USO DE BALON MEDICADO

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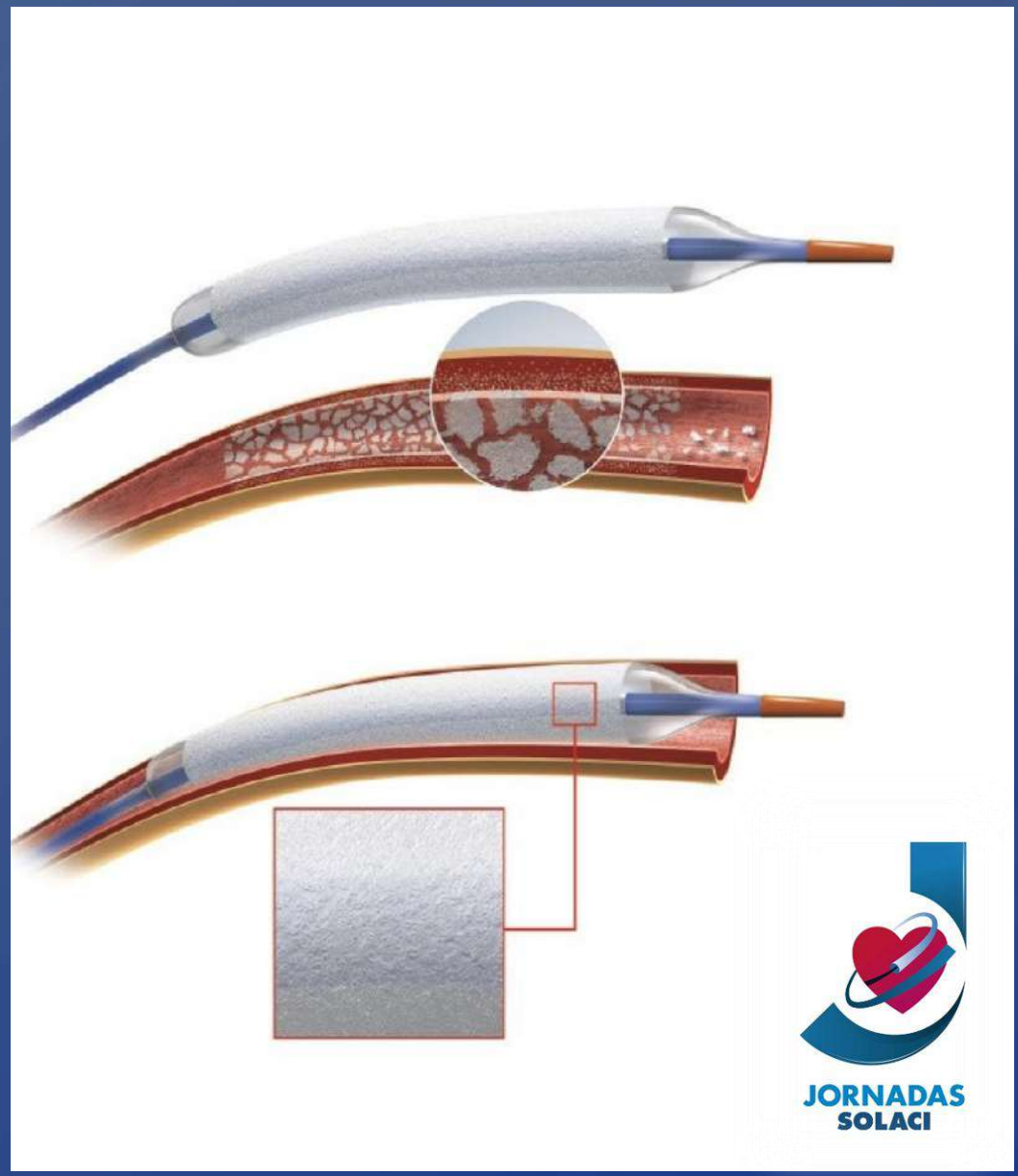
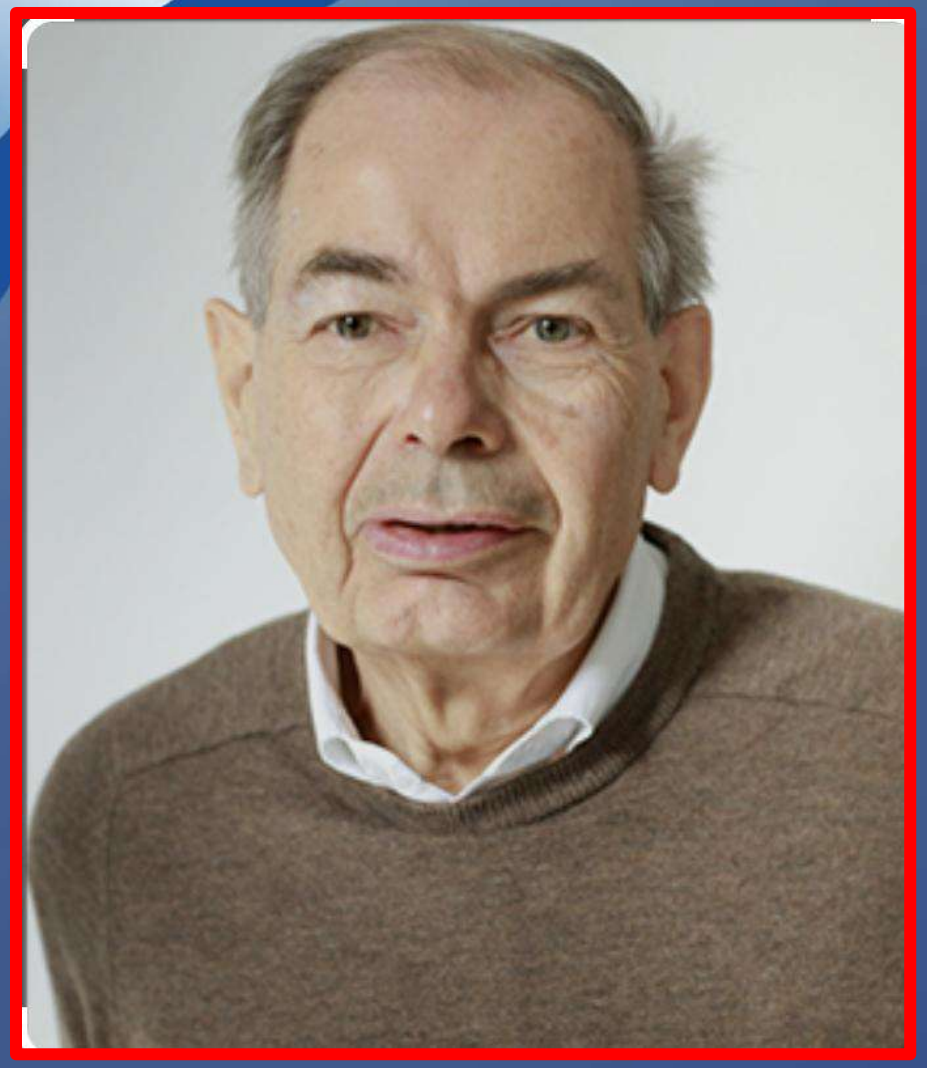


CONFLICTO DE INTERES

- NINGUNO



DR. ULRICH SPECK (CLARITE, BERLIN)

EN LOS 90’

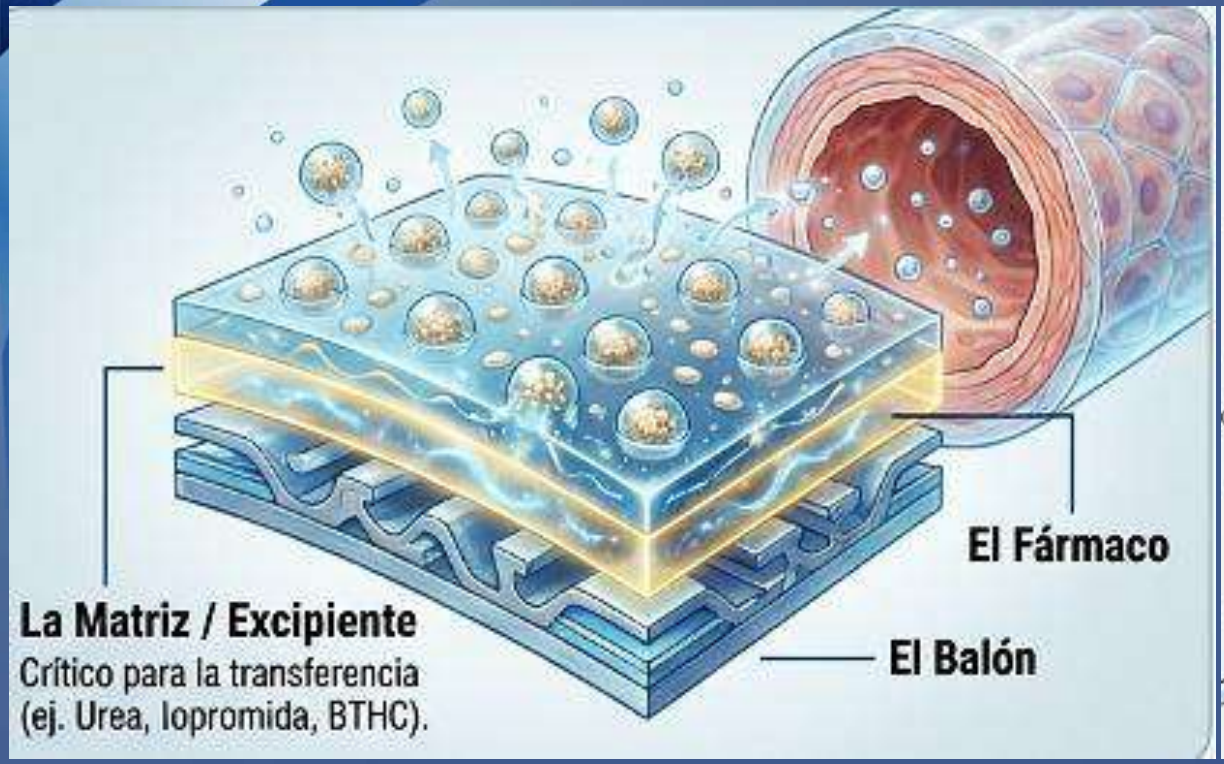
Demuestra transferencia rapida de

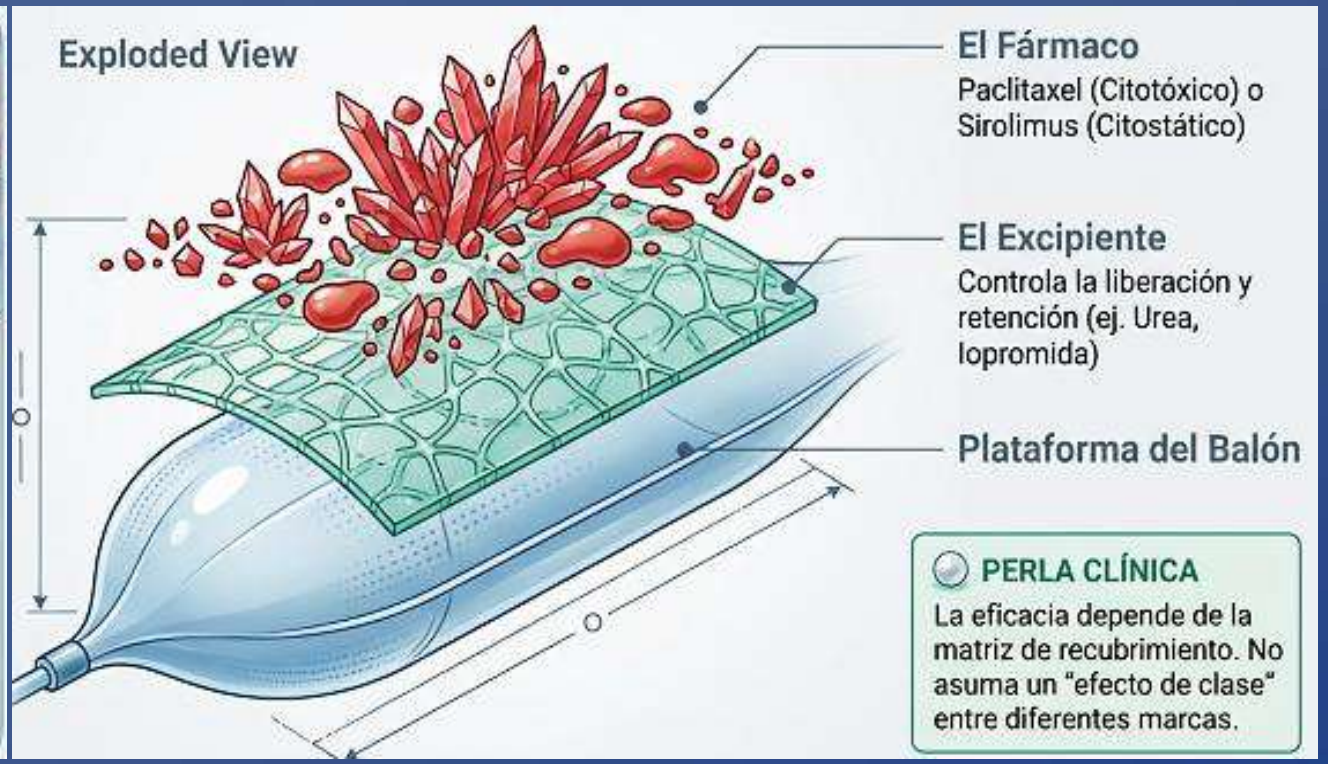
PACLITAXEL a la pared arterial

Introduce la idea de ATC farmacologica

sin implante

BALONES RECUBIERTOS CON FÁRMACOS





Paclitaxel

- Lipofilico, retención rápida
- Citotóxico (fase M)

