The FAME Trial

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Fractional Flow Reserve Versus Angiography For Guiding PCI In Patients With Multivessel Coronary Artery Diseased

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FAME study: BACKGROUND (1)

- Stenting of non-ischemic stenoses has no benefit compared to medical treatment only
- Stenting of ischemia-related stenoses improves symptoms and outcome
- In multivessel coronary disease (MVD), identifying which stenoses cause ischemia is difficult:

  Non-invasive tests are often unreliable in MVD and coronary angiography often results in both under- or overestimation of functional stenosis severity

FAME study: BACKGROUND (2)

- Fractional Flow Reserve (FFR), is the most accurate and selective index to indicate whether a particular stenosis is responsible for inducible ischemia
- FFR can be easily determined in the cathlab just prior to stenting

Therefore:

- ***FFR guidance of PCI in patients with multivessel disease may improve outcome***

FAME study: Study Population

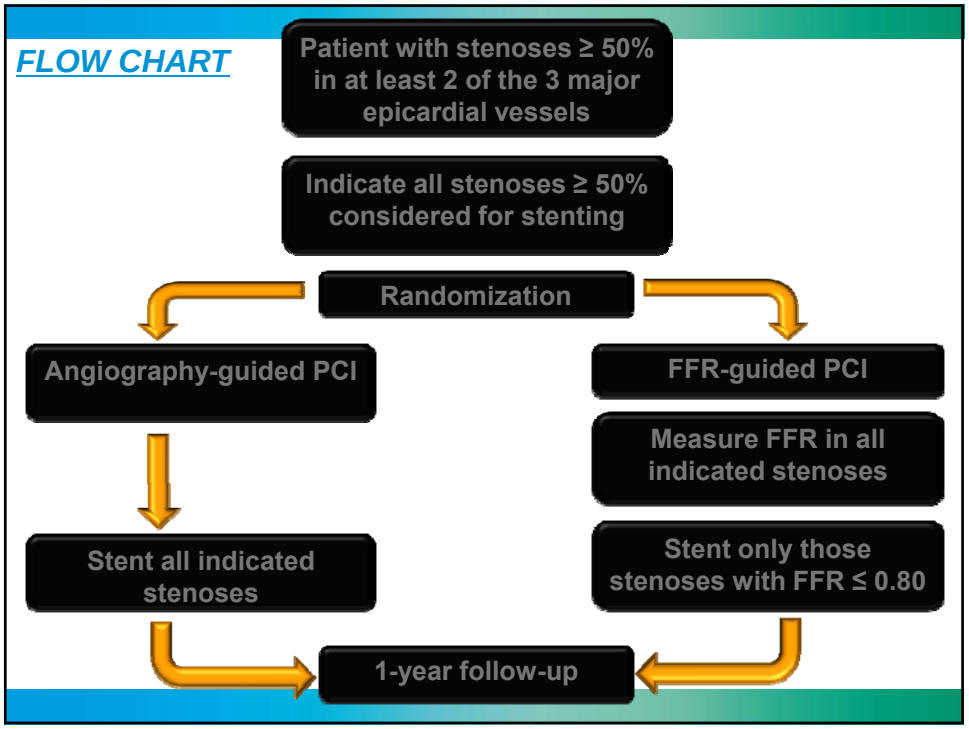
The FAME study was designed to ***reflect daily practice*** in performing PCI in patients ***with multivessel disease***

Inclusion criteria:

- ***ALL*** patients with multivessel disease
- At least 2 stenoses ≥ 50% in 2 or 3 major epicardial coronary artery disease, amenable for stenting

Exclusion criteria:

- Left main disease or previous bypass surgery
- ST-elevation MI with CK > 1000 U/l within last 5 days
- extremely tortuous or calcified coronary arteries



