**MHIF FEATURED STUDY: AEGIS 2**

**DESCRIPTION:**
CSL112 is being developed for use in patients with ACS (diagnosed with either STEMI or NSTEMI and exclusive of unstable angina) to reduce the risk of CV death, MI, and stroke upon delivery of CSL112.

Evidence from the Apo-I Event Reducing in Ischemic Syndromes-I (AEGIS-I) study has demonstrated that administration of apoA-I increases cholesterol efflux in MI patients.

**CRITERIA LIST/QUALIFICATIONS:**

**Inclusion**
- Positive Troponin with at least 50% stenosis on >1 epicardial artery or prior cath with at least 50% stenosis on >1 epicardial artery or prior CABG
- Additional risk factor: DM, >65 y.o., prior hx of MI or PAD

**Exclusion**
- EF < 30%
- ALT > 3 x ULN
- GFR < 30
- Body weight < 50 kg
- Allergy to soy beans or peanuts
- Plan for CABG

**CONDITION:**
Acute Coronary Syndrome

**PI:**
Thomas Knickelbine, MD

**RESEARCH CONTACT:**
Stephanie Ebnet  
[Stephanie.ebnet@allina.com](mailto:Stephanie.ebnet@allina.com) | 612-863-6286

**SPONSOR:**
CSL Behring

**OPEN AND ENROLLING:**
Please Refer Patients to Steph!
Liquid Drano for Coronary Arteries

Apolipoprotein A-I (apoA-I) is the primary component of HDL

CSL 112 is apoA-I, purified from human plasma
Role of HDL in Reverse Cholesterol Transport

[Diagram showing the role of HDL in reverse cholesterol transport]
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AEGIS 2

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OPEN AND ENROLLING:
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Minneapolis Heart Institute Foundation® Cardiovascular Grand Rounds

Title: Nuclear Cardiology - Beyond Perfusion Imaging
Speaker(s): Desmond B. Jay, MD
Medical Director, Nuclear Cardiology
Minneapolis Heart Institute® at Abbott Northwestern Hospital
Date: September 10, 2018
Time: 7:00 – 8:00 AM
Location: ANW Education Building, Watson Room

OBJECTIVES
At the completion of this activity, the participants should be able to:
1. Recognize positron emission tomography (PET) imaging for cardiac sarcoidosis.
2. Identify options for nuclear imaging for cardiac amyloid.
3. Recognize the value of coronary flow reserve (CFR) measurements obtained with cardiac PET imaging.

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Moderator(s)/Speaker(s)
Dr. Desmond Jay has disclosed that he DOES NOT have any real or apparent conflicts with any commercial interest as it relates to presenting their content in this activity/course.

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Signature: __________________________________________________________________________

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
Nuclear Cardiology: Beyond perfusion imaging

Desmond Jay, MD
MHI Cardiovascular Grand Rounds
Sep 10, 2018

• Nuclear cardiology is a “mature” technology
• Used mainly for stress perfusion imaging
• LV systolic function
• Newer detector technology, processing, SPECT alternatives (PET), novel radiotracers
Overview

- Myocardial viability
- Coronary blood flow measurement
- Cardiac sarcoidosis
- Cardiac amyloidosis
- Inflammatory disorders
  - Vasculitis
  - Device infections
  - Endocarditis
Assessing myocardial viability

• Ischemic cardiomyopathy is the most common cardiomyopathy in developed countries
• These patients are at high risk for complications during revascularization
• Noninvasive imaging to detect myocardial ischemia and viability is reasonable in patients presenting with de novo HF, who have known CAD and no angina, unless the patient is not eligible for revascularization of any kind. (Level of Evidence: C)
• Viability assessment is reasonable in select situations when planning revascularization in HF patients with CAD. (Level of Evidence: B)

Viability testing and impact of revascularization on prognosis

![Graph showing death rates for different conditions.](JAmCollCardiol2002;39:1151-8)
Methods for assessing myocardial viability

- Thallium scan
- DSE
- CMR
- FDG-PET

Hibernating myocardium

- Characterized by impaired function (loss of contractility)
- Can regain function with resolution of ischemia/hypoxia
- Hibernating myocardial cells exhibit altered metabolic pathways
Cardiac myocyte metabolism