Sirolimus

- Citostático (fase G1)
- Ventana terapéutica amplia

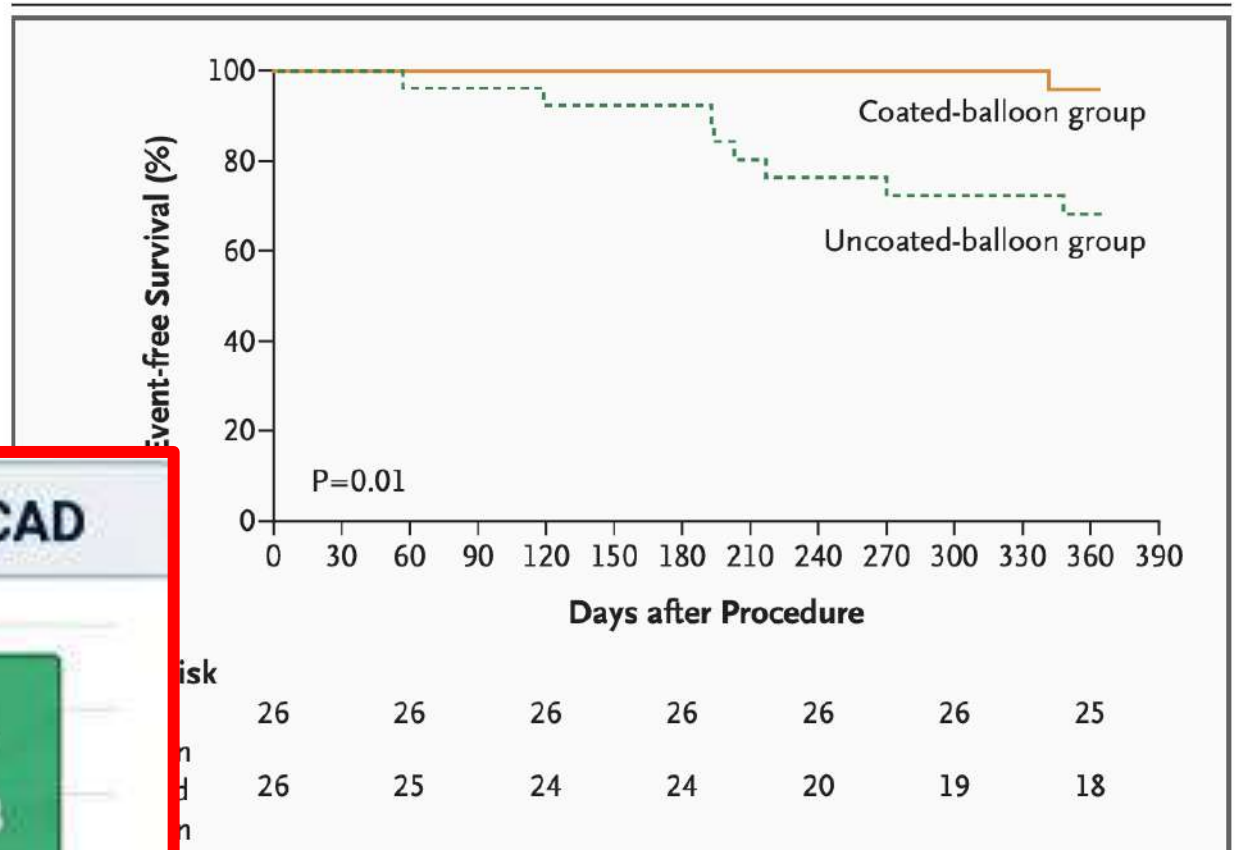
1. Yerasi C, Case BC, Forrestal BJ, Torguson R, Weintraub WS, Garcia-Garcia HM, et al. Drug-Coated Balloon for De Novo Coronary Artery Disease: JACC State-of-the-Art Review. J Am Coll Cardiol. 2020;75(9):1061-73.
2. Verde N, Ciliberti G, Pittorino L, Ferrone M, Franzese M, Russo M, et al. Contemporary Use of Drug-Coated Balloons for Coronary Angioplasty: A Comprehensive Review. J Clin Med. 2024;13(20):6243.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Treatment of Coronary In-Stent Restenosis with a Paclitaxel-Coated Balloon Catheter

Bruno Scheller, M.D., Christoph Hehrlein, M.D., Wolfgang Bocksch, M.D., Wolfgang Rutsch, M.D., Dariush Haghi, M[illegible] Michael Böhm, M.D., and Ulrich [illegible]



Event-free Survival in the Two Groups at 1 Year.

free from acute and subacute vessel closure, target-lesion revascu-
, myocardial infarction, and death was compared by Kaplan–Meier
with the use of the Mantel–Cox log-rank test.

N Engl J Med 2006;355:2113-24.

JAMA

QUESTION Is treatment with a coronary paclitaxel-coated balloon superior to an uncoated balloon for 1-year target lesion failure in patients undergoing percutaneous coronary intervention for in-stent restenosis?

CONCLUSION This clinical trial found that treatment with a paclitaxel-coated balloon offers a potentially beneficial treatment strategy for the management of coronary in-stent restenosis.

POPULATION

443 Men
157 Women

Adults with in-stent restenosis (lesion length <26 mm and reference vessel diameter >2.0 mm to ≤4.0 mm)

Mean age: 68 years

LOCATIONS

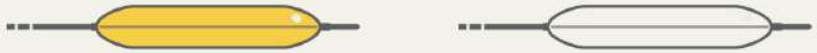
40 Centers in the US

INTERVENTION

600 Patients randomized

406 **Paclitaxel-coated balloon**
Coronary angioplasty with a paclitaxel-coated balloon

194 **Uncoated balloon**
Coronary angioplasty with an uncoated balloon



PRIMARY OUTCOME

1-year target lesion failure, defined as the composite of ischemia-driven target lesion revascularization, target vessel-related myocardial infarction, or cardiac death

FINDINGS

Target lesion failure

Paclitaxel-coated balloon
71 of 406 patients

Uncoated balloon
54 of 194 patients

Target lesion failure was significantly lower in the paclitaxel-coated balloon group:

Between-group difference, −10.7%
(95% CI, −18.2% to −3.2%)

Hazard ratio, 0.59 (95% CI, 0.42 to 0.84)

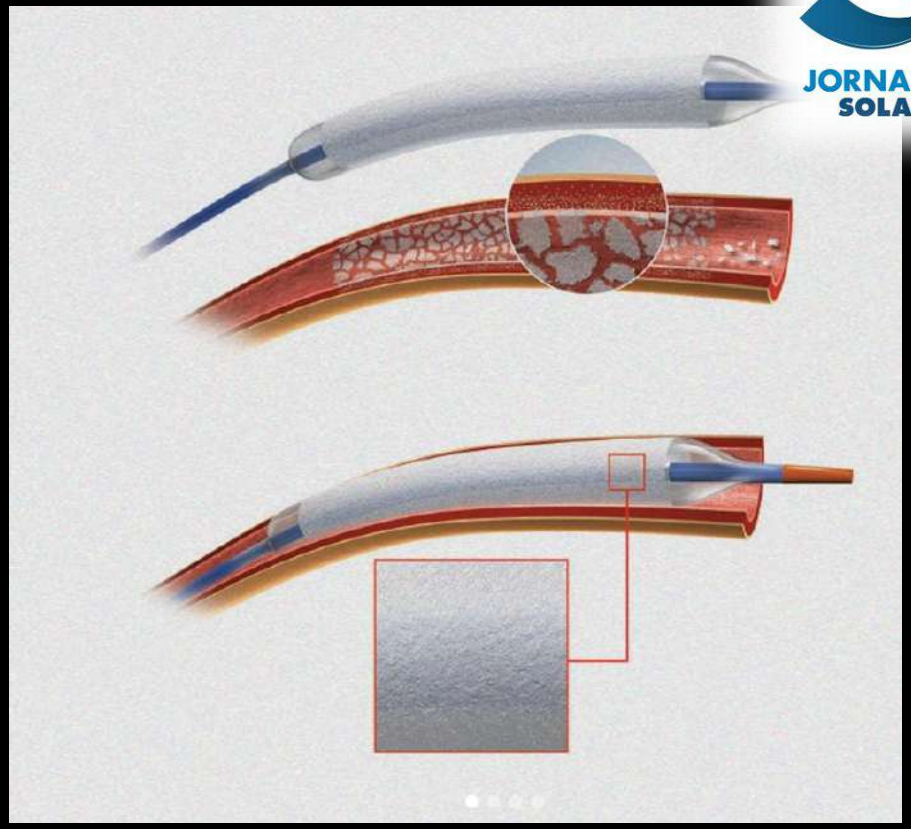
Yeh RW, Shlofmitz R, Moses J, et al; AGENT IDE Investigators. Paclitaxel-coated balloon vs uncoated balloon for coronary in-stent restenosis: the AGENT IDE randomized clinical trial. *JAMA*. Published March 9, 2024. doi:10.1001/jama.2024.1361

JAMA
Published Online: March 9, 2024

Punto de inflexión en EE. UU.: primera aprobación FDA (2024)

- Ensayo AGENT IDE (JAMA 2024): DCB con paclitaxel superior a balón no medicado en “target lesion failure” para ISR.
- PMA FDA P230035 define la indicación: ISR en arterias coronarias 2.0–4.0 mm (lesión ≤26 mm) tras preparación adecuada.
- Racional: tratar ISR evitando nuevas capas de stent (“leave nothing behind”).

Mini-timeline (simplificada)

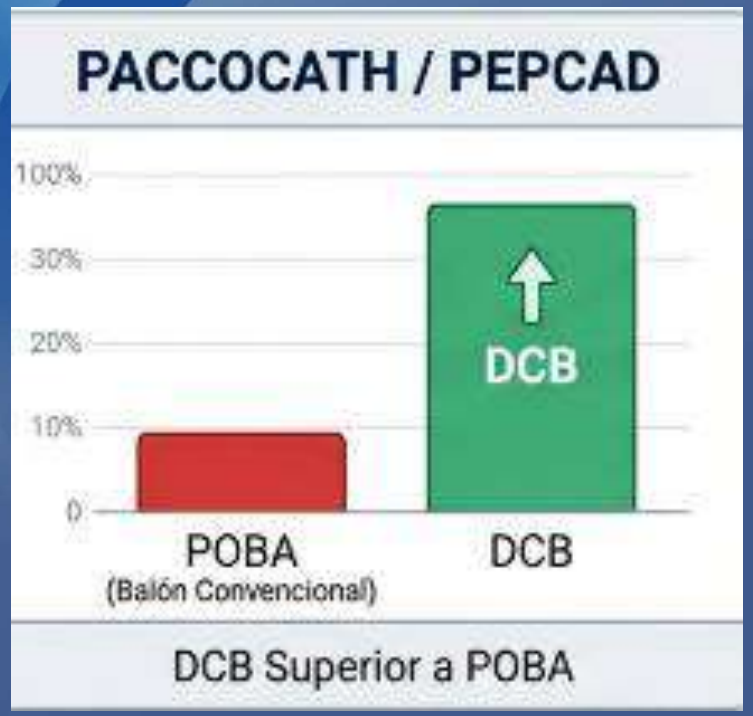


En ISR, el DCB actúa como “segunda oportunidad” sin añadir otra malla metálica.

