

Current Technology and Technique for Percutaneous Coronary Intervention



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Disclosures

I, Doyeon Hwang, have no financial relationship with any commercial interest related to the contents of this activity.

When revascularization for CCS patients?

2019 European CCS guideline



2023 American guideline

Recommendations for Revascularization Referenced studies that support the recommendations are summarized in the Online Data Supplement.					
COR	LOE	Recommendations			
Goals of Reva	Goals of Revascularization				
1	A	 In patients with CCD and lifestyle-limiting angina despite GDMT and with significant coronary artery stenoses amenable to revascularization, revascularization is recom- mended to improve symptoms.*1-7 			
1	B-R	 In patients with CCD who have significant left main disease or multivessel disease with severe LV dysfunction (LVEF ≤ 35%), CABG in addition to medical therapy is rec- ommended over medical therapy alone to improve survival.*⁸⁻¹¹ 			
Decision-Making for Revascularization					
1	A	 In patients with CCD who have angina or an anginal equivalent, no previous evaluation for ischemia, and angiographically intermediate stenoses, the use of FFR or other proven nonhyperemic pressure ratios (eg, iFR) is recommended before proceeding with PCI.^{*2,22,23} 			

Eur Heart J. 2020 Jan 14;41(3):407-477. J Am Coll Cardiol. 2023 Aug 29;82(9):833-955.

We are in the era of post ISCHEMIA Trial

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Initial Invasive or Conservative Strategy for Stable Coronary Disease

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ABSTRACT

BACKGROUND

Among patients with stable coronary disease and moderate or severe ischemia, The authors' full names, academic degrees, and affiliations are listed in the Ap whether clinical outcomes are better in those who receive an invasive intervention pendix. Address reprint requests to Dr. plus medical therapy than in those who receive medical therapy alone is uncertain.

METHODS

We randomly assigned 5179 patients with moderate or severe ischemia to an initial invasive strategy (angiography and revascularization when feasible) and medical therapy or to an initial conservative strategy of medical therapy alone and angiography if medical therapy failed. The primary outcome was a composite of death from cardiovascular causes, myocardial infarction, or hospitalization for unstable angina, heart failure, or resuscitated cardiac arrest. A key secondary outcome was death from cardiovascular causes or myocardial infarction.

RESULTS

Over a median of 3.2 years, 318 primary outcome events occurred in the invasivestrategy group and 352 occurred in the conservative-strategy group. At 6 months, the cumulative event rate was 5.3% in the invasive-strategy group and 3.4% in the This article was published on March 30, conservative-strategy group (difference, 1.9 percentage points: 95% confidence 2020, at NEIM.org. interval [CI], 0.8 to 3.0); at 5 years, the cumulative event rate was 16.4% and 18.2%, respectively (difference, -1.8 percentage points; 95% CI, -4.7 to 1.0). Results were DOI: 10.1056/NEJMoa1915922 similar with respect to the key secondary outcome. The incidence of the primary Copyright © 2020 Massachusetts Medical Society outcome was sensitive to the definition of myocardial infarction; a secondary analysis yielded more procedural myocardial infarctions of uncertain clinical importance. There were 145 deaths in the invasive-strategy group and 144 deaths in the conservative-strategy group (hazard ratio, 1.05; 95% CI, 0.83 to 1.32).

CONCLUSIONS

Among patients with stable coronary disease and moderate or severe ischemia, we did not find evidence that an initial invasive strategy, as compared with an initial conservative strategy, reduced the risk of ischemic cardiovascular events or death from any cause over a median of 3.2 years. The trial findings were sensitive to the definition of myocardial infarction that was used. (Funded by the National Heart, Lung, and Blood Institute and others: ISCHEMIA ClinicalTrials.gov number. NCT01471522.)

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*A full list of ISCHEMIA Research Group members is provided in the Supplemen tary Appendix, available at NEJM.org.

Drs. Maron and Hochman contributed equally to this article

N Engl | Med 2020:382:1395-407.



B Death from Cardiovascular Causes or Myocardial Infarction 100-25-



298

282

No. at Risk 2591 1325 Conservative strategy Conservative strategy 2453 1933 746 2588 2383 742 Invasive strategy 1933 1314



747

742

298

283

How to determine the presence of ischemia?



Eur Heart J. 2020 Jan 14;41(3):407-477.

Invasive Physiologic Assessment

Fractional Flow Reserve



Korean J Radiol. 2016 May-Jun;17(3):307-20.

Conceptual Relationship Between FFR and Outcomes



J Am Coll Cardiol 2014;64:1641–54

Concrete Evidence for FFR-guided PCI

Robust scientific evidence

- Various Major clinical trials (DEFER, FAME 1, FAME 2, FAMOUS-NSTEMI)
- Around 5,000 studies has been published.

