SWEDEHEART

iFR vs FFR-guided coronary revascularization
iFR-Swedeheart 5-year outcome

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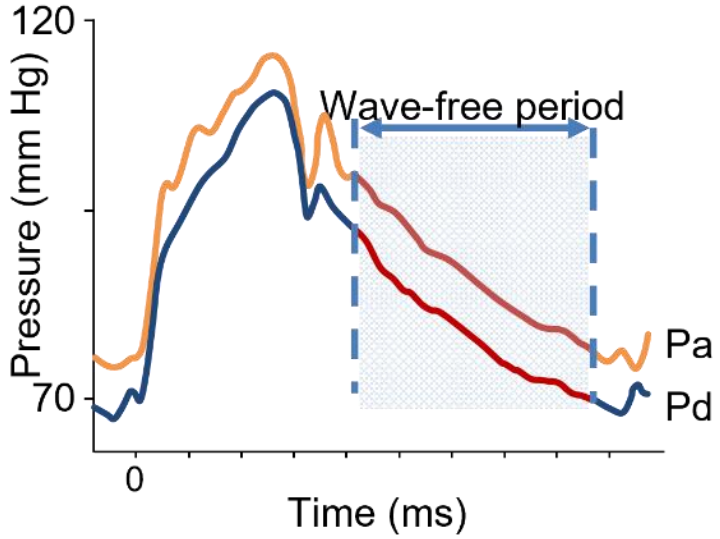
Disclosure

- Grant/Research Support — Boston Scientific, Philips Healthcare
- Consulting Fees/Honorari — Abbott, Boston Scientific, Medtronic

Background

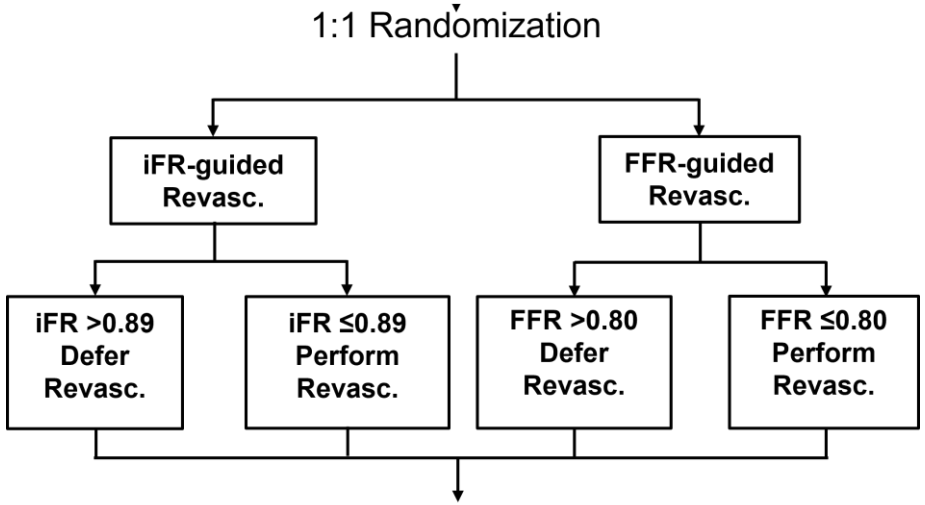


Instantaneous Wave-free ratio (iFR) is a non-hyperemic (resting) index for assessment of coronary lesion severity

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

Study Design iFR-Swedeheart

- 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 presented at ACC 2017 and published in NEJM
- 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 web-based quality registers as an electronic Case report form (CRF):