BALONES RECUBIERTOS CON FÁRMACOS

Nivel de Evidencia: ALTO (Consenso CIAT Statement 1)

Reestenosis Intra – stent



Estrategia de primera línea para evitar el efecto piel de cebolla

1. Yerasi C, Case BC, Forrestal BJ, Torguson R, Weintraub WS, Garcia-Garcia HM, et al. Drug-Coated Balloon for De Novo Coronary Artery Disease: JACC State-of-the-Art Review. J Am Coll Cardiol. 2020;75(9):1061-73.
2. Verde N, Ciliberti G, Pittorino L, Ferrone M, Franzese M, Russo M, et al. Contemporary Use of Drug-Coated Balloons for Coronary Angioplasty: A Comprehensive Review. J Clin Med. 2024;13(20):6243.

JORNADAS SOLACI

BALONES RECUBIERTOS CON FÁRMACOS

ESC European Society of Cardiology

European Heart Journal (2025) **46**, 1586–1599
https://doi.org/10.1093/eurheartj/ehaf002

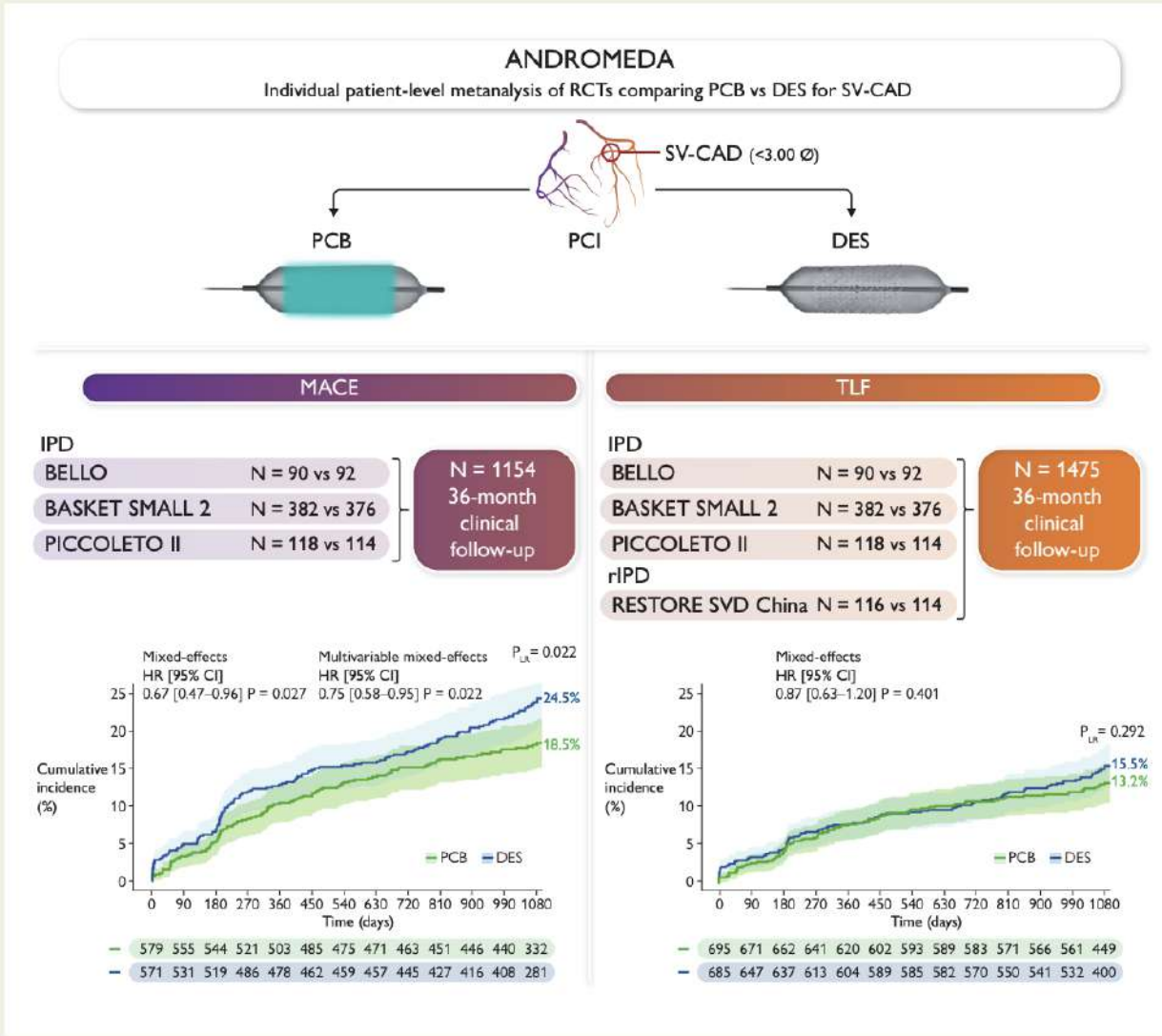
FASTTRACK – CLINICAL RESEARCH
Interventional cardiology

Individual patient data meta-analysis of paclitaxel-coated balloons vs. drug-eluting stents for small-vessel coronary artery disease: the ANDROMEDA study

Simone Fezzi [1,†], Daniele Giacoppo [2,3,4,†], Gregor Fahrni[5], Azeem Latib [6], Fernando Alfonso [7], Antonio Colombo [8], Felix Mahfoud [9], Bruno Scheller [10], Raban Jeger [5,11], and Bernardo Cortese [12,13,14,*]

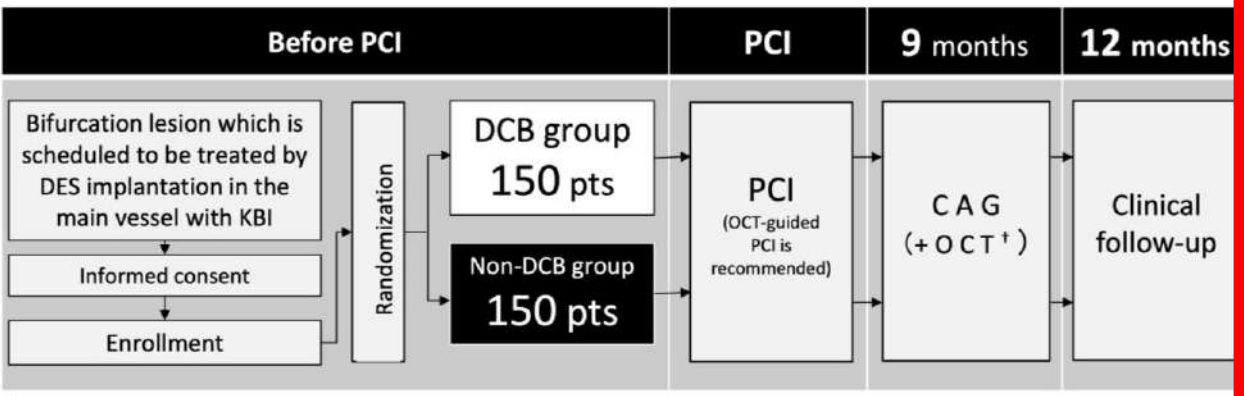
[1]Division of Cardiology, Department of Medicine, Verona University Hospital, Verona, Italy; [2]Department of General Surgery and Medical-Surgical Specialties, University of Catania, Catania, Italy; [3]Cardiovascular Research Institute Dublin, Royal College of Surgeons in Ireland, Dublin, Ireland; [4]ISAResearch Zentrum, Deutsches Herzzentrum München, Munich, Germany; [5]Division of Cardiology, Department of Medicine, Triemli Hospital Zürich, Switzerland; [6]Montefiore-Einstein Center for Heart and Vascular Care, Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, NY, USA; [7]Servicio de Cardiología, Hospital Universitario de la Princesa, IIS-IP, CIBERCV, Universidad Autónoma de Madrid, Madrid, Spain; [8]Cardio Center, Humanitas Clinical and Research Hospital IRCCS, Rozzano, Milan, Italy; [9]Department of Cardiology, University Hospital Basel, Switzerland; [10]Clinical and Experimental Interventional Cardiology, University of Saarland, Homburg/Saar, Germany; [11]University of Basel, Basel, Switzerland; [12]Fondazione Ricerca e Innovazione Cardiovascolare, Via E. Ponti, 49, 20136, Milan, Italy; [13]DCB Academy, 20136, Milan, Italy; and [14]University Hospitals Harrington Heart & Vascular Institute, Cleveland, OH, USA

Received 26 August 2024; revised 22 October 2024; accepted 1 January 2025; online publish-ahead-of-print 21 February 2025



1. Yerasi C, Case BC, Forrestal BJ, Torguson R, Weintraub WS, Garcia-Garcia HM, et al. Drug-Coated Balloon for De Novo Coronary Artery Dise
2. Verde N, Ciliberti G, Pittorino L, Ferrone M, Franzese M, Russo M, et al. Contemporary Use of Drug-Coated Balloons for Coronary Angiopla
3. Suwannasom P, Towashiraporn K, Roongsangmanoon W, Kanjanarutjawiwat W, Surunchupakorn P, Muenkaew M, et al. Consensus State
2025;14(21):7505.
4. Ng P, Maehara A, Kirtane AJ, McEntegart M, Jaffer FA, Doshi D, et al. Management of Coronary Stent Underexpansion: JACC State-of-the-
5. Korjian S, McCarthy KJ, Larnard EA, Cutlip DE, McEntegart MB, Kirtane AJ, et al. Drug-Coated Balloons in the Management of Coronary Art

Procedures



- In the DCB group, DCB inflation is added for side branch after kissing balloon inflation.

† Follow-up OCT evaluation is also performed for the patients who underwent OCT-guided PCI.

CRF TCT

jRCT: CRB5180000

Osaka CardioVascular Conference (OCVC)

35 hospitals around Osaka area

Advanced Clinical Practice and Research

Empowering Education

Transformative Research

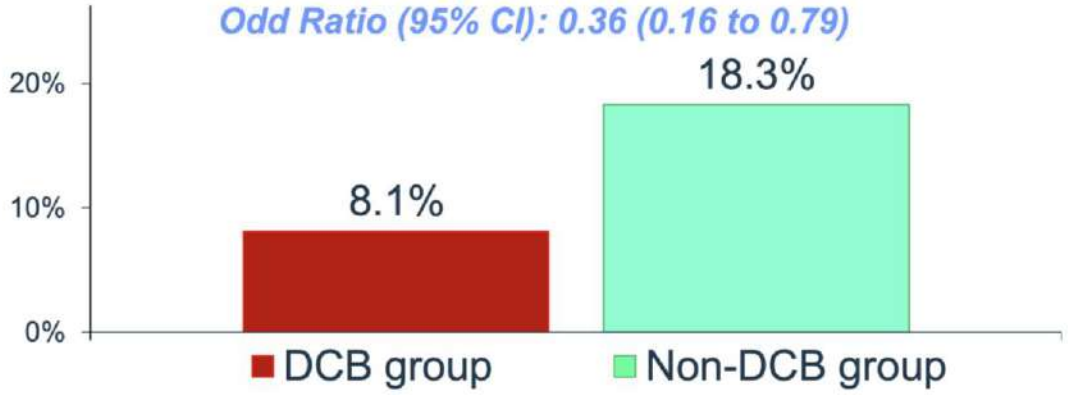
8 hospitals of OCVC were participated in the OCVC-BIF Study.

