

Impact of Pullback Pressure Gradient (PPG) on Patient-Reported Outcomes in Patients With Coronary Artery Disease

Carlos Collet MD, PhD

On behalf of the PPG Global investigators



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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

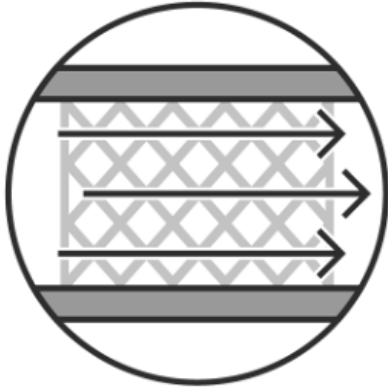
- Abbott Vascular
- HeartFlow Inc
- GE Healthcare
- Boston Scientific
- Insight Lifetech
- Early Bird
- Pfizer
- Siemens

Others

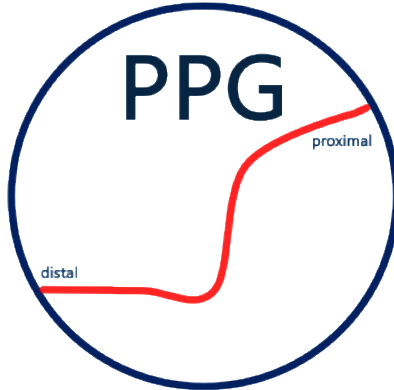
CoreAalst BV

Patents filed: US20220164950A1,
US20220175260A1, WO2022136637A1 and
WO2021224458A1

Background



The effectiveness of PCI is influenced by CAD patterns (focal vs diffuse).



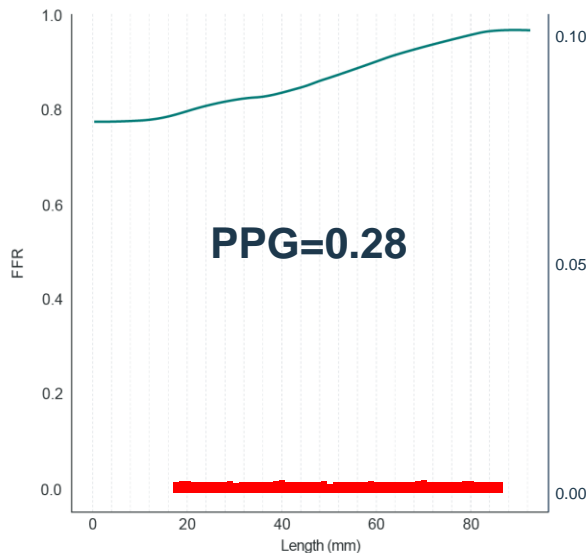
PPG quantifies focal and diffuse CAD and predicts blood flow improvements following PCI.



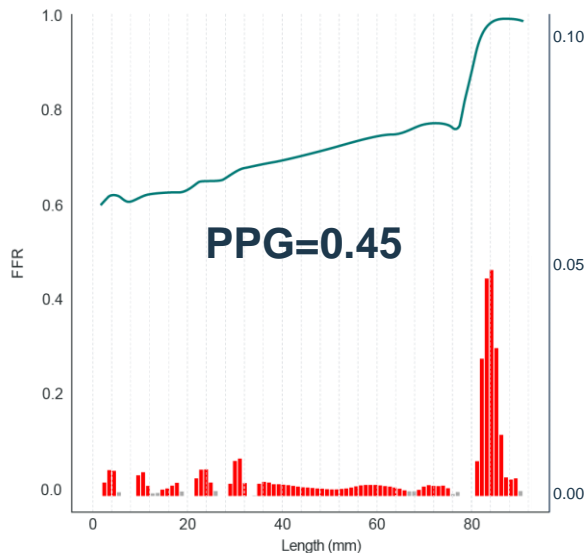
The magnitude of flow improvement (ΔFFR) is directly correlated with the relief of symptoms.

