Medical Cost and Prognostic Impact of FFR-guided PCI

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Disclosure

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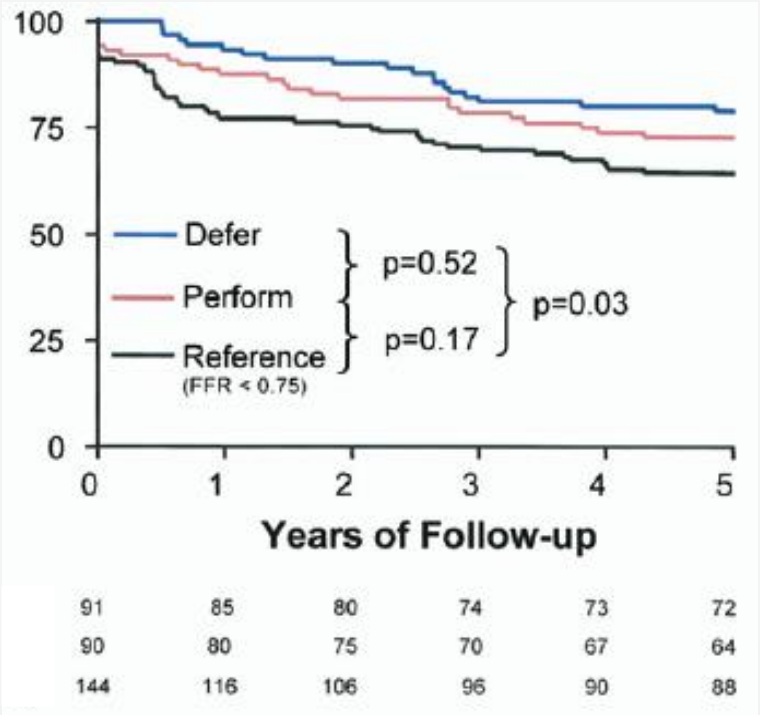
- **Other: None**

Clinical Benefit of Physiology-Guided PCI

DEFER

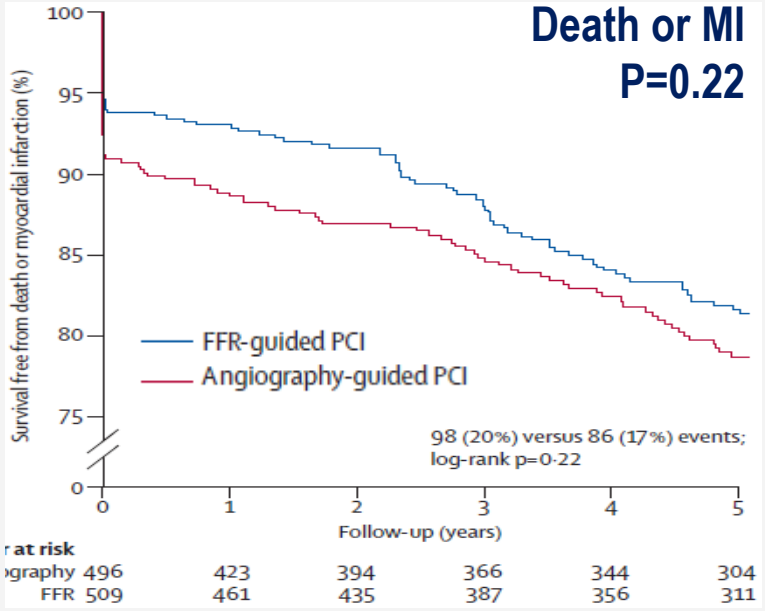
Defer vs. PCI in FFR≥0.75



Safety of deferral of PCI based on negative FFR

FAME

Angio- vs. FFR-guided PCI in MVD

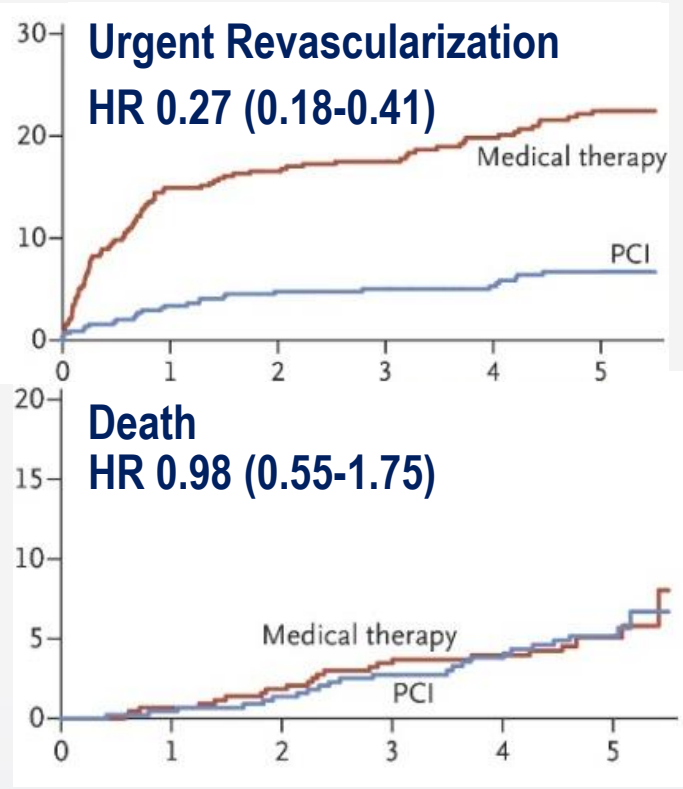


No. Stents: 2.7 vs. 1.9, P<0.001

Long-term safety of FFR-guided PCI with lower cost

FAME2

Medical Tx. vs. PCI in FFR≤0.80



PCI was beneficial with lesions with positive FFR

Pijls et al. J Am Coll Cardiol 2007;49:2105–11,
Nunen et al. Lancet 2015; 386: 1853–60, Xaplanteris et al. N Engl J Med 2018;379:250-9.

Current Status of Coronary Physiology to Guide PCI

2018 ESC Guideline for Myocardial Revascularization

Recommendations	Class[a]	Level[b]
When evidence of ischaemia is not available, FFR or iwFR are recommended to assess the haemodynamic relevance of intermediate-grade stenosis.[15,17,18,39]	I	A

2021 ACC/AHA/SCAI Coronary Revascularization Guideline

COR	LOE	RECOMMENDATIONS
1	A	1. In patients with angina or an anginal equivalent, undocumented ischemia, and angiographically intermediate stenoses, the use of fractional flow reserve (FFR) or instantaneous wave-free ratio (iFR) is recommended to guide the decision to proceed with PCI (1-6).
3: No benefit	B-R	2. In stable patients with angiographically intermediate stenoses and FFR >0.80 or iFR >0.89, PCI should not be performed (7-10).

Both guidelines have recommended the FFR-guided decision making as Class IA.

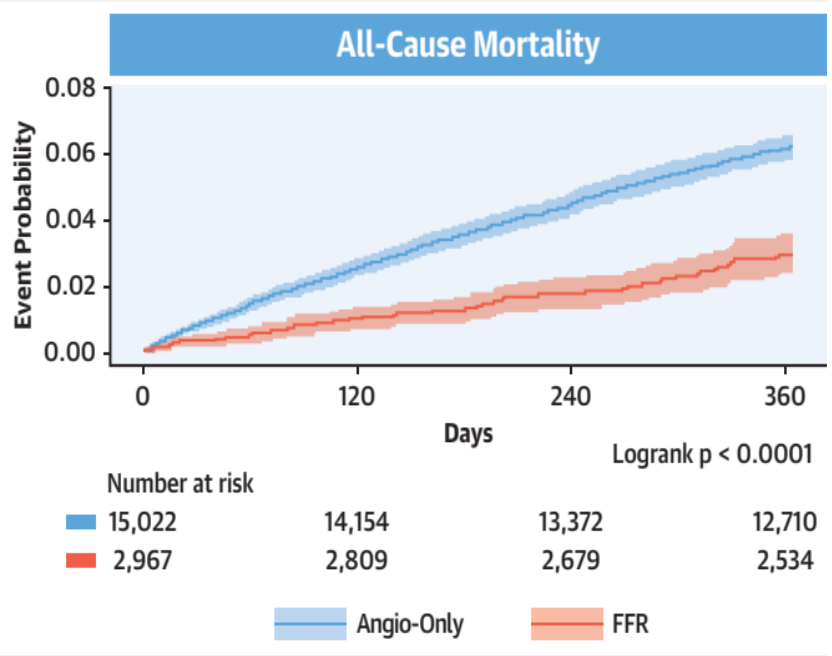
What about real-world data and adoption rate?