Myocyte energy metabolism

Myocyte Response to Ischemia

Myocardial Substrate Use

- Fasting state: higher FFA, lower glucose
- Fed state: lower FFA, higher glucose
- Glucose uptake is increased during hypoxia and mild-moderate ischemia and decreased with severe ischemia
- FFA uptake is decreased during all levels of ischemia
- Acipimox is used in Europe, but not available in the US

18FDG
18FDG

- Radioactive glucose analog
- Half life of 110 min
- Phosphorylated, then needs to decay before it can be metabolized further
- Produced by cyclotron

Myocardial FDG uptake can be nonuniform

Temporal and spatial variability in myocardial FDG uptake

Patterns of FDG uptake in patients “without” CV disease

- a) No uptake
- b) Diffuse uptake
- c) Focal uptake
- d) Focal on diffuse uptake

Glucose manipulation for viability

- Oral loading
  - Inadequate uptake in 10% of patients
- Euglycemic hyperinsulinemic clamp
  - Laborious and impractical
- Simplified IV loading with insulin and glucose
- Too high a glucose level (>150 mg/dL) can result in poor images

Patterns of FDG-PET uptake

<table>
<thead>
<tr>
<th>Perfusion</th>
<th>FDG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preserved</td>
<td>Normal</td>
</tr>
<tr>
<td>Reduced</td>
<td>Normal</td>
</tr>
<tr>
<td>Reduced</td>
<td>Reduced</td>
</tr>
<tr>
<td>Preserved</td>
<td>Reduced</td>
</tr>
</tbody>
</table>

- Perfusion: Preserved, Reduced
- FDG: Normal, Reduced
- Match: non-viable
- Mismatch: viable
- Reverse mismatch: altered glucose metabolism (LBBB, stunning, probably viable)
Functional recovery after revascularization depends on the amount of viable myocardium.
A higher mismatch size derives greater benefit from revascularization

STICH

- Evaluated the effectiveness of CABG in patients with CAD and LV systolic dysfunction (EF ≤35%)
- Patients randomized to CABG or medical therapy
- Viability substudy included 601 patients (not randomized)
- SPECT or DSE was used for viability assessment
- No difference in mortality in viability substudy
STICH

- SPECT viability: “...patients with viability were defined as those with 11 or more viable segments on the basis of relative tracer activity.”
- DSE viability: “...patients with viability were defined as those with 5 or more segments with abnormal resting systolic function but manifesting contractile reserve during dobutamine administration.”
- “We also did not incorporate other approaches, such as positron-emission tomography (PET) or contrast-enhanced magnetic resonance imaging (MRI).”
- Viability testing not obtained randomly- selection was based only on the physician’s discretion -> possible selection bias
PARR-2

- Assessed the effectiveness of FDG-PET-assisted management of patients with severe LV dysfunction (EF <35%) and CAD
- Randomized 430 patients: 218 PET, 212 standard care
- F/U one year
- No difference in outcomes

Ottawa FIVE subsubstudy

- 18F-FDG PET Imaging of Myocardial Viability in an Experienced Center with Access to 18F-FDG and Integration with Clinical Management Teams
- 111 patients: 56 PET-guided therapy, 55 standard therapy

25% of patients in original study deviated from PET-recommended therapy

Long term beneficial effect of revascularization
Other factors that determine functional recovery

• Baseline LVEF
• Amount of infarcted myocardium
• Degree of myocardial remodeling/LV size
• Time to revascularization
Coronary blood flow measurement

- The percent stenosis on angiography does not reliably predict coronary flow reserve (anatomy ≠ physiology)
- Flow-guided revascularization appears to reduce subsequent coronary events when compared to percent stenosis-guided revascularization
- Nuclear stress tests are not reliable at predicting the extent of disease
- “balanced ischemia”
- Transplant vasculopathy
- Coronary vasomotor abnormalities - microvascular disease
- CFR - coronary flow reserve = stress flow/rest flow

How bad is the stenosis?
How bad is the stenosis?

