SWEDEHEART

iFR vs FFR-guided coronary revascularization

iFR-Swedeheart 5-year outcome

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- on behalf of the iFR-Swedeheart investigators

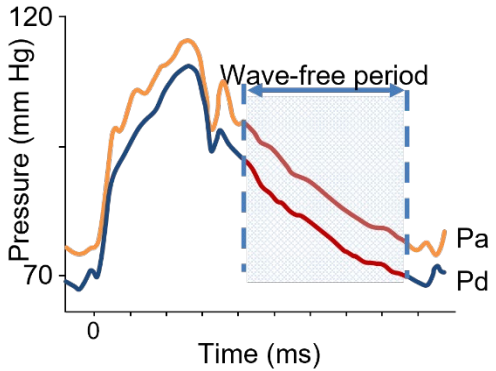
Disclosure Statement of Financial Interest

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	Company
Grant/Research Support	Boston Scientific, Philips Healthcare
Consulting Fees/Honoraria	Abbott, Boston Scientific, Medtronic

Faculty disclosure information can be found on the app

Background



Instantaneous Wave-free ratio (iFR) is a non-hyperemic (resting) index for assessment of coronary lesion severity

Previous validation studies have demonstrated similar or improved ability to accurately detect ischemia compared with Fractional Flow Reserve (FFR)

Sen S et al. Circ. Int. 2014;7:492-502, van de Hoef TP et al. Circ Cardiovasc Interv. 2012;5:508-14
de Waard G et al. J Am Coll Cardiol. 2014;63:A1692

Study Design iFR-Swedeheart

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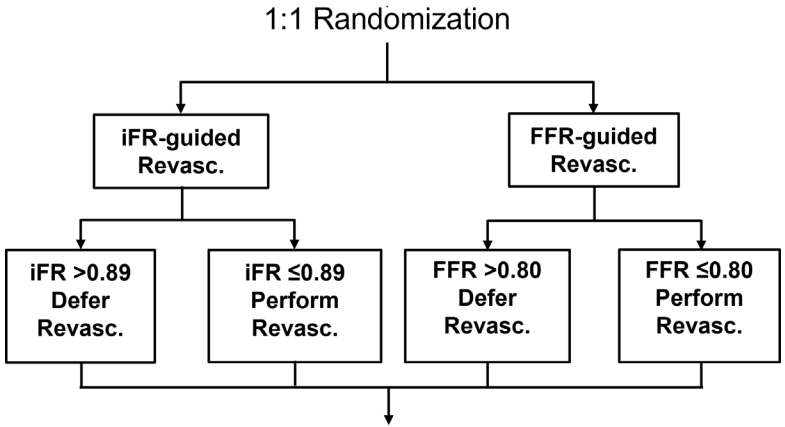
- Hypothesis : iFR is non-inferior to FFR at 1 year regarding a composite of all-cause death, MI, and unplanned revascularization
- Non-inferiority margin of 1.4 (3.2%) (upper 1-sided 97.5% CI)
- 2000 patients with 85% power to test hypothesis
- Primary endpoint at 1 year
- Final follow-up at 5 years



Final follow-up at 5 years

Study Design iFR-Swedeheart

Registry based Randomized Clinical Trial (RRCT)

Trial design utilizing national quality registers as an electronic CRF:

- baseline characteristics
- data-input
- online randomization
- follow-up

Proven pragmatic and cost-effective trial design facilitated by use of unique personal identifiers in Scandinavia allowing for 100% tracking of patients

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Major inclusion and exclusion criteria

- Patients with suspected stable angina pectoris or unstable angina pectoris/NSTEMI
- A clinical indication for physiology-guided assessment of coronary lesions (30-80% stenosis grade)

- Known terminal disease with a life expectancy <1 year
- Unstable hemodynamics (Killip class III-IV)
- Inability to tolerate adenosine
- Previous CABG with patent graft to the interrogated vessel
- Heavily calcified or tortuous vessel where inability to cross the lesion with a pressure wire was expected
- Previous randomization in iFR-SWEDEHEART trial