FFR-guided PCI improve patient survival in nationwide cohort studies

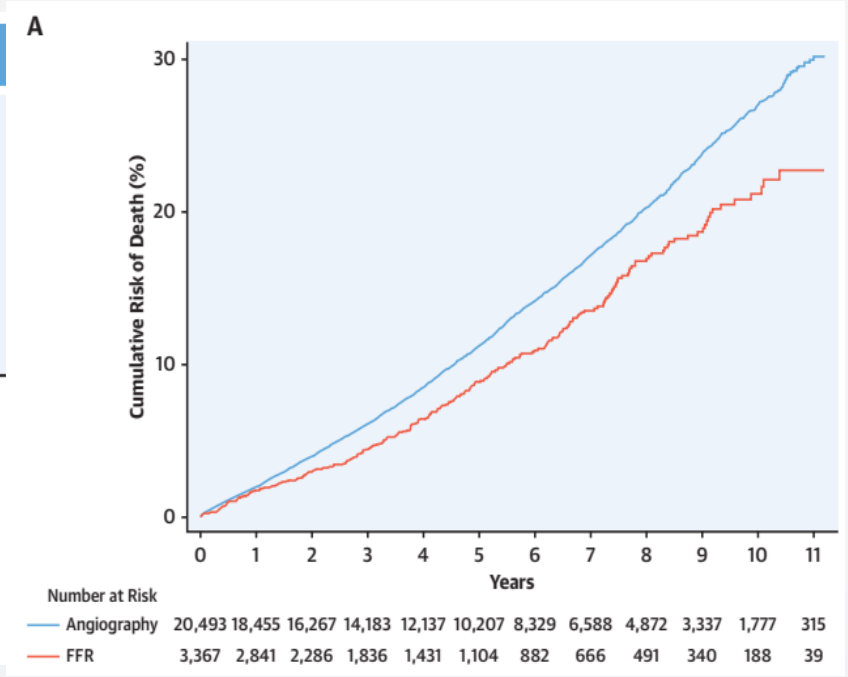
All-Cause Mortality

FFR-Guided PCI versus Angiography-Only PCI

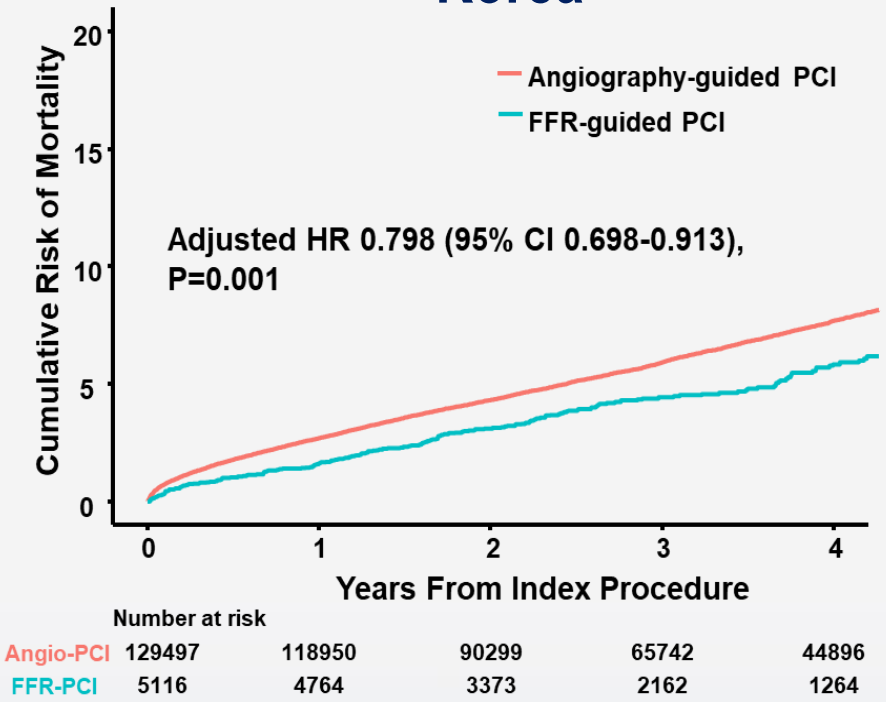
USA



Europe (Sweden)



Korea



Veterans Affairs registry 2009-2017
(Stable IHD N=17,989, 1 Year)

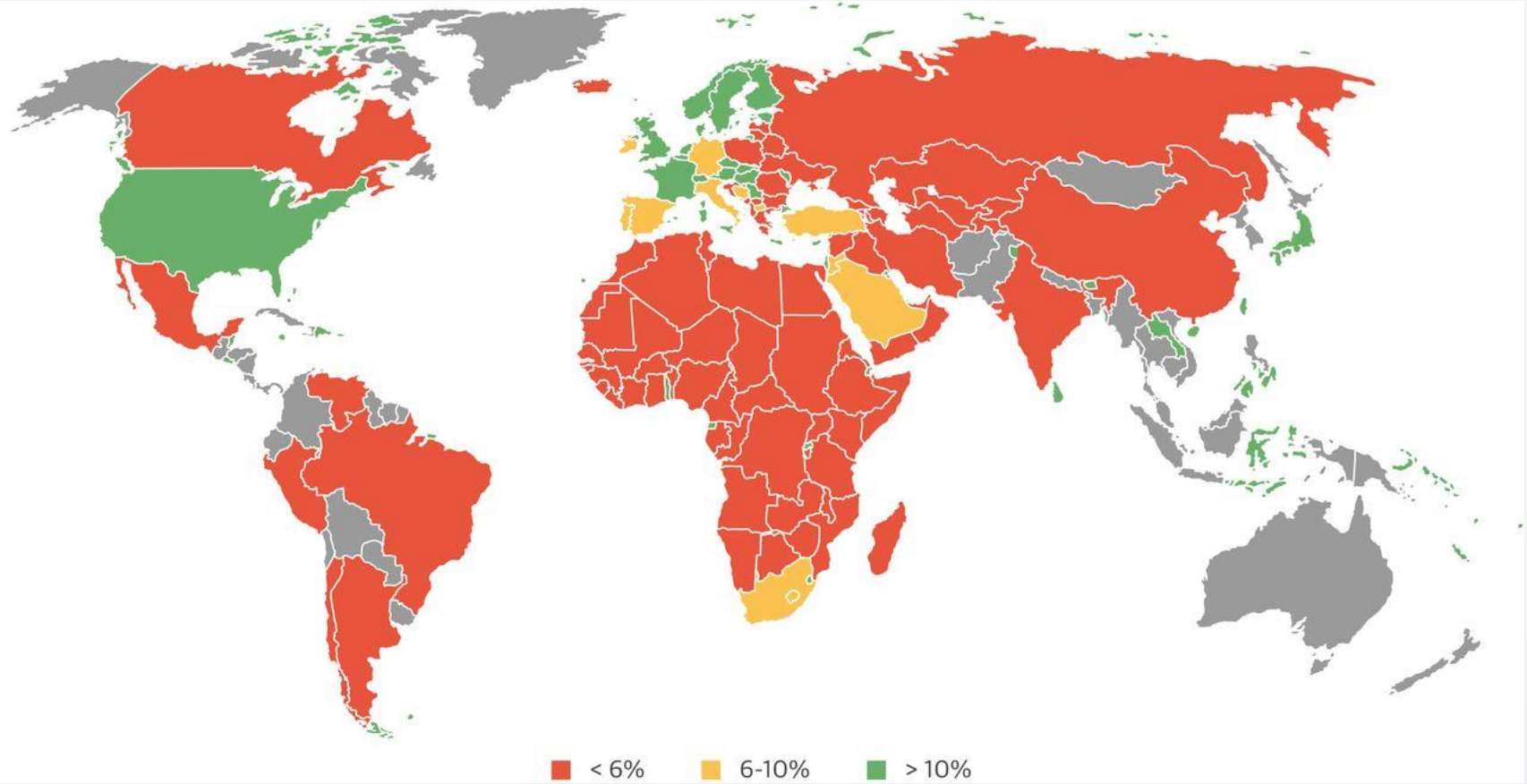
SCAAR registry 2005-2016
(Stable IHD N=23,860, Median 4.7 Years)

Korean NHIS-HIRA 2013-2018
(Total N=134,613, 4 Years)

Parikh et al. J Am Coll Cardiol 2020;75:409–19 / Volz et al. J Am Coll Cardiol 2020;75:2785–99 / Hong D, Lee SH,,, Lee JM, JACC Asia 2022

Low Adoption Rate of FFR in Contemporary Practice

Experts emphasized the role of FFR.
Guidelines endorsed Class IA.
RWDs showed reductions in mortality.



