Critical Review Form

Therapy

A randomized controlled trial of multi-slice coronary computed tomography for evaluation of acute chest pain, *J Am Coll Cardiol* 2007; 49: 863-871.

Objectives: **"...this study in ED patients with acute chest pain was designed to compare the diagnostic safety, efficacy, and efficiency of 2 diagnostic strategies: initial MSCT angiography versus a SOC nuclear stress testing protocol."**

Methods: **This is, to date, the only RCT to compare standard of care stress testing to multidetector coronary CT coronary angiography (MDCTA). Patients were block randomized to receive either MDCTA or stress testing. Those with negative tests were discharged and followed for 6 months. Those who required additional testing were also followed for 6 months. The primary outcome of interest was 6 month major adverse cardiovascular events including cardiac death, AMI, or unstable angina. Secondary outcomes included diagnostic efficacy, efficiency, and costs (based on institutional cost to charge ratios).**

Guide		Comments
I.	**Are the results valid?**	
A.	**Did experimental and control groups begin the study with a similar prognosis (answer the questions posed below)?**	
1.	Were patients randomized?	Yes. Block randomized of varying sizes to keep physician from knowing assessments.
2.	Was randomization concealed (blinded)?	Not explicitly stated but it blinding inferred.
3.	Were patients analyzed in the groups to which they were randomized?	Unsure. No mention of intent-to-treat analysis or per-protocol analysis.
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	In reference to table 2. All risk factors except for age were not statistically significant. Age-difference likely not clinically relevant.

B.	**Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?**	
1.	Were patients aware of group allocation?	Yes they were – patients had to be aware of which group they were in.
2.	Were clinicians aware of group allocation?	The radiologist reading the MDCTA was not however it seems as if all other physicians were aware. It is not mentioned if physicians reading the stress tests were also blinded.
3.	Were outcome assessors aware of group allocation?	It is not stated so we cannot assume that the 6 month outcome was blinded. Nor are the methods for conducting this clearly explained.
4.	Was follow-up complete?	Yes. All patients are accounted for and there was no mention of lost to follow-up.
II.	**What are the results (answer the questions posed below)?**	
1.	How large was the treatment effect?	1) Secondary Outcome Treatment Effects Late Dx w/u: Int. 10/99, Control 15/98, Δ -5%, 95% CI -4% to 15% Late CV Testing*: Int. 2/99, Control 7/98, Δ -5%, 95% CI -1% to 12% Efficiency Time (hrs): Int. 3.4, Control 15, Δ 11.6 hrs, None given $: Int. 1586, Control 1872, Δ 286, None given
2.	How precise was the estimate of the treatment effect?	95% CI given. The estimates have narrow CIs but cross 0.

III.	How can I apply the results to patient care (answer the questions posed below)?	
1.	Were the study patients similar to my patient?	Yes, but we don't have a systematic method of ordering MDCTAs. To the author's credit, it appears that this study was a population at low risk for ACS.
2.	Were all clinically important outcomes considered?	Current stress testing studies quote 6-month survival so in this respect, yes. Radiation exposure was unfortunately not considered. The ordering of additional testing was not considered. 24/99 have indeterminate testing 21 had a negative stress testing, three have negative coronary angiography.
3.	Are the likely treatment benefits worth the potential harm and costs?	Ethnical question: What amount of radiation exposure will we allow to our patients in order to expedite care? Also 25% of MDCTA required additional testing. Is saving 6-23 hours of observation admission time worth the exposure to additional testing, radiation, and contrast media?

Limitations

1) **Unclear blinding strategy: MDCTA readers were clearly blinded but it's unclear if the SOC arm was blinded as well introducing possible bias.**

2) **Unclear if the 6-month outcome assessors were blinded as to group allocation or what the methods for obtaining the information were.**

3) **Nobody had a major cardiac event after 6 months in either group. It's unclear if the study was really powered to obtain a difference or if there was just no difference.**

4) **Efficiency evaluation is institutional specific and had limited external validity.**

Bottom Line

In the only RCT to date, MDCTA and standard of care strategies to assessing ED patients at low risk for a cardiac event are similar with respect to 6 month cardiac outcomes. Overall ~24% of MDCTA patients will require further testing due to

indeterminate findings or technical difficulties. However, the overall diagnostic efficacy for both strategies appears equal. While the efficiency of MDCTA appears beneficial, the external validity of this measure is questionable given that most institutions lack systematic methods for conveying MDCTA results in a more timely method than SOC strategies. Furthermore, ED physicians must ask themselves whether exposing ~20% of their patient to unnecessary radiation and additional testing is worth saving $30 in testing and ~$250 in terms of length of stay, and ~11.5 hrs in LOS. On a side note, readers must be aware that patients who undergo MDCTA must have their heart rates reduced to ~60 BPM in order to have a technically adequate study.