

Usefulness of coadjutant techniques, co- registration and tri- registration for PCI decision making

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ESC Guidelines on CCS

Intracoronary imaging guidance by IVUS or OCT is recommended for performing PCI on anatomically complex lesions, in particular left main stem, true bifurcations and long lesions.

I	A
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Intracoronary pressure measurement (FFR or iFR) or computation (QFR):

- is recommended to guide lesion selection for intervention in patients with multivessel disease;
- should be considered at the end of the procedure to identify patients at high risk of persistent angina and subsequent clinical events;
- may be considered at the end of the procedure to identify lesions potentially amenable to treatment with additional PCI.

I	A
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IIa	B
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IIb	B
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Recommendations	Class ^a	Level ^b
During ICA, selective assessment of functional severity of intermediate ^c diameter stenoses is recommended to guide the decision to revascularize, using the following techniques:		
• FFR/iFR (significant ≤ 0.8 or ≤ 0.89 , respectively); ^{49,308,310,311,313,321–323,332,373}	I	A
• QFR (significant ≤ 0.8). ^{325,355,374,375}	I	B

I	A
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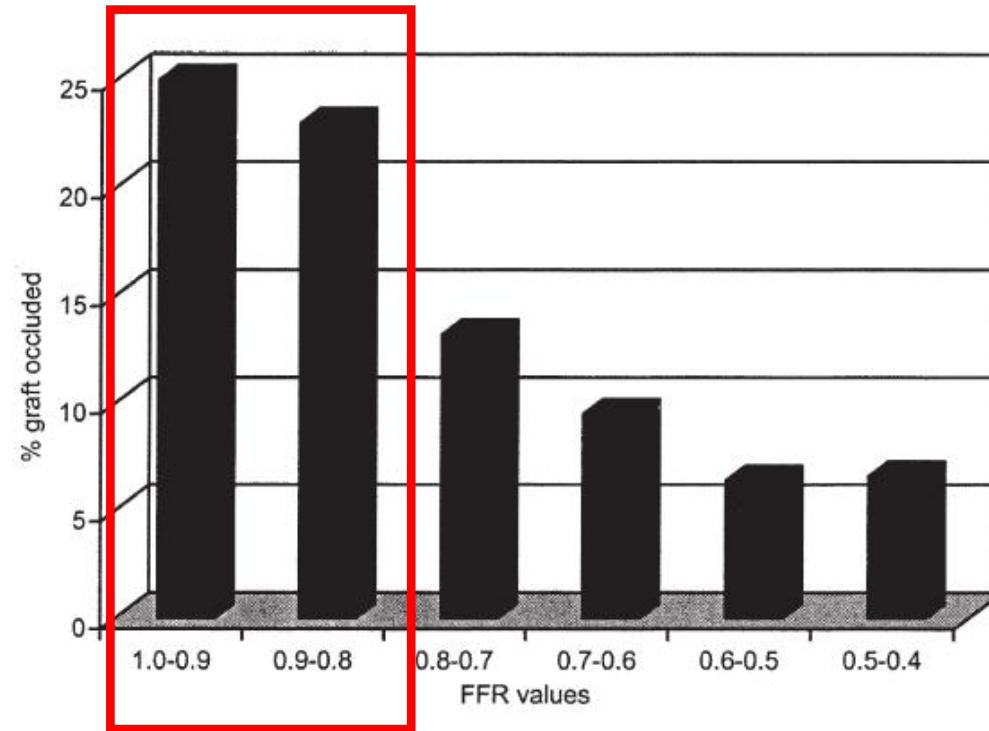


IIIA?

Hay una cosa clara.....

The consequences of unneeded revascularisation: lessons from studies on FFR in CABG patients

Documented graft occlusion according to FFR in the grafted vessel
N = 525 grafts



Botman CI et al. Ann Thorac Surg 2007;83:2093-7.

Occlusion of **68 grafts** led to only **8 cardiovascular events**

Angiografía



Imagen y Fisiología



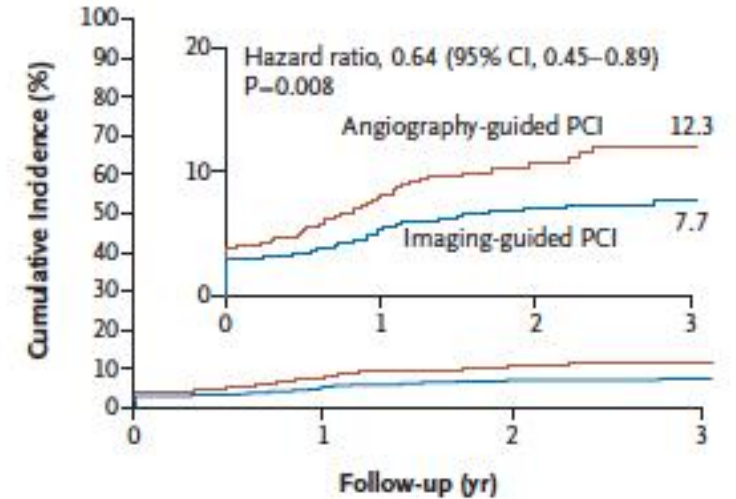
Intravascular Imaging–Guided or Angiography–Guided Complex PCI

- RCT 2:1
- 1639 patients complex coronary-artery lesions
- IVI vs Angiography-guided PCI

Table 2. Target-Lesion and Procedural Characteristics.*

Characteristic	Total (N=1639)	Intravascular Imaging– Guided PCI Group (N=1092)	Angiography–Guided PCI Group (N=547)
Target-lesion characteristics			
Complex coronary lesions — no. (%) [†]			
True bifurcation lesion	359 (21.9)	233 (21.3)	126 (23.0)
Chronic total occlusion	319 (19.5)	220 (20.1)	99 (18.1)
Unprotected left main coronary artery disease	192 (11.7)	138 (12.6)	54 (9.9)
Diffuse long coronary-artery lesion	898 (54.8)	617 (56.5)	281 (51.4)
Multivessel PCI involving ≥2 major coronary arteries	622 (37.9)	409 (37.5)	213 (38.9)
Lesion necessitating use of ≥3 stents	305 (18.6)	208 (19.0)	97 (17.7)
Lesion with in-stent restenosis	236 (14.4)	158 (14.5)	78 (14.3)
Severely calcified lesion	231 (14.1)	157 (14.4)	74 (13.5)
Ostial lesions of major coronary artery	251 (15.3)	182 (16.7)	69 (12.6)
≥3 Complex coronary lesions — no. (%)	505 (30.8)	352 (32.2)	153 (28.0)
No. of vessels with disease — no. (%)			
1	526 (32.1)	342 (31.3)	184 (33.6)
2	621 (37.9)	420 (38.5)	201 (36.7)
3	492 (30.0)	330 (30.2)	162 (29.6)

A Target-Vessel Failure



No. at Risk

	0	1	2	3
Angiography-guided PCI	547	496	280	120
Imaging-guided PCI	1092	1023	591	255

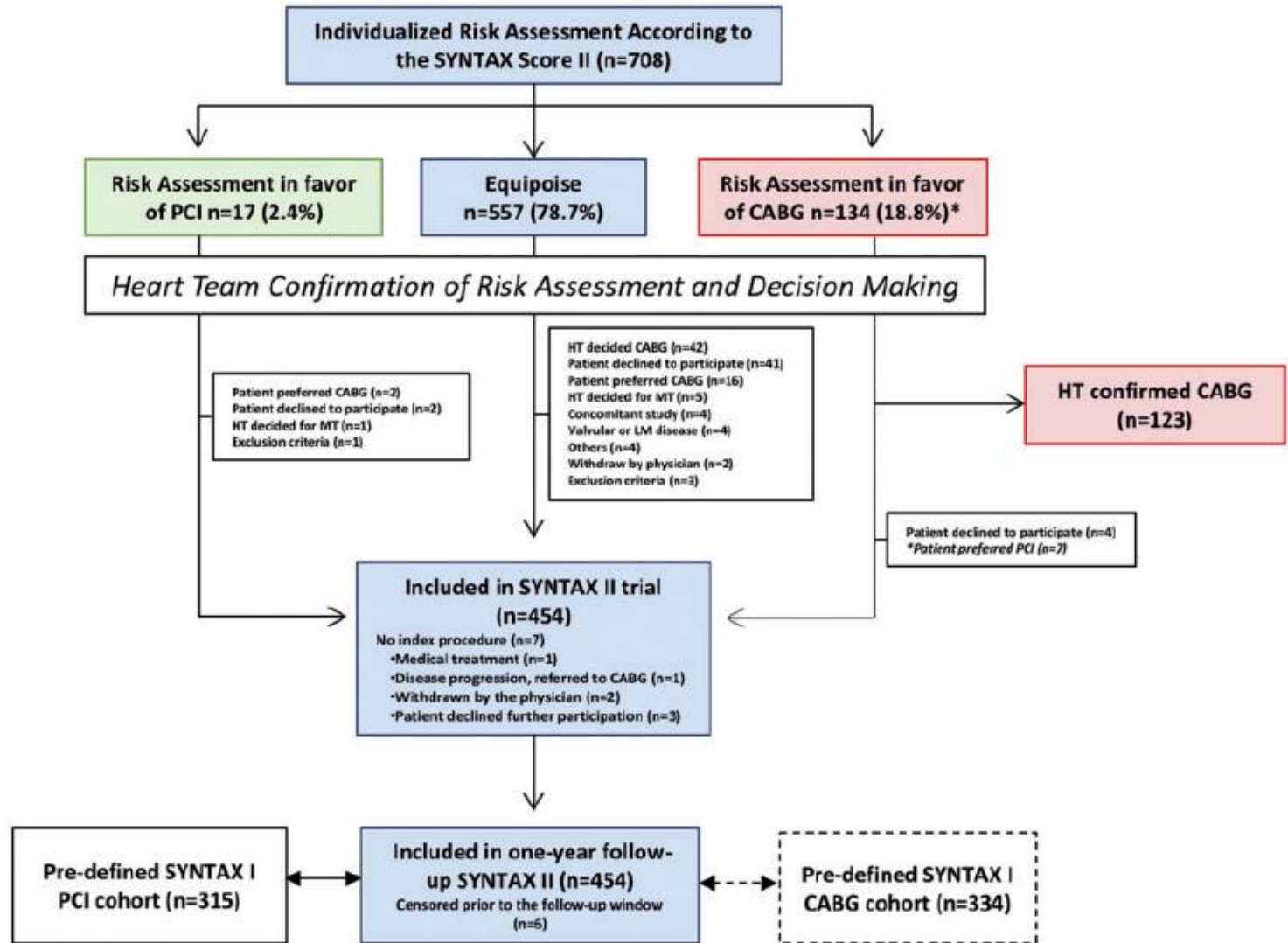
Death from any cause [¶]	70 (5.6)	42 (5.3)	28 (6.4)	0.71 (0.44–1.15)
Death from cardiac causes	33 (2.4)	16 (1.7)	17 (3.8)	0.47 (0.24–0.93)
Myocardial infarction	75 (5.0)	43 (4.4)	32 (6.2)	0.78 (0.48–1.25)



