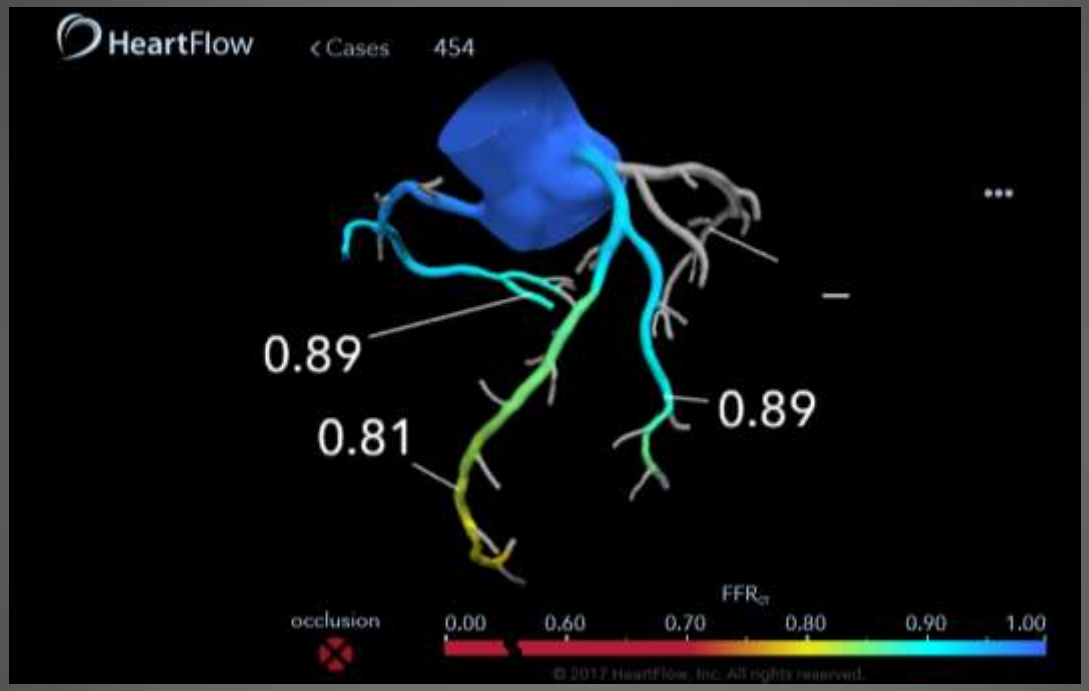
FFR_{CT}
-Real world practice in GHC -



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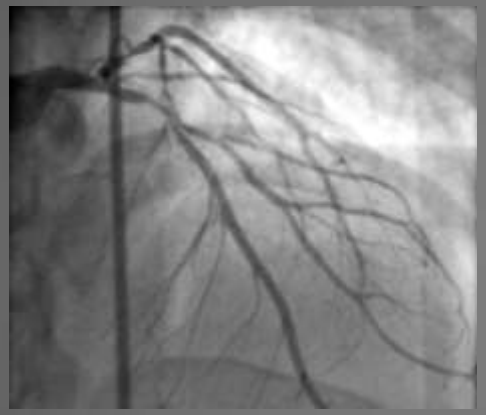
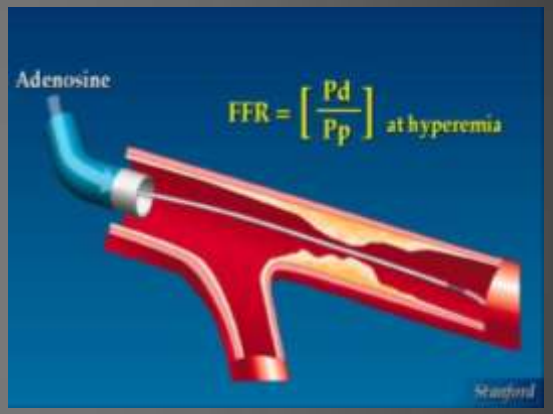
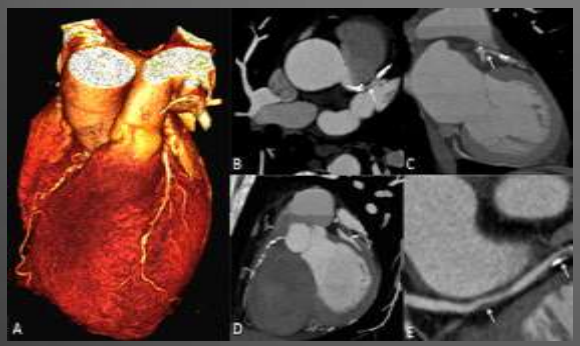
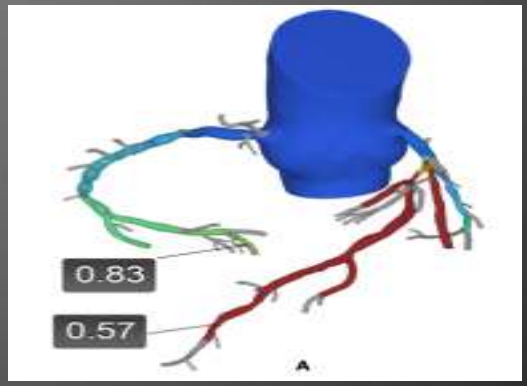
Gifu Heart Center, Japan

GIFU HEART CENTER

Anatomical and physiological evaluation of coronary artry disease

	Anatomical stenosis severity	Physiological stenosis severity
invasive		
Non-invasive		

ADVANCE Registry

HeartFlow

OBJECTIVE : Evaluate clinical outcomes and resource utilization of FFR_{CT} guided evaluation in patients with suspected CAD to further inform patients, health care providers, and other stakeholders about which technologies are most effective and efficient in the diagnosis and management of CAD.

