



10° ANIVERSARIO CSC

MADRID

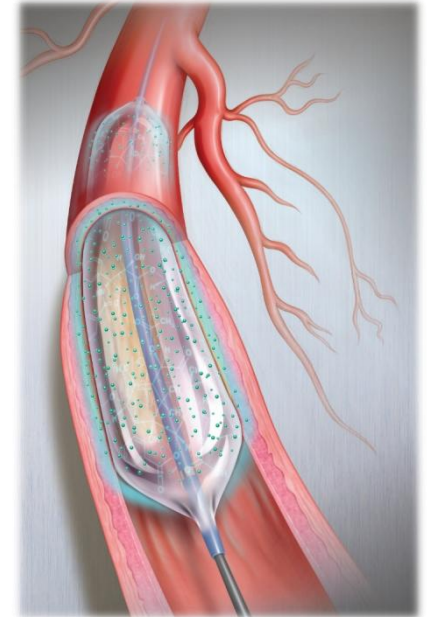
6, 7 y 8 noviembre
2024



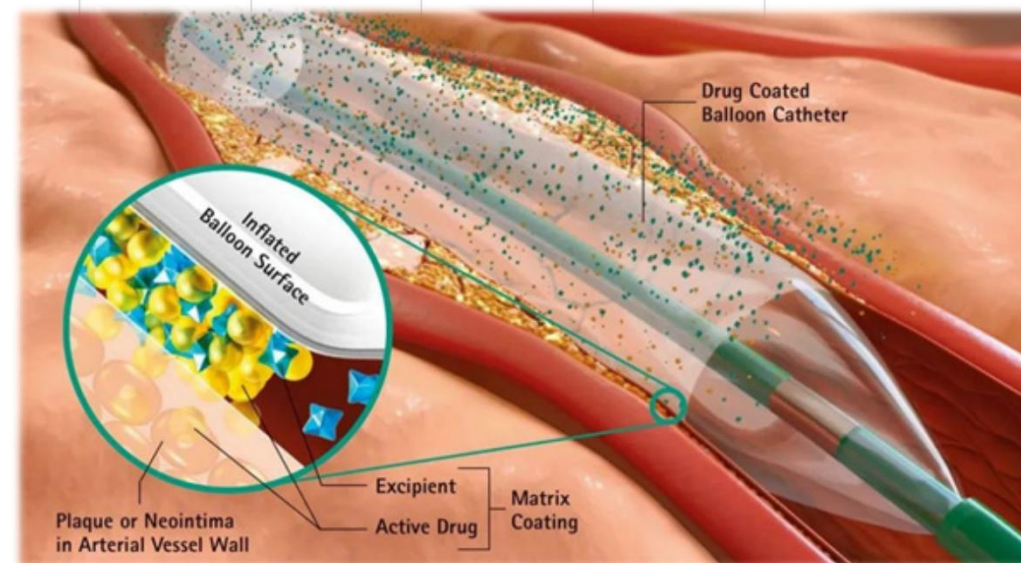
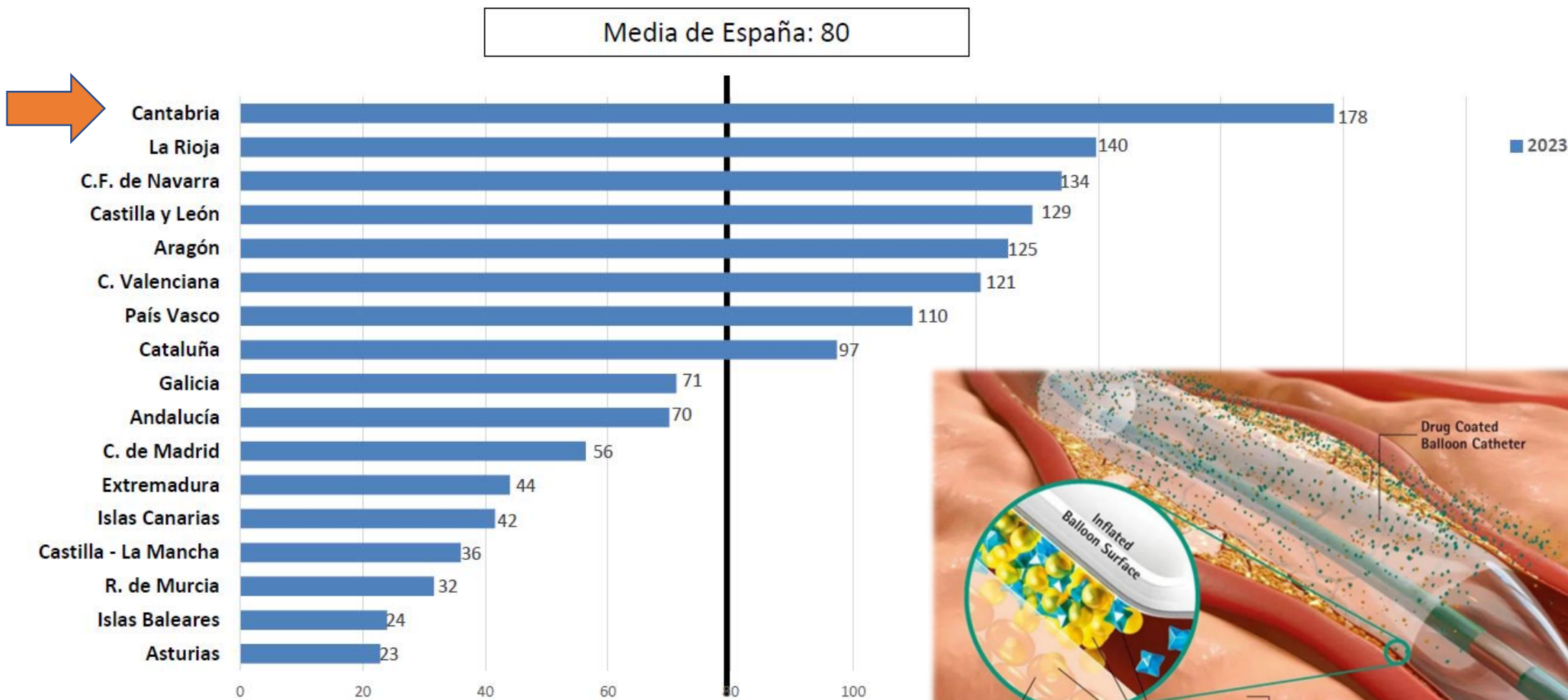
Por una menor huella metálica en las bifurcaciones coronarias

Jose M de la Torre Hernandez

Jefe del Servicio de Cardiología, HUMV, Santander
Vicepresidente de la Sociedad Española de Cardiología



Nº ICP CON BALÓN FARMACOACTIVO EXCLUSIVAMENTE POR MILLÓN DE HABITANTES



When a DCB is a good alternative ?

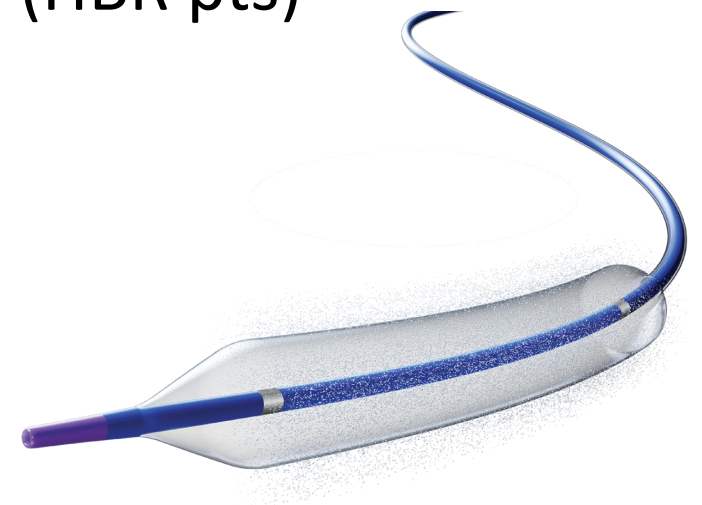
Situations favouring avoidance of implantation of metal stent layers

- **In-stent restenosis** to avoid additional stent layers
- **Bifurcation lesions** requiring intervention in both limbs to avoid excess metal at the neocarina
- **Diffuse high-grade coronary disease** to avoid long total stent length
- **Arterial segments** subject to external compressive force e.g. lesions of the femeropopliteal tract

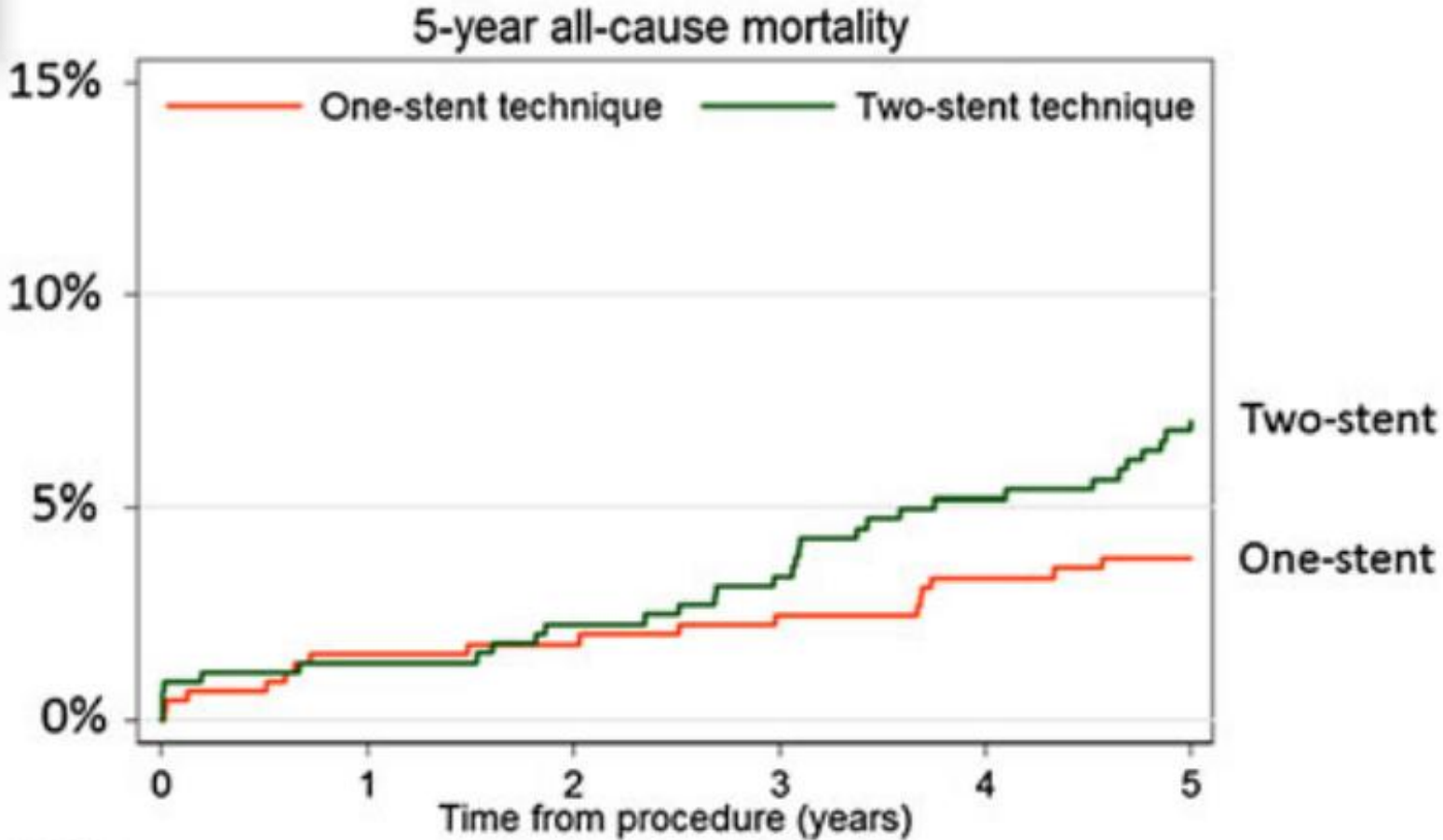
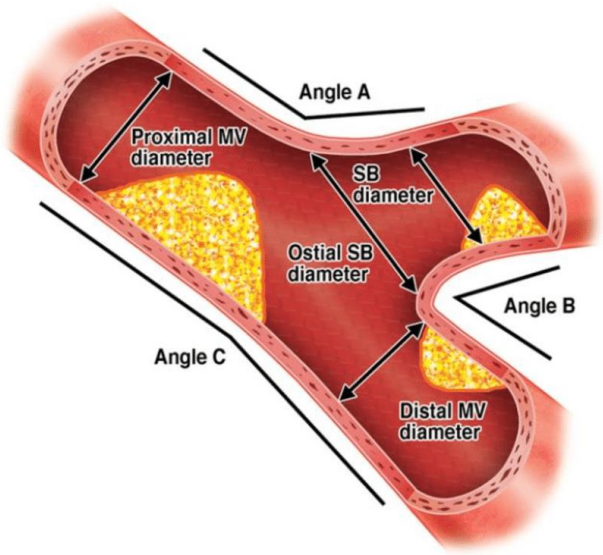
DCB in the treatment of coronary bifurcation lesions

Potential benefits of DCB in the treatment of bifurcations:

- Administration of drug to the vessel wall, especially the SB ostium
- Lack of distortion of the original anatomy of the bifurcation
- Minimization of strut deformation at the carina
- Decrease in duration of dual antiplatelet therapy (HBR pts)

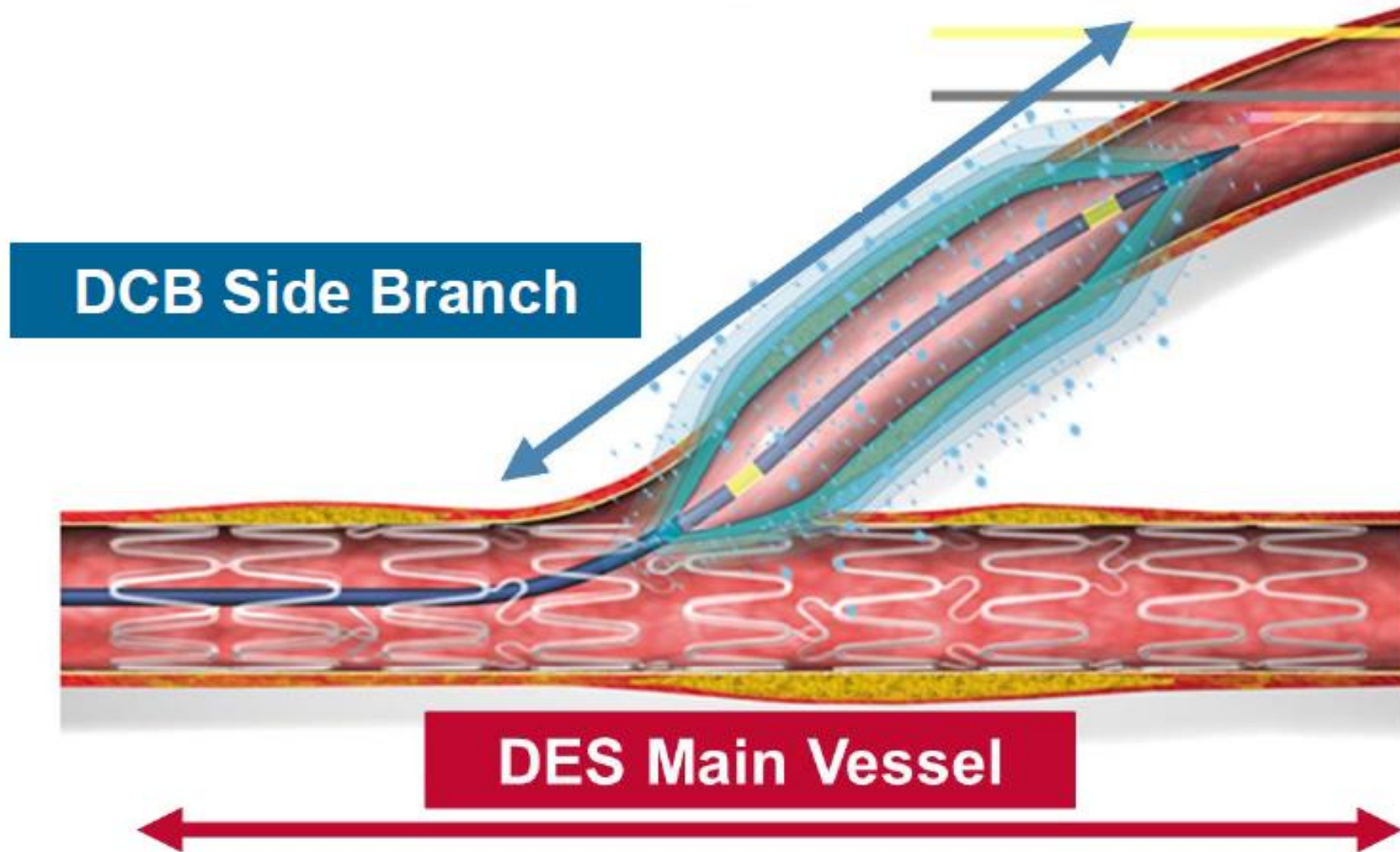


Coronary bifurcation lesions treated with simple or complex stenting: 5-year survival from patient-level pooled analysis of the Nordic Bifurcation Study and the British Bifurcation Coronary Study



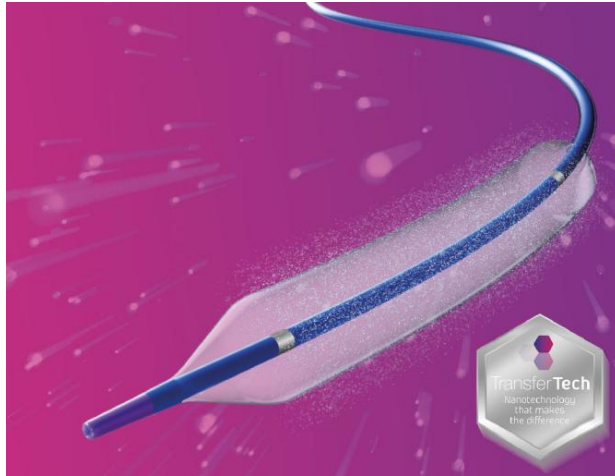
Number at risk		0	1	2	3	4	5
Two-stent tech.	443	436	432	427	419	412	412
One-stent tech.	447	440	439	436	432	430	430

DCB for the SB in provisional stenting



Essential pro

DCB



BALLOON CATHETER

COATING

Xperience pro

* with hydrophilic coating



DRUG

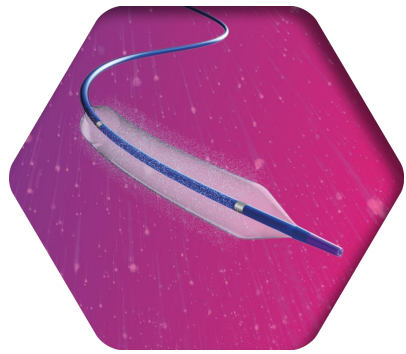
Paclitaxel - 3 $\mu\text{g}/\text{mm}^2$