Interventional cardiology

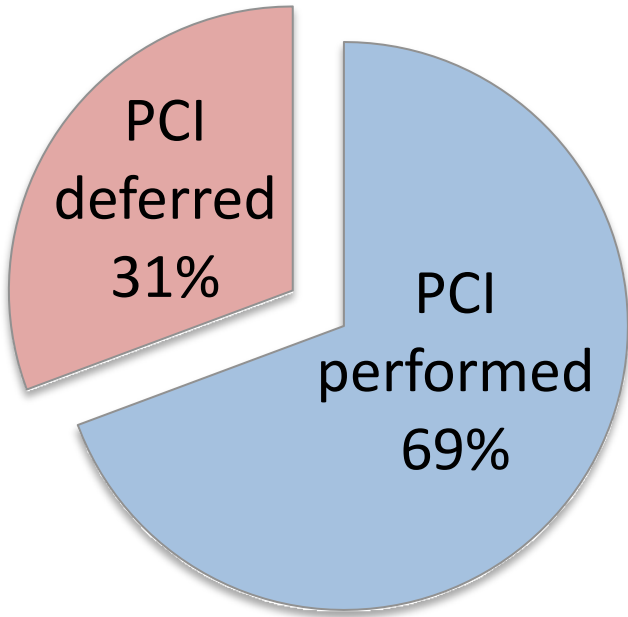
Clinical outcomes of state-of-the-art percutaneous coronary revascularization in patients with *de novo* three vessel disease: 1-year results of the SYNTAX II study

Javier Escaned¹, Carlos Collet², Nicola Ryan¹, Giovanni Luigi De Maria³, Simon Walsh⁴, Manel Sabate⁵, Justin Davies⁶, Maciej Lesiak⁷, Raul Moreno⁸, Ignacio Cruz-Gonzalez⁹, Stephan P. Hoole¹⁰, Nick Ej West¹⁰, J. J. Piek², Azfar Zaman¹¹, Farzin Fath-Ordoubadi¹², Rodney H. Stables¹³, Clare Appleby¹³, Nicolas van Mieghem¹⁴, Robert Jm. van Geuns¹⁴, Neal Uren¹⁵, Javier Zueco¹⁶, Pawel Buszman¹⁷, Andres Iniguez¹⁸, Javier Goicolea¹⁹, David Hildick-Smith²⁰, Andrzej Ochala²¹, Dariusz Dudek²², Colm Hanratty⁴, Rafael Cavalcante^{4,4}, Arie Pieter Kappetein¹⁴, David P. Taggart³, Gerrit-Anne van Es^{23,24}, Marie-Angèle Morel²³, Ton de Vries²³, Yoshinobu Onuma^{14,23}, Vasim Farooq¹², Patrick W. Serruys^{6*}, and Adrian P. Banning³



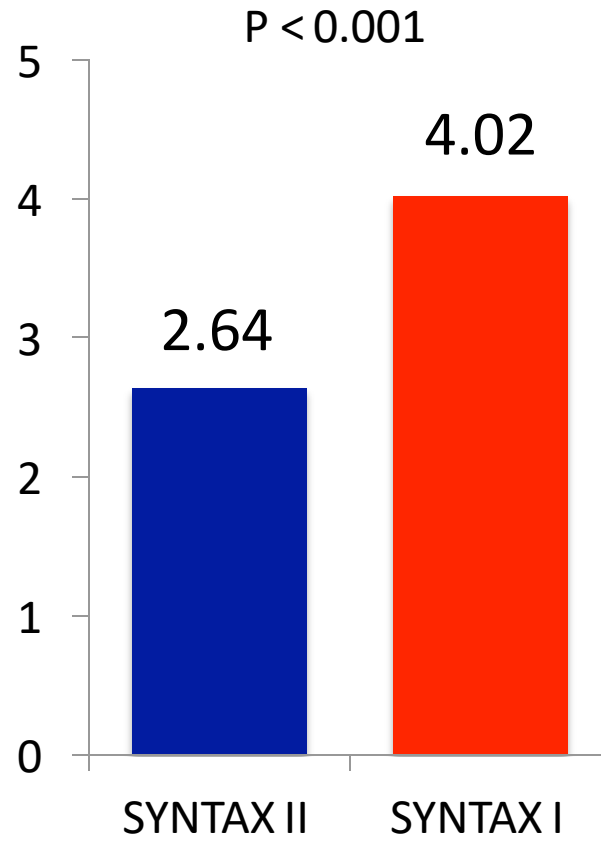
Impact of intracoronary physiology on PCI

Lesion treatment after iFR/FFR interrogation (n=1177)

