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LI Jornadas SOLACI

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DCB : UNA ALTERNATIVA AL STENT SISTEMÁTICO ?
DCB: Consideraciones generales

Dr Daniel Aníbal Zanuttini

Director del Departamento de Cardiologia Intervencionista y Hemodinamia.
Instituto de Cardiologia de Sanatorio Británico. Rosario . Argentina

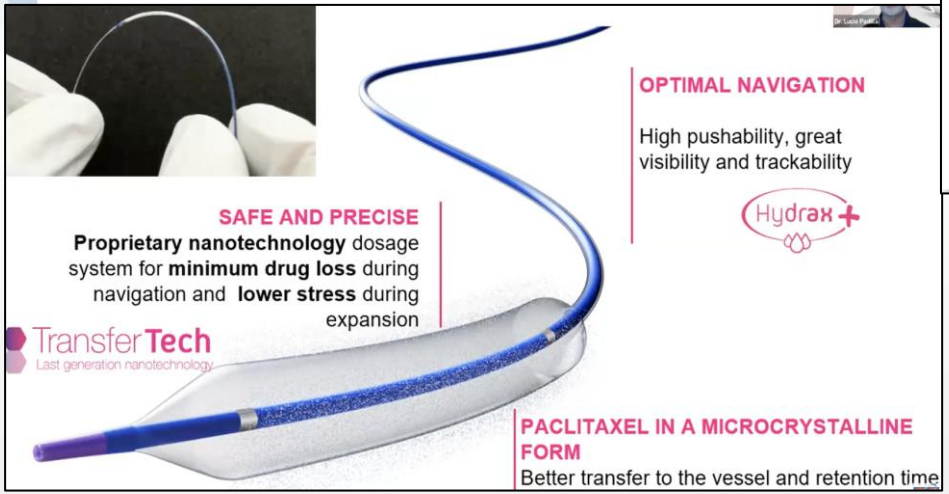
Ex staff de Hemodinamia y enfermedades vasculares periféricas Hospital Costantini. 1998- 2018. Curitiba. Brasil.

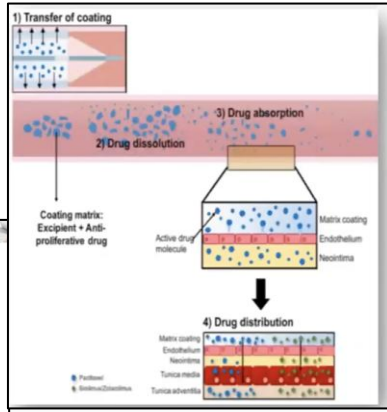
Fundador y coordinador del Servicio de Hemodinamia Del Hospital Jose Maria CULLEN. Santa Fe. Argentina (2005 –2008)

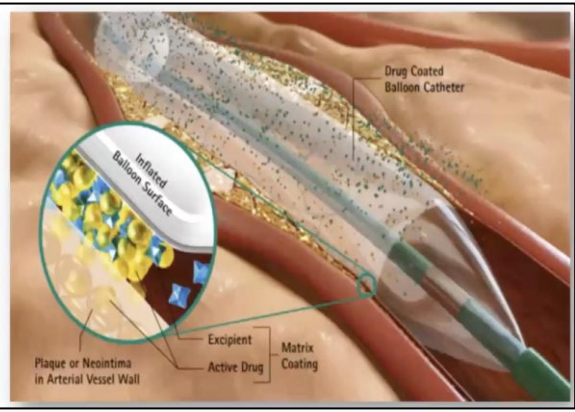
Formación en enfermedades vasculares periféricas Saint Blasius Hospital, Dendermonde. Bélgica.