Multifactorial reasons for limited adoption rates.

Whether FFR can reduce

1. **Cost-Effectiveness**
2. Additional procedural time
3. Knowledge Barrier
4. Physician attitude

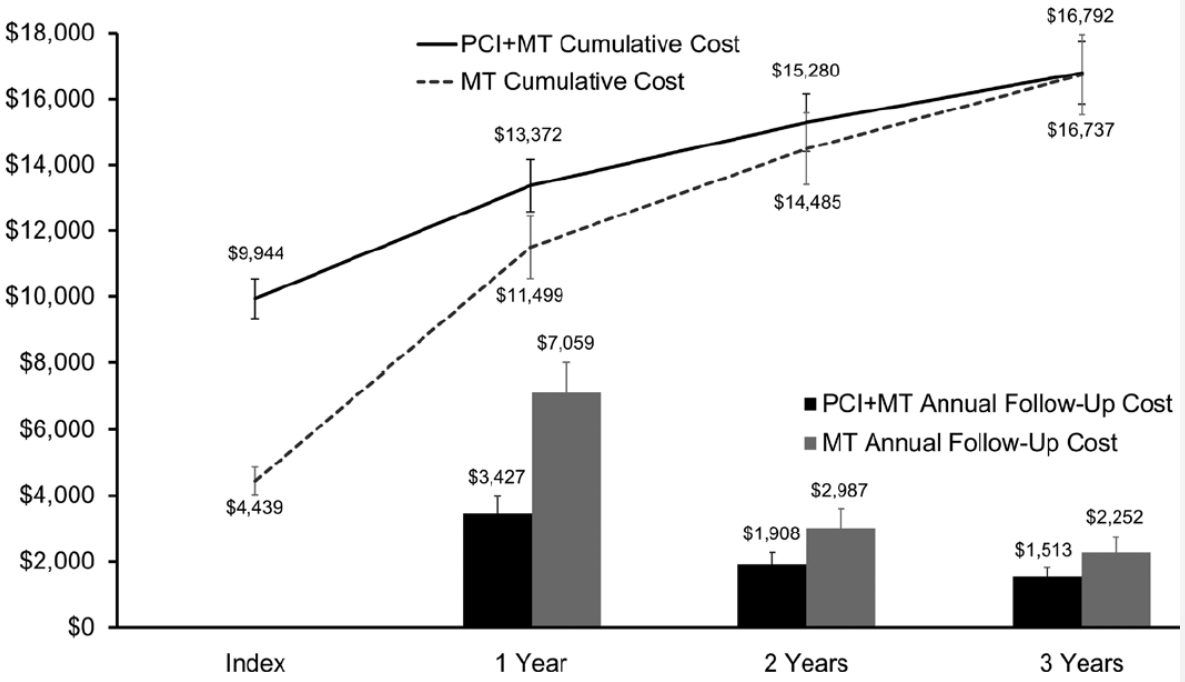
remains questionable…

Götberg et al. J Am Coll Cardiol 2017;70:1379–402; Rev Esp Cardiol 2018

Cost-Effectiveness of FFR-Guided PCI

Patients with FFR<0.80 from FAME2

3-Year Cumulative Medical Costs



Mean initial costs were higher in the PCI group, but by 3 years were similar between the 2 groups.

Decision Tree Model of SIHD undergoing ICA from Multicenter-Registry

3-Month Cumulative Medical Costs

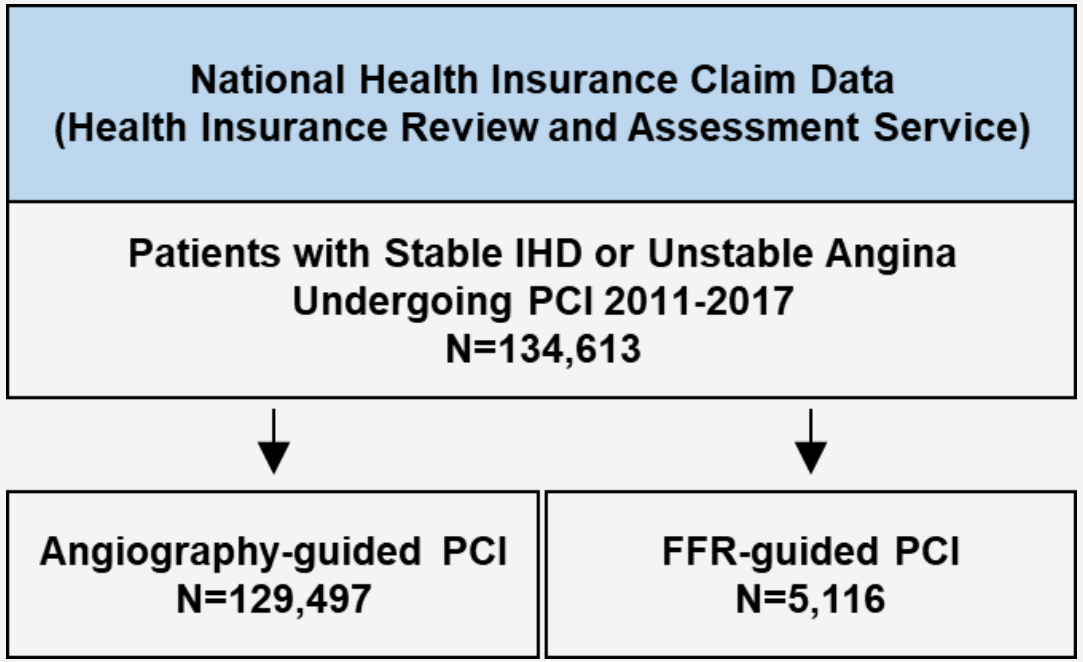
	Angiography-guided group	FFR-guided group	Difference
Test cost			
Angiography	54,000	54,000	0
FFR	0	185,660	185,660
Treatment cost			
CABG	99,792	90,455	−9337
PCI	995,497	522,485	−473,012
Medical treatment	189,983	362,066	172,083
Total medical cost	**1,339,272**	**1,214,666**	**−124,606**

