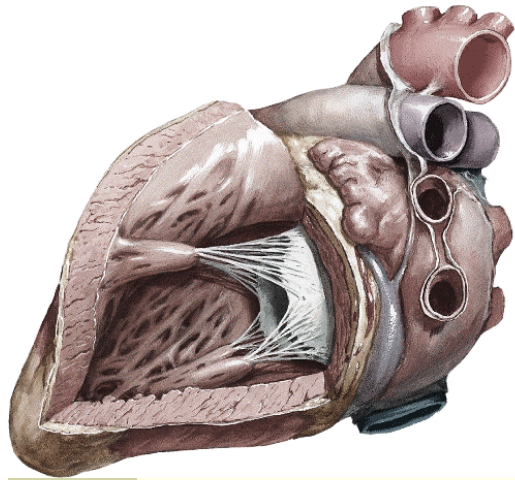


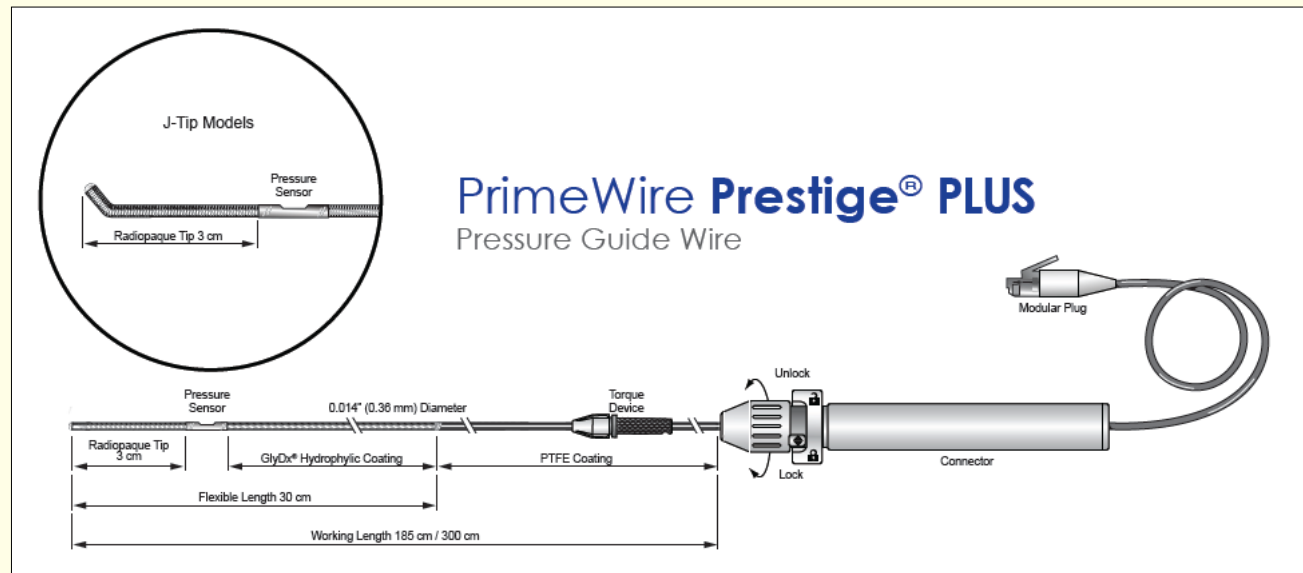
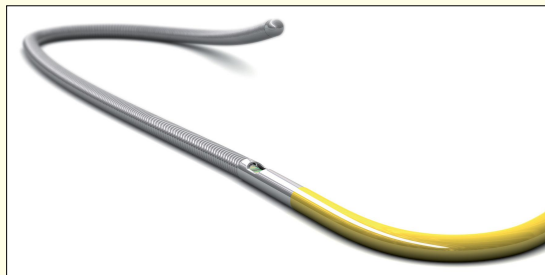
Utilidad de la Guía de presión (FFR)

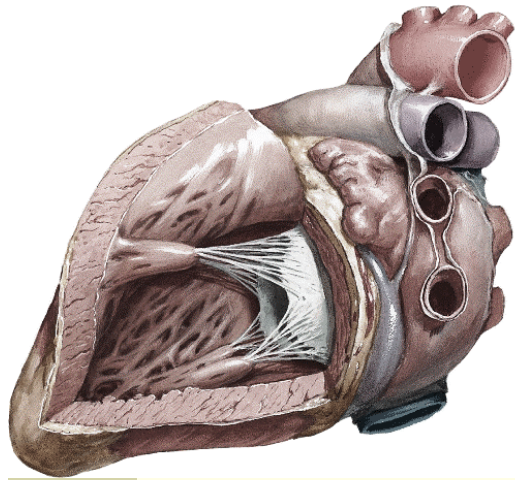
Dr. Eduard Bosch



Qué es la guía de presión?

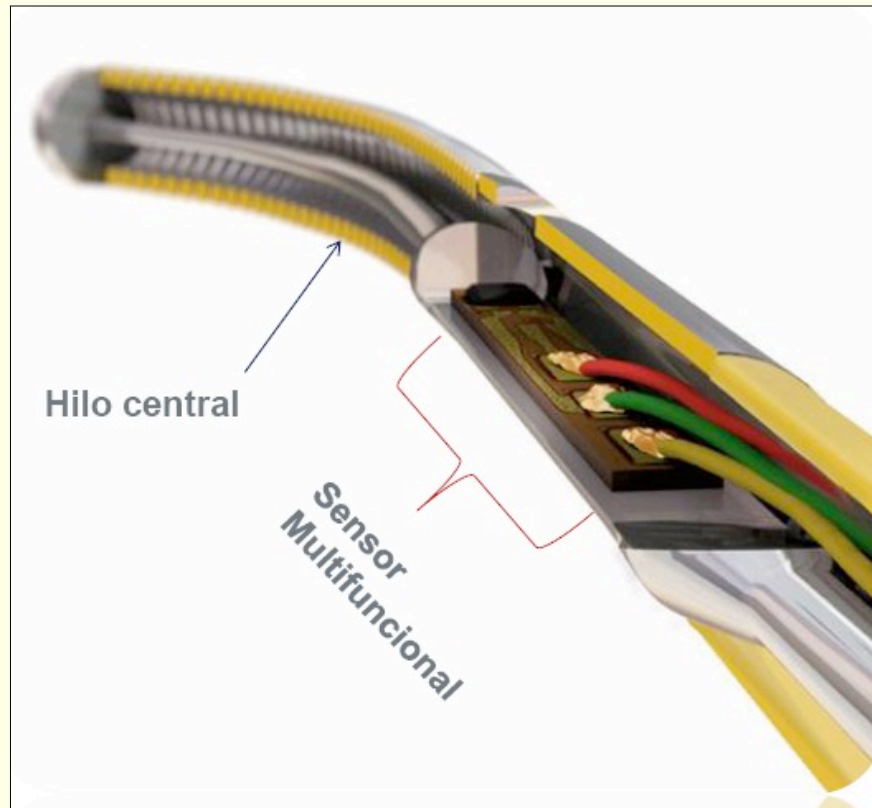
- Es una guía de angioplastia (0.014 “).
- Con un sensor de presión en la parte distal (a 30 mm de la punta).
- Además del proceso diagnóstico (FFR), permite realizar la angioplastia (dilataciones con balón e implantación de stents).

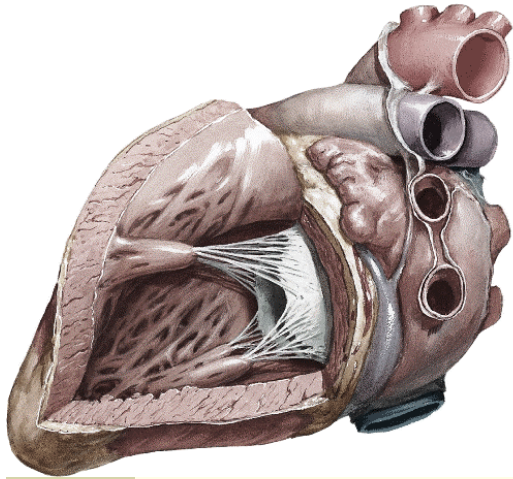




Qué es la guía de presión?

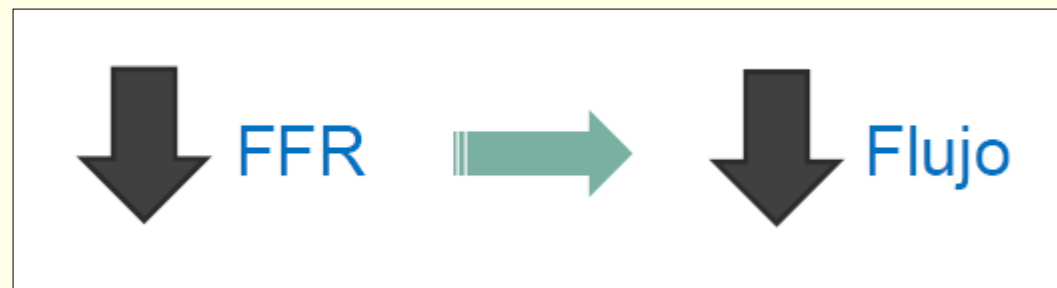
- Con un sensor de presión en la parte distal (a 30 mm de la punta).

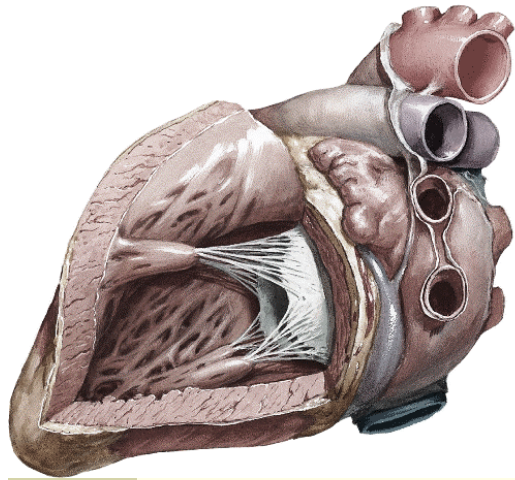




Qué es el FFR?

- FFR = Fractional Flow Reserve.
- Reserva de Flujo Fraccional.
- Es un valor que nos indica la **severidad hemodinámica** de una lesión coronaria.

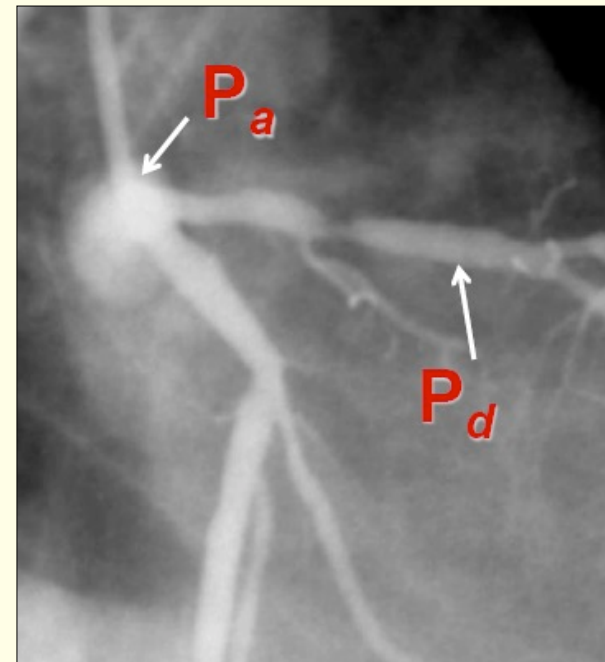


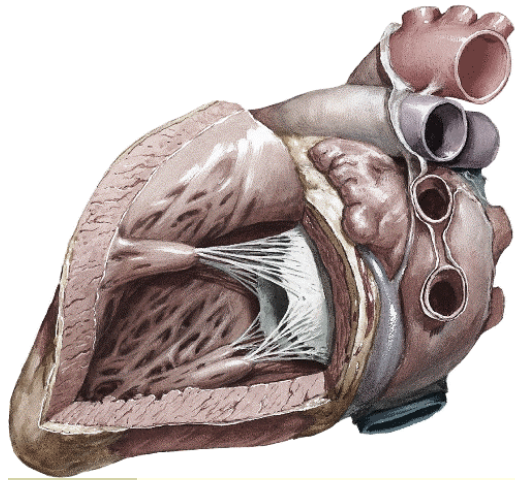


Qué es el FFR?

