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Noninvasive Screening for Coronary Atherosclerosis and Silent Ischemia in Asymptomatic Type 2 Diabetic Patients

Is it Appropriate and Cost-Effective?

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Coronary artery disease (CAD) accounts for 65% to 80% of deaths in diabetic patients. The merits of screening asymptomatic type 2 diabetic patients for either (A) the presence of coronary atherosclerosis by imaging of coronary calcification using cardiac computed tomography or (B) silent ischemia by stress myocardial perfusion imaging (MPI) remain controversial. Some observers have advocated for such noninvasive screening in at least the subset of the diabetic population who have significant clinical CAD risk factors, so that the highest risk patients for future cardiac events can be identified and offered more aggressive intensive medical therapy or coronary revascularization and optimum medical therapy. Computed tomography coronary calcium scanning could be the first noninvasive screening test in these clinically high-risk diabetic patients, followed by stress MPI to detect silent ischemia in those who exhibit high coronary calcium scores. (J Am Coll Cardiol 2007;49:1918–23)
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Considerable discussion and debate are ongoing regarding the value of noninvasive screening for noncritical coronary atherosclerosis or silent ischemia secondary to flow-limiting stenoses in asymptomatic type 2 diabetic patients. This controversy about the merits of noninvasive screening for coronary artery disease (CAD) in asymptomatic diabetic patients has arisen for a number of reasons. Coronary artery disease accounts for 65% to 80% of deaths (1) in diabetic patients, and in 2007 approximately 17 million Americans have diabetes. By 2050, this number could increase to 48 million (2). Women with type 2 diabetes are particularly prone to cardiovascular disease and its complications. In one study, the hazard ratio for cardiovascular mortality for women with both metabolic syndrome and diabetes was approximately 9.5, compared with women without diabetes or metabolic syndrome (3). The age-adjusted risk of CAD in diabetic women, compared with nondiabetic women, is 5.1, whereas in men this value is 2.4 (4). The actual prevalence of significant coronary atherosclerosis in a truly representative population of type 2 diabetic patients has not been ascertained. One estimate is that 20% of diabetic patients have established CAD (5). In an asymptomatic and uncomplicated cohort of type 2 diabetic patients, 46.3% had evidence of coronary calcification indicative of coronary atherosclerosis (6). In an autopsy study of diabetic patients, the prevalence of anatomic CAD was 50% to 81% (7).

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Diabetic patients with inducible ischemia on stress myocardial perfusion imaging, using single-photon emission computed tomography (SPECT), have a significantly higher subsequent annual cardiac death or myocardial infarction rate than nondiabetic patients with ischemia (10% vs. 6%) (8). In this pooled analysis of studies in the literature, female diabetic patients with an abnormal SPECT study had an annual rate of approximately 11.5% for cardiac death/myocardial infarction, compared with just above 6% for men. In one study of female diabetic patients with a high-risk stress SPECT perfusion scan, characterized by a multivessel disease pattern, only 60% survived, without infarction, in the ensuing 3 years. For the male diabetic patients with a high-risk scan, this value was 79% (9). Similarly, diabetic patients with an abnormal ischemic stress echocardiographic response have a worse prognosis than nondiabetic patients with stress-induced ischemia (10). The true prevalence of silent ischemia using noninvasive stress imaging in asymptomatic type 2 diabetic patients is not known, but ranges from 16% to 59% have been reported (11–15), depending on the pretest clinical risk profile of the patient groups studied. The DIAD (Detection of Ischemia in Asymptomatic Diabetics) study (14) comprised a lower-risk group of type 2 diabetic patients than those imaged in the other studies. For example, diabetic patients with an abnormal resting electrocardiogram (ECG) were not enrolled in the DIAD study. Fifty percent of patients in the Mayo Clinic cohort were referred for preoperative risk assessment, and 43% had ECG Q waves while 28% had peripheral vascular disease (12). Female diabetic patients

with normal perfusion scans or normal stress echocardiograms still have an annual hard cardiac event rate of ≥3.0% (8,10). In one observational database, diabetic patients with ischemia had a better survival rate with revascularization rather than with medical therapy (16).

