Routine Use of FFR in Clinical Practice: 5 Years Outcomes

Mineok Chang, MD

Cardio-cerebrovascular Center, Seoul St. Mary's hospital
The Catholic University of Korea

Background

- Randomized trials have demonstrated that FFR-guided PCI produces more favorable outcomes than angiographic guided PCI.
- Practical guidelines recommend FFR measurement prior to revascularization in the absence of objective evidence of ischemia.

Background

- The ASAN PCI registry is composed of two distinct periods separated by the introduction of mandated routine FFR use. The use of FFR in this prospective registry has increased from 1.9% between 2008 and 2009 to 50.7% between 2010 and 2011.
- At 1 year, the risk of cardiac events was significantly reduced along with less use of coronary stents in the cohort after the routine FFR use.

Objective

- Since, the generalizability of findings from clinical trials and guideline recommendations can only take place by evaluating clinical practice, we examine whether the early beneficial effect of routine FFR use in daily practice persist up to 5 years of follow-up.

Study Population (1)

- **The ASAN PCI registry** (clinicaltrials.gov number NCT 0178859) is a prospective, single-center registry to assess the contemporary practice and outcomes of PCI in a tertiary, high-volume center in Korea.

- Between January 2008 and December 2011, a total of 5,097 patients were enrolled.

Study Population (2)

Inclusion Criteria

- All consecutive patients who have ≥1 coronary lesion with a visual estimated DS of >50%.
- Revascularization was clinically indicated

Exclusion Criteria

- STEMI
- Cardiogenic shock
- A contraindication to the placement of DESs
- life expectancy <12 months.

Study Endpoints

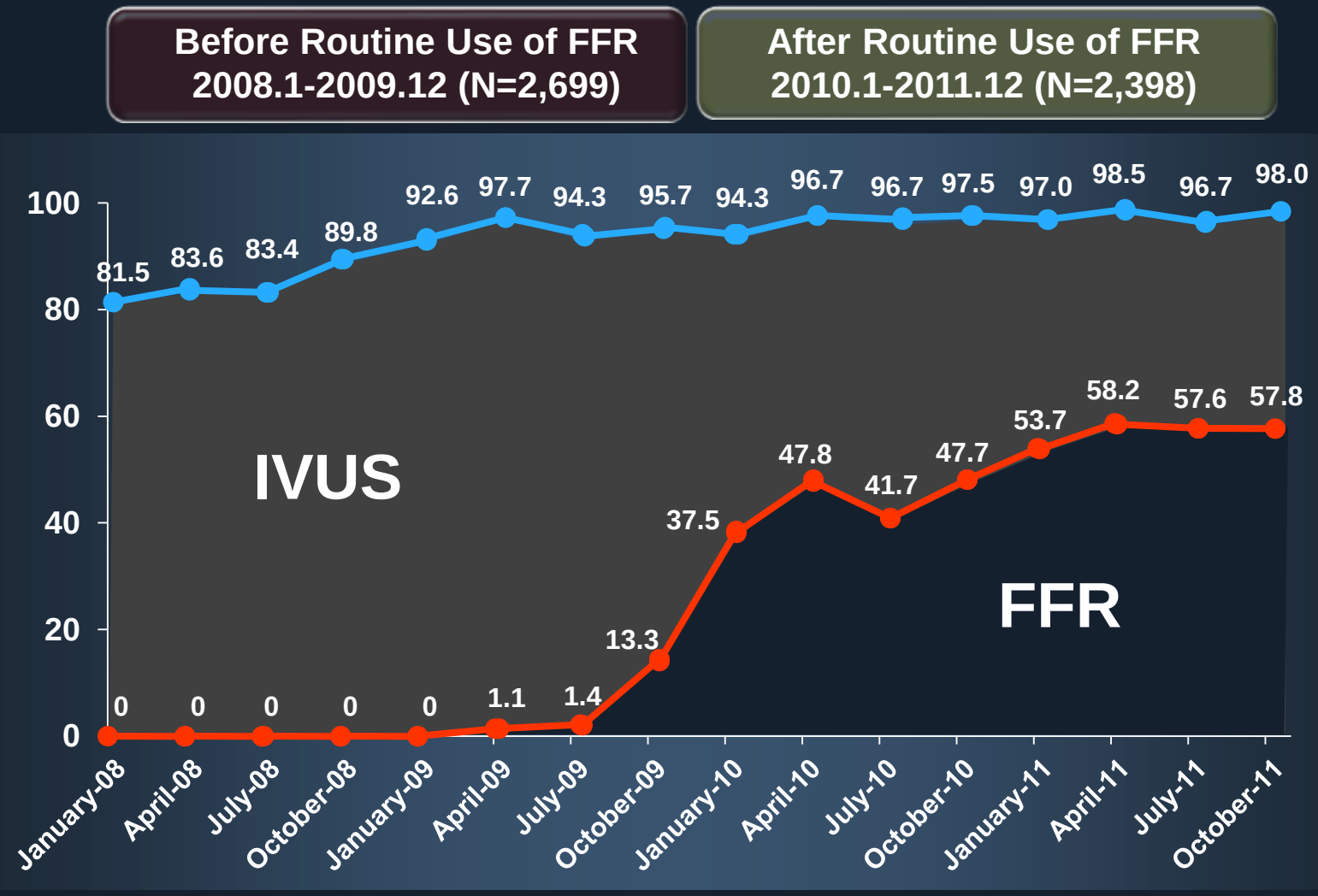
Primary Endpoint

- Death
- Myocardial Infarction
- Repeat Revascularization

Secondary End Point

- Cardiac and non-cardiac deaths.
- Periprocedural MI (Q wave MI or CKMB>3UNL)
- Spontaneous MI (cardiac enzyme elevation).
- Repeat revascularization: TVR, TLR, & NLR
- Stent number implanted