+

EXCIPIENT

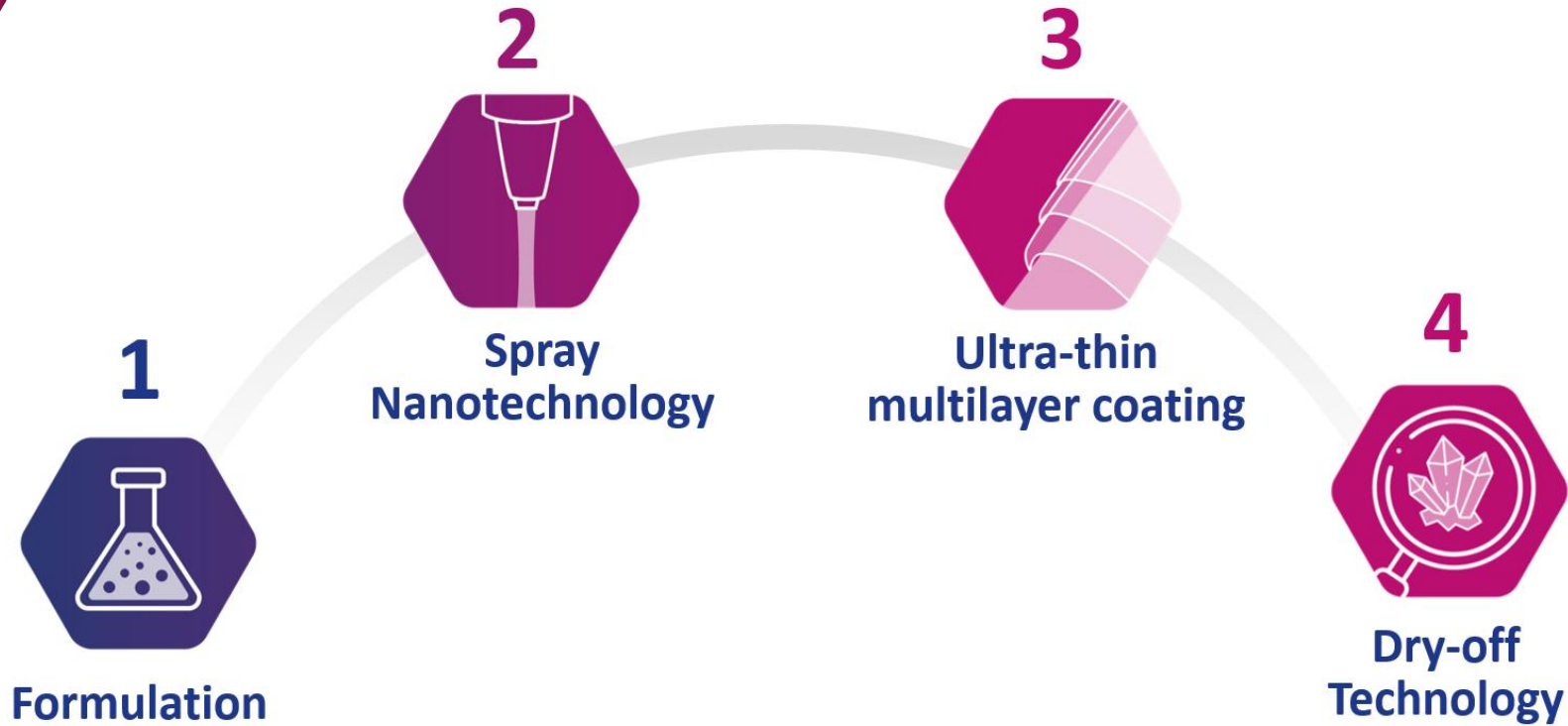
Water Reduced Ester





TransferTech

Last generation nanotechnology



1. Minimum drug loss during navigation

2. Fast and high drug transfer

3. Long retention time

iVasTriam

The iVascular Clinical Trial Program



2015

Registry ESSENTIAL in SV

International, multicenter, prospective, observational registry
N = 71, 12 months follow up

12 months published in "Coronary Artery Disease", Sept 2018

2017

ESSENTIAL ISR study

Investigator initiated. prospective and multicenter study
N = 33, 24 months follow up

J. De La Torre Cardiovasc Revasc Med. 2019 Jul 23. pii: S1553-8389(19)30433-6

CASO 1

Varón 81 años

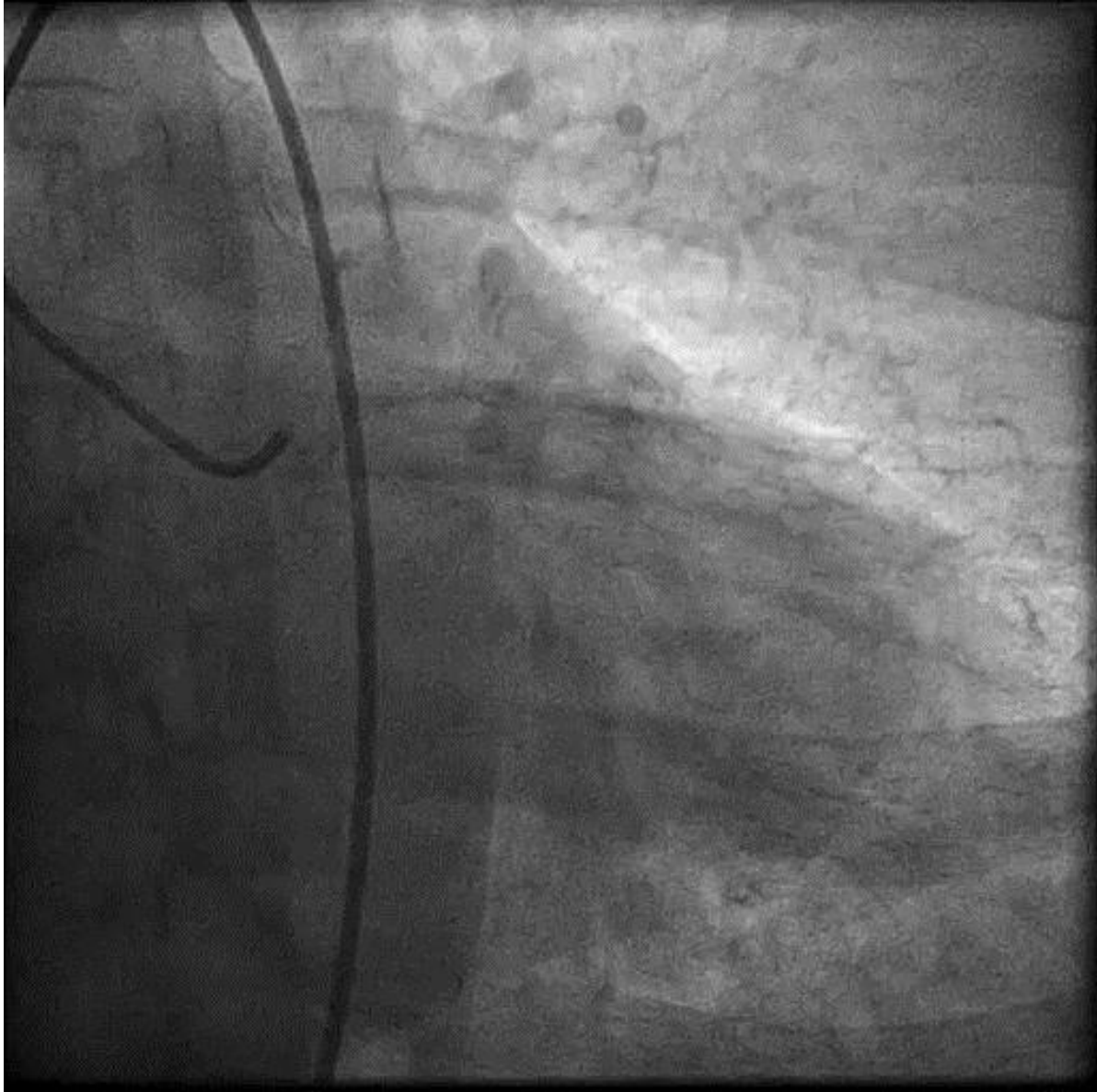
DLP, DM, HTA, Obesidad

Angina con esfuerzos moderados progresiva

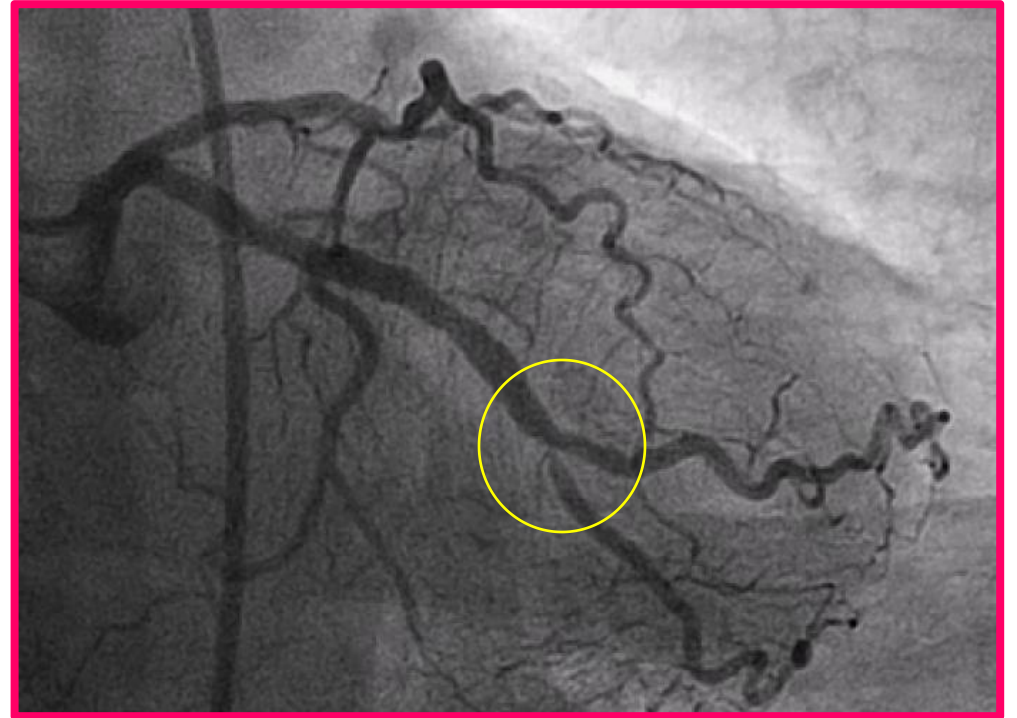
Eco de esfuerzo: positiva en segmentos inf-lat.

FEVI basal 55%.

Hospitalización programada para Angiografía Coronaria

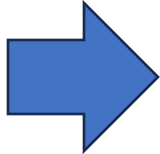
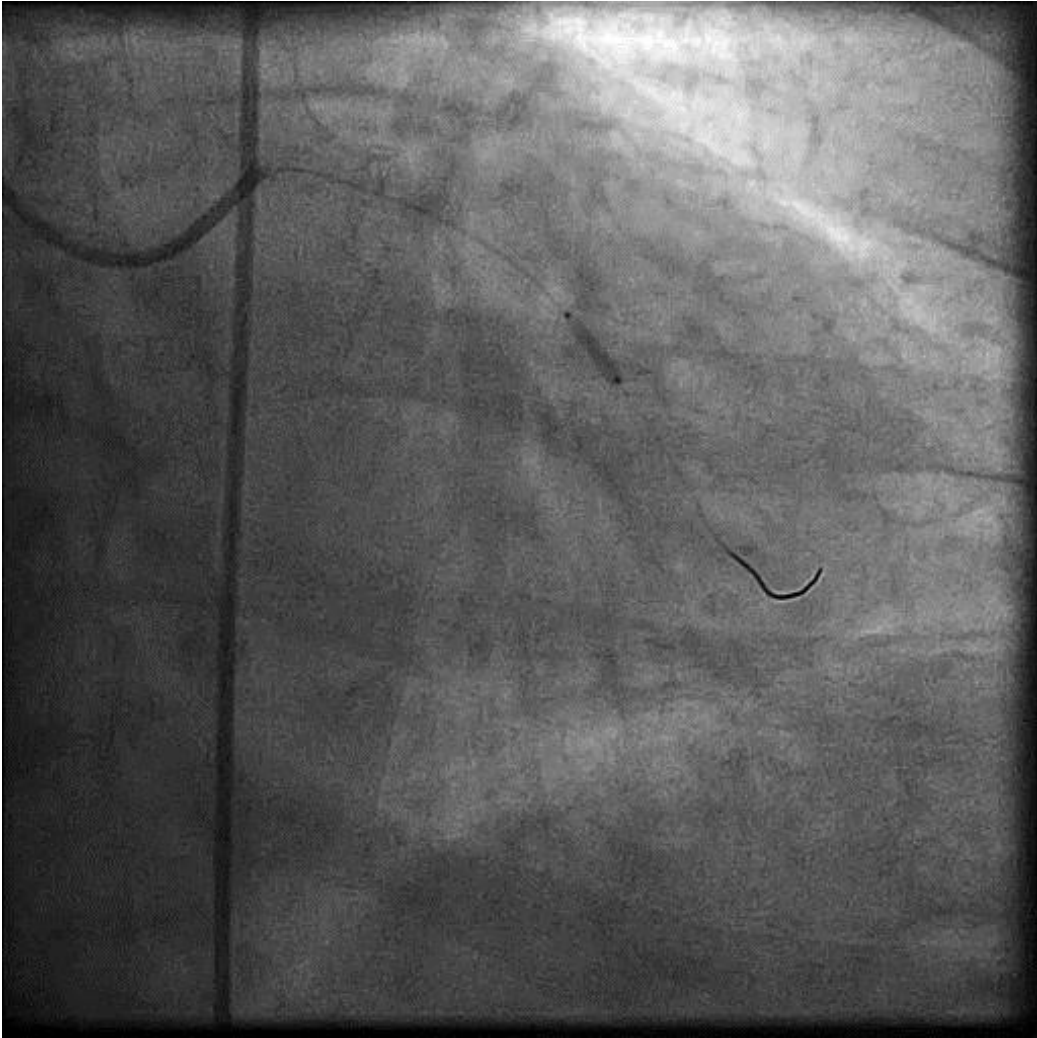


Estenosis en subrama de MOB

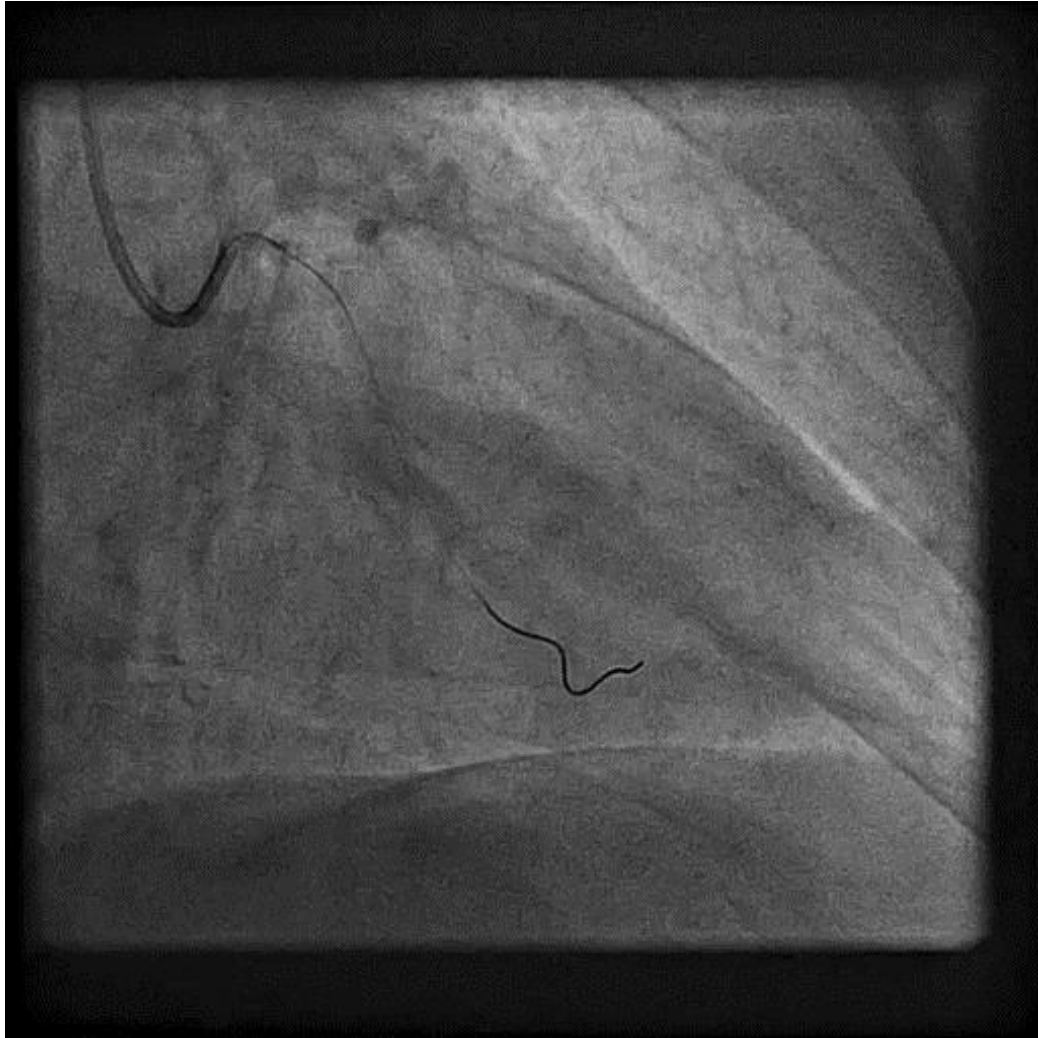


DCB en subrama de MOB

Essential pro 2 mm

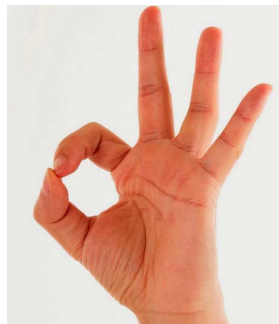
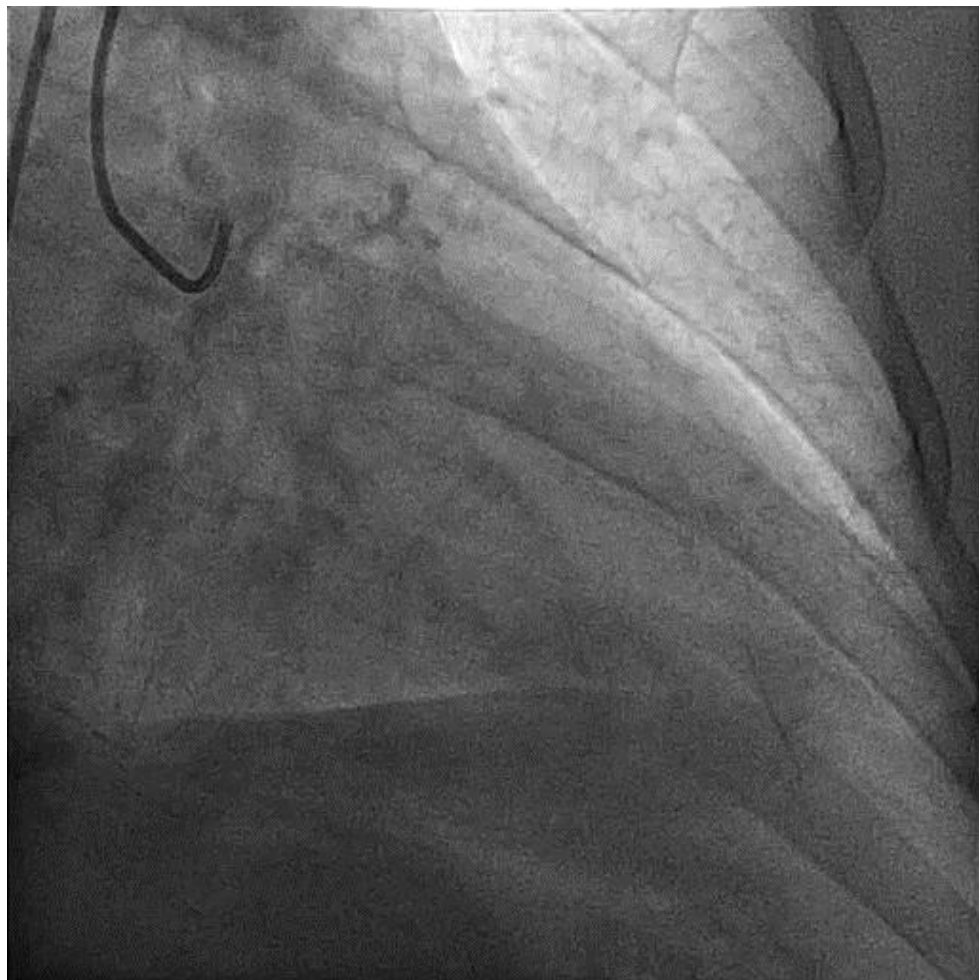