2018 European guideline

Recommendations on functional testing and intravascular imaging for lesion assessment

Recommendations	Class ^a	Level ^b
When evidence of ischaemia is not avail- able, FFR or iwFR are recommended to assess the haemodynamic relevance of intermediate-grade stenosis. ^{15,17,18,39}	I	A
FFR-guided PCI should be considered in patients with multivessel disease under- going PCI. ^{29,31}	lla	в

2021 American guideline

Recommendations for the Use of Coronary Physiology to Guide Revascularization With PCI Referenced studies that support the recommendations are summarized in Online Data Supplement 5.			
COR	LOE	Recommendations	
1	A	 In patients with angina or an anginal equiva- lent, undocumented ischemia, and angio- graphically intermediate stenoses, the use of fractional flow reserve (FFR) or instantaneous wave-free ratio (iFR) is recommended to guide the decision to proceed with PCI.¹⁻⁶ 	
3: No benefit	B-R	 In stable patients with angiographically inter- mediate stenoses and FFR >0.80 or iFR >0.89, PCI should not be performed.⁷⁻¹⁰ 	

The clinical studies on FFR have been focused on its prognostic value and treatment decision-making before PCI.

Computational Fluid Dynamic and CT-FFR



J Am Coll Cardiol. 2011 Nov 1;58(19):1989-97.

Long-term Prognostic Implications of CT-FFR

Cardiac Imaging

Cumulative events

10-year outcomes of the DISCOVER-FLOW study

Diagnosis of Ischemia-Causing Coronary Stenoses by Noninvasive Fractional Flow Reserve Computed From Coronary Computed Tomographic Angiograms

Results From the Prospective Multicenter DISCOVER-FLOW (Diagnosis of Ischemia-Causing Stenoses Obtained Via Noninvasive Fractional Flow Reserve) Study

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- Objectives The aim of this study was to determine the diagnostic performance of a new method for quantifying fractional flow reserve (FFR) with computational fluid dynamics (CFD) applied to coronary computed tomography angiography (CCTA) data in patients with suspected or known coronary artery disease (CAD).
- Background Measurement of FFR during invasive coronary angiography is the gold standard for identifying coronary artery lesions that cause ischemia and improves clinical decision-making for revascularization. Computation of FFR from CCTA data (FFR_{cT}) provides a noninvasive method for identifying ischemia-causing stenosis; however, the diagnostic performance of this new method is unknown.
- Methods
 Computation of FFR from CCTA data was performed on 159 vessels in 103 patients undergoing CCTA, invasive coronary anglography, and FFR. Independent core laboratories determined FFR_{cT} and CAD stenosis severity by CCTA. Ischemia was defined by an FFR_{cT} and FFR ≤0.80, and anatomically obstructive CAD was defined as a CCTA with stenosis ≥50%. Diagnostic performance of FFR_{cT} and CCTA stenosis was assessed with invasive FFR as the reference standard.
- Results
 Fifty-six percent of patients had \geq 1 vessel with FFR \leq 0.80. On a per-vessel basis, the accuracy, sensitivity, specificity, positive predictive value, and negative predictive value were 84.3%, 87.9%, 82.2%, 73.9%, 92.2%, respectively, for FFR_{cT} and were 58.5%, 91.4%, 39.6%, 46.5%, 88.9%, respectively, for CCTA kerosis. The area under the receiver-operator characteristics curve was 0.90 for FFR_{cT} and 0.75 for CCTA (p = 0.001). The FFR_{cT} and FFR were well correlated (r = 0.717, p < 0.001) with a slight underestimation by FFR_{cT} (0.022 ± 0.116, p = 0.016).
- Conclusions Noninvasive FFR derived from CCTA is a novel method with high diagnostic performance for the detection and exclusion of coronary lesions that cause ischemia. (The Diagnosis of ISChemia-Causing Stenoses Obtained Via NoninvasivE FRactional FLOW Reserve; NCT01189331) (J Am Coll Cardiol 2011;58:1989-97) © 2011 by the American College of Cardiology Foundation



Koo et al. J Am Coll Cardiol. 2011 Nov 1;58(19):1989-97. Yang, Chung, Koo, et al. J Cardiovasc Comput Tomogr. 2024 Feb 19:S1934-5925(24)00027-3.