Population

5000 patients
~50 sites
US, CA, EU, Japan

- **Symptomatic, suspected stable CAD**
- **No contraindications for cCTA**

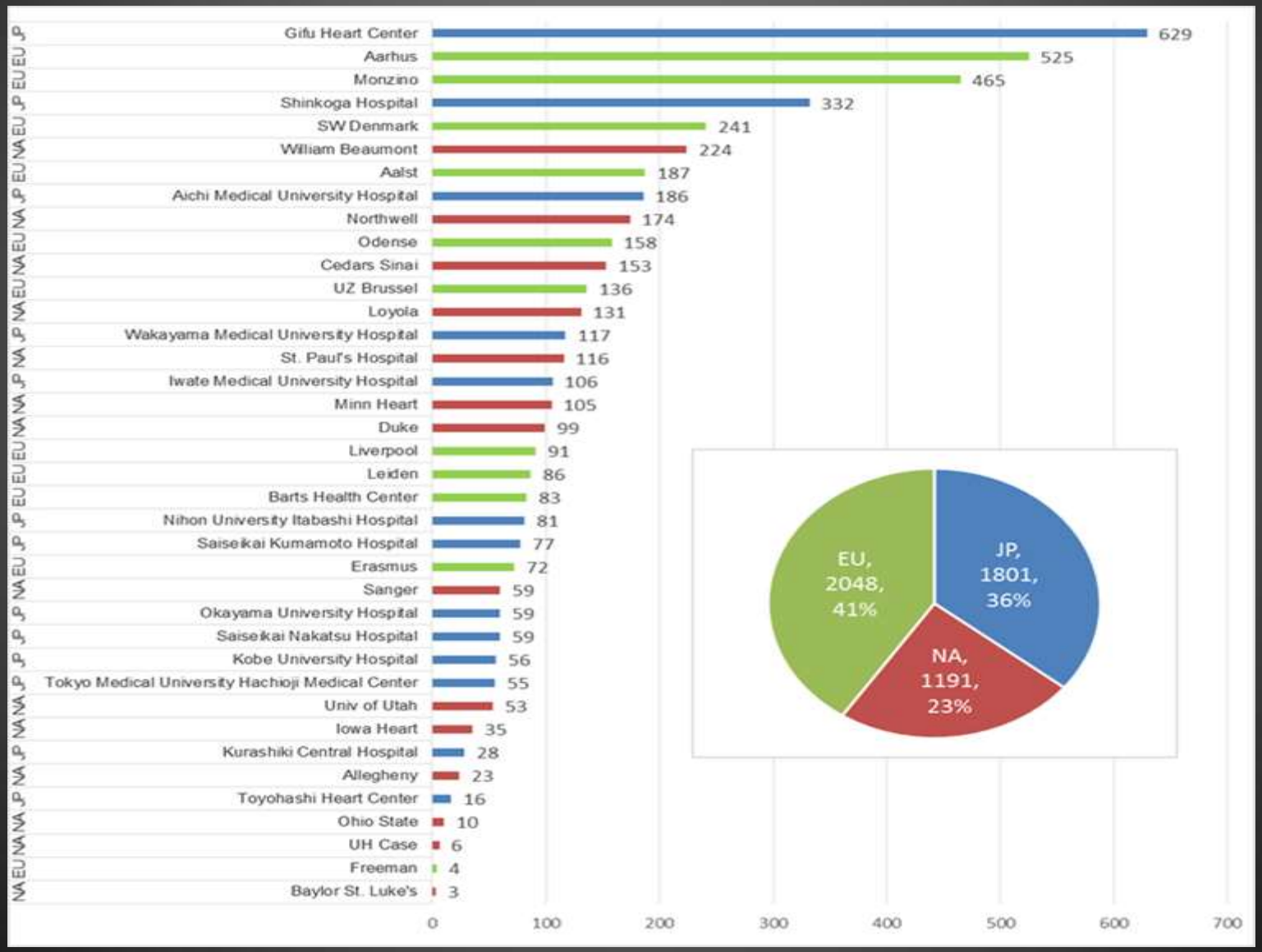
Primary Endpoint: Rate of invasive catheterization without obstructive disease (lumen diameter stenosis >50% (or 70%) by CAG or cCTA) at 90 days

Secondary Endpoints: MACE rates at 90 days, 180 days and 1 - 3 years, Individual components of MACE at 90 days, 180 days and 1 - 3 years, cumulative medical radiation exposure at 1 year.