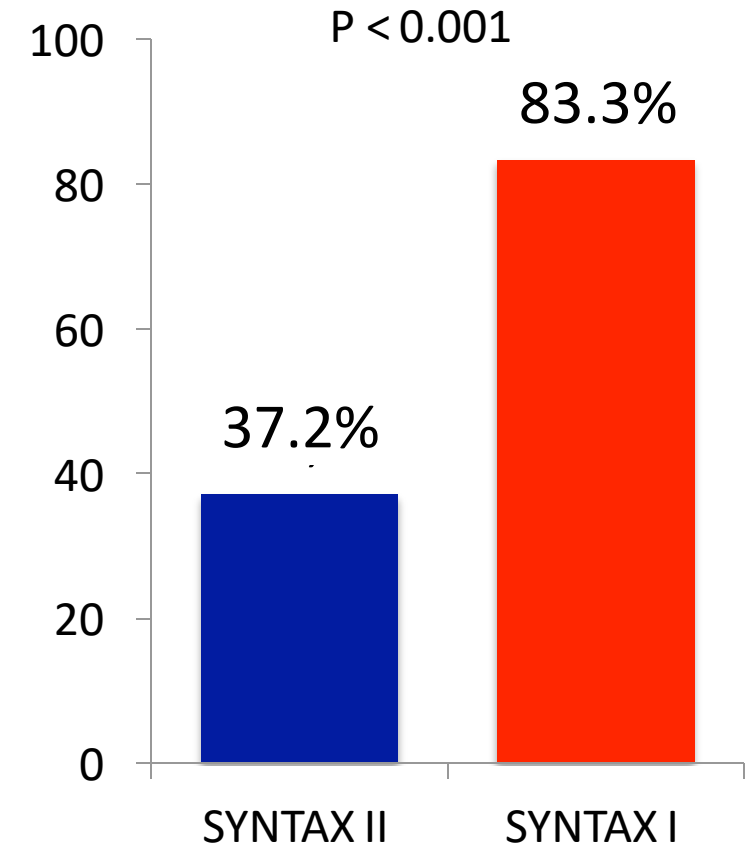


SYNTAX II

Lesions treated per patient (n) in SYNTAX II and SYNTAX I

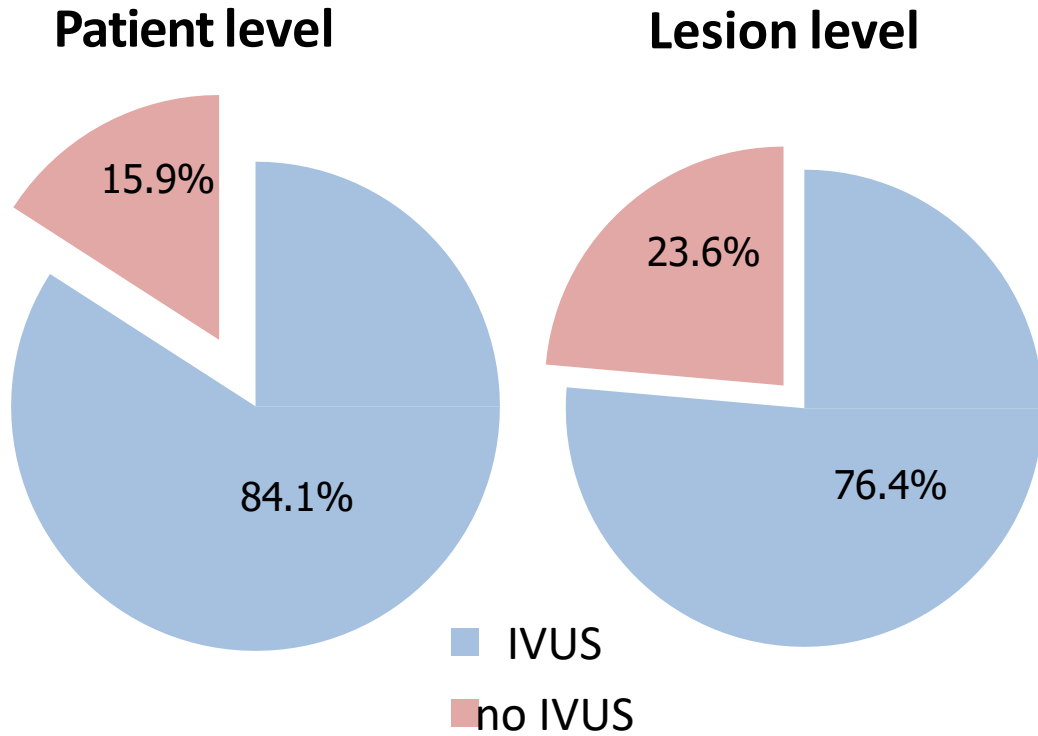


Cases of three-vessel PCI (%) in SYNTAX II and SYNTAX I



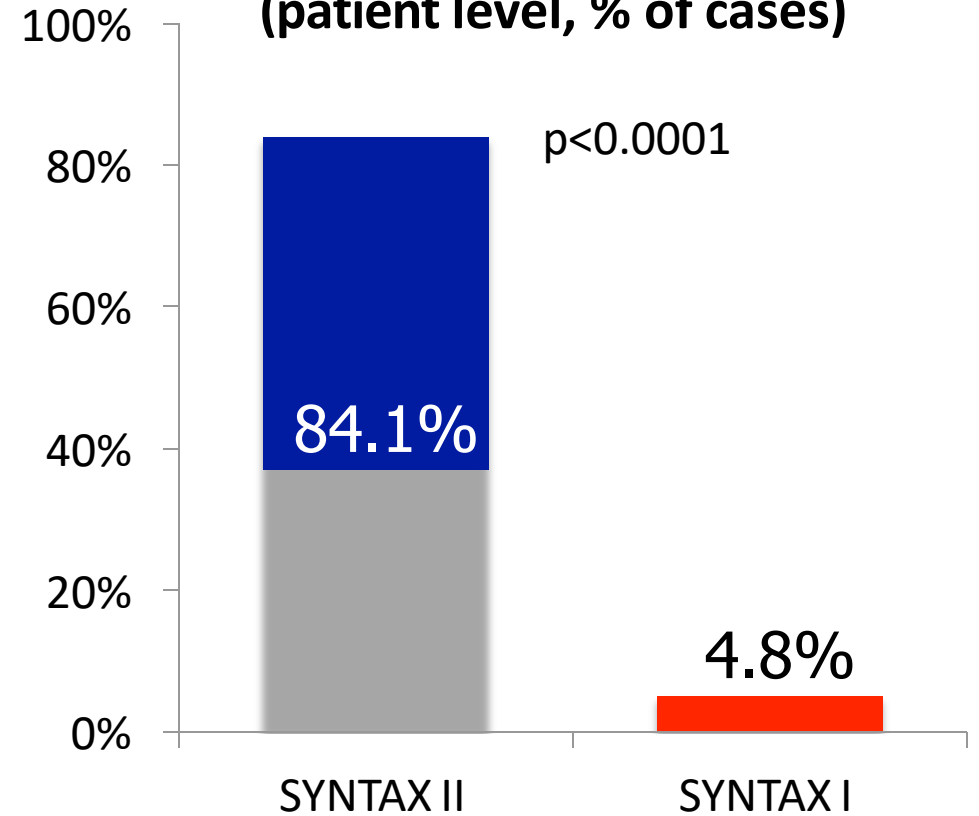
Use of intravascular ultrasound (IVUS)

SYNTAX II

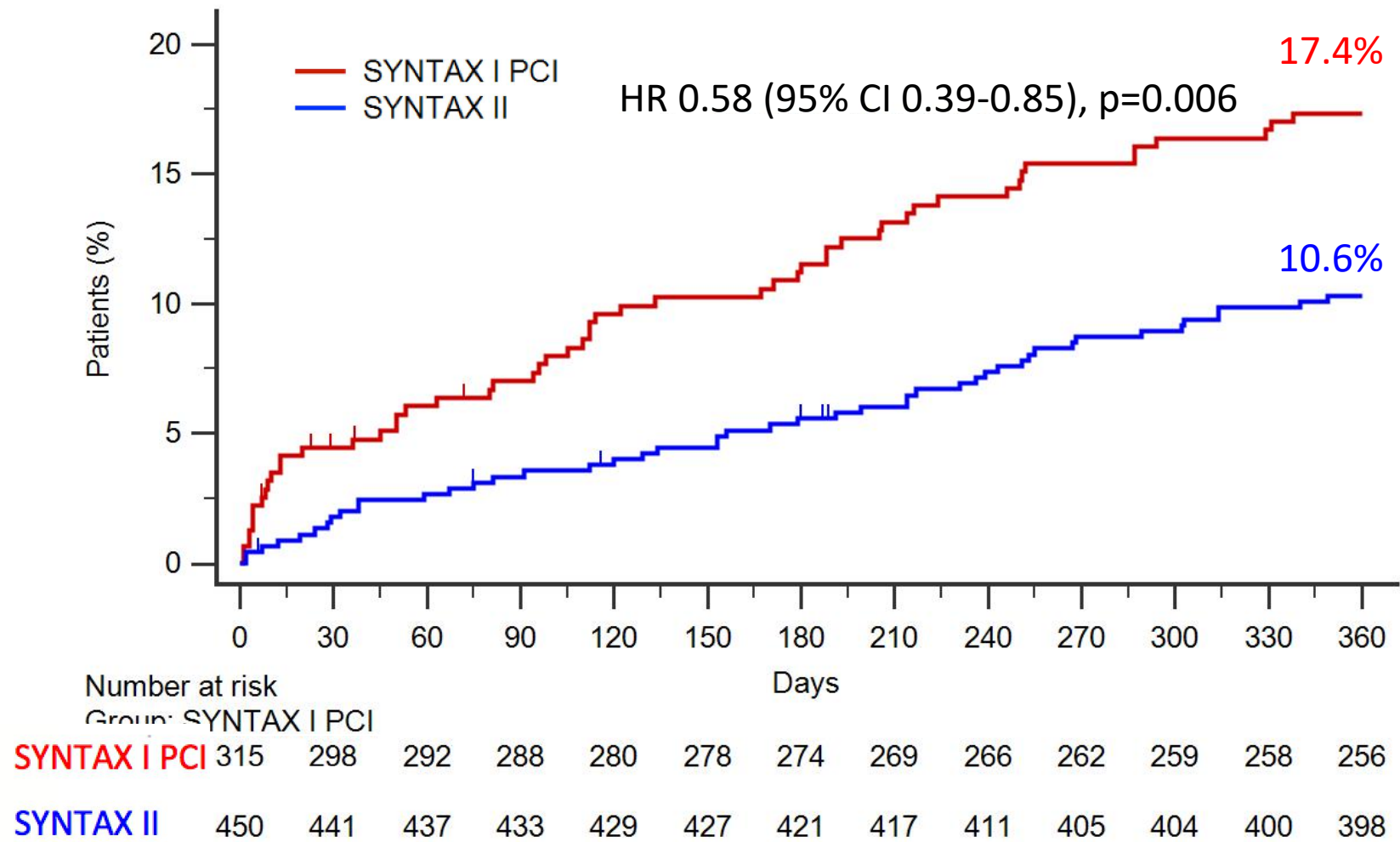


Post-implantation IVUS led to further optimisation of the stented lesion in 30.2%.

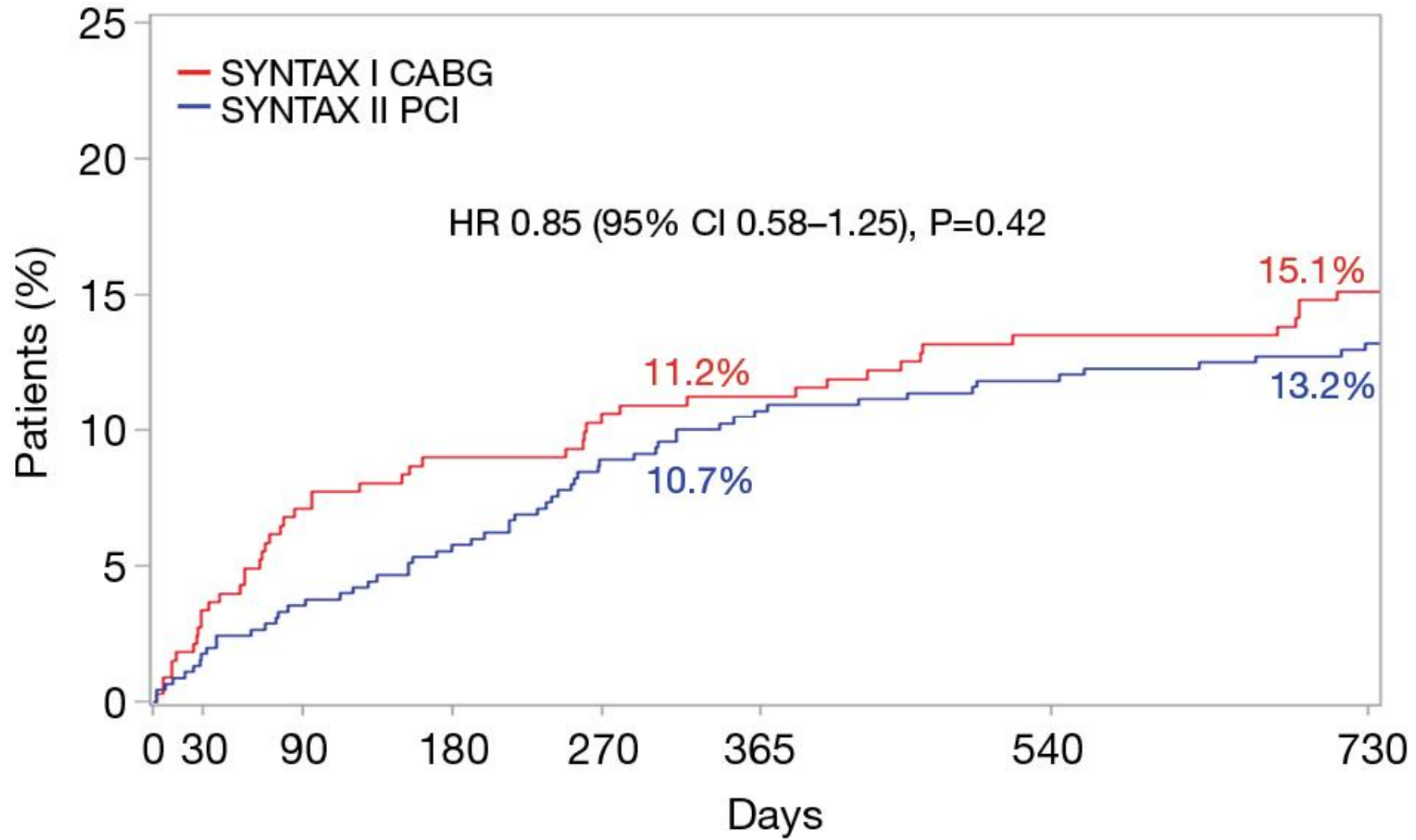
IVUS use in SYNTAX II and SYNTAX I (patient level, % of cases)



