

FFR- versus Angiography-Guided Multivessel Revascularization in ST-Elevation Myocardial Infarction Patients

The FLOWER MI trial : 3-year outcomes

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Disclosures – Nicolas Danchin, MD

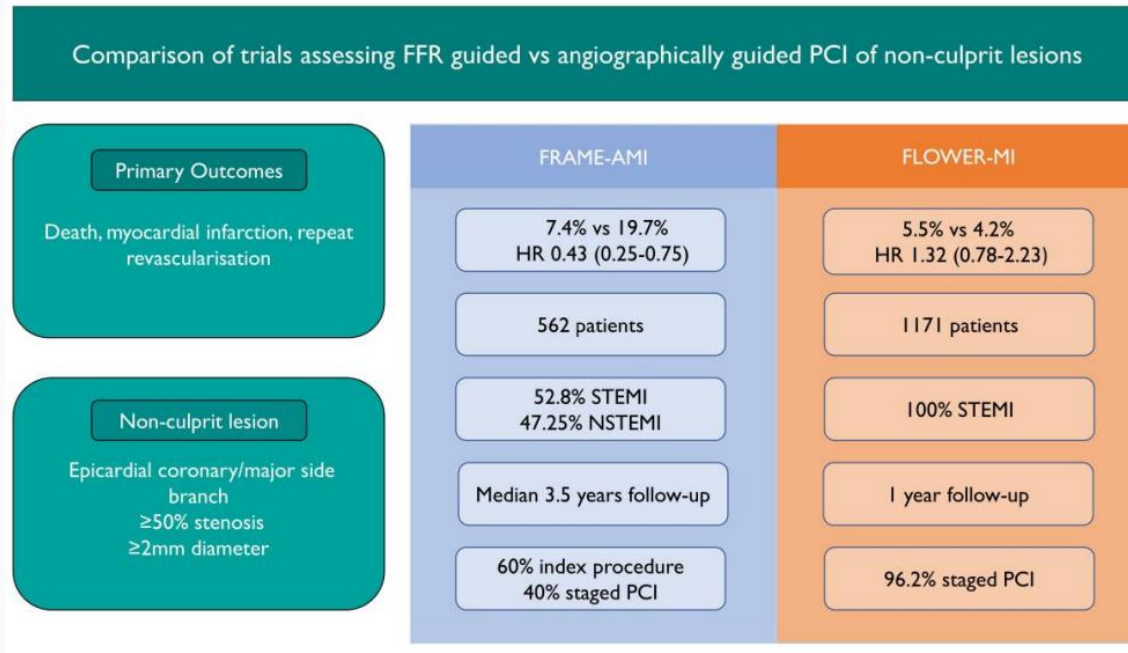
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• Research Support	None
• Lecture and/or Consulting Fees	Amgen, AstraZeneca, Bayer, BMS, Boehringer-Ingelheim, Maincare, MSD, Pfizer, Sanofi, Servier, Socar, UCB

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Background

- The value of a fractional flow reserve (FFR)-guided strategy for non-culprit lesions in AMI patients is controversial

