

Post-PCI iFR Assessment ~Insights from DEFINE-PCI Trial~

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

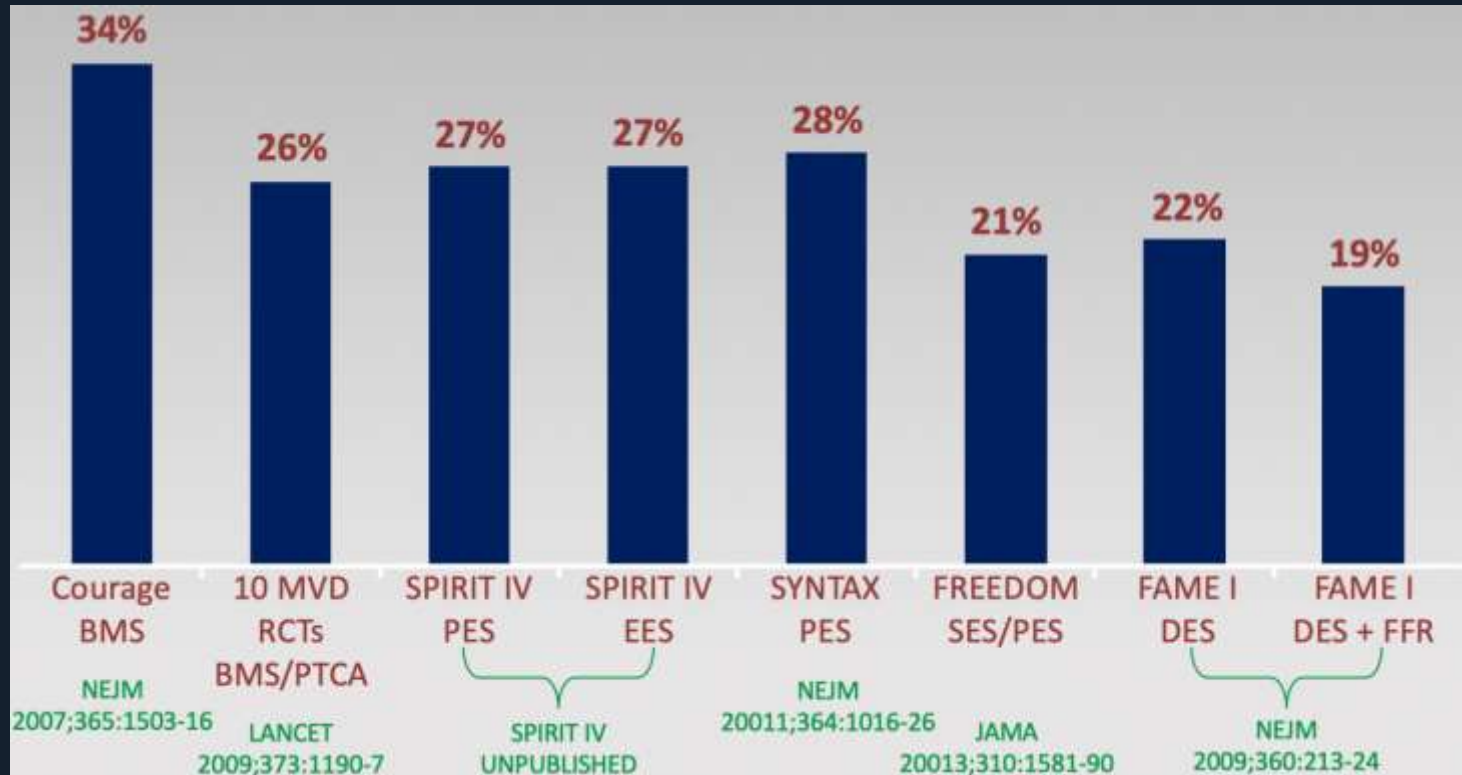
Affiliation/Financial Relationship

- Consulting Fees/Honoraria

Company

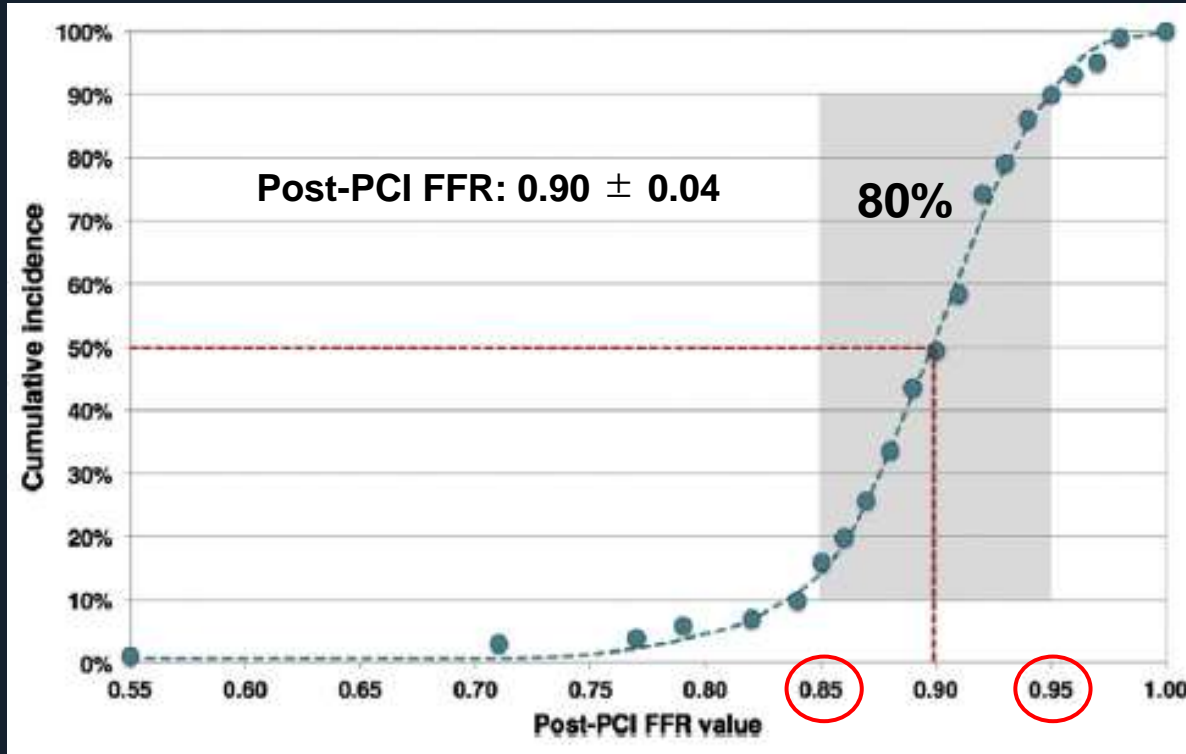
- TERUMO Corporation

