
Fractional Flow Reserve Trials: *Review and Update*

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest /arrangement or affiliation with the organization(s) listed below

Affiliation/Financial Relationship

Grant/ Research Support:

Grant/ Research Support:

Consulting Fees/Honoraria:

Major Stock Shareholder/Equity Interest:

Royalty Income:

Ownership/Founder:

Salary:

Intellectual Property Rights:

Other Financial Benefit (minor stock options):

Company

St. Jude Medical

NIH-R01 HL093475 (PI)

Medtronic

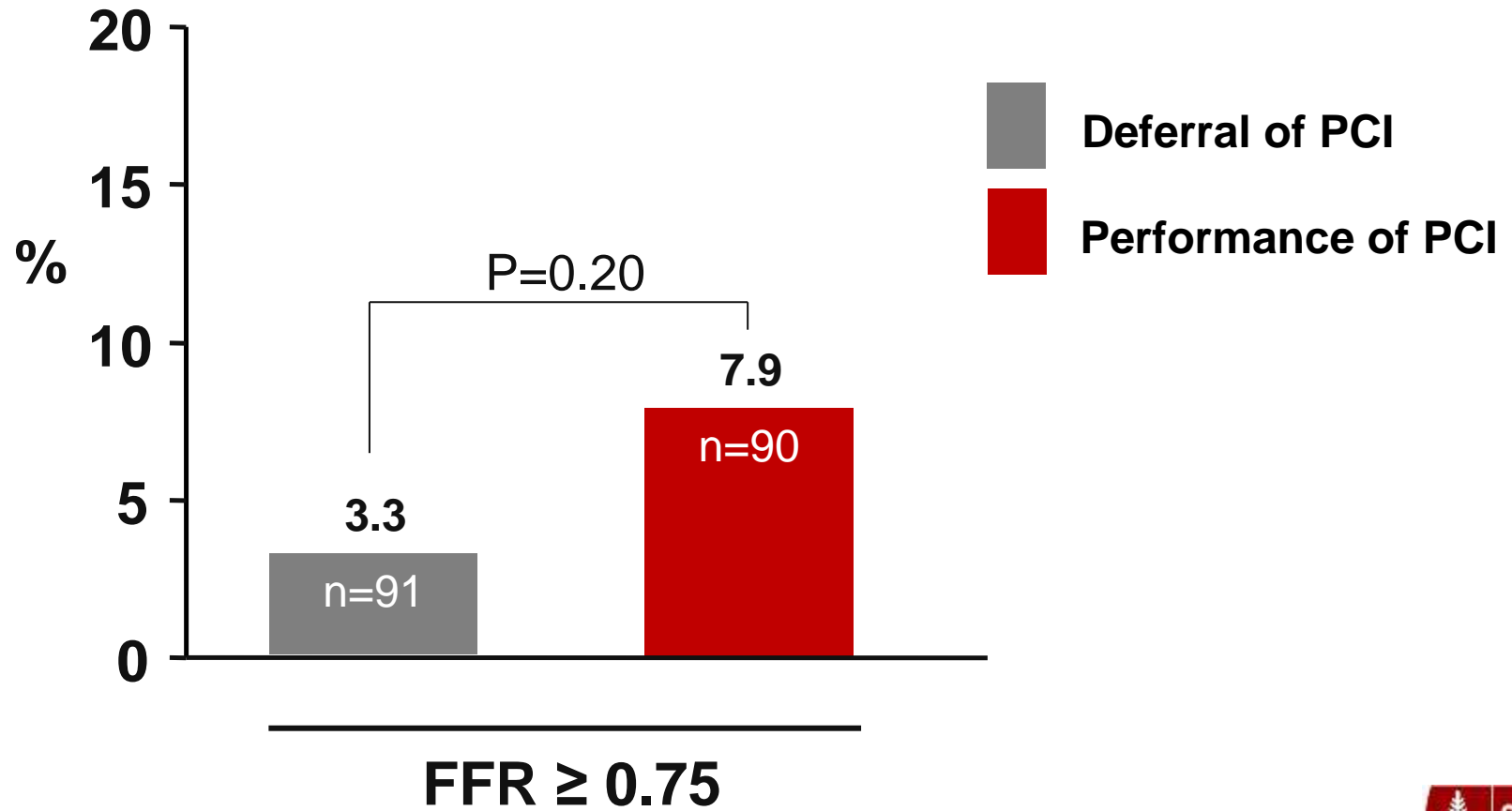
NIH-R01 HL093475 (PI)

