Optimising Sync Vision

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EVERYBODY LOVES PROGRESS
NOBODY LIKES CHANGE
Radial access used less than femoral approach for emergency angioplasty

Radial approach associated with less bleeding; research needed to understand slow adoption
A statistician crossed a river of 10 cm deep (+/- 241 cm) and he drowned.

W.F. Hermans
Appropriateness of percutaneous coronary intervention.

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Abstract

CONTEXT: Despite the widespread use of percutaneous coronary intervention (PCI), the appropriateness of these procedures in contemporary practice is unknown.

OBJECTIVE: To assess the appropriateness of PCI in the United States.

DESIGN, SETTING, AND PATIENTS: Multicenter, prospective study of patients within the National Cardiovascular Data Registry undergoing PCI between July 1, 2009, and September 30, 2010, at 1091 US hospitals. The appropriateness of PCI was adjudicated using the appropriate use criteria for coronary revascularization. Results were stratified by whether the procedure was performed for an acute (ST-segment elevation myocardial infarction, non-ST-segment elevation myocardial infarction, or unstable angina with high-risk features) or nonacute indication.

MAIN OUTCOME MEASURES: Proportion of acute and nonacute PCIs classified as appropriate, uncertain, or inappropriate; extent of hospital-level variation in inappropriate procedures.

RESULTS: Of 500,154 PCIs, 355,417 (71.1%) were for acute indications (ST-segment elevation myocardial infarction, 103,245 [20.6%]; non-ST-segment elevation myocardial infarction, 105,708 [21.1%]; high-risk unstable angina, 146,464 [29.3%]), and 144,737 (28.9%) for nonacute indications. For acute indications, 350,469 PCIs (98.6%) were classified as appropriate, 1055 (0.3%) as uncertain, and 3893 (1.1%) as inappropriate. For nonacute indications, 72,911 PCIs (50.4%) were classified as appropriate, 54,988 (38.0%) as uncertain, and 16,838 (11.6%) as inappropriate. The majority of inappropriate PCIs for nonacute indications were performed in patients with no angina (53.8%), low-risk ischemia on noninvasive stress testing (71.6%), or suboptimal (≤1 medication) antianginal therapy (95.8%). Furthermore, although variation in the proportion of inappropriate PCI across hospitals was minimal for acute procedures, there was substantial hospital variation for nonacute procedures (median hospital rate for inappropriate PCI, 10.8%; interquartile range, 6.0%-16.7%).
139 patients (77% female) with angina without obstructive CAD (no stenosis >50%) underwent complete coronary evaluation:

- **100% had atherosclerosis on IVUS**
- **5% had FFR ≤0.80**
- **44% had endothelial dysfunction (>20% lumen reduction with Ach)**
- **21% had microvascular dysfunction (IMR>25)**
- **58% had myocardial bridging**
- **Only 23% had no coronary explanation**

Ref: Lee et al. Circulation 2015
**Definition:** Instantaneous pressure ratio, across a stenosis during the wave-free period, when resistance is naturally constant and minimised in the cardiac cycle.

\[ \text{iFR} = \frac{P_a}{P_d} \]

During the Wave Free period

All studies show diagnostic equivalence between iFR and FFR.
Two Large RCTs: iFR vs FFR; Many Strengths

Rigorous RCT testing of **diagnostic** strategies

N=4X FFR data; Current technology

Harmonized designs

  - Same population/randomization schemes
  - Same primary endpoint
  - Same noninferiority hypothesis=3.4% margin (HR 1.4)

RCT vs RRCT enrollment/follow up
Overall Results are Highly Comparable: iFR is Noninferior to FFR

Nearly identical primary endpoint event rates

DEFINE FLAIR: iFR 6.8% v FFR 7.0%
iFR-SWEDEHEART: iFR 6.7% v FFR 6.1%

Both well within noninferiority margins
SyncVision Functionality
iFR and IVUS Co-Registration and Angiographic Enhancement

iFR Co-Registration
- iFR drop is displayed on angio
- Length measurement without pullback device

IVUS Co-Registration
- Localization of IVUS with angiography
- Easy length/area/diameter measurements with manual pullback

Angio+ Enhanced Angiography
- Vessel Enhancement
- QCA & Device Detection
iFR Co-Registration

With iFR co-registration there is no need for hyperemic drugs, no need for time consuming pullback devices and no need for guesswork

- Make length measurements without a cumbersome pullback device
- Plan your procedure with physiologic guidance
Understand Focal vs Diffuse Disease

iFR co-registration graphically displays the iFR drop along the angiogram, highlighting which portion of the vessel is ischemic.

