Cost-Effectiveness of Fractional Flow Reserve

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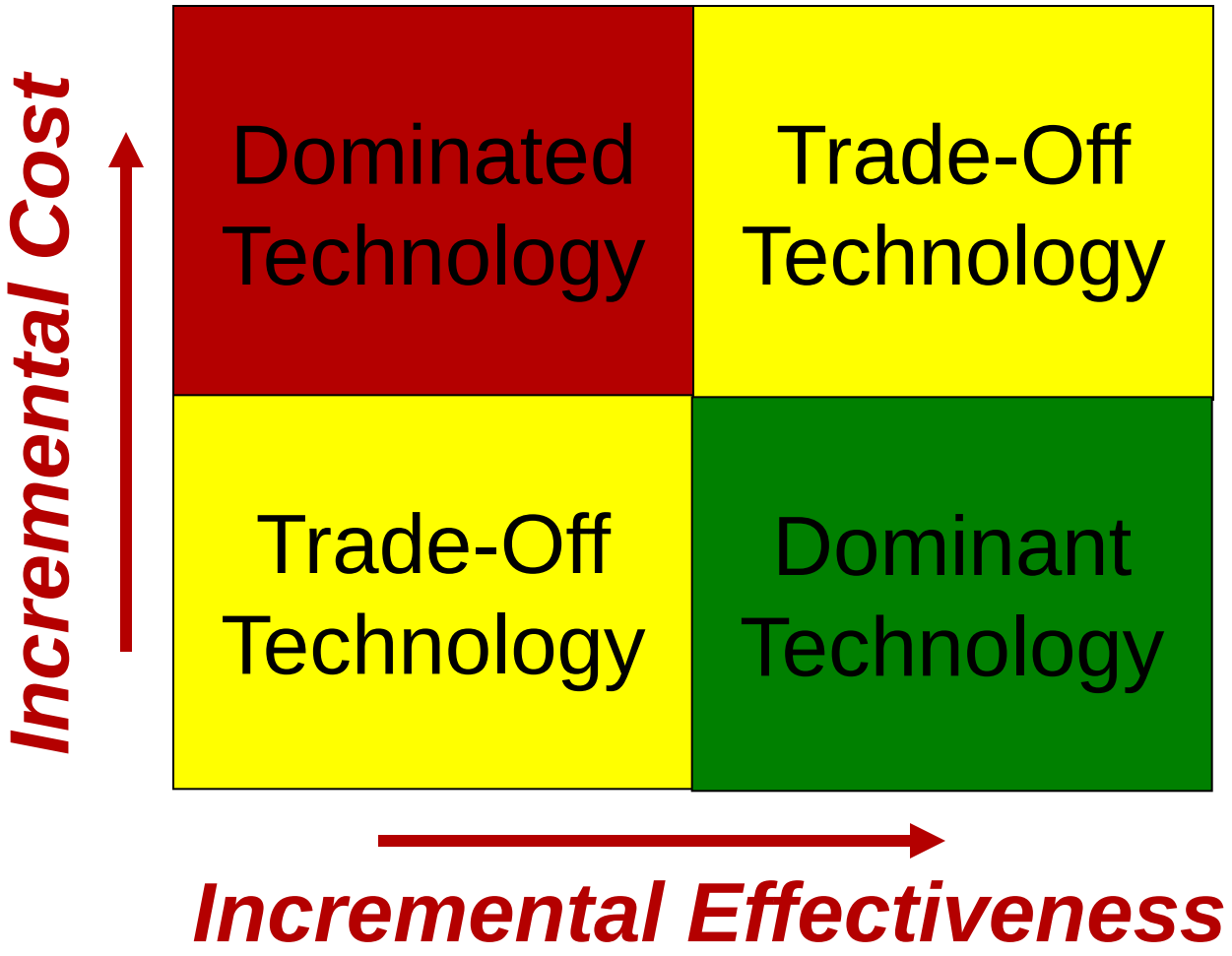
Cost-Effectiveness of FFR

- What impact does measuring FFR have on patient outcomes and costs?

Cost-Effectiveness Plane



Courtesy of Uwe Siebert, MD

Perspectives:

New Yorker's View of the World

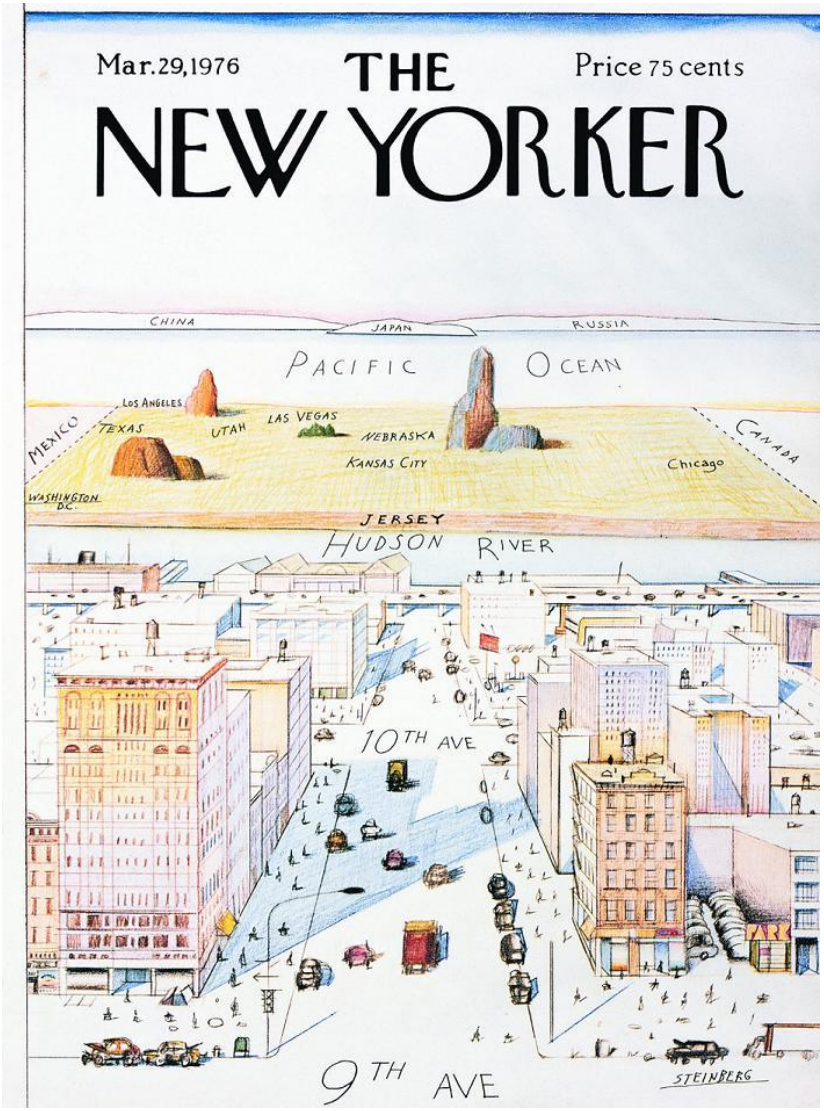
Interventionalist

vs.

