2019 euroPCR

Benefits of Obtaining information for planning With noninvasive FFR_{CT} prior to Invasive Evaluation- The BOWIE study

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Background

- Despite an apparently well-conducted PCI procedure, ischemia is not relieved in 15-30% of patients and is associated with a 3-fold increase of MACE.[1,2.]
- Ideally, this issue should be identified up-front, in order to adapt the procedure and achieve a proper relief of ischemia.
- FFR_{CT} is a highly accurate test for the discrimination of lesion-specific ischemia. Recently, the ability to model post-treatment FFR_{CT} has been developed.
- The real-time, interactive FFR_{CT} planner* (HeartFlow, Inc.) is a novel non-invasive revascularization planning tool intended to help determine optimal CAD treatment decisions by facilitating the virtual modeling of treatment and calculation of post-treatment FFR_{CT}.

1. Fournier et al. JAMA Card 2019
2. Choi et al. JACC CI 2018

*Not yet commercially available, pending Regulatory Review

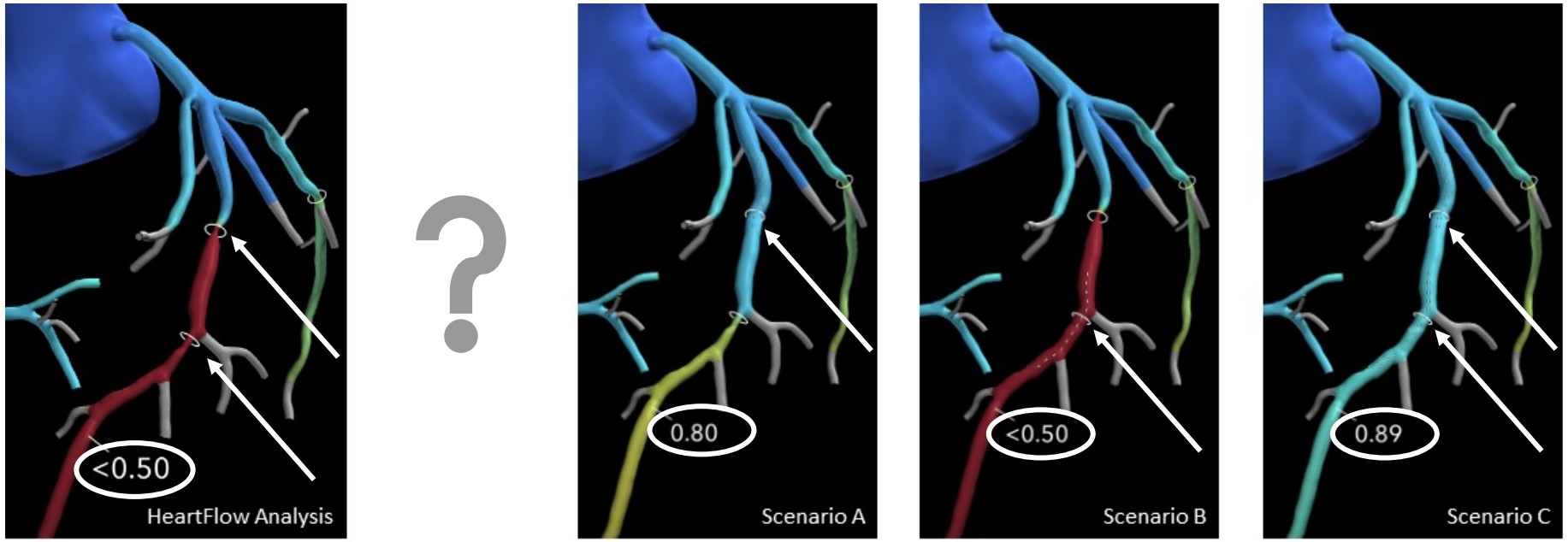
Study Aims

To determine the impact of the interactive FFR_{CT} planner, as compared to Invasive Coronary Angiography (ICA) alone, on CAD treatment decision making.

