Noninvasive Coronary FFR<sub>CT</sub> Evaluation in Patients Undergoing Peripheral Vascular Surgery With no History of Coronary Artery Disease

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

**Affiliation/Financial Relationship**

- Grant/Research Support
- Consulting Fees/Honoraria

**Company**

- Abbott Vascular, Boston Scientific
- Amgen, Abbott Laboratories, Astra-Zeneca, Bayer, Boehringer Ingelheim, GlaxoSmithKline, Berlin Chemie / Menarini, Merck, Pfizer, Sandoz, Sanofi, Servier Laboratories, Siemens laboratories, Abbott Vascular, Boston Scientific, Biotronik, Biosensors, Cordis, MVRx

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Multisite artery disease is common in patients with atherosclerotic involvement in one vascular bed, ranging from 10 to 15% in patients with coronary artery disease (CAD) to 60 to 70% in patients with severe carotid stenosis or lower extremity artery disease (LEAD).

The effect of postoperative myocardial ischemia on survival after peripheral vascular surgery

The Vascular Study Group of New England registry identified all patients who underwent carotid revascularization, open abdominal aortic aneurysm repair (AAA), endovascular AAA repair, or infrainguinal lower extremity bypass (2003-2011). The association of postoperative troponin elevation and myocardial infarction with 5-year survival was evaluated. N=16363

Indication for screening of associated atherosclerotic disease in additional vascular territories

Multisite artery disease is invariably associated with worse clinical outcomes; however, screening for asymptomatic disease in additional vascular sites has not been proven to improve prognosis.

<table>
<thead>
<tr>
<th>Leading disease</th>
<th>Screened disease</th>
<th>CAD</th>
<th>LEAD</th>
<th>Carotid</th>
<th>Renal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Scheduled for CABG</td>
<td></td>
<td>Ila&lt;sup&gt;a&lt;/sup&gt;</td>
<td>I&lt;sup&gt;Ⅰ&lt;/sup&gt;</td>
<td>Ilb&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Not scheduled for CABG</td>
<td></td>
<td>Ilb</td>
<td>NR</td>
<td>U</td>
</tr>
<tr>
<td>LEAD</td>
<td>Scheduled for CABG</td>
<td>I&lt;sup&gt;Ⅰ&lt;/sup&gt;</td>
<td></td>
<td>NR</td>
<td>U</td>
</tr>
<tr>
<td></td>
<td>Not scheduled for CABG</td>
<td>NR</td>
<td></td>
<td>NR</td>
<td>U</td>
</tr>
<tr>
<td>Carotid stenosis</td>
<td>Scheduled for CEA/CAS</td>
<td></td>
<td>Ilb</td>
<td>NR</td>
<td>U</td>
</tr>
<tr>
<td></td>
<td>Not scheduled for CEA/CAS</td>
<td>NR</td>
<td></td>
<td>NR</td>
<td>U</td>
</tr>
</tbody>
</table>

CAD = coronary artery disease, LEAD = lower extremity artery disease
CABG = coronary artery bypass grafting, CEA = Carotid endarterectomy CAS = Carotid artery stenting
Non-invasive assessment of human blood flow from CT angiography: CT-FFR, Heartflow

Charley Taylor and Chris Zarins

Computational fluid dynamics (CFD), quantifies fluid pressure and velocity, based on physical laws of mass conservation and momentum balance.

$\rho \frac{\partial \vec{v}}{\partial t} + \rho \vec{v} \cdot \nabla \vec{v} = -\nabla p + \nabla \cdot \tau$

$\nabla \cdot \vec{v} = 0$

CFD is widely used in the aerospace and automotive industries for design and testing. CFD techniques have now been applied to analyze problems of human blood flow.
First in World Clinical Validation of $\text{FFR}_\text{CT}$

$\text{FFR}_\text{CT}$ compared to FFR measured in the cath lab

- First-in-man study at Pauls Stradins University Hospital, Riga, Latvia
- First 20 patients $\text{FFR}_\text{CT}$ compared to measured FFR
  - Presented at European Society of Cardiology, August 2010, Stockholm, Sweden