Hospital

vs.

Health Care System



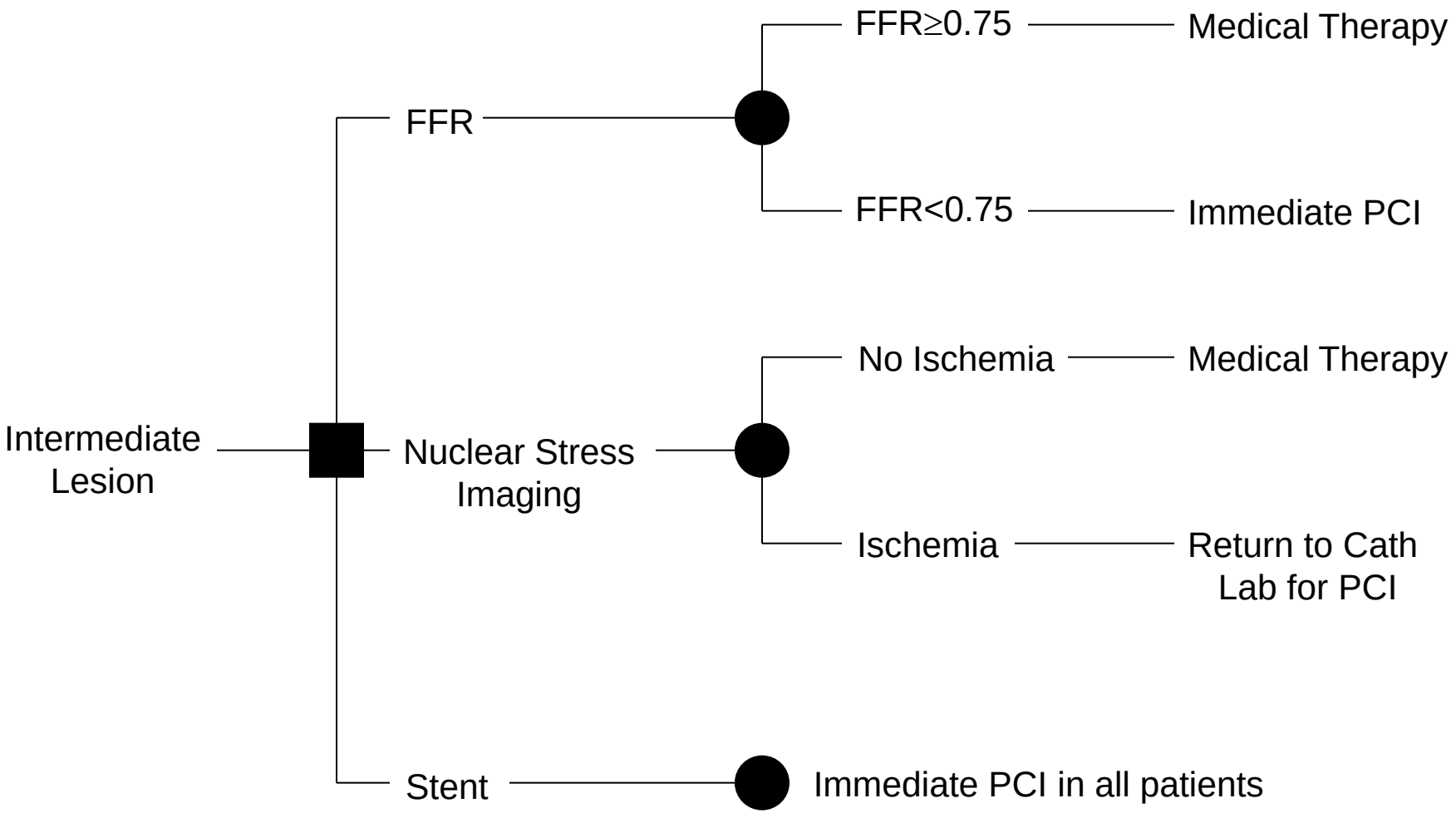
Is FFR Cost Effective?

Computer Modeling

- Evaluate and compare the cost implications of three strategies for intermediate lesions:
  - obtain a nuclear stress imaging study (*NUC Strategy*)
  - stent all patients with intermediate lesions (*STENT Strategy*)
  - measure FFR at the time of angiography to help guide the decision for PCI (*FFR Strategy*)

Am Heart J 2003;145:882-887.

Decision Tree:

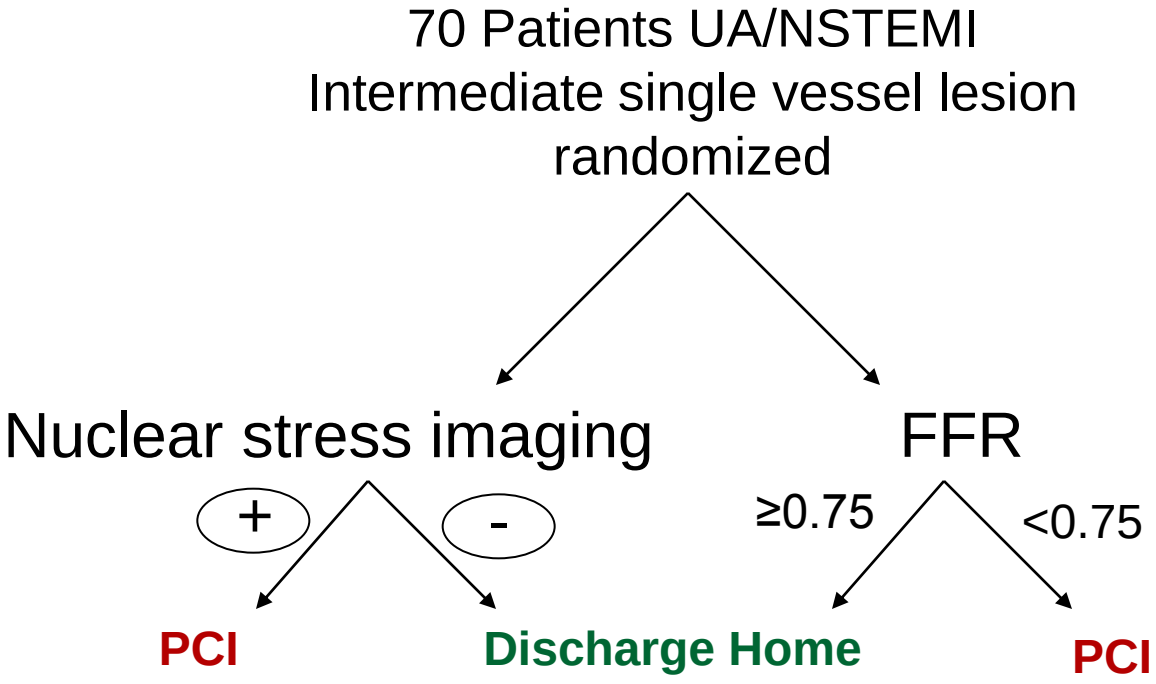


FFR is Cost Effective

	Total Cost	QALYs*	Cost / QALY Gained
NUC Strategy	$13,190	14.7962	
FFR Strategy	$11,395	14.7940	
Difference	**$1,795**	**0.0022**	**$808,000**
STENT Strategy	$15,225	14.7761	
FFR Strategy	$11,395	14.7940	
Difference	**$3,830**	**- 0.0179**	**FFR Dominates**

IS FFR Cost-Effective?

Clinical Validation: Single Vessel CAD



Endpoints: clinical outcome,
duration/cost of hospitalization

Leesar, et al. JACC 2003;41:1115-21.

Is FFR Cost-Effective?

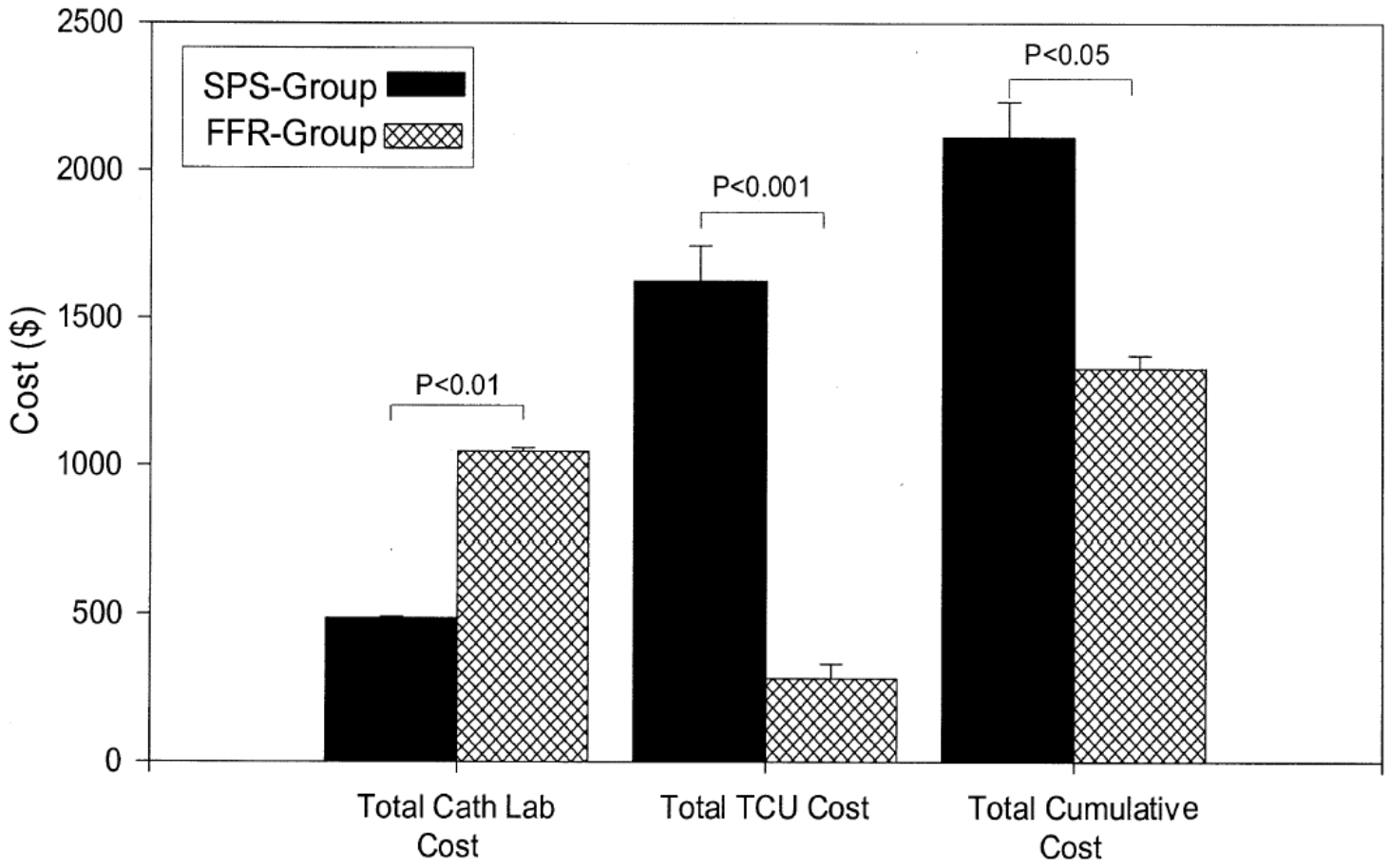
FFR Resulted in Shorter Hospital Stay

	Group 1 (SPS) (n = 35)	Group 2 (FFR) (n = 35)	p Value
Procedure time (min)	36 ± 2	47 ± 3	NS
Radiation exposure time (min)	7 ± 1	9 ± 1	NS
Amount of contrast media used (ml)	167 ± 8	182 ± 12	NS
Duration of hospitalization (h)	49 ± 5	11 ± 2	< 0.001
Post-procedural time in the cath lab (min)	75 ± 7	162 ± 25	< 0.01

Leesar, et al. JACC 2003;41:1115-21.

Is FFR Cost-Effective?

FFR resulted in lower costs



Leesar, et al. JACC 2003;41:1115-21.

