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CHIP Percutaneous Coronary Intervention: Learning Cases and Technique Reviews

Management of In-Stent Restenosis

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Wednesday, Aug. 6th 2025 – 11:30am to 1:20pm (lecutre: 20 min)
ProEducar and Coronary, Room B1
Expo Santa Fe, Mexico City, Mexico

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Management of ISR

- Definition and types of recurrences
- Clinicial impact in contemporaneous daily practice
- Identifying mechanisms of (stent) failure
- Role of intravascular imaging modalities
- Treatment alternatives
- Optimal technique
- Current recommendations

Management of ISR

- **Definition and types of recurrences**

Angiographic Binary Restenosis

- Angiographic binary restenosis (ABR) is defined as stenosis **≥50%** at angiographic follow-up – usually >1 month after index procedure is the minimal timeline qualified in studies with serial quantitative coronary angiography (QCA) analyses
- % diameter stenosis (DS) is a QCA parameter calculated taking in consideration the reference diameter (DR) and the minimum lumen diameter (MLD), as follows:

DS = (1 – MLD / RD) x 100

Clinical Restenosis

- Clinically-driven revascularizations (TLR/TVR) are those in which the subject has a positive functional study (non-invasive or invasive), ischemic ECG changes at rest in a distribution consistent with the target vessel, or ischemic symptoms in patient with ABR
- Revascularization of a target lesion with a diameter stenosis **≥70%** (by QCA) in the absence of the above-mentioned ischemic signs or symptoms is also considered clinically-driven
- If the absence of QCA data for relevant follow-up angiograms, the clinical need for revascularization is adjudicated using the presence or absence of ischemic signs and symptoms

Classic Mehran Classification

Angiographic Patterns of In-Stent Restenosis

Classification and Implications for Long-Term Outcome

Roxana Mehran, MD; George Dangas, MD, PhD; Andrea S. Abizaid, MD; Gary S. Mintz, MD; Alexandra J. Lansky, MD; Lowell F. Satler, MD; Augusto D. Pichard, MD; Kenneth M. Kent, MD, PhD; Gregg W. Stone, MD; Martin B. Leon, MD

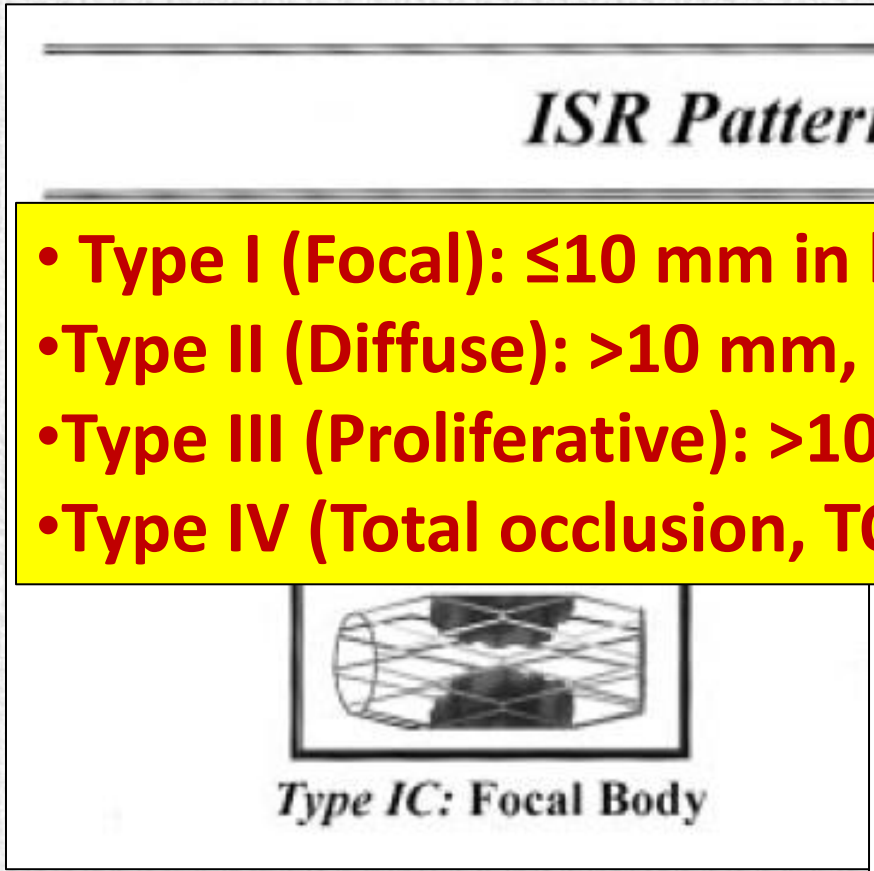
***Background*—**The angiographic presentation of in-stent restenosis (ISR) may convey prognostic information on subsequent target vessel revascularizations (TLR).

