

*Session I: PCI vs. Medical Tx in Stable CAD*

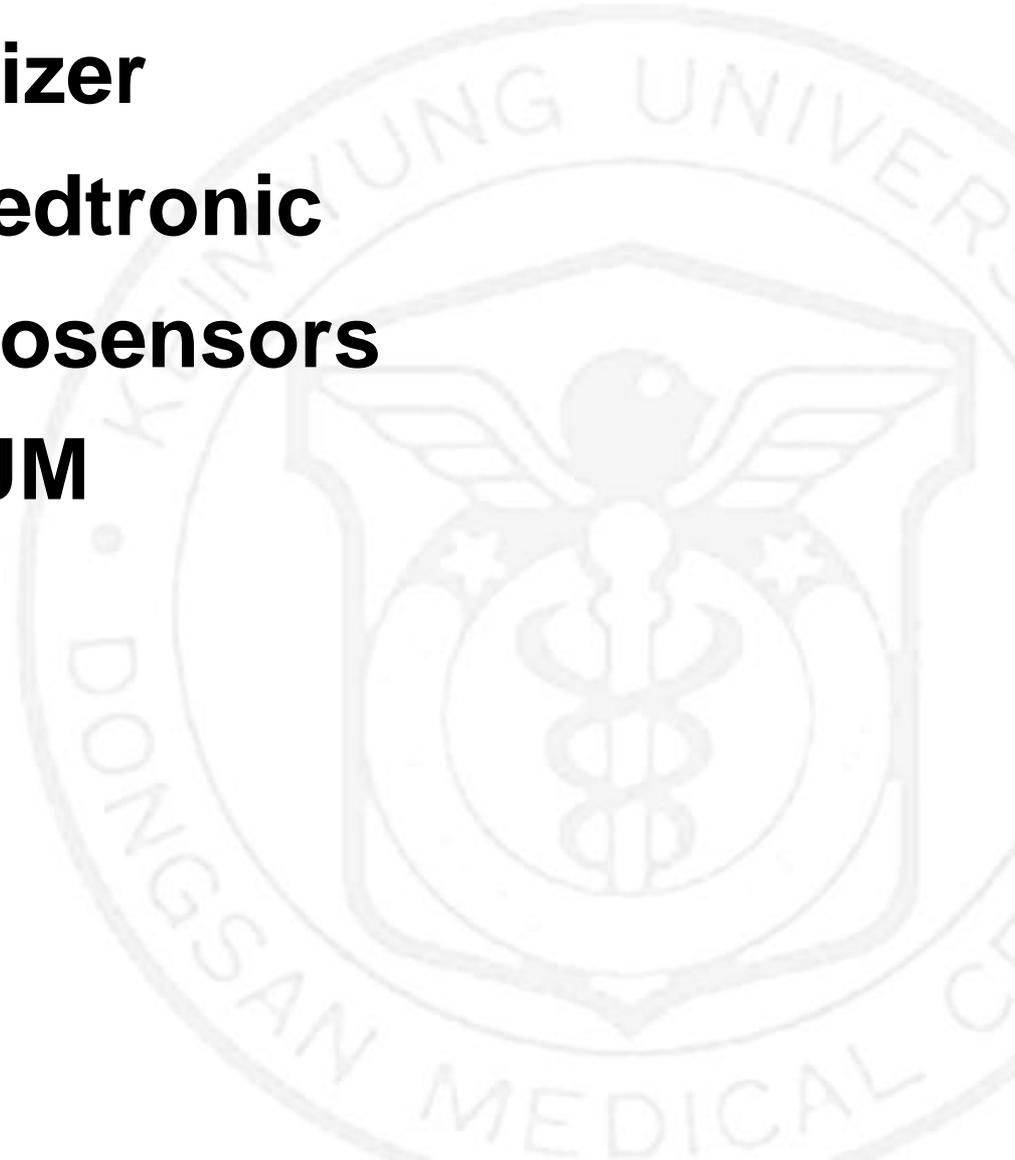
**FFR Guided PCI : Future Direction**

**Keimyung University Dongsan Medical Center**

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# DISCLOSURE

- **Research grant: Pfizer**  
**Medtronic**  
**Biosensors**
- **Consultant: SJM**



# *In Stable CAD*

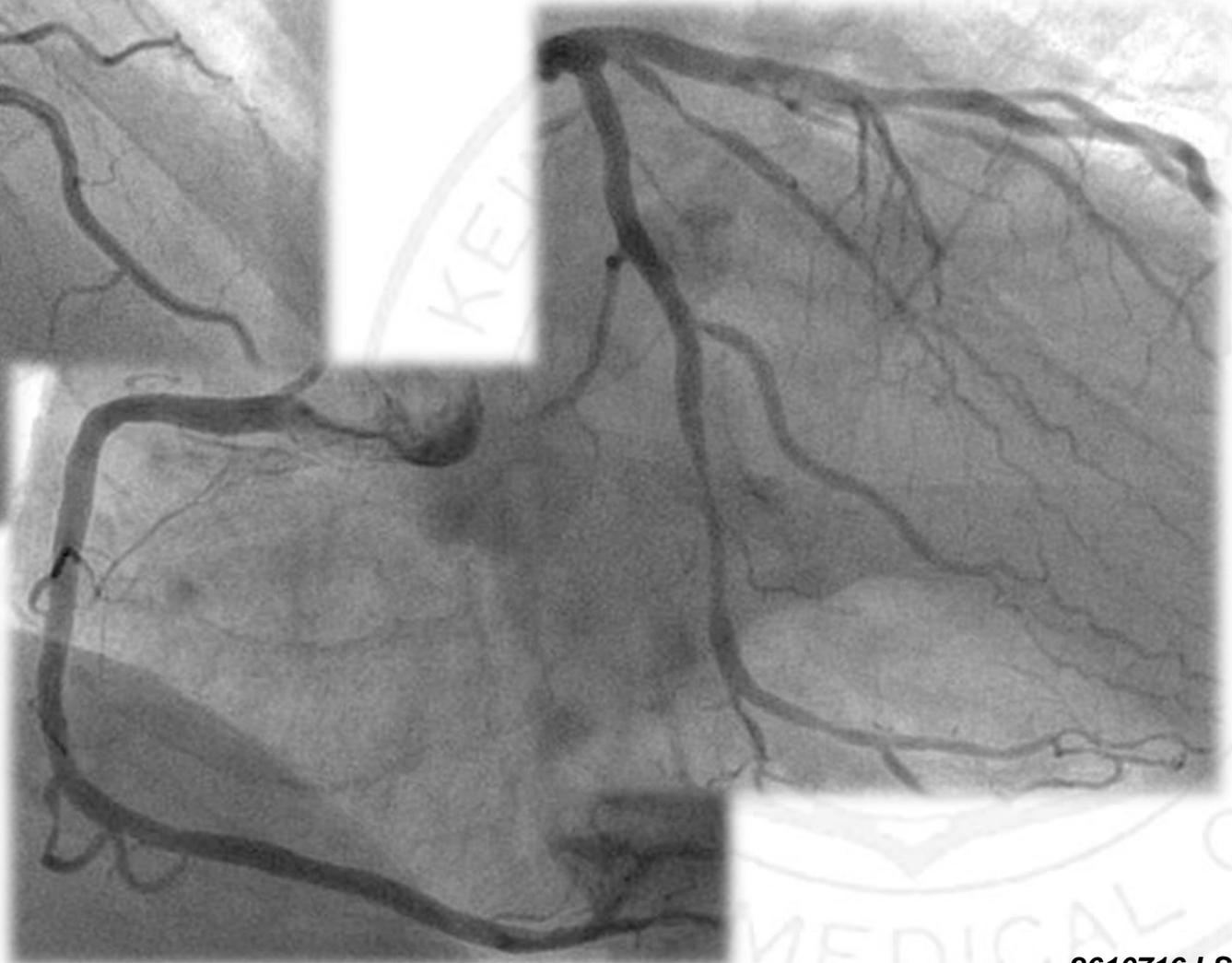


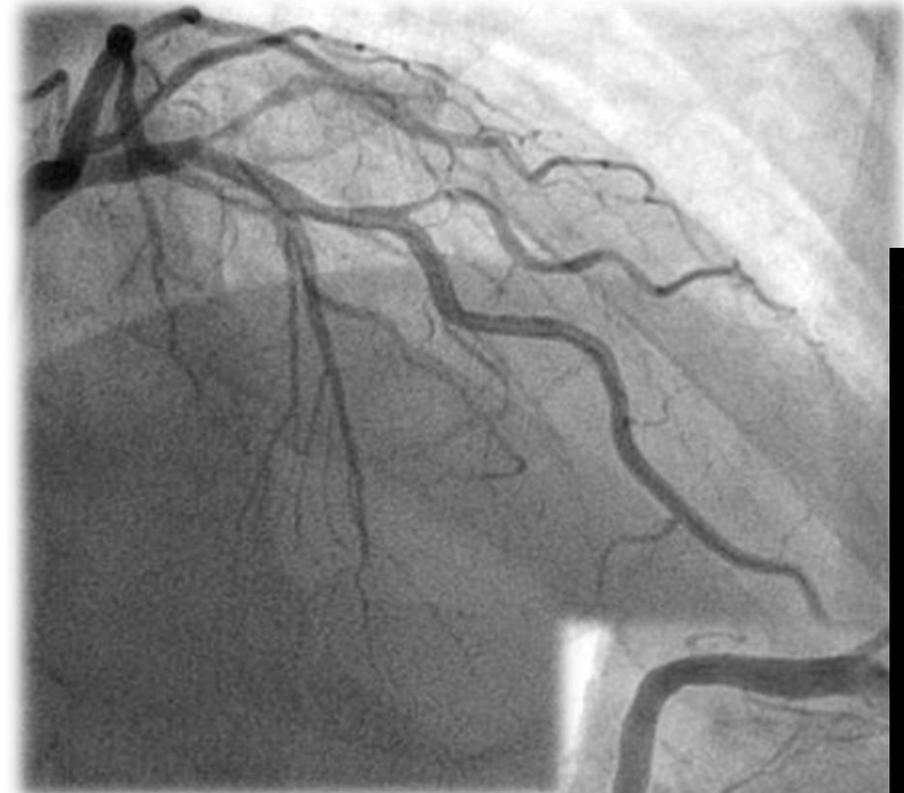
*VS.*



# Case 1

- 72 YO / Male CCS II for 4 months
- CV risk factor: DM, HTN, Smoking
- ECG & TTE: unremarkable