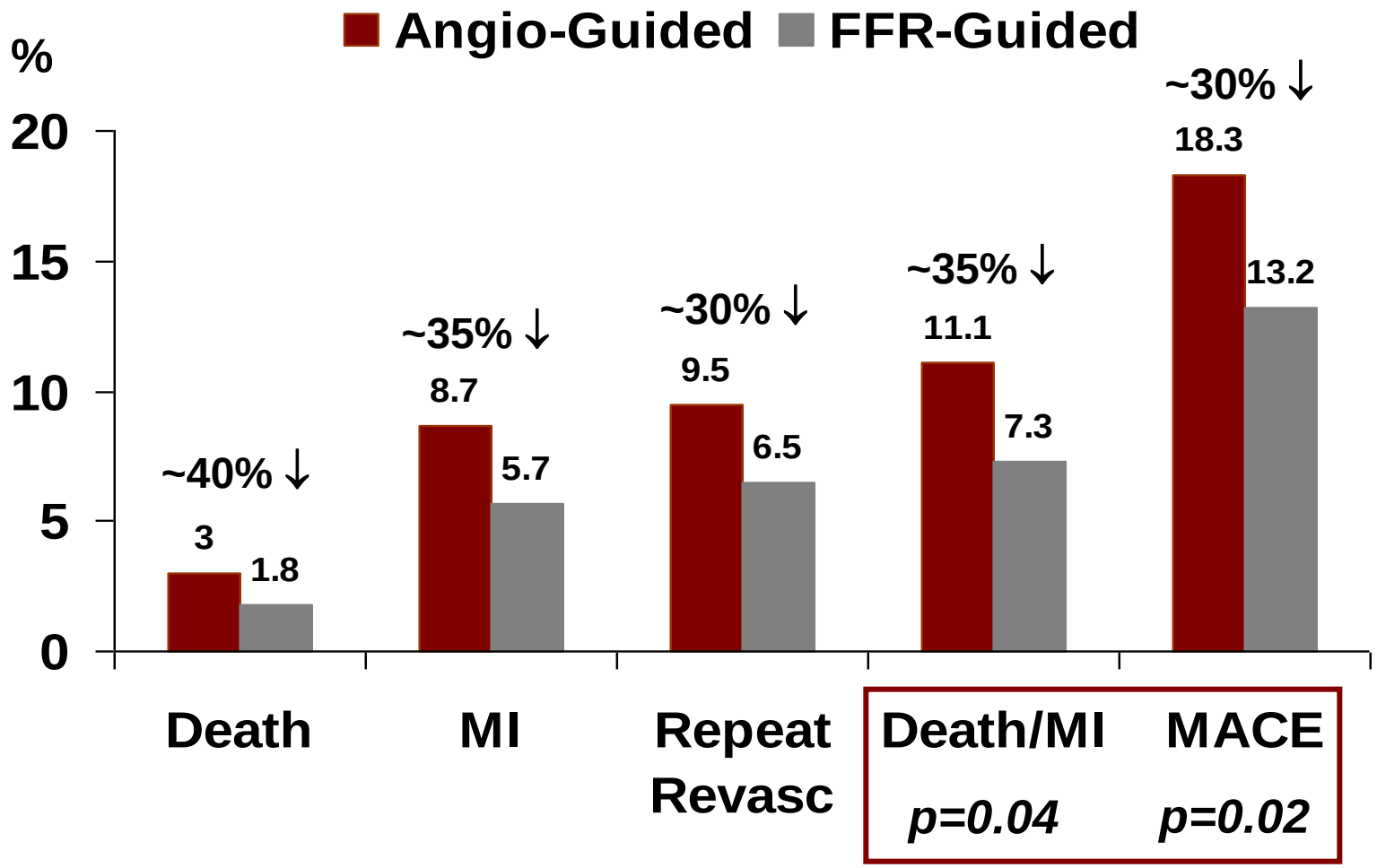
Is FFR Cost-Effective?

FFR guidance resulted in similar clinical outcomes

	Group 1 (SPS) (n = 34)	Group 2 (FFR) (n = 34)
Average follow-up (months)	12.0 ± 0.8	14.0 ± 1.0
Death	0	0
Angina		
No angina (n)	17	24
CCS classification of angina (n)		
1–2	17	10
3–4 (admitted to the hospital)	6	5
Stress perfusion scintigraphy	4	4
Negative (n)	4	4
Cardiac catheterization	2	3
Results (no change)	2	2
Disease progression	0	1
MI	1	1
CABG including target vessel	1	2
PCI	0	0

Leesar, et al. JACC 2003;41:1115-21.

FAME Study: One Year Outcomes



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

FAME: Economic Evaluation

Methods

- Economic evaluation in the context of the US health care system
- Calculated the incremental cost effectiveness ratio (ICER)
  - Net incremental costs of each strategy divided by net incremental health outcomes
    - Resource consumption
    - Health related quality of life (EQ-5D)
- One year time horizon
- Societal perspective, using direct costs

Circulation 2010;122:2545-50.