- FFR = Fractional Flow Reserve.
- Es un valor que nos indica la **severidad hemodinámica** de una lesión coronaria.

$$FFR = \frac{P_d}{P_a}$$

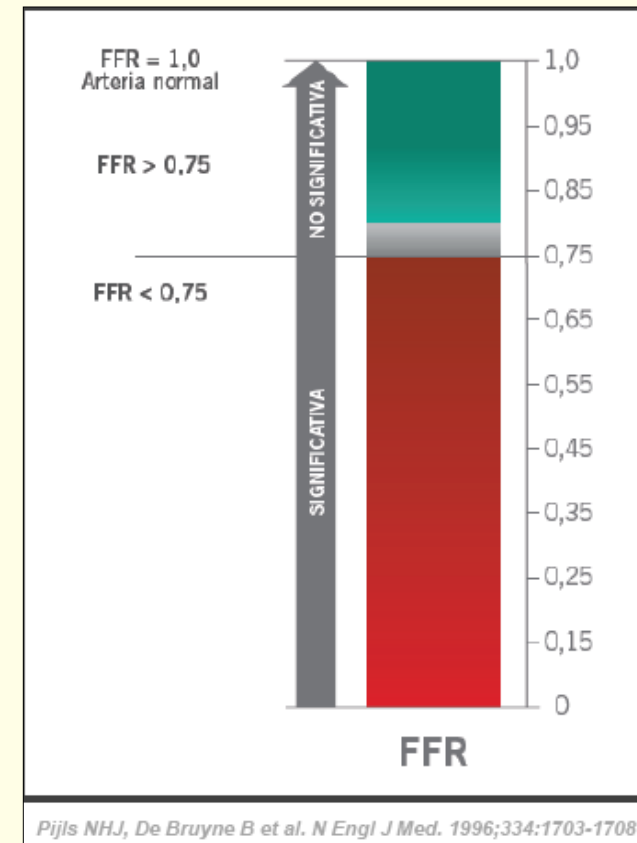


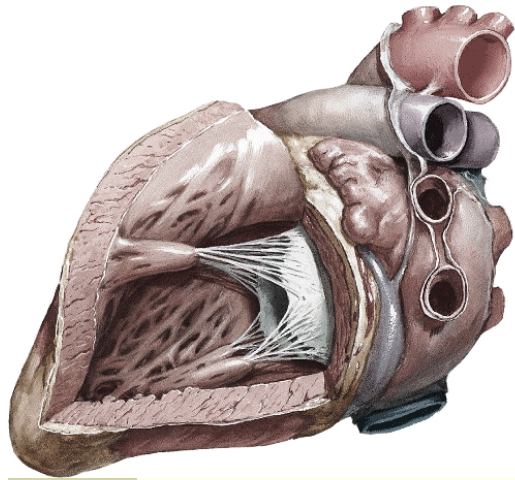


Qué es el FFR?

- FFR : medida cuantitativa y reproducible de la severidad de una lesión.

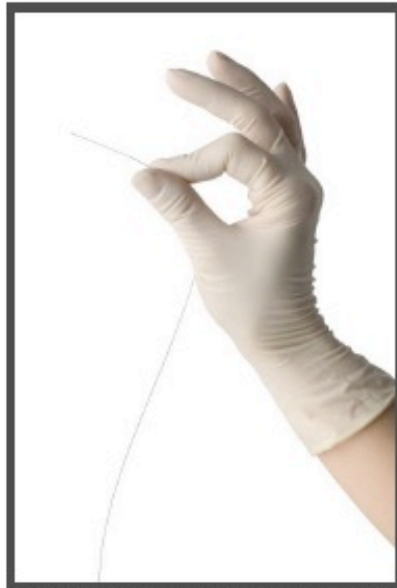
$$FFR = \frac{P_d}{P_a}$$





Como se mide el FFR?

- FFR = Fractional Flow Reserve.



Guía PressureWire®

Para medir la presión dentro de las arterias coronarias.



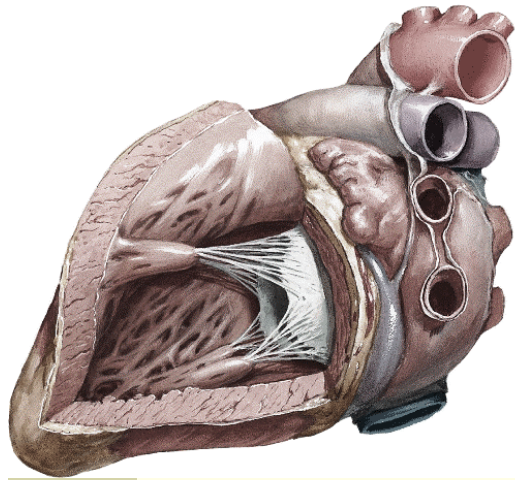
Monitor RadiAnalyzer®

Para hacer los cálculos con las diferentes presiones y mostrarlos en la pantalla.



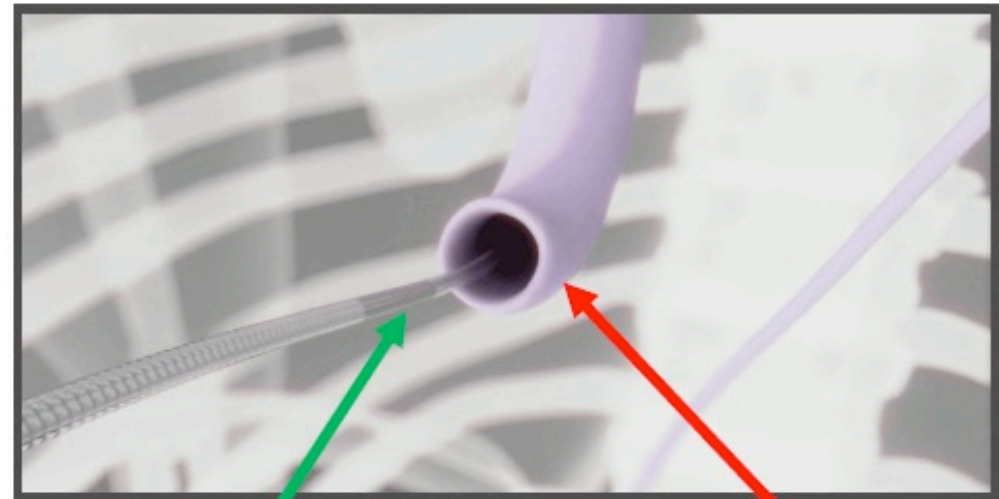
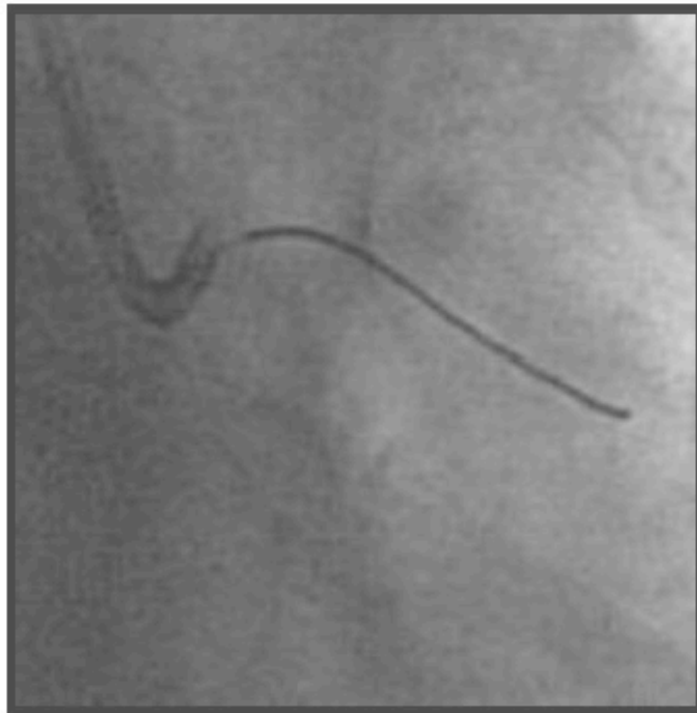
Hiperemia

Para simular ejercicio.



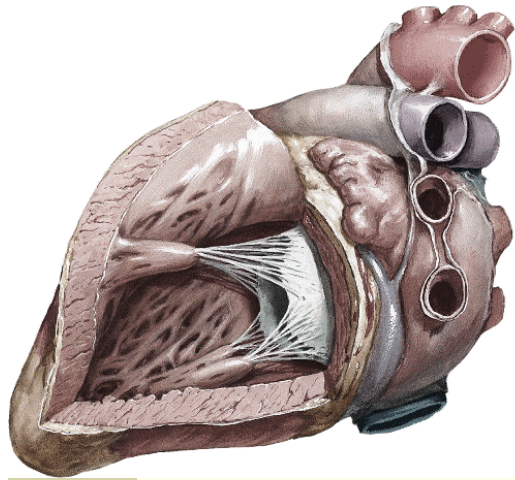
Como se mide el FFR?

- Ecuación (normalización) de presiones.
- Avanzar el sensor hasta la salida del catéter guía.



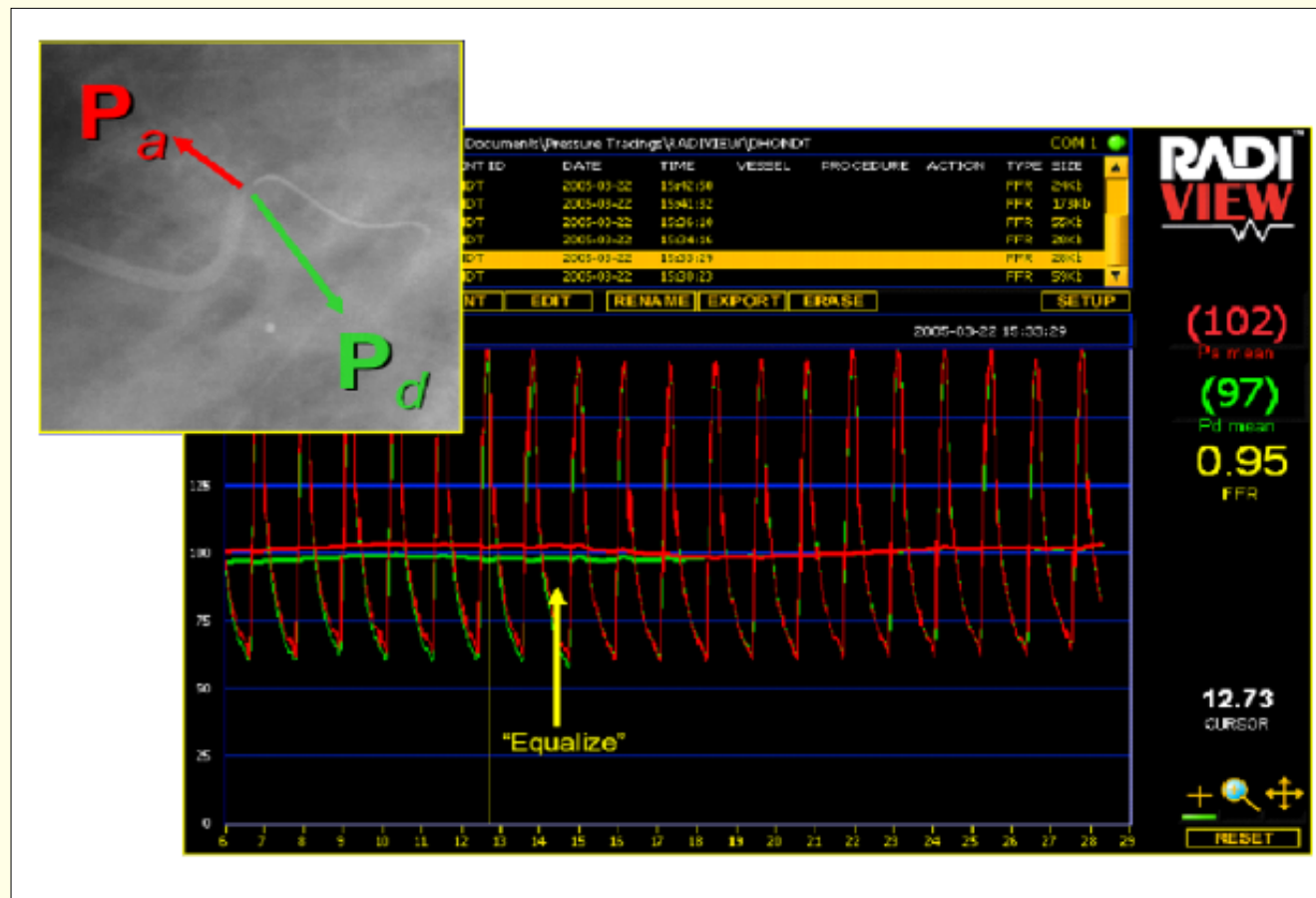
Sensor de la guía
PressureWire

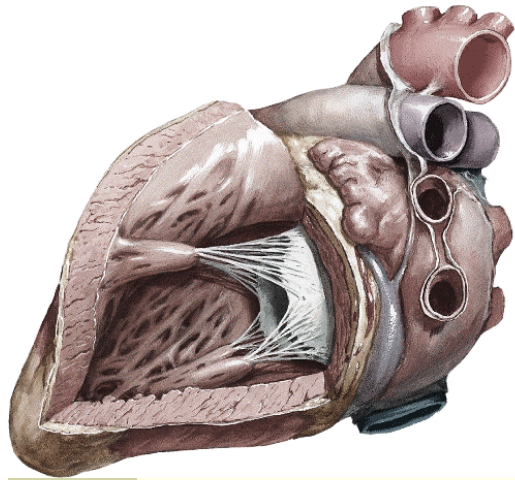
Cateter guia



Como se mide el FFR?

