Will CT-FFr Replace the Diagnostic Angiogram in the Next 5 Years?
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DISCLOSURES

I have no disclosures relevant to today’s talk
Stress Testing Leads to Inappropriate Invasive Procedures

Findings During Invasive Coronary Angiograms

- **Obstructive CAD**: 55%
- **Non-obstructive CAD**

Because standard non-invasive stress testing is low yield

**Over half of patients** who undergo an additional invasive test **have no disease**

and could have avoided ICA if better non-invasive testing was available

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Data includes nearly 400,000 patients at over 650 US hospitals


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Diagnosing Anatomic and Functionally-Significant CAD

<table>
<thead>
<tr>
<th>ANATOMY</th>
<th>FUNCTION</th>
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<tbody>
<tr>
<td>Identify obstructive CAD</td>
<td>Identify lesion-specific ischemia that may benefit from PCI</td>
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**Invasive**

**Noninvasive**

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\[ FFR = \frac{P_d}{P_s} \] at hyperemia

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HeartFlow: Advancing Cardiovascular Disease Diagnosis and Treatment

1995

- Development of image-based modeling for coronary blood flow begun in 1995

2007

- Founded HeartFlow in 2007, Silicon Valley CA

2014

- FDA Clearance
  - De Novo 510(k) clearance received November 2014
  - CE Mark in July 2011
  - Commercially available in the US and Europe

2016

- >100 issued US and worldwide patents
  - >110 peer-reviewed publications
**FFR\textsubscript{CT} Provides Non-Invasive, Lesion-Specific Functional Information**

- **Non-Invasive**
  - Exercise Stress
  - Stress Echo
  - SPECT
  - CMR

- **Lesion-Specific Assessment**
  - Invasive FFR

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**HeartFlow FFR\textsubscript{CT} Process**

- A standard cardiac **CT scan** is performed and the data is uploaded to HeartFlow.
HeartFlow FFR\textsubscript{CT} Process

- A standard cardiac CT scan is performed and the data is uploaded to HeartFlow.
- HeartFlow Analysts use proprietary software to create a personalized, digital 3D model of the coronary arteries.

*Image not representative of actual product.
HeartFlow FFR\textsubscript{CT} Process

- A standard cardiac CT scan is performed and the data is uploaded to HeartFlow.
- HeartFlow Analysts use proprietary software to create a **personalized, digital 3D model of the coronary arteries**.
- **Powerful computer algorithms** solve millions of complex equations to assess the impact that blockages have on blood flow.
- Physicians **interrogate the model and interpret the FFR\textsubscript{CT} results** to determine, vessel-by-vessel, if sufficient blood is reaching the heart.

Case 1:

- 48 y.o. M with HTN presented to ER with chest pain and underwent stress echo
- Stress echo: Hypertensive response to exercise, patient experienced worsening chest pain and echo showed no wall motion abnormalities; however, EF did not augment with exercise
- What would you do next?
  - CCTA with FFR
  - Invasive coronary angiography
Case 1

FFR\(_{CT}\) 0.87

Case 1 Continued

FFR\(_{CT}\) 0.87
Case 1

High Accuracy of FFR<sub>CT</sub> Compared to Gold Standard

**DISCOVER-FLOW**
- Completed 2011
- N=103 patients

**DeFACTO**
- Completed 2012
- N=252 patients

**NXT**
- Completed 2013
- N=254 patients

**NXT Per-Vessel Performance**
- Specificity: 86%
- Sensitivity: 84%
- Accuracy: 86%

Data supported 2014
FDA Clearance

Koo et al, JACC 2011.
Min et al, JAMA 2012.
Norgaard et al, JACC 2014.
Performance of Coronary Diagnostic Tests for Functional Disease

Results of the FFR\textsubscript{CT} RIPCORD Trial

Initial Decision – CT Angio only

- N=67
- Optimal Medical Therapy (OMT)
  - N=47
  - Intervention (PCI or CABG)
  - N=20

More information needed
  - N=38

Final Decision – Post FFR\textsubscript{CT}

- N=113 (68.7% increase)
- Optimal Medical Therapy (OMT)
  - N=97
- Intervention (PCI or CABG)
  - N=87 (8.4% decrease)

44% of patients had decisions altered after physicians incorporated FFR\textsubscript{CT}

Change in disease management pathway for 36% of patients

Change in vessel assigned to PCI for an additional 8% of patients

Curzen et al. JACC CV Imaging 2016
PLATFORM Trial

Prospective clinical utility trial comparing two distinct patient management strategies.

**FFR\textsubscript{CT}-Guided Strategy**

**Usual Care**


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Dramatic Reduction in Invasive Catheterization (ICA) with No Obstructive Disease

**Usual Care**

- 27% Obstructive CAD
- 73% Non-obstructive CAD

**FFR\textsubscript{CT}-Guided**

- 27% Obstructive CAD
- 12% ICA Canceled
- 61% Reduction

83% reduction

PLATFORM: The HeartFlow Analysis did not Change Overall Revascularization Rates

HeartFlow Analysis aids in identifying the appropriate patients in need of revascularization

Invasive Angiography
Revascularization (all)
Stent placement (PCI)
CABG

HeartFlow Analysis
Standard pathway

Diagnostic Catheterization and Revascularization Rates¹

¹ Total revascularization includes stent placements (PCI) and Coronary Artery Bypass Graft surgery


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Case 2

- 64 y.o. M with abnormal pre-op ECG referred for coronary CTA with FFRct
  - Started on high-intensity statin therapy and aspirin
  - Underwent repeat CTA with FFRct after six months of medical therapy
Case 3

- 64 y.o. M with seasonal allergies, awoke 2 days in a row with chest congestion and inability to “fill his lungs with air”
- Evaluation by PCP, referred for treadmill ECG which was abnormal
- What would you do next?
  - Coronary CTA with FFR
  - Invasive coronary angiography
Will CT-FFr Replace the Diagnostic Angiogram in the Next 5 Years?

- CT-FFR provides both anatomic and functional data
- Early studies suggest that CT-FFR may play a useful role in reducing rates of invasive coronary angiography
- Unlikely to have a significant impact on rates of revascularization
- Long-term studies are ongoing

Thank you