MD, MPH, Massachusetts General Hospital, Boston, Massachusetts, USA, presented results from the study.

The first prospective, multicenter, randomized, controlled trial to compare CCTA screening with standard ED evaluation for patients with chest pain that is suggestive of acute coronary syndrome (ACS), ROMICAT II randomized 1000 patients at 9 sites in a 1:1 ratio to either CCTA screening or standard care. The hypothesis was that CCTA may enable earlier but safe triage, reducing LOS and hospital admissions compared with standard ED evaluation. The primary endpoint was LOS.

Inclusion criteria included chest pain or equivalent symptoms that were suggestive of ACS; patient age between 40 and 74 years; the ability of the patient to hold their breath for at least 10 seconds; and sinus rhythm. Baseline characteristics were similar between the two groups. The main complaint at presentation was anginal pain or equivalent (88.6% in the CCTA group, n=501; 90.6% in the standard ED evaluation group, n=499).

Average time to diagnosis was 10.4 hours in the CCTA group versus 18.7 hours in the standard ED evaluation group (p=0.0001). At discharge, 8.6% of CCTA patients versus 6.4% of those patients in the standard care group had ACS. Agreement between site and independent adjudication for discharge diagnosis was 96.5% (kappa 0.9). There were no missed diagnoses of ACS in either group.

The mean LOS for all CCTA patients was 23.2±37.0 hours versus 30.8±28.0 hours (p=0.0002) for the standard care group. For those without a final diagnosis of ACS, mean LOS was on average 10 hours shorter for the CCTA group (17.2±24.6 vs 27.2±19.5 hours; p<0.0001; Table 1).

The differences in patient disposition were significant, with direct ED discharge of 46.7% for the CCTA group versus 12.4% for the controls (p<0.001). Observation unit admission was 26.6% in the CCTA group versus 53.7% of controls (p=0.001). The respective figures for admission to the hospital and leaving against medical advice were both lower in the CCTA group—25.4% versus 31.7% and 1.3% versus 2.2%, respectively (both p=0.001).

Major adverse events (death, myocardial infarction, unstable angina, urgent revascularization) within 30 days were similar in both groups (0.4 and 1.0, respectively; p=0.37). There was higher cumulative radiation exposure in the CCTA group (14 mSv vs 5.3 mSv; p<0.0001).

Hospital billing data demonstrated no difference in mean total cost ($4004 vs $3828; p=0.72). However, the CCTA-first approach was associated with reduced mean ED costs of $2053±1076 versus $2532±1346 for the standard evaluation group (p<0.0001) that were partially offset by a higher mean hospital cost ($1950 vs $1297; p=0.17) with CCTA. Of note, use of a CCTA-first approach was associated with an increased use of conventional coronary angiography (12% vs 8%; p=0.04) and a numerically greater number of coronary revascularization procedures (6.4% vs 4.2%; p=0.16).

Table 1. LOS by Diagnosis.

	CCTA	Standard ED Eval	p value
Dx testing during index stay* n (%)			
Patients with 0 tests	9 (1.8%)	110 (22.1%)	<0.0001
Patients with 1 test	376 (75.0%)	336 (67.3%)	
Patients with ≥2 tests	116 (23.2%)	54 (10.6%)	
Cumulative invasive coronary angiography n (%)**	60 (12.0%)	48 (8.0%)	0.04
Cumulative Interventions n (%)**	32 (6.4%)	21 (4.2%)	0.16
PCI	27 (5.4%)	17 (3.4%)	
CABG	5 (1.0%)	4 (0.8%)	
Cumulative radiation exposure ** (CCTA/SPECT/ICA: mean ± SD per patient, mSv)	14.3±10.9	5.3±9.6	<0.0001

*Includes CCTA, SPECT, Echo, ETT and ICA; **Includes index hospitalization and 28 day follow-up; PCI=percutaneous coronary intervention; CABG=coronary artery bypass grafting; Dx=diagnosis.

Overall, ROMICAT II shows that CCTA is feasible in the ED for patients who present with suspected ACS and reduces both LOS and time to diagnosis. There was no significant increase in total cost associated with this approach; however, there was increased radiation exposure. Further studies are necessary to see if the use of CCTA in the ED has an effect on clinical outcomes.

Elective PCI at Community Hospitals With Versus Without On-Site Surgery

Written by Rita Buckley

Performance of elective percutaneous coronary intervention (PCI) at hospitals with and without on-site open heart surgery backup produces similar rates of mortality and major adverse cardiac events (MACE), according to clinical outcomes from the Cardiovascular

Patient Outcomes Research Team (CPORT) Non-Primary PCI Trial [CPORT-E; NCT00549796]. Thomas Aversano, MD, Johns Hopkins University, Baltimore, Maryland, USA, presented findings from the study [Aversano T et al. *N Engl J Med* 2012].

