Critical Review Form

Diagnostic Test

Udelson JE, et al. Myocardial Perfusion Imaging for Evaluation and Triage of Patients with Suspected Acute Cardiac Ischemia: A Randomized Controlled Trial, JAMA 2002, 288: 2693-2700

Summary

Objective: Assess impact of resting sestamibi scan on ED chest pain patients with low- to moderate-risk for acute cardiac ischemia (ACI) in a randomized controlled trial.

Methods: 2475 patients were randomized to one of two groups: usual care (placebo-arm) or resting sestamibi scan within 60-minutes of injection in the ED + usual care (study-arm). The sestamibi images were read and immediately communicated to the ED physician who had no specific protocol in place as to how to use this extra information. For those patients discharged home, all returned within 36 hours for repeat EKG and cardiac enzyme measurement and stress testing. All patients also had phone follow-up at 30-days.

Guide		Comments
I.	**Are the results valid?**	Answer questions IA, IB, & IC below
A.	**Did clinicians face diagnostic uncertainty?**	Yes, the study population was chest pain patients presenting to 7 academic and community hospitals between July 1997 & May 1999 with a 2% rate of MI and 11% rate of unstable angina (p. 2699).

B.	**Was there a blind comparison with an independent gold standard applied similarly to the treatment group and to the control group?**	PI were blinded to the randomization assignment and to the initial scan results for patients randomized to scan strategy (p. 2695). The final diagnosis (ACI or not ACI) was determined by follow-up EKG, measurement of cardiac enzyme levels, and protocol-specified stress testing (perfusion imaging or echocardiography) for all patients. Medical records were reviewed at the coordinating center by an independent investigator who was blinded to the original confirmed diagnosis assignment and a 98% diagnostic concordance was observed. This independent reviewer did not look at all the records, but rather all MI, "most" USA, and equal numbers of scan and no-scan patients without evidence of ACI. Additionally, 99% were contacted at 30-days following the ED visit to detect delayed cardiac events or subsequent procedures. Note: This follow-up represents a "surrogate gold standard" which is probably more important to clinicians and patients than the defined gold standard, cardiac catheterization, which is probably more like a "bronze standard" as the plaques most at risk of rupture are <50% occluding and not routinely stented when found. A future gold standard may be intra-luminal ultrasound to define the plaque content and thickness of the apical cap which would then define the likelihood of plaque rupture & subsequent ACI.
C.	**Did the results of the test being evaluated influence the decision to perform the gold standard?**	No, as evidenced by Table 3 & 4 (p. 2697) showing equal numbers in the two groups triaged to the CCU, Telemetry, chest pain unit, or

		discharged home from the ED. Equal numbers had cardiac catheterization performed and all had surrogate gold standard (see discussion above).

II.	What are the results?	Answer questions IIA below.
A.	**What likelihood ratios were associated with the range of possible test results?**	Likelihood Ratios were not calculated in this paper (Why not? Answer Below), but the authors did report on Relative Risk which tells us the proportion of the original risk that is still present when patients receive the experimental treatment. In the control group (usual care), 52% of patients who were hospitalized and who were retrospectively classified as unnecessary admissions (p. 2697) compared with 42% in the study arm (sestamibi scan) representing a 10% absolute reduction and a 20% relative change (RR 0.84, 95% CI 0.77-0.92, $P < 0.001$). On the contrary, for those who were hospitalized and retrospectively had ACI, the study arm offered no benefit (RR 0.98, 95% CI 0.90-1.08, $p = 0.74$). Answer: Likelihood ratios would require that sensitivity and specificity were obtained for the diagnostic study being tested. In this case, that would be sestamibi scans. To calculate sensitivity, specificity, or Likelihood ratios one needs to define 2 x 2 Tables (true positive, true negative, false positive, false negative) which would entail comparing the diagnostic study to the gold standard (cardiac catheterization, endoluminal coronary ultrasound, or whatever you believe is the gold standard to define CAD). That was not done in this case and therefore the authors cannot define these factors or derive LR.

III.	How can I apply the results to patient care?	Answer questions III A-D below.
A.	**Will the reproducibility of the test result and its interpretation be satisfactory in my clinical setting?**	Depends on obtaining two factors locally: a) cooperation from Nuclear Cardiology; b) follow-up equal to that in this study

B.	**Are the results applicable to the patients in my practice?**	Probably, though access to 36-hour follow-up is questionable at best.
C.	**Will the results change my management strategy?**	Currently no, though with Nuclear Cardiology input and acceptance and appropriate follow-up, yes.
D.	**Will patients be better off as a result of the test?**	Yes, if inappropriate hospitalization rates are avoided and ED length of stay is diminished. Remember, this is a big picture paper. With the "demographic tsunami" awaiting health care providers caring for the aging baby-boomers combined with an ever increasing budget crisis, we need to be searching for safe, reliable, well-accepted methods to manage common (or uncommon) problems on an outpatient basis. This paper offers a glimmer of hope for the chest pain segment of that population.

Bottom Line: Resting sestamibi scans may serve as a valuable adjunct test for those chest pain patients who do not meet your admission criteria. Further research should identify cost-benefit strategies and subpopulations most likely to benefit from such ED strategies.