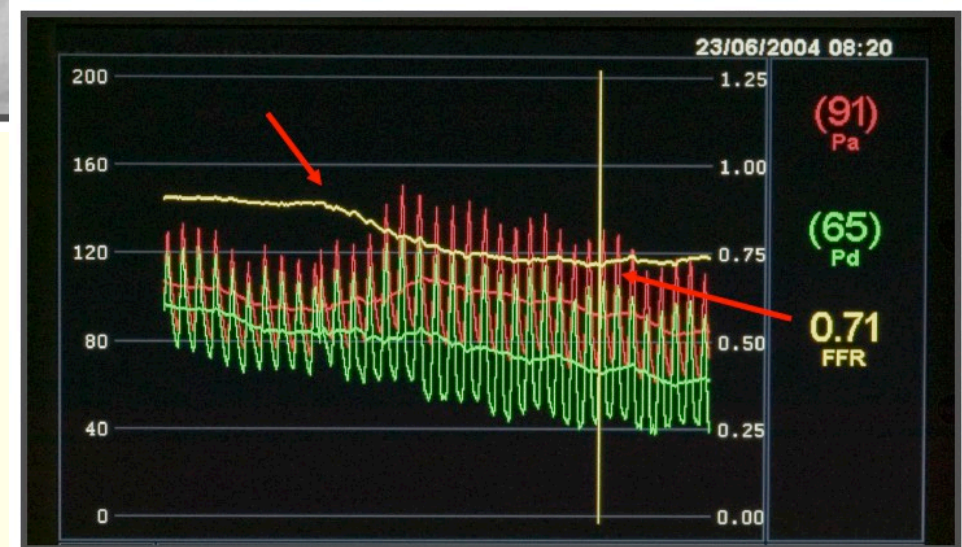
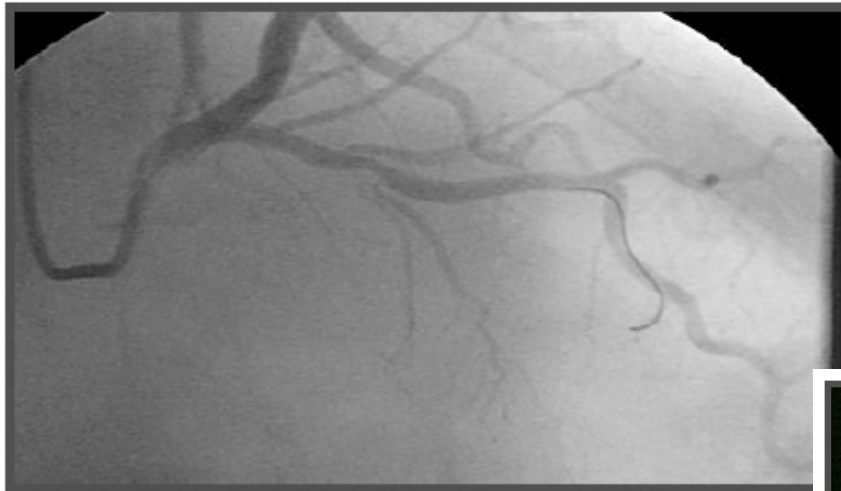
- Ecuación (normalización) de presiones.
- Verificar que la P_a y la P_d son iguales.

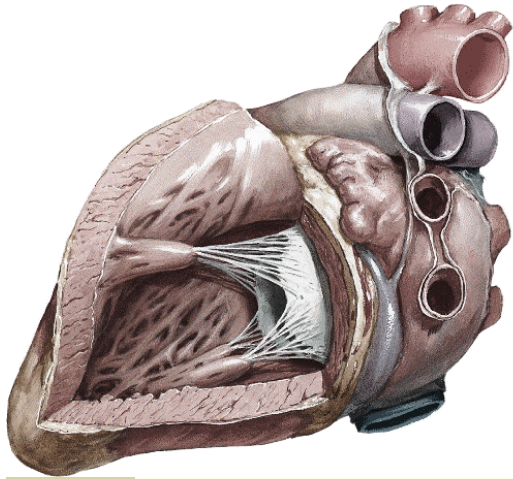




Como se mide el FFR?

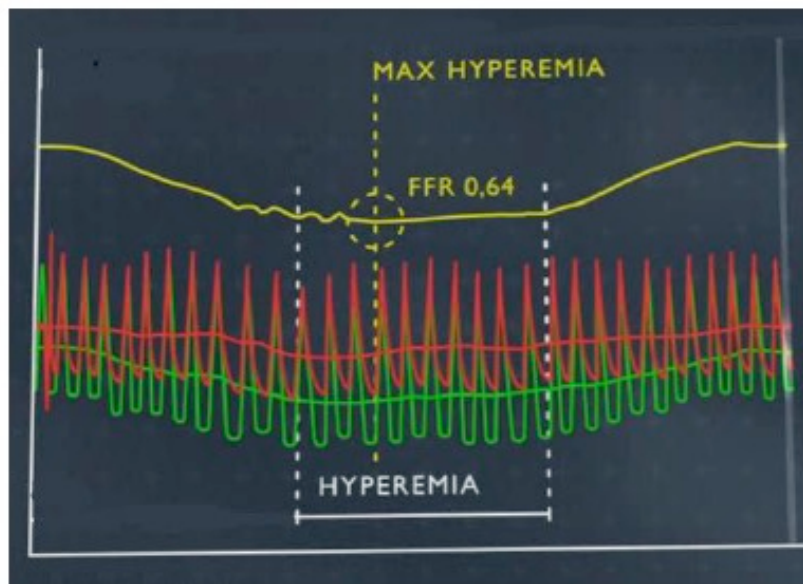
- Avanzar el sensor hasta superar la lesión.
- Esperar a obtener valores estables de presión.





Como se mide el FFR?

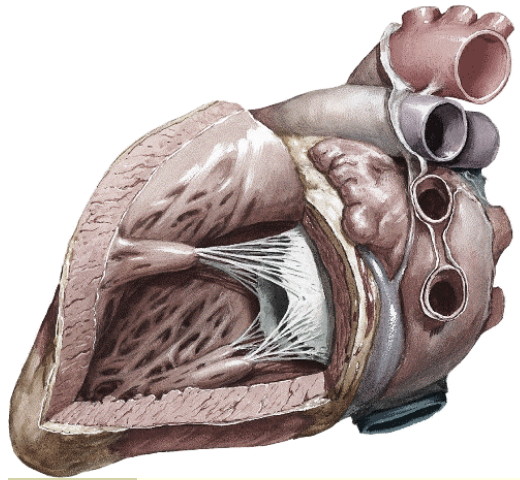
- Si la lesión es muy severa, el FFR será positivo en situación basal.
- Si no es positivo, hay que simular el ejercicio: produciendo máxima hiperemia.
- Requisitos: Vasodilatación, dilatación microvascular, e incremento en el flujo sanguíneo.
- Como se consigue? Adenosina en bolo intracoronario o perfusión intravenosa.



$$FFR_{myo} = \frac{\text{Max flow in presence of a stenosis}}{\text{Normal maximum flow}}$$

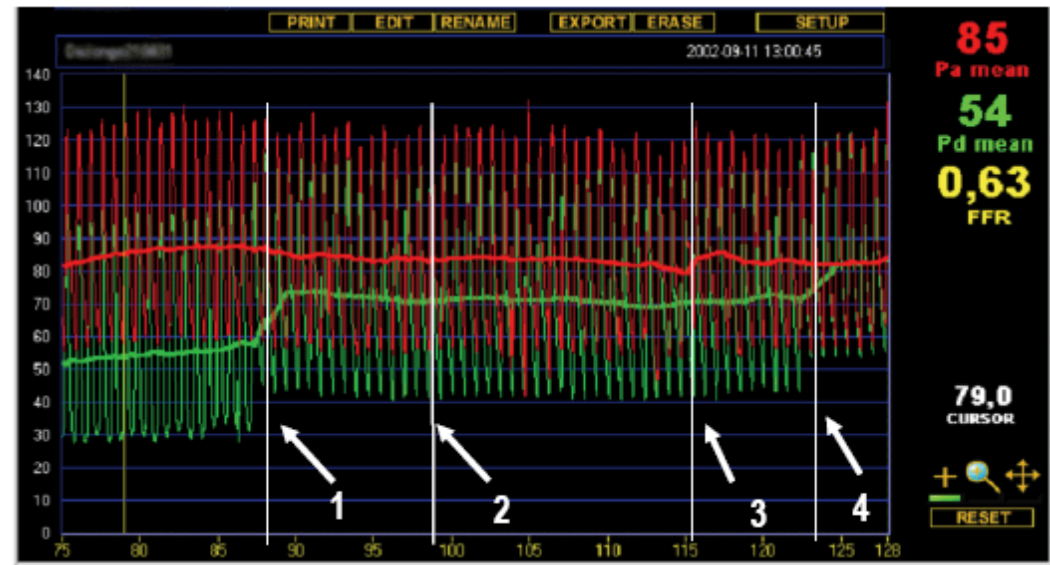
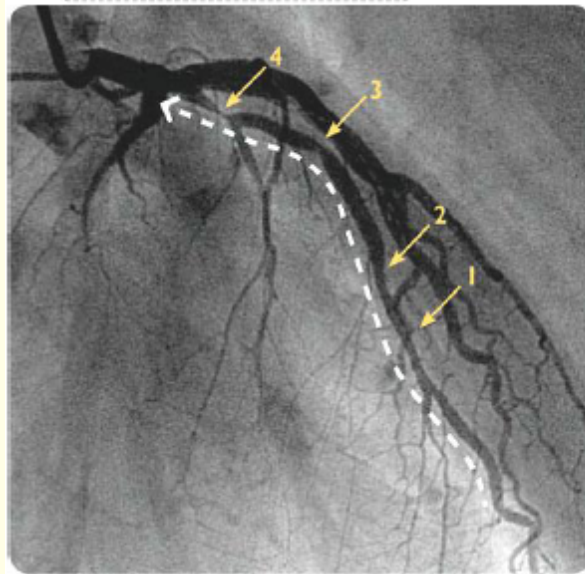
$$FFR_{myo} = \frac{Q_{max}^s}{Q_{max}^n} = \frac{(P_d - P_v) / R_{myo}}{(P_a - P_v) / R_{myo}}$$

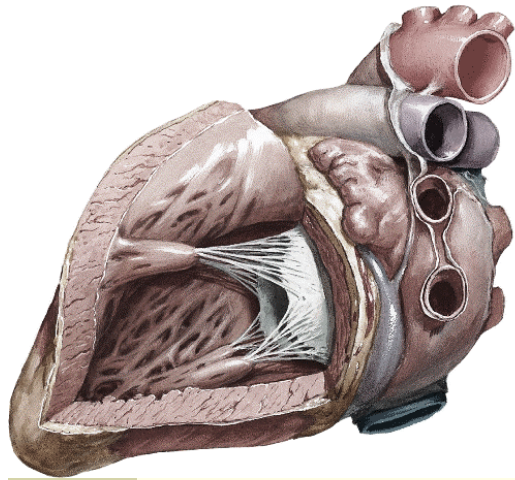
$$FFR_{myo} = \frac{P_d}{P_a} = \frac{(P_d - \cancel{P_v}) / \cancel{R_{myo}}}{(P_a - \cancel{P_v}) / \cancel{R_{myo}}}$$



Como se mide el FFR?

- Adenosina en perfusión intravenosa.

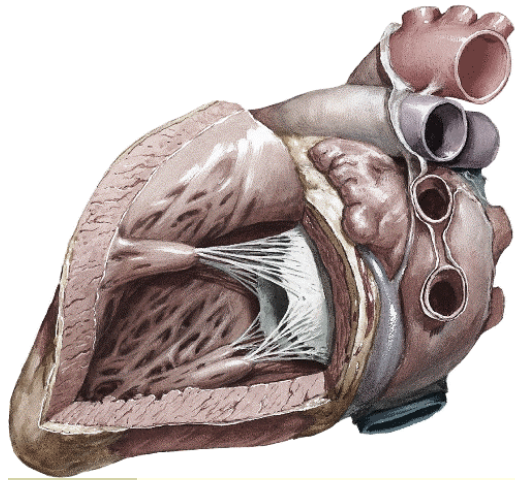




Por qué es necesaria la guía de presión?

Limitaciones de la angiografía coronaria “visual”.

- Variabilidad intra e interobservador en la cuantificación de estenosis.
 - Estenosis $<20\%$ o $>80\%$: buena concordancia.
 - Entre $20-80\%$: baja concordancia.
- Discordancia entre grado de estenosis (%) y el significado funcional de la estenosis (isquemia). Depende de:
 - Grado de estenosis.
 - Longitud de la lesión.
 - Área luminal.
 - Circulación colateral.
 - Tono vasomotor.
 - Microcirculación.
- QCA: muchas limitaciones.



Por qué es necesaria la guía de presión?

Limitaciones de la angiografía coronaria “visual”.

FFR / LINDSTAEDT

How good are experienced interventional cardiologists at predicting the functional significance of intermediate or equivocal left main coronary artery stenoses?

Lindstaedt M, Spiecker M, Perings C, Lawo T, Yazar A, Holland-Letz T, Muegge A, Bojara W, Germing A. Int J Cardiol. 2007 Aug 21; 120(2):254-61.

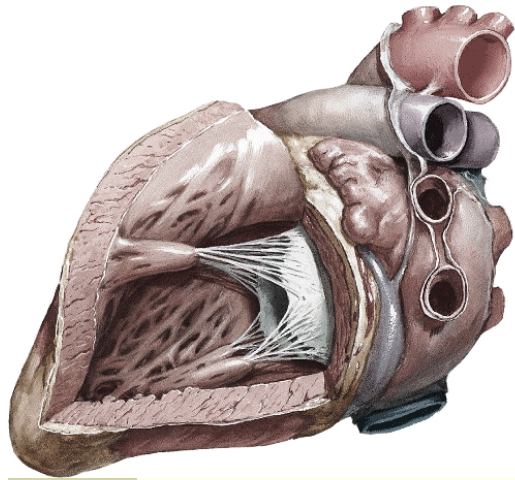
OBJECTIVES:

Assess the accuracy of visual angiographic assessment of intermediate or equivocal left main coronary artery (LMCA) stenoses by experienced interventional cardiologists when taking fractional flow reserve (FFR) measurements as the gold standard.

METHODS:

- 51 patients
- Intermediate lesions (40 - 80 % diameter stenosis by angiography) and equivocal LMCA disease
- Evaluation of all lesions by FFR
- Angiograms were reviewed by 4 experienced interventionalists blinded to FFR results
- Lesion significance had to be classified as 'significant', 'not significant', or 'unsure' by observer

Lindstaedt M, Spiecker M, Perings C, Lawo T, Yazar A, Holland-Letz T, Muegge A, Bojara W, Germing A. Int J Cardiol. 2007 Aug 21; 120(2):254-61.



Por qué es necesaria la guía de presión?

Limitaciones de la angiografía coronaria “visual”.

