ACRIN PA 4005: CCTA in the ED Identifies Low-Risk Patients and Shortens Length of Stay

Written by Maria Vinall

Coronary computed tomographic angiography (CCTA) is a noninvasive test with a very high negative predictive value for the detection of coronary artery disease (CAD) [Janne d'Othee B et al. *Eur J Radiol* 2008]. It has the potential to safely expedite discharge or admission of potential acute coronary syndrome (ACS) patients who present in emergency departments (EDs); yet, a lack of sufficient data has kept the approach from widespread use.

Harold Litt, MD, PhD, University of Pennsylvania, Philadelphia, Pennsylvania, USA, presented results from the CT Coronary Angiogram Versus Traditional Care in Emergency Department Assessment of Potential ACS Trial [Litt HI et al. *N Engl J Med* 2012] to determine the safety and efficacy of a CCTA-based strategy compared with traditional ED approaches.

This Phase 4 randomized, controlled, multicenter trial was conducted by the American College of Radiology Imaging Network (ACRIN) and compared CCTA-based strategy with traditional "rule out" approaches for low-to-intermediate-risk patients with chest pain and possible ACS.

The primary hypothesis was that those patients without clinically significant CAD by CCTA (ie, no coronary artery stenosis ≥50%) will have <1% rate of 30-day cardiac death or myocardial infarction (MI). Secondary aims were to compare CCTA with traditional care with respect to ED discharge rate and length of stay (LOS); 30-day major adverse cardiac event and revascularization; and 30-day resource utilization (Table 1).

Table 1. Safety Results.

Outcome	CCTA (n=908)	Traditional Care (n=462)	% Difference (95% CI)
Cardiovascular Events			
Death	0		0
AMI	10 (1%)	5 (1%)	0.02 (-5.6 to 5.7)
Composite Death & AMI	10 (1%)	5 (1%)	0.02 (-5.6 to 5.7)
Revascularization	24/893 (2.7%)	6/457 (1.3%)	1.40 (-4.3 to 7.0)

CCTA= coronary computed tomographic angiography; AMI=acute myocardial infarction.

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Eligibility criteria included patients aged >30 years with signs/symptoms of potential ACS; TIMI score 0 to 2; no acute ischemia on electrocardiogram (ECG); and a need for admission or testing to exclude ACS. CCTA was performed with a 64-slice or greater multidetector CT scanner that could be used to perform ECG-synchronized cardiac studies.

A total of 1370 low-to-intermediate-risk patients who presented with possible ACS were randomized in a 2:1 ratio to undergo CCTA (n=908) or traditional care (n=462). Baseline characteristics were similar; mean age was 50 years, and 60% of patients were black. Of patients who were randomized to CT, 16% could not receive the CT (27% due to elevated heart rate).

Of 640 patients with a negative CCTA examination, none died or had an MI within 30 days (0%; 95% CI, 0 to 0.57%). Compared with the traditional care group, those who received CCTA had a higher rate of discharge from the ED (49.6% vs 22.7%; absolute difference, 26.8%; 95% CI, 21.4 to 32.2%), a shorter LOS (median, 18.0 hours vs 24.8 hours; p<0.001), and a higher rate of detection of coronary disease (9.0% vs 3.5%; difference 5.6 percentage points; 95% CI, 0 to 11.2). Numerically, more CCTA patients were diagnosed with CAD (9.0 vs 3.5%; 95% CI, 0 to 11.2). One serious adverse event took place in each

group (bradycardia which was determined to be related to medication for heart rate control). No significant differences in 30-day resource use (CCTA vs traditional care) were observed (Table 2).

Table 2. Resource Utilization.

Use of Resources	CCTA-Based (%)	Tradtional Care (%)	95% CI for Difference
Catheterization	5.1	4.2	-4.8 to 6.6
Revascularization	2.7	1.3	-4.3 to 7.0
Repeat ED visit	8.0	7.5	-5.2 to 6.2
Re-hospitalization	3.1	2.4	-4.9 to 6.4
Cardiologist visit	7.1	3.8	-2.4 to 9.0

Dr. Litt noted that this trial had a wider range of traditional care and "real world" management and disposition of patients, but the results only applied to low-to-intermediate-risk individuals. He concluded that a CCTA-first strategy for low–intermediate-risk potential ACS patients was safe and efficient, with increased ED discharge rates and reduced LOS. Larger randomized controlled trials are needed, as well as long-term follow-up on resource use and effects of CAD diagnosis on outcomes.