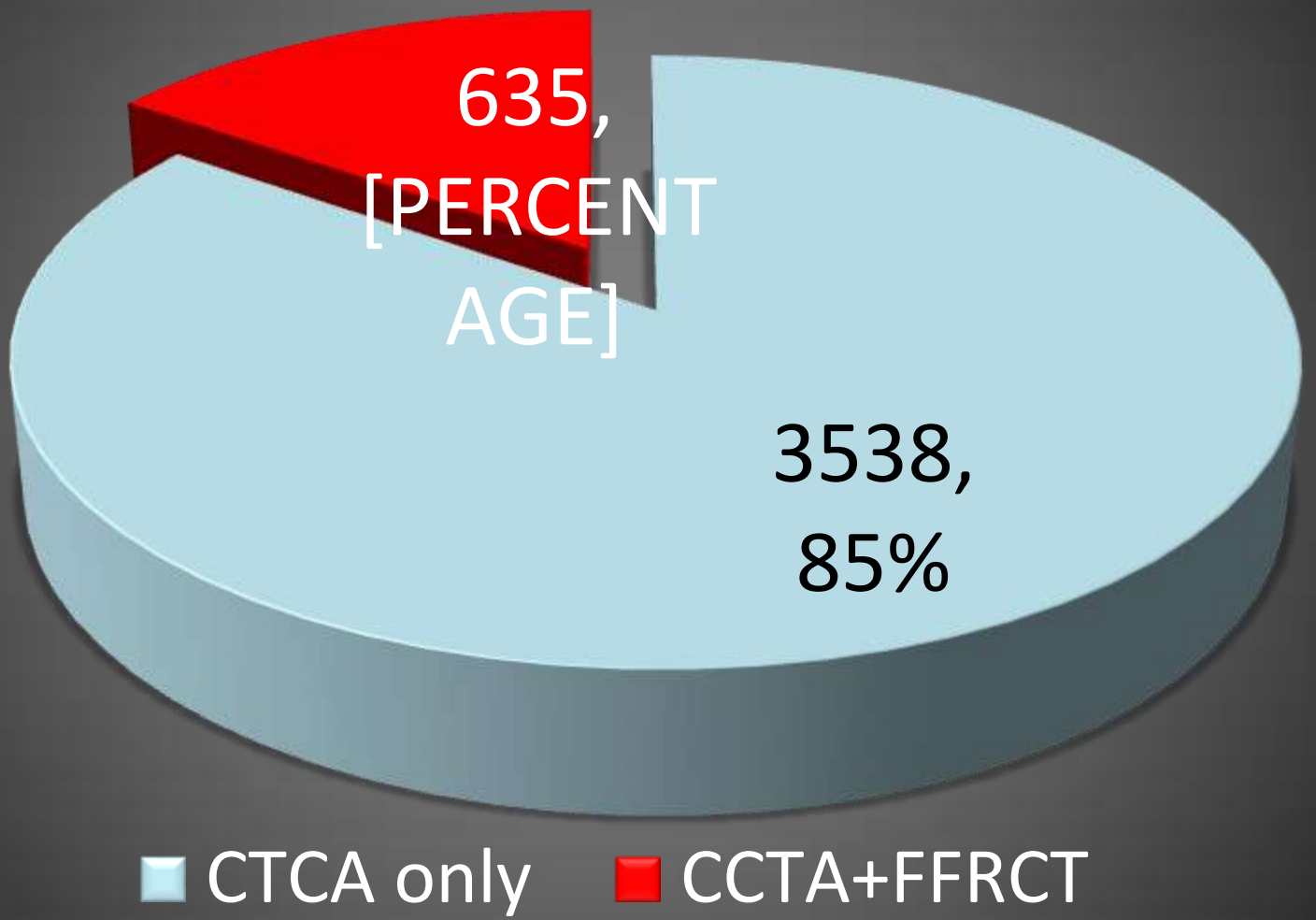
Current Status
Finalizing Protocol

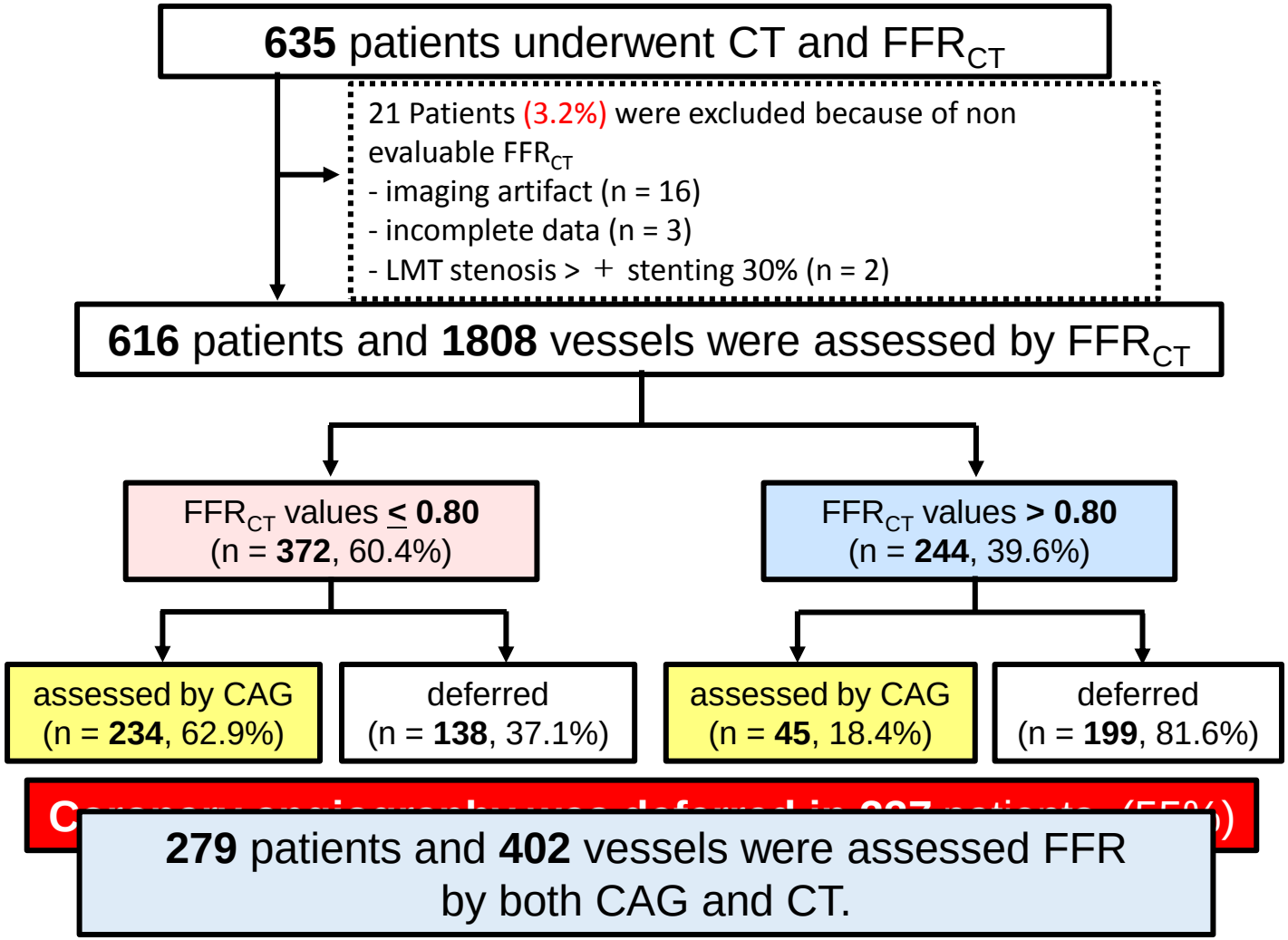
Principal Investigators
Patel (US), Leipsic (Canada), Nieman (Netherlands), Sabik (US), Akasaka (Japan)