**Anatomic view: significant**

**Physiologic view: significant**

**Patient view:**





# *Round 1*



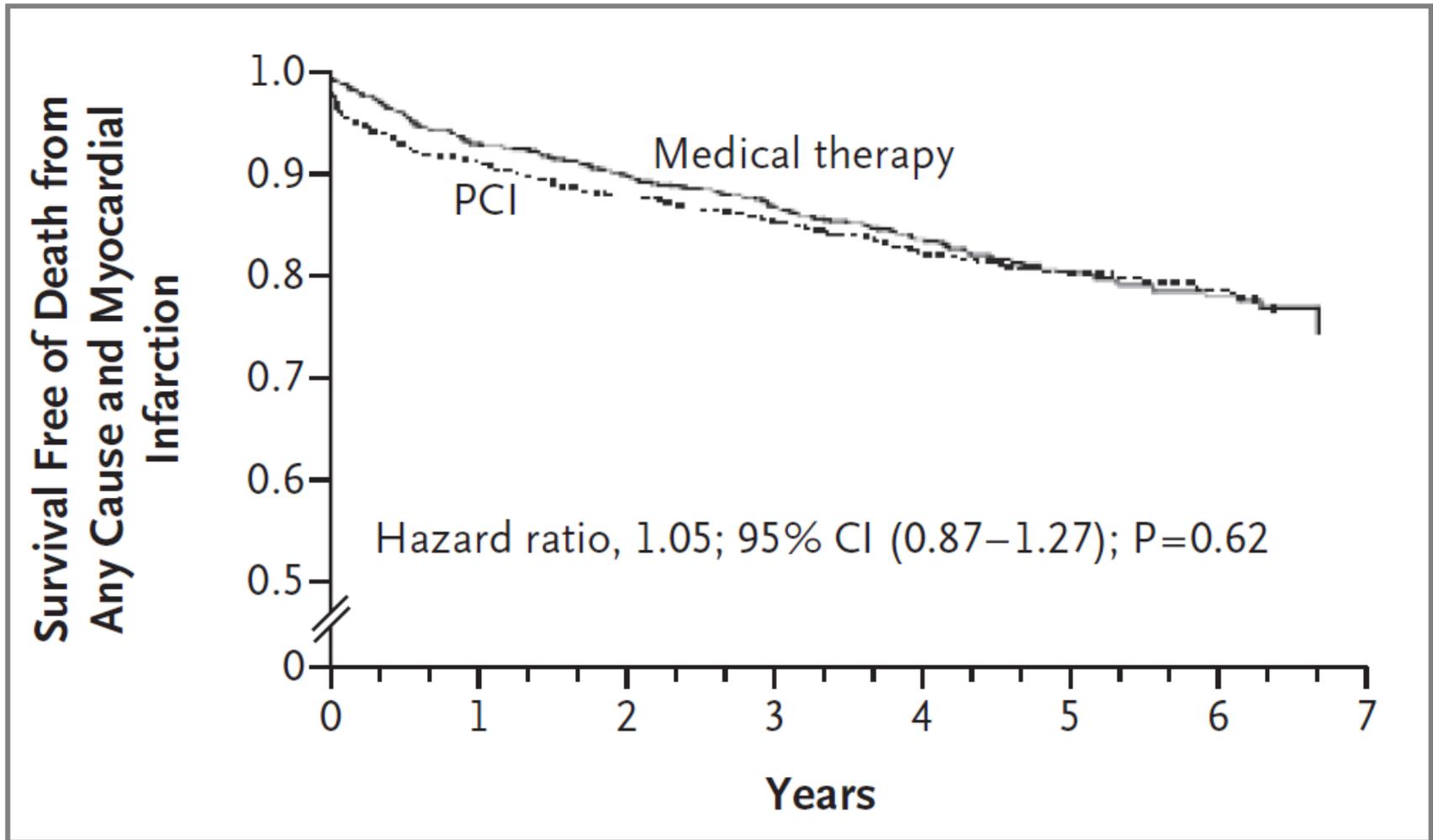
*VS.*





Characteristic	PCI Group (N = 1149)	Medical-Therapy Group (N = 1138)	P Value
<b>Demographic</b>			
Age — yr	61.5±10.1	61.8±9.7	0.54
Sex — no. (%)			0.95
Male	979 (85)	968 (85)	
Female	169 (15)	169 (15)	
Race or ethnic group — no. (%) †			0.64
White	988 (86)	975 (86)	
Black	57 (5)	57 (5)	
Hispanic	68 (6)	58 (5)	
Other	35 (3)	47 (4)	
<b>Clinical</b>			
Angina (CCS class) — no. (%)			0.24
0	135 (12)	148 (13)	
I	340 (30)	341 (30)	
II	409 (36)	425 (37)	
III	261 (23)	221 (19)	
Missing data	3 (<1)	2 (<1)	
Duration of angina — mo			0.53
Median	5	5	
Interquartile range	1–15	1–15	
Episodes/wk with exertion or at rest within last mo			0.83
Median	3	3	
Interquartile range	1–6	1–6	
<b>History — no. (%)</b>			
Diabetes	367 (32)	399 (35)	0.12
Hypertension	757 (66)	764 (67)	0.53
Congestive heart failure	57 (5)	51 (4)	0.59
Cerebrovascular disease	100 (9)	102 (9)	0.83
Myocardial infarction	437 (38)	439 (39)	0.80
Previous PCI	174 (15)	185 (16)	0.49
CABG	124 (11)	124 (11)	0.94
<b>Stress test ‡</b>			

# Death and MI in the COURAGE study



# What we learn from COURAGE



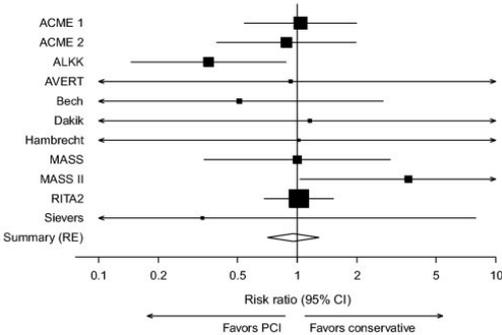
**COURAGE underscore the feasibility of achieving important reductions in ischemia with antianginal therapy combined with a strategy of optimal risk factor control and lifestyle modification.**

**➔ *Defer with medical therapy is safe in patients with stable CAD***

***(Current ESC and ACC/AHA guidelines)***

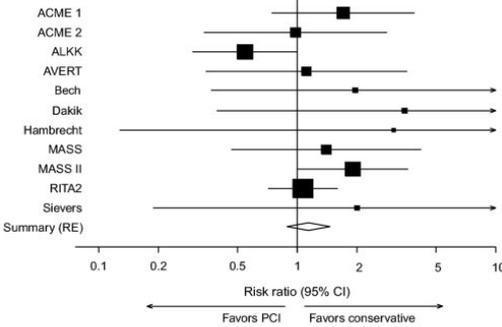
# PCI vs Medical therapy in nonACS

## A. Death

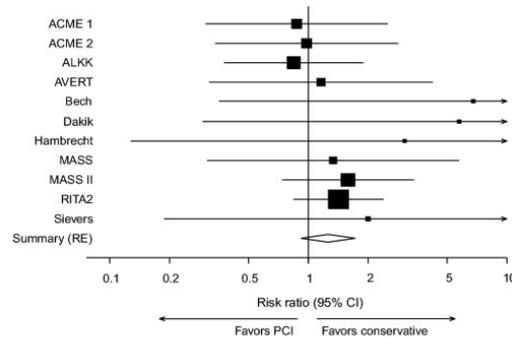


A total of 2950 patients were included in the meta-analysis (1476 received PCI, and 1474 received conservative treatment).