RESULTADO

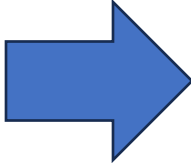
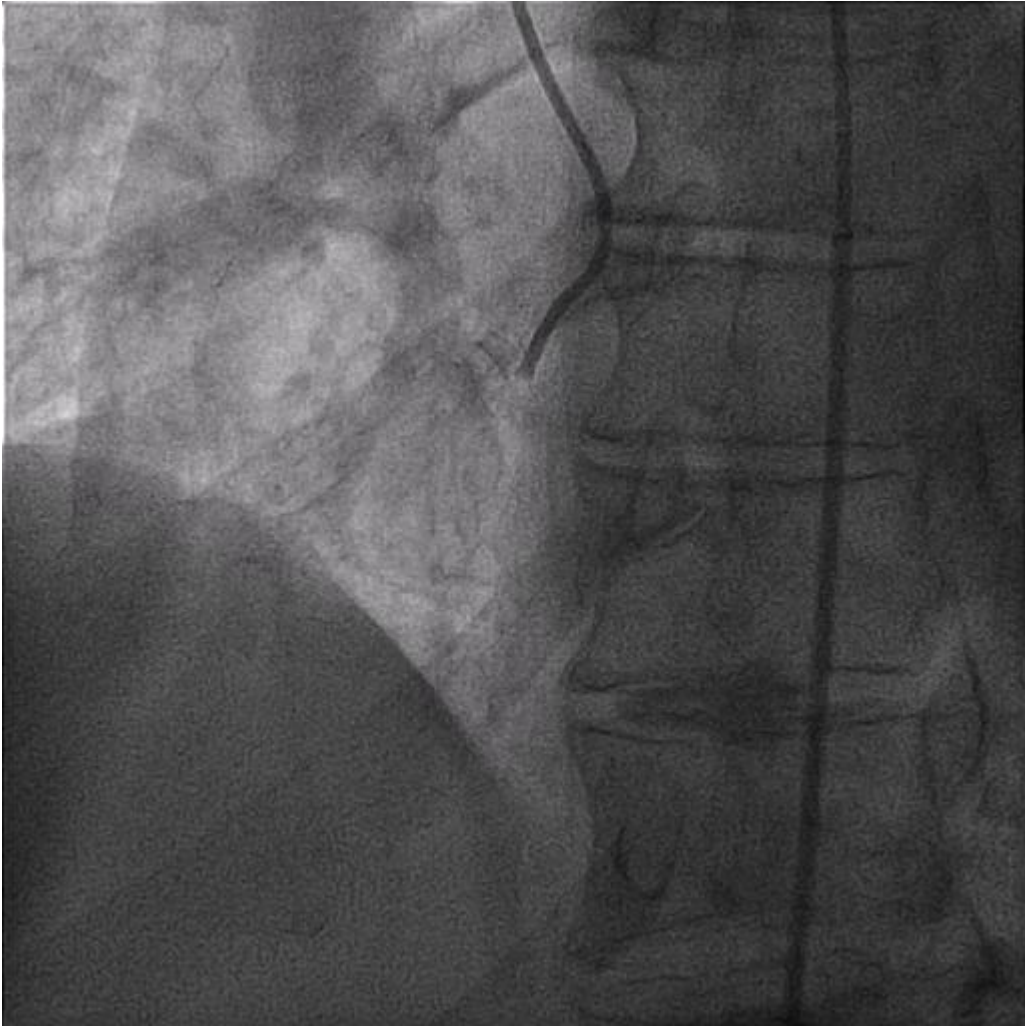


18 meses después

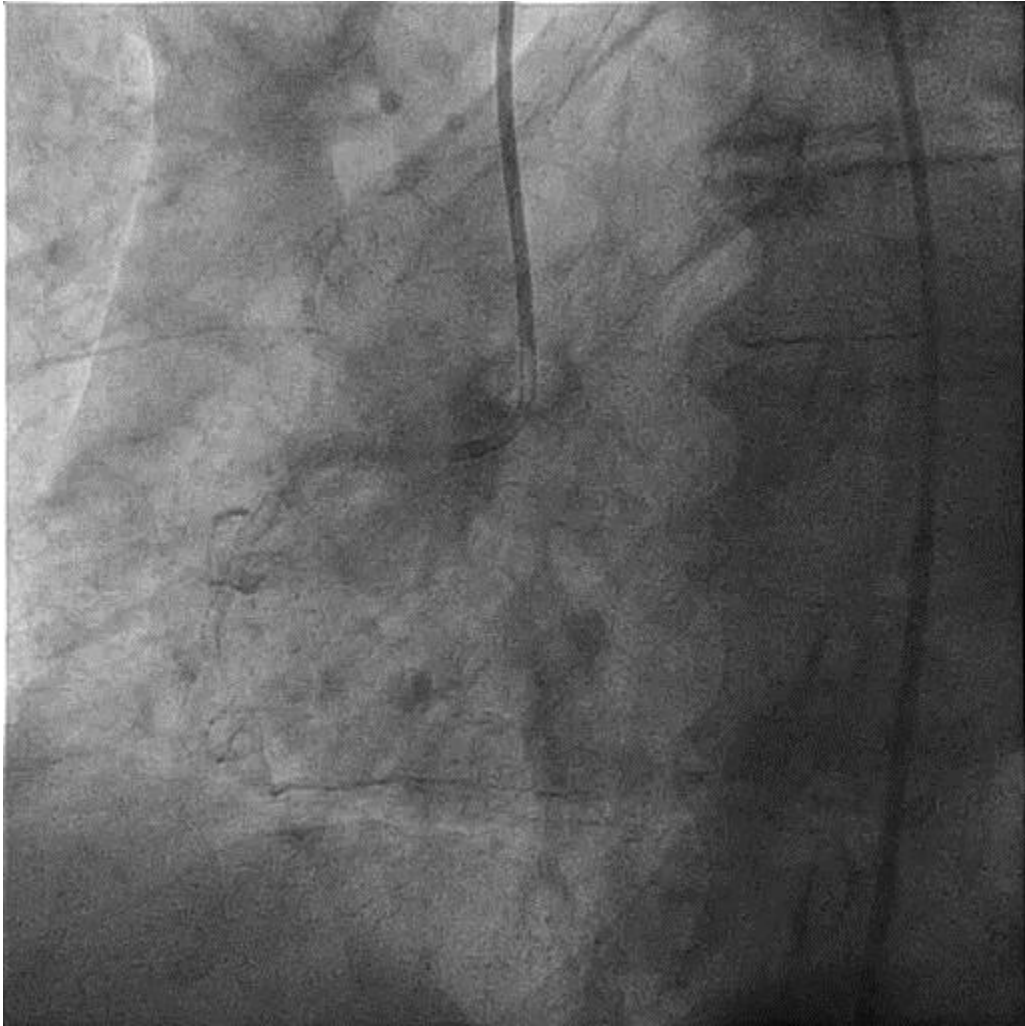
Paciente es ingresado con diagnóstico de SCASEST inferior



Lesión severa en CD



ICP con DES en CD



CASO 2

Mujer 77 años

DM, DLP, EPOC

Ex fumadora

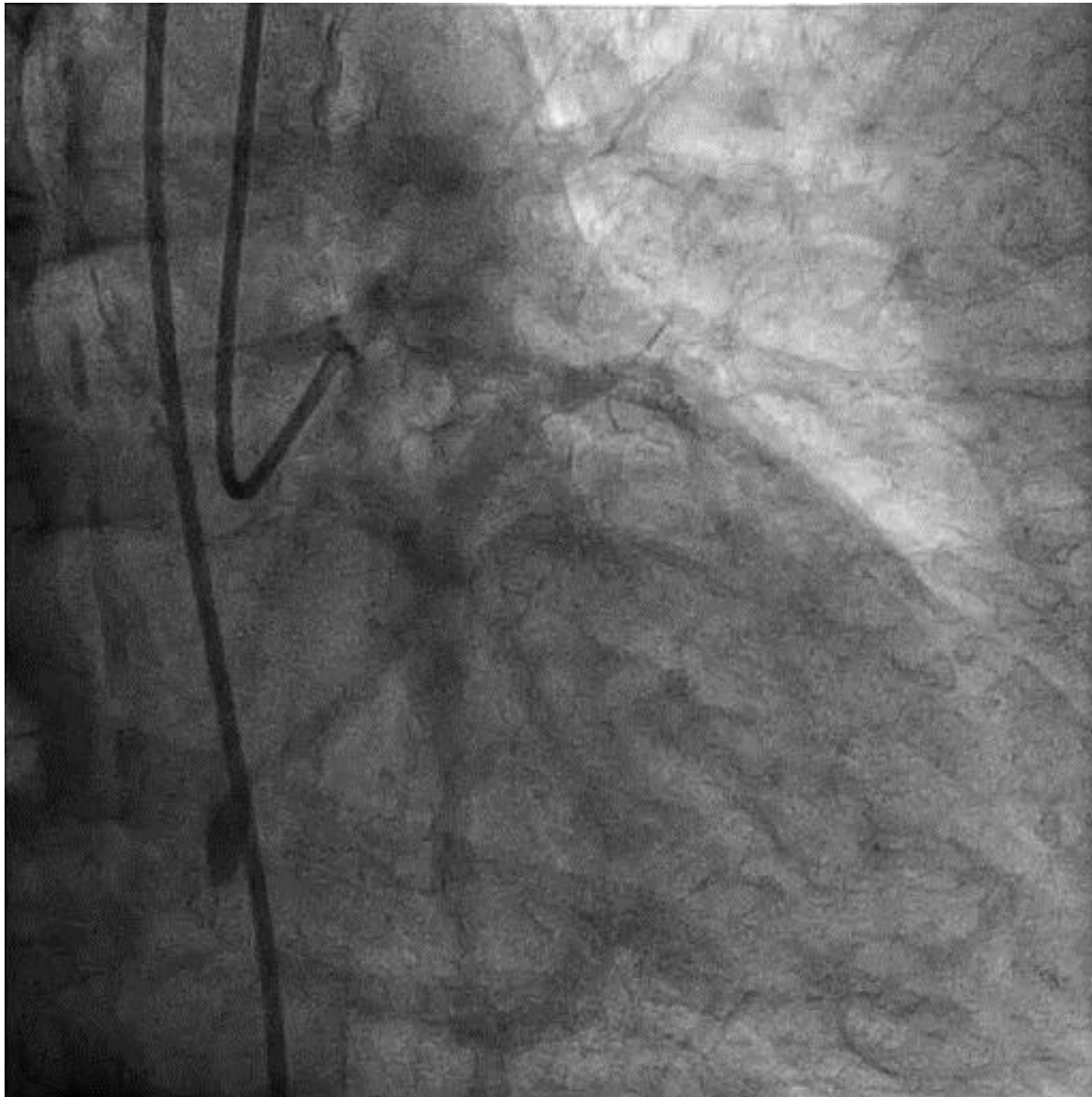
En 2007 PCI: DES en DA media y CD distal.

Episodio actual

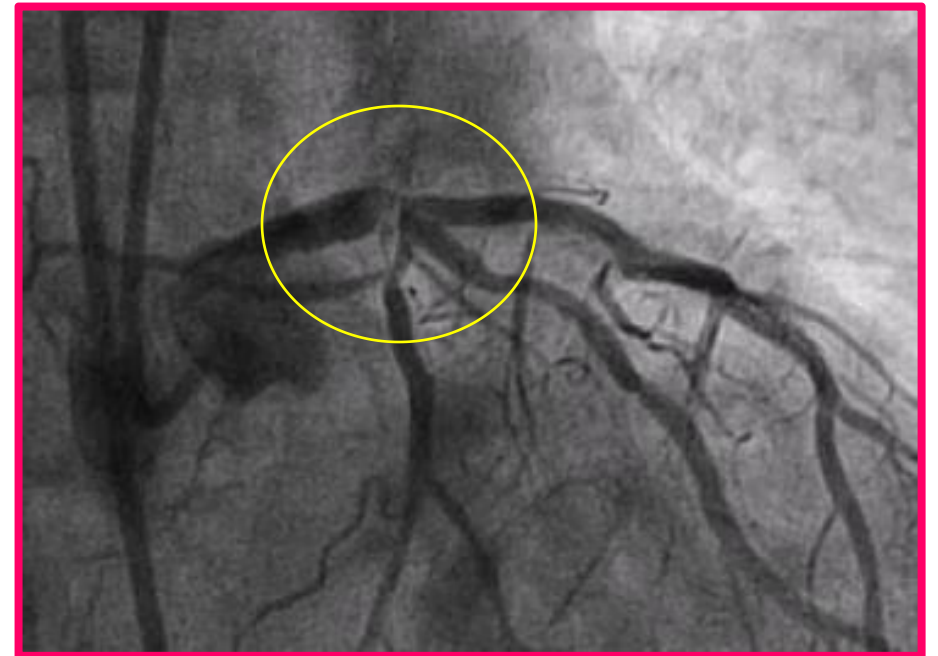
IAMSEST con cambios extensos (sugiere TCI)

ECO: HK anterior, AK infero-posterior, FEVI 45%.

Emergent coronary angiography



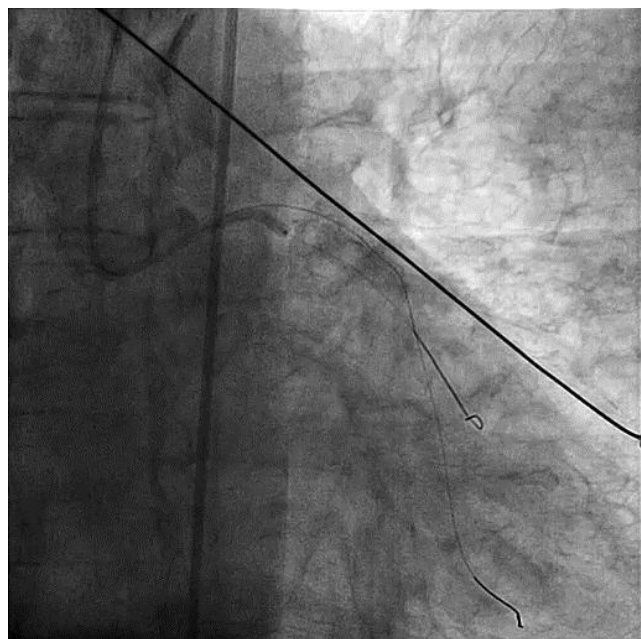
**Lesión crítica
en TC distal**



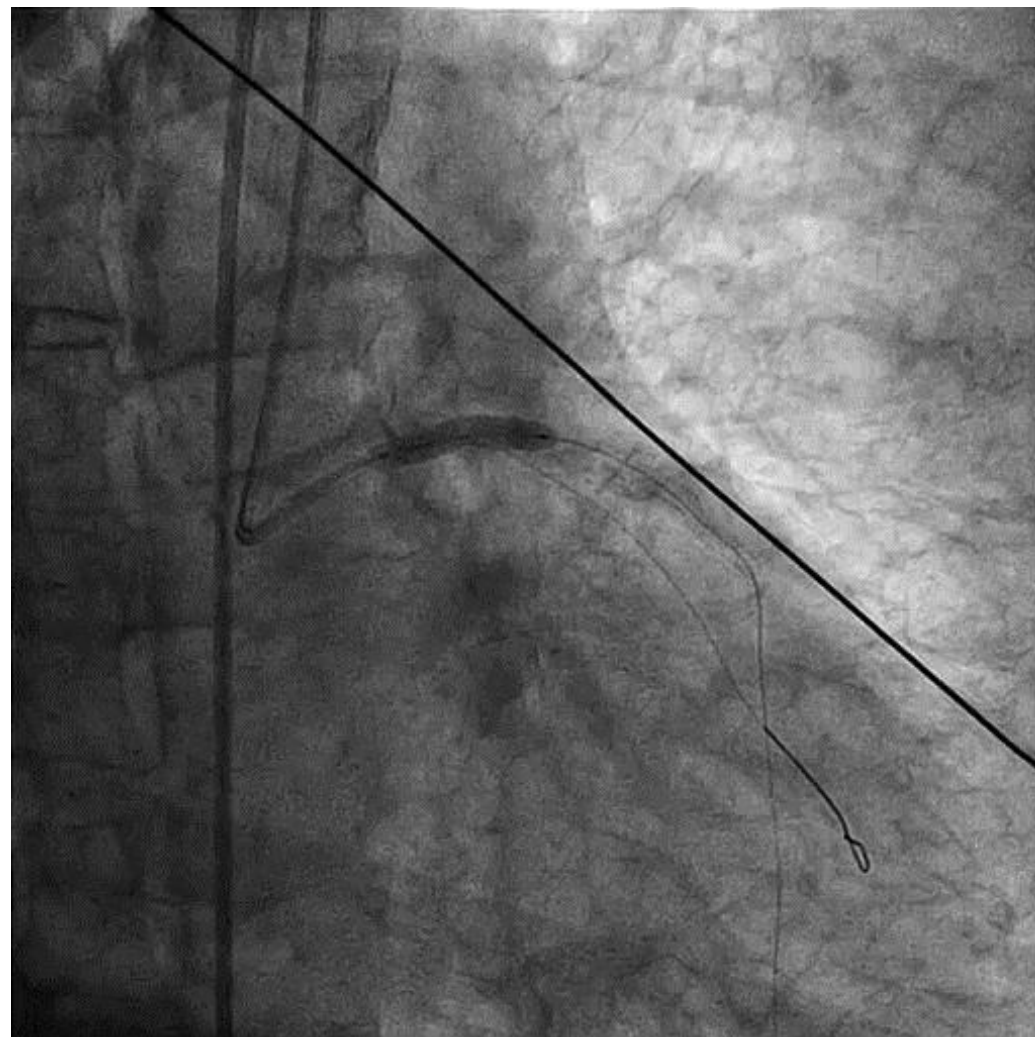
Balón en DA



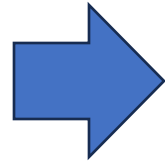
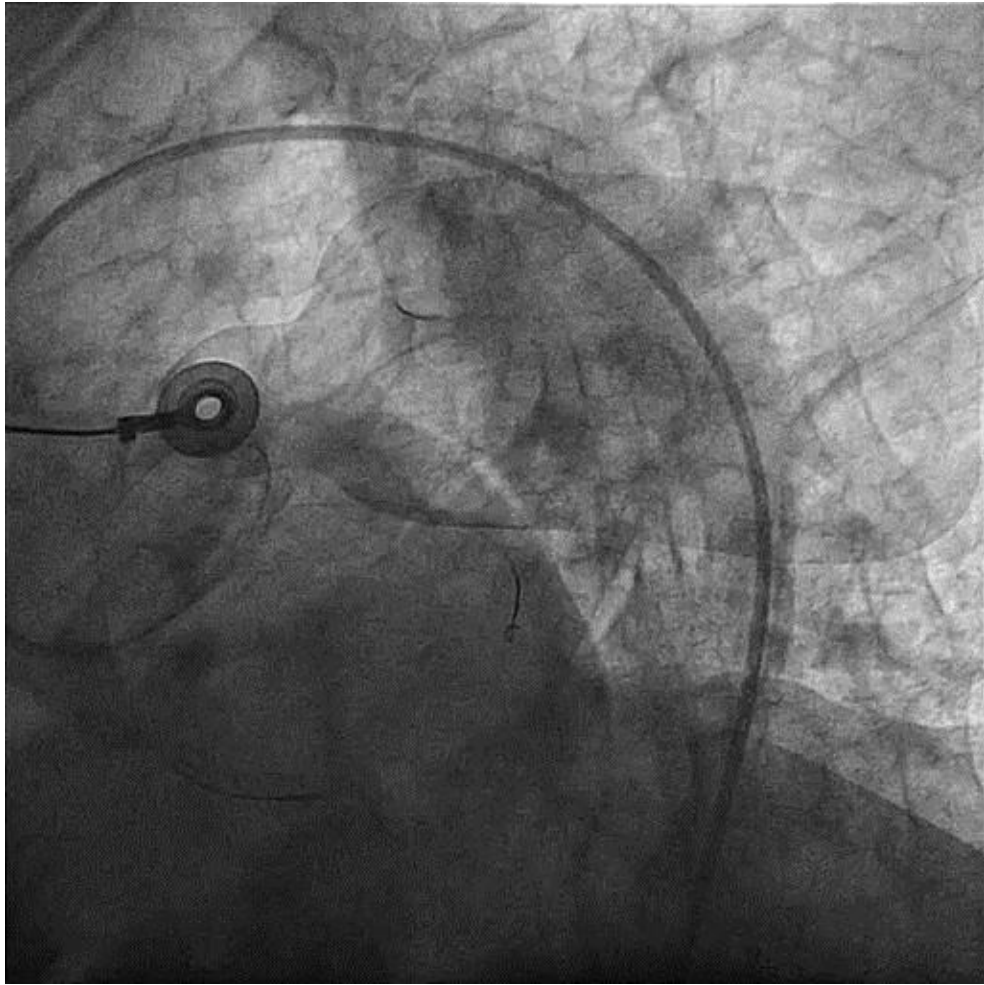
Balón en Cx