***Methods and Results*—**We developed an angiographic classification of ISR according to the geographic distribution of intimal hyperplasia in reference to the implanted stent. Pattern I includes focal (≤10 mm in length) lesions, pattern II is ISR>10 mm within the stent, pattern III includes ISR>10 mm extending outside the stent, and pattern IV is totally occluded ISR. We classified a total of 288 ISR lesions in 245 patients and verified the angiographic accuracy of the classification by intravascular ultrasound. Pattern I was found in 42% of patients, pattern II in 21%, pattern III in 30%, and pattern IV in 7%. Previously recurrent ISR was more frequent with increasing grades of classification (9%, 20%, 34%, and 50% for classes I to IV, respectively; P=0.0001), as was diabetes (28%, 32%, 39%, and 48% in classes I to IV, respectively; P<0.01). Angioplasty and stenting were used predominantly in classes I and II, whereas classes III and IV were treated with atheroablation. Final diameter stenosis ranged between 21% and 28% (P=NS among ISR patterns). TLR increased with increasing ISR class; it was 19%, 35%, 50%, and 83% in classes I to IV, respectively (P<0.001). Multivariate analysis showed that diabetes (odds ratio, 2.8), previously recurrent ISR (odds ratio, 2.7), and ISR class (odds ratio, 1.7) were independent predictors of TLR.

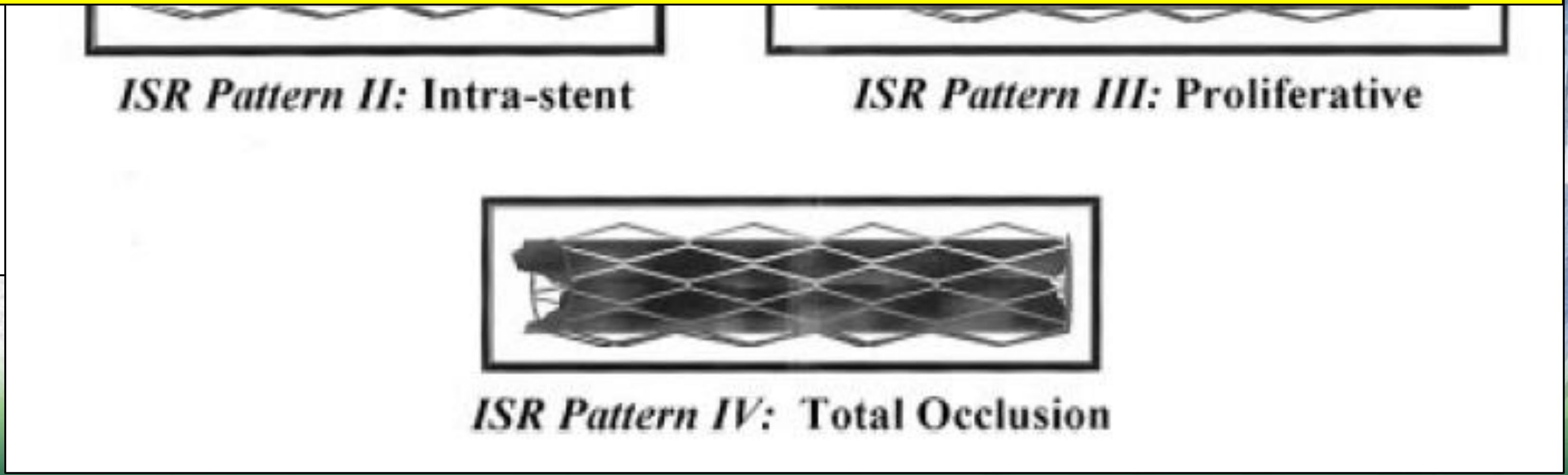
Conclusions*—**The introduced angiographic classification is prognostically important, and it may be used for appropriate and early patient triage for clinical and investigational purposes. (Circulation*. 1999;100:1872-1878.**)