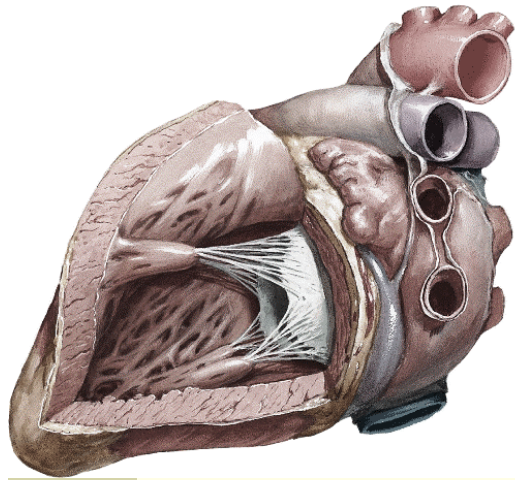
SUMMARY:

- Results were compared with two different FFR cutoff values (< 0.75 and hemodynamically significant lesions).
- The 4 reviewers achieved correct lesion classification in no more than approximately 50 % of cases each, regardless of FFR threshold.
- The interobserver agreement between two reviewers in excess of the agreement expected due to chance was outperformed on average by only 16 %.
- The interobserver variability was large resulting in unanimously correct lesion classification in only 29 % of all cases.

CONCLUSIONS:

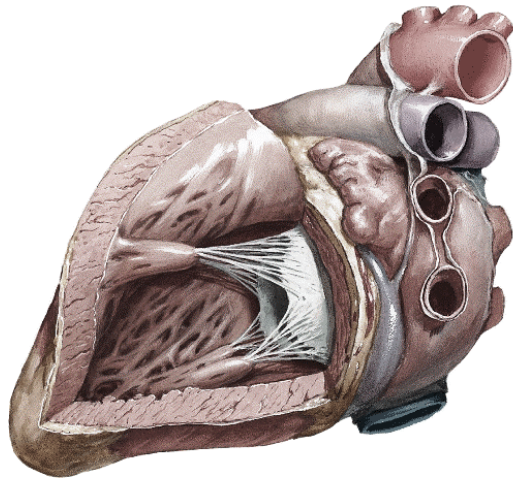
The evaluation of the functional significance of intermediate or equivocal LMCA stenoses should not be based on visual assessment, even when performed by experienced interventional cardiologists. The study is a strong plea to be prudent and self-critical with respect to one's own ability to appraise the functional significance of left main lesions correctly. Increased application of FFR measurements in this patient population should be recommended.

Lindstaedt M, Spiecker M, Perings C, Lawo T, Yazar A, Holland-Letz T, Muegge A, Bojara W, Germing A. Int J Cardiol. 2007 Aug 21; 120(2):254-61.



Para qué es útil la guía de presión?

- Lesiones intermedias.
 - Lesiones en tandem en una misma arteria.
 - Enfermedad difusa y lesiones largas.
 - Tronco común.
 - Lesiones ostiales.
 - Ramas secundarias “atrapadas” por stent.
 - Angina y enfermedad multivaso.
-
- Alternativa a test de isquemia no invasivo.
 - Normalización FFR tras ACTP con stent: valor pronóstico.



Hay que usar la guía de presión?

Guidelines on myocardial revascularization



European Heart Journal (2010) 31, 2501–2555
doi:10.1093/eurheartj/ehq277

Table 33 Recommendations for specific percutaneous coronary intervention devices and pharmacotherapy

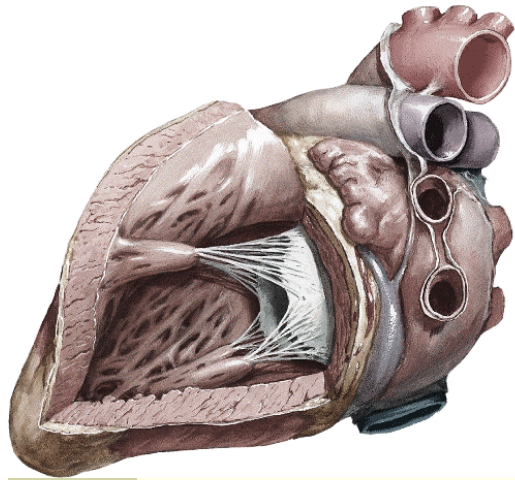
	Class ^a	Level ^b	Ref. ^c
FFR-guided PCI is recommended for detection of ischaemia-related lesion(s) when objective evidence of vessel-related ischaemia is not available.	I	A	15, 28

Pressure-derived fractional flow reserve

Although non-invasive stress imaging should be the gold standard for evaluation of patients with known or suspected CAD, many patients come to the catheterization laboratory without prior functional testing. When a non-invasive imaging stress test is unavailable, FFR can be useful, especially in the presence of MVD. The concept that avoiding unnecessary stenting actually improves outcome was demonstrated in the DEFER¹⁵ and FAME²⁸ trials. FFR is a valuable tool to determine whether or not an intermediate stenotic segment can cause downstream ischaemia in stable and unstable patients with MVD, in-stent restenosis, LM stenosis, and post-MI.

5.4 Invasive tests

In common practice, many patients with intermediate or high pretest CAD likelihood are catheterized without prior functional testing. When non-invasive stress imaging is contraindicated, non-diagnostic, or unavailable, the measurement of FFR or coronary flow reserve is helpful. Even experienced interventional cardiologists cannot predict accurately the significance of most intermediate stenoses on the basis of visual assessment or quantitative coronary angiography.^{27,28} Deferral of PCI^{15,28} or CABG²⁷ in patients with FFR >0.80 is safe and clinical outcome is excellent. Thus, FFR is indicated for the assessment of the functional consequences of moderate coronary stenoses when functional information is lacking.



Estudio FAME

The NEW ENGLAND JOURNAL *of* MEDICINE

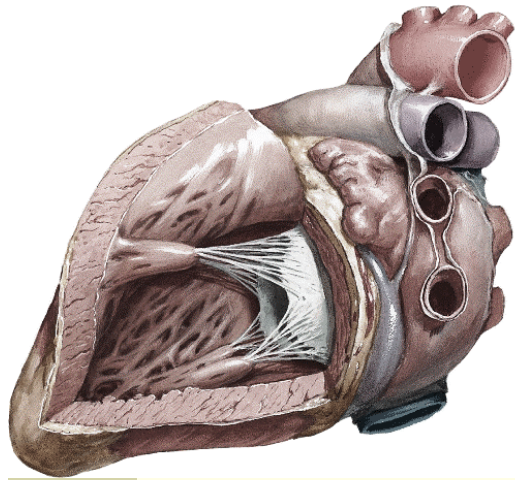
ESTABLISHED IN 1812

JANUARY 15, 2009

VOL. 360 NO. 3

Fractional Flow Reserve versus Angiography for Guiding Percutaneous Coronary Intervention

Pim A.L. Tonino, M.D., Bernard De Bruyne, M.D., Ph.D., Nico H.J. Pijls, M.D., Ph.D.,
Uwe Siebert, M.D., M.P.H., Sc.D., Fumiaki Ikeno, M.D., Marcel van 't Veer, M.Sc., Volker Klauss, M.D., Ph.D.,
Ganesh Manoharan, M.D., Thomas Engstrøm, M.D., Ph.D., Keith G. Oldroyd, M.D., Peter N. Ver Lee, M.D.,
Philip A. McCarthy, M.D., Ph.D., and William F. Fearon, M.D., for the FAME Study Investigators*



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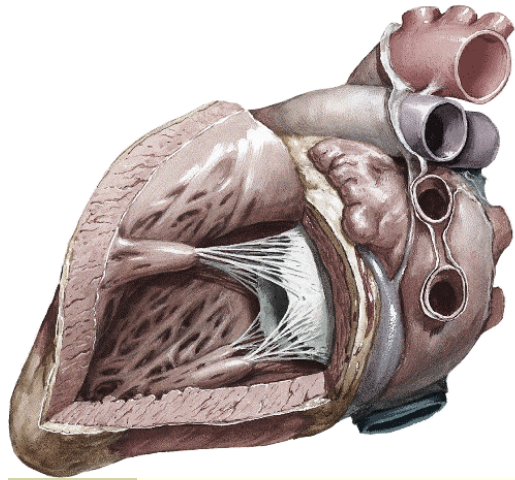
OBJECTIVES:

Investigate whether routine measurement of fractional flow reserve (FFR; the ratio of maximal blood flow in a stenotic artery to normal maximal flow), in addition to angiography, improves outcomes of patients with multivessel disease (MVD).

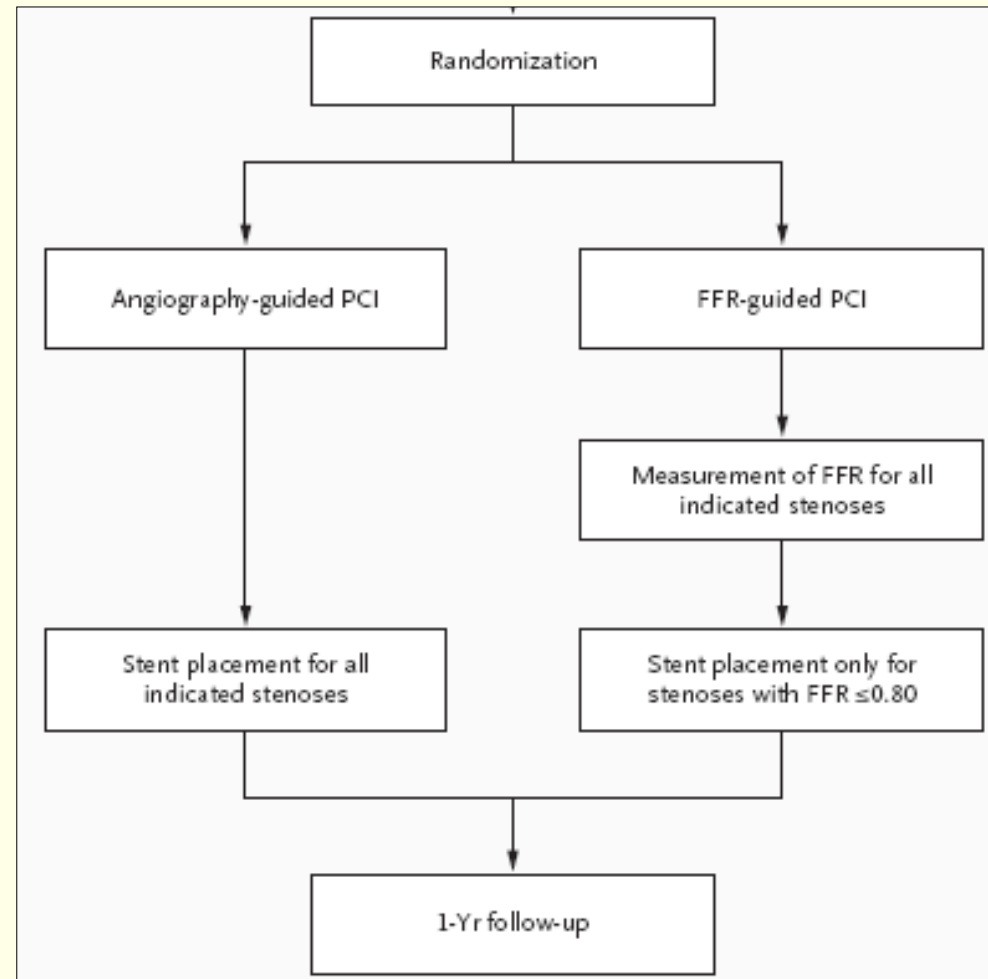
METHODS:

- 1,005 patients
- 20 European and U.S. centers
- Randomized
- DES only
- Multivessel coronary artery disease only
- Angiography guidance alone versus angiography plus FFR
- PCI for every lesion with $FFR \leq 0.80$
- No PCI for FFR group patients with $FFR > 0.80$
- 1 year follow-up

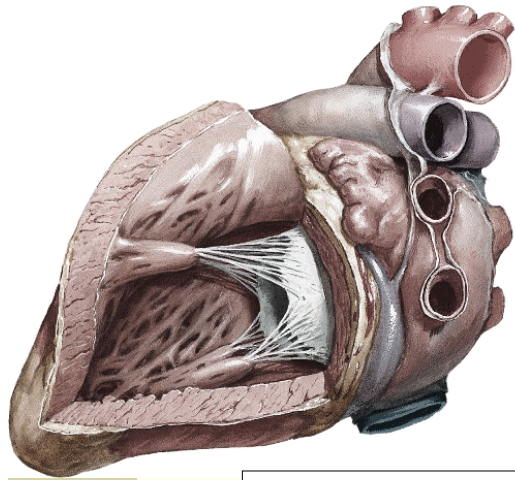
- Criterios exclusión: Tronco común, by-pass previo, shock cardiogénico, coronarias extremadamente tortuosas o calcificadas, contraindicación para DES.
- DES de 1^a-2^a generación: Cypher, Taxus, y Endeavor.
- Comité independiente de asignación de eventos: “ciego”.