PPG: Focal and Diffuse Disease on a Scale from 0 to 1

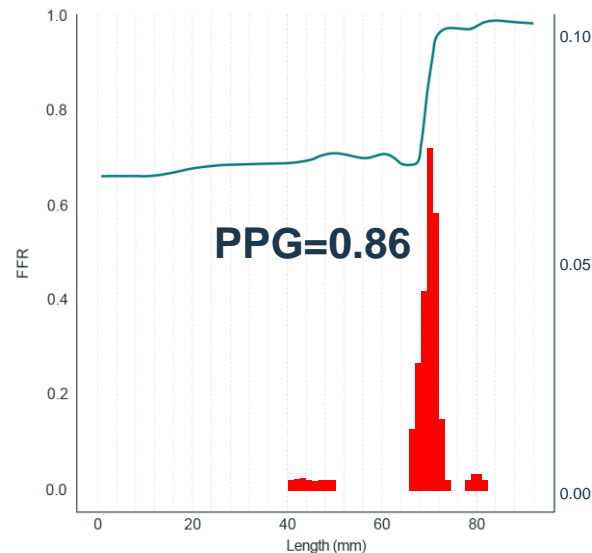
Diffuse CAD



Combined CAD



Focal CAD

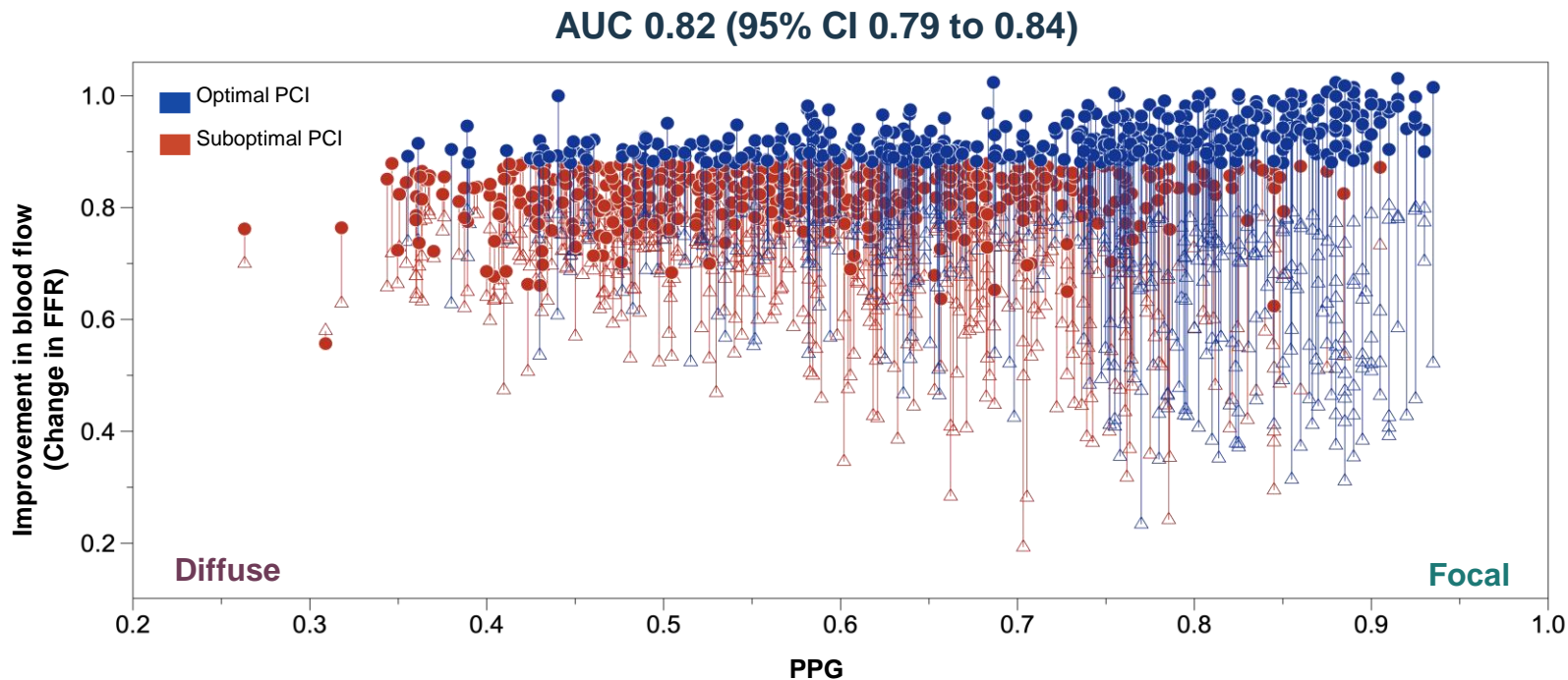


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Pullback Pressure Gradient (PPG)

1

PPG and Blood Flow Improvement after PCI



Study Objectives



To evaluate the impact of PPG on patient-reported outcomes in patients with hemodynamically significant CAD after one year.



To explore the impact of various treatment strategies on patient-reported outcomes, stratified by PPG.

Methods

Study design



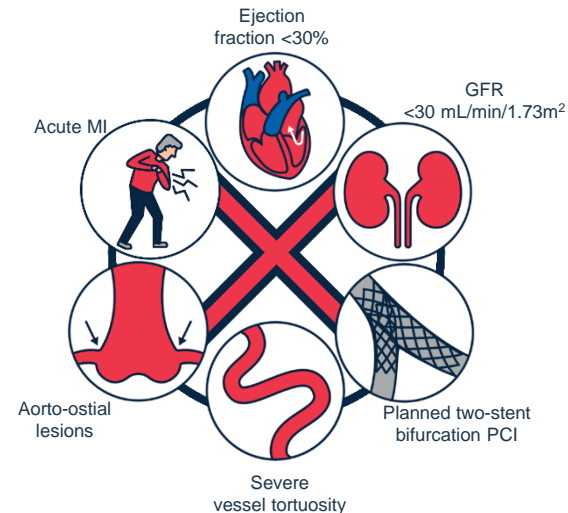
Investigator-initiated*,
multicenter, international,
and single-arm study
(NCT04789317)

*Research grant from Abbott Vascular



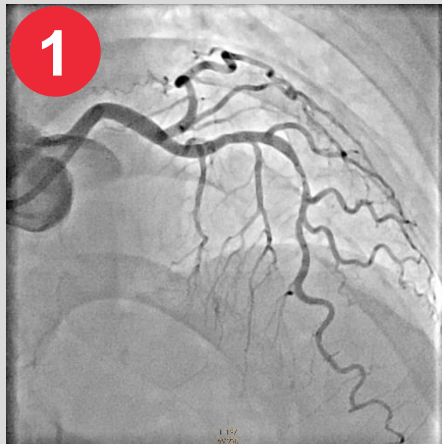
Stable patients* with at least
one hemodynamically
significant lesion ($FFR \leq 0.80$)
intended to be treated with
PCI