- Primary Endpoint: Reclassification
  - Differences between the ICA-based and FFR_{CT}– based treatment plans *per patient, per vessel,* and *per lesion*
- Secondary Endpoints:
  - Usage of invasive physiology
  - Nature of the treatment plan change

What is FFR_{CT} Planner* ?

Pre-procedure evaluation of alternate treatment strategies to optimize coronary flow

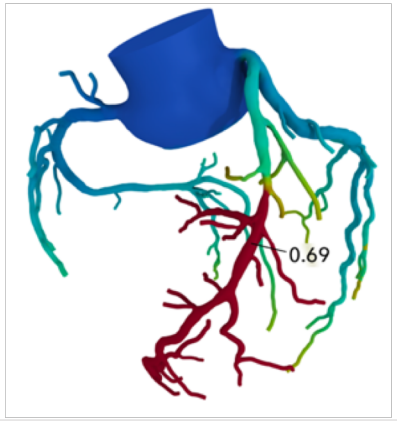


- Real-time non-invasive interactive tool
- Explore different clinical scenarios by virtually removing stenoses
- Assess resulting FFR_{CT} value(s) from any scenario

*Not yet commercially available, pending Regulatory Review

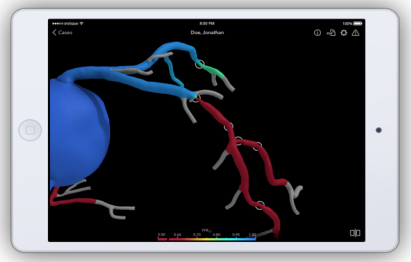
FFR_{CT} Planner* Core Components

1 Starts with the HeartFlow Analysis

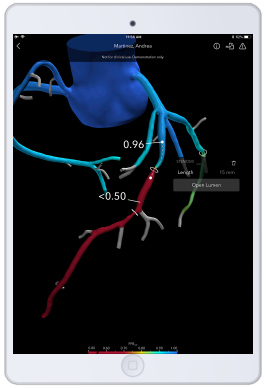


2 Interactive Mobile Platform

- iOS, interactive viewer

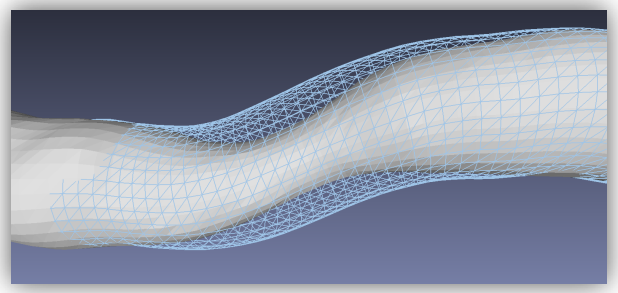


HeartFlow Planner



3 Ideal Geometry

- Contains a second anatomic model representing the “ideal” vessel



4 Real-time FFR_{CT} calculation

- Modified vessel combined with updated physiology

*Not yet commercially available, pending Regulatory Review

How was the study executed?

8 patients (7%) excluded due to poor ICA image quality

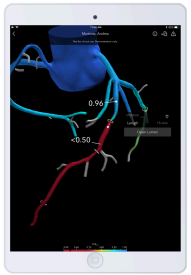
109 patients with CAD and available CTA, FFR_{CT}, and ICA

→ 101 patients (n=327 lesions)

Invasive Coronary Angiography
evaluated independently by 3 interventional cardiologists

→ **Consensus ICA Management Plan**
per lesion, per vessel, and *per patient*
OMT only/invasive FFR/PCI/CABG

△ = Reclassification



FFR_{CT} and FFR_{CT} Planner
evaluated independently by the same 3 interventional cardiologists