Recurrent Angina at 1 Year After PCI

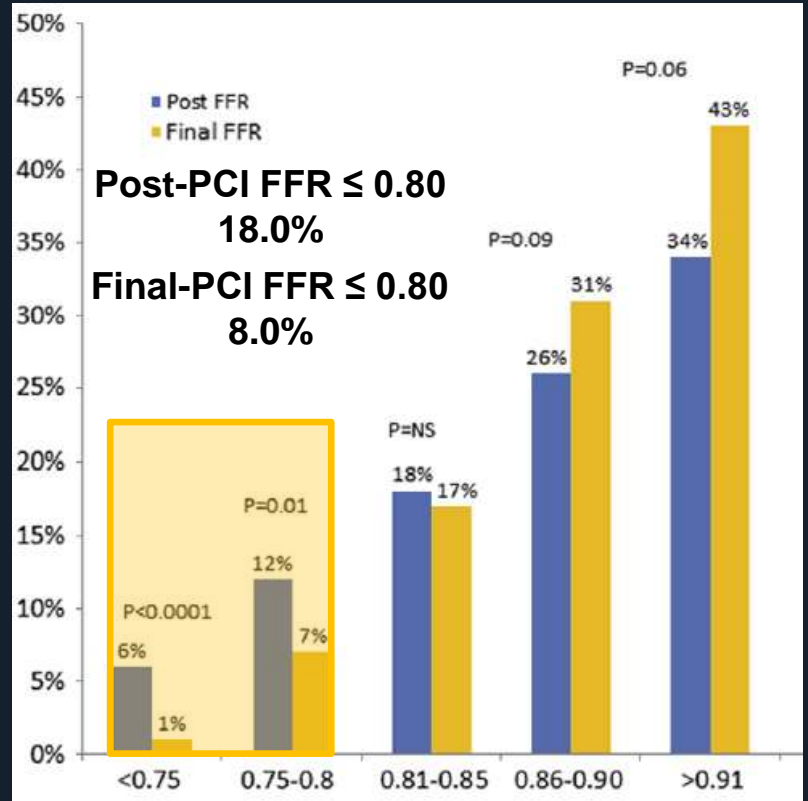
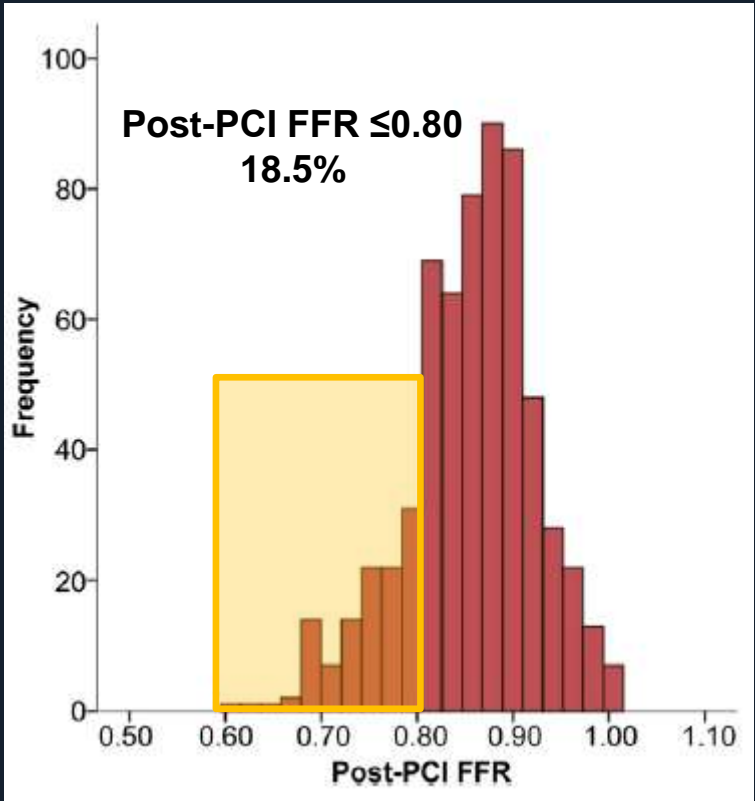


Meta Analysis Post-PCI FFR

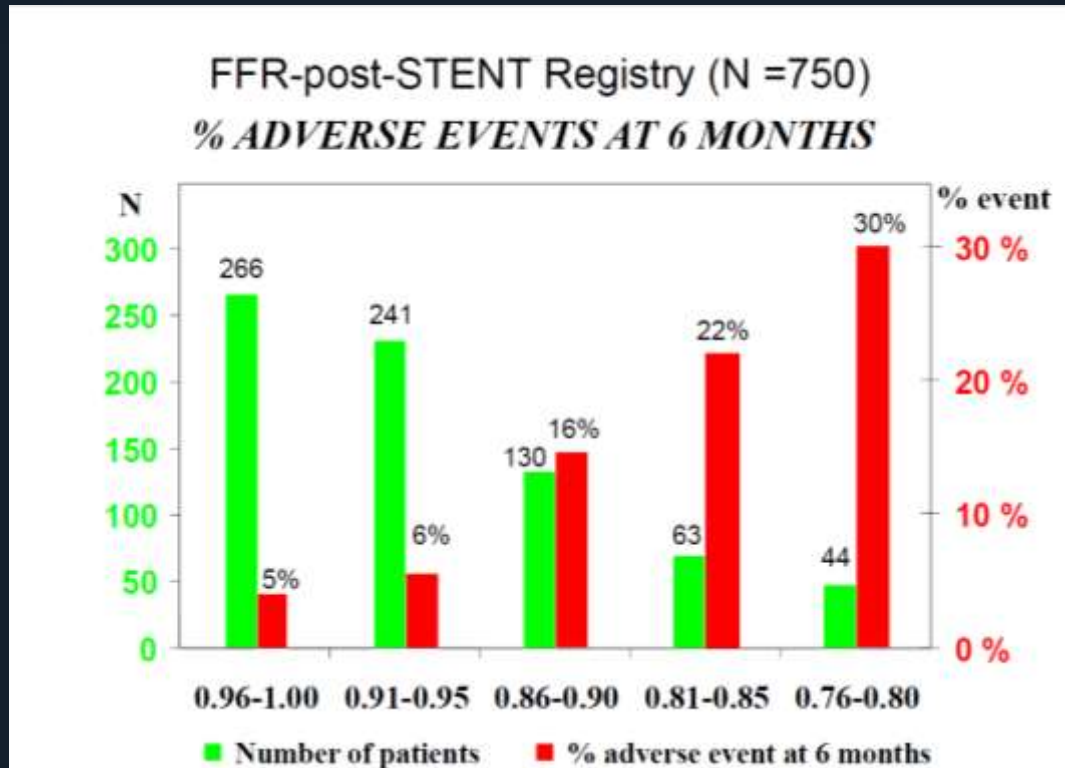
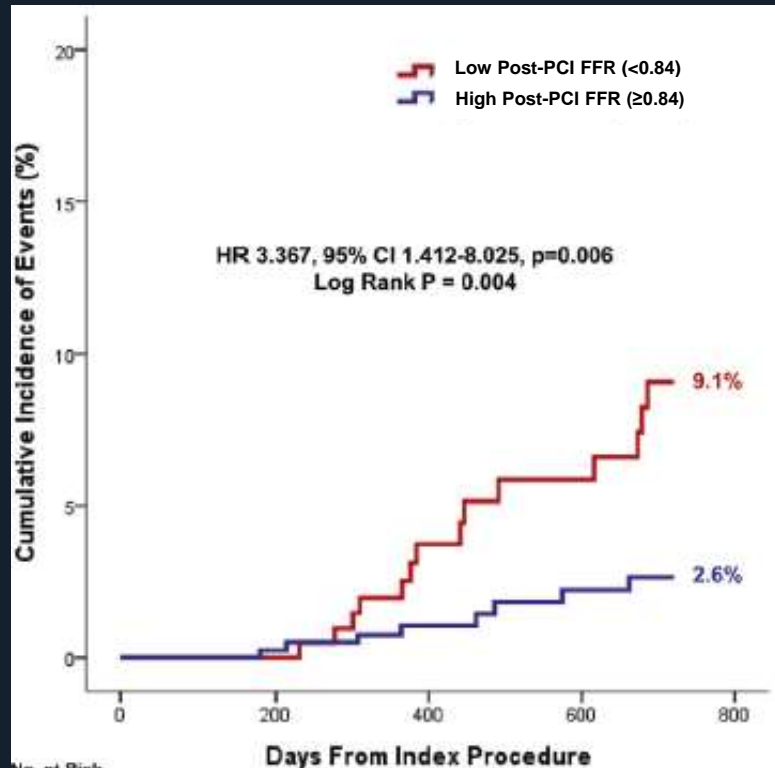
7470 patients in 105 studies in 1995-2015 were included