Miembro Titular de sociedades: FAC, CACI, SBC, SBHCI, SOLACI

DCB CARACTERISTICAS

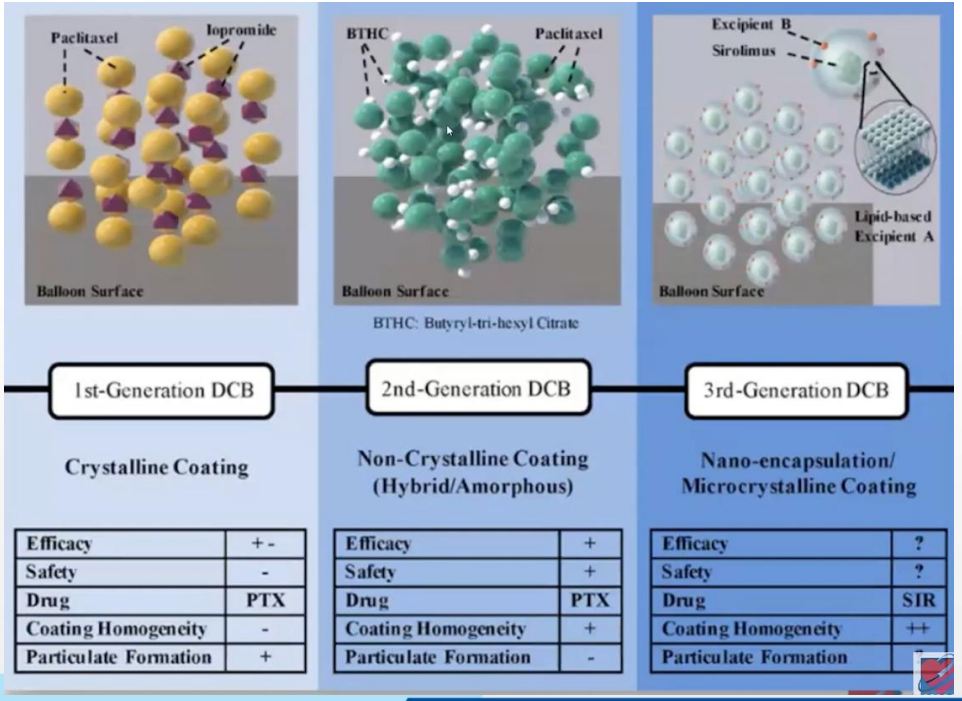






Attribute	Paclitaxel	Sirolimus (or Analogs)
Mode of action	Cytotoxic	Cytostatic
Margin of safety	100 fold	10,000 fold
Therapeutic range	Narrow	Wide
Anti - restenotic	Yes	Yes - lower late lumen loss
Anti - inflammatory	No	Yes
Drug Potency	1x	1x
Tissue absorption	Fast	Slow*
Tissue retention	Long	Short*

1. Effects of paclitaxel on the vascular wall
2. Inhibition of smooth muscle cell proliferation
3. Effects not only on neointimal growth but also on medial thinning and enlargement



DCB: Indicaciones angiográficas

In-stent restenosis

Small Vessel Disease

De novo coronary lesions

Bifurcations

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LESIONES CORONARIAS “DE NOVO”

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PASSWORD Observational Study

Systematic Scoring Balloon Lesion Preparation for Drug-Coated Balloon Angioplasty in Clinical

Preparo da lesão com "scoring balloon"

Prospective, multicenter, single-armed
all-comers study in patients with de-novo lesions, ISR,
481 patients (496 lesions)

Scoring Balloon (Lacrosse NSE®) + **DCB** (Sequent Please Neo®)

Primary endpoint: Target lesion failure (TLF) @ 9 months

Bonaventura K et al. Adv Ther. 2020 May;37(5):2210-2223.

Baixa taxa de eventos (TLR/TLF/MI) em 9.4 meses

Clinical outcomes for **de-novo lesions** @ 9.4 months

	de-novo lesions
Target Lesion Revascularization	0.8 %
Target Lesion Failure	1.1 %
Myocardial Infarction	0 %

De-novo lesions: With/without **vessel calcification**

	Calcified lesions (119 patients)	**Vessel calcification** (241 patients)	p
TLF	0%	1.7%	0.158

Baixa necessidade de “bailout-stenting”

Needed bailout-stenting in **target de-novo lesions**
5 of 386 patients:

1.3%

Trial Designs

Comparing a strategy of sirolimus-eluting balloon treatment to drug-eluting stent implantation in de novo coronary lesions in all-comers: Design and rationale of the SELUTION DeNovo Trial

Summary

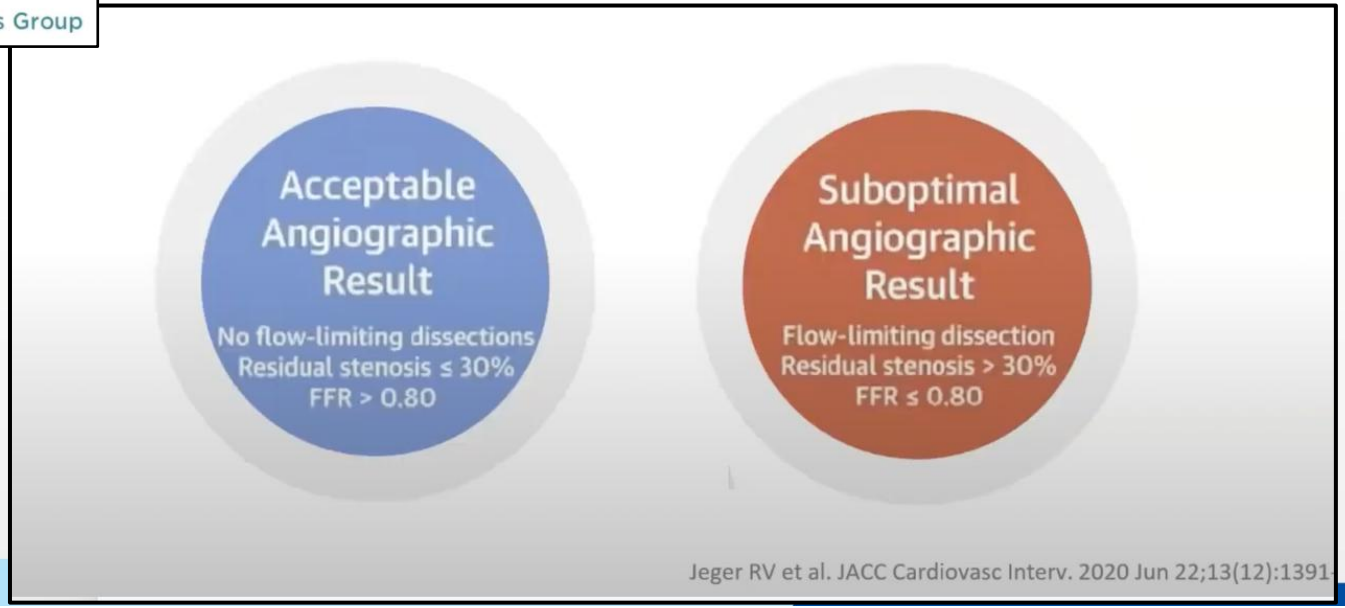
SELUTION DeNovo trial is an open-label, multi-center international randomized trial comparing a strategy of PCI with SEB and provisional DES to a strategy of PCI with systematic DES on TVF at one and five years. Non-inferiority will be tested at one and five years. If non-inferiority is met at five years, superiority will be tested.

