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

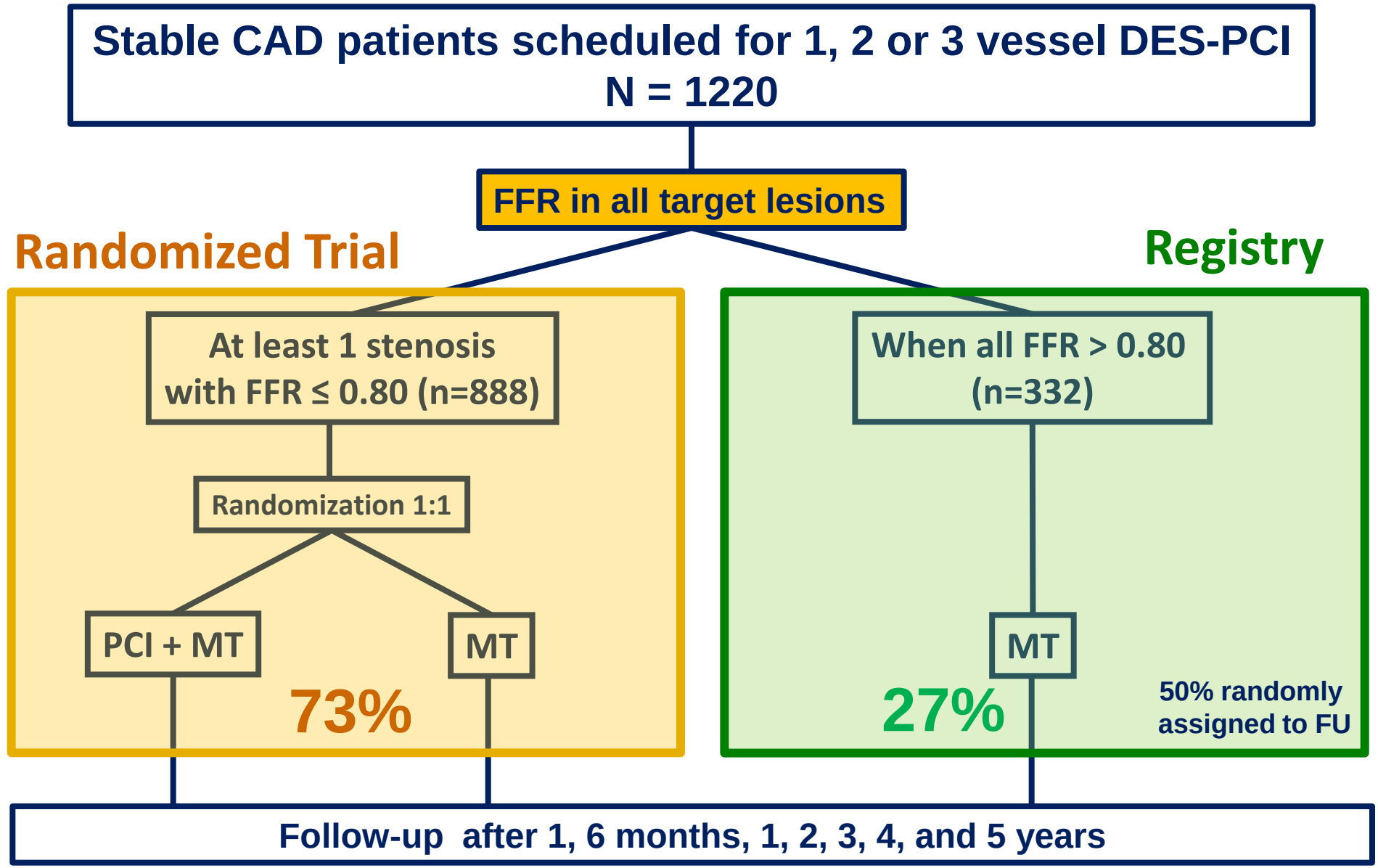
Background

- 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

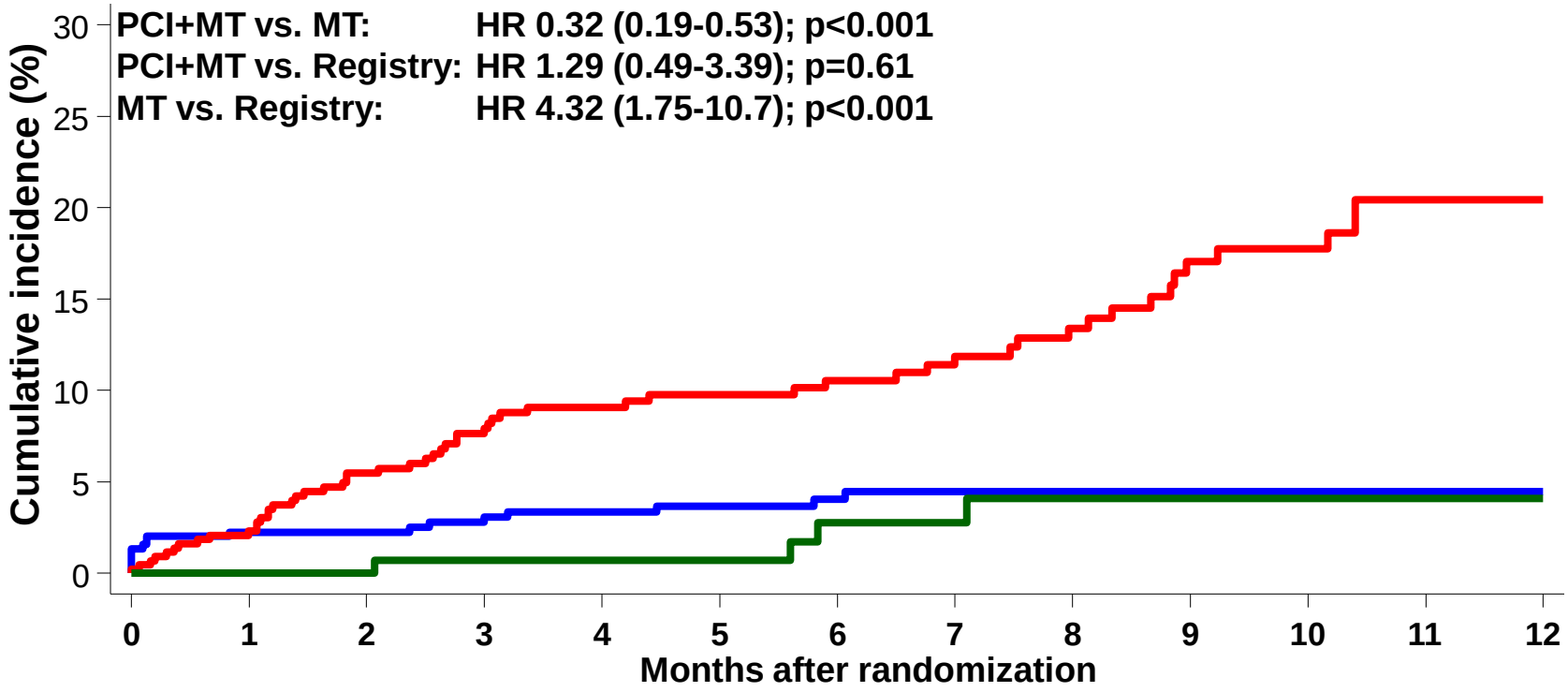
Objective

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
Registry
At least 1 stenosis with FFR ≤ 0.80 (n=888)
Randomization 1:1
PCI + MT
MT
73%
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