Primary Endpoint

Restenosis of side branch

p = 0.012

Odd Ratio (95% CI): 0.36 (0.16 to 0.79)



CRF TCT

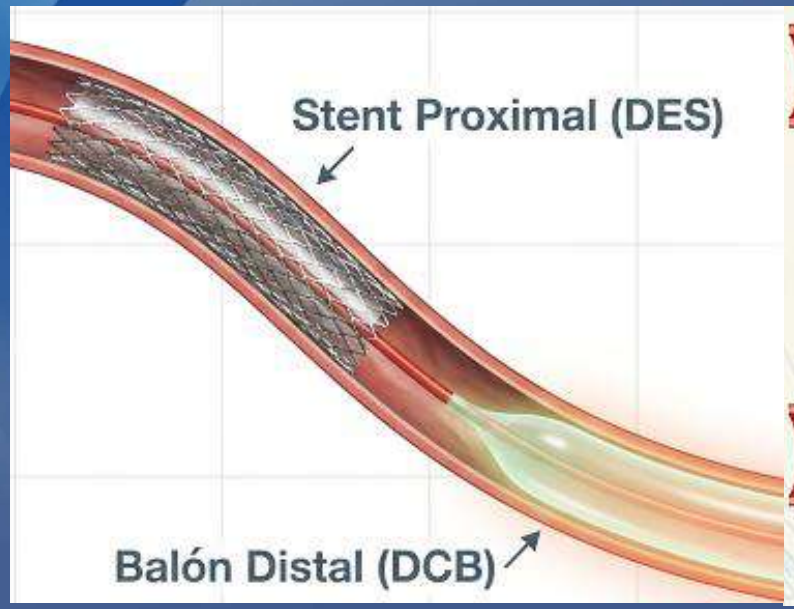
Summary

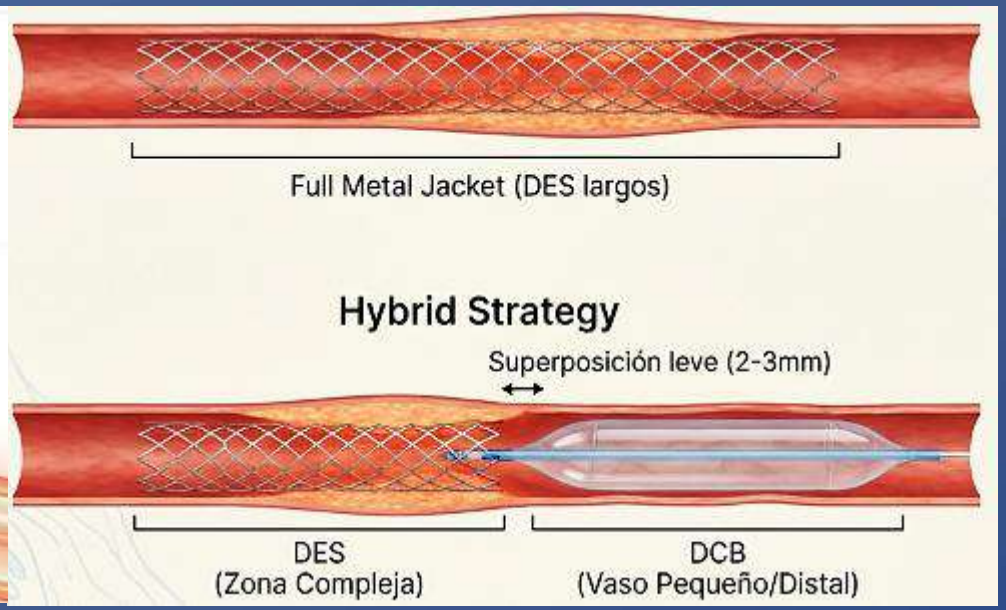
- Additional DCB inflation in the side branch after main vessel DES implantation with KBI resulted in a lower incidence of restenosis in the side branch than without additional DCB inflation.
- The rates of CD-TLR in the side branch were similar between the DCB and non-DCB groups.
- The 1-year MACE rates were similar between the two groups.
- The 1-year cumulative incidence of CD-TLR tended to be lower in the DCB group than in the non-DCB group.

CRF TCT

BALONES RECUBIERTOS CON FÁRMACOS

ESTRATEGIA HIBRIDA





- Segmento libre de metal
- Longitud total de stent minimizada
- Menor riesgo de trombosis
- Evita implantes metálicos excesivos
- Preserva la vasomotilidad en segmentos distales

1. Yerasi C, Case BC, Forrestal BJ, Torguson R, Weintraub WS, Garcia-Garcia HM, et al. Drug-Coated Balloon for De Novo Coronary Artery Disease: JACC State-of-the-Art Review. J Am Coll Cardiol. 2020;75(9):1061-73.
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4. Ng P, Maehara A, Kirtane AJ, McEntegart M, Jaffer FA, Doshi D, et al. Management of Coronary Stent Underexpansion: JACC State-of-the-Art Review. JACC. 2025;85(6):625-644.
5. Korjian S, McCarthy KJ, Larnard EA, Cutlip DE, McEntegart MB, Kirtane AJ, et al. Drug-Coated Balloons in the Management of Coronary Artery Disease. Circ Cardiovasc Interv. 2024;17(2):e013302

JACC Journals › JACC › Archives › Vol. 86 No. 15
GET ACCESS | JACC State-of-the-Art Review | 6 October 2025

Indications for Use of Drug-Coated Balloons in Coronary Intervention: Academic Research Consortium Position Statement

Authors: Simone Fezzi, Patrick W. Serruys ✉, Bernardo Cortese, Bruno Scheller, Fernando Alfonso, Raban Jeger, Antonio Colombo, … SHOW ALL … , and Yoshinobu Onuma | AUTHORS INFO & AFFILIATIONS

Publication: JACC • Volume 86, Number 15

CENTRAL ILLUSTRATION: DCB Academic Research Consortium Indications for Use of DCBs in Coronary Intervention: A Step-by-Step Approach for the DCB-Only Strategy

OPTIMAL LESION PREPARATION BEFORE DCB

- Standard balloon (SC, NC) 1:1 sized on distal RVD [9] — Exp
- **Long inflations** (>30 sec) are recommended [134,135] — Exp
- **Specialty balloons** (scoring, cutting) are recommended to improve lesion preparation and decrease the risk of flow-limiting dissections [133,136] — RCT
- **Intravascular imaging** is encouraged for more precise assessment of vessel size and calibrated DCB selection, plaque composition and morphology [25,85] — RCT
  - IVI may lead to superior angiographic outcomes after DCB-only PCI [85]
- **Calcium debulking** (IVL, RA, OA) is recommended in case of moderate-to-severe calcification [98,99] — Exp

ACCEPTABLE RESULT FOLLOWING LESION PREPARATION

ANGIOGRAPHY

RESIDUAL STENOSIS

- **Visual estimation** [9]: ≤30% — Exp
- **QCA** *, [12,13]: *Optimal* ≤25%; *Suboptimal* 25-40% — Exp

INTRAVASCULAR IMAGING

- Media dissections may facilitate drug transfer to the vessel wall [75] — Exp
- No evidence-based IVI criteria is currently established for DCB optimization

NON FLOW-LIMITING DISSECTIONS — Exp

- TIMI 3 flow
- No ECG changes
- No chest pain

CORONARY PHYSIOLOGY (FFR/QFR/NHPR)

No evidence-based threshold is currently available

- Pd/Pa >0.90 [137]
- QFR/FFR >0.80 [9]

— Exp

YES / NO

DCB

- **SHORT DELIVERY TIME** <2 minutes [9]
- **LONG INFLATION TIME** ≥60 seconds [134,135] — Exp

BAIL-OUT DES

FURTHER LESION PREPARATION

Fezzi S, et al. JACC. 2025;86(15):1170-1202.

BALONES RECUBIERTOS CON FÁRMACOS

Evaluación

- Angiografía
- Ecografía

Modificación de placa

- Scoring balloon
- Lithotripsy

Dilatación

- Ratio balón / vaso

Tránsito < 45”

- Minimizar pérdida de fármaco

Inflación > 60”

- Asegurar absorción cristalina

Evaluación >5´

1. Yerasi C, Case BC, Forrestal BJM, Franzese M, Russo M, et al. Contemporary Use of Drug-Coated Balloons for Coronary Angioplasty: A Comprehensive Review. J Clin Med. 2024;13(20):6243.
3. Suwannasom P, Towashirapor, Torguson R, Weintraub WS, Garcia-Garcia HM, et al. Drug-Coated Balloon for De Novo Coronary Artery Disease: JACC State-of-the-Art Review. J Am Coll Cardiol. 2020;75(9):1061-73.
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JACC: CARDIOVASCULAR INTERVENTIONS
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COLLEGE OF CARDIOLOGY FOUNDATION

VO

JACC VOL. 17. No 13. 2024

ORIGINAL RESEARCH

CORONARY

Outcomes With Limus- vs Paclitaxel-Coated Balloons for Percutaneous Coronary Intervention

Meta-Analysis of Randomized Controlled Trials

Ramy Sedhom, MD, MS,[a]
Pooja Swamy, MD,[a] Ahme

AsiaIntervention
2026;12:17-27
DOI: 10.4244/AIJ-D-25-00029

ORIGINAL RESEARCH

AsiaIntervention 2026;12:17-27

Head-to-head comparison of limus- versus paclitaxel-coated balloons in the treatment of in-stent restenosis: a meta-analysis

Marios Sagris[1,2]*, MD, MSc, PhD; Stergios Soulaidopoulos[1], MD, MSc, PhD; Nikolaos Ktenopoulos[1], MD, MSc; Angelos Papanikolaou[1], MD, MSc; Kyriakos Dimitriadis[1], MD, MSc, PhD; Nikolaos Patsourakos[2], MD, MSc; Dimitris Tousoulis[1], MD, PhD; Bruno Scheller[3], MD, PhD; Antonio Colombo[4,5], MD, PhD; Konstantinos Tsioufis[1], MD, PhD

*Corresponding author: Hippokration Hospital, Vasilissis Sofias 114, 11528, Athens, Greece.
E-mail: masagris1919@gmail.com

European Heart Journal Supplements (2026) 28 (Suppl 3) iii185

Interventional Cardiology And Cardiovascular Surgery – Interventional Cardiology, Percutaneous Coronary Intervention (PCI), Devices

Sirolimus-coated versus paclitaxel-coated balloons in the treatment of coronary lesions: a systematic review and meta-analysis

A. Moftah[1]; A. Adel[2]; M. Lasheen[3]; T. Al Freijat[4]; A. Shehata[5]; I. Solah[6]; O. Mahmood[7]; M. F Abdrabo[3]; B. Abusalah[8]; E. Ghawanmeh[9]; A. Hegazy[10]

[1]Ain Shams University, Faculty of Medicine, Cairo, Egypt
[2]Zagazig University, Faculty of Medicine, Zagazig, Egypt
[3]Tanta University, Faculty of Medicine, Tanta, Egypt
[4]University of Jordan, Faculty of Medicine, Amman, Jordan
[5]South Valley University, Faculty of Medicine, Qena, Egypt
[6]Menofia University, Faculty of Medicine, Menoufia, Egypt
[7]Liv Hospital Ulus, Faculty of Pharmacy, Istanbul, Turkiye
[8]An-Najah National Univers
[9]Jordan University of Scienc
[10]Medway NHS Foundation Trust, Internal Medicine, Gillingham, United Kingdom of Great Britain & Northern Ireland

European Heart Journal Supp (2026) 28 (suppl 3)

Funding Acknowledgements: None.

JORNADAS SOLACI

Outcomes with limus-coated vs. paclitaxel-coated balloons for percutaneous coronary intervention: An updated meta-analysis and reconstructed time-to-event analysis of randomized controlled trials

Search & Selection of Studies

We searched **PubMed, Embase, Cochrane CENTRAL, Scopus, and Web of Science** through 10 July 2025

10 RCTs
1,471 patients

- Limus-DCBs: **770** patients
- Paclitaxel-DCBs: **701** patients

Primary Outcomes

TLF is defined as cardiac death, TV MI, or TVR

13.7% Vs 11.6%

Sirolimus *vs* Biolimus-DCBs **(P = 0.32)**

ISR *vs* De novo lesions **(P = 0.26)**

Secondary Outcomes

MACE	Limus-DCBs	20.6%
	Paclitaxel-DCBs	18.3%
TLR		12.9%
		10.1%
Cardiac Mortality		0.65%
		1%
TV-MI		1.1%
		1.3%

Angiographic Outcomes

Binary restenosis	RR: 1.25	P = 0.24
LLL	MD: 0.09	P = 0.06
MLD	MD: -0.04	P = 0.33
Acute gain	MD: 0.01	P = 0.64
Diameter stenosis	MD: 2.	

