

# Appropriate test selection for single-photon emission computed tomography imaging: Association with clinical risk, posttest management, and outcomes

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**Background** Appropriate use criteria (AUC) for stress single-photon emission computed tomography (SPECT) are only one step in appropriate use of imaging. Other steps include pretest clinical risk evaluation and optimal management responses. We sought to understand the link between AUC, risk evaluation, management, and outcome.

**Methods** We used AUC to classify 1,199 consecutive patients ( $63.8 \pm 12.5$  years, 56% male) undergoing SPECT as inappropriate, uncertain, and appropriate. Framingham score for asymptomatic patients and Bethesda angina score for symptomatic patients were used to classify patients into high ( $\geq 5\%/y$ ), intermediate, and low ( $\leq 1\%/y$ ) risk. *Subsequent patient management* was defined as appropriate or inappropriate based on the concordance between management decisions and the SPECT result. Patients were followed up for a median of 4.8 years, and cause of death was obtained from the social security death registry.

**Results** Overall, 62% of SPECTs were appropriate, 18% inappropriate, and 20% uncertain (only 5 were unclassified). Of 324 low-risk studies, 108 (33%) were inappropriate, compared with 94 (15%) of 621 intermediate-risk and 1 (1%) of 160 high-risk studies ( $P < .001$ ). There were 79 events, with outcomes of inappropriate patients better than uncertain and appropriate patients. Management was appropriate in 986 (89%), and appropriateness of patient management was unrelated to AUC ( $P = .65$ ).

**Conclusion** Pretest clinical risk evaluation may be helpful in appropriateness assessment because very few high-risk patients are inappropriate, but almost half of low-risk patients are inappropriate or uncertain. Appropriate patient management is independent of appropriateness of testing. (Am Heart J 2013;166:581-8.)

Noninvasive cardiac imaging using single-photon emission computed tomography myocardial perfusion (SPECT MPI) has shown immense growth ( $>15\%$  per year) in the last decade.<sup>1</sup> Indeed, use of imaging stress tests increased 3-fold, from 1993 to 2001,<sup>2</sup> reaching  $>9$  million SPECT MPI procedures in 2002,<sup>3</sup> before a reduction in recent years. Although SPECT MPI may facilitate the selection of patients for invasive procedures and intervention,<sup>4,5</sup> the associated costs are high, the risks from radiation exposure are uncertain, and the economic repercussions at current levels are alarming.<sup>3,6</sup> To address this issue, the American College of Cardiology and the American Society

of Nuclear Cardiology (ASNC) developed appropriate use criteria (AUC) for SPECT MPI in 2005.<sup>3,7</sup> An update of these appropriateness criteria for stress SPECT MPI was published in 2009 by the American College of Cardiology Foundation/ASNC and endorsed by 8 other societies to reflect changes in published evidence and experience with the application of the original criteria.<sup>8</sup>

Selection of patients for testing is but one point in a sequence of decisions that govern the appropriate use of imaging, starting with clinical evaluation of risk and finishing with posttest optimal management decisions.<sup>9</sup> It is noteworthy that evaluation of posttest management was not a goal of the appropriateness criteria. Our goal in this study was to link pretest cardiovascular risk and symptoms, AUC, downstream management decisions, and outcomes.

## Methods

### Study design

Our study comprised the first test of 1,199 consecutive patients who had SPECT and a clinical evaluation permitting

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calculation of the Framingham score<sup>10</sup> at Cleveland Clinic between January 1 and March 15, 2006. Because of loss of 94 patients (8%), the association between test result and management was only calculated for 1,105 patients. Because the end point was cardiac mortality, the association with mortality was studied in 954 Ohio residents, in whom we had access to death certificates.

The study was approved by the institutional review board, and all authors had involvement in 1 or more aspects of design and conduction of the study, study analysis, and drafting and editing the manuscript.