Rate of FFR and IVUS Use

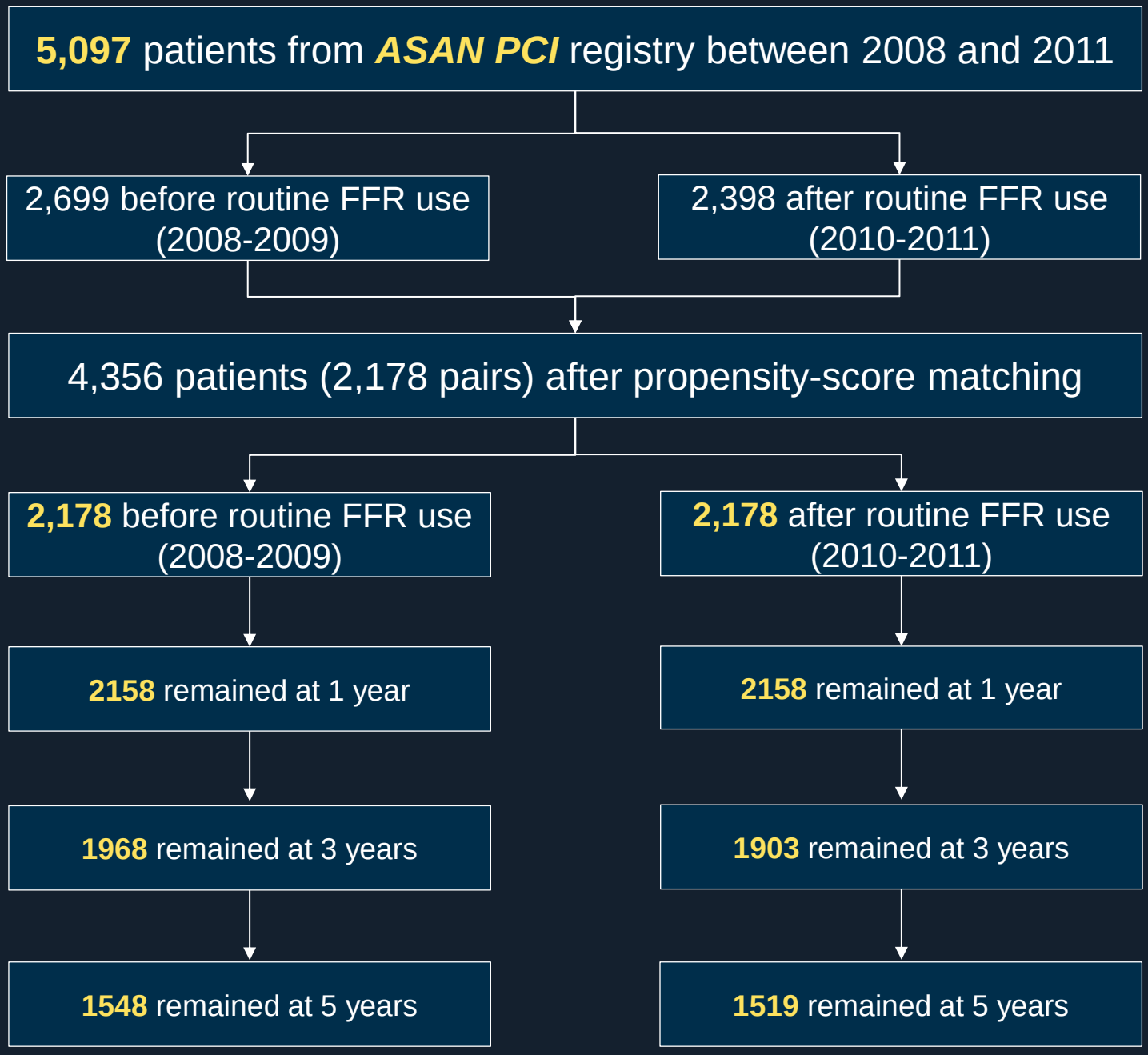


FFR measurement and Procedure

- FFR measured by Pressure Wire (St. Jude Medical)
- Hyperemia induced by IV adenosine 140 – 200 μg/kg/min through the large peripheral or central vein.
- PCI with FFR < 0.75 and deferred with FFR>0.80.
  For FFR between 0.75 and 0.80, operator's discretion.
- PCI was performed with the use of standard techniques with drug-eluting stent.

Follow-up

- Clinical, angiographic, procedural, and outcome data were prospectively recorded in the dedicated PCI database by independent research personnel.
- Patients were clinically followed up at 1, 6, and 12 months, via office visits or telephone contact.
- Angiographic follow-up was not recommended.
- All outcomes of interest were carefully verified and adjudicated by independent clinicians.


5,097 patients from ASAN PCI registry between 2008 and 2011
2,699 before routine FFR use (2008-2009)
2,398 after routine FFR use (2010-2011)
4,356 patients (2,178 pairs) after propensity-score matching
2,178 before routine FFR use (2008-2009)
2,178 after routine FFR use (2010-2011)
2158 remained at 1 year
2158 remained at 1 year
1968 remained at 3 years
1903 remained at 3 years
1548 remained at 5 years
1519 remained at 5 years

Statistics

- A propensity-matching method was conducted to adjust for potential confounding using the Greedy algorithm.
- For the matched pair comparison, the Wilcoxon signed-rank test for continuous variables and the McNemar's test for categorical variables were used.
- The Kaplan-Meier method and Cox proportional hazards regression were used.
- We performed separate analyses according to a landmark point of 1 year (365 days) after the index procedure.
- All reported P-values are two-sided, and P-values of less than 0.05 were considered statistically significance.

Baseline Characteristics

Propensity Matched Group

	Before Routine FFR (N=2,178)	After Routine FFR (N=2,178)	P
Age, year	62.4±9.8	62.3±10.3	0.87
Male sex	1585 (72.8)	1574 (72.3)	0.73
Hypertension	1328 (61.0)	1333 (61.2)	0.90
DM	705 (32.4)	705 (32.4)	>0.99
Current smoker	634 (29.1)	632 (29.0)	0.97
Hyperlipidemia	1388 (63.7)	1396 (64.1)	0.77
Previous CABG	51 (2.3)	44 (2.0)	0.40
Previous MI	106 (4.9)	108 (5.0)	0.95
Previous PCI	369 (16.9)	363 (16.7)	0.84

Baseline Characteristics

Propensity Matched Group

	Before Routine FFR (N=2,178)	After Routine FFR (N=2,178)	P
Previous CHF	19 (0.9)	22 (1.0)	0.76
Previous stroke	131 (6.0)	126 (5.8)	0.79
Peripheral vascular Disease	46 (1.9)	44 (2.0)	0.91
Chronic renal failure	57 (2.6)	59 (2.7)	0.92
COPD	36 (1.7)	30 (1.4)	0.53
LVEF, %	58.7±7.9	59.2±9.1	0.37
Clinical presentation			0.10
Stable angina	1394 (64.0)	1411 (64.8)	
Unstable angina	582 (26.7)	584 (26.8)	
AMI	202 (9.3)	183 (8.4)	

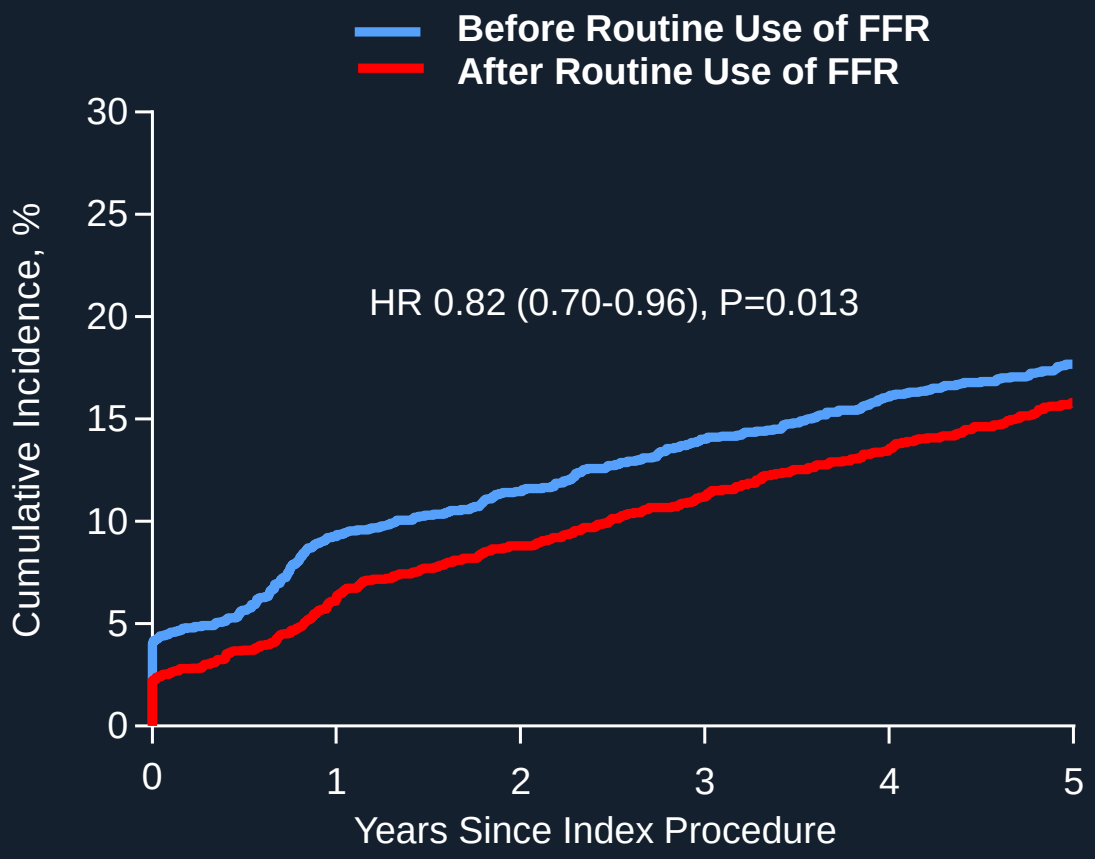
Baseline Characteristics

Propensity Matched Group

	Before Routine FFR (N=2,178)	After Routine FFR (N=2,178)	P
Extent			0.38
1VD	994 (45.6)	1051 (48.3)	
2VD	637 (29.2)	570 (26.2)	
3VD	313 (14.4)	306 (14.0)	
LMCA stenosis	234 (10.7)	251 (11.5)	
Bifurcation	1205 (55.3)	1200 (55.1)	0.90
Restenotic lesion	155 (7.1)	151 (6.9)	0.86
Long lesion (>20mm)	1742 (80.0)	1748 (80.3)	0.84
CTO	141 (6.5)	129 (5.9)	0.48
Calcified lesion	147 (6.7)	144 (6.6)	0.90