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

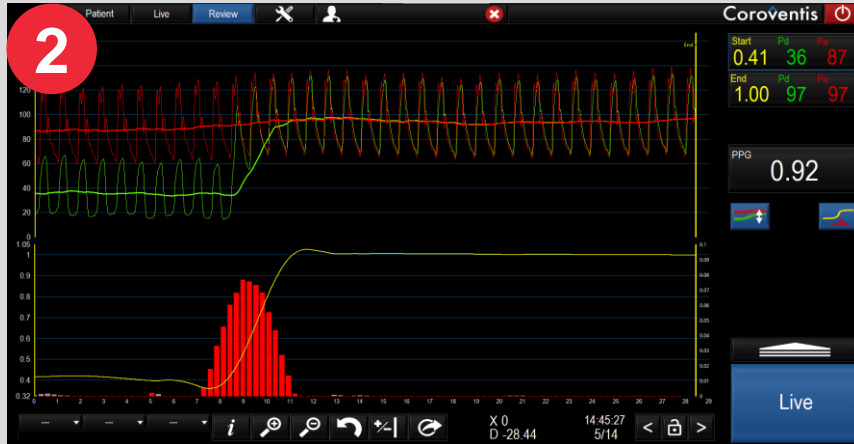


Exclusion Criteria

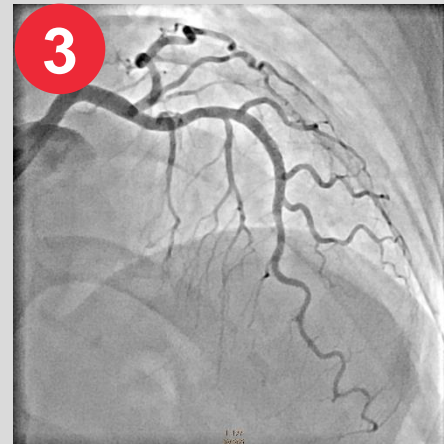
Invasive protocol



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

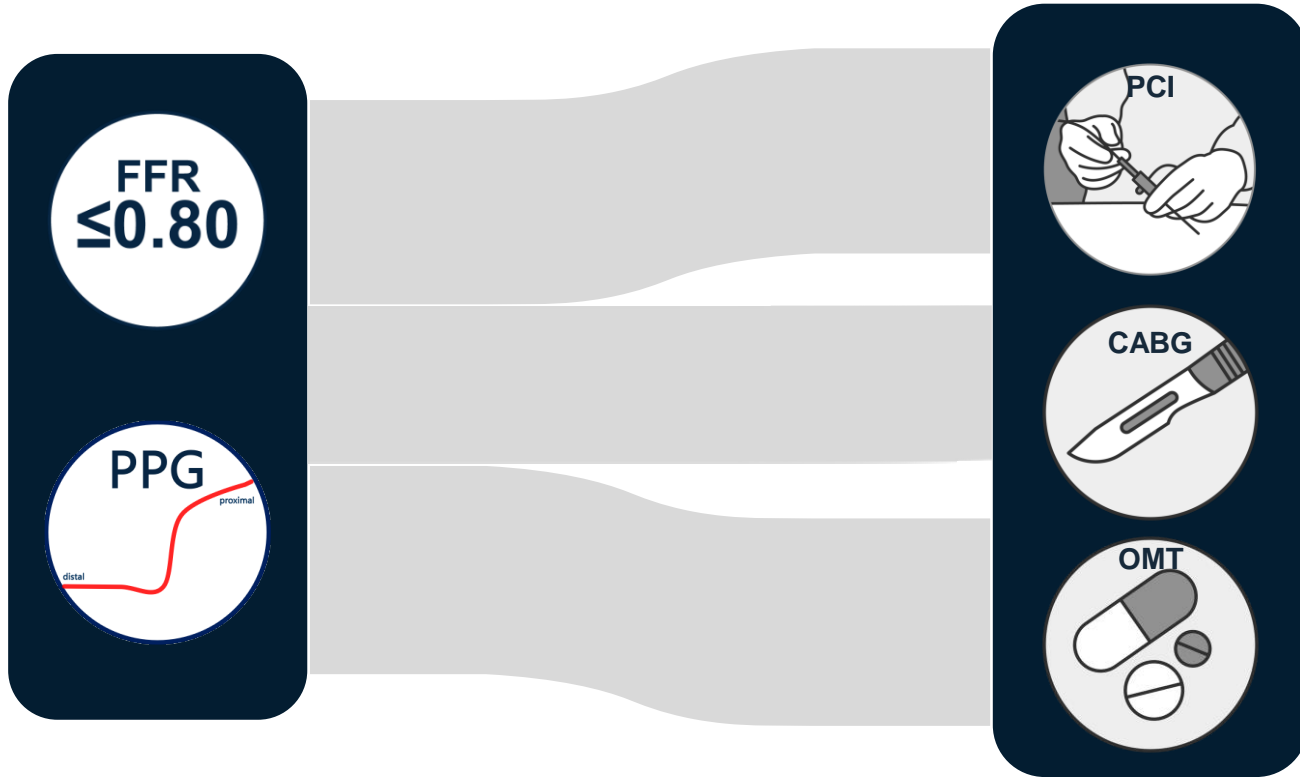


Manual FFR pullbacks
Online PPG calculation



Post-PCI FFR

Invasive protocol and decision making



Methods



Patient-reported outcomes (PRO)

Seattle Angina Questionnaire (SAQ-7) at baseline and 1-year follow-up.



CoreLab analysis

Angiographic and physiologic data underwent centralized analysis by CoreAalst BV core laboratory.

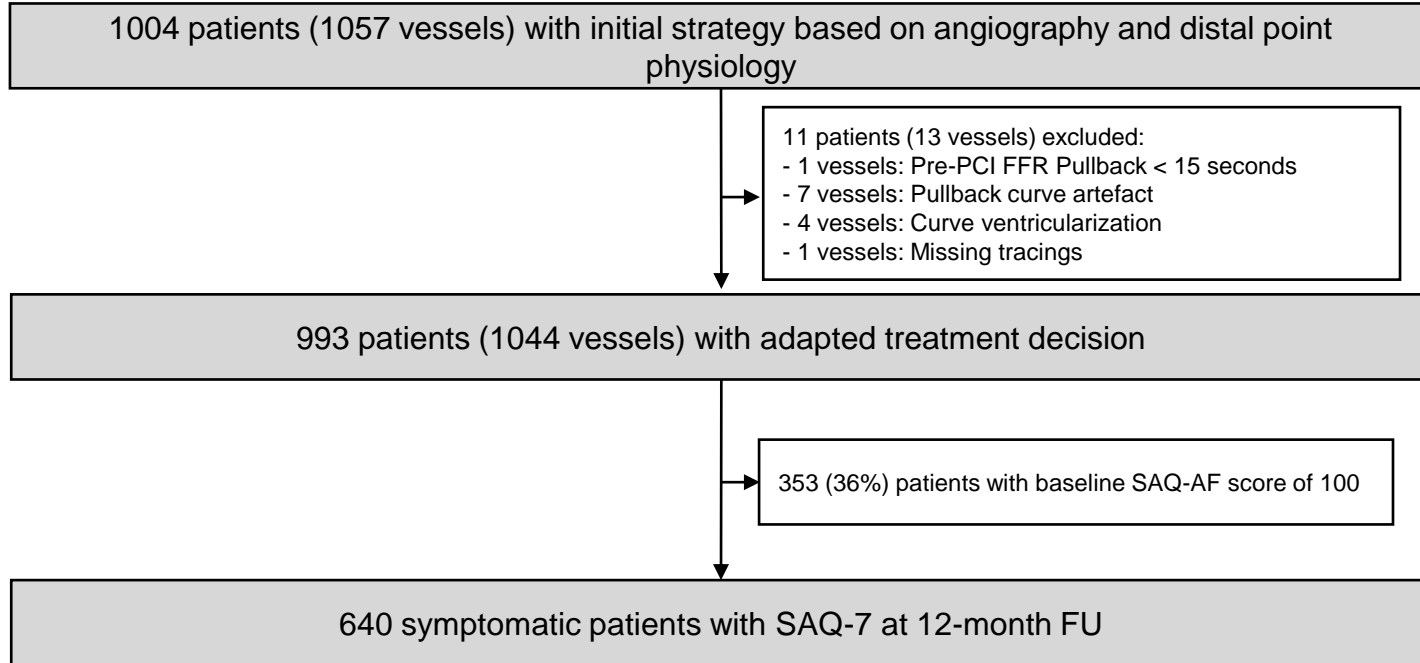


Definitions and adjudication

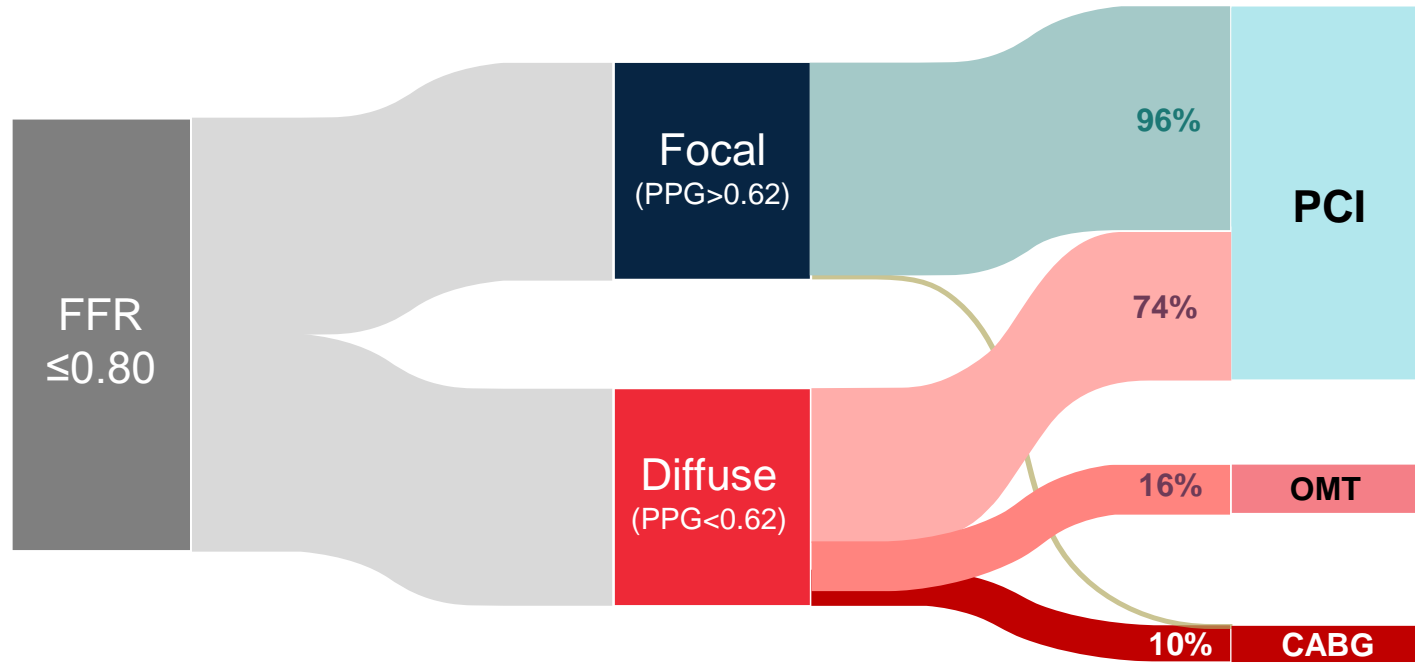
An independent clinical events committee (CEC) adjudicated adverse events.