Initial Risk-Based Testing Strategy with CT-FFR

PRECISE trial

1046 Usual Testing (UT)

Initial testing modality

including imaging or

catheterization

chosen by site clinicians,

nonimaging stress tests or

RCT: Comparison of an Initial Risk-Based Testing Strategy vs Usual Testing in Stable Symptomatic Patients With Suspected Coronary Artery Disease

POPULATION

1056 Men, 1047 Women



Symptomatic adults with suspected coronary artery disease (CAD)

Mean age, 58.4 y

SETTINGS / LOCATIONS



INTERVENTION

2103 Participants randomized



1057 Precision Strategy (PS) PROMISE minimal risk score used to select low-risk participants for deferred testing. All others received coronary computed tomographic (CT) angiography with CT-derived fractional flow reserve for 30%-90% stenoses

PRIMARY OUTCOME

Safety and clinical efficiency composite end point at 1y; safety events included were death or nonfatal myocardial infarction, and clinical efficiency was determined by catheterization without obstructive CAD

FINDINGS

The primary end point was significantly less frequent in PS compared with UT participants due to a lower rate of catheterization without obstructive CAD in PS

Death or nonfatal MI



Douglas et al., JAMA Cardiol. 2023 Oct 1;8(10):904-914. doi: 10.1001/jamacardio.2023.2595.

CT-FFR in Treatment Strategy

TARGET trial



The primary end point was the proportion of patients undergoing invasive coronary angiography without obstructive coronary artery disease or with obstructive disease who did not undergo intervention within 90 days.

Yang et al., Circulation. 2023 May 2;147(18):1369-1381.

Korean Version of CT-FFR

On-site automatic CT-FFR from CCTA



Al-based CCTA evaluation



Angio-FFR / Quantitative Flow Ratio (QFR)

Process of QFR Acquisition







FAVOR II EUROPE-JAPAN

1.00-

0.75

0.50

0.25

0.00

0.00

0.25

0.50

Sensitivity





J Am Coll Cardiol 2017;70:3077-87. J Am Coll Cardiol Intv 2016;9:2024-35. J Am Heart Assoc. 2018;7: e009603. Circ Cardiovasc Imaging. 2018;11:e007107.

- Computation of FFR from Coronary Angiography
- No need of pressure wire or hyperemic agent
- Easy to measure •

Angio-vs. QFR-guided PCI

FAVOR III China trial





A QFR-guided strategy of lesion selection improved 1-year clinical outcomes compared with standard angiography guidance.

> J Am Coll Cardiol 2017;70:3077–87. J Am Coll Cardiol Intv 2016;9:2024–35. J Am Heart Assoc. 2018;7: e009603. Circ Cardiovasc Imaging. 2018;11:e007107.

QFR-Based Virtual PCI - AQVA Trial



The primary outcome was the rate of study vessels with a suboptimal post-PCI QFR value.



Reasons for suboptimal results.



Biscaglia et al., JACC Cardiovasc Interv. 2023 Apr 10;16(7):783-794.

Diagnostic Performance of QFR



Multimethod Core Laboratory Assessment of Diagnostic Accuracies of 4 Angiographic FFR Software Versus Wire-Based FFR or iFR, N = 390 Vessels

All analysts were blinded to the results of the wire-FFR/iFR and other angio-FFR software



Key Findings

- 1. All five angio-FFR software/methods had comparable diagnostic accuracies with a higher discrimination compared to 2D-QCA.
- 2. The diagnostic performances of angio-FFR did not reach the diagnostic performance (AUC ≥0.9) reported in validation studies from the various vendors.
- 3. Pressure-wire based physiologic evaluation is still needed in specific lesion subsets.

AMI with Multivessel disease – FRAME-AMI



Eur Heart J. 2023 Feb 7;44(6):473-484.

QFR in Nonculprit PCI after AMI – FRAME-AMI substudy

FRAME-AMI Trial Data: QFR Analysis of 552 Non-IRA Lesions in 443 Patients With AMI and Multivessel Disease Assigned to FFR-Guided or Angiography-Guided PCI





No. at risk

IVUS-quided

PCI

The IVUS-XPL trial

Major adverse cardiac events, including cardiac death, target lesion-related myocardial infarction, or ischemiadriven target lesion revascularization at 1 year

Hazard ratio: 0.530 (95% CI: 0.312, 0.901) 8 Log-Rank: p = 0.019HR, 0.48; 95% CI, 0.28-0.83 Target Vessel Failure (%) Log-rank P = .0076 Patients With Primary End Point Event, % 5.4% 6 4 Angiography-guided PCI 7 2 2.9% IVUS-guided PCI 0 12 0 6 9 3 6 9 12 0 Time Since Randomization, mo Time Since Randomization (Months) Number at risk Angiography 724 706 698 685 676 Angiography-guided 700 673 660 643 624 724 715 710 704 696 IVUS 700 671 665 654 641

8

Image-guided PCI is associated with better clinical outcomes.