Post PCI Ischemia Based on $FFR \leq 0.80$ Occurs in 10-20% of Cases



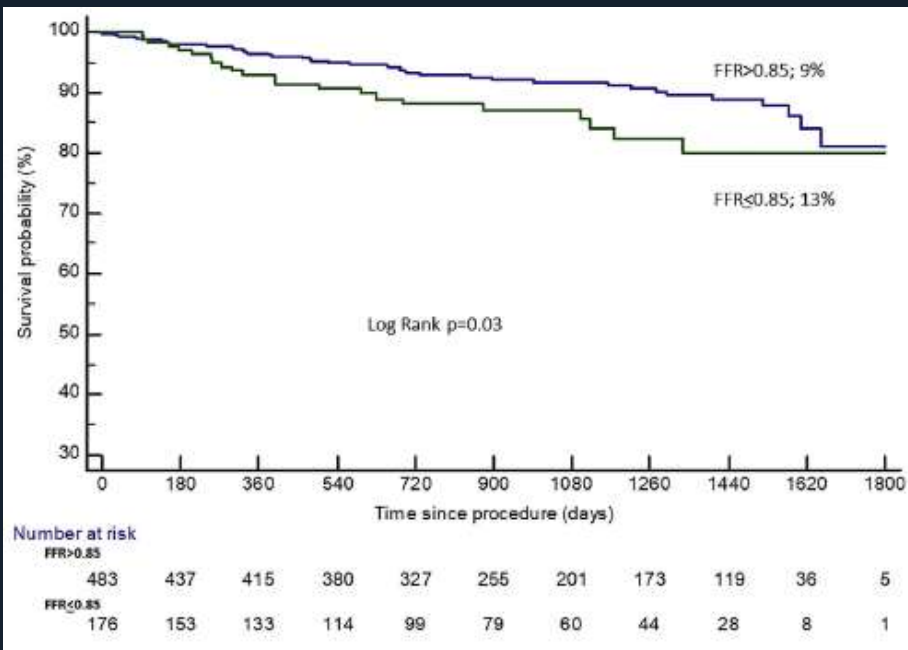
Low Post-PCI FFR is Related to Adverse Events



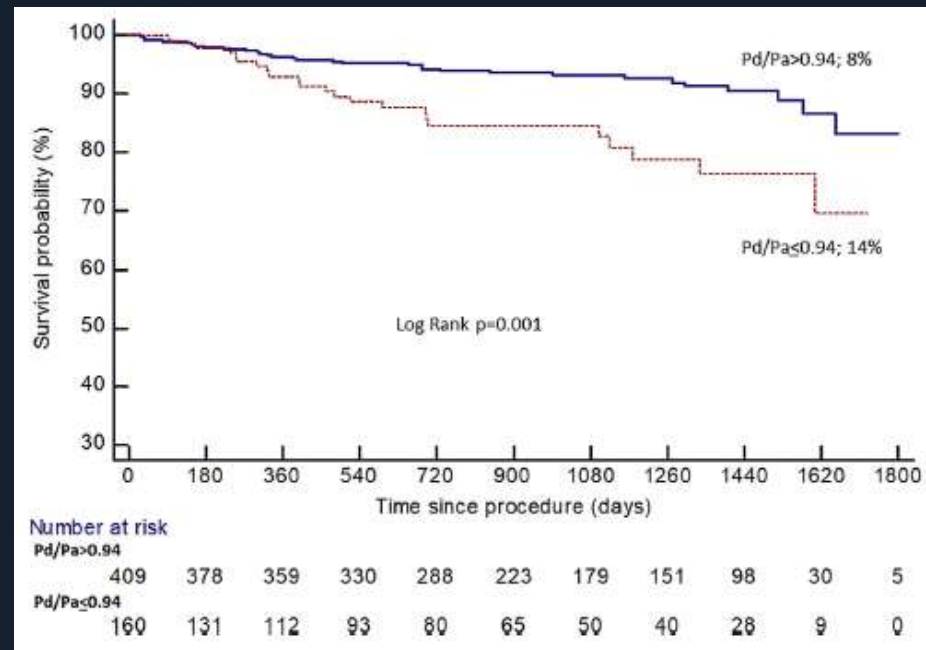
Low Post-PCI FFR and Pd/Pa are related to TVF

574 pts (68% stable CAD), median FU 2.5 (1.5, 3.8) years
 TVF = TVR or TV-MI (60 TVR and 12 spontaneous MI events)