FAME study: Treatment

- PCI according to local routine
- Only drug-eluting stents (DES)
- FFR measured by Pressure Wire (***Certus wire, RADI Medical Systems***)
- hyperemia induced by i.v. adenosine 140 µg/kg/min in femoral vein
- EKG, CK, CK-MB, etc during hospital stay
- Follow-up at 1 month, 6 months, 1 year
- *Also in case of repeat-procedure , strictly adherence to initial randomization*

FAME study: Lesion Characteristics

	ANGIO-group N=496	FFR-group N=509	P-value
# indicated lesions per patient	**2.7±0.9**	**2.8±1.0**	0.34
Reference diameter (mm)	**2.5±0.6**	**2.5±0.7**	0.81
% stenosis severity	**61±17**	**60±18**	0.24
MLD (mm)	**1.0±0.4**	**1.0±0.5**	0.35
50-70% narrowing, No (%)	**550 (41)**	**624 (44)**	-
70-90% narrowing, No (%)	**553 (41)**	**530 (37)**	-
90-99% narrowing, No (%)	**207 (15)**	**202(14)**	-
Total occlusion, No (%)	**40 (3)**	**58 (4)**	-
Patients with ≥1 total occlusion (%)	**7.5**	**10.6**	0.08

FAME study: Procedural Results (1)

	ANGIO-group N=496	FFR-group N=509	P-value
# indicated lesions per patient	**2.7 ± 0.9**	**2.8 ± 1.0**	0.34
FFR results			
Lesions succesfully measured, No (%)	-	**1329 (98%)**	-
Lesions with FFR ≤ 0.80 ,No (%)	-	**874 (63%)**	-
Lesions with FFR > 0.80 ,No (%)	-	**513 (37%)**	-
stents per patient	**2.7 ± 1.2**	**1.9 ± 1.3**	<0.001
Lesions succesfully stented (%)	**92%**	**94%**	-
DES, total, No	**1359**	**980**	-

FAME study: Procedural Results (2)

	ANGIO-group N=496	FFR-group N=509	P-value
Procedure time (min)	70 ± 44	71 ± 43	0.51
Contrast agent used (ml)	302 ± 127	272 ± 133	<0.001
Materials used at procedure (US $)	6007	5332	<0.001
Length of hospital stay (days)	3.7 ± 3.5	3.4 ± 3.3	0.05

FAME study: Adverse Events at 1 year

	ANGIO-group N=496	FFR-group N=509	P-value
Events at 1 year, No (%)			
Death, MI, CABG, or repeat-PCI	91 (18.4)	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
CABG or repeat PCI	47 (9.5)	33 (6.5)	0.08
Total no. of MACE	113	76	0.02
Myocardial infarction, specified			
All myocardial infarctions	43 (8.7)	29 (5.7)	0.07
Small periprocedural CK-MB 3-5 x N	16	12	
Other infarctions (“late or large”)	27	17	

FAME study: CONCLUSIONS (1)

Routine measurement of FFR during PCI with DES in patients with multivessel disease, when compared to current angiography guided strategy

- ***reduces the rate of the composite endpoint of death, myocardial infarction, re-PCI and CABG at 1 year by ~ 30%***
- ***reduces mortality and myocardial infarction at 1 year by ~ 35 %***

FAME study: CONCLUSIONS (2)

Routine measurement of FFR during PCI with DES in patients with multivessel disease, when compared to current angiography guided strategy, *furthermore:*

- ***is cost-saving and does not prolong the procedure***
- ***reduces the number of stents used***
- ***decreases the amount of contrast agent used***
- ***results in a similar, if not better, functional status***

FAME study: CONCLUSIONS (3)