HeartFlow

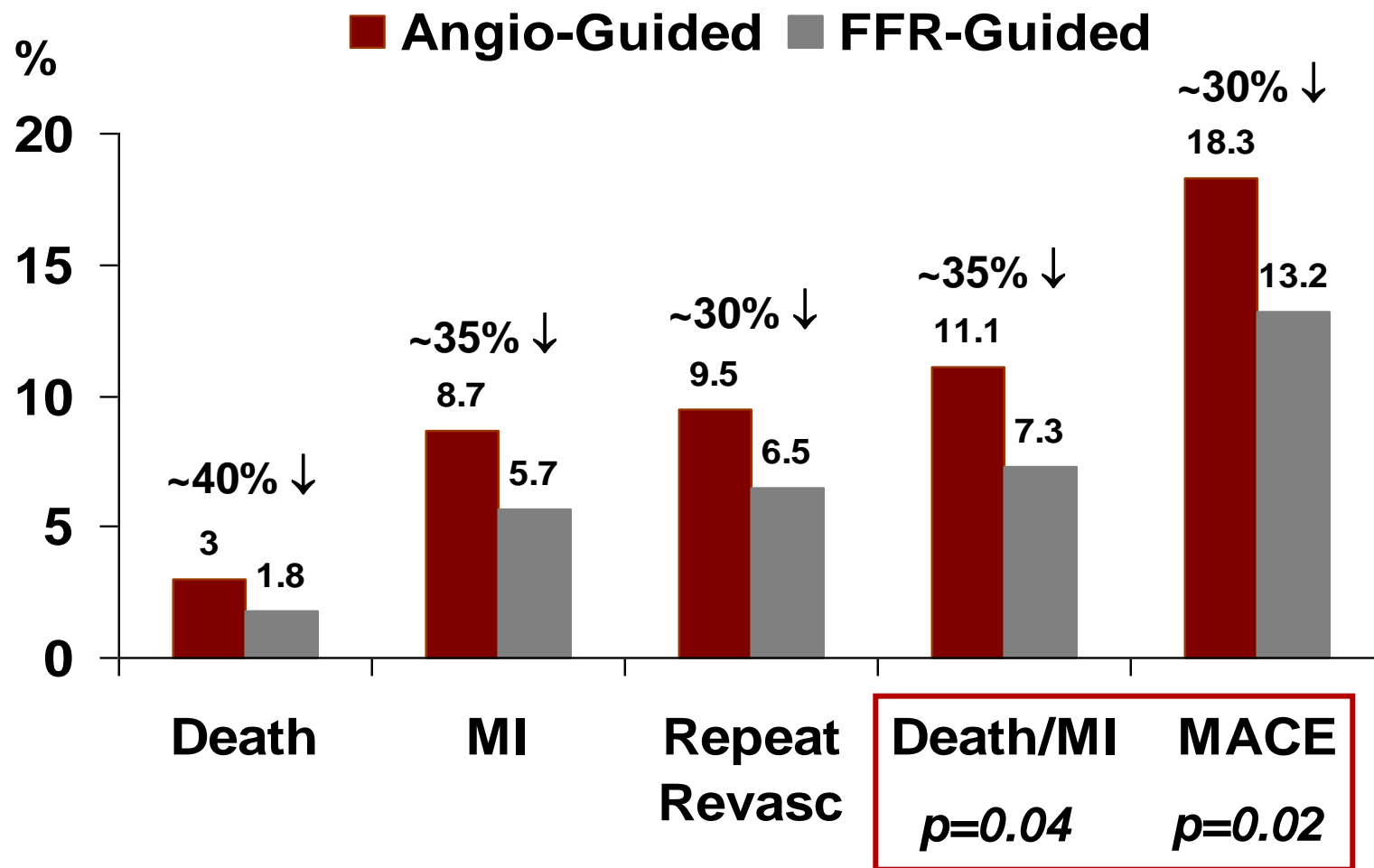


Safety of Deferring PCI Based on FFR

5 Year Cardiac Death and MI rate in DEFER trial



FAME Trial: One Year Outcomes

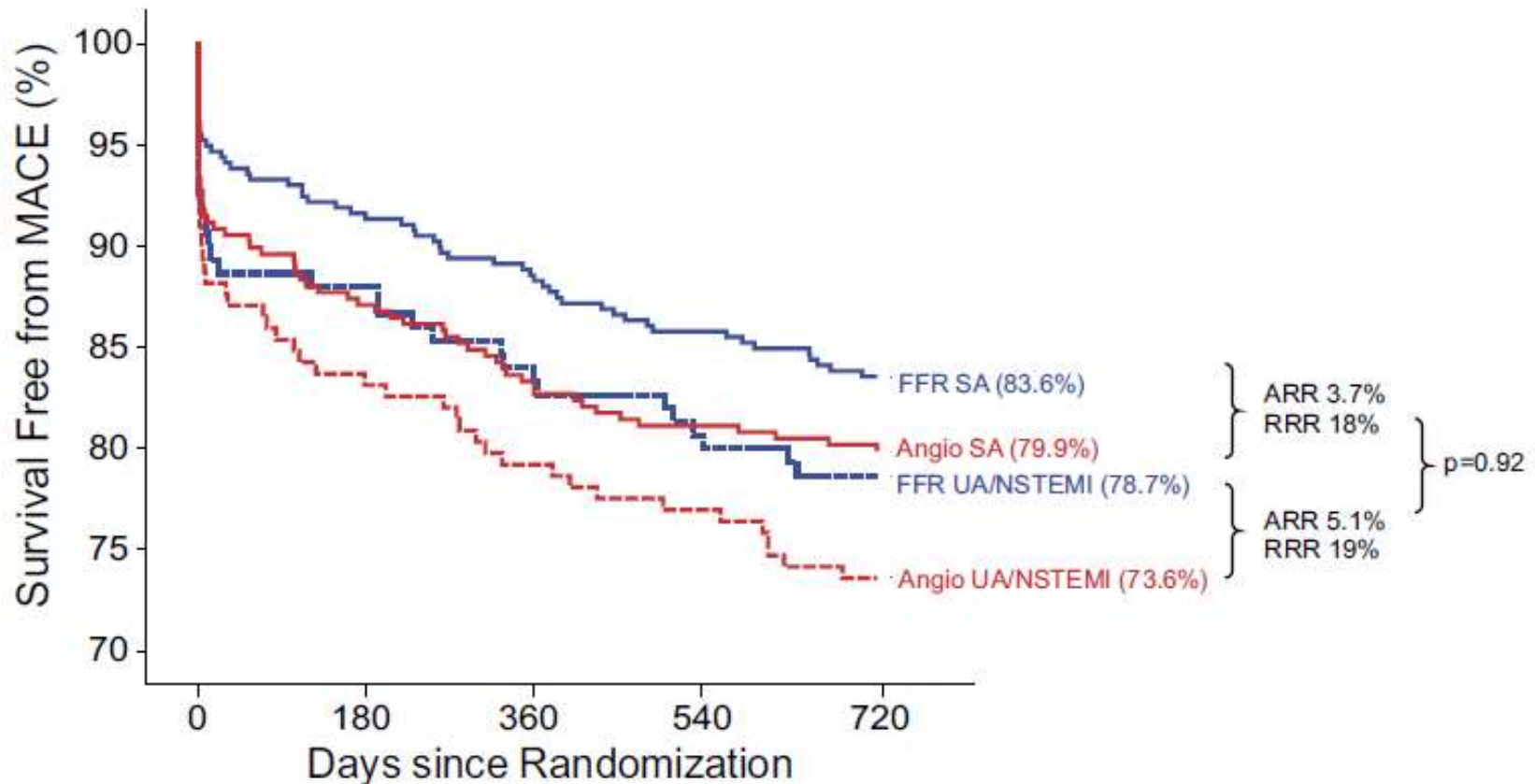


Tonino, et al. New Engl J Med 2009;360:213-24.



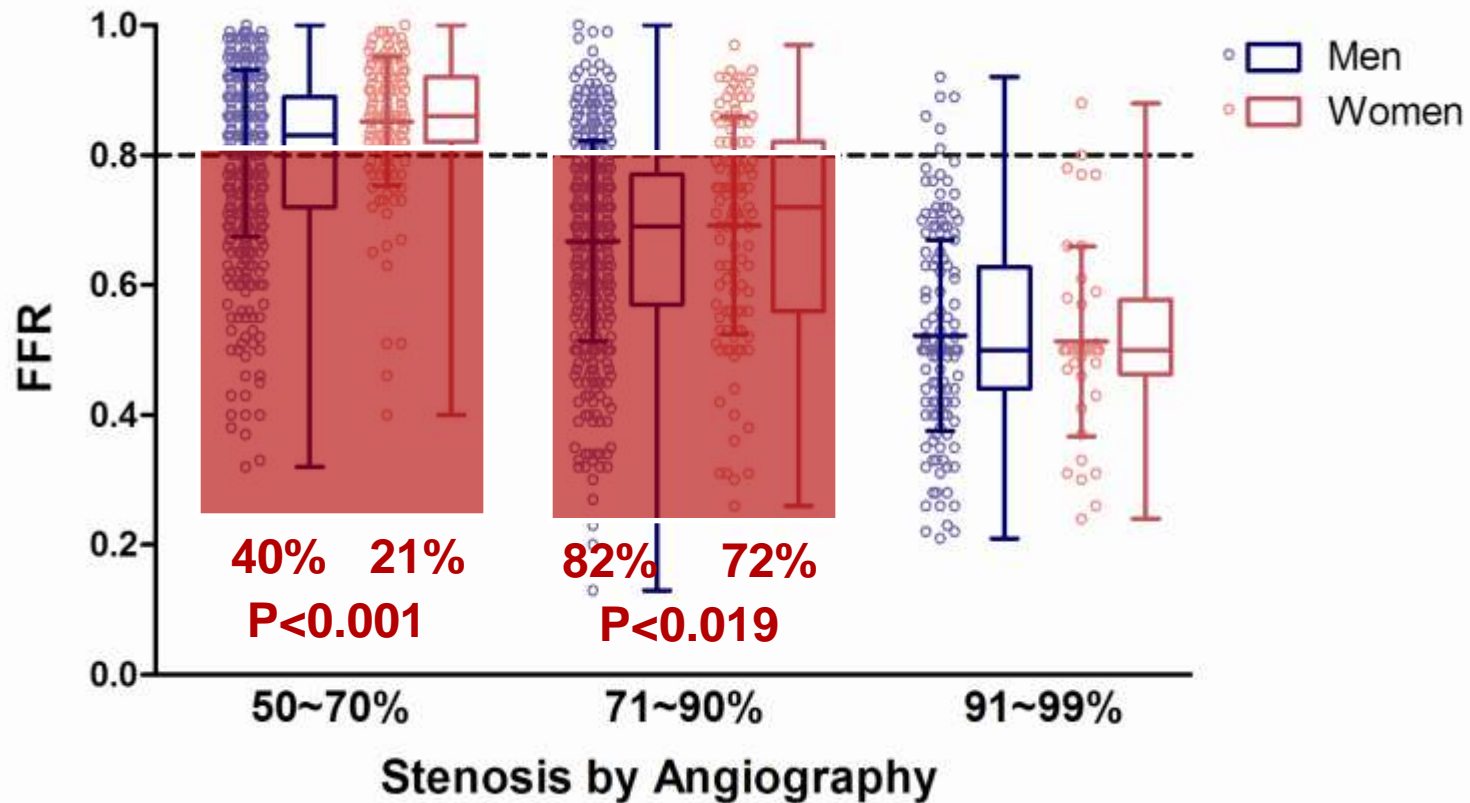
FFR and Acute Coronary Syndromes

328 of the 1,005 patients in FAME had UA or NSTEMI



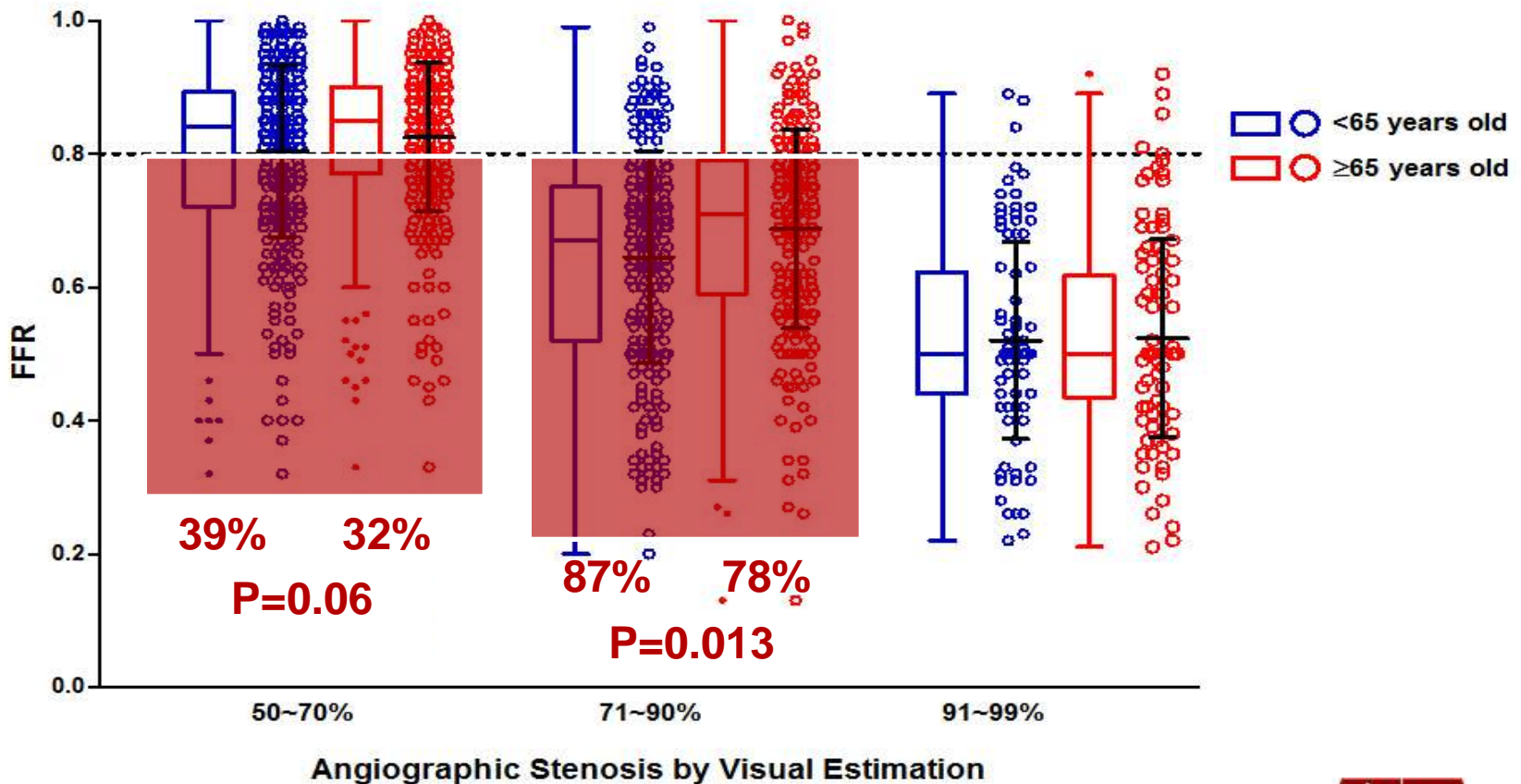
FFR-Guided PCI in Women

FFR was significantly higher in women than men in the FAME Trial (0.75 ± 0.18 vs. 0.71 ± 0.17 , $p=0.001$)