RECOMENDACIONES DEL TRATAMIENTO CON DCB. CONSENSO INTERNACIONAL

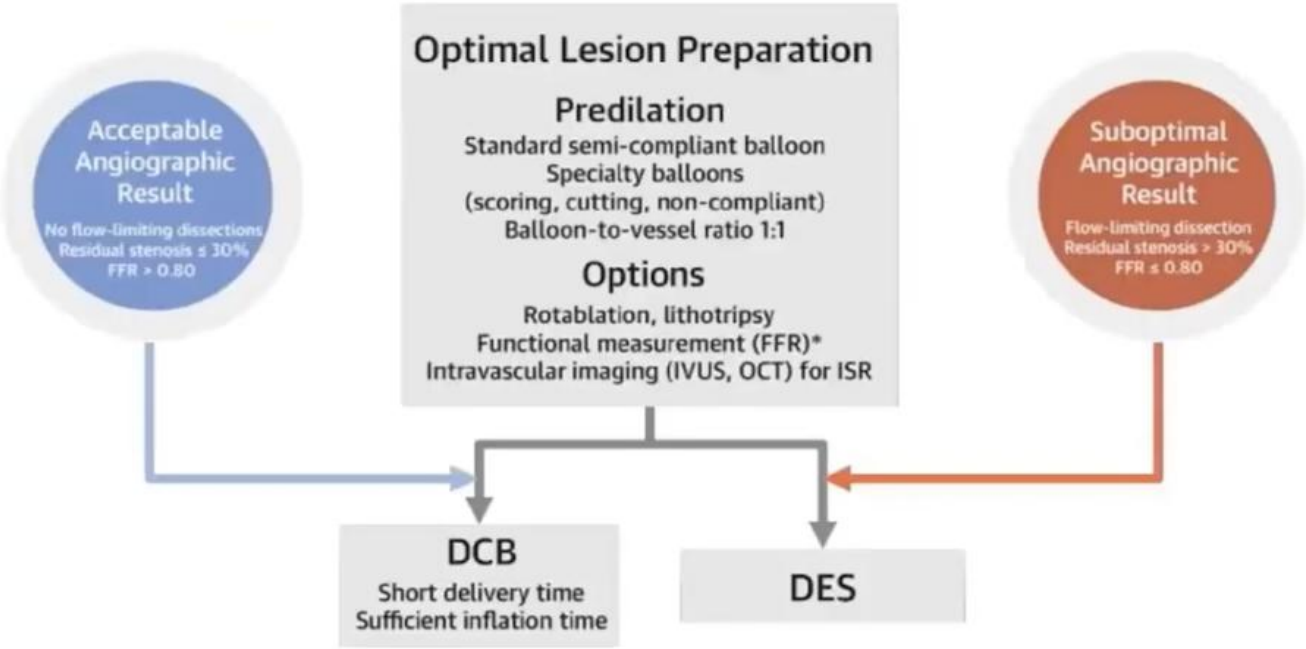
STATE-OF-THE-ART REVIEW

Drug-Coated Balloons for Coronary Artery Disease

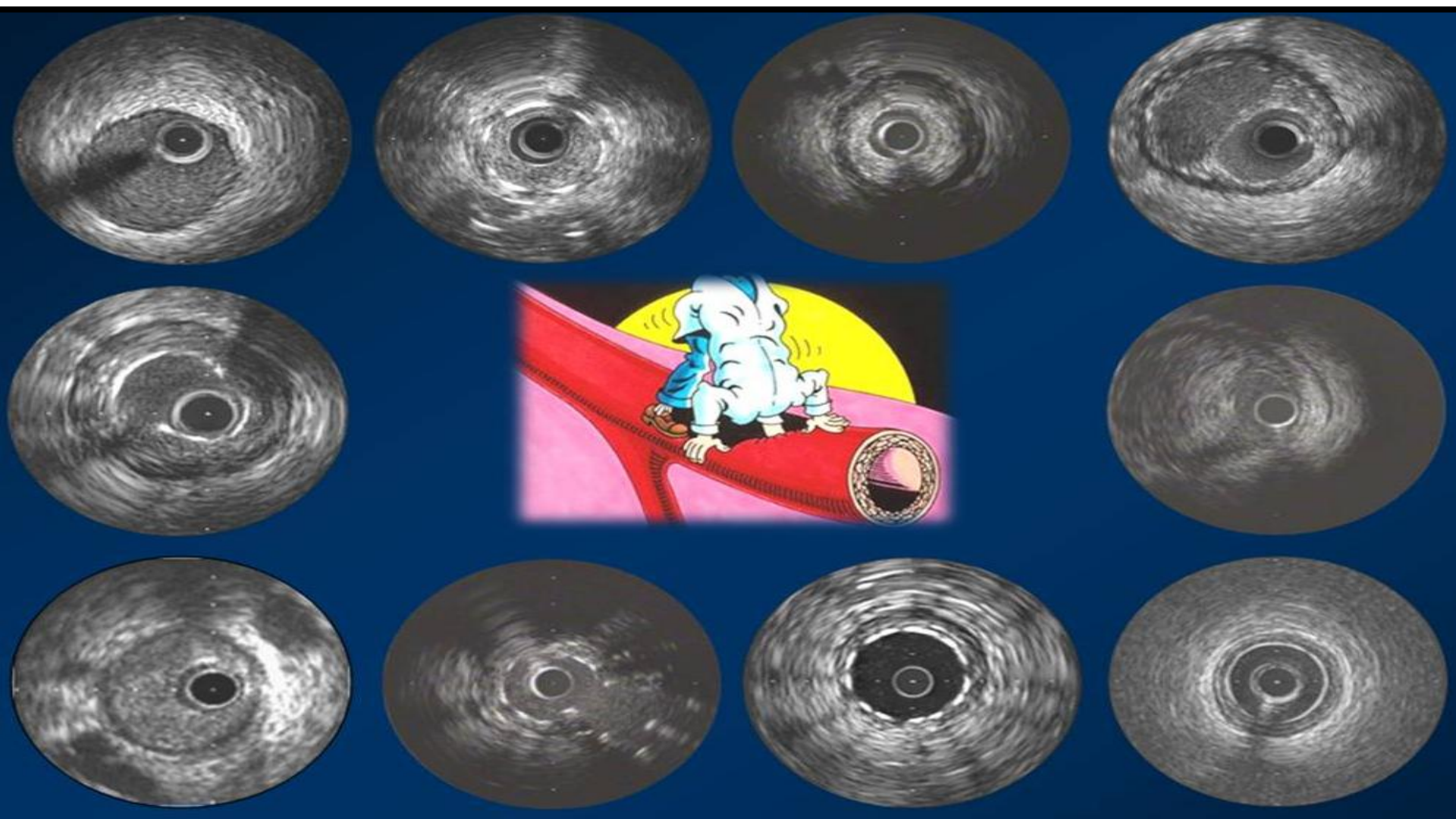