15 Participating sites in Scandinavia

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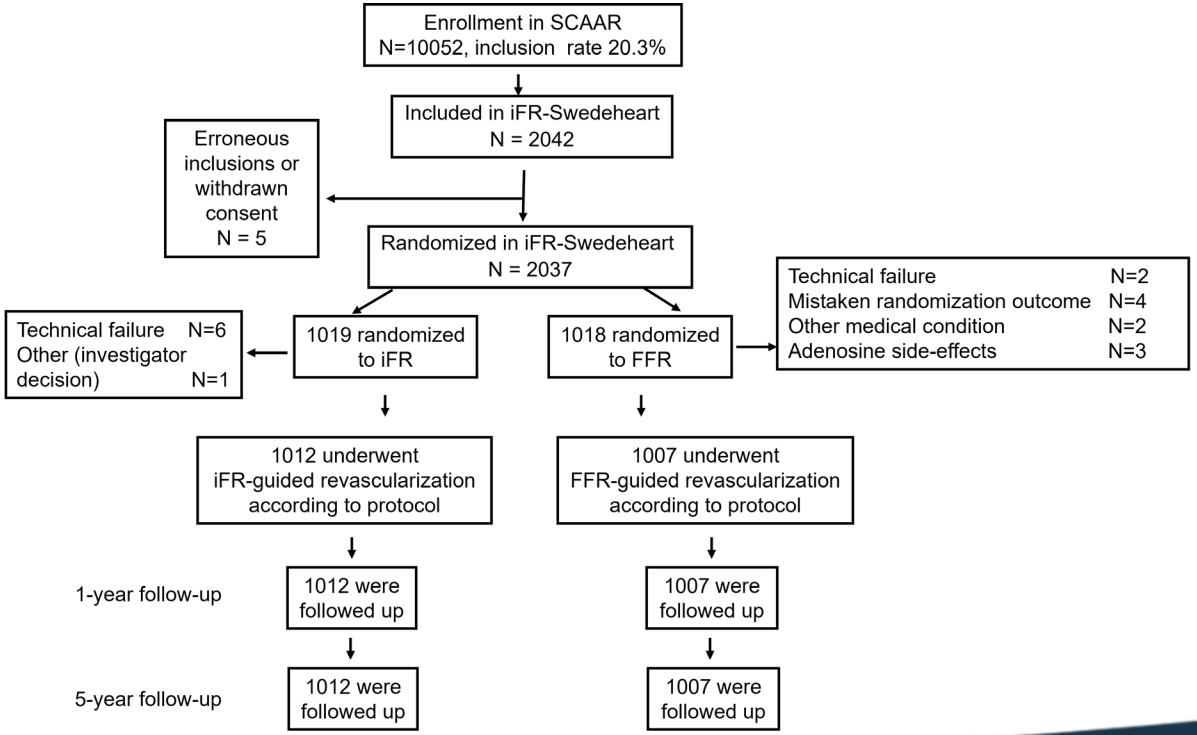
Lund/Malmö
Helsingborg
Halmstad
Kalmar
Göteborg
Linköping
Örebro
St Göran
Uppsala
Västerås
Karlstad
Sundsvall
Aarhus (Denmark)
Reykjavik (Iceland)

Steering committee

Matthias Götberg (PI)
Evald H. Christiansen
David Erlinge
Elmir Omerovic
Stefan K. James
Ole Fröbert (chairman)

Enrollment

- 2037 patients enrolled between May 2014- Oct 2015
- No patients were lost to follow-up



Baseline clinical characteristics

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	iFR (N=1019)	FFR (N = 1018)
Age - yr. (mean (± SD))	67.6 (9.6)	67.4 (9.2)
Male sex - no. (%)	756 (74.2)	766 (75.3)
Indication for angiography - no. (%)		
Stable angina	632 (62.0)	632 (62.0)
Unstable angina	211 (20.7)	208 (20.4)
NSTEMI	176 (17.3)	178 (17.5)
Diabetes mellitus - no. (%)	232 (22.8)	213 (20.9)
Hypertension - no. (%)	730 (71.6)	710 (69.7)
Hyperlipidemia - no. (%)	733 (71.9)	704 (69.1)
Current smoker	159 (15.6)	167 16.3)
Previous myocardial infarction - no. (%)	337 (33.1)	335 (32.9)
Previous PCI - no. (%)	429 (42.1)	425 (41.7)
Previous coronary artery by-pass grafting - no. (%)	49 (4.8)	43 (4.2)