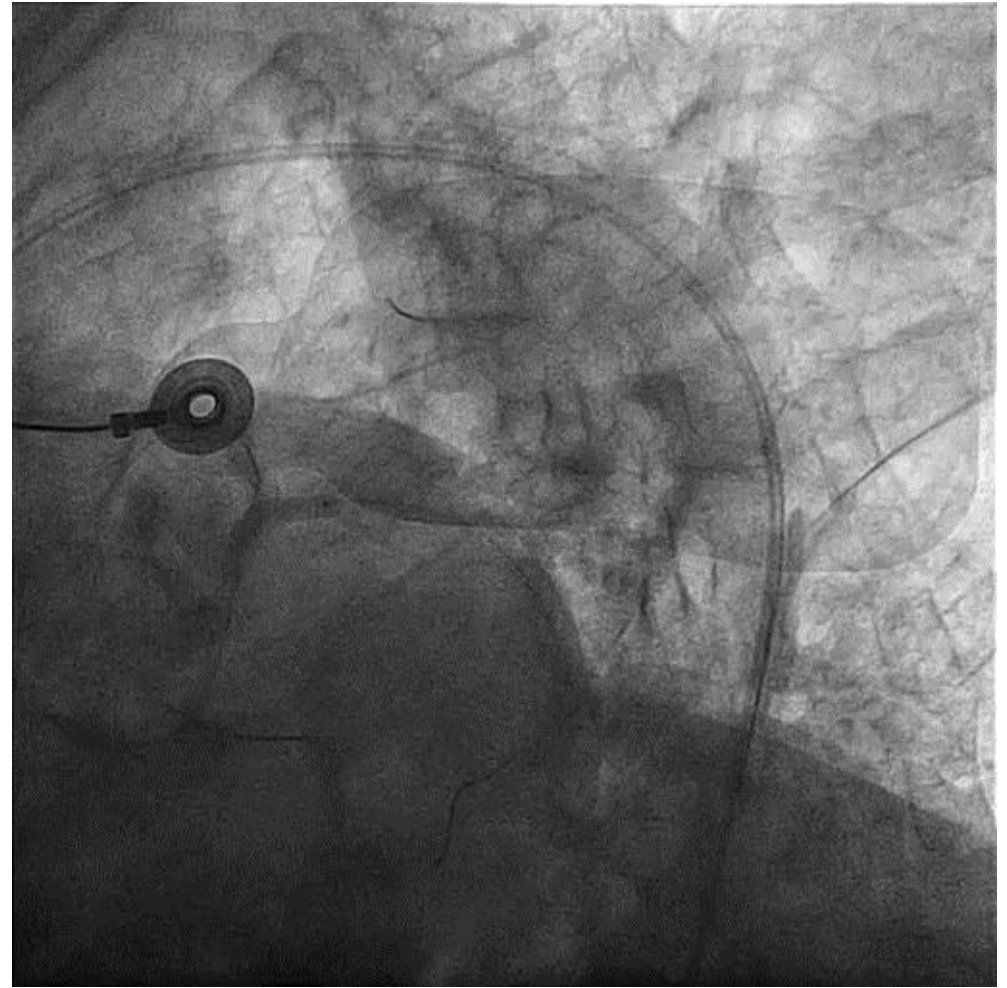
DES en TC-DA
Angiolite 3.5 / 19 mm



Post-stent en TC-DA + POT



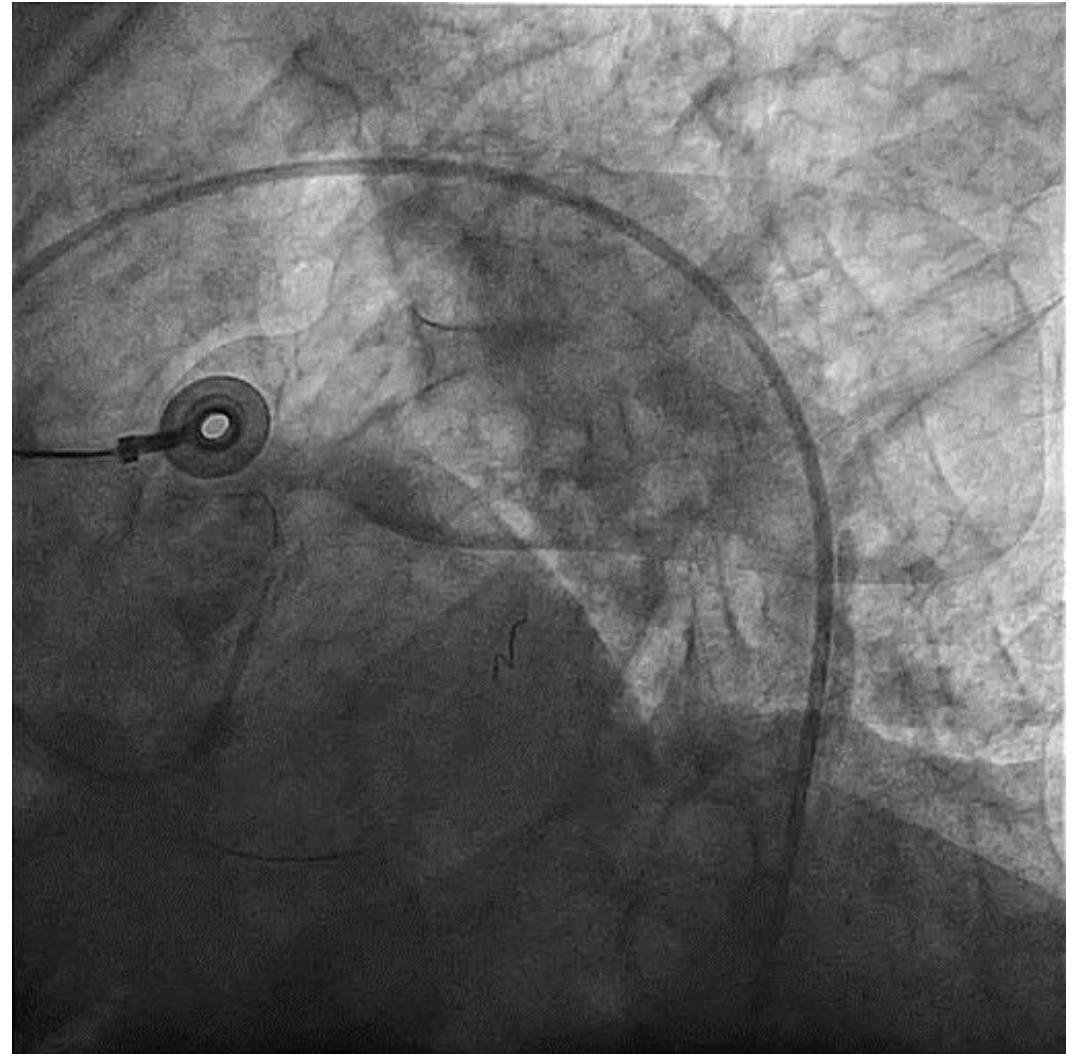
DCB a Cx
Essential pro 2.5 mm

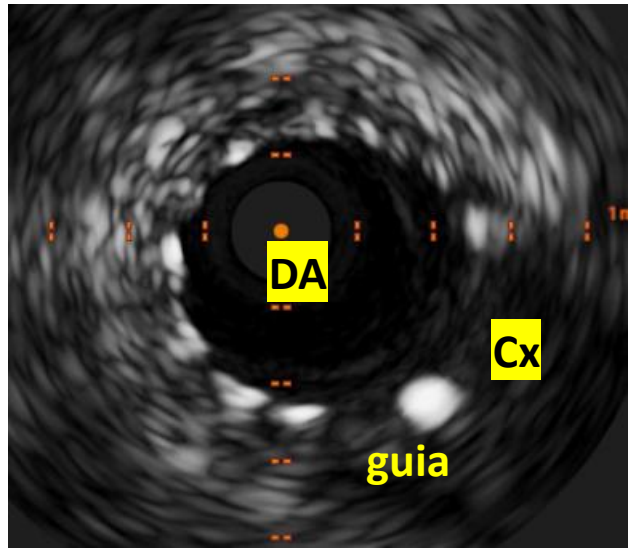
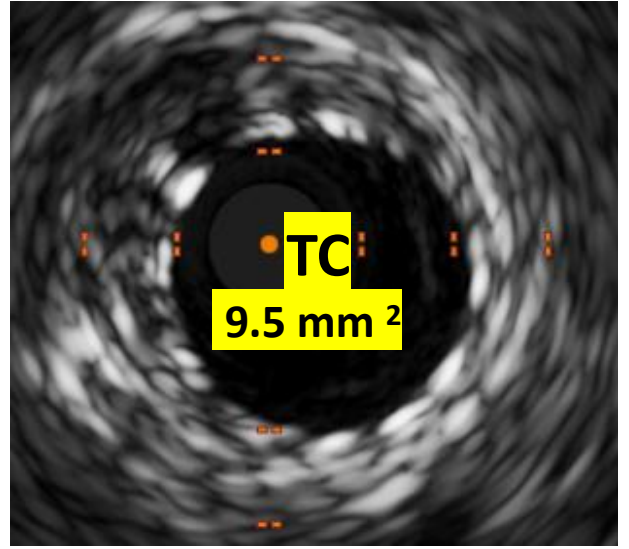
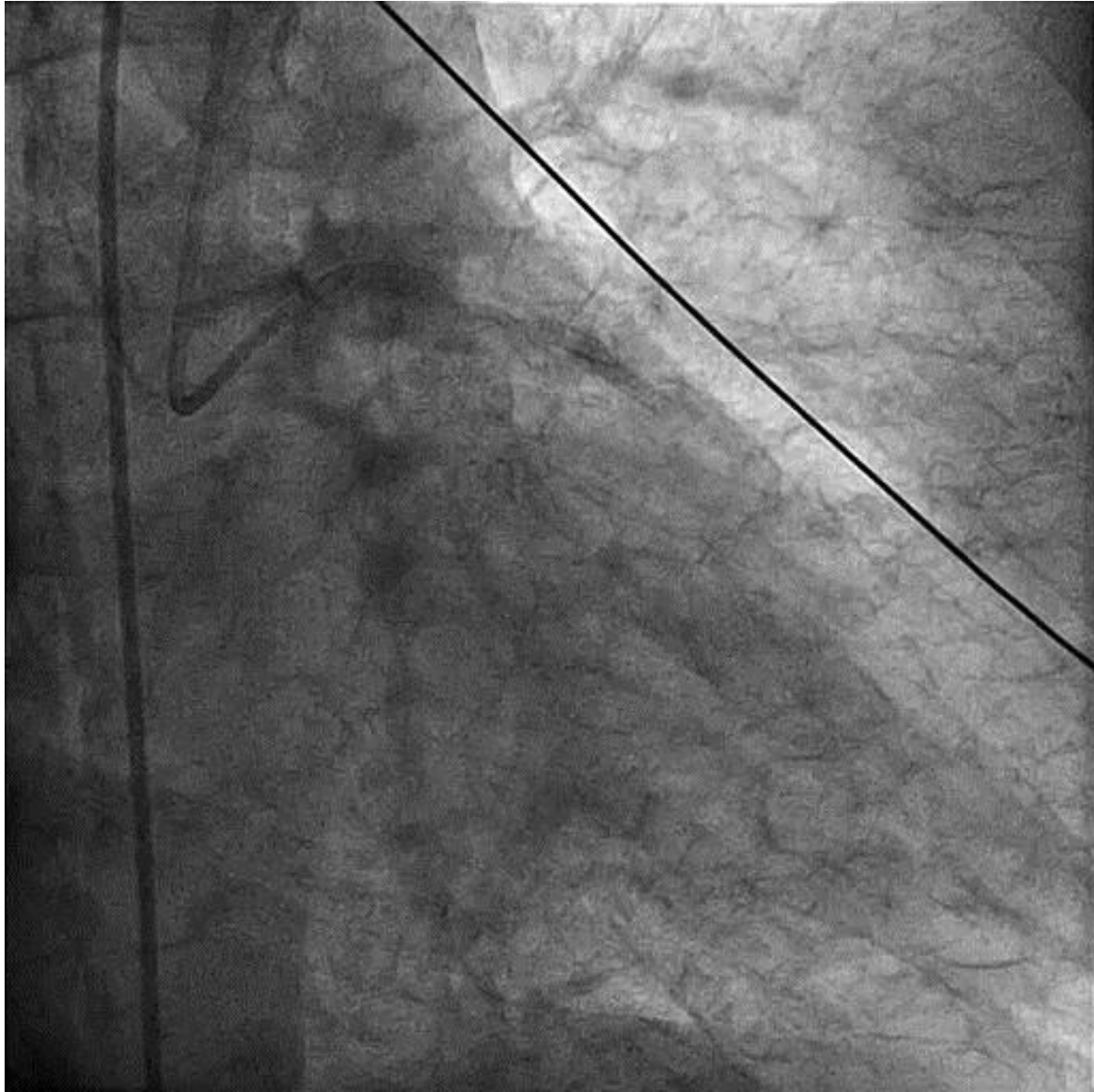


Re-POT



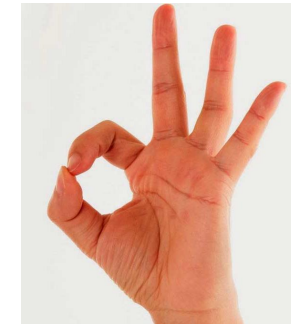
Resultado final



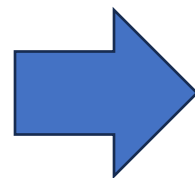
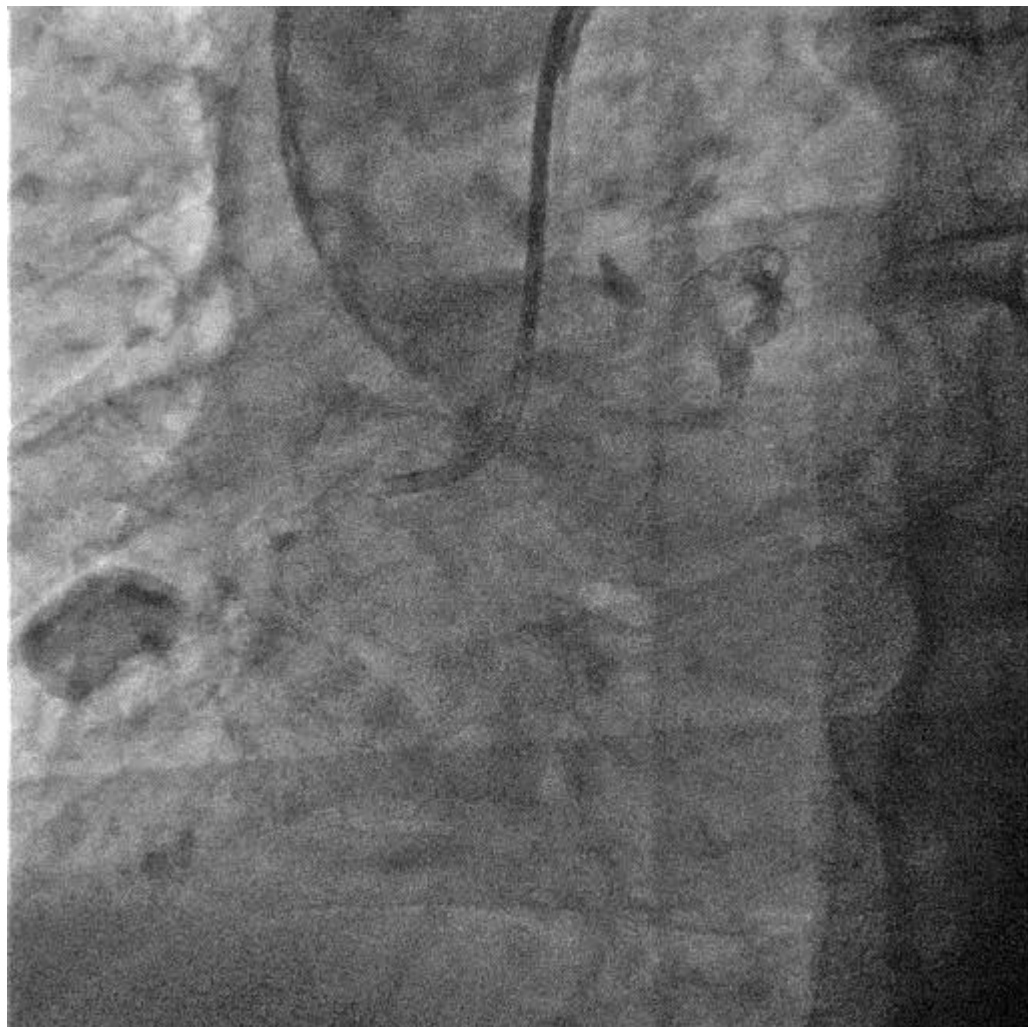


11 meses después

El paciente es ingresado por angina inestable



Lesión en CD



ICP con DES en CD



CASO 3

Varón 68 años

Sin FRCV

Heterocigoto para Factor V Leiden

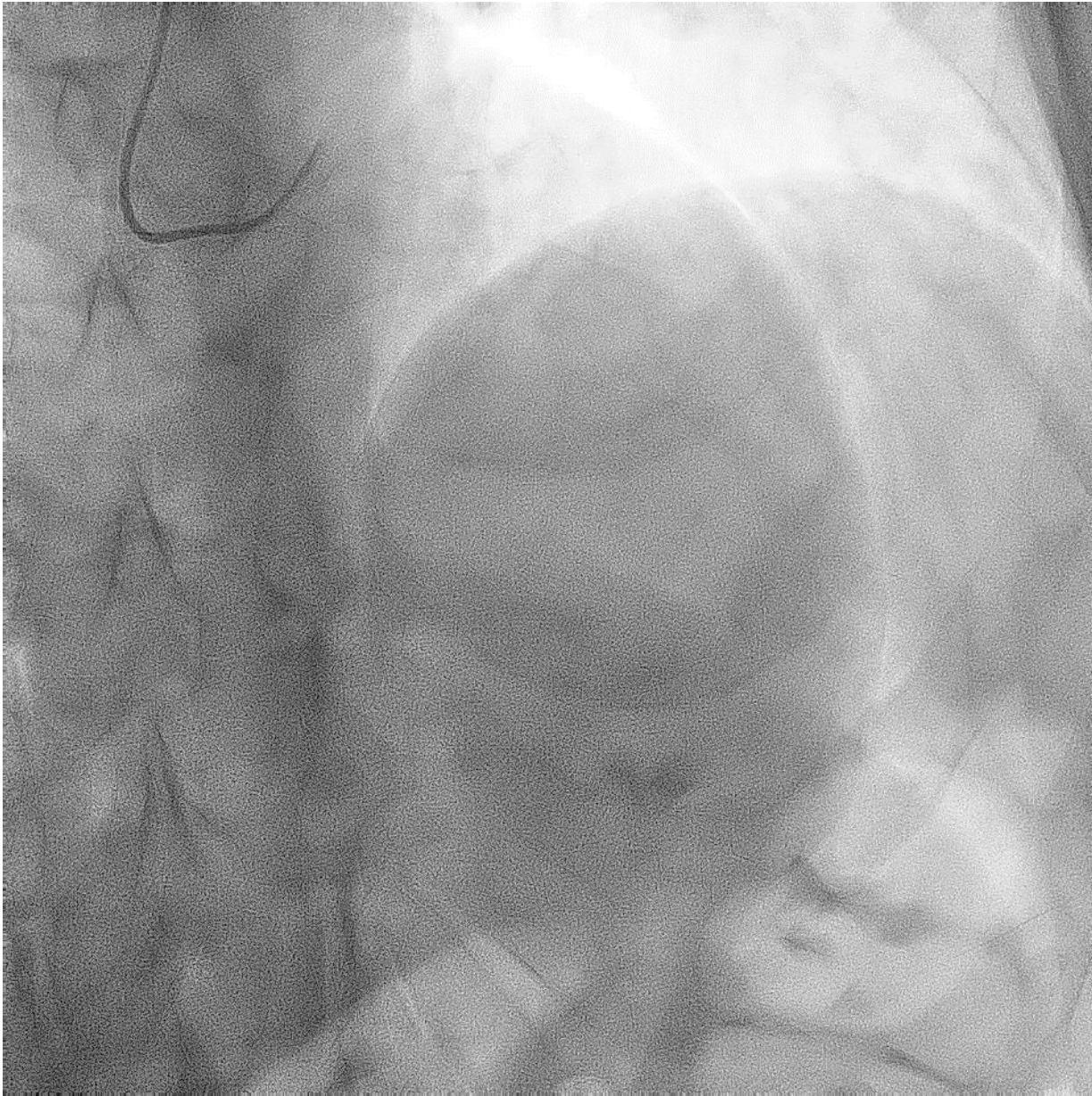
TVP en 2020, Anticoagulación con acenocumarol.

