

QUÉ HACER Y CÓMO RESOLVER UNA OCLUSIÓN CRÓNICA...

...Incruzable

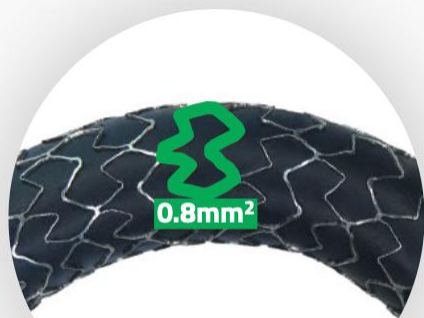
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 @JuradoRomanAl

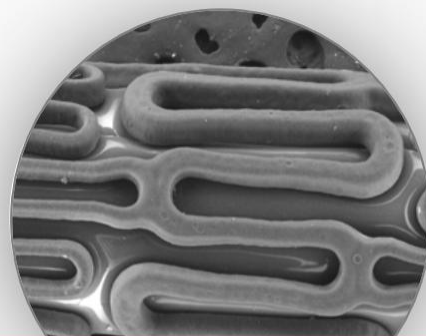
ELuNIR and ELuNIR PERL



WiZeCell™ DESIGN

Dual Pattern Strut Stent Design

- Ultra narrow and narrow CoCr struts
- Excellent conformability
- Uniform scaffolding and vessel support
- Optimal drug release



ELASTOMERIC COATING

The first and only elastomer drug-eluting stent

- Ridaforolimus limus analogue
- Improved surface quality and coating integrity
 - Uniform elution



SUPERIOR DELIVERABILITY

No stent delivers more

- Tapered Spring Tip Reduces tip flare-out and buckling
- The perfect balance of flexibility and pushability
 - Radiopaque tip



OUTSTANDING CLINICAL OUTCOMES

ELuNIR Family Remarkable Safety

- 0.1% Extremely low rates of Late/Very Late Stent Thrombosis through 24 months
- 7.0% TLF at 24 months

Case 1

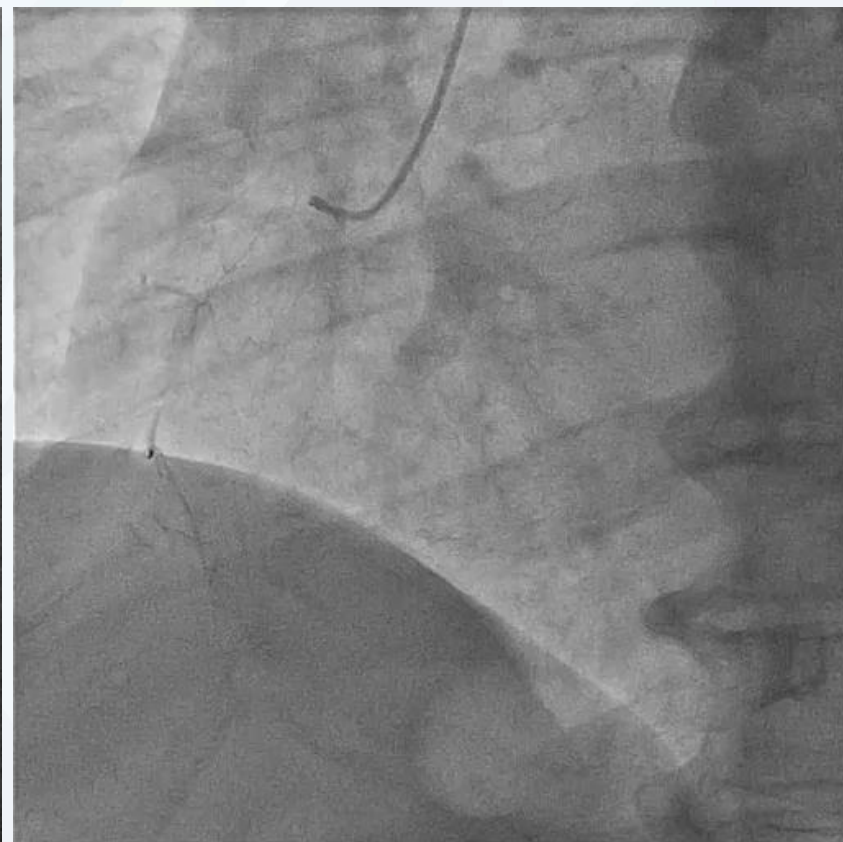
- 59 yo male
- DL, HT
- Stable Angina CCS III

- Positive Treadmill test
- LVEF 57% without WMA
- Normal renal function

Coronary angiography



No lesions at LAD



CTO at mid RCA

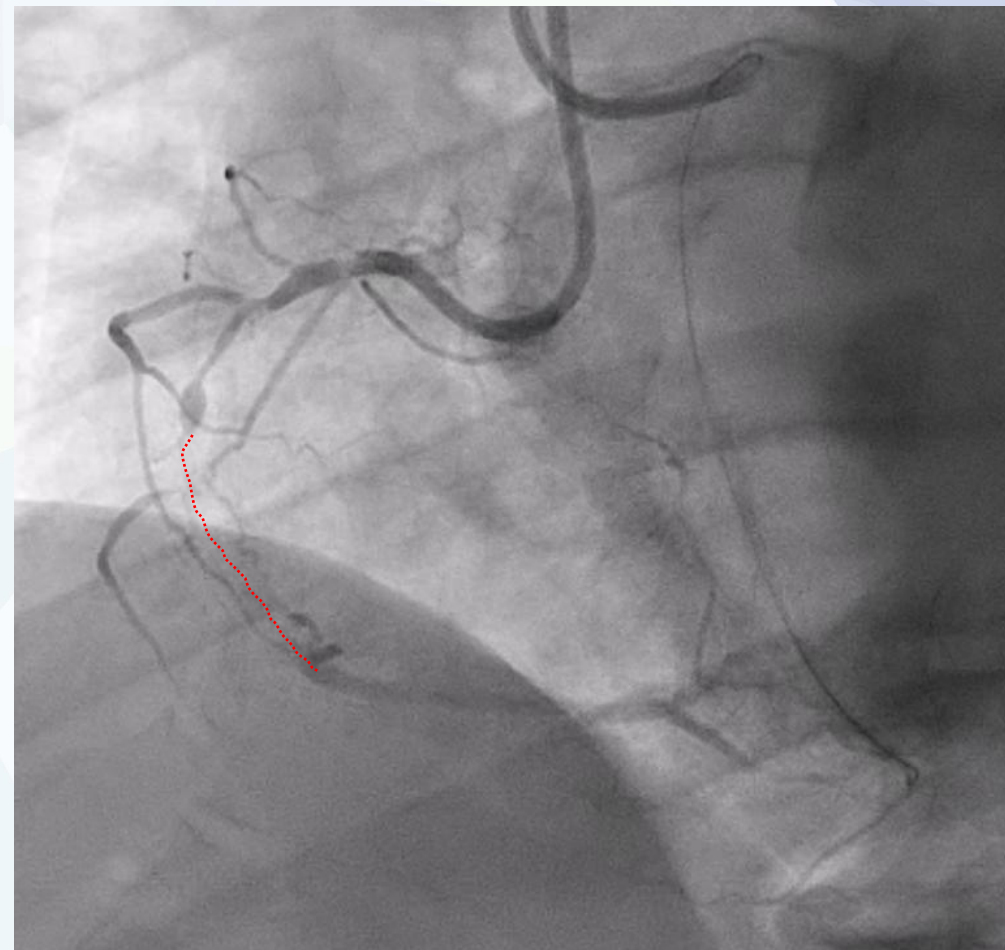


CTO PCI Plan

- **Biradial (distal left radial)**
- **7F (Glidesheath slender)**
 - **EBU 4 7F (90 cm)**
 - **AL 0.75 7F (SH)**

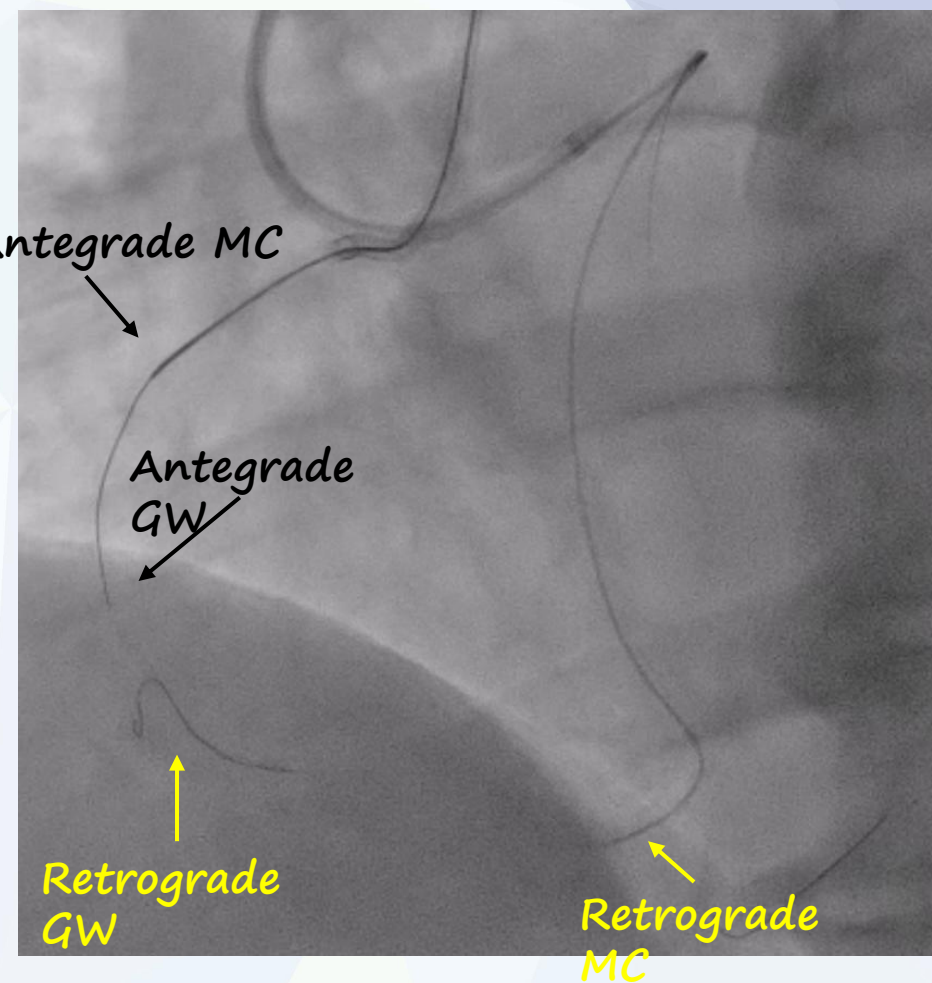
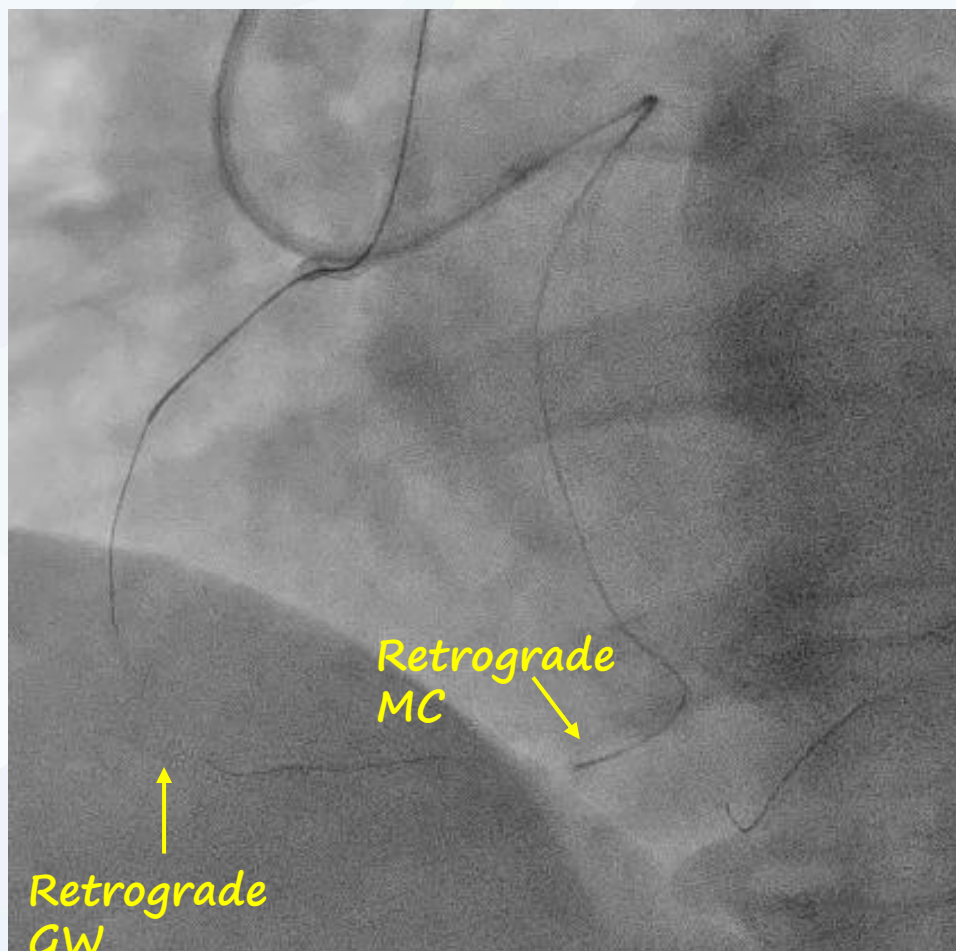
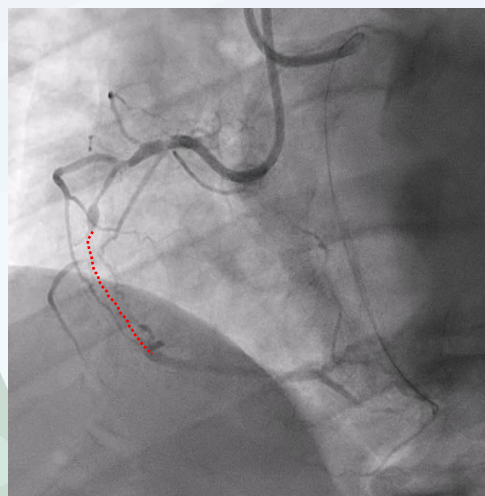
- A. AWE**
- B. Retrograde (Septal)**
- C. ADR**
- D. Retrograde (Epicardial)**

Bilateral injection

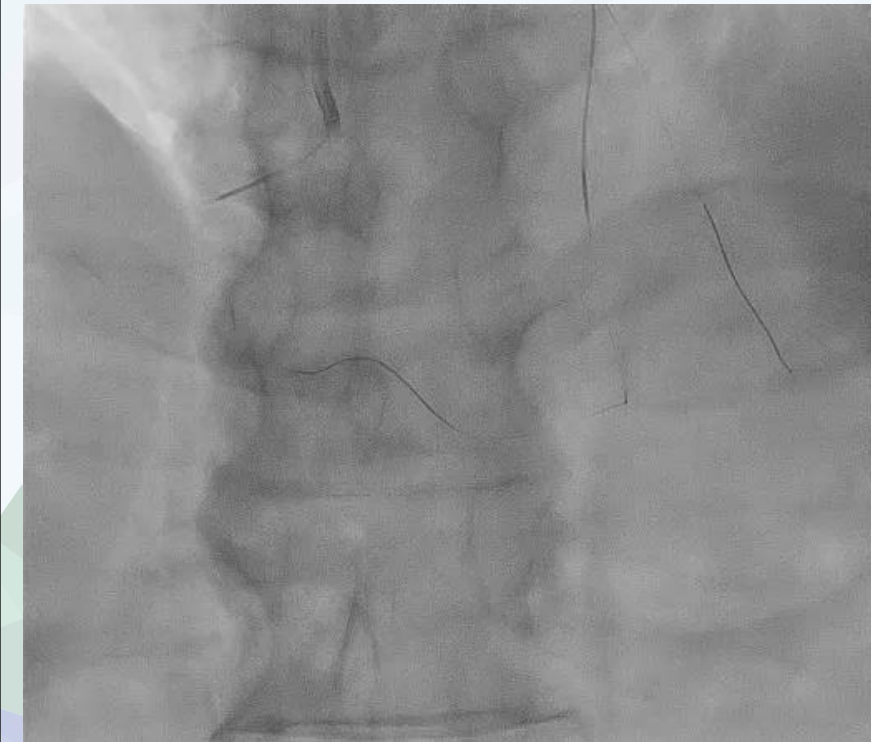


Proximal disease, some ambiguity at prox cap, long CTO.

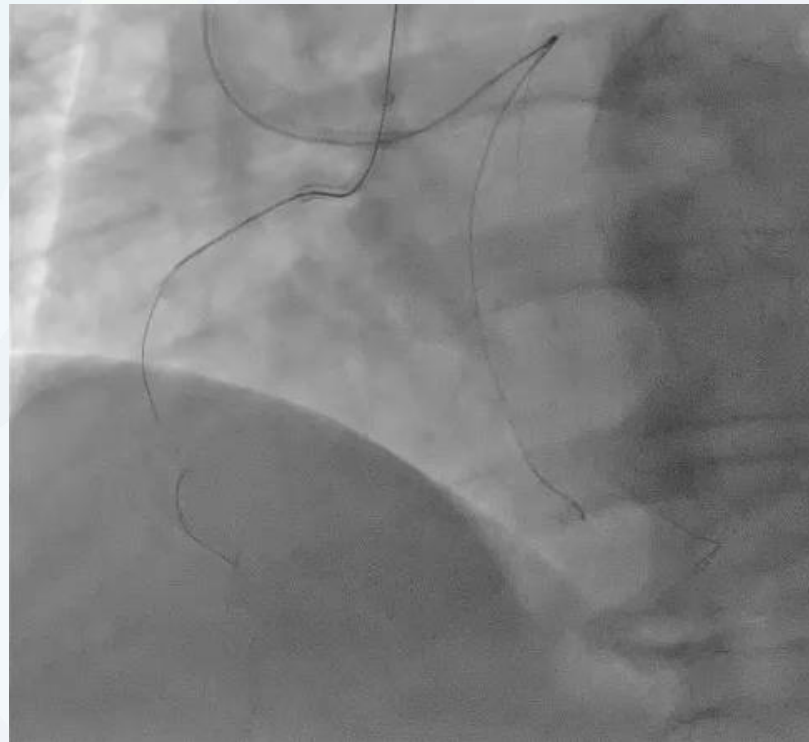
AWE -> Retrograde



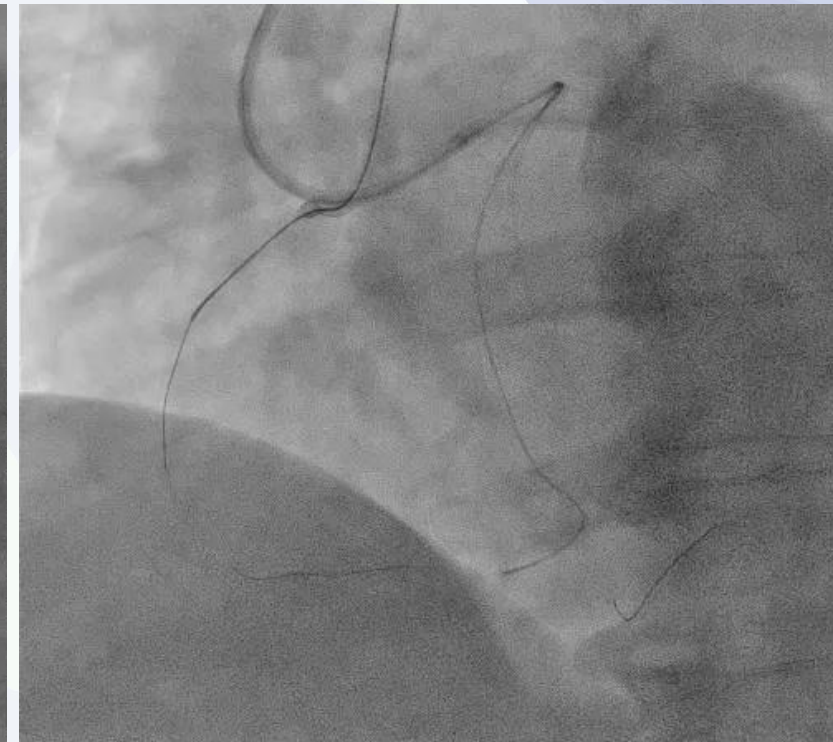
AWE failed. Retrograde Sion Black at distal cap but retro MC cannot advance



*Retrograde Sion Black through
Corsair Pro XS at PD*

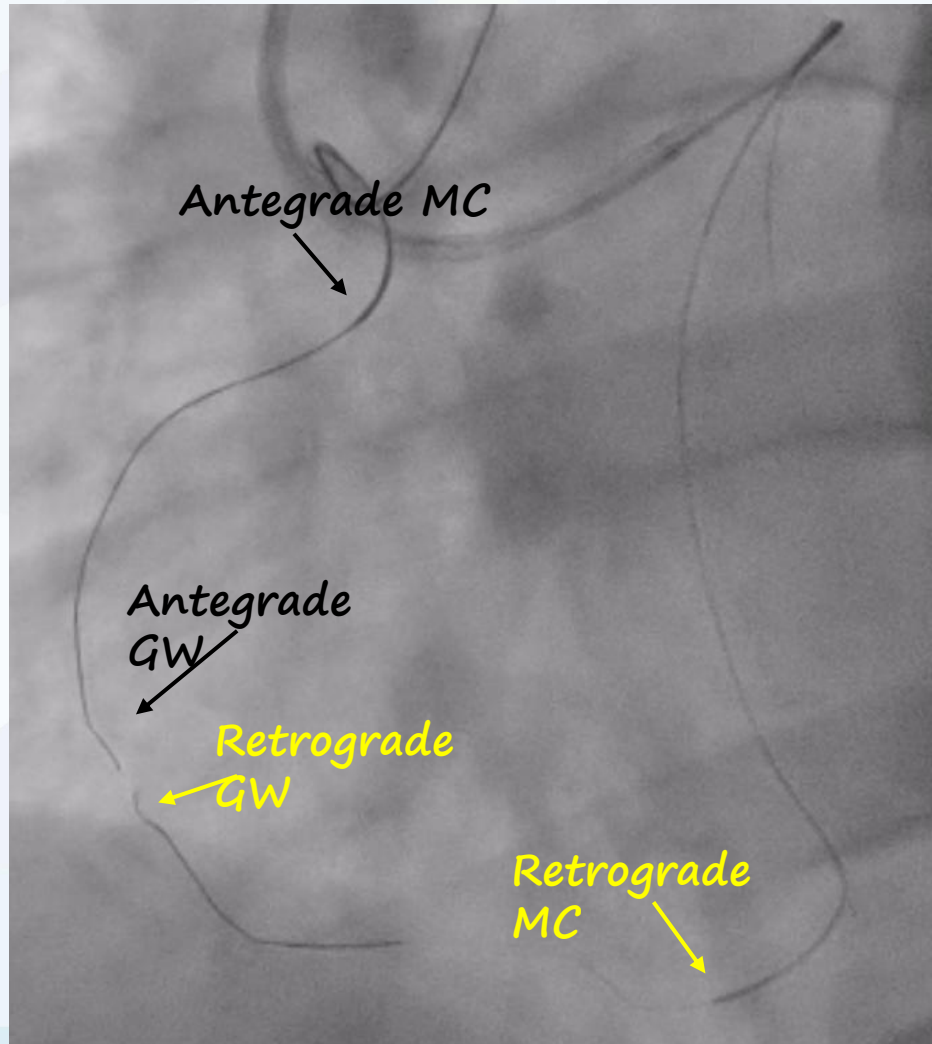


*Retrograde Corsair Pro
XS difficult
advancement*

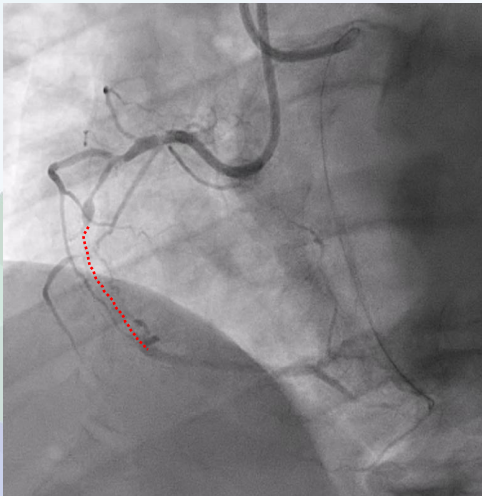
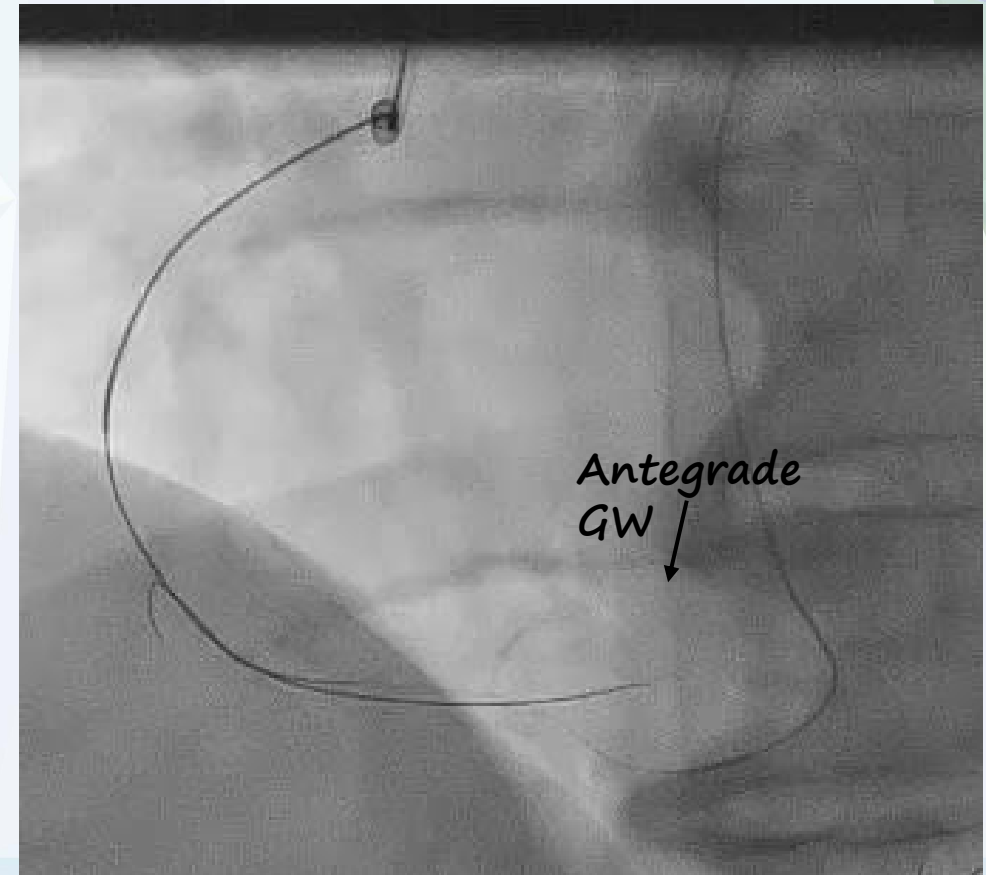


*Retrograde Corsair Pro
XS at RCA but high
friction*

Retrograde -> AWE (retrograde marker)