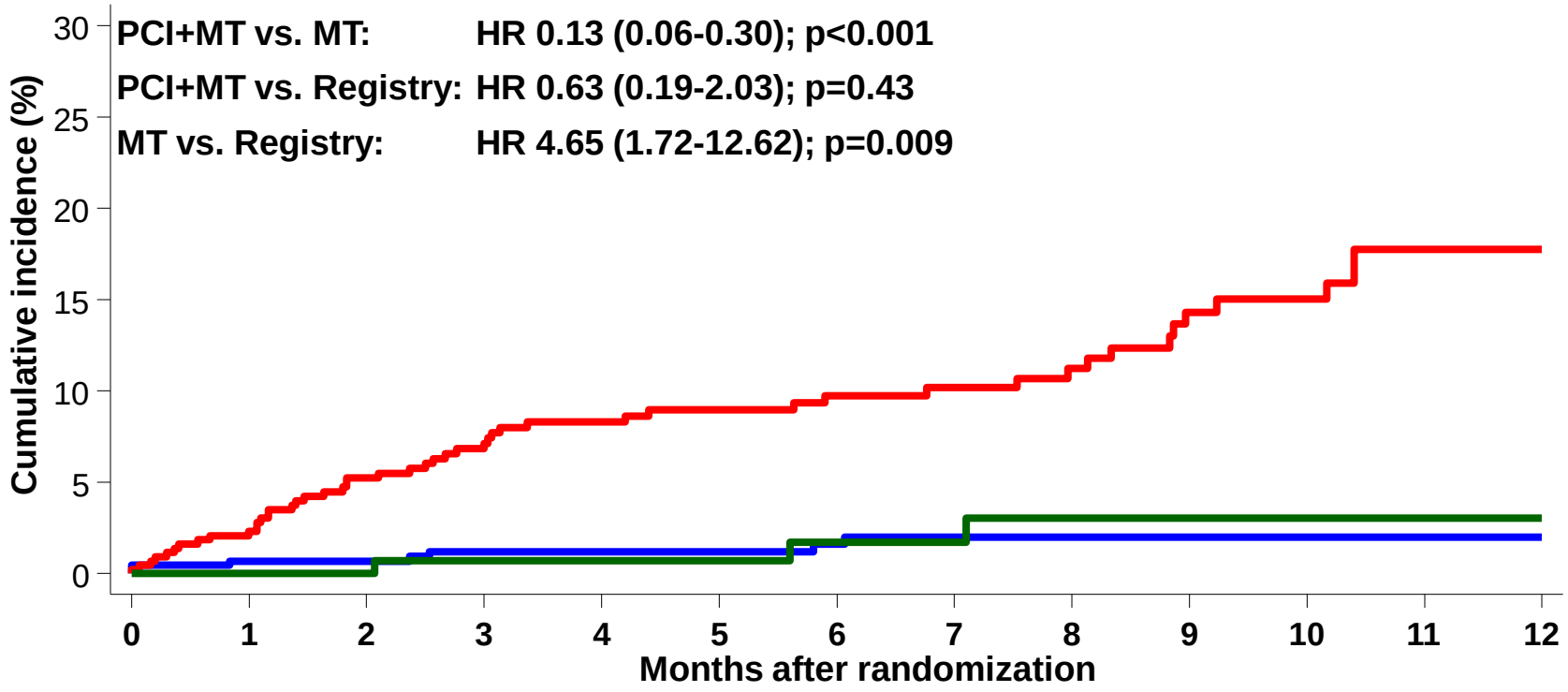
Primary Outcomes



No. at risk

MT	441	414	370	322	283	253	220	192	162	127	100	70	37
PCI+MT	447	414	388	351	308	277	243	212	175	155	117	92	53
Registry	166	156	145	133	117	106	93	74	64	52	41	25	13

