Maine Medical Center Department of Emergency Medicine

Journal Club / Research Article Summary - (Adapted from Schultz Table)

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ARTICLE:

Country: USA

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PURPOSE:
Research Question(s): Is an evaluation incorporating coronary computed tomographic angiography (CCTA) more effective than standard evaluation in the emergency department in patients with symptoms suggestive of acute coronary syndromes.

Hypothesis: Incorporating CCTA in ED evaluation of chest pain for low-intermediate risk patients will decrease their length of stay without altering miss rate of major adverse cardiovascular events including undetected ACS.

DESIGN:
Study Design: Prospective, multicenter, randomized, strategy-controlled trial.

Dependent / outcome Variable(s): The prespecified primary end point was the length of the hospital stay, defined as the time from presentation in the emergency department to the time of the discharge order. Secondary effectiveness end points included the time to diagnosis, resource utilization, cumulative radiation exposure, health care cost

Independent / research Variable: CCTA vs. Standard eval

SETTING / SUBJECTS:
Research Setting: Multicenter emergency department on weekdays during daylight hours between April 2010 and January 2012.

Study population: 1000 total patients selected and randomized. Table 1 has breakdown. Briefly: mean age 54, 46-48% female, majority White, approx 30% Black, approx 50% had 2 or 3 cardiac risk factors.
Inclusion / Exclusion criteria: Eligible patients were 40 to 74 years of age, presented to the emergency department with chest pain (or the anginal equivalent) of at least 5 minutes’ duration within 24 hours before presentation in the emergency department, were in sinus rhythm, and warranted further risk stratification to rule out acute coronary syndromes, as determined by an attending physician in the emergency department.

Major exclusion criteria were a history of known coronary artery disease, new diagnostic ischemic changes on the initial ECG, an initial troponin level, impaired renal function (creatinine level, >1.5, hemodynamic or clinical instability, known allergy to an iodinated contrast agent, a body mass index greater than 40, or currently symptomatic asthma.

Number (control / intervention groups): 1000 total patients. 501 CCTA, 499 Standard eval.

Attrition: CCTA was not performed in 28 patients (6%) because of the patient’s decision to decline CCTA (9 patients), safety concerns (5 patients), unavailability of CCTA (5 patients), or technical difficulties (9 patients). Overall, 987 of 1000 randomly assigned patients (99%) had complete follow-up at 28 days.

METHODS:

Interventions: Before the start of the study, participating sites were not routinely performing CCTA in patients in the emergency department to detect acute coronary syndromes, but they were required to use at least 64-slice CT technology for patient assessment. Protocols involving both retrospectively ECG-gated and prospectively ECG-triggered CCTA were permitted, with use according to published guidelines. The use of tube modulation to lower radiation exposure was strongly encouraged. CCTA images were interpreted on-site in real time, and the results were communicated to the responsible clinician.

Study Groups: randomized

Data Collection: To ascertain potentially undetected acute coronary syndromes and as a safety measure, patients discharged within 24 hours after presentation in the emergency department were contacted by telephone within 72 hours to assess their clinical status. A follow-up telephone call to all patients was also conducted 28 days after discharge. During telephone calls, information on repeat visits to the emergency department or rehospitalizations for recurrent chest pain was obtained and verified by the collection of medical records.
DATA ANALYSIS:

- **Level of Data:**
  - *Categorical*
  - *Ordinal*
  - *Interval*

*Statistics Used:* intention-to-treat analysis. Continuous data are presented as means ±SD and medians with interquartile ranges. Comparisons between groups were performed with the use of an independent sample t-test for continuous variables, Fisher’s exact test for categorical variables, and the Wilcoxon rank-sum test for ordinal variables. A twosided P value of less than 0.05 was considered to indicate statistical significance. Concordance between the discharge diagnosis made at the study site and the independently adjudicated diagnosis in a selected subpopulation was assessed with the use of the kappa statistic.

*What, if any, confounding variables were controlled for / adjusted for:* The individual practitioners decided final diagnosis. This was audited by an independant board. They looked at both a random selection a a predetermined set of patients. Agreement between the site and independent adjudication for the discharge diagnosis was very high (concordance, 98% [236 of 242 patients]; kappa, 0.94).

RESULTS:

*Brief answers to research questions:* The primary end point met the prespecified criterion for significance, since the average length of the hospital stay in the group of patients randomly assigned to CCTA was decreased by 7.6 hours, as compared with the group randomly assigned to a standard emergency department evaluation (P<0.001). Notably, 50% of the patients in the CCTA group were discharged within 8.6 hours after presentation, as compared with 10% of the patients randomly assigned to a standard evaluation in the emergency department.