Diabetic patients with coronary atherosclerosis as determined by computed tomography (CT) calcium scanning have a worse outcome with respect to cardiac death and nonfatal infarction than nondiabetic patients with the same coronary artery calcium (CAC) score (17). Interestingly, compared with nondiabetic patients, diabetic patients with a zero CAC score had a similar annual mortality rate of 0.36%. One group found that 48% of diabetic patients had a CAC score compatible with significant CAD (18). In asymptomatic diabetic patients, the prevalence of stress-induced ischemia increases the higher the CAC score is on CT scanning (6). In that study, 23% of asymptomatic diabetic patients with a CAC of 101 to 400 had a positive stress SPECT scan. Those with CAC >400 had a 48% prevalence of silent ischemia, and this number increased to 71.4% for the asymptomatic diabetic patients with a CAC of >1,000. The greater the extent of ischemia, the worse the clinical outcome, and the CAC score was superior to established risk factors for predicting silent ischemia and cardiac events (6). The prevalence of silent ischemia for any given CAC score range was higher in this study than in 2 prior reports (19,20). Conversely, in the study by Anand et al. (6), all diabetic patients with a CAC score between 0 and 10 had normal SPECT studies and excellent prognoses.

Some thought leaders have recommended the adoption of decision-making algorithms that advocate noninvasive screening for CAD in the asymptomatic diabetic population, and some have suggested that screening at least some subset of the diabetic population may be clinically valuable (21–24). These ideas are supported by the high prevalence of CAD and high cardiovascular mortality rate in the diabetic population, the substantial risk of future cardiac events in asymptomatic diabetic patients with subclinical atherosclerosis (as assessed by CT calcium scanning), the prevalence of silent ischemia in diabetic patients, and the higher cardiac event rate with inducible ischemia for diabetic patients versus nondiabetic patients. Other experts, however, remain skeptical or cautious regarding the worth and cost-effectiveness of screening diabetic patients for coronary atherosclerosis or silent ischemia (25,26). Some observers are open to the concept of screening asymptomatic diabetic patients but want to see a randomized clinical trial of screening versus no screening to establish efficacy, recognizing that the cost of such a trial would be enormous and could only be funded by a governmental agency (27).

Certainly, diabetic patients with symptoms such as chest pain or dyspnea are presently being evaluated appropriately with noninvasive and/or invasive strategies, depending upon their clinical presentation. In one combined report from Cedars Sinai, Los Angeles, and the Basel groups, 51% of 151 diabetic patients with dyspnea and no chest pain had objective evidence of CAD by SPECT criteria (13). Asymptomatic diabetic patients are already being treated as CAD equivalents with respect to guidelines for lipid lowering (low-density lipoprotein [LDL] cholesterol <100 mg/dl). In diabetic patients with established CAD, LDL cholesterol levels should be lowered to below 70 mg/dl (28).

Abbreviations and Acronyms

- **CAC** = coronary artery calcium
- **CAD** = coronary artery disease
- **CT** = computed tomography
- **ECG** = electrocardiogram
- **LDL** = low-density lipoprotein
- **MPI** = myocardial perfusion imaging
- **SPECT** = single-photon emission computed tomography

In this issue of the *Journal*, Diamond et al. (29) analyze the expected costs and benefits associated with routine screening of asymptomatic diabetic patients for subclinical atherosclerotic disease, using myocardial perfusion imaging. They discuss the merits of a conditional test-treatment strategy in which scintigraphic testing is followed by statin treatment in positive test responders, compared with an unconditional treatment strategy involving no testing, but rather treating all diabetic patients with statins. Their analysis shows that unconditional treatment costs 24% less and prevents 25% more atherosclerotic events annually. This essay was written primarily in response to the review by Bax et al. (22) representing a group of physicians from Europe and the U.S. identified as the "Global Dialogue Group for Evaluation of Cardiovascular Risk in Patients With Diabetes." Bax et al. (22) reviewed all the data in the literature pertaining to screening asymptomatic diabetic patients for silent ischemia. The evidence they cited suggested a "potential algorithm," summarized in Figure 1. Asymptomatic diabetic patients over 40 years old, who are

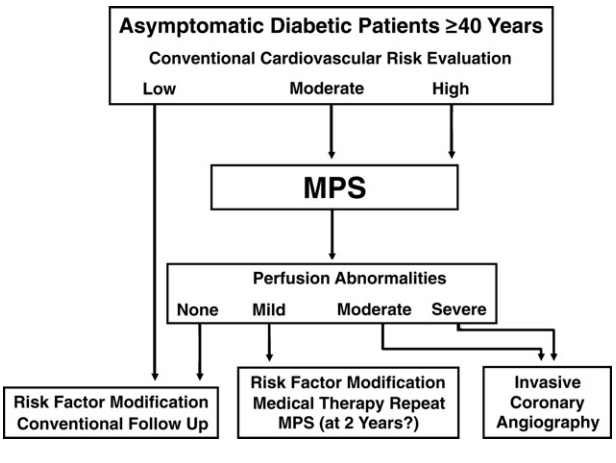

Figure 1 Algorithm for Risk Assessment and Management in Asymptomatic Type 2 Diabetic Patients

MPS = myocardial perfusion imaging.
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