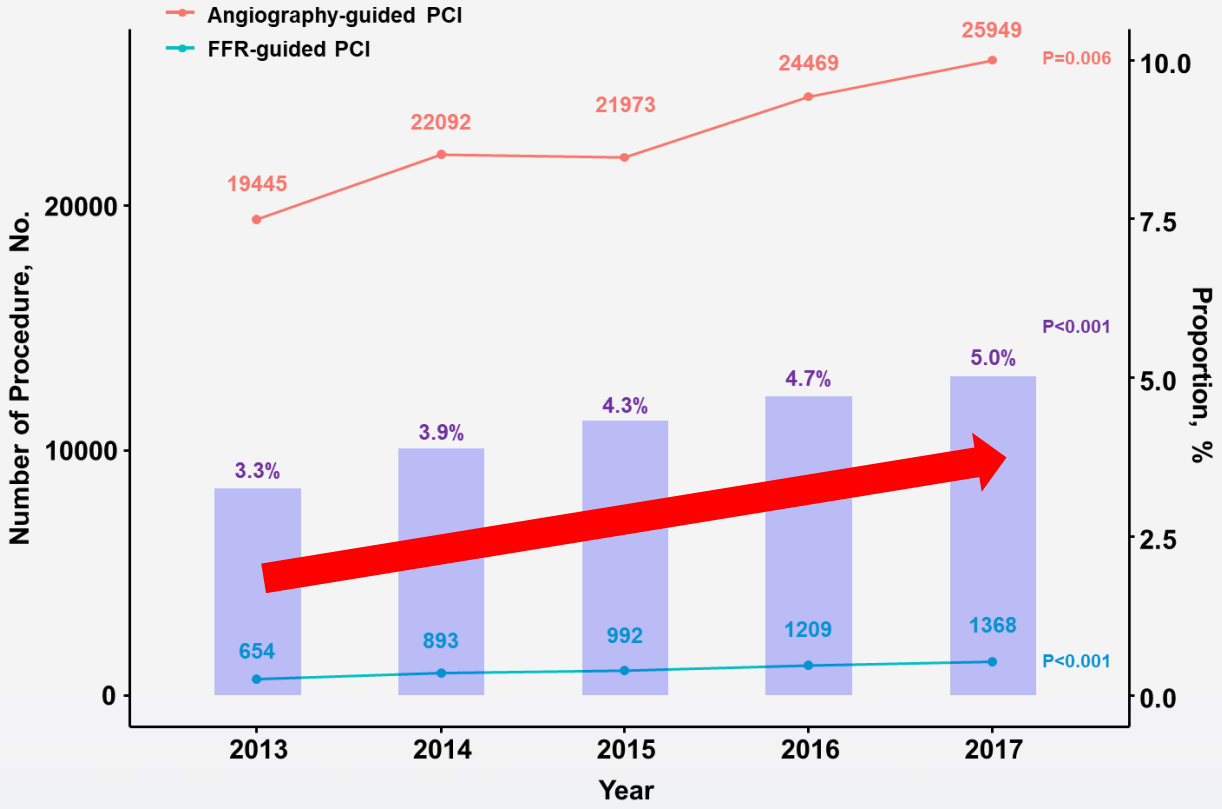
Fearon et al. Circulation. 2018;137:480–487, Tanaka et al. J Cardiol 2019;73:38-44.

Real-world Data of FFR-guided PCI in Korea

Health Insurance Review and Assessment Service Data

134,613 Patients with Stable and Unstable Angina (2011~2017)





Although the annual number and proportion of FFR-guided PCI significantly increased, only 3.8% were FFR-guided PCI in Korea.

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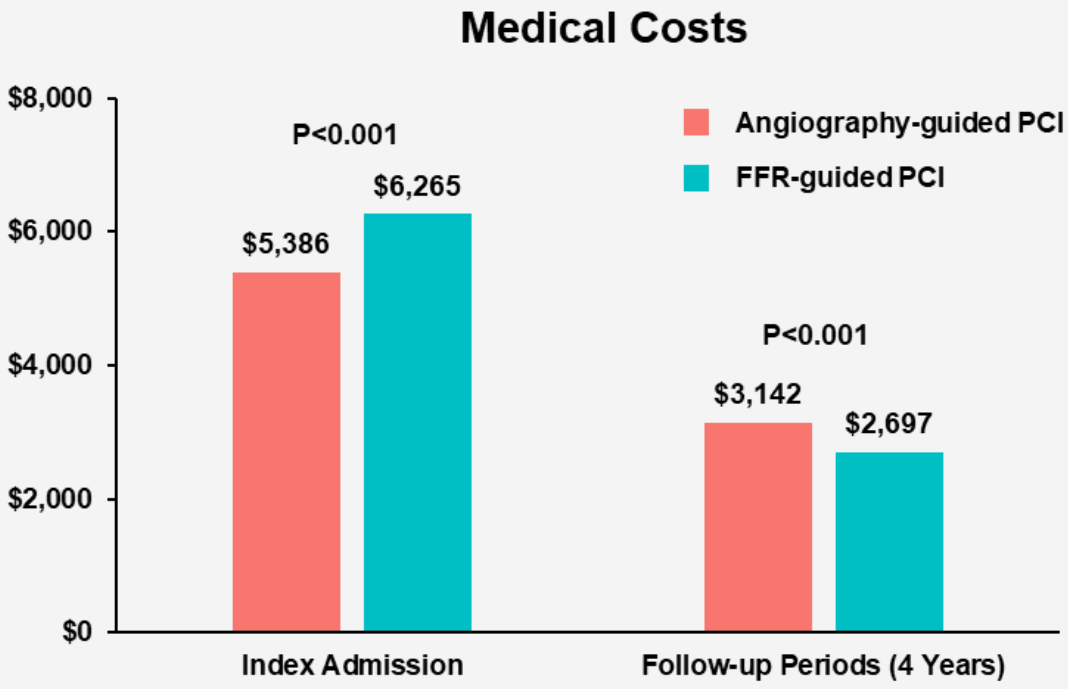

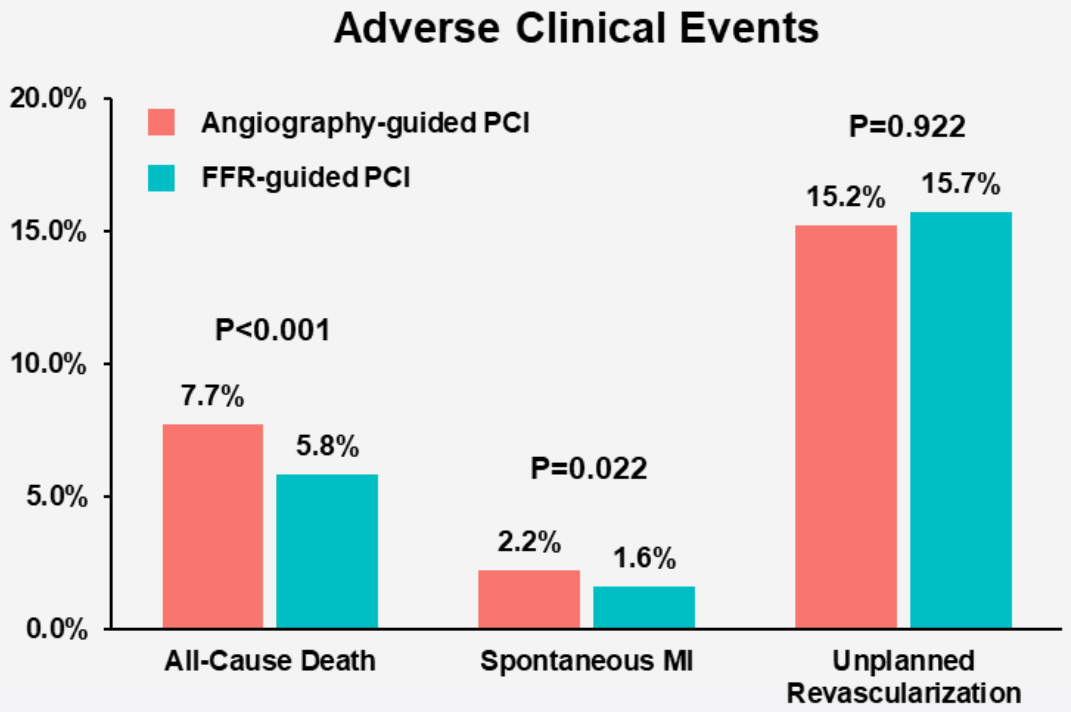

- FFR-guided PCI showed significantly lower risk of all-cause death or spontaneous MI at 4 years.
- Although FFR group showed higher medical cost during index admission, cumulative medical cost after index admission was significantly lower in the FFR group.

