Pullback Pressure Gradients (PPG) Predicts Revascularization Outcomes

Carlos Collet MD, PhD
Co-director Catheterization Laboratory
OLV Aalst, Belgium

On behalf of the PPG Global Investigators

Disclosure of relevant financial relationships

Within the past 12+ months, Carlos Collet has had a financial interest/arrangement or affiliation with the organization(s) listed below.

Institutional support
- Abbott Vascular
- HeartFlow Inc
- GE Healthcare
- ShockWave Medical
- Boston Scientific
- Insight Lifetech
- Pie Medical
- Medis Medical Imaging

Equity/stock options
- Medyria
- Xenter

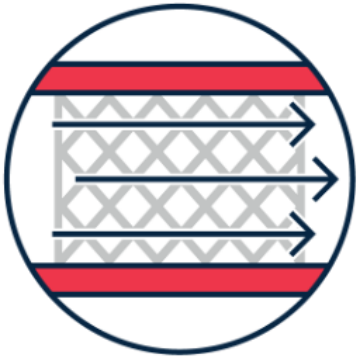
Consultancy fee
- Abbott Vascular
- HeartFlow Inc
- GE Healthcare
- Boston Scientific
- Insight Lifetech
- Early Bird
- Pfizer
- Siemens

Others

CoreAalst BV

Patents filed: US20220164950A1, US20220175260A1, WO2022136637A1 and WO2021224458A1

Background

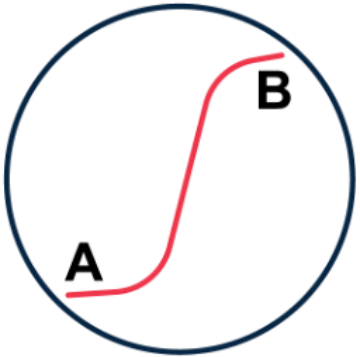


Revascularization aims to improve blood flow.

However, a sizable proportion of patients remain with suboptimal physiology after ‘successful’ PCI.

Low FFR after PCI is associated with a worse prognosis.

The magnitude of FFR improvement tracks directly with angina relief.

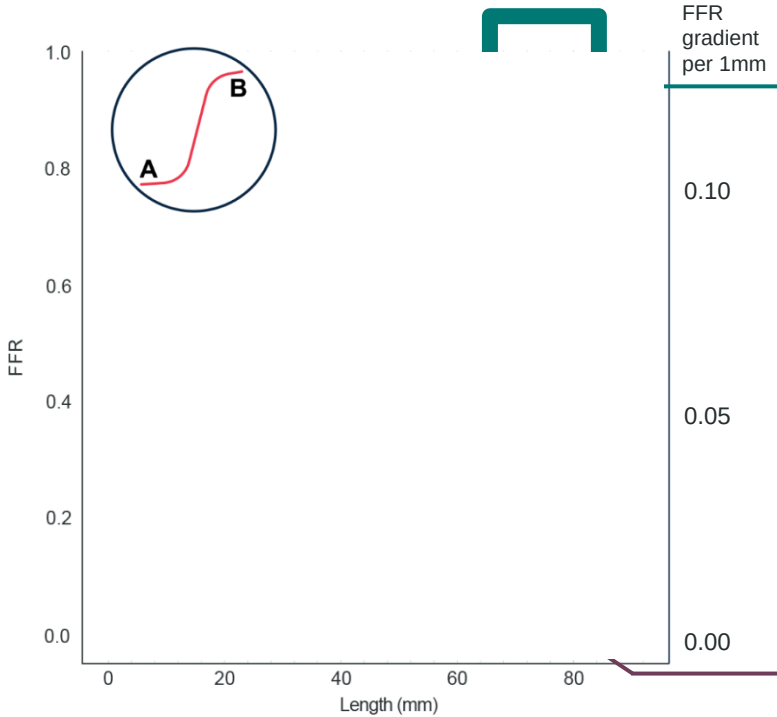


Pressure pullbacks characterize CAD patterns (focal vs diffuse).

PCI may be more effective in focal disease defined by coronary physiology.

Hwang D et al. JAMA Netw Open. 2022 Sep 1;5(9):e2232842.
Collet C et al. JACC Cardiovasc Interv. 2023 Oct 9;16(19):2396-2408.
Collet C et al. J Am Coll Cardiol 2019 Oct 8;74(14):1772-1784.

PPG ‘focality’ and diffuseness



Maximal pressure gradient in 20% of the pullback

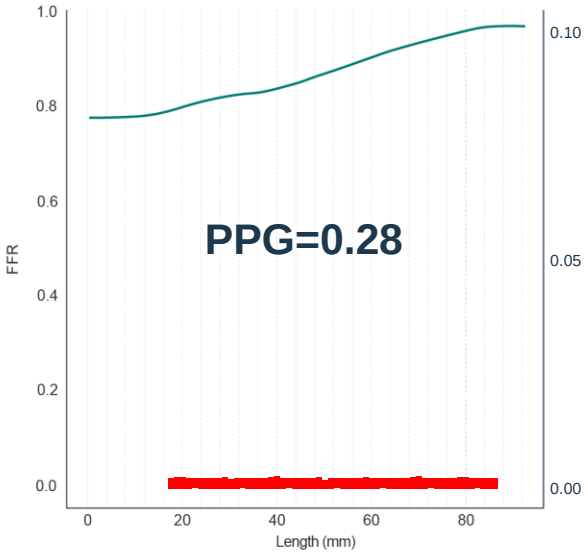
$$PPG = \frac{\left(\frac{\text{Maximal gradient}}{\text{Vessel FFR gradient}}\right) + \left(1 - \frac{\text{Length of disease}}{\text{Vessel length}}\right)}{2}$$

Length of disease (%)

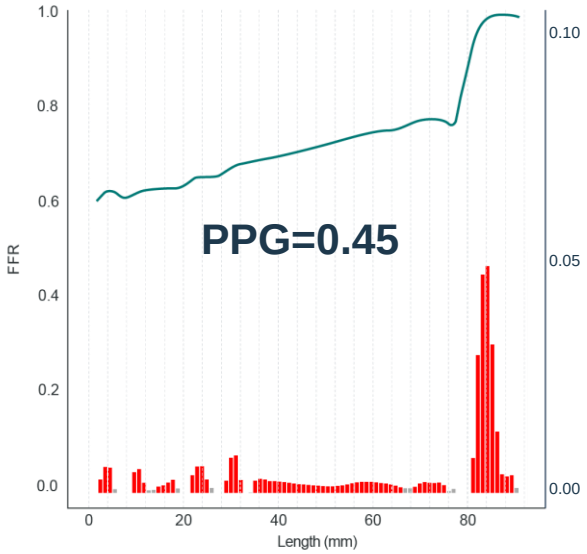
Collet C et al. J Am Coll Cardiol 2019 Oct 8;74(14):1772-1784.