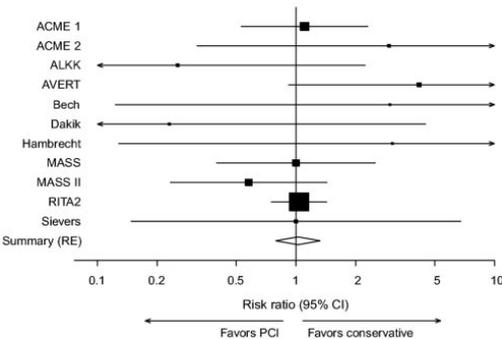
## B. Cardiac death or myocardial infarction



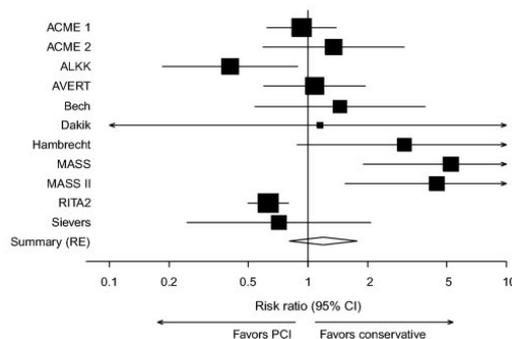
## C. Non-fatal myocardial infarction



## D. Coronary artery bypass grafting



## E. Percutaneous coronary intervention

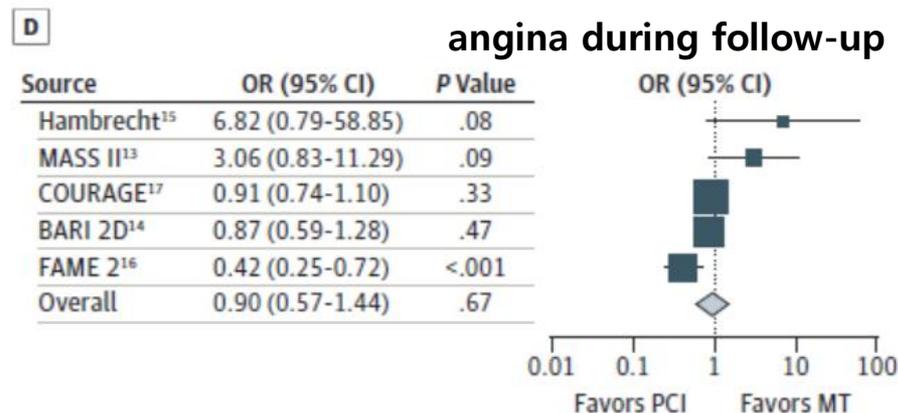
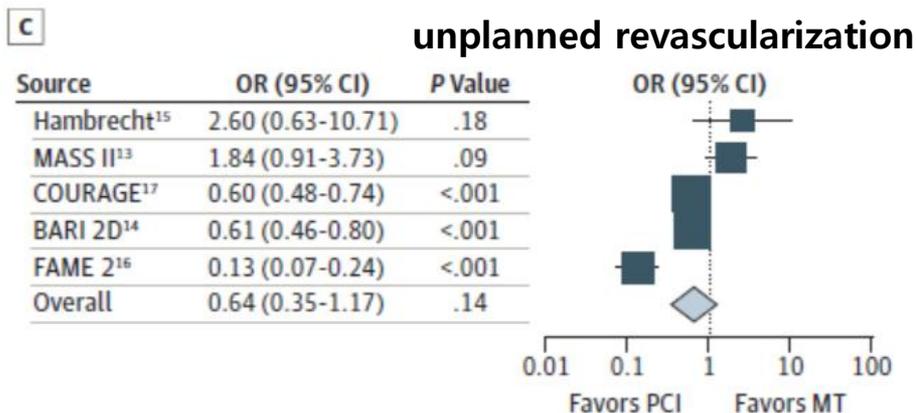
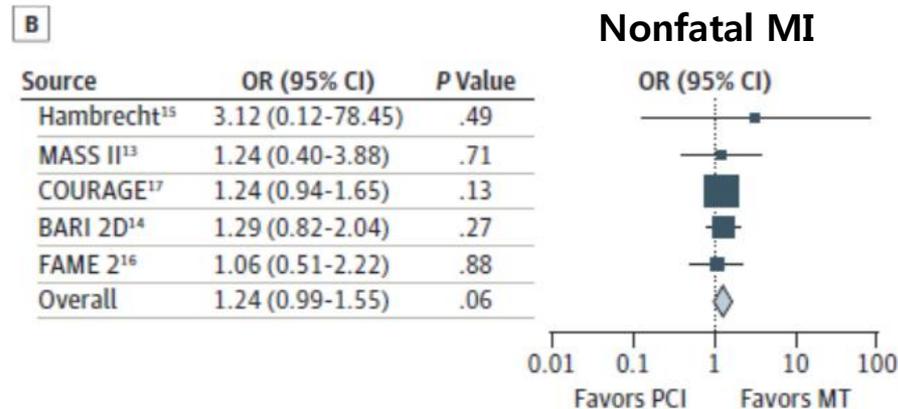
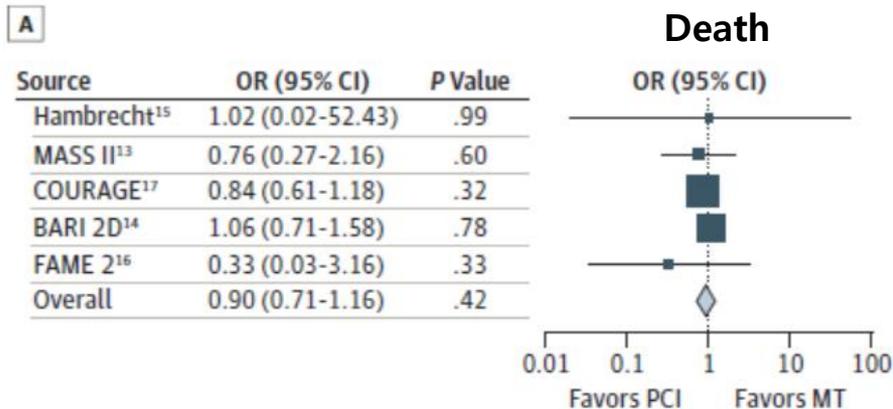


In patients with **chronic stable CAD**, **PCI does not offer any benefit** in terms of death, myocardial infarction, or the need for subsequent revascularization compared with conservative medical treatment.

# PCI vs Medical therapy in Stable CAD



In 5 trials enrolling 5286 patients, ischemia was diagnosed in 4064 patients



*Who is winner ?*



*vs.*





# Round 2



*vs.*



# FAME II Flow Chart

Stable CAD patients scheduled for 1, 2 or 3 vessel 2<sup>nd</sup> Gen DES-PCI  
N = 1220

FFR in all target lesions

Randomized Trial

Registry

At least 1 stenosis  
with FFR  $\leq 0.80$  (n=888)

Randomization 1:1

PCI + MT

MT

73%

When all FFR  $> 0.80$   
(n=332)

MT

27%

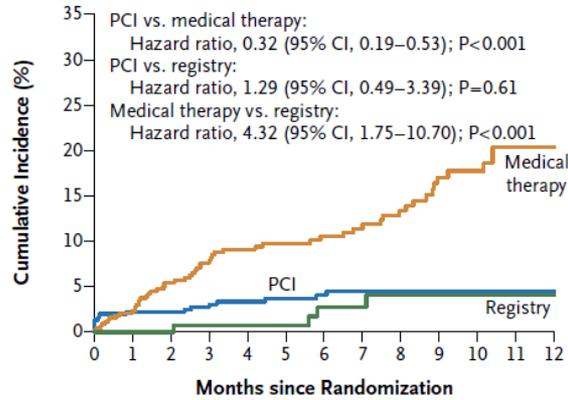
50% randomly  
assigned to FU

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

# FAME II



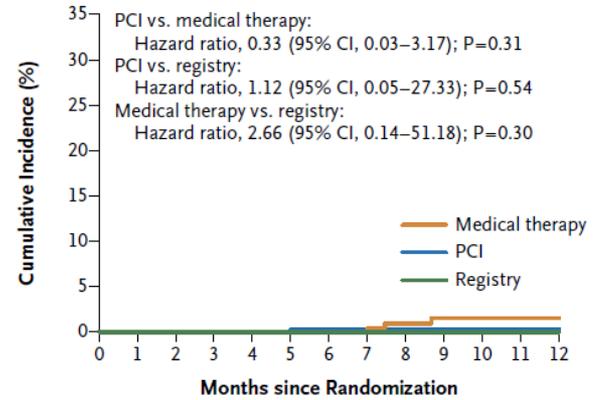
## A Primary End Point



### No. at Risk

Medical therapy	441	414	370	322	283	253	220	192	162	127	100	70	37
PCI	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

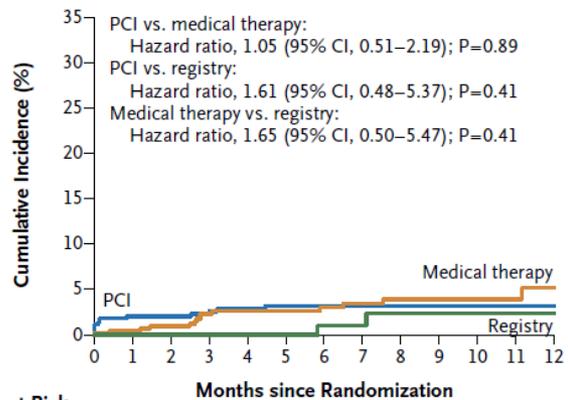
## B Death from Any Cause



### No. at Risk

Medical therapy	441	423	390	350	312	281	247	219	188	154	122	90	54
PCI	447	423	396	359	318	288	250	220	183	163	122	95	54
Registry	166	156	145	134	118	107	96	76	67	55	43	27	13