Percent stenosis does not always correlate with flow
CF measurements with cardiac PET

- Do not involve another injection - performed with standard stress test protocol
- No additional radiation
- Values can be mapped to the standard myocardial segments/territories

CF measurements with cardiac PET

- Obtained by analyzing time-activity curves from dynamic acquisition of myocardial tracer uptake
- Tracer kinetic models and corrections for partial volume and myocardial spillover are applied to obtain CBF in mL/min/g
Time activity curves

Radiotracers used for CBF measurements

<table>
<thead>
<tr>
<th>Property</th>
<th>(^{18})Fb-chloride</th>
<th>(^{15})N-ammonia</th>
<th>(^{18})O-water</th>
<th>(^{18})F-flurpiridaz</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isotope production method</td>
<td>Generator</td>
<td>Cyclotron</td>
<td>Cyclotron</td>
<td>Cyclotron</td>
</tr>
<tr>
<td>Isotope half-life (min)</td>
<td>1.27</td>
<td>10</td>
<td>2.0</td>
<td>110</td>
</tr>
<tr>
<td>Positron range (mm RMS)</td>
<td>2.6</td>
<td>0.57</td>
<td>1.0</td>
<td>0.23</td>
</tr>
<tr>
<td>Image resolution (mm FWHM)</td>
<td>8</td>
<td>5</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Effective dose (mSv/GBq)</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Peak stress/rest extraction (%)</td>
<td>35/70</td>
<td>95/100</td>
<td>100</td>
<td>95/100</td>
</tr>
<tr>
<td>Peak stress/rest retention (%)</td>
<td>25/70</td>
<td>50/90</td>
<td>0</td>
<td>55/90</td>
</tr>
<tr>
<td>Spillover from adjacent organs</td>
<td>Stomach well</td>
<td>Liver and lung</td>
<td>Liver</td>
<td>Early liver</td>
</tr>
<tr>
<td>Regulatory status</td>
<td>FDA-approved; 2 suppliers</td>
<td>FDA-approved; ANDA required for onsite production</td>
<td>Not FDA-approved</td>
<td>Phase 3 trials partially completed</td>
</tr>
<tr>
<td>Typical rest dose for 3D/2D (mCi)</td>
<td>30/45</td>
<td>10/15</td>
<td>20/30</td>
<td>2/3</td>
</tr>
<tr>
<td>Typical stress dose for 3D/2D (mCi)</td>
<td>30/45</td>
<td>10/15</td>
<td>20/30</td>
<td>2/3</td>
</tr>
<tr>
<td>Protocol features</td>
<td>Rapid protocol</td>
<td></td>
<td>Rapid protocol; no tracer retention for routine MPI</td>
<td>Permits exercise; different doses for rest and stress required</td>
</tr>
</tbody>
</table>
CBF by PET correlates well with MS flow

Similar perfusion patterns with different CFR results
Flow reserve aids to improve diagnostic accuracy
Flow reserve gives additional prognostic information
CFR measurement by PET may aid in assessing for transplant vasculopathy
Cardiac sarcoidosis

- Myocardial involvement is present in 20-76% of patients with sarcoidosis
- Patients with cardiac involvement typically die of CV complications
- Isolated cardiac sarcoidosis is not uncommon - difficult to diagnose

Cardiac sarcoidosis - diagnosis

<table>
<thead>
<tr>
<th>HRSJ</th>
<th>Japanese</th>
</tr>
</thead>
<tbody>
<tr>
<td>Histologic dx</td>
<td>+EMBx</td>
</tr>
<tr>
<td></td>
<td>+EMBx</td>
</tr>
<tr>
<td>Clinical dx</td>
<td>Biopsy-proven extra cardiac sarcoid AND 1 or more of:</td>
</tr>
<tr>
<td></td>
<td>- steroid/immunosuppressant responsive CM or HB</td>
</tr>
<tr>
<td></td>
<td>- Unexplained low EF (&lt;40%)</td>
</tr>
<tr>
<td></td>
<td>- Unexplained VT</td>
</tr>
<tr>
<td></td>
<td>- Mobitz type II or 3rd degree HB</td>
</tr>
<tr>
<td></td>
<td>- Patchy uptake on cardiac PET</td>
</tr>
<tr>
<td></td>
<td>- DE on CMR</td>
</tr>
<tr>
<td></td>
<td>- +gallium scan AND</td>
</tr>
<tr>
<td></td>
<td>Other causes have been excluded</td>
</tr>
<tr>
<td></td>
<td>“Probable” CS</td>
</tr>
<tr>
<td></td>
<td>2 or more major or 1 major and 2 or more minor criteria</td>
</tr>
<tr>
<td>Major</td>
<td>High deg AVB or VF/VT</td>
</tr>
<tr>
<td>Minor</td>
<td>Abnl EKG</td>
</tr>
<tr>
<td>Other causes have been excluded</td>
<td>Perfusion defect on SPECT</td>
</tr>
<tr>
<td></td>
<td>Monocyte infiltration and interstitial fibrosis on EMBx</td>
</tr>
<tr>
<td>LVEF &lt;50%</td>
<td>+gallium scan or + FDG PET</td>
</tr>
<tr>
<td>DE on CMR</td>
<td></td>
</tr>
</tbody>
</table>
• Active areas of sarcoidosis are glucose-avid
• Unaffected myocardium should be FFA-avid
• Pt is instructed to eat a high protein, high fat, and low carbohydrate diet
• No strenuous exercise for 24h prior to test
• Active myocardial inflammation (e.g. active myocarditis) can also cause preferential glucose uptake