PPG: standardizing the definition of diffuse disease

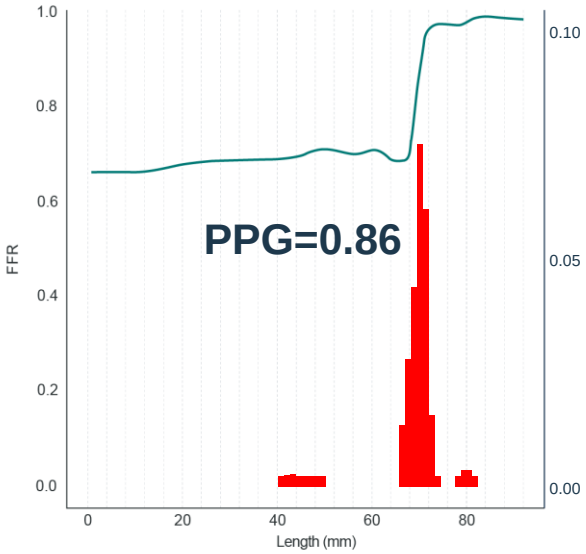
Diffuse CAD



Combined CAD



Focal CAD

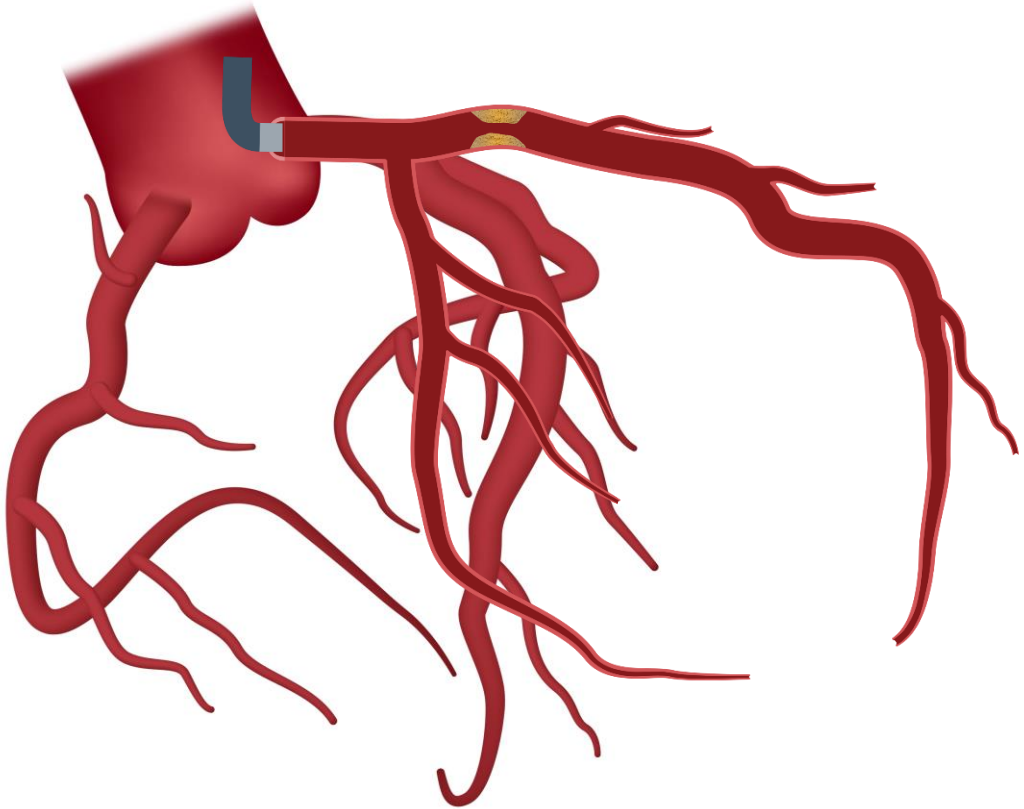


0 Pullback Pressure Gradient (PPG) **1**

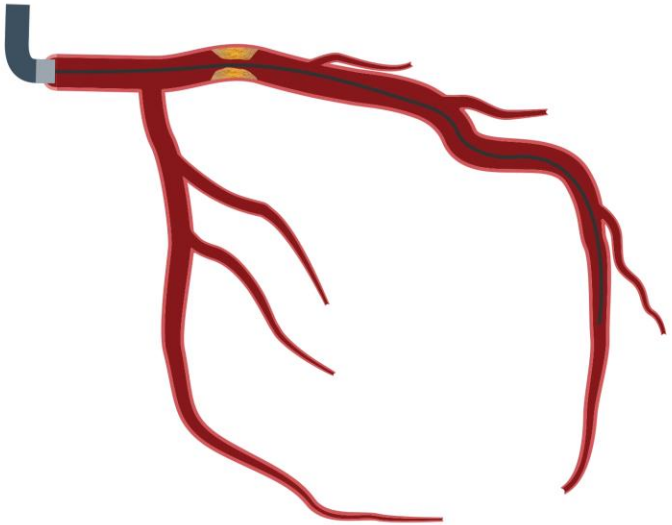
Collet C et al. J Am Coll Cardiol 2019 Oct 8;74(14):1772-1784.

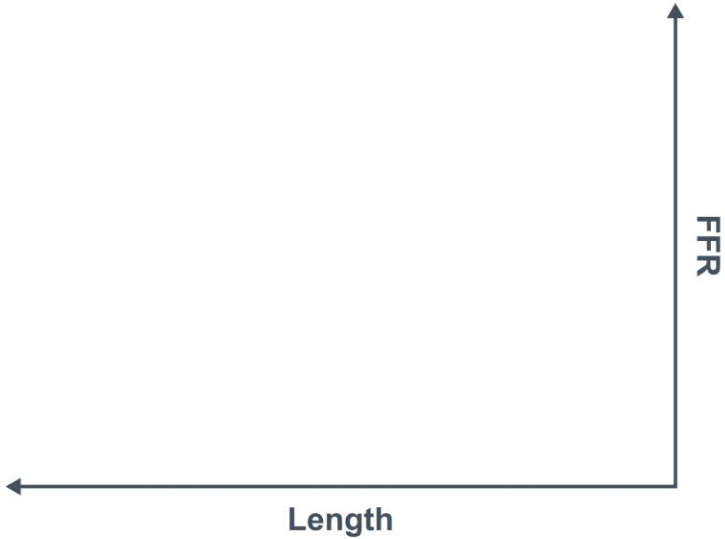
Study hypothesis

Outcomes of PCI in focal vs diffuse disease



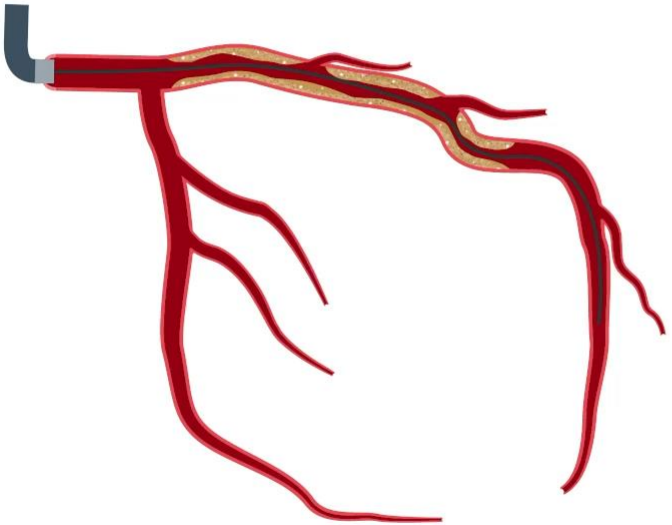
Outcomes of PCI in focal disease

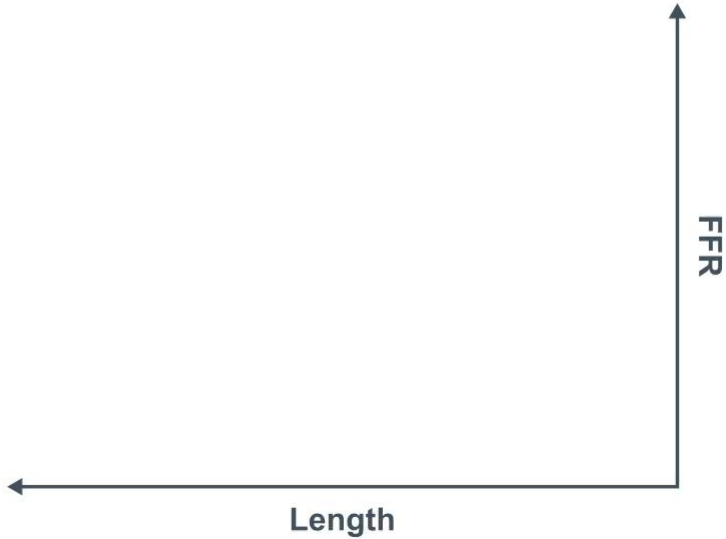




Designed by OPTIMA

Outcomes of PCI in diffuse disease





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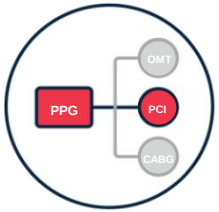
PPG Global: Study objectives

Primary

To assess the capacity of PPG to predict post-PCI FFR.

Key secondary



To investigate the influence of PPG on treatment decisions.

To assess the impact of PPG on procedural outcomes.

Methods

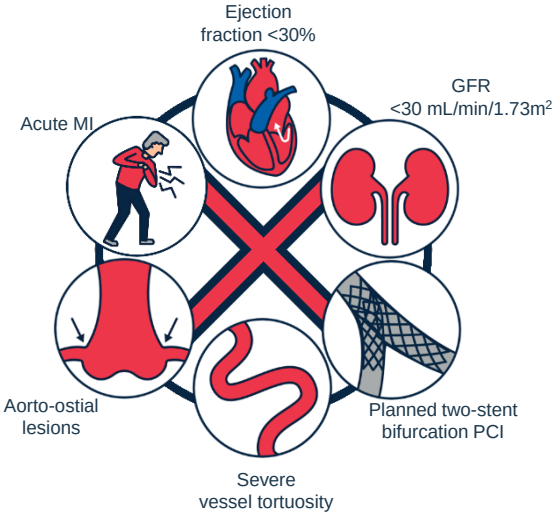
PPG Global: Study design

Investigator-initiated*, multicenter, international, and single-arm study (NCT04789317)

*Research grant from Abbott Vascular

Stable patients* with at least one hemodynamically significant lesion (FFR ≤ 0.80) intended to be treated with PCI

*Non-culprit lesion after an acute coronary syndrome (ACS)



Exclusion Criteria

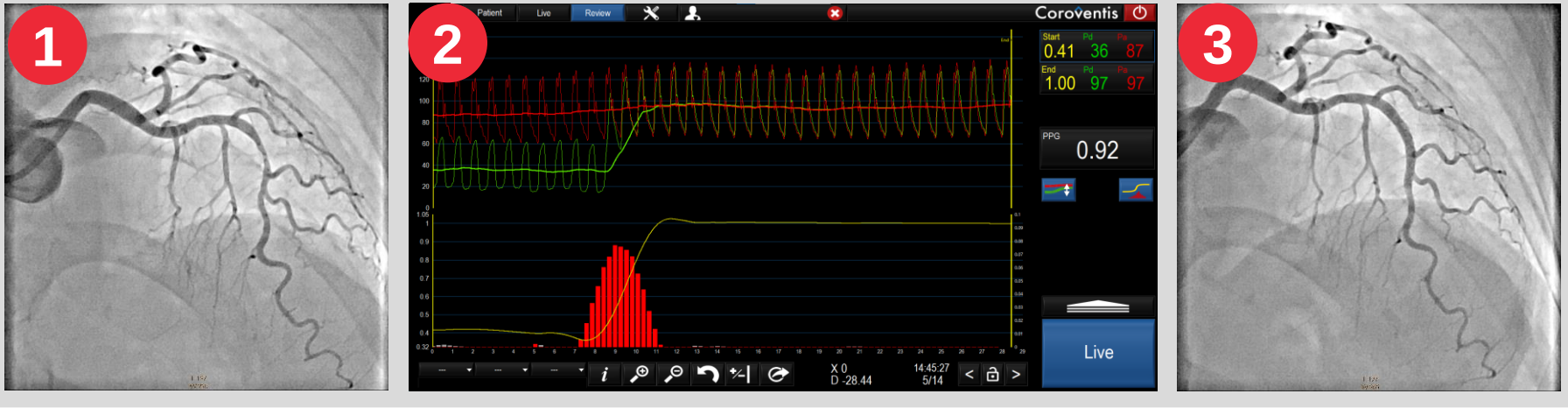
Munhoz D at el . Am Heart J. 2023 Nov;265:170-179.

PPG Global: Participating sites

Munhoz D at el . Am Heart J. 2023 Nov;265:170-179.

Invasive protocol

PPG GLOBAL



Lesion intended to be treated with PCI with FFR (single point) ≤ 0.80

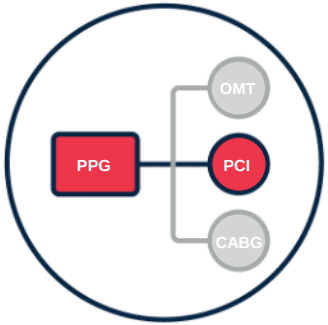
Manual FFR pullbacks
Online PPG calculation

Post-PCI FFR

Munhoz D at el . Am Heart J. 2023 Nov;265:170-179.