Primary End Point

(Death, MI, or Repeat Revascularization)

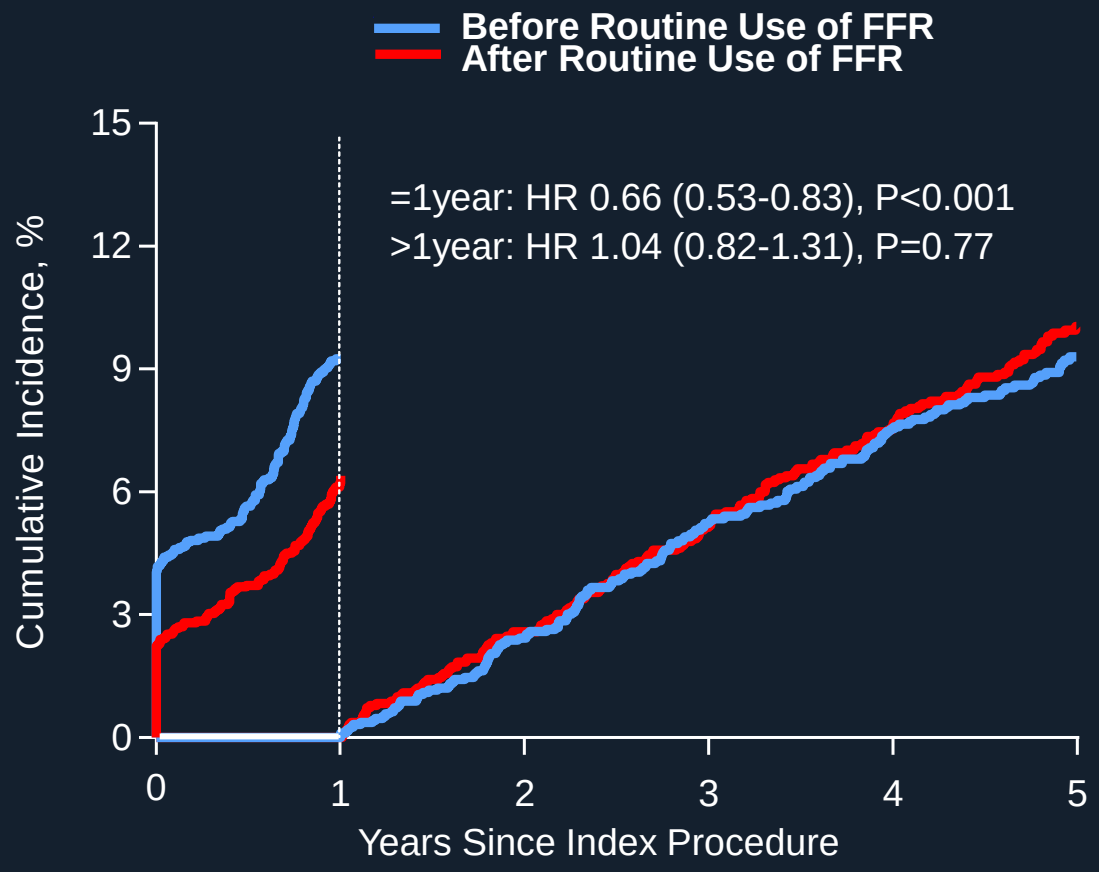


No. at Risk

Before Routine Use	2178	1965	1827	1735	1596	940
After Routine Use	2178	2035	1826	1722	1606	966

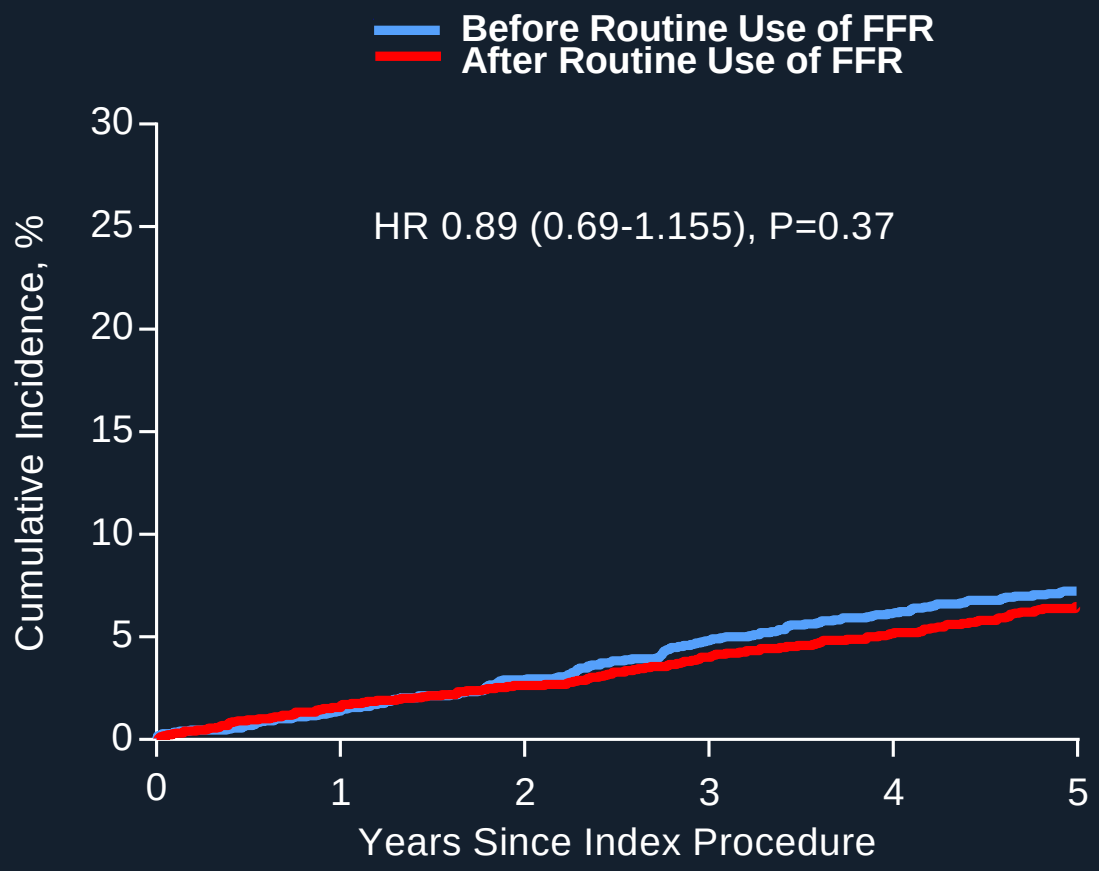
Primary End Point

(Death, MI, or Repeat Revascularization)