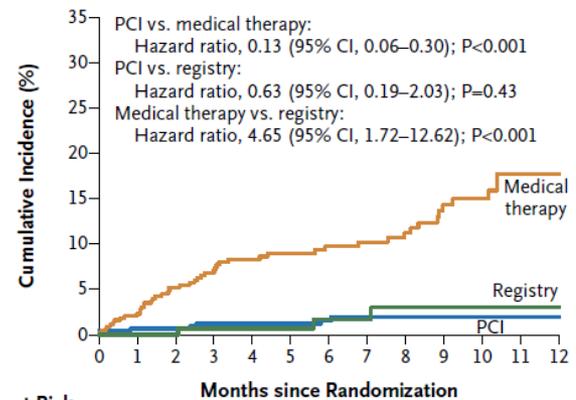
## C Myocardial Infarction



### No. at Risk

Medical therapy	441	421	386	341	304	273	239	212	182	148	117	85	48
PCI	447	414	388	352	309	278	244	214	177	157	119	94	54
Registry	166	156	145	134	118	107	95	75	65	53	42	26	13

## D Urgent Revascularization



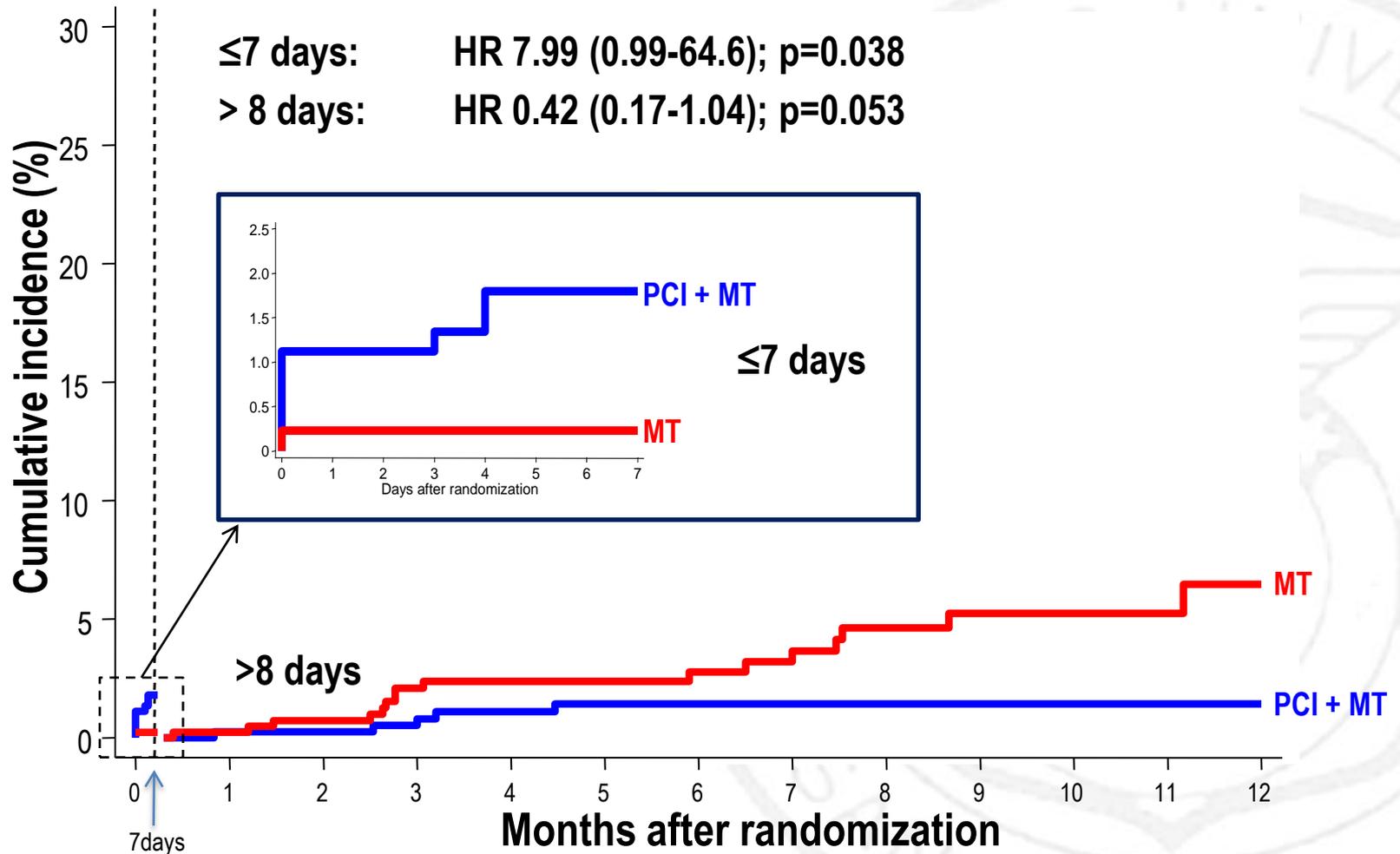
### No. at Risk

Medical therapy	441	414	371	325	286	256	223	195	164	129	101	71	38
PCI	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