Methods

PPG GLOBAL



Decision Making

Based on the PPG value, operators could opt for medical therapy or coronary artery bypass graft surgery (CABG) instead of PCI.

CoreLab analysis

All angiographic and physiologic data underwent centralized, independent review at the CoreAalst BV core laboratory

Patient-reported outcomes

Using the 7-item Seattle Angina Questionnaire (SAQ-7) at baseline repeated at 1-year follow-up.

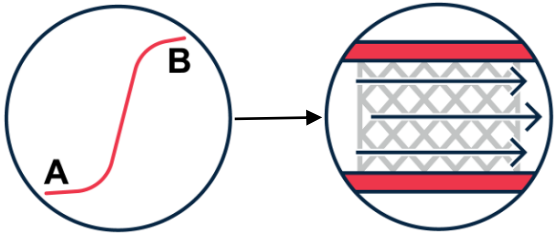
Definitions and adjudication

Periprocedural myocardial infarction was defined according to the Fourth Universal definition.

An independent clinical events committee (CEC) adjudicated adverse events blinded to the invasive data.

Munhoz D at el . Am Heart J. 2023 Nov;265:170-179.
Thygesen K et al. J Am Coll Cardiol. 2018 Oct 30;72(18):2231-2264.

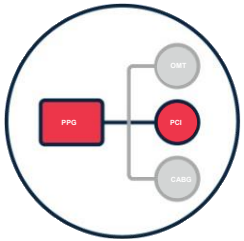
Methods: Sample Size



Powered to assess the predictive capacity of PPG for **post-PCI FFR of ≥ 0.88** using the area under the curve (AUC) method and assuming an AUC > 0.80*

Power of 90% and 2.5% two-sided alpha

*Adjusted for epicardial vessel and baseline FFR.



Powered to assess the influence of PPG on clinical decisions with an anticipated **20% shift** from the initial intent for PCI to either CABG or medical therapy.

After accounting for a 95% confidence interval margin of 5%.

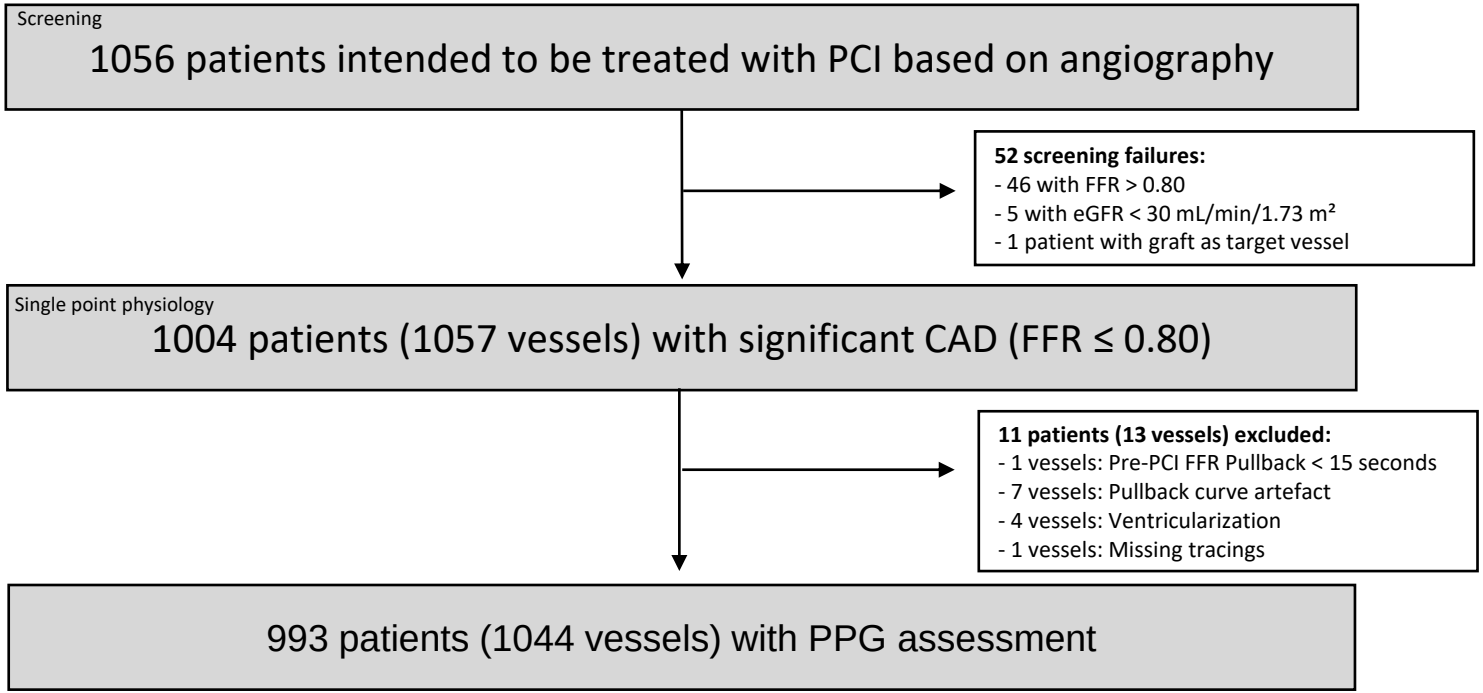
982 patients were required

Piroth Z et al. Circ Cardiovasc Interv. 2022 Nov;15(11):884-891.

Munhoz D at el . Am Heart J. 2023 Nov;265:170-179.