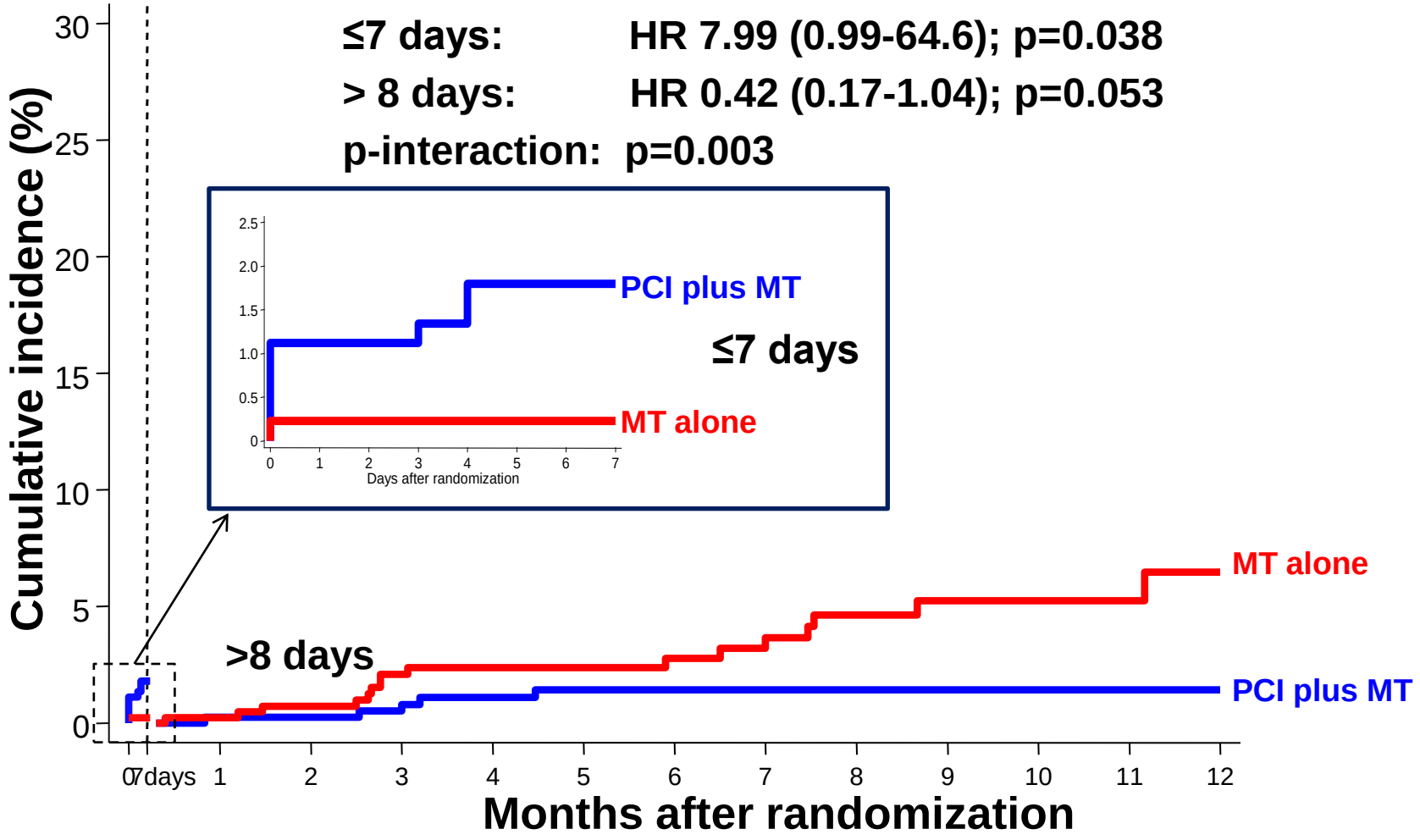
Urgent Revascularization



No. at risk

MT	441	414	371	325	286	256	223	195	164	129	101	71	38
PCI+MT	447	421	395	356	315	285	248	217	180	160	119	93	53
Registry	166	156	145	133	117	106	94	75	65	53	42	26	13

Kaplan-Meier plots of Landmark Analysis of Death or MI



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