Third Report of the International DCB Consensus Group

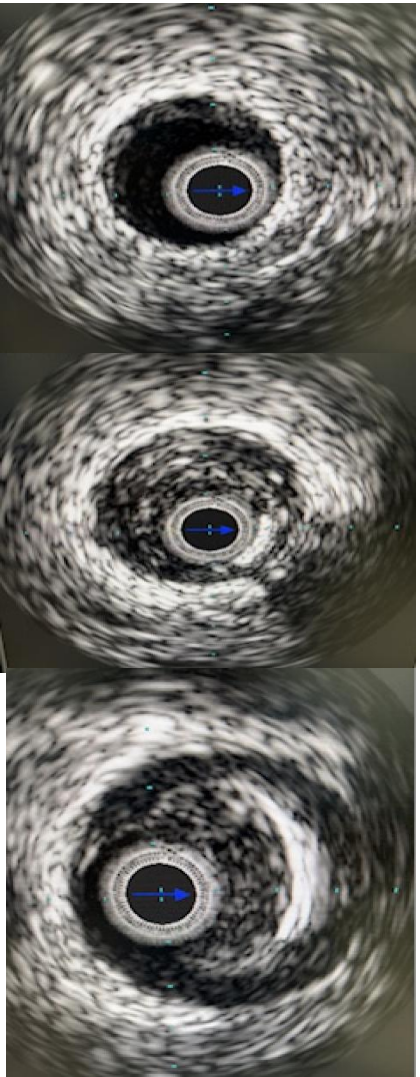


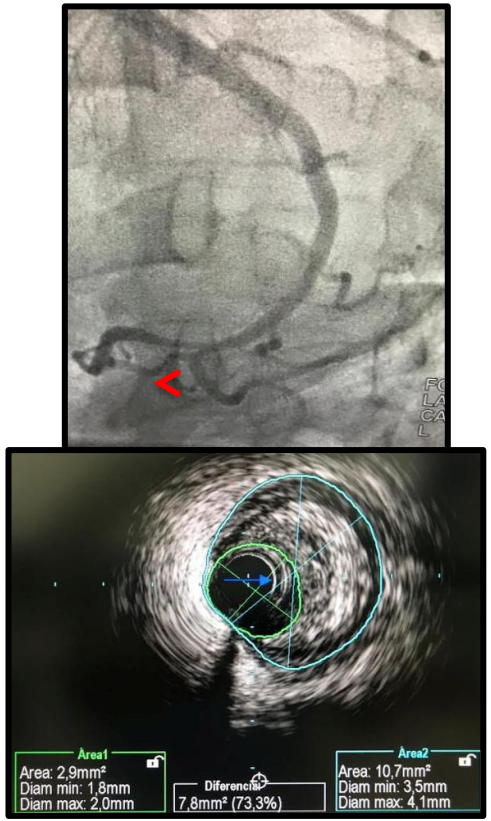
Jeger RV et al. JACC Cardiovasc Interv. 2020 Jun 22;13(12):1391.