Primary endpoint: MACCE

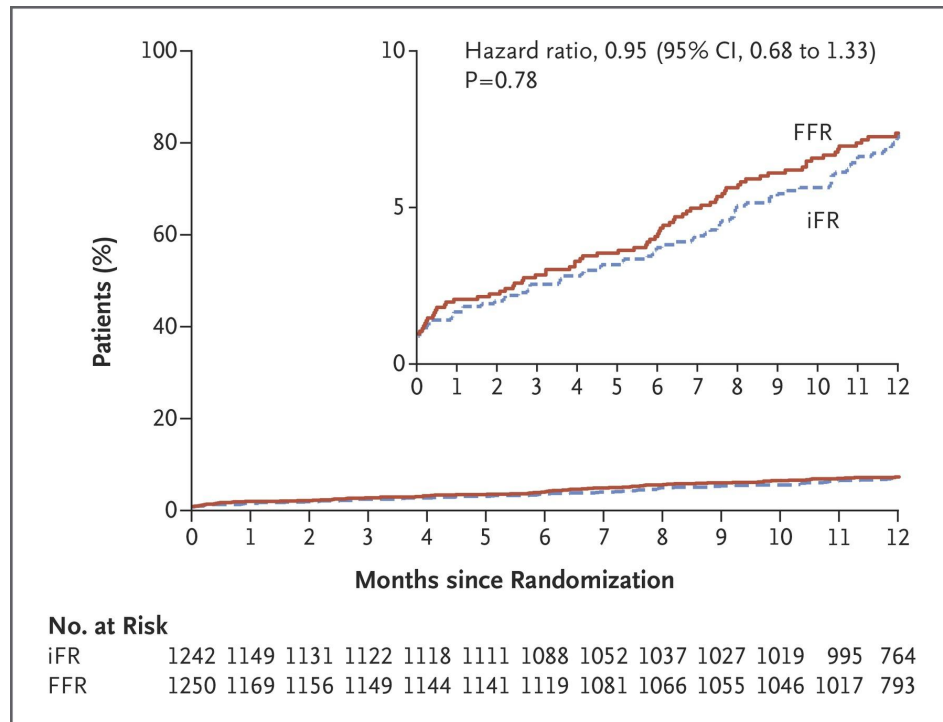


2 years follow-up



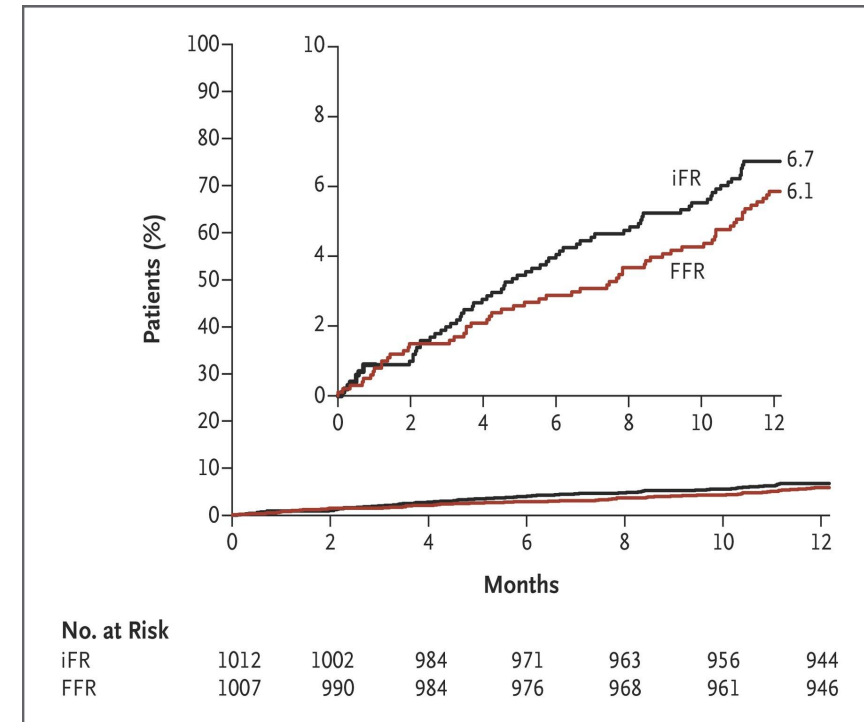
FFR vs iFR

DEFINE-FLAIR trial: **p no-inferioridad <0.001**



Davies JE et al. N Engl J Med 2017; 376:1824-1834

iFR-SWEDEHEART trial: **p no-inferioridad <0.001**

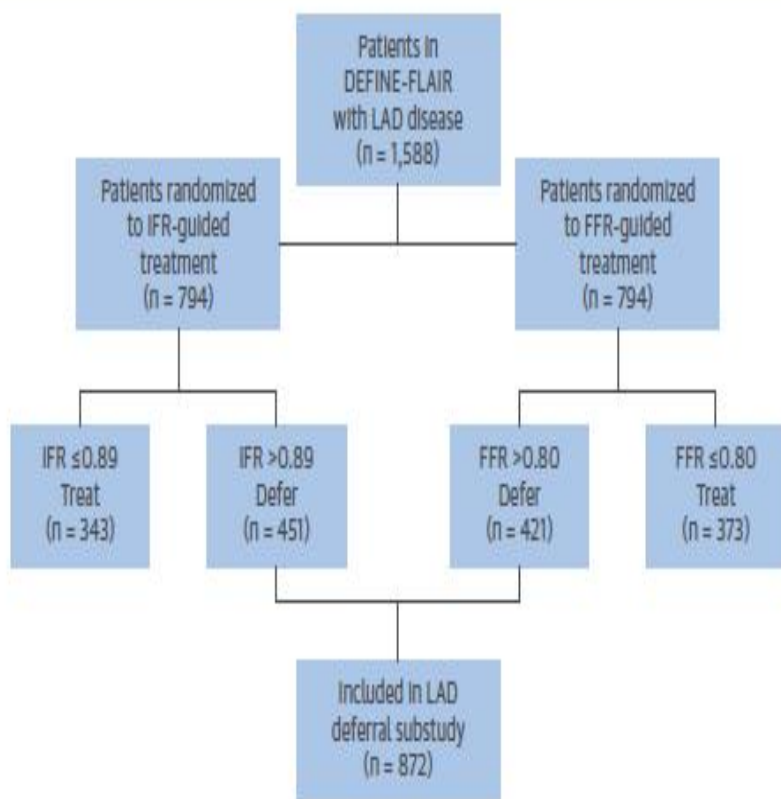


Göteborg M et al. N Engl J Med 2017; 376:1813-1823

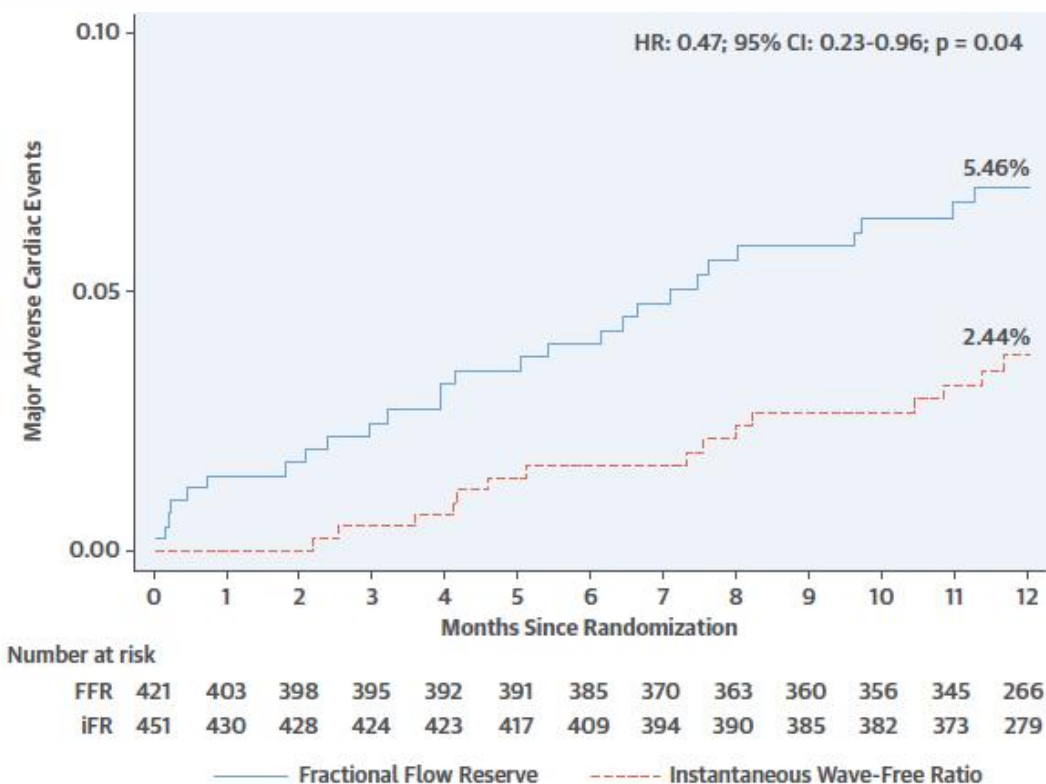
Clinical Events After Deferral of LAD Revascularization Following Physiological Coronary Assessment