Effect of Age on FFR-Guided PCI

Patients ≥ 65 years old had a significantly higher mean FFR across all lesions as compared to patients < 65 years old (0.73 vs. 0.70, $p=0.029$)



Anatomic vs. Functional CAD

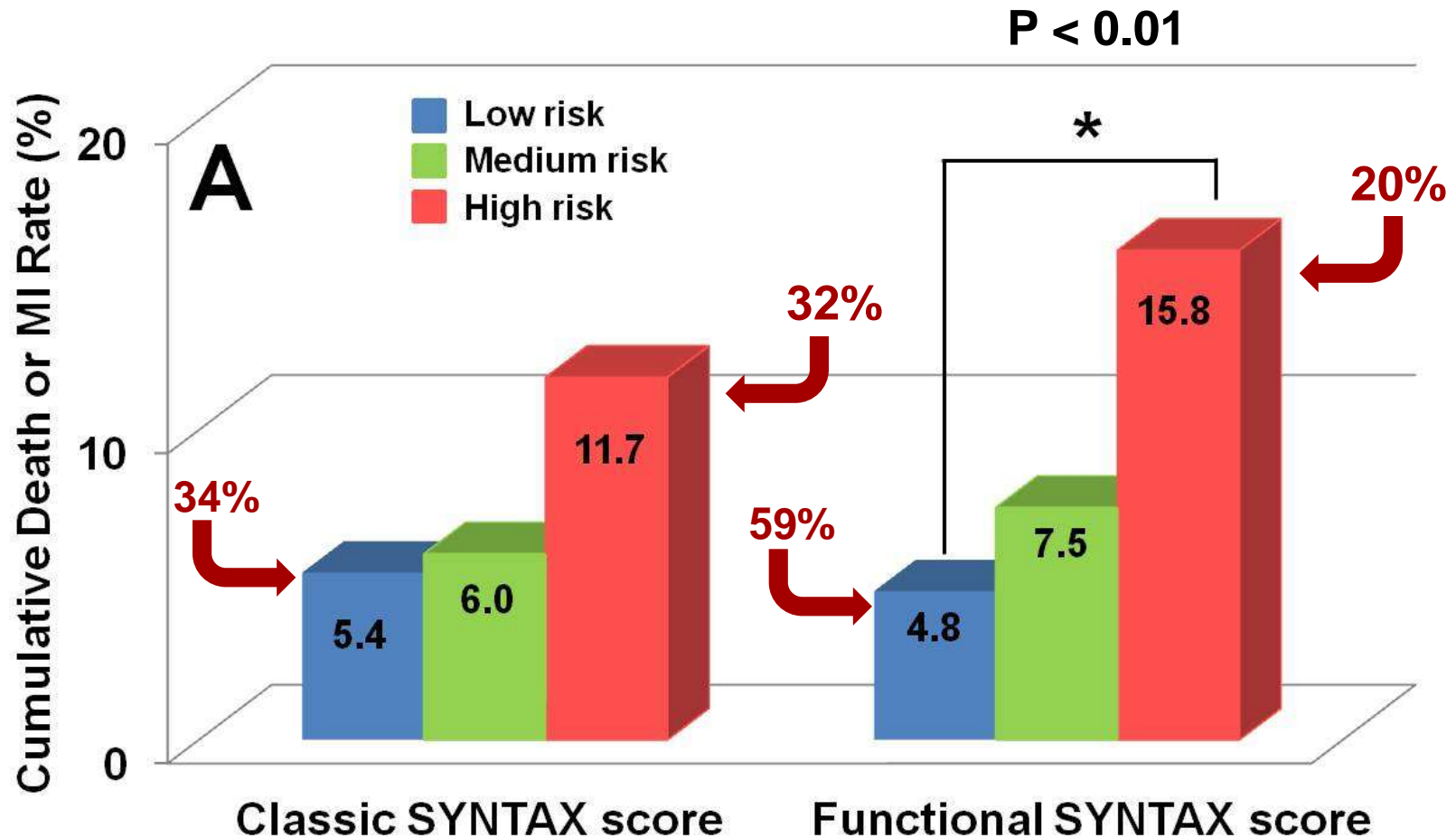
Patients with angiographically 3VD (N=115), proportions per number of diseased vessels after assessment by FFR

***Angiographic
3 Vessel
Disease***



Functional SYNTAX Score

FSS Discriminates Risk for Death/MI



FAME 2

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 $\text{FFR} \leq 0.80$ (n=888)

Randomization 1:1

PCI + MT

MT

73%

When all $\text{FFR} > 0.80$
(n=332)