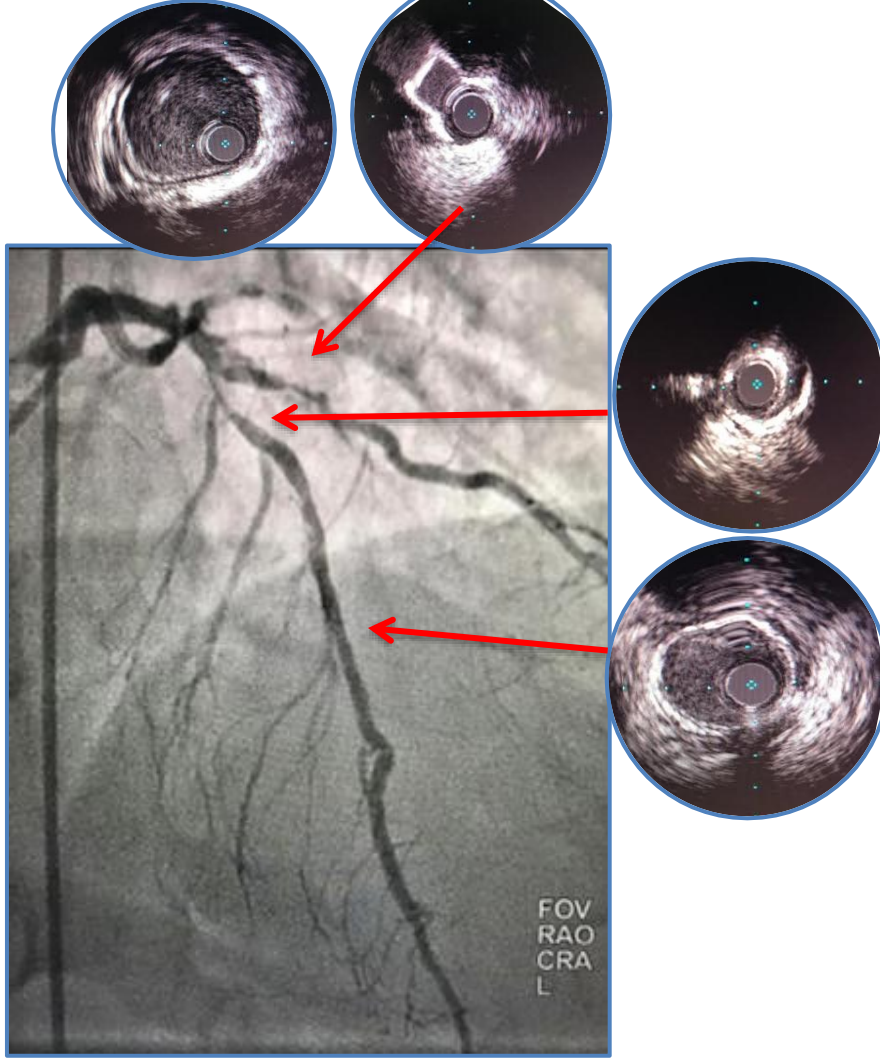


Jeger RV et al. JACC Cardiovasc Interv. 2020 Jun 22;13(12):1391-1402.






Area1
Area: 2,9mm²
Diam min: 1,8mm
Diam max: 2,0mm
Diferencial
7,8mm² (73,3%)
Area2
Area: 10,7mm²
Diam min: 3,5mm
Diam max: 4,1mm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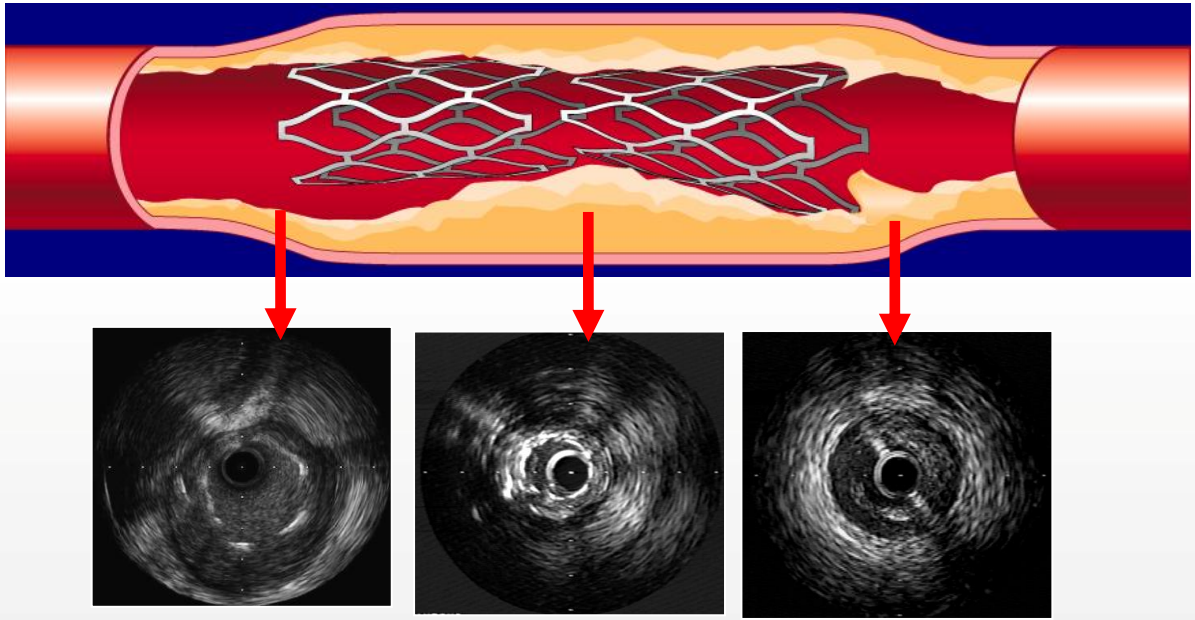
REESTENOSIS INTRA STENT

Ensayos clínicos aleatorios que compararon dispositivos contemporáneos mostraron tasas acumuladas de revascularización de la lesión diana (TLR) de 7 a 10. % a los 5 años de seguimiento

Angioplastia con balón recubierto de paclitaxel (PCB) y la colocación repetida de stent con implantación de DES han surgido como las opciones terapéuticas más efectivas.