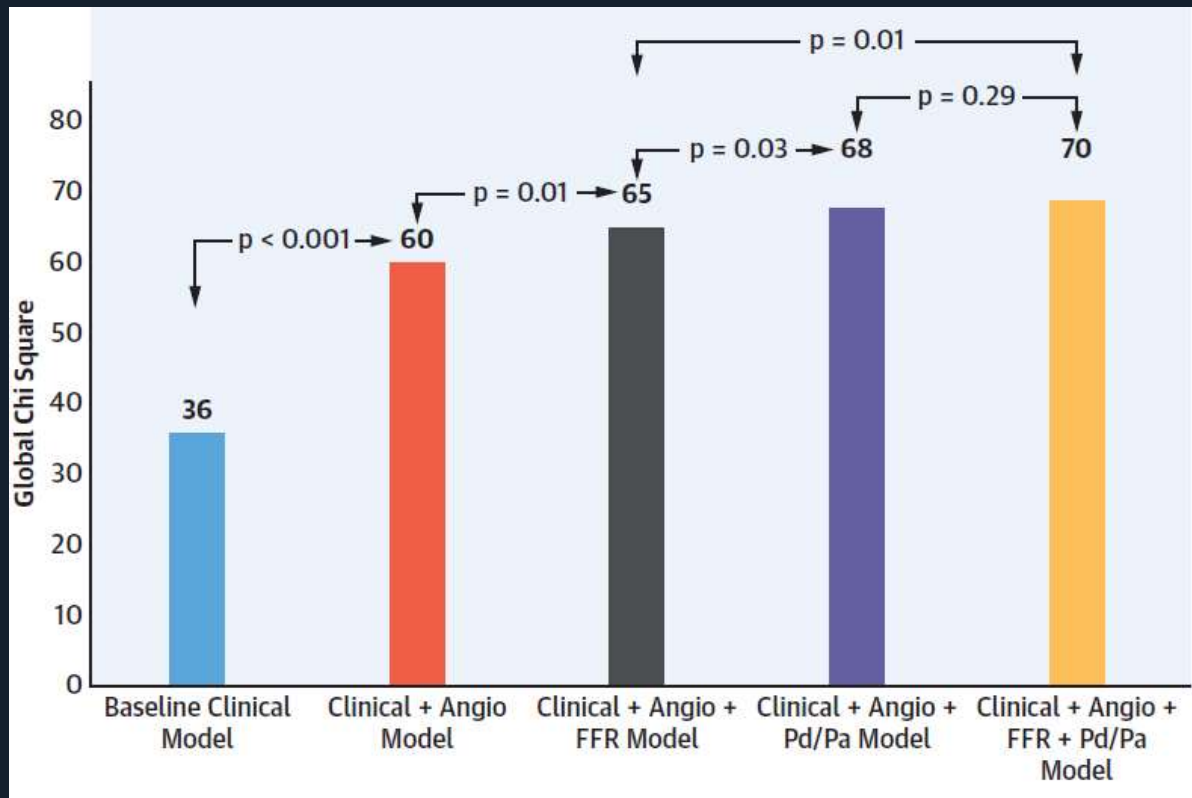
Post-PCI FFR ≤ 0.85



Post-PCI Resting Pd/Pa ≤ 0.94



Incremental Prognostic Value of Post-PCI Pd/Pa in Outcome Prediction



DEFINE PCI

Patients with stable and unstable angina (N = 500)

iFR of all vessels with angiographic lesions $\geq 40\%$ stenosis

Baseline iFR ≤ 0.89

Baseline iFR > 0.89

Standard of care algorithm for PCI as per local operators (Intravascular imaging optional)

Guideline Directed Medical Therapy

Successful angiographic PCI result

Blinded final iFR with iFR pullback

Guideline Directed Medical Therapy

30 days, 6 month & 1 year follow up

500 pts Enrolled

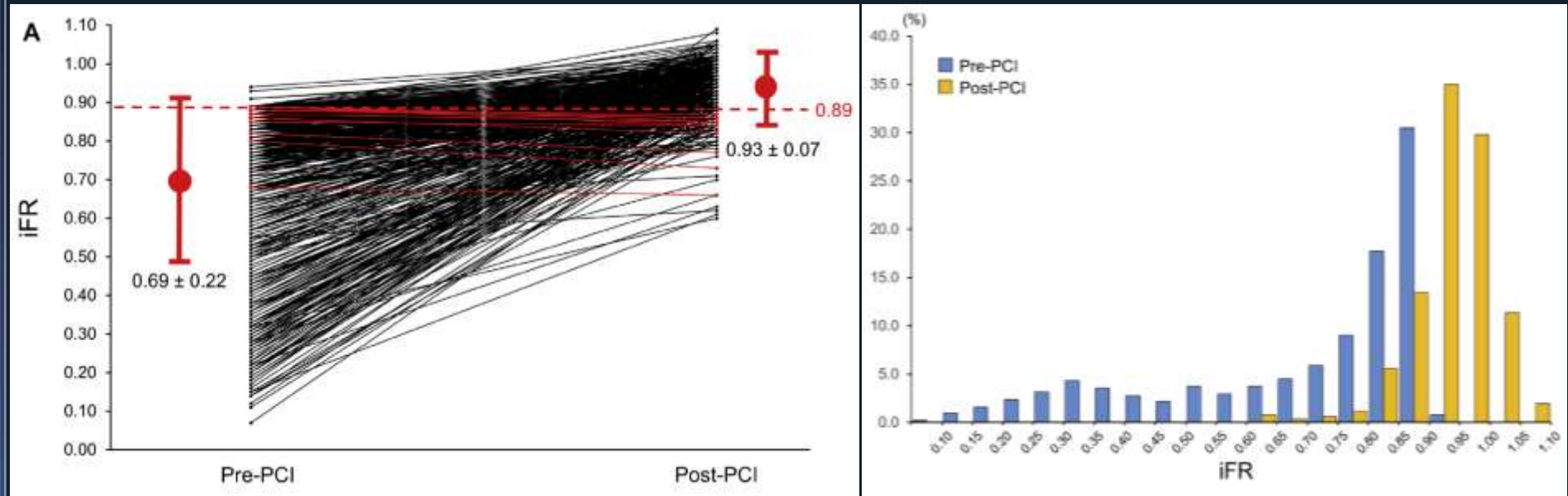
- 8 pts due to patient instability
- 9 pts inadequate recording
- 3 pts pressure wire not cross

Post-iFR analyzable in 535 vessels in 480 pts

- 10 vessels drift
- 5 vessels wave form abnormality

Post-iFR available in 520 vessels in 467 pts

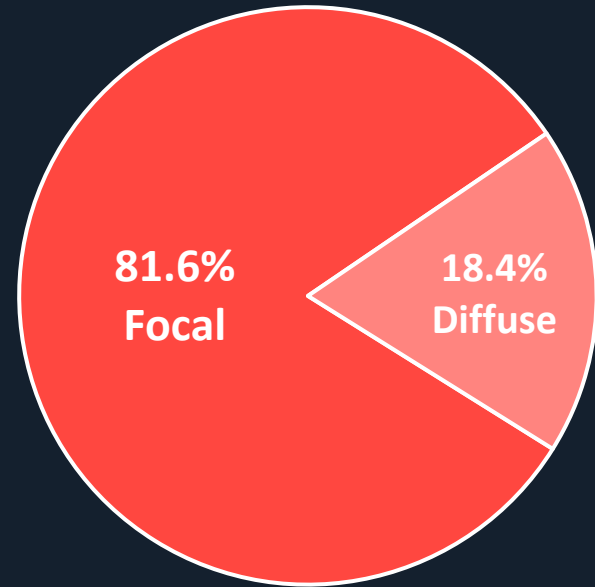
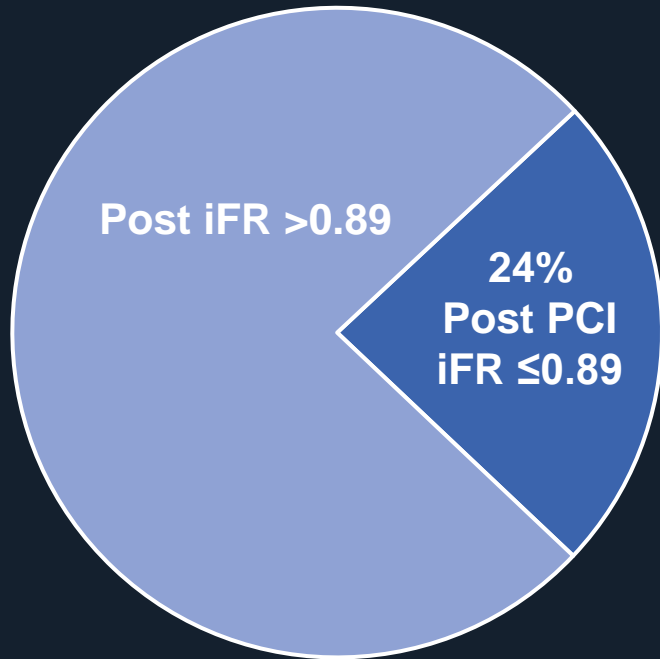
Pre- and Post-PCI iFR After Angiographically Successful PCI