MT

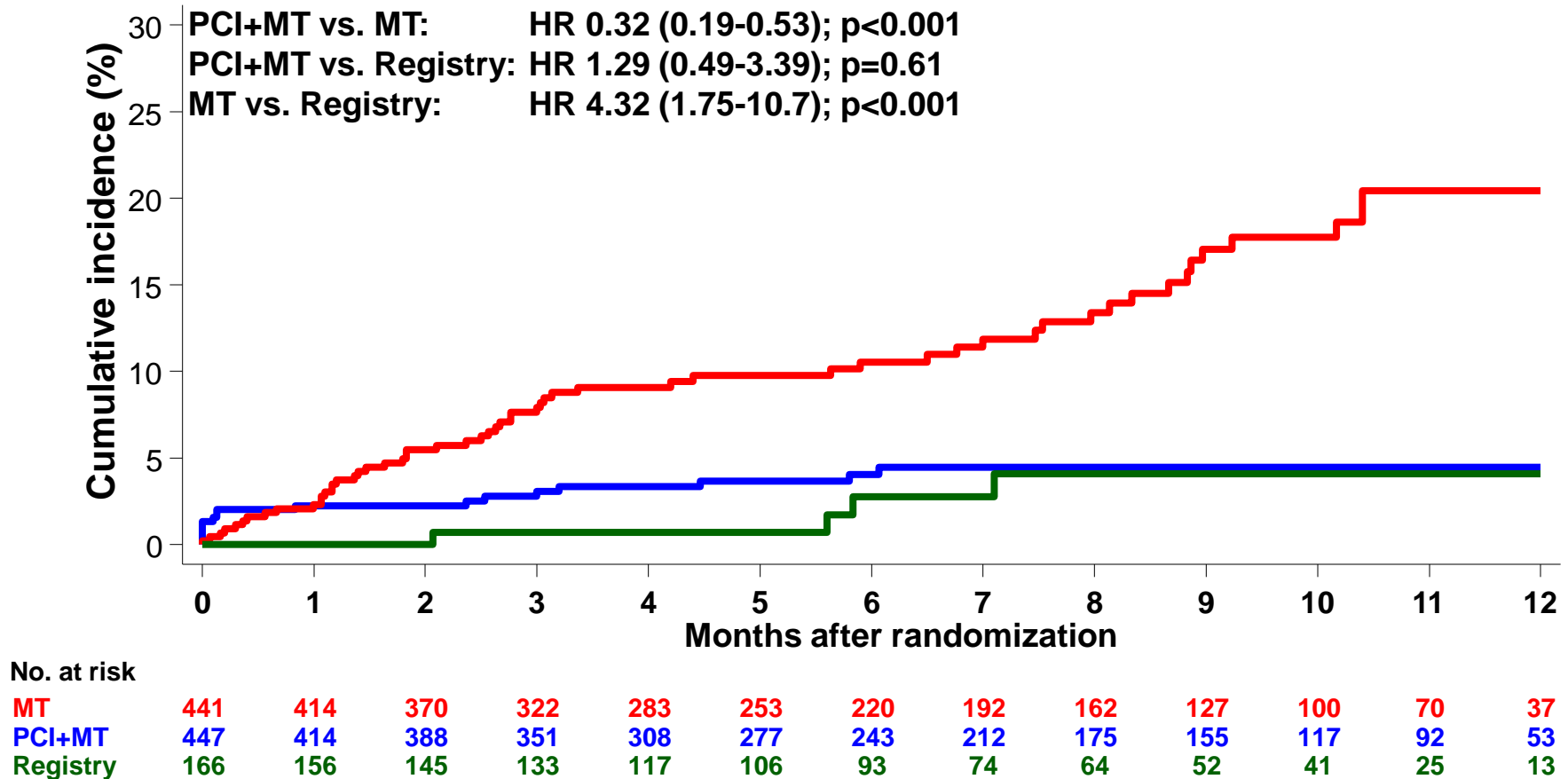
27%

50% randomly
assigned to FU

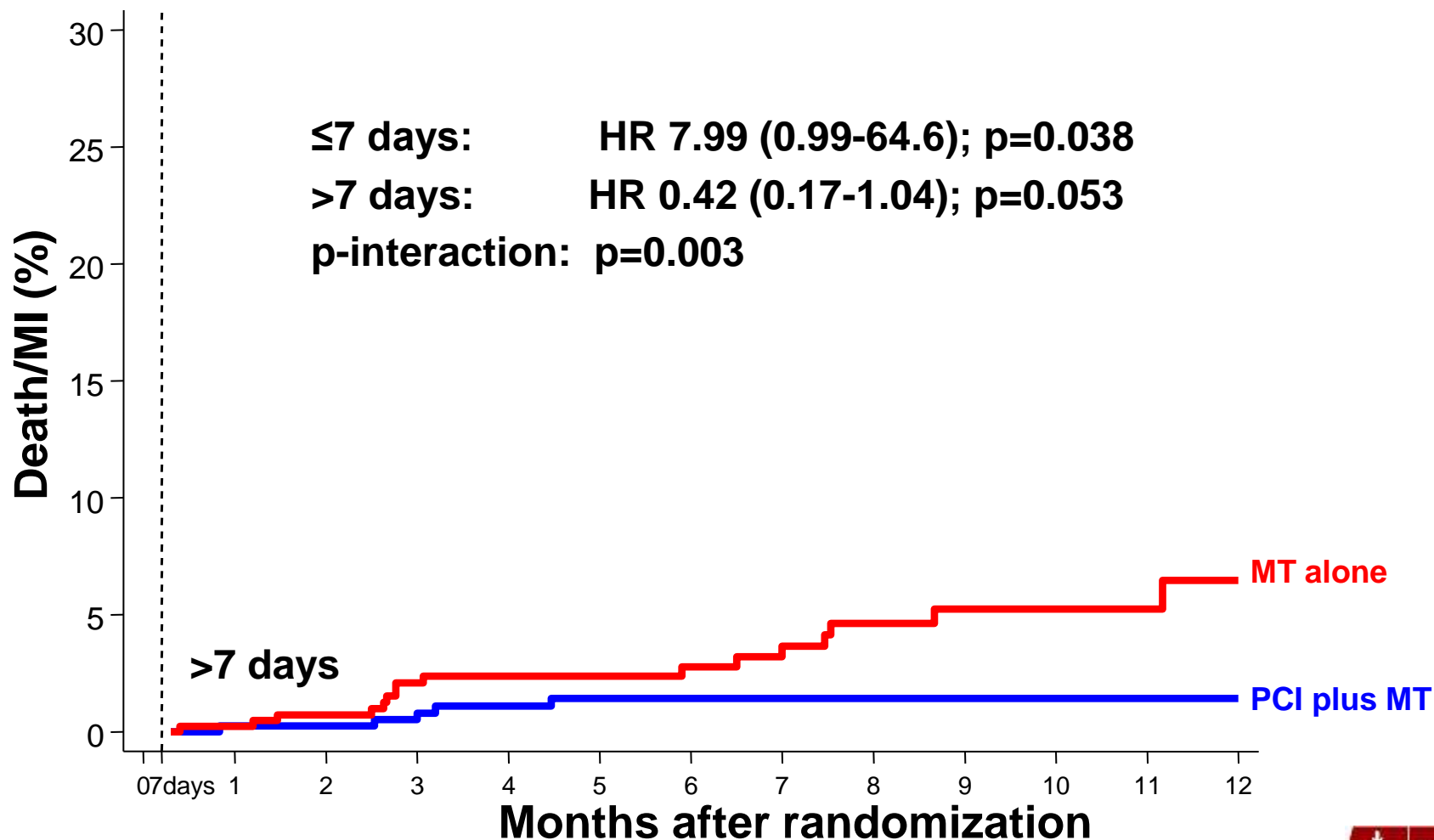
Primary Endpoint: Death, MI or Urgent Revascularization at 2 Yr



Primary Endpoint: *Death, MI, Urgent Revasc*

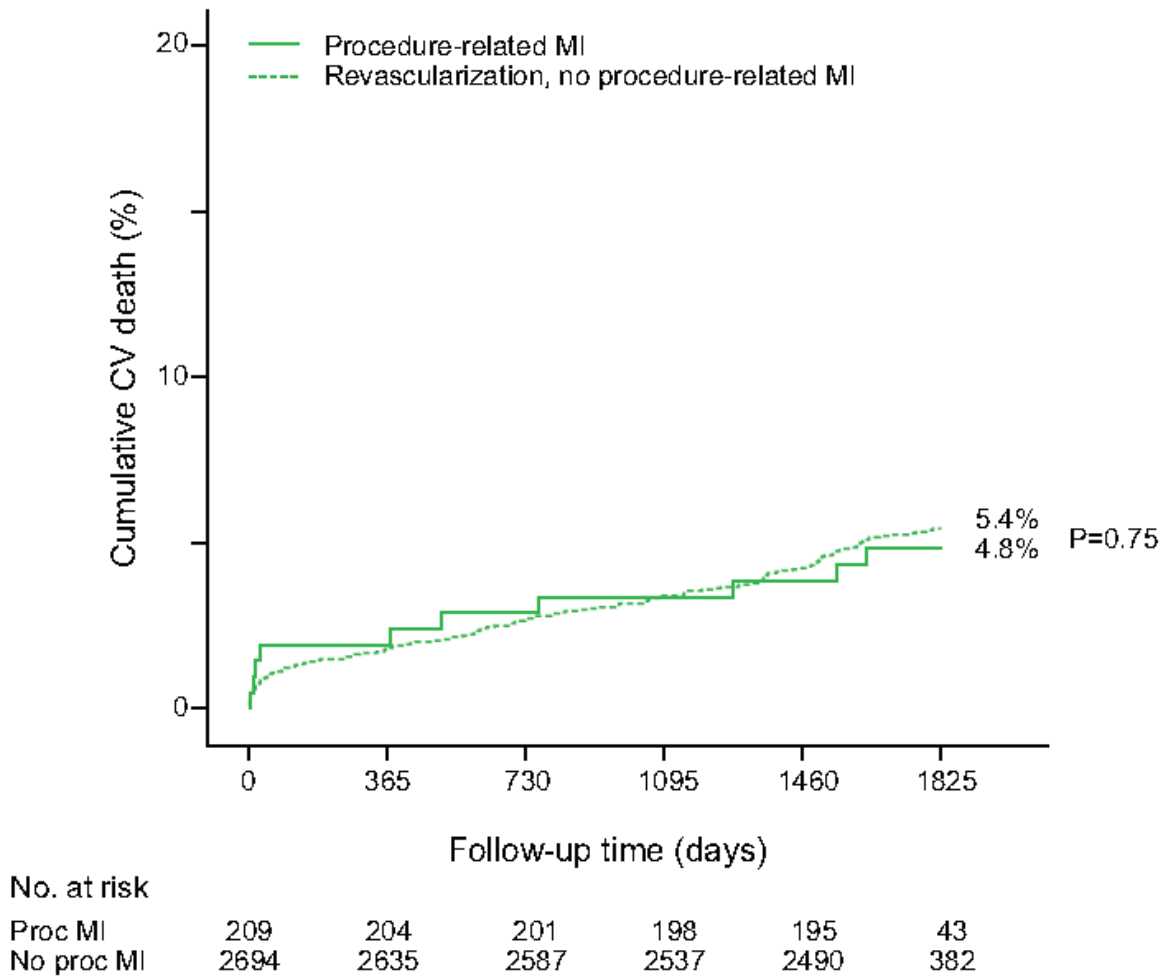


Landmark Analysis for Death/MI



Spontaneous vs. Procedural MI

5 year F/U in 5,467 patients from RITA-3, ICTUS, and FRISC-II

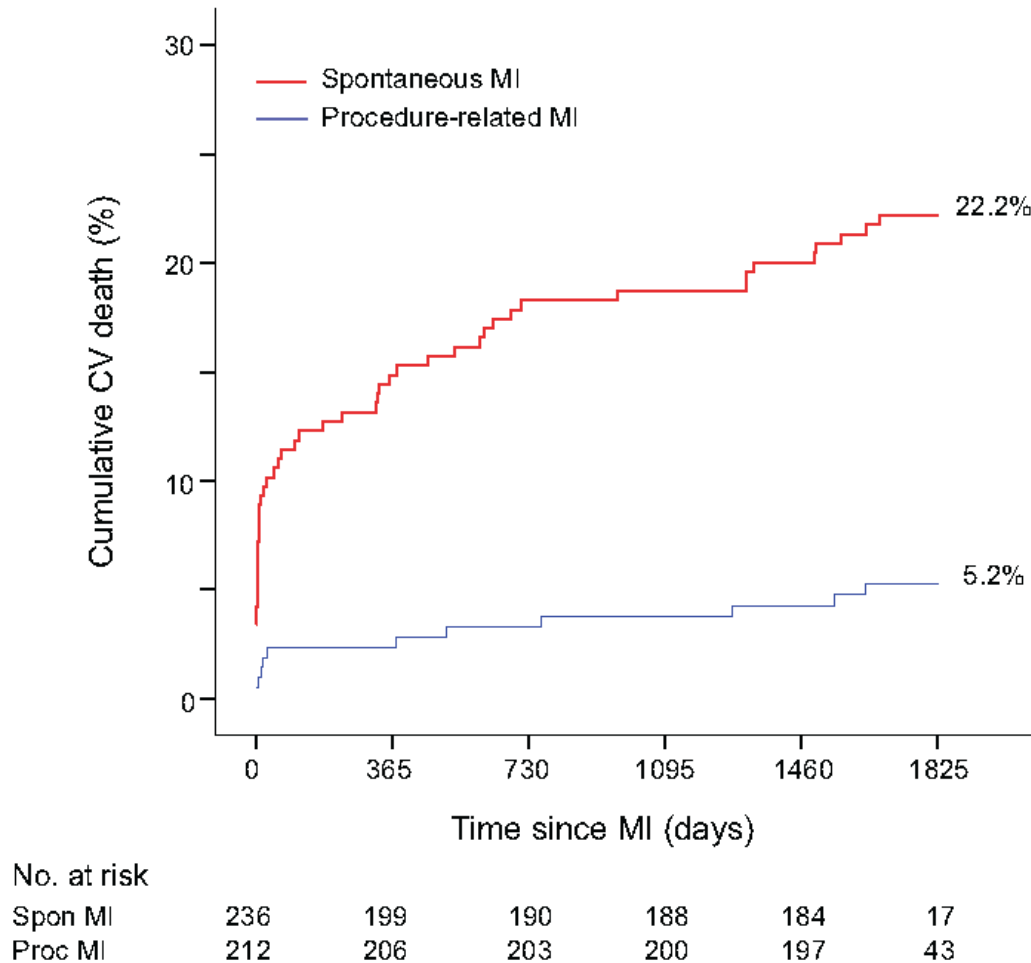


Damman, et al. Circulation 2012;125:568-576.