- Baseline characteristics
- Procedural data
- Online randomization
- Follow-up

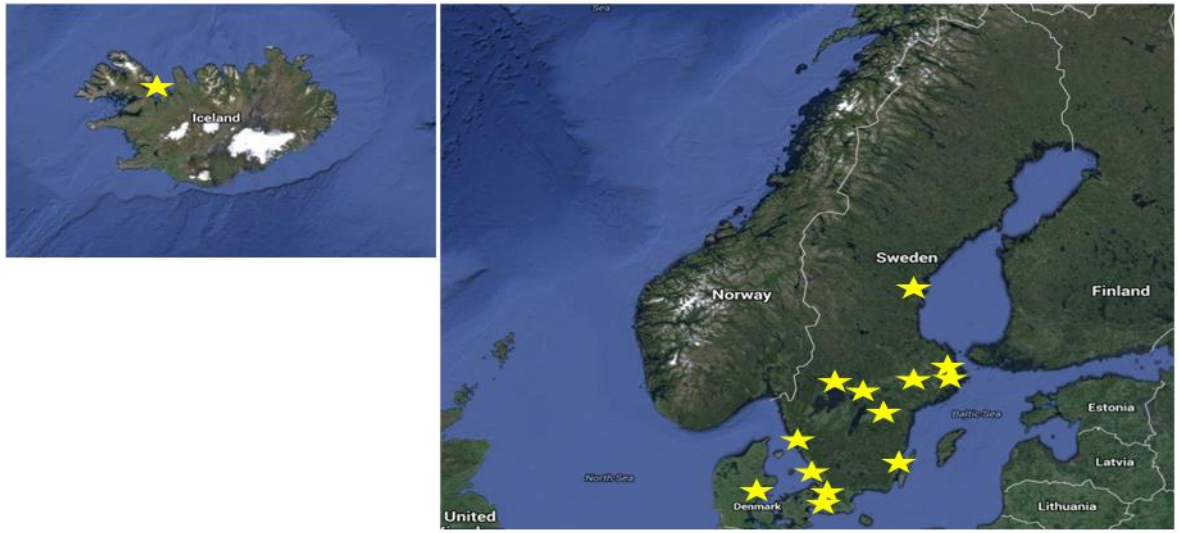
Proven pragmatic and cost-effective trial design facilitated by use of unique personal identifiers in Scandinavia allowing for 100% tracking of patients

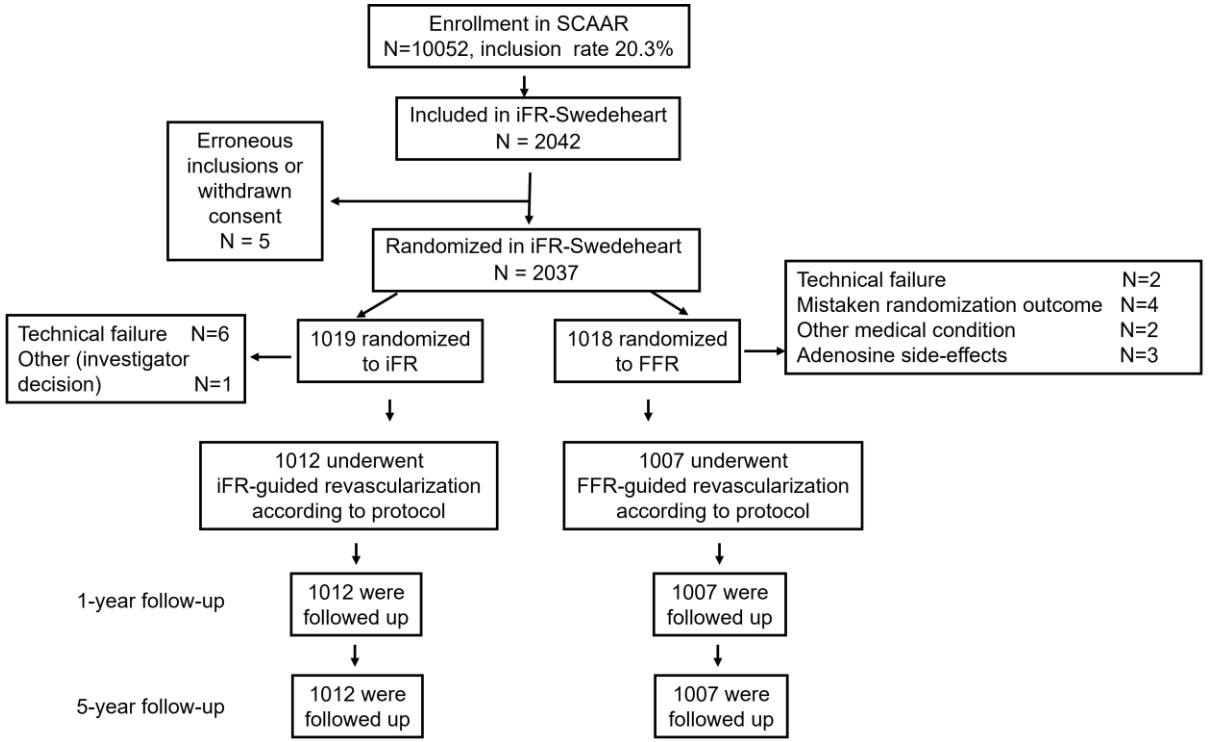
Major inclusion and exclusion criteria

- 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

Enrollment





2037 patients enrolled at 15 Scandinavian sites between May 2014- Oct 2015

No patients were lost to follow-up!