FIGURE 1 Flow Chart Outlining Patient Selection

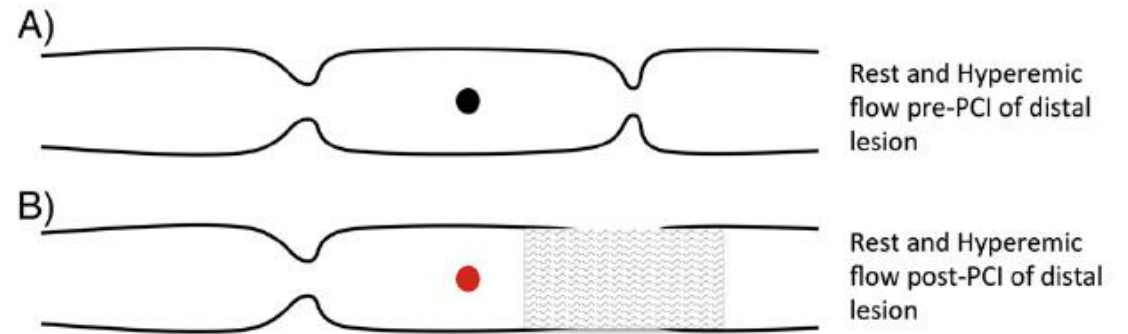
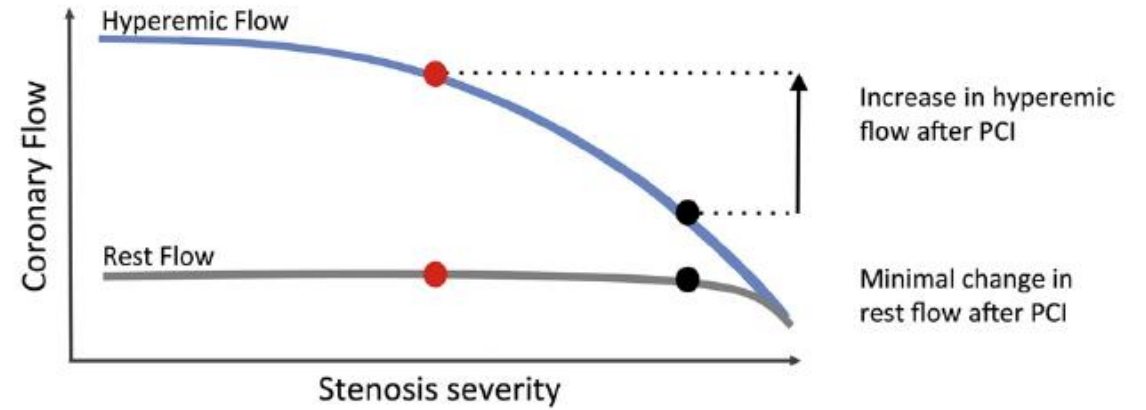


CENTRAL ILLUSTRATION Major Adverse Cardiac Events in Left Anterior Descending-Deferred Patients: Kaplan-Meier Curves



Sen, S. et al. *J Am Coll Cardiol.* 2019;73(4):444-53.

- Nijjer SS et al.
Cardiovasc Revasc Med .
 Apr-May
 2015;16(3):167-71.

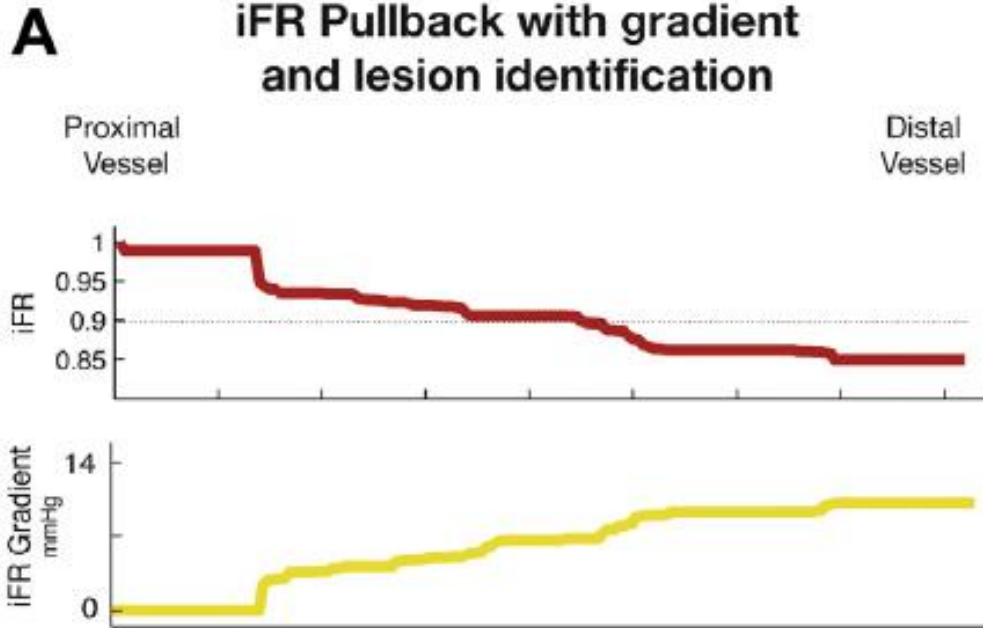
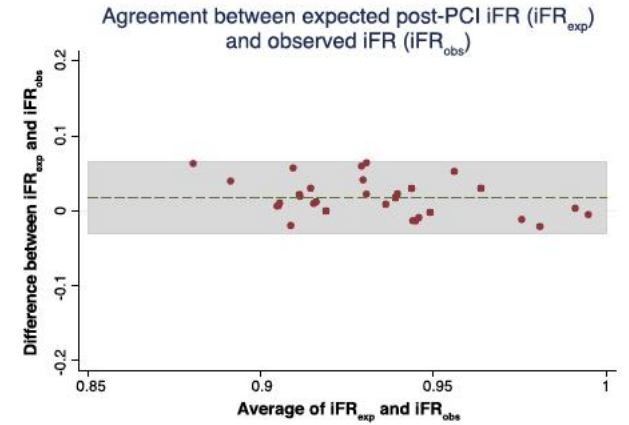


Pre-Angioplasty Instantaneous Wave-Free Ratio Pullback Provides Virtual Intervention and Predicts Hemodynamic Outcome for Serial Lesions and Diffuse Coronary Artery Disease



JACC CI 2014

Sukhjinder S. Nijjer, MB ChB,* Sayan Sen, MBBS, PhD,* Ricardo Petraco, MD,* Javier Escaned, MD, PhD,† Mauro Echavarría-Pinto, MD,‡ Christopher Broyd, MBBS,* Rasha Al-Lamee, MBBS,* Nicolas Foin, PhD,* Rodney A. Foale, MD,* Iqbal S. Malik, MBBS, PhD,* Ghada W. Mikhail, MBBS, MD,* Amarjit S. Sethi, MBBS, PhD,* Mahmud Al-Bustami, MD,* Raffi R. Kaprielian, MBBS, MD,* Masood A. Khan, MB ChB, MA,* Christopher S. Baker, MBBS, PhD,* Michael F. Bellamy, MBBS, PhD,* Alun D. Hughes, PhD,‡ Jamil Mayet, MB ChB, MD,* Darrel P. Francis, MB ChB, MA, MD,* Carlo Di Mario, MD, PhD,‡ Justin E.R. Davies, MBBS, PhD*

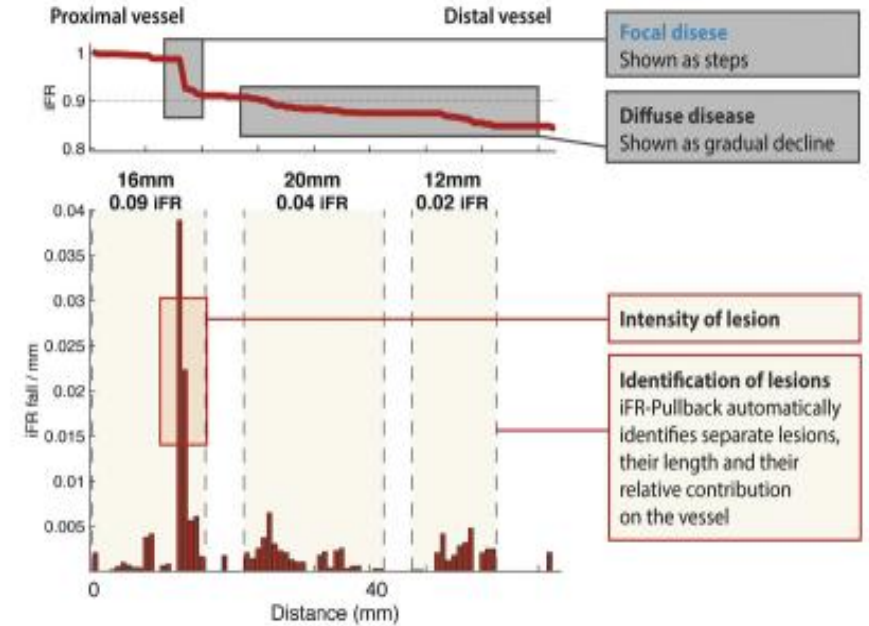


A iFR Pullback recording: iFR throughout vessel

iFR intensity overlaid onto angiogram



Angiographic stenosis corresponds to region with highest change in iFR fall/mm (intensity)