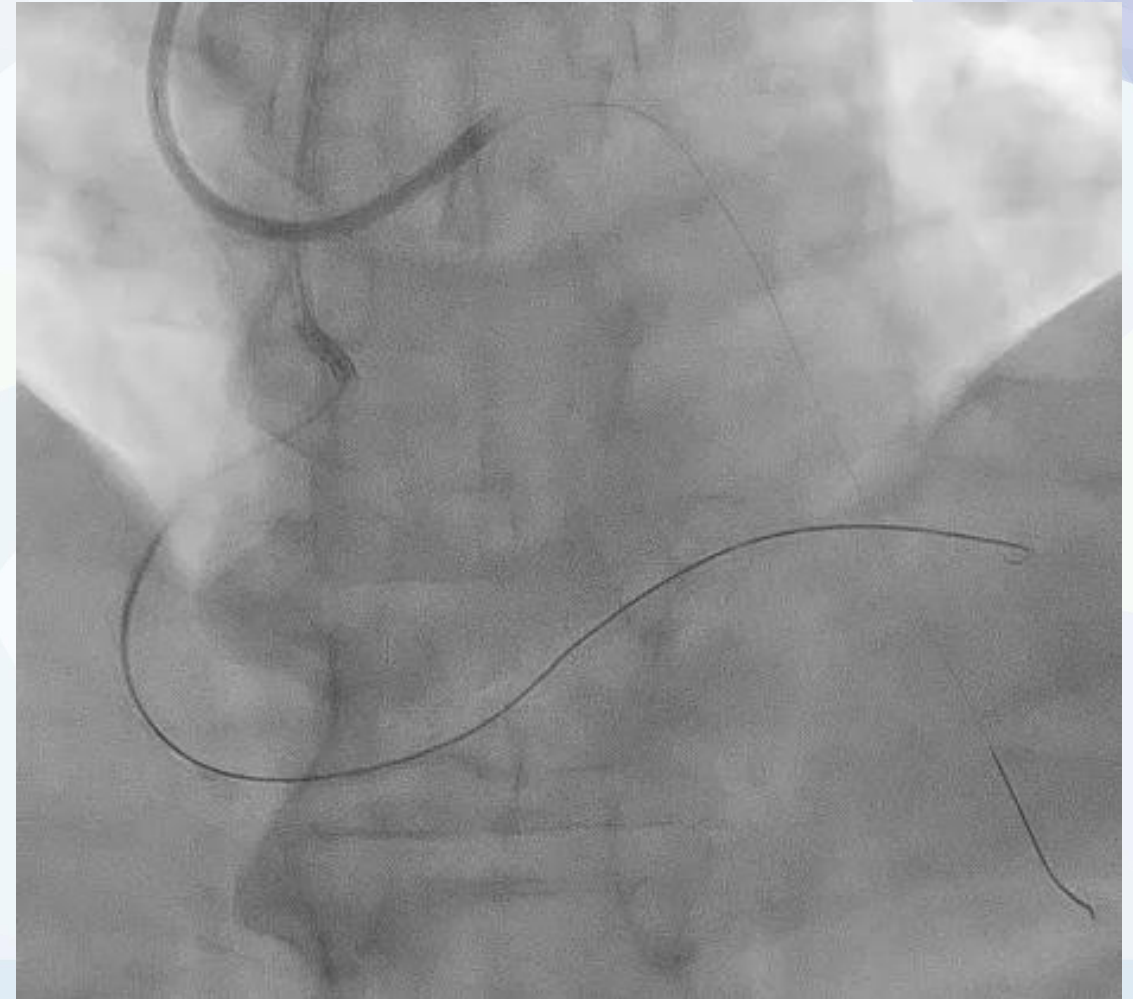
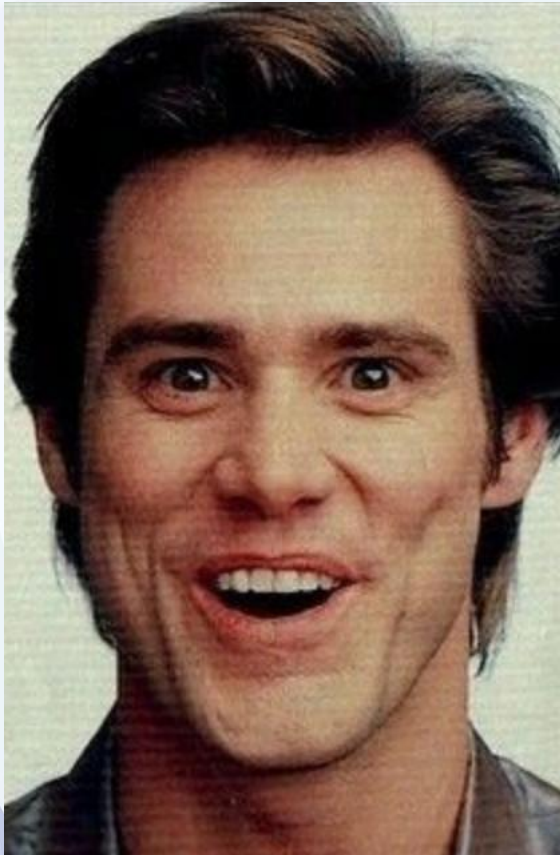


Antegrade Gaia 2nd using retrograde wire as a marker



Antegrade wire in the true lumen

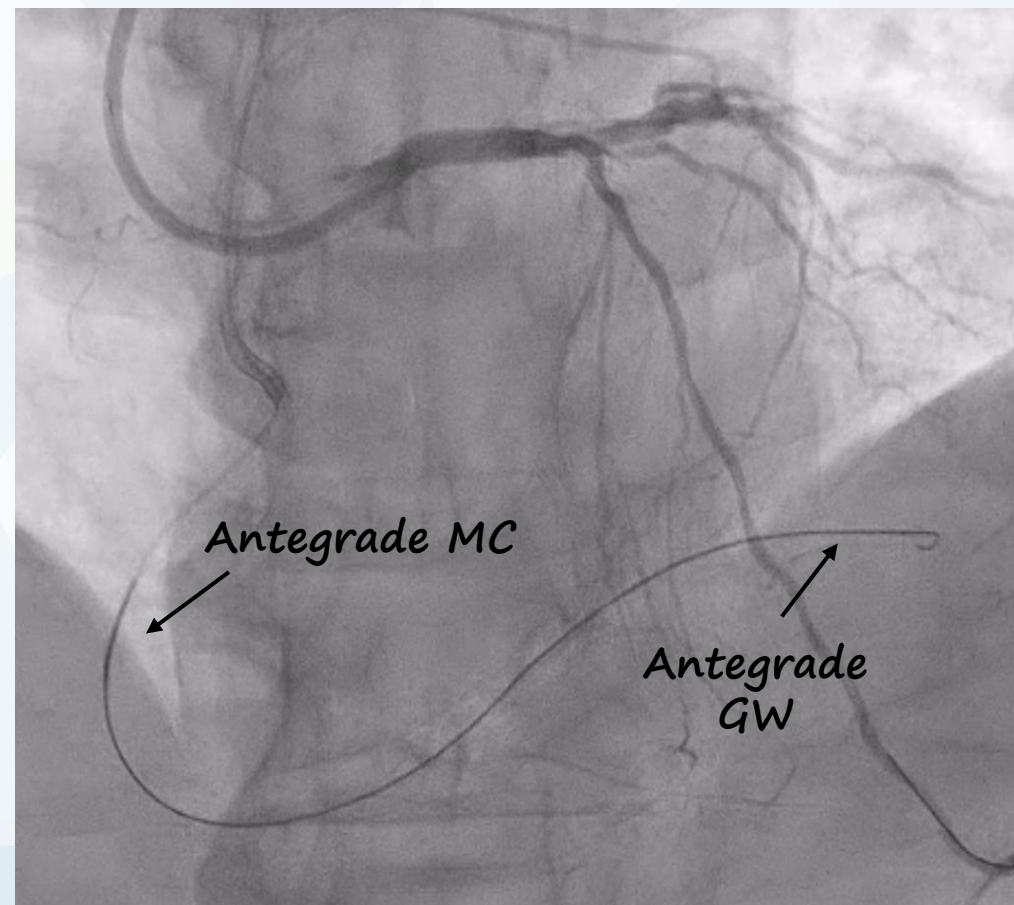
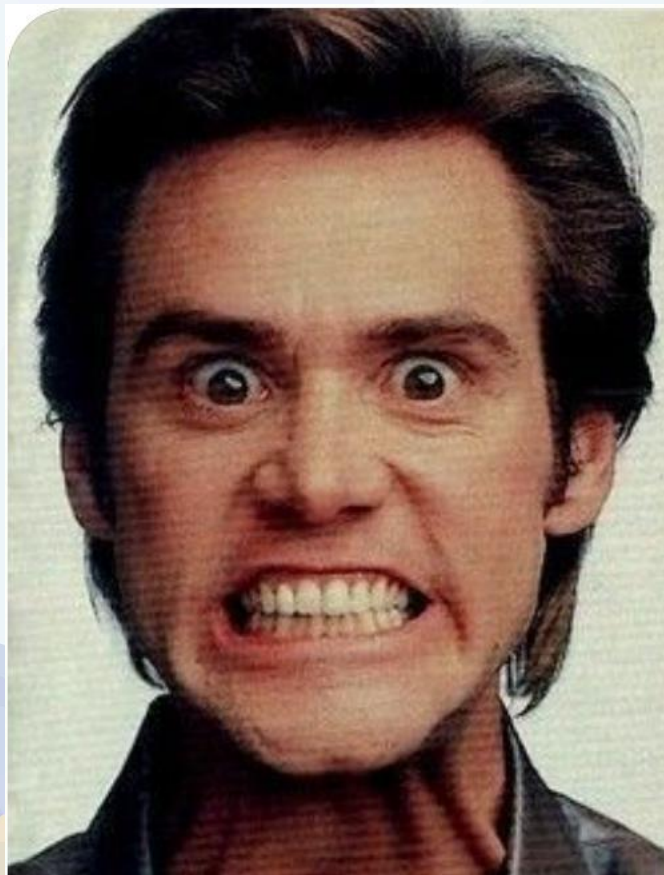
It is almost done....



But...

...Uncrossable lesion

*Gaia 2nd in distal PL but Caravel and Turnpike Spiral cannot advance...
...neither small-profile balloons...even with GEC*

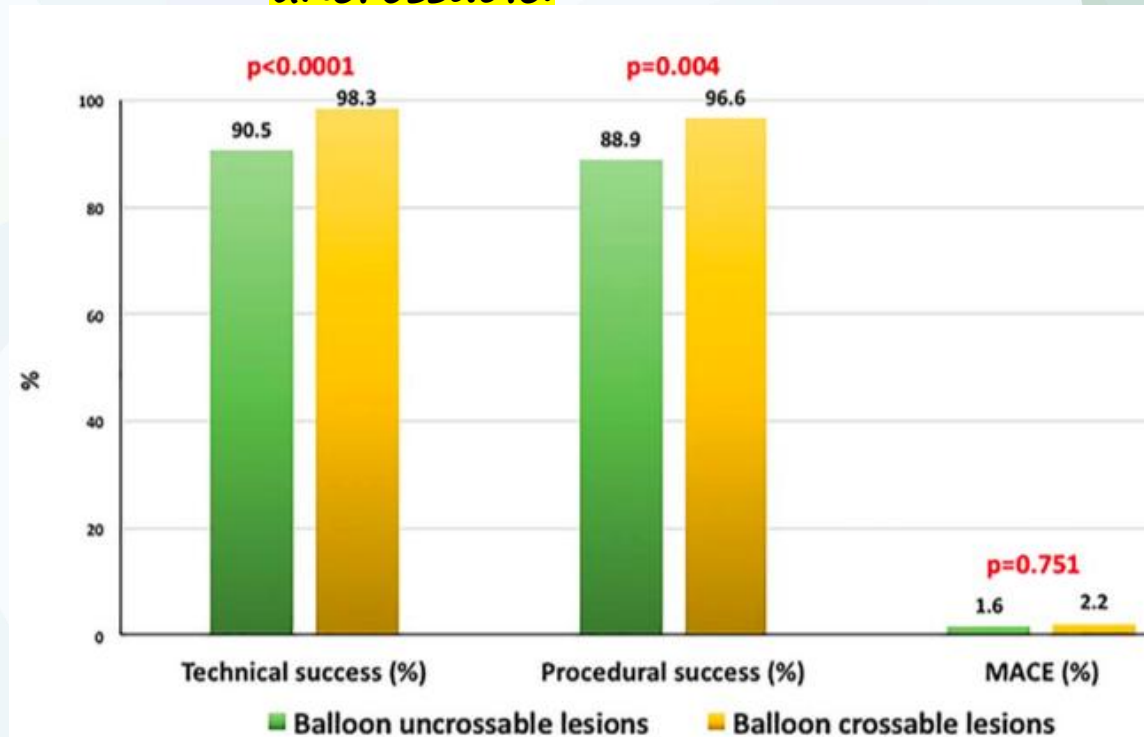


Prevalence, Indications and Management of Balloon Uncrossable Chronic Total Occlusions: Insights from a Contemporary Multicenter US Registry

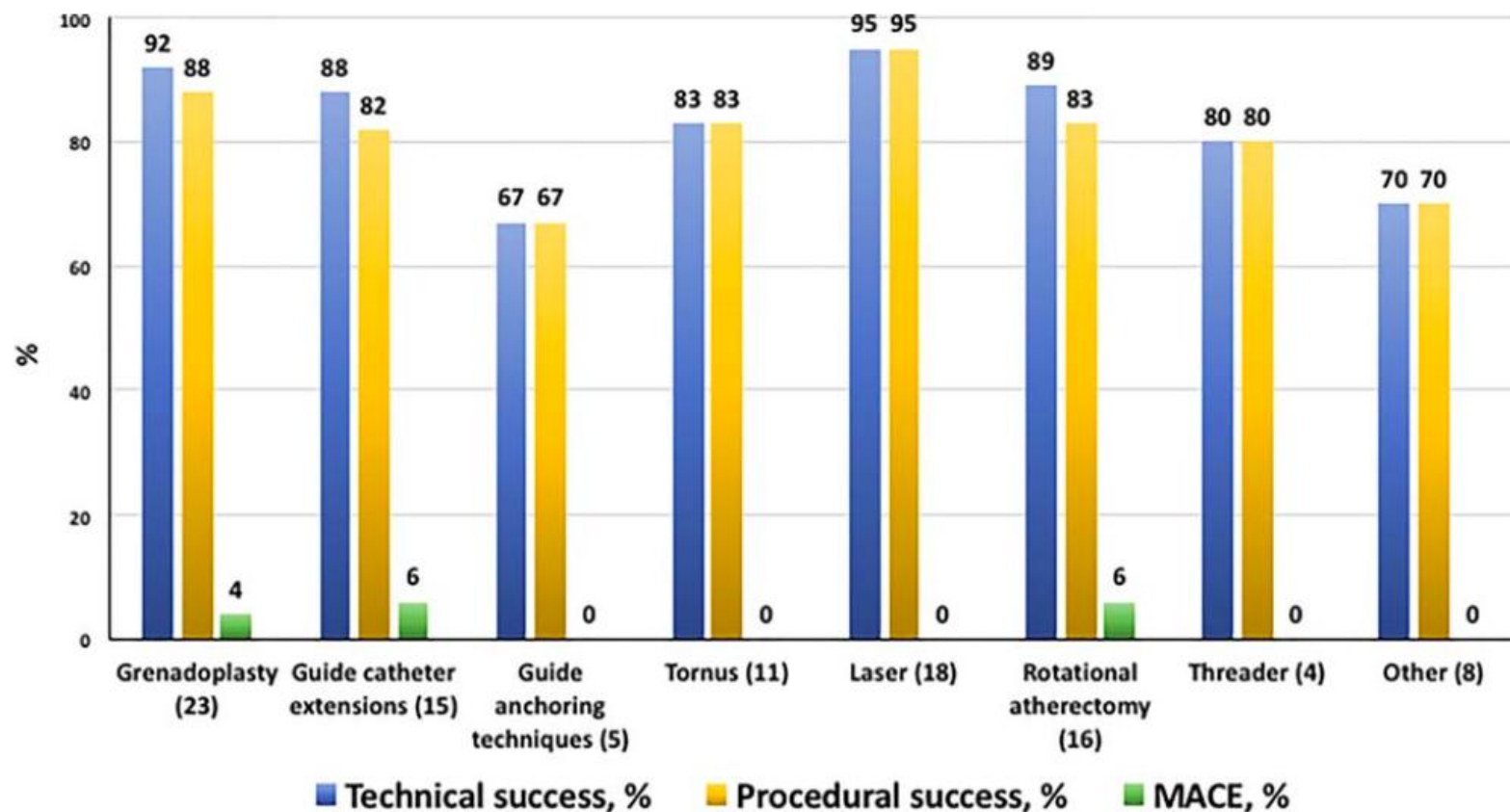
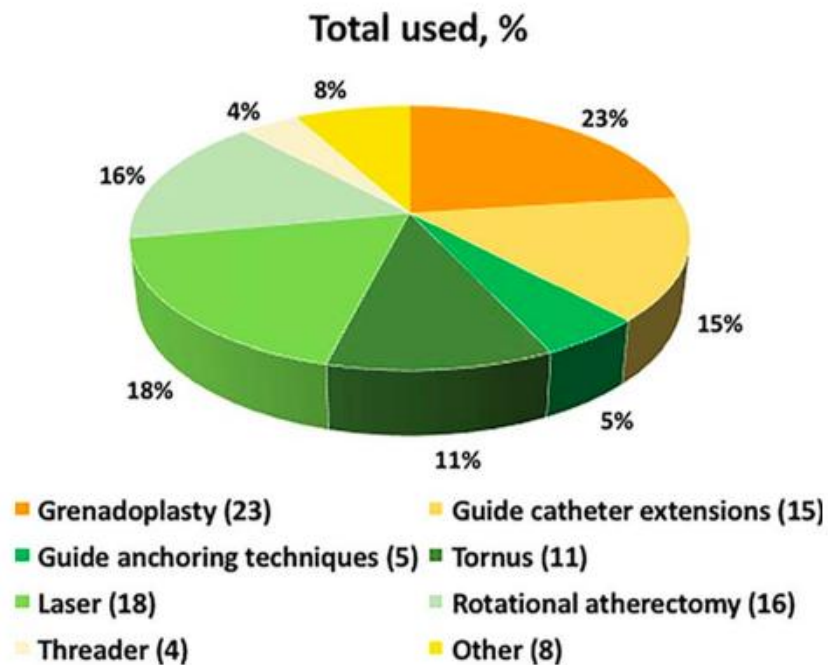
PROGRESS CTO Registry

- 718 CTO PCI in which wire crossed
- 9% of CTO were Balloon uncrossable.

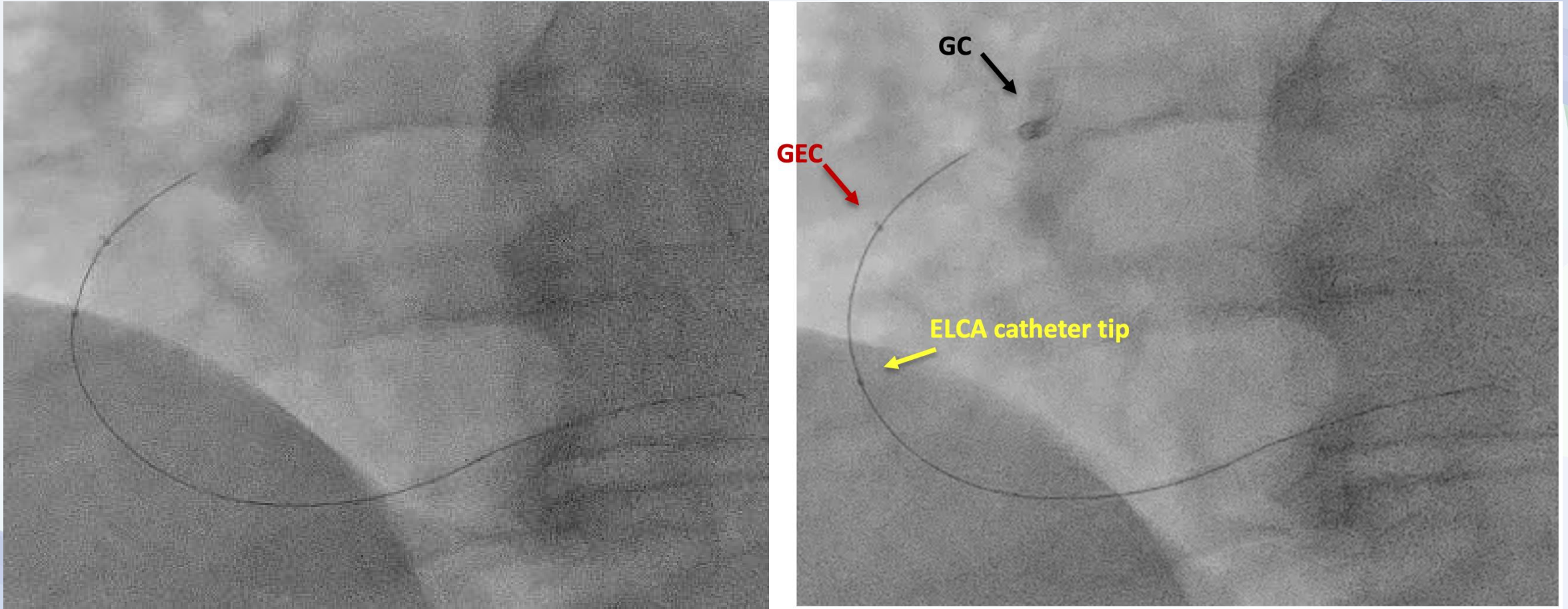
Variable	Overall (n = 718)	Balloon uncrossable CTOs (n = 63)	Balloon crossable CTOs (n = 655)	P
CTO target vessel				0.005
• RCA	52%	56%	52%	
• LAD	25%	16%	26%	
• LCX	22%	26%	22%	
Successful crossing strategy				0.064
• Antegrade wiring	52%	65%	51%	
• Retrograde	26%	22%	26%	
• Antegrade dissection and re-entry	22%	13%	23%	
First crossing strategy				0.856
• Antegrade wiring	76%	76%	76%	
• Retrograde	16%	14%	16%	
• Antegrade dissection and re-entry	8%	10%	8%	
Retrograde crossing attempt	38%	32%	38%	0.315
J-CTO score ^a	2.48 ± 1.25	2.95 ± 1.32	2.43 ± 1.23	0.005
Progress-CTO score ^a	1.21 ± 1.02	1.41 ± 1.14	1.19 ± 1.00	0.142
Calcification (moderate/severe)	55%	82%	52%	<0.0001
Tortuosity (moderate/severe)	37%	61%	35%	<0.0001
Proximal cap ambiguity	30%	22%	31%	0.165
In-stent restenosis	16%	25%	15%	0.043
Prior failure to open CTO	19%	30%	18%	0.023
Interventional collaterals	55%	56%	55%	0.86
Side branch at the proximal cap	49%	47%	49%	0.846
Blunt/no stump, %	56%	52%	57%	0.5
Vessel diameter (mm) ^b	3.0 (2.5, 3.0)	3.0 (2.5, 3.0)	3.0 (2.5, 3.0)	0.827
Occlusion length (mm) ^b	25 (15, 40)	30 (15, 50)	25 (15, 40)	0.162
Number of stents used	2.5 ± 1.2	2.8 ± 1.4	2.5 ± 1.2	0.084



Prevalence, Indications and Management of Balloon Uncrossable Chronic Total Occlusions: Insights from a Contemporary Multicenter US Registry



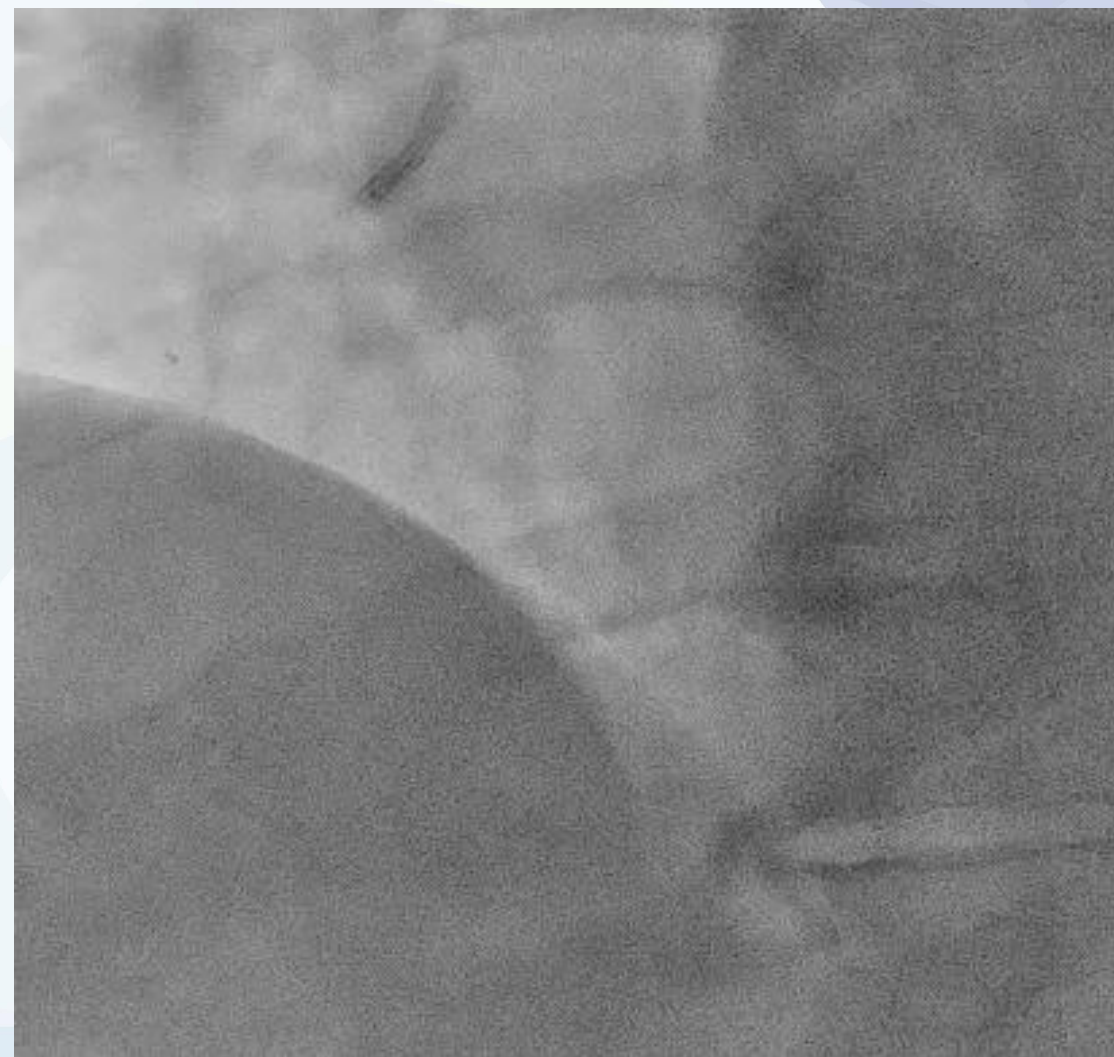
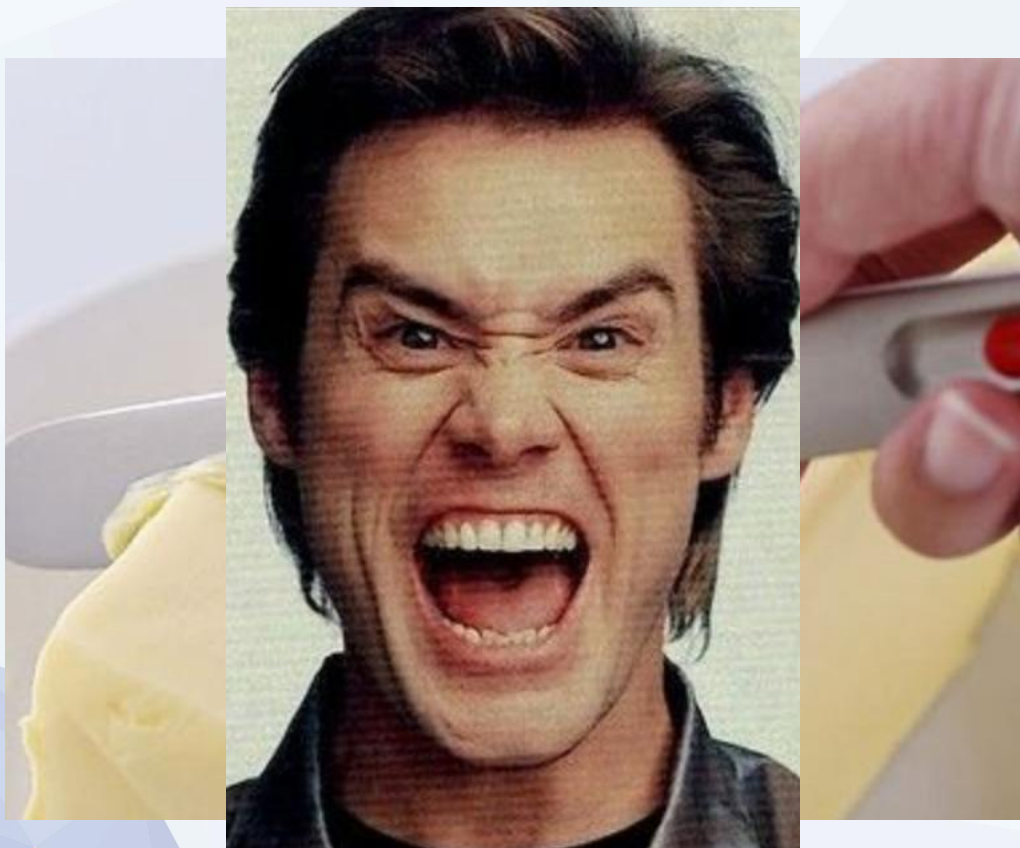
ELCA