Results

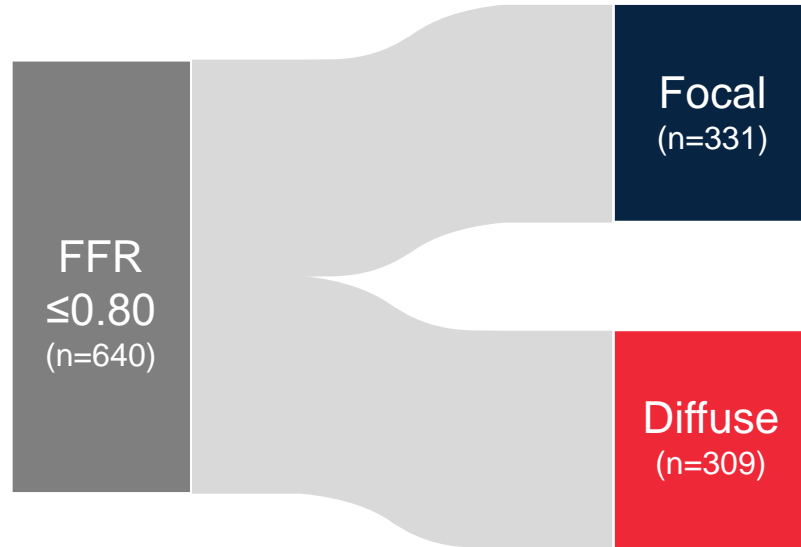
Study Flowchart



Treatment decision in focal vs diffuse disease



Treatment decision in symptomatic patients



Baseline and clinical characteristics stratified by PPG

Variable	Focal CAD	Diffuse CAD	p-value
Number of patients*	331	309	
Age (years), mean \pm SD	68.3 \pm 10.4	67.2 \pm 10.2	0.211
Gender (male), n (%)	238 (71.9)	239 (77.3)	0.137
BMI, kg/m ² (%), mean \pm SD	26.7 \pm 9.6	27.5 \pm 9.7	0.272
Dyslipidemia, n (%)	234 (70.7)	224 (72.5)	0.677
Hypertension, n (%)	231 (69.8)	218 (70.6)	0.901
Diabetes mellitus, n (%)	92 (27.8)	88 (28.5)	0.917
Current smoking, n (%)	53 (16.0)	49 (15.9)	1.000
Prior MI, n (%)	55 (16.6)	60 (19.4)	0.413
Clinical presentation, n (%)			0.117
Acute Coronary syndrome**, n (%)	38 (11.5)	50 (16.2)	
Stable angina, n (%)	293 (88.5)	259 (83.8)	
Symptoms severity***			0.117
Silent ischemia	16 (4.8)	22 (7.2)	
CCS I	125 (37.8)	92 (30.0)	
CCS II	96 (29.0)	90 (29.3)	
CCS III	39 (11.8)	29 (9.4)	
CCS IV	9 (2.7)	7 (2.3)	

**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.*

Physiological and procedural characteristics stratified by PPG

Variables	Focal CAD	Diffuse CAD	p-value
Number of vessels	359	312	
Vessel type			<0.001
LAD	194 (54.0)	276 (88.5)	
LCX	68 (18.9)	11 (3.5)	
RCA	97 (27.0)	25 (8.0)	
Serial lesions, n (%)	53 (14.8)	69 (22.2)	0.017
Reference vessel diameter (mm), mean \pm SD	2.75 \pm 0.60	2.58 \pm 0.52	<0.001
Diameter stenosis (%) QCA, mean \pm SD	57.2 \pm 13.2	44.7 \pm 12.4	<0.001
FFR, mean \pm SD	0.62 \pm 0.14	0.71 \pm 0.08	<0.001
PPG, mean \pm SD	0.76 \pm 0.09	0.49 \pm 0.08	<0.001
Number of stents*, mean \pm SD	1.16 \pm 0.41	1.35 \pm 0.57	<0.001
Stent length (mm)*, mean \pm SD	27.5 \pm 12.8	37.7 \pm 18.8	<0.001
Stent diameter (mm)*, mean \pm SD	3.08 \pm 0.48	2.96 \pm 0.39	0.002
Intracoronary imaging PCI (%)*, n (%)	170 (49.4)	91 (40.1)	0.035
Pre dilatation*, n (%)	301 (87.5)	199 (87.7)	1.000
Post dilatation*, n (%)	239 (69.5)	178 (78.8)	0.019
Post-PCI FFR*, mean \pm SD	0.89 \pm 0.07	0.84 \pm 0.06	<0.001
Delta FFR*, mean \pm SD	0.27 \pm 0.14	0.13 \pm 0.08	<0.001