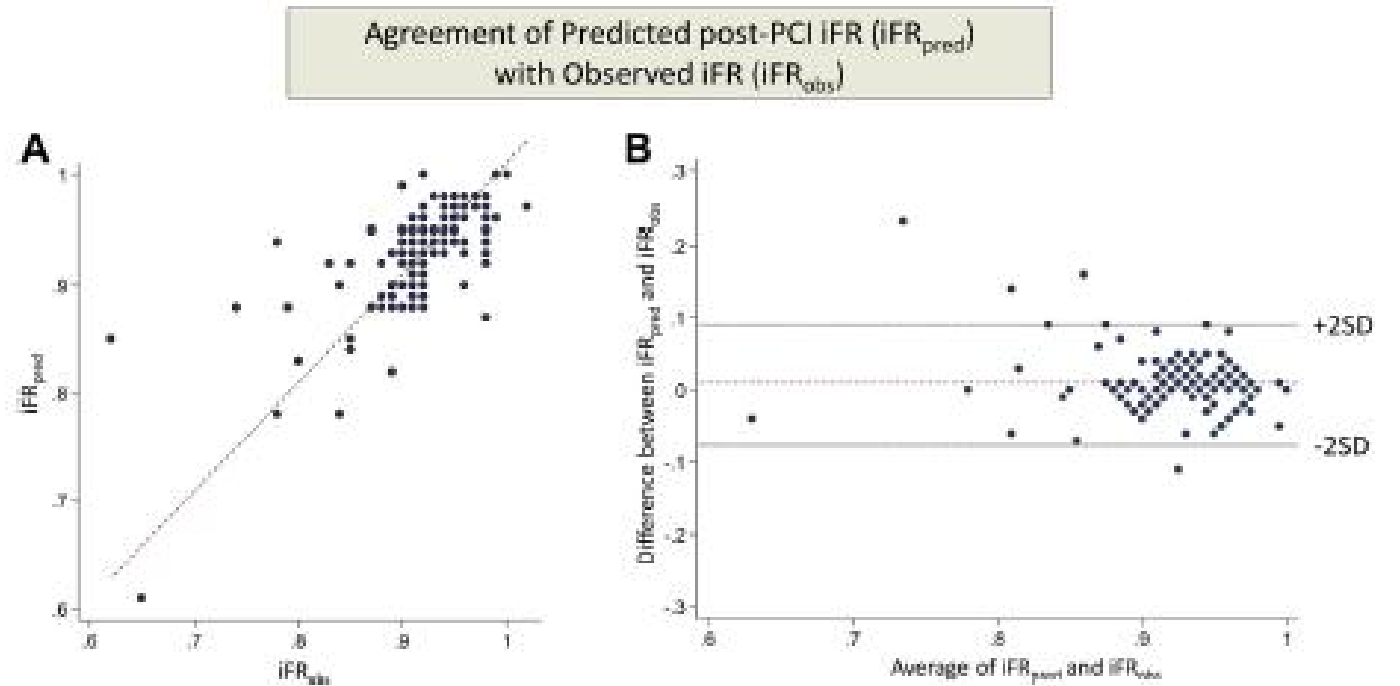


Pre-Angioplasty Instantaneous Wave-Free Ratio Pullback Predicts Hemodynamic Outcome In Humans With Coronary Artery Disease

Primary Results of the International Multicenter
iFR GRADIENT Registry

JACC CI 2018

FIGURE 3 Bland-Altman Analysis of Post-Procedural iFR: Pullback-Predicted iFR Versus Observed iFR Outcome Post-PCI



(A) A strong linear relationship was found between pullback-predicted iFR (iFR_{pred}) and observed iFR (iFR_{obs}). **(B)** No large systematic bias was observed between iFR_{pred} and iFR_{obs} . Abbreviations as in Figure 1.

Software Syncvision

- To transform iFR-pressure changes to visual dots
- To quantify the lesion length.
- To perform a prediction about the final iFR after PCI.
- To establish the diagnosis between focal lesion (with clear benefit) vs diffuse lesion (without clear benefit).





Usefulness of a co-registration strategy with iFR in long and/or diffuse coronary lesions (iLARDI): study protocol

Francisco Hidalgo,^{a,*} Soledad Ojeda,^a Javier Suárez de Lezo,^a Miguel Romero,^a Adrián Lostalo,^b Rafael González,^a Cristina Pericet,^a Nick Paredes,^a Juan C. Elizalde,^a Aurora Luque,^a Francisco Mazuelos,^a José Segura,^a and Manuel Pan^a

^a Servicio de Cardiología, Hospital Universitario Reina Sofía, Instituto Maimónides de Investigación Biomédica de Córdoba (IMIBIC), Córdoba, Spain
^b Departamento de Cardiología Intervencionista, Hospital de México, San José, Costa Rica

F. Hidalgo et al. REC Interv Cardiol. 2021;3(3):190-195

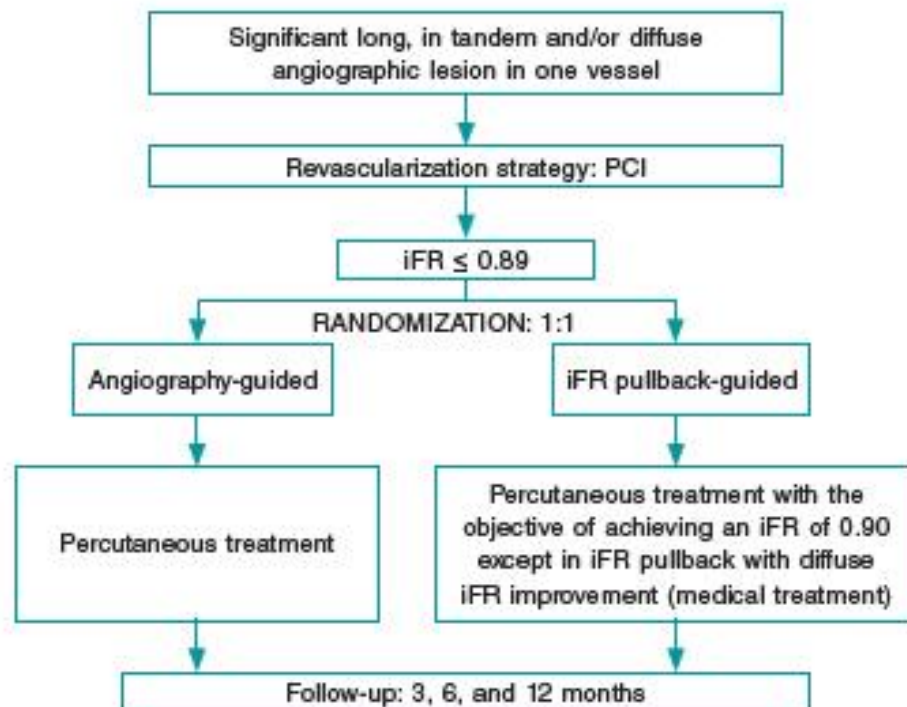


Figure 1. Summary of randomization, treatment targets, and follow-up of the iLARDI study. iFR, instantaneous wave-free ratio; MACE, major adverse cardiovascular events; PCI, percutaneous coronary intervention.

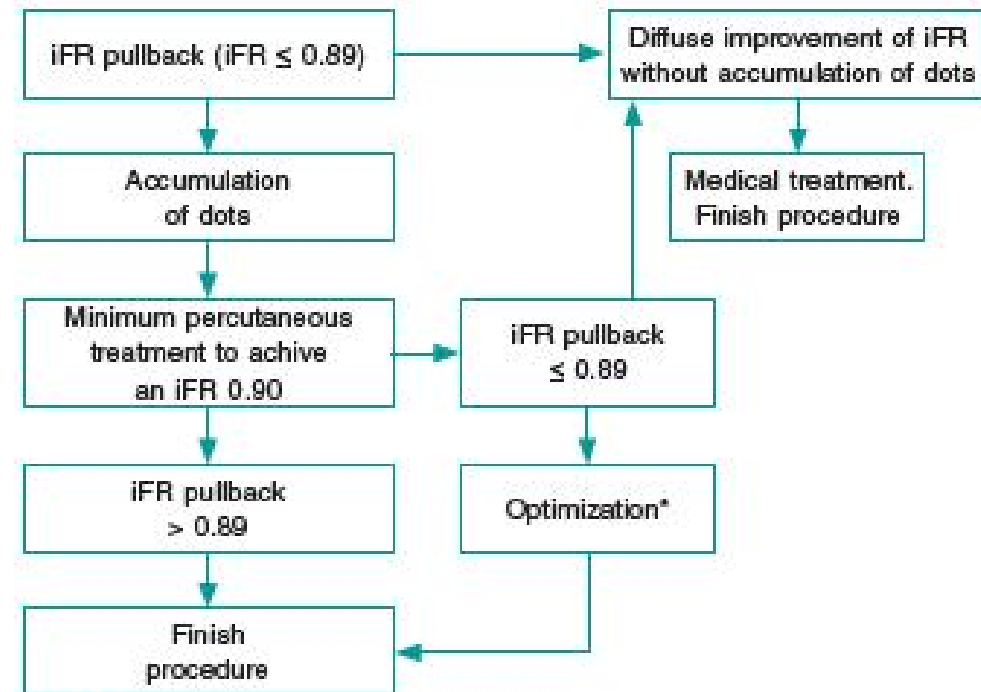
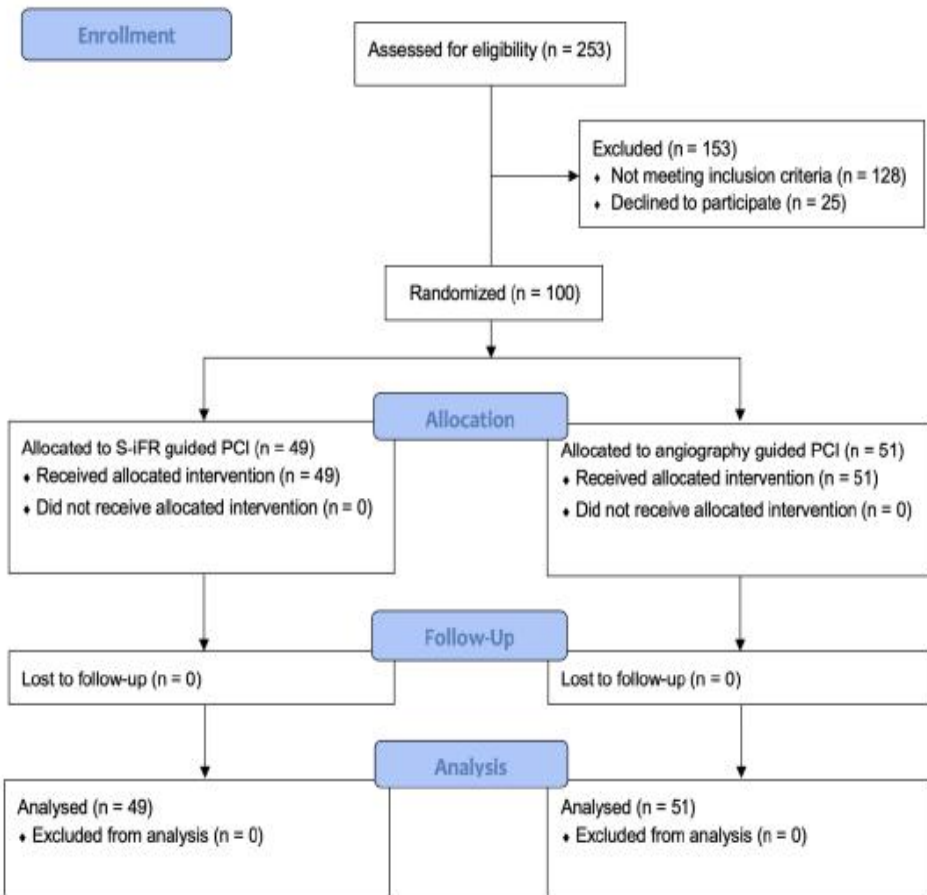


Figure 2. Flowchart of technical treatment details of patients randomized to the intervention group.