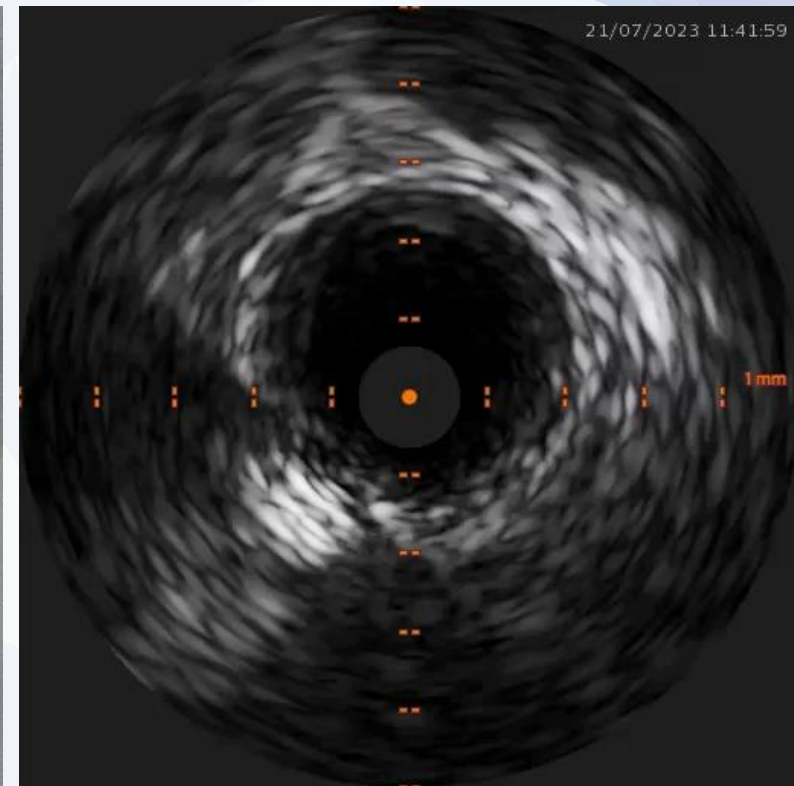
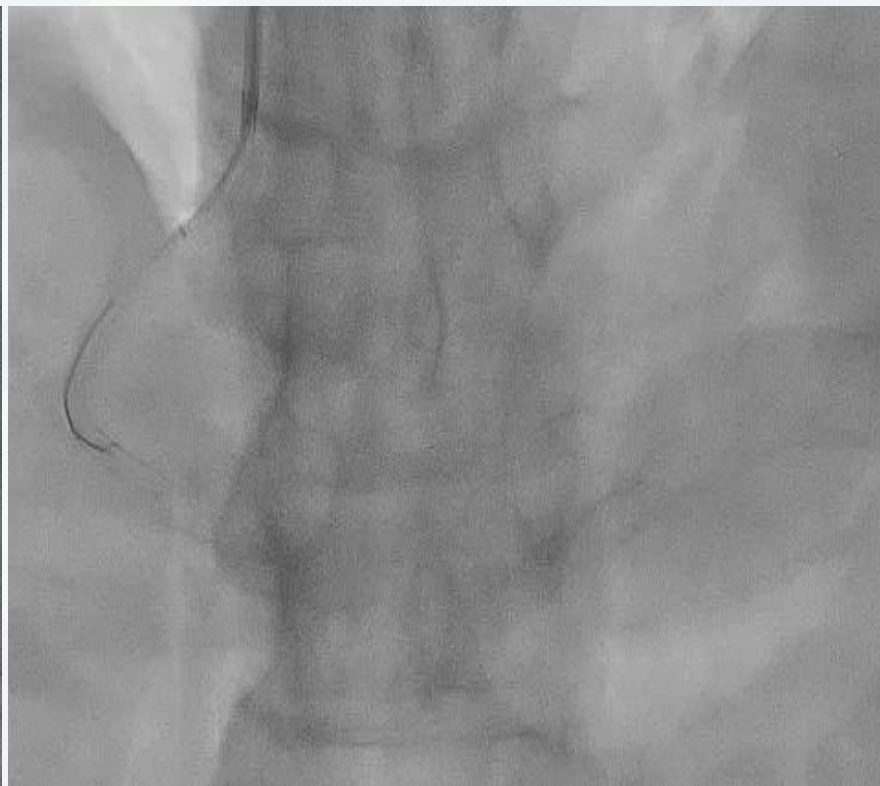
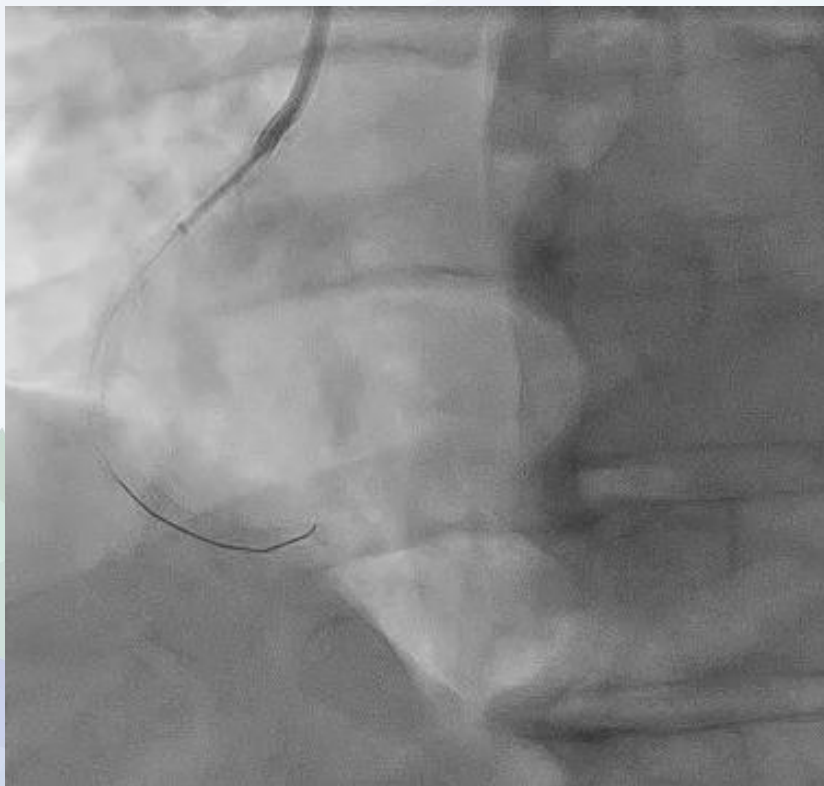
*0.9 mm ELCA catheter slow advancement through the uncrossable part
(saline; 60 mJ/mm²; 60 Hz; 1315 pulses, 21 s)*

ELCA

3.0 mm NC balloon crossed easily (Good expansion)



2 overlapped EuNIR 3.5 mm



Why the lesion is balloon uncrossable?

Lesion

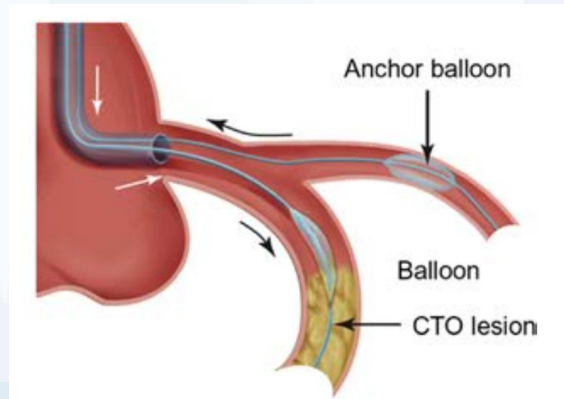
- CTO
- Severely calcified
- Tortuous
- Ostial
- ISR

Techniques and materials

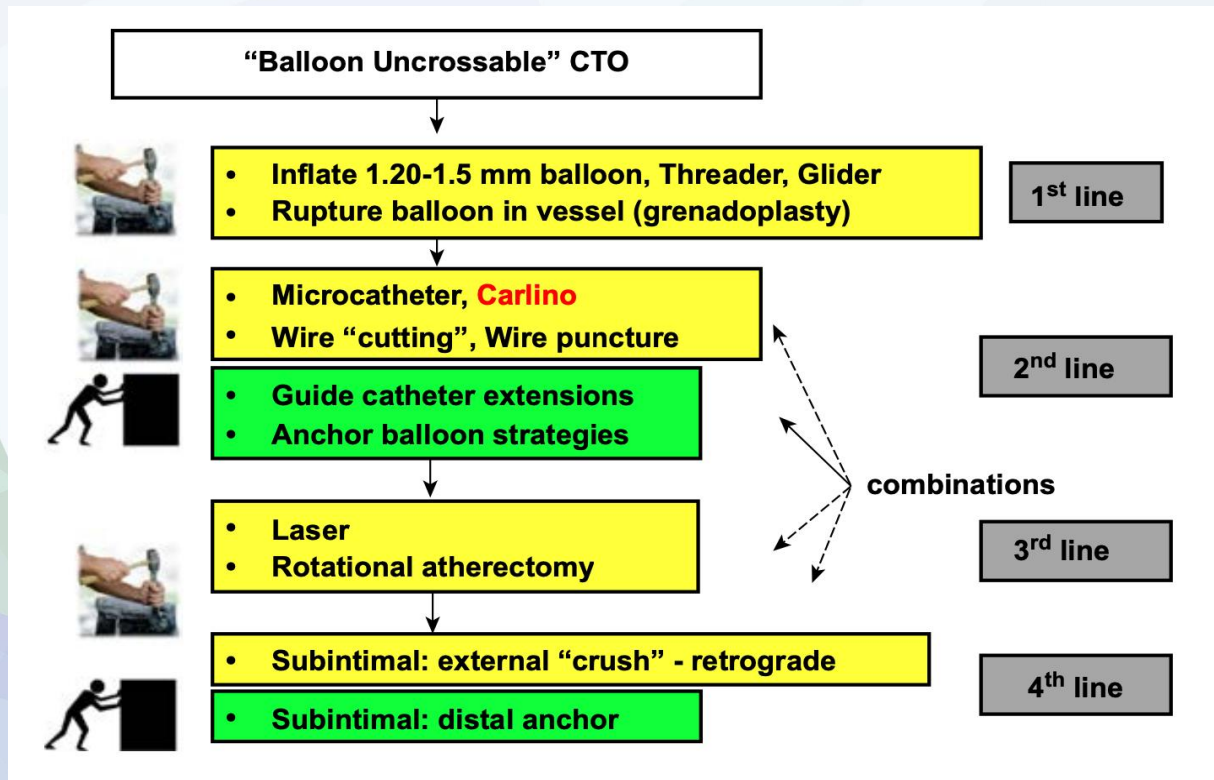
- Guiding support
- Balloon's characteristics
- Techniques:
 - Anchoring
 - Mother and Child

Operator

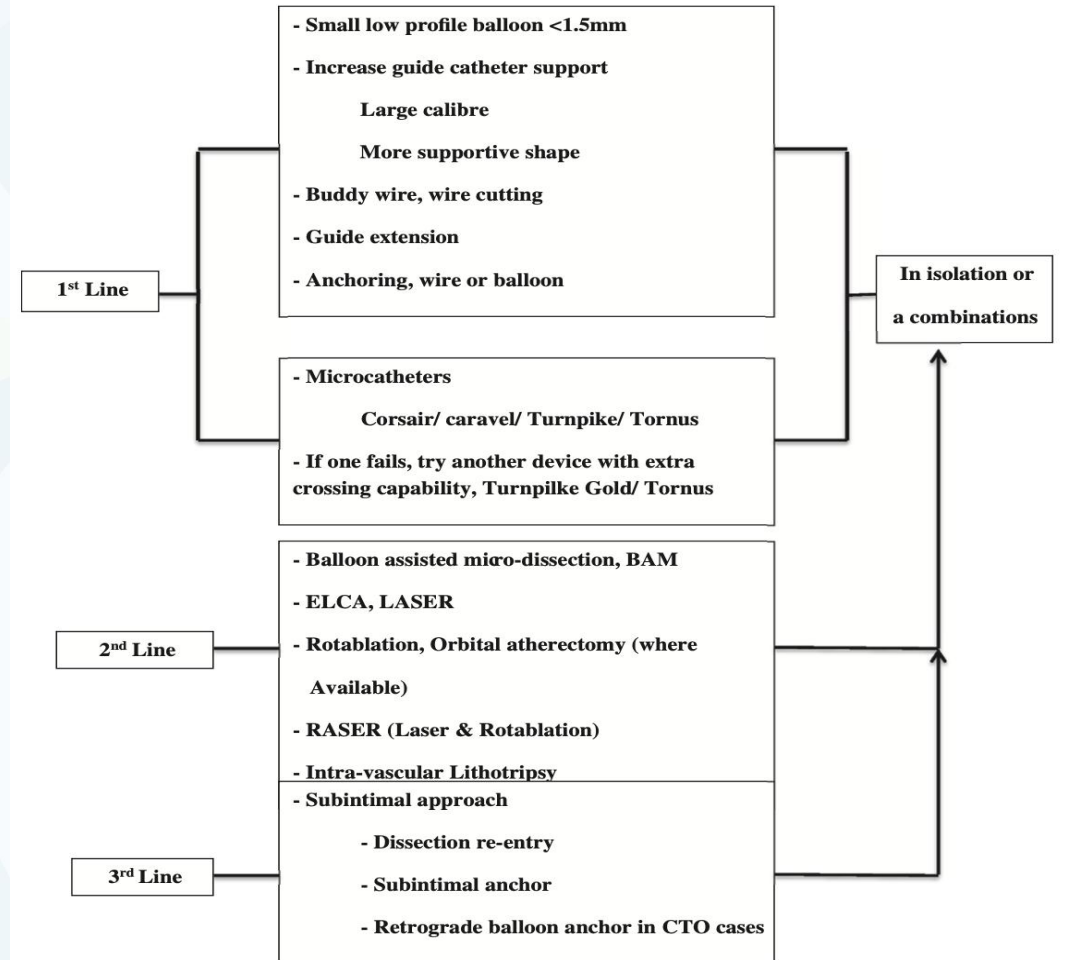
- Training
- Patience
- Persistence



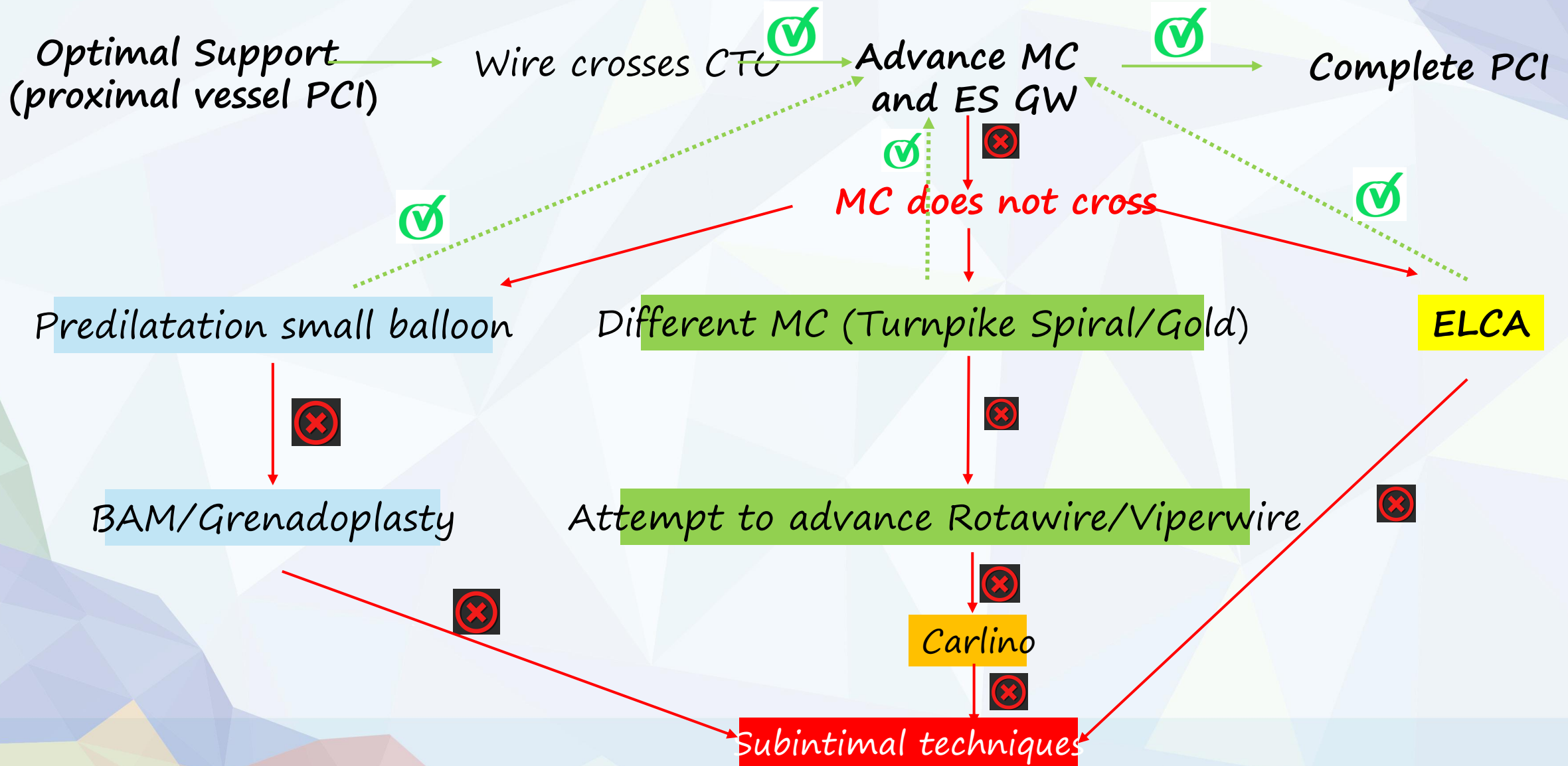
Several algorithms



Uncrossable and undilatable lesions—A practical approach to optimizing outcomes in PCI

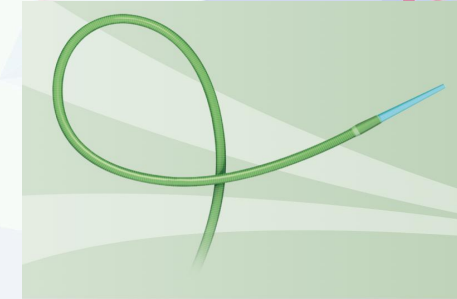


Our algorithm

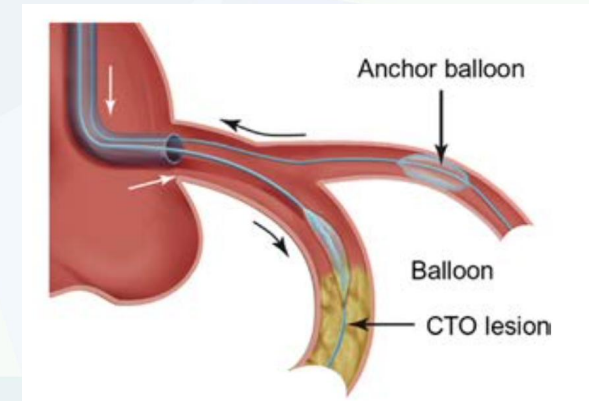


Optimal Support (proximal vessel PCI)

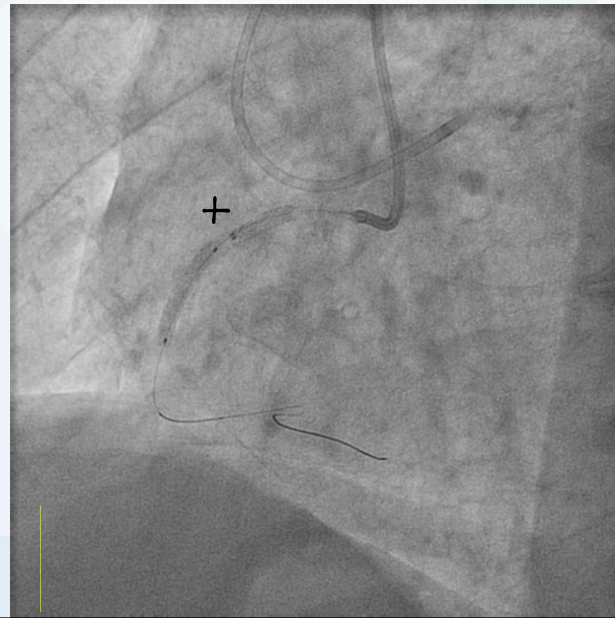
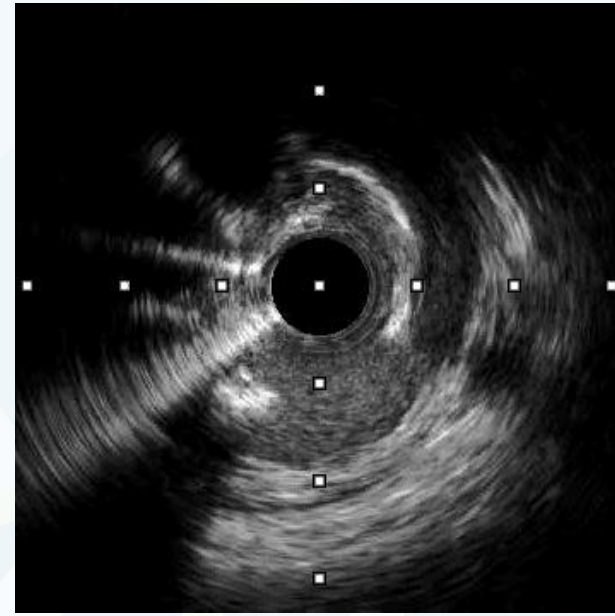
- Acceso (Femoral 8F casos seleccionados)
- CG adecuado (7F/SH/Longitud)
- GEC/Anchoring
- Retrógrado (Guía externalizada)



Destination™
Guiding Sheath



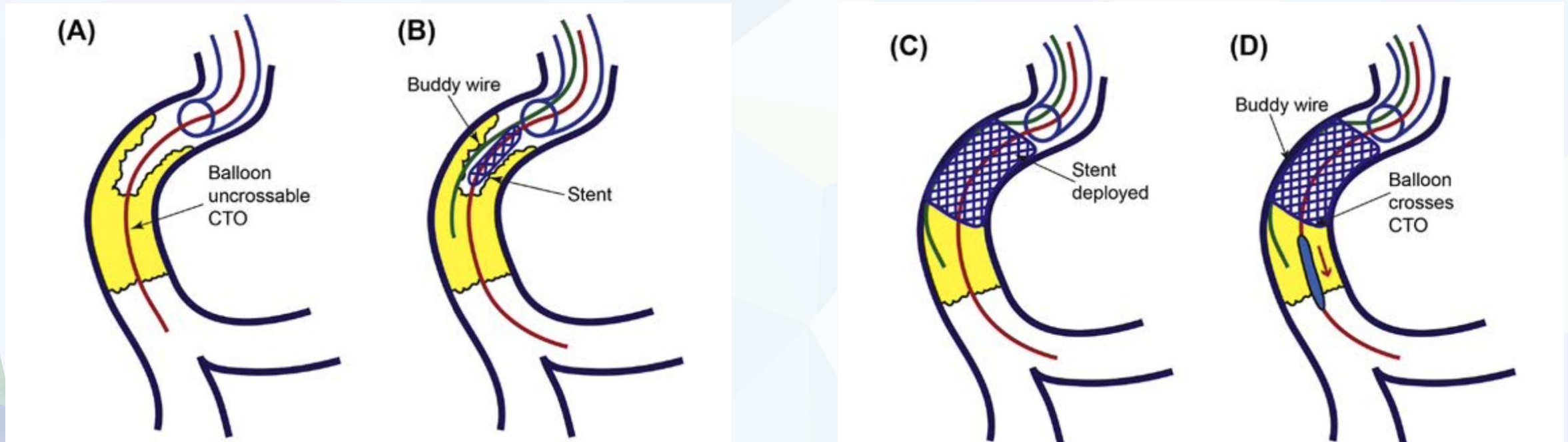
Optimal Support (proximal vessel PCI)



- 70 yo male. RCA CTO since 2007.
- Angina CCS 2-3. Inf viability
- Hybrid approach:
- Plan A: AWE with DL MC at marginal branch.
- Some friction at prox RCA.
- Predilatation (severe underexpansion*)
- IVUS (severe calcification)
- IVL: SB 3mm (anchoring needed) Guideliner+ and 2 overlapped DES at prox-mid RCA

Optimal Support (proximal vessel PCI)

Buddy-wire stent anchor technique



Our algorithm

Optimal Support
(proximal vessel PCI)

Wire crosses CTU

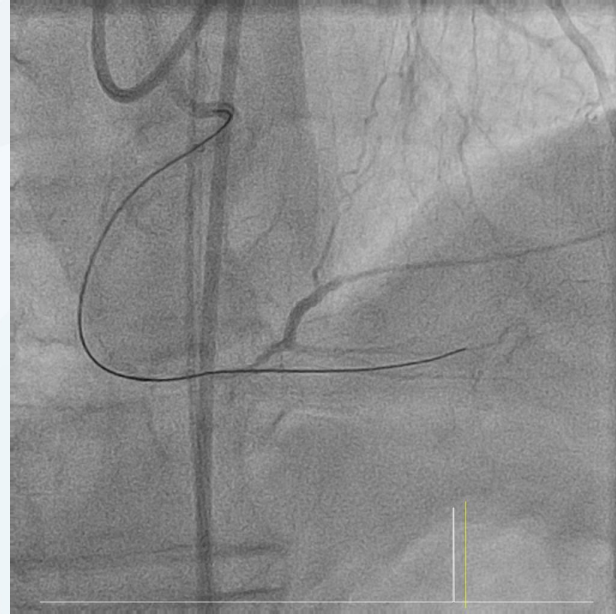
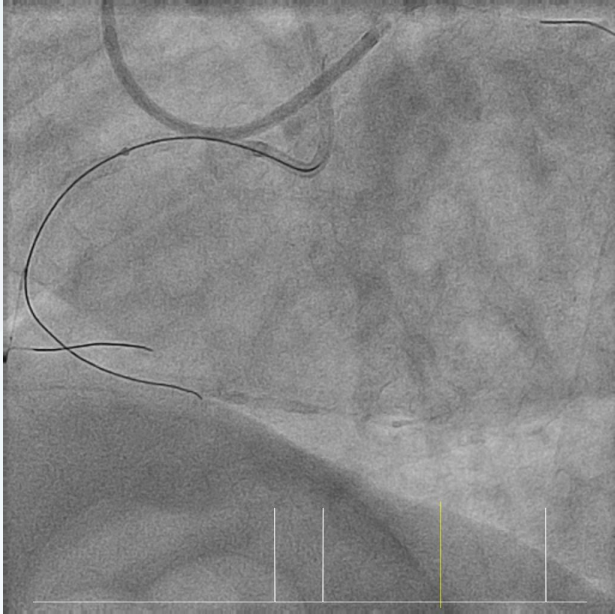


