographic images of the heart at 0.8-cm intervals at the rate of 17 per second," said Dr. Marcus. He presented data from several studies of canine hearts, and said that cine CT shows promise in providing quantitative measurements related to all major areas of CAD with the exception of myocardial metabolism.

[A video package, recorded to include each speaker's slides and oral presentations at The Joint International Symposium on the Role of Noninvasive Imaging Modalities in Clinical Decision Making: Coronary Artery Disease, is available from Convention News Television (CNTV). For more information, contact CNTV, 1101 Connecticut Ave. NW, Suite 700, Washington, DC 20036, (202) 429-5100.]

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