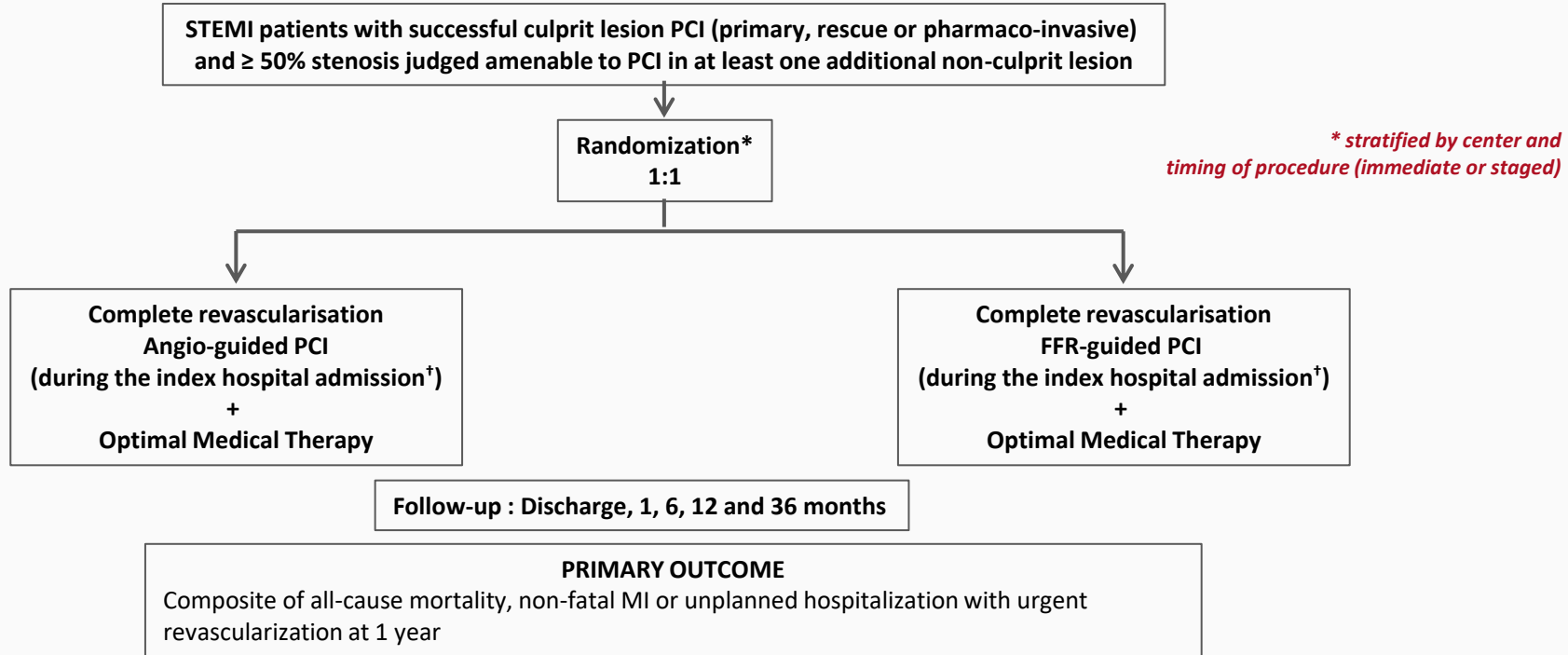


Mehta SR et al. EHJ 2023

Lee JM et al. EHJ 2023

Puymirat E et al. N Engl J Med 2021

FLOWER MI Study Design



Anticipated rate of primary EP at one year 9.5% vs 15%

Puymirat E et al. Am Heart J 2020

Patient selection

INCLUSION CRITERIA

STEMI patients

Age ≥ 18 y

Successful culprit lesion PCI (primary, rescue or pharmaco-invasive) and $\geq 50\%$ stenosis judged amenable to PCI in at least one additional non-culprit lesion

Willing and able to provide informed, written consent

EXCLUSION CRITERIA

Cardiogenic shock

Previous coronary bypass surgery

Extremely tortuous, calcified coronary vessels or CTO

Patients with single-VD

MVD patients referred to surgery

Hypersensitivity to adenosine

Life expectancy < 2 years

Pregnancy

Participation in another study

Participant not affiliated to the French social security

Baseline characteristics

Characteristics	FFR-Guided PCI (n=586)	Angio-Guided PCI (n=577)
Age (year)	62.5 ± 11.0	61.9 ± 11.4
BMI (kg/m ²)	26.7 (24.2-29.1)	26.6 (24.4-29.7)
Male	85.0	81.1
Hypertension	43.2	45.4
Diabetes mellitus	18.3	14.2
Hypercholesterolemia	39.6	41.1
Current smoker	40.1	36.4
Previous MI	7.7	5.4
Previous PCI	10.1	7.6
Previous stroke	2.7	3.0
Peripheral-vessel disease	2.7	4.0
Chronic renal insufficiency	1.9	12.1

Clinical presentation	FFR-Guided PCI (n=586)	Angio-Guided PCI (n=577)
Location of infarction		
• Anterior	29.8	34.6
Arteries with stenosis		
• 2	72.4	77.5
• 3	25.8	19.9
Killip class ≥ 2	6.7	5.3
LVEF (%)	50 (45-60)	50 (45-58.3)

