



The Series of FAME Studies:

A Paradigm Shift in Our Thinking About Interventional Cardiology

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Disclosures

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

Consulting Fees/Stock Options

Major Stock Shareholder/Equity

Royalty Income

Ownership/Founder

Intellectual Property Rights

Other Financial Benefit

Company

Abbott, Medtronic

NIH R61 HL139929-01A1 (PI)

CathWorks (previous), HeartFlow



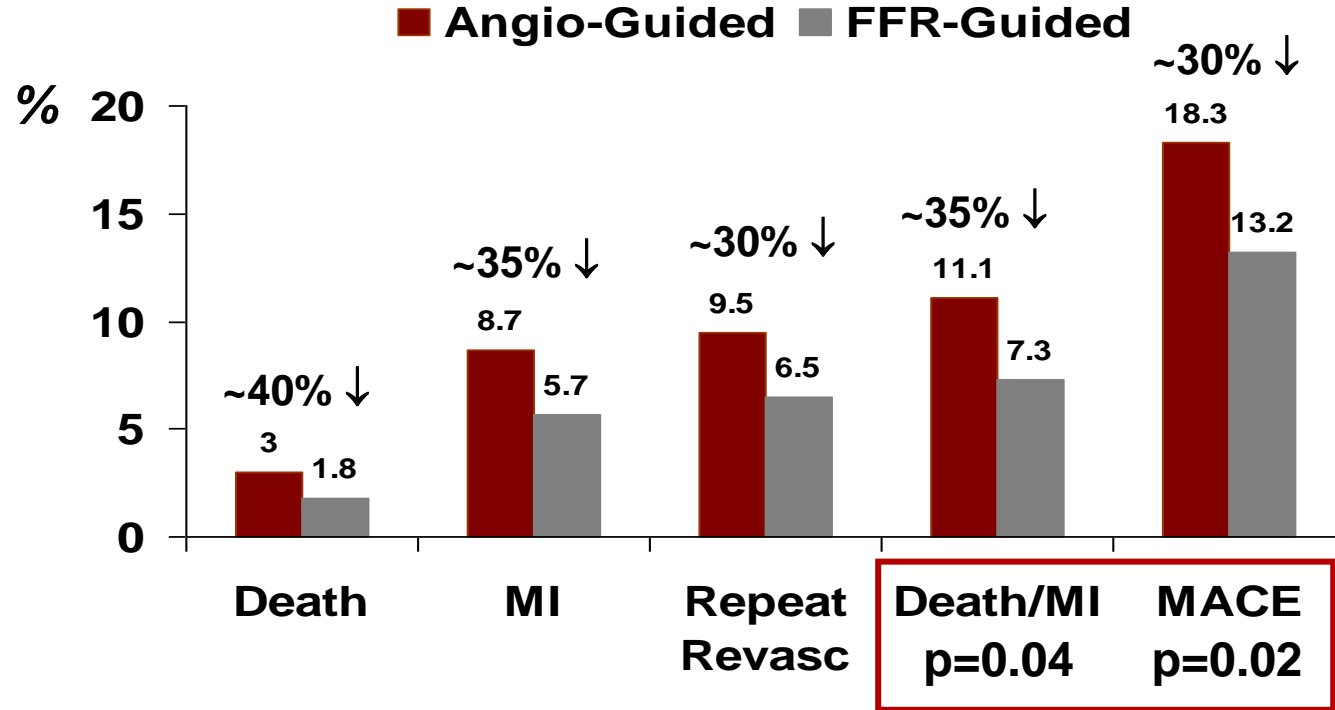
What has the FAME series taught us?

- Physiology-guided PCI simplifies treatment and improves outcomes in patients with multivessel CAD undergoing PCI.
- Physiology-guided evaluation identifies lesions which benefit most from PCI in patients with stable CAD.
- Physiology-guided evaluation identifies patients with complex, three-vessel CAD who will have an excellent outcome with PCI when compared with CABG.