Patterns of In-Stent Restenosis

288 ISR lesions in 245 patients classified according to its patterns



- Type I (Focal): ≤10 mm in length, usually within the body or edge of the stent
- Type II (Diffuse): >10 mm, confined to the stent
- Type III (Proliferative): >10 mm, extends beyond the stent margins (or edges)
- Type IV (Total occlusion, TO): TIMI 0 flow within the stent



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Treatment & Recurrences @ 1-Yr

TABLE 3. Devices Used for Treatment of ISR

	Patterns of ISR			
	Focal (n	Intrastent	Proliferative	Total Occlusion
PTCA*				
Stent alone*				
RA±stent*				
ELCA±stent*				

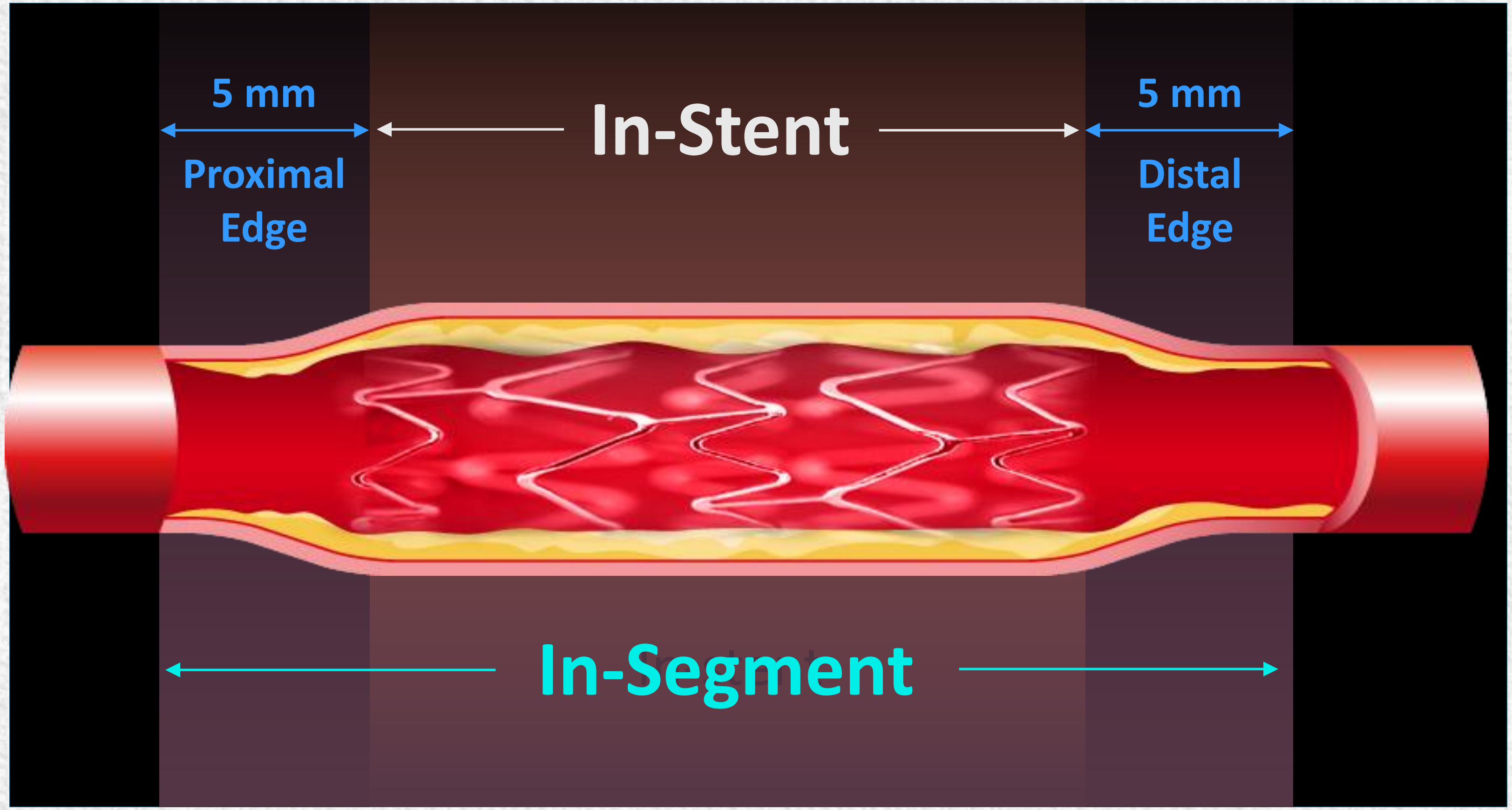
Values are expressed
*$P<0.01$ by ANOVA.