* We consider as optimization the postdilatation of the previous stented area if an in-stent accumulation of yellow dots is seen; or the percutaneous treatment of a new segment with physiological compromise not seen in the baseline iFR-pullback study. iFR, instantaneous wave-free ratio.

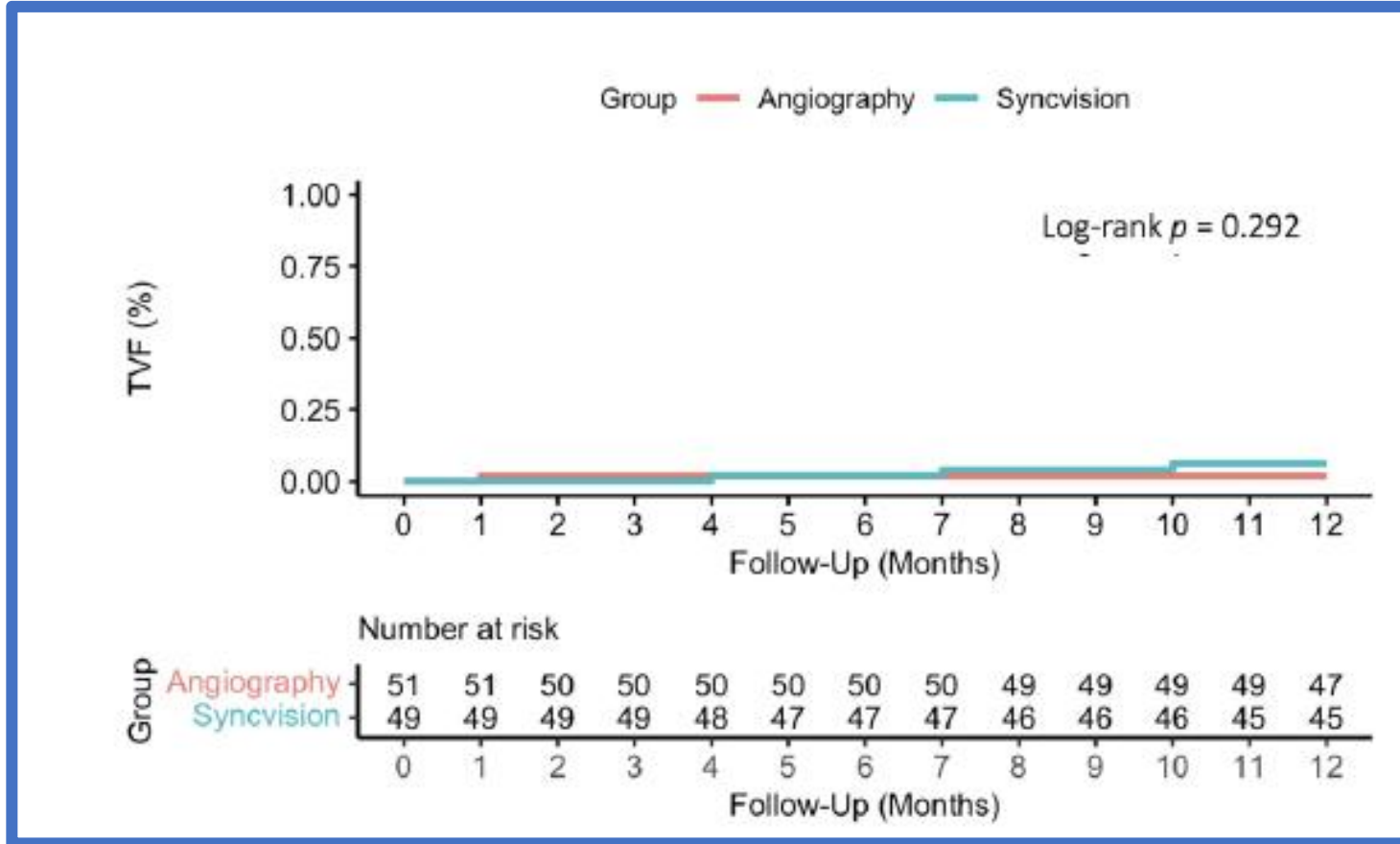
Article
The Usefulness of Coregistration with iFR in Tandem or Long Diffuse Coronary Lesions: The iLARDI Randomized Clinical Trial

Francisco Hidalgo ^{1,2,3,4,*}, Rafael Gonzalez-Manzanares ^{1,2,3,4}, Javier Suárez de Lezo ^{1,2,3}, Ignacio Gallo ^{1,2}, Marco Alvarado ^{1,2}, Jorge Perea ^{1,2}, Luis Carlos Maestre-Luque ^{1,2}, Adriana Resúa ^{1,2}, Miguel Romero ^{1,2,3,4}, María López-Benito ⁵, Armando Pérez de Prado ⁵, Soledad Ojeda ^{1,2,3,4,4} and Manuel Pan ^{1,2,3,4,4}



	S-iFR n = 49	Angiography n = 51	Difference (CI 95%)	p
Primary endpoint				
Implanted stent length (mm)	32.7 ± 17.2	43.1 ± 14.9	-10.4 (-16.9 to -4.0)	0.002
Other endpoints				
Difference implanted—estimated (mm)	-10.7 ± 13.2	2.1 ± 7.7	-12.8 (-17.2 to -8.5)	0.001
Final iFR	0.91 ± 0.03	-	-	-
Estimated stent length by Syncvision to achieve an iFR > 0.89 (mm)	29.2 ± 14.0	-	-	-
Dots accumulation to predict an iFR improvement	47 (94)	-	-	-

S-iFR: Syncvision/iFR guided percutaneous coronary intervention strategy.



Distal Evaluation of Functional performance with Intravascular sensors to assess the Narrowing Effect: Guided Physiologic Stenting

Image Guided Therapy Devices



Site Initiation Training V10.0 11 Mar 2022
For Protocol V2.0 16 MAR 2021

DEFINE-PCI 1 year follow-up results

"How you treat, not just who you treat"

DEFINE PCI 1 year data

68% reduction in adverse events

Post-PCI iFR ≥ 0.95

DEFINE PCI 1-year data demonstrates 68% relative reduction in clinical events among patients achieving post-PCI iFR ≥ 0.95 ($p=0.04$).

DEFINE PCI reveals the final picture is often incomplete. **iFR Co-registration** uncovers focal ischemia producing lesions missed visually.

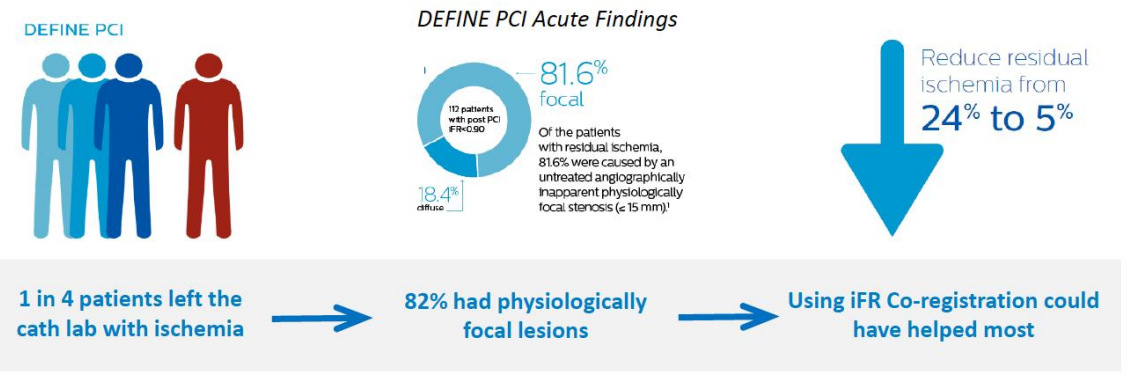
DEFINE PCI 1 year data

Define PCI 1-year data suggests treating focal ischemia-producing lesions only visible through iFR guidance can improve patient outcomes

Patel M et al. One-year outcomes of patients with residual physiologic ischemia after percutaneous coronary intervention: the DEFINE PCI trial. Presentation at conference TCT 2020 virtual

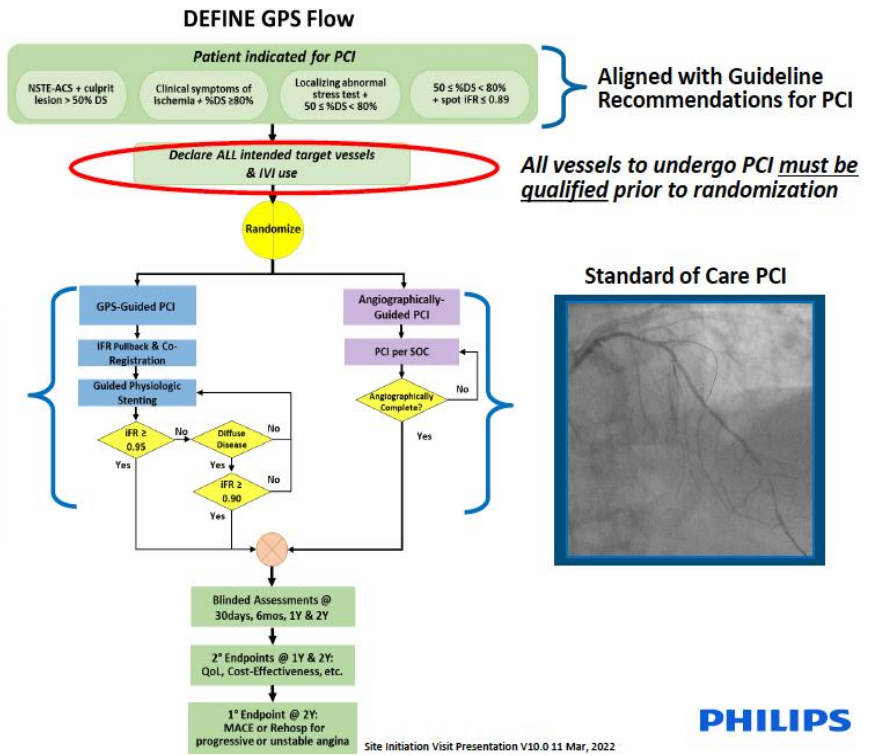
Why DEFINE GPS?