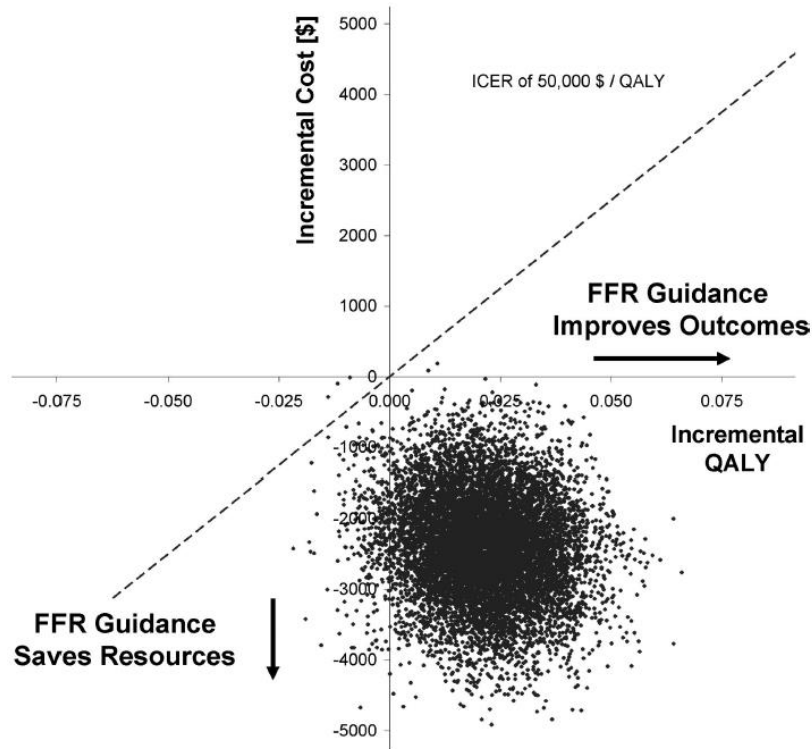
FAME 1: Primary Outcome

1,005 patients with multivessel CAD randomized to angio- or FFR-guided PCI



FAME 1: *Economic Evaluation*

Bootstrap Analysis



***FFR-guided PCI
saved >\$2,000 per
patient at one year
compared to Angio-
guided PCI***

FAME 1: *Visual:Functional Mismatch*