This first randomized noninferiority trial that was designed to address concerns about the need for emergency cardiac surgery to treat complications that are related to nonprimary PCI, CPORT-E had two primary endpoints: 1) all-cause mortality 6 weeks after the index PCI, and 2) composite of MACE 9 months after the index PCI, including death from all causes, Q-wave myocardial infarction (MI), or target-vessel revascularization (TVR).

Inclusion criteria included patients aged ≥18 years with stable coronary disease or an acute coronary syndrome. Patients with an acute ST-segment elevation MI (STEMI) or an ejection fraction of <20%, patients who required PCI of an unprotected left main coronary artery, and others who were considered to be at too high a risk in the judgment of the treating physician were excluded. A total of 60 centers with an annual mean procedural volume of 150 cases participated in the trial.

CPORT-E randomized a total of 18,867 patients in a 3:1 ratio to undergo PCI at a hospital without on-site cardiac surgery (n=14,149) or with on-site cardiac surgery (n=4718). Noninferiority margins for the risk difference were an absolute increase in risk of no more than 0.4% for mortality at 6 weeks and 1.8% for MACE at 9 months.

The 6-week mortality rates were 0.9% at hospitals without versus 1.0% with on-site surgery (ie, an absolute risk difference of -0.04%; 95% CI, -0.31% to +0.23%; the upper 95% CI was less than the noninferiority margin of 0.4%; p value for noninferiority=0.004; Table 1). The respective 9-month rates of MACE were 12.1% and 11.2% at hospitals without and with on-site surgery (ie, an absolute risk difference of +0.92%; 95% CI, +0.04% to +1.80%; the upper 95% CI was equal to the noninferiority margin of 1.8%; therefore, the one-sided p value for noninferiority=0.05; Table 2). The rate of TVR was significantly higher in hospitals without on-site surgery (6.5% vs 5.4%; p value for superiority of on-site surgery=0.01).

Table 1. Mortality at 6 Weeks.

	Hospitals without SOS n (%)	Hospitals with SOS n (%)	Δ in rate (%)	Asymptomatic one-side 95% CI (%)	p value for noninferiority
n	14,149	4718			
Death	132 (0.9)	46 (1.0)	-0.04	-0.31 to 0.23	0.004

SOS=surgery on site.

When only patients who were treated per protocol were analyzed (excluding patients who crossed over), the respective 9-month rates of MACE were 12.0% and 10.4% at hospitals without and with on-site surgery (ie, an absolute risk difference of +1.64%; 95% CI, +0.77% to +2.51%); the upper 95% CI was higher than the noninferiority margin of 1.8%; therefore, the one-sided p value for noninferiority was not significant and treatment at non-on-site surgery hospitals were not equivalent to treatment at on-site surgery hospitals.

Table 2. MACE at 9 Months.

	Hospitals without SOS n (%)	Hospitals with SOS n (%)	Δ in rate (%)	Asymptomatic one-side 95% CI (%)	p value for noninferiority	p value for superiority
n	14,149	4718				
Death	3.2%	3.2%				
TVR	6.5%	5.4%				0.0098
Q wave MI	3.1%	3.1%				
MACE	12.1%	11.2%	0.92	0.04 to 1.80	0.05	

SOS=surgery on site.

Six weeks after the index PCI, mortality was similar among hospitals with and without on-site surgery; in addition, the incidence of bleeding, renal failure, and stroke was similar among both kinds of facilities. However, unplanned coronary artery bypass grafting (CABG) surgery, especially emergency CABG, was more frequent among patients who were assigned to hospitals with on-site surgery; yet, unplanned catheterization and PCI procedures were more frequent among patients who were assigned to non-on-site surgery hospitals. The rate of PCI failure was higher among participants who were treated at hospitals without on-site surgery.

Dr. Aversano and colleagues concluded that "nonprimary PCI outcomes at hospitals without on-site cardiac surgery are noninferior to those with on-site cardiac surgery, if the former completes a formal PCI development program, adheres to C-PORT-E participation requirements, and has outcomes monitored."

However, higher rates of subsequent TVR among patients who were treated at non-on-site surgery hospitals contributed to a 0.92% absolute higher rate of MACE at 9 months, with a 95% upper CI of 1.8% that equaled the noninferiority border. The authors suggested within their manuscript that the reasons for an incomplete initial revascularization were unclear "but may reflect a lower initial success rate and a more conservative approach by interventionalists practicing at relatively inexperienced centers that began PCI programs only as part of the CPORT-E trial." Additional studies would be helpful to further clarify the comparison of longer-term results of PCI between these two types of facilities.