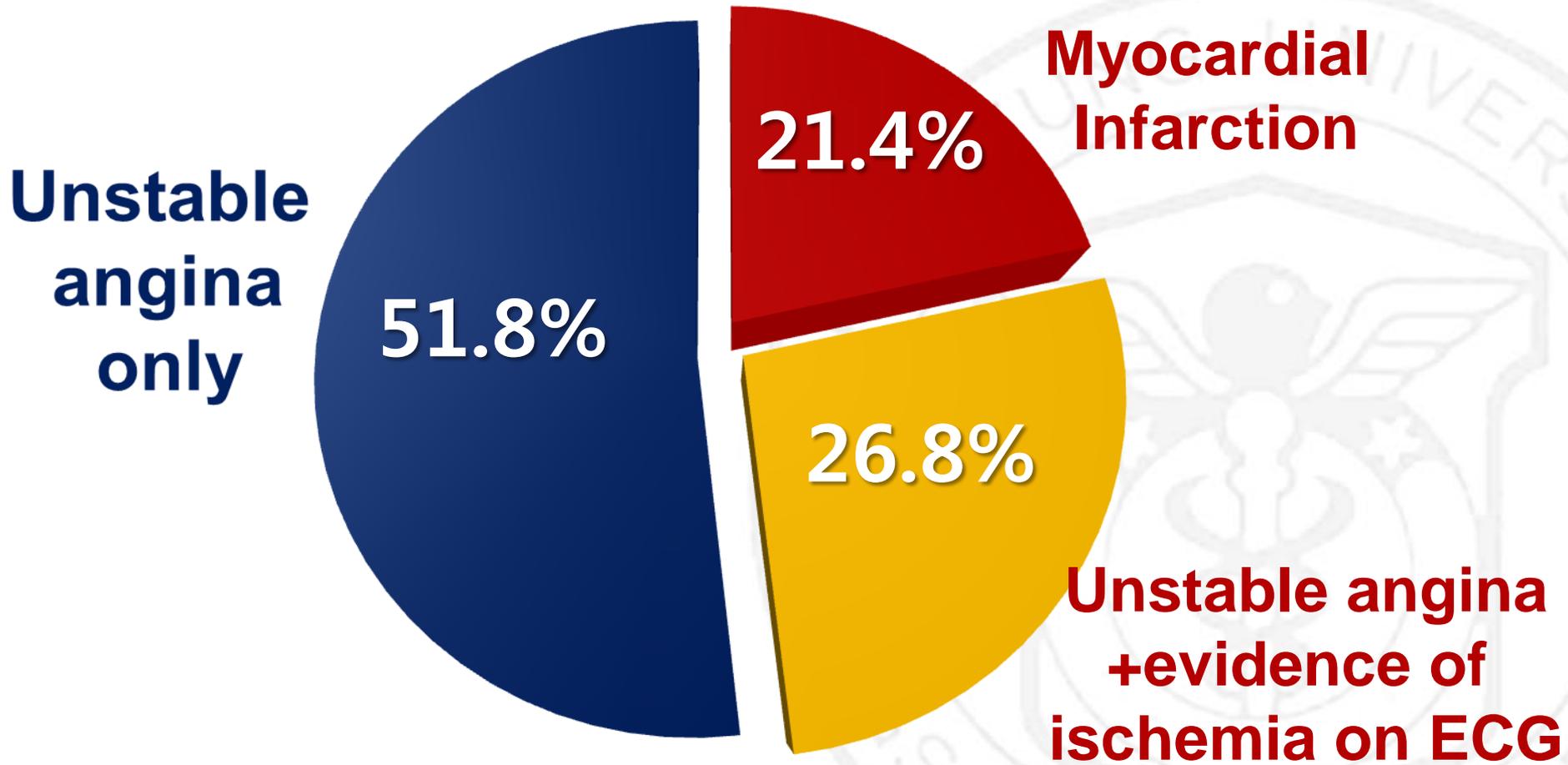
# FAME II Outcomes



## Kaplan-Meier plots of landmark analysis of Death or MI



# Patients with urgent revascularization



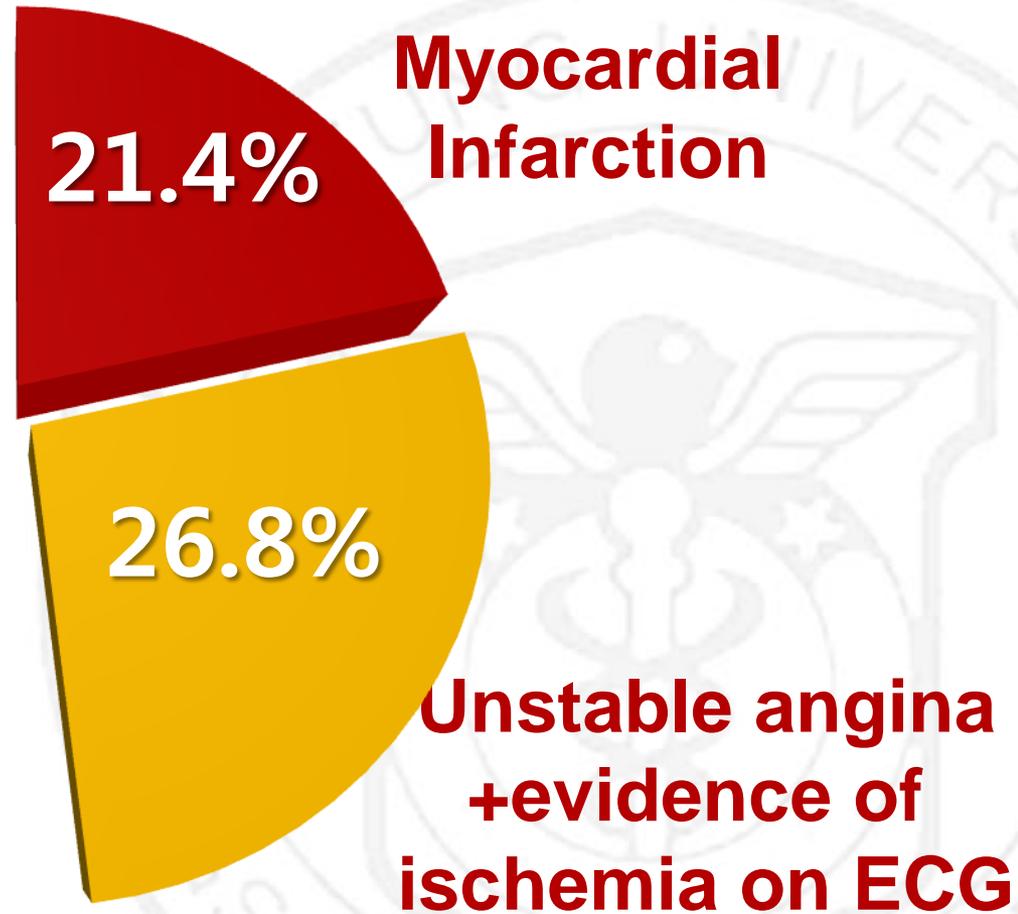
# Patients with urgent revascularization



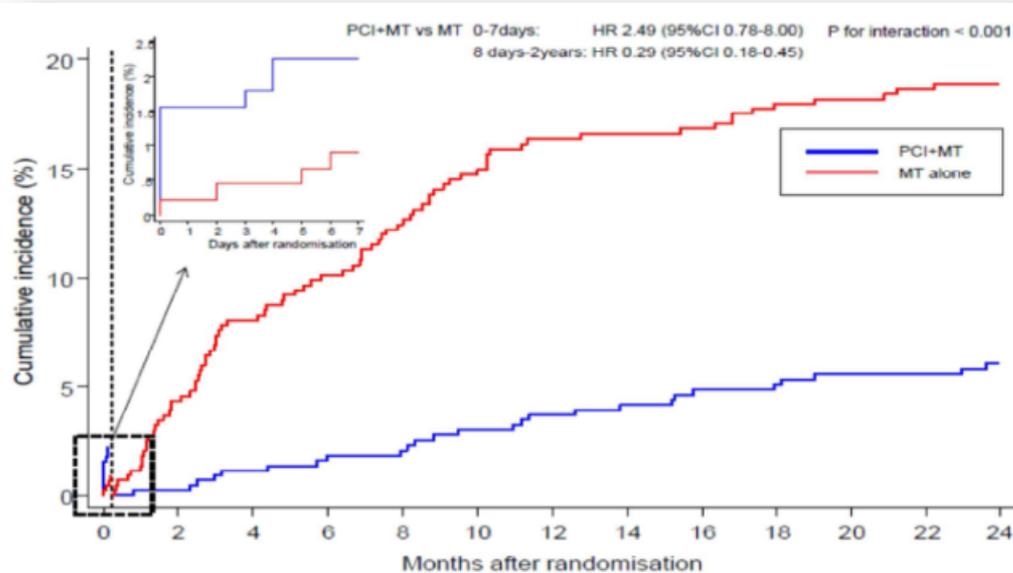
**Urgent revascularization driven by MI or unstable angina with ECG changes**

<b>FFR-Guided PCI + MT</b>		<b>MT</b>
<b>0.9%</b>	<b>vs.</b>	<b>5.2%</b>

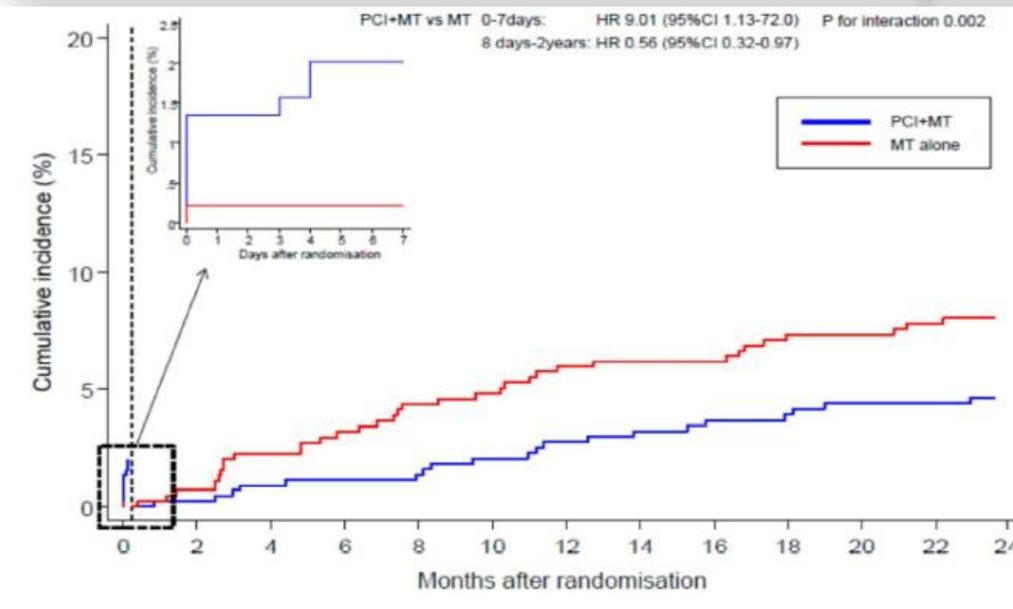
**p<0.001**  
**83% Relative Risk Reduction**



# FAME II: 2 years outcomes



The rate of **death, MI, or urgent revascularization at 2 years** was significantly lower with FFR-guided PCI than MT alone (8.1% vs 19.5%,  $p < 0.001$ )



FFR-guided PCI plus MT reduced the rate of **death or MI** beyond 7 days from randomization by 44% when compared to MT alone (4.6% vs 8.0%,  $p < 0.002$ )



*Who is winner ?*



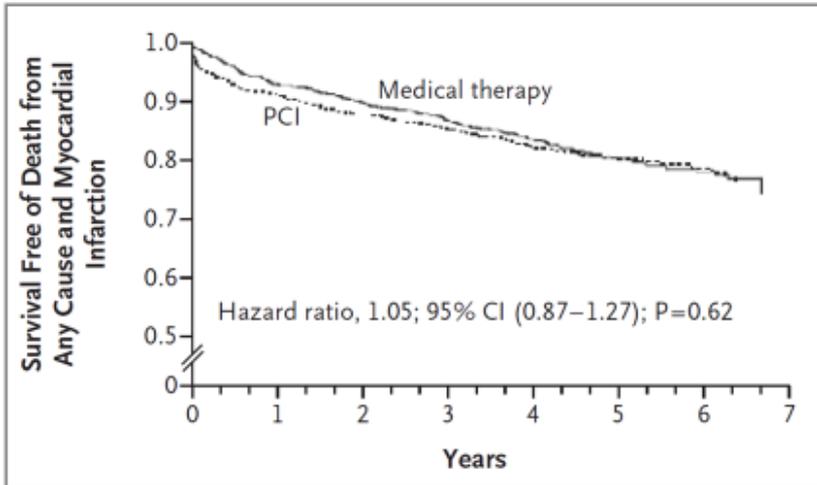
*vs.*



# 1. Issues for only medical therapy

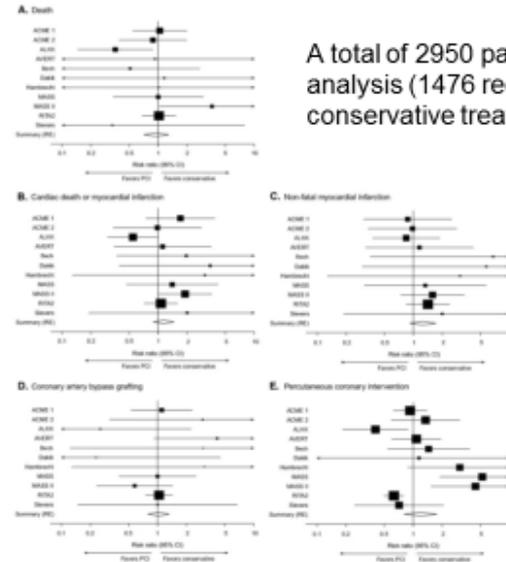


## Death and MI in the COURAGE study



Boden et al. *NEJM* 2007;356:1503

## PCI vs Medical therapy in nonACS



In patients with **chronic stable CAD**, PCI does not offer any benefit in terms of death, myocardial infarction, or the need for subsequent revascularization compared with conservative medical treatment.