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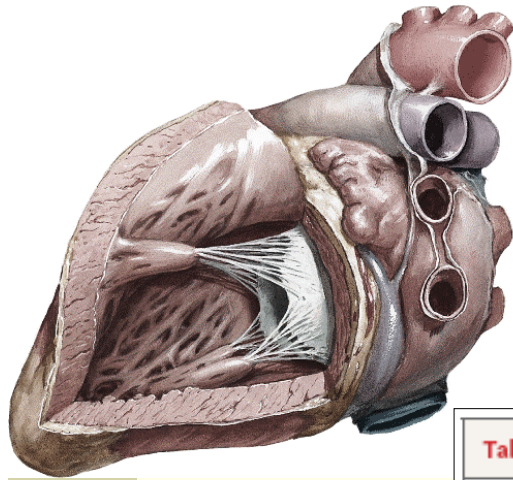
Primary end point: death + nonfatal myocardial infarction + repeat revascularization



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Table 1. Baseline Characteristics of the Patients.*

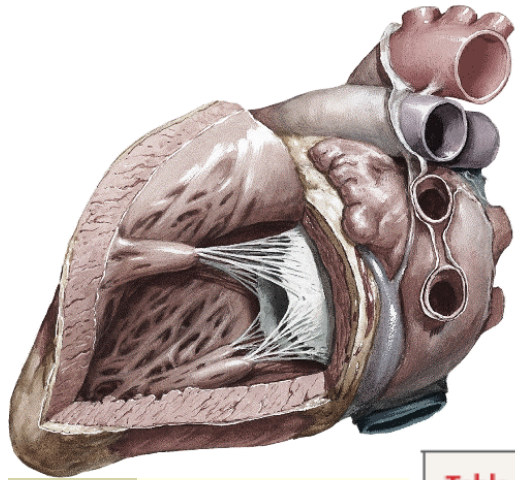
Characteristic	Angiography Group (N= 496)	FFR Group (N= 509)	P Value†
Demographic			
Age — yr	64.2±10.2	64.6±10.3	0.47
Sex — no. (%)			0.30
Male	360 (72.6)	384 (75.4)	
Female	136 (27.4)	125 (24.6)	
Previous myocardial infarction — no. (%)	180 (36.3)	187 (36.7)	0.84
Previous PCI — no. (%)	129 (26.0)	146 (28.7)	0.34
Diabetes — no. (%)	125 (25.2)	123 (24.2)	0.65
Hypertension — no. (%)	327 (65.9)	312 (61.3)	0.10
Hypercholesterolemia — no. (%)	362 (73.0)	366 (71.9)	0.62
Family history — no. (%)	190 (38.3)	205 (40.3)	0.49
Current smoker — no. (%)	156 (31.5)	138 (27.1)	0.12



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Table 2. Results of PCI.*

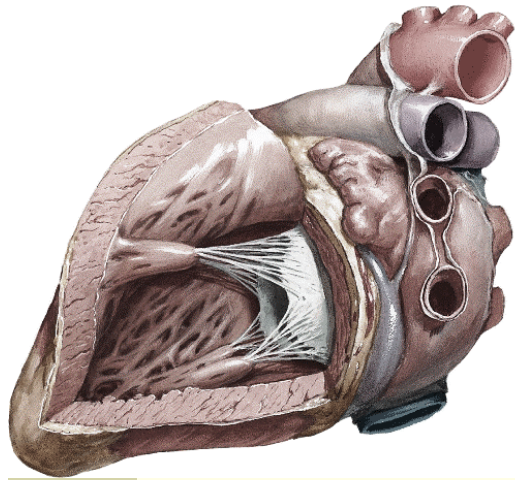
Variable	Angiography Group (N= 496)	FFR Group (N= 509)	P Value [†]
Procedure time — min [‡]	70±44	71±43	0.51
Volume of contrast agent used — ml	302±127	272±133	<0.001
Drug-eluting stents			
No. of stents per patient			
Mean	2.7±1.2	1.9±1.3	<0.001
Median (interquartile range)	3 (2–3)	2 (1–3)	
Total length per patient — mm	51.9±24.6	37.9±27.8	<0.001
Average diameter per patient — mm	2.96±0.33	2.92±0.36	0.13
Total no. of stents	1359	980	
FFR-guided strategy			
Lesions successfully measured for FFR — no./total no. (%) [¶]	NA	1329/1414 (94.0)	
FFR	NA	0.71±0.18	
Ischemic lesions	NA	0.60±0.14	
Nonischemic lesions	NA	0.88±0.05	
Lesions with FFR ≤0.80 — no./total no. (%)	NA	874/1387 (63.0)	
Lesions with FFR >0.80 — no./total no. (%)	NA	513/1387 (37.0)	
Cost of materials — \$	6,007±2,819	5,332±3,261	<0.001
Hospital stay at baseline admission — days	3.7±3.5	3.4±3.3	0.05



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Table 3. Primary and Secondary End Points at 1 Year.*

End Point	Angiography Group (N= 496)	FFR Group (N= 509)	P Value [†]	Relative Risk with FFR Guidance (95%CI)
Events at 1 year				
Composite of death, myocardial infarction, and repeat vascularization — no. (%) [‡]	91 (18.3)	67 (13.2)	0.02	0.72 (0.54–0.96)
Death — no. (%)	15 (3.0)	9 (1.8)	0.19	0.58 (0.26–1.32)
Myocardial infarction — no. (%)	43 (8.7)	29 (5.7)	0.07	0.66 (0.42–1.04)
Repeat vascularization — no. (%)	47 (9.5)	33 (6.5)	0.08	0.68 (0.45–1.05)
Death or myocardial infarction — no. (%)	55 (11.1)	37 (7.3)	0.04	0.66 (0.44–0.98)
Total events — no.	113	76		
Events per patient — no.	0.23±0.53	0.15±0.41	0.02	
Functional status at 1 year				
Patients without event and free from angina — no./total no. (%)	326/482 (67.6)	360/493 (73.0)	0.07	
Patients free from angina — no./total no. (%)	374/480 (77.9)	399/491 (81.3)	0.20	
Antianginal medications — no. [§]	1.23±0.74	1.20±0.76	0.48	
Score on EQ-5D visual-analogue scale [¶]	73.7±16.0	74.5±15.7	0.65	



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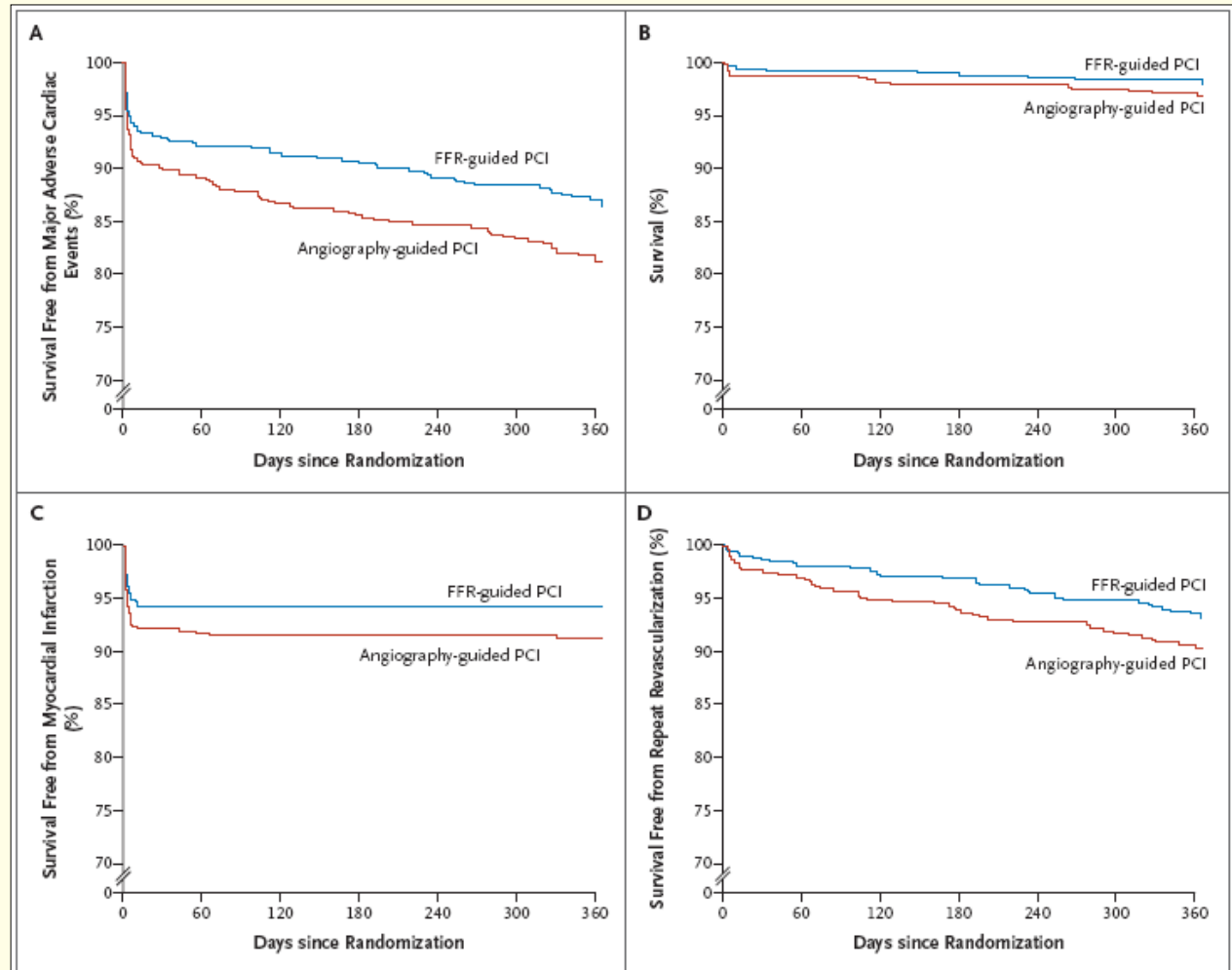
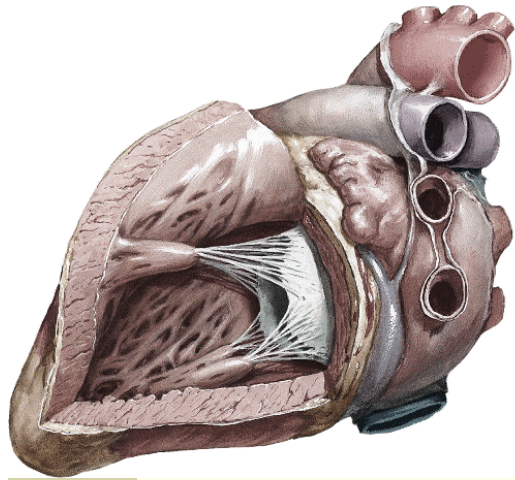


Figure 3. Kaplan–Meier Survival Curves According to Study Group. FFR denotes fractional flow reserve, and PCI percutaneous coronary intervention.

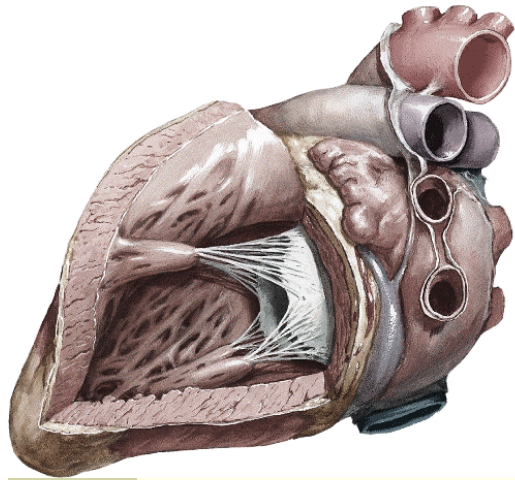


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CONCLUSIONS

Routine measurement of FFR in patients with multivessel coronary artery disease who are undergoing PCI with drug-eluting stents significantly reduces the rate of the composite end point of death, nonfatal myocardial infarction, and repeat revascularization at 1 year. (ClinicalTrials.gov number, NCT00267774.)

also significantly reduced. Without prolonging the procedure, the FFR-guided strategy reduced the number of stents used, decreased the amount of contrast agent used, and resulted in a similar, if not improved, functional status with no decrease in health-related quality of life. Furthermore, the procedure-related costs were significantly lower with the FFR-guided strategy. These results were



Estudio FAME (a 2 años)

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doi:10.1016/j.jacc.2010.04.012

