### MHIF FEATURED STUDY: HITSOVA

**CONDITION:**
Heparin Induced Thrombocytopenia  

**PI:**
Nedaa Skeik, MD  

**RESEARCH CONTACTS:**
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**SPONSOR:**
Aspen Global, Inc.  

**OBJECTIVE:**
Prove that danaparoid use is not inferior to argatroban in terms of efficacy in HIT

**ENDPOINTS:**
1. Approximately Day 14 end study medication  
2. Subject considered a treatment responder if none of the following occur @D44  
   - New or extended venous and/or arterial thrombosis, including gangrene/skin necrosis  
   - All-cause mortality  
   - Unplanned amputation, including ischemic gut resection
DESCRIPTION: Open-Label, Randomized, Active Controlled, Multi-Centre Phase 3 Study to Evaluate the Safety and Efficacy of Danaparoid vs Argatroban in Treatment of Subjects with Acute HIT (HITSOVA study)

CRITERIA LIST/ QUALIFICATIONS:

**Inclusion**
Males or females aged ≥2 weeks
Subjects with suspected HIT by 4Ts of >3 and with reduction of platelet count of ≥ 30% at either:
  a) Between Day 4 and 14 of the start of heparin exposure OR
  b) At Day 1 of heparin exposure with pre-treatment with heparin within the last 30 days
Have adequate renal function: Glomerular filtration rate ≥ 15 mL/min/1.73 m²

**Exclusion**
- Cardiac surgery within 44 days
- Intra-aortic balloon pump or VAD
- Life expectancy less than study duration of 44 days
- Spinal/epidural access within past 48 hrs
- Severe hepatic impairment (Child-Pugh Class C)
- Active bleeding
- Hemorrhagic cerebrovascular accident within previous 3 mos.
- Severe, uncontrolled hypertension (>180/110 mmHg)
- Long-term (>3wks) HD or continuous renal replacement
Minneapolis Heart Institute Foundation® Cardiovascular Grand Rounds

Title: Cardiac CT: An Update
Speaker: Marc C. Newell, MD, FACC, FSCCT
Chief of Clinical Cardiology
VP of Operations
Minneapolis Heart Institute® at Abbott Northwestern Hospital

Date: December 9, 2019
Time: 7:00 - 8:00 AM
Location: Minneapolis Heart Institute Building, Suite 100, Learning Center

OBJECTIVES
At the completion of this activity, the participants should be able to:
1. Describe the current state of coronary CT.
2. Understand the non-invasive role of cardiac CT in plaque assessment.
3. Discuss the concepts of FFR-CT.

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My signature verifies that I have attended the above stated number of hours of the CME activity.

Allina Health - Learning & Development - 2925 Chicago Ave - MR 10701 - Minneapolis MN 55407
Coronary CTA in 2019

Marc Newell, MD, FACC, FSCCT
Minneapolis Heart Institute

Outline

• CAD: are we asking the right questions?
• Coronary CTA for symptomatic patients
• FFR CT
• Coronary CT in Prognosis and Risk Prediction
  - Identification, quantification, or exclusion of atherosclerosis
  - High risk plaque features
  - Impact on outcomes and treatment
• CTA as the first test for CAD?
Cardiac CT All-Star Team

- Best techs and nurses in the country!
- Stars: Longe, Knickelbine, Schwartz, Han
- New Stars:
  - Joao Cavalcante
  - Victor Cheng
  - Mike Miedema
- The Leader: John Lesser

“Dr. Lesser has put together the best Cardiac CT program and team in the country” Dr. Jim Min, FSCCT, Past President of SCCT

Acute Chest Pain

- Accounts for 10% of all ED visits in the US
  - 128 million visits/year = almost 13 million CP cases in the ED/year
- CAD remains the leading cause of death in the US
- Chest pain remains the predominant symptom of CAD
Acute Myocardial Infarction

- Incidence*: 660,000 cases/year
  - One new MI in US every 42 seconds
  - Lowest incidence: Minnesota
- 2-5% of AMI patients were discharged from an ED prior to diagnosis**
  - Leading cause of malpractice in the ED
- Cost of admission to the hospital for “rule out MI” chest pain admission estimated at $6 Billionª.

A little math...

660,000 Acute Myocardial Infarctions

12-13 million ER chest pain evaluations

19 of 20 patients presenting to the ED with chest pain are not having an Acute Myocardial Infarction

AHA Stats 2012ª and 2016*
**Storrow & Gibler, Acad Emerg Med.
That other problem...