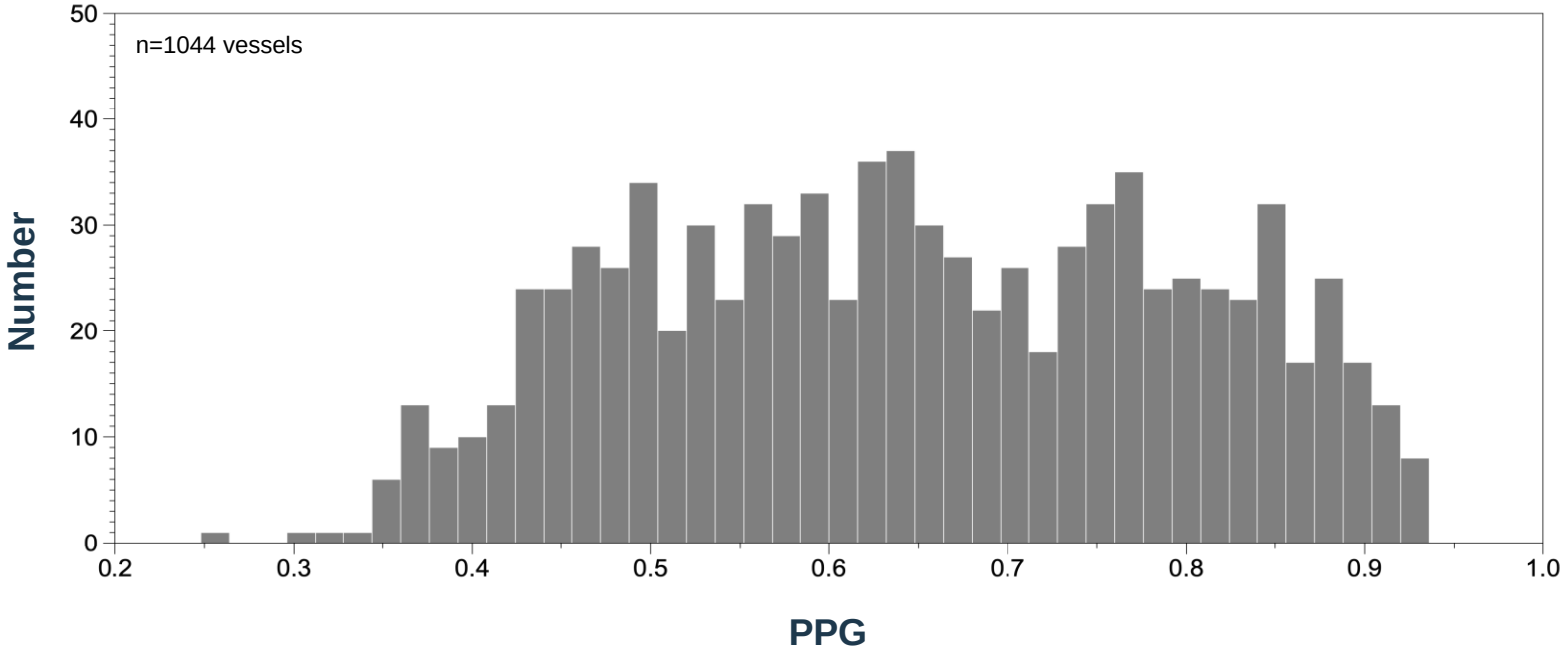
Results

Study Flowchart



Definition of focal vs diffuse disease

PPG GLOBAL



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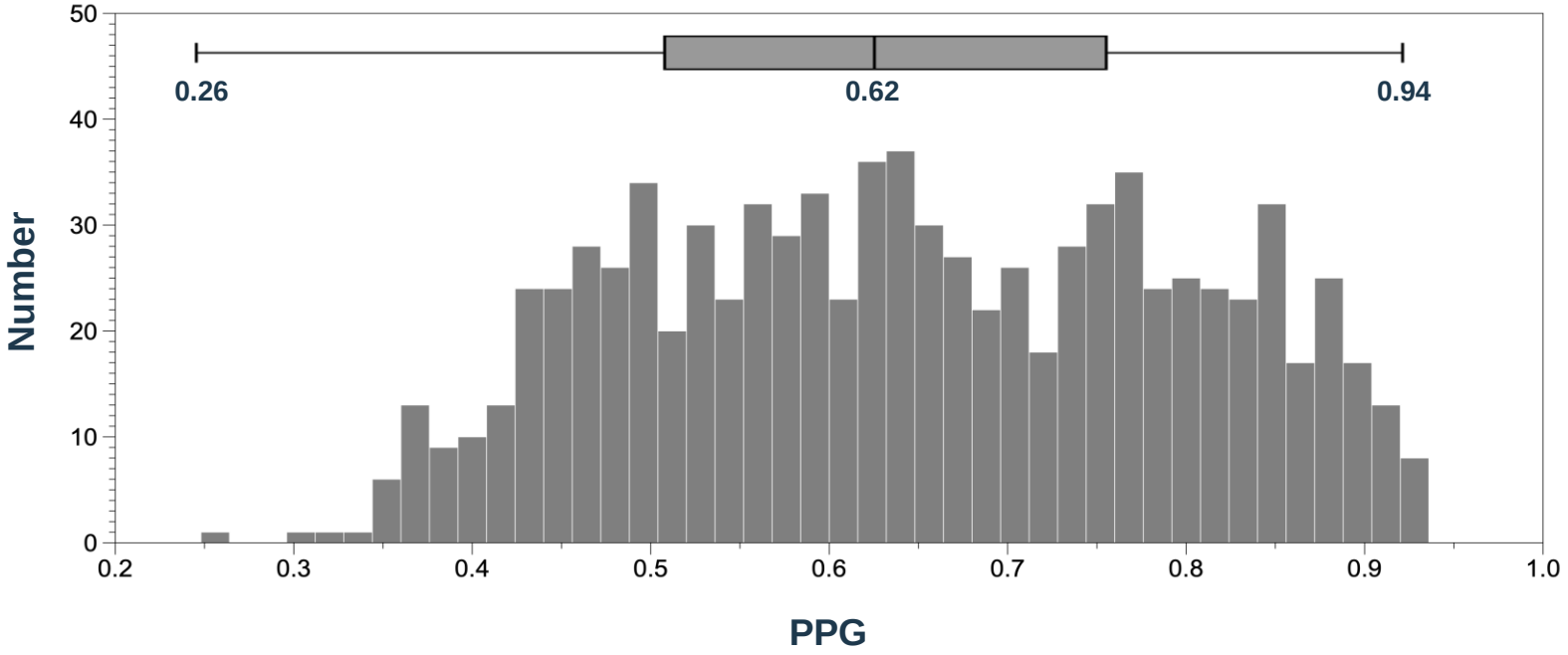

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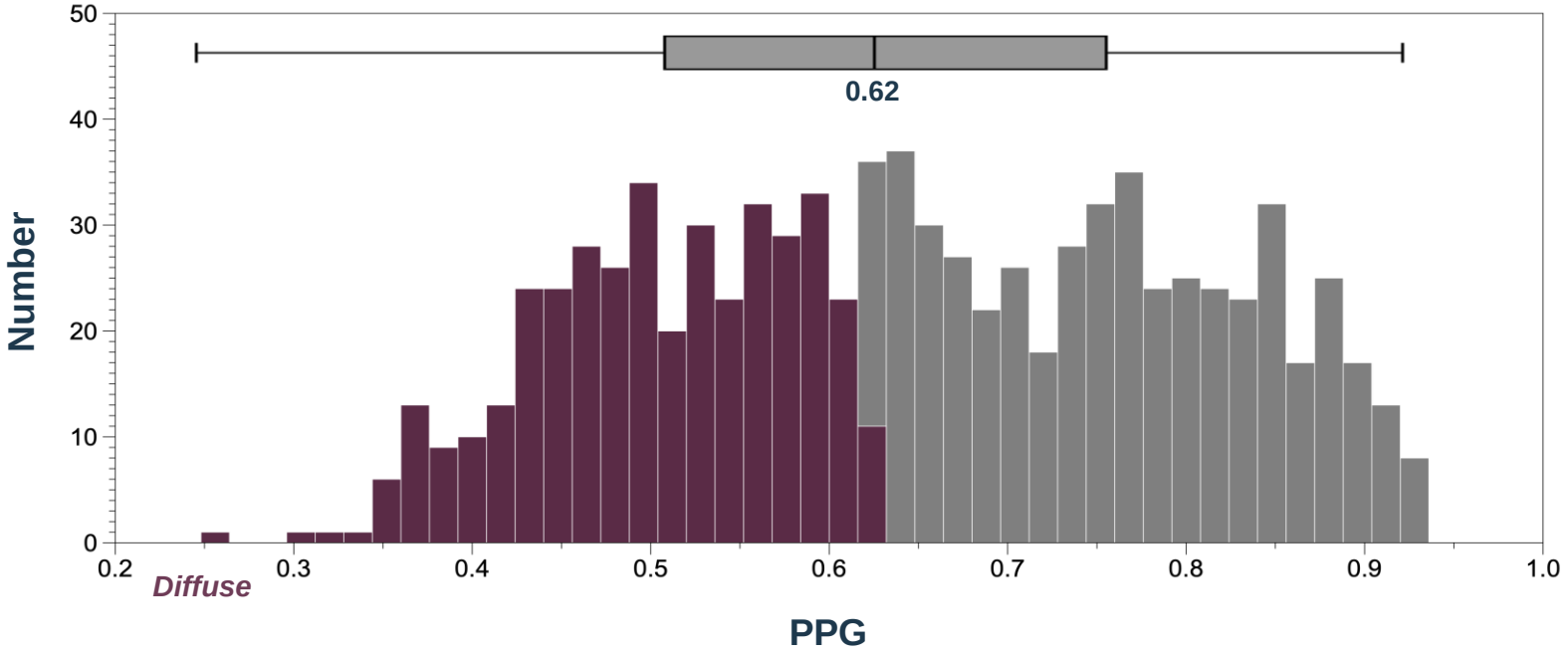

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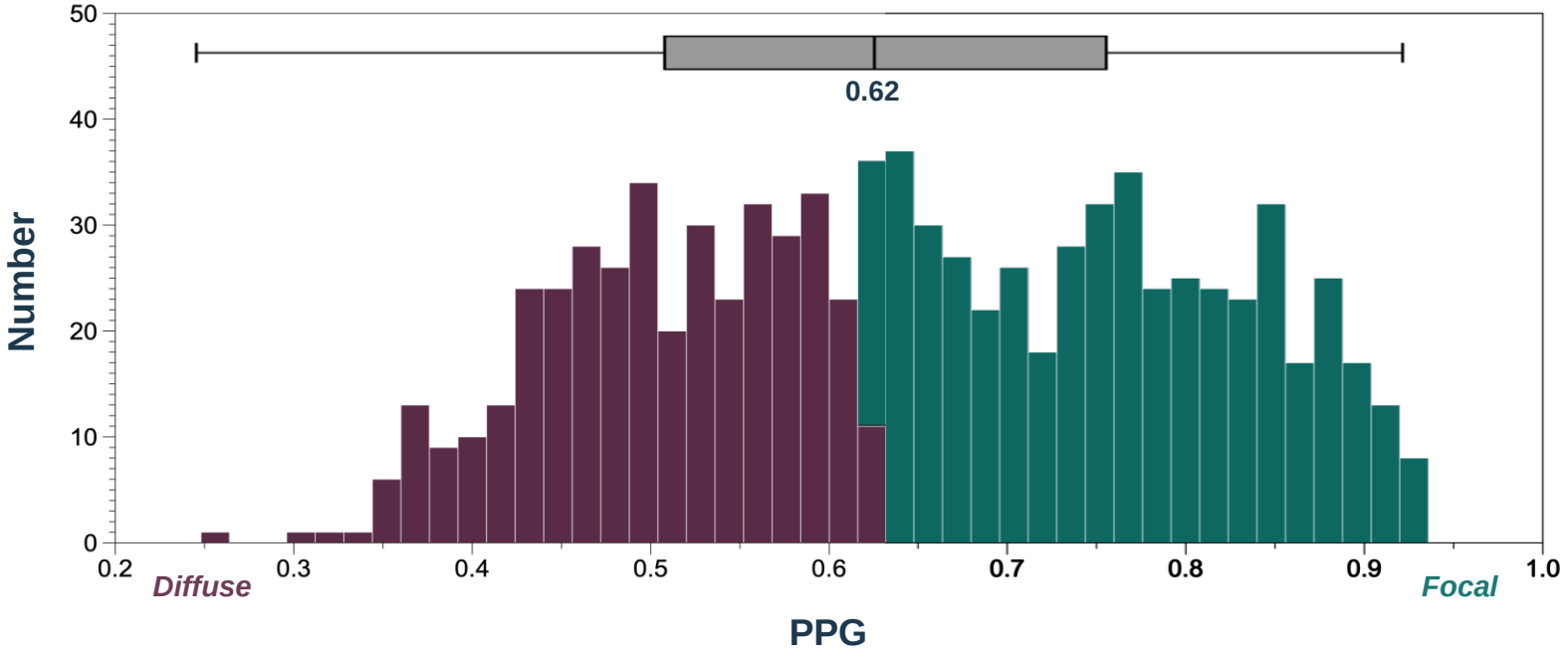

Baseline and clinical characteristics stratified by PPG

PPG GLOBAL

Variable	Overall	Focal	Diffuse	p-value
Number of patients*	993	470	523	
Age (years), mean ± SD	67.7 ± 10.2	67.7 ± 10.4	67.6 ± 10.1	0.873
Gender (male), n (%)	757 (76.2)	347 (73.8)	410 (78.4)	0.107
BMI, kg/m2 (%), mean ± SD	27.0 ± 8.9	26.7 ± 8.4	27.4 ± 9.3	0.221
Dyslipidemia, n (%)	727 (73.2)	343 (73.0)	384 (73.4)	0.932
Hypertension, n (%)	694 (69.9)	322 (68.5)	372 (71.1)	0.407
Diabetes mellitus, n (%)	292 (29.4)	136 (28.9)	156 (29.8)	0.812
Current smoking, n (%)	164 (16.5)	85 (18.1)	79 (15.1)	0.239
Prior MI, n (%)	197 (19.8)	82 (17.4)	115 (22.0)	0.087
Clinical presentation, n (%)				0.156
Acute Coronary syndrome**, n (%)	110 (11)	45 (9.6)	65 (12.4)	
Stable angina, n (%)	881 (89)	425 (90)	456 (87.5)	
Symptoms severity***				0.003
Silent ischemia	260 (26.2)	98 (20.8)	162 (31)	
CCS I	304 (30.7)	162 (34.5)	142 (27.3)	
CCS II	223 (22.5)	112 (23.8)	111 (21.3)	
CCS III	76 (7.7)	43 (9.1)	33 (6.3)	
CCS IV	18 (1.8)	10 (2.1)	8 (1.5)	
LVEF (%), mean ± SD	58.3 ± 9.5	59.3 ± 9.4	57.4 ± 9.5	0.001