Keimyung University, Korea

*Circulation*. 2005;111:2906-2912

*These trials are underway in the era of BMS.*

*NEJM* 2007;356:1503  
*Circulation*. 2005;111:2906-2912

# PCI vs Medical therapy in Stable CAD



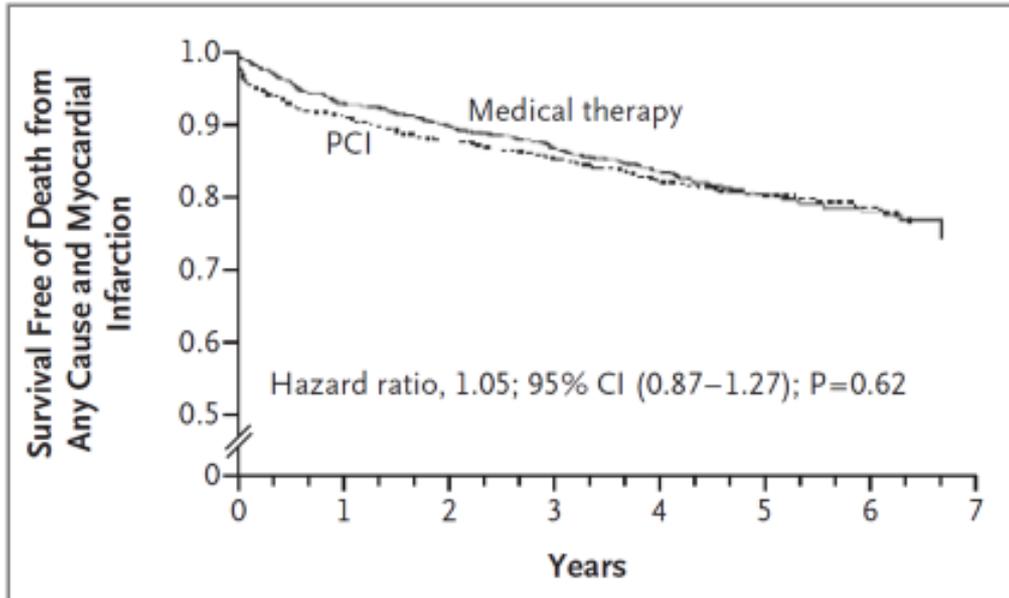
Characteristic	MASS II <sup>13</sup>		Hambrecht <sup>15</sup>		COURAGE <sup>17</sup>		BARI 2D <sup>14</sup>		FAME 2 <sup>16</sup>	
	MT+PCI	MT	MT+PCI	MT	MT+PCI	MT	MT+PCI	MT	MT+PCI	MT
Participants, No.	68	97	50	51	968	970	483	489	447	441
Age, mean, y	59	59	61	62	62	62	62	62	64	64
Male	62	79	100	100	86	85	73	73	80	77
Diabetes	22	31	22	24	33	35	100	100	28	27
Prior MI	38	33	40	51	35	40	26	25	37	37
Ejection fraction, mean	69	68	62	64	61	61	57	57	NR	NR
Vessels with stenosis >50%, mean No.	2.35	3.37	1.52	1.6	1.98	2.0	1.55	1.63	1.87	1.73
Stent placed	66	NA	100	NA	94	NA	90	NA	97	NA
Drug-eluting stent	0	NA	0	NA	3	NA	37	NA	95	NA
Medications										
Aspirin	100	97	98	98	93	93	97	95	87	90
β-Blocker	85	85	86	88	83	83	92	91	76	78
ACEI or ARB	28	28	88	75	74	73	94	94	69	70
Statin	74	59	80	71	89	90	96	96	83	82



# 2. Issues for only medical therapy



## Death and MI in the COURAGE study



Boden et al, NEJM 2007;356:1503

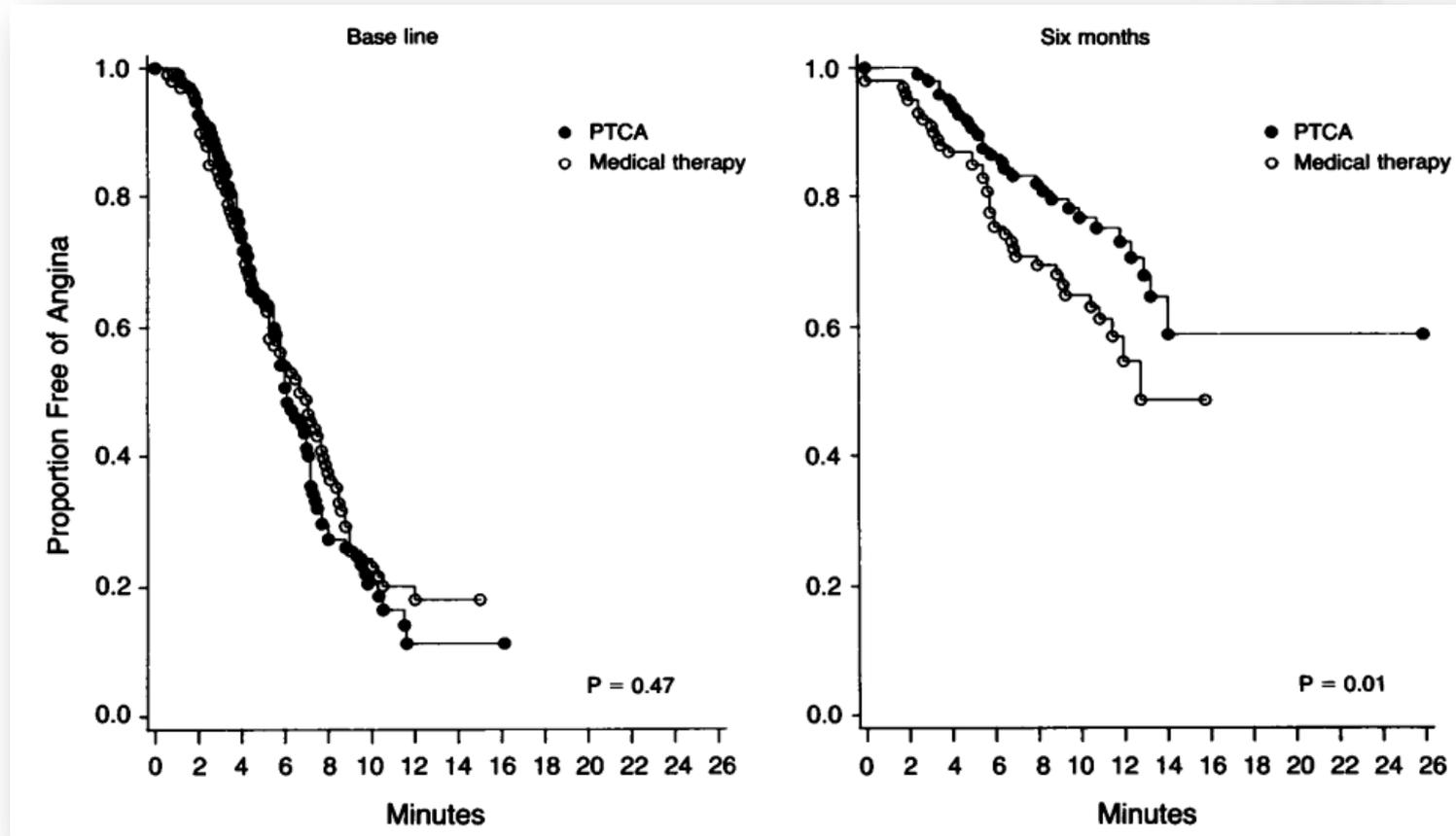
At a median follow-up of 4.6 years, **21.1% of patients in the PCI** group had additional revascularization, as compared with **32.6% of those in the medical-therapy** group (**hazard ratio, 0.60; 95% CI, 0.51 to 0.71; P<0.001**).