Advance MC
and ES GW



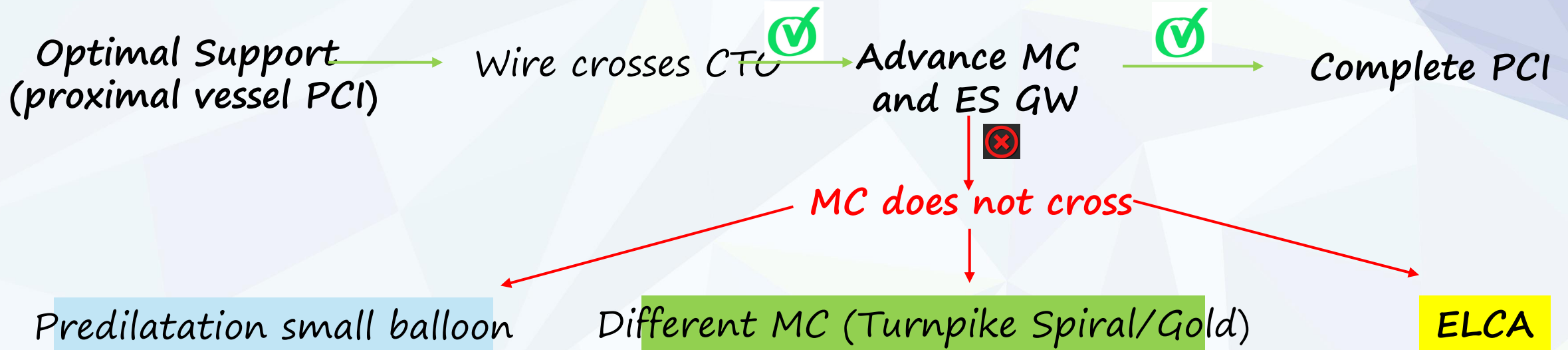
Complete PCI

Wire crosses CTO  Advance MC  Complete PCI
and ES GW

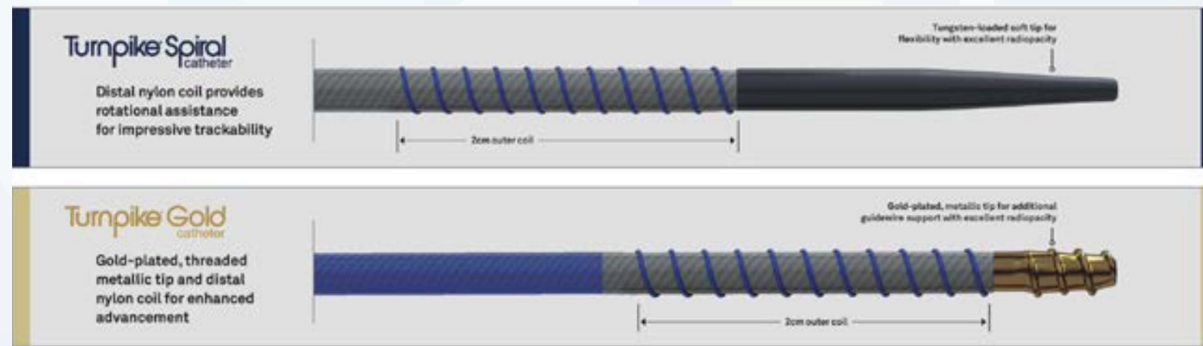


- Sasuke DLMC.
- Fighter couldn't advance/Miracle extraplaque.
- Sasuke did not cross/Exchange for Caravel
- Gaia 2 reentry proximal to the crux.
- Step down to Sion Blue ES.
- Predilatation and IVUS
- Overlapped DES and optimization

Our algorithm



- Single-marker, R-X, “long”
- Balloon-wedge technique
- Bigger balloon at prox can



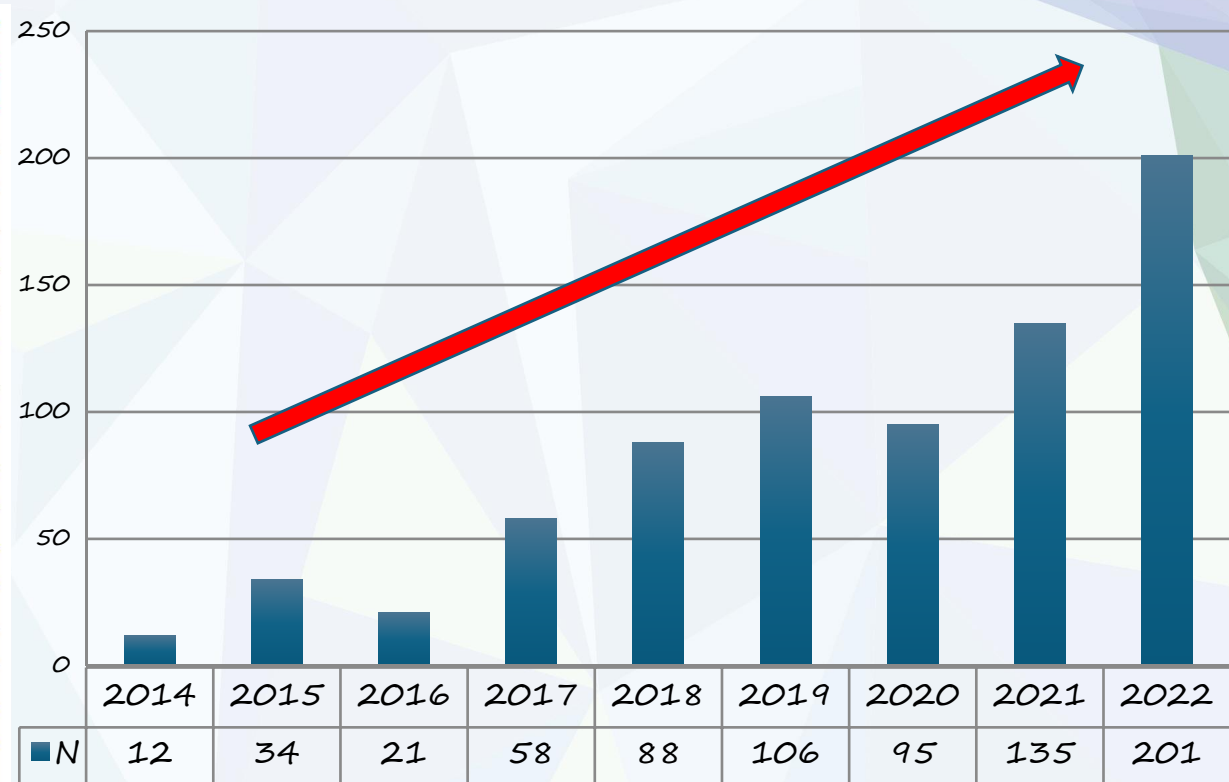
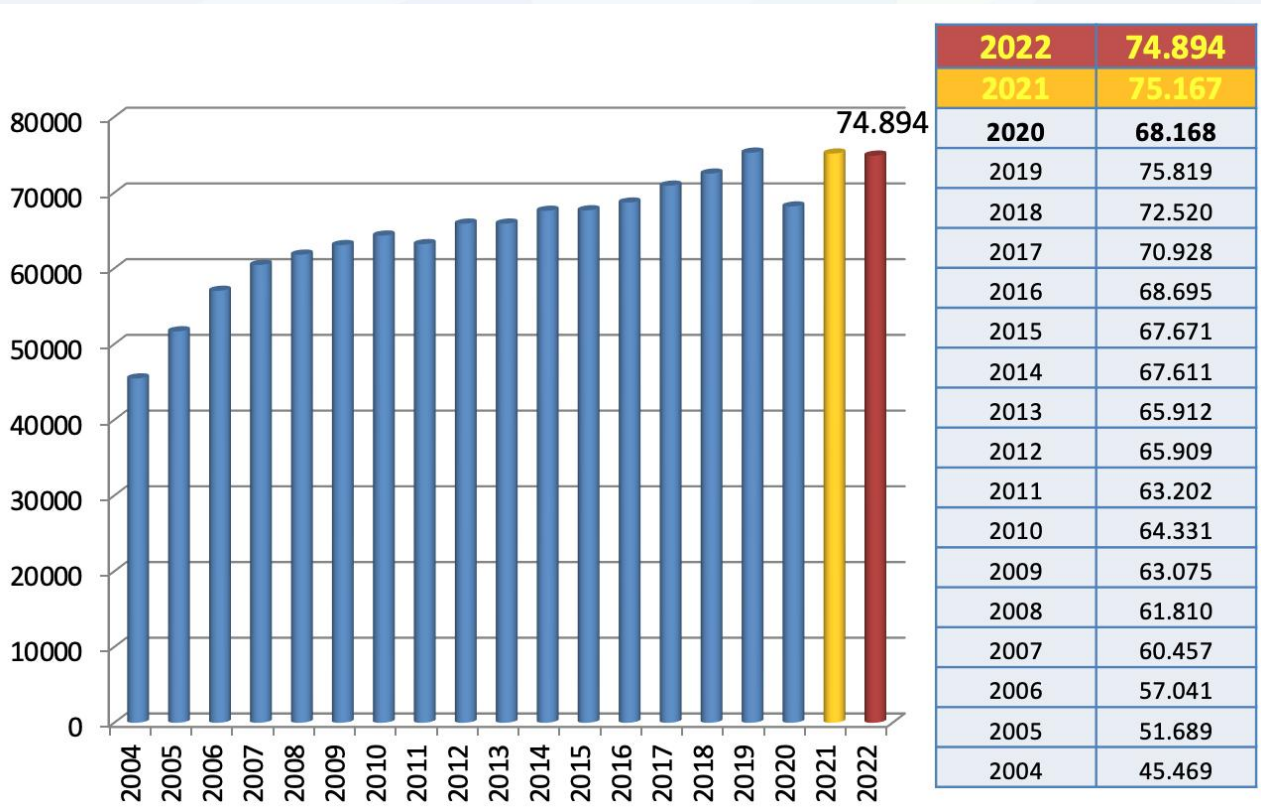
ELC

A

Last 8 years: ELCA x 17

PCI

ELCA



A. Jurado-Román et al.

Excimer Laser Coronary Angioplasty in Coronary Lesions

Use and Safety From the NCDR/CATH PCI Registry

ELC

A

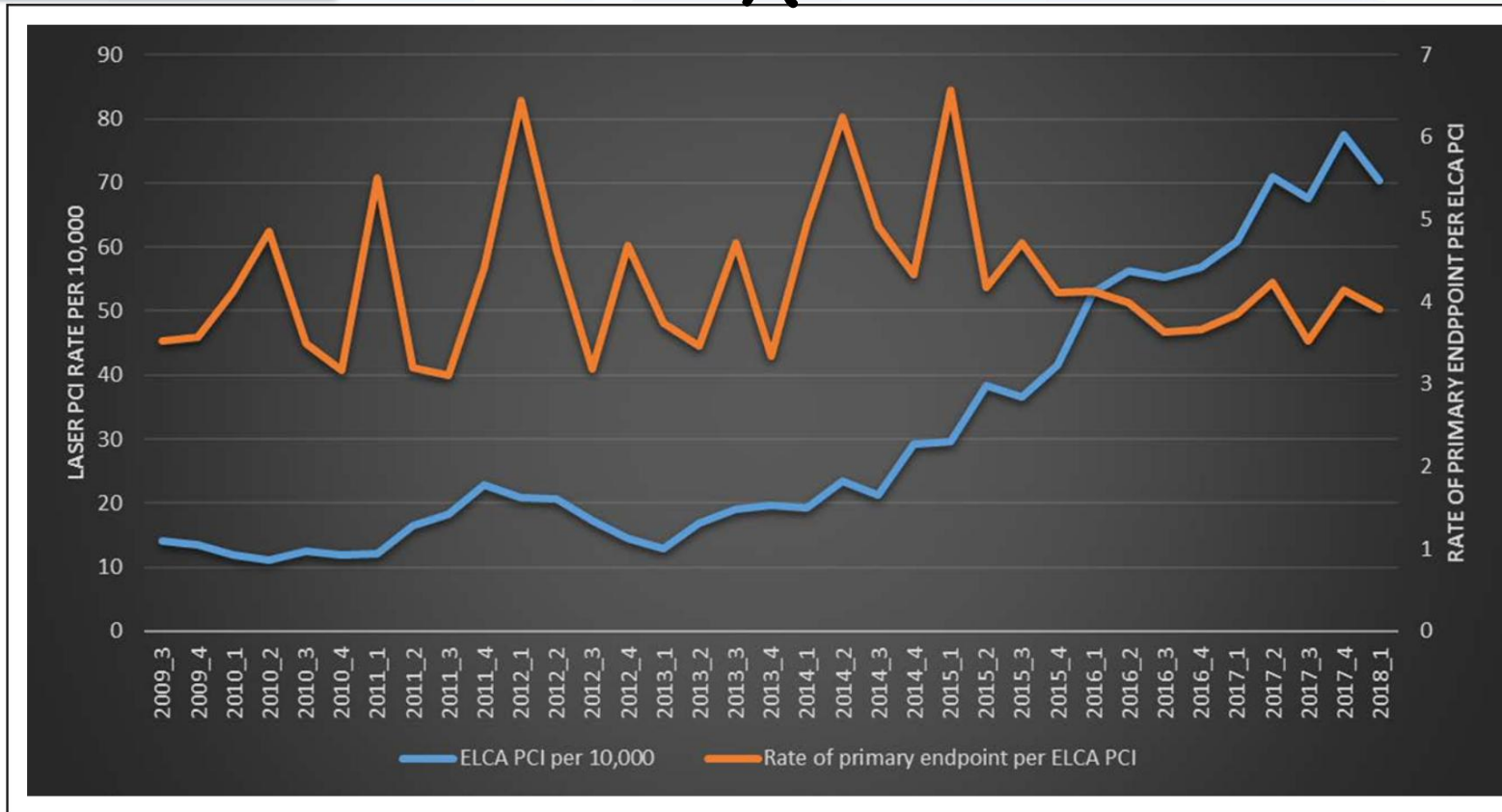
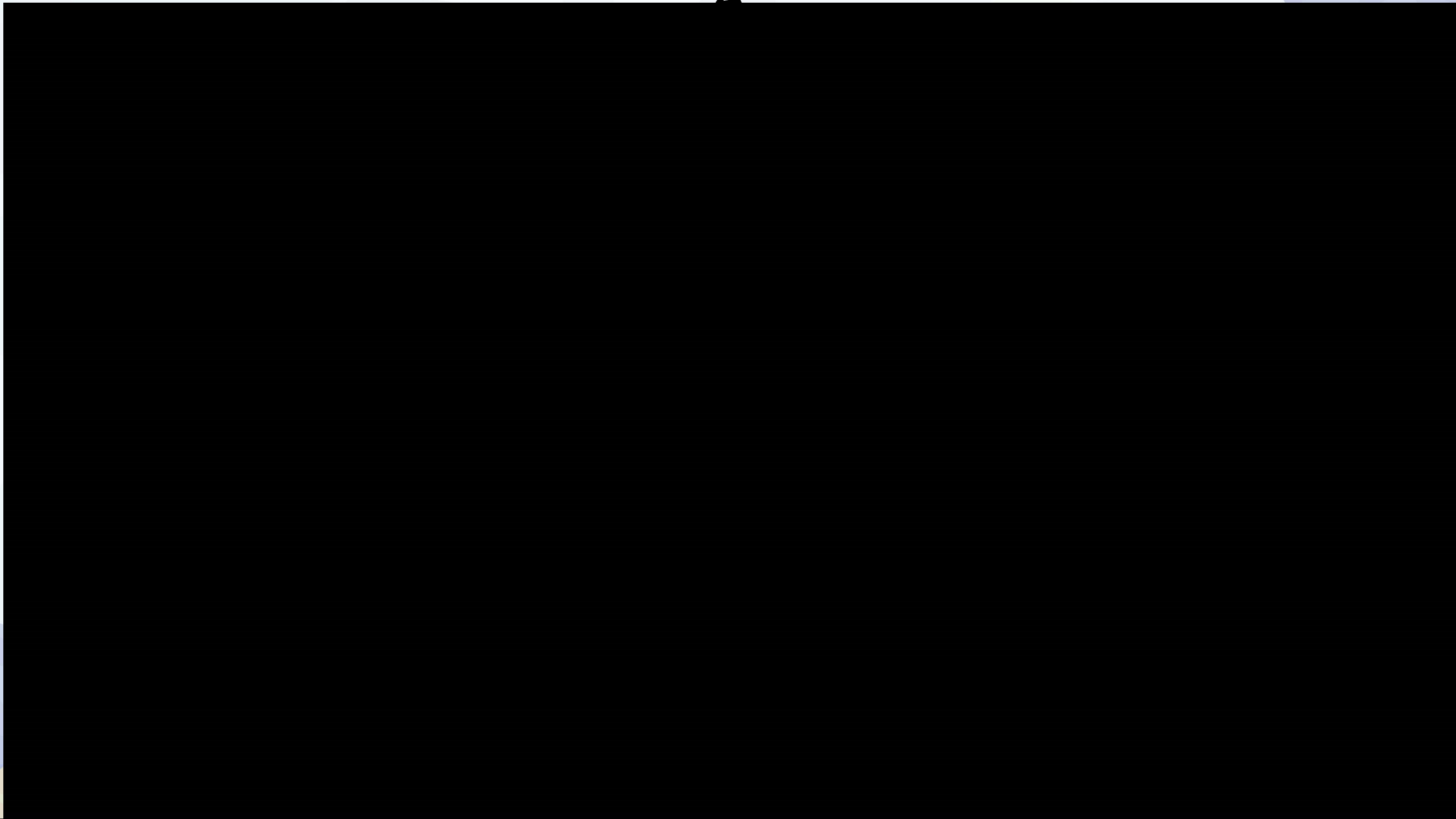


Figure 1. Excimer laser coronary angioplasty (ELCA) use and complication rate in the National Cardiovascular Data Registry/ CATH percutaneous coronary intervention (NCDR/CATH PCI) registry version 4.4.

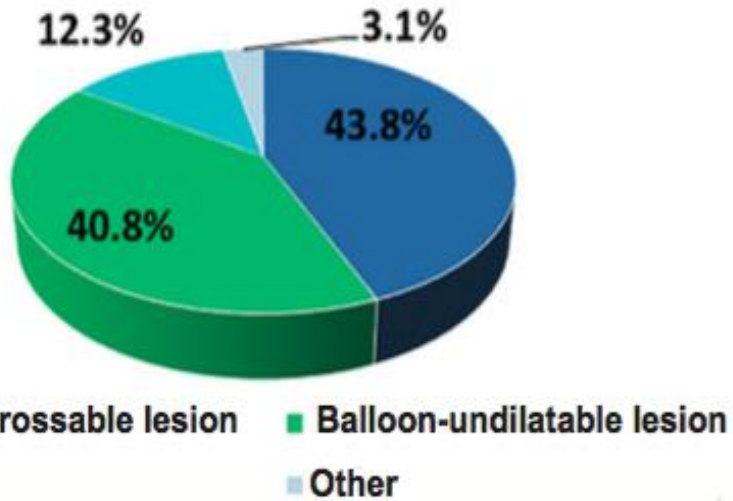
ELCA use is reported per 10000 interventions for each year_quarter available. The rate of the combined primary end point of any perforation, dissection, tamponade, or death before discharge from the index procedure is plotted for each quarter and is not significantly different over time ($P=0.169$).

ELC

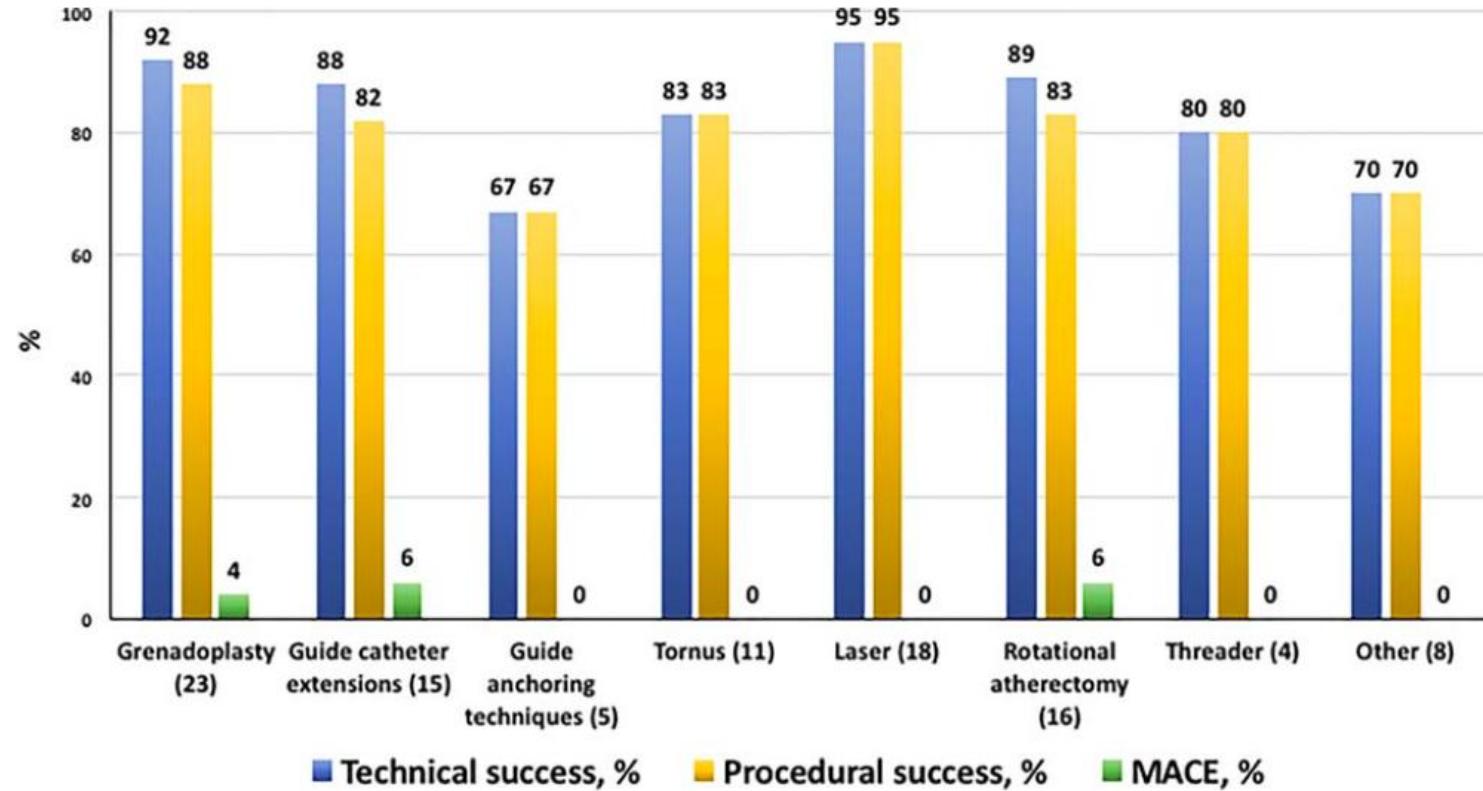
A



ELC
A



Karacsonyi et al, J Invasive Cardiol 2018; 30: 195-201



Karacsonyi et al. Catheterization and Cardiovascular Interventions 2017; 90:12-2

ELC

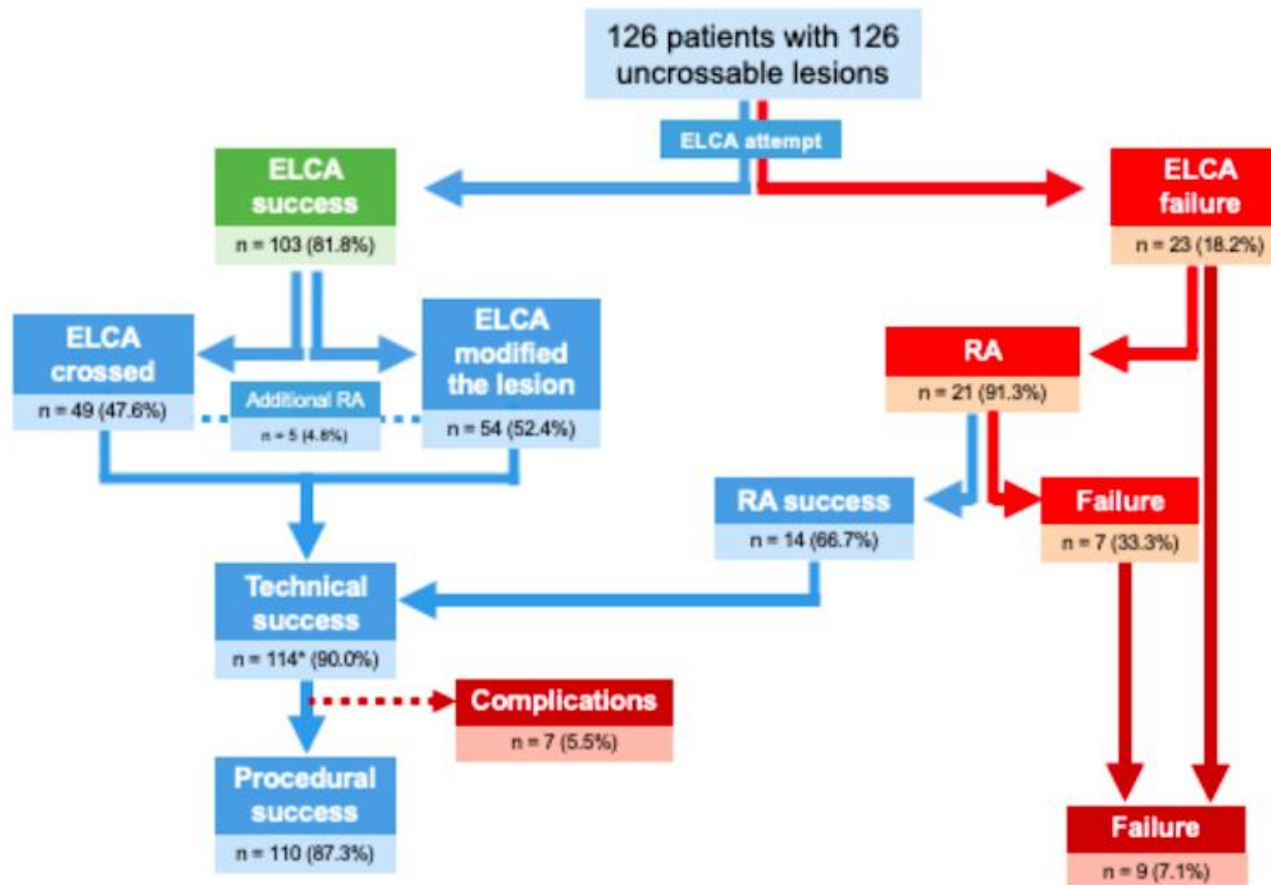
A

Angiographic and procedural results of the study population

Excimer laser coronary atherectomy for uncrossable coronary lesions. A multicenter registry

Soledad Ojeda MD, PhD¹ | Lorenzo Azzalini MD, PhD, MSc^{2,3} |
 Javier Suárez de Lezo MD, PhD¹ | Gurpreet S. Johal MD³ | Rafael González MD¹ |
 Nitin Barman MD³ | Francisco Hidalgo MD, PhD¹ | Neus Bellera MD, PhD⁴ |
 George Dangas MD, PhD³ | Alfonso Jurado-Román MD, PhD⁵ |
 Annapoorna Kini MD³ | Miguel Romero MD, PhD¹ | Raúl Moreno MD, PhD⁵ |
 Bruno García del Blanco MD, PhD⁴ | Roxana Mehran MD³ |
 Samin K. Sharma MD³ | Manuel Pan MD, PhD¹

- Moderate or severe calcification 62.7%
- 46% CTO
- ELCA success: 82%
- Technical success: 90.5%
- Procedural success 87.3%