Spontaneous vs. Procedural MI

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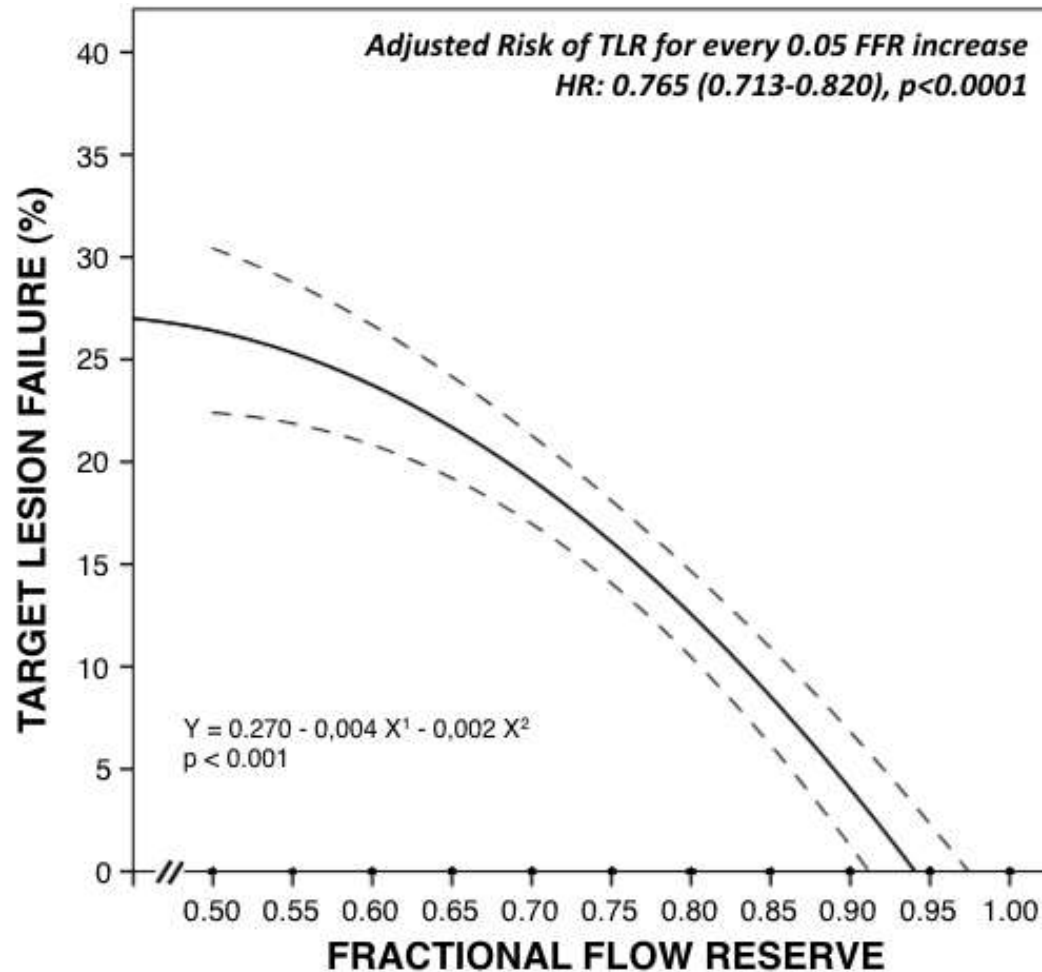


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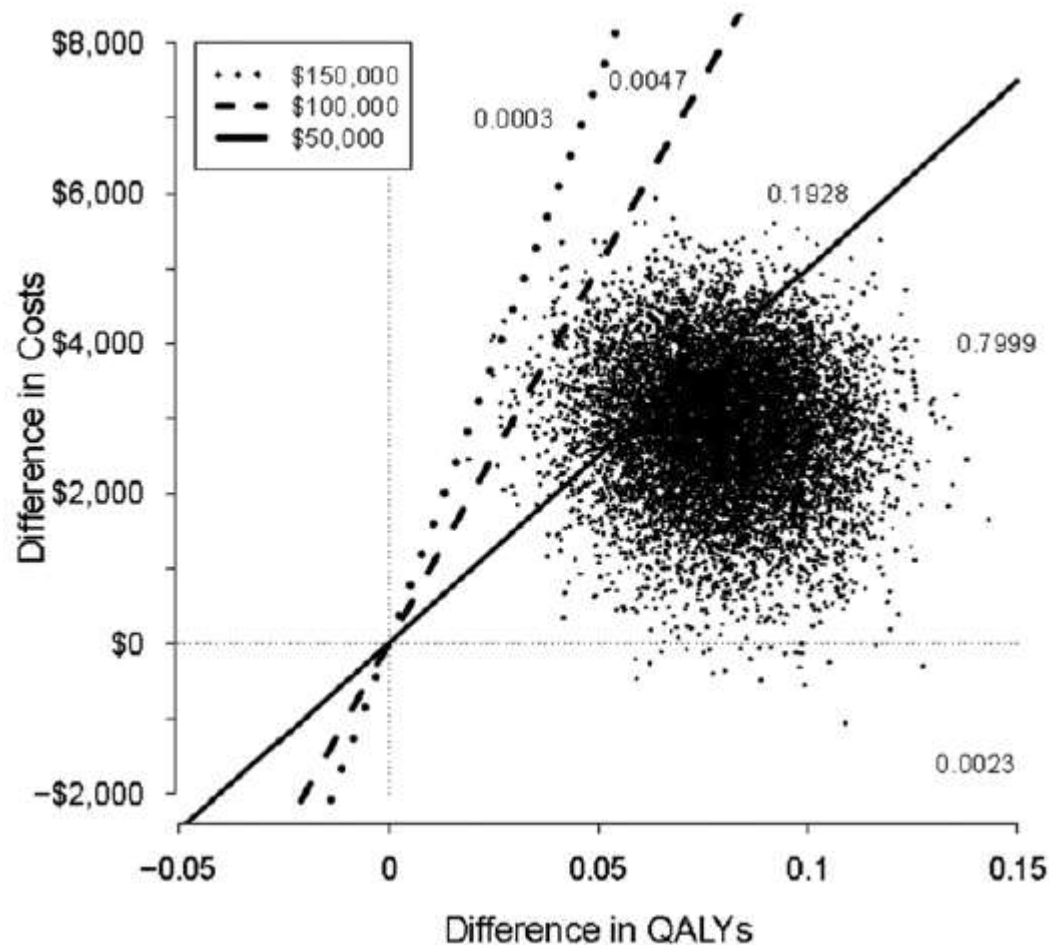


Relationship between FFR and MACE

607 medically treated patients in FAME 2



FAME 2: Cost-Effectiveness



80% of the 10,000 replications were below the \$50,000/QALY willingness-to-pay threshold and 99.5% were below the \$100,000/QALY threshold