HeartFlow is very pleased to announce that the ADVANCE registry has successfully completed enrollment of our 5,000th subject!
10/21/2017



CT exam 2015/07/01-2017/10/31

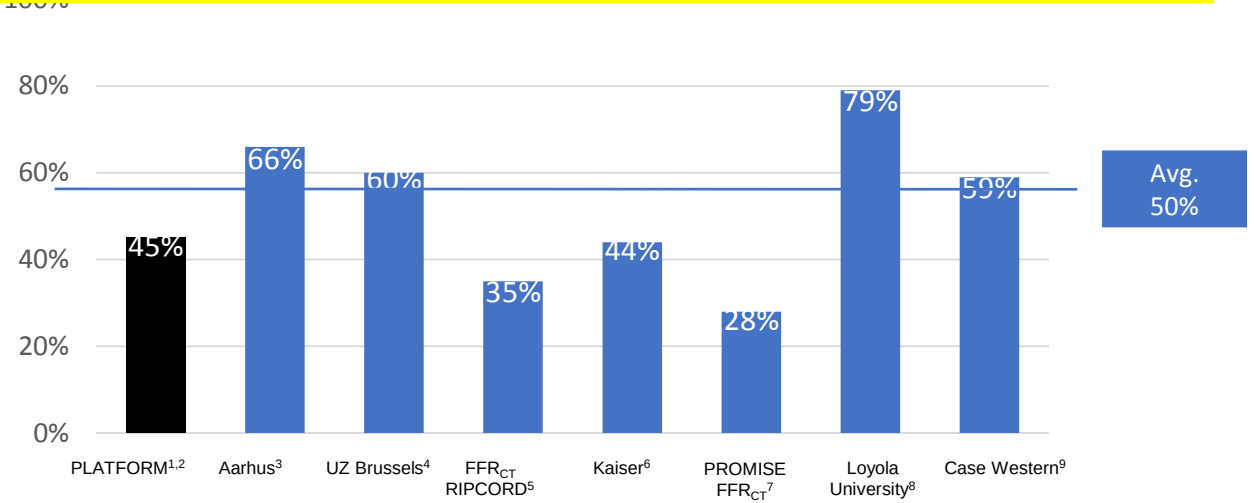



635 patients underwent CT and FFRCT
21 Patients (3.2%) were excluded because of non evaluable FFRCT
- imaging artifact (n = 16)
- incomplete data (n = 3)
- LMT stenosis > + stenting 30% (n = 2)
616 patients and 1808 vessels were assessed by FFRCT
FFRCT values ≤ 0.80 (n = 372, 60.4%)
FFRCT values > 0.80 (n = 244, 39.6%)
assessed by CAG (n = 234, 62.9%)
deferred (n = 138, 37.1%)
assessed by CAG (n = 45, 18.4%)
deferred (n = 199, 81.6%)
279 patients and 402 vessels were assessed FFR by both CAG and CT.

Lesson 1: Use of FFR_{CT} decreases cath rate and increases cath lab efficiency

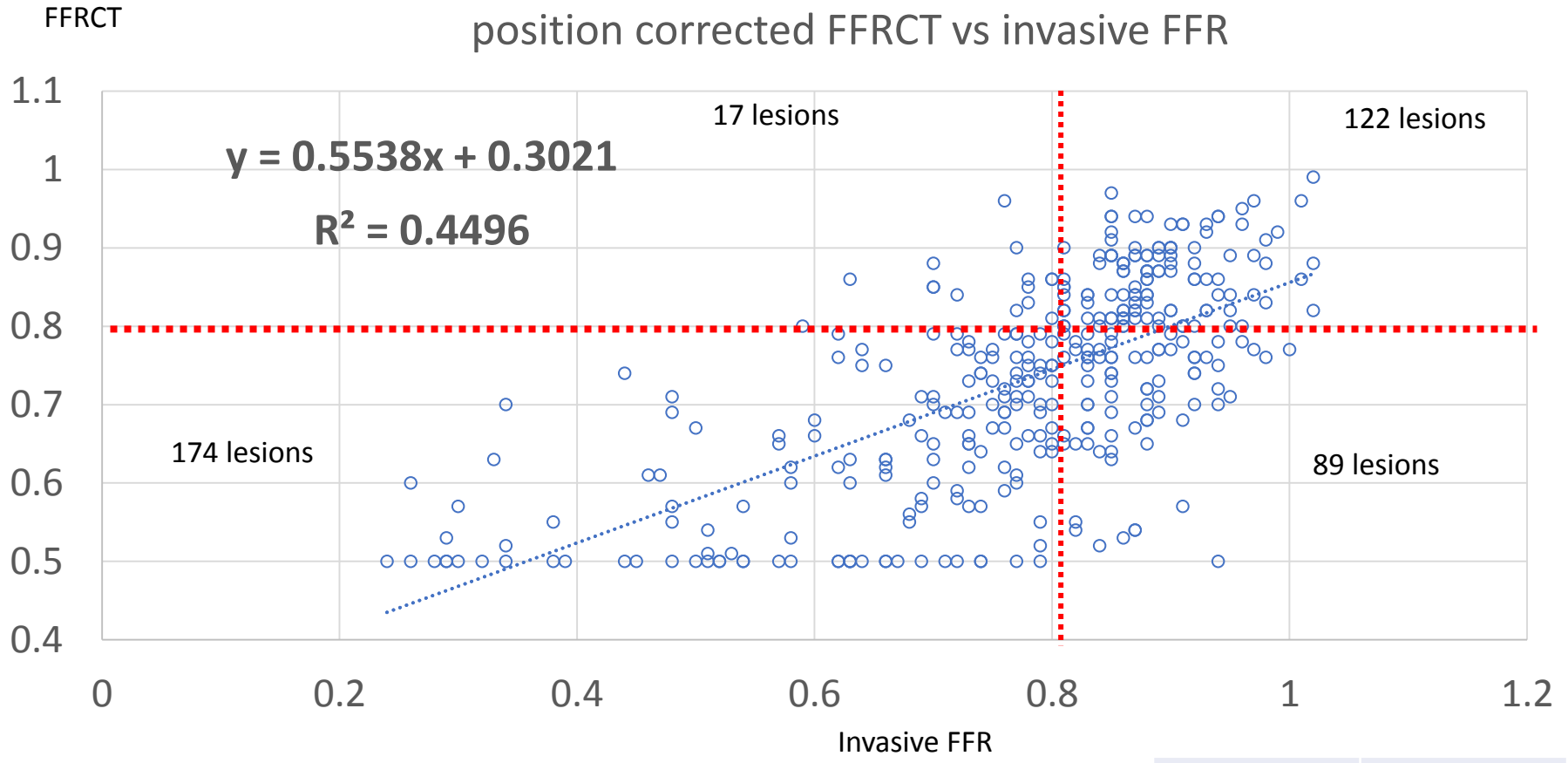
ICA Cancellation Rate with FFR_{CT} Analysis, compared to coronary CTA alone