Baseline clinical characteristics

	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

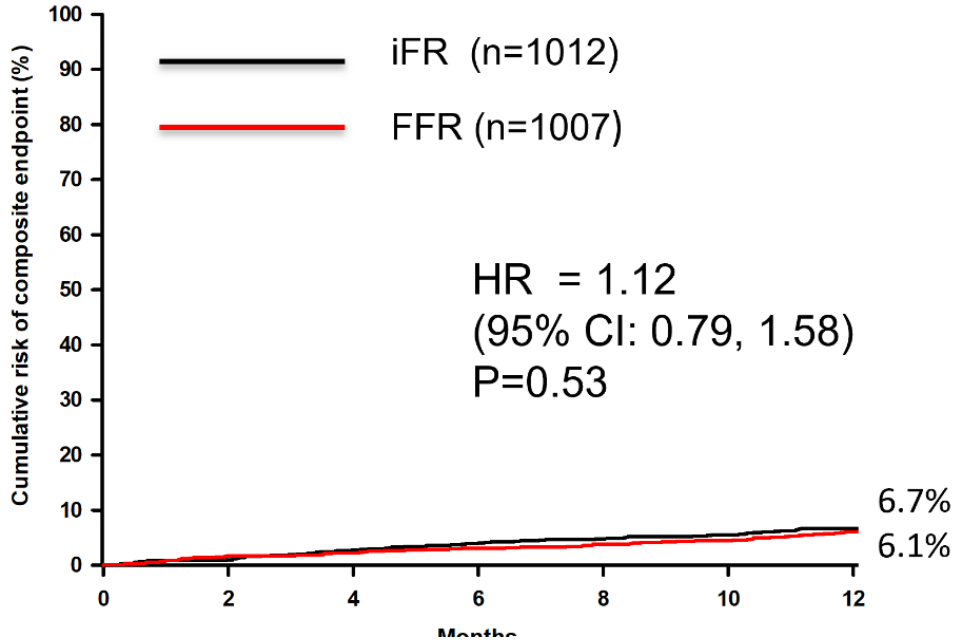
	iFR (N=1012)	FFR (N = 1007)	P Value
Radial artery approach - no. (%)	841 (83.1)	811 (80.5)	0.13
Contrast use, ml (median (IQR))	110 (80-155)	115 (80-160)	0.10
Procedure time, min (IQR)	50.8 (13.8-87.8)	53.1 (18.1-88.1)	0.09
Fluoroscopy time, min (median (IQR))	10.5 (6.3-16.8)	10.2 (6.5-16.0)	0.57
Total 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)	-

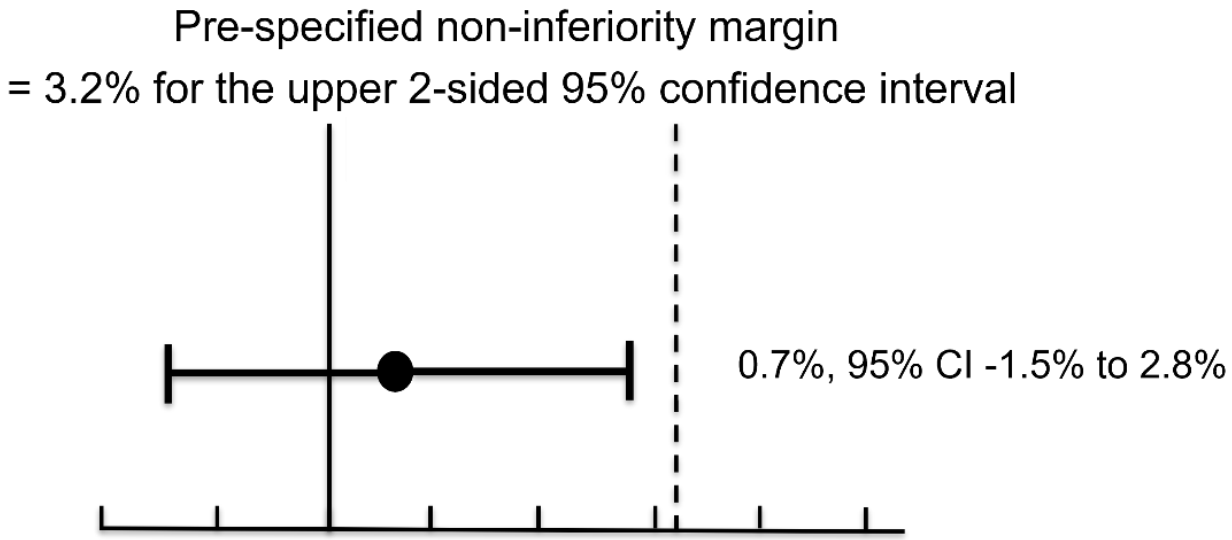
More lesions evaluated in iFR-group but fewer significant lesions