Diet for sarcoid scan

• Please fast (no food) for at least 12 hours prior to this procedure.
• Plan to eat dinner between 5:00 and 6:00 p.m. the evening before your procedure.
• Follow a high protein, high fat, low carbohydrate diet for dinner.
• Eat a high fat, low carbohydrate meal for breakfast.
• Drink plenty of fluids.
• Forbidden foods:
  - Sugar in any form is strictly forbidden (including natural sugars in fruit)
  - No pastas, breads, cereals, rice
  - No candy or gum
  - Processed products such as deli meats are discouraged. These products often contain hidden sugars.
  - Starchy vegetables are not permitted (potatoes, etc.)
  - Corn, peas, carrots, most legumes, grains are not permitted.
Uptake in CS is typically heterogeneous


Uptake in CS is typically heterogeneous

Figure 1: Representative FDG-PET images from:

- A: healthy subject (no CS, non-ischemic, no infarction, no CS)
- B: diabetic subject (non-CS)
- C: CS patients (infarction)
- D: non-CS patients (infarction)
- E: CS patient (infarction)
- F: DCM patient (infarction)

Abbreviations:
- CS: coronary artery stenosis
- DCM: dilated cardiomyopathy
- FDG: 18F-fluorodeoxyglucose
- PET: positron emission tomography
PET pattern in CS

FDG uptake and perfusion abnormalities suggest poorer prognosis
RV uptake of FDG gives poorer prognosis
Treatment can alter FDG uptake pattern


Treatment can improve LV systolic function
Use of FDG PET to evaluate for cardiac sarcoidosis

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Specifics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with histologic evidence of extraCS, and abnormal screening for CS, defined as one or more of the following:</td>
<td>Abnormal electrocardiographic findings of complete left or right bundle branch block or presence of unexplained pathologic Q waves in two or more leads</td>
</tr>
<tr>
<td>Echocardiographic findings of regional wall motion abnormality, wall aneurysm, basal septum thinning, or LVFP &gt; 50%</td>
<td></td>
</tr>
<tr>
<td>Holter findings of sustained or nonsustained ventricular tachycardia</td>
<td></td>
</tr>
<tr>
<td>Cardiac MRI findings suggestive of CS</td>
<td></td>
</tr>
<tr>
<td>Unexplained palpitations or syncope</td>
<td></td>
</tr>
<tr>
<td>Young patients (&lt; 65 y) with unexplained, new onset, significant conduction system disease (such as sustained second- or third-degree atrioventricular block)</td>
<td></td>
</tr>
<tr>
<td>Patients with idiopathic sustained ventricular tachycardia, defined as not fulfilling any of the following criteria:</td>
<td></td>
</tr>
<tr>
<td>Typical outflow tract ventricular tachycardia</td>
<td></td>
</tr>
<tr>
<td>Fascicular ventricular tachycardia</td>
<td></td>
</tr>
<tr>
<td>Ventricular tachycardia secondary to other structural heart disease (coronary artery disease or any cardiomyopathy other than idiopathic)</td>
<td></td>
</tr>
<tr>
<td>Patients with proven CS as adjunct to follow response to treatment</td>
<td></td>
</tr>
</tbody>
</table>
Amyloidosis