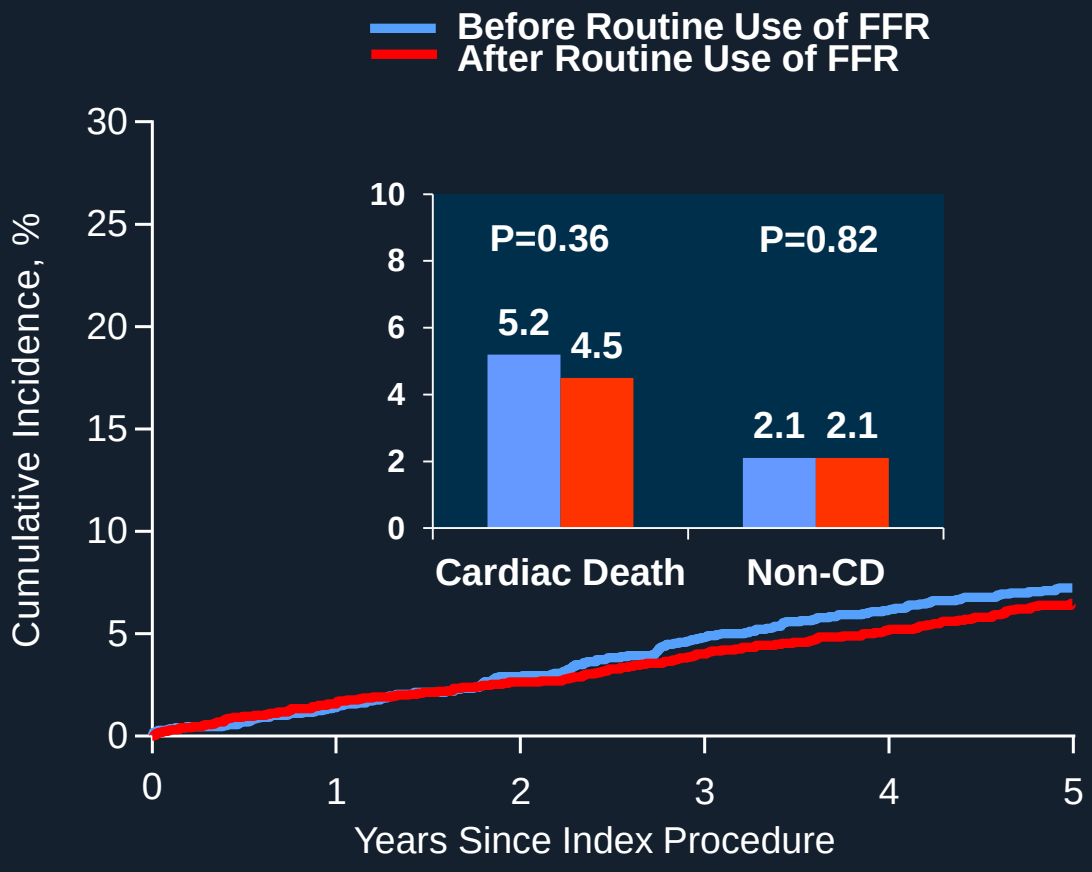
No. at Risk						
Before Routine Use	2178	1965	1827	1735	1596	940
After Routine Use	2178	2035	1826	1722	1606	966

Death



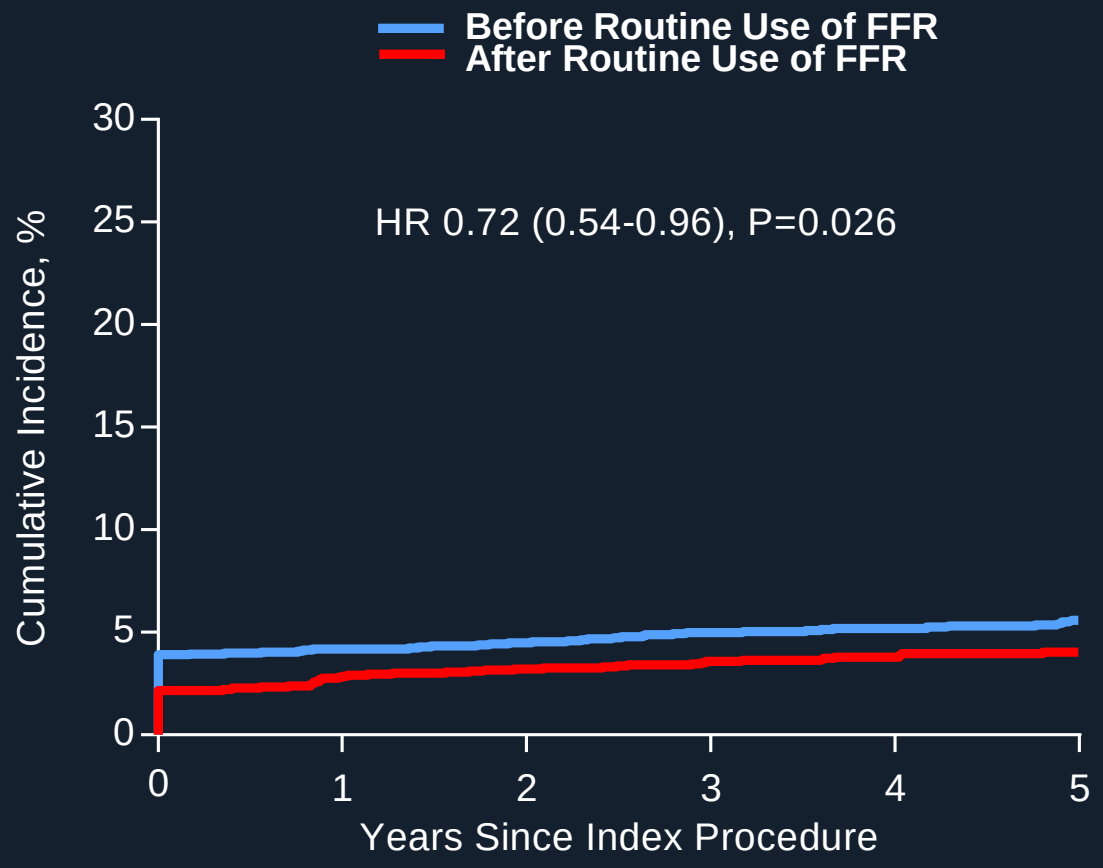
No. at Risk						
Before Routine Use	2178	2136	2006	1922	1787	1077
After Routine Use	2178	2135	1953	1862	1761	1089

Death



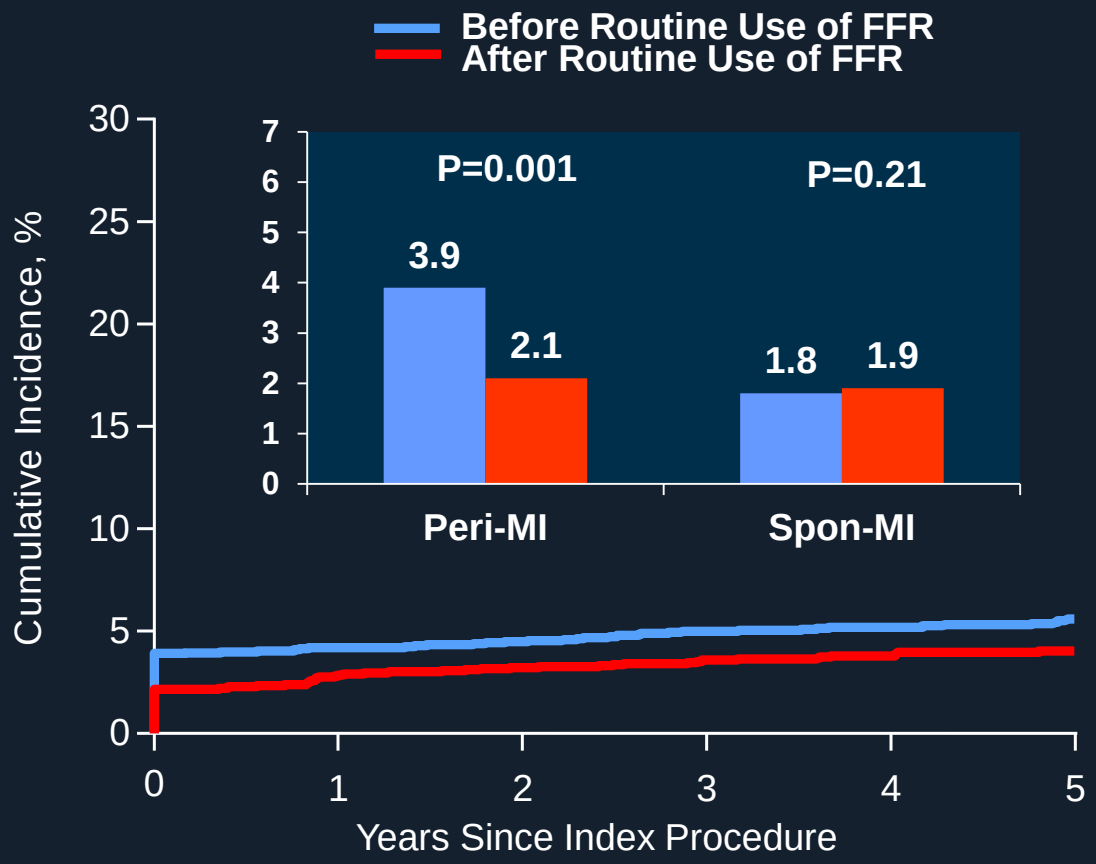
No. at Risk						
Before Routine Use	2178	2136	2006	1922	1787	1077
After Routine Use	2178	2135	1953	1862	1761	1089