No cases of undetected acute coronary syndromes were identified in either study group. Overall, there were eight major adverse cardiovascular events during the 28-day follow-up: six after standard evaluation in the emergency department (four myocardial infarctions and two cases of unstable angina pectoris for which percutaneous coronary intervention was required) and two after CCTA (one myocardial infarction and one case of unstable angina pectoris for which percutaneous coronary intervention was required) (P = 0.18). In both of the latter patients, CCTA established clinically significant coronary artery disease during the index hospitalization, but both patients had negative stress tests and were initially treated medically.

*Additional findings:* Overall, more diagnostic testing was performed in the CCTA group than in the standard-evaluation group (P<0.001). Both the cumulative rate of invasive coronary angiography during the index hospitalization and follow-up and the rate of coronary revascularization were higher among patients in the CCTA group than among patients in the standard-evaluation group, but the differences were not significant (P = 0.06 and P = 0.16, respectively) (Table 3).

Nearly all patients in the CCTA group (484 of 501 patients; 97%), but only 167 of 499 patients randomly assigned to standard evaluation (33%) received radiation exposure
from an imaging test or procedure. Hence, cumulative radiation exposure was significantly higher in the CCTA group (Table 3).

The mean costs of care from the initial visit in the emergency department through the 28-day follow-up were similar in the CCTA group and the group that received standard evaluation in the emergency department ($P = 0.65$).

**Limitations:** 1) Lack of blinding to the intervention. 2) Enrollment occurred only during weekday hours when all imaging testing was available with technologists and readers on site. 3) Long-term outcome data are not available; such data might have allowed a determination of whether CCTA results in fewer repeat visits to the emergency department and hospitalizations over a longer time course.

**Other possible explanation for findings:** There may have been a bias in decision making toward earlier discharge in the CCTA group, since discharge was independently determined by treating clinicians based on their judgment alone.

Information on the presence of anatomical coronary artery disease may influence clinical decision making toward invasive angiography. This concept is consistent with recent data suggesting that in a Medicare population, imaging of the coronary anatomy with CCTA in a nonemergency setting led to greater use of downstream testing and procedures, as compared with functional stress testing.

**IMPLICATIONS FOR PRACTICE:**

*Applicable to this clinical practice:* Should we integrate CCTA into clinical practice? Speeds discharge time during daylight hours, but does not improve sensitivity or specificity, plus adds to patient cumulative radiation and diagnostic testing without saving cost.

*Feasibility (cost, resources, etc.):* Training and equipment costs not accounted for. Study finds no difference, but we would have to train radiologist, cardiologist and emergency providers to use technology.

*Clinically Relevant:* Interesting perspective in accompanying editorial:

“Both studies confirm the somewhat unremarkable fact that CCTA provides faster diagnostic results than standard evaluation (which meant some type of stress test in 74% of the patients in the study by Hoffmann et al. and 64% of the patients in the study by Litt et al.)… Although shorter lengths of stay in the hospital are highly desirable, especially from the patient’s point of view, the ROMICAT-II study reveals a deeper flaw in the approach to chest pain in the emergency department… The underlying assumption of the studies by Hoffmann et al. and Litt et al. is that some diagnostic test must be performed before discharging these low-to-intermediate-risk patients from the emergency department. This assumption is unproven and probably unwarranted. The rationale for any test, as compared with no testing, should be that it will lead to an improved outcome, and here there is no evidence that the tests performed led to improved outcomes. Indeed, event rates for major adverse cardiac events among all patients in the studies by Hoffmann et al. and Litt et al. (whether the patients underwent CCTA, stress testing, or no testing at all) were so low — less than 1% had a myocardial infarction and no patients died — that it is impossible to know whether the CCTA groups received any benefit whatsoever. These very low event rates were observed in other similar studies.”
Moreover, in light of the certainty that the patients in the CCTA group were exposed to substantial doses of radiation (from both CCTA and nuclear stress tests) and were at risk for nephrotoxicity and adverse reactions from the CCTA contrast dye, clinicians may legitimately ask whether the tests did more harm than good … In short, the question is not which test leads to faster discharge of patients from the emergency department, but whether a test is needed at all.”


LEVEL OF EVIDENCE / DECISION FOR USE:

- Background  Consider Replication  Ready for use

- Level of Evidence:
  Ia  Evidence obtained from meta-analysis of randomized controlled trials
  Ib  Evidence obtained from at least one RCT
  IIa  Evidence obtained from at least one well-designed controlled study without randomization
  IIb  Evidence obtained from at least one other type of well-designed quasi-experimental study
  III  Well-designed non-experimental studies
  IV  Expert committee reports, opinions of experts