Post-PCI iFR

467 Patients with Angiographically Successful PCI
and Qualified iFR Pullbacks

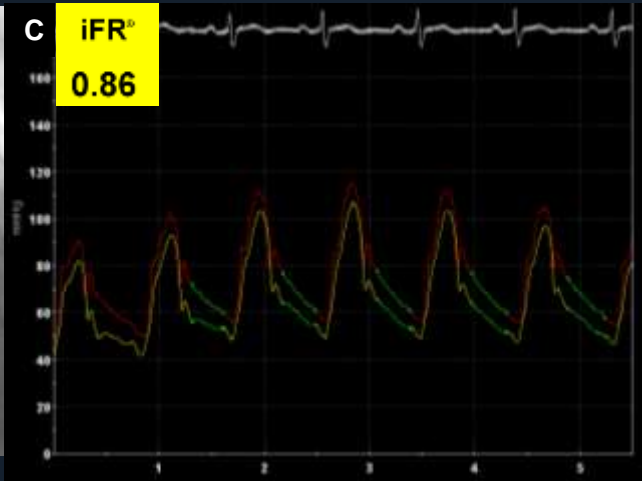
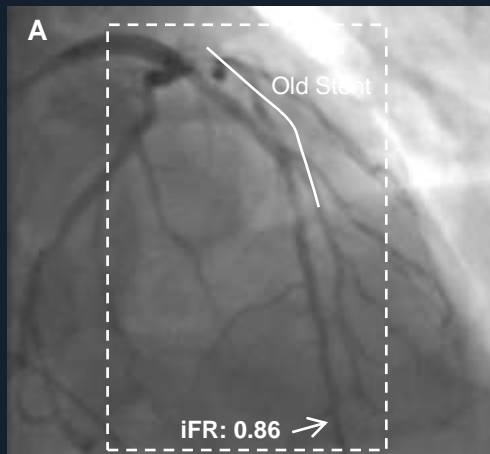
24% Residual Ischemia
(112 patients with Post PCI iFR ≤ 0.89)



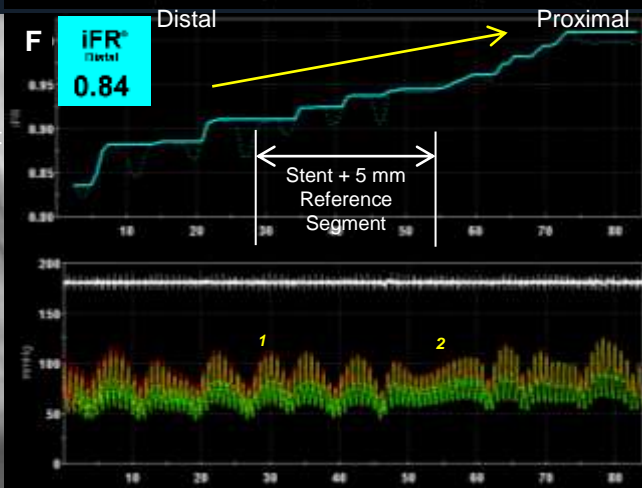
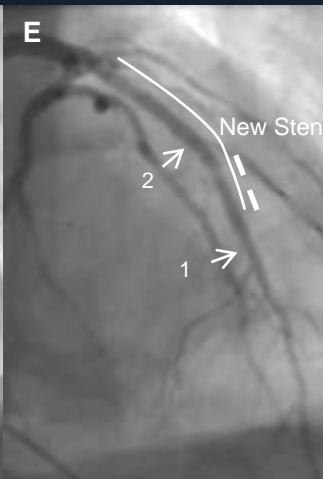
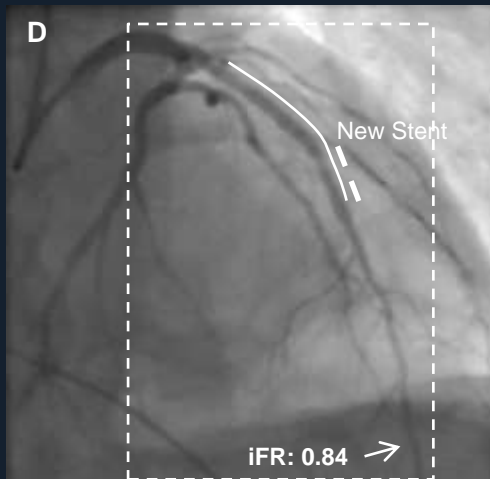
Focal defined as step-up of ≥ 0.03 units in ≤ 15 mm segment
Diffuse defined as >15 mm segment