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Cost-Effectiveness Analysis with Nationwide Data

1. Patient-Level Analysis (Korea)

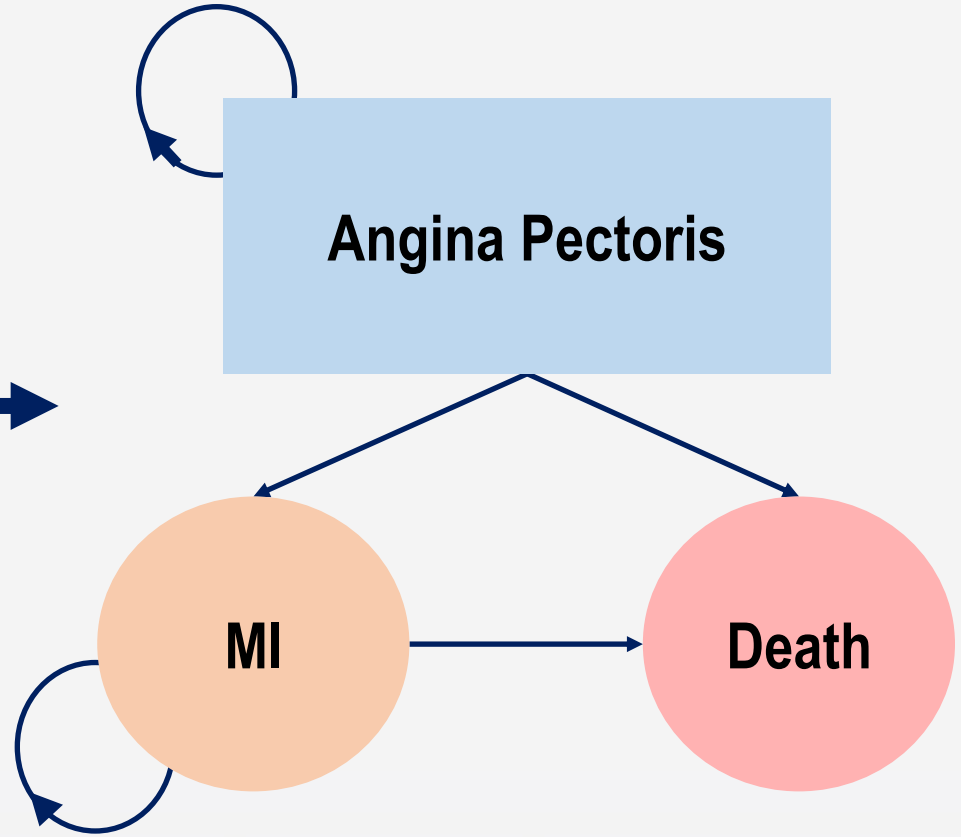
National Health Insurance Claim Data
(Health Insurance Review and Assessment Service)

Patients with Stable or Unstable Angina
Undergoing PCI 2011-2017
N=134,613

Angiography-guided PCI	FFR-guided PCI
N=129,497	N=5,116

2. Markov Model-Based Analysis (Korea, US, UK)

Previous Evidence



Outcomes

- **Cost**
- **Quality-adjusted life year (QALY):** ∑ (Utility of each status × Time in each status)
- **Incremental cost-effectiveness ratio (ICER)** = ΔQALY / Δ Cost

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Cost-Effectiveness Analysis with Nationwide Data

Patient-Level: Cost-Effectiveness Analysis at 4-Year (Korea)

Base-Case Analysis	Cost, $		QALYs		Cost-Effectiveness ICER(US$/QALY)
	Total	Incremental	Total	Incremental	
Angio-PCI	10,503	Reference	3.037	Reference	-7,748
FFR-PCI	10,200	**-303**	3.076	**0.039**	

FFR-based PCI was shown to achieve better quality of life at lower cost compared to angiography-based PCI.

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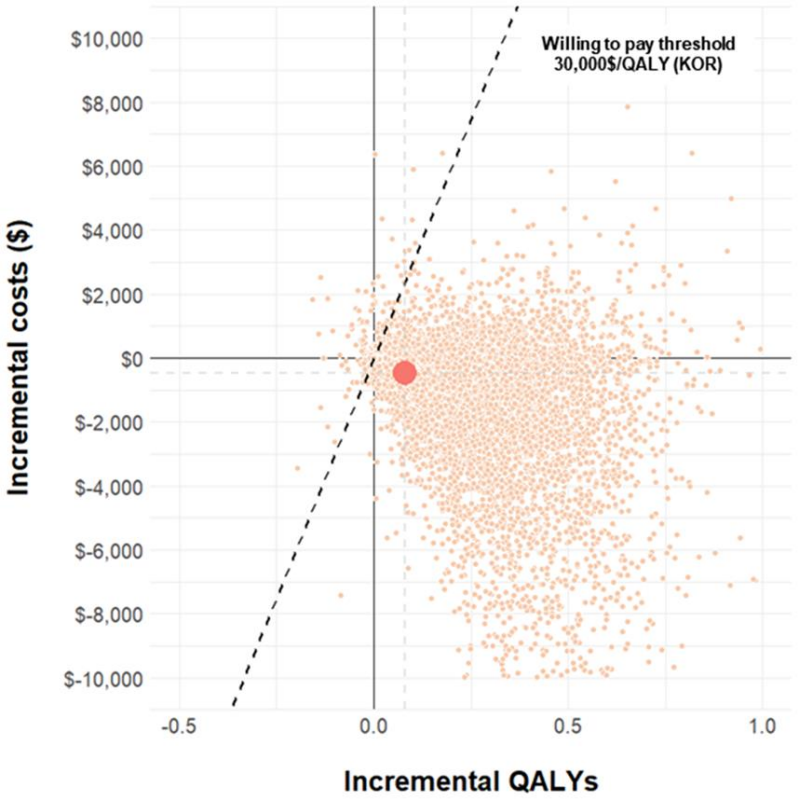
Cost-Effectiveness Analysis with Nationwide Data

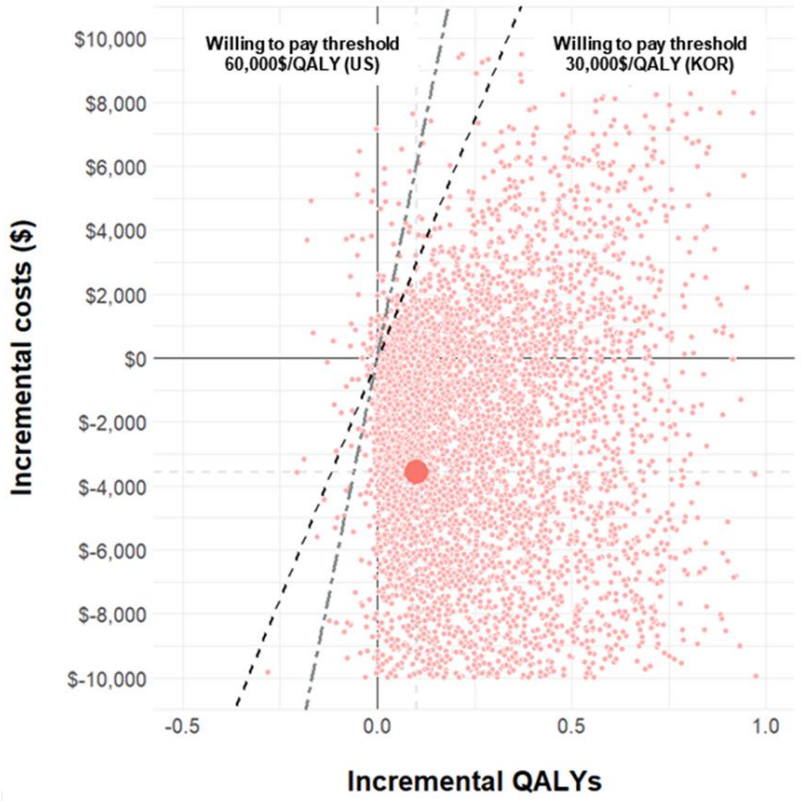
Model-Based: Probabilistic Sensitivity Analysis (PSA)

Bootstrap Technique with 25,000 Replications

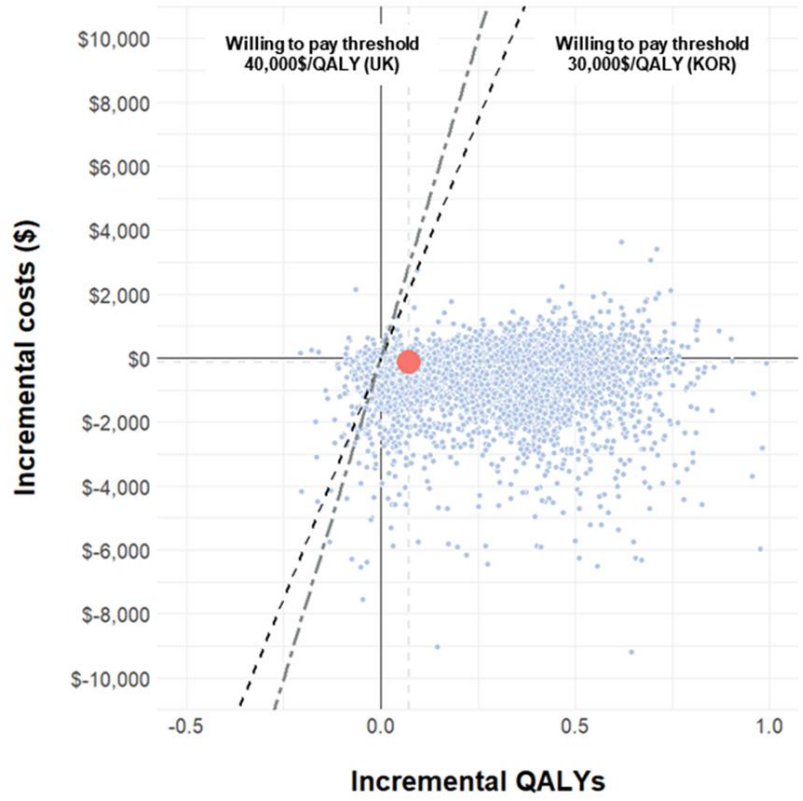
Korea



US



UK



Given the GDP per capita in each country, cost-effectiveness for FFR-based PCI were 93.5%, 92.3% and 90.8% for Korea, US and UK in PSA analysis, respectively.