Myocardial Infarction



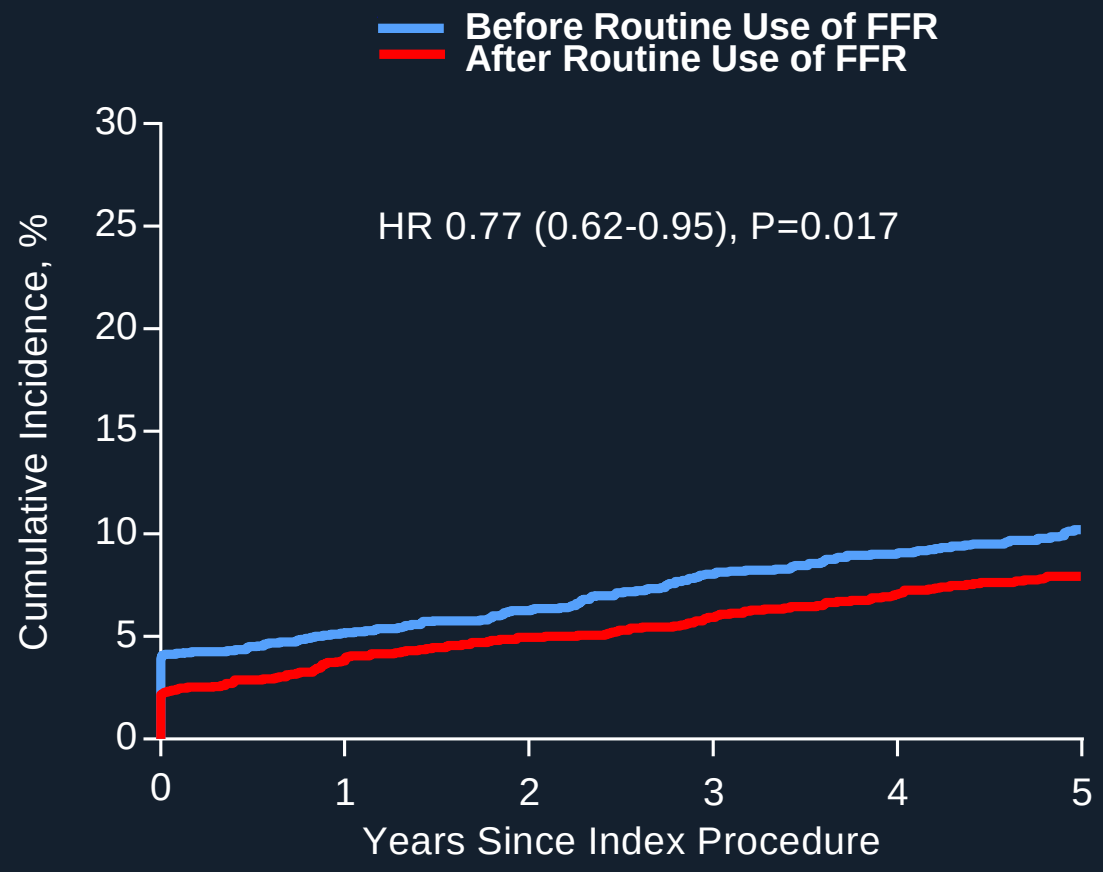
No. at Risk						
Before Routine Use	2178	2045	1916	1828	1699	1014
After Routine Use	2178	2078	1893	1804	1705	1046

Myocardial Infarction



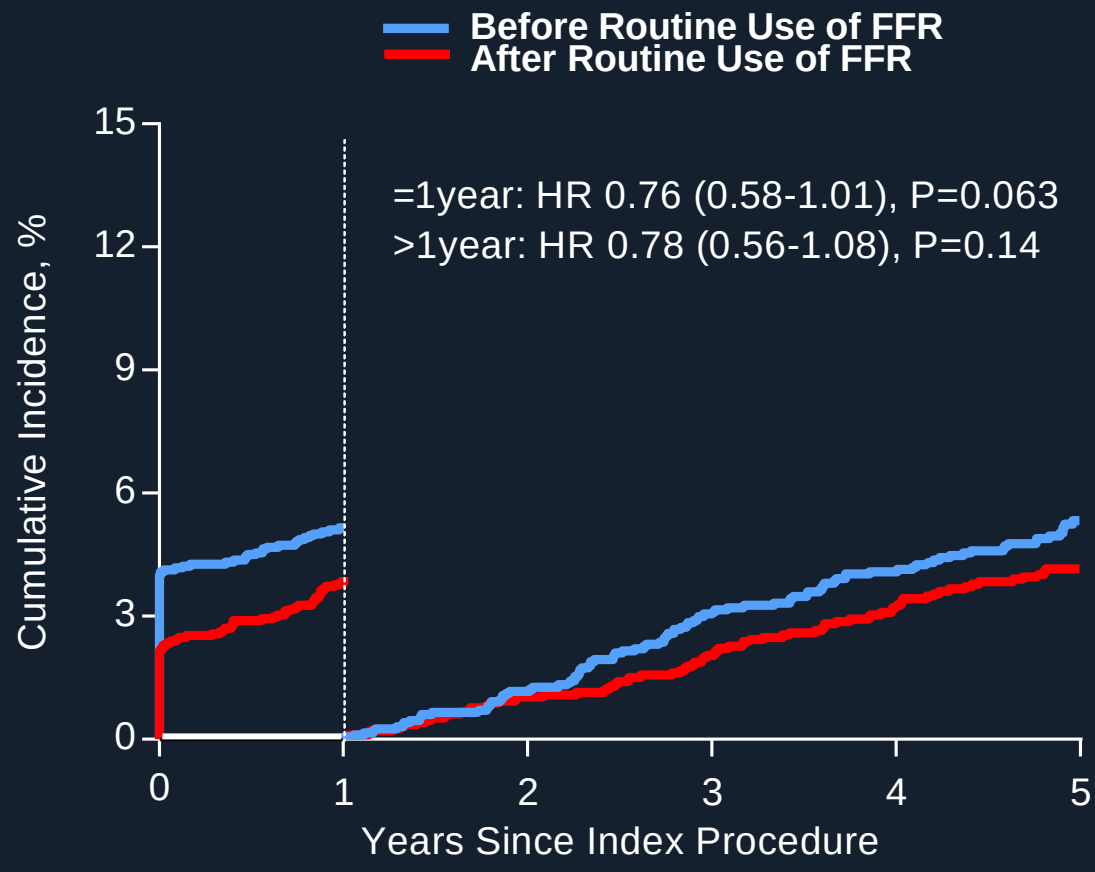
No. at Risk						
Before Routine Use	2178	2045	1916	1828	1699	1014
After Routine Use	2178	2078	1893	1804	1705	1046

