Image Based Coronary Computational Flow Analysis (FFR<sub>CT</sub>)

How does it work?

Can it reduce peri-op MI and improve outcomes in patients with AAA and occlusive disease?

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DISCLOSURE

I have a significant financial interest in HeartFlow, Inc

CT Image Based Coronary Computational Flow Analysis

Non-invasive fractional flow reserve (FFR<sub>CT</sub>)

Non-invasive fractional flow reserve (FFR<sub>CT</sub>)

Validation of FFR<sub>CT</sub> vs FFR – 3 controlled clinical trials
- 2011, 2012, 2014 - >600 patients, >1000 vessel comparisons
- High diagnostic accuracy compared to FFR

Clinical utility studies
- Improves selection of pts for diagnostic cath and revascularization
- Safe deferral of unneeded cath
- Significant cost savings to healthcare system

Regulatory approval – Safe and effective
- 2011 CE mark, Europe
- 2014 FDA clearance, US
- 2016 PMDA, Japan

Evidence Reviews – favorable
- 2017 UK NICE – accurate and cost savings
- 2017 BCBS Evidence Street – positive evidence

>180 peer-reviewed publications

Clinical Adoption – US, Europe, Canada, Japan

Over 15,000 Patients have received the HeartFlow FFR<sub>CT</sub> Analysis worldwide

2017 Building Momentum with Payers and Partners
HeartFlow FFR<sub>CT</sub> Process

- A standard cardiac CT scan is performed and the data is uploaded to HeartFlow via AWS
- HeartFlow proprietary software, using deep learning, creates a personalized, digital 3D model of the coronary arteries. Model is then inspected and corrected by HeartFlow analysts
- Powerful computer algorithms solve incompressible Navier-Stokes equations to assess the impact of coronary artery disease
- Physicians interrogate the model and interpret the FFR<sub>CT</sub> results to assess, vessel-by-vessel, if sufficient blood is reaching the heart

Computational Flow Analysis in PAD Patients

- When will this be available for patients with peripheral arterial disease?
- Can it reduce peri-op myocardial infarctions and improve outcomes in PAD patients?

Peripheral Arterial Disease (PAD) patients have Coronary Artery Disease (CAD)

- CAD is primary cause of death in patients with PAD
  - 55% of patients with severe PAD requiring revascularization have severe CAD
  - 20% 1st year mortality in patients with CLI – ongoing risk
  - 50% mortality at 4 years in CLI patients
- CAD is often unrecognized and undiagnosed in PAD pts
  - Patients are sedentary, have no chest pain or cardiac symptoms
  - Low sensitivity of cardiac stress tests – significant disease often missed
- PAD pts receive sub-optimal care/control of CV risk factors
  - Low use of statins, antiplatelet agents, smoking cessation

Improved diagnosis of CAD in PAD patients

- Pre-op evaluation CAD in PAD patients
- Coronary CT + CFD analysis of flow (FFR<sub>CT</sub>)
- Combined anatomic-functional assessment
  - Identifies patients with hemodynamically significant coronary lesions which may increase cardiac risk
  - And may modify treatment plan

Case Example

- 59 y.o. man with ischemic rest pain and limiting claudication
  - No chest pain or cardiac history, normal EKG
  - Admitted for femoral-popliteal bypass

Danish Nationwide Registry
133,772 patients

- Risk of death at 7 years
  - PAD, no CAD 48% n= 35,628
  - MI hx, no PAD 36% n= 71,115 p<0.001
  - PAD + MI 60% n= 7,029

- Higher long-term risk of death with PAD than with MI
  - True in both men and women
  - True even in the absence of diabetes

PAD is CAD risk equivalent
**Case Example**

- **61 y.o. diabetic woman with ischemic toe ulceration**
  - No chest pain or cardiac history; normal EKG
  - Failed prior endovascular treatment of SFA occlusion
  - Admitted for femoral-distal bypass

**Case Example**

- **49 y.o. man with ischemic rest pain and limiting claudication**
  - No chest pain or cardiac history; normal EKG
  - Admitted for femoral-popliteal bypass

**Conclusion**

- PAD patients are at high risk for MI and CV death
- Pre-op evaluation with coronary CT and FFR<sub>CT</sub> can identify patients with hemodynamically significant CAD who are at risk for coronary events
- This will allow improved treatment planning and management of both PAD and CAD and may reduce peri-op MI and improve long-term survival

Thank you for your attention