*The goal of treatment is not only outcome, but also symptom*

# Issues for only medical therapy



212 patients (105 to PTCA and 107 to medical therapy) with SVD proven ischemia

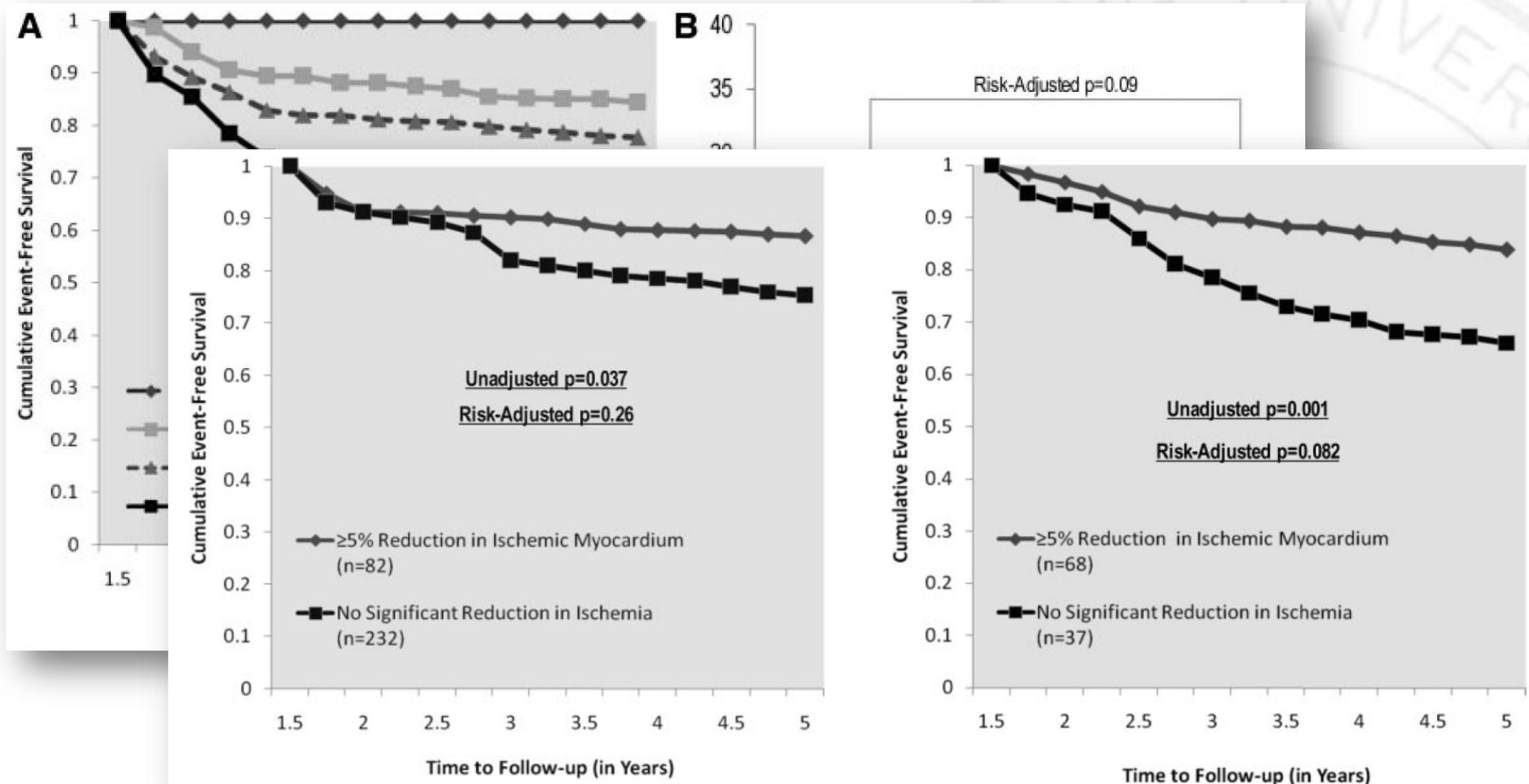


*The goal of treatment is not only outcome, but also symptom*

# 3. Issues for only medical therapy

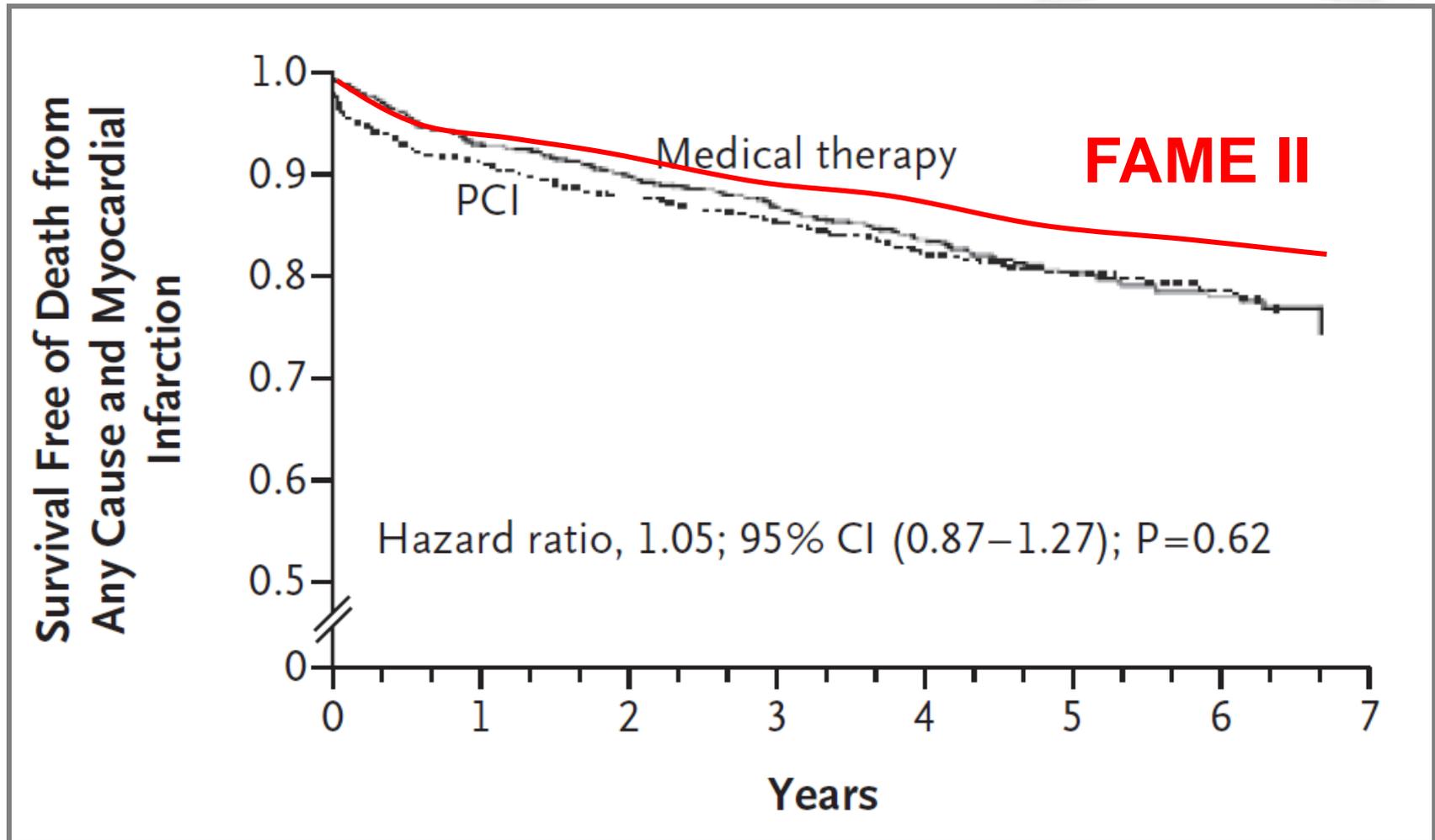


## COURAGE Nuclear Substudy Residual Ischemia and Event Rates (n=314)



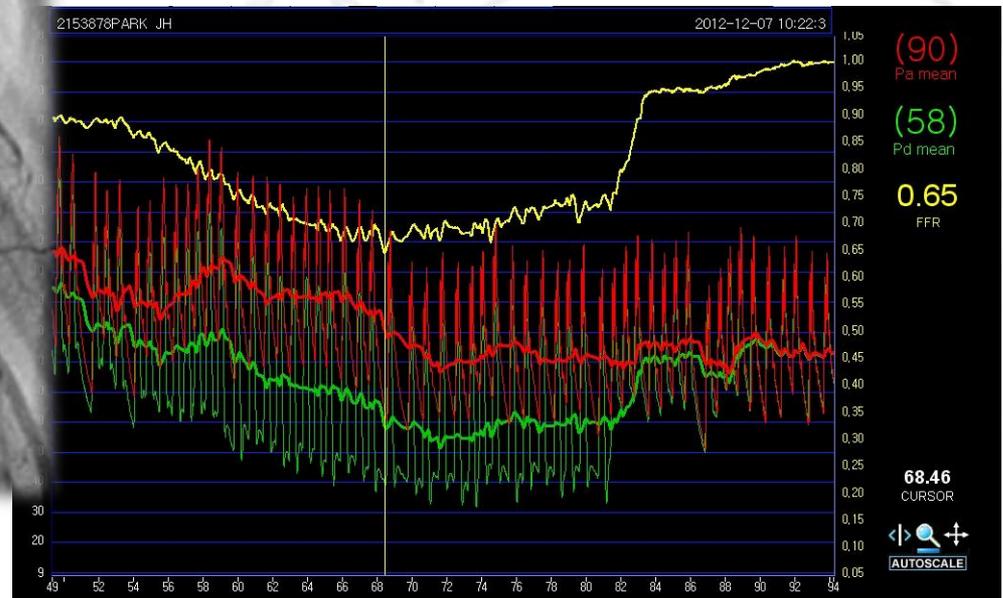
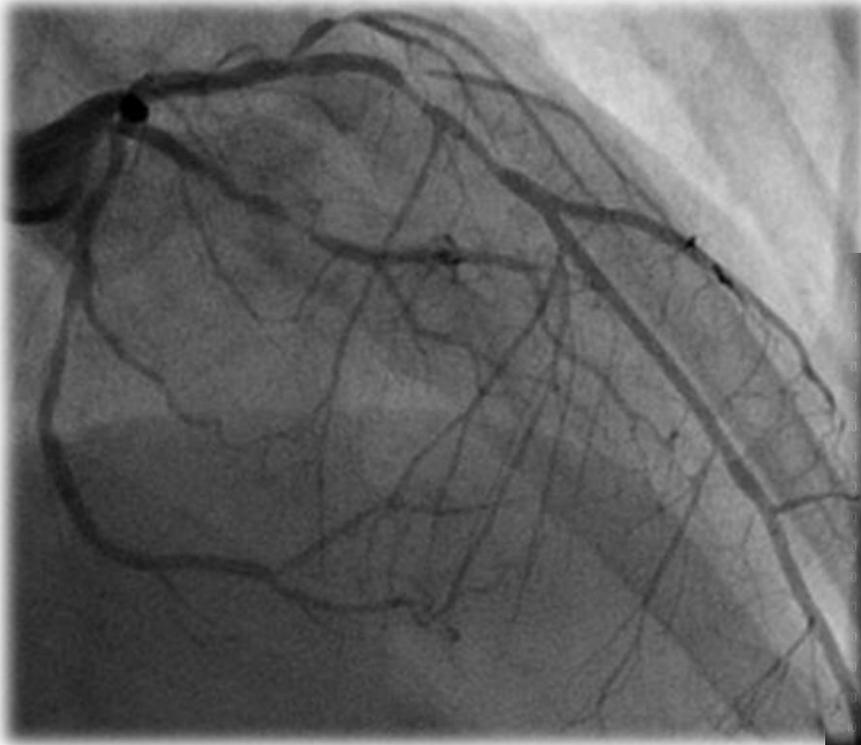
# Implications of FAME II