Lower threshold to perform iFR compared with FFR

Primary Composite Endpoint at 12 months

All-cause death, MI, unplanned revascularization

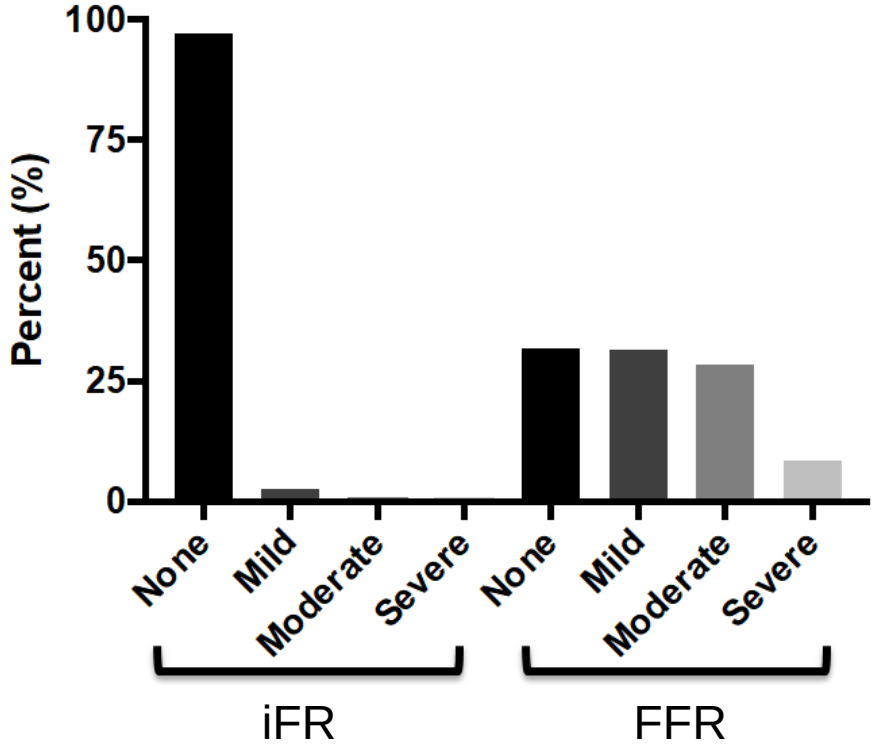




iFR was non-inferior to FFR regarding primary composite endpoint at 12 months

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

Discomfort during the procedure



i.v. adenosine 69%

i.c. adenosine 31%

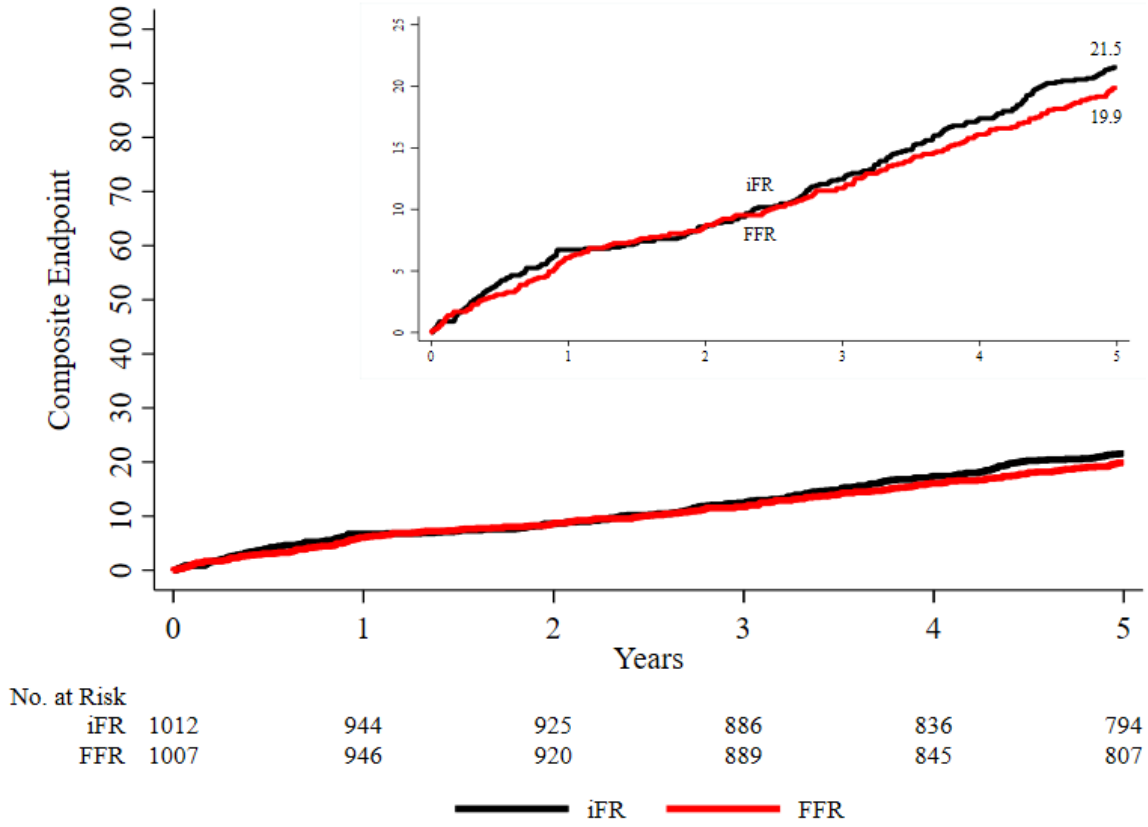
3% of patients in iFR-group experienced mild discomfort

2/3 of patients FFR-group experienced discomfort ranging from mild to severe (adenosine)