TABLE 6. One-Year Events

	Patterns of ISR			
	Focal	Intrastent	Proliferative	Total Occlusion
Death	2.5	2.6	3.3	0.0
Myocardial infarction	1.2	2.6	0.0	0.0
TLR*	19.1	34.5	50.0	83.4
PTCA*	14.8	26.3	36.3	66.7
CABG*	4.3	8.2	13.7	16.7

Values are expressed as percentages. CABG indicates coronary artery bypass surgery.
*$P<0.0001$ by ANOVA.

QCA Method in the DES Era



Management of ISR

- Definition and types of recurrences
- **Clinical impact in contemporaneous daily practice**

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Impact of DES

Serial QCA studies in 701 patients w

TABLE 3. Angiographic Patterns of Restenosis in the SIRIUS Angiographic Substudy

Variable	Sirolimus, n (%)	Control, n (%)	*P*
In-			
Foc			
Dif			
II	1 (3.2)	46 (35.9)	<0.001
III	2 (6.5%)	17 (13.3)	0.372
IV (total occlusion)	2 (6.5)	10 (7.8)	1.00
ISR length, mm	9.1	14.8	<0.001
Aneurysm	2 (0.6)	4 (1.1)	0.686

In-stent restenosis (ISR) patterns classified using the Mehran criteria.[10]

TABLE 5. Predicted In-Segment Restenosis Rates in the SIRIUS Angiographic Substudy

Reference Vessel Size, mm	Lesion Length, mm <10	10–15	>15
Standard stent			
Nondiabetics			
<2.5	36.8	40.1	45.7
2.5–3.0	5.6	6.4	7.9
>3.0	3.4	3.9	4.9
Diabetics			
<2.5	17.7	19.8	23.7
2.5–3.0	12.4	14.0	17.0
>3.0	7.8	8.9	10.9

In-segment ABR = DES 8.6% vs. BMS 36.3%, p<0.001

In-stent ABR = DES 3.2% vs. 35.4%, p<0.001

Focal pattern = DES 83.8% vs. 43%, p<0.001

TLR = 4.1% vs. 16.6%, p<0.001

Prevalence of ISR in Current PCI

Binary restenosis rates with new generations DES among real-world pts

- ISR rates with early-generation DES were around 4.9% at 1-year
- New-generation DES have further reduced this to approximately 2.5% Most modern studies report angiographic ISR rates with newer DES platforms consistently below 10%, with many trials citing a 5 to 7% range under optimal conditions
- However, ISR may still account for about **10%** of all percutaneous coronary intervention (PCI) procedures in real-world practice, reflecting complex lesions and high-risk subgroups