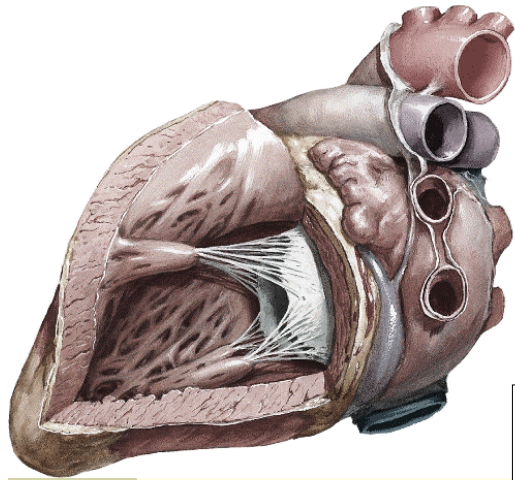
CLINICAL RESEARCH

Interventional Cardiology

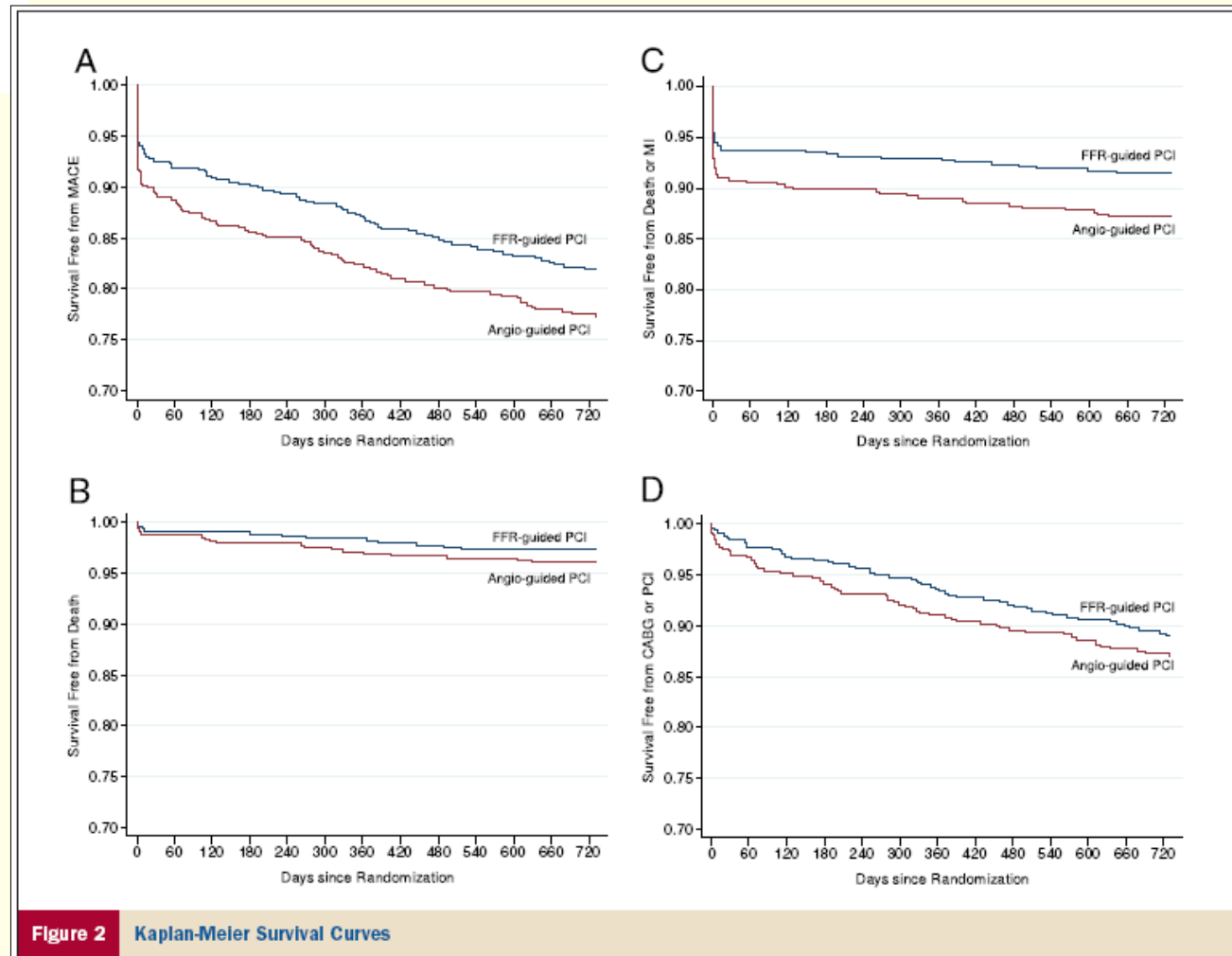
Fractional Flow Reserve Versus Angiography for Guiding Percutaneous Coronary Intervention in Patients With Multivessel Coronary Artery Disease

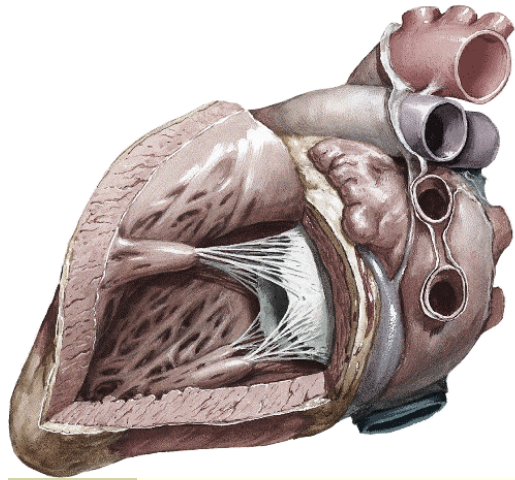
2-Year Follow-Up of the FAME (Fractional Flow Reserve
Versus Angiography for Multivessel Evaluation) Study

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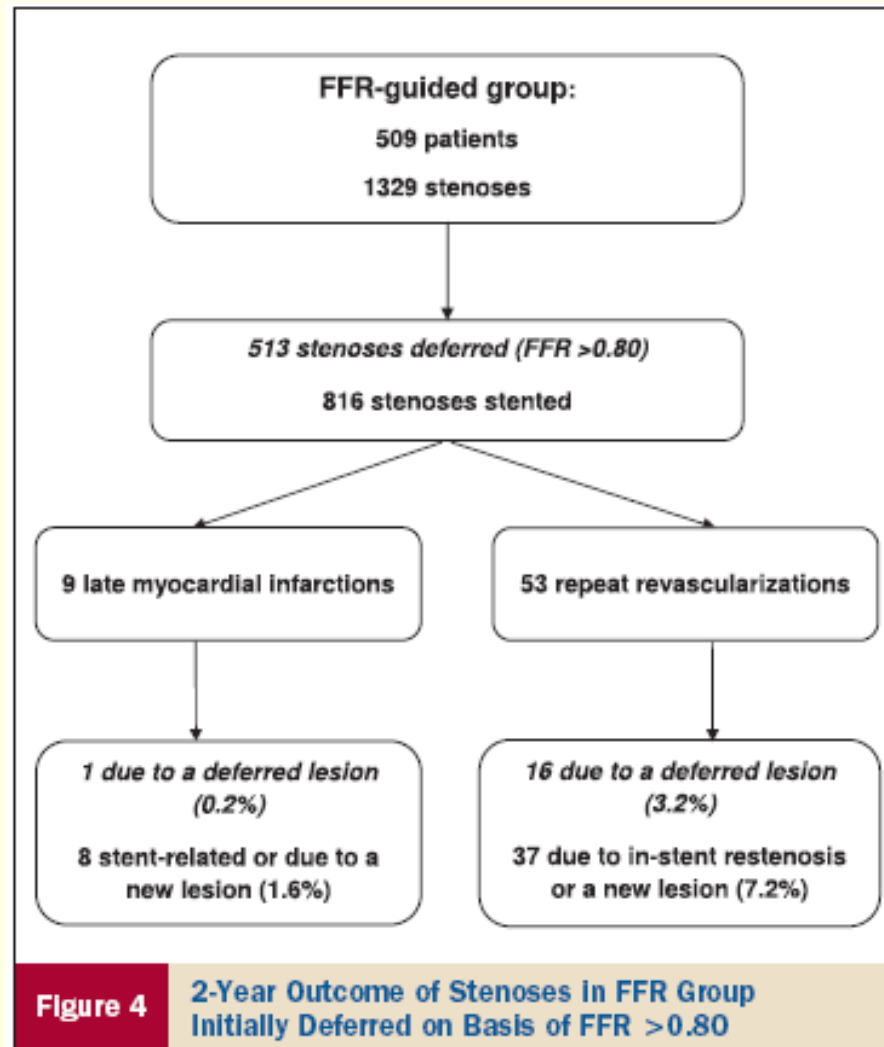


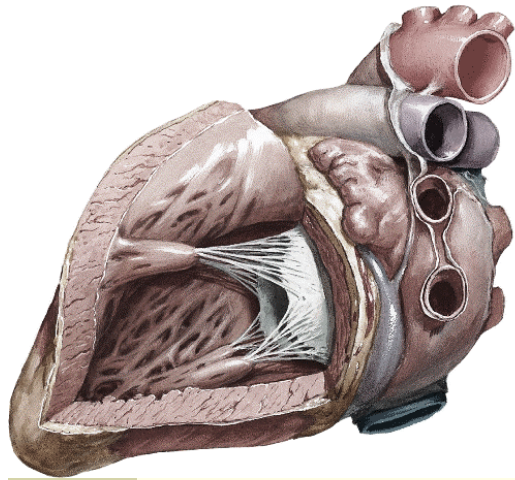
Estudio FAME (a 2 años)





Estudio FAME (a 2 años)





Estudio FAME 2

The NEW ENGLAND JOURNAL *of* MEDICINE

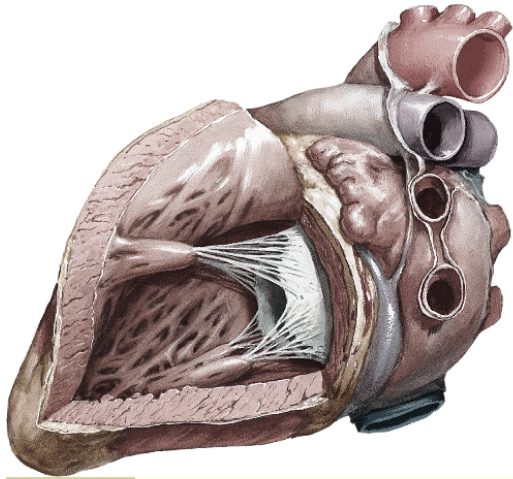
ESTABLISHED IN 1812

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Fractional Flow Reserve–Guided PCI versus Medical Therapy in Stable Coronary Disease

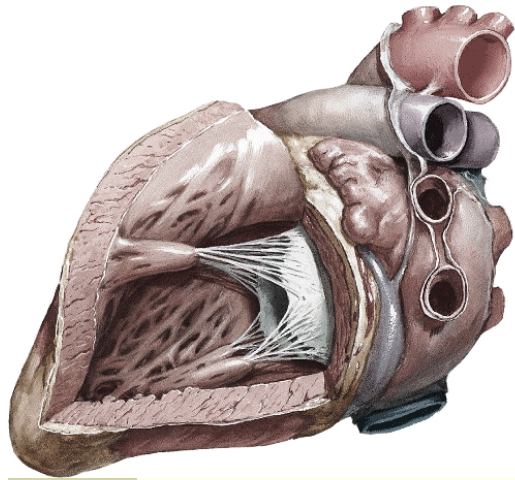
Bernard De Bruyne, M.D., Ph.D., Nico H.J. Pijls, M.D., Ph.D., Bindu Kalesan, M.P.H., Emanuele Barbato, M.D., Ph.D., Pim A.L. Tonino, M.D., Ph.D., Zsolt Piroth, M.D., Nikola Jagic, M.D., Sven Möbius-Winkler, M.D., Gilles Rioufol, M.D., Ph.D., Nils Witt, M.D., Ph.D., Petr Kala, M.D., Philip MacCarthy, M.D., Thomas Engström, M.D., Keith G. Oldroyd, M.D., Kreton Mavromatis, M.D., Ganesh Manoharan, M.D., Peter Verlee, M.D., Ole Frobert, M.D., Nick Curzen, B.M., Ph.D., Jane B. Johnson, R.N., B.S.N., Peter Jüni, M.D., and William F. Fearon, M.D., for the FAME 2 Trial Investigators*



Estudio FAME 2

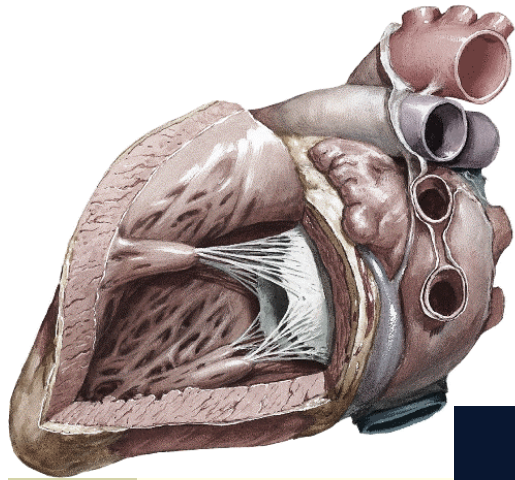
BACKGROUND

- El ICP en el SCA mejora el pronóstico.
- En la enfermedad coronaria estable, persiste la controversia sobre el beneficio del ICP versus el tratamiento médico óptimo (COURAGE...).
- El potencial beneficio del ICP radica en la presencia de isquemia (y su extensión) provocada por una lesión potencialmente tratable.
- Tratar lesiones que no producen isquemia NO es beneficioso y podría ser contraproducente.



Estudio FAME 2

- “All comers” trial: todos los pacientes elegibles consecutivos.
- 28 países en Norte América y Europa.
- Pacientes con enfermedad coronaria estable.
- Con enfermedad de 1, 2, o 3 vasos, factible para ICP.
- Se predefinen las lesiones a tratar.
- Se mide el FFR en dichas lesiones.
- Los pacientes con al menos una lesión con $FFR < 0.80$ son randomizados a:
 - ICP guiada con FFR + OMT.
 - OMT.
- Los pacientes con $FFR > 0.80$ en todas las lesiones, fueron incluidos en un registro.



Estudio FAME 2

Trial Design

Stable patients with 1, 2, or 3 vessel CAD evaluated for PCI with DES
n=1220

FFR in all target lesions

Randomized Trial

At least 1 stenosis with
FFR ≤ 0.80 (n=888)

Randomization 1:1

PCI + MT

MT

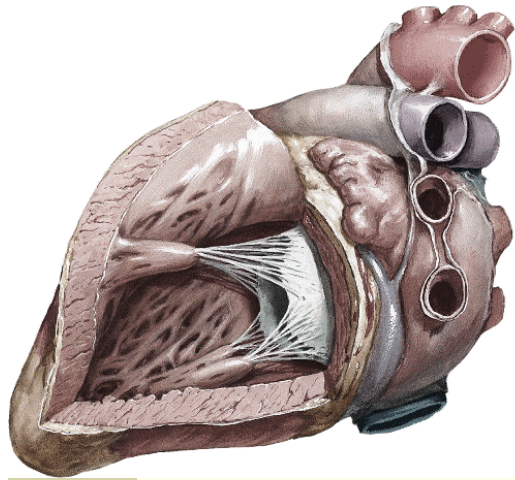
Registry

All FFR > 0.80
(n=322)

MT

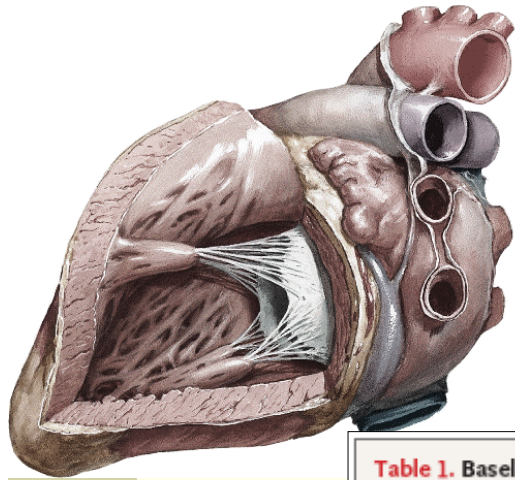
50% randomly assigned
to follow-up

Primary Endpoint: Death, MI, Urgent Revascularization at 2 years



Estudio FAME 2

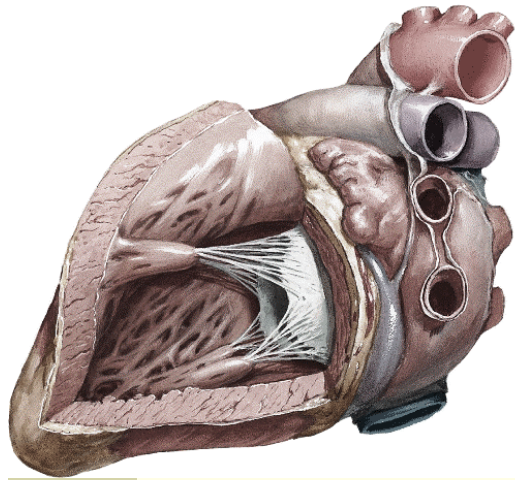
- Inicio: Mayo 2010.
- Fin: enero 2012.
- El “data and safety monitoring board” suspende la inclusión por una diferencia muy significativa en la incidencia de endpoint primario a favor del grupo ICP respecto al grupo MT.
- 1220 pacientes incluidos.
- 888 con al menos un $\text{FFR} < 0.80$: randomizados.
- 332 con $\text{FFR} > 0.80$: registro.
- Seguimiento medio: 210 días.