Conclusion

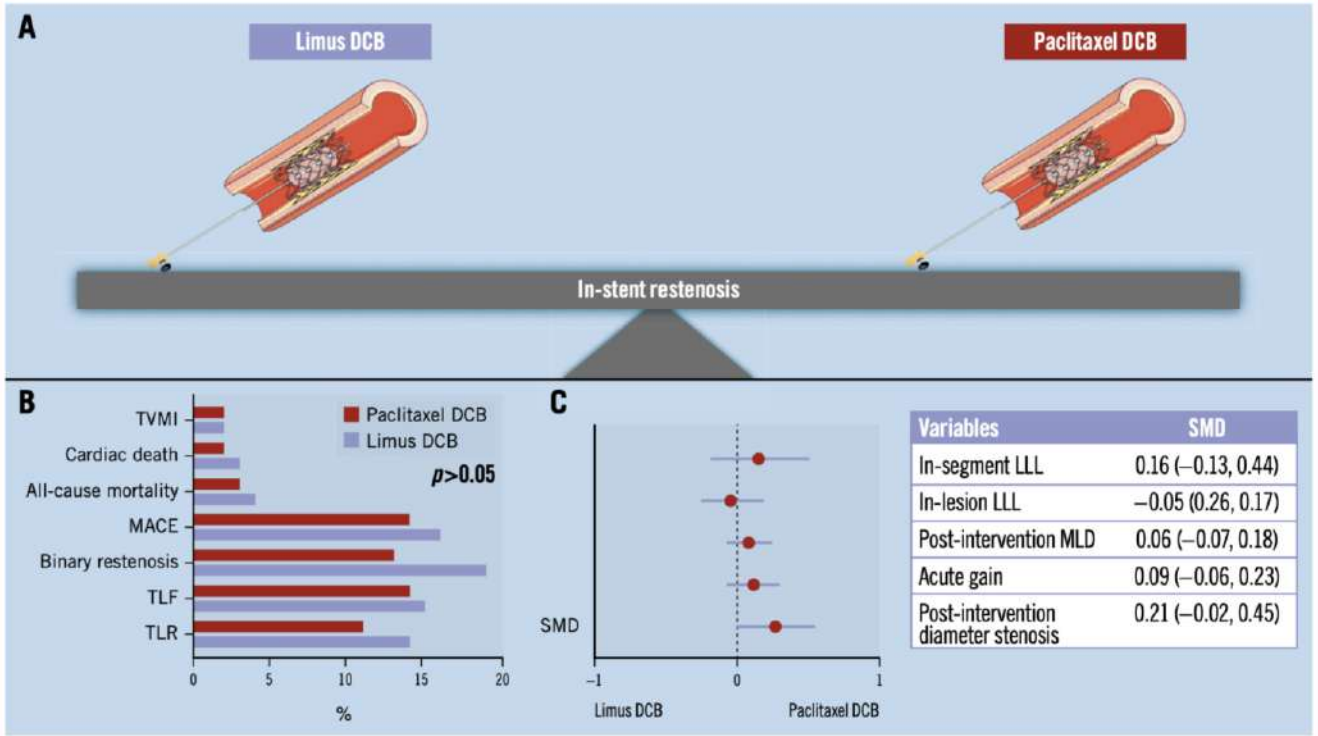
Among patients undergoing DCB-only PCI, there was no statistically significant difference bet
paclitaxel-DCBs regarding clinical and angiographic outcomes. Larger RCTs with extended follow
needed to confirm these findings.

JORNADAS SOLACI

...adas SOLACI
...d de Panamá

AsiaIntervention — Central **Illustration**

Comparison of limus- versus paclitaxel-coated balloons for treating ISR.



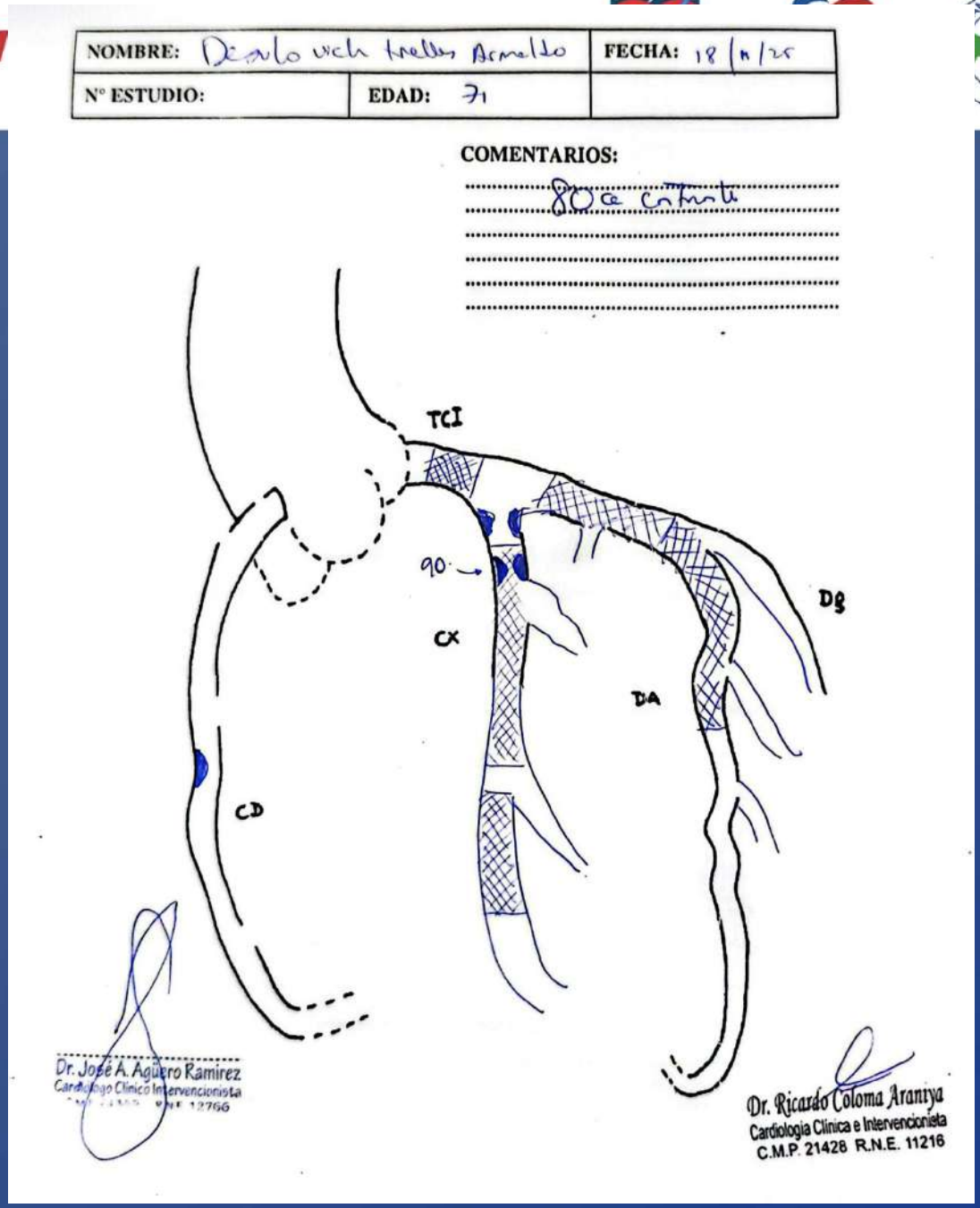
Variables	SMD
In-segment LLL	0.16 (−0.13, 0.44)
In-lesion LLL	−0.05 (0.26, 0.17)
Post-intervention MLD	0.06 (−0.07, 0.18)
Acute gain	0.09 (−0.06, 0.23)
Post-intervention diameter stenosis	0.21 (−0.02, 0.45)

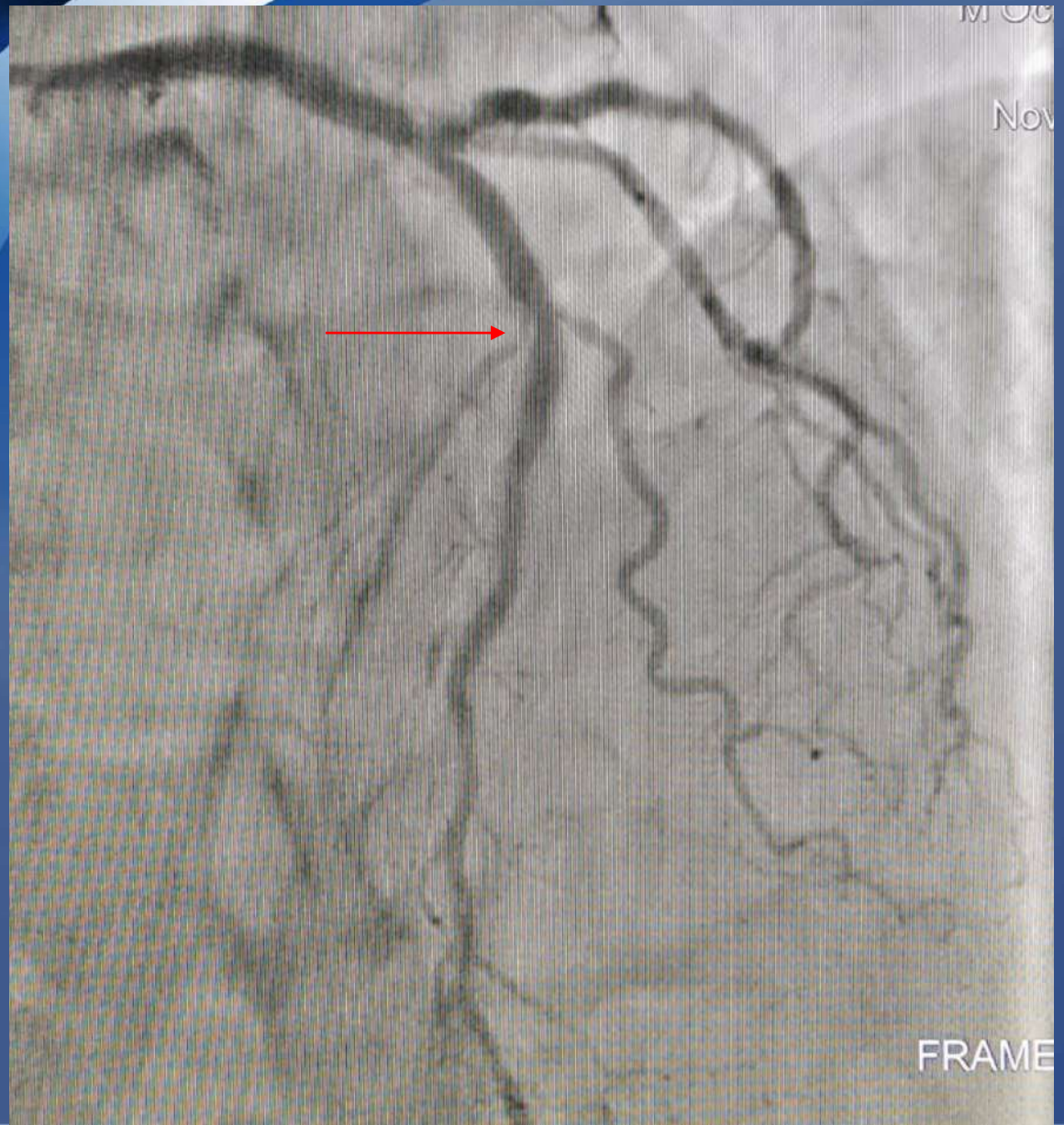
PCI DIAGNOSTICO 18/11/2025

USO DE:
iFR + IVUS

SE REALIZA ESTUDIO ATC DIAGNOSTICA CON APOYO DE IVUS +iFR.
CD: OBSTRUCCION SEVERA 70% EN CD MEDIA + ATEROMATOSIS DIFUSA EN POSICION DISTAL
TCI: STENT PERMEABLE
DA: OBSTRUCCION MODERADA INTRASTENT 60 – 65% PORCION PROXIMAL
CX: OBSTRUCCION SEVERA EN CX PROXIMAL INTRA STENT APROXIMADAMENTE 95%
iFR EN DA 0,92
iFR EN CX PROXIMAL 0.81

- IVUS NO LOGRA PASAR STENT CX PROXIMAL.