CONOCER EL MECANISMO DE REESTENOSIS DE STENT



Aposición incompleta

Hipo expansión

Trauma de bordes

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2025 ACC/AHA/ACEP/NAEMSP/SCAI Guideline for the Management of Patients With Acute Coronary Syndromes

A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

Recommendation for Use of Intracoronary Imaging
Referenced studies that support recommendation are summarized in the Evidence Table.

COR	LOE	RECOMMENDATION
1	A	1. In patients with ACS undergoing coronary stent implantation in left main artery or in complex lesions, intracoronary imaging with intravascular ultrasound (IVUS) or optical coherence tomography (OCT) is recommended for procedural guidance to reduce ischemic events.*[1-11]

*Adapted from the "2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization."[12]

ESC European Society of Cardiology

European Heart Journal (2024) **00**, 1–123
https://doi.org/10.1093/eurheartj/ehae177

ESC GUIDELINES

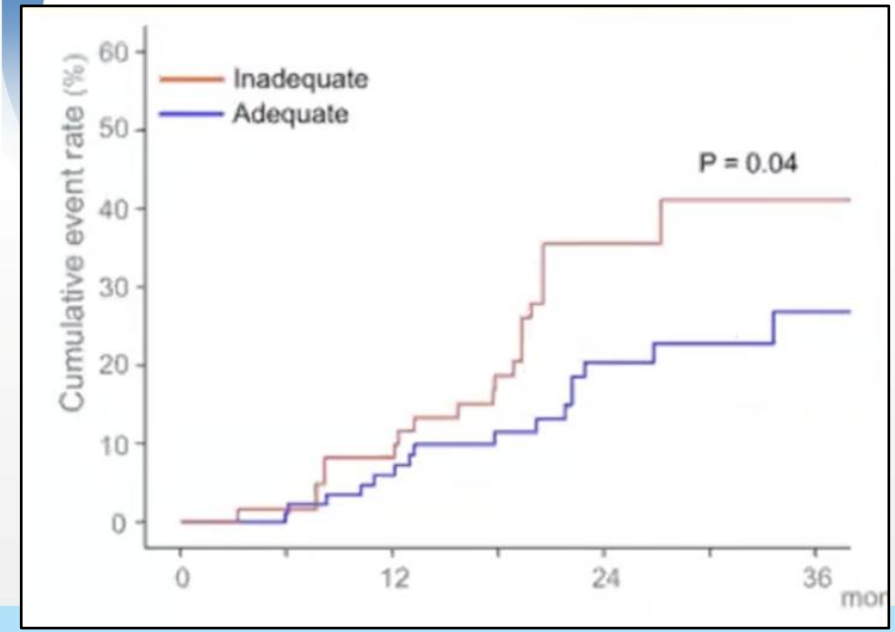
2024 ESC Guidelines for the management of chronic coronary syndromes

Developed by the task force for the management of chronic coronary syndromes of the European Society of Cardiology (ESC)

Endorsed by the European Association for Cardio-Thoracic Surgery (EACTS)

Assessment of procedural risks and post-procedural outcomes		
In patients with complex CAD in whom revascularization is being considered, it is recommended to assess procedural risks and post-procedural outcomes to guide shared clinical decision-making.	I	C
Calculation of the STS score is recommended to estimate in-hospital morbidity and 30-day mortality after CABG.[777,862–864]	I	B
In patients with multivessel obstructive CAD, calculation of the SYNTAX score is recommended to assess the anatomical complexity of disease.[786,865]	I	B
Intracoronary imaging guidance by IVUS or OCT is recommended when performing PCI on anatomically complex lesions, in particular left main stem, true bifurcations, and long lesions.[866,337,810,840,841]	I	A

Impact of Angiographic Result After Predilatation on Outcome After Drug-Coated Balloon Treatment of In-Stent Coronary Restenosis



Lesion preparation

Angiographic results after lesion preparation appear to be a good predictor of TLR after DCB treatment