**For patients with multivessel interrogation, the lowest PPG was used for the patient-level analysis.*

*** Non-culprit vessels after an acute coronary syndrome.*

****As assessed by the treating physician.*

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*** Non-culprit vessels after an acute coronary syndrome.*

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Physiological and procedural characteristics stratified by PPG

Variables	Overall	Focal	Diffuse	p-value
Number of vessels	1044	515	529	
Vessel type				<0.001
LAD	756 (72.5)	283 (55.0)	473 (89.6)	
LCX	123 (11.8)	105 (20.4)	18 (3.4)	
RCA	164 (15.7)	127 (24.7)	37 (7.0)	
Serial lesions, n (%)	212 (20.3)	83 (16.1)	129 (24.5)	<0.001
Reference vessel diameter (mm), mean ± SD	2.65 ± 0.57	2.75 ± 0.60	2.55 ± 0.53	<0.001
Diameter stenosis (%), mean ± SD	50.1 ± 14.1	56.5 ± 13.0	44.0 ± 12.3	<0.001
FFR, mean ± SD	0.68 ± 0.12	0.63 ± 0.13	0.72 ± 0.08	<0.001
PPG, mean ± SD	0.62 ± 0.16	0.76 ± 0.09	0.49 ± 0.08	<0.001
Number of stents, mean ± SD	1.14 ± 0.37	1.08 ± 0.29	1.21 ± 0.44	<0.001
Stent length (mm), mean ± SD	32.4 ± 16.6	28.6 ± 13.7	37.3 ± 18.7	<0.001
Stent diameter (mm), mean ± SD	3.04 ± 0.44	3.09 ± 0.48	2.97 ± 0.38	<0.001
Intracoronary imaging PCI (%), n (%)	395 (44.4)	234 (47.4)	161 (40.7)	0.046
Pre dilatation, n (%)	780 (87.7)	429 (87.0)	351 (88.6)	0.465
Post dilatation, n (%)	662 (74.5)	347 (70.4)	315 (79.7)	0.002
Post-PCI FFR, mean ± SD	0.87 ± 0.07	0.89 ± 0.07	0.84 ± 0.06	<0.001
Delta FFR, mean ± SD	0.20 ± 0.13	0.26 ± 0.14	0.13 ± 0.08	<0.001

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Diameter stenosis (%), mean ± SD	50.1 ± 14.1	56.5 ± 13.0	44.0 ± 12.3	<0.001
FFR, mean ± SD	**0.68 ± 0.12**	**0.63 ± 0.13**	**0.72 ± 0.08**	**<0.001**
PPG, mean ± SD	0.62 ± 0.16	0.76 ± 0.09	0.49 ± 0.08	<0.001
Number of stents, mean ± SD	1.14 ± 0.37	1.08 ± 0.29	1.21 ± 0.44	<0.001
Stent length (mm), mean ± SD	32.4 ± 16.6	28.6 ± 13.7	37.3 ± 18.7	<0.001
Stent diameter (mm), mean ± SD	3.04 ± 0.44	3.09 ± 0.48	2.97 ± 0.38	<0.001
Intracoronary imaging PCI (%), n (%)	395 (44.4)	234 (47.4)	161 (40.7)	0.046
Pre dilatation, n (%)	780 (87.7)	429 (87.0)	351 (88.6)	0.465
Post dilatation, n (%)	662 (74.5)	347 (70.4)	315 (79.7)	0.002
Post-PCI FFR, mean ± SD	0.87 ± 0.07	0.89 ± 0.07	0.84 ± 0.06	<0.001
Delta FFR, mean ± SD	0.20 ± 0.13	0.26 ± 0.14	0.13 ± 0.08	<0.001

Physiological and procedural characteristics stratified by PPG

Variables	Overall	Focal	Diffuse	p-value
Number of vessels	1044	515	529	
Vessel type				<0.001
LAD	756 (72.5)	283 (55.0)	473 (89.6)	
LCX	123 (11.8)	105 (20.4)	18 (3.4)	
RCA	164 (15.7)	127 (24.7)	37 (7.0)	
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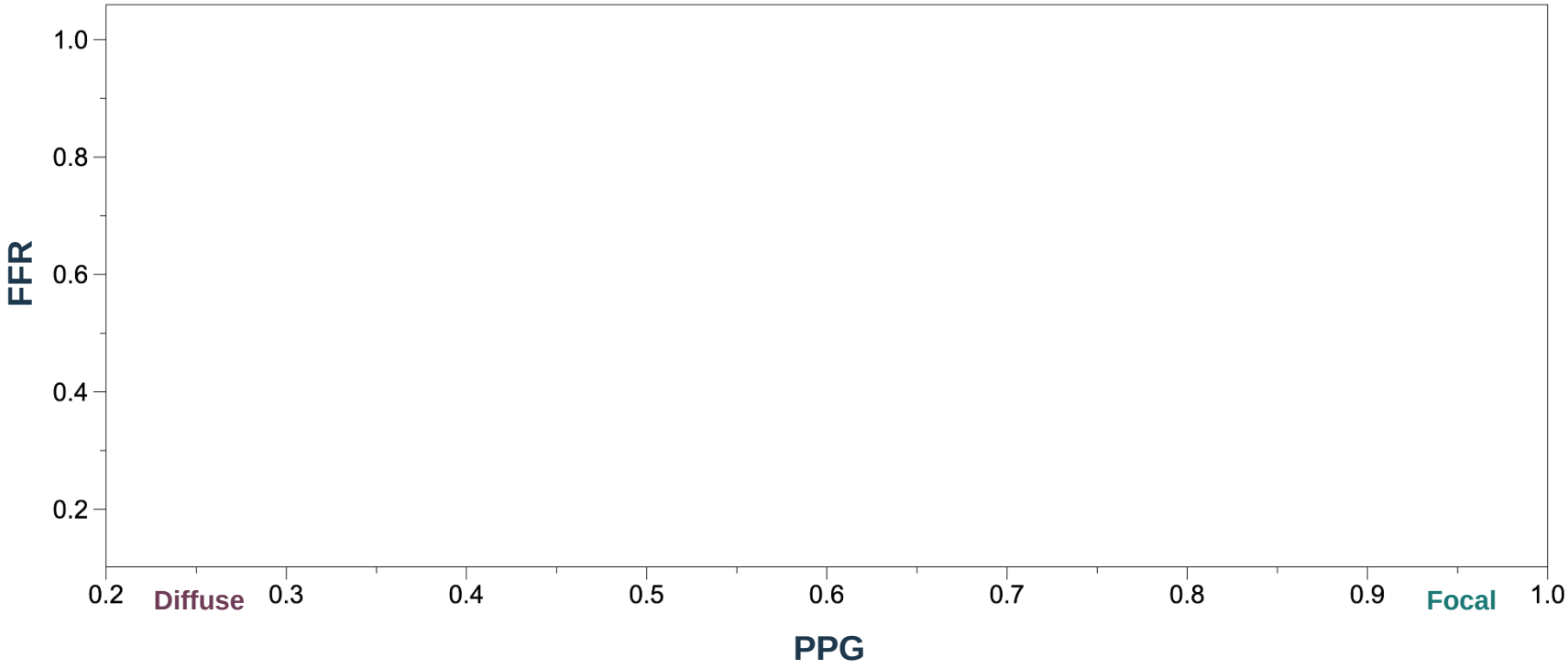
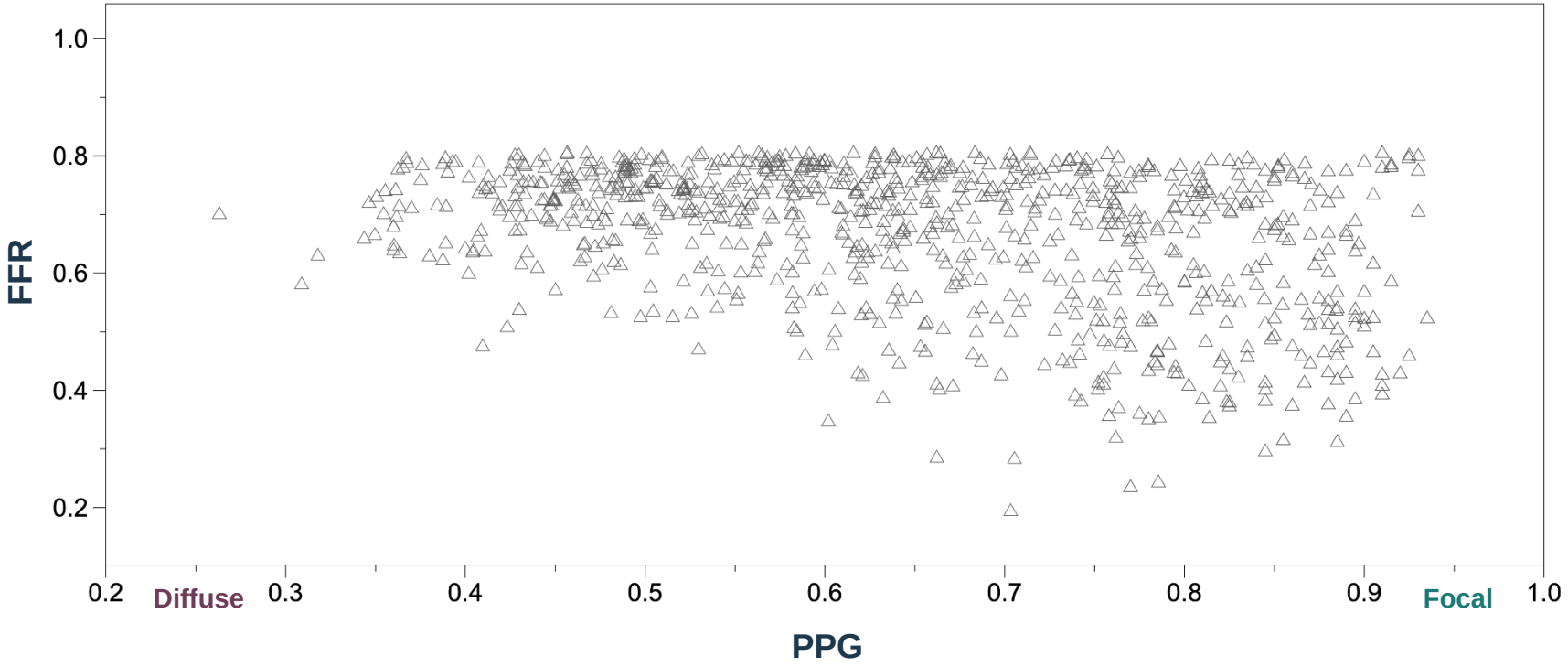
FFR before PCI