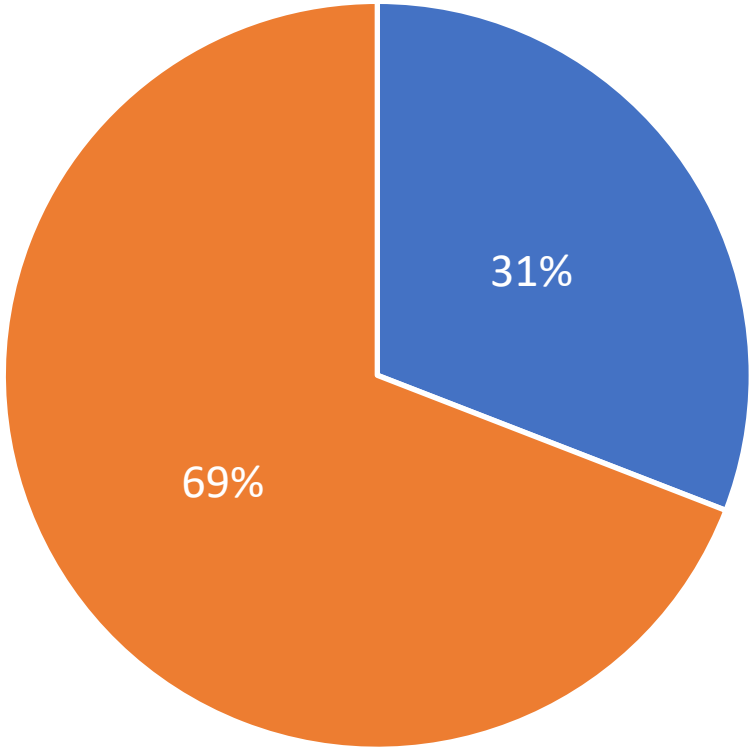
→ **Consensus FFR_{CT} Management Plan**
per lesion, per vessel, and *per patient*
OMT only/invasive FFR/PCI/CABG

Results: anatomical and physiological disease burden

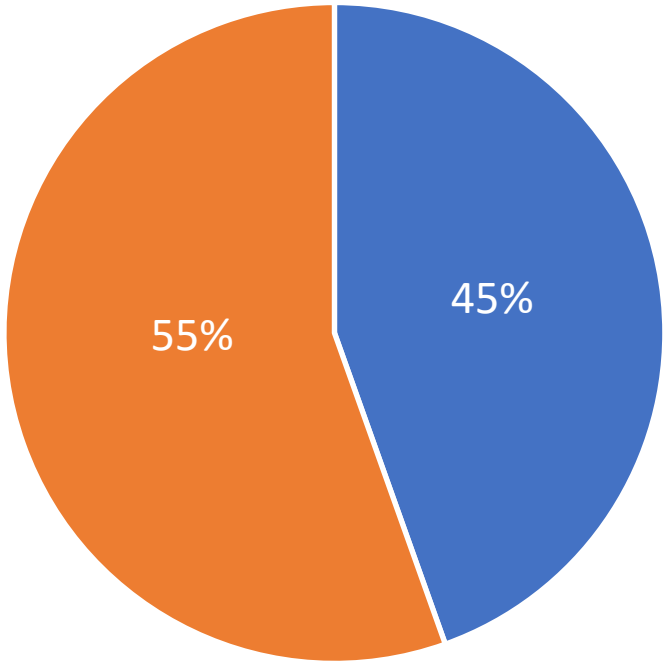
- 101 patients, 327 stenoses
- Mean number of stenoses: 3.2 ± 1.6 per patient
- **Serial stenoses (≥ 2 lesions in a row in the same territory) were present in 81% on ICA**
- Baseline distal FFR_{CT} values were lower in LAD, as compared with LCX and RCA territories (0.62 ± 0.17, 0.68 ± 0.18, 0.80 ± 0.13 respectively; p=0.001)

Reclassification rates per lesion and per patient

Lesion level (n=327)