**For patients undergoing PCI.*

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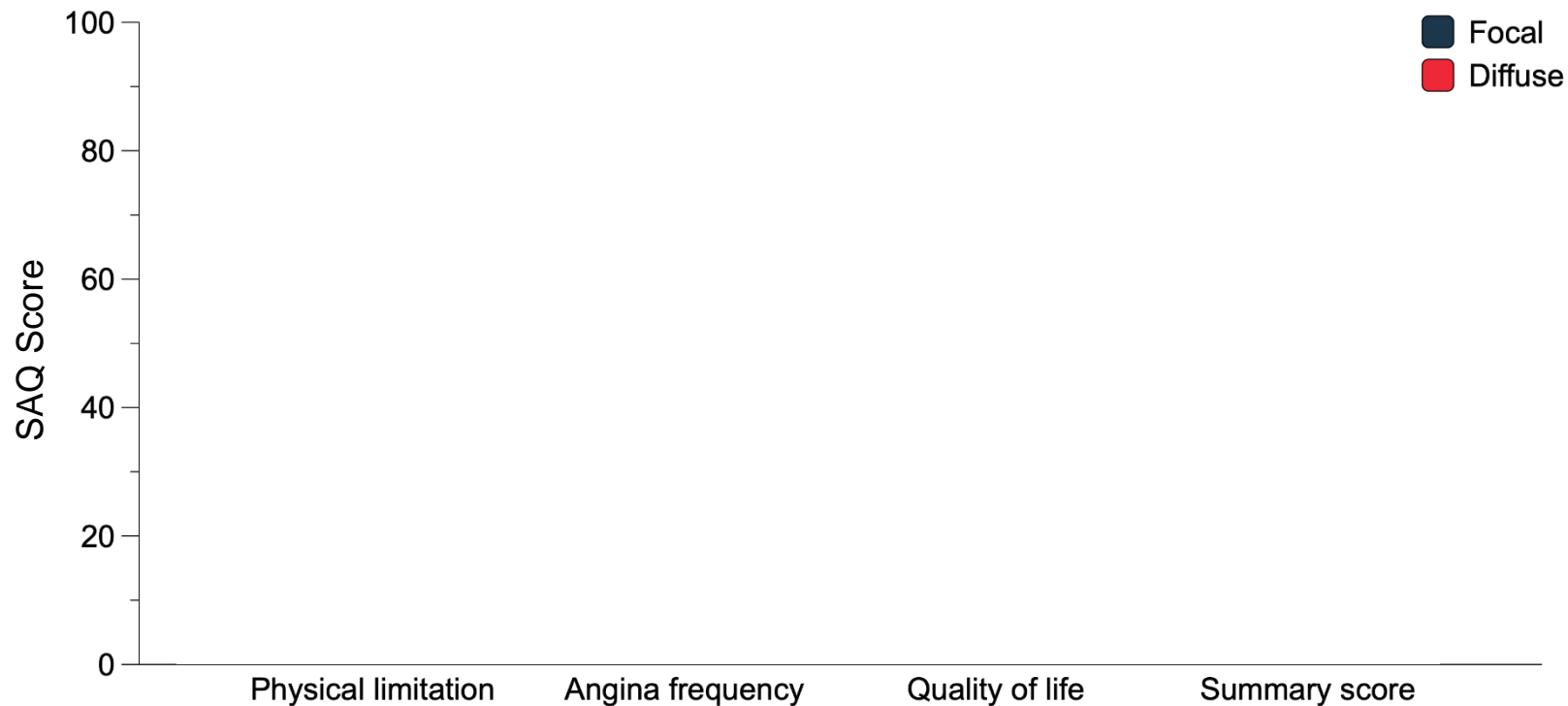
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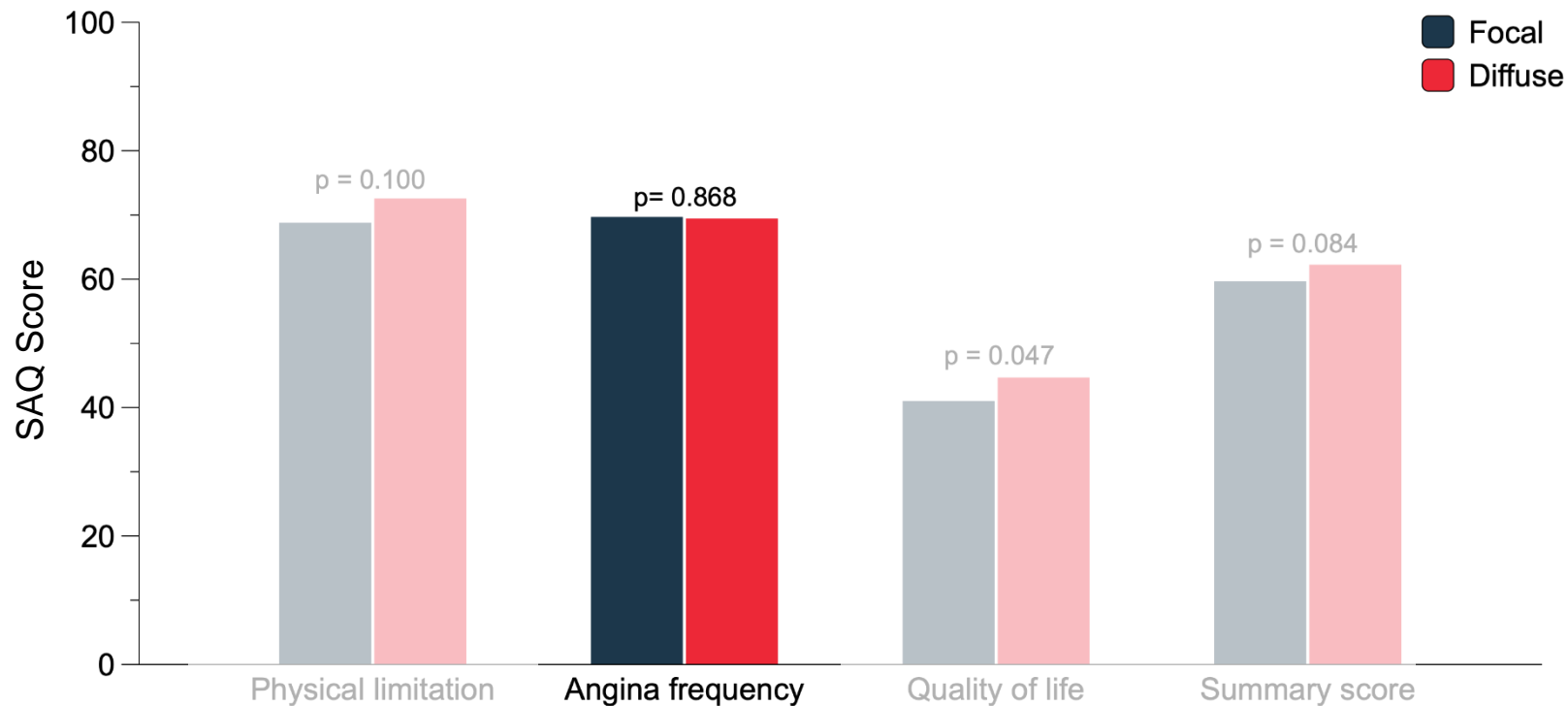
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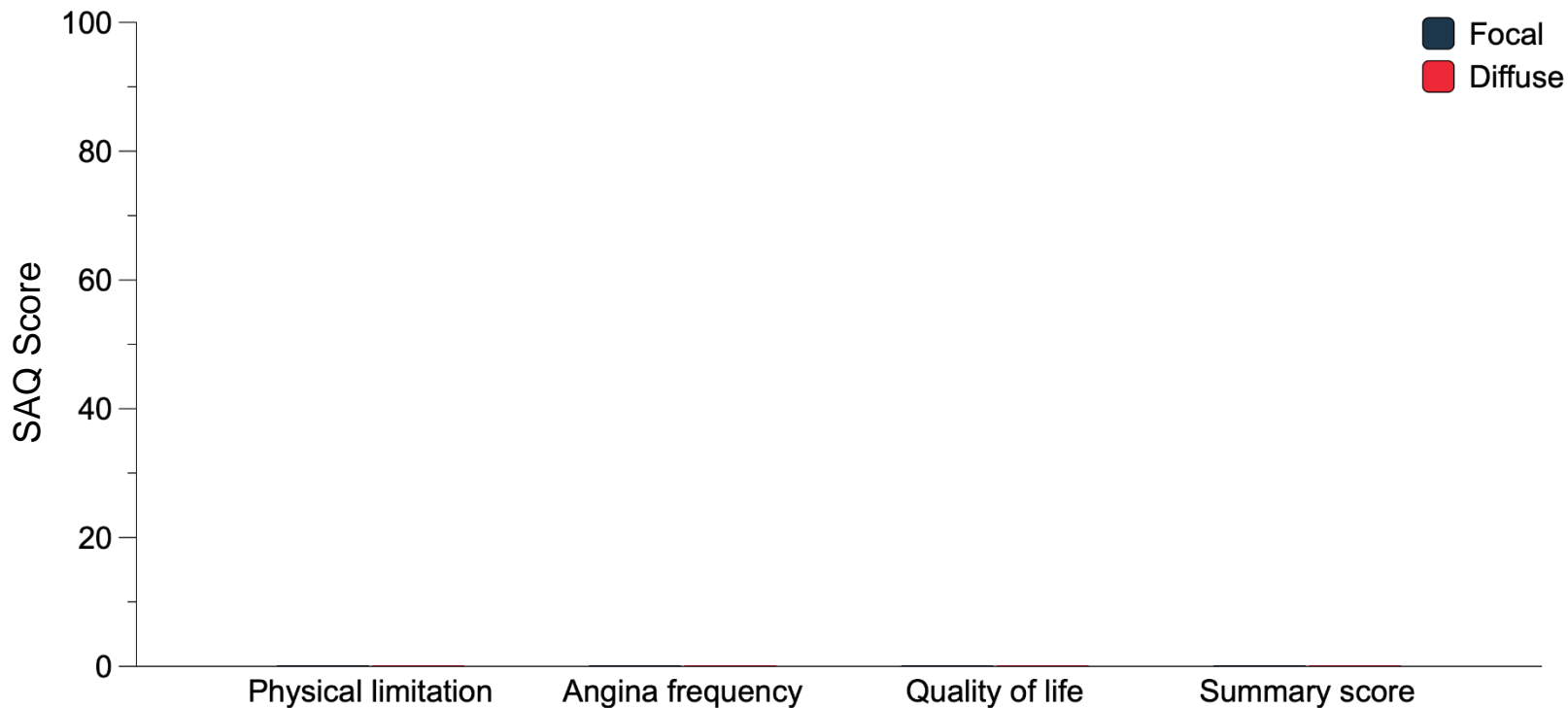
Baseline Symptoms Stratified by PPG