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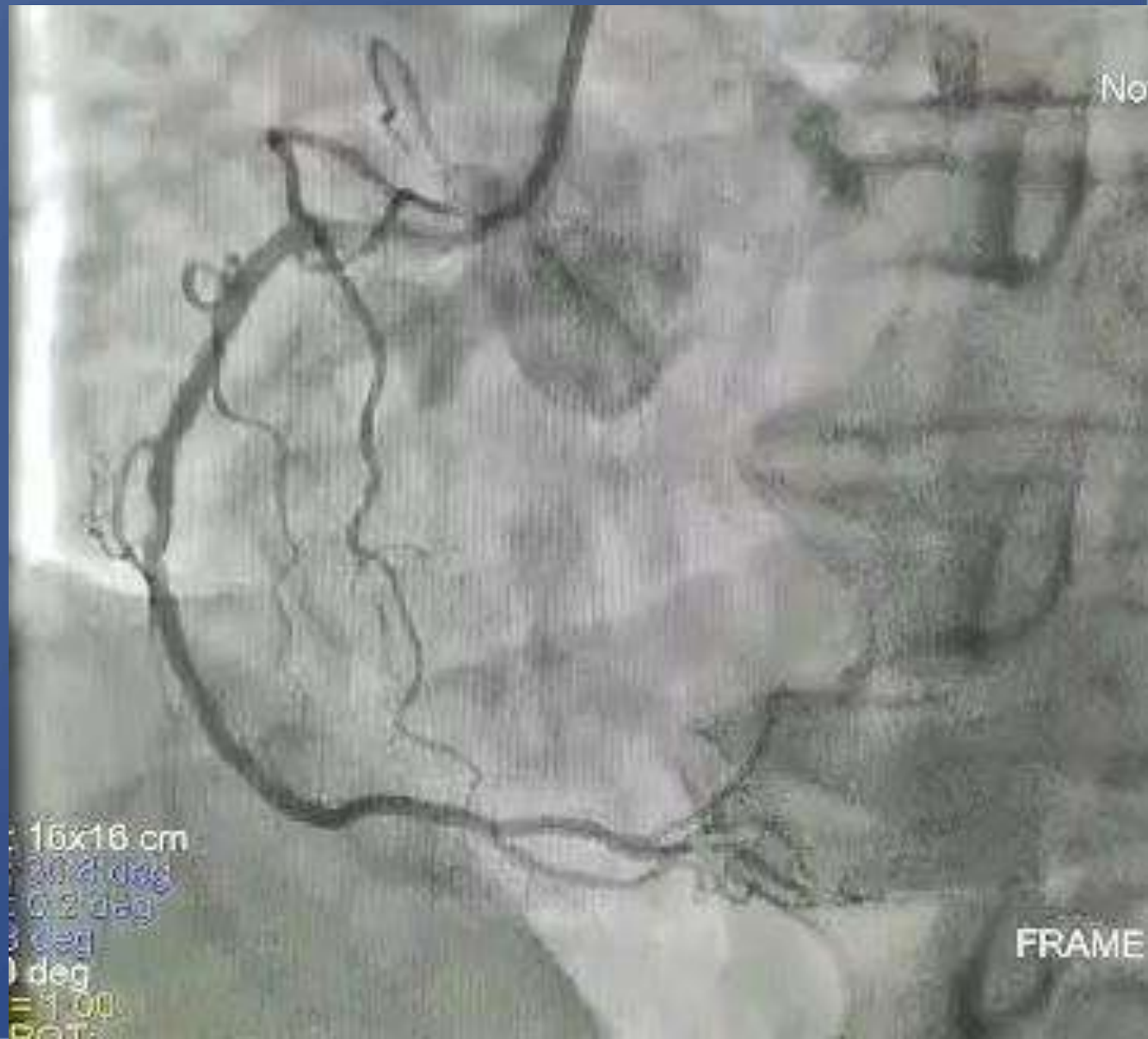
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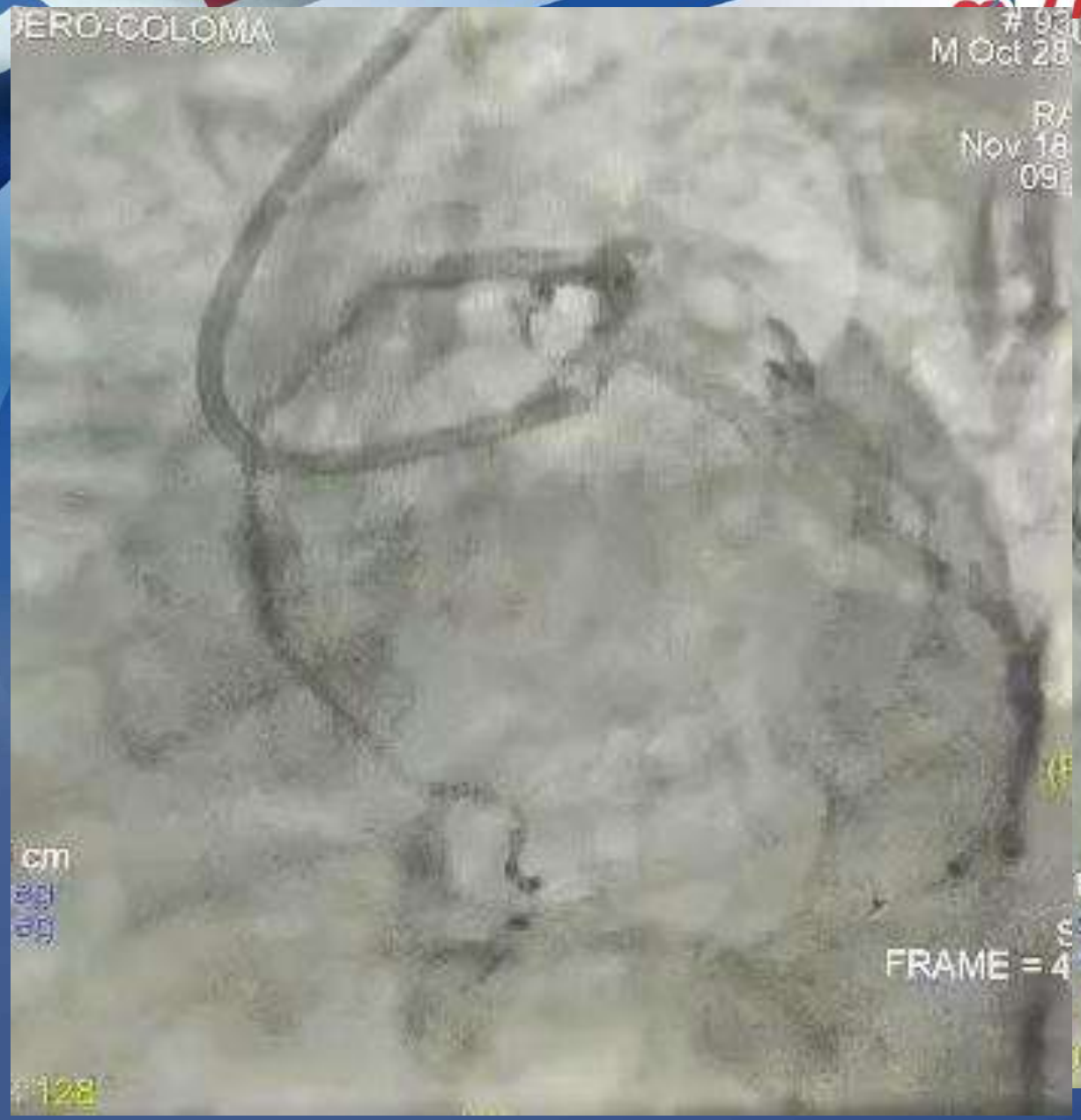
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M Oct 28
Nov 18
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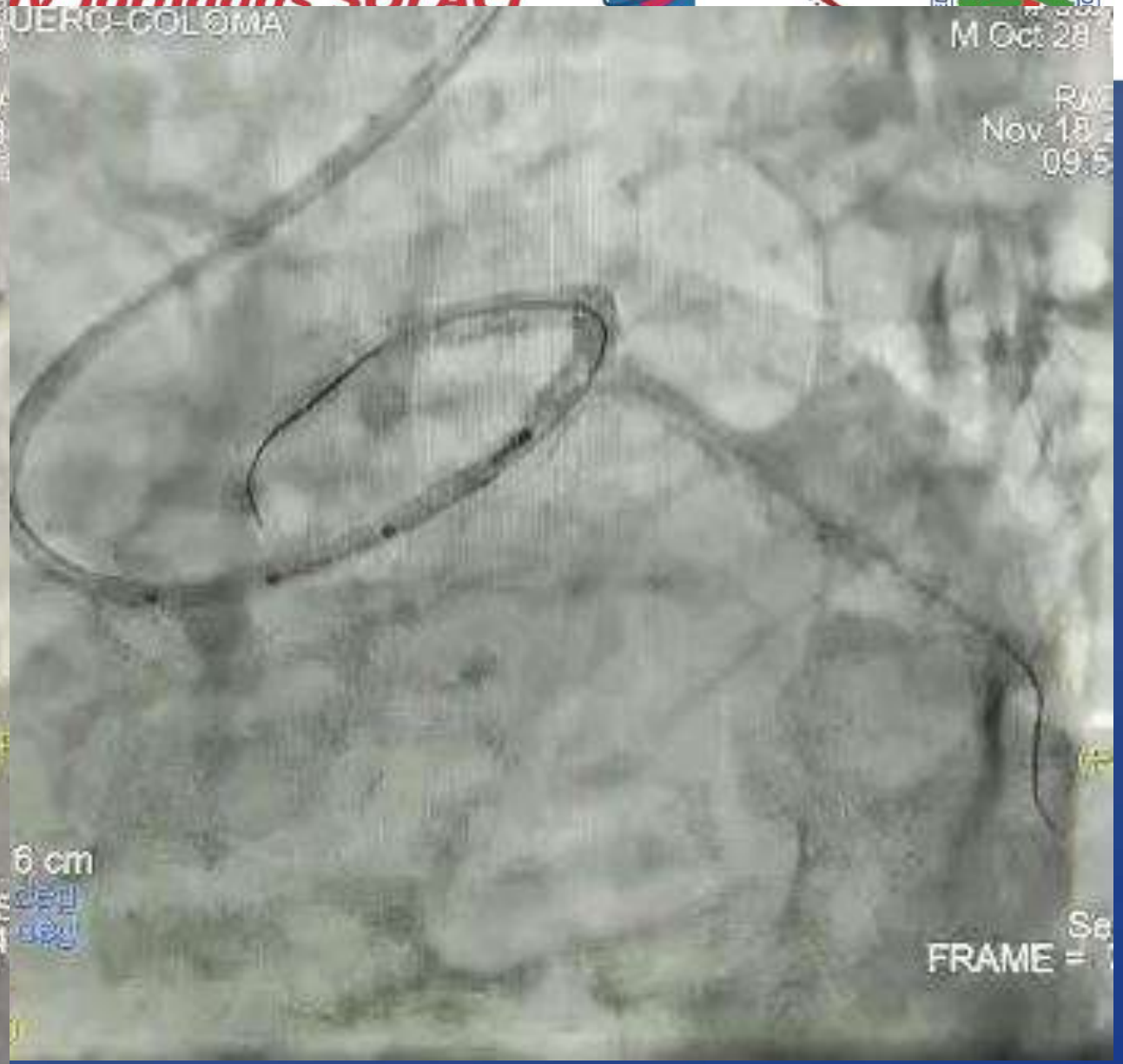
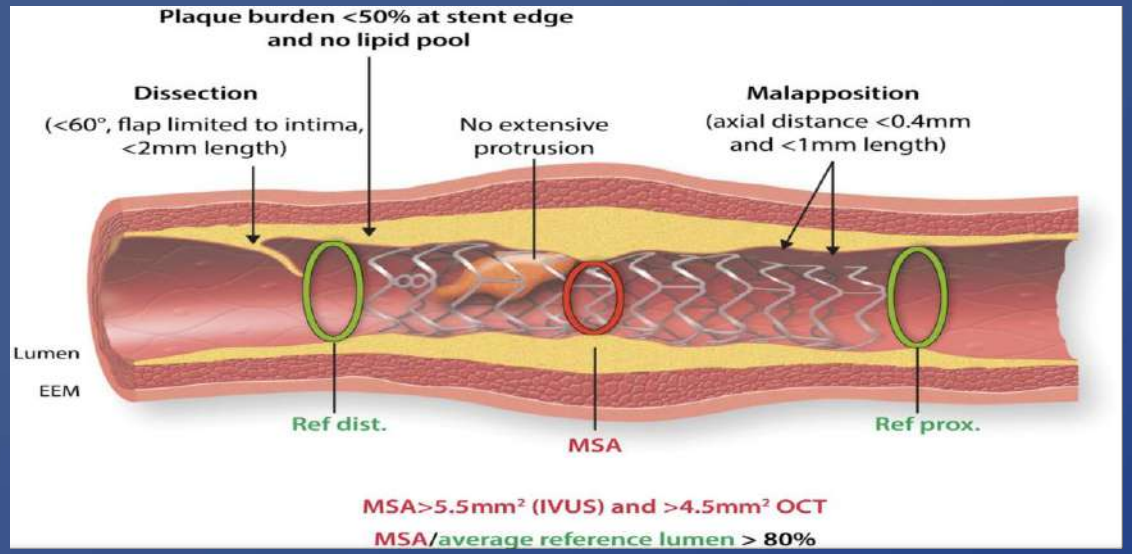