## Death and MI in the COURAGE study



# Case 2

- 57 YO / Male, CCS II for 6months
- CV risk factor: DM, Smoking
- ECG & TTE: unremarkable

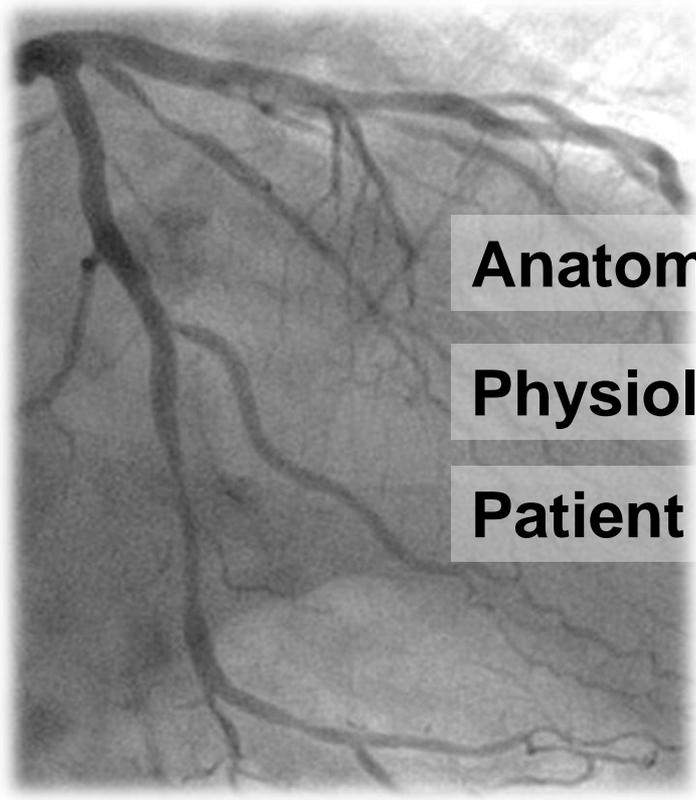


*Do you really want to defer this patient with only medical therapy?*



# **Current issues of Medical therapy Compared to Physiology-guided PCI**

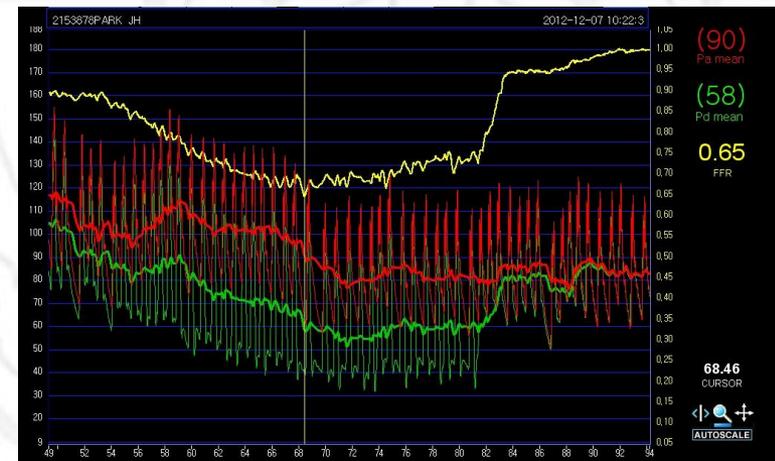
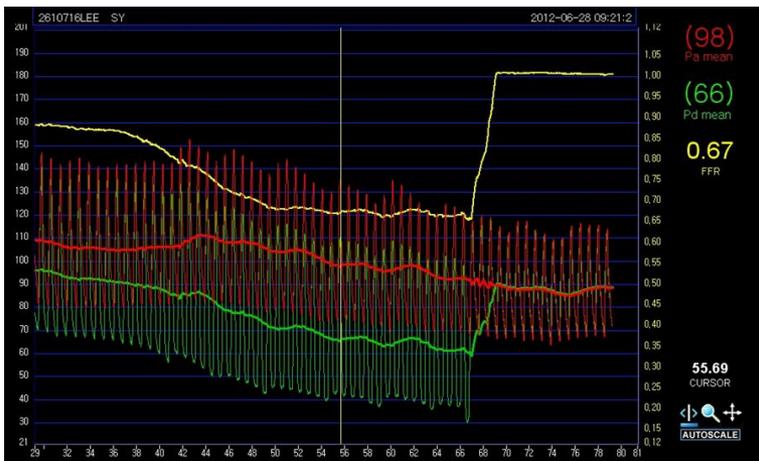
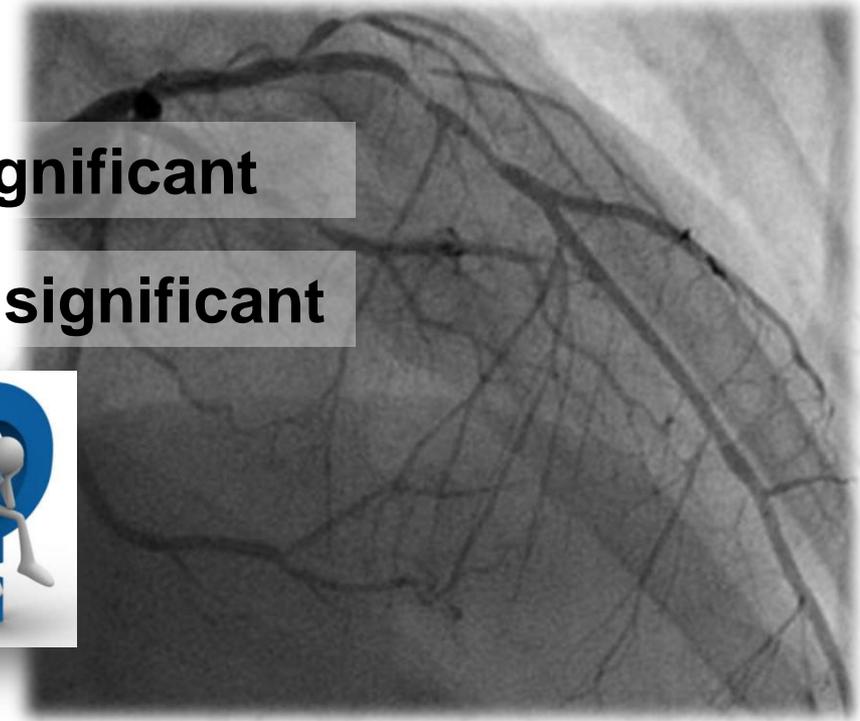
- 1. Optimal medical therapy is not an option...**
- 2. Burden of ischemia is more important for prognosis...**
- 3. Never ending advance in interventional devices...**
- 4. Also, advanced interventional techniques...**
- 5. FFR-guided PCI demonstrated better result...**



**Anatomic view: significant**

**Physiologic view: significant**

**Patient view:**





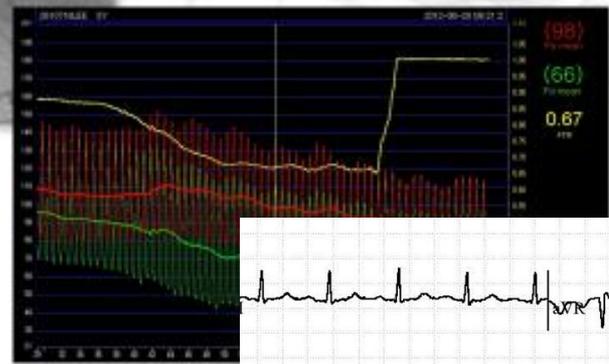
Anatomic view: significant

Physiologic view: significant

Patient view:



# Medical Therapy



Keimyung University, Korea



10.2 METs

Keimyung University, Korea

# Goal for Treatment of CAD



Best practice should be based on the appropriate patient selection. Therefore, Physiology-guided decision making can help your practical decision in your daily cath lab.



**Thank You**

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**FFR Guided PCI : Future Direction**