Procedural characteristics

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	iFR (N=1012)	FFR (N = 1007)	P Value
Radial artery approach - no. (%)	841 (83.1)	811 (80.5)	0.13
Contrast use, ml (median (IQR))	110 (80-155)	115 (80-160)	0.10
Procedure time, min (IQR)	50.8 (13.8-87.8)	53.1 (18.1-88.1)	0.09
Fluoroscopy time, min (median (IQR))	10.5 (6.3-16.8)	10.2 (6.5-16.0)	0.57
Total no. of lesions evaluated	1568	1436	
Mean no. of lesions evaluated (SD)	1.55 (0.86)	1.43 (0.70)	0.002
Functionally significant lesions - no. (%)	457 (29.2)	528 (36.8)	<0.0001
Mean no. of functionally significant lesions per patient (SD)	0.45 (0.71)	0.52 (0.68)	0.05
Mean iFR value (SD)	0.91 (0.10)		-
Mean FFR value (SD)		0.82 (0.10)	-

More lesions evaluated in iFR-group but fewer significant lesions

Procedural characteristics (ii)

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	iFR (N=1012)	FFR (N = 1007)	P Value
Treated vessel - no. (%)			0.68
Left Main	14 (1.5)	16 (1.6)	
LAD	434 (47.4)	469 (47.9)	
LCx	176 (19.3)	179 (18.3)	
RCA	164 (17.9)	196 (20.0)	
Missing data	127 (13.9)	120 (12.2)	
Mean no. of stents per patient undergoing PCI mean (SD)	1.58 (1.08)	1.73 (1.19)	0.048
Drug eluting stent - no. (%)	696 (99.7)	770 (97.8)	0.50
PCI as primary revascularization strategy - no. (%)	443 (43.8)	456 (45.3)	0.50
CABG as primary revacularization strategy - no. (%)	93 (9.2)	113 (11.2)	0.13
Total revascularization rates - no (%)	536 (53.0)	569 (56.5)	0.11

More stents deployed in FFR-group

Primary Composite Endpoint at 12 months

all-cause death, MI, unplanned revascularization

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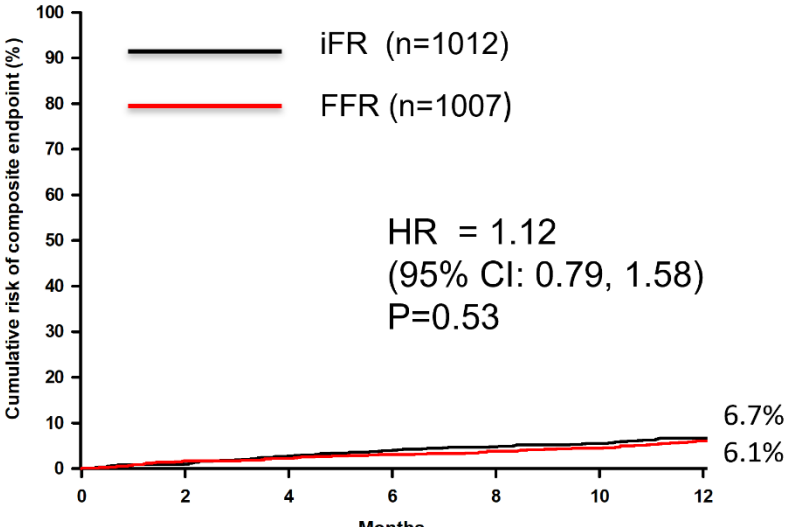
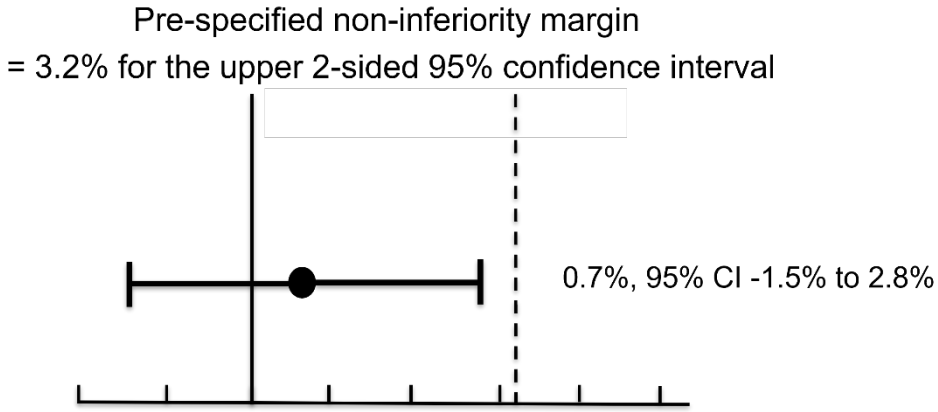