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

Composite Endpoint at 5 years

All-cause death, MI, unplanned revascularization

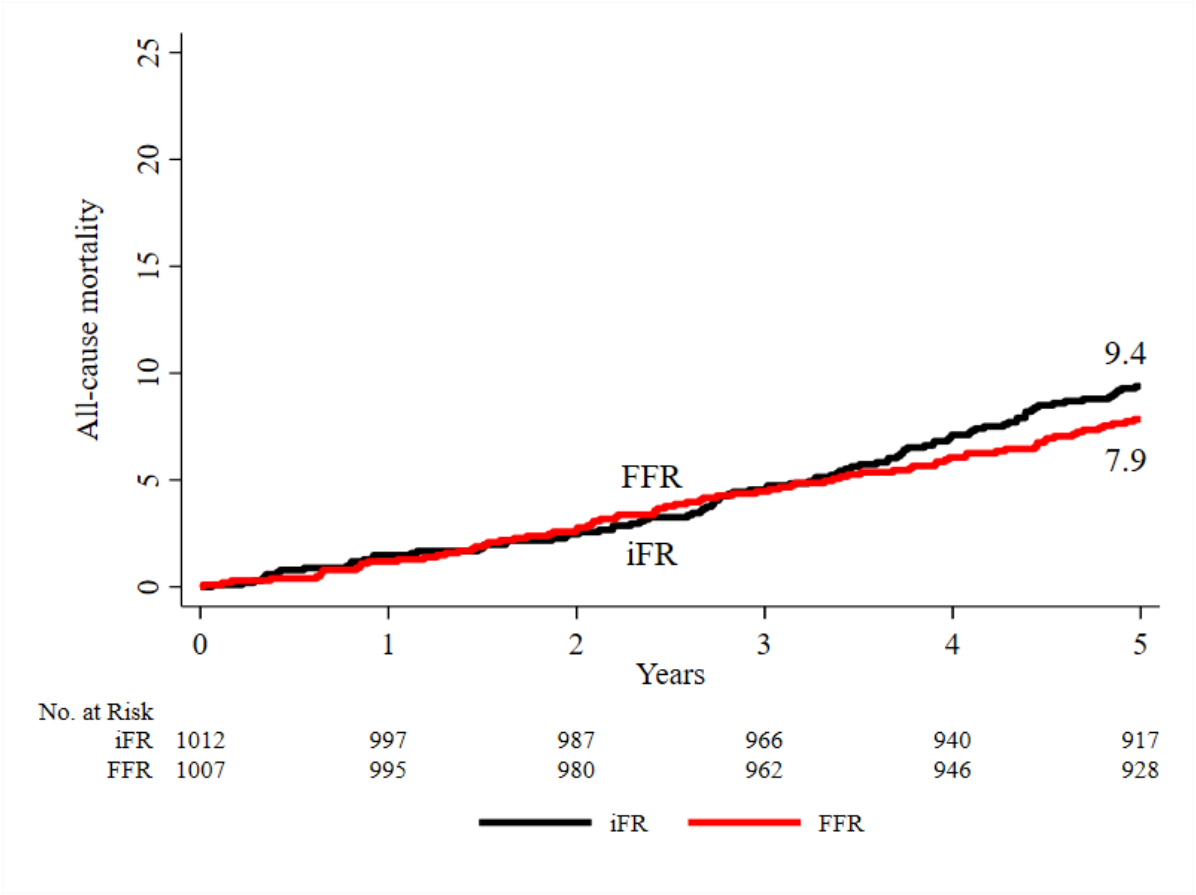


iFR 21.5%
FFR 19.9%

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

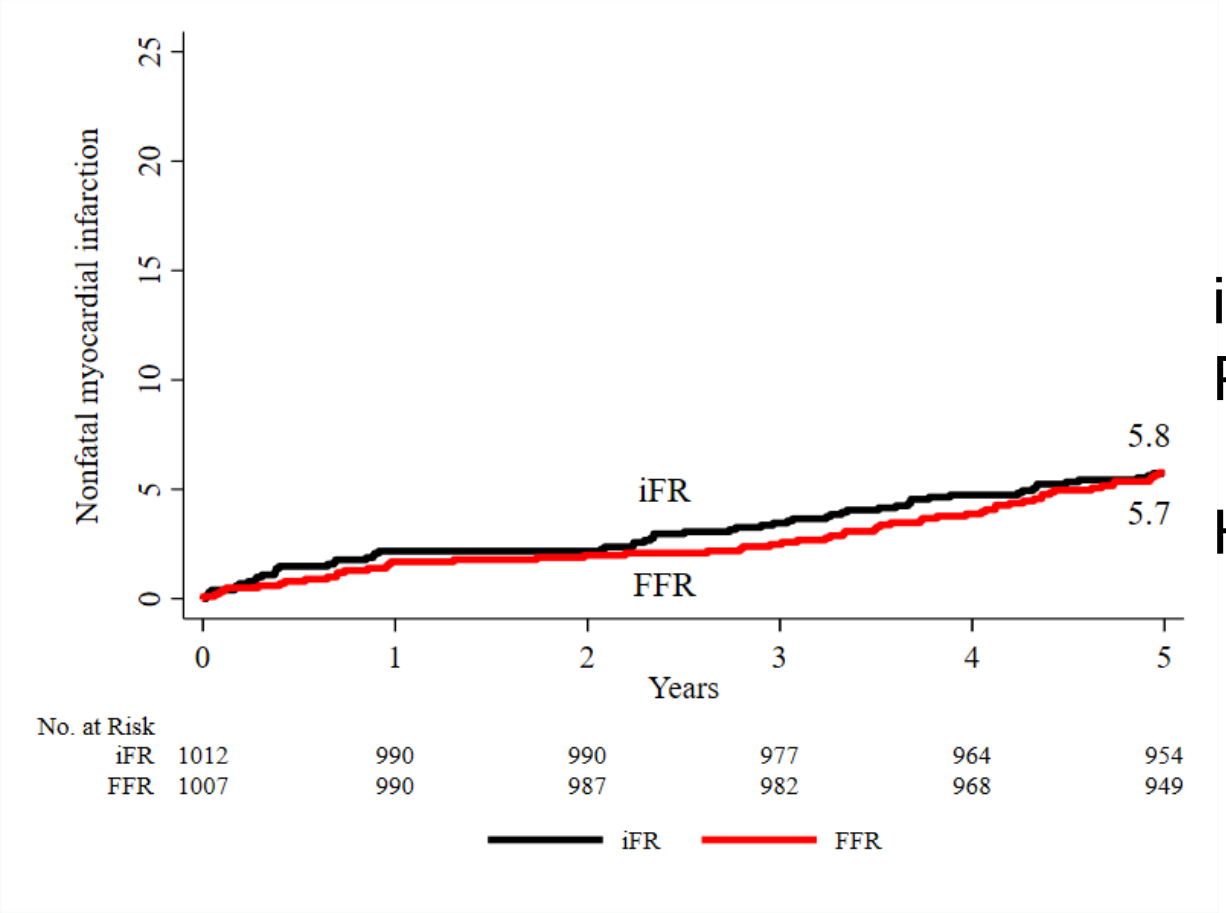


iFR 9.4%
FFR 7.9%

HR 1.20; 95% CI: 0.89, 1.62

iFR no difference in all-cause mortality compared with FFR

Myocardial infarction at 5 years

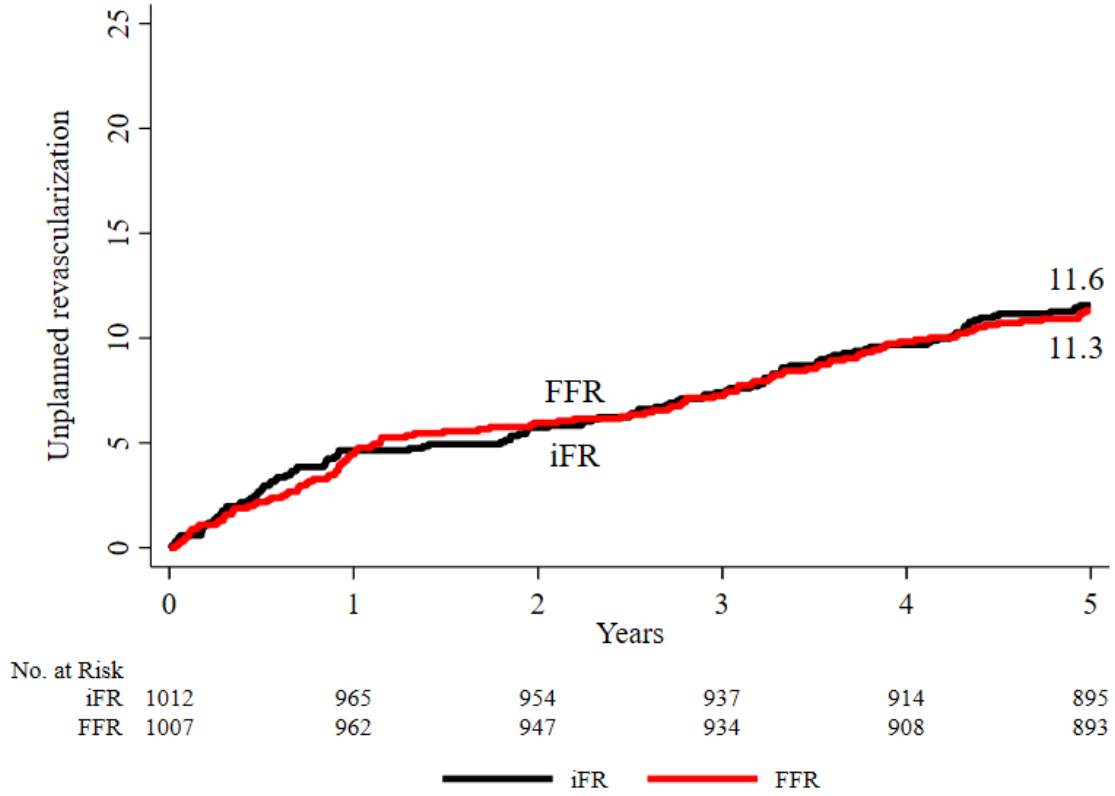


iFR 5.8%
FFR 5.7%

HR 1.00; 95% CI: 0.70, 1.44