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



***Angiographic
3 Vessel
Disease***

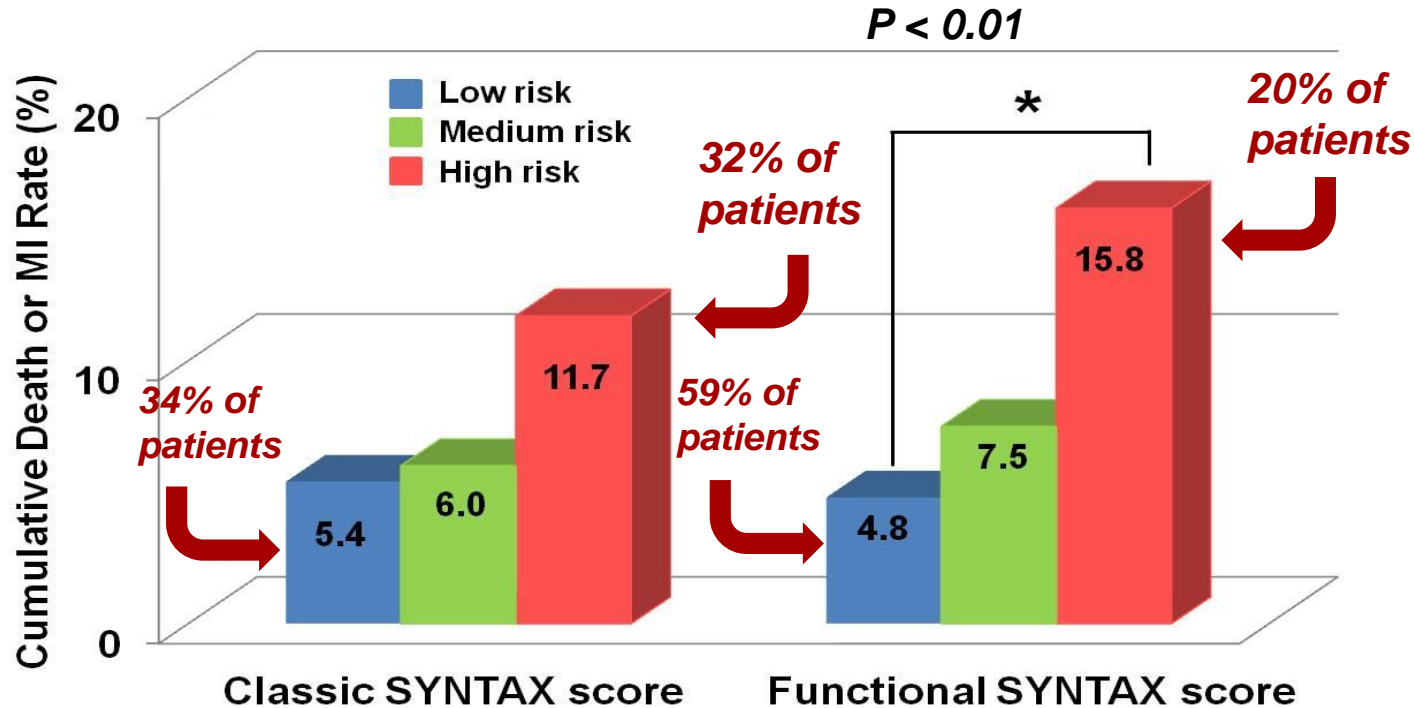
FAME 1: *Functional SYNTAX Score*

FSS Reclassifies > 30% of cases

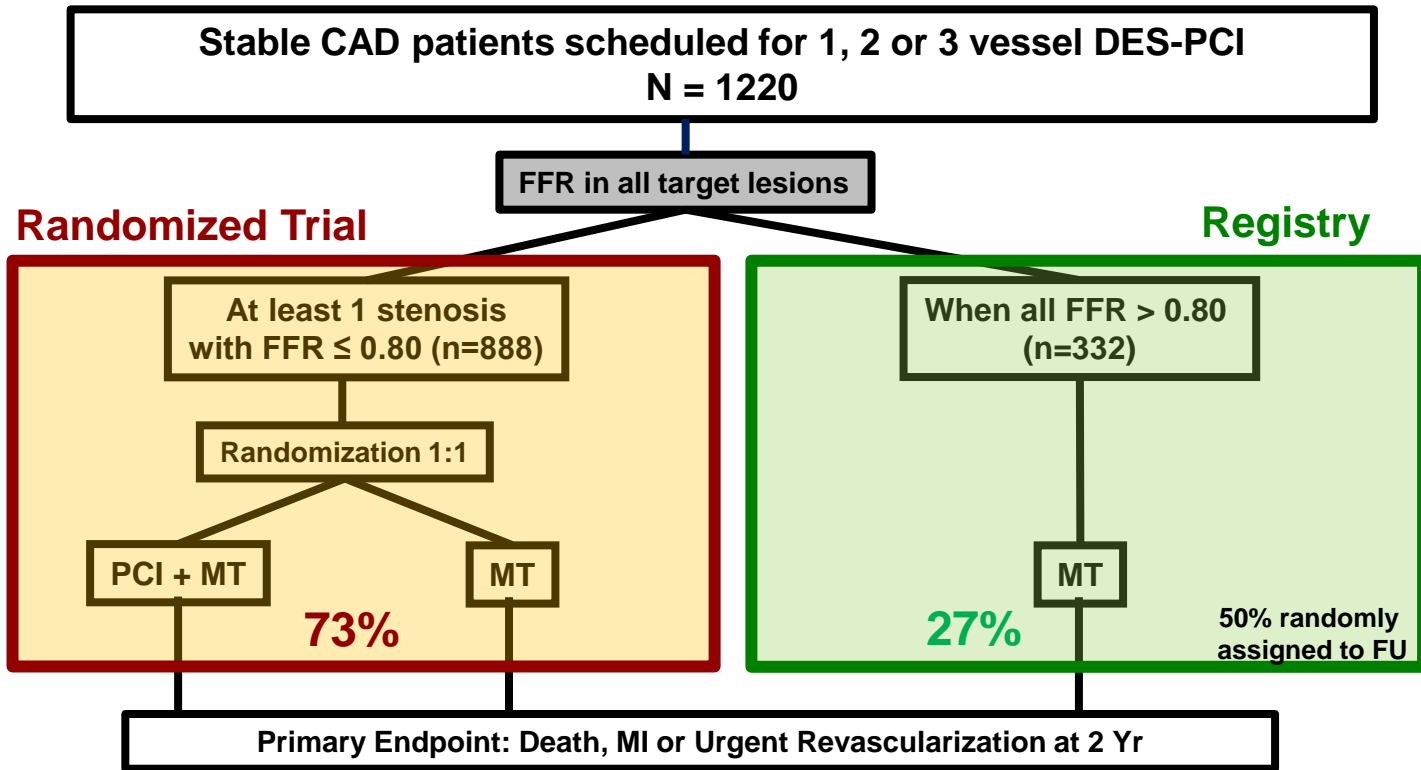


FAME 1: *Functional SYNTAX* Score

Discriminates Risk for Death/MI

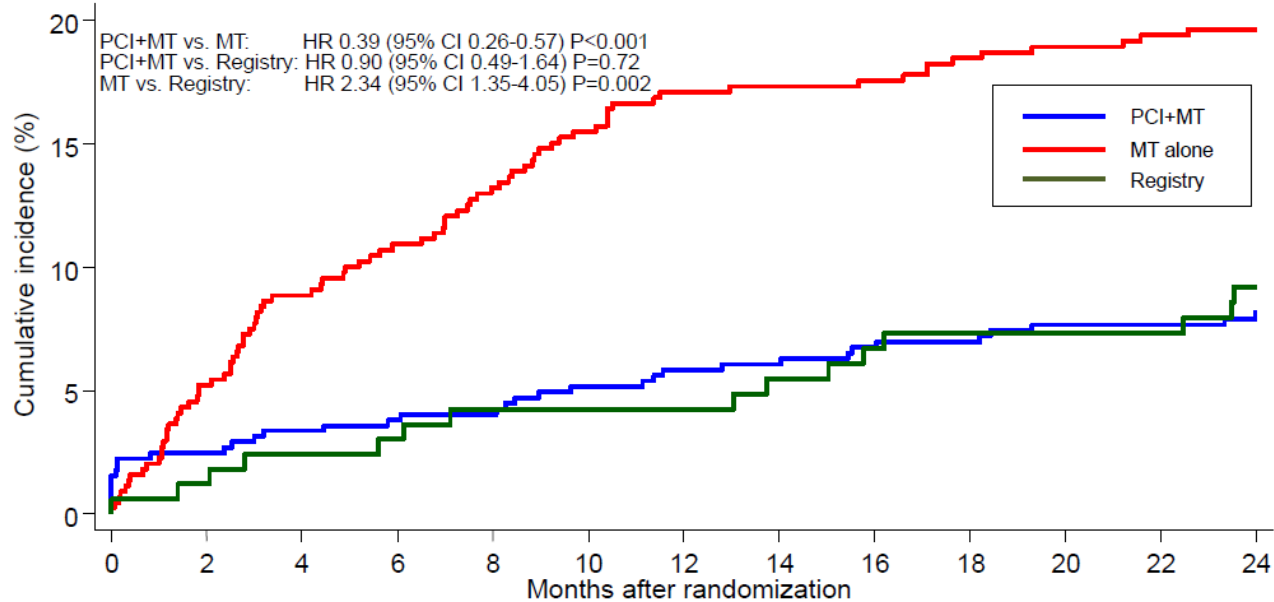


FAME 2