Cardiac Death or MI



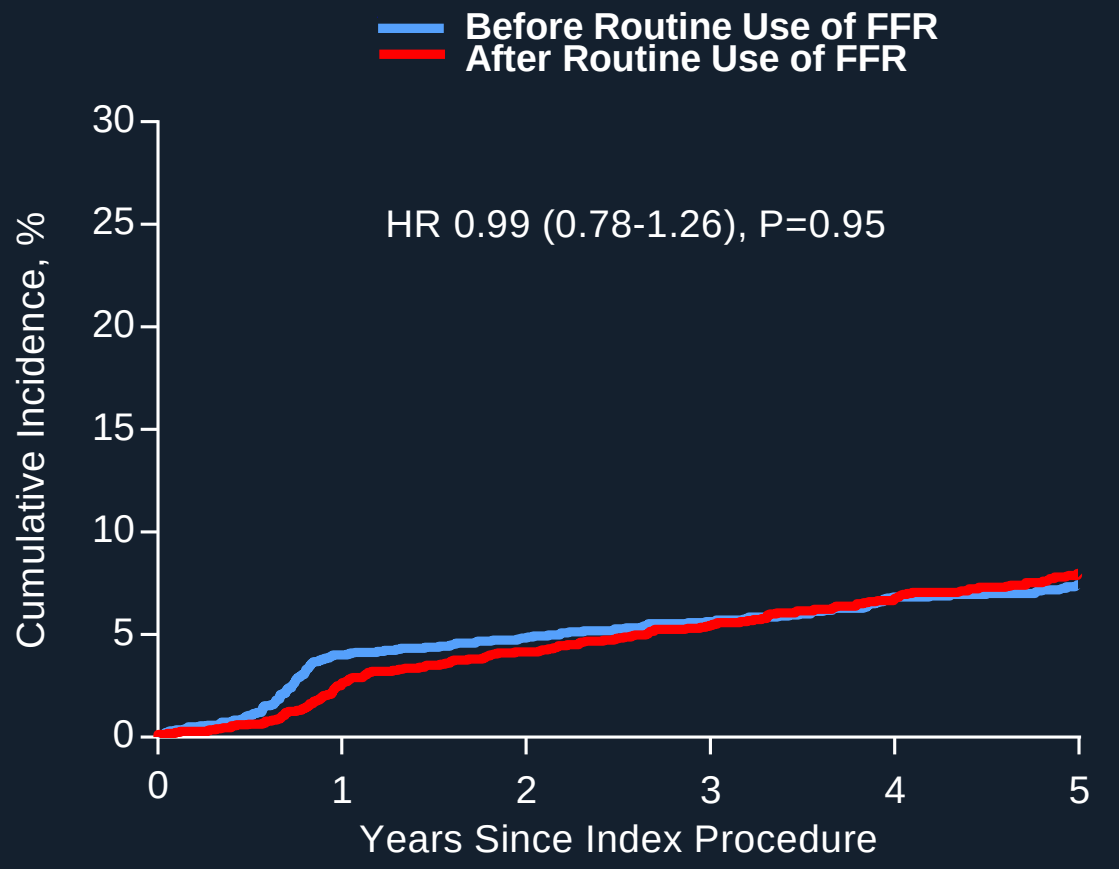
No. at Risk						
Before Routine Use	2178	2045	1916	1828	1699	1014
After Routine Use	2178	2078	1893	1804	1705	1046

Cardiac Death or MI



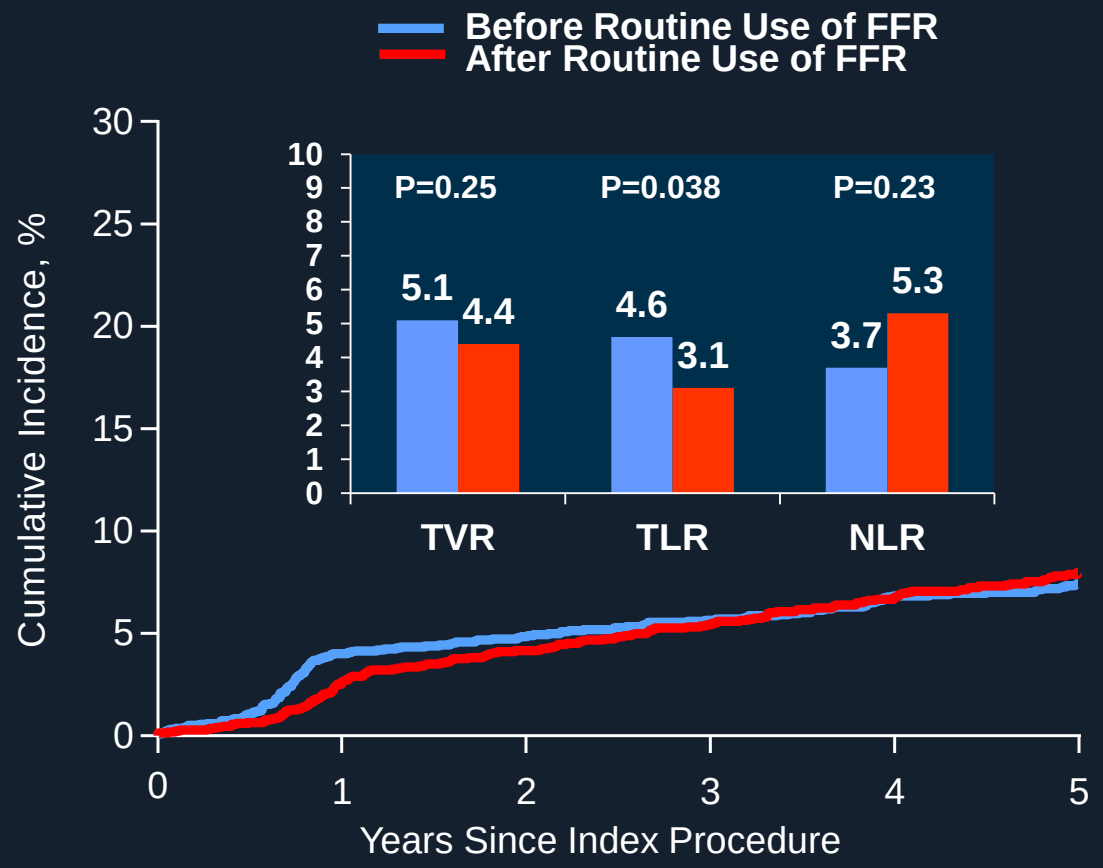
No. at Risk						
Before Routine Use	2178	2045	1916	1828	1699	1014
After Routine Use	2178	2078	1893	1804	1705	1046

Repeat Revascularization



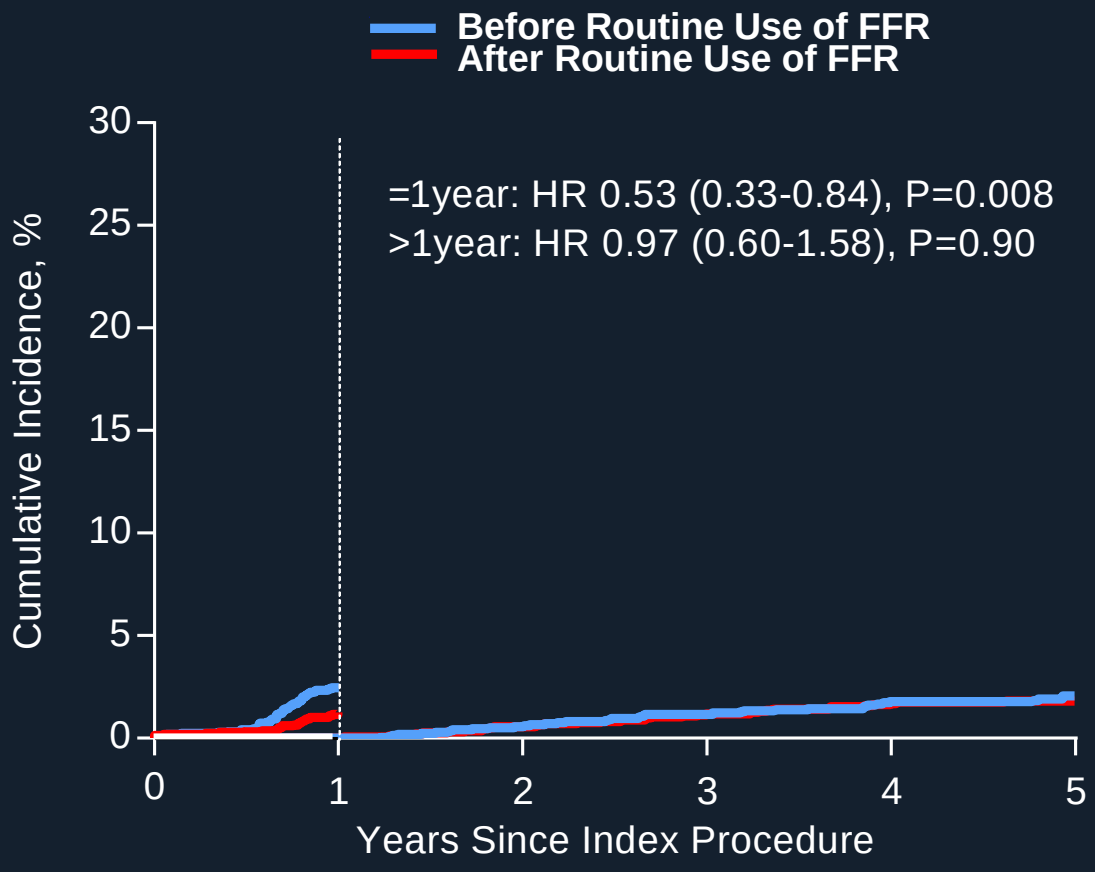
No. at Risk						
Before Routine Use	2178	2050	1908	1814	1665	986
After Routine Use	2178	2083	1871	1764	1646	994