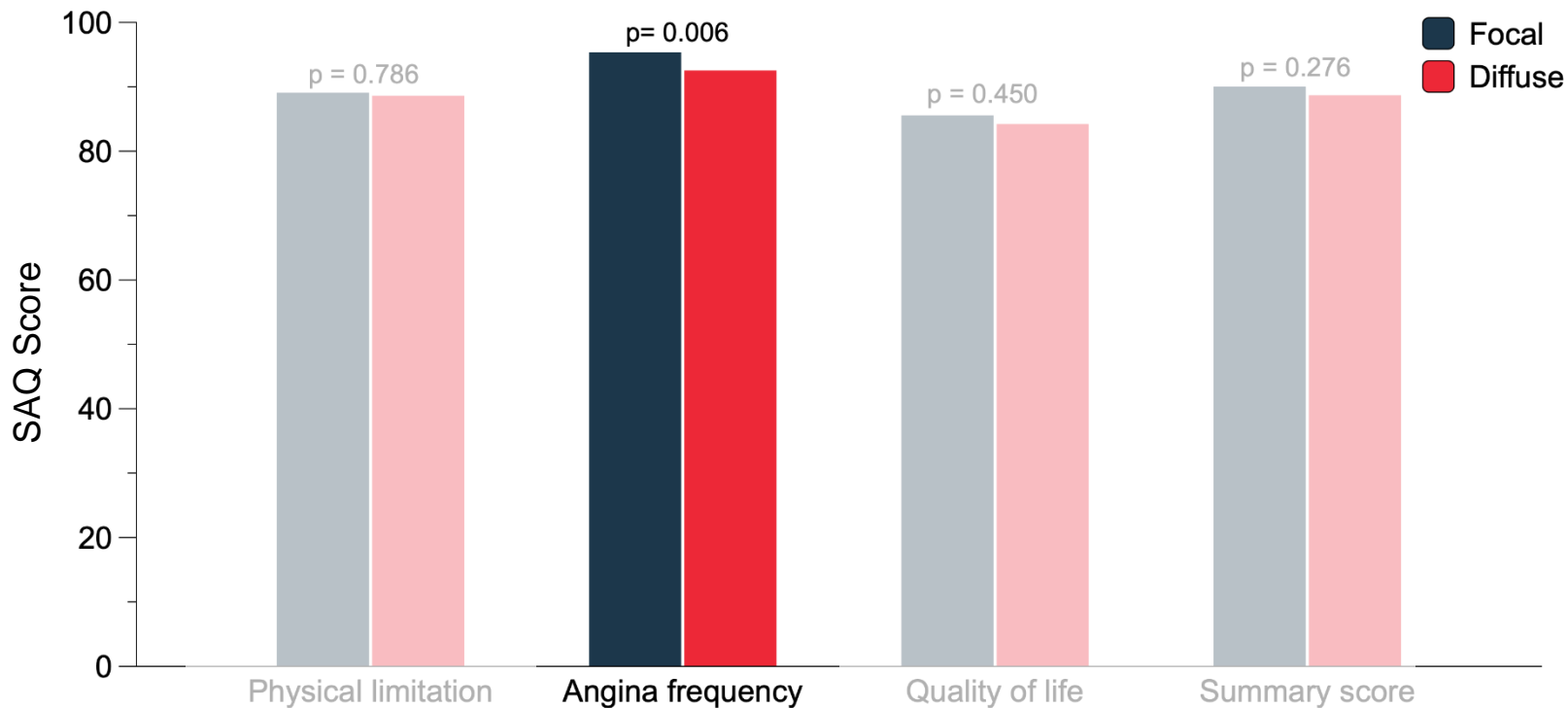
Baseline Symptoms Stratified by PPG



PPG and Patient Symptoms at 1-Year Follow-Up

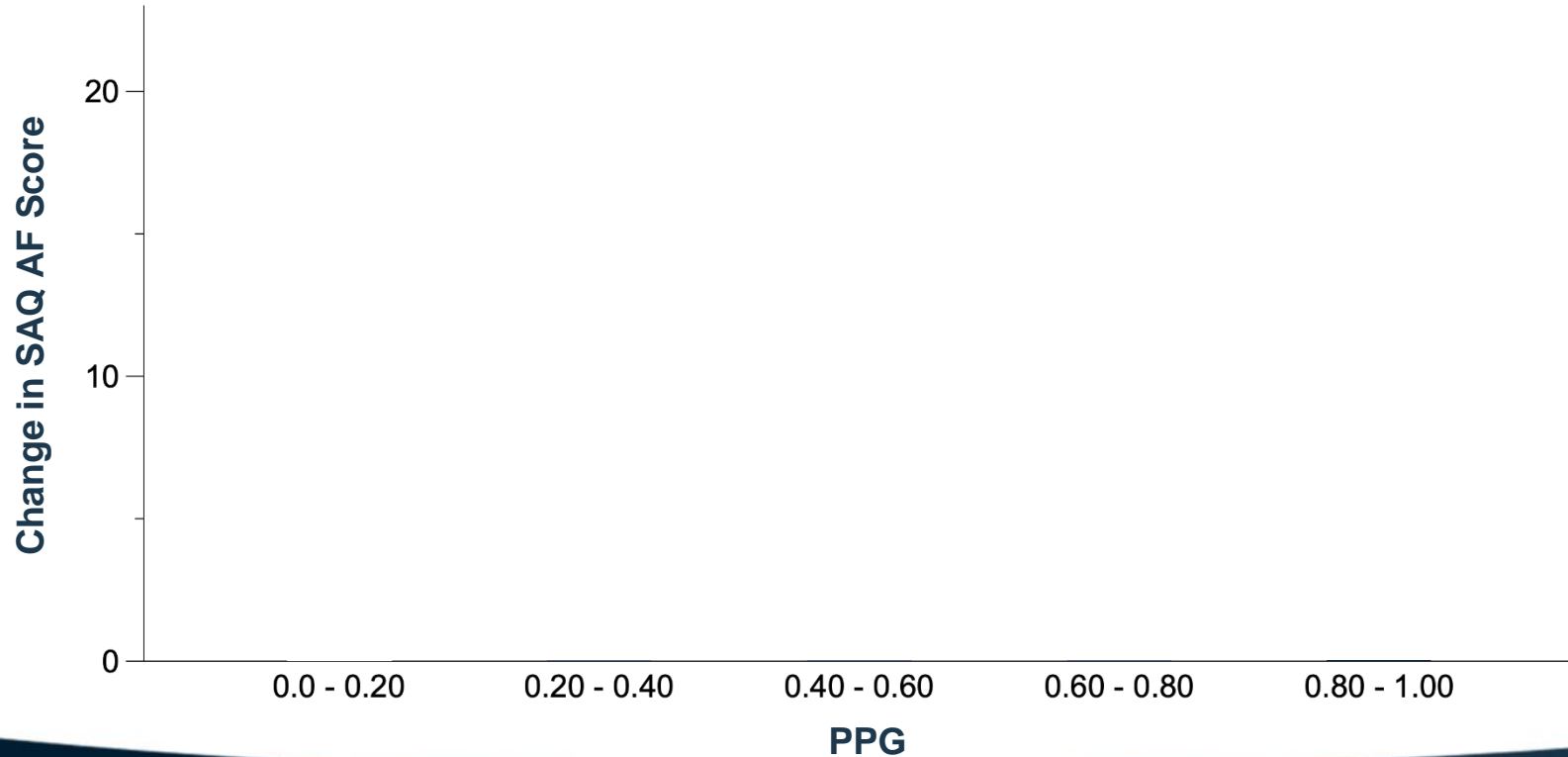


PPG and Patient Symptoms at 1-Year Follow-Up



Angina improvement and PPG

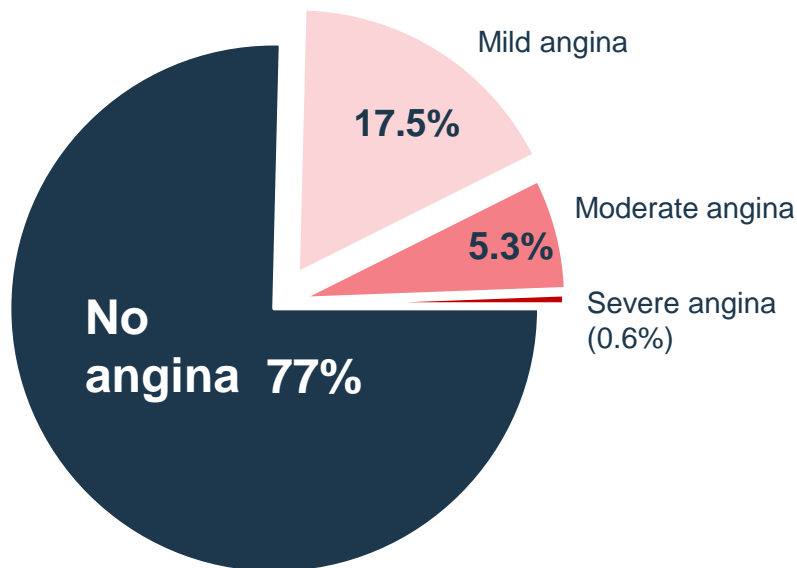
Change in Angina Frequency from Baseline to 1-year Follow-Up