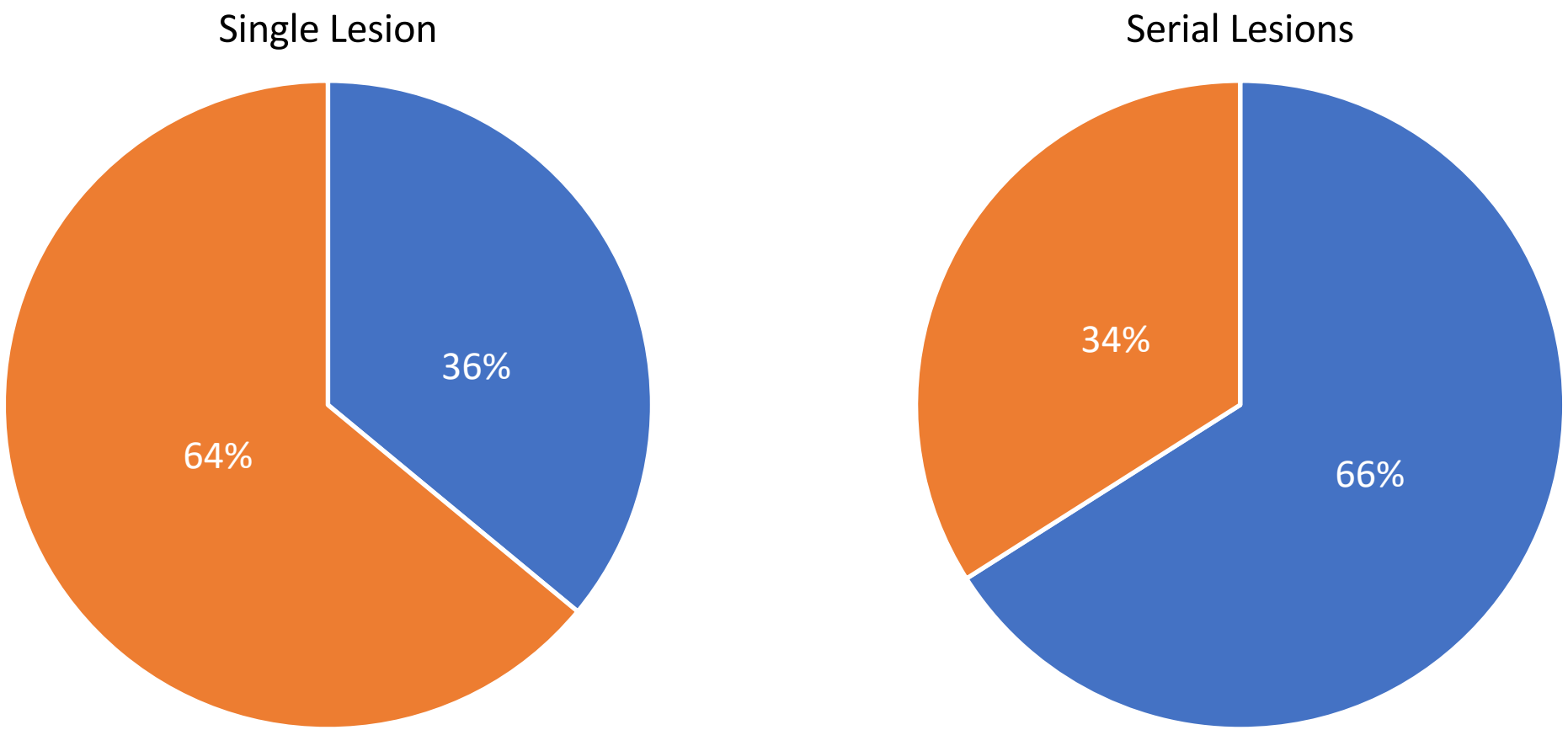
Patient level (n=101)