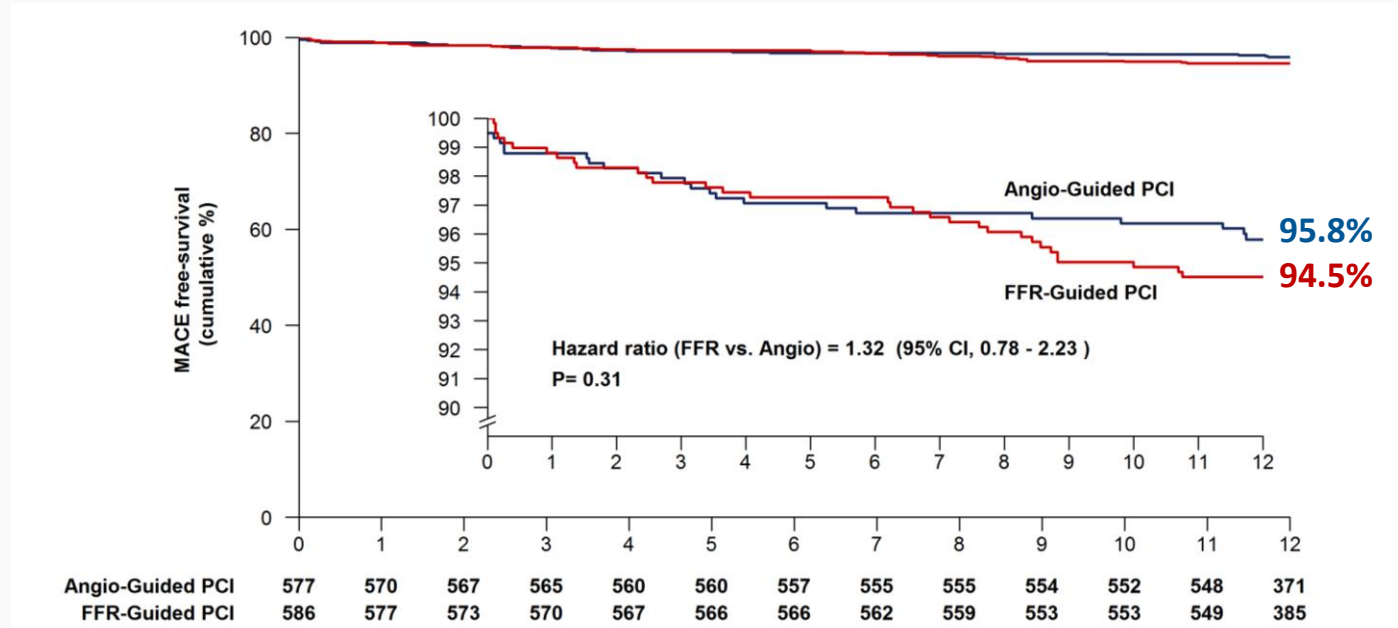
Procedural Data

Characteristics of lesions	FFR-Guided PCI (n=586)	Angio-Guided PCI (n=577)
Location of CL ‡		
• LMCA	3/718 (0.4)	4/706 (0.6)
• LAD	222/718 (30.9)	241/706 (34.1)
• LCX	135/718 (18.8)	144/706 (20.4)
• RCA	358/718 (49.9)	317/706 (44.9)
Location of non-CL ‡		
• LMCA	7/980 (0.7)	9/891 (1.0)
• LAD	458/980 (46.7)	402/891 (45.1)
• LCX	303/980 (30.9)	262/891 (29.4)
• RCA	212/980 (21.6)	218/891 (24.5)
Diameter of non-CL (mm)	2.86 ± 0.48	2.97 ± 0.53

PCI of non-culprit lesion	FFR-Guided PCI (n=586)	Angio-Guided PCI (n=577)
Staged procedure of non-CL	96.6	95.8
FFR procedure attempted†	95.7	NA
Mean FFR value		
• FFR before PCI	0.79 ± 0.11	NA
• FFR post PCI	0.90 ± 0.06	NA
Lesions with FFR ≤0.80	55.7	NA
PCI (≥1) per patient	66.2	97.1*
Mean no. of stents used†	1.01 ± 0.99	1.50 ± 0.86*
Type of stent used		
• Zotarolimus eluting	16.1	13.5
• Sirolimus eluting	17.9	20.0
• Everolimus eluting	51.9	52.8
• Others drug-eluting	13.2	12.9
• Bare-metal stent	0.8	0.7

Primary outcome at 1 Year

FFR-guided strategy was not superior to an angiography-guided strategy for reducing the risk of the composite of death from any cause, non-fatal MI, and unplanned hospitalization leading to urgent revascularization at 1-year