PPG GLOBAL



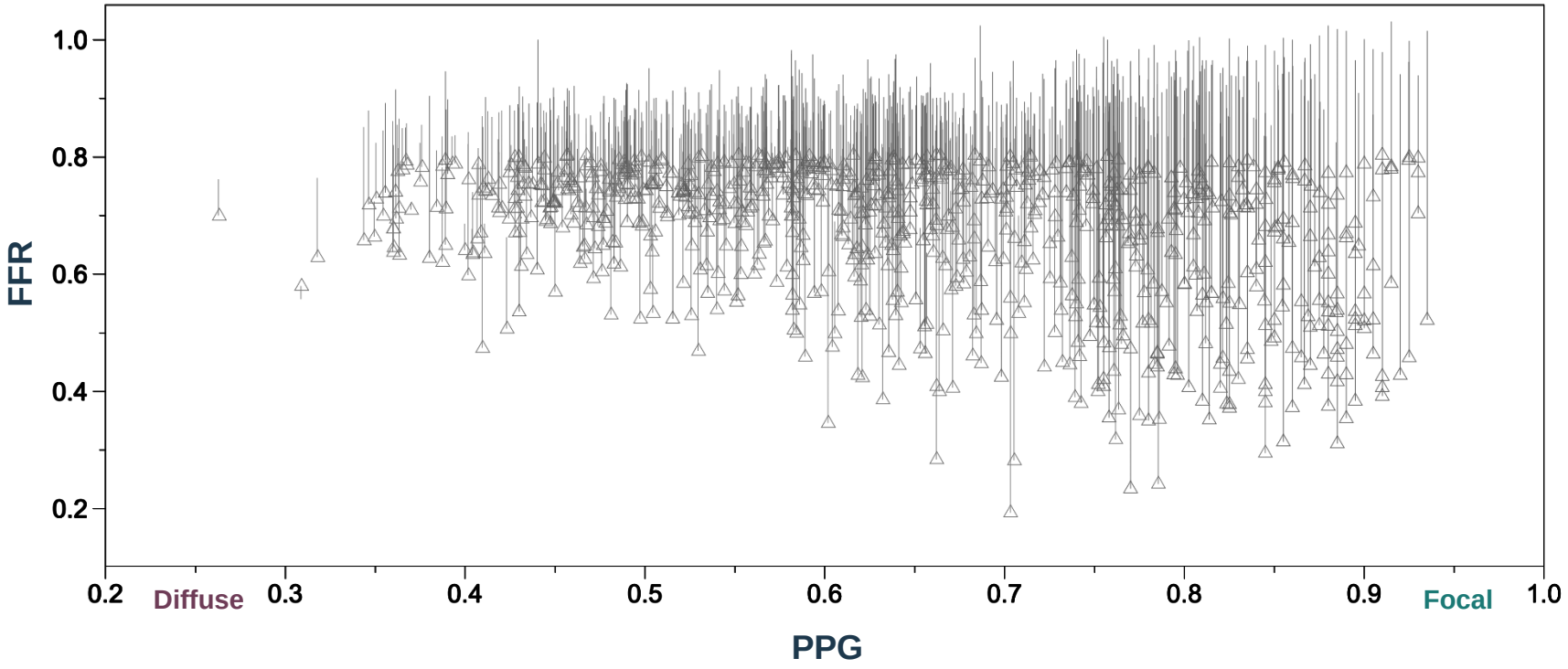
FFR before PCI

PPG GLOBAL



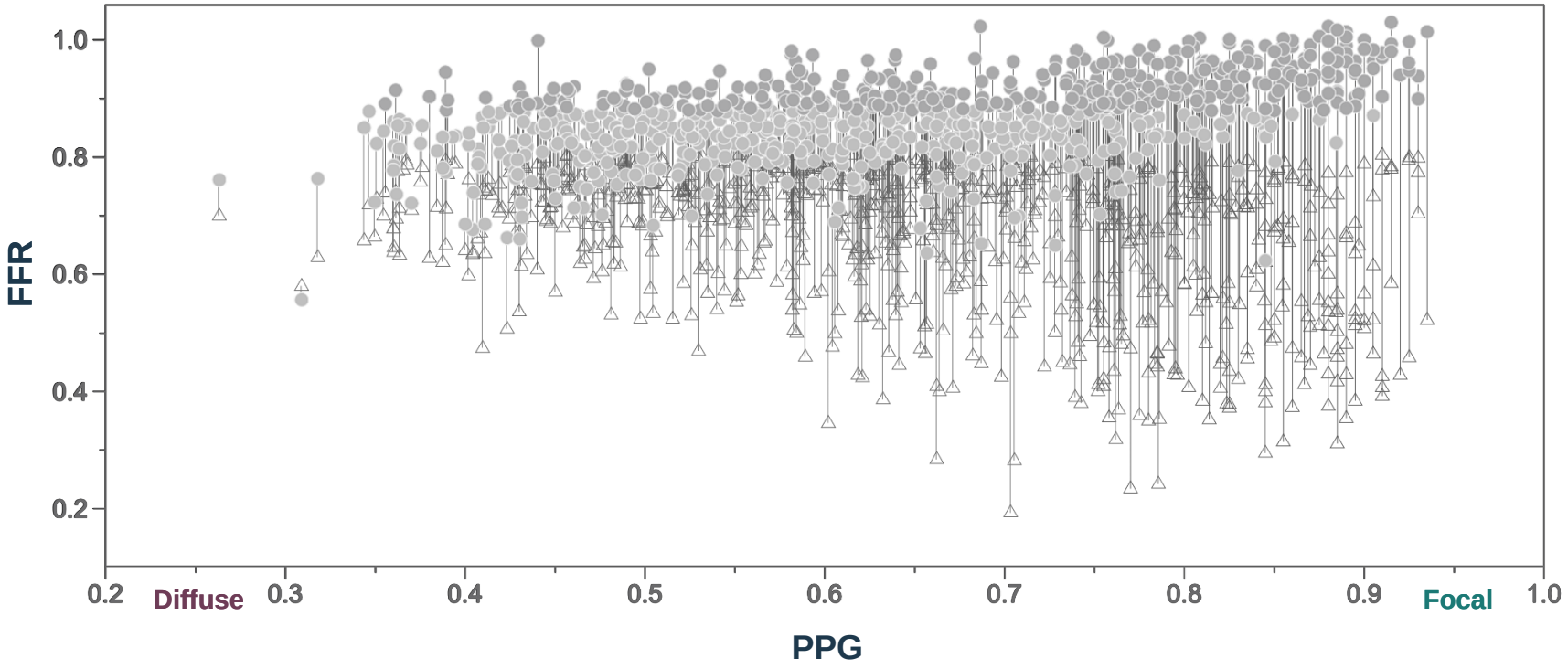
Improvement in FFR after PCI

PPG GLOBAL



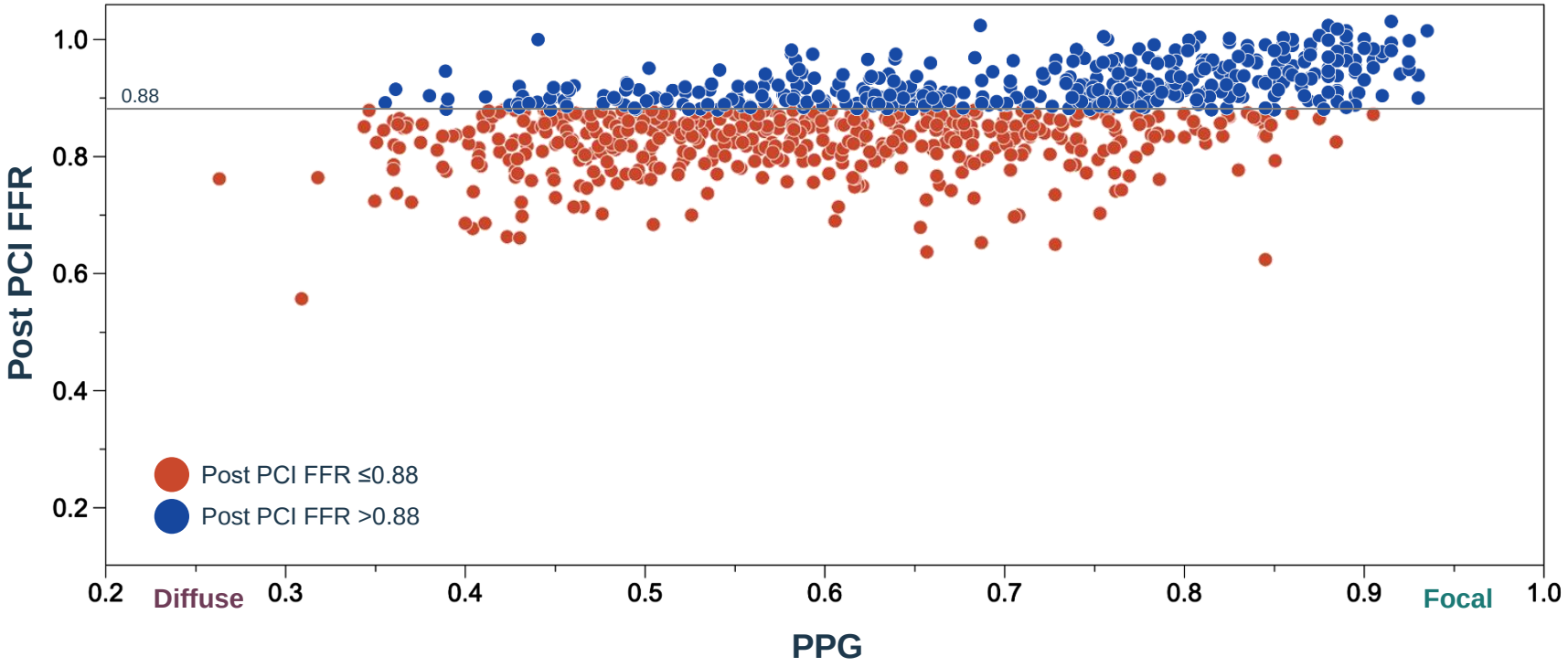
Improvement in FFR after PCI

PPG GLOBAL

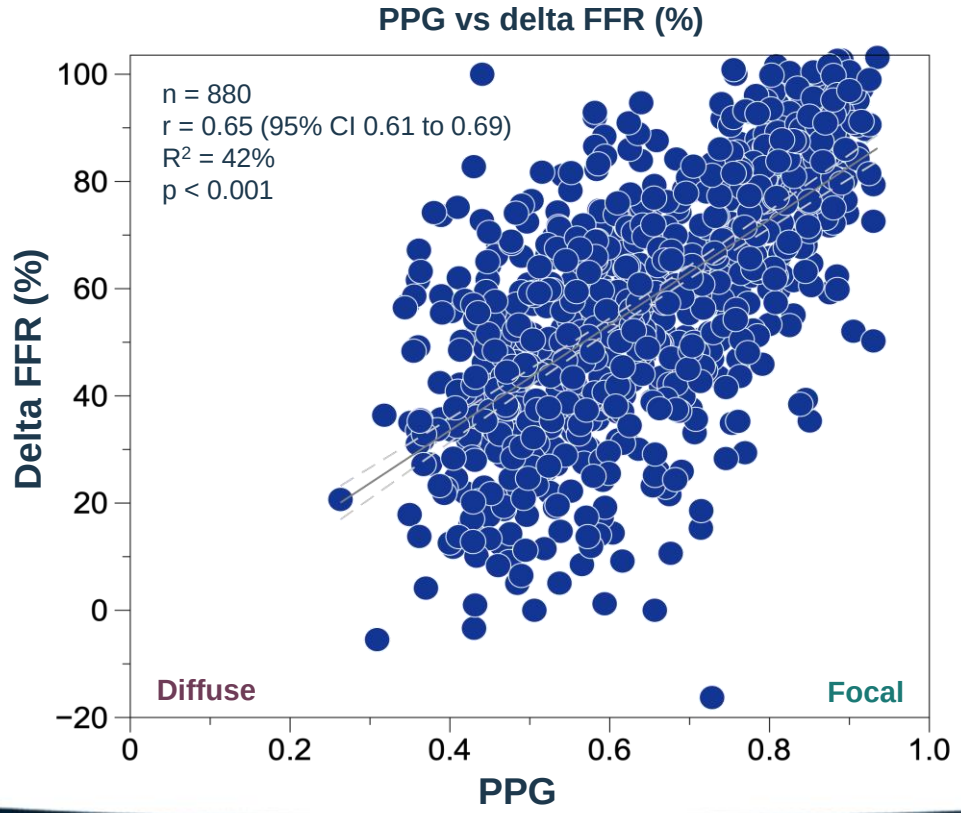


PPG Predicts Optimal PCI

PPG GLOBAL

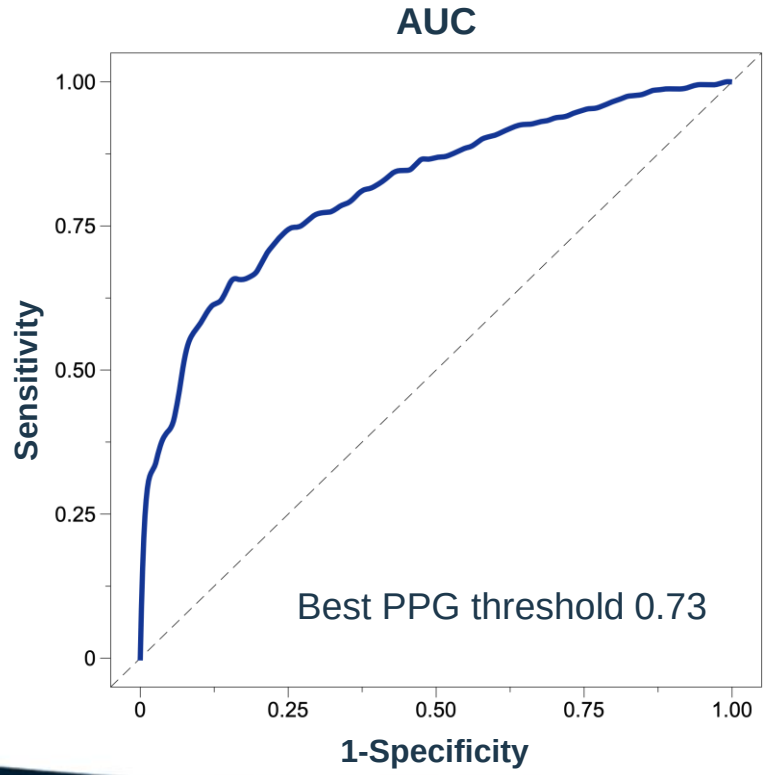


