

FAME STUDY ONE-YEAR RESULTS

A publication delivering concise clinical data

Fractional Flow Reserve (FFR) versus Angiography for Multivessel Evaluation

Tonino PA, De Bruyne B, Pijls NH, et al. Fractional Flow Reserve versus Angiography for Guiding Percutaneous Coronary Intervention. *New Engl J Med.* 2009;360(3):213-24.

OBJECTIVE

The objective of the FAME (FFR versus Angiography for Multivessel Evaluation) study was to determine if routine measurement of fractional flow reserve, when combined with angiography, improves outcomes in patients undergoing percutaneous coronary intervention (PCI).

BACKGROUND

In patients with multivessel coronary artery disease, determining which lesions cause ischemia and warrant stenting can be difficult. Noninvasive stress imaging studies are limited in their ability to accurately localize ischemia-producing lesions in this patient population.

The information provided by FFR measurements is more specific and has a better spatial resolution because every artery or segment is analyzed separately.

METHODS

- Randomized, prospective study – angiography alone or angiography plus FFR
- 20 centers in U.S. and Europe
- 1,005 PCI patients undergoing DES stenting for multivessel disease

RESULTS

- St. Jude Medical's PressureWire™ Certus was exclusively used in the study with a 94% success rate in this complex patient population

Compared to angiography-alone procedures, FAME shows that FFR;

- Reduces composite rates of death, myocardial infarction, re-PCI, and CABG at one year by 30%
- Reduces mortality and myocardial infarction at one year by 34%

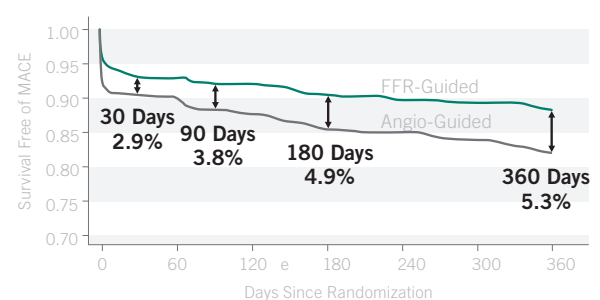
CONCLUSION

FAME reports integrating FFR into procedures improves outcomes and reduces costs. Routine measurement of FFR in patients with complex coronary artery disease reduces MACE and makes stent placement more efficient and more cost-effective.

FAME documents that FFR, compared to angiography-alone procedures:

- Is cost-saving and does not prolong procedure time
- Decreases amount of contrast agent used
- Results in similar, if not better, functional status

Absolute difference in MACE-free survival



ST. JUDE MEDICAL™
MORE CONTROL. LESS RISK.

MACE

Events at One year, No. (%)	ANGIO-Group n=496	FFR-Group n=509	P-Value
Death, MI and Repeat Vascularization	91 (18.3)	67 (13.2)	0.02
Death	15 (3.0)	9 (1.8)	0.19
Death or Myocardial Infarction	55 (11.1)	37 (7.3)	0.04
Repeat Vascularization	47 (9.5)	33 (6.5)	0.08
Total No. of MACE	113	76	0.02

Costs and equipment usage

Stents	ANGIO-Group n=496	FFR-Group n=509	P-Value
DES per Patient	2.7 ± 1.2	1.9 ± 1.3	< 0.001
Lesions Successfully Stented, No. (%)	1237 (92)	819 (94)	
DES, Total No.	1359	980	
Procedure Time (min.)	70 ± 44	71 ± 43	0.51
Contrast Agent Used (ml)	302 ± 127	272 ± 133	< 0.001
Materials Used at Procedure (mean USD)	6007 ± 2819	5332 ± 3261	< 0.001
Length of Hospital Stay (days)	3.7 ± 3.5	3.4 ± 3.3	0.05

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Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

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