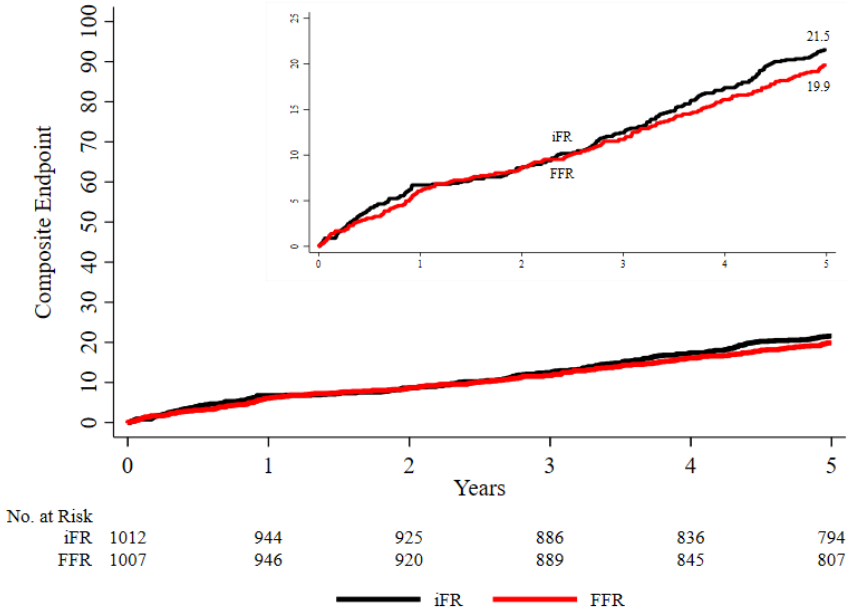


iFR was non-inferior to FFR regarding primary composite endpoint at 12 months

Götberg et al. N Engl J Med 2017; 376:1813-1823

Composite Endpoint at 5 years

all-cause death, MI, unplanned revascularization



iFR 21.5%
FFR 19.9%

HR 1.09; 95% CI: 0.90, 1.33

iFR no difference in composite outcome

compared with FFR at 5 years

All-cause mortality at 5 years

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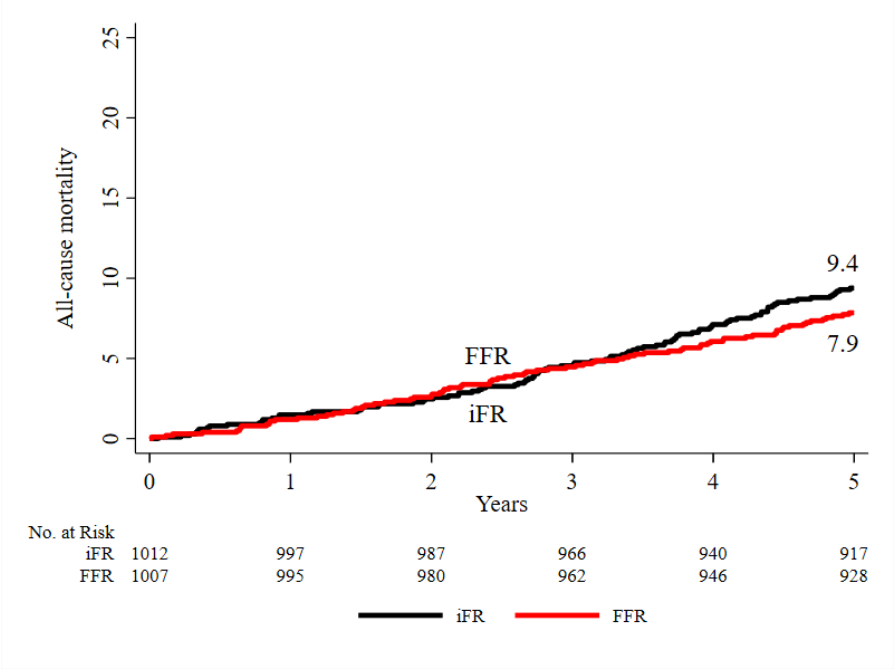

