

Is Appropriate Use Criteria for Cardiac Radionuclide Imaging in Asymptomatic Diabetic Patients Evidence Based?

We write in reference to the recent article in the *Journal*, the 2009 Appropriate Use Criteria for Cardiac Radionuclide Imaging (RNI), which was published by the American College of Cardiology and endorsed by many other professional societies (1). This document was anticipated to impact physician decision making, test performance, and reimbursement policy.

We find the use of RNI for asymptomatic patients with diabetes mellitus (patients >40 years old) and other coronary risk equivalents that were considered appropriate in that document without sufficient evidence. Diabetic patients have a high incidence of coronary artery disease (CAD); therefore, an intensive primary and secondary prevention is recommended by various professional societies. But the strategy of routine RNI for all asymptomatic patients cannot be considered appropriate. The DIAD (Detection of Ischemia in Asymptomatic Diabetics) study was a prospective randomized trial evaluating outcomes after screening for asymptomatic CAD in type 2 diabetic patients (2). Although the study was underpowered to detect the pre-specified difference, due to a low rate of cardiac events, it ruled out any major benefit of routine screening. Even moderate or large defects had a positive predictive value of just 12% for cardiac events. Also, there was no apparent difference in the use of interventions for risk modifications between the 2 groups based upon results of screening. The recent BARI 2D (Bypass Angioplasty Revascularization Investigation in Type 2 Diabetes) trial, which randomly assigned patients with type 2 diabetes and stable CAD to immediate revascularization with intensive medical therapy versus only intensive medical therapy, failed to show to any difference in mortality or major cardiovascular events (3). The COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) trial also showed that percutaneous intervention with optimal medical therapy was no better than optimal medical therapy alone for patients with stable CAD in general and for a subgroup of patients with diabetes specifically (4).

Thus, so far, revascularization has not proven beneficial for patients with asymptomatic or stable patients with CAD in terms of mortality and major cardiac events. A possible benefit of relief from angina does not hold true for subjects who are asymptomatic at baseline. In all of these trials, large proportions of patients in both groups received aggressive evidence-based interventions for cardiovascular risk reduction as recommended by various professional societies, and that could explain the low event rates. So, if an aggressive risk reduction strategy for asymptomatic high-risk patients can lead to a substantial decrease in cardiac events without any additional benefit from revascularization, the role of additional cardiac RNI is unclear. Routine RNI can be of use, if we can identify a subgroup of asymptomatic patients with additional risk factors who can benefit from revascularization or screening. The American Diabetic Association acknowledges the dearth of evidence in support of screening asymptomatic diabetic patients for CAD, and deemed it controversial (5).

The Centers for Disease Control estimates that about 33.9% of the U.S. population older than 40 years of age have diabetes (6). As per the appropriate use criteria, these patients would represent a high-risk group for whom cardiac RNI would be considered appropriate. In most places, a cardiac RNI would cost about U.S. \$700 to \$1,400. That would put enormous pressure on health care resources without any clear benefit.

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Reply

We greatly appreciate the comments of Dr. Sethi and colleagues regarding the use of radionuclide imaging (RNI) in an asymptomatic but high-risk patient, such as one with diabetes mellitus, which constitutes one of the indications noted in the recently published RNI appropriate use criteria (AUC) (1). Their letter correctly describes the low event rate noted in the DIAD (Detection of Ischemia in Asymptomatic Diabetics) study (2). Furthermore, information from the BARI-2D (Bypass Angioplasty Revascularization Investigation in Type 2 Diabetes) study (3), as well as that from the COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) study (4), fails to support the benefit of revascularization, at least with regard to major cardiovascular events. At the present time, diabetic patients are still considered by clinical practice guidelines to be a high-risk/coronary artery disease-equivalent cohort, although that may change in the future. However, neither the BARI-2D study nor the DIAD study data were available at the time of the rating for the radionuclide AUC. Additionally, both of these