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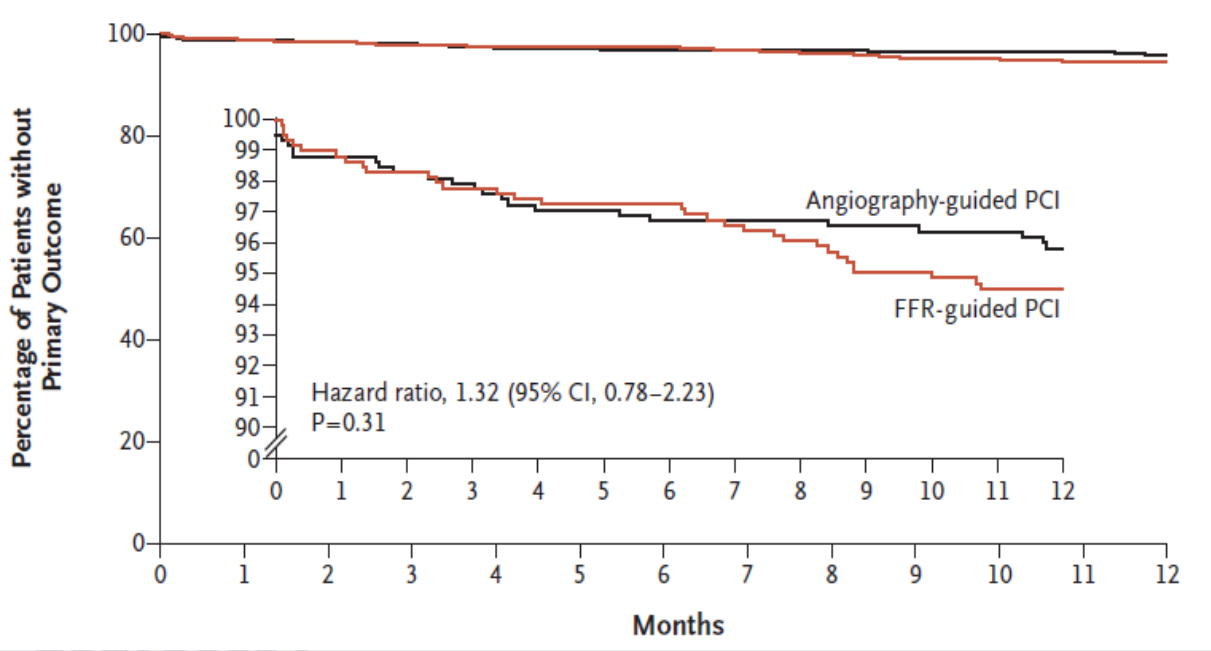
FFR-guided vs. Angio-guided PCI for Non-IRA Lesions

FLOWER-MI Trial

Prospective, Multi-center, Open-Label Randomized Trial
1171 MV-STEMI Patients from 41 French Centers

Primary Endpoint: all-cause death, nonfatal MI (+ preiprocedural MI), revascularization

FFR 5.5% vs. Angiography 4.2% at 1 Year
96.2% staged PCI



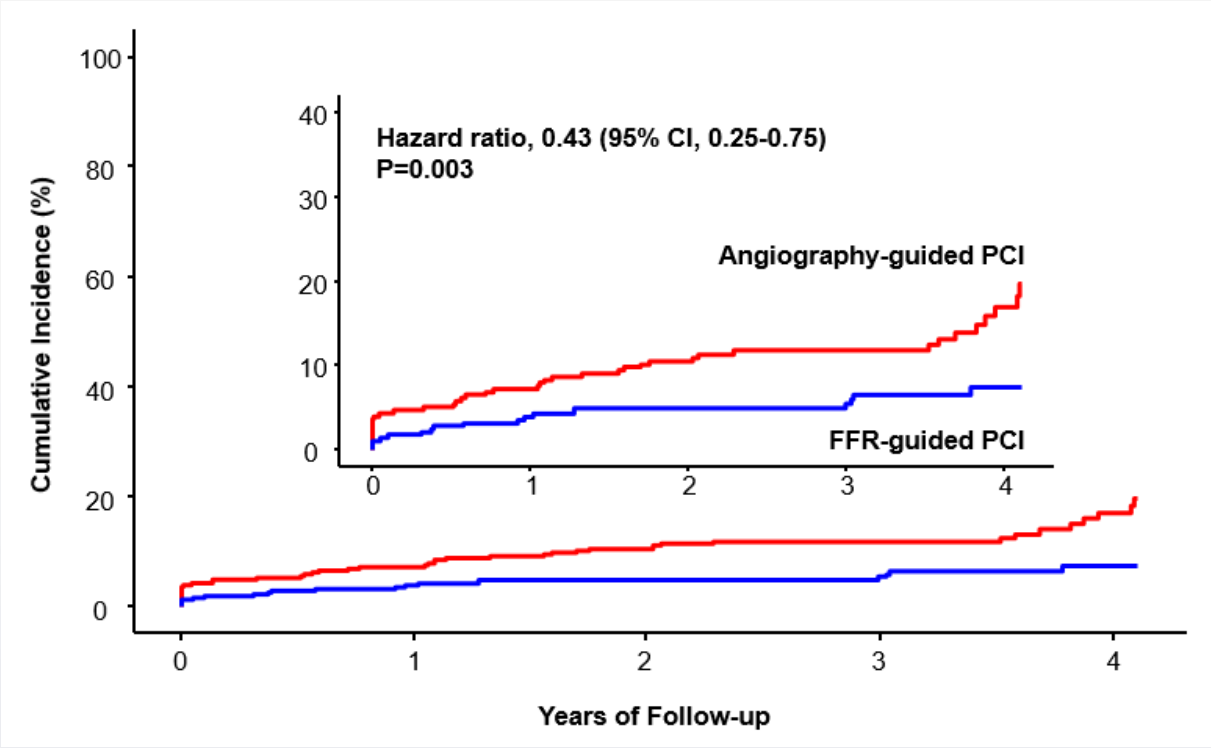
N Engl J Med. 2021 Jul 22;385(4):297-308.