• What percent of acute MI’s occur in patients with:
  - <50% stenosis?

The Right Question...

• “If I had an hour to solve a problem and my life depended on the solution, I would spend the first 55 minutes determining the proper question to ask... for once I know the proper question, I could solve the problem in less than five minutes.”
  - Albert Einstein
CAD: The right question(s)?

- Previous questions:
  - Is there ischemia?
  - Clinical risk scores
  - Is there a 70% (or more) lesion?

- New questions:
  - Which patient is at risk for future coronary event?
  - Can we effect mortality with better identification of disease?
  - Can we identify high risk plaques?
  - Should we stop using surrogates and educated guesses and start identifying and treating atherosclerosis-based risk?
Number of All Cardiac Events, Predicted by Framingham Risk Score Versus Observed on Coronary CT

Kaplan-Meier Curve for All Cardiac Events

Cardiac CT Angiography
Strengths

• Definitive anatomical coronary assessment
  - As diagnostic for predicting need for revascularization as invasive catheterization*

• Very high negative predictive value
  - “safe and reliable exclusion of CAD”**

• Excellent prognostic value and risk prediction

*Miller et al. NEJM 2008
**Min et al. JCCT 2018

Coronary CT in the ER/Acute Chest Pain

• High rates of discharge from the ED
• Time savings
• Cost savings
• Safe
• Low rates of downstream testing

CT-STAT trial. JACC 2011  Hoffman et al. NEJM 2012  Litt et al. NEJM 2012
Case

- 61 year old male, presents to PMD for pre-op Left shoulder surgery/rotator cuff
- Describes “burning” chest pain with exertion
  - Two negative stress tests in past 10 years
  - Brother with MI/stent age 59
  - Risk factors: Fam Hx, Former tobacco use, treated HTN
- Referred for stress echo pre-op
  - Positive symptoms of chest burning
  - EKG equivocal
Follow-up

- Abnormal stress echo
  - Subjectively positive (typical symptoms)
  - Objectively ? mild ischemia/small territory on images
- Next steps?
  - Options?

RCA lesion
LAD Lesion

FFR-CT
Coronary Angiography

LAD lesion: invasive FFR

<table>
<thead>
<tr>
<th>FFR</th>
<th>0.77</th>
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<tbody>
<tr>
<td>Pd/Pa</td>
<td>0.77</td>
</tr>
<tr>
<td>Pa:iPa</td>
<td>86:120</td>
</tr>
<tr>
<td>Pd:iPd</td>
<td>66:102</td>
</tr>
<tr>
<td>Pa-Pd(m)</td>
<td>20</td>
</tr>
<tr>
<td>HR</td>
<td>57</td>
</tr>
</tbody>
</table>

List of Runs | IFRI | FFR |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>02:14:50 AM</td>
<td>0.91</td>
<td></td>
</tr>
<tr>
<td>02:15:28 AM</td>
<td>0.77</td>
<td></td>
</tr>
</tbody>
</table>
FFR-CT

- Based on computational flow dynamics
- Adding physiology to the anatomical coronary CTA
  - No additional image acquisition
  - No additional contrast or radiation
- May have potential to be a “gate-keeper” to the cath lab in the future

Physiologic Significance of CAD Stenoses Relationship to FFR

Figure 1 Correlation between diameter stenosis (DS) vs. fractional flow reserve (FFR) in the overall population (A) and specifically in the left main stem (B) and the three major branches (C–E). The x-axes indicate the functional metric (FFR), and the y-axes indicate the angiographic metric (DS).

Patient n = 2986; invasive FFR

CONFIRM registry of 23,854 patients
- No known CAD
- Primary endpoint - time to death from all causes
- Mean f/u >5 years

<table>
<thead>
<tr>
<th>Category</th>
<th>Normal</th>
<th>Non-Obstructive</th>
<th>1-Vessel</th>
<th>2-Vessel</th>
<th>3-Vessel/Let Min</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>1314</td>
<td>8114</td>
<td>2118</td>
<td>1340</td>
<td>930</td>
</tr>
<tr>
<td>Age</td>
<td>59</td>
<td>67</td>
<td>58</td>
<td>55</td>
<td>56</td>
</tr>
<tr>
<td>10-Year Survival (%)</td>
<td>0.10</td>
<td>0.25</td>
<td>0.30</td>
<td>0.40</td>
<td>0.50</td>
</tr>
</tbody>
</table>

