Medis QFR®

Study FAVOR III China*

Quantitative flow ratio-guided coronary angiography intervention: a multicenter, randomized, sham-controlled trial

Findings

- The 1-year incidence of MACE events in the QFR®-guided group is significantly lower than in the angiography-guided group (5,8% vs 8.8%).
- A highly significant absolute difference of -3% (57 fewer events; hazard ratio [HR] 0-65 [95% CI** 0-51 to 0-83]; p=0-0004) in the QFR group, meaning that the relative risk of MACE was reduced by 34%.

Study design

FAVOR III China* is a prospective, multicenter study of 3825 randomized 1:1 patients comparing QFR®-guided PCI versus angiography-guided PCI (visual interpretation)

Evaluation criteria

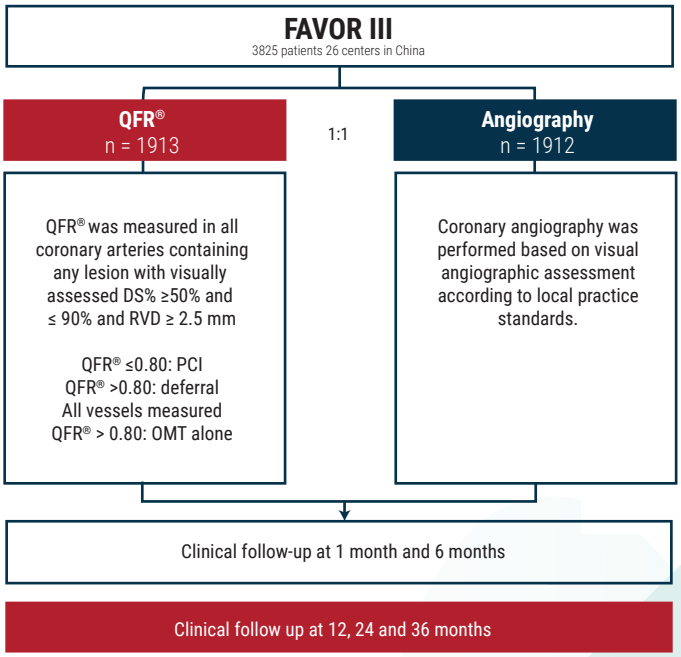
Primary endpoint

Major cardiac events at 12 months defined as the primary endpoint:

- All-cause cardiac death
- Myocardial infarction or revascularization related to ischemia

Selected secondary criteria

- MACE rate at 1 year, excluding periprocedural infarctions resulting from the reference intervention or interventions planned in stages



Patient characteristics

	QFR® n = 1913	Angiography n = 1912
Age, years	62.7 ± 10.1	62.7 ± 10.2
Male	70.5%	70.6%
BMI [kg/m2]	25.1 (22.9, 27.0)	24.7 (22.7, 27.0)
Diabetes mellitus	33.9	33.8
Hypertension	66.4%	65.5%
Hypercholesterolemia	38.1%	38.1%
Current smoker	30.0%	29.7%
Family History of coronary artery disease	7.7%	7.8%
Previous myocardial infarction	9.4%	9.4%
Previous percutaneous coronary intervention	25.4%	24.4%
Previous stroke	9.6%	9.2%
Peripheral artery disease	2.9%	3.7%

Characteristics of the procedure

	QFR® n = 1913	Angiography n = 1912	P Value
PCI performed	90.5%	99.1%	<0.0001
Number of stents placed per patient	1.45 ± 1.02	1.58±0.97	<0.0001
Use of intravascular imaging	6.2%	6.3%	0.89
Mean of contrast used / patient, ml	163.0 ± 75.6	169±74.2	0.00060
Fluoroscopy time, min	14.1±8.0	14.9±7.4	0.0013
Procedure time, min	53.7±30.4	59.4±30.4	<0.0001
Adjusted procedure time, min	44.6±28.8	49.5±30.2	<0.0001
PCI lesion success	99.0%	99.3%	0.38
Residual anatomic SYNTAX score	2.4±3.6	2.4±4.0	0.49
Residual functional SYNTAX score	0.7±2.3	1.0±2.8	<0.0001
Residual functional SYNTAX score = 0	88.1%	82.2%	<0.0001

** Bayesian Credibility Interval / Data are expressed as mean ± SD MACE = Major Adverse Cardiac Events; Major adverse cardiac event, QFR = Quantitative Flow Ratio