Repeat Revascularization



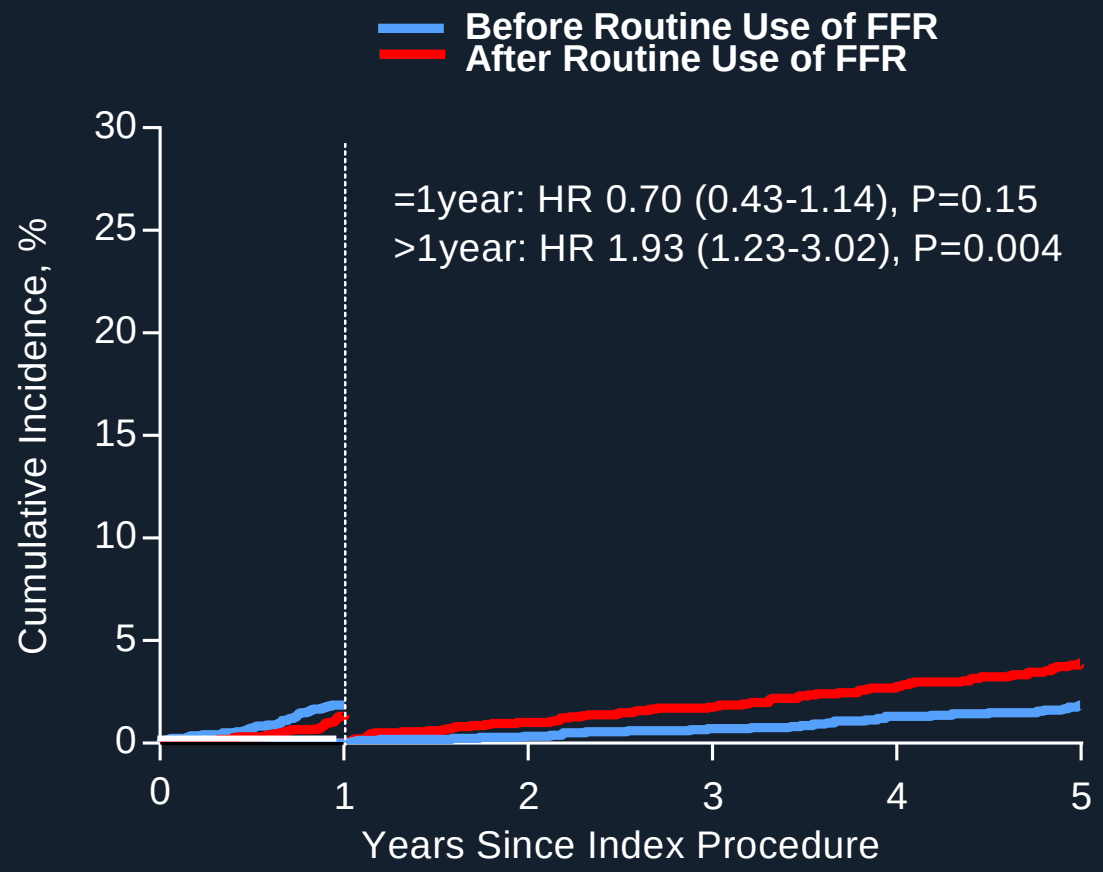
No. at Risk						
Before Routine Use	2178	2050	1908	1814	1665	986
After Routine Use	2178	2083	1871	1764	1646	994

Target Lesion Revascularization



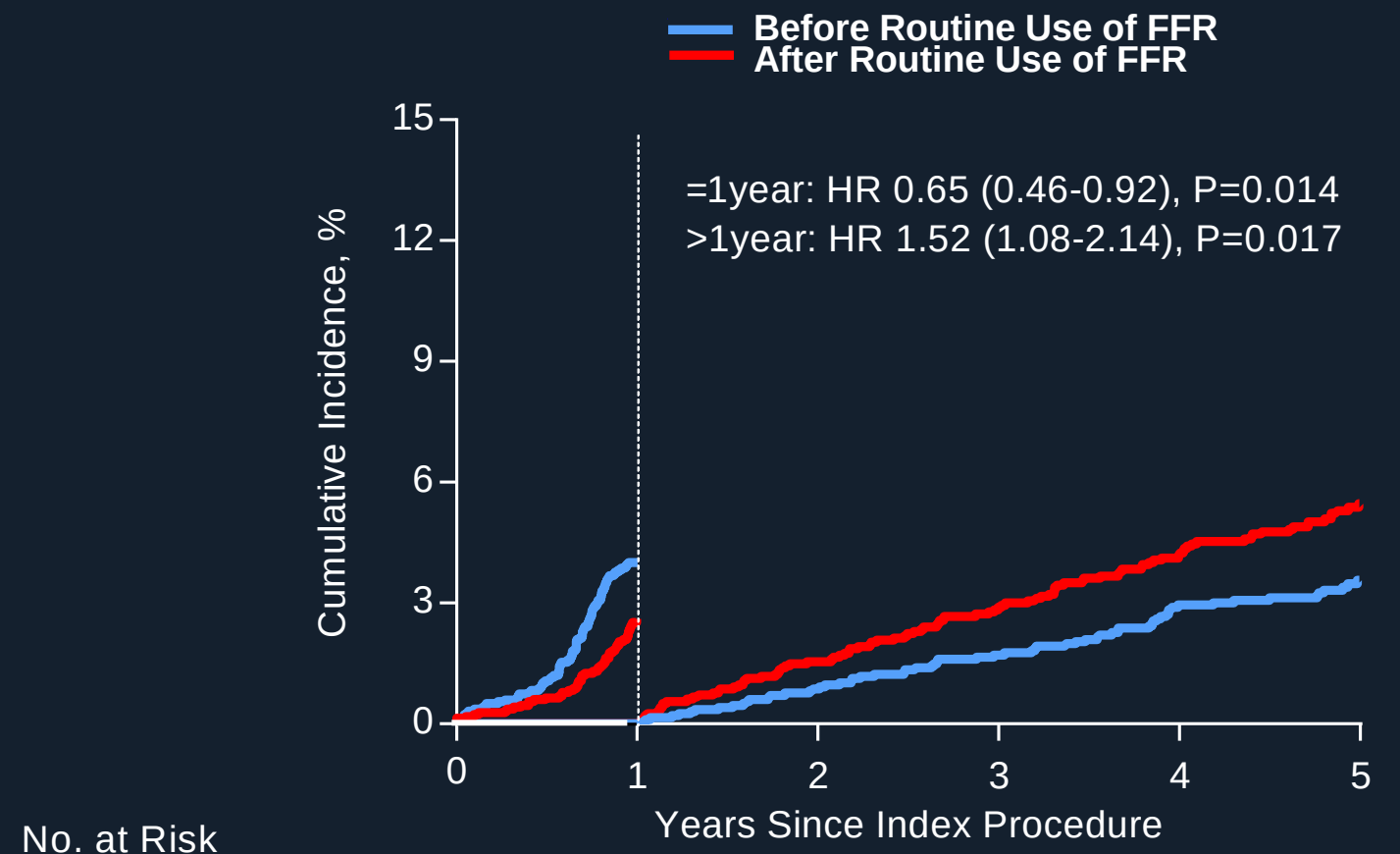
No. at Risk						
Before Routine Use	2178	2083	1946	1852	1708	1020
After Routine Use	2178	2110	1917	1821	1715	1055