Real World FFR Use

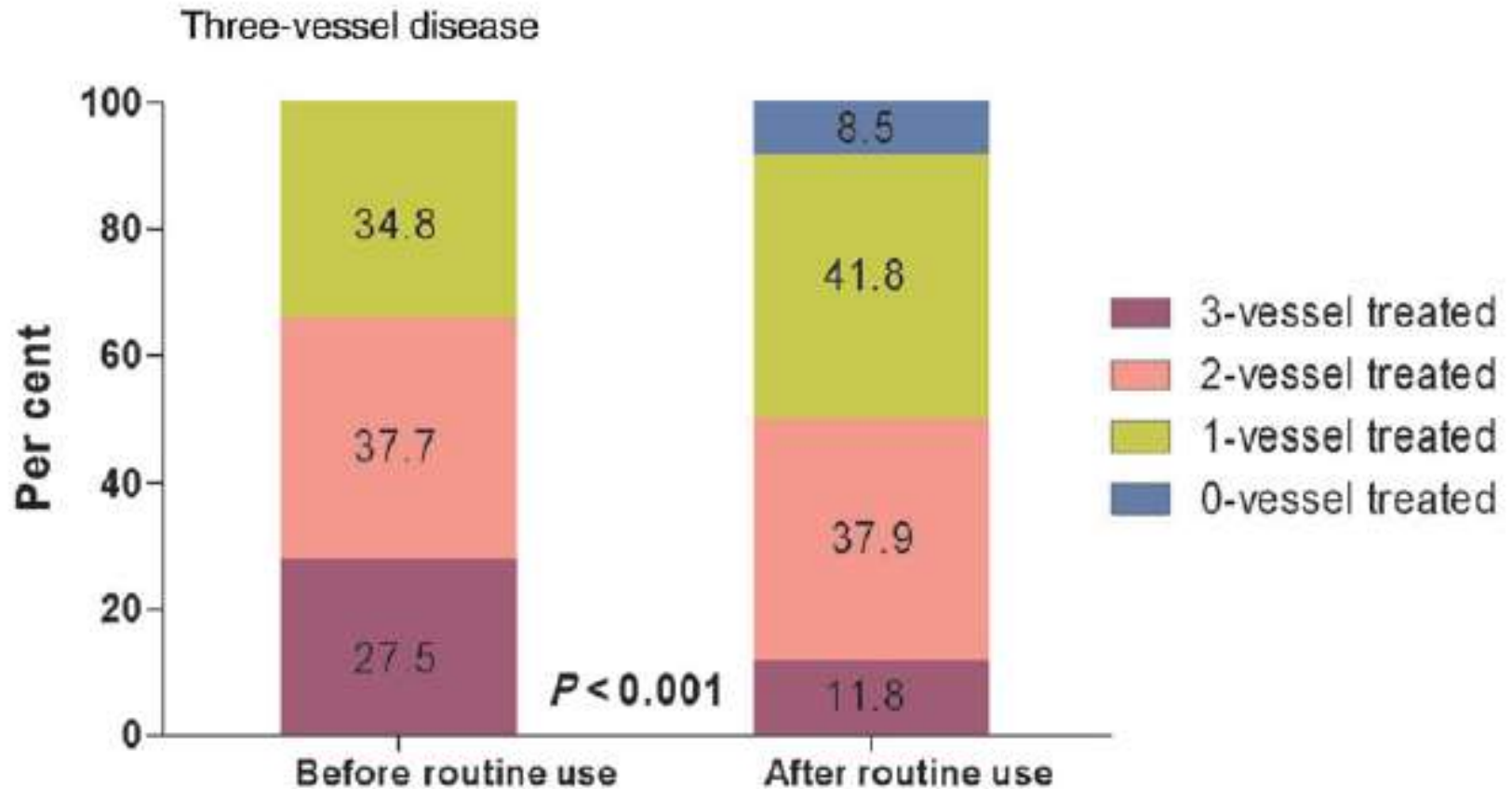
7,358 consecutive patients referred for PCI (1,090 FFR-Guided)

Events	Adjusted ^a HR	95% CI	P-value
.....			
FFR use vs. no FFR			
MACE	1.01	0.89–1.14	0.93
Death	0.89	0.73–1.10	0.28
MI	0.79	0.58–1.07	0.12
Death/revascularization	1.003	0.88–1.14	0.96
Death/MI	0.85	0.71–1.01	0.06



Real World FFR Use

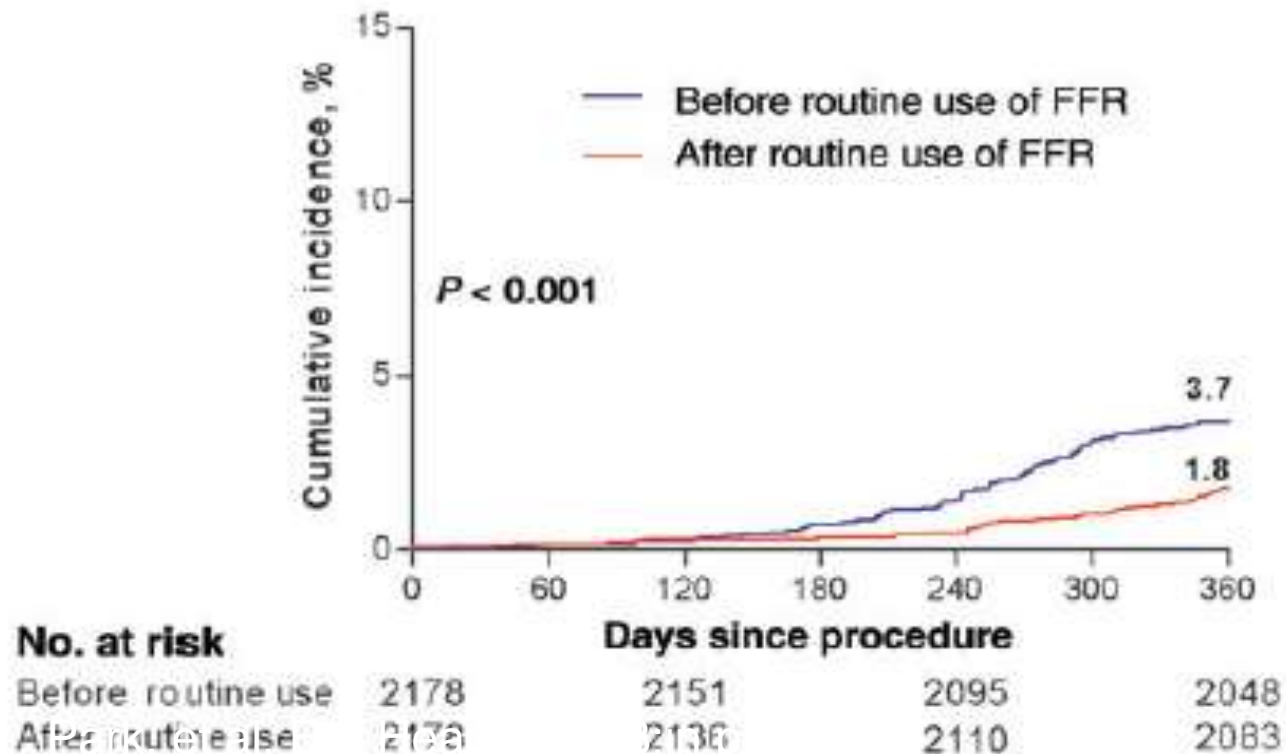
2,178 pairs of propensity matched patients before and after routine FFR use



Real World FFR Use

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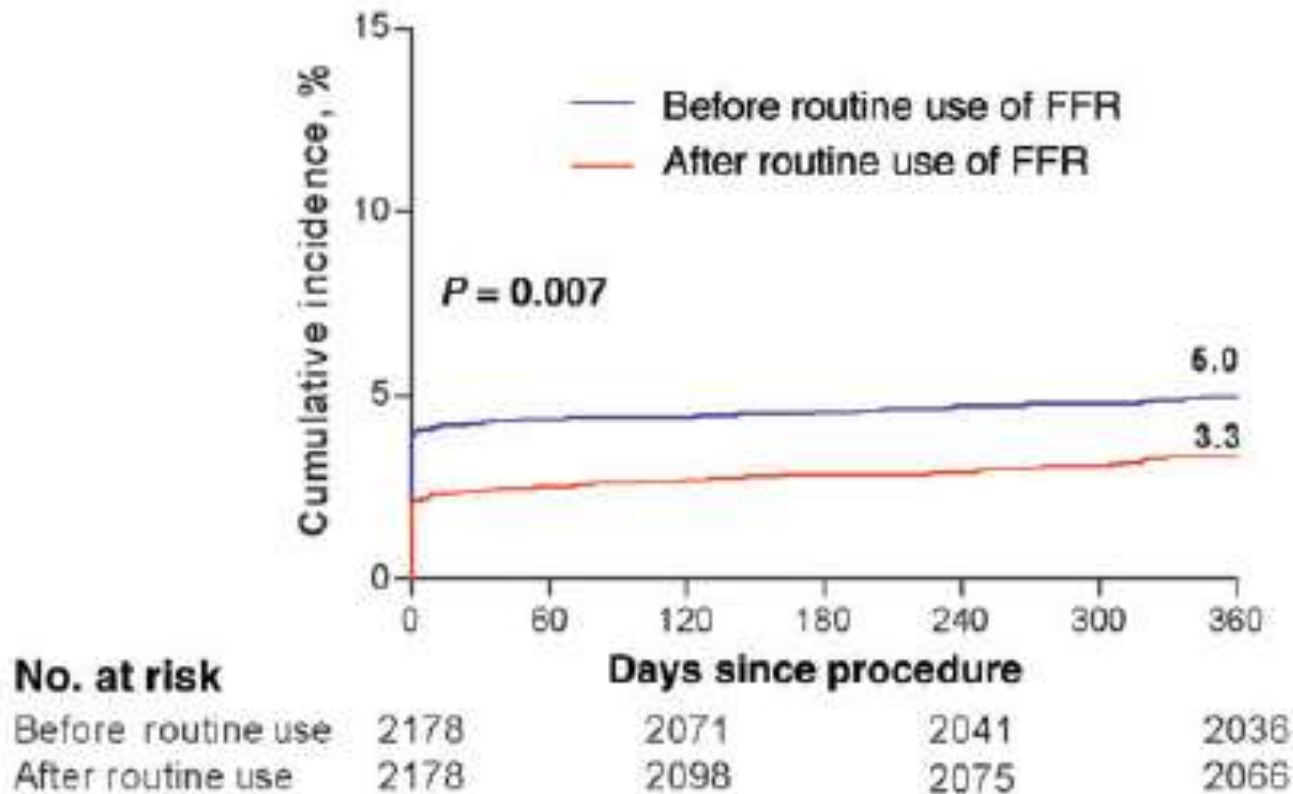
Repeat revascularization