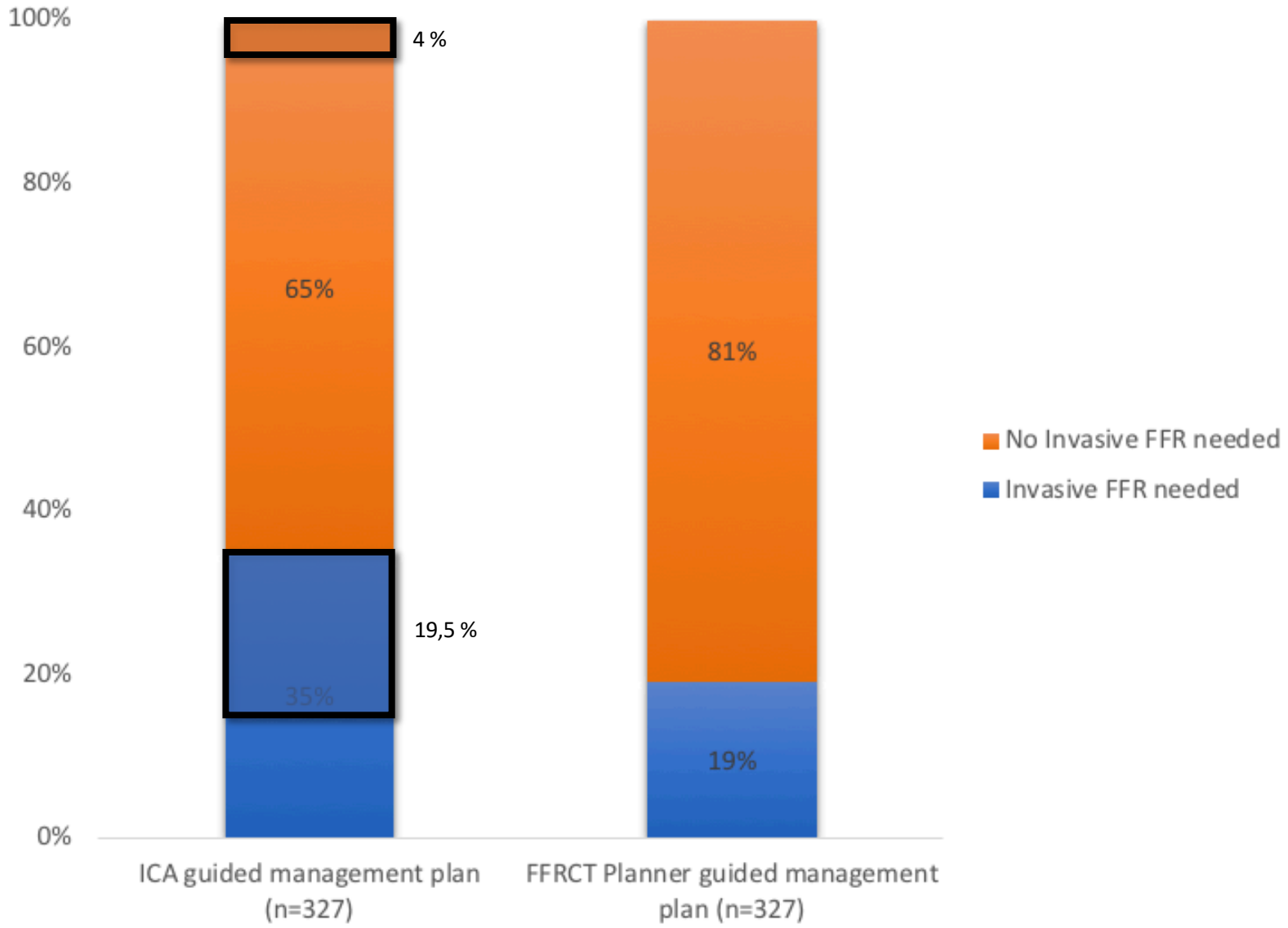
No Reclassification

Reclassified by FFR_{CT} Planner

Reclassification rates by lesion complexity



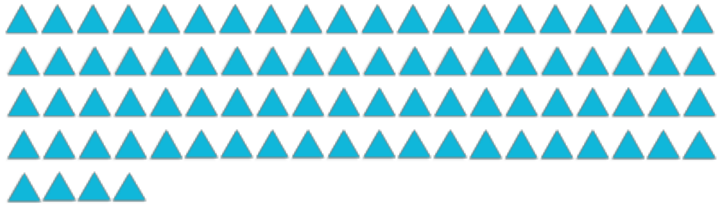
Change of physiology usage by FFR_{CT} Planner