FAME 2: Primary Outcome

Two year rate of primary endpoint: Death, MI, Urgent Revascularization

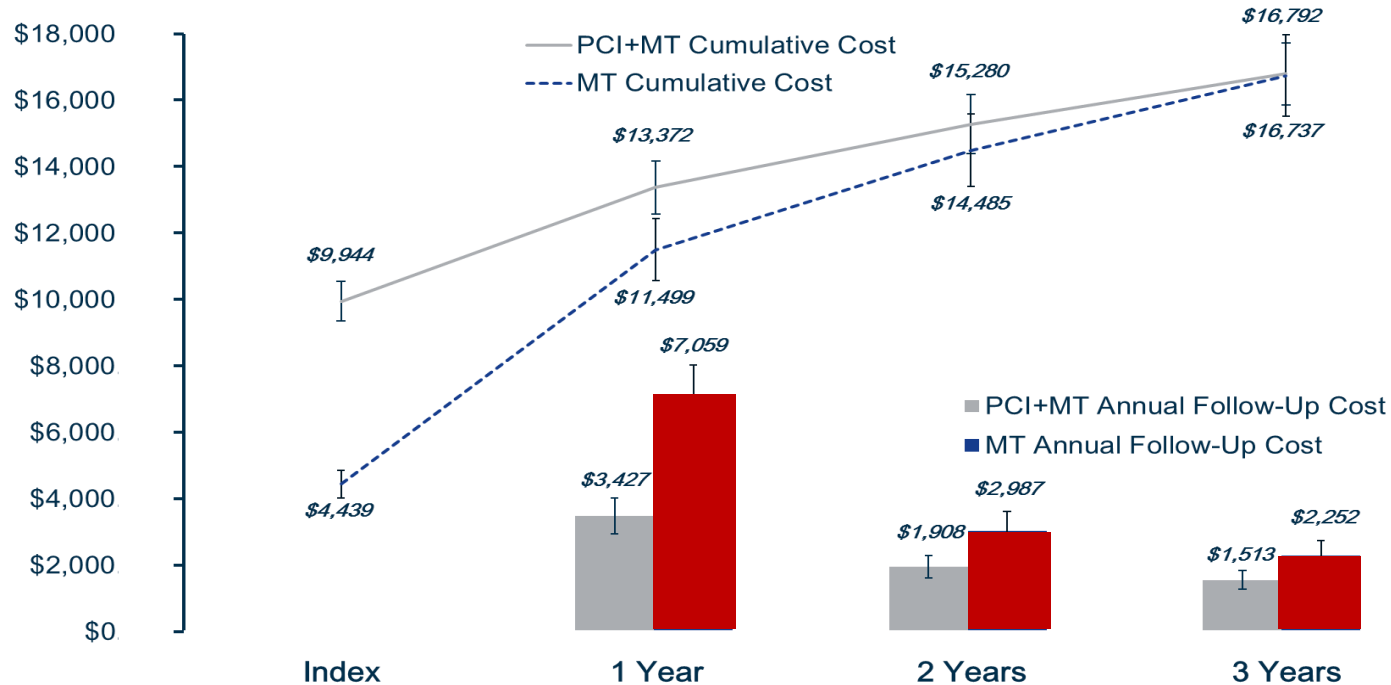


No. at risk	0	2	4	6	8	10	12	14	16	18	20	22	24
MT	441	417	398	389	379	369	362	360	359	355	353	351	297
PCI+MT	447	434	429	426	425	420	416	414	410	408	405	403	344
Registry	166	164	162	160	157	157	156	153	151	150	150	150	122