Estudio FAME 2

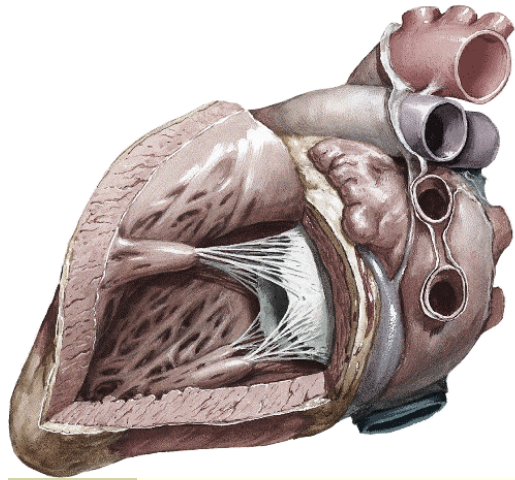
Table 1. Baseline Clinical, Angiographic, and Fractional Flow Reserve (FFR) Characteristics.*

Variable	Randomly Assigned Groups		Registry Cohort	P Value†‡
	PCI plus Medical Therapy	Medical Therapy Alone		
Patient characteristics				
Total no. of patients	447	441	166	
Age — yr	63.52±9.35	63.86±9.62	63.58±9.75	0.90
Male sex — no. (%)	356 (79.6)	338 (76.6)	113 (68.1)	0.005
Body-mass index‡	28.29±4.27	28.44±4.55	27.83±3.94	0.14
Family history of coronary artery disease — no. (%)	216 (48.3)	207 (46.9)	76 (45.8)	0.65
Current smoking — no. (%)	89 (19.9)	90 (20.4)	35 (21.1)	0.79
Hypertension — no. (%)	347 (77.6)	343 (77.8)	136 (81.9)	0.23
Hypercholesterolemia — no. (%)	330 (73.8)	348 (78.9)	118 (71.1)	0.15
Diabetes mellitus — no. (%)				
Any	123 (27.5)	117 (26.5)	42 (25.3)	0.65
Angina — no./total no (%)¶				0.64
Asymptomatic	53/447 (11.9)	46/440 (10.5)	17/166 (10.2)	
CCS class I	82/447 (18.3)	98/440 (22.3)	42/166 (25.3)	
CCS class II	204/447 (45.6)	197/440 (44.8)	74/166 (44.6)	
CCS class III	80/447 (17.9)	65/440 (14.8)	23/166 (13.9)	
CCS class IV, stabilized	28/447 (6.3)	34/440 (7.7)	10/166 (6.0)	
Silent ischemia — no. (%)	73 (16.3)	73 (16.6)	27 (16.3)	0.96
Left ventricular ejection fraction <50% — no./total no. (%)	83/423 (19.6)	56/410 (13.7)	27/150 (18.0)	0.69



Estudio FAME 2

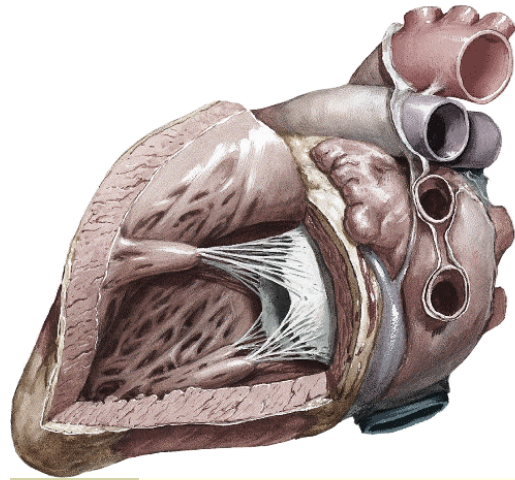
Variable	Randomly Assigned Groups		Registry Cohort	P Value [†]
	PCI plus Medical Therapy	Medical Therapy Alone		
Angiographic findings				
Angiographically significant lesions — no. per patient	1.87±1.05	1.73±0.94	1.32±0.59	<0.001
Vessels with at least one significant lesion — no. of patients (%)				<0.001
1	251 (56.2)	261 (59.2)	136 (81.9)	
2	156 (34.9)	146 (33.1)	26 (15.7)	
3	40 (8.9)	34 (7.7)	4 (2.4)	
At least one significant lesion in proximal or middle left anterior descending artery — no. (%)	291 (65.1)	276 (62.6)	74 (44.6)	<0.001
FFR findings				
Functionally significant lesions — no. per patient	1.52±0.78	1.42±0.73	0.03±0.17	<0.001
Vessels with at least one significant lesion — no. of patients (%)				<0.001
1	331 (74.0)	343 (77.8)	5 (3.0)	
2	102 (22.8)	85 (19.3)	0	
3	14 (3.1)	13 (2.9)	0	
At least one significant lesion in proximal or middle left anterior descending artery — no. (%)	279 (62.4)	263 (59.6)	1 (0.6)	<0.001



Estudio FAME 2

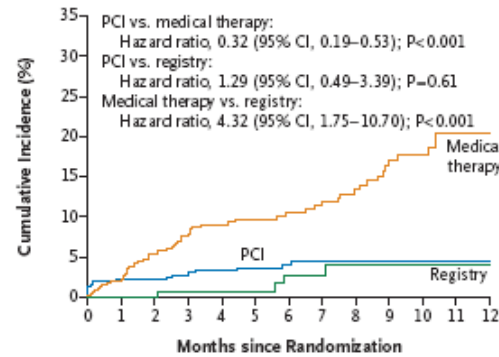
Table 2. Clinical Events.

Event	Randomly Assigned Groups			P Value	Registry Cohort (N = 166)
	PCI plus Medical Therapy (N = 447)	Medical Therapy Alone (N = 441)	Hazard Ratio with PCI (95% CI)		
	no. (%)	no. (%)			
Primary end point	19 (4.3)	56 (12.7)	0.32 (0.19–0.53)	<0.001	5 (3.0)
Components of primary end point					
Death from any cause	1 (0.2)	3 (0.7)	0.33 (0.03–3.17)	0.31	0
Myocardial infarction	15 (3.4)	14 (3.2)	1.05 (0.51–2.19)	0.89	3 (1.8)
Urgent revascularization	7 (1.6)	49 (11.1)	0.13 (0.06–0.30)	<0.001	4 (2.4)
Death or myocardial infarction	15 (3.4)	17 (3.9)	0.61 (0.28–1.35)	0.22	3 (1.8)
Cardiac death	1 (0.2)	1 (0.2)	0.96 (0.06–15.17)	0.98	0
Revascularization					
Any	14 (3.1)	86 (19.5)	0.14 (0.08–0.26)	<0.001	6 (3.6)
Nonurgent revascularization	7 (1.6)	38 (8.6)	0.17 (0.08–0.39)	<0.001	2 (1.2)
Stroke	1 (0.2)	2 (0.5)	0.49 (0.04–5.50)	0.56	1 (0.6)
Definite or probable stent thrombosis	5 (1.1)	1 (0.2)	4.98 (0.59–42.25)	0.10	1 (0.6)



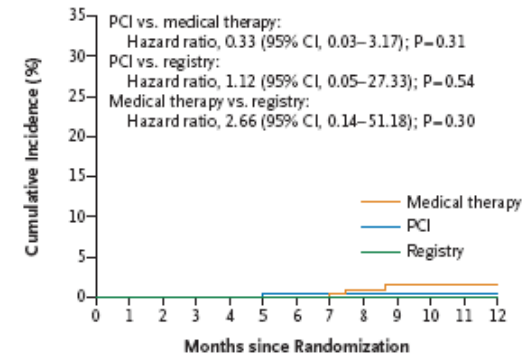
Estudio FAME 2

A Primary End Point



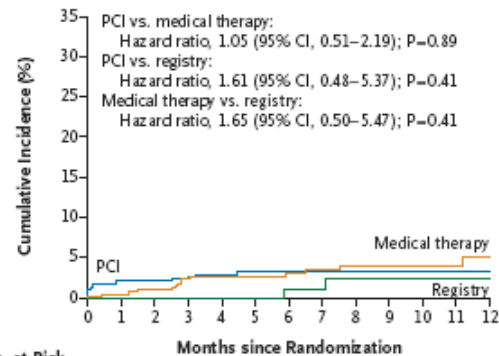
No. at Risk	0	1	2	3	4	5	6	7	8	9	10	11	12
Medical therapy	441	414	370	322	283	253	220	192	162	127	100	70	37
PCI	447	414	388	351	308	277	243	212	175	155	117	92	53
Registry	166	156	145	133	117	106	93	74	64	52	41	25	13

B Death from Any Cause



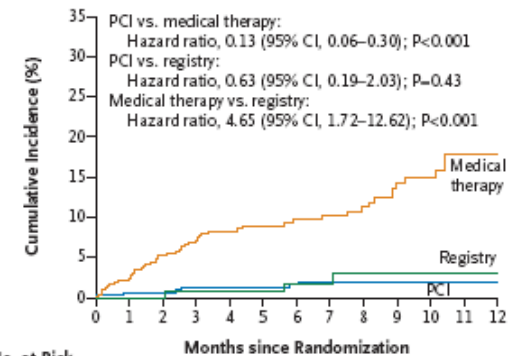
No. at Risk	0	1	2	3	4	5	6	7	8	9	10	11	12
Medical therapy	441	423	390	350	312	281	247	219	188	154	122	90	54
PCI	447	423	396	359	318	288	250	220	183	163	122	95	54
Registry	166	156	145	134	118	107	96	76	67	55	43	27	13

C Myocardial Infarction



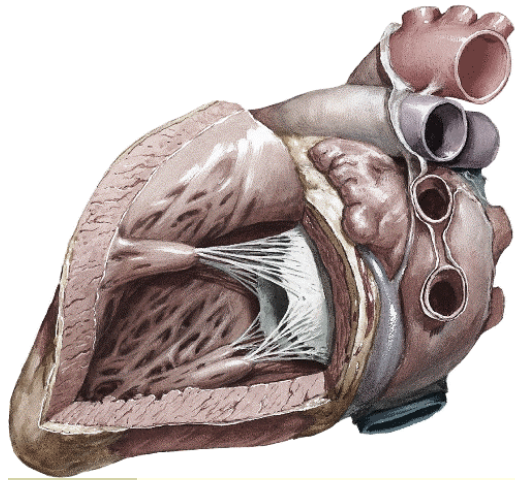
No. at Risk	0	1	2	3	4	5	6	7	8	9	10	11	12
Medical therapy	441	421	386	341	304	273	239	212	182	148	117	85	48
PCI	447	414	388	352	309	278	244	214	177	157	119	94	54
Registry	166	156	145	134	118	107	95	75	65	53	42	26	13

D Urgent Revascularization



No. at Risk	0	1	2	3	4	5	6	7	8	9	10	11	12
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

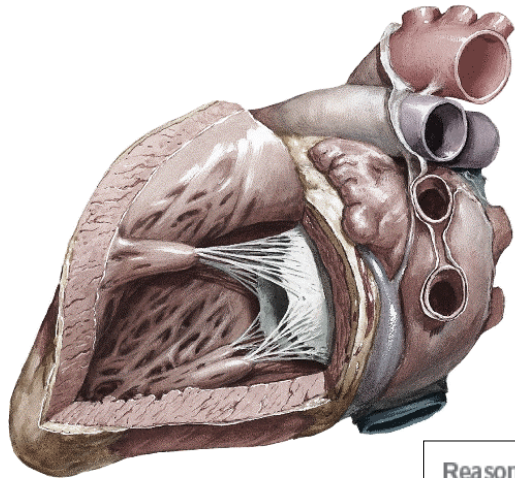
Figure 1. Cumulative Incidence of the Primary End Point and Its Components.



Estudio FAME 2

MT: 8 x riesgo de revascularización urgente en el seguimiento.