Correlation PPG and delta FFR



Delta FFR = FFR post-PCI minus FFR pre-PCI / 1 – FFR pre-PCI

Predictive capacity of PPG for post-PCI FFR ≥0.88



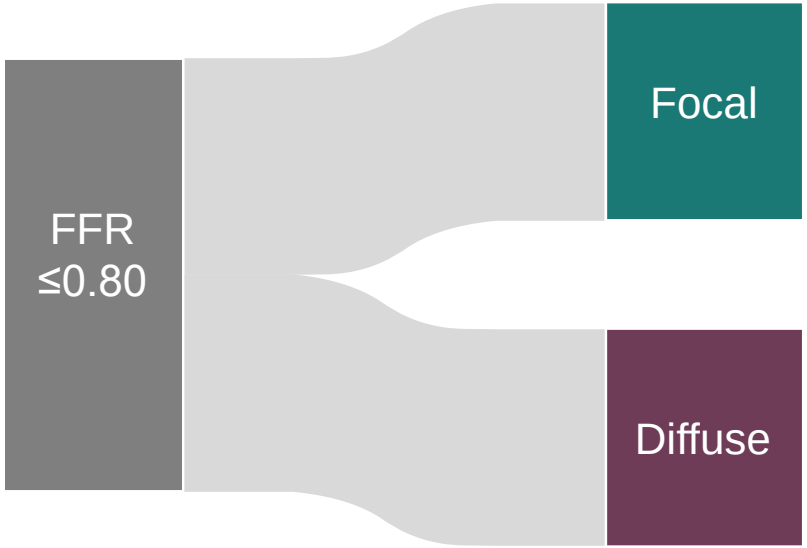
AUC 0.82 (95% CI 0.79 to 0.84)

AUC adjusted by pre-PCI FFR and vessel type

Impact on clinical decision making

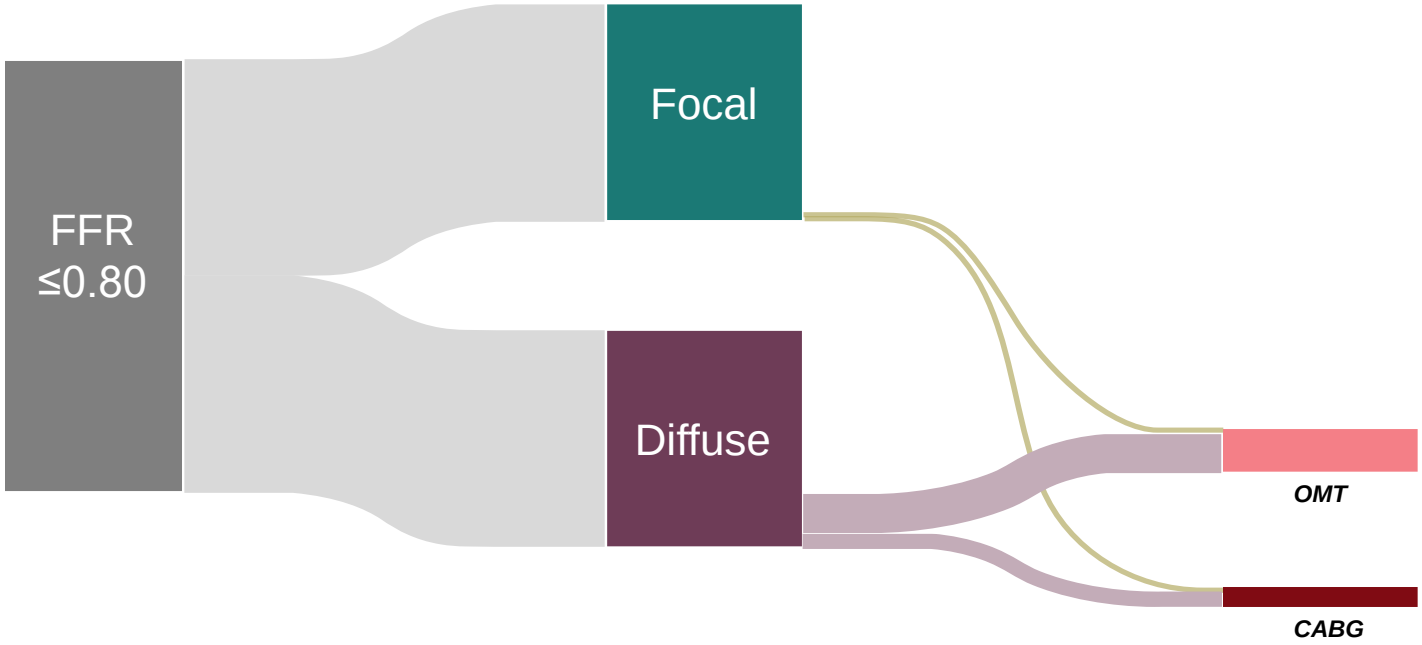
Patients intended to be treated with PCI