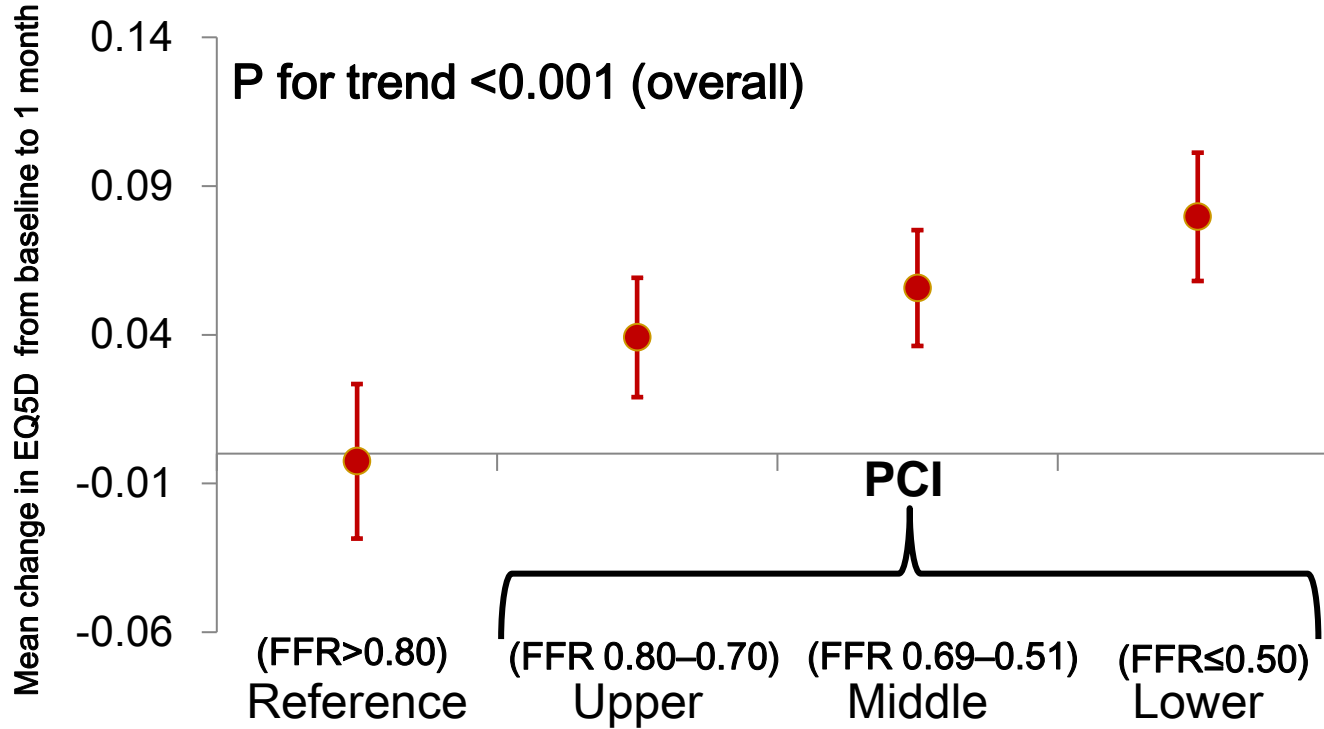
FAME 2: *Economic Evaluation*

The incremental cost-effectiveness ratio for PCI was \$1,600 / QALY



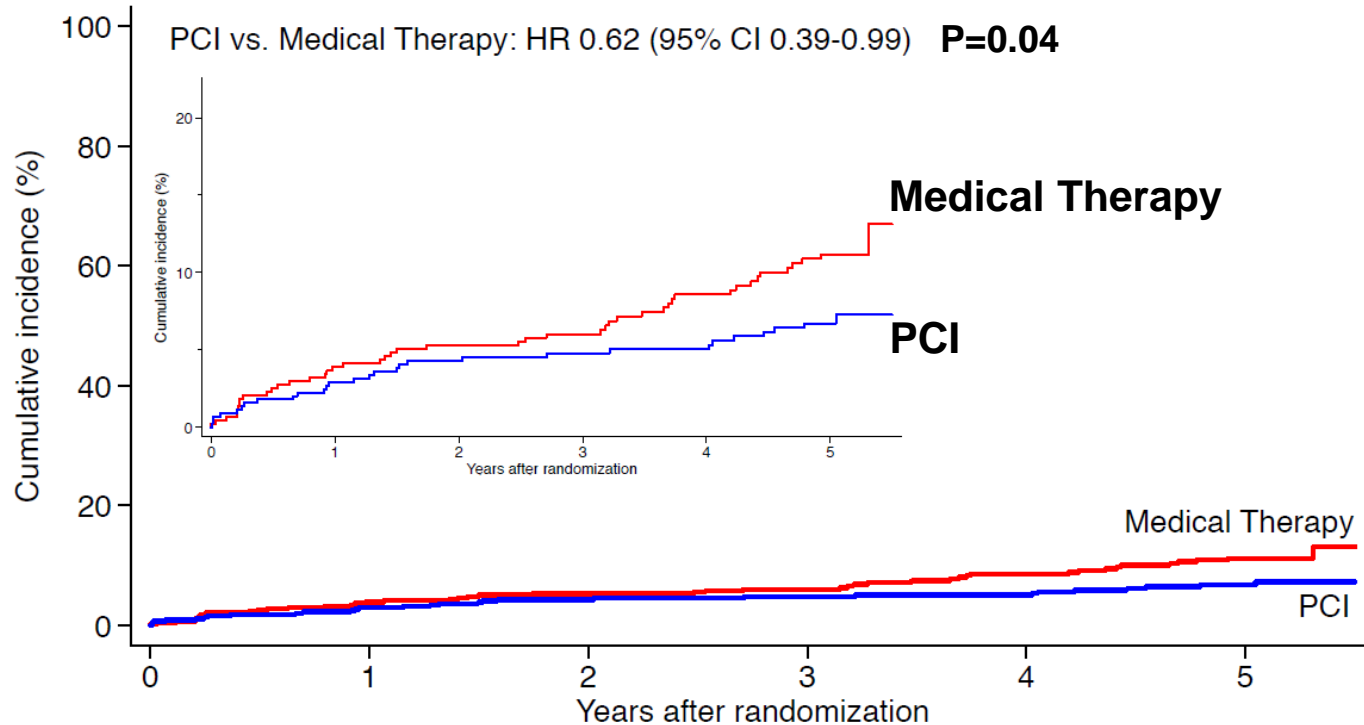
FAME 2: *Biologic Effect of PCI*

Change in QOL in 706 stable patients treated with PCI in FAME 1 and FAME 2



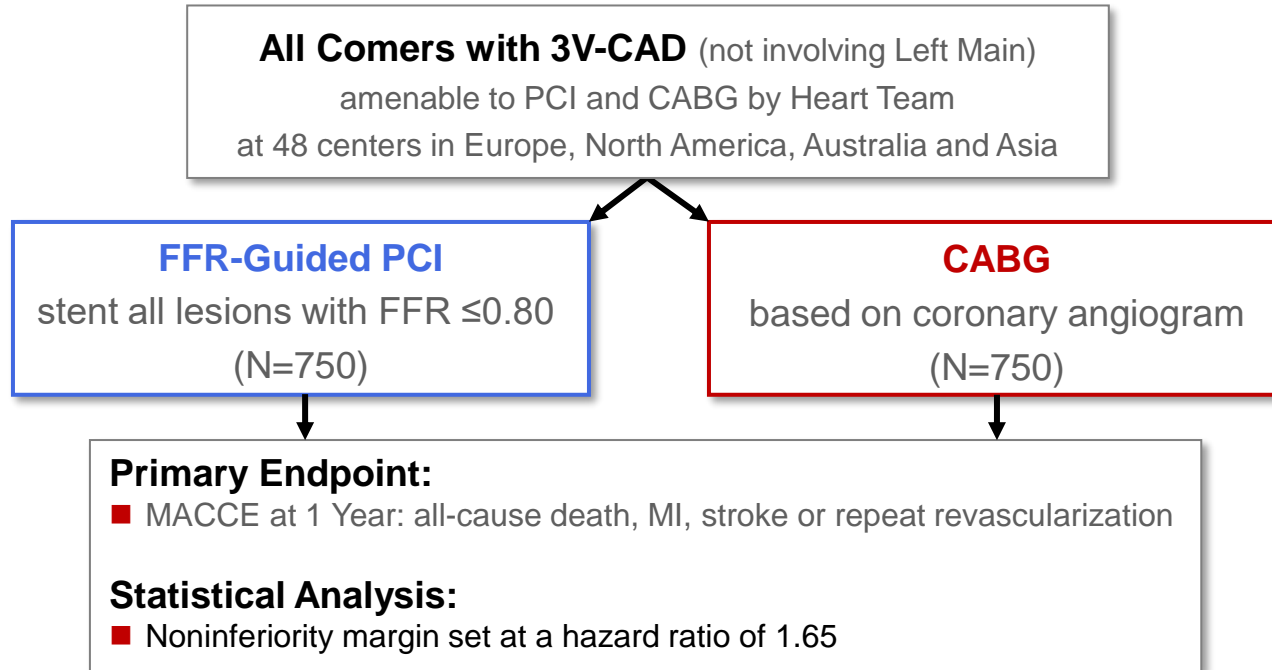
FAME 2: *Biologic Effect of PCI*

5 year rate of spontaneous MI after randomization to PCI or medical therapy