Measured FFR

$\text{FFR}_\text{CT}$

Diagnostic Performance

*Per-patient $\text{FFR} \leq 0.80$ threshold*

Erglis A et al., Eur Heart J 2010; 31: 151
Introduction and objective

• Peripheral vascular surgery (PVS) patients are at increased risk of post-op MI / death but pre-op cardiac testing is not recommended unless there are symptoms of coronary ischemia

• Coronary CT-derived fractional flow reserve (FFR_{CT}) can reliably identify ischemia-producing coronary stenosis but has not yet been used to evaluate PVS patients with no coronary symptoms

• **OBJECTIVE:** To determine the prevalence of unsuspected ischemia-producing stenosis in PVS patients with no history of cardiac disease who are undergoing surgery for symptomatic peripheral vascular disease
Methods

• Prospective, ongoing IRB-approved study – pre-op CTA-FFRCT
  – Patients with no cardiac history or coronary symptoms admitted for elective carotid, aortic or peripheral vascular surgery were evaluated with pre-op coronary CT angiography (CTA) and FFR<sub>CT</sub> analysis

• CTA datasets were sent for offsite FFRCT analysis via web interface with results returned in < 24 hours

• Patient management was guided by the Heart Team comprised of vascular surgeon, cardiologist, anesthesiologist, cardiac surgeon and radiologist

• MACE events (death, MI, acute coronary syndrome): at 30 and 90 days
**Patient characteristics**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N=106</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>66±9</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>84 (79)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>22 (21)</td>
</tr>
<tr>
<td>Hypertension, n (%)</td>
<td>83 (78)</td>
</tr>
<tr>
<td>Dyslipidemia, n (%)</td>
<td>45 (43)</td>
</tr>
<tr>
<td>Diabetes mellitus, n (%)</td>
<td>15 (14)</td>
</tr>
<tr>
<td>Smoking history, n (%)</td>
<td>41 (39)</td>
</tr>
<tr>
<td>Medications, n (%):</td>
<td></td>
</tr>
<tr>
<td>Antihypertensive Tx</td>
<td>64 (60)</td>
</tr>
<tr>
<td>Statins</td>
<td>47 (44)</td>
</tr>
<tr>
<td>Insulin</td>
<td>13 (12)</td>
</tr>
<tr>
<td>Antiplatelet/anticoagulants</td>
<td>58 (55)</td>
</tr>
</tbody>
</table>

**Indication for PVS surgery**

- **LEAD** = lower extremity artery disease
- **Carotid**
- **AAA**

- LEAD: 81%
- Carotid: 16%
- AAA: 3%

LEAD = lower extremity artery disease
Coronary CT Angiography (CTA)

- Coronary CTA performed in 106 patients
- Coronary calcium: mean Agatston score $1127 \pm 1110$, (median 697 IQR 311- 1620).
- CTA stenosis ≥50% present in 74 patients (70%), left main stenosis in 8 (8%)

Pt. 022
67 yo male with diabetes mellitus no history of CAD (no symptoms, normal ECG) admitted for femoro-tibial bypass

CTA:
- RCA 70% stenosis
- LAD <50% stenosis
- Agatston score 3873 (LM 37; LAD 1512; LCx 198, RCA 2126)
FFR<sub>CT</sub> analysis

- FFR<sub>CT</sub> was performed in 97/106 patients (92%), not done in 9 patients (8%) due to CT image quality (motion or misregistration artifacts).

65/97 patients (67%) had ischemia-producing stenosis (FFR<sub>CT</sub> ≤ 0.80 distal to stenosis)

45/97 patients (46%) had severe lesion-specific ischemia (FFR<sub>CT</sub> ≤ 0.70 distal to stenosis)

59 y.o. man with limiting claudication

77 y.o. man with ischemic rest pain of the lower extremity
# CTA and FFR<sub>CT</sub> results

CTA - FFR<sub>CT</sub> stenosis severity in peripheral vascular surgery patients with no cardiovascular disease symptoms