New Lesion Revascularization



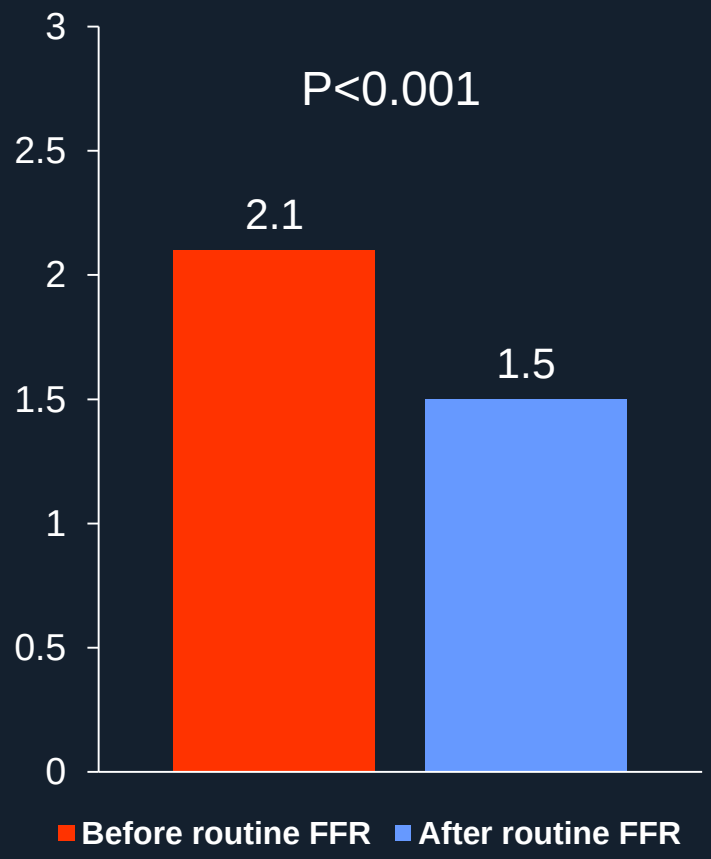
No. at Risk						
Before Routine Use	2178	2096	1962	1875	1735	1035
After Routine Use	2178	2108	1906	1803	1689	1024

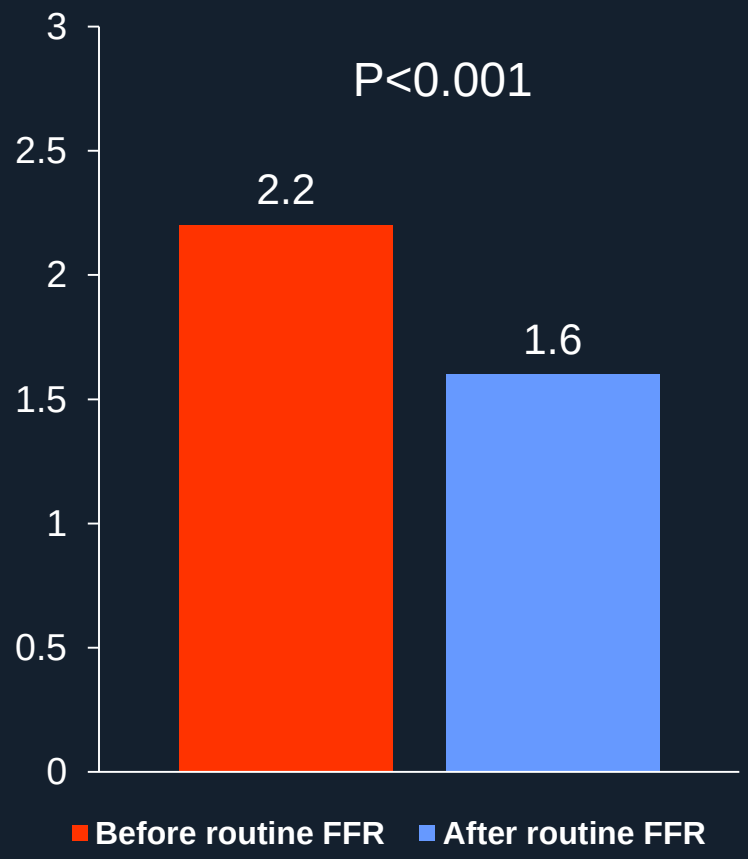
Repeat Revascularization



No. at Risk						
Before Routine Use	2178	2050	1908	1814	1665	986
After Routine Use	2178	2083	1871	1764	1646	994

Number of Stent Used

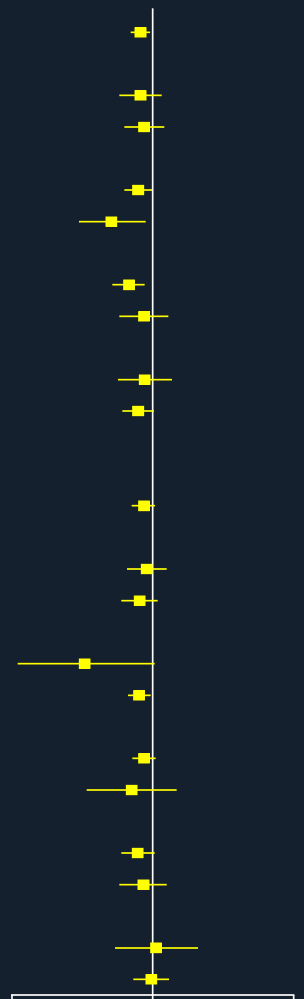




Propensity Score Matched Population

Subgroup Analysis

Subgroup	5 Year Event Rate (%) of Primary Endpoints		Hazard Ratio (95% CI)	P value	Interaction P value
	Before Routine Use (N=2178)	After Routine Use (N=2178)			
Overall	17.7	15.8	0.82 (0.70-0.96)	0.013	
Age					0.79
≥65 yo (N=1917)	21.7	19.8	0.82 (0.58-1.16)	0.26	
<65 yo (N=2439)	14.5	12.7	0.87 (0.63-1.21)	0.41	
Sex					0.66
Male (N=3159)	17.7	15.7	0.79 (0.63-0.99)	0.038	
Female (N=1197)	17.8	16.2	0.51 (0.30-0.89)	0.018	
Presentation					0.15
sAP (N=2805)	16.4	13.2	0.68 (0.52-0.88)	0.003	
ACS (N=1551)	20.0	20.5	0.87 (0.58-1.29)	0.48	
Diabetes					0.65
Yes (N=1410)	22.9	20.5	0.88 (0.57-1.37)	0.58	
No (N=2946)	15.2	13.6	0.79 (0.61-1.02)	0.07	
Ejection fraction					0.59
≤40% (N=154)	30.5	29.8	NA	NA	
>40% (N=3840)	16.8	15.8	0.87 (0.72-1.04)	0.13	
Bifurcation					0.63
Yes (N=1951)	20.2	17.4	0.91 (0.66-1.26)	0.56	
No (N=2405)	15.7	14.6	0.81 (0.60-1.09)	0.17	
Left main disease					0.36
Yes (N=485)	25.1	25.2	0.33 (0.11-1.03)	0.057	
No (N=3871)	16.8	14.6	0.81 (0.67-0.97)	0.025	
Long (>20mm) lesion					0.43
Yes (N=3490)	19.1	16.9	0.87 (0.72-1.05)	0.15	
No (N=866)	12.1	11.4	0.71 (0.34-1.48)	0.36	
Multivessel disease					0.63
Yes (N=2311)	22.7	19.4	0.78 (0.60-1.03)	0.083	
No (N=2045)	11.7	12.0	0.86 (0.58-1.26)	0.43	
Type of DES					0.84
Early DES (N=1589)	18.0	17.0	1.06 (0.54-2.10)	0.86	
New DES (N=2351)	17.3	15.9	0.98 (0.73-1.31)	0.88	



Conclusion

- In this large, prospective, real-world registry, we demonstrated that early benefit of FFR-guided PCI was maintained over the long-term.
- At 5 years, the cohort after routine FFR use was associated with a significantly lower risk of major adverse cardiac events compared with those before routine FFR use. In addition, the rate of cardiac death and myocardial infarction was significantly lower after routine FFR use.

Conclusion

- Although the long-term risk of any repeated revascularization was similar between the two periods, the temporal pattern was significantly different.
- An early increased risk of target lesion revascularization was observed in the cohort before routine FFR use, which was offset by a late increased risk of new lesion revascularization in the cohort after routine FFR use.
- Further studies regarding the identification of high risk deferred lesions would be necessary.