iFR no difference in myocardial infarction compared with FFR

Unplanned revascularization at 5 years



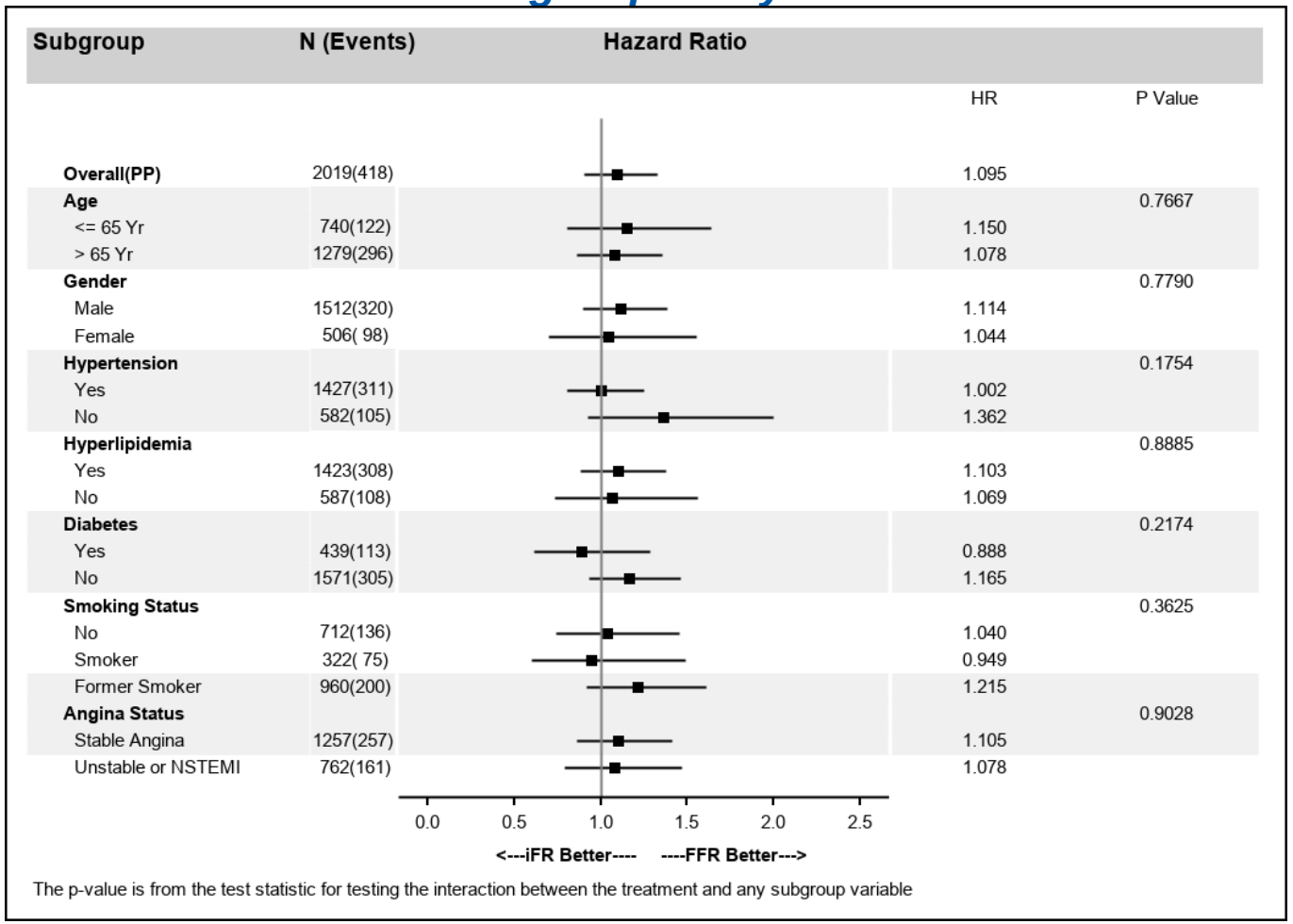
iFR 11.6%
FFR 11.3%

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

Analysis of cause of death

	iFR* (n=1012)	FFR* (n=1007)	HR	95% CI
Composite endpoint – n (%)	218 (21.5)	200 (19.9)	1.09	0.90-1.33
All-cause mortality – n (%)	95 (9.4)	79 (7.9)	1.20	0.89–1.62
Nonfatal myocardial infarction – n (%)	58 (5.7)	58 (5.8)	1.00	0.70-1.44
Unplanned revascularization – n (%)	117 (11.6)	114 (11.3)	1.02	0.79-1.32
Cardiovascular death – n (%)	28 (2.8)	33 (3.3)	0.85	0.51-1.40
Non-Cardiovascular death – n (%)	67 (6.6)	46 (4.6)	1.46	1.00-2.12

*FFR = fractional flow reserve; iFR = instantaneous wave-free ratio; HR = Hazard ratio.

2/3 of death were non-CV origin (all-comers population)

Borderline significantly more non-CV death in iFR-group

CV-death similar between iFR and FFR

Summary iFR-Swedeheart

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In patients presenting with stable angina or acute coronary syndrome, performing invasive physiology with iFR provides similar long-term outcome 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

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5-Year Outcomes of PCI Guided by Measurement of Instantaneous Wave-Free Ratio Versus Fractional Flow Reserve

Paper “in press”

at

Journal of The American College of Cardiology

On behalf of the iFR-Swedeheart investigators

Thank you!

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LUND UNIVERSITY