FAME: Economic Evaluation

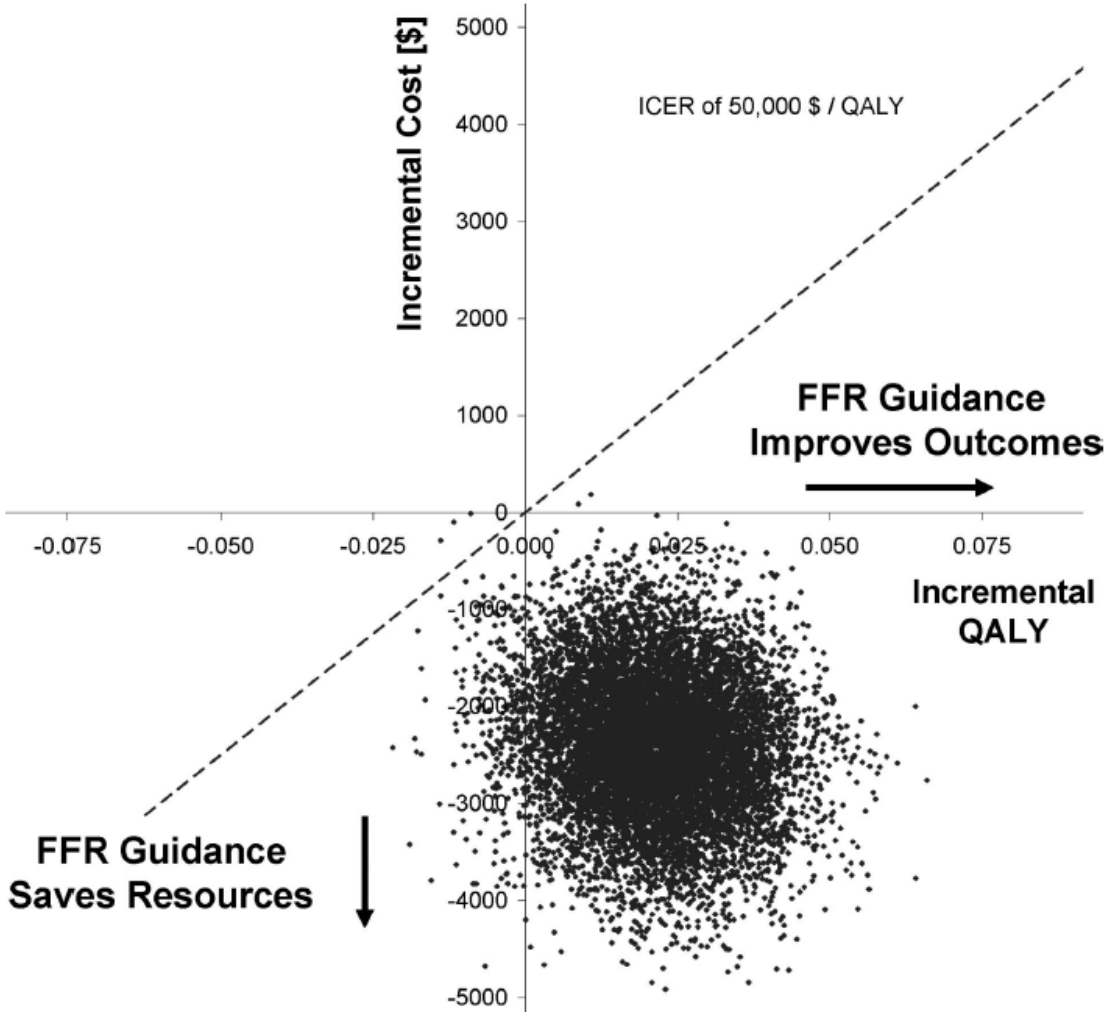
Overall Health Outcomes and Costs

Outcome	Angiography Guided	FFR Guided	Difference (95% CI)
MACEs, %	18.3	13.2	5.2 (0.7–9.7)
MI, %	8.7	5.7	3.0 (−0.2–6.2)
Death, %	3.0	1.8	1.3 (−0.6–3.2)
MI or death, %	11.1	7.3	3.8 (0.3–7.4)
QALY	0.838	0.853	0.015 (−0.008–0.037)
Costs of initial procedure, $	6007	5332	
Costs of initial hospitalization, $	14 878	13 182	−1697 (−2893–−510)
Cost of events during 12-mo follow-up	1821	1134	−668 (−1383–−25)
Overall costs, $	16 700	14 315	−2384 (−3826–−1011)

Circulation 2010;122:2545-50.

FAME: Economic Evaluation

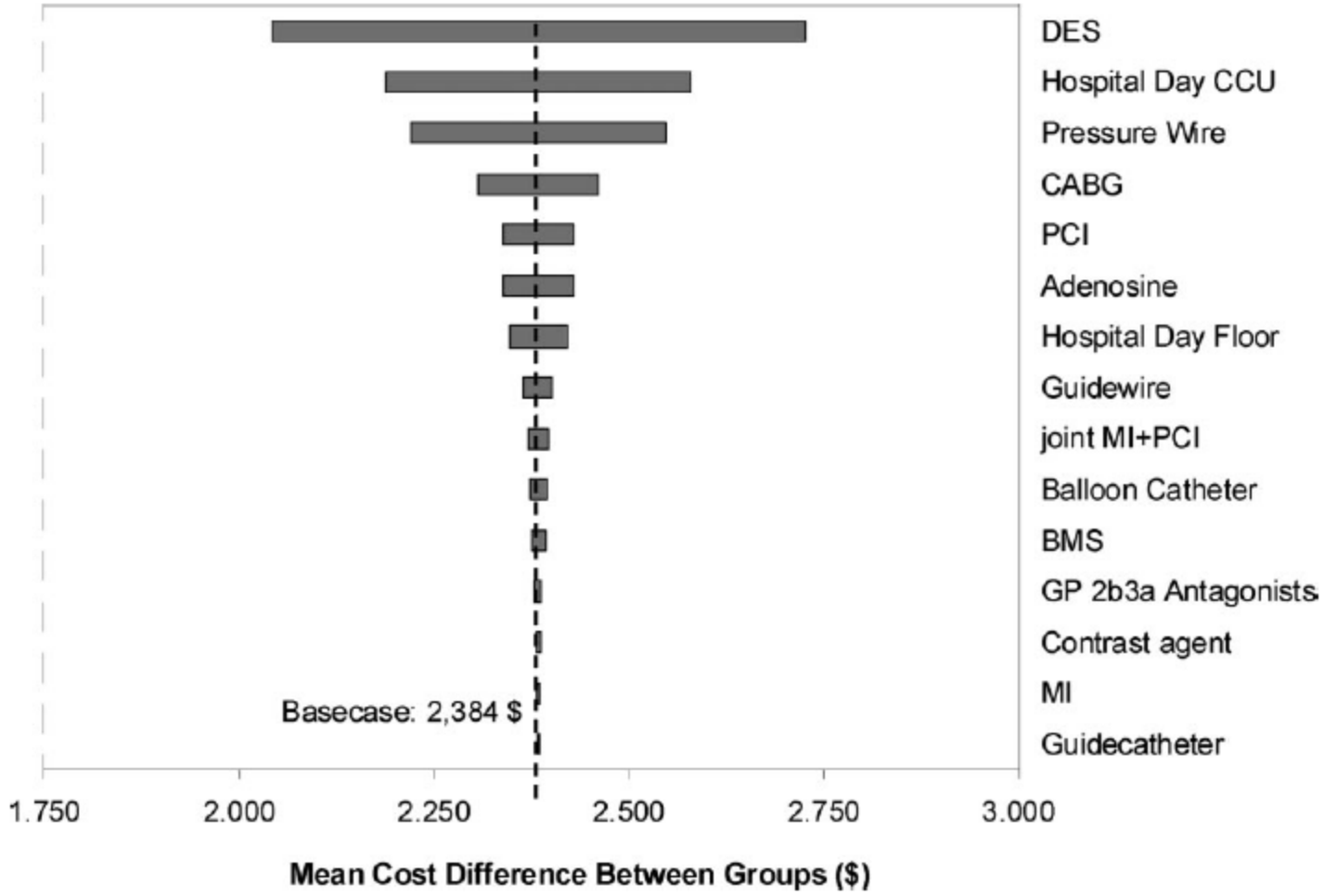
Bootstrap Analysis



Circulation 2010;122:2545-50.

FAME: Economic Evaluation

Sensitivity Analysis



Circulation 2010;122:2545-50.