TLR: 20,3% vs. 35,5% at 2 years

Table I Main characteristics of the included randomized clinical trials

Trial	Design	Centres Region	Investigation time	Patients (lesions) Total	PCB	DES	PCB type	DES type	Restenotic stent
PEPCAD II	1:1 Open-Label Core lab CEC	10 Germany	Jan 2006 – Dec 2006	131 (131)	66 (66)	65 (65)	3 μg/mm² Iopromide	Paclitaxel-eluting Durable-polymer Stainless steel (132 μm)	Bare-metal
ISAR DESIRE 3	1:1 Open-Label Core lab CEC	3 Germany	Aug 2009 – Oct 2011	268 (340)	137 (172)	131 (168)	3 μg/mm² Iopromide	Paclitaxel-eluting Durable-polymer Stainless steel (132 μm)	Drug-eluting
PEPCAD China ISR	1:1 Open-Label Core lab CEC	17 China	Mar 2011 – Apr 2012	215 (221)	109 (113)	106 (108)	3 μg/mm² Iopromide	Paclitaxel-eluting Durable-polymer Stainless steel (132 μm)	Drug-eluting
RIBS V	1:1 Open-Label Core lab CEC	25 Spain	Jan 2010 – Jan 2012	189 (189)	95 (95)	94 (94)	3 μg/mm² Iopromide	Everolimus-eluting Durable-polymer Cobalt-Chromium (81 μm)	Bare-metal
SEDUCE	1:1 Open-Label Core lab CEC	2 Belgium	Jun 2009 – Oct 2011	49 (49)	24 (24)	25 (25)	3 μg/mm² Iopromide	Everolimus-eluting Durable-polymer Cobalt-chromium (81 μm)	Bare-metal
RIBS IV	1:1 Open-Label Core lab CEC	23 Spain	Jan 2010 – Aug 2013	309 (309)	154 (154)	155 (155)	3 μg/mm² Iopromide	Everolimus-eluting Durable-polymer Cobalt-chromium (81 μm)	Drug-eluting
TIS	1:1 Open-Label Core lab CEC	1 Czech Republic	Jan 2012 – Aug 2014	136 (148)	68 (74)	68 (74)	3 μg/mm² Iopromide	Everolimus-eluting Durable-polymer Cobalt-chromium (81 μm)	Bare-metal
DARE	1:1 Open-Label Core lab CEC	8 Netherlands	May 2010 – Jun 2015	278 (278)	137 (137)	141 (141)	3 μg/mm² Iopromide	Everolimus-eluting Durable-polymer Cobalt-chromium (81 μm)	Bare-metal Drug-eluting
RESTORE	1:1 Open-Label Core lab CEC	10 South Korea	Apr 2013 – Oct 2016	172 (172)	86 (86)	86 (86)	3 μg/mm² Iopromide	Everolimus-eluting Durable-polymer Cobalt-chromium (81 μm)	Drug-eluting
BIOLUX-RCT	2:1 Open-Label Core lab CEC	14 Germany, Latvia	Aug 2012 – Jan 2015	229 (243)	157 (163)	72 (80)	3 μg/mm² BTHC	Sirolimus-eluting Bioresorbable-polymer Cobalt-chromium (60–80 μm)	Bare-metal Drug-eluting