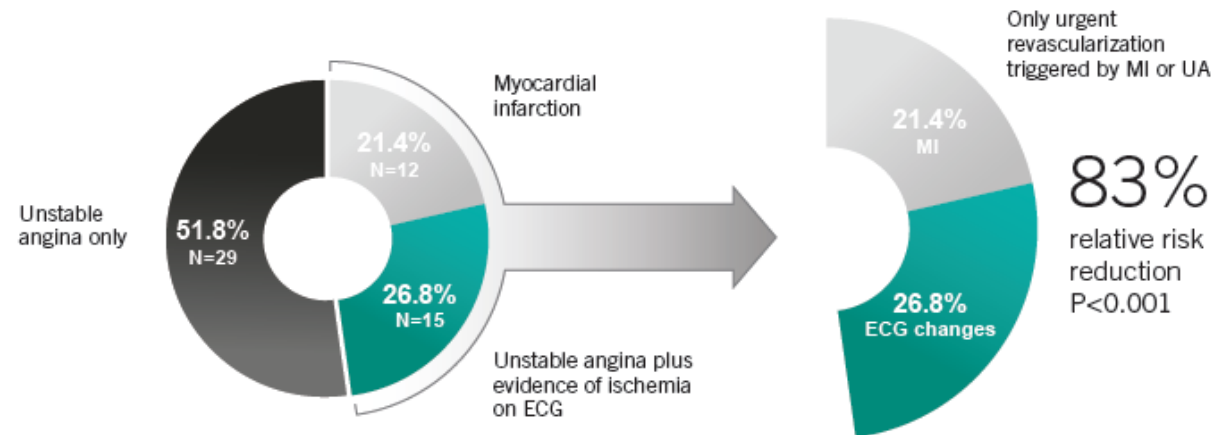
	FFR-Guided PCI (n=447)	%	MT (n=441)	P-Value
Primary Endpoint	4.3		12.7	<0.001
Death	0.2		0.7	0.31
Myocardial Infarction	3.4		3.2	0.89
Urgent Revascularization	1.6		11.1	<0.001
Free from Angina (1 month)	71		48	<0.001



Estudio FAME 2

MT: 8 x riesgo de revascularización urgente en el seguimiento.

Reasons for urgent revascularization



If you only count the urgent revascularizations triggered by MI or UA with evidence of ischemia on ECG, the difference between FFR-guided PCI and MT alone is still statistically significant, and the relative risk reduction is still 83%.

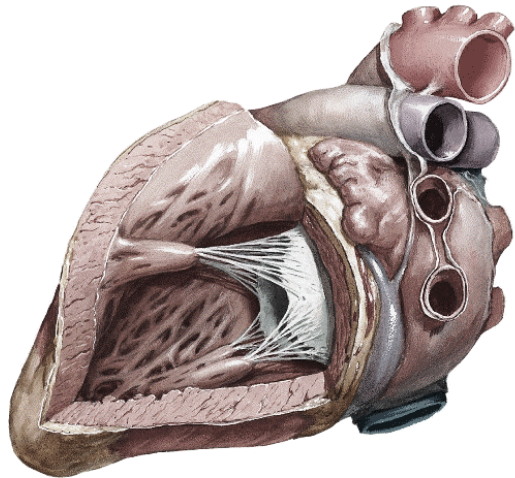
Reasons for urgent revascularization		
MI	UA and ischemia on ECG	UA only*
N = 12 (21.4%)	N = 15 (26.8%)	N = 29 (51.8%)

* Resting symptoms (i.e., unstable) that were refractory to medication and therefore required hospitalization. Fulfilled criteria of ACS based on the judgement of the blinded CEC, who adjudicated each case.

Only urgent revascularization triggered by MI or UA	
PCI group	MT group
N = 4 (0.9%)	N = 23 (5.2%)

UNEQUIVOCAL EVIDENCE OF ACS

Urgent revascularization triggered by MI or unstable angina with evidence of ischemia on ECG: 0.9% (PCI) vs. 5.2% (MT). Hazard ratio with PCI, 0.13; 95% CI, 0.04 to 0.43; P<0.001



Estudio FAME 2

CONCLUSIONES

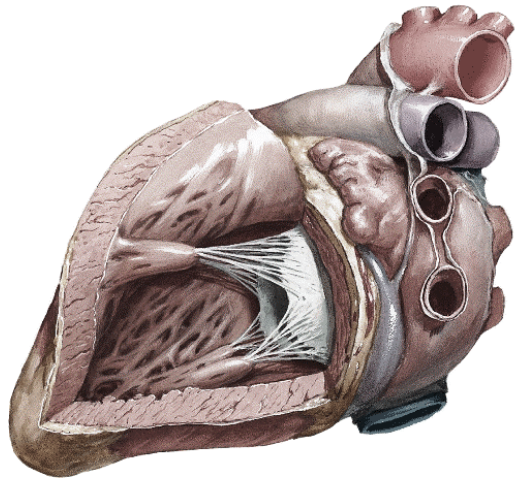
- En pacientes con enfermedad coronaria estable y con alguna lesión significativa ($\text{FFR} < 0.80$), el tratamiento con ICP + OMT (versus OMT) disminuye la incidencia de revascularización urgente.
- En los pacientes con estenosis “angiográficamente significativas” pero “funcionalmente no significativas” (registro), el pronóstico fue excelente solo con OMT.

In conclusion, among patients with stable coronary artery disease and at least one stenosis with an FFR of 0.80 or less, FFR-guided PCI with drug-eluting stents plus the best available medical therapy, as compared with the best available medical therapy alone, decreased the rate of urgent revascularization. Among patients with stenoses

that were not functionally significant, the best available medical therapy alone resulted in an excellent outcome, regardless of the angiographic appearance of the stenoses.

Supported by St. Jude Medical.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.



Es coste-efectiva la guía de presión?

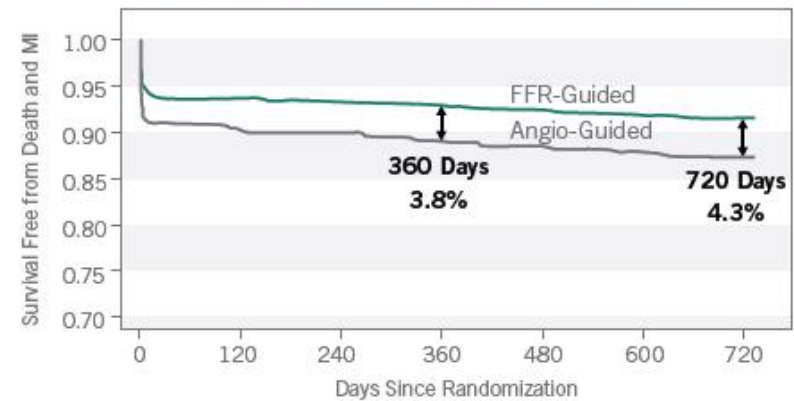
Claramente beneficiosa en el FAME-1

Improved Outcomes at Lower Costs



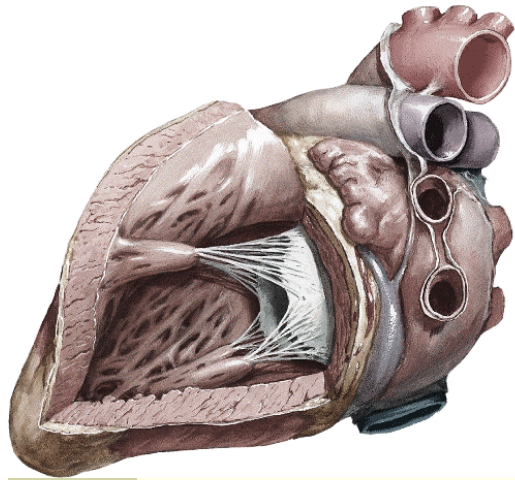
Bootstrap simulation indicated that the FFR-guided strategy was cost-saving in 99.8% and cost-effective in all 1,000 scenarios.

Two-year Survival Free of Death/MI



Procedural Characteristics

	ANGIO-Group N=496	FFR-Group N=509	P-Value
DES per Patient, No.	2.7 ± 1.2	1.9 ± 1.3	< 0.001
Procedure Time, Min.	70 ± 44	71 ± 43	0.51
Contrast Agent Used, ML	302 ± 127	272 ± 133	< 0.001
Materials Used at Procedure, Mean USD	6007 ± 2819	5332 ± 3261	< 0.001
Length of Hospital Stay, Days	3.7 ± 3.5	3.4 ± 3.3	0.05

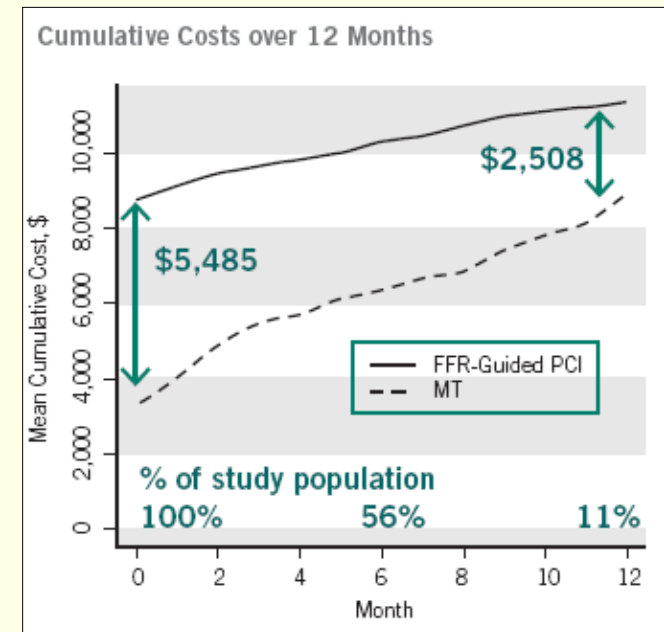


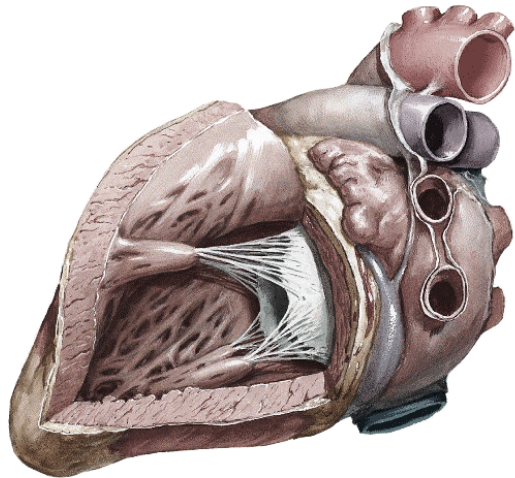
Es coste-efectiva la guía de presión?

Análisis de coste-efectividad en el FAME-2

One Year Cost Estimates Per Patient

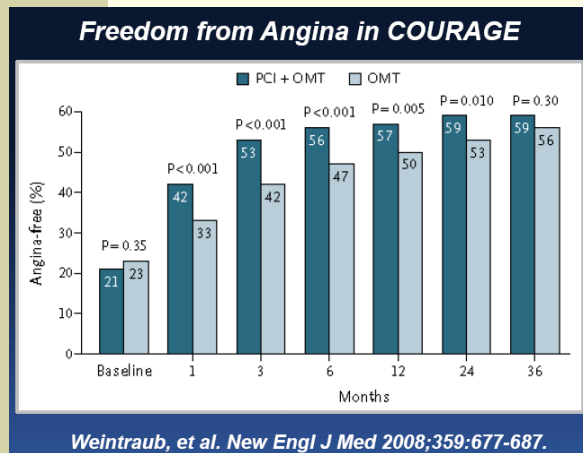
	FFR-Guided PCI	MT
Baseline	\$8,790	\$3,305
Drug-Eluting Stent(s)	\$4,304	\$48
Follow-up	\$2,584	\$5,561
Revascularization	\$442	\$3,928
Total	\$11,374	\$8,866





Es coste-efectiva la guía de presión?

Análisis de coste-efectividad en el FAME-2



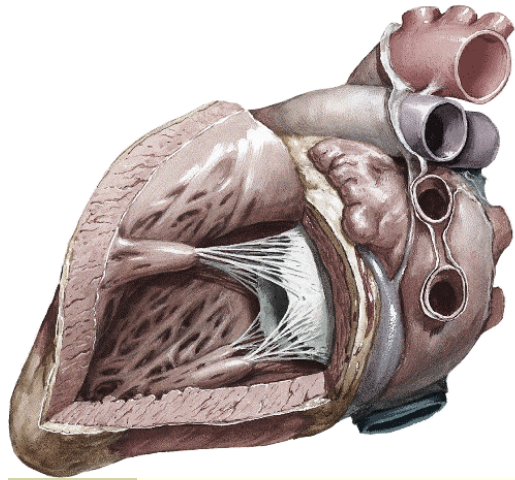
CE Benchmarks:

Hemodialysis ≈ \$50,000 / QALY
 WHO GDP std ≈ \$150,000 / QALY

- >\$150,000 / QALY
- \$50K-150K / QALY
- <\$50,000 / QALY

Study	Comparators	CE Ratio
COURAGE	Angio-Guided PCI vs Medical Therapy	≥ \$168,000 / QALY
FAME 1	Angio-Guided PCI vs FFR-Guided PCI	FFR-Guided PCI is Dominant (↓\$ / ↑QALY)
FAME 2	FFR-Guided PCI vs Medical Therapy	\$32,000 / QALY

Conclusión: en pacientes con enfermedad coronaria estable sintomática, el ICP (guiado por FFR) mejora la angina y la calidad de vida, y es económicamente coste-efectivo comparado con el tratamiento médico óptimo.



CONCLUSIONES

Guía de presión (FFR)

- Herramienta muy útil para el **mejor diagnóstico** y para la elección del **mejor tratamiento** en algunos pacientes, especialmente:
 - Lesiones **ostiales**.
 - Lesiones **intermedias**.
 - Enfermedad **multivaso** (localizar isquemia).
- En ocasiones encarece el procedimiento y en otras lo hace más barato.
- **Limitaciones**: da información funcional, no anatómica (lesiones inestables, con trombo, disección...). No se debe caer en una mala interpretación del FFR.
- En ocasiones puede (o debería) ser sustituida por un test de isquemia **no invasivo** (conociendo también sus limitaciones).