Comparison of Bariatric Surgical Procedures and IMT for the Treatment of T2DM in Patients with Moderate Obesity: One-Year STAMPEDE Trial Results

Written by Rita Buckley

Results from the 1-year Surgical Therapy And Medications Potentially Eradicate Diabetes Efficiently trial [STAMPEDE; NCT00432809], comparing bariatric surgery with intensive medical therapy (IMT) for the treatment of type 2 diabetes (T2DM) in patients with moderate obesity, concluded that bariatric surgery is more effective than IMT. Philip Raymond Schauer, MD, Cleveland Clinic, Cleveland, Ohio, USA, who reported the results, noted that many of the surgical patients achieved glycemic control without the use of diabetic medications. In addition, improvement in cardiovascular (CV) risk factors after surgery allowed many of these patients to reduce their use of CV medications.

This was the first study to compare IMT with IMT plus bariatric surgery to achieve resolution of T2DM in moderate to severely obese patients (body mass index [BMI] >30 kg/m^2). IMT was based on 2011 American Diabetes Association clinical care guidelines but with an increased focus on reducing HbA1C to ≤6% through the use of diet and lifestyle counseling and potent diabetes medications (eg, insulin sensitizers, GLP-1 agonists, sulfonylureas, and insulin). All patients were evaluated and counseled by dieticians and psychologists in preparation for possible bariatric surgery and were instructed in frequent home glucose monitoring and self-titration of medications.

The primary endpoint was the success rate of achieving HbA1C ≤6% at 12 months. Secondary endpoints included changes in fasting plasma glucose (FPG), BMI, lipids, blood pressure, hsCRP, and the use of diabetic and CV medications, as well as safety and adverse events. Patients (n=150) were randomized to IMT alone, IMT plus gastric bypass, or IMT plus sleeve gastrectomy, a procedure that involves vertically stapling and excising the stomach to achieve approximately 75% to 80% stomach volume reduction, leaving a narrow tubular stomach. Both procedures are performed laparoscopically and require a very small abdominal incision, resulting in a hospital stay of about 2 days and recovery time of 2 to 4 weeks.

Eligible patients were aged 20 to 60 years with HbA1C >7% and BMI 27 to 43 kg/m^2. The average patient age was 49 years, average BMI was 37 kg/m^2, and average duration of diabetes was 8 years. Mean baseline HbA1C was 9.2±1.5%. Subjects were well treated at baseline, with the majority on at least 3 diabetes medications. Approximately half were on insulin; 80% were on a lipid-lowering agent, and 66% were on an ACEI/ARB.

The primary endpoint, HbA1C ≤6%, was achieved in 12% of IMT patients, compared with 42% of gastric bypass patients (p=0.002 relative to IMT) and 37% of sleeve gastrectomy patients (p=0.008 relative to IMT). All of the gastric bypass patients and 27% of the sleeve gastrectomy patients achieved the primary endpoint target without requiring an increase in their diabetes medications. Patients who were undergoing surgery had an average weight loss of 25 to 30 kg (55 to 65 lbs) compared with 4 to 5 kg (10 lbs) in patients who were receiving IMT. Changes in FPG, hsCRP, and triglycerides and increases in high-density lipoprotein cholesterol also favored surgery over IMT (Table 1). The average number of diabetes medications that were used was significantly reduced (p<0.001) in the surgery groups relative to IMT patients. At 12 months, insulin was withdrawn in 92% to 96% of the surgical patients compared with ~40% of the IMT patients.

In addition, at 12 months, 94% of gastric bypass and 71% of sleeve gastrectomy patients were on only 0 to 1 CV medications, while 72% of the IMT patients were on 3 or more CV medications. There were no differences