1.976 pacientes

PCB, 1.033 pts

DES, 943 pts

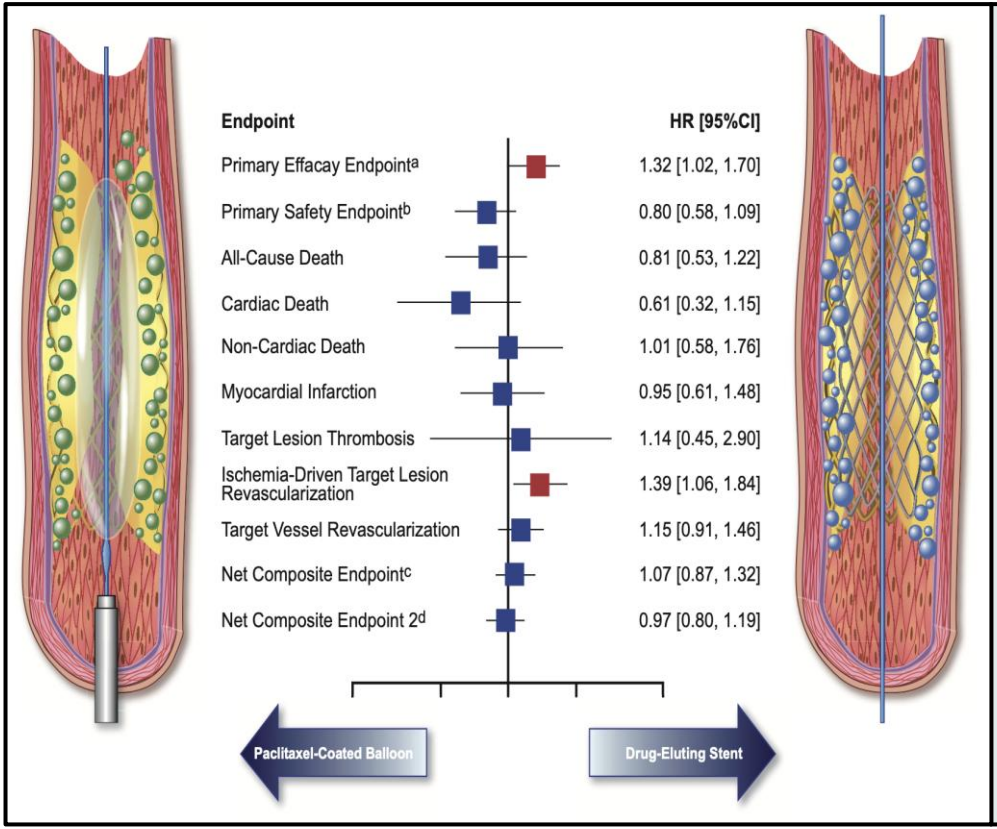


Table 4 Three-year clinical outcomes

	PCB (n = 1033)	DES (n = 943)	P_{LR}	HR (95% CI)	P_W	HR_{adj} (95% CI)	P_{adj}
Target lesion revascularization (primary efficacy endpoint)	144 (16.0)	99 (12.0)	0.020	1.32 (1.02–1.70)	0.035	1.38 (1.05–1.82)	0.020
All-cause death, myocardial infarction, or target lesion thrombosis (primary safety endpoint)	75 (9.0)	85 (10.9)	0.182	0.80 (0.58–1.09)	0.152	0.74 (0.52–1.04)	0.085
Death	42 (5.5)	48 (6.6)	0.334	0.81 (0.53–1.22)	0.310	0.68 (0.42–1.10)	0.116
Cardiac death	16 (2.0)	24 (3.3)	0.134	0.61 (0.32–1.15)	0.128	0.61 (0.32–1.19)	0.148
Non-cardiac death	26 (3.6)	24 (3.4)	0.964	1.01 (0.58–1.76)	0.973	0.80 (0.44–1.46)	0.474
Myocardial infarction	41 (4.7)	38 (4.4)	0.941	0.95 (0.61–1.48)	0.820[a]	0.95 (0.59–1.53)	0.829
Target lesion thrombosis	10 (1.2)	8 (0.9)	0.765	1.14 (0.45–2.90)	0.777	1.09 (0.39–3.03)	0.869
Ischaemia-driven target lesion revascularization	129 (14.3)	84 (10.1)	0.011	1.39 (1.06–1.84)	0.018	1.43 (1.07–1.92)	0.016
Target vessel revascularization	161 (17.9)	126 (15.2)	0.173	1.15 (0.91–1.46)	0.235	1.19 (0.92–1.55)	0.184
All-cause death, myocardial infarction, target lesion thrombosis, or target lesion revascularization	197 (22.1)	167 (20.6)	0.384	1.07 (0.87–1.32)	0.518[b]	1.07 (0.84–1.35)	0.593
All-cause death, myocardial infarction, target lesion thrombosis, or target vessel revascularization	207 (23.0)	191 (23.2)	0.945	0.97 (0.80–1.19)	0.796[c]	0.98 (0.78–1.23)	0.851

Seguimiento 3 años

PCB se asoció con un incremento en el riesgo de revascularización de la lesión diana (TLR) comparado con DES (riesgo relativo [RR] 1,32; intervalo de confianza al 95% [IC 95]: 1,02-1,70; p = 0,035; número necesario para dañar 28,5).
Se detectó una interacción significativa entre el efecto del tratamiento y el tipo de *stent* reestenosado (p = 0,029) con una marcada diferencia en pacientes con reestenosis de DES y efectos comparables en pacientes con reestenosis de *stent* metálico (BMS).

El objetivo primario de seguridad de muerte por cualquier causa, infarto de miocardio o trombosis de lesión diana fue comparable entre ambos tratamientos (*hazard ratio* [HR] 0,80, IC 95%: 0,58-1,09; p = 0,152).

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ENFERMEDAD DE VASOS PEQUEÑOS

Drug-coated balloons for small coronary artery disease (BASKET-SMALL 2): an open-label randomised non-inferiority trial

Prof Raban V Jeger, MD [a] · Ahmed Farah, MD [b] · Prof Marc-Alexander Ohlow, MD [c] · Norman Mangner, MD [d,e] · Sven Möbius-Winkler, MD [f] · Gregor Leibundgut, MD [g] · et al. Show more

BASKET-SMALL 2 was a multicentre, open-label, randomised non-inferiority trial. 758 patients with de-novo lesions (<3 mm in diameter) in coronary vessels and an indication for percutaneous coronary intervention were randomly allocated (1:1) to receive angioplasty with DCB versus implantation of a second-generation DES after successful predilatation via an interactive internet-based response system. Dual antiplatelet therapy was given according to current guidelines. The primary objective was to show non-inferiority of DCB versus DES regarding major adverse cardiac events (MACE; ie, cardiac death, non-fatal myocardial infarction, and target-vessel revascularisation) after 12 months. The non-inferiority margin was an absolute difference of 4% in MACE. This trial is registered with ClinicalTrials.gov, number NCT01574534.

After 12 months, the proportions of MACE were similar in both groups of the full-analysis population (MACE was 7·5% for the DCB group *vs* 7·3% for the DES group; hazard ratio [HR] 0·97 [95% CI 0·58–1·64], p=0·9180).

There were five (1·3%) cardiac-related deaths in the DES group and 12 (3·1%) in the DCB group (full analysis population).
Probable or definite stent thrombosis (three [0·8%] in the DCB group *vs* four [1·1%] in the DES group; HR 0·73 [0·16–3·26]) and major bleeding (four [1·1%] in the DCB group *vs* nine [2·4%] in the DES group; HR 0·45 [0·14–1·46]) were the most common adverse events.

CONCLUSIÓN

- En términos de eficacia, la angioplastia con DCB presentó tasas moderadamente mayores de TLR que el implante de un DES.
- En cuanto a seguridad (mortalidad total, infarto de miocardio, trombosis de lesión diana) ambos tratamientos fueron similares, con un ligero aumento del riesgo tras implante de DES intrastent después de un ajuste multivariado.
- Un análisis combinado de seguridad y eficacia mostró resultados similares entre ambos tratamientos.
- El tratamiento con DCB no aumentó la mortalidad, cardiaca o no cardiaca, a largo plazo.