Residual Angina at 1-Year Stratified by PPG

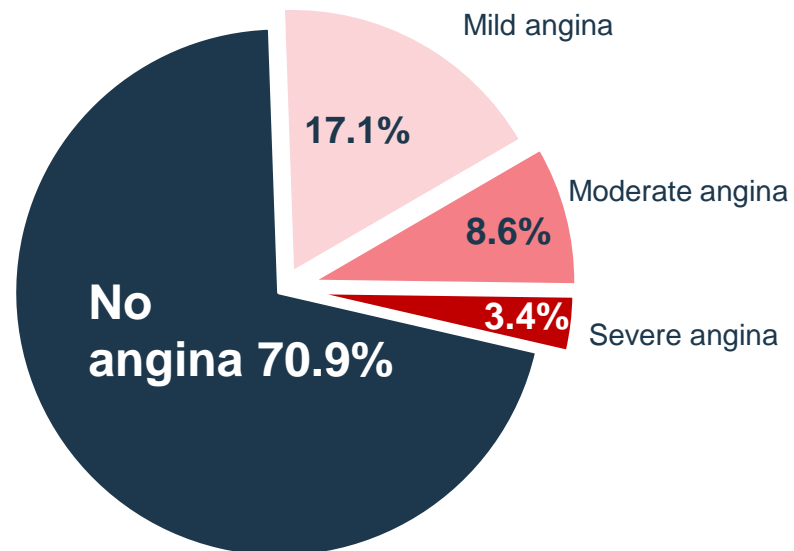
Focal CAD

PPG > 0.62



Diffuse CAD

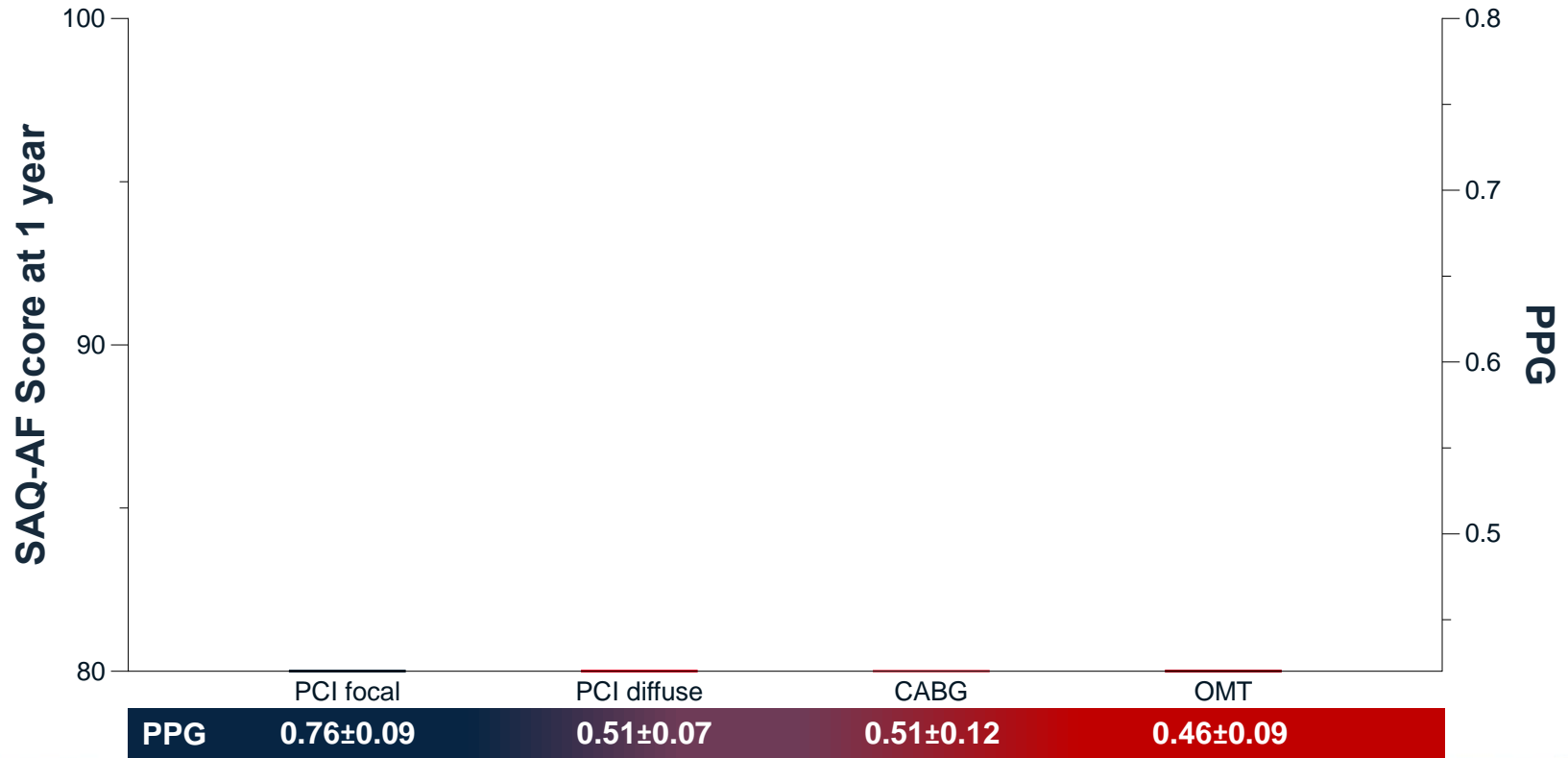
PPG < 0.62



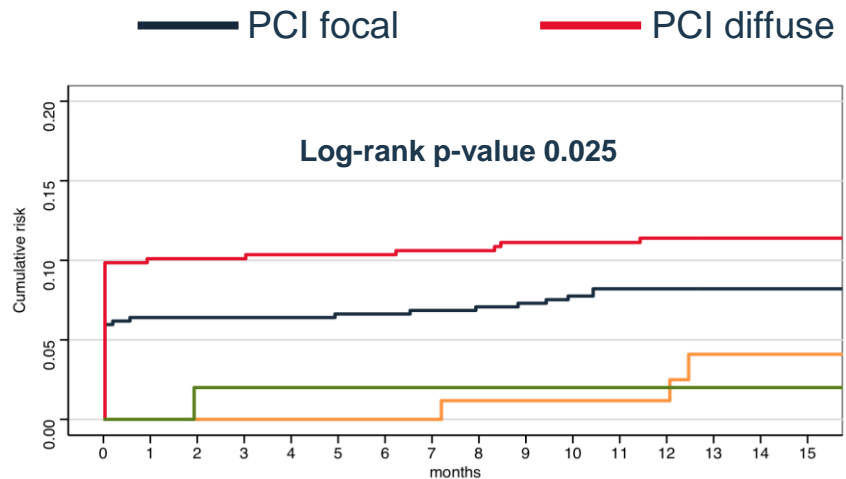
P value = 0.028

Outcomes by treatment modality

SAQ Angina Frequency by Treatment at 1-Year

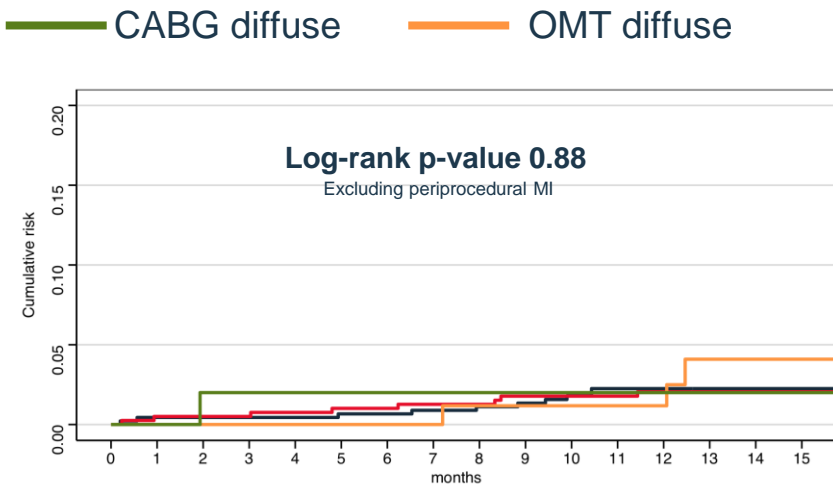


Target Vessel Failure Stratified by PPG and Treatment at One year



Number at risk

■	453	422	422	422	421	420	418	417	412	411	407	402	357	258	232	226	2
■	396	356	355	355	354	353	353	352	350	347	346	340	299	211	191	185	4
■	85	85	85	85	85	85	85	85	84	84	82	82	75	54	51	48	1
■	50	50	49	49	49	49	49	49	49	48	48	48	40	24	22	20	1



Number at risk

■	452	448	448	448	447	446	444	443	438	437	433	428	380	270	240	234	2
■	396	394	393	393	392	390	390	389	386	383	382	375	330	229	208	202	4
■	85	85	85	85	85	85	85	85	84	84	82	82	75	54	51	48	1
■	50	50	49	49	49	49	49	49	49	48	48	48	40	24	22	20	1

TVF: cardiac death, target vessel MI, and target vessel revascularization

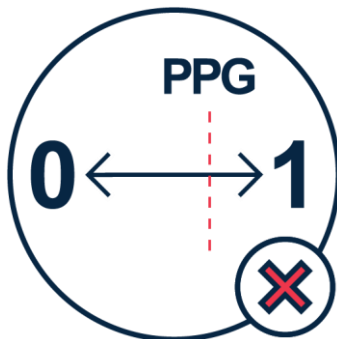
Study limitations



SAQ-7

Utilization of the 7-Item Seattle Angina Questionnaire at Two Time Points.

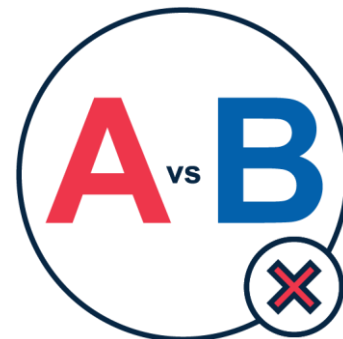
Demonstrates less sensitivity to change, particularly in populations with milder symptoms.



PPG Cutoff

No pre-specified PPG threshold for clinical decision-making.

PPG was different for patients treated with PCI, optimal medical therapy, and CABG.



Clinical Outcomes

The study was not powered to detect differences in clinical outcomes.

An RCT is required to assess the benefit of PPG for clinical decision-making

In conclusion

Take-home Message



Patients with high PPG
treated with PCI reported
less angina at 1-year follow-
Up



PPG was independently
associated with angina