The ULTIMATE trial

Target vessel failure

From recent guidelines

2018 ESC/EACTS guideline

Recommendations on intravascular imaging for procedural optimization

Recommendations	Class ^a	Level ^b
IVUS or OCT should be considered in selected patients to optimize stent implantation. ^{603,612,651–653}	lla	В
IVUS should be considered to optimize treatment of unprotected left main lesions. ³⁵	lla	В

2021 ACC/AHA/SCAI guideline

Recommendations for Use of Intravascular Imaging Referenced studies that support the recommendations are summarized in Online Data Supplement 25.

COR	LOE	Recommendations
2a	B-R	 In patients undergoing coronary stent implan- tation, IVUS can be useful for procedural guidance, particularly in cases of left main or complex coronary artery stenting, to reduce ischemic events.¹⁻¹⁰
2a	B-R	2. In patients undergoing coronary stent implan- tation, OCT is a reasonable alternative to IVUS for procedural guidance, except in ostial left main disease. ¹¹⁻¹³
2a	C-LD	3. In patients with stent failure, IVUS or OCT is reasonable to determine the mechanism of stent failure. ¹⁴⁻¹⁷

ILUMIEN III: OPTIMIZE PCI

OCT-guided PCI using a specific reference segment external elastic lamina-based stent optimisation strategy was safe and resulted in similar minimum stent area to that of IVUS-guided PCI.

	OCT (n=140)	IVUS (n=135)	Angiography (n=140)	OCT vs IVUS p value	OCT vs angiography p value
Minimum stent area (mm²)	5.79 (4.54–7.34)	5.89 (4.67–7.80)	5·49 (4·39–6·59)	0.42	0.12
Minimum stent expansion (%)	87.6% (16.6)	86.5% (15.9)	82.9% (12.9)	0.77	0.02
Mean stent expansion (%)	105.8% (97.8–119.8)	106·3% (96·7–116·6)	101.4% (91.9–110.2)	0.63	0.001
Acute procedural success					
Optimal (≥95%)	36(26%)	32/130(25%)	23/136 (17%)	0.84	0.07
Acceptable (90 to <95%)	22(16%)	16/130 (12%)	5/136(4%)	0.42	0.0008
Unacceptable (<90%)	82(59%)	82/130(63%)	108/136(79%)	0.45	0.0002
Intrastent flow area (mm²)	5.54 (4.34–7.05)	5.71 (4.59–7.58)	5.42 (4.25–6.36)	0.56	0.32
Total flow area (mm²)	5.68 (4.59–7.30)	5.87 (4.76–7.59)	5.52 (4.42–6.63)	0.72	0.27
Any dissection	39(28%)	53/134(40%)	61(44%)	0.04	0.006
Major	19 (14%)	35/134(26%)	26(19%)	0.009	0.25
Minor	20(14%)	18/134(13%)	35(25%)	0.84	0.02
Intimal	16(11%)	11/134 (8%)	21(15%)	0.37	0.38
Medial	27(19%)	45/134(34%)	40(29%)	0.007	0.07
Adventitial	1(1%)	0/134	0	1	1
Any malapposition	58 (41%)	52 (39%)	83 (59%)	0.62	0.003
Major	15(11%)	28(21%)	44(31%)	0.02	<0.0001
Minor	43(31%)	24 (18%)	39(28%)	0.01	0.60
Any plaque or thrombus protrusion	94(67%)	100(74%)	95 (68%)	0.21	0.90
Major	27(19%)	27(20%)	25(18%)	0.88	0.76
Minor	67(48%)	73(54%)	70(50%)	0.30	0.72
Reference segment disease	44(31%)	45(33%)	39(28%)	0.74	0.51

RENOVATE-COMPLEX-PCI

A total of 1,639 patients with complex coronary artery lesions were randomized

Also showed mortality benefits.



B Target-Vessel Failure without Procedure-Related Myocardial Infarction



N Engl J Med. 2023 May 4;388(18):1668-1679.

Physiology-based vs. Image-based Assessment



- Physiology-based and image-based assessments reflect different aspects of coronary atherosclerosis and have developed with different objectives.
- However, many clinicians substitute one method for the other to a certain extent.