Split into focal and diffuse disease by median PPG 0.62

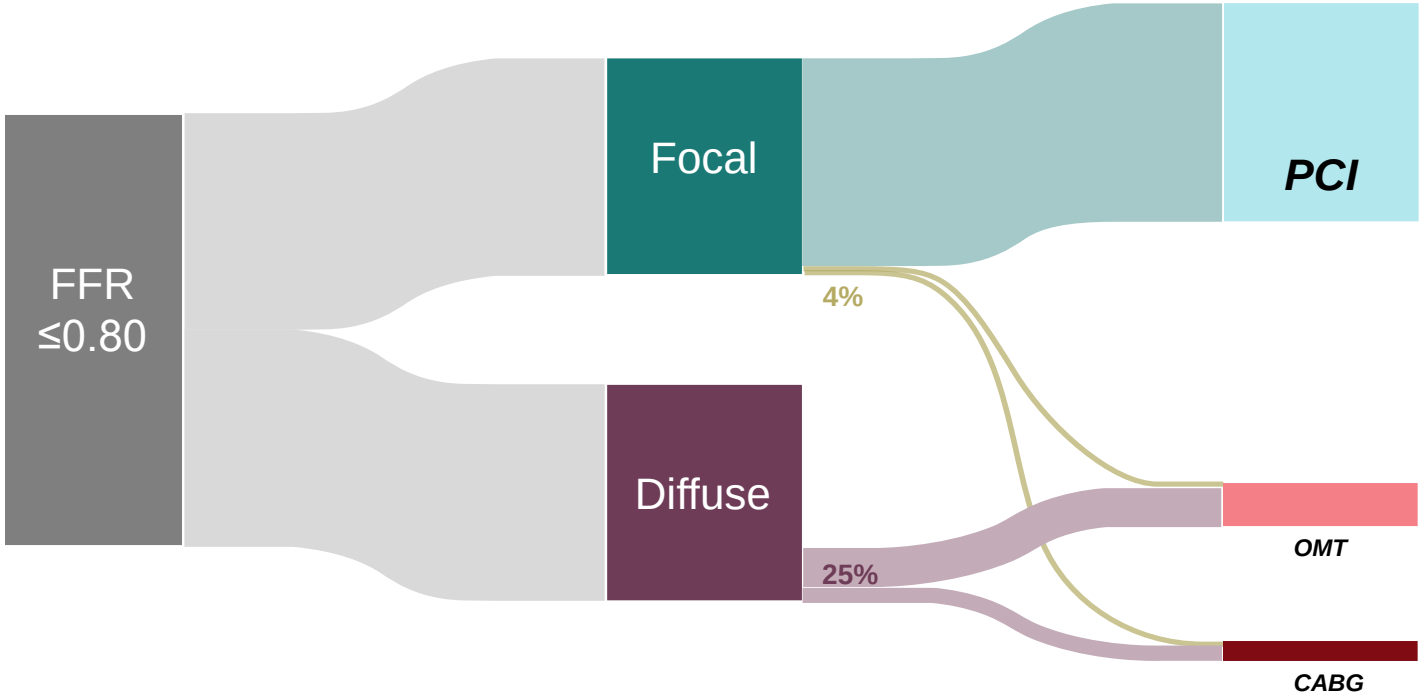


Change in Decision Making after PPG

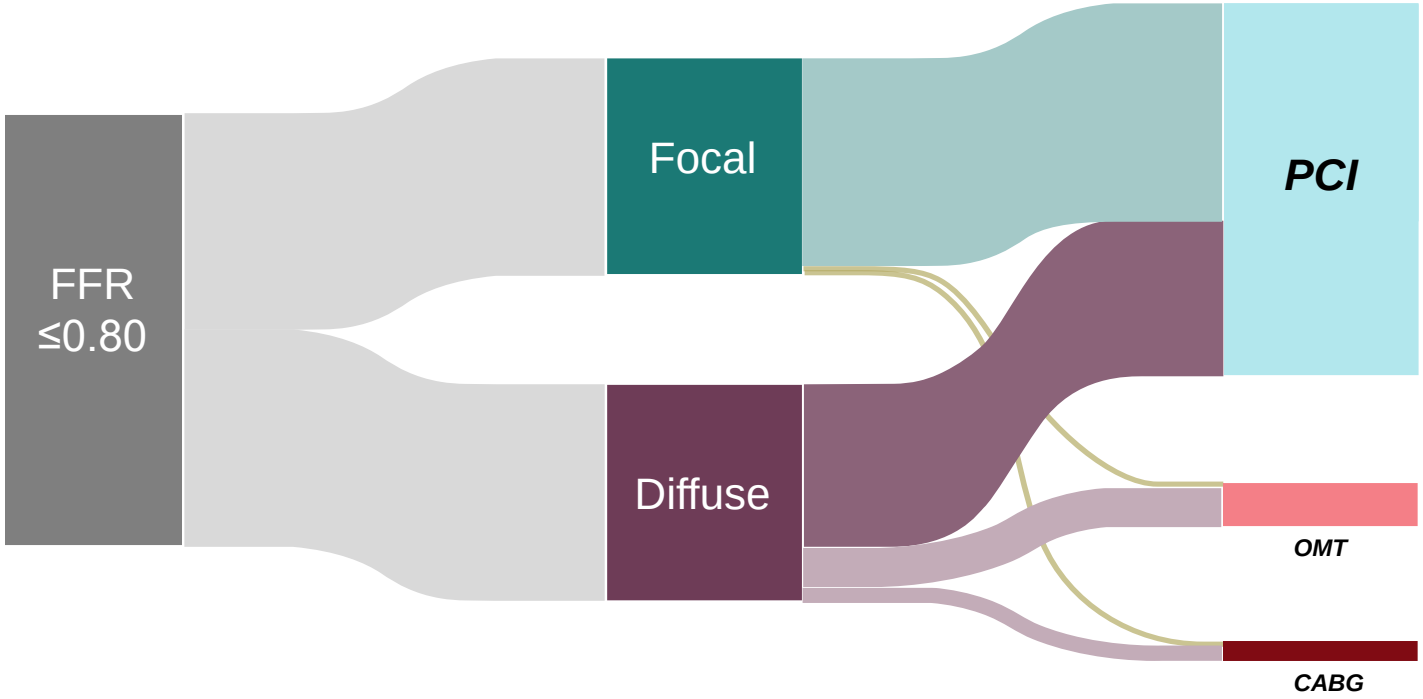
PPG GLOBAL



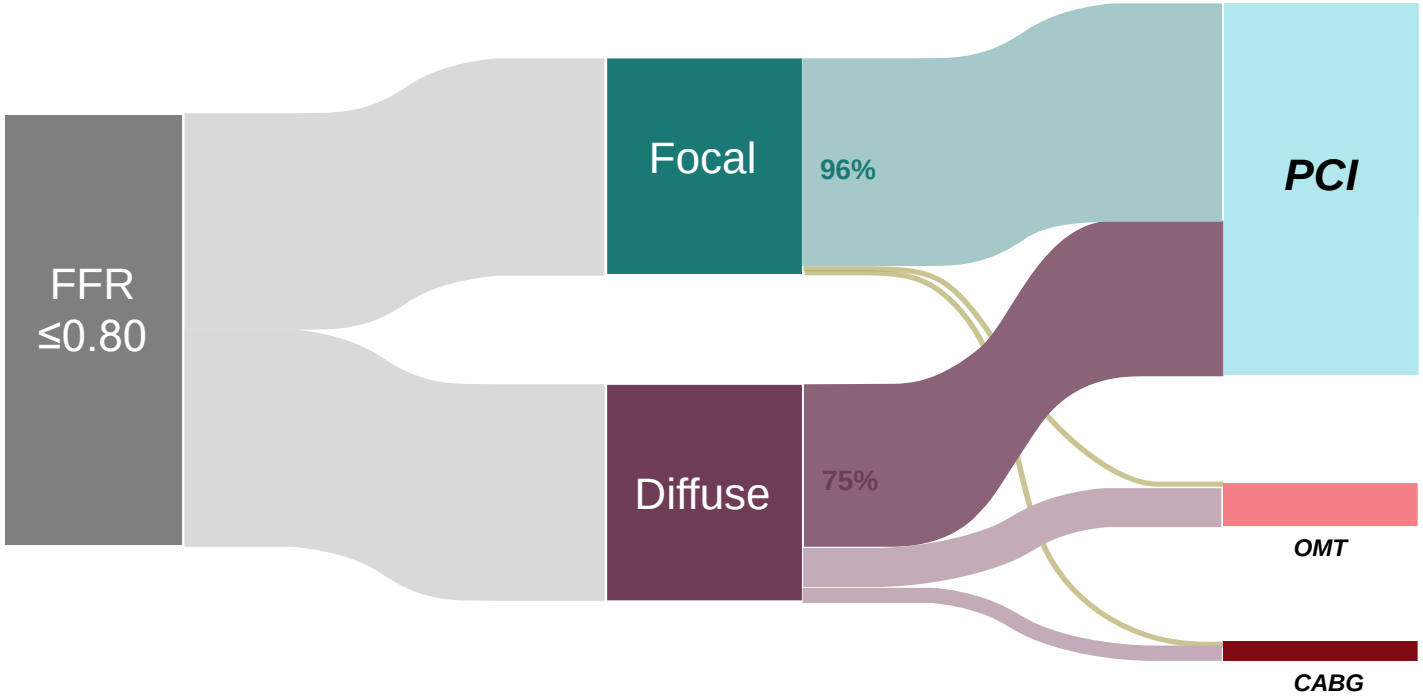
Majority of focal treated with PCI



Diffuse treated with PCI



Diffuse treated with PCI

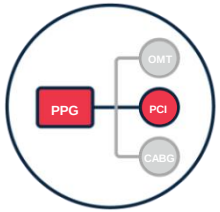


In conclusion

Conclusion

PPG before intervention predicted post-PCI FFR.

CAD patterns influenced the improvement in flow with PCI



PPG changed revascularization decisions in one out of seven patients.

PPG GLOBAL

PPG adds clinical value to FFR in decision-making about revascularization in patients with obstructive coronary artery disease