UERO-COLOMA
M Oct 28
Nov 18
6 cm
FRAME =

IMPRESIÓN DX

1. RE ESTENOSIS INTRASTENT CX PROXIMAL, EOS PRE STENT CX PROXIMAL
2. ECOC MULTIVASO
3. HTA
4. DM2
5. DLP
6. HIPOTIROIDISMO

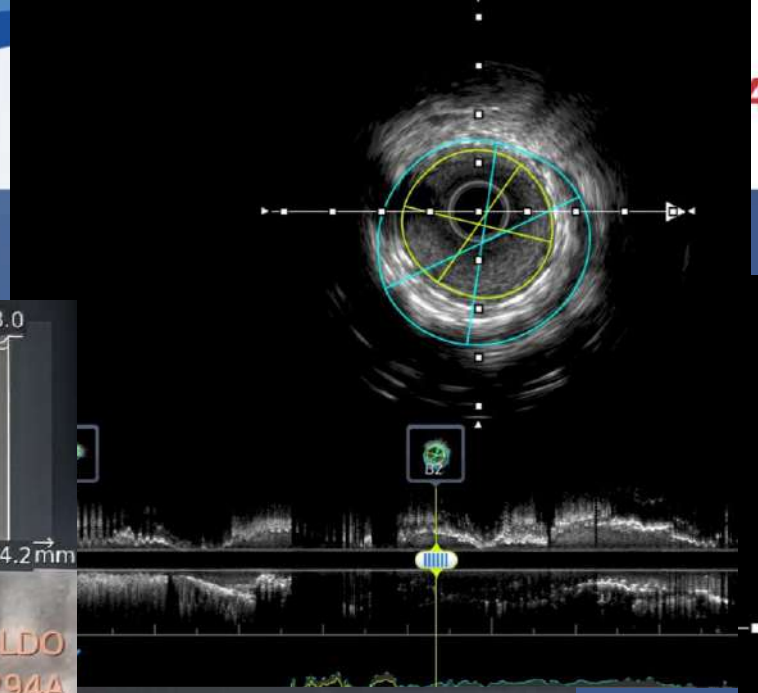
EOS:
- CX PROXIMAL 70 – 75%, PRE STENT CORNARIO.
- CX PROXIMAL 90% INTRA STENT CORNARIO.
- CD PROXIMAL Y MEDIA 70%

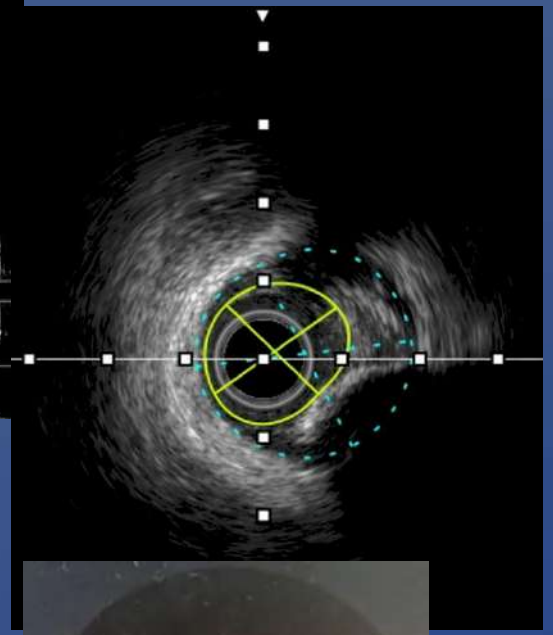


SYNTAX II: 9PTS

PLAN:

ANGIOPLASTIA CORONARIA, USO DE SHOCKWAVE INTRAVASCULAR LITHOTRIPSY (IVL), BALON NO COMPLACIENTE, BALON MEDICADO, IMÁGENES INTRACORONARIAS (IVUS – OCT).



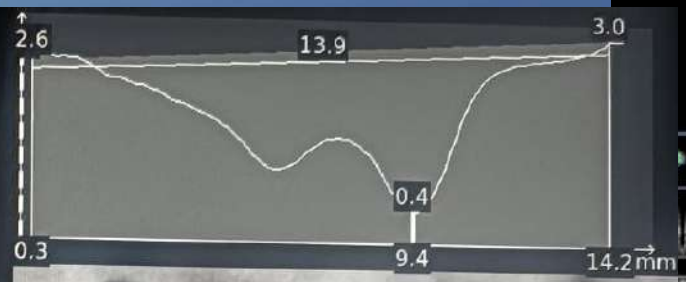


: 82.2% diámetro
: 96.8% área

: 2.5 ± 0.3 mm
LD) : 0.4 ± 0.1 mm
osis : 2.6 ± 0.3 mm

: 13.9 ± 1.5 mm

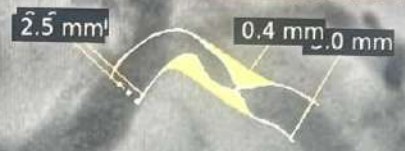
el resultado no se puede conservar.