Episodio actual

Dolor torácico y disnea de esfuerzo.

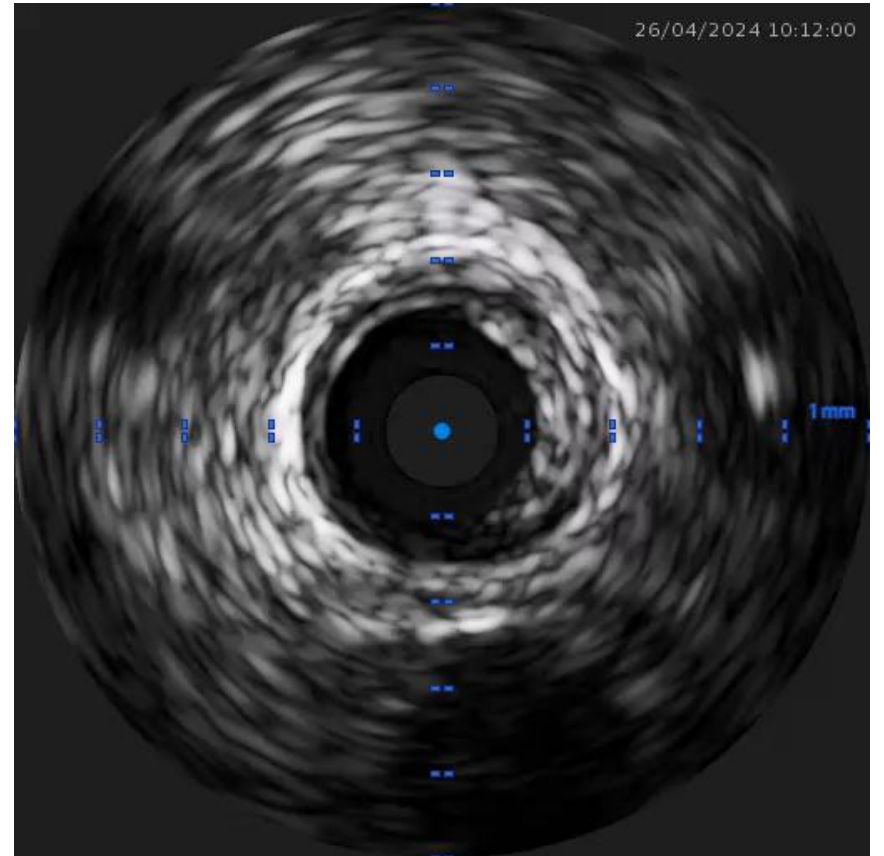
ECG: depresión del ST en derivaciones anteriores.

Angiografía coronaria.

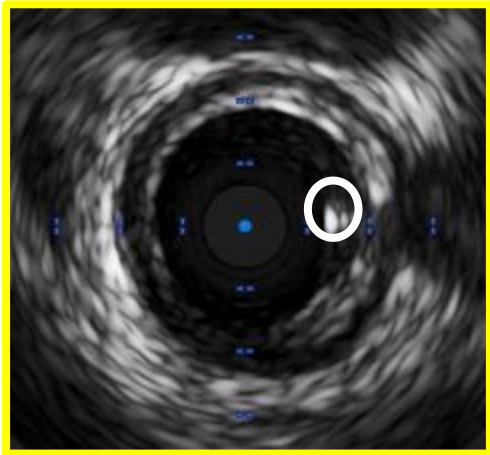


**Estenosis critica ostial Dg
0,0,1**

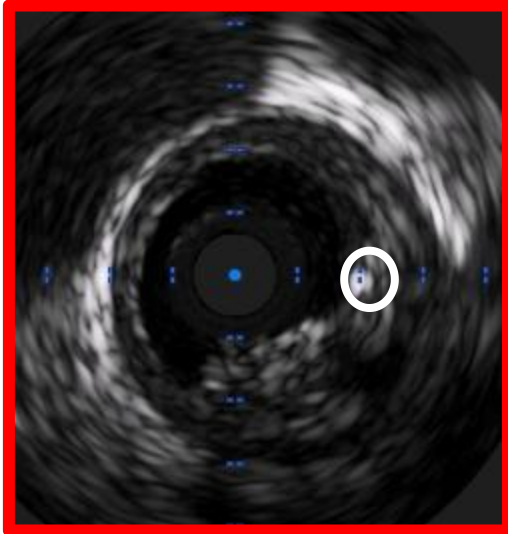
DA IVUS run



VP Proximal

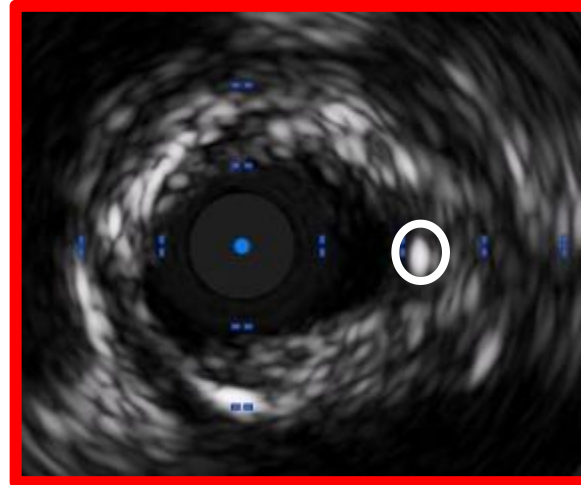


VP Proximal



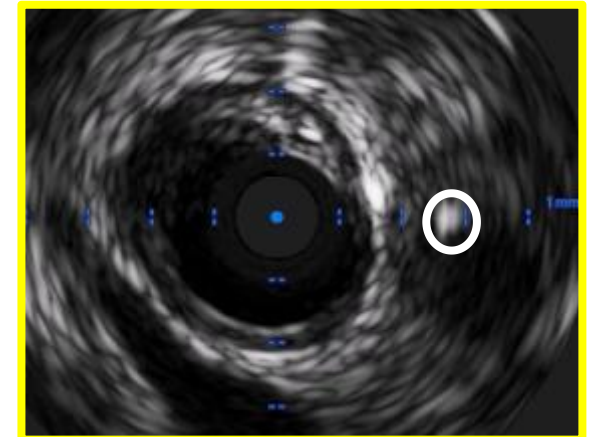
VP con moderada enfermedad proximal

POC



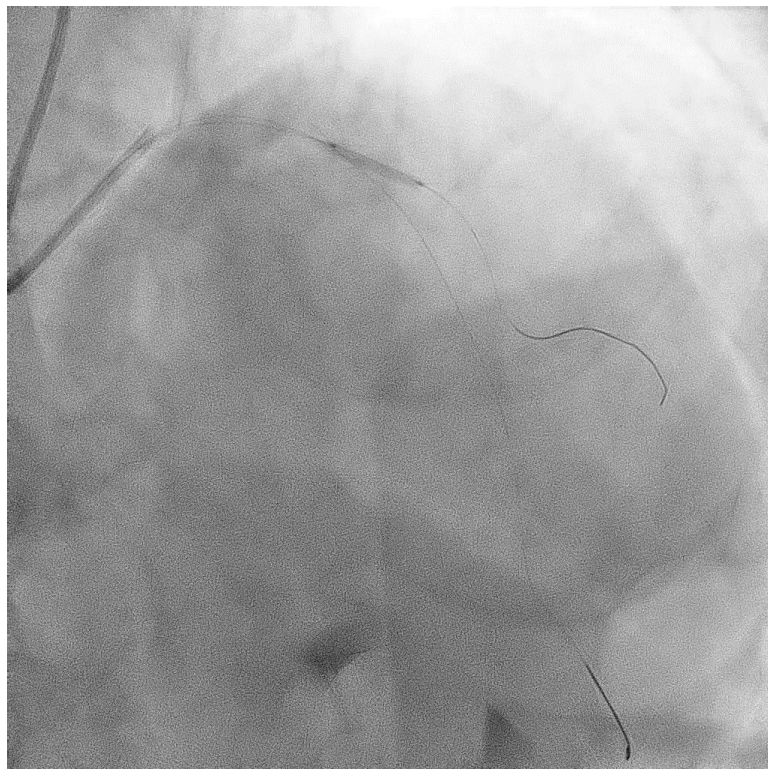
VP con ligera enfermedad distal

VP Distal



Stenting de RL a VP

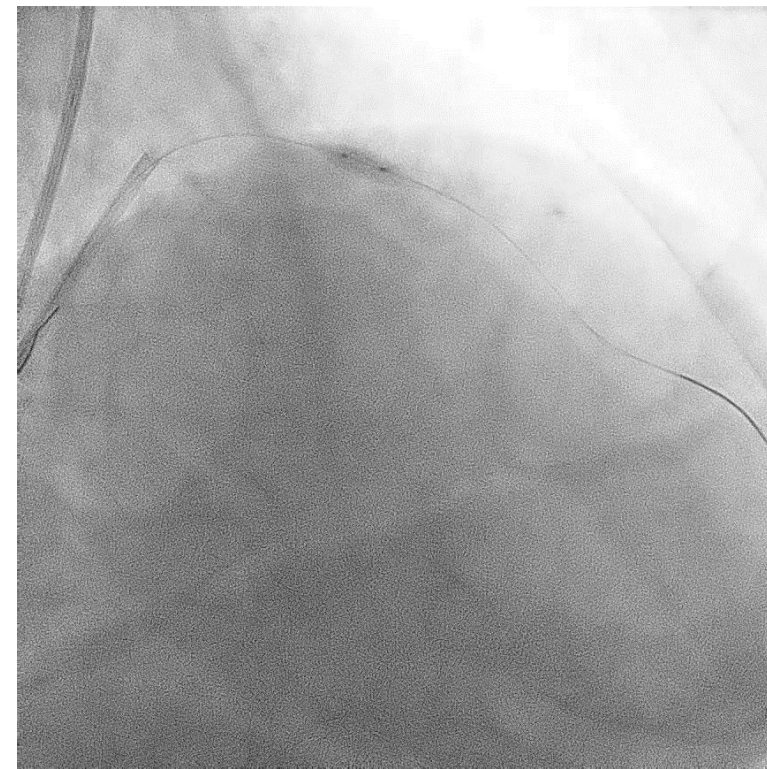
Balón a Dg



DES en DA-Dg

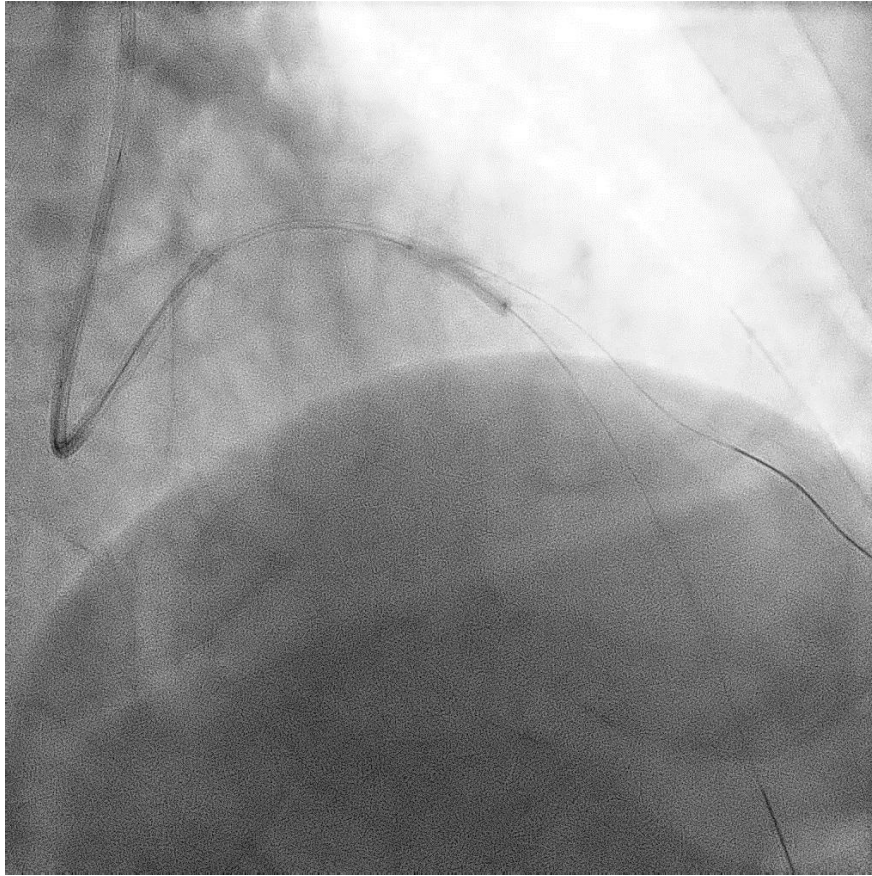


POT en DA



Angiolite 2.5/19 mm

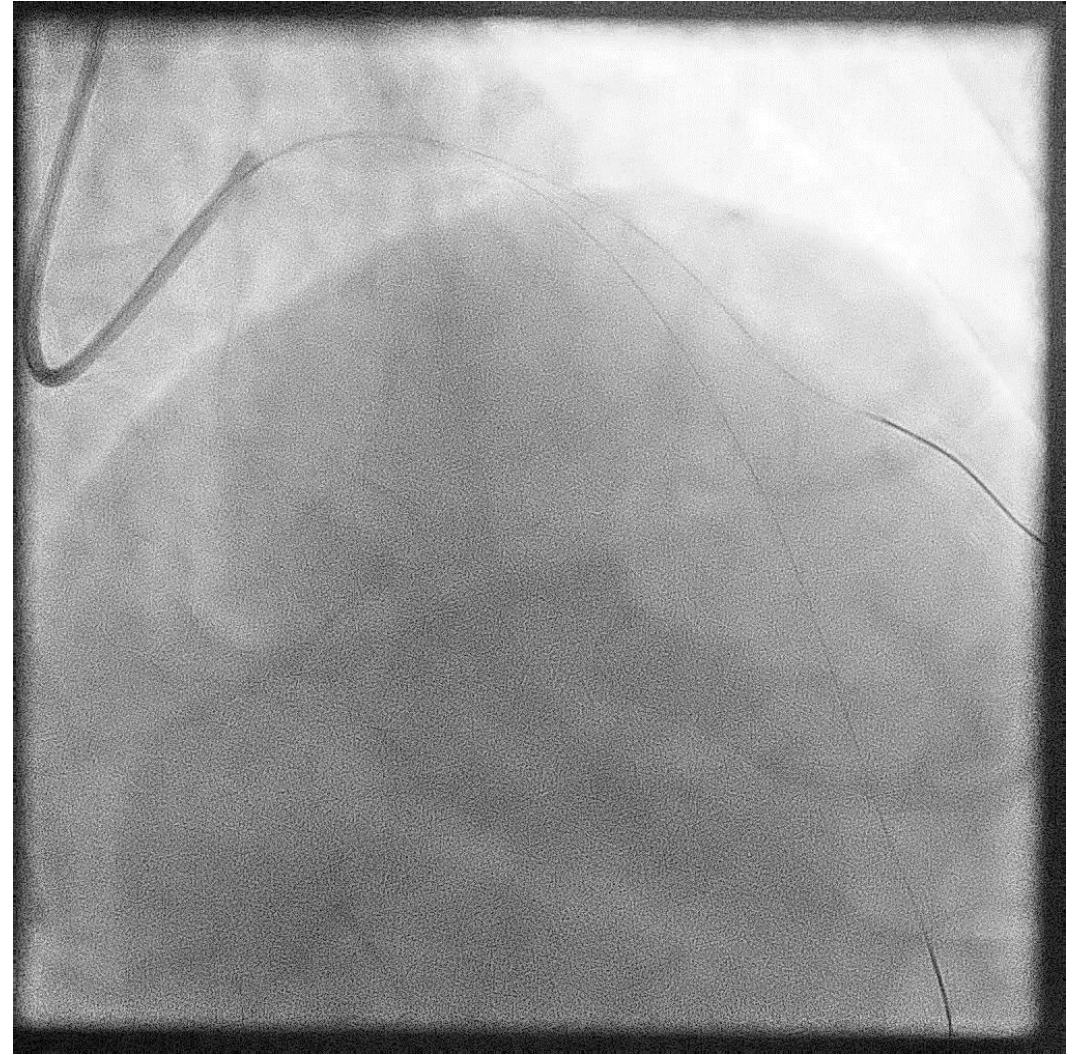
Balon 3 mm

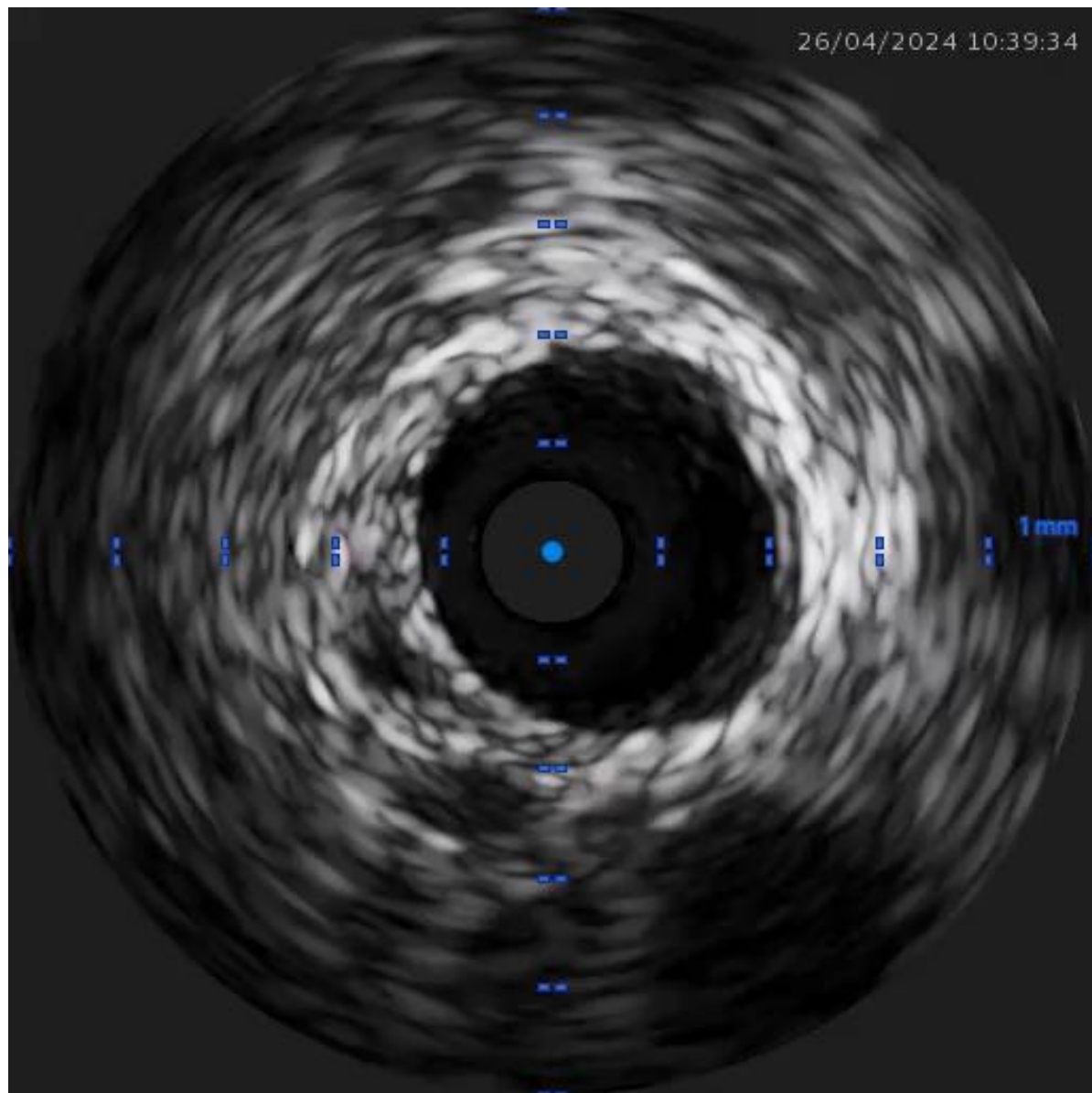


Balón a DA

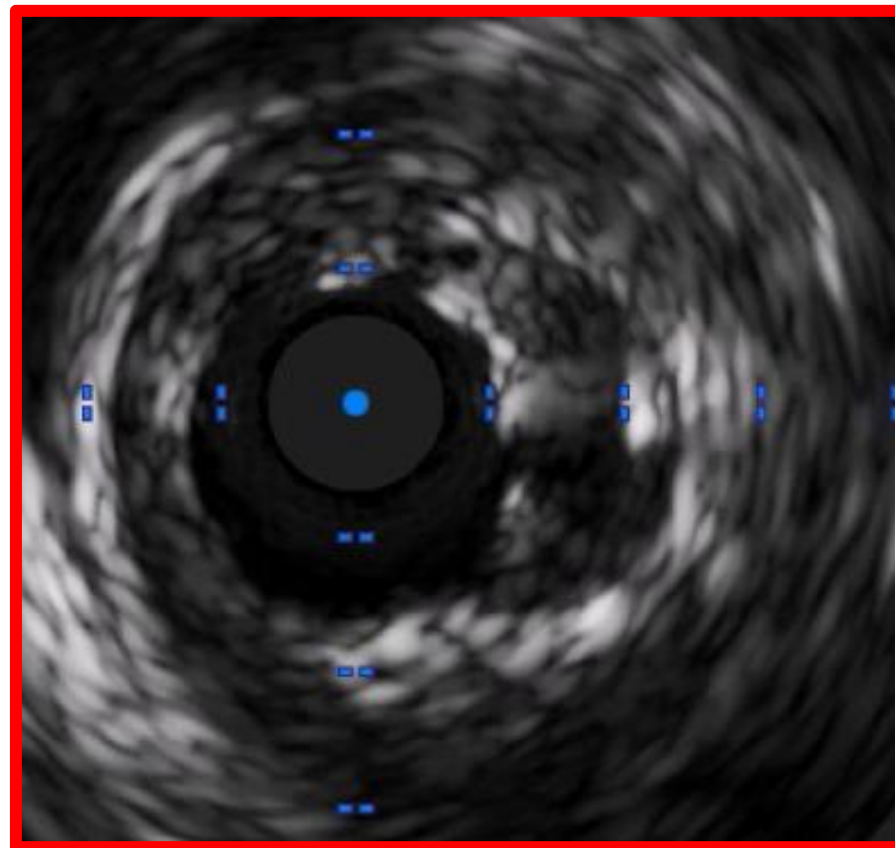
DCB a DA

(Essential pro 2.5 mm)