FRAME-AMI Trial

Prospective, Multi-center, Open-Label Randomized Trial
562 MV-AMI Patients from 14 Korean Centers

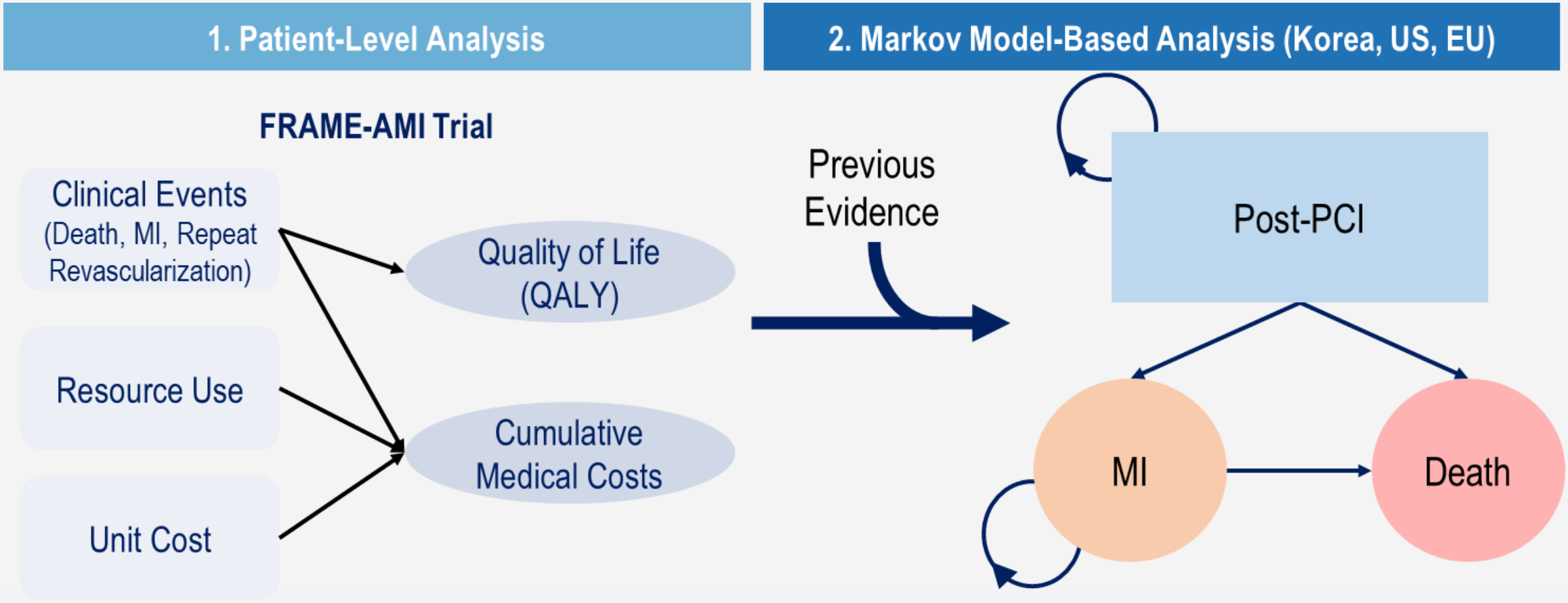
Primary Endpoint: all-cause death, nonfatal MI (+ preiprocedural MI), revascularization

FFR 7.4% vs. Angiography 19.7% at 3.5 Years
60.0% immediate non-culprit PCI



Eur Heart J. 2023 Feb 7;44(6):473-484

Cost-Effectiveness Analysis of FFR-guided PCI in AMI and MVD



Main Outcomes:	• **Cost:** Cumulative medical cost, excluding non-medical, indirect costs • **Quality-adjusted life year (QALY):** ∑ (Utility of each status × Time in each status) • **Incremental cost-effectiveness ratio (ICER)** = ΔCost / Δ QALY • **Incremental net monetary benefit (INB)** = INB = (ΔQALY×willingness to pay) − ΔCost

Eur Heart J. 2023 Feb 7;44(6):473-484

Cost-Effectiveness Analysis of FFR-guided PCI in AMI and MVD

Key Inputs in the Model

	Korean population		US population		EU population	
	Value	Source	Value	Source	Value	Source
Cost*						
Medical cost at index hospitalization						
Angio-guided PCI	9,842	FRAME-AMI	14,878	FAME	7,226	FLOWER-MI
FFR-guided PCI	9,326	FRAME-AMI	13,182	FAME	7,647	FLOWER-MI
Unit cost per service/product, $						
Performance fee for IRA PCI	2,126	FRAME-AMI	2,005	FAME 2	202	FLOWER-MI
Performance fee for immediate non-IRA PCI	435	FRAME-AMI	796	FAME 2	202	FLOWER-MI
Performance fee for staged non-IRA PCI	1,357	FRAME-AMI	567	Fearon WF et al.	194	FLOWER-MI
DES, 1EA	1,431	FRAME-AMI	1,656	Fearon WF et al.	613	FLOWER-MI
Pressure wire	709	FRAME-AMI	650	FAME	428	FLOWER-MI
Guidewire	16	FRAME-AMI	85	FAME	50	FLOWER-MI
Intensive care unit cost per day	74	FRAME-AMI	2,877	FAME	346-863	FLOWER-MI
Hospitalization cost per day	15	FRAME-AMI	2,000	FAME	578-820	FLOWER-MI
Medical cost at event						
Death from any cause	9,235	HOST-EXAM	35,818	Kazi DS et al.	1,586	FLOWER-MI
Non-fatal MI	7,338	HOST-EXAM	16,544	FAME	5,370	FLOWER-MI
Repeat revascularization	7,292	HOST-EXAM	12,780	FAME	4,633	FLOWER-MI
Utility						
After PCI	0.79	Kodera S et al.	0.92	COURAGE	0.85	Pocock S et al.
Recurrent MI (disutility)	-0.06	VALIANT	-0.06	VALIANT	-0.06	VALIANT

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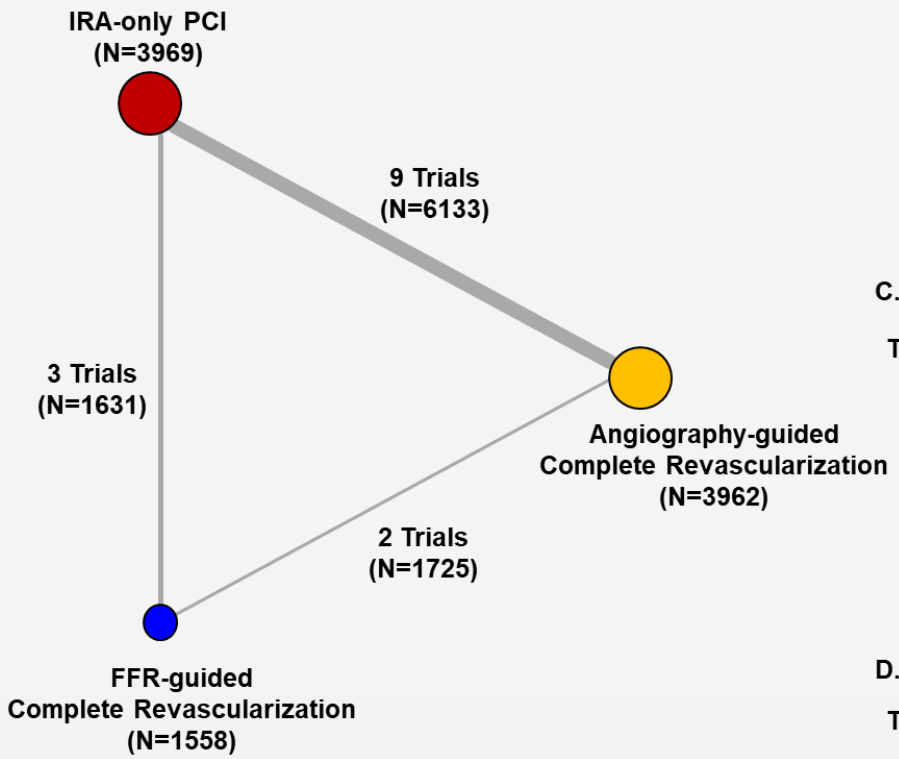
Cost-Effectiveness Analysis of FFR-guided PCI in AMI and MVD

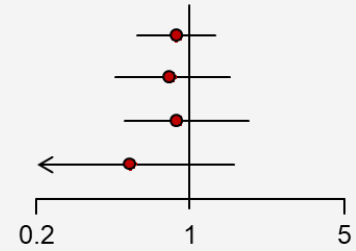
Meta-Analysis for Transition Probabilities

A. Network Plot



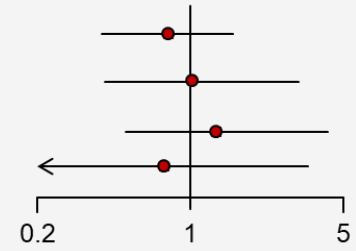
B. Death

Treatment 1 vs. Treatment 2	Odds Ratio (95% CrI)
Angio-PCI vs. IRA-only	0.86 (0.58, 1.31)
FFR-PCI vs. IRA-only	0.81 (0.45, 1.53)
FFR-PCI vs. Angio-PCI (Network)	**0.86 (0.50, 1.83)**
FFR-PCI vs. Angio-PCI (Pairwise)	**0.53 (0.18, 1.54)**