FAME: Economic Evaluation

Limitations

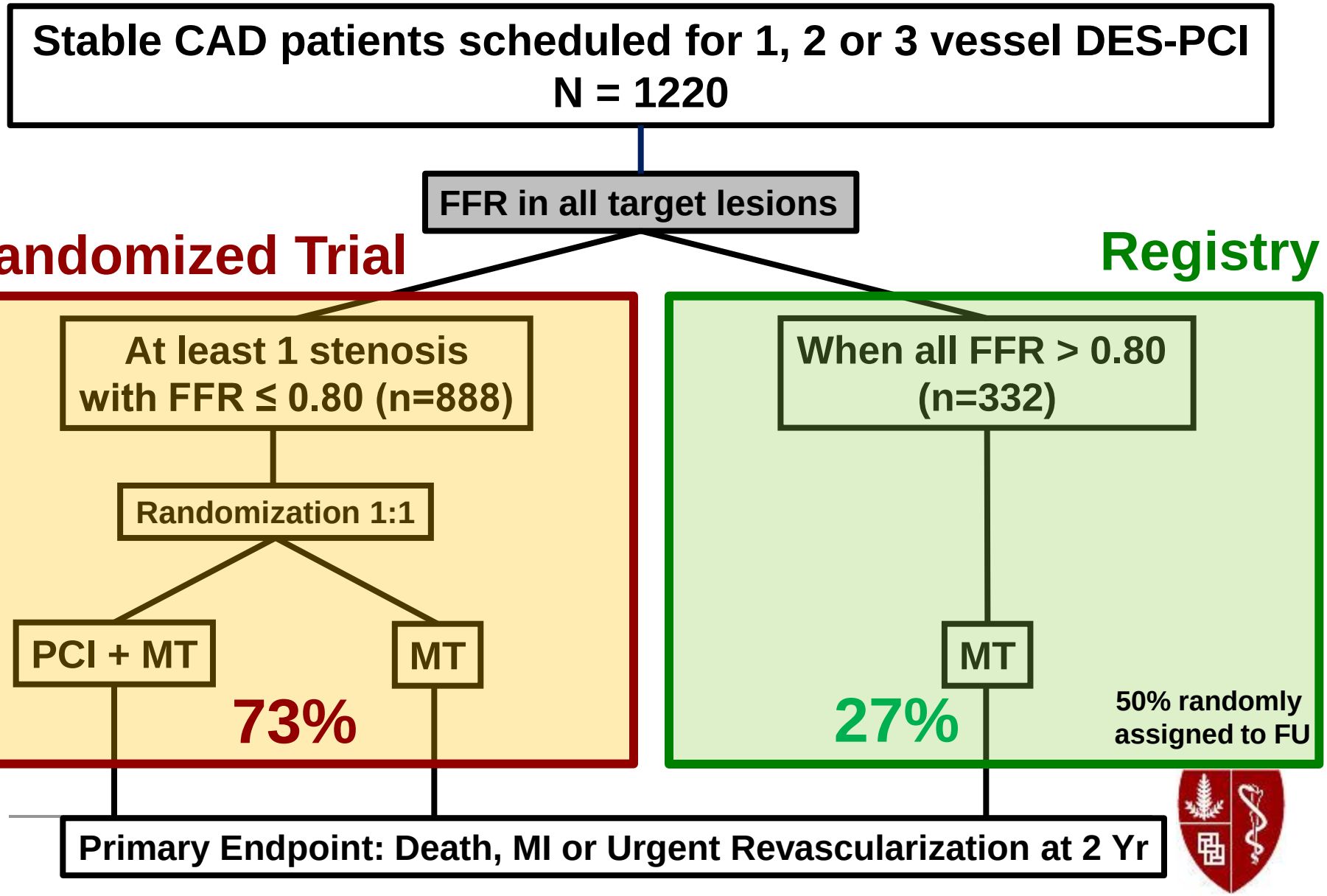
- Short time horizon
- Missing quality of life values and relatively large time intervals
- Did not account for indirect costs
- Results apply to US health care system
- Majority of patients were enrolled outside of the US

Cost-Effectiveness of FFR

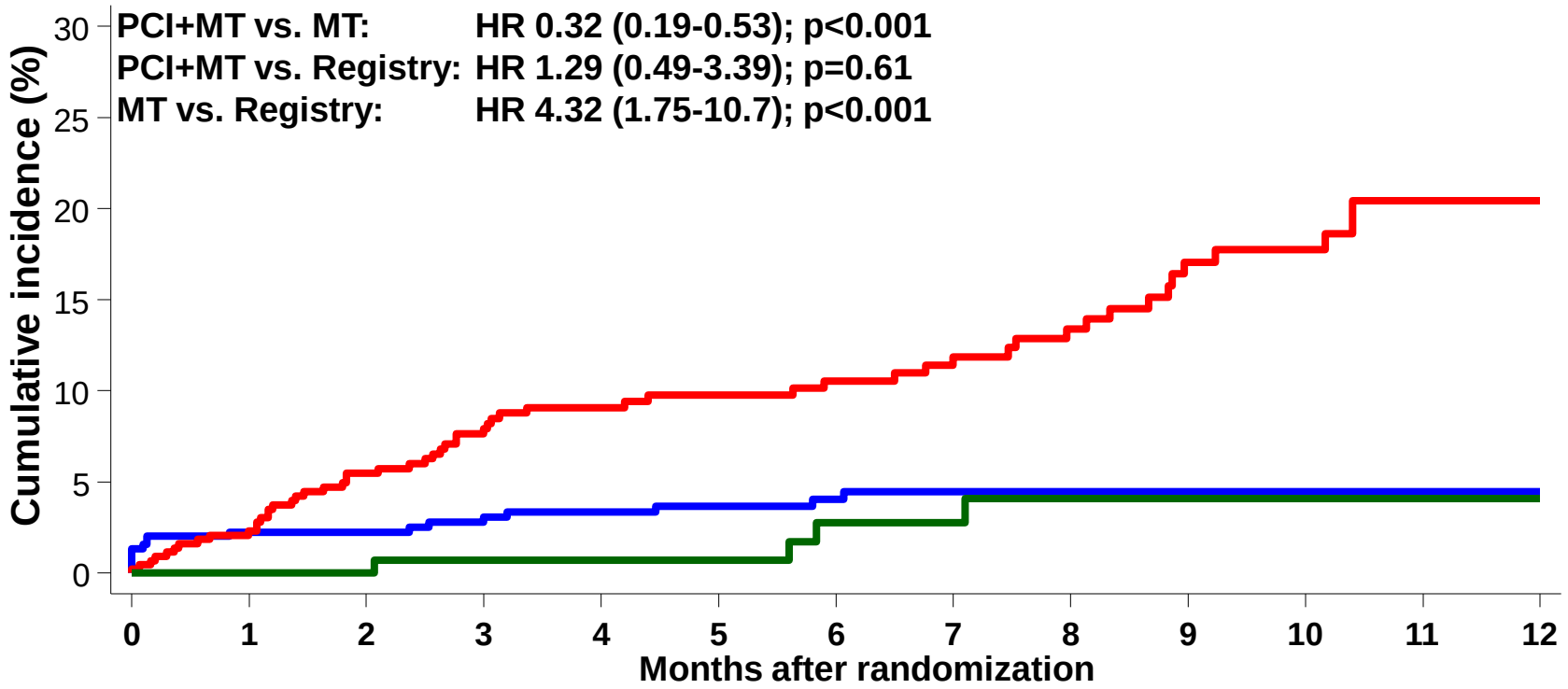
- FFR-guided PCI is a “dominant” strategy when compared to angiography-guided PCI in patients with multivessel CAD.