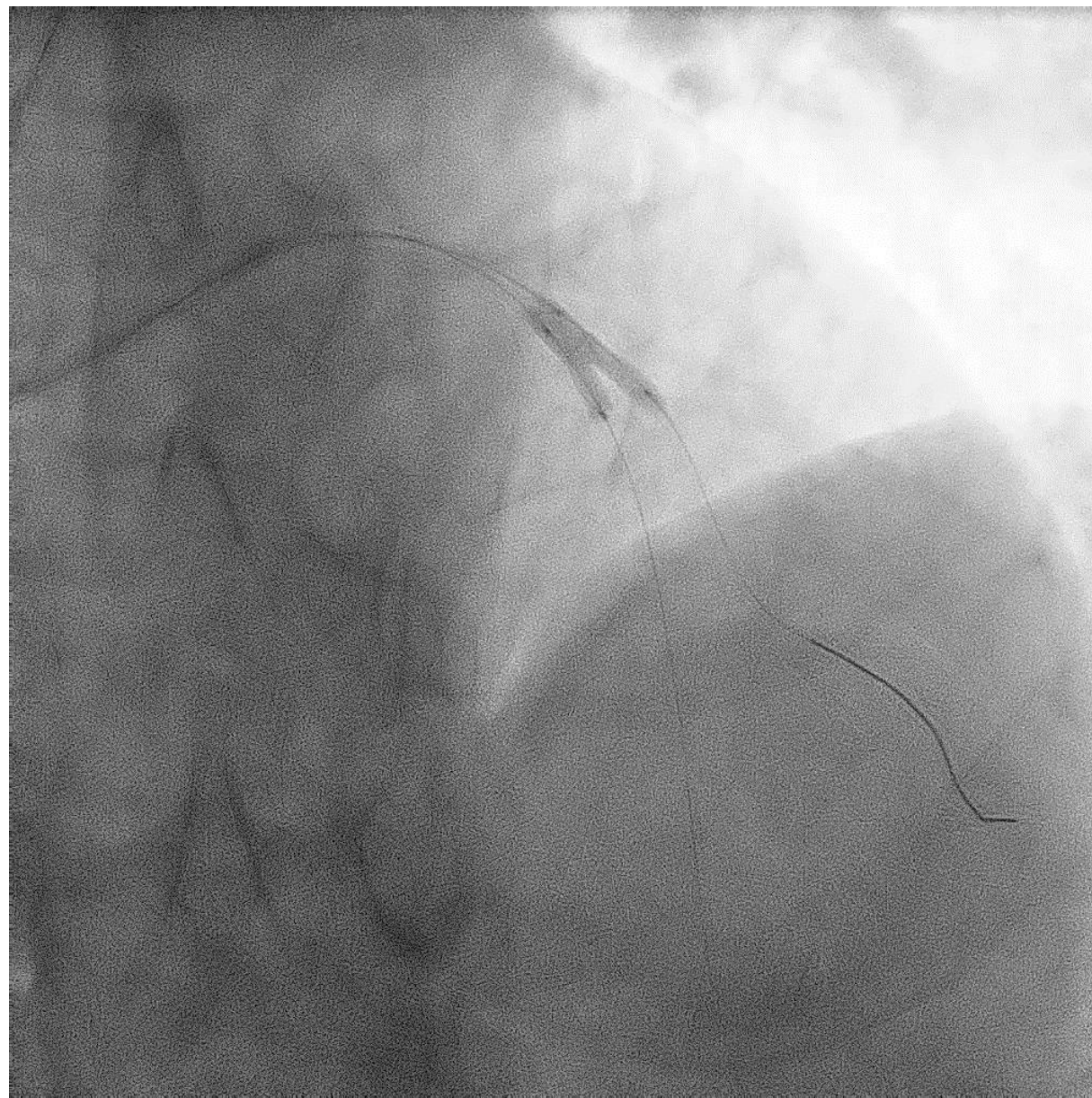


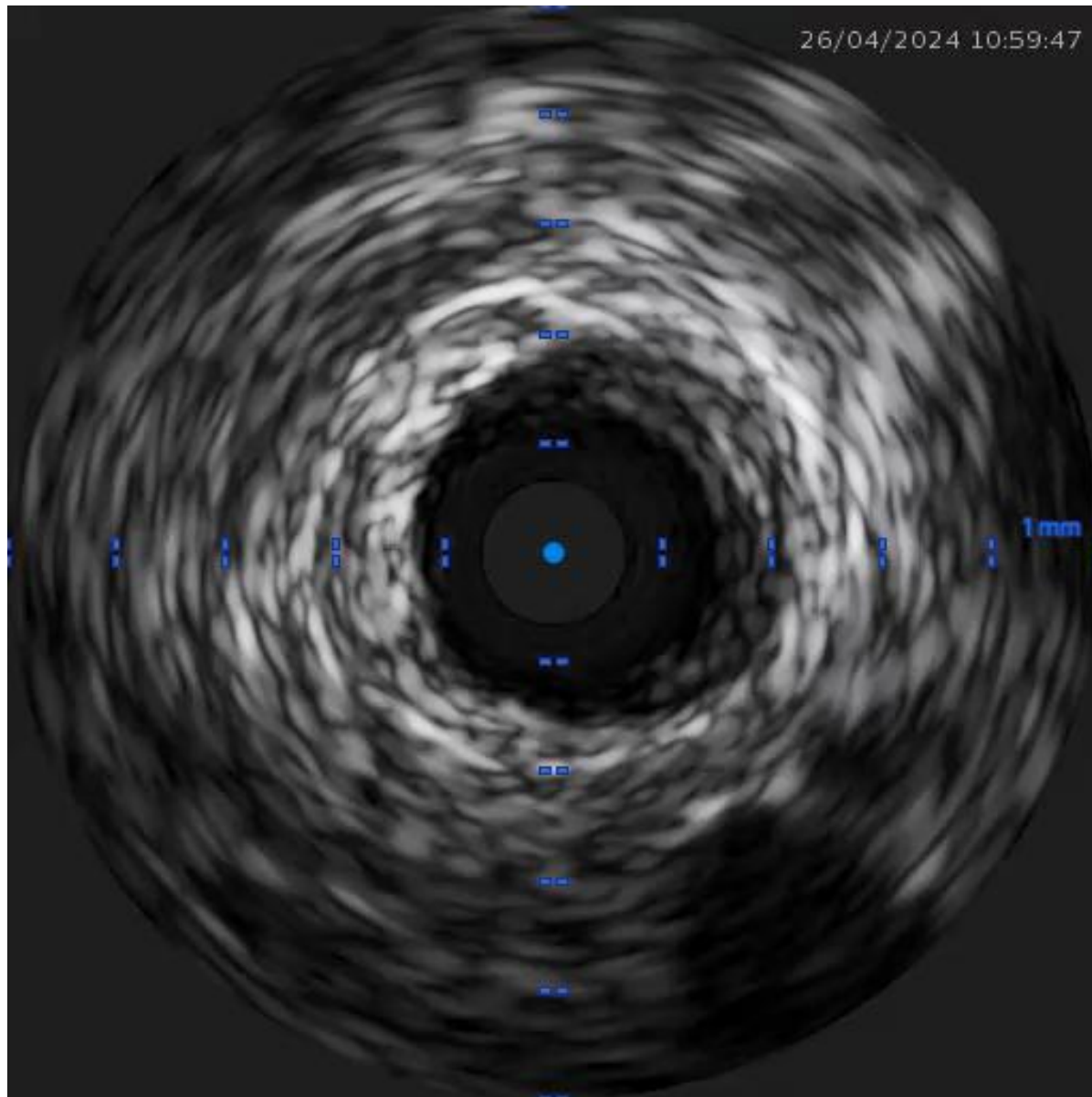
Pre-KB



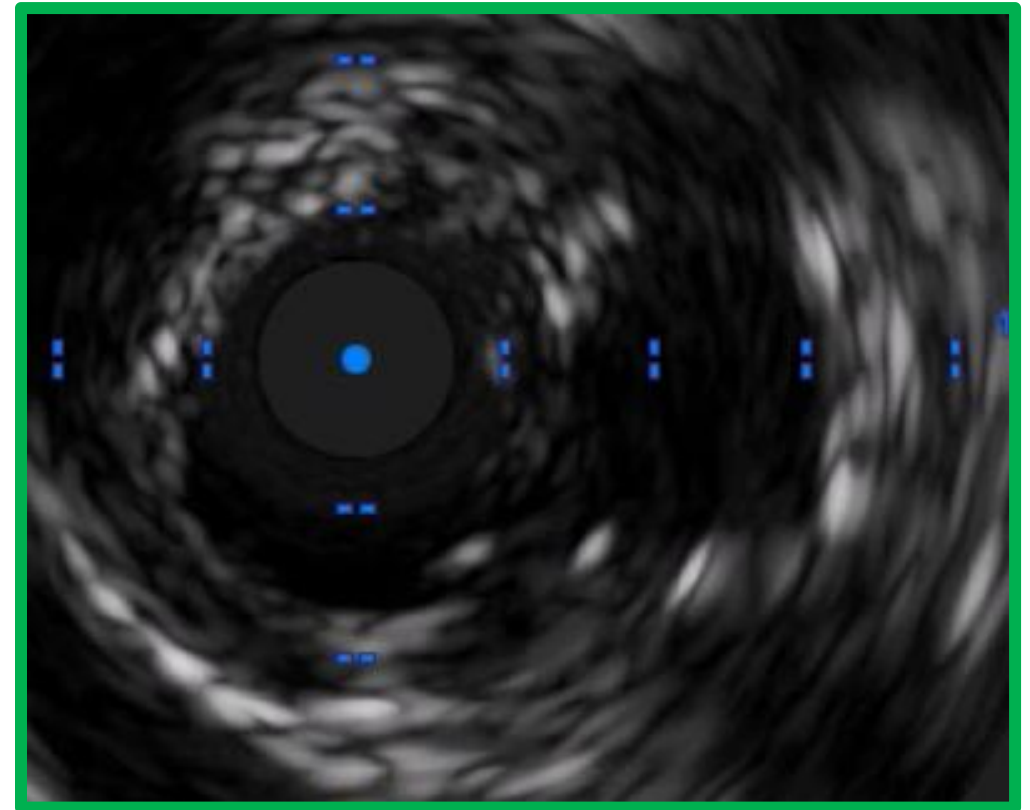
FKB

Xperience pro
2.5 / 2.5 mm

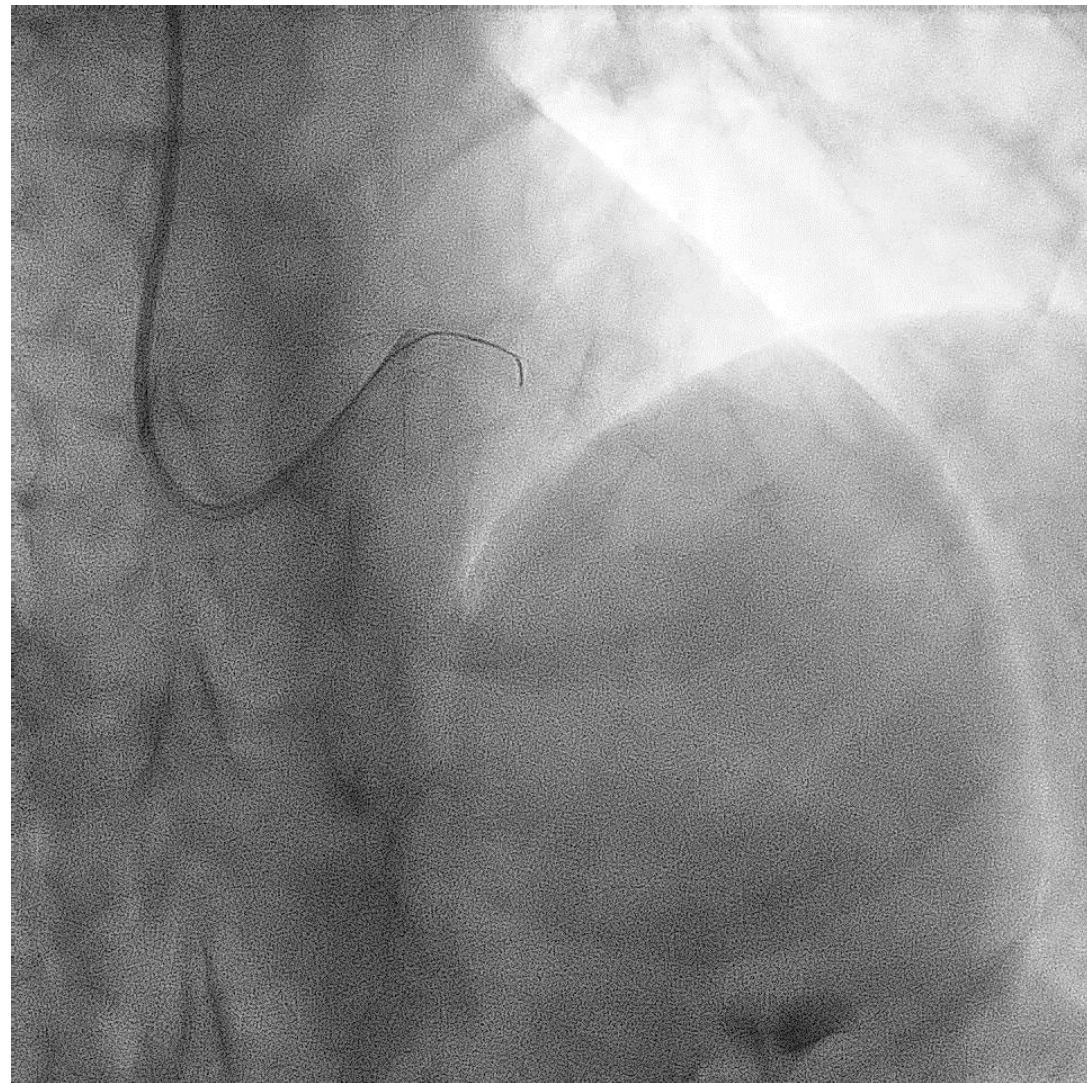
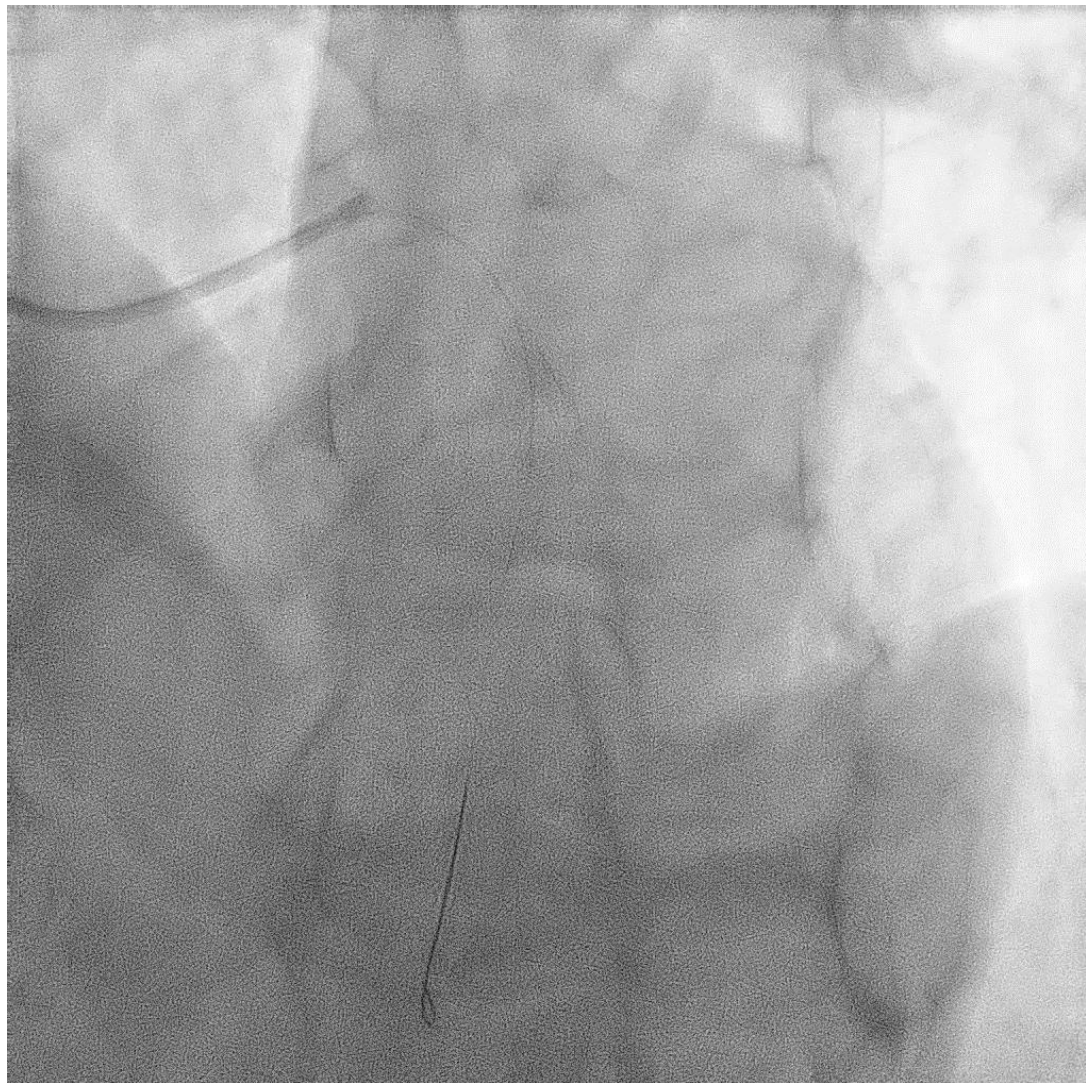