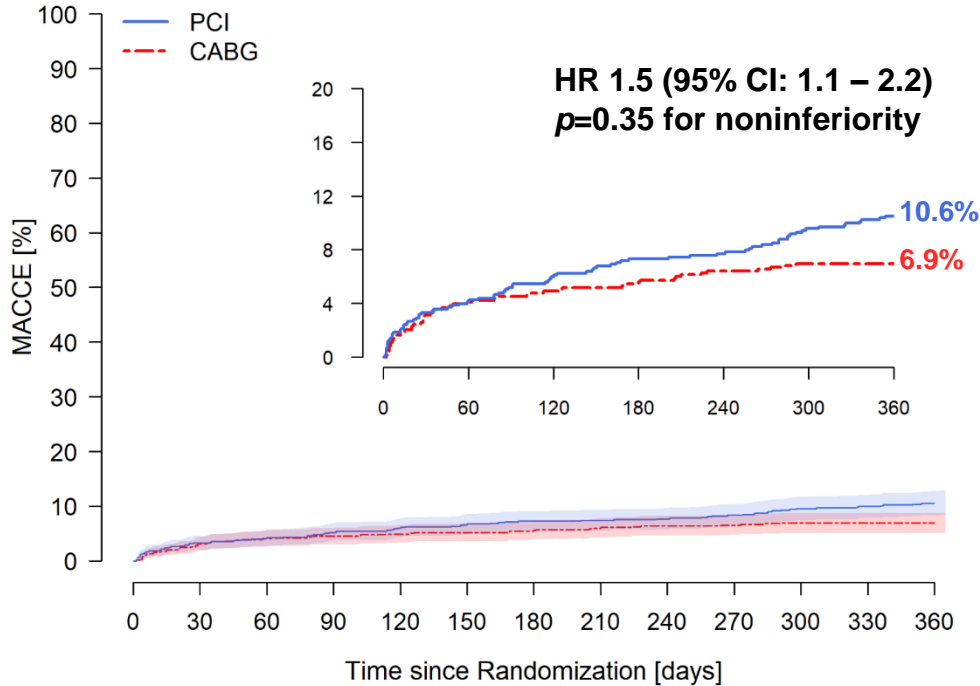


FAME 3: *Study Design*

Investigator-initiated, multicenter, randomized, controlled study



FAME 3: *Primary Endpoint*



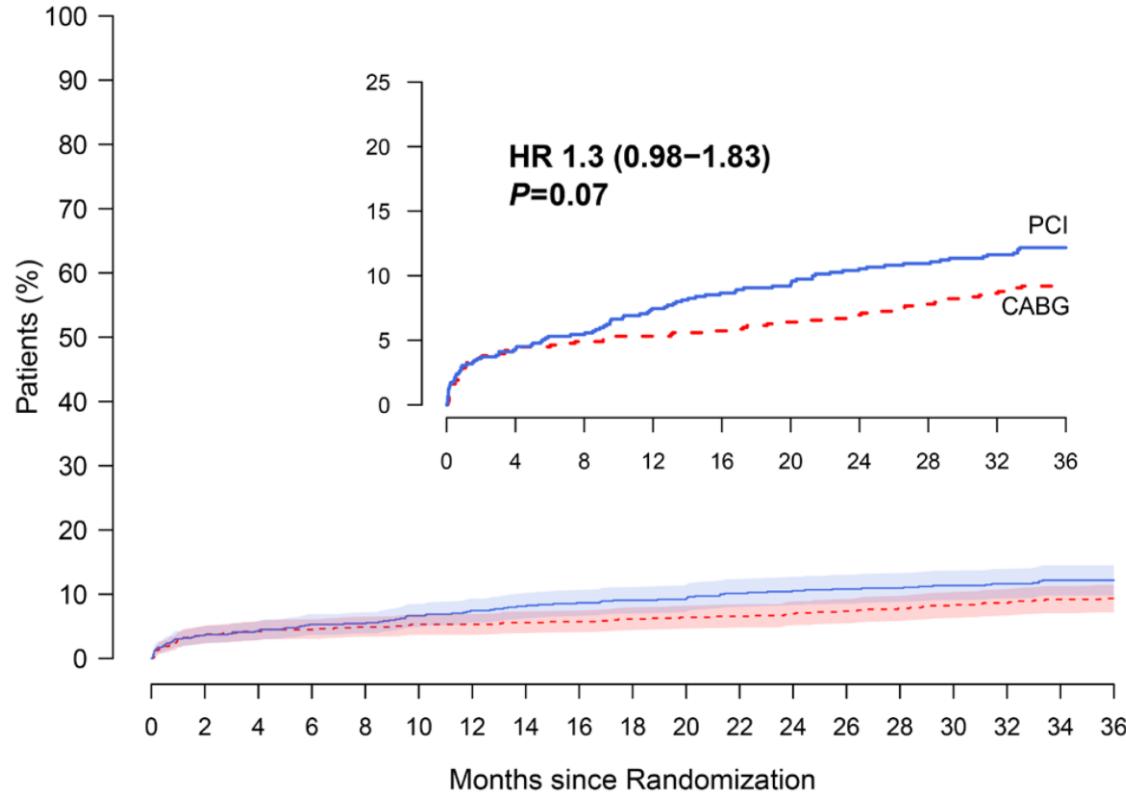
MACCE (Death, MI, stroke or repeat revascularization) at 1 Year

	No. at Risk												
PCI	757	728	721	713	707	702	697	696	693	687	678	674	670
CABG	743	709	701	698	695	693	691	686	683	682	679	679	679