- What about the cost-effectiveness of FFR-guided PCI in comparison with best medical therapy in patients with stable CAD?

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

Primary Endpoint: *Death, MI, Urgent Revasc*



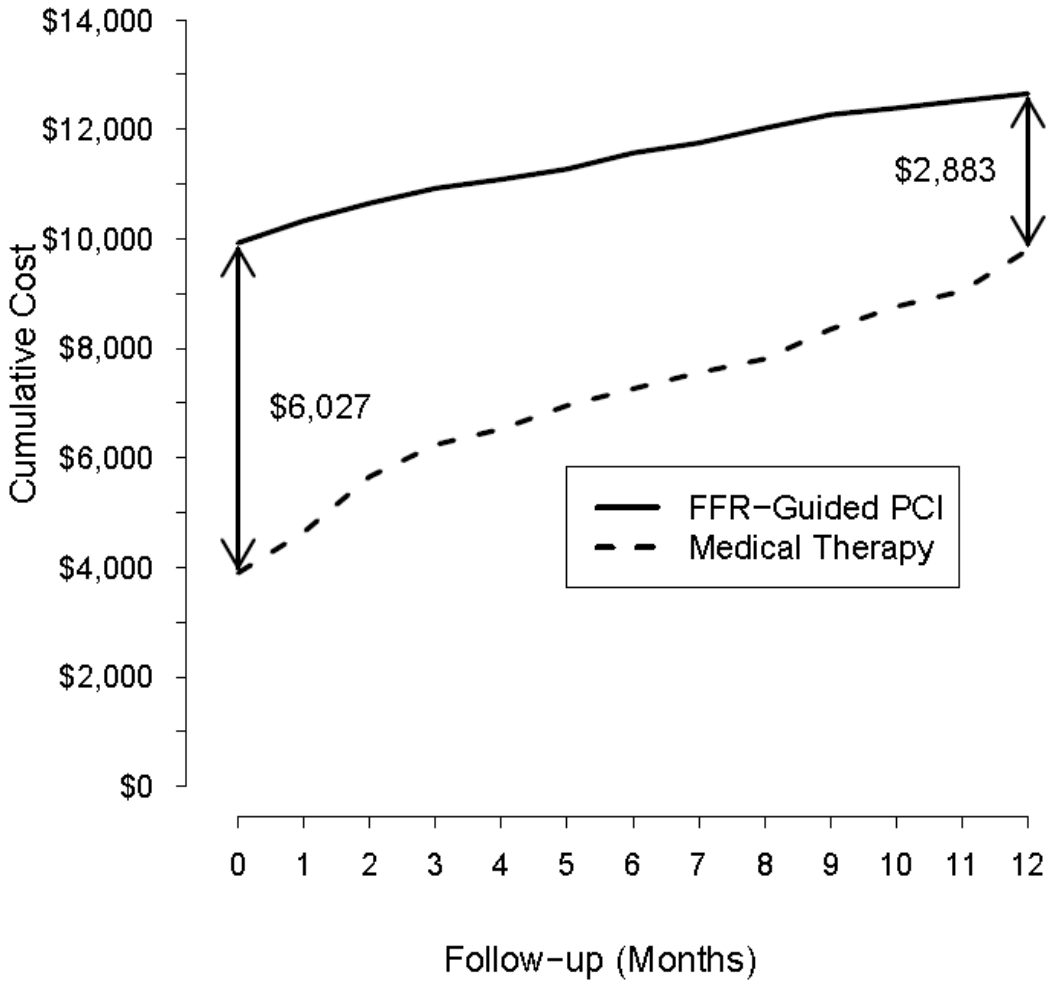
No. at risk

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

De Bruyne, et al. New Engl J Med 2012;367:991-1001

FAME 2: Cost-Effectiveness

Change in Costs over Time



Updated from TCT 2012 Late Breaking Trial

FAME 2: Cost-Effectiveness

Change in Quality of Life

Treatment Arm	*Baseline*	*1 Month*	*Difference*
FFR-Guided PCI	0.817	0.871	0.054
Medical Therapy	0.845	0.846	0.001

FAME 2: Cost-Effectiveness

- Assuming the difference in QALY between PCI and Medical Therapy would gradually narrow and disappear over three years…