Real World FFR Use

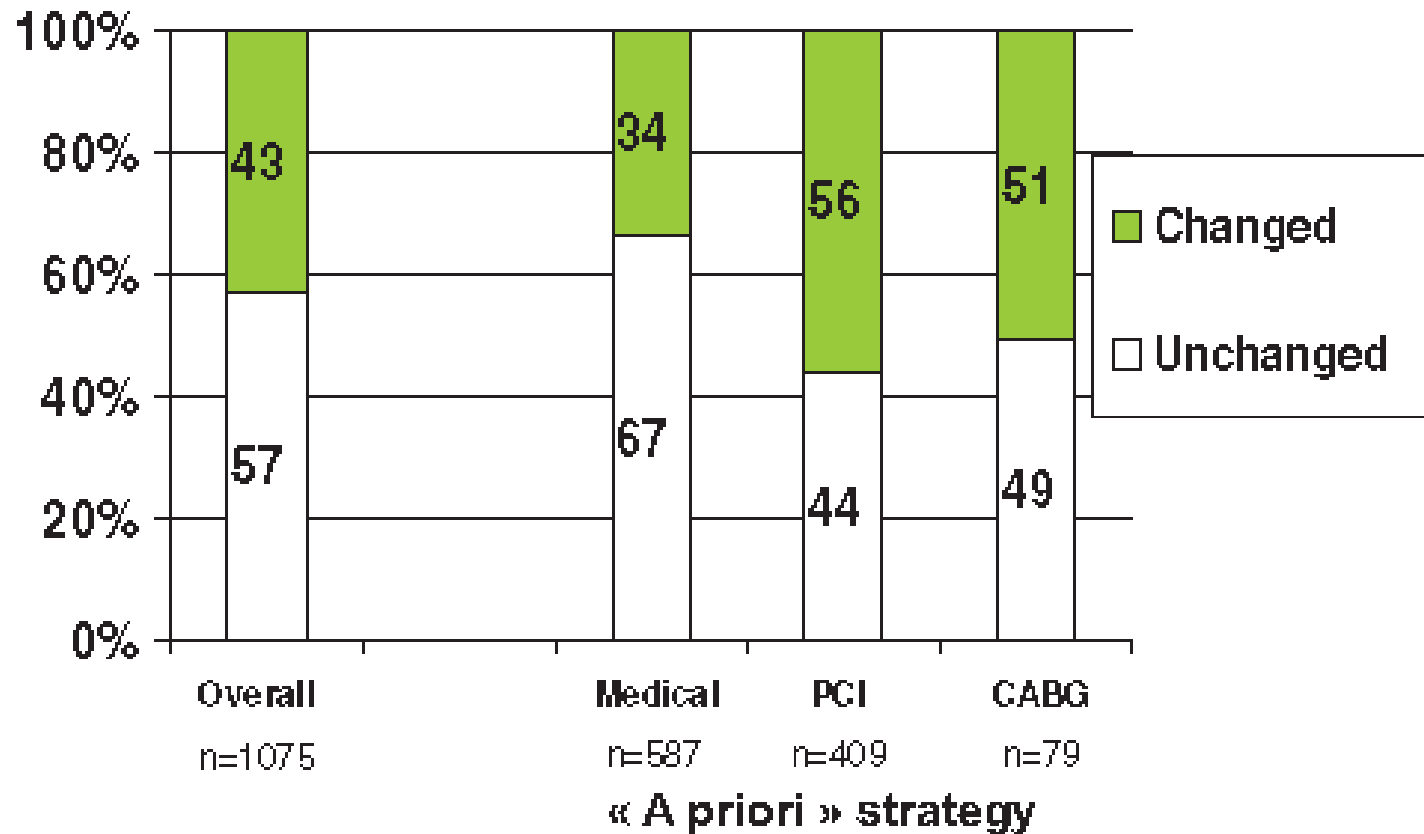
2,178 pairs of propensity matched patients before and after routine FFR use