EMS

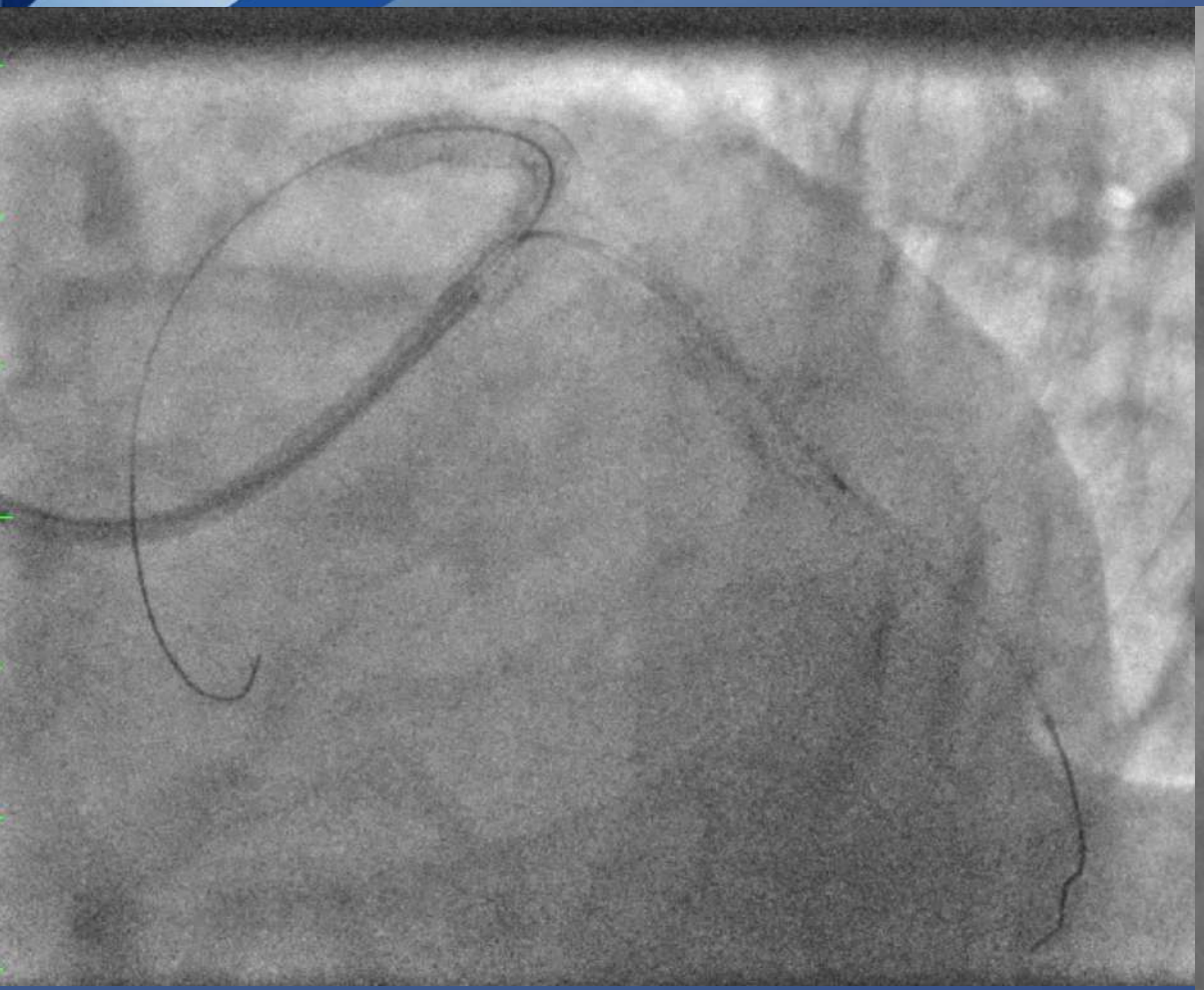
LOMA

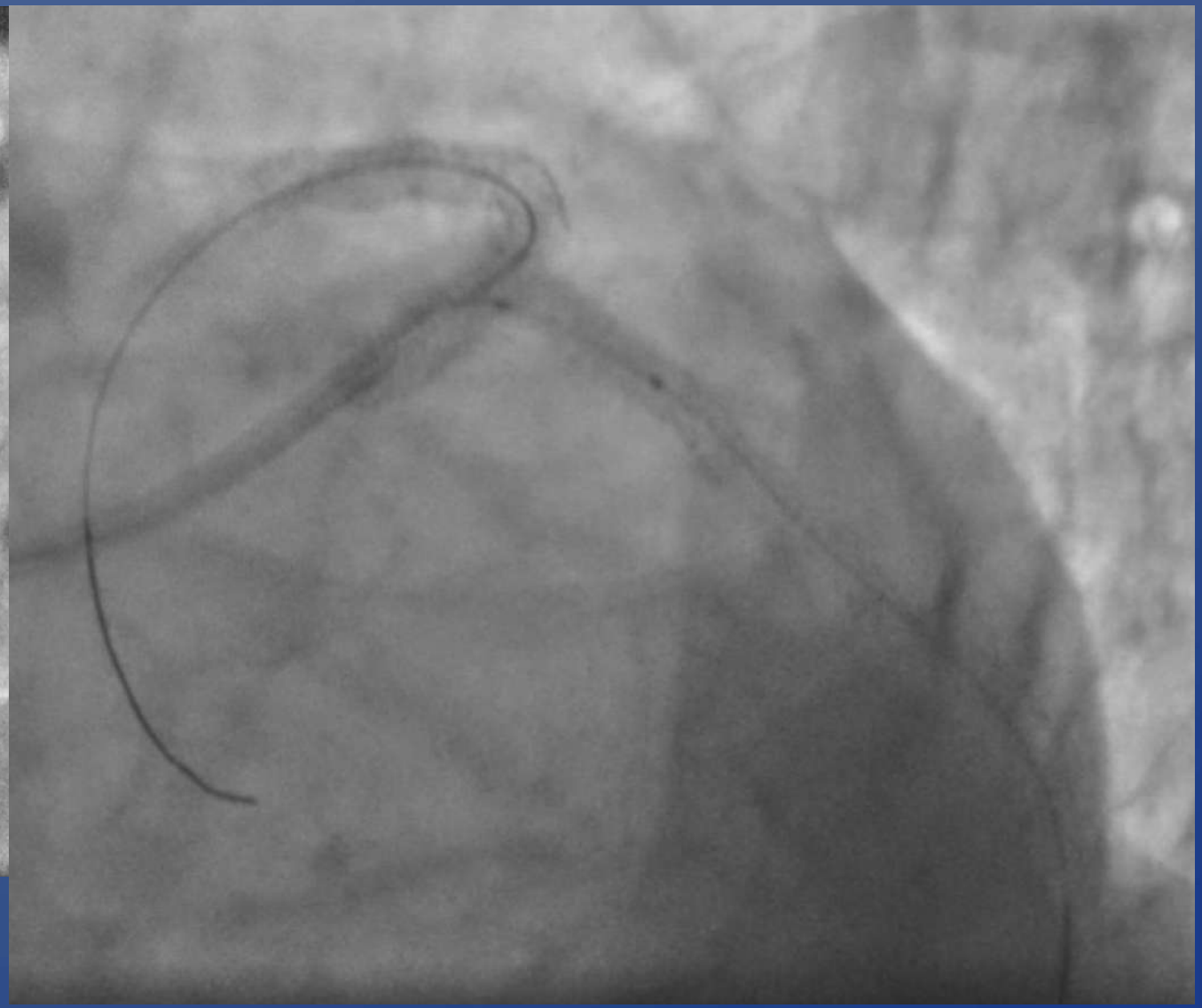
DESULOVICH TRELLES ARNALDO
93294A
M

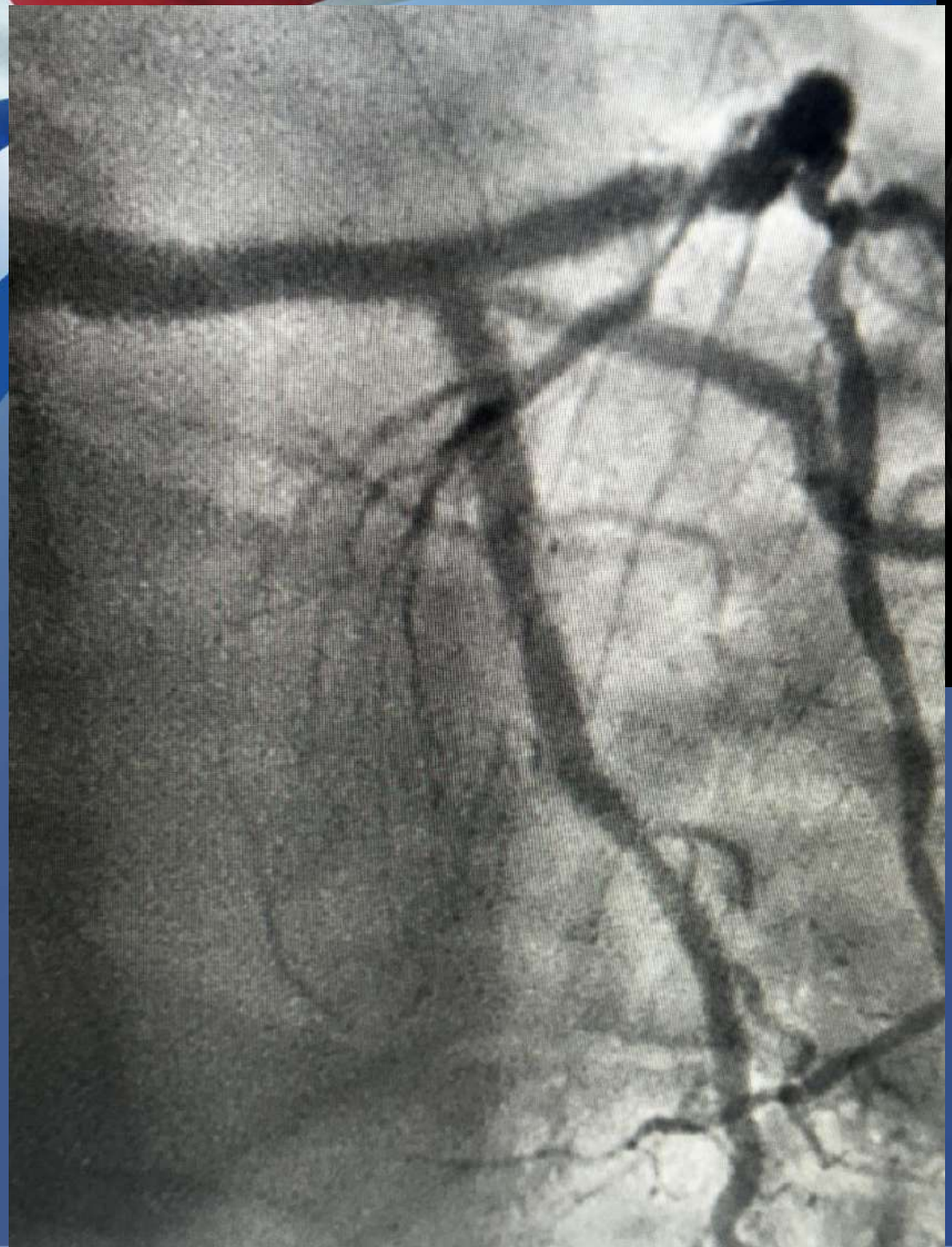


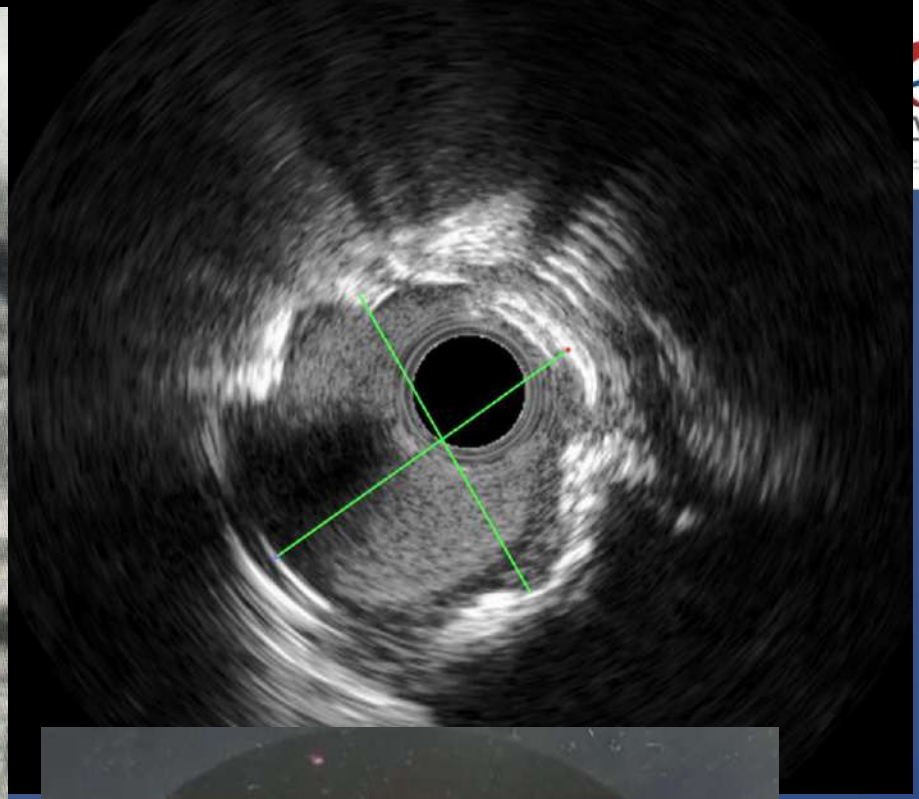
Sec.: 4

FRAME = 32 / 58

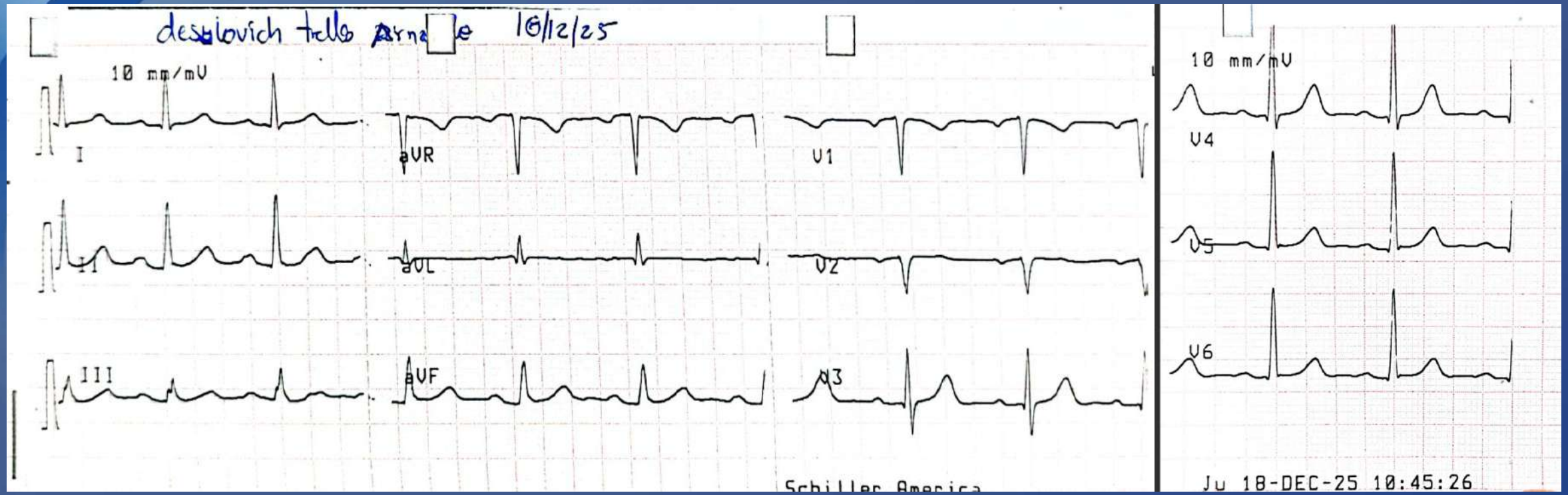








ELECTROCARDIOGRAMA 18/12/25



RS/FC:75LPM/PR: 200MS/QRS:100MS/QT: 360MS EJE:+ 60
RITMO SINUSAL DE BASE, FRAGMENTACION DEL SEGMENTO QRS EN DIII, P NEGATIVA EN V1, T NEGATIVA EN V1

MENSAJES PARA LLEVAR

INDICACION MAS SOLIDA: Reestenosis intrastent.

INDICACION EN CRECIMIENTO: Vasos pequenos, de novo; bifurcaciones.

NOVEDADES Y EN ESTUDIOS: Vasos grandes (de novo), SICA, Oclusiones cronicas, etc

EN GUIAS: Reconocidas en Guias Europeas Sindrome Coronario Cronico 2024, lo recomiendan, en Reestenosis Intrastent. Actual FDA lo aprobo.

IGUALES RESULTADOS LOS BALONES CON LIMUS VS PACLITAXEL.

Gracias, por su atención