<table>
<thead>
<tr>
<th>CTA stenosis (%)</th>
<th>CTA (n=patients)</th>
<th>Agatston score median (IQR)</th>
<th>FFR&lt;sub&gt;CT&lt;/sub&gt; ≤0.80 *</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;30%</td>
<td>11 (10%)</td>
<td>118 (28-321)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>30-49%</td>
<td>21 (20%)</td>
<td>623 (310-1750)</td>
<td>12/19 (12%)</td>
</tr>
<tr>
<td>50-69%</td>
<td>30 (28%)</td>
<td>902 (424-1934)</td>
<td>19/28 (20%)</td>
</tr>
<tr>
<td>≥70%</td>
<td>44 (42%)</td>
<td>1097 (459-1622)</td>
<td>34/39 (35%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>106</strong></td>
<td><strong>697 (311-1620)</strong></td>
<td><strong>65/97 (67%)</strong></td>
</tr>
</tbody>
</table>

* indicates functionally significant stenoses
Patient management

• Peripheral vascular surgery was performed as scheduled in 98/106 patients (92%)

• Peripheral vascular surgery was postponed in 8% of patients:
  • 3 patients underwent coronary revascularization;
  • 5 patients received medical therapy

• Post-operative elective coronary angiography at 1-3 months performed in 42 patients with $\text{FFR}_{CT} \leq 0.70$ or multivessel disease with coronary revascularization in 31
  • 25 PCI and 6 CABG with no complications
Post-operative invasive evaluation (Pt 022): Preintervention data

- 67 yo male with diabetes mellitus, no history of CAD (no symptoms, normal ECG) admitted for femoro-tibial bypass
- CTA: RCA 70% stenosis, LAD <50% stenosis, Agatston score 3873
Post-operative invasive evaluation (Pt 022): Coronary angiography
Post-operative invasive evaluation (Pt 022):

PCI

PCI LAD with DES

- 6F XB3.5 guiding catheter and Guidezilla catheter
- Predilation: Cutting balloon 3.0x6 mm
- DES: 3.0x8 mm
- Postdilatation: NC balloon 3.0x8 mm
Post-operative invasive evaluation (Pt 002): Preintervention data

- 79 yo male with history of TIA, diabetes mellitus no history of CAD (no symptoms, normal ECG) admitted for carotid endarterectomy

- CTA: RCA 60% stenosis, LAD 70-80% stenosis, Agatston score 3941
Post-operative invasive evaluation (Pt 002):
Coronary angiography
Post-operative invasive evaluation (Pt 002):

PCI

PCI LAD with DES (3.0x38mm) after plaque pretreatment with cutting balloon (2.5x6mm), NC balloon postdilatation (3.25x20mm)

PCI RCA with DES 3.0x18 mm (dist) and 3.0x16 mm (mid)
MACE

• MACE events (death, MI, acute coronary syndrome) were evaluated at 30 and 90 days
  – During perioperative period:
    • Deaths 0%
    • MI 0.9% (1 of 106 patients: One patient who did not have FFR_{CT} analysis because of CT image artifact (RCA motion) had MI 3 days post-op with successful emergent PCI
  – During 90 days follow up 0.9% (1 of 106 patients)
• Longer term follow up ongoing
MACE (Pt 057, Pre)

- 66 yo old male admitted for aortofemoral bypass due to critical limb ischemia; (-) previous coronary artery disease; (+) diabetes
- FFR<sub>CT</sub> analysis not performed because of CT image artifact (RCA motion)
- 3 days after surgery patient develops chest pain, ECG – atrial flutter with 2:1 conduction and hemodynamic instability
MACE (Pt 057, Post)

- 66 yo old male admitted for aortofemoral bypass due to critical limb ischemia; (-) previous coronary artery disease; (+) diabetes
- \( \text{FFR}_\text{CT} \) analysis not performed because of CT image artifact (RCA motion)
- 3 days after surgery patient develops chest pain, ECG – atrial flutter with 2:1 conduction and hemodynamic instability

Ad hoc RCA with DES

Elective PCI with DES in LM-LAD and LCX
Conclusions

• Patients with no cardiac symptoms who undergo elective peripheral vascular surgery have a high prevalence of unsuspected ischemia-producing coronary stenosis.

• Pre-op diagnosis with CTA-FFRCT may increase focus on peri-operative and post-operative cardiac care and may help reduce myocardial infarction and death.

• Longer term studies are needed to determine the value of elective coronary revascularization in PVS patients with asymptomatic ischemia-producing CAD.
Thank You!

Kemeri moorland, Instagram/latvia.eu