Adding FFR_{CT} Reduces the Rate of ICAs by 50% on Average



- **Zero adverse events** seen in patients whose ICA was cancelled (n=1406)
- PLATFORM: Within the FFR_{CT}-guided pathway, 45% of patients who would have been referred to ICA based on coronary CTA results were deferred based on FFR_{CT}

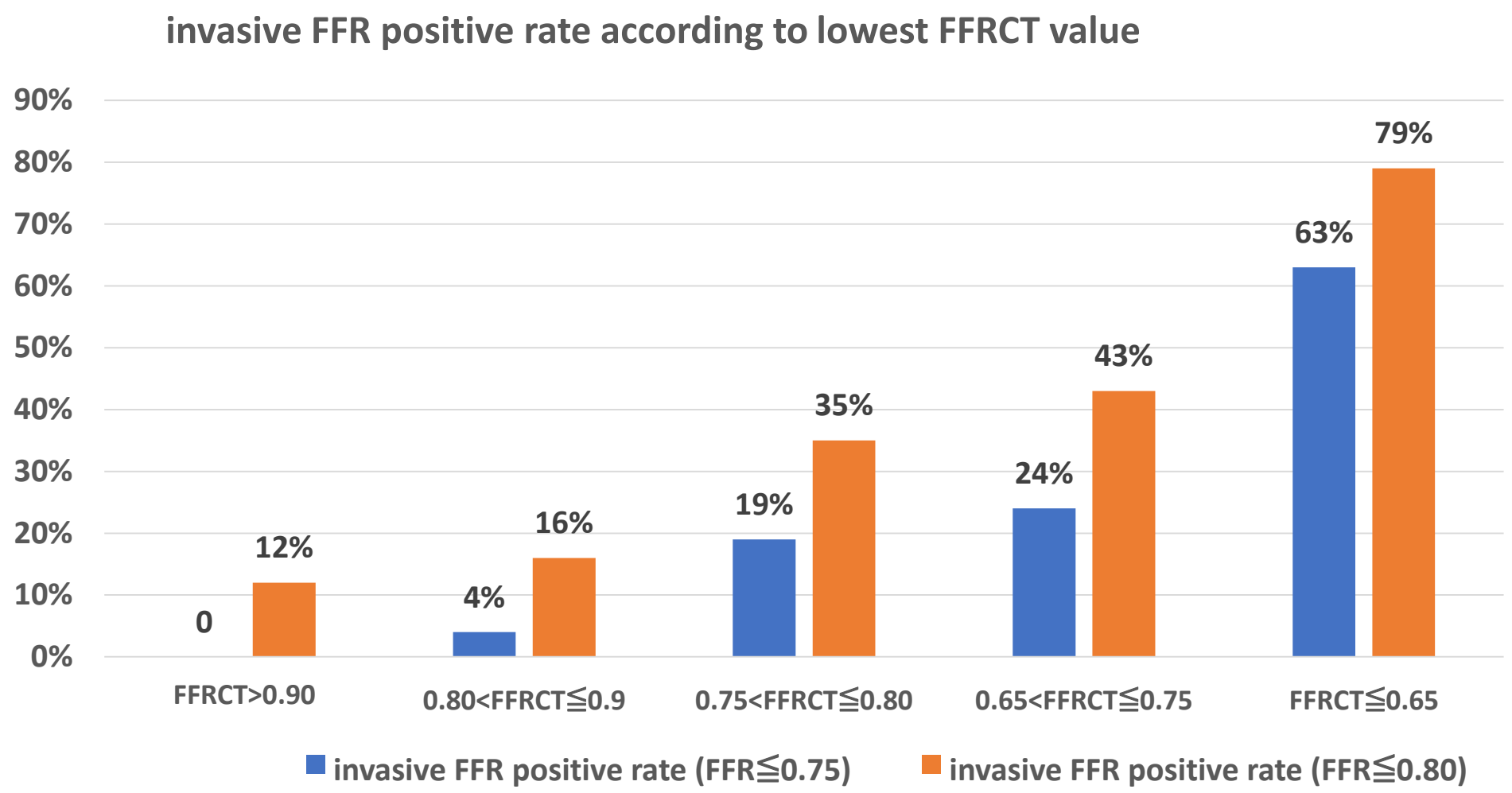
References slide follows



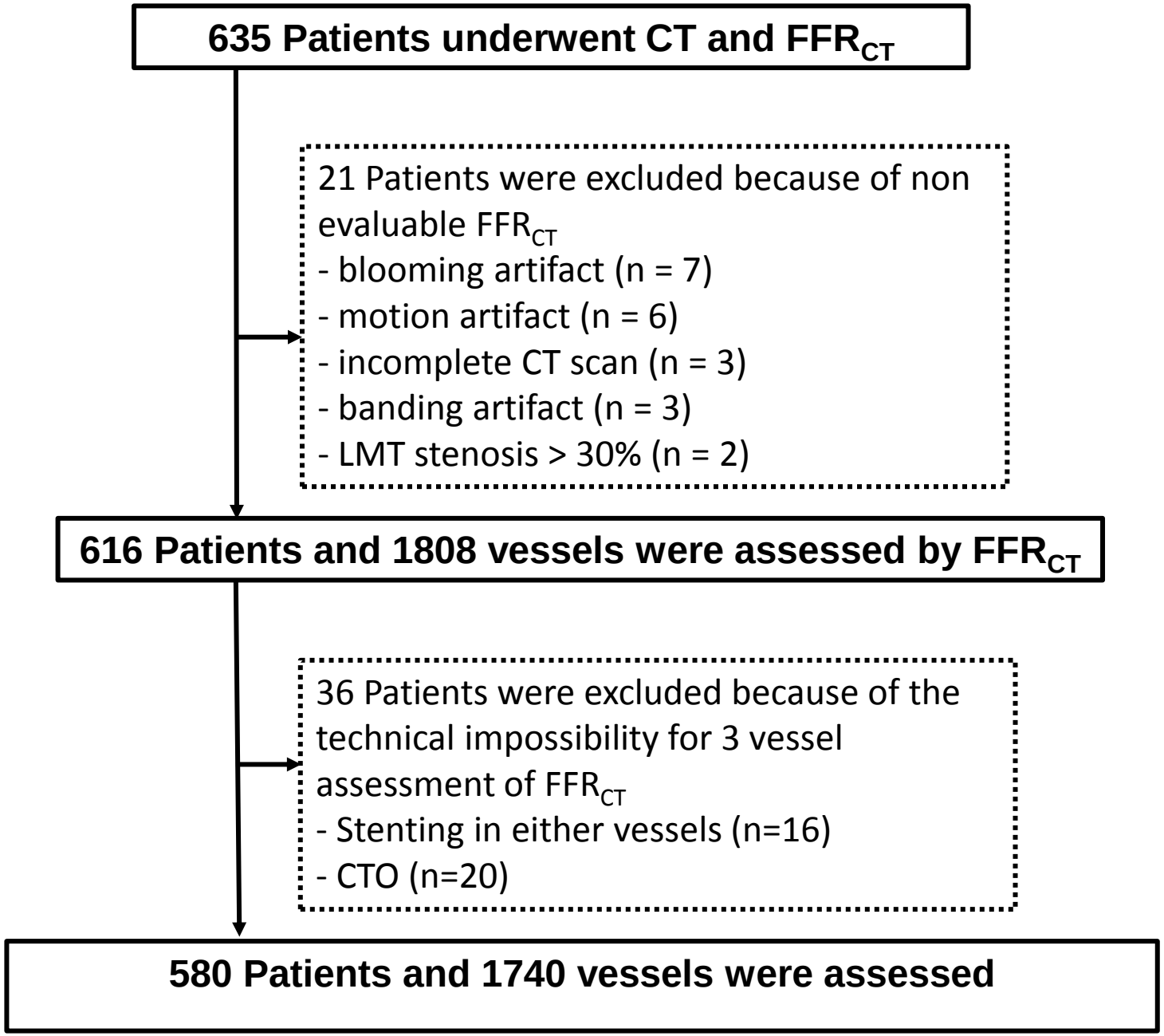
279 patients and **406** vessels were assessed FFR by both CAG and CT.

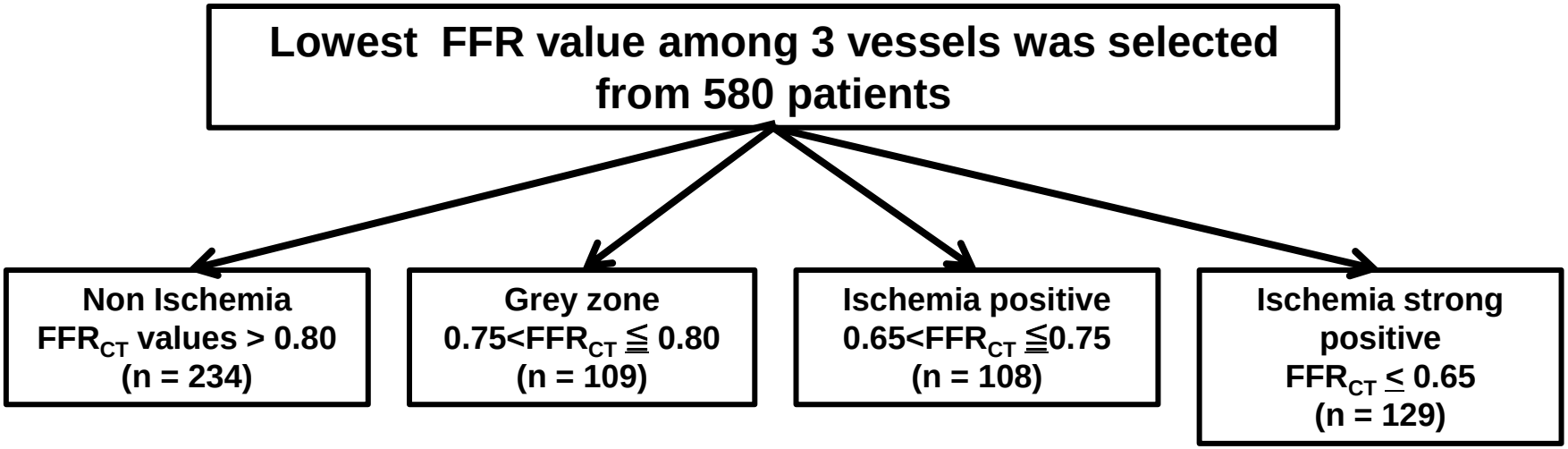
LAD : 238 lesions LCX : 87 lesions RCA : 77 lesions