Death or myocardial infarction



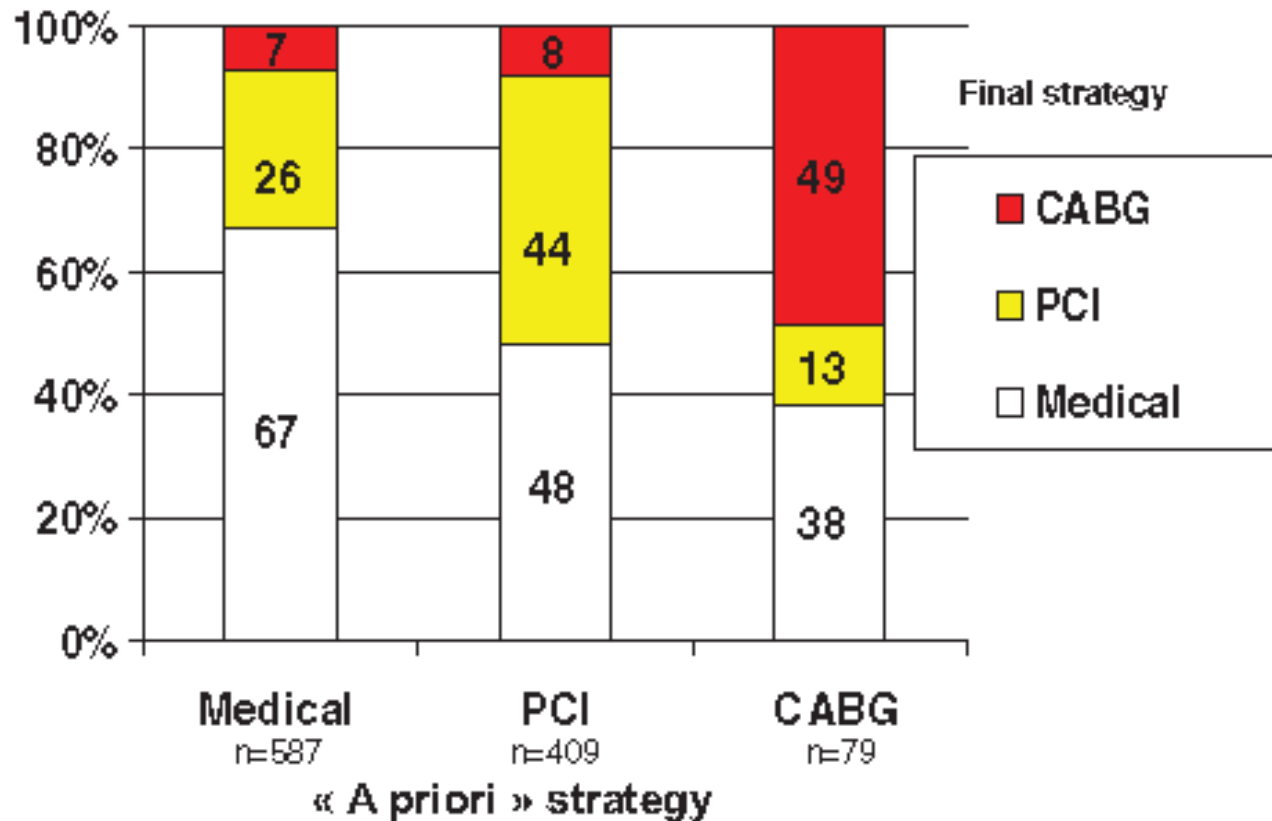
Real World FFR Use

1,075 consecutive patients undergoing FFR at 20 French centers



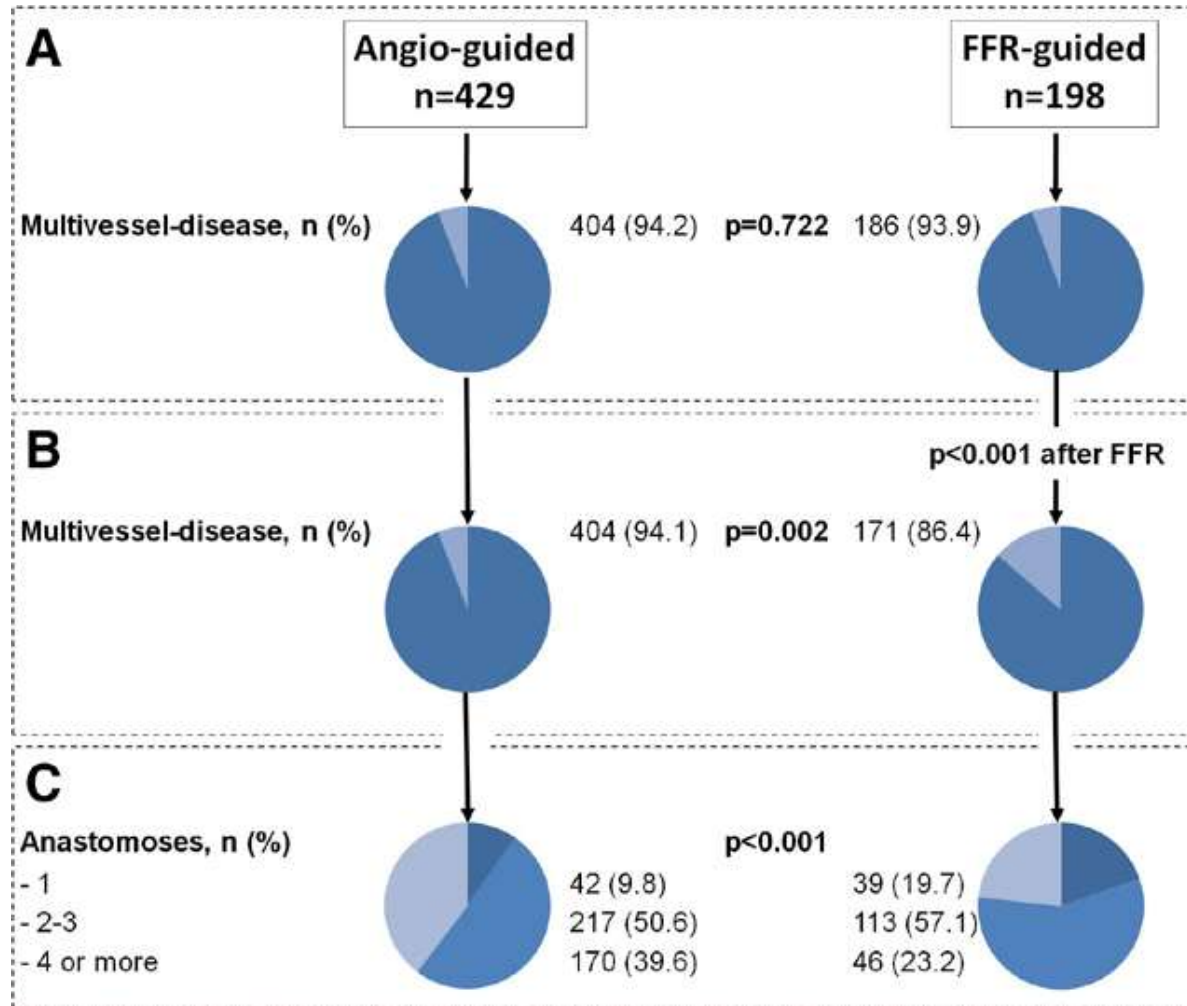
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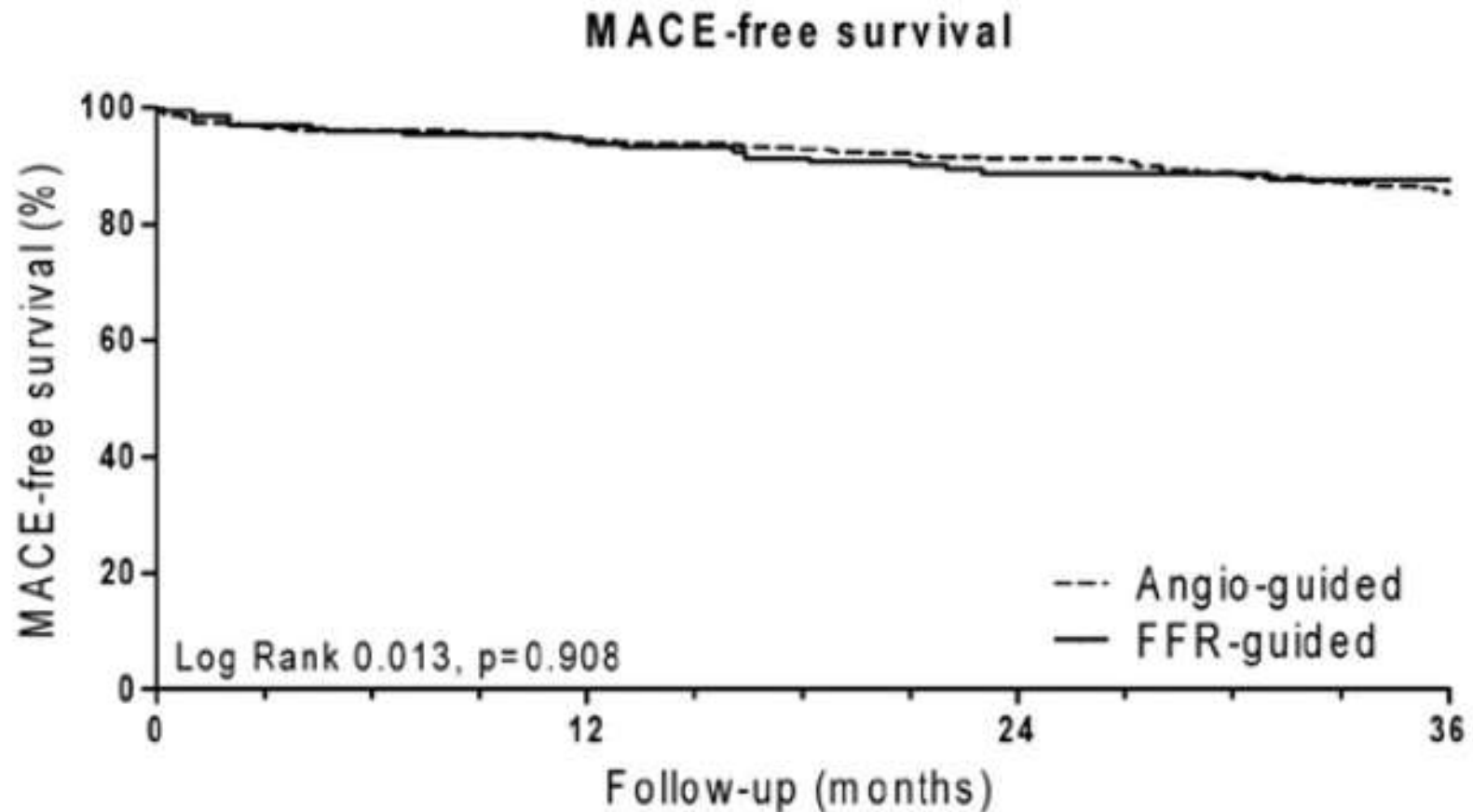
FFR-Guided CABG?

Of 627 consecutive CABG patients, 198 had FFR guidance on at least one lesion



FFR-Guided CABG?

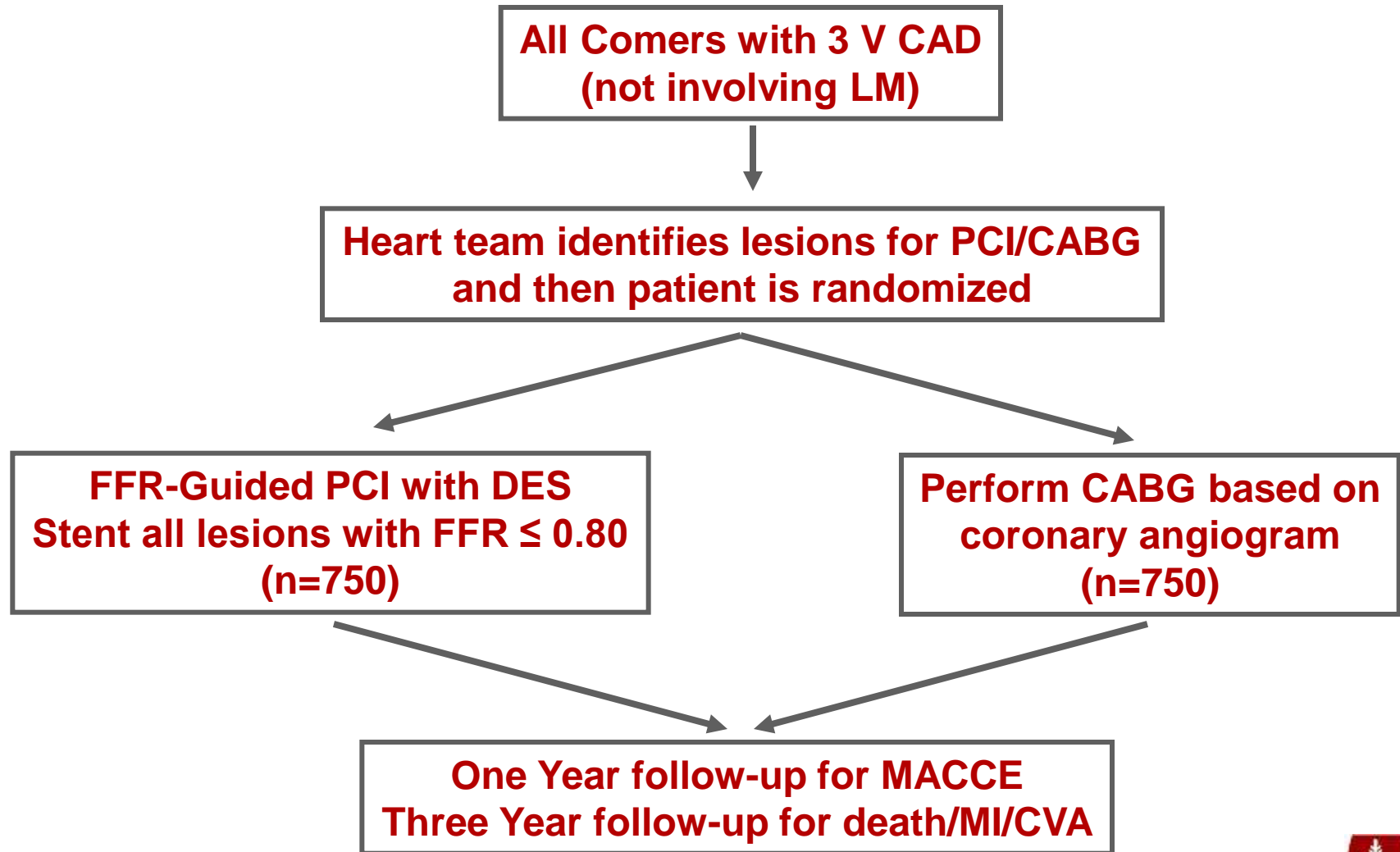
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What's Next?



FAME 3 Trial:



Conclusions:

- Sub-studies from FAME 1 highlight the role of FFR-guided PCI in various subgroups.
- FAME 2 demonstrated the benefit of FFR-guided PCI in stable patients, as compared to medical therapy.
- Real world registries support the findings of the randomized studies showing that FFR-guided PCI improves outcomes.