Post-KB



FINAL



Essential pro DCB en Bifurcaciones

*Experiencia en H. U. M. de Valdecilla
Santander, Spain*



HUMV *Essential pro-DCB* en Bifurcaciones

Variable	(N= 50)
Age	71 ±10,80
Women	15%
Men	85%
Hypertension	63%
Diabetes Mellitus	32%
Dyslipidemia	71%
Smoker	
Active	36%
Former	38%
GFR	71±21,5
Hepatic disease	8%
Previous Stroke	10%
<i>Stroke type</i>	
Ischemic	6%
TIA	4%
COPD	10%
PAD	14%
Previous ACS	14%
Previous PCI	40%

HUMV *Essential pro-DCB* en Bifurcaciones

Variable	(N = 50)
<i>Index Event</i>	
Chronic Coronary Syndrome	18%
NSTEMI	38%
STEMI	38%
Other (valvular)	4%
LVEF	48 ±11
LVEF <40%	24%
Movility alts.	81%
<i>Coronary Angiography findings</i>	
1 vessel disease	40%
2 vessel disease	24%
3 vessel disease	34%
<i>Diseased vessel</i>	
LMA	34%
LAD	71%
CX	18%
RCA	8%

Essential pro DCB in SB
 Mean diameter of 2.38 m

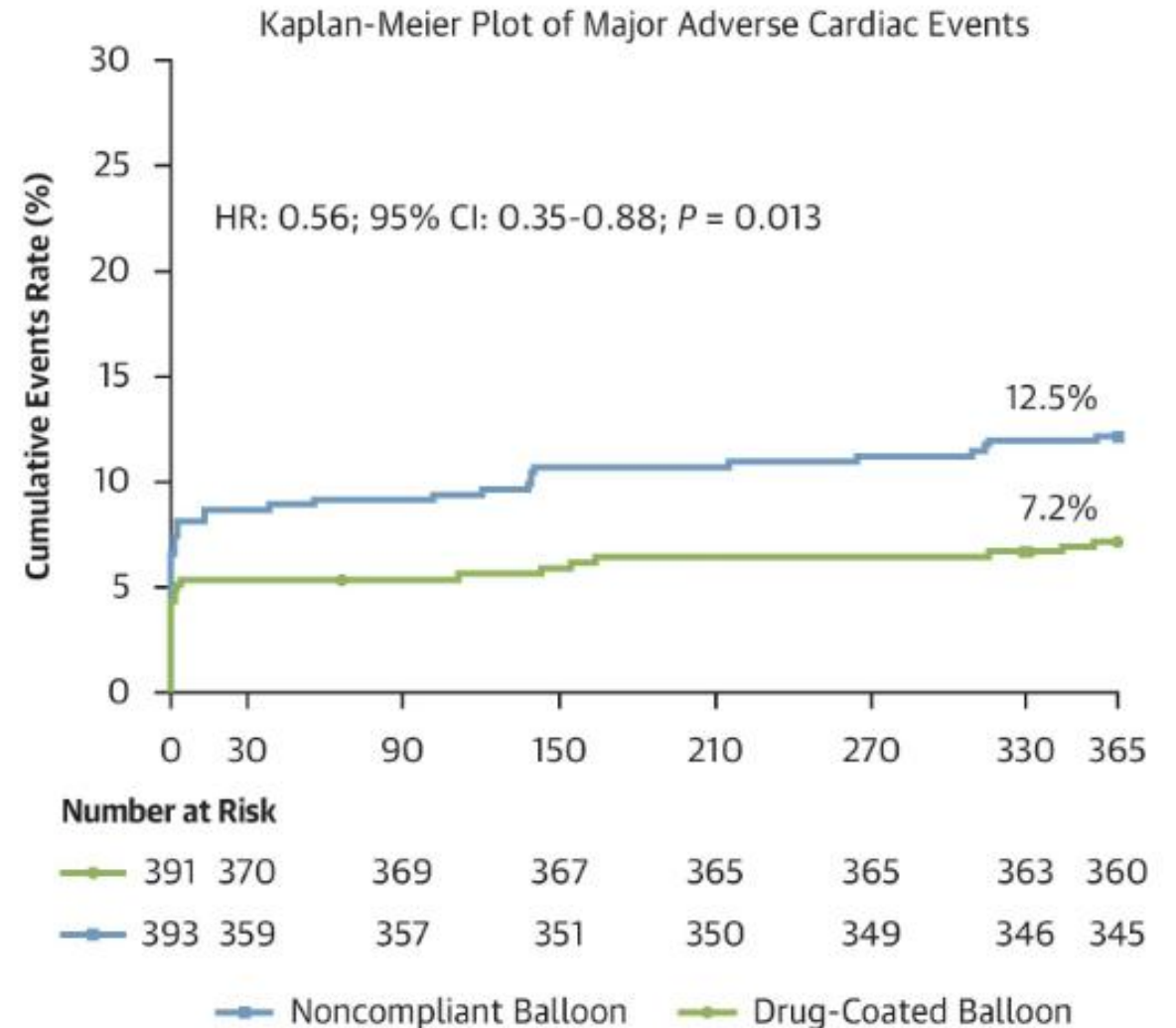
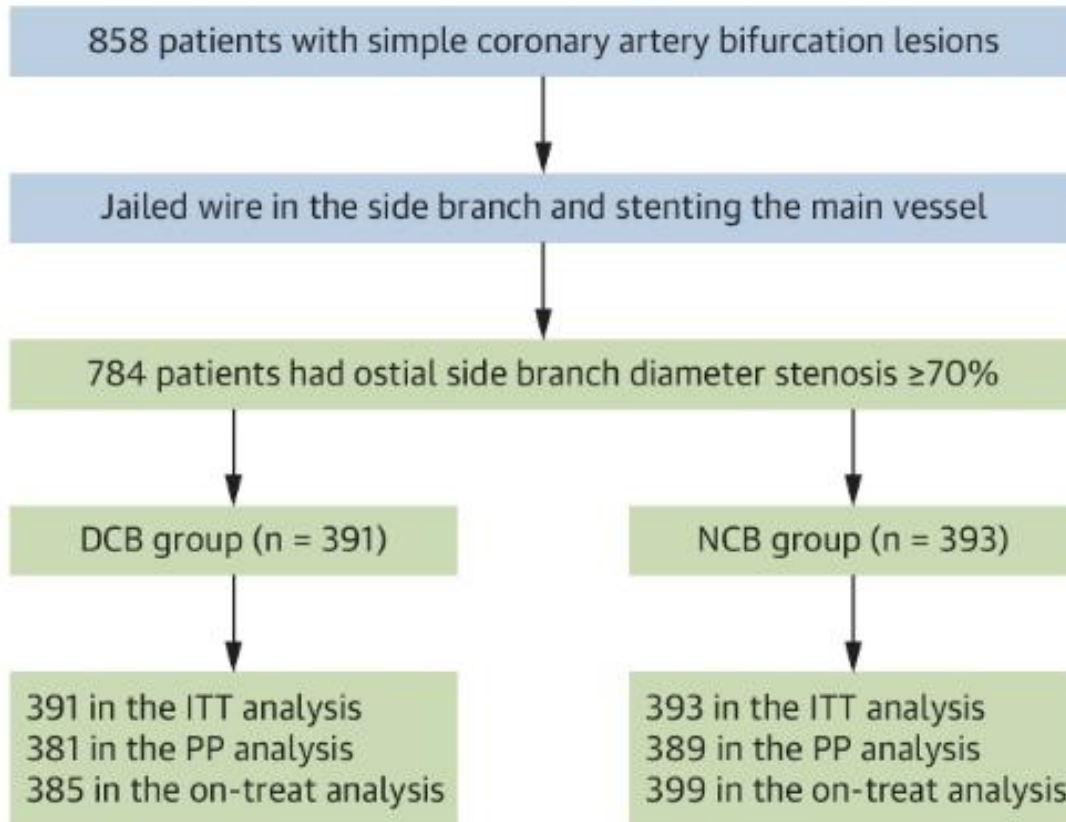
Angiolite DES in MB
 Mean size 3 mm / 19 mm

MACE en seguimiento (24 ± 11 meses)

	N = 50
Cardiovascular death	2%
Myocardial infarction	2%
Revascularization	6%
TLR	2%
Major bleeding	6%
Stroke	2%

DCB-BIF trial

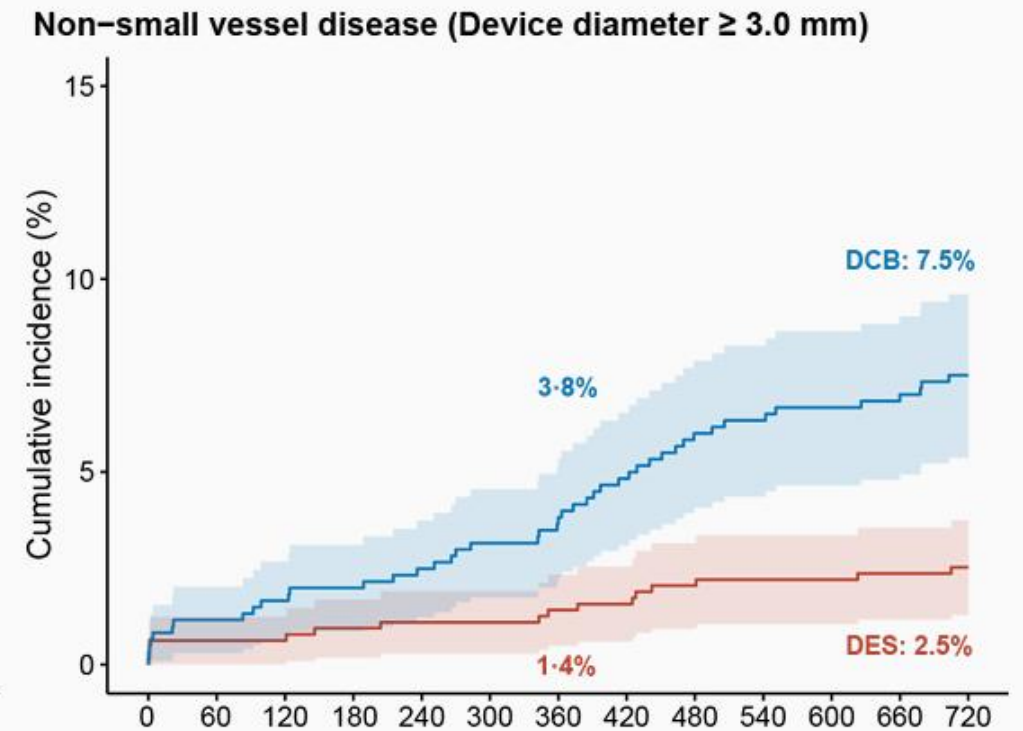
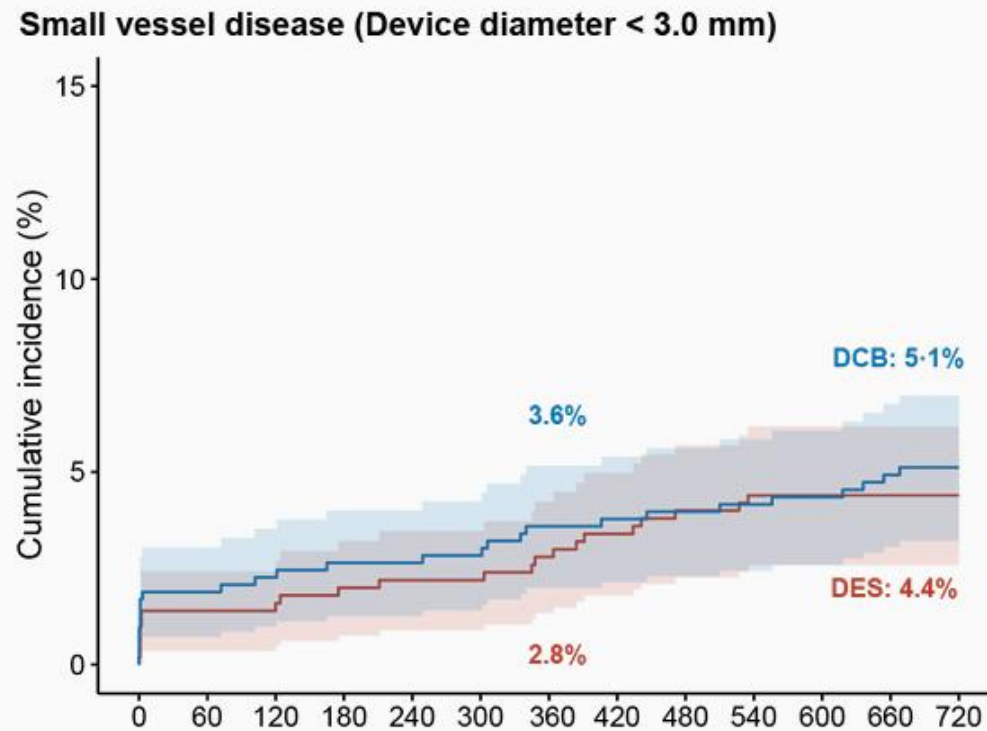
En bifurcaciones con stent provisional, el uso de DCB para la RL comprometida redujo los MACE a 1 año en comparación con el uso de NCB para la RL.



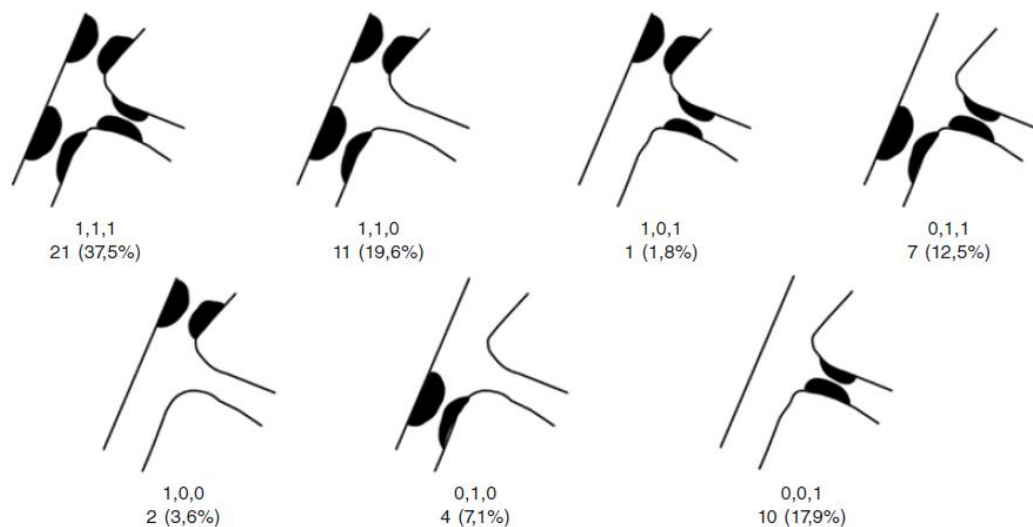
DCB with rescue stenting versus intended stenting for de novo CAD: a multicenter, non-inferiority trial

The REC-CAGEFREE I Study

SVD vs non-SVD subgroup (DoCE, ITT)

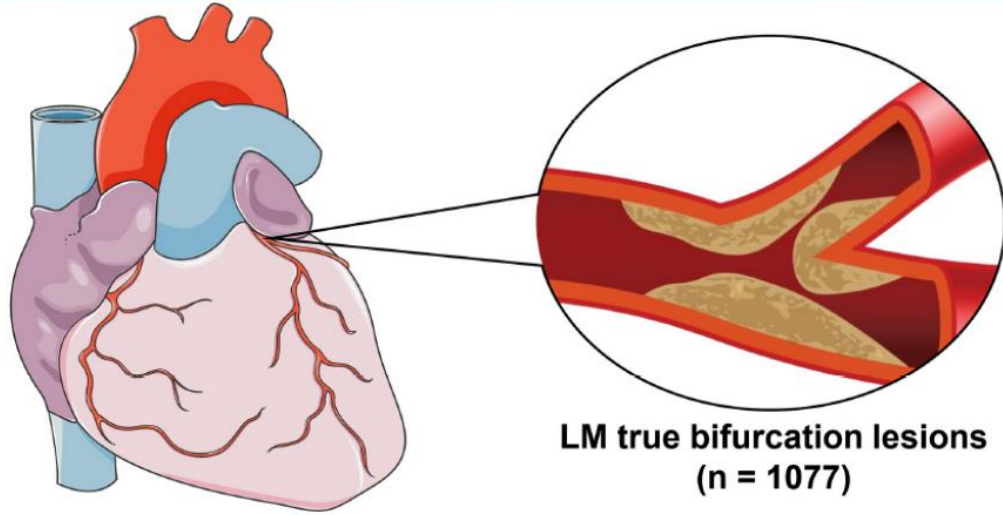


Long-term effectiveness of drug-coated balloon in the side branch treatment of bifurcation lesions



N	54/55
Follow-up days	377 ± 244 [range, 79-734]
All-cause mortality	2/54 (3,7%)
Cardiac death	1/54 (1,8%)
Myocardial infarction/target lesion device thrombosis	0/55 (0%)
Target lesion revascularization	2/55 (3,6%)
Target vessel failure outside the target lesion	0/55 (0%)
Revascularization of other lesions outside the target vessel	5/54 (9,3%)

DCB in treatment of LM true bifurcation lesions: A patient-level propensity-matched analysis

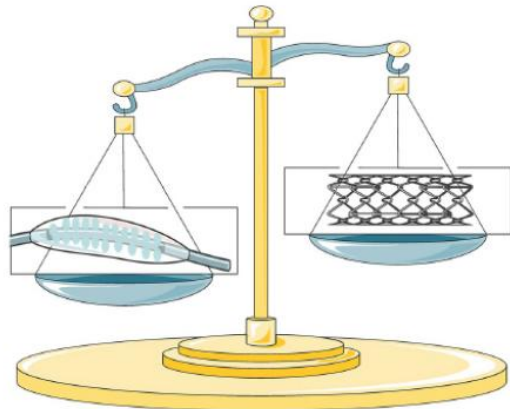


LM true bifurcation lesions
(n = 1077)



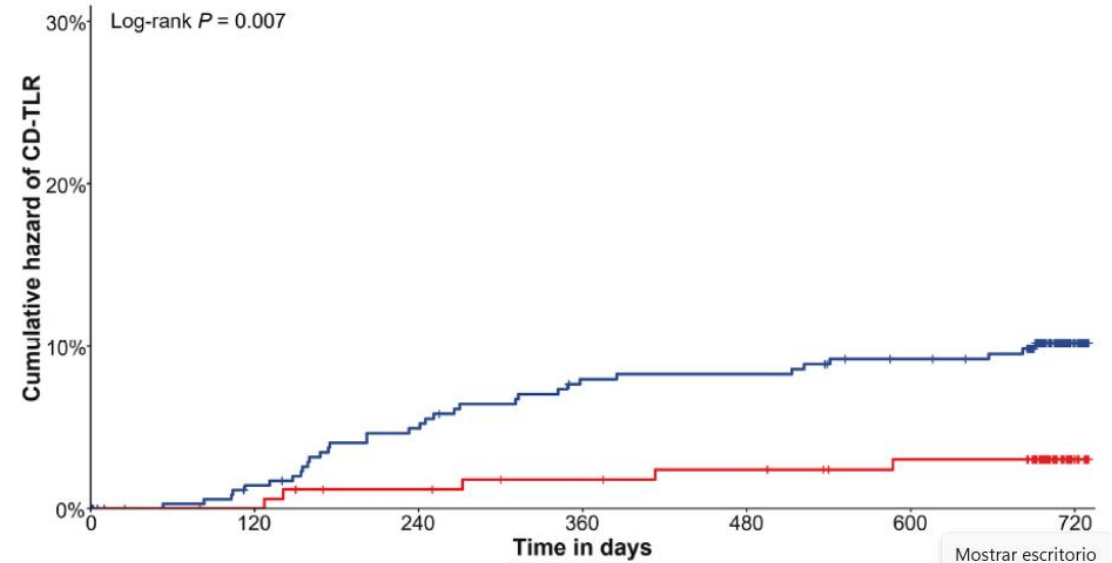
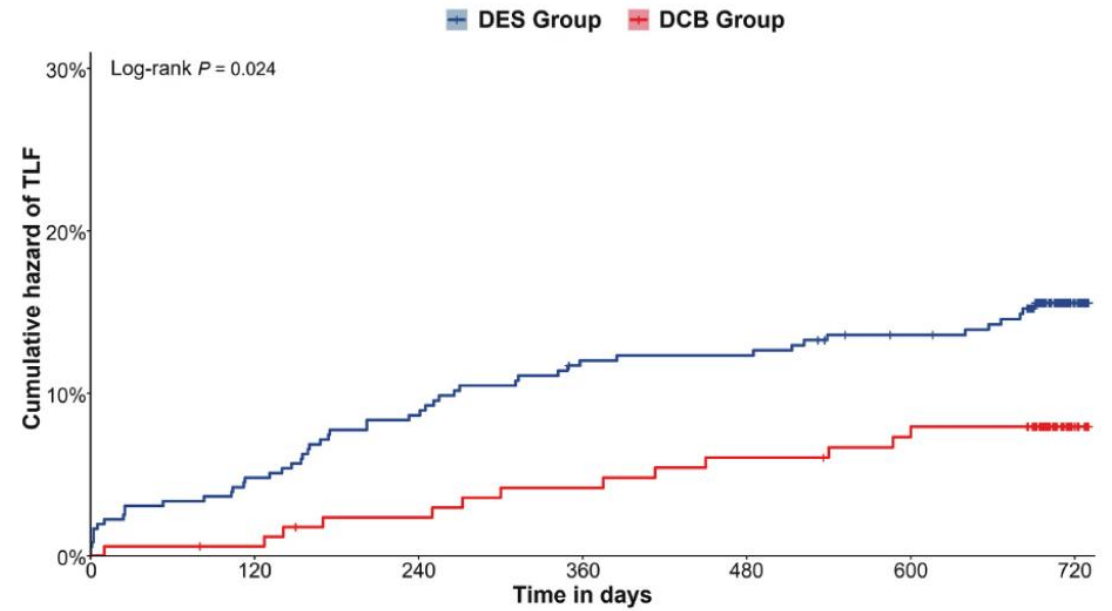
DCB group