iFR 9.4%
FFR 7.9%

HR 1.20; 95% CI: 0.89, 1.62

iFR no difference in all-cause mortality compared with FFR

Myocardial infarction at 5 years

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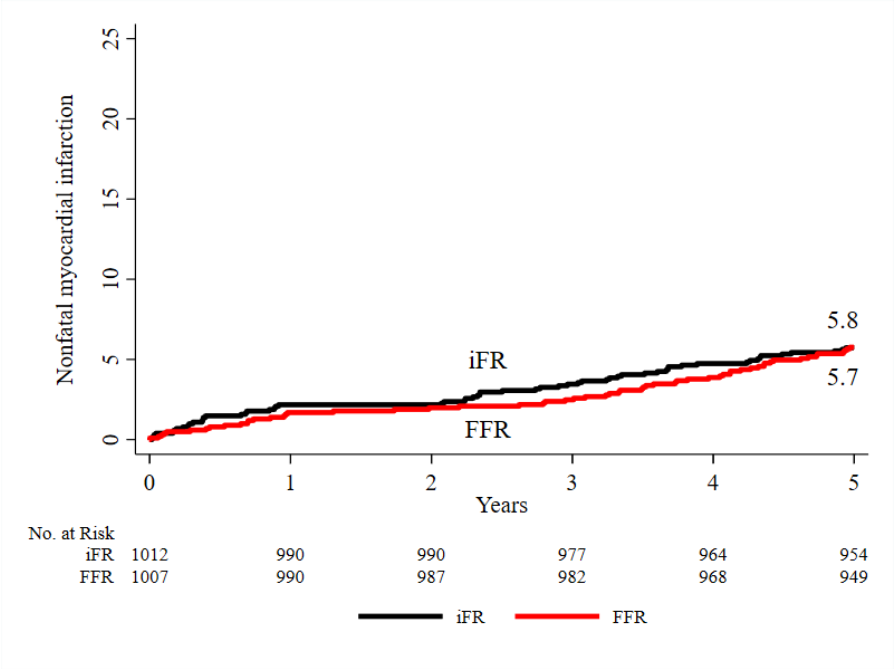