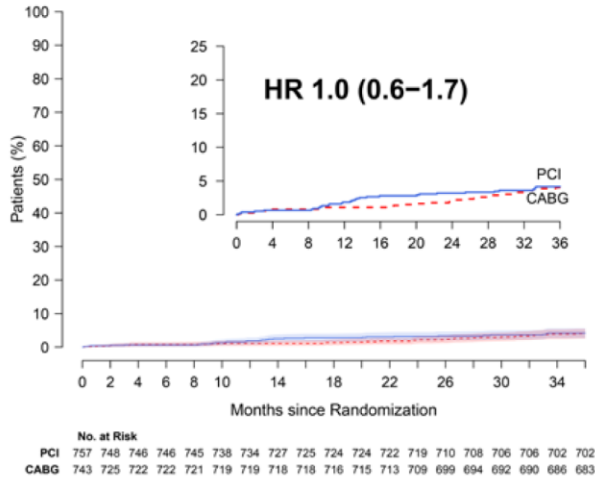
FAME 3: *Three-Year Outcomes*

Death, MI, or stroke at 3 Years

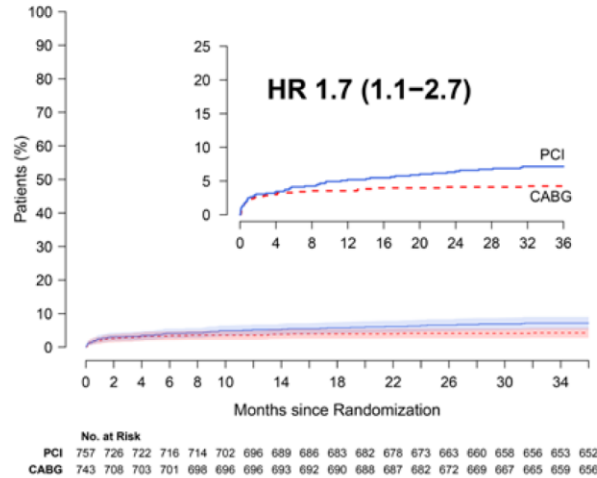


FAME 3: Three-Year Outcomes

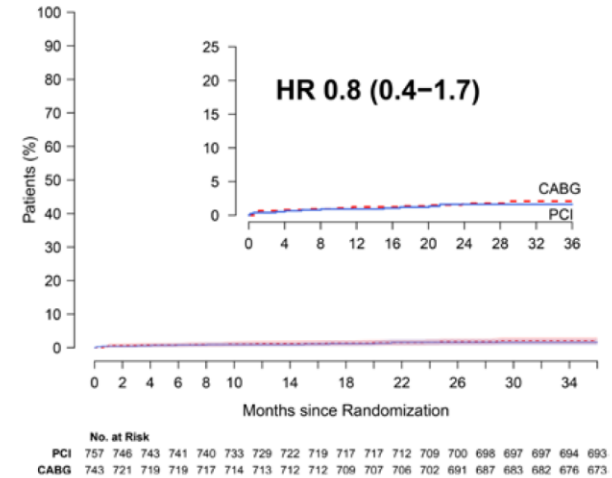
Death from any cause



Myocardial infarction

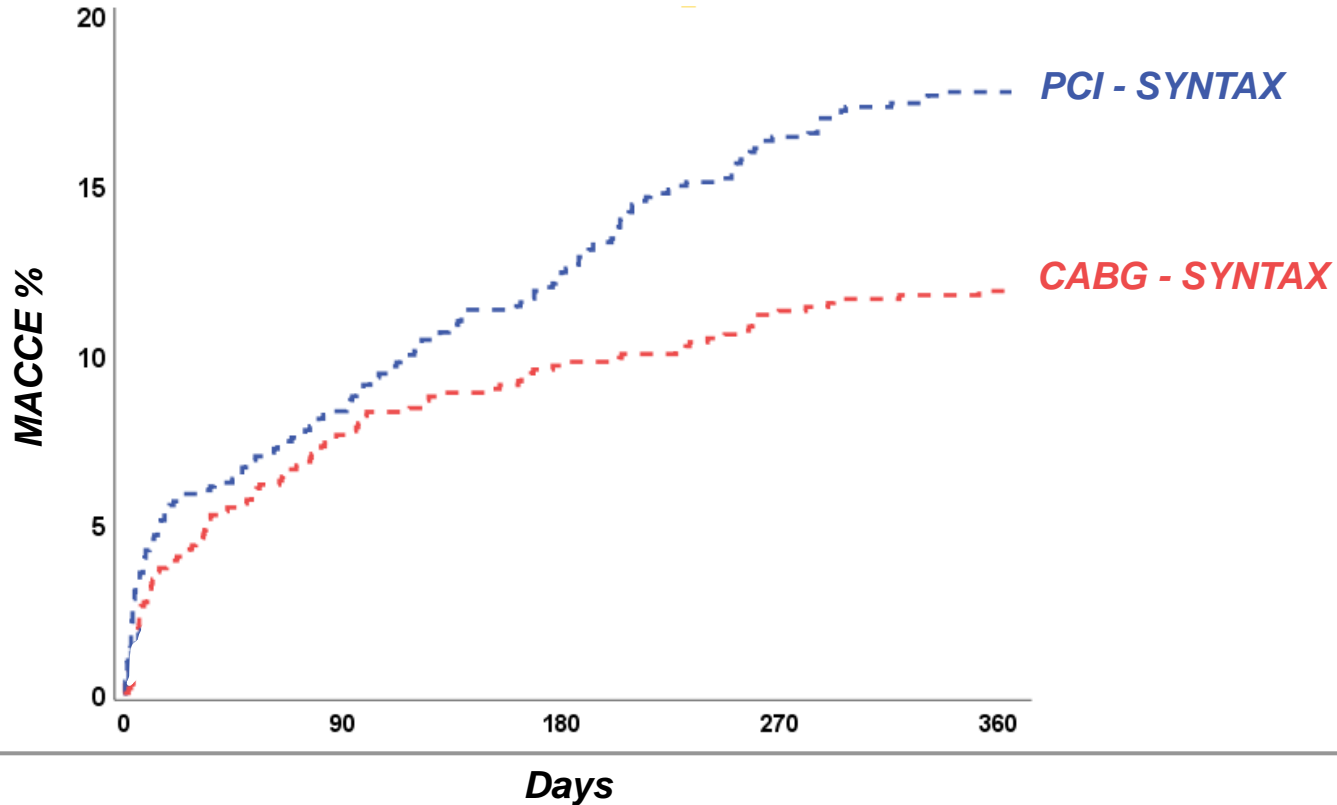


Stroke

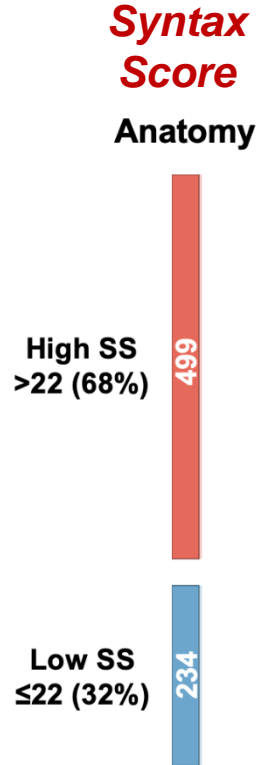


FAME 3 and SYNTAX Trials

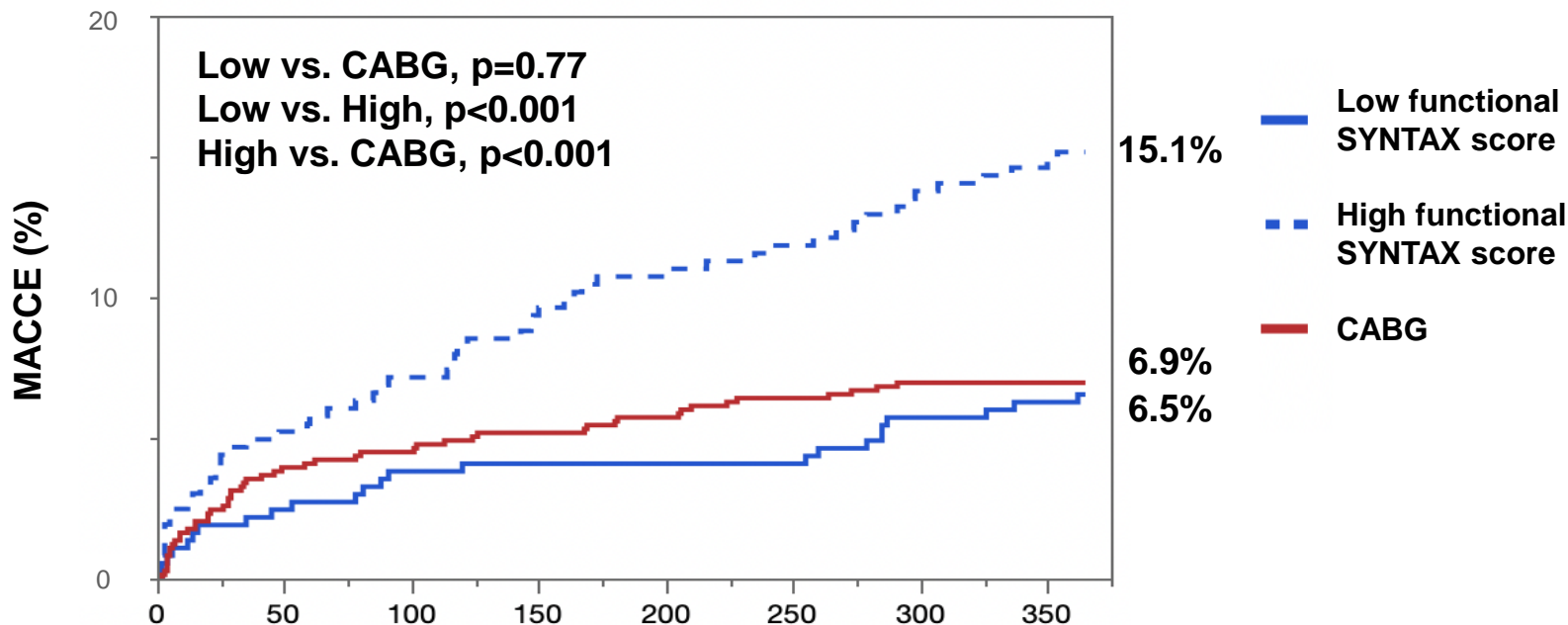
MACCE (Death, MI, Stroke, or Repeat Revascularization) at 1 Year



Reclassification with FFR Information



MACCE According to Functional SYNTAX Score

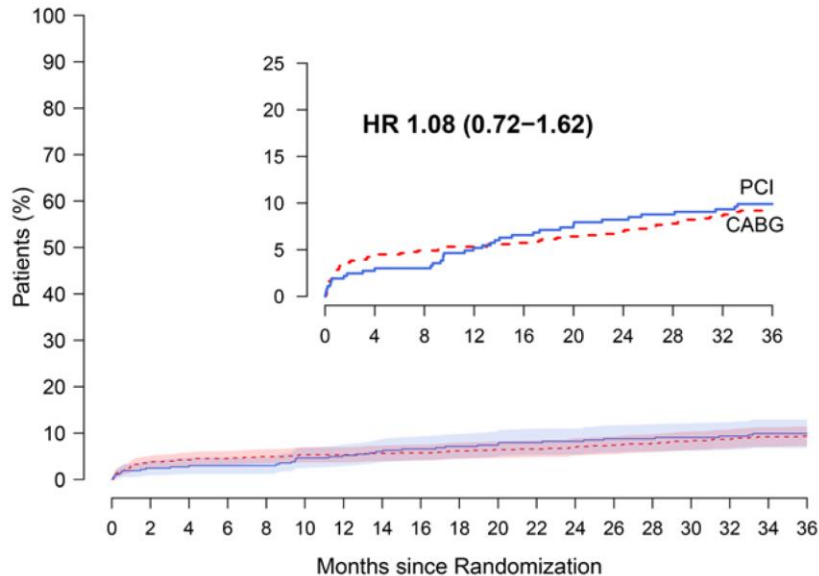


Low	368	354	353	346	342
High	365	338	325	313	306
CABG	743	699	689	680	678

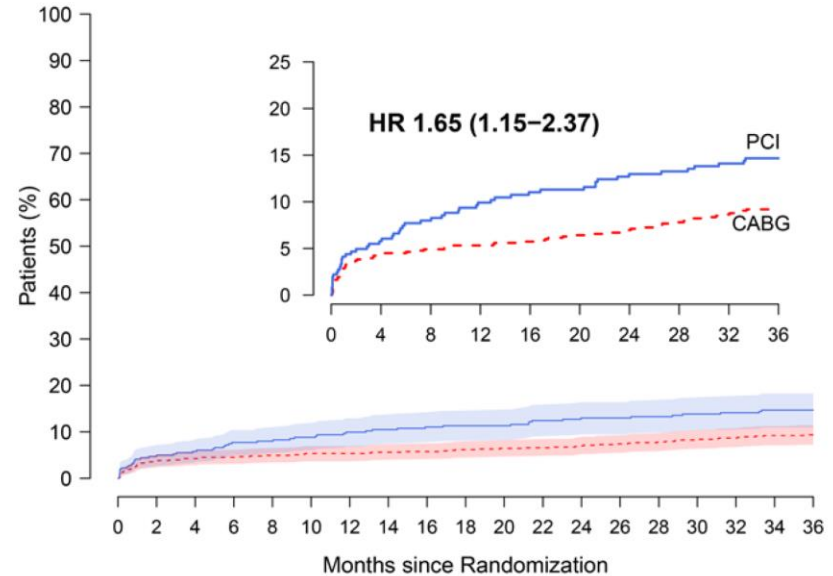
Death, MI or Stroke at 3 Years Based on FSS

50% of PCI patients had a low Functional SYNTAX Score

PCI patients with FSS ≤ 22 vs. CABG



PCI patients with FSS > 22 vs. CABG



	No. at Risk																		
PCI	368	357	356	355	347	345	342	340	337	336	334	332	326	326	325	324	322	322	
CABG	743	704	700	698	694	691	691	688	687	684	682	681	676	665	661	657	655	651	648

	No. at Risk																		
PCI	365	346	342	335	333	330	326	322	320	319	319	315	312	309	306	304	303	301	301
CABG	743	704	700	698	694	691	691	688	687	684	682	681	676	665	661	657	655	651	648



What is next for FAME 3?

FAME 3: Three Year Cost-Effectiveness of CABG



***Presented by Frederik Zimmermann, MD, PhD
Wednesday, May 15th at 9:13-9:19 am
Paris, France***



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FAME 1

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FAME 2

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FAME 3



Thank You!