Low event rates of MACE at 1 year

4.2%

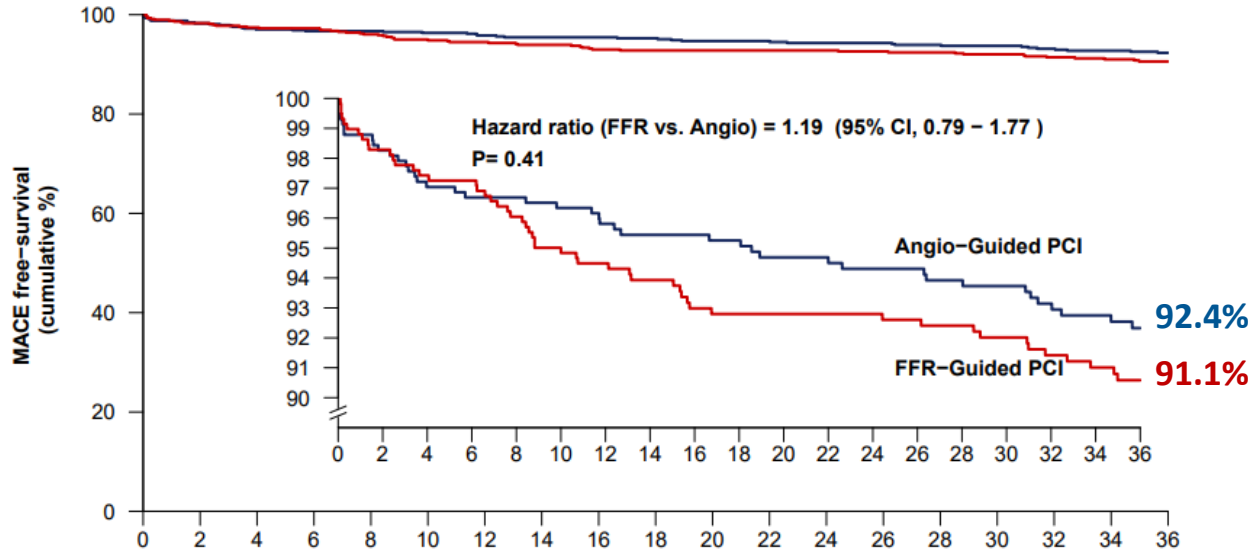
5.5%

* Major Adverse Cardiac Events (MACE) denotes the composite of all-cause mortality, nonfatal MI, and unplanned hospitalization leading to urgent revascularization

Purpose

- The pre-specified extension phase of the FLOWER MI trial was designed to determine whether a difference in outcomes would be observed beyond the initial one-year follow-up

Primary outcome at 3 Years



Angio-Guided PCI	577	563	556	553	553	551	530	509	508	507	502	498	493	490	486	484	473	461	409
FFR-Guided PCI	586	572	565	564	556	549	519	498	492	489	489	485	481	475	470	463	456	442	399

Low event rates of MACE at 3 years

7.6%
8.9%

* Major Adverse Cardiac Events (MACE) denotes the composite of all-cause mortality, nonfatal MI, and unplanned hospitalization leading to urgent revascularization

Primary and secondary outcomes at three years

Primary outcome at 3 years	FFR-Guided PCI (n=586)	Angio-Guided PCI (n=577)	HR (95% CI)	P Value
MACE*	8.9 (n=52)	7.6 (n=44)	1.19 (0.79-1.77)	0.41
Death from any cause	3.8 (n=22)	4.0 (n=23)	0.96 (0.53-1.71)	-
Myocardial infarction	3.9 (n=23)	2.4 (n=14)	1.63 (0.84-3.16)	-
Unplanned hospitalization leading to urgent revascularization	3.6 (n=21)	3.1 (n=18)	1.15 (0.61-2.16)	-

* Major Adverse Cardiac Events (MACE) denotes the composite of all-cause mortality, nonfatal MI, and unplanned hospitalization leading to urgent revascularization

Prespecified clinical outcomes at 3 Years

Secondary outcomes at 3 years	FFR-Guided PCI (n=586)	Angio-Guided PCI (n=577)	HR (95% CI)
Stent thrombosis (%)	0.7	1.2	0.56 (0.16-1.91)
Any revascularization (%)	9.0	7.1	1.30 (0.86-1.95)
Hospitalization for heart failure (%)	1.7	2.6	0.66 (0.29-1.48)
Hospitalization for recurrent ischemia (%)	7.5	5.0	1.54 (0.96-2.46)
Any hospitalization in Cardiology (%)	15.7	12.1	1.34 (0.98-1.83)

Functional status at 3 years	FFR-Guided PCI (n=586)	Angio-Guided PCI (n=577)	HR (95% CI)
Number of anti-anginal medications used *	0.88 ± 0.5	0.9 ± 0.5	0.98 (0.86-1.12)
QALY based on EQ-5D score	0.88 ± 0.14	0.87 ± 0.23	-0.01 (-0.03-0.02)

* Antianginal medications included beta-blockers, calcium antagonists, and nitrates. Rate of means estimated by a negative binomial model

Analysis of FFR-guided versus angio-guided PCI in STEMI patients with multivessel disease: a pooled analysis of the FRAME-AMI and FLOWER-MI trials

Composite outcomes (death, re-MI or any repeat revascularization)
in the FRAME-AMI and FLOWER-MI trials



Conclusions

- **In patients presenting with STEMI and MVD treated with multivessel revascularization during the index hospitalization:**
 - Event rates up to 3 years are low
 - FFR-guided PCI of non-infarct-related lesions does not reduce the risk of a composite outcome of death, re-infarction or urgent revascularization at 3-years, as compared with an angiography-guided strategy
 - A pooled analysis using data from the FLOWER-MI and FRAME-AMI trials confirms the lack of benefit of an FFR-guided versus angiography-guided strategy in STEMI patients with multivessel disease

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