relief



No differences in hard
clinical outcomes between
diffuse and focal CAD
regardless of the treatment
strategy

PPG Global highlights the utility of PPG as a predictive tool for improving patient outcomes in stable CAD, representing a novel application of coronary physiology.

With thanks to all investigators



Onze-Lieve-Vrouw Ziekenhuis, Aalst, Belgium

Jeroen Sonck



Gifu Heart Center, Gifu, Japan

Hitoshi Matsuo & Masafumi Nakayama



Aichi Medical University, Aichi, Japan

Tetsuya Amano



Showa University, Tokyo, Japan

Toshiro Shinke



Monash Cardiovascular Research Centre, Melbourne, Australia

Brian Ko



Ferrara University, Ferrara, Italy

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Rigshospitalet, Copenhagen, Denmark

Thomas Engstrøm



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Memorial Hermann Texas Medical Center, Houston, United States of America

Nils P. Johnson



CHUV, Laussane, Switzerland

Stéphane Fournier



Concord Repatriation General Hospital, Sydney, Australia

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Karolinska Institutet, Stockholm, Sweden

Liyeuw Desta



Institut Arnault Tzanck, Nice, France

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Hospital Clinico San Carlos, Madrid, Spain

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Radboud UMC, Nijmegen, The Netherlands

Lokien X Van Nunen



Guy's and St. Thomas' NHS Foundation Trust, London, United Kingdom

Divaka Perera



Aalborg University Hospital, Aalborg, Denmark

Ashkan Eftekhari



St. Francis Hospital, New York, United States of America

Ziad Ali



Catharina Ziekenhuis, Eindhoven, The Netherlands

Frederik Zimmermann



Aarhus University Hospital, Aarhus, Denmark

Evald Christiansen



With thanks to