Unadjusted All-Cause 3-Year Kaplan-Meier Survival by the Presence, Extent, and Severity of CAD by CCTA

Min et al JACC 2011

CONFIRM Registry: Non-Obstructive Disease

6% mortality increase for each segment (17 segment model) with plaque

Normal Coronary Arteries = Excellent Outcome

SCOT-Heart analysis
n=646 normal coronary arteries
(< 0.5% death/MI at 5 years)

Williams MC, et al. JACC 2019;73:291-301

Linear Relationship of Plaque Burden and MACE

Invasive Angio  CCTA

Calcium Scoring

Coronary CTA Enhances Risk Assessment

n=3242, F/U median 3.6 yrs

- SIS - Segment Involvement Score (marker of disease extent) helps predict risk
  - ** Non-obstructive CAD in 4 or more segments has the same risk as single vessel obstructive disease


Patient Risk: Risk Re-classification

N=2011
- Event rate at 10 years with normal CTA = 0.04%
- Risk reclassification = 68%
  - (most from intermediate to low)

Knowing the anatomy changes risk assessment in 2 of 3 patients

Flick_Hadamitzky JACC 2018
Plaque Risk: High Risk Plaque Assessment

**Figure 2.** Case 1: With Acute Coronary Syndrome

- **A**: Volume rendering.
- **B**: Coronal MPR.
- **C**: Sagittal MPR.
- **D**: Magnified view of the region of interest in (B).

**Figure Caption:** The CT characteristics of a culprit lesion in a 40-year-old male patient presenting with acute coronary syndrome. (A) Volume rendering. (B) Coronal MPR. (C) Magnified view of the region of interest in (B). (D) Coronal enface. The white arrows in (A) and (D) show the site of luminal obstruction. A nodule in the culprit lesion is opacified in (B) and (C) compared with the normal coronary segment proximal to the lesion. The yellow line is in this patient was LAD. An NCP <150 HU represents the probability of a soft plaque that is prone to rupture. Patients with both minimum diameter stenosis of 50% and HU >150 HU had a high-risk plaque according to the JACC 2007 algorithm. When NCP <150 HU, 30 HU ≤ NCP <150 HU is defined as a low-risk plaque (further explained in the JACC 2007 algorithm).

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**Plaque Characteristics in Acute Coronary Syndrome versus Stable Angina Pectoris**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Positive Remodeling</th>
<th>NCP &lt;30HU</th>
<th>30HU ≤ NCP &lt;150HU</th>
<th>Spotty Calcification</th>
<th>Large Calcification</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACS</td>
<td>87%</td>
<td>79%</td>
<td>100%</td>
<td>63%</td>
<td>55%</td>
</tr>
<tr>
<td>SAP</td>
<td>12%</td>
<td>9%</td>
<td>100%</td>
<td>21%</td>
<td>22%</td>
</tr>
</tbody>
</table>

High-Risk Atherosclerotic Plaque Characteristics

2 features assessed by CTA:
1) Low Attenuation Plaque
2) Positive Remodeling

40-fold higher event rates if both features present versus neither

Motoyama, JACC 2009

Vulnerable Plaque Study

High Risk Plaque features were an independent predictor of ACS at 3.9 year follow-up (n=3158)

Motyama et al. JACC 2015
Vulnerable Plaque is Higher Risk for Future Event than Severe Stenosis!

Both Plaque Burden and Plaque Character Predict Outcome

- Multicenter registry with serial CCTA > 2 years apart
- n = 1345 patients

Conclusion: Quantitative plaque burden and character predict outcome

Lee S-E. et al. Circ CV Imaging. 2018;11:e007562. DOI: 10.1161/CIRCIMAGING.117.007562
High Risk Plaque and FFR

772 vessel segments over 5 years

Coronary CTA

- Recap to this point:
  - CCTA is great for ruling out CAD, and carries a great prognosis if the scan is normal
  - Non-obstructive CAD seen on CCTA predicts risk
  - Plaque burden confers risk (more plaque = more risk)
  - Plaque character confers risk and even effects coronary flow
  - Knowing this...

Can We Effect Risk of Future Coronary Event?