- Hybrid (DCB+DES)
- n = 199



DES group

- Provisional stenting
- 2-stent strategies
- n = 398

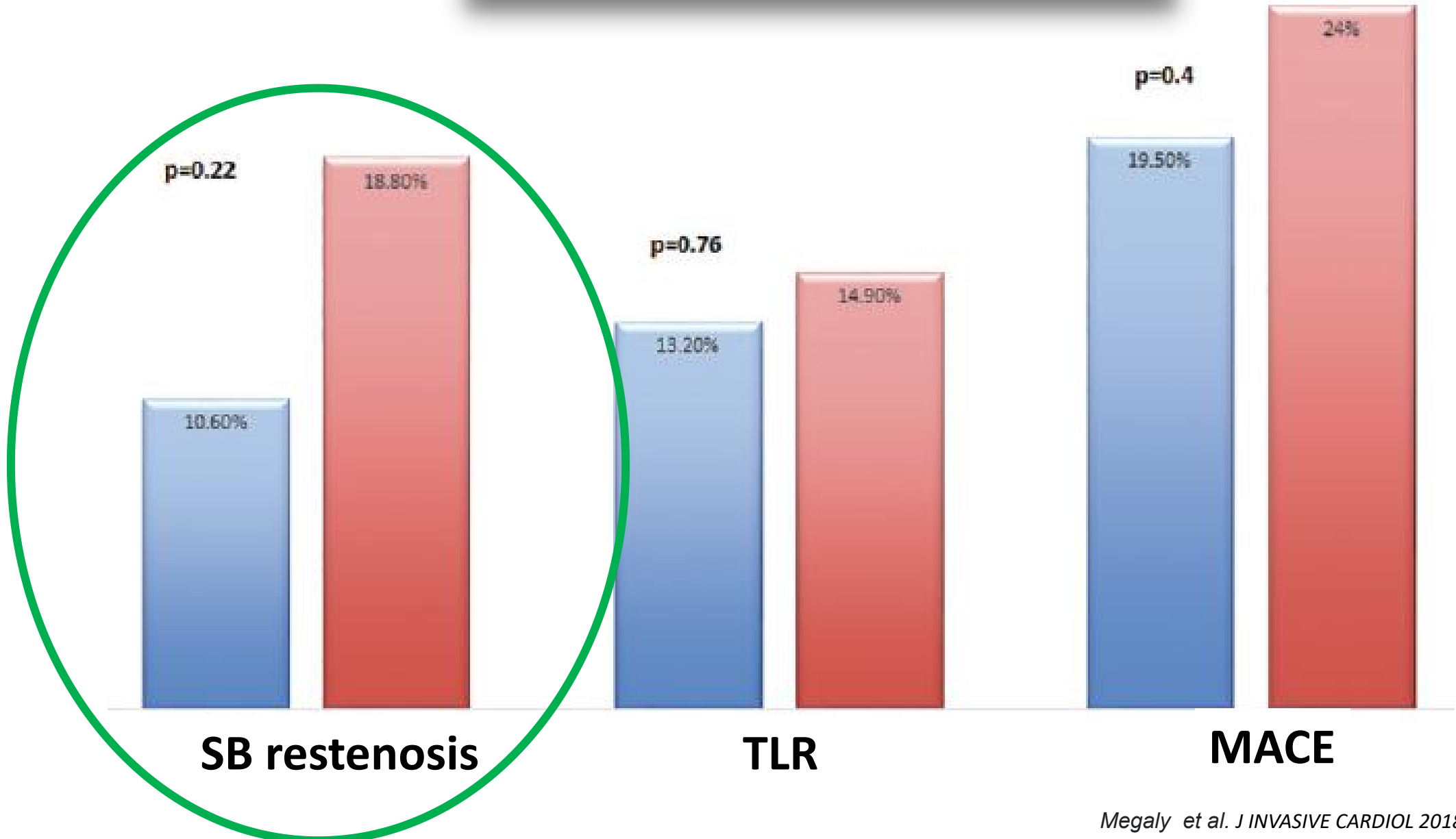


Mostrar escritorio

DCB vs BA

ORIGINAL CONTRIBUTION

Outcomes With Drug-Coated Balloons for Treating the Side Branch of Coronary Bifurcation Lesions



CONCLUSIONES

Los **DCB** son una alternativa muy atractiva para el tratamiento de las **bifurcaciones**, especialmente para el tratamiento de la rama lateral en las técnicas de stent provisional.

El alto riesgo hemorrágico puede ser un factor promotor del uso.

El ***Essential pro DCB*** ha demostrado ofrecer excelentes resultados en vasos pequeños y en RIS.

En nuestra experiencia local, estos resultados del ***Essential pro DCB*** son transferibles a las bifurcaciones, donde se ha observado una TLR del 2% en 50 casos con rama lateral tratada con DCB y vaso principal con ***Angiolite DES***.

REC Interv Cardiol. 2023;5(1):1-4

<https://doi.org/10.24875/RECICE.M22000341>

Editorial

Current state of knowledge on the use of drug-coated balloon in coronary bifurcation lesions

Estado actual del conocimiento sobre el uso del balón farmacactivo en las lesiones en bifurcación

José Ramón López-Mínguez,* and Rosa Navarro Romero

Departamento de Cardiología, Hospital Universitario de Badajoz, Badajoz, Spain



No randomized studies

Trial	Name or author and DCB	No. of patients	LLL TLR events, and restenosis	Restenosis, and MACE
DCB into both branches and BMS into the main branch	PEPCAD-V ⁴ (Sequent Please B. Braun, Germany)	28	0.21 ± 0.48 in the SB 0.38 ± 0.46 mm in the MB Only 1 TLR (3.57%) and 3 restenoses (10.7%)	2 patients (7.14%) had late thrombosis at 6 and 8 months
Paclitaxel DES into the MB, and DCB into the SB	DEBSIDE (NCT01485081) (Danubio, France)	50	LLL in the SB: -0.04 ± 0.34 mm and in the MB: 0.54 ± 0.60 mm TLR in 1 patient (2%) Restenosis, 7.5.	1 AMI (2%) without cardiac deaths
-limus DES into the MB, and DCB into the SB	BIOLUX-A (www.anzctr.org.au, ID 335843) (Pantera Lux, Biotronik AG, Switzerland)	35	LLL in the SB: 0.1 ± 0.43 mm 1 TLR (2.85%) No restenosis	1 patient died, and 3 AMIs were reported in different vessels
	SARPEDON ⁵ (Pantera Lux, BIOTRONIK AG, Bülach, Switzerland)	50	TLR, 5.2% at 1 year 4% of restenosis in the MB, and 6% in the SB	Stent thrombosis, 0%
	Estudio de Valencia et al. ⁶ (Sequent Please)	54	TLR, 3.6%	Overall mortality, 3.7%
DCB alone into both branches	Schulz et al. ⁷ (Sequent Please)	39	10% restenosis, and all in the left main coronary artery bifurcation	
	Bruch et al. ⁸ (Sequent Please)	127	TLR, 4.5	MACE, 6.1% Use of bailout stent in 45%
DCB alone into 1 branch	Her et al. ⁹ (Sequent Please) (Only in the MB)	16	There was a significant increase in the SB luminal area at 9 months, 0.37 mm ² ± 0.64 mm ² ; (<i>P</i> = .013), with a similar increase in the MB luminal area	The use of DCB alone in the MB also had a favorable impact on an area gain of 52% in the SB ostium
	Vaquerizo et al. (NCT01375465) (Eurocor GmbH, Germany) (Only in the SB and 001 lesions)	31	LLL in the SB, 0.32 mm ² ± 0.73 mm ² , and binary restenosis, and TLR of 22.5%	High need for bailout BMS (14%) 1 AMI (3.2%)

Randomized studies

Trial	Name and no. of patients	LLL	Restenosis and MACE, TLR events	Takeaway
DCB alone vs CB as a first-line therapy in lesions without damage to the proximal segment	PEPCAD-BIF ¹⁰ (Sequent Please) 64 patients	LLL in the DCB group, 0.08 mm ± 0.31 mm vs 0.47 ± 0.61 mm in the CB group (<i>P</i> = .006).	Rates of restenosis of 26% vs 6% Rates of TLR of 9% vs 3% Favorable to DCB	In this type of lesions, stents were required in < 10% of the cases only
DCB vs CB in the SB with the use of BMS in the MB	DEBIUT ¹¹ (Dior-I, Eurocor GmbH, Germany) 117 patients A) DCB in both branches and BMS in the MB B) BMS in the MB, and CB in the SB C) Paclitaxel DES in the MB, and CB in the SB	LLL in the SB was 0.19 mm ± 0.66 mm in group A, 0.21 mm ± 0.57 mm in group B, and 0.11 mm ± 0.43 mm in group C (<i>P</i> = .001) LLL in the MB, 0.31 mm ± 0.48 mm in group A vs 0.16 mm ± 0.38 mm in group B (<i>P</i> = .15)	The rates of binary restenosis were 24.2%, 28.6%, and 15%; (<i>P</i> = .45), and the rates of MACE were 20%, 29.7%, and 17.5%; (<i>P</i> = .40) in groups A, B, and C, respectively	With this strategy, pretreatment of both branches with DCB was not superior to conventional BMS with the provisional stenting technique. Also, the use of DES was superior to DCB plus BMS
	BABILON ¹² (Sequent Please) 108 patients A) DCB in both branches, and BMS in the MB B) Everolimus DES in the MB, and CB in the SB	LLL in the SB, -0.04 mm ± 0.76 mm in group A vs -0.03 mm ± 0.51 mm in group B (<i>P</i> = .983)	The rates of MACE and TLR were higher in group A in the MB (17.3% vs 7.1% [<i>P</i> = .10], and 15.4% vs 3.6%; [<i>P</i> = .045]) due to more restenosis in the MB (13.5% vs 1.8%; <i>P</i> = .027)	Bifurcation pretreatment with DCB with BMS in the MB had more LLL and higher rates of MACE vs DES in the MB and CB in the SB Also, both strategies gave similar and very good results in the SB
Paclitaxel DES in the MB with CB vs DCB in the SB	Herrador et al. ¹³ (Sequent Please) 50 patients	LLL, 0.40 mm ± 0.50 mm vs 0.09 mm ± 0.40 mm, (<i>P</i> = .01) favorable to the DCB group	The rates of SB restenosis were 20% vs 7%, (<i>P</i> = .08), and the rates of TLR, 22% vs 12% (<i>P</i> = .16)	The rates of MACE at 12 months were 24% vs 11% (<i>P</i> = .11)
-limus DES in the MB with CB vs DCB in the SB	BEYOND ¹⁴ , (Bingo, Yinyi Biotech, China) 222 patients with coronary bifurcation lesions excluding the left main coronary artery	Significantly lower LLL in the DCB compared to the CB group (-0.06 mm ± 0.32 mm vs 0.18 mm ± 0.34 mm; <i>P</i> < .0001)	The rates of restenosis were 28.7% vs 40% (<i>P</i> < .0001)	No differences regarding MACE (0.9% vs 3.7%, <i>P</i> = .16) or non-fatal AMI were found (0% vs 0.9%, <i>P</i> = .49)
	Li et al. ¹⁵ (Sequent Please) NON-randomized	LLL of SB in the DCB group was lower compared to the CB group (0.11 mm ± 0.18 mm vs 0.19 mm ± 0.25 mm; <i>P</i> = .024) at 12-month follow-up	Multivariate COX analysis indicated that the DCB group had less MACE (23.9% vs 12.8%; <i>P</i> = .03)	Better results in the SB with DCB and fewer composite endpoints, but basically at the expense of unstable angina

Outcomes With Drug-Coated Balloons for Treating the Side Branch of Coronary Bifurcation Lesions

Table 1. Baseline characteristics of the included studies.

	Mingues et al. [BABILON]	Herrador et al.	Stella et al. [DEBIUT]	Kleber et al. [PEPCAD BIF]
Year	2014	2013	2012	2016
Country	Spain	Spain	Four countries in Europe	Germany
Study design	RCT	Observational	RCT	RCT
Side branch definition	≥2 mm in diameter	>2.5 mm in diameter and <10 mm in length	>2 mm in diameter	Within 5 mm of bifurcation point, 2-3.5 mm in diameter, and <10 mm in length
Total study population	108 patients	100 patients	77 patients	64 patients
Intervention to main branch	BMS in DCB group and DES in the BA group	DES in both groups	BMS in both groups	No proximal main branch lesions
Study groups	52 DCB patients 56 BA patients	50 DCB patients 50 BA patients	40 DCB patients 37 BA patients	32 DCB patients 32 BA patients
Stenting performed	7.8% in DCB group 8.9% in BA group	10% in DCB group 4% in BA group	10% in DCB group 5.4% in BA group	0% in DCB group 18.8% in BA group
Type of side-branch stent (if used)	BMS in DCB group and DES in BA group	BMS in DCB group and DES in BA group	BMS in both groups	At the discretion of the interventionalist
Follow-up period	24 months	12 months	12 months	9 months
Type of DCB	SeQuent Please [B. Braun, Germany]	SeQuent Please [B. Braun, Germany]	Dior I [EuroCor, Germany]	SeQuent Please [B. Braun, Germany]
Angiographic follow-up	82.6% DCB 76.7% BA	80% DCB 86% BA	82.5% DCB 95% BA	78.1% DCB 71.9% BA

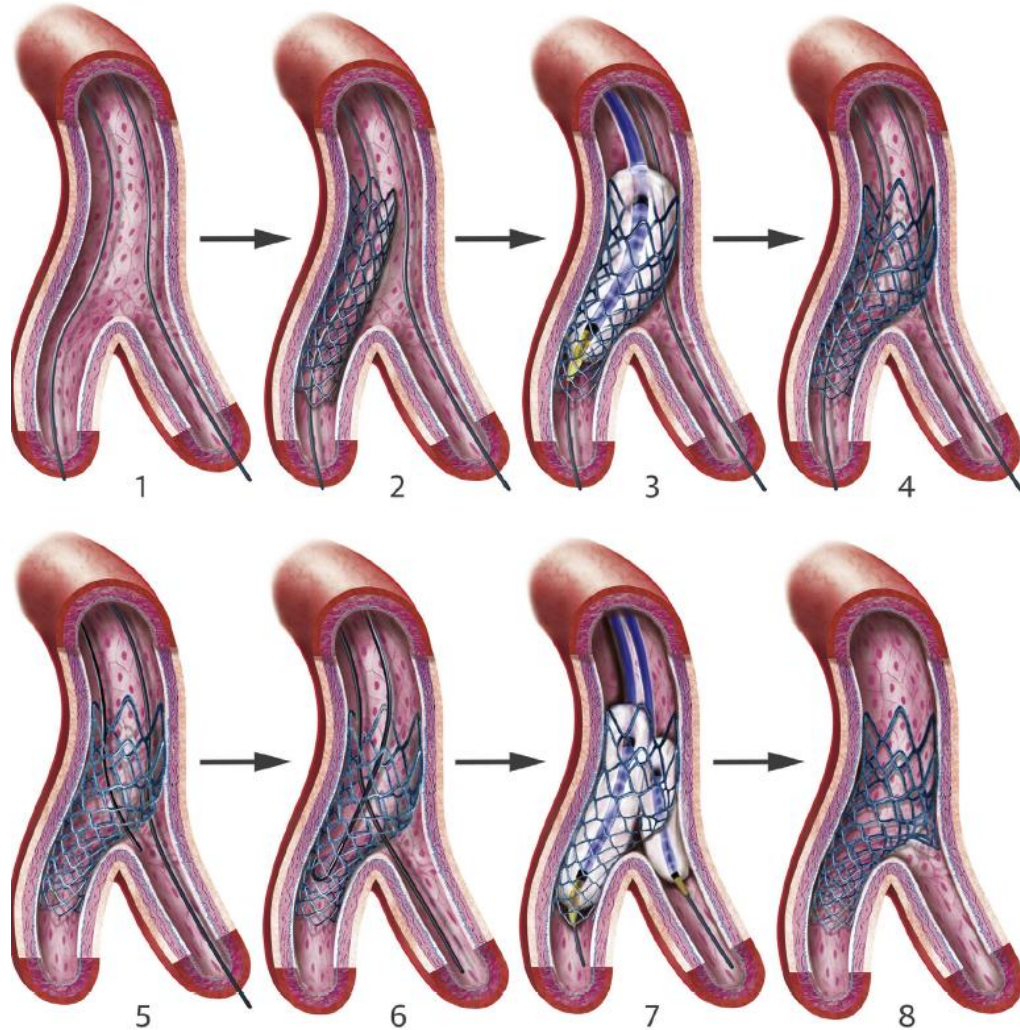
Results From the International Drug Coated Balloon Registry for the Treatment of Bifurcations. Can a Bifurcation Be Treated Without Stents?

Bruch et al. *J Interv Cardiol*.
2016 Aug;29(4):348-56.

Variable	All Patients	DCB Only	DCB + Stenting	P-value
Number of patients	127	70	57	-
In-hospital MACE	1 (0.8%)	1 (1.4%)	0 (0.0%)	0.365
In-hospital death	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
In-hospital MI	1 (0.8%)	1 (1.4%)	0 (0.0%)	0.365
In-hospital TLR	1 (0.8%)	1 (1.4%)	0 (0.0%)	0.365
Patients with 9-month follow-up	121 (95.3%)	66 (94.3%)	55 (96.5%)	0.560
Follow-up time (months)	9.8 ± 2.0	9.8 ± 1.8	9.8 ± 2.1	0.805
9-month MACE	8 (6.6%)	4 (6.1%)	4 (7.3%)	0.789
9-month death	2 (1.7%)	1 (1.5%)	1 (1.8%)	0.342
Cardiac	1 (0.8%)	0 (0.0%)	1 (1.8%)	
Non-cardiac	1 (0.8%)	1 (1.5%)	0 (0.0%)	
9-month MI	1 (0.8%)	1 (1.5%)	0 (0.0%)	0.359
9-month TLR	5 (4.1%)	3 (4.5%)	2 (3.6%)	0.802
9-month TVR	6 (5.0%)	3 (4.5%)	3 (5.5%)	0.819
9-month vessel thrombosis	0 (0.0%)	0 (0.0%)	0 (0.0%)	-

Provisional stent

2018 ESC/EACTS Guidelines on myocardial revascularization



Recommendations	Class ^a	Level ^b
<p><u>Stent implantation in the main vessel only, followed by provisional balloon angioplasty with or without stenting of the side branch, is recommended for PCI of bifurcation lesions.</u>^{654–658}</p>	I	A