• Caused by extra or intracellular deposition of amyloid protein
• Aggregates of misfolded proteins that are produced by cells at the site of deposition or originate from a distant location and precipitate locally
• Other constituents include glycosaminoglycans, apolipoprotein-E, and serum amyloid P-component

Amyloidosis- pathology

• HE staining-amorphous eosinophilic staining
• Apple green birefringence on Congo red staining
• Beta-pleated sheet structure on x-ray diffraction
Systemic amyloidoses

• A amyloidosis (AA)
• Light chain amyloidosis (AL)
• Heavy chain amyloidosis (AH)
• Transthyretin amyloidosis (TTR)
• Beta2-macroglobulin amyloidosis
• Cryopyrin-associated amyloidosis
Cardiac amyloidosis

- **EKG**
  - Low voltage, arrhythmia, conduction abnormalities
- **Echo**
  - LVH
  - Restrictive diastolic function
  - Systolic dysfunction
- **CMR**
- **Definitive diagnosis requires EMBx?**
- ?nuclear imaging
Nuclear radiotracers used for cardiac amyloid

- 99m Tc-DPD
- 99m Tc-MDP
- 99m Tc-PYP
- I-123 SAP
- 18F florbetapir
- 18F florbetapen
- 11C Pittsburgh B compound

99m Tc RNI grading

- Scan interpretation
- Grade 0- absent cardiac uptake
- Grade 1- mild uptake less than bone
- Grade 2- moderate uptake equal to bone
- Grade 3- high uptake with less or no bone uptake
99m Tc-PYP uptake is less in AL than ATTR


99m Tc-PYP uptake is less in AL than in ATTR

99m Tc-PYP images

Examples of Tc99-PYP scans
Sensitivity and specificity of RNI for ATTR

Gillmore, JD et al. Circulation. 2016;133:2404-2412

Proposed diagnostic algorithm

Gillmore, JD et al. Circulation. 2016;133:2404-2412
F18 florbetapir

- FDA-approved for brain imaging for amyloid
- Binds to amyloid protein

Taken up by both AL and ATTR amyloid in the heart

---

F-18 florbetapir

New treatments for ATTR are on the horizon

Tafamidisis a transthyretin stabilizer that has been shown to slow the progression in TTR polyneuropathy.

Inoteresen and Palisiran improve symptoms of polyneuropathy in patients with hereditary ATTR.
Tafamidis improves outcomes in patients with ATTR cardiomyopathy

FDG PET for device infection

• ~240,000 implants were performed in the US in 2003
• Incidence of PPM/ICD infections is 1.9 cases/1000 implants/yr
• Infections can be associated with endocarditis (leads) or just the generator pocket
• ~70% of patients present with signs of pocket infection
• Lead extraction results in ~2% morbidity and ~0.8 % mortality rates
• Diagnostic delays can result in poorer outcomes
A negative PET can help rule out infection

- 26 pts with possible infection:
  - 12 extracted
  - 12/12 +PET

- 20 pts with definite infection:
  - All extracted
  - 17 with +PET

Pocket infection

- 14 not extracted
  - 1/13 +PET
Epicardial lead infection

Negative FDG PET for CIED infection
FDG PET and device infections

FDG PET may help in patients with possible CIED infection
FDG uptake is greater in patients who underwent extraction

Proposed algorithms for CIED diagnosis
Large vessel vasculitis

Endocarditis
Take home points

- Myocardial viability assessment by FDG-PET has been validated and may improve outcomes
- Myocardial blood flow data from cardiac PET may aid in identifying targets for revascularization and also aid in the identification and prognosis for patients with MVD and CAV
- FDG-PET is useful in the treatment algorithm for cardiac sarcoidosis
- PYP scans can make the diagnosis of cardiac ATTR without the need for EMBx
- FDG-PET may also aid in the diagnosis of some inflammatory conditions (including infection)

Nuclear cardiology

- Wendy Beasley, CNMT
- Kelli Lemke, CNMT
- Joel Graham, CNMT
- Xiao Lor, CNMT
- Jake Boerboom, CNMT
- Carol Carron, CNMT
- Miranda Weaver, CNMT
Thanks!