<table>
<thead>
<tr>
<th></th>
<th>Myocardial Infarctions</th>
<th>Coronary Revascularizations</th>
<th>Preventive Therapies*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statin</td>
<td>42%</td>
<td>70%</td>
<td>42%</td>
</tr>
<tr>
<td>Aspirin</td>
<td>36%</td>
<td>60%</td>
<td>36%</td>
</tr>
</tbody>
</table>

Meta-analysis of RCTs • Danish registry

-15,000 people; -85,000 people
- 2,839 patients, followed for 3.9 yrs
- All underwent CTA and EMR review to follow physician behavior and outcomes following CTA
- Grouped into three groups - no CAD, severe (>50% lesion), or non-obstructive
- Intensification of statin= Odds Ratio
  - 3.6 in non-obstructive patients
  - 5.6 in severe patients

Among patients with non-obstructive but extensive CAD, statin use after CCTA was associated with a reduction in CV death or MI”
  - Hazard Ratio 0.18
  - (0.05-0.66, p=0.01)
  - “extensive CAD” considered 4 or more segments involved, non-obstructive CAD
CONFIRM Registry: Statin Use Relates to Outcome

No Plaque

Non-obstructive Plaque

Kaplan-Meier survival curves as a function of statin use in patients without and with non-obstructive coronary plaque.


Danish Registry

53,744 in functional arm, 32,961 CTA arm; Single payer system; 3.6 years of follow-up

**CENTRAL ILLUSTRATION: Long-Term Risks of All-Cause Mortality and MI**

<table>
<thead>
<tr>
<th>Events (n)</th>
<th>Absolute risk (%)</th>
<th>Adjusted Hazard ratios</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All-Cause Mortality</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Functional testing</td>
<td>2,339</td>
<td>3.97</td>
</tr>
<tr>
<td>Coronary CTA</td>
<td>699</td>
<td>2.12</td>
</tr>
<tr>
<td><strong>Myocardial Infarction</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Functional testing</td>
<td>830</td>
<td>1.54</td>
</tr>
<tr>
<td>Coronary CTA</td>
<td>299</td>
<td>0.79</td>
</tr>
<tr>
<td><strong>Combined Endpoint</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Functional testing</td>
<td>2,847</td>
<td>5.30</td>
</tr>
<tr>
<td>Coronary CTA</td>
<td>929</td>
<td>2.82</td>
</tr>
</tbody>
</table>


Med use higher in CTA group:
- Statin use (15.9% v 9.1%)
- Aspirin (12.7% v 8.5%)
SCOT-HEART

- n=4146
- 4-fold increase in statin use CCTA vs functional (HR 4.03)
- Same cath rates; however:
  - Less normal cath with CCTA HR 0.39 (0.28-0.63)
  - More obstructive CAD seen HR 1.29

Coronary CT Angiography and 5-Year Risk of Myocardial Infarction

- 4,146 patients
  - 2,073 CTA vs 2,073 Standard Care
- Primary Endpoint - death or nonfatal MI
- Follow-up 4.8 years
- More medication use in CTA arm:
  - Preventative Meds: 1.4 in CTA arm (1.19-1.65)
  - Anti-anginals: 1.27 (1.05-1.54)
Coronary CT Angiography and 5-Year Risk of Myocardial Infarction

A. Death from Coronary Heart Disease or Nonfatal Myocardial Infarction

B. Nonfatal Myocardial Infarction

HR 0.6 (0.41-0.87)

No. at Risk
Standard care 2073 2083 2089 1994 1572 856
CTA 2073 2083 2089 1994 1572 812

HR 0.59 (0.41-0.84)

No. at Risk
Standard care 2073 2057 2048 2041 1618 891
CTA 2073 2057 2048 2041 1618 891

The SCOT-HEART Investigators

PROMISE Trial

• Superiority trial with very low event rate (n=10,003 pts)
  • No superior noninvasive test
  • Min f/u 1 year with mean 2 year f/u
  • No prescribed approach with results
  • Prevalence of obstructive CAD ~12%

• CTA obstructive CAD on cath (p=0.022)
  • CT - 72.1%
  • Functional test - 47.5%

• CT more use of prevention strategies and more catheterizations

• CCTA best predicting outcome
  • Stratifying by gradations of severity

Stress Testing Versus CT Angiography in Patients With Diabetes and Suspected Coronary Artery Disease