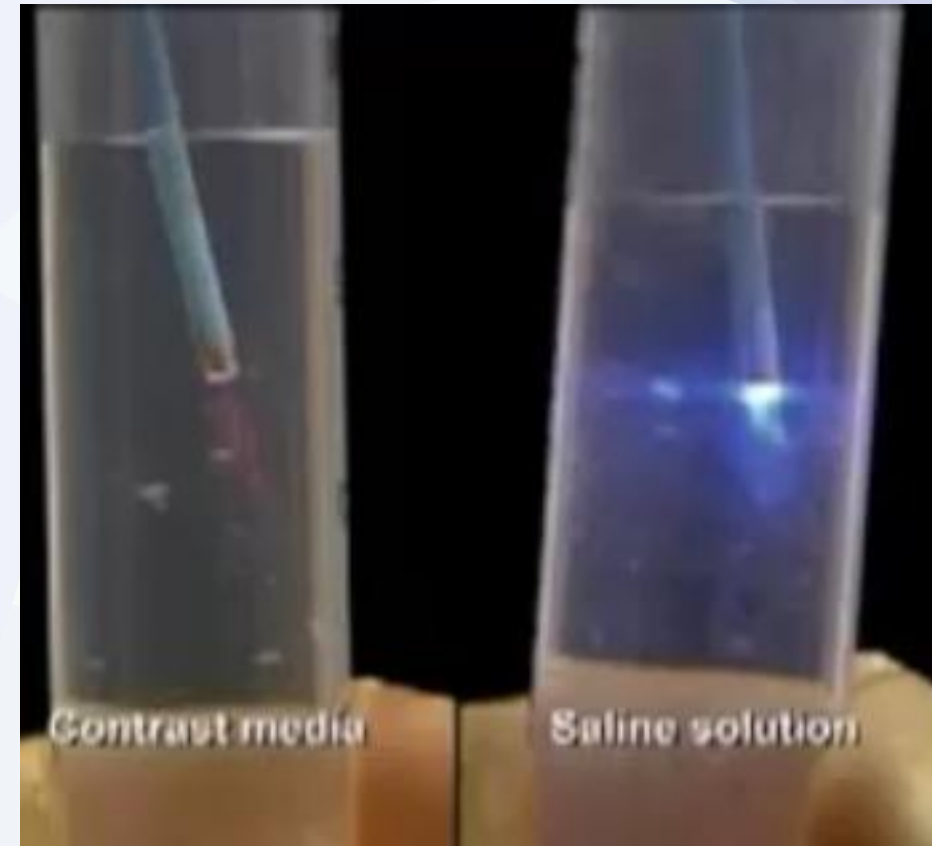
* 2 patients with final TIMI flow < 3 and 1 patient with residual stenosis > 30%

Variable	Univariate			Multivariate		
	OR	95% CI	p	OR	95% CI	p
CTO	0.92	0.37-2.26	.85	0.72	0.27-1.89	.51
In-stent restenosis	1.57	0.60-4.16	.36	1.19	0.43-3.32	.74
Severe calcification	3.60	1.36-9.52	.01	3.73	1.35-10.32	.011

ELC

A Laser in Contrast and Saline

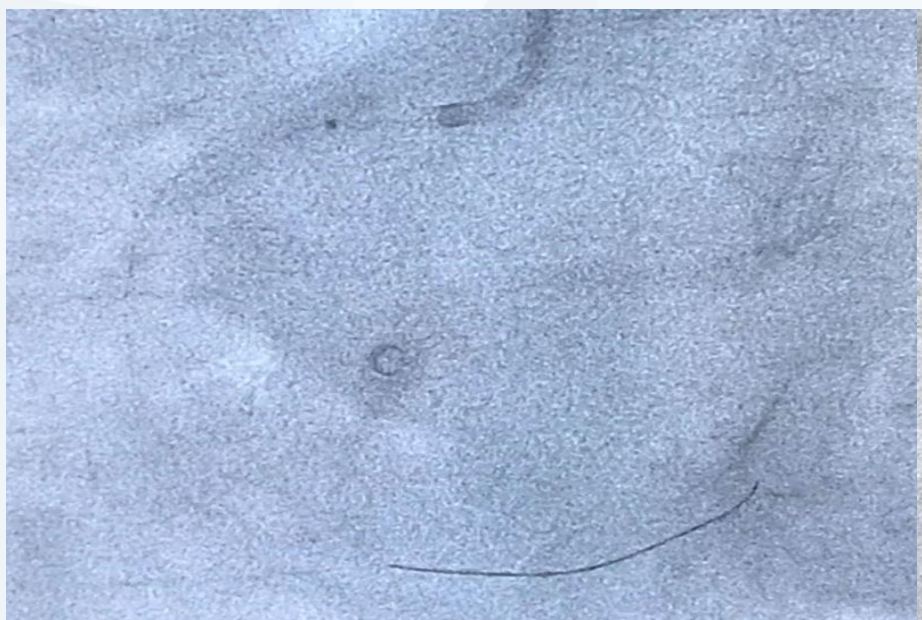
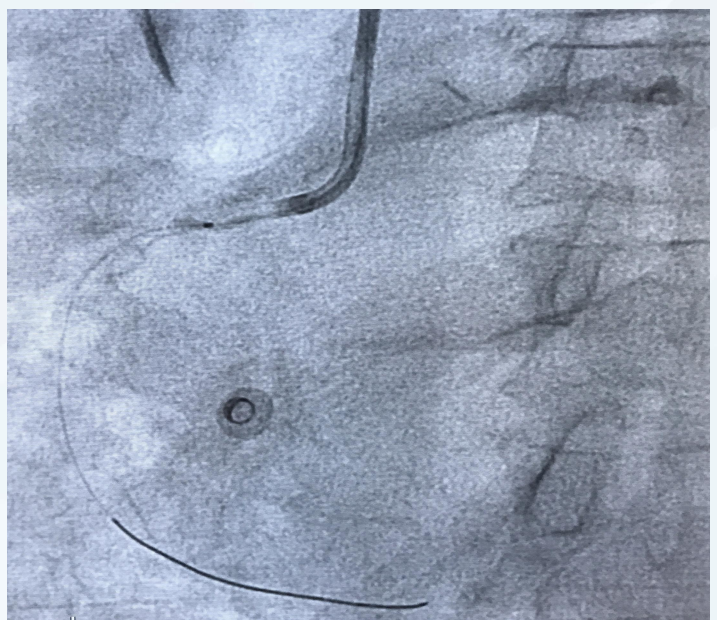
- To remove contrast and blood from the lasing field.
- Photon beam is absorbed by blood and contrast media, leading to the production of insoluble gas and rapidly expanding cavitation bubbles.
- Bubbles generate intense pressure wave pulses: higher complications.
- Saline flushing technique is now a routine part of the procedure.



ELCA



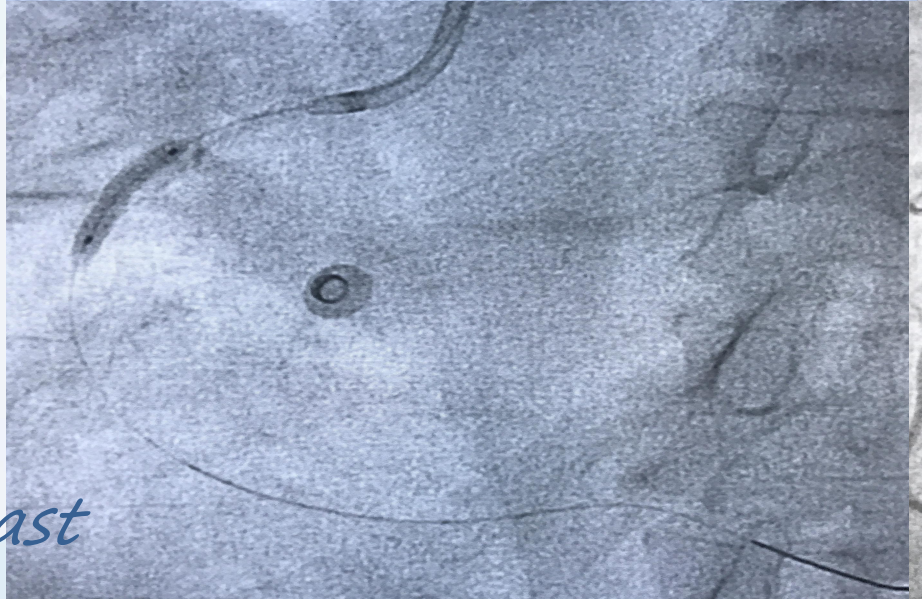
RA/OA



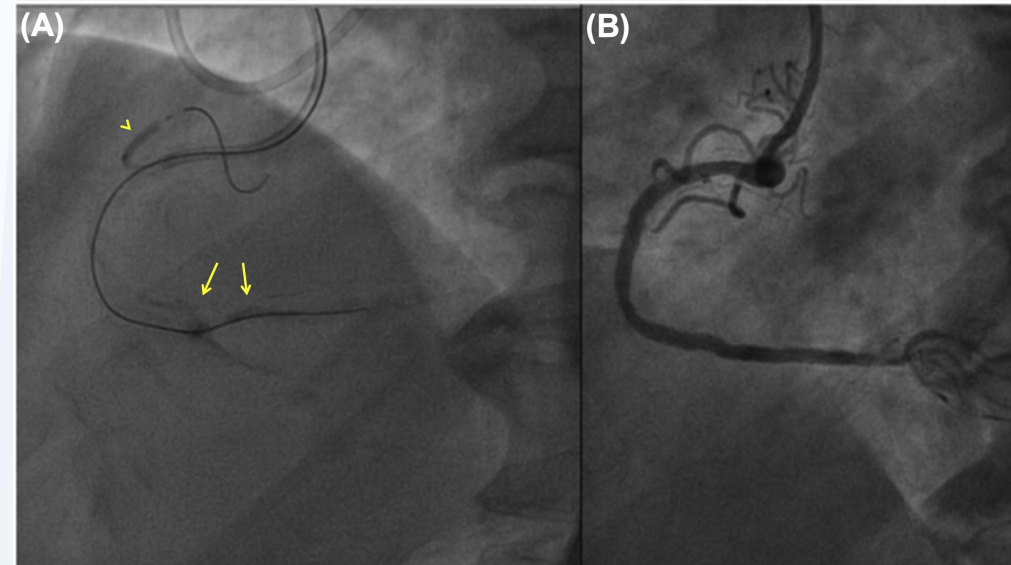
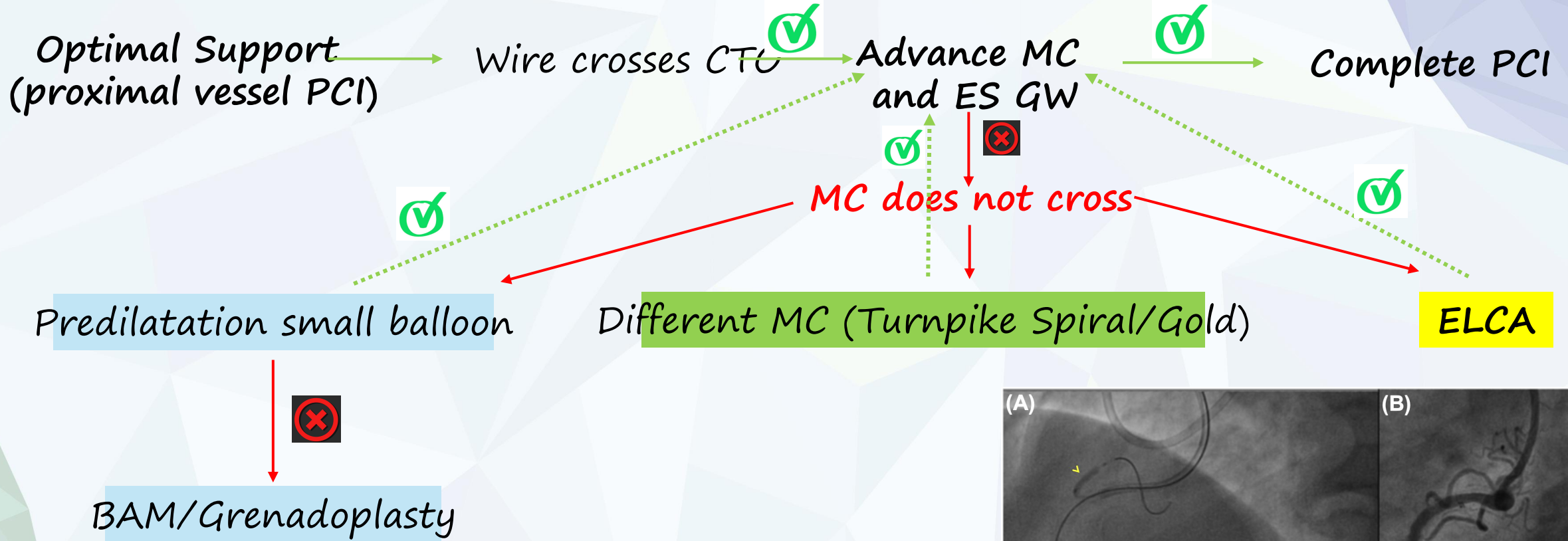
RASER

ELCA:

- 60/60
- 80/80
- 80/80 with contrast

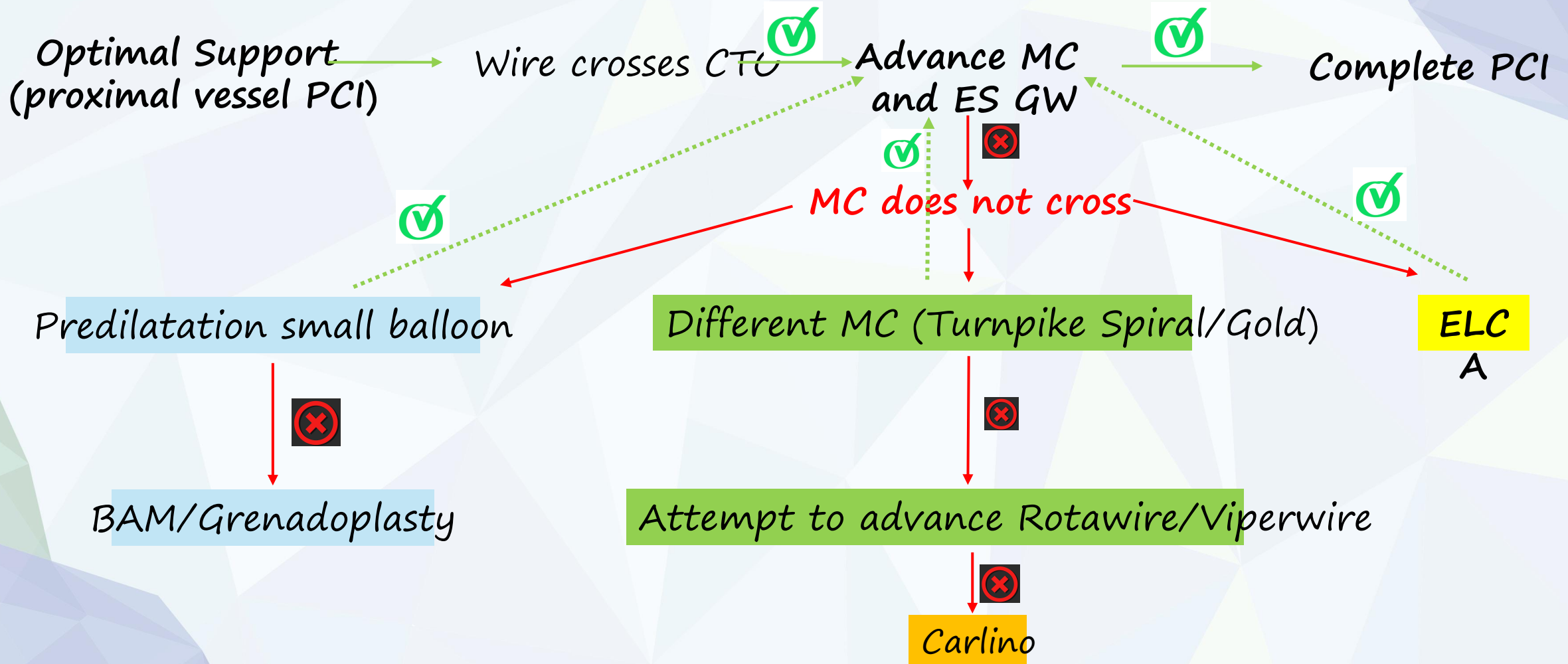


Our algorithm

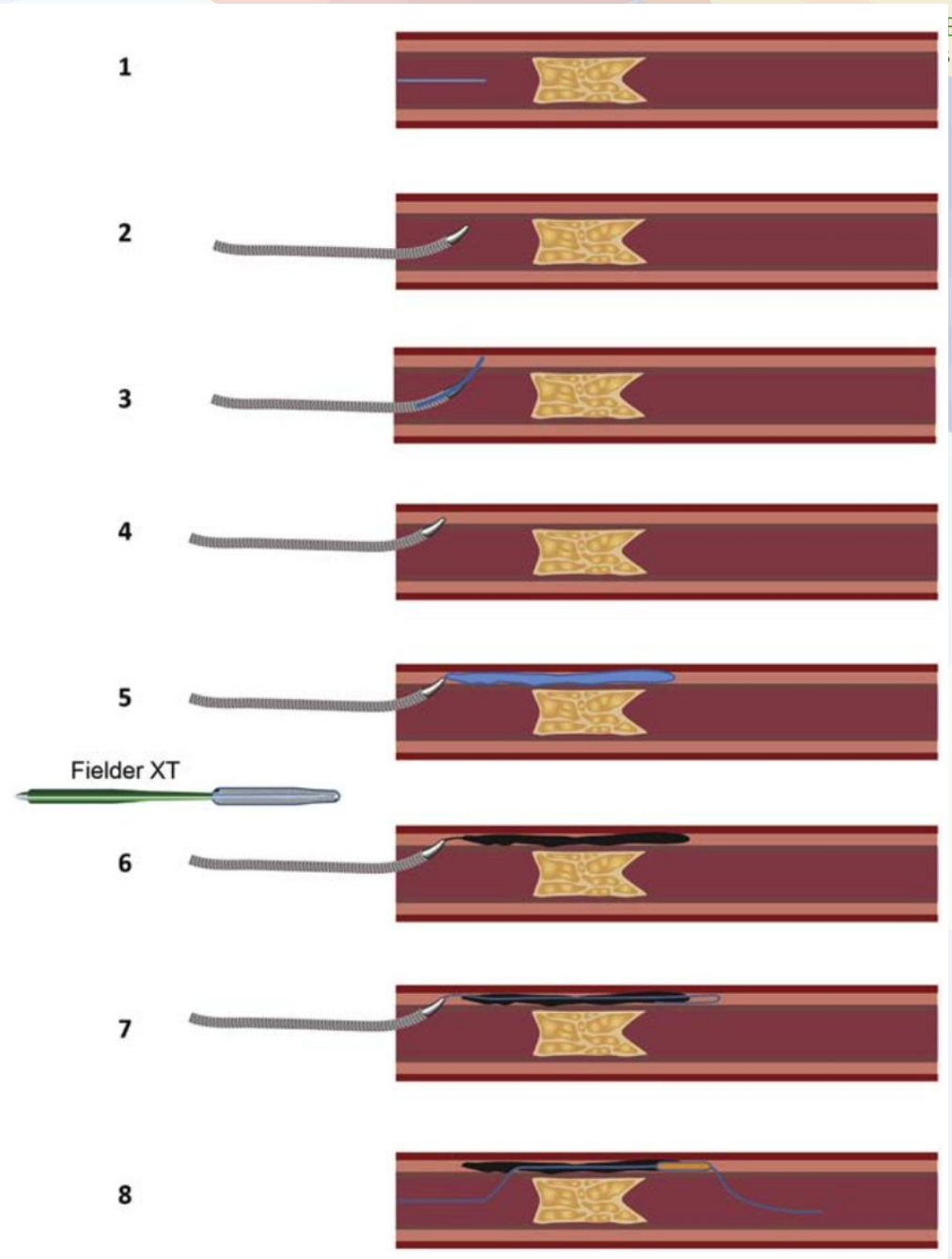


- Balloon meticulously prepared to minimize risk for air embolism
- Balloon advanced as far as possible and inflated until it ruptures

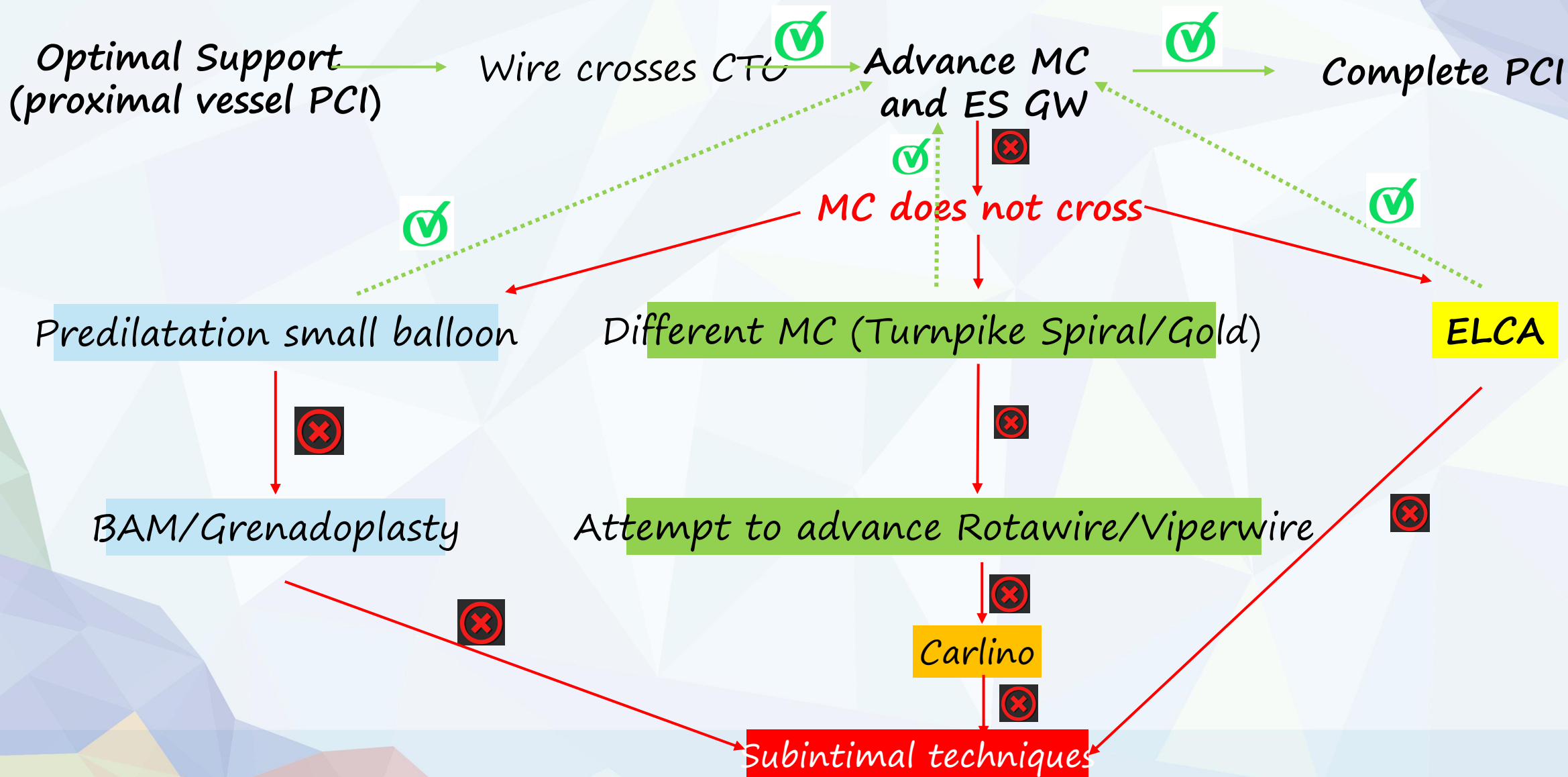
Our algorithm



- MC advanced as close to the proximal cap as possible.
- 0.5–1.0 mL contrast injected under cineangiography.
- Can cause microdissection and facilitate subsequent advancement of a balloon/MC.
- **Four Patterns:**
 1. Tubular dissection: MC within vessel architecture.
 2. Storm-cloud dissection: MC within a small branch. MC should be withdrawn and redirected.
 3. Patchy appearance: MC within vessel architecture, indicating patches of loose tissue adjacent to a highly calcific occlusion.
 4. Dissection

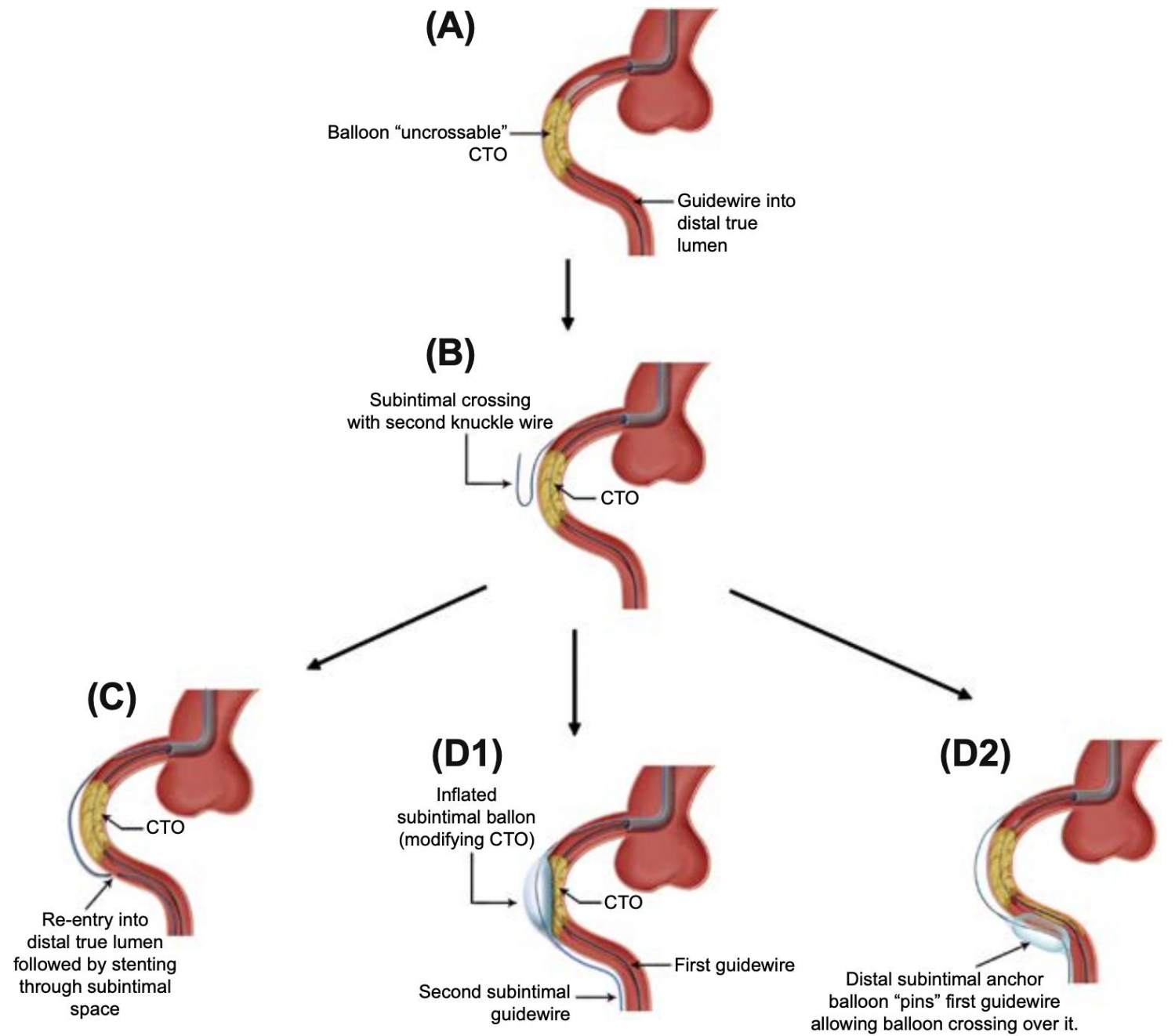


Our algorithm

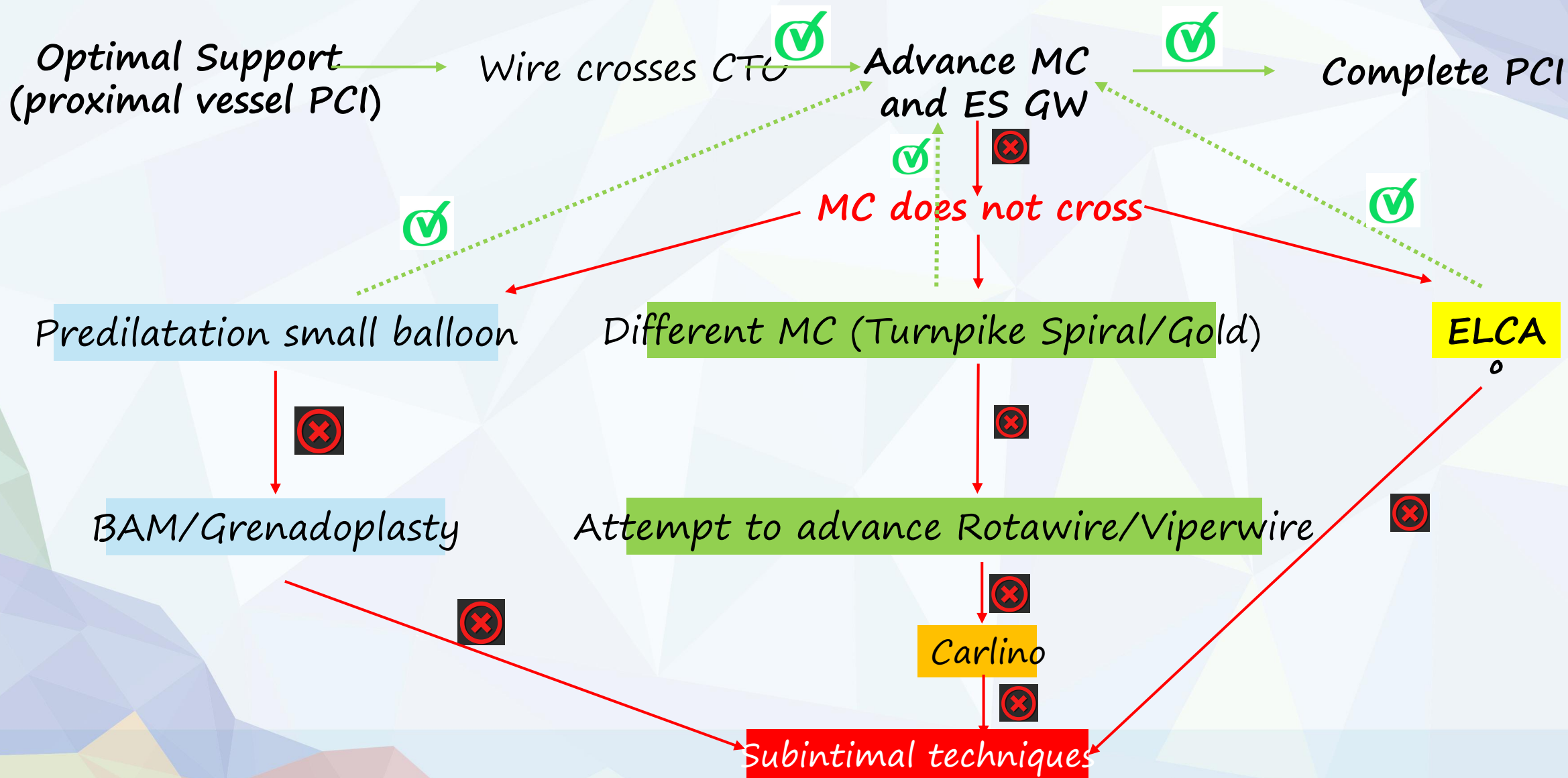


Subintimal techniques

1. ADR
2. External Crush
3. Subintimal Distal Anchor



Our algorithm



'Balloon-uncrossable' lesion^a

a. If a microcatheter, Rotawire or Viper wire can cross the lesion, then RA or OA may be considered as an option.