Sensitivity	**91%**
Specificity	**58%**
PPV	**66%**
NPV	**88%**
Accuracy	**74%**


invasive FFR positive rate according to lowest FFRCT value
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
0
12%
4%
16%
19%
35%
24%
43%
63%
79%
FFRCT>0.90
0.80<FFRCT≦0.9
0.75<FFRCT≦0.80
0.65<FFRCT≦0.75
FFRCT≦0.65
invasive FFR positive rate (FFR≦0.75)
invasive FFR positive rate (FFR≦0.80)


Prognostic information by FFR_{CT}


635 Patients underwent CT and FFR$_{CT}$
21 Patients were excluded because of non evaluable FFR$_{CT}$
- blooming artifact (n = 7)
- motion artifact (n = 6)
- incomplete CT scan (n = 3)
- banding artifact (n = 3)
- LMT stenosis > 30% (n = 2)
616 Patients and 1808 vessels were assessed by FFR$_{CT}$
36 Patients were excluded because of the technical impossibility for 3 vessel assessment of FFR$_{CT}$
- Stenting in either vessels (n=16)
- CTO (n=20)
580 Patients and 1740 vessels were assessed



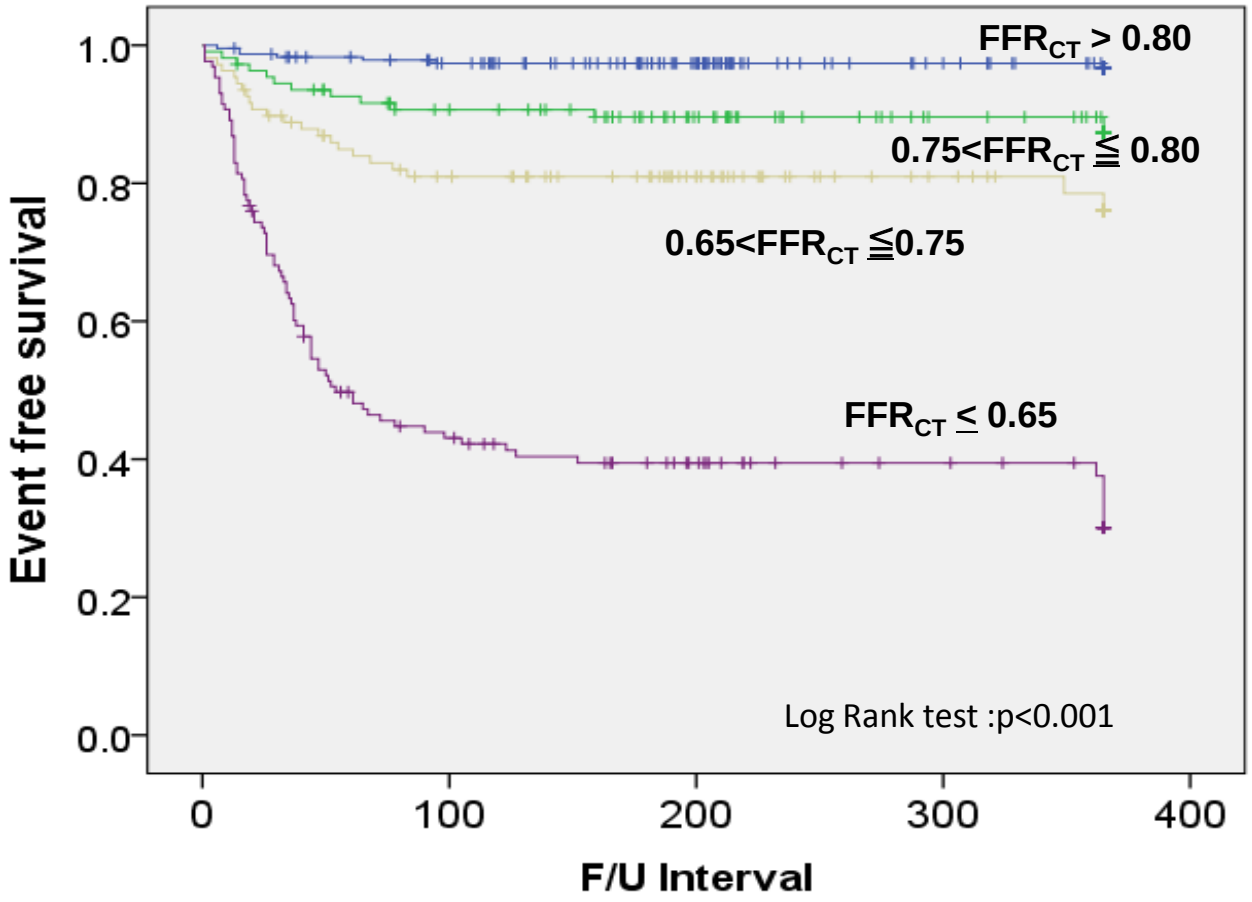
Clinical follow-up : mean F/U 366±208 days

MACE: All cause death, MI, CVA, revascularization

MACE among 580 patients with FFRCT analysis : mean F/U 366±208 days

Cardiac event	N
death	1
cardiac death	0
non-cardiac death	1
Cerebrovascular event	1
Acute MI	1
Coronary revascularization	121
PCI	118
CABG	3
MACE	122 (21%)