- PROMISE Trial (a priori) analysis of diabetic patients
  - CTA vs Functional Testing
  - Primary End-Point of CV Death or nonfatal MI
    - 1.1% CTA group
    - 2.6% Functional Testing group
    - HR 0.38 (0.18-0.79)

JACC
JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
2019;73:893-902

Stress Testing Versus CT Angiography in Patients With Diabetes and Suspected Coronary Artery Disease

A Patients With Diabetes

<table>
<thead>
<tr>
<th>Months Since Randomization</th>
<th>Stress Test</th>
<th>Computed Tomographic Angiography</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (0)</td>
<td>936</td>
<td>972</td>
</tr>
<tr>
<td>6 Mo.</td>
<td>894</td>
<td>888</td>
</tr>
<tr>
<td>12 Mo.</td>
<td>823</td>
<td>804</td>
</tr>
<tr>
<td>18 Mo.</td>
<td>667</td>
<td>651</td>
</tr>
<tr>
<td>24 Mo.</td>
<td>505</td>
<td>452</td>
</tr>
<tr>
<td>30 Mo.</td>
<td>340</td>
<td>297</td>
</tr>
<tr>
<td>36 Mo.</td>
<td>170</td>
<td>172</td>
</tr>
<tr>
<td>42 Mo.</td>
<td>58</td>
<td>54</td>
</tr>
</tbody>
</table>
Can We Effect Risk of Future Coronary Event?

- YES!
- Higher statin use
- Higher anti-anginal medication use
- More accurate obstructive CAD diagnosis and appropriate revascularization
- Therefore, should Coronary CTA be the first test for all new chest pain patients?

Proposed Framework for non-ACS Chest Pain Patients

ACS — acute coronary syndrome, CTA — coronary computed tomographic angiography, CVD — cardiovascular disease.

With diet and lifestyle modification!
Wouldn’t it be Nice?

The Updated NICE Guidelines: Cardiac CT as the First-Line Test for Coronary Artery Disease

NICE accredited 2016
www.nice.org.uk/accreditation

Nice Guidelines (2016)

- No assessment of pretest probability
- CCTA as first test


- No additional information
- Consider causes of chest pain other than angina (such as gastrointestinal or musculoskeletal pain)

Diagnostic investigations

Include the typicality of anginal pain features (i.e., assess the typicality of chest pain (e.g., take into consideration whether the chest pain is central, substernal, and increases with activity and decreases with rest) and the presence of atypical chest pain (i.e., chest pain that is not typical of angina)).

Offer CT coronary angiography if:
- Clinical assessment indicates typical or atypical chest pain, or
- Clinical assessment indicates atypical chest pain and the 12-lead ECG shows ST-T wave changes or Q waves.

Offer non-invasive functional imaging for myocardial ischemia if atypical chest pain (or angina) and CT coronary angiography has shown coronary artery disease of uncertain functional significance or the patient is non-diagnostic.

If clinical assessment indicates typical or atypical chest pain, offer diagnostic testing.

Typical or atypical chest pain

No additional information

Non-anginal chest pain

Consider causes of chest pain other than angina (such as gastrointestinal or musculoskeletal pain)
Identify and treat the disease. Acute vs chronic coronary...
Lower risk with:
appropriate revascularization, controlled risk factors, lifestyle changes, and preventative meds: ASA, statin, ACE
Gatekeeper to Cath?
Conserve Trial
Direct Referral to CA: Selective CA (CT 1st) vs all CA

- 823 vs 808 pts
- 23 (2.8%) vs 100% had CA
- Same event rate 4.6%, f/u 1 yr (includes re-hospitalization)
- Fewer revascularizations
  - 13 vs 18%
- 25% vs 61% insignificant disease
- 57% lower cost in CT 1st group

Summary
- Coronary CTA is effective as a first test in chest pain patients
  - High negative predictive value
  - FFR-CT for intermediate lesions (and possible gatekeeper?)
- Coronary CTA has significant impact on risk assessment and prognosis
  - Significant value for future risk prediction and risk reclassification
  - Non-invasive plaque assessment and plaque burden
Summary

• Are we asking the right questions?
  - Is it time to stop using CAD surrogates and instead characterize and quantify CAD to facilitate appropriate risk reduction and treatment?
  - Should all (symptomatic) patients have non-invasive risk assessment with CTA?

Thank you!

Marc Newell, MD, FACC, FSCCT
marc.newell@allina.com