Three Year Projection

$2,883 / 0.079 QALY = $36,000 / QALY

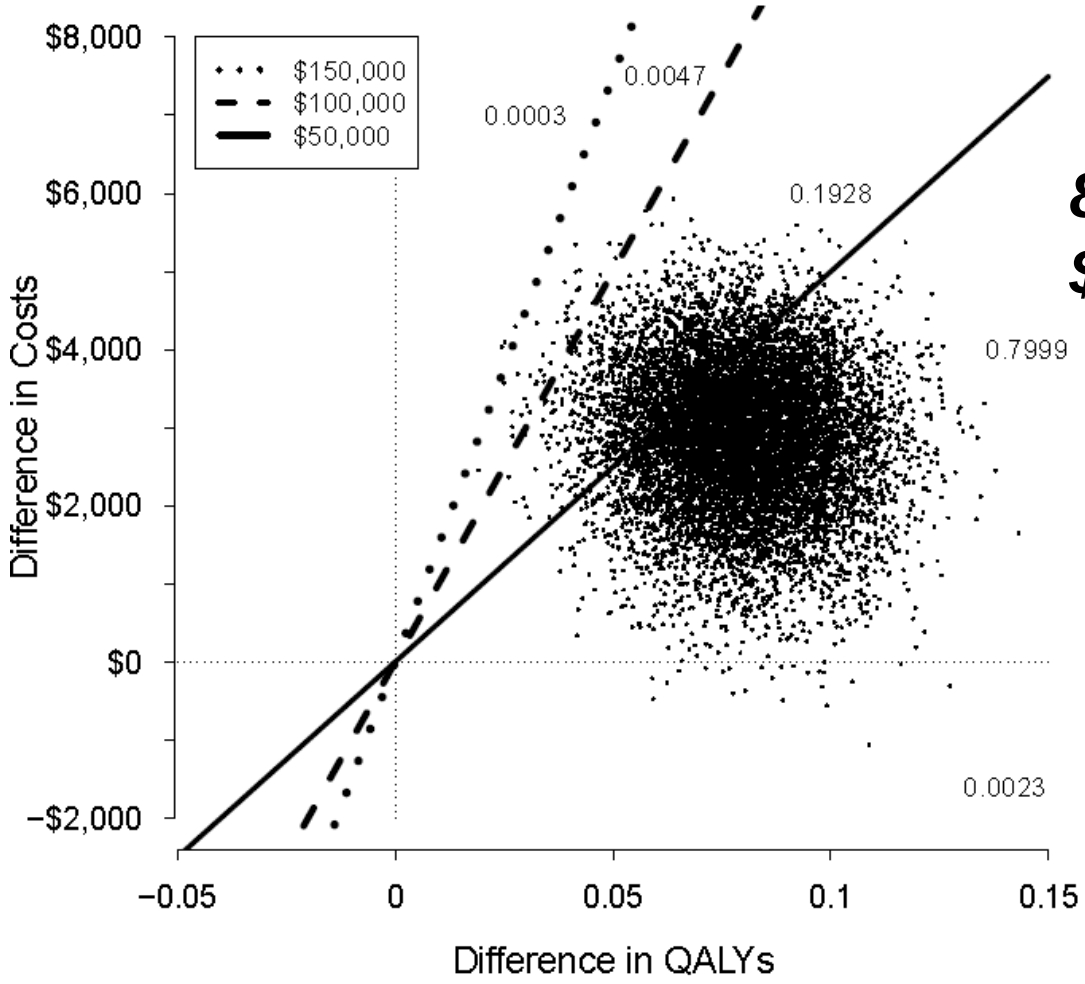
FAME 2: Cost-Effectiveness

Sensitivity Analyses

Variable	***$ / QALY***
DES + $400	44,000
DES - $400	29,000
No pressure wire in MT arm	44,000
Benefit of PCI lasts 2 years	54,000
Benefit of PCI lasts 4 years	27,000
Non-urgent PCI in MT arm = $0	55,000

FAME 2: Cost Effectiveness

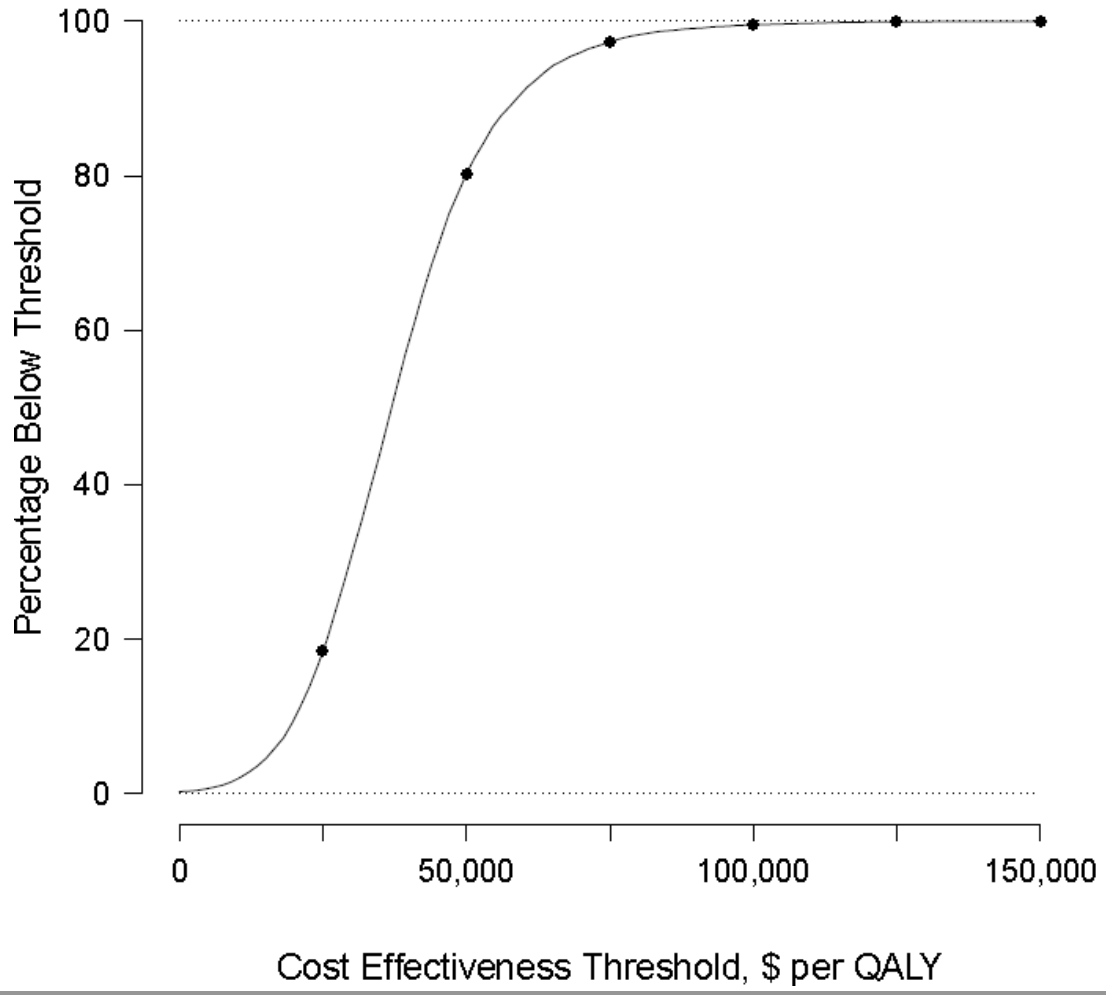
Bootstrap Simulation



80% are less than $50,000 / QALY

FAME 2: Cost Effectiveness

Cost Acceptability Curve



Cost-Effectiveness of FFR

Conclusion

- Although measuring FFR does add cost to a procedure, because it improves patient outcomes in all settings and avoids unnecessary PCI in some, FFR is a cost-effective technique in almost all scenarios.