Diffuse Residual Pressure Gradient

Pre-PCI

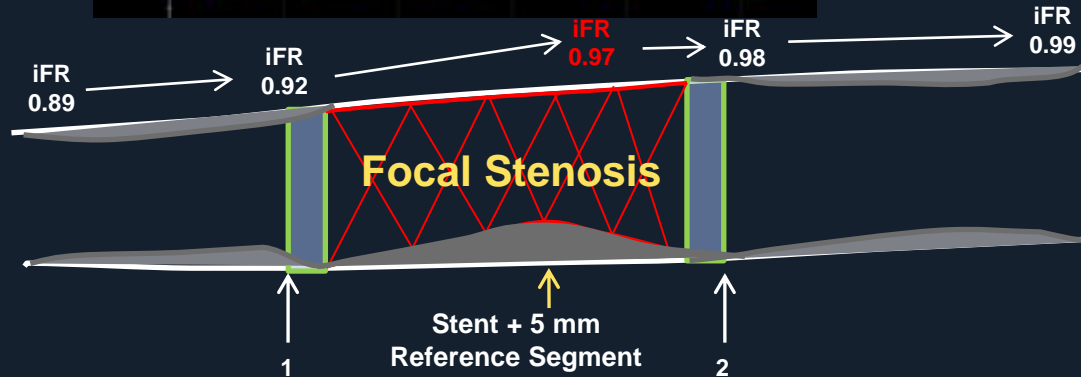
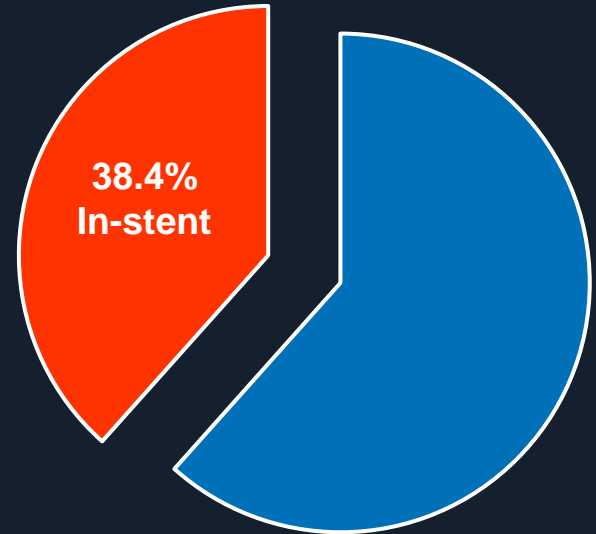
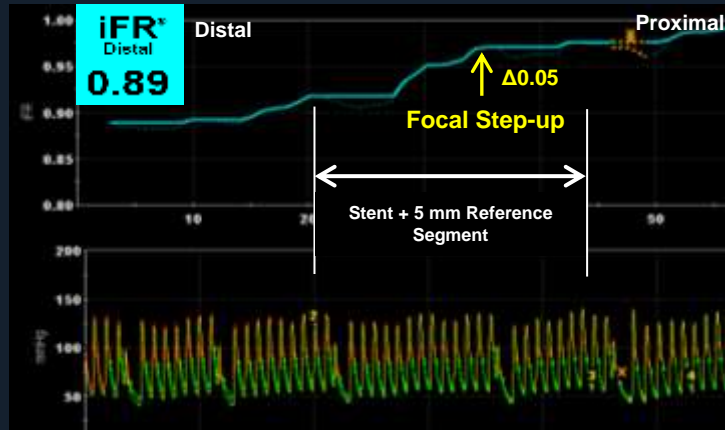


Post-PCI



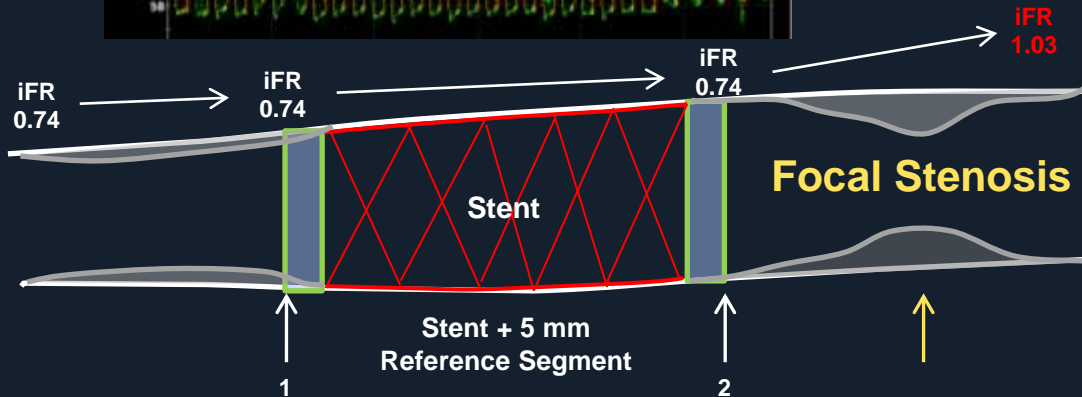
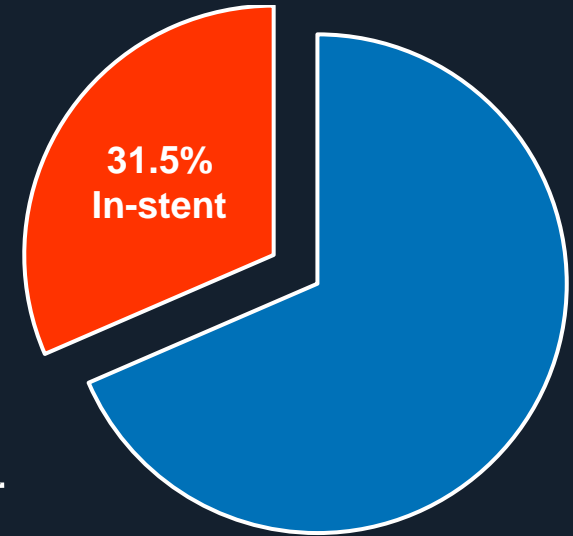
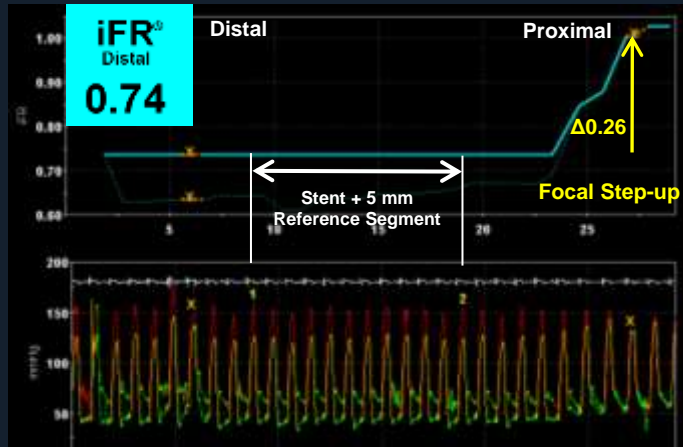
Focal Residual Pressure Gradient in-stent

Among the 93 vessels with focal disease, there were 146 segments (stent, proximal or distal) that had significant residual pressure gradients