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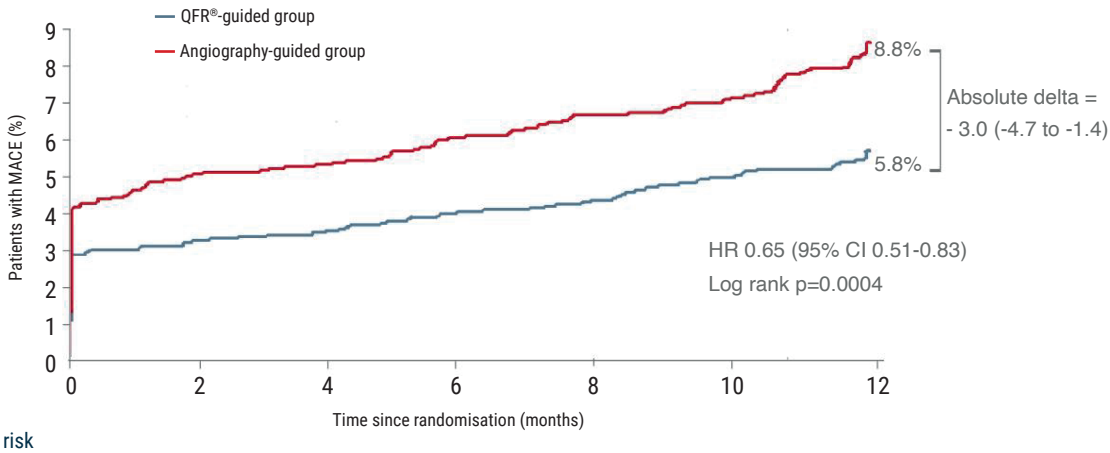
MEDICAL IMAGING

Primary endpoint - Major Cardial Events at 12 months (ITT)



Number at risk

QFR-guided group	1913	1845	1840	1828	1821	1809	1795
Angiography-guided group	1912	1804	1798	1783	1770	1762	1732

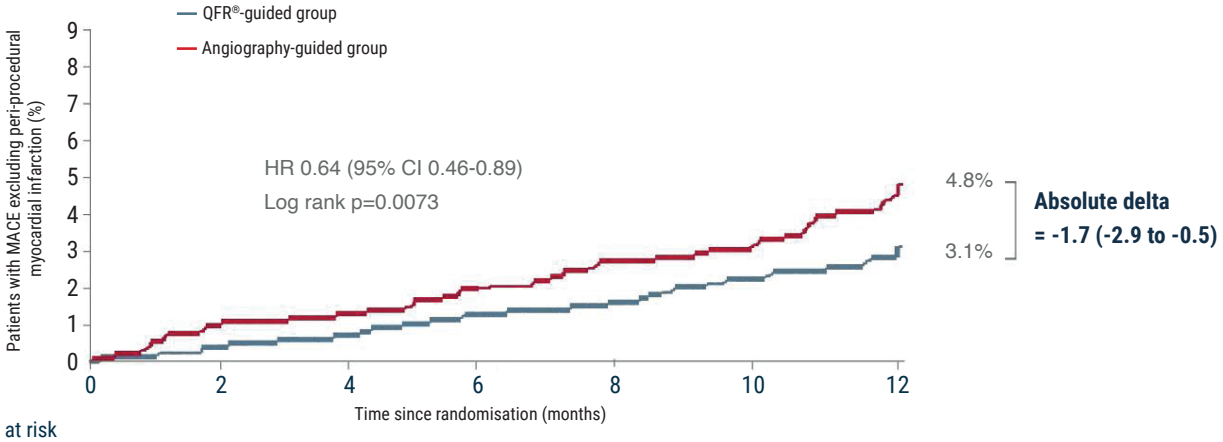
-34%

Significant reduction in MACE in 12 months with QFR

MACE in 12 months

8.8% Angiography-guided group | **5.8%** QFR®-guided group

Secondary criteria selected at 12 months



Number at risk

QFR-guided group	1913	1900	1894	1881	1874	1862	1846
Angiography-guided group	1912	1883	1877	1862	1847	1839	1808

Other secondary endpoints

	QFR® n = 1913	Angiography n = 1912	Hazard ratio (95% BCI)	p-value n = 1912
Cardiovascular deaths	0.5%	0.4%	1.28 (0.48-3.44)	0.62
Peri-procedural myocardial infarction	2.9%	4.2%	0.69 (0.49-0.97)	0.033
Non-procedural myocardial infarction	0.5%	1.6%	0.33 (0.16-0.68)	0.0025
Any revascularization	2.6%	3.5%	0.73 (0.50-1.05)	0.089
Target vessel revascularization	1.2%	1.3%	0.88 (0.50-1.56)	0.66
Stent thrombosis, definite or probable	0.2%	0.3%	0.50 (0.12-1.99)	0.33

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