Post-PCI iFR can reduce residual ischemia from 24% to 5%



Jeremias A, Davies JE, Maehara A, et al. Blinded Physiological Assessment of Residual Ischemia After Successful Angiographic Percutaneous Coronary Intervention: The DEFINE PCI Study. JACC Cardiovasc Interv. 2019;12(20):1991-2001.

Physiology-Guided PCI



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Site Initiation Visit Presentation V10.0 11 Mar, 2022



Tips and Tricks:

- Hidratación de guía durante al menos 1 minuto
- Proyección adecuada donde se visualice toda la arteria con el mínimo acortamiento posible.
- Ampliación de imagen para que se vea desde el catéter guía hasta el segmento más distal de la arteria para no tener que mover mesa
- NTG ic para evitar espasmos
- Lavado con SSF para que la curva de presión aórtica sea perfecta y se visualice perfectamente la incisura dicrota
- Normalización en ostium de coronaria (en caso de lesión ostial o presión aórtica inadecuada normalizar con el catéter guía en aorta)
- Pasar guía de presión lo más distal posible
- Si se utiliza contraste yodado lavar con SSF y esperar al menos 30 segundos y hasta que el iFR se estabilice durante 5-10 segundos
- Realizar la retirada bajo fluoroscopia continua sin mover la mesa ni el tubo, a una velocidad constante pero lenta (mientras más lenta mejor).
- No “hacer caso” a posibles saltos puntuales de iFR
- Confirmar que al llegar al ostium el iFR vuelve a 1.00 ± 0.02
- Realizar una angiografía con adecuado flujo y volumen para que el software reconozca de forma correcta el vaso y lo pueda correlacionar con la fisiología y/o con el IVUS.

Tri-registry:

Physiology and imaging fusion

Anatomic and physiology correlation

Time increase

Utility in daily practice?

Clinical studies?

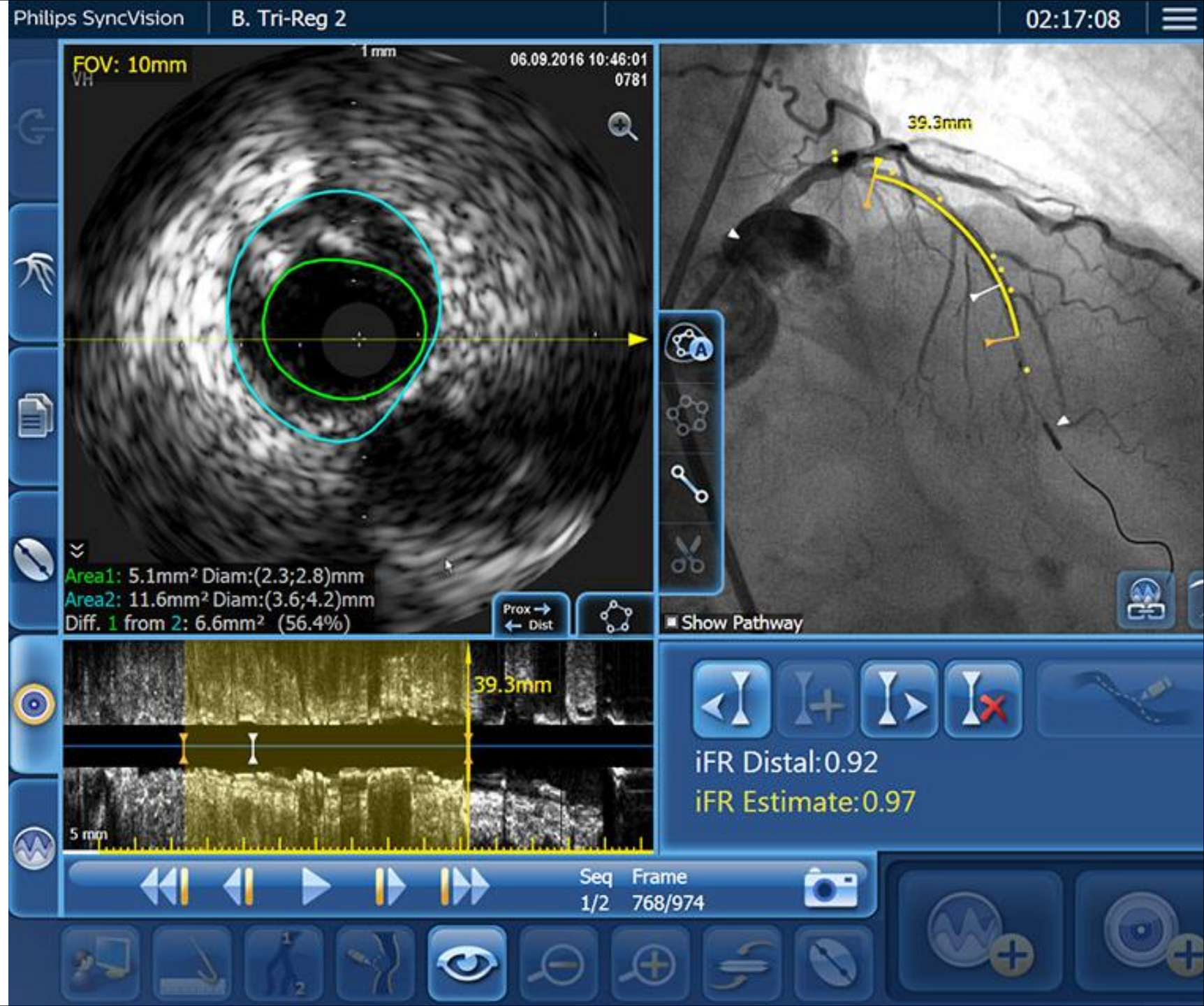
Limitations:

Manual withdrawal.

Correlation should not be perfect

Bringing of IVUS catheter

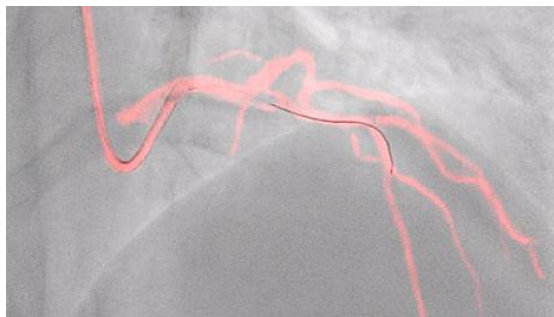
IVUS catheter doesn't cross



Solutions for ultra-low contrast PCI

Dynamic Coronary Roadmap

A Philips exclusive technology, creates a dynamic, motion-compensated, real-time view of the coronary arteries. The system overlays a highlighted coronary angiogram on a 2D fluoroscopic image, creating a colored map that adjusts automatically, providing continuous and specific visual feedback on positioning of wires and

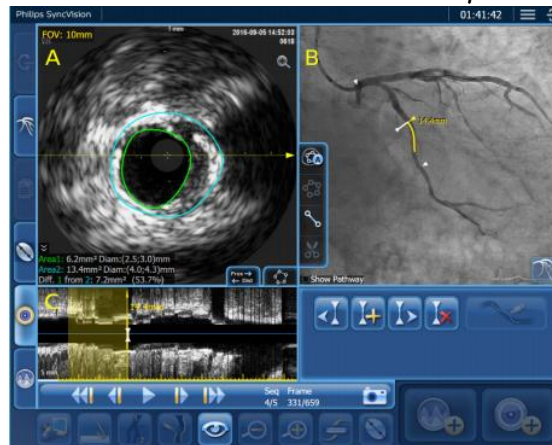


iFR Co-registration

Graphically displays the iFR drop along the angiogram, highlighting which portion of the vessel is ischemic.

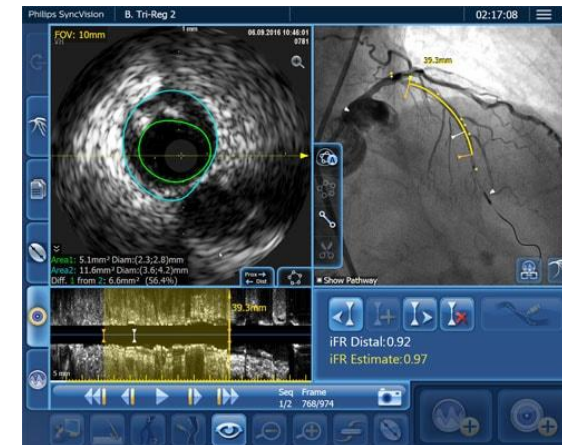
Device detection

Enhanced live stent visualization, allows to quickly verify positioning both before and after deploying balloons, stents, and BVS devices, to display under-deployed stents, and to confirm fully expanded stents. It features instantaneous processing, eliminating the need to wait for new images before stent repositioning.



IVUS Co-registration

IVUS images obtained during pullback are merged with the corresponding angiogram obtained with the IVUS catheter in situ. Subsequently, information on the location of the imaging element within the vessel is derived during a manual pullback under continuous fluoroscopy. The presence of radiopaque markers in the IVUS catheter allows calculation of length correcting for vessel foreshortening



Tri-Registration

iFR data and IVUS images, collected during the pullback recordings, are merged within the same angiogram. iFR data, which are co-registered with the angiography image, are displayed into the roadmap picture (B) and iFR drops dots, iFR value at cursor, and iFR Distal value are provided.

The ugly truth

In 2023 TVR is more likely to be the failure of the operator than the stent?

Functional result of PCI (non-hyperaemic indices, FFR)

Heart Team discussion

IVUS/OCT optimisation and guidance

Physiology-guided PCI (non-hyperaemic indices + FFR, longitudinal mapping, co-registration)



Co-registration

3er generation of DES

Muchas gracias!