Focal Disease

Diffuse Disease
Make Length Measurements Without a Cumbersome Pullback Device

iFR co-registration is calibrated for distance, so with a simple manual pullback you can make measurements on the angiogram and trend line.

Click and Drag length measurements help with procedural planning
1. Make an angiogram
2. Perform an iFR Pullback
3. Select Pathway
4. iFR co-registration is performed automatically, in real-time
5. Make length measurements and treatment decisions
iFR Pullback Stenosis Mapping

- Pressure Wire Pullback (iFR Scout) produces a physiological map of the entire vessel as a function of time.
iFR Pullback Stenosis Mapping

- Pressure Wire Pullback (iFR Scout) produces a physiological map of the entire vessel as a function of time.
- SyncVision iFR Co-Registration maps that physiological data onto an angiogram as a function of distance.
iFR Pullback Mapping to Identify Focal and Diffuse Disease

FOCAL (high pressure drop intensity)

DIFFUSE (low pressure drop intensity)
Pullback Requirements

For Optimal iFR Co-Registration Results:

• Perform the pullback under continuous fluoro at 15 fps
• Pullback speed should be less than 2 mm/sec
  (a pullback in a 10 cm long vessel should last ~40-50 sec or heartbeats)
• Presence of CABG wires, additional guide wires, surgery clips or other metallic objects within the frame may lead to inaccurate calibration and Co-Registration results
Click & drag for length measurement

iFR Distal: 0.46
iFR drop in Selection: 0.23

Length: 10.08 mm
Adjust by grabbing and moving the edges of the length segment.
3 Way Co-Registration

If IVUS Co-Registration was performed prior to pressure wire pullback, Co-Registration is available for 3 modalities.
SyncVision Functionality
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Angio+ Enhanced Angiography
- Vessel Enhancement
- QCA & Device Detection
After placing a stent in the mid-vessel, the physician is deciding if he needs to treat the proximal LAD. Tri-registration shows an iFR value of 0.98 and a cross section of 7.9 mm² by IVUS. The physician decides this intervention is complete.
3 Way Co-Registration

- Same Roadmap used to obtain IVUS Co-Registration **MUST** be used for iFR Co-Registration
- Hence, the zoom, table and C-Arm position **MUST** remain the same from the IVUS pullback throughout the iFR pullback
Study Flow and Follow-Up

DEFINE PCI
Patients with stable and unstable angina (N = 500)

iFR of all vessels with angiographic lesions ≥ 40% stenosis

Baseline iFR ≤ 0.89
- Standard of care algorithm for PCI as per local operators (Intravascular imaging optional)
- Successful angiographic PCI result
- Blinded final iFR with iFR pullback
- Guideline Directed Medical Therapy

Baseline iFR > 0.89
- Guideline Directed Medical Therapy

30 day, 6 month & 1 year follow up
Primary Study Endpoint

- 467 Patients with Angiographically Successful PCI and qualified iFR pullbacks
- 24% Residual Ischemia (112 patients with Post PCI iFR ≤0.89)

- 81.6% Focal
- 18.4% Diffuse

Post iFR ≤0.89  Post iFR >0.89

Focal defined as step-up of ≥0.03 units in ≤15 mm segment
Diffuse defined as >15 mm segment
Focal Residual Pressure Gradient in-stent

Among the 93 vessels with focal disease, there were 146 segments (stent, proximal or distal) that had significant residual pressure gradients.
Focal Residual Pressure Gradient Prox to stent

‘Physiologicmiss’ occurred in 31.5% of focal lesions proximally
Focal Residual Pressure Gradient Distal to stent

‘Physiologic miss’ occurred in 30.1% of focal lesions distally.
Conclusions

- Coronary physiology is not only useful to assess vessel based ischemia but also to evaluate the contribution of individual lesions to the overall ischemic burden.
- An iFR pullback at rest minimizes cross-talk between lesions and is useful before and after PCI.
- An iFR pullback allows for distinction of focal vs. diffuse disease.
- Co-registration to the angiogram allows for improved procedural planning.
A pessimist sees the **difficulty** in every opportunity; an optimist sees the **opportunity** in every difficulty.

- Winston Churchill