Conventional strategies

Ultra low-profile balloon dilatation

Increase support

- *Guide extension catheters*
- *Anchor balloon techniques*

Grenadoplasty

Microcatheter injection; Carlino

Specialised microcatheters;

Tornus/Turnpike gold

Subintimal crush with re-entry

Contemporary Alternative*

ELCA 0.9 mm fibre

- To lase across the obstruction
- Or modify it enough to enable microcatheter crossing

**quick, predictable, and prevents multiple materials usage*

Kirti Punamiya, Piotr J. Wacinski, Peter D. O'Kane, Alfonso Jurado-Román, Mohaned Egred

Case 2

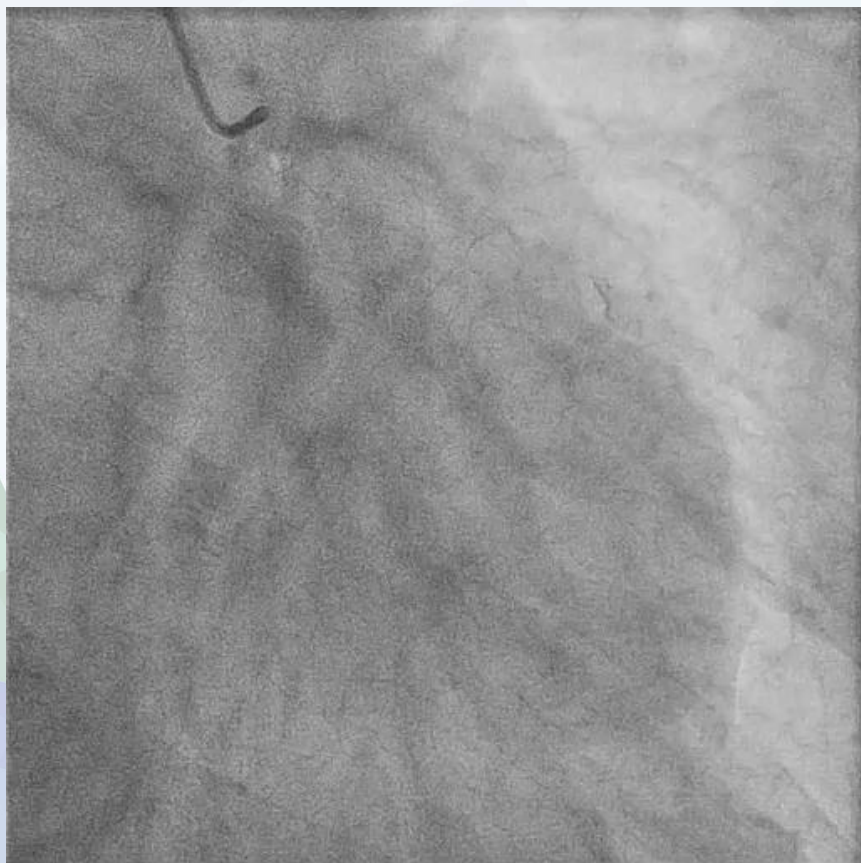
50 yo female

Former smoker

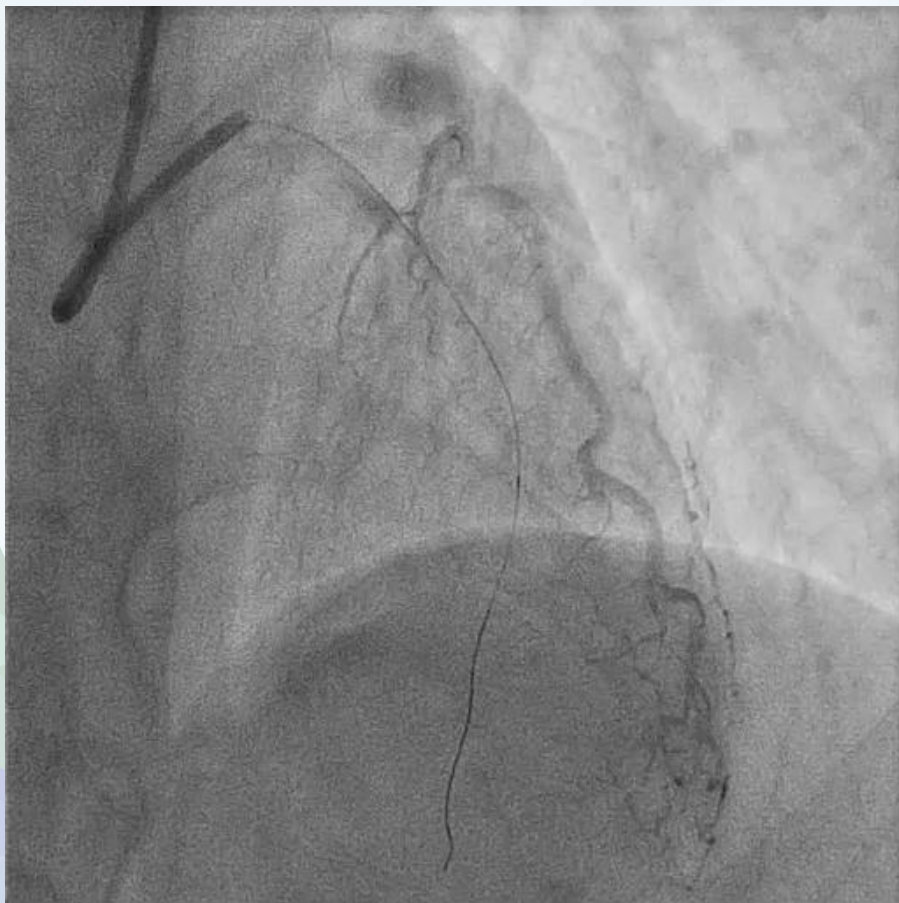
Stable Angina CCS III

- Anterior ischemia.
- LVEF 65% without WMA
- Normal renal function

Coronary angiography



Ad hoc PCI



*EBU 3.5 6F
Pilot 50*

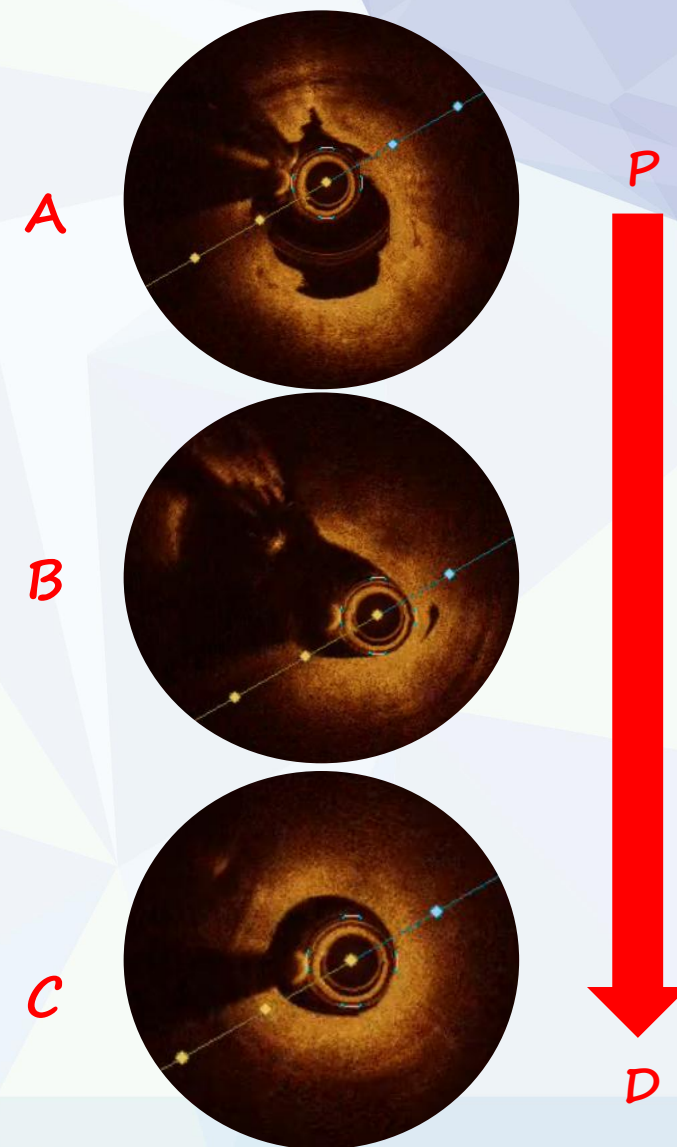
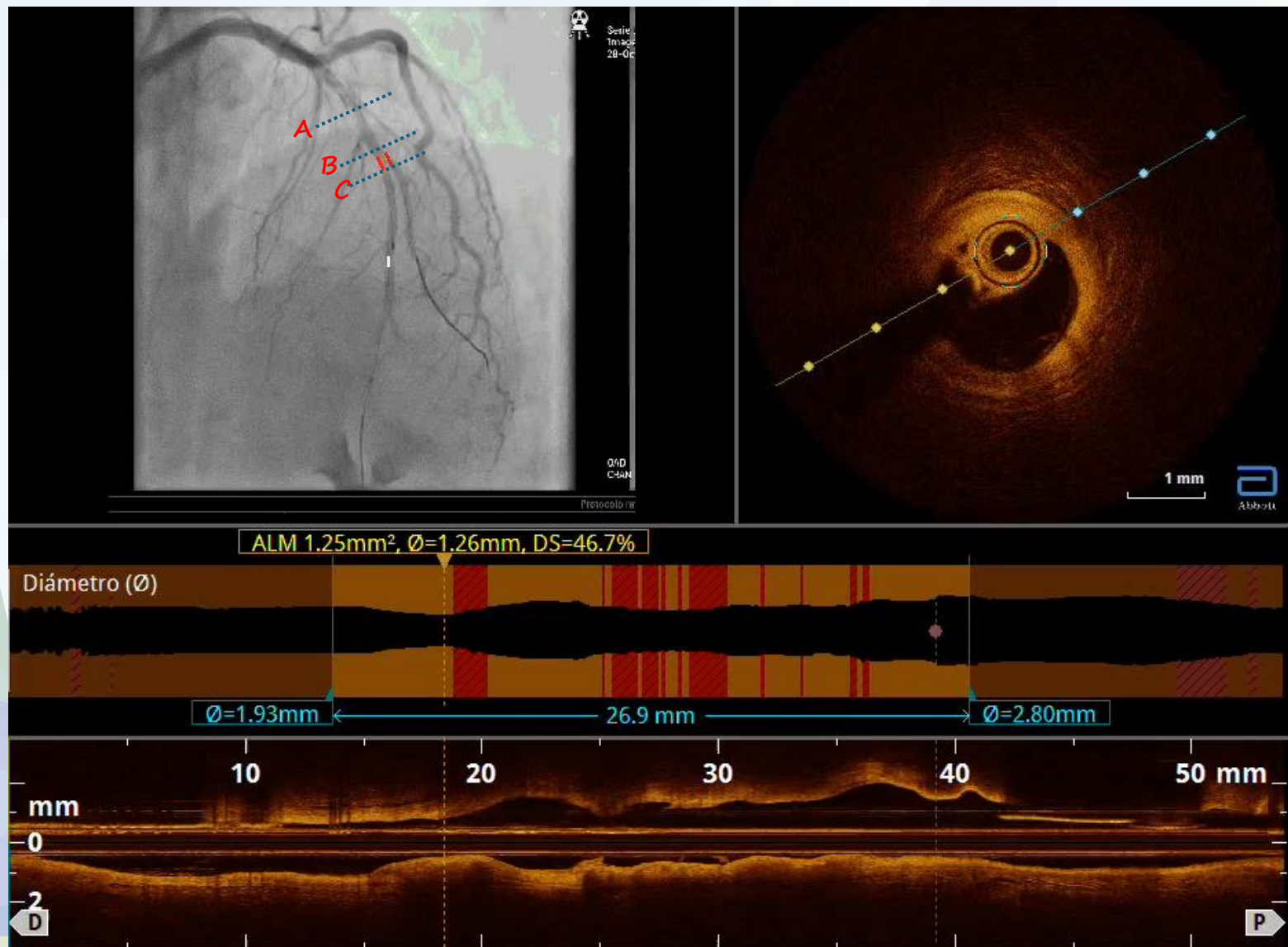


1.5 SC balloon

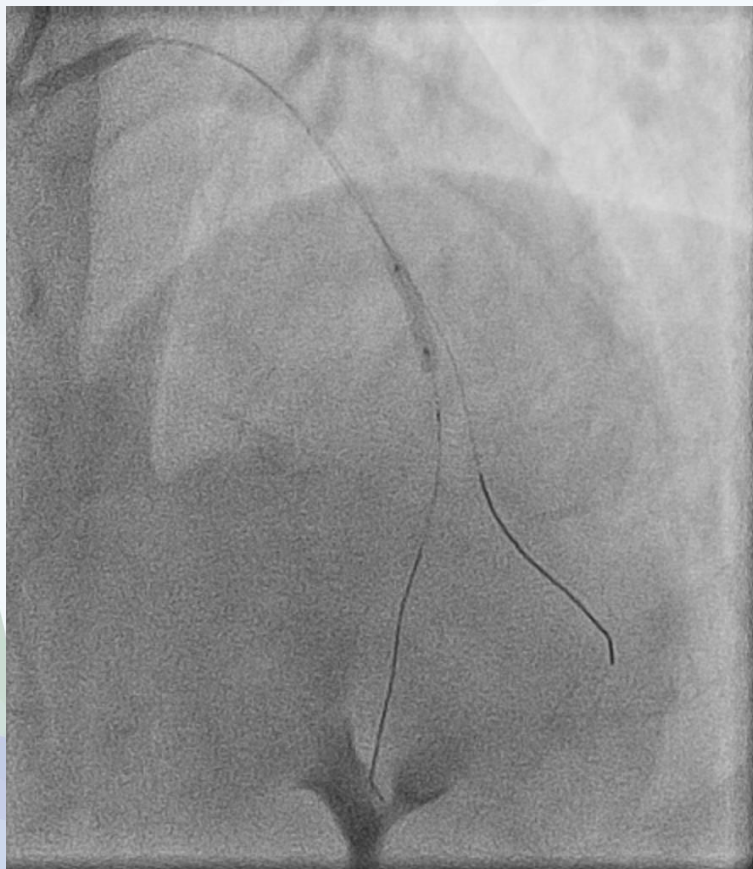


After predilatation

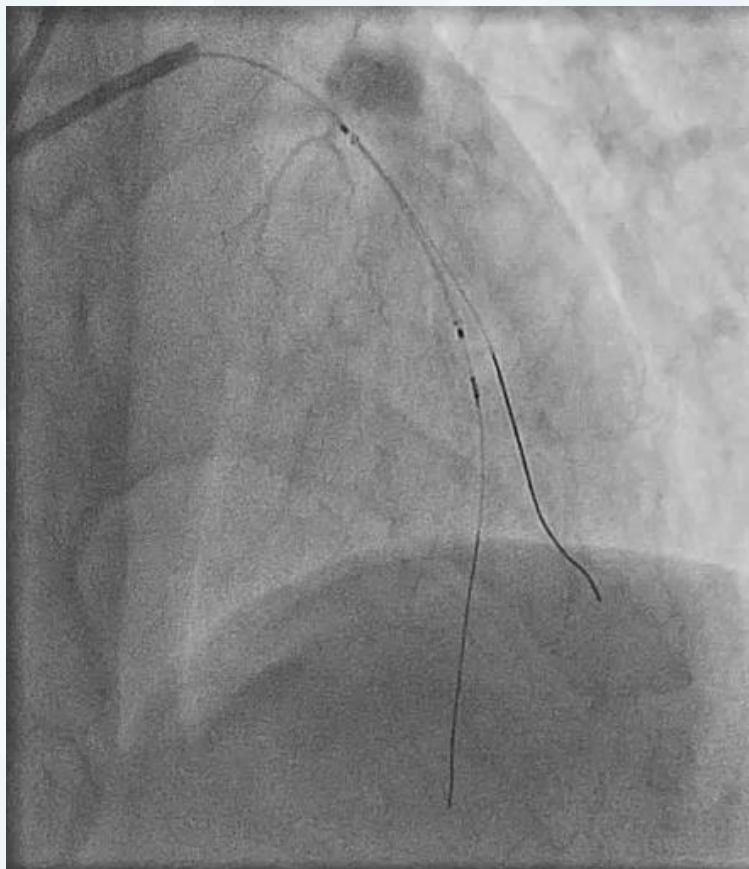
Ad hoc PCI



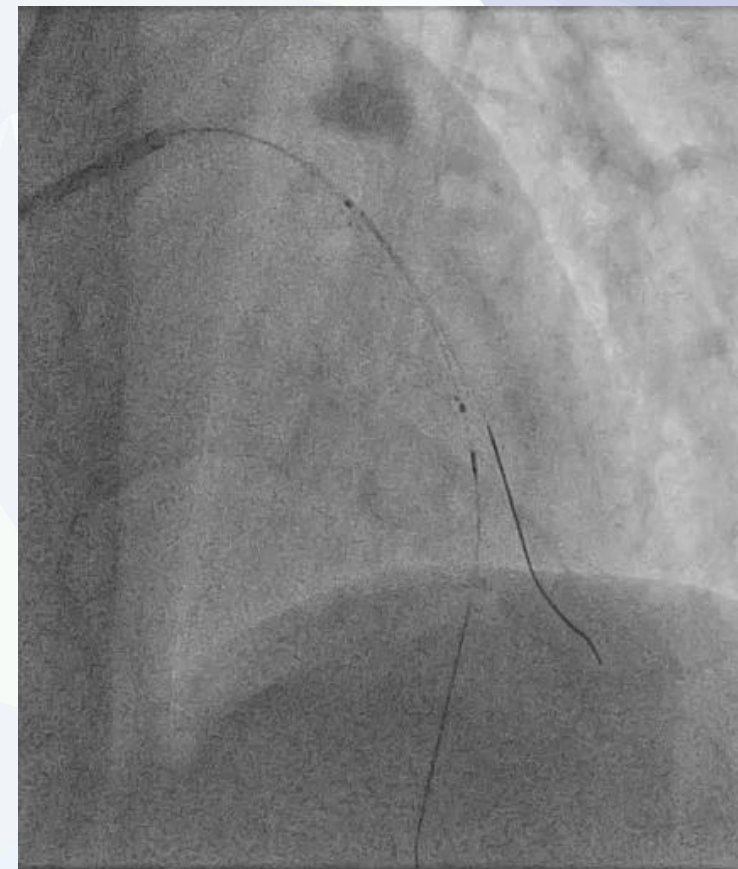
Ad hoc PCI



Predilatation 2.5 NC balloon

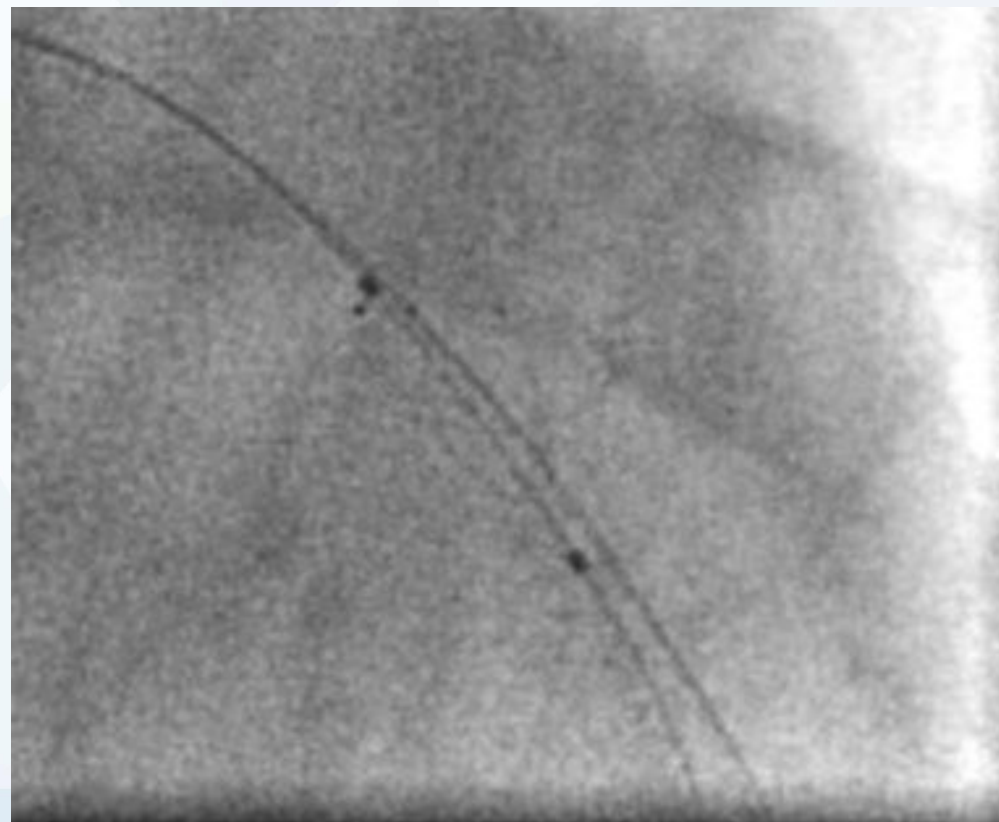
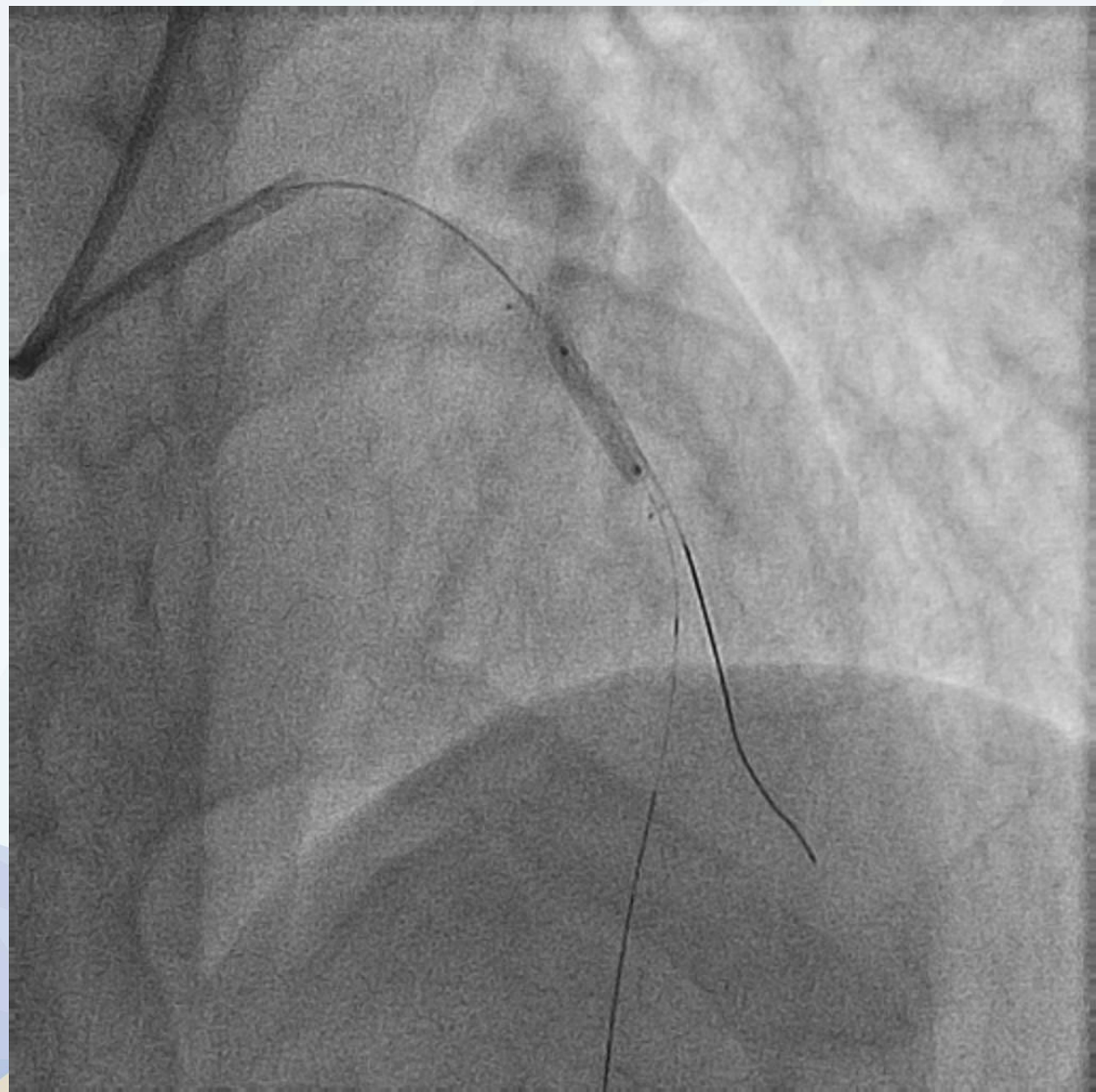