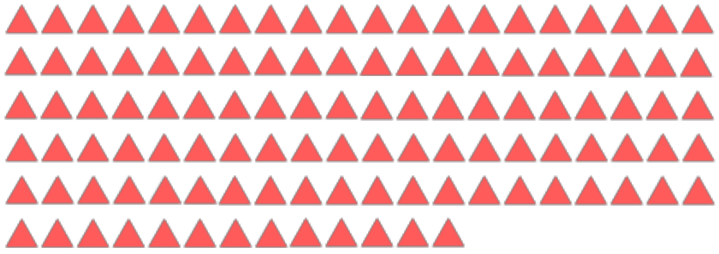
Impact of FFR_{CT} Planner: Lesion-level reclassification

ICA-Guided Management Plan

Optimal Medical Therapy (OMT) *n=84 lesions*



Invasive FFR Needed *n=113 lesions*



PCI *n=105 lesions*

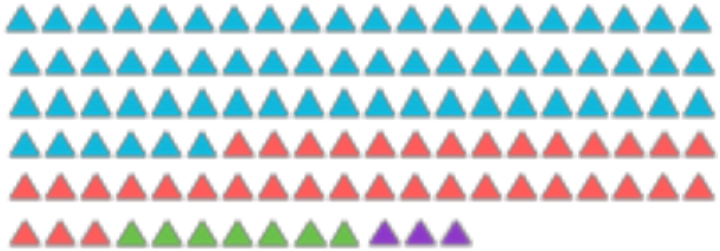
CABG *n=25 lesions*

FFR_{CT} Planner

Treatment plans were altered for **31% of lesions**

FFR_{CT} Planner-Guided Management Plan

Optimal Medical Therapy (OMT) *n=113 lesions*

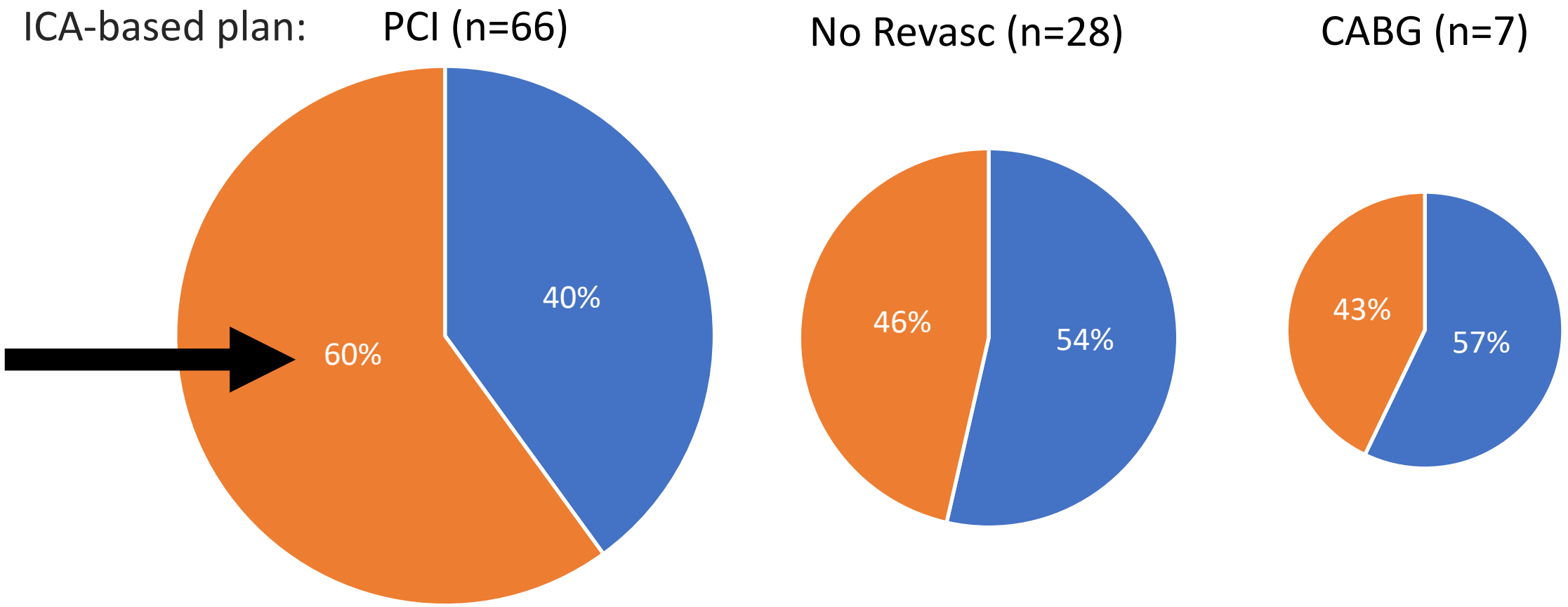


Invasive FFR Needed *n=62 lesions*

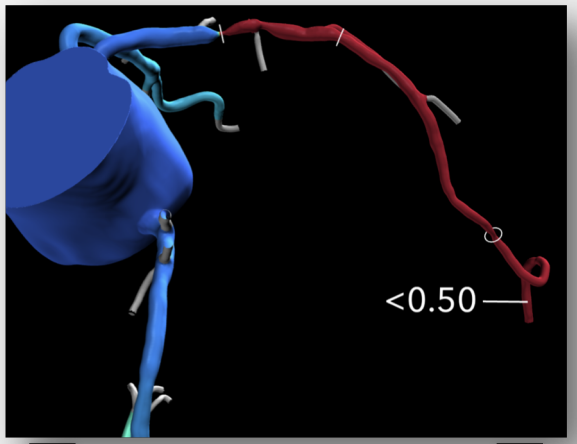
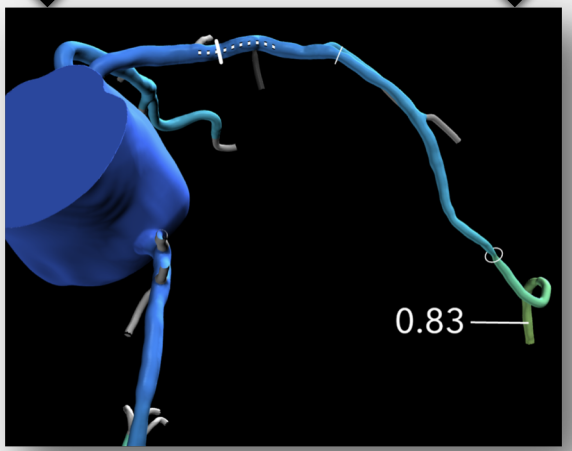
PCI *n=119 lesions*

CABG *n=33 lesions*

Reclassification rates by ICA-based management plan



Non-invasive interactive FFR_{CT} Planner reclassifies the "PCI strategy"

	ICA	FFR_{CT} Planner
Pre-PCI	ICA-based plan **38mm stent**	 Baseline FFR_{CT}
Post-PCI	ICA-based plan reproduced on FFR_{CT} Planner **38mm stent**	 FFR_{CT} Plan **15mm stent**

Reduced stent length using FFR_{CT} Planner strategy yielded similar physiologic result as ICA-based plan

Summary

- In patients with coronary artery disease, the use of the interactive FFR_{CT} planner prior to invasive angiography may:
  - Change the revascularization strategy in **31% of lesions and 45% of patients**
  - Reduce the need for invasive physiology
  - Not reduce the rate of PCI but **change the PCI strategy in 50% of cases**

- The results emphasize the potential benefit of the use of a real-time interactive FFR_{CT} planner pre-angiography to help inform revascularization decision making, optimize completeness of revascularization, and streamline resource utilization among CAD patients.