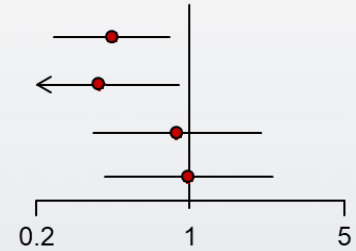
C. Myocardial Infarction

Treatment 1 vs. Treatment 2	Odds Ratio (95% CrI)
Angio-PCI vs. IRA-only	0.79 (0.40, 1.58)
FFR-PCI vs. IRA-only	1.03 (0.41, 3.10)
FFR-PCI vs. Angio-PCI (Network)	**1.31 (0.51, 4.21)**
FFR-PCI vs. Angio-PCI (Pairwise)	**0.76 (0.14, 4.07)**



D. Repeat Revascularization

Treatment 1 vs. Treatment 2	Odds Ratio (95% CrI)
Angio-PCI vs. IRA-only	0.44 (0.24, 0.81)
FFR-PCI vs. IRA-only	0.39 (0.17, 0.88)
FFR-PCI vs. Angio-PCI (Network)	**0.87 (0.37, 2.09)**
FFR-PCI vs. Angio-PCI (Pairwise)	**0.99 (0.42, 2.37)**



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Cost-Effectiveness Analysis of FFR-guided PCI in AMI and MVD

Patient-Level: Cost-Effectiveness of FFR-Guided PCI (4 Year)

	Cost, $		QALYs		Cost-Effectiveness	Incremental Net Monetary Benefit ($)
	Total	Incremental	Total	Incremental	ICER ($/QALY)	
Utilities estimated from data						
Angiography-guided PCI	11,057	Reference	3.40	Reference		
FFR-guided PCI	**9,849**	**-1,208**	**3.46**	**0.062**	**-19,484**	**3,378**
Utilities extrapolated						
Angiography-guided PCI	11,057	Reference	3.12	Reference		
FFR-guided PCI	**9,849**	**-1,208**	**3.21**	**0.087**	**-13,885**	**4,253**

FFR-guided PCI was a more cost-effective treatment than the angiography-guided PCI

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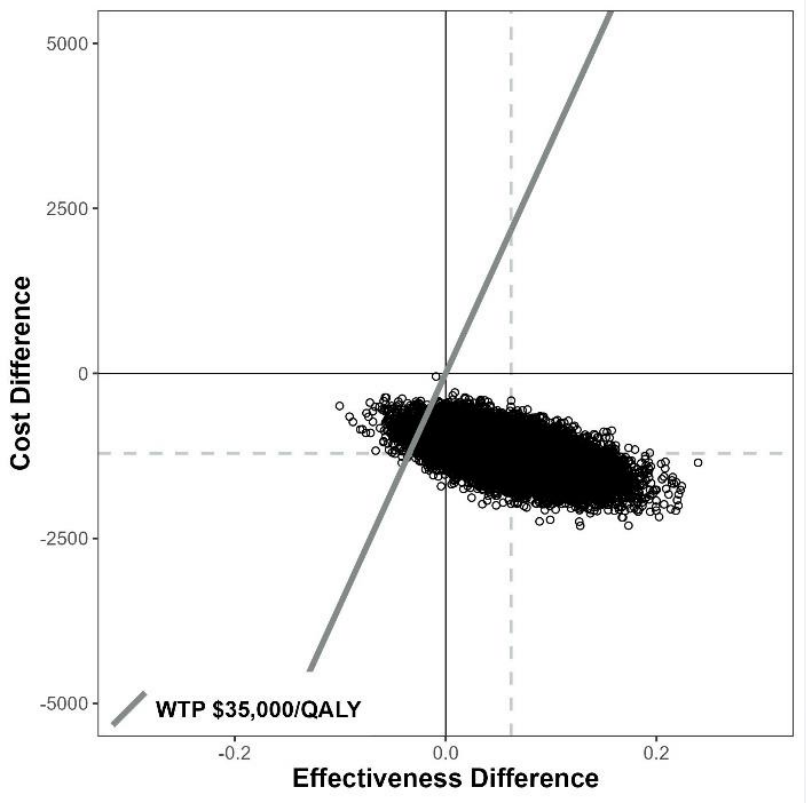
Cost-Effectiveness Analysis of FFR-guided PCI in AMI and MVD

Model-Based: Probabilistic Sensitivity Analysis (PSA)

Bootstrap Technique with 25,000 Replications



According to Willingness-to-pay threshold based on GDP per capita,
FFR-based decision making was cost-effective in 97%.

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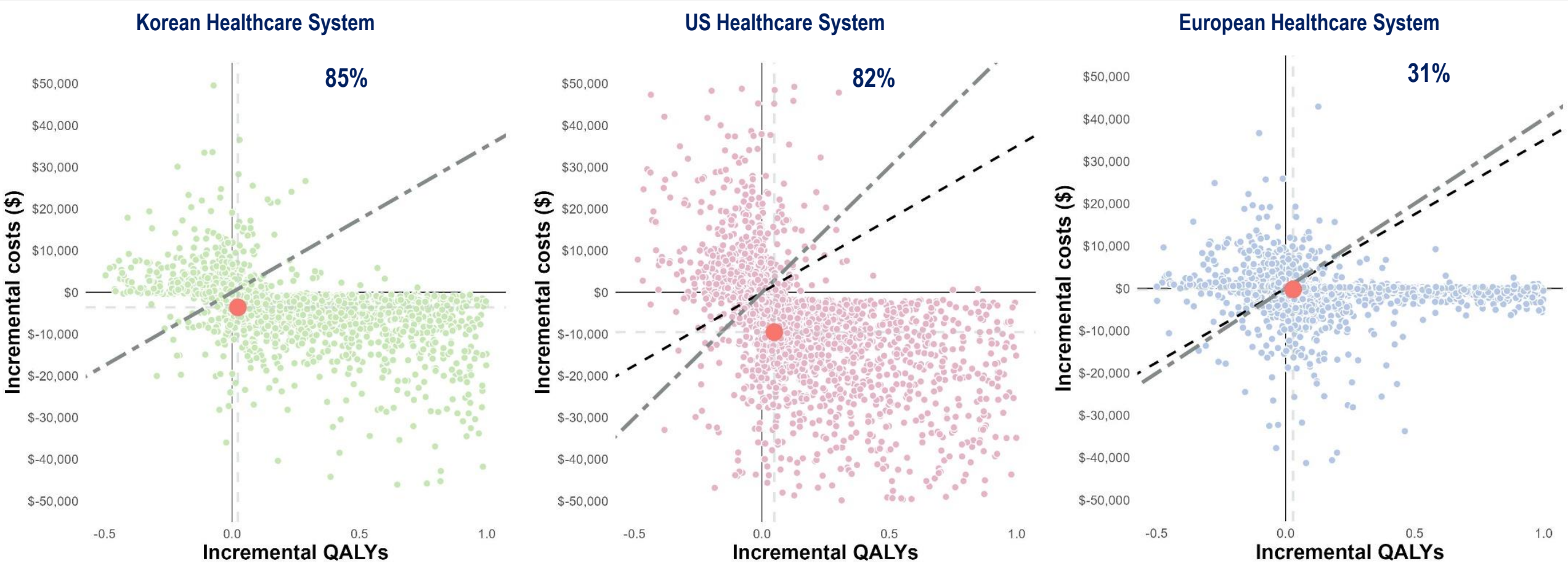
Cost-Effectiveness Analysis of FFR-guided PCI in AMI and MVD

Cost-Effectiveness of FFR-Guided PCI in 3 Different Healthcare Systems
Probabilistic Sensitivity Analysis (PSA)



FFR-guided PCI was a more cost-effective across Korea, USA, and Europe.

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Conclusion

- FFR-guided PCI continuously showed clinical benefit and cost-effective strategy among patients with stable ischemic heart disease.
- FFR-guided PCI for Non-IRA lesions in AMI patients has been tested compared with angiography-guided PCI, and two RCTs (FLOWER-MI and FRAME-AMI) showed inconclusive results.
- CEA of FFR-guided PCI in the FRAME-AMI study showed that the FFR-guided strategy was a more cost-effective approach for AMI patients with MVD.