iFR 5.8%
FFR 5.7%

HR 1.00; 95% CI: 0.70, 1.44

iFR no difference in non-fatal myocardial infarction compared with FFR

Unplanned revascularization at 5 years

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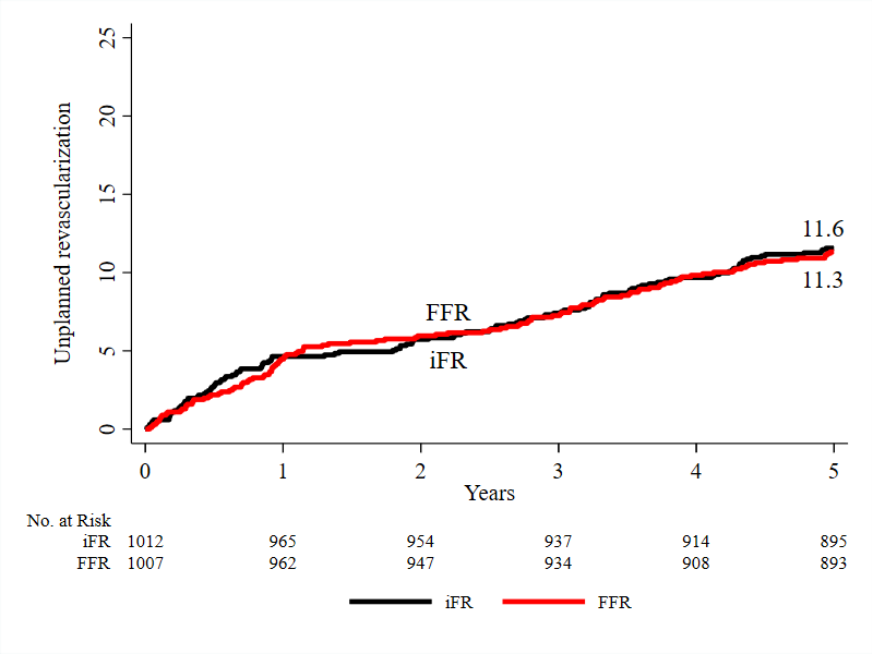


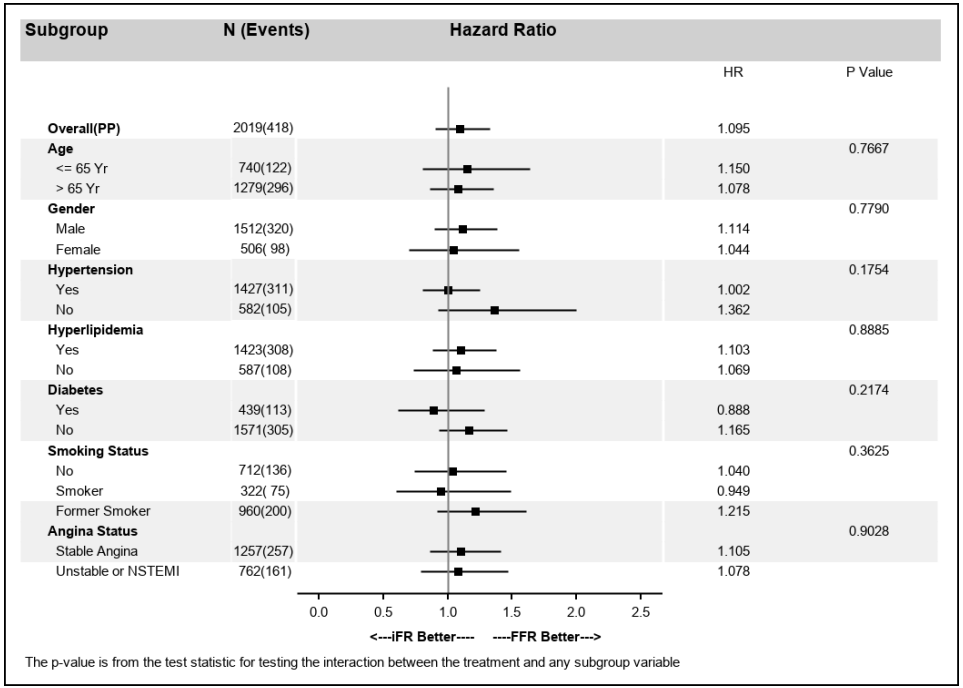
iFR 11.6%
FFR 11.3%

HR 1.02; 95% CI: 0.79, 1.32

iFR no difference in unplanned revascularization compared with FFR

Composite endpoint at 5-years

Subgroup analysis



No difference in outcome in any of the pre-specified subgroups

Summary iFR-Swedeheart

In patients with stable angina or acute coronary syndrome

iFR provides no difference in outcome at 5-years compared with FFR

- The composite endpoint (all-cause death, MI, unplanned revasc)
- All-cause death
- Non-fatal myocardial infarction
- Unplanned revascularization
- Composite endpoint in pre-specified subgroups

Conclusions

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The 5-year follow-up of iFR-SWEDEHEART showed no difference in outcome, confirming the long-term safety and efficacy of revascularization guided by iFR compared with FFR