Fractional Flow Reserve–Guided PCI versus Medical Therapy in Stable Coronary Disease

FAME 2

Clinicaltrials.gov NCT01132495

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Potential conflicts of interest

Speaker’s name: Bernard De Bruyne

☐ I have the following potential conflicts of interest to report:

☑ Research contracts
☑ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest

Study Supported by St. Jude Medical
In patients with stable coronary disease, PCI has not been shown to improve prognosis.

FAME 1 demonstrated the superiority of FFR-guided over angiography-guided PCI.

In previous trials, revascularization has been guided by the angiographic appearance of the lesions.

It is likely that in previous trials a sizable proportion of patients had no or little ischemia.
Objective

To compare clinical outcomes of FFR-guided contemporary PCI plus the best available medical therapy (MT) versus MT alone in patients with stable coronary disease.
Flow Chart

Stable CAD patients scheduled for 1, 2 or 3 vessel DES-PCI
N = 1220

FFR in all target lesions

Randomized Trial

At least 1 stenosis with FFR ≤ 0.80 (n=888)

Randomization 1:1

PCI + MT

MT

73%

Registry

When all FFR > 0.80 (n=332)

MT

27%

50% randomly assigned to FU

Follow-up after 1, 6 months, 1, 2, 3, 4, and 5 years
Primary Outcomes

- PCI+MT vs. MT: HR 0.32 (0.19-0.53); p<0.001
- PCI+MT vs. Registry: HR 1.29 (0.49-3.39); p=0.61
- MT vs. Registry: HR 4.32 (1.75-10.7); p<0.001
Urgent Revascularization

PCI+MT vs. MT: HR 0.13 (0.06-0.30); p<0.001
PCI+MT vs. Registry: HR 0.63 (0.19-2.03); p=0.43
MT vs. Registry: HR 4.65 (1.72-12.62); p=0.009

No. at risk

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Kaplan-Meier plots of Landmark Analysis of Death or MI

≤7 days: HR 7.99 (0.99-64.6); p=0.038
> 8 days: HR 0.42 (0.17-1.04); p=0.053
p-interaction: p=0.003
Conclusions

• In patients with stable coronary artery disease, FFR-guided PCI, improves patient outcome as compared with medical therapy alone.

• This improvement is driven by a dramatic decrease in the need for urgent revascularization for ACS.

• In patients with functionally non-significant stenoses, medical therapy alone resulted in an excellent outcome, regardless of the angiographic appearance of the stenoses.