### Evaluation of clinical status

We defined a number of assumptions to apply the AUC in a consistent, standardized, and accurate manner. Inability to exercise was confirmed when there was a specific comment to that effect, or in the presence of chronic renal or lung disease, amputation, arthritis or joint replacement, weakness or neurologic disease, dementia, obesity, peripheral vascular disease, heart failure, or severe aortic stenosis. The presence of an uninterpretable electrocardiogram (ECG) was confirmed when there was a specific comment to that effect or left bundle-branch block, digoxin use, and paced rhythm; baseline abnormalities of the ST segment; or preexcitation. The following were accepted as potential symptoms of coronary disease: chest pain, tightness and burning, shoulder or jaw pain, dyspnea, and other cardiac symptoms (eg, fatigue and palpitations). Clinical risk was quantified for asymptomatic and symptomatic patients. The Framingham score was used to estimate cardiovascular risk in patients without diagnosed coronary artery disease (CAD).<sup>10</sup> This score is unsuited to define risk in patients with known CAD, so we used the Bethesda score (based on age, gender, recent infarction or unstable angina, ejection fraction [EF], CAD extent, heart failure, vascular disease, and mitral regurgitation) to estimate annualized cardiovascular risk in these patients.<sup>11</sup> Low risk was defined as  $\leq 1\%/y$ ; intermediate risk, 1% to 5%/y; and high risk,  $\geq 5\%/y$ .

Data regarding appropriateness were abstracted from the electronic medical record (N.A.), and interobserver variability was verified by a separate observer (W.J.) in 10% of subjects. The same approach of examining interobserver variability (T.M.) was used for verifying the reproducibility of outcome assessment.

### Appropriate use criteria classification

Indications for testing were classified using the AUC<sup>8</sup> by first allocating them to categories as follows: detection of symptomatic CAD, detection or risk assessment in the absence of an ischemic equivalent, risk assessment of known CAD, preoperative risk assessment, after acute coronary syndrome, or postrevascularization. The initial basis for that allocation depended on whether the patient was symptomatic or asymptomatic, and the hierarchy of the indications used in the 2009 SPECT AUC was used to score the SPECT tests.<sup>8</sup> For example, revascularized patients were subdivided into symptomatic and asymptomatic groups. Asymptomatic patients were evaluated according to the time after revascularization; studies performed  $>2$  years after percutaneous coronary intervention and  $>5$  years after coronary artery bypass graft surgery were considered appropriate. If the patient had undergone prior

SPECT or angiograms, then only the recent result was considered. A previous abnormal SPECT was defined by scar, ischemia, ventricular dilatation, or an abnormal EF. For the perioperative risk frame, we used the surgical risk classification used in the AUC documents.<sup>5,7</sup> The intraobserver agreement for allocation of AUC was 0.85, and the interobserver agreement was 0.80.

### Single-photon emission computed tomography methodology

Images were acquired in accordance with the ASNC guidelines for gated SPECT single- or 2-day technetium-99m tracer (tetrofosmin) protocols.<sup>12</sup> We used a 17-segment model of the left ventricle to semiquantitatively score stress and rest perfusion images using standard software (4DMSPECT, Ann Arbor, MI).<sup>13,14</sup> Each segment was scored by consensus of 2 observers using a 5-point scoring system, supervised by M.C. and W.J. On the basis of the overall evaluation, including the number and severity of segmental scores, the observers judged the study results as normal, probably normal, equivocal, probably abnormal, or definitely abnormal, and for the purpose of this analysis, we identified the study as negative for ischemia or ischemic. Abnormal studies without ischemia (eg, caused by infarction, left ventricular enlargement, and reduced EF) were not used in the definition of ischemia. Clinical interpretations were made with the a priori knowledge of the clinical setting.

### Optimal management

To our knowledge, there have been no previous studies integrating AUC with optimal management, possibly reflecting the subjectivity of defining appropriate management. For the purpose of this analysis, *optimal management* was defined as concordance between the management decision and the SPECT result based on review of the patient's electronic medical record directly following the SPECT study. The interobserver agreement for this was 0.83, and the intraobserver agreement was 0.88. An extensive literature<sup>15</sup> supports 2 important principles—that a normal study defines patients at low risk (in whom further testing or procedures are likely inappropriate) and that an abnormal study identifies risk of subsequent cardiac events, with this risk being related to extent of perfusion abnormality and ancillary findings (including EF, lung uptake, and transient ischemic dilatation). Because appropriate responses to positive test result are quite nuanced, depending on the extent of abnormality and clinical setting, we did not restrict an appropriate response to performance of angiography. Thus, after a SPECT scan indicating any degree of ischemia, management was considered appropriate if the physician ordered angiography, revascularization, a viability study; confirmed appropriate medication or changed to appropriate medication; or made an assessment of surgical risk for noncardiac surgery. Optimal management after negative SPECT scan for ischemia was defined by reassurance, discharge of the patient from hospital or follow-up from the presenting episode (over a duration of a week to 3 years), or preoperative risk stratification of the patient for noncardiac surgery. Suboptimal management was identified in the absence of the above responses for each scenario.

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