ELuNIR 2.5 x 28 mm

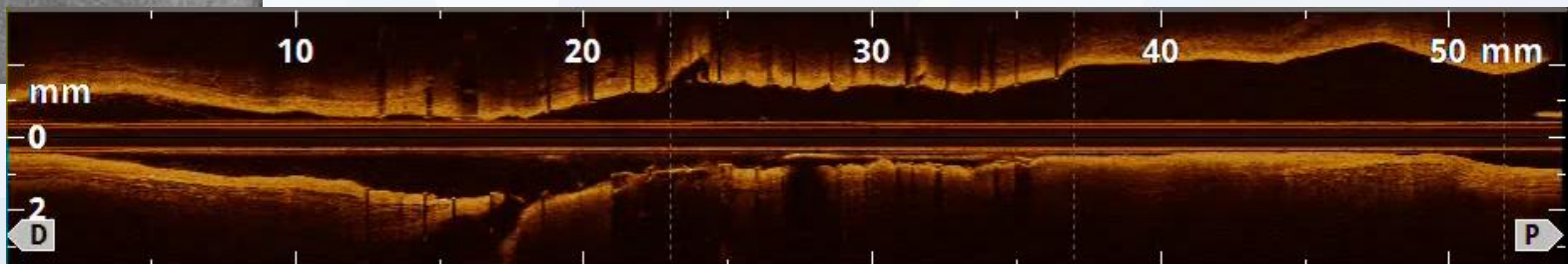
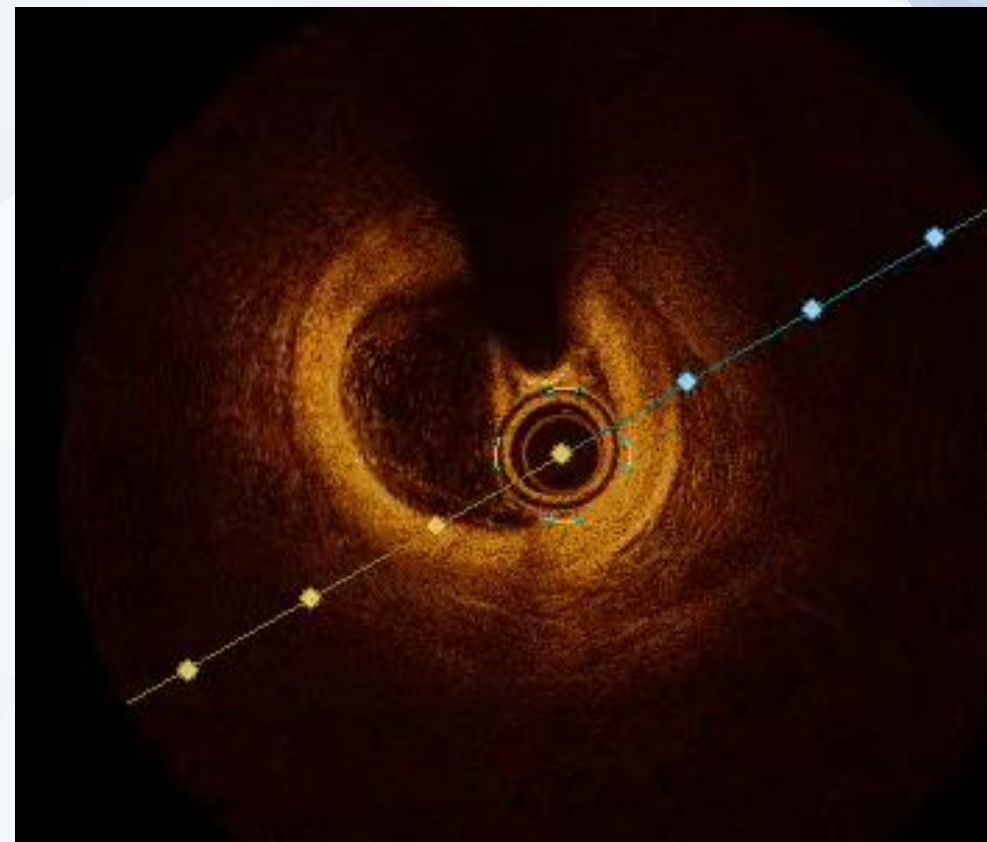
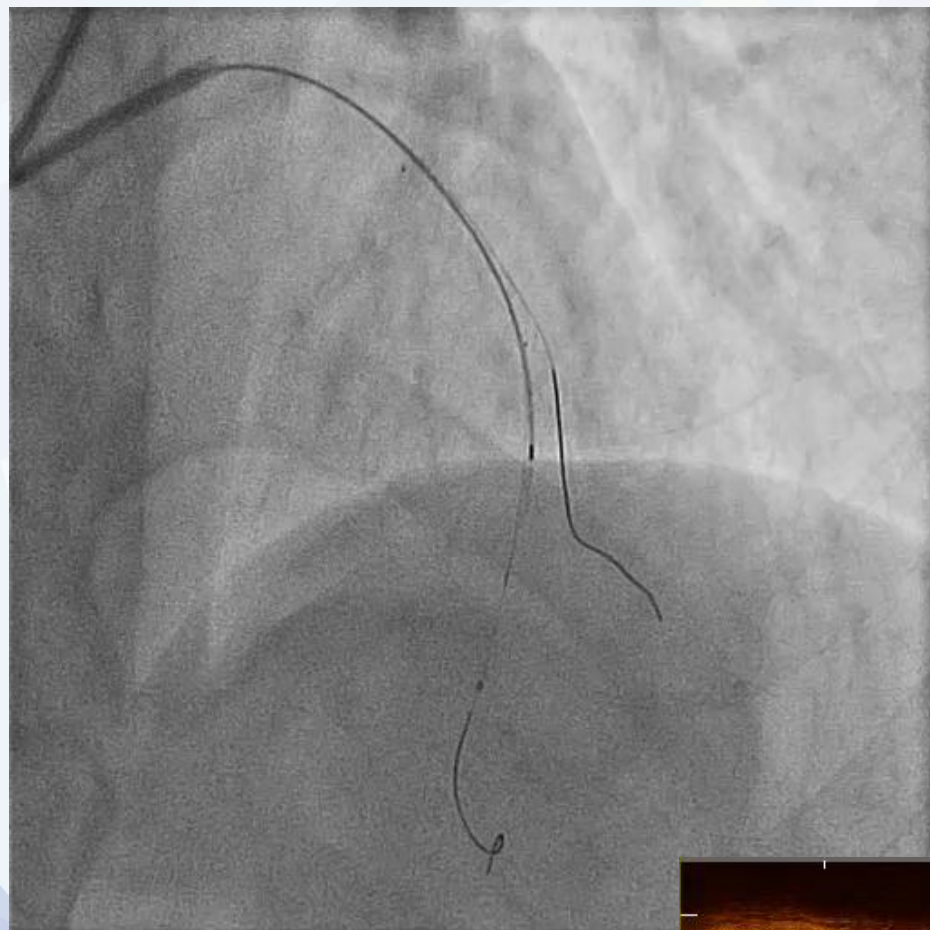


Ad hoc PCI

POT 3.0 NC balloon



Ad hoc PCI



World Medica se complace en anunciar el lanzamiento del **EluNIR-PERL**, la más reciente innovación de **Medinol** en tecnología de stents coronarios, ahora disponible en España y Portugal. Este stent de séptima generación incorpora un diseño revolucionario que ofrece una solución avanzada para la intervención coronaria percutánea (PCI), mejorando significativamente la precisión y el control durante los procedimientos intervencionistas.

Innovación en diseño y tecnología

El **EluNIR-PERL** presenta su tecnología **WiZeCell**, un diseño de celda híbrido con struts de 40 y 72 micras, lo que proporciona una flexibilidad y adaptabilidad sin precedentes. Además, integra **marcadores radiopacos** directamente en su estructura, permitiendo una visibilidad excepcional y facilitando una colocación precisa.

Características clave del EluNIR-PERL

1. **Capacidad de administración mejorada:** Su punta de resorte de metal flexible y radiopaca está diseñada para navegar con facilidad por anatomías complejas, optimizando la entrega y posicionamiento del stent.
2. **Integridad de la superficie:** Gracias a su recubrimiento elastomérico de última generación, garantiza una **elución uniforme** del fármaco análogo de la rapamicina, contribuyendo a una cicatrización más controlada de los vasos.
3. **Visibilidad incomparable:** Los marcadores de stent integrados y la punta radiopaca reforzada proporcionan una visibilidad precisa, mejorando la colocación en entornos anatómicos desafiantes.
4. **Adaptabilidad y resistencia:** Su exclusivo diseño permite una **resistencia radial y flexibilidad óptimas**, asegurando un soporte vascular eficaz y adaptándose a las necesidades específicas de cada paciente.

Un avance para procedimientos más seguros y eficaces

El **EluNIR-PERL** se posiciona así como una herramienta fundamental clave para mejorar la seguridad y eficacia durante los procedimientos intervencionistas. Con su lanzamiento, **World Medica** y **Medinol** refuerzan su compromiso con la innovación en el tratamiento de enfermedades coronarias.

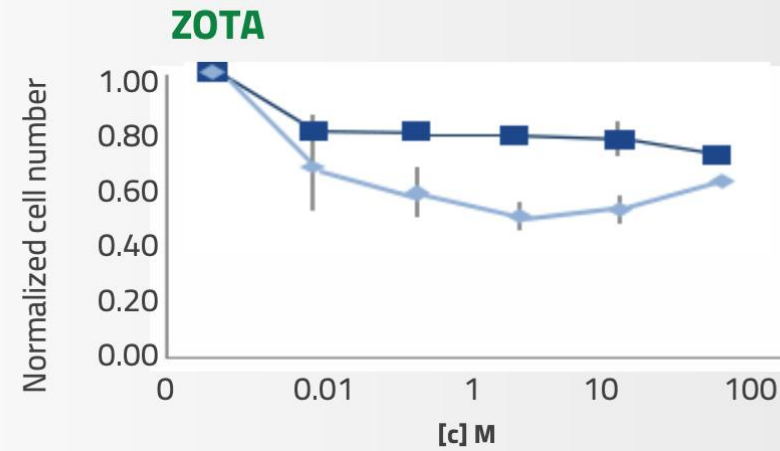
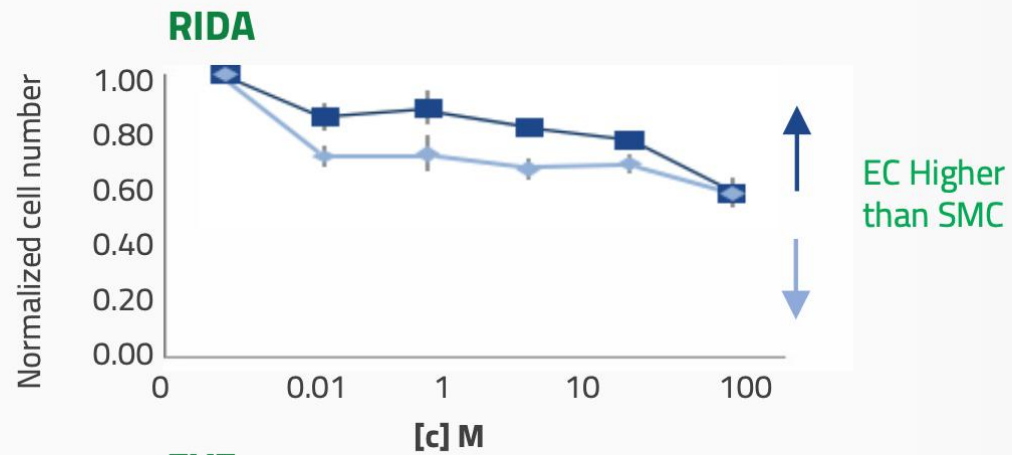
Esta disponible una nueva generación del *stent* coronario EluNIR, el modelo ELunNIR-PERL (Medinol, Israel). Esta evolución del *stent* coronario liberador de ridaforólimus incorpora varias innovaciones a su ya exclusivo diseño de balón con punta metálica, que facilita la flexibilidad de esta, la visibilidad y la capacidad de avance en las arterias coronarias tortuosas.

El diseño de este *stent* tiene unos puntales en «W» de 72 μm con conectores en «Z» de 40 μm que le dan una gran flexibilidad y fuerza radial, facilitando el acceso a las ramas secundarias en las bifurcaciones. El recubrimiento elastomérico del polímero facilita su estabilidad y reduce el riesgo de fractura al navegar y dilatarse en las peores condiciones.

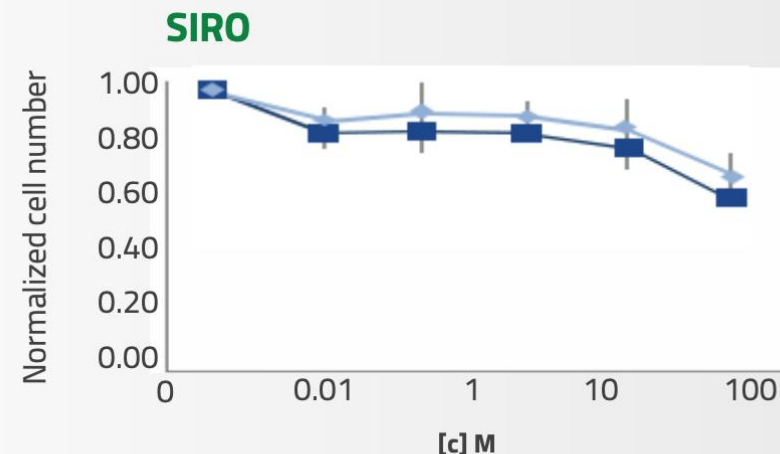
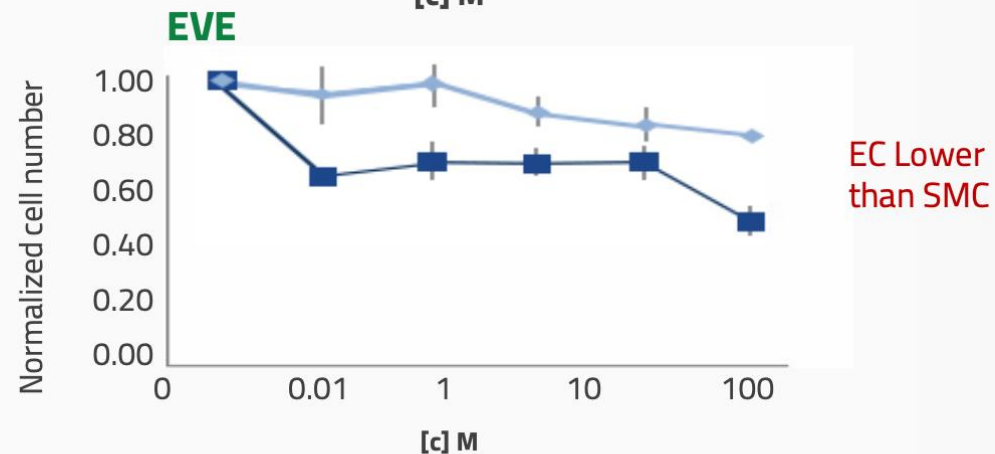
Incorpora dos marcas radiopacas proximales y distales para ayudar al posicionamiento preciso en la lesión, minimizando los tiempos de exposición e implantación. Esta última cualidad será de gran utilidad para facilitar su implante.

Ridaforolimus

The goal of DES is inhibition of Smooth Muscle Cells (SMC) while not hindering Endothelial Cells (EC) growth



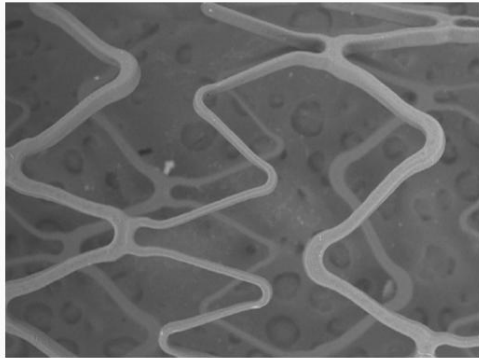
■ Endothelial Cells (EC) ↑ Higher is Better
◆ Smooth Muscle Cells (SMC) ↓ Lower is Better



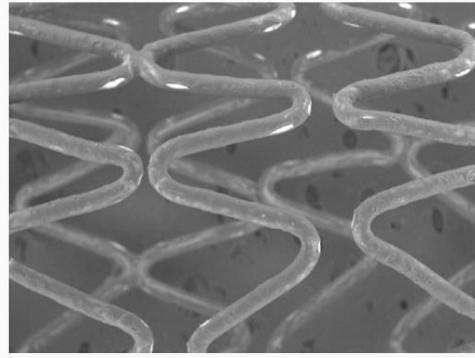
Elastomeric Polymer for Long Term Durability

- Polymer coatings of drug eluting stents often present **surface deformations, webbing, cracking and peeling**
- These surface imperfections can be associated with **inflammation and thrombogenicity** and may also result in **non-uniform drug release**

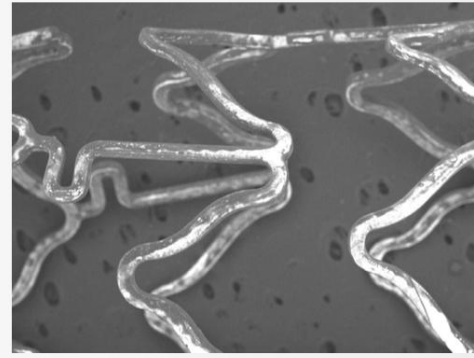
DES polymers following deployment and drug elution



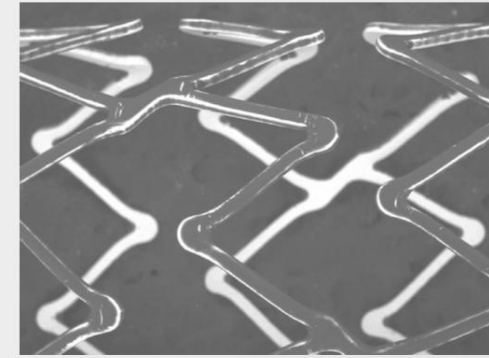
EluNIR-PERL



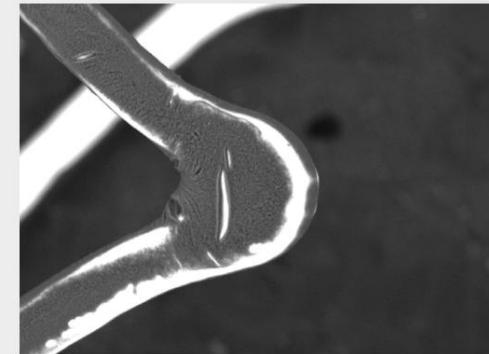
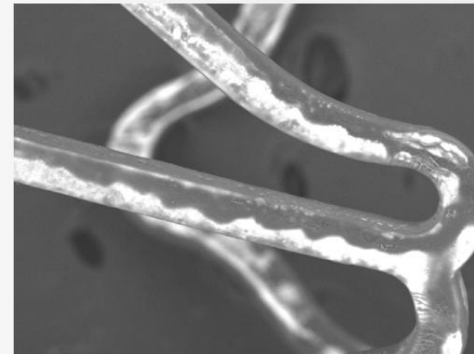
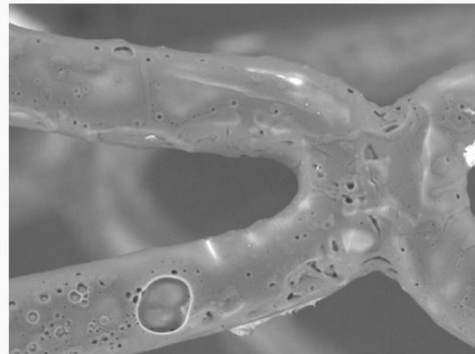
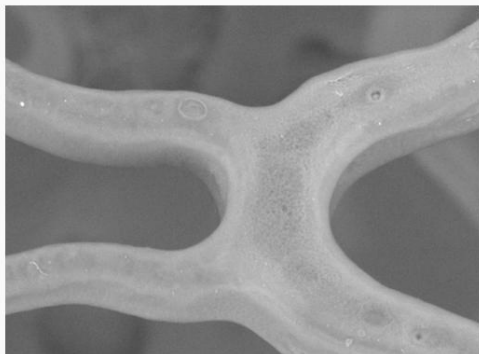
Resolute



Xience

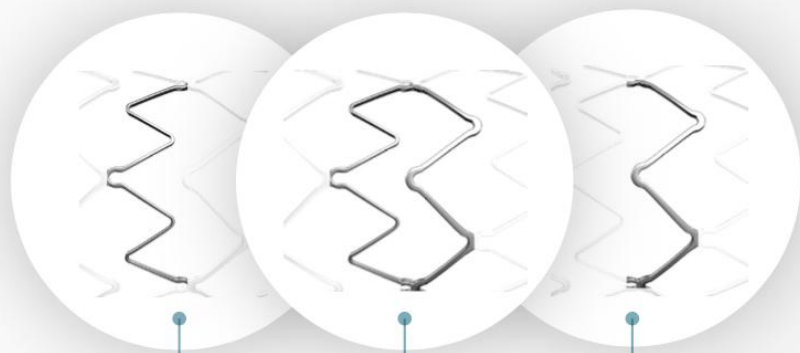


Synergy



WizeCell™ Stent Design

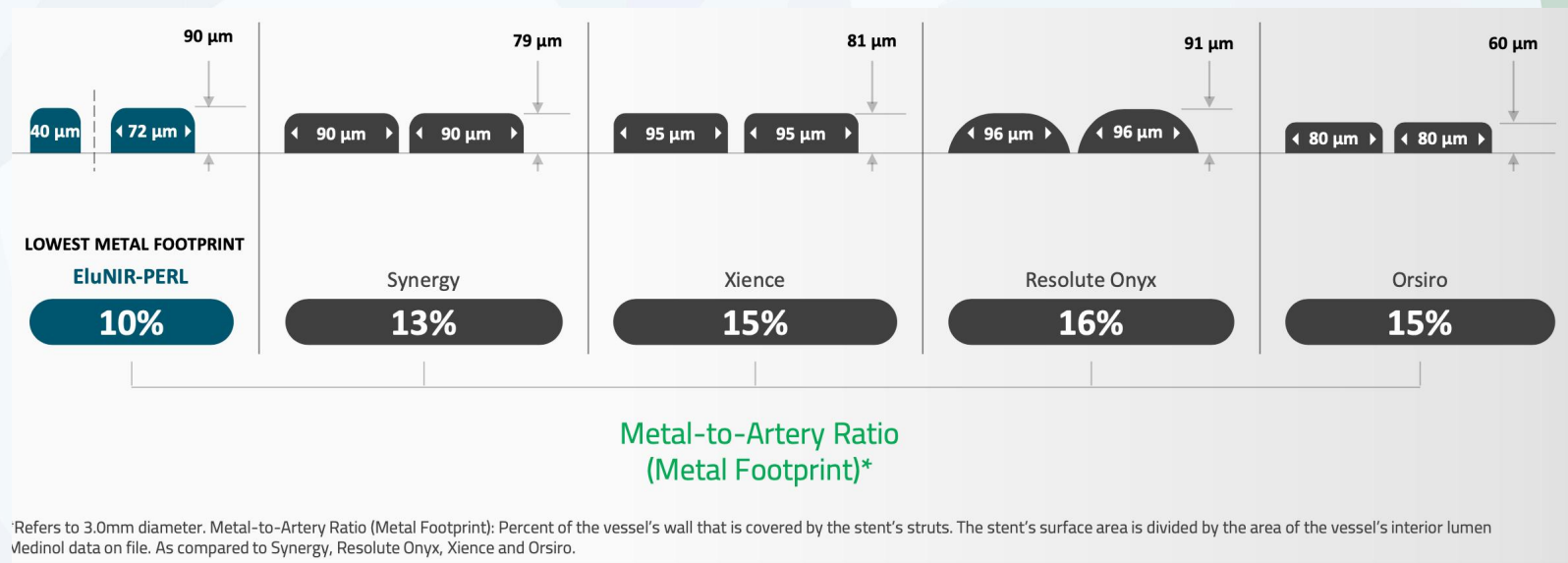
Narrow Strut Width and Low Metal Footprint Promote Healing



Ultra-Narrow 40 µm struts
provide flexibility and conformability

Narrow 72 µm struts
provide excellent radial strength

Optimal cell size
provides uniform scaffolding and helps prevent tissue prolapse and strut overlap

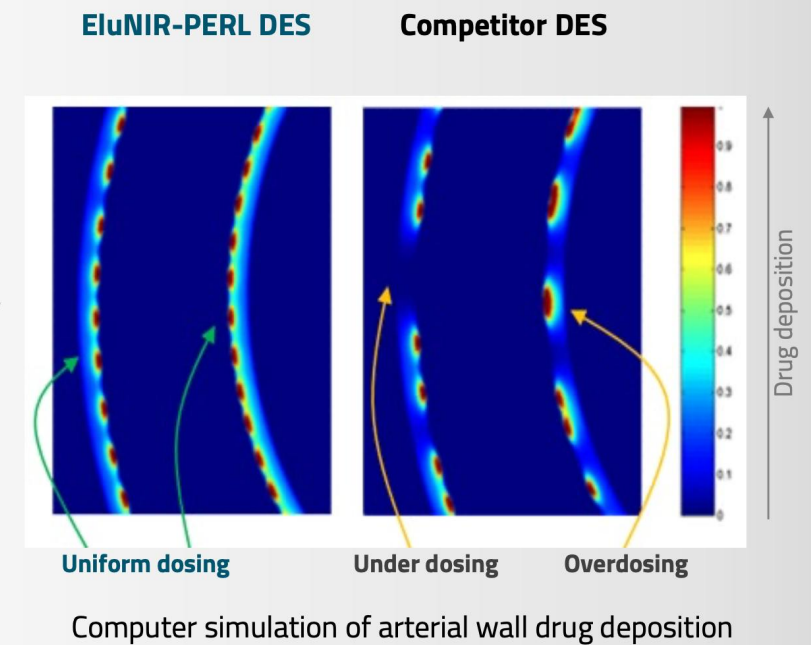


Designed for Conformability and Uniform Scaffolding

- Reduce Gaps in the outer curve and struts overlapping in the inner curve.