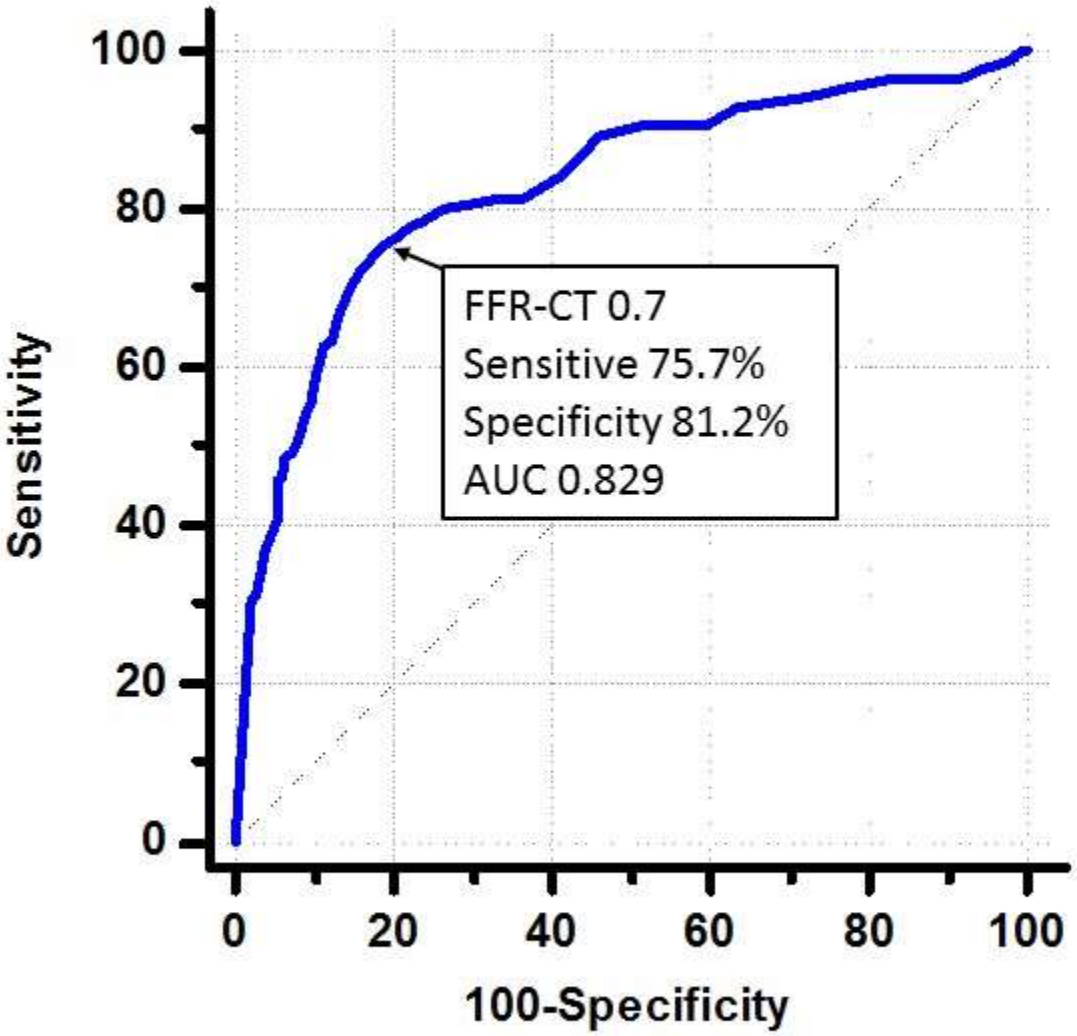
Kaplan Meier event free curve according to the lowest FFR value among 3 vessels



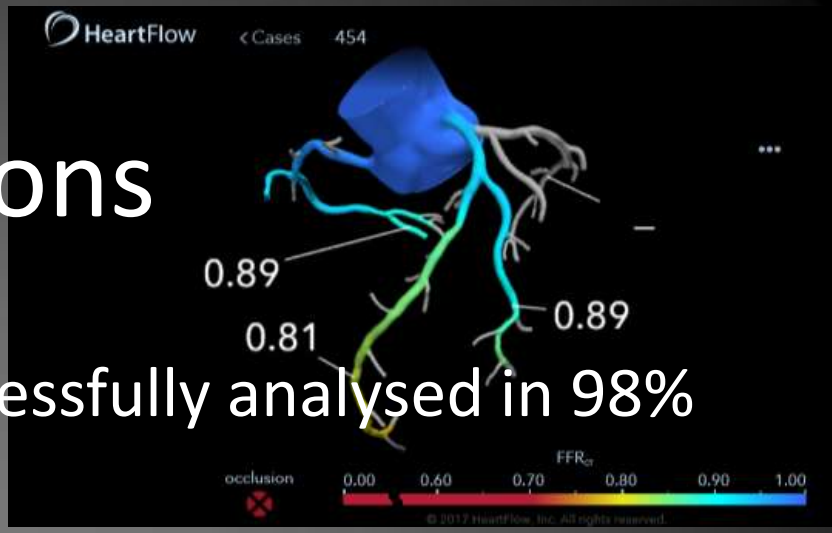
Characteristics of FFR_{CT} and FFR_{inv} in patients with FFR_{CT}>0.8 and required for PCI

	FFR_{CT}			FFR_{inv}		
	LAD	LCX	RCA	LAD	LCX	RCA
1	0.83	0.96	0.96	0.78		
2	0.9	0.93	0.92	0.77		
3	0.9	0.95	0.85	0.78		0.78
4	0.92	0.95	0.91			
5	0.84	0.95	0.87		0.76	
6	0.89	0.92	0.86	0.87		
7	0.83	0.87	0.85	0.75		

Best cutoff value of FFRCT to discriminate the MACE occurrence



Conclusions



- Heartflow FFRCT could be successfully analysed in 98% of the patients.
- The lesions with FFRCT >0.80 showed low incidence of positive invasive FFR.
- Minimum FFRCT value among 3 vessel can be used for the risk stratification of the future cardiac event. Minimum FFRCT above 0.80 showed very low rate of MACE and less than 0.65 showed strongly high rate of MACE compared with above 0.70 patients.
- FFRCT can be used safely and accurately as the gatekeeper to catherization study.

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