Study Flow of the FLAVOUR trial

1,700 eligible patients (Patients with de novo intermediate stenosis (40-70% stenosis by visual estimation) eligible for PCI) from 18 centers in China and Korea





FFR-guided PCI	IVUS-guided PCI			
Indication for PCI				
FFR ≤ 0.80	Minimum lumen area (MLA) ≤ 3mm² or 3< MLA ≤ 4mm² & Plaque burden > 70%			
Criteria for optimal PCI				
Post-PCI FFR ≥ 0.88 or Post-PCI ∆FFR (FFR across the stent) < 0.05	Plaque burden at stent edge ≤ 55% Minimal stent area ≥ 5.5mm² or Minimal stent area ≥ distal reference lumen area			

Results of the FLAVOUR trial

Characteristic	FFR Group	IVUS Group	Difference (95% Cl)†
Angiographic findings			
No. of patients	838	844	
Multivessel disease — no. (%)	445 (53.1)	430 (50.9)	2.2 (–2.7 to 7.0) <u>†</u>
Diseased vessels — no. (%)∬			
Nonobstructive	15 (1.8)	16 (1.9)	
l vessel	378 (45.1)	398 (47.2)	
2 vessels	295 (35.2)	273 (32.3)	
3 vessels	150 (17.9)	157 (18.6)	
Trial target vessels — no. (%)			
l vessel	763 (91.1)	791 (93.7)	
2 vessels	69 (8.2)	49 (5.8)	
3 vessels	6 (0.7)	4 (0.5)	
Patients who underwent PCI — no. (%)			
Any procedure	372 (44.4)	551 (65.3)	–20.9 (–25.7 to –16.1) <u>†</u>
Multivessel	66 (7.9)	125 (14.8)	–6.9 (−10.1 to –3.8) <u>†</u>
Stent data			
Total no. per patient	0.6±0.9	0.9±1.0	-0.3 (-0.4 to -0.3)
Total length per patient — mm	16.5±24.1	25.2±28.1	-8.7 (-11.2 to -6.2)
Total no. per patient who underwent PCI	1.4±0.8	1.5±0.8	-0.1 (-0.2 to 0.0)
Total length per patient who underwent PCI — mm	37.2±23.2	38.6±26.4	-1.4 (-4.7 to 1.9)
SYNTAX score¶			
At baseline	8.4±5.8	8.9±6.2	-0.5 (-1.1 to 0.1)
After PCI	5.4±4.6	4.6±4.7	0.8 (0.3 to 1.2)

Less procedure was done, And less stents were used In the FFR-guided PCI group.



Results of the FLAVOUR trial





Vulnerable Plaque

PB (MLA) ≥ 70%

VH-TCFA

 $MLA \leq 4.0 mm^2$



< 0.001

< 0.001

0.001

5.03 (2.51-10.11)

3.35 (1.77-6.36)

3.21 (1.61-6.42)

ATHEROREMO Presence of TCFA with P8.220% (large TCFA) - Presence of TOFA with PB<70% (small TOFA)

122

2.90 (1.60-5.25)

1.98 (1.09-3.60)

1.23 (0.67-2.26)

ROMICAT-II Trial



Vulnerable features from IVUS and CCTA is associated with worse clinical outcome.

PB (MLA) ≥ 70%

VH-TCFA

 $MLA \leq 4.0 mm^2$

N Engl J Med. 2011 Jan 20;364(3):226-35. Eur Heart J. 2014 Mar;35(10):639-47. J Am Coll Cardiol. 2014 Aug 19;64(7):684-92.

How to treat vulnerable plaque

PREVENT trial

The **PREVENT**ive Coronary Intervention on Stenosis With Functionally Insignificant Vulnerable Plaque

PREVENT Trial

Any Significant Epicardial Coronary Stenosis (DS>50%) with <u>FFR >0.80</u> and with <u>Two</u> of the following

1. IVUS MLA <4.0mm² 2. IVUS Plaque Burden >70% 3. Lipid-Rich Plaque on NIRS (maxLCBl_{4mm}>315) 4. TCFA by OCT or VH-IVUS PCI+GDMT N=800 CDMT N=800

Primary endpoint: Target Vessel Failure at 2 years

(Death from cardiac cause, target vessel myocardial infarction, ischemic-driven target vessel revascularization, or unplanned hospitalization due to unstable or progressive angina)



Lancet. 2024 May 4;403(10438):1753-1765.

Conclusion



- Although the decision strategy for the revascularization of CCS patients has been changed, the invasive physiologic test still plays a role in that.
- CT-FFR is associated with even long-term clinical outcomes, can change our daily practice, and can improve the efficacy of treatment decision-making.
- Recent studies regarding QFR demonstrated the benefit of risk stratification when combined with image modalities and procedure planning. However, its diagnostic performance is still controversial.
- Imaging guidance for PCI optimization has shown its consistent benefits.
- Revascularization of non-obstructive vulnerable plaque is a recent concern for cardiologists.



Thank you for your attention.

SNU