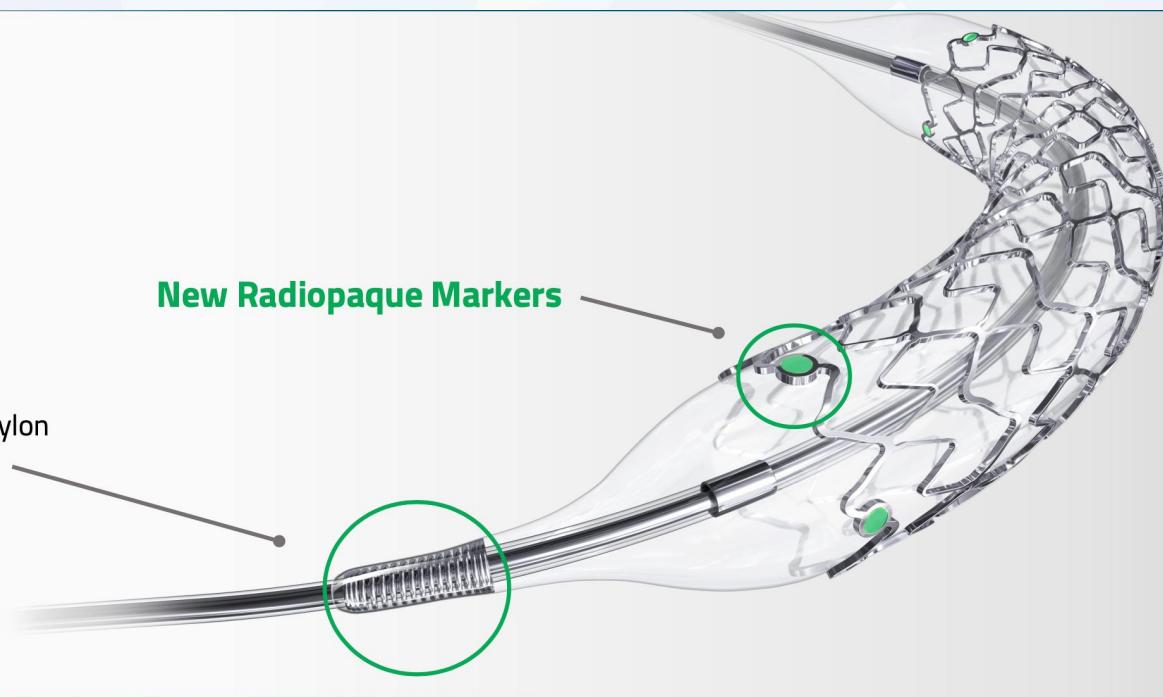


Helps reduce tissue prolapse by maintaining uniform scaffolding even on a curved vessel



Hybrid Spring Tip

- Low tip entry profile
- Reduced tip friction with a nylon (Pellethane) covered jacket
- Improved radiopacity



Hybrid Spring Tip for Improved Deliverability

Designed for Flexibility & Agility

The open coil of the tip offers flexibility and agility to navigate through and around challenges

Unparalleled Durability

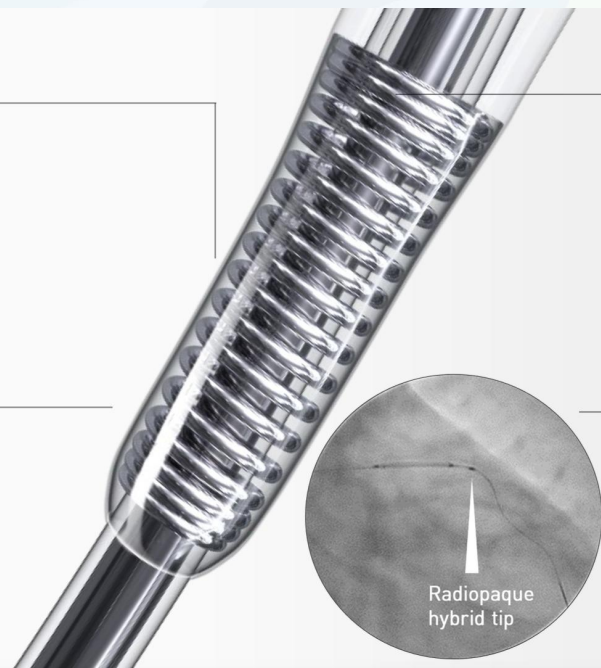
Metallic spring tip closely tracks the wire and maintains tip structure where plastic tips may flare, buckle or tear

Enhanced Crossability and Pushability

The closed coil of the tip is designed to navigate through complex anatomy including tortuosity, calcification and previously implanted stents

Enhanced Tip Visibility

Metallic spring tip can be easily seen under fluoroscopy



Enhanced Metal Spring Tip

- Low tip entry profile
- Reduced tip friction with a nylon covered jacket
- Improved radiopacity
Radiopaque material PtW8%

EluNIR-PERL EluNIR



No "Fish-Mouth" effect with the enhanced hybrid metal spring tip even in extreme vessel curvatures.



EluNIR-PERL

**Xience
Xpedition**

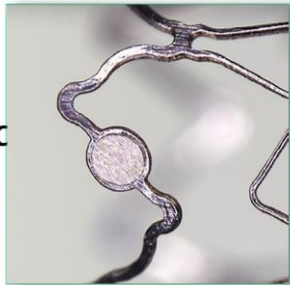
Synergy

**Resolute
Onyx**

Stent Visibility from any angle

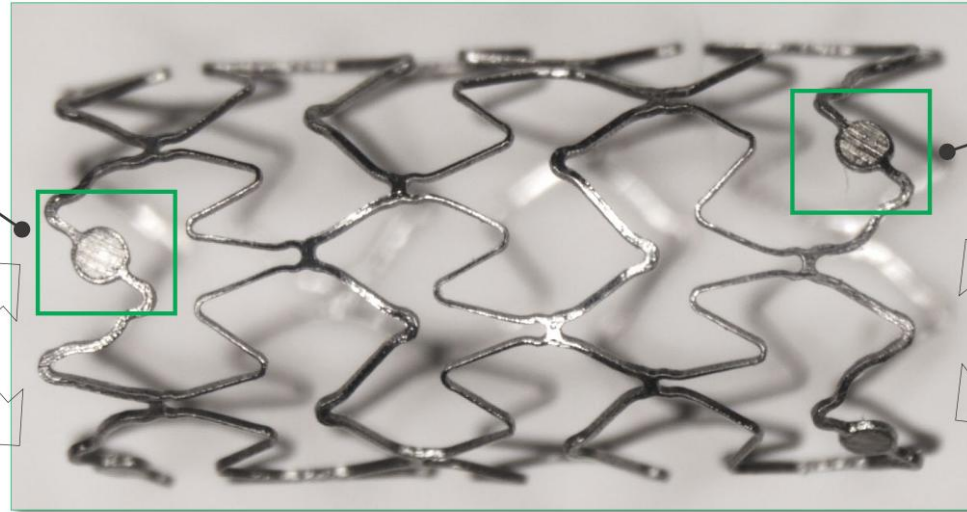
Distal radiopaque **markers**

Deployed marker



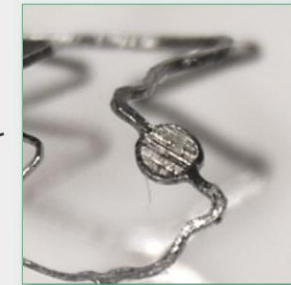
Two Φ 0.38mm markers placed at 90° angle

Deployed stent



Proximal radiopaque **markers**

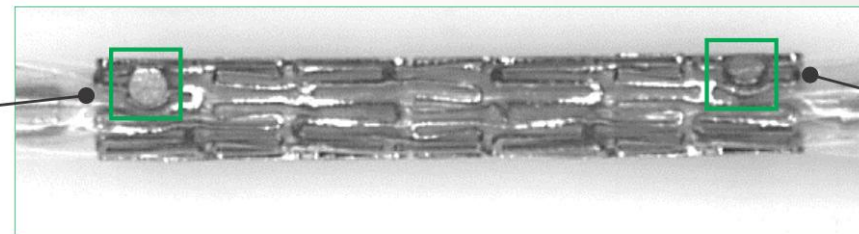
Deployed marker



Two Φ 0.38mm markers placed at 90° angle

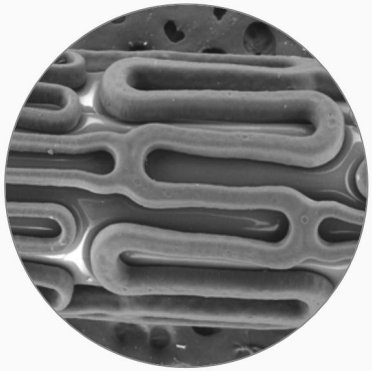
Crimped stent

Crimped marker

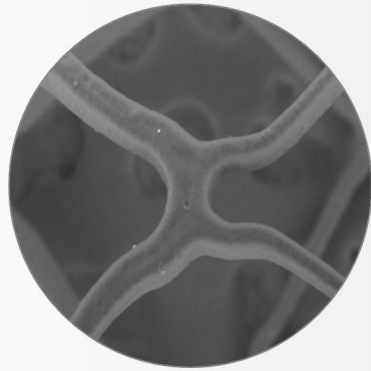


Crimped marker

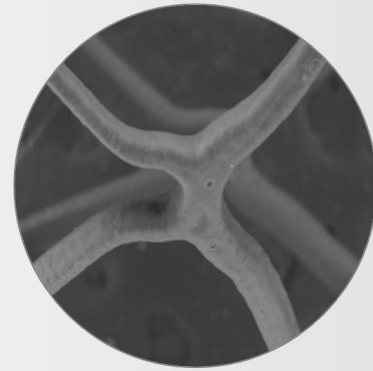
The Only DES with Elastomeric Polymer for Long Term Durability The EluNIR-PERL DES novel coating has elastic properties that resists cracking and is designed to reduce surface irregularities providing controlled drug elution



CRIMPED



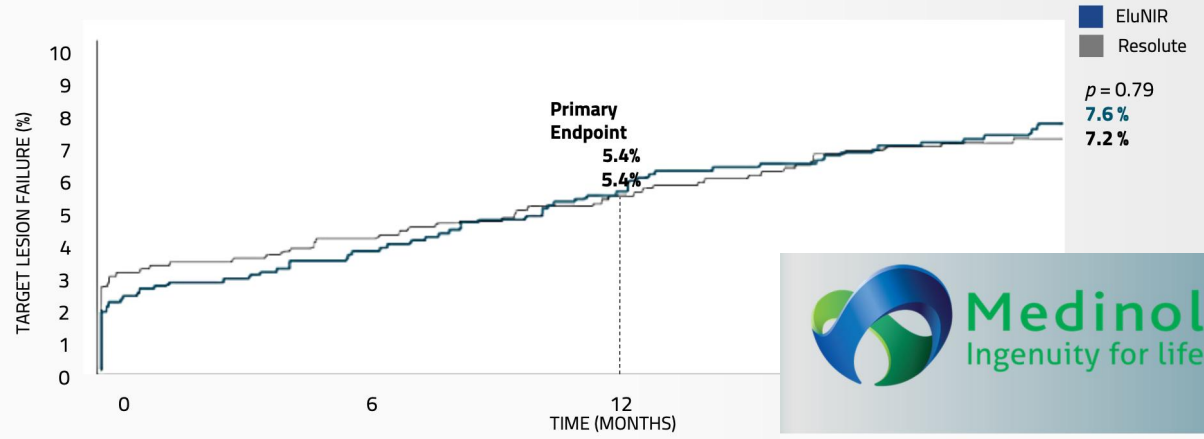
**NOMINAL
PRESSURE**



**RATED BURST
PRESSURE (RBP)**

Optimal combination of coating and process design offers predictable and uniform release of Ridaforolimus

TLF at 24 months



24-month outcomes continue to support the safety and efficacy

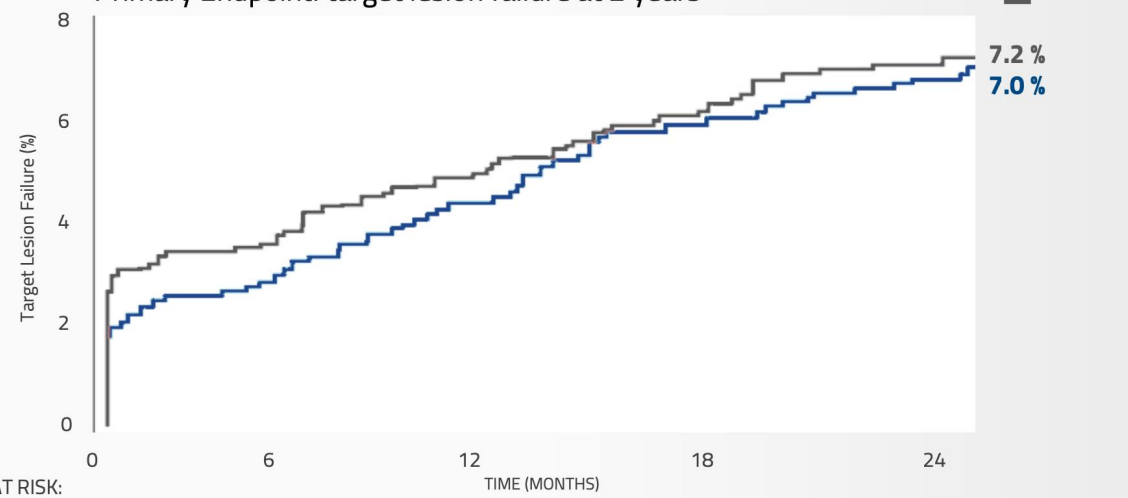
Pooled BIONICS and NIREUS Trials

Equivalent TLF rate at 24 months with statistically similar composite

TIME (MONTHS)	0	6	12
NUMBER AT RISK:			
EluNIR	958	913	885
Resolute	961	910	888

TLF at 24 months

Primary Endpoint: target lesion failure at 2 years



Continued safety and efficacy of the EluNIR in the pooled BIONICS and NIREUS randomized trials¹

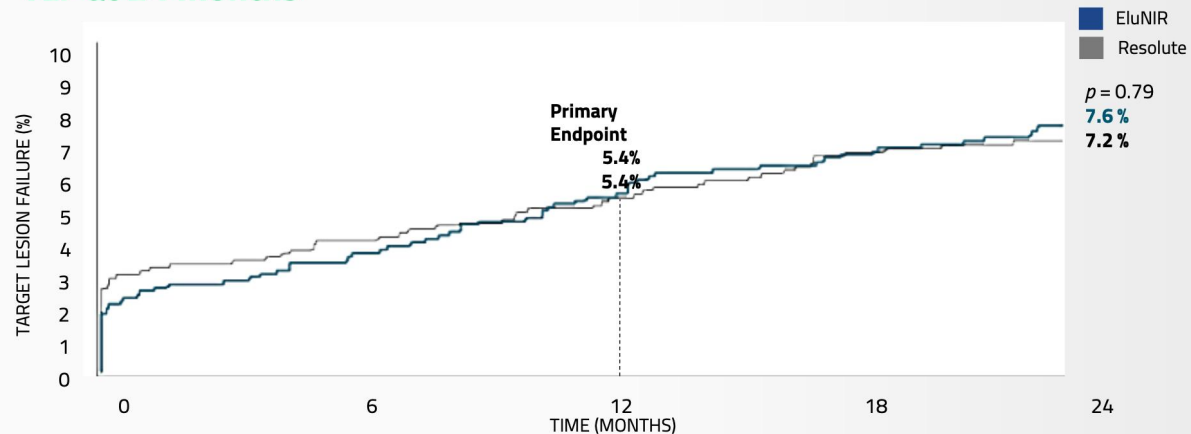
No significant differences in 2-year composite or individual clinical events

Favorably low rates of target vessel-related MI, TLR and ST despite patient and lesion complexity

NUMBER AT RISK:	0	6	12	18	24
EluNIR	1,159	1,107	1,075	1,051	640
Resolute	1,062	1,007	982	958	583

1.Konigstein et al_ JACC CVI 2020

TLF at 24 months

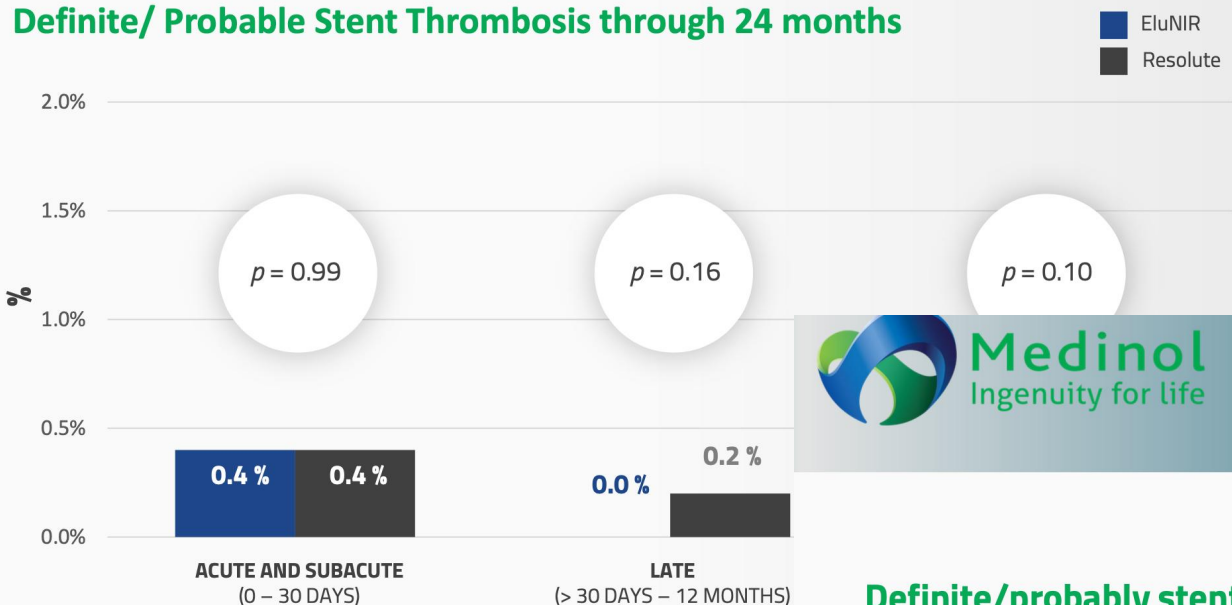


24-month outcomes continue to support the safety and efficacy of the EluNIR family.

Equivalent TLF rate at 24 months with statistically similar component event rates

TIME (MONTHS)	0	6	12	18	24
NUMBER AT RISK:					
EluNIR	958	913	885	864	493
Resolute	961	910	888	864	499

Definite/ Probable Stent Thrombosis through 24 months

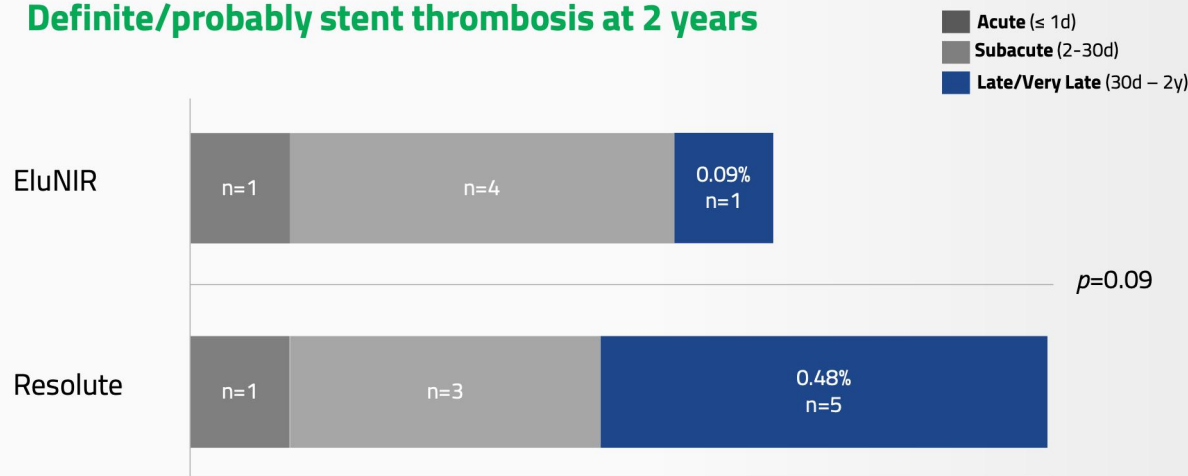


The EluNIR demonstrated an extremely low rate of 0.1% Late/Very Late Stent Thrombosis through 2 years



Pooled BIONICS and NIREUS Trials

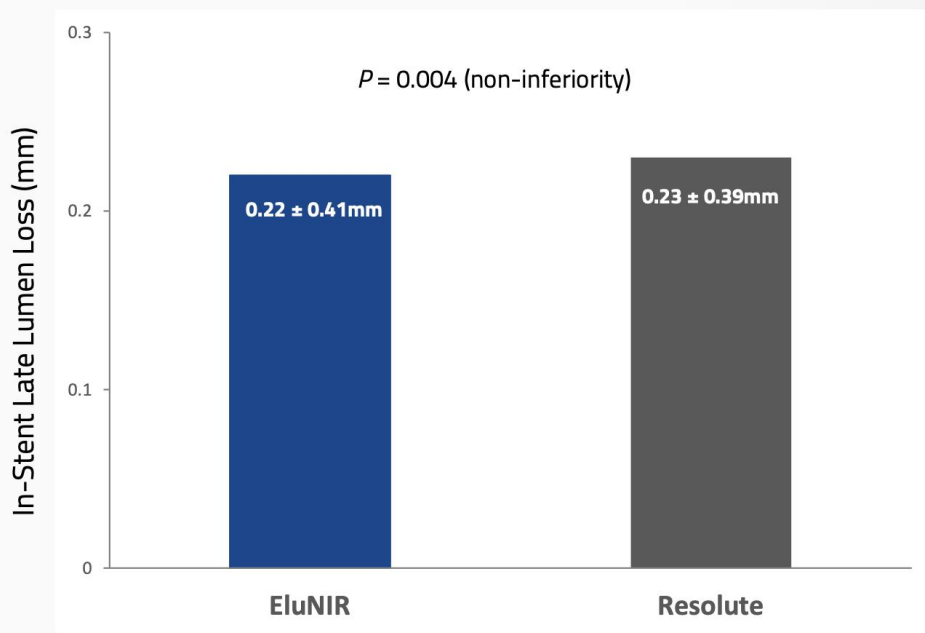
Definite/probably stent thrombosis at 2 years



Trend toward lower late and very late stent thrombosis through 2-years with EluNIR¹ (0.09% vs. 0.48%, p=0.09)

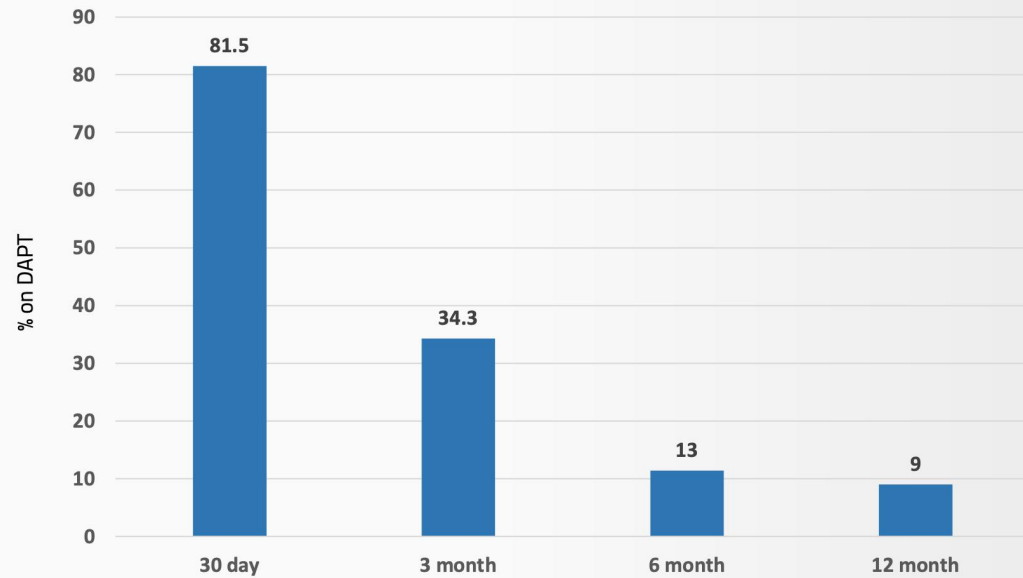
1.Konigstein et al_ JACC CVI 2020

Late Lumen Loss at 13 months



EluNIR was non-inferior to Resolute at 13 months for the angiographic endpoint

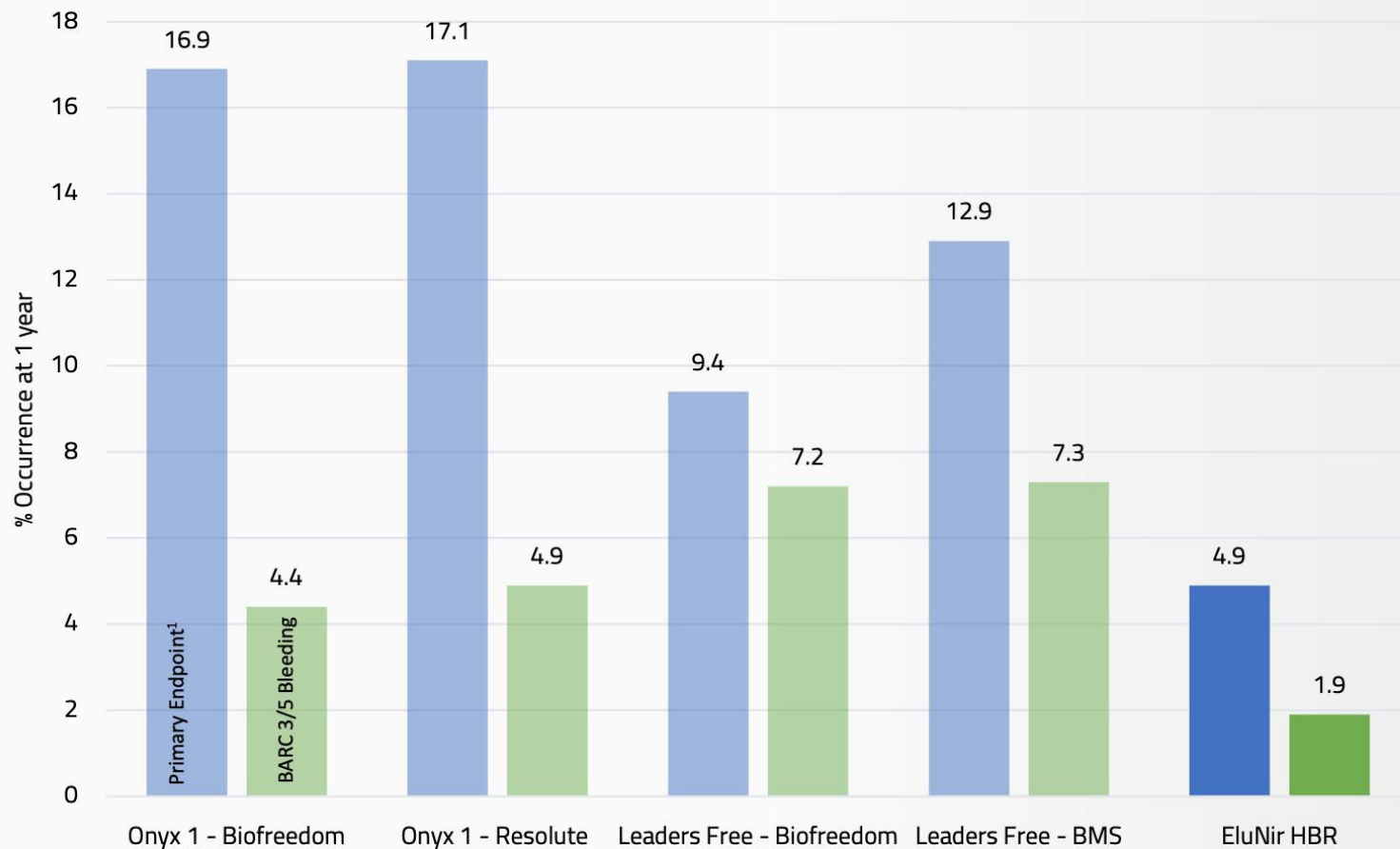
Angiography was performed on 85 patients (105 lesions) in the EluNIR group and on 73 patients (96 lesions) in the Resolute group



EluNIR HBR included ACS patients in its 'more-comomers' inclusion/exclusion criteria. Consequently, the duration of DAPT was determined at the discretion of the treating physician.

EluNIR HBR in comparison

Comparative HBR/Short DAPT Studies



EluNIR HBR has similar design to ONYX ONE and Leaders Free trials.

EluNIR presenting outstanding results for the primary endpoint as well as the bleeding endpoints

1. Primary endpoint includes Cardiac Death, MI, and Stent Thrombosis

Take-home messages

- *Uncrossable CTO 6-9% of cases.*
 - *Lower success rate.*
- *Several options: consider availability and experience.*
 - *Techniques usually should be combined.*
- *ELuNIR (PERL) is a good option for complex cases.*

*HOPE FOR THE BEST, PREPARE FOR THE WORST AND RECEIVE
WHAT COMES*


Thanks for your attention



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 [JuradoRomanA1](https://twitter.com/JuradoRomanA1)