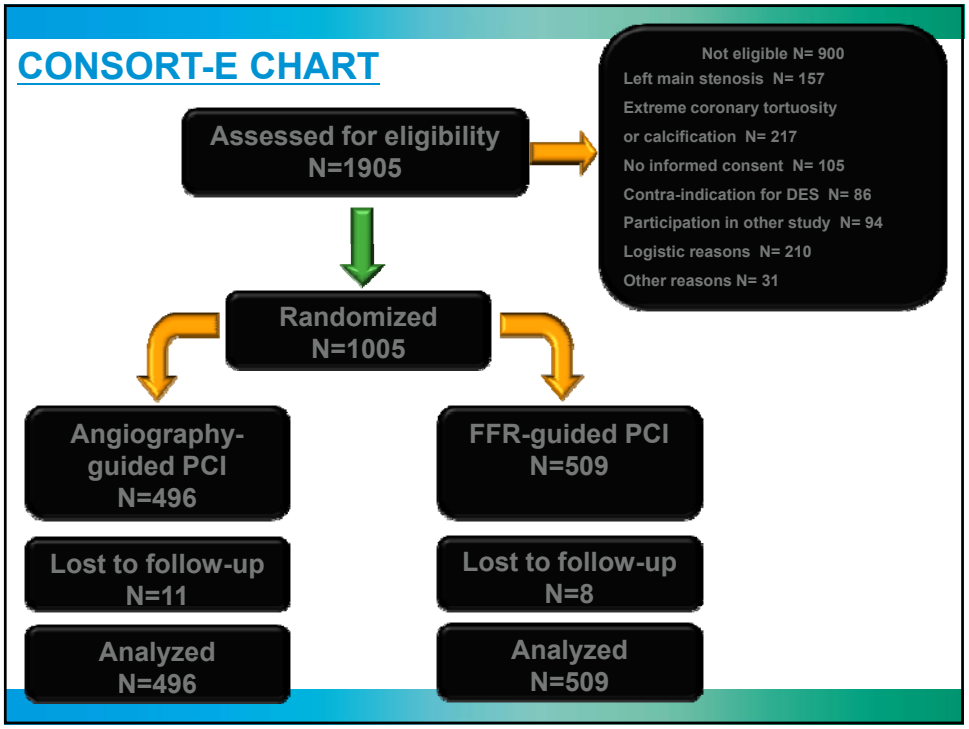
Routine measurement of FFR during DES-stenting in patients with multivessel disease is superior to current angiography guided treatment.

It improves outcome of PCI significantly

It supports the evolving paradigm of

"Functionally Complete Revascularization", i.e. stenting of ischemic lesions and medical treatment of non-ischemic ones.

IS IT REALLY LIKE THAT ?



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Lesions with FFR > 0.80 ,No (%)	-	**513 (37%)**	-
FFR in ischemic lesions	-	**0.60 ± 0.14**	-
FFR in non-ischemic lesions	-	**0.88 ± 0.05**	-

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FAME study: CONCLUSIONS (1)

Routine measurement of FFR during PCI with DES in patients with multivessel disease, when compar trategy

This conclusion is much overstretched !

- ***reduc nt of death, CABG at 1 ye***

- ***reduces mortality and myocardial infarction at 1 year by ~ 35 %***

FAME study: CONCLUSIONS (2)

Routine measurement of FFR during PCI with DES in patients with multivessel disease, when compar trategy, *further*

This conclusion is much overstretched !

- ***is cos rocedure***
- ***reduces the number of stents used***
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Routine measurement of FFR during DES-stenting in pat perior to ent.

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This conclusion is much overstretched !

"Functionally Complete Revascularization", i.e. stenting of ischemic lesions and medical treatment of non-ischemic ones.

Conclusions:

- FFR is an reliable tool for determining the hemodynamic significance of a lesion although neither sensitivity nor specificity reach 100%.
- It should not replace angiography and should not deprive the operator from his clinical skills.
- It should not be performed in clear cut lesions > 90%
- In clinical practice it should be confined to particular situations in which other criteria remain equivocal:

1. Intermediate lesions in absence of pre-cath ischemia study and inconclusive symptoms.
2. Intermediate lesions in absence of symptoms in a prognostically important location e.g. proximal LAD.

- PCI/DES should not be performed in non-significant lesions among chronic stable coronary artery disease patients.