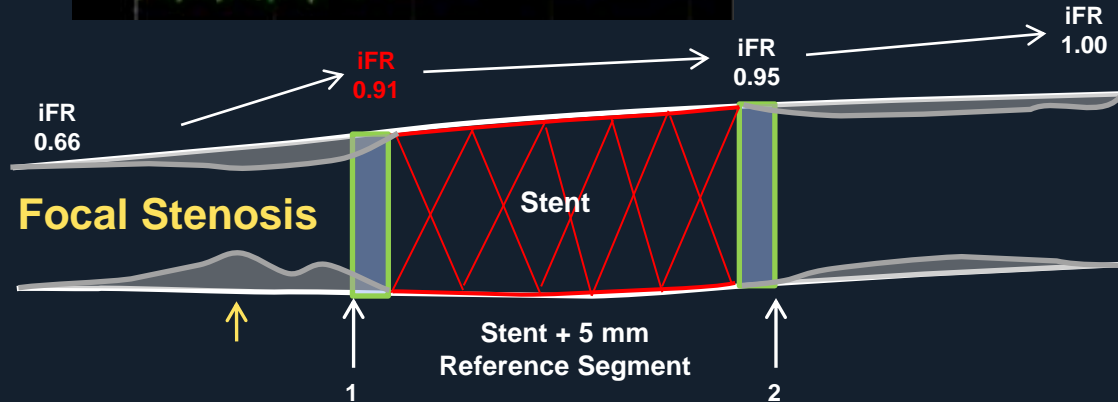
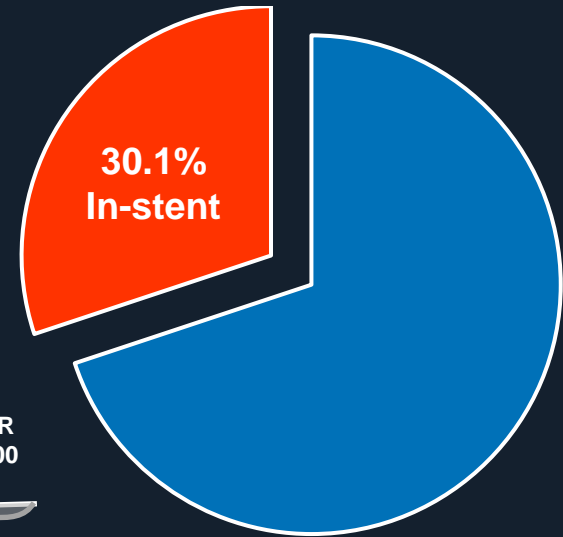
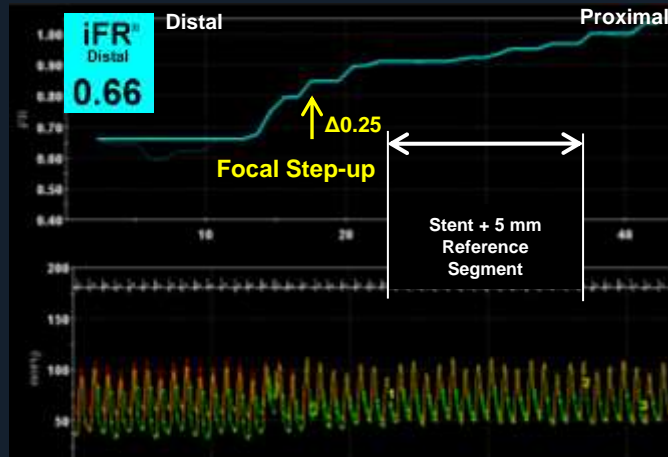
Focal Residual Pressure Gradient Proximal to Stent

“Physiologic miss” 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



Angiographic Diameter Stenosis Correlates Poorly With Post PCI iFR

	Residual DS $\geq 50\%$	Residual DS $< 50\%$	P-Value
iFR ≤ 0.89	29.7%	21.4%	0.24

Predictors of post-PCI iFR ≤ 0.89 by multi-variate analysis

	OR	95% CI	P-value
Reference Vessel Diameter	0.32	0.18-0.58	0.0002
LAD	5.65	3.07-10.40	< 0.0001
Post-PCI DS	1.01	1.00-1.03	0.08

1-Year Follow-Up Outcome

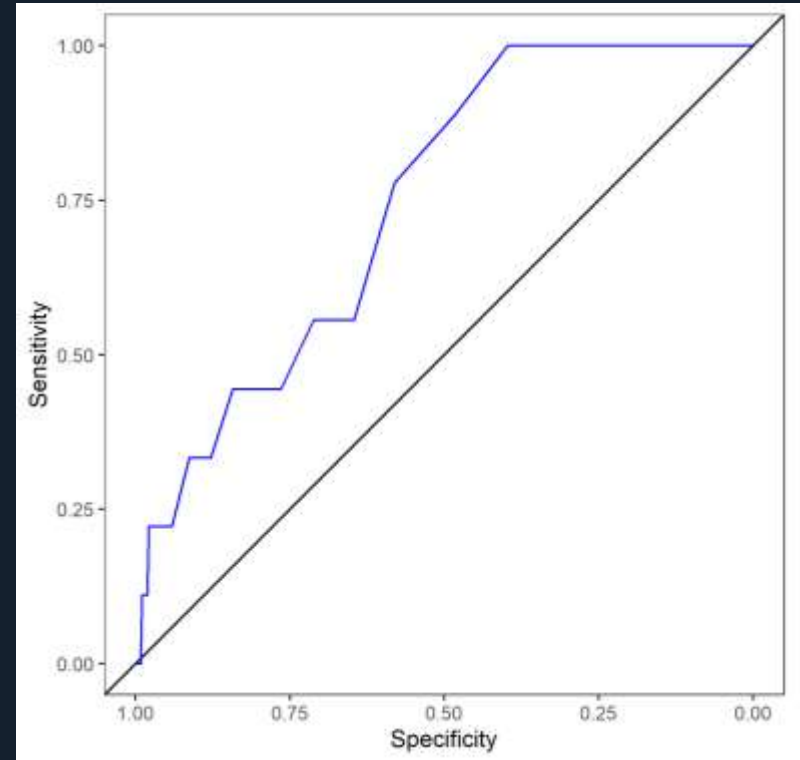
- To assess the change in the Seattle Angina Questionnaire Angina Frequency (SAQ-AF) score during 1-year follow-up
- To assess clinical events (CV death, MI, and target vessel revascularization) at 1-year
- Perform post-hoc analysis to determine if there is a target post-PCI iFR value associated with improved outcomes

Identification of Post PCI iFR Target

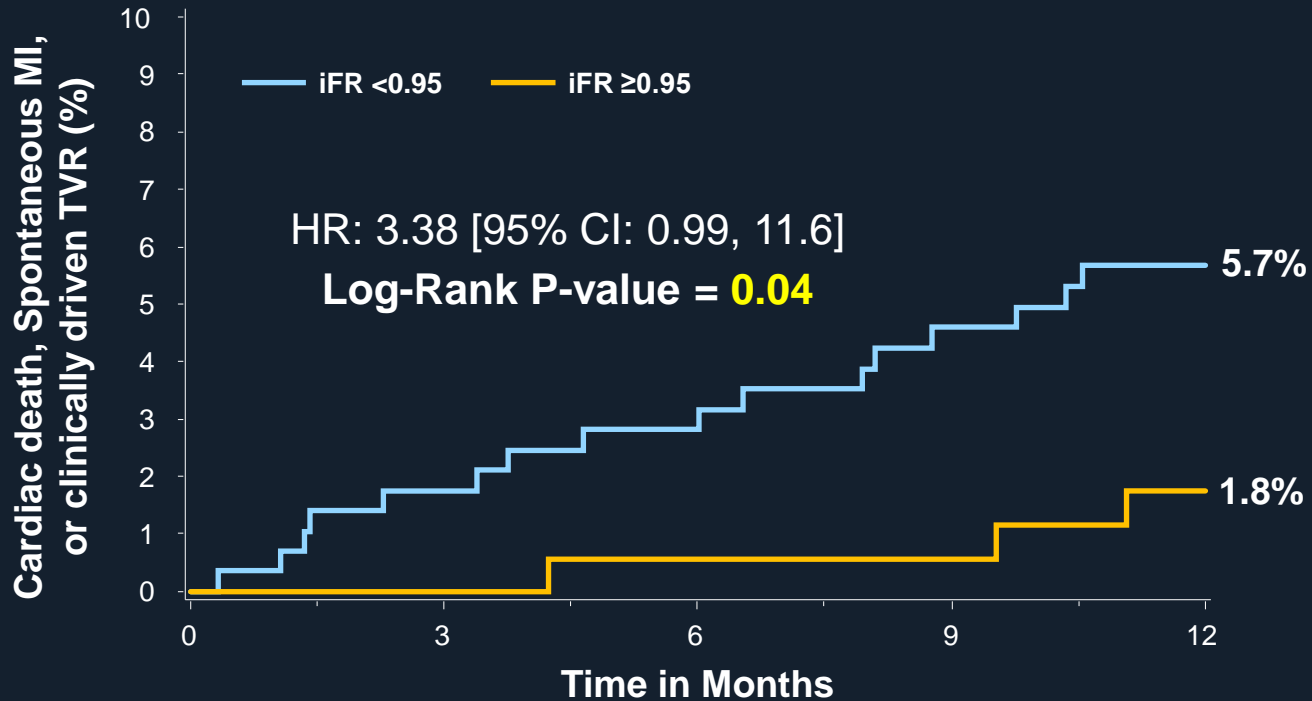
Cardiac Death or Spontaneous MI

Cut-off value < 0.95

AUC (95%CI)=0.74 (0.61, 0.88)



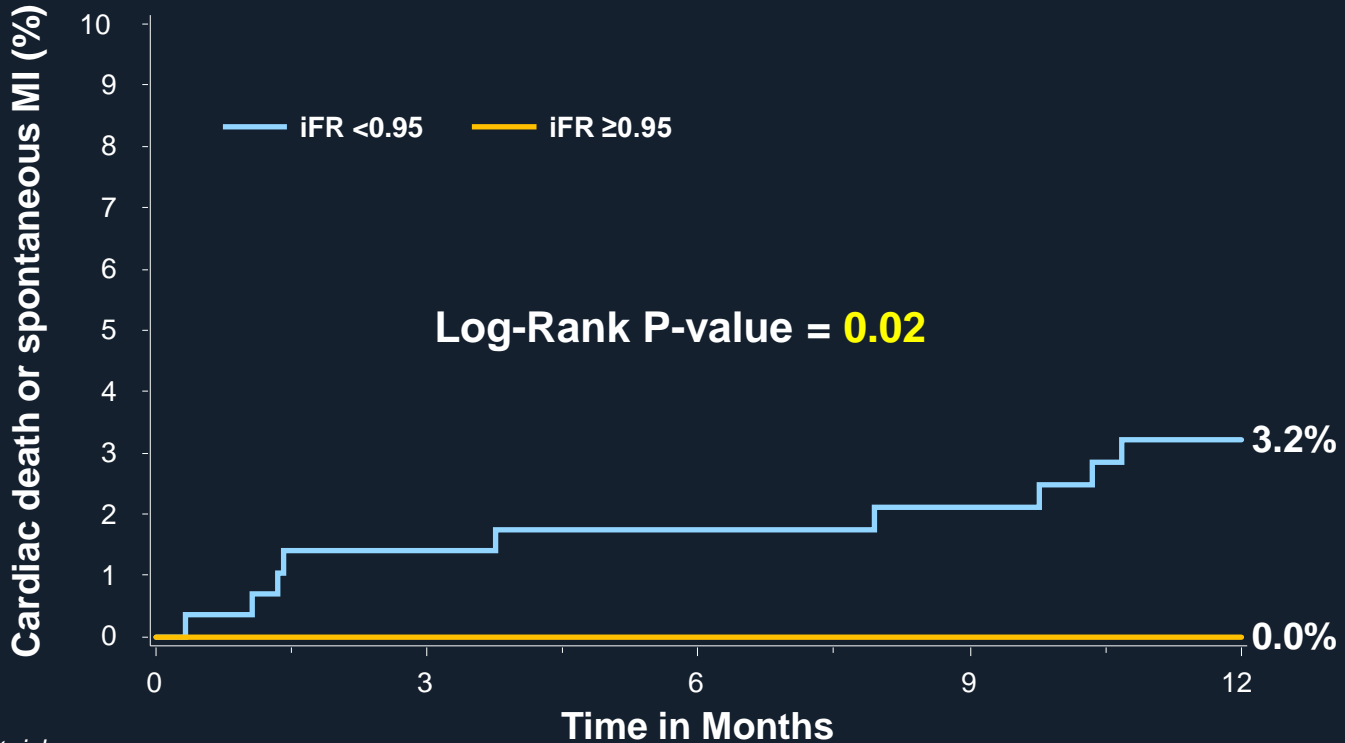
Cardiac Death, Spontaneous MI, or Clinically Driven TVR



Number at risk:

iFR < 0.95	285	279	275	264	252
iFR ≥ 0.95	182	179	175	166	162

Cardiac Death or Spontaneous MI (%)



Number at risk:

iFR <0.95	285	280	278	271	259
iFR ≥0.95	182	179	176	167	165

Identification of Post PCI iFR Target

	iFR <0.95 (N=285)	iFR ≥0.95 (N=182)	Total (N=467)	P value
Death	1.4% (4)	1.1% (2)	1.3% (6)	0.81
Cardiac	0.4% (1)	0.0% (0)	0.2% (1)	0.44
Non-cardiovascular	1.1% (3)	1.1% (2)	1.1% (5)	0.93
MI	3.9% (11)	1.1% (2)	2.8% (13)	0.08
Peri-procedural MI	1.1% (3)	1.1% (2)	1.1% (5)	0.96
Spontaneous MI	2.8% (8)	0.0% (0)	1.8% (8)	0.02
Target Vessel MI	2.1% (6)	1.1% (2)	1.7% (8)	0.42

Multivariable Cox Regression Model for Cardiac Death, Spontaneous MI, or Clinically Driven TVR

	Hazard Ratio (95% CI)	p-value
Post-iFR <0.95	3.35 (0.97, 11.49)	0.055
Age, year	1.01 (0.96, 1.06)	0.74
Diabetes Mellitus	1.47 (0.59, 3.70)	0.41
Acute Coronary Syndrome Presentation	1.33 (0.53, 3.31)	0.54

Take Home Message

- The correlation between residual stenosis by QCA and post-PCI iFR was poor.
- 24% of the cases had post PCI iFR ≤ 0.89 , and focal residual pressure gradient occurred 80% of the cases, and thus could be potentially treated with additional PCI.
- A post-PCI iFR ≥ 0.95 was associated with less cardiac death, spontaneous MI, or clinically-driven TVR compared with a post-PCI iFR < 0.95 .
- The clinical effectiveness of iFR guidance (target iFR ≥ 0.95) to identify and eliminate post-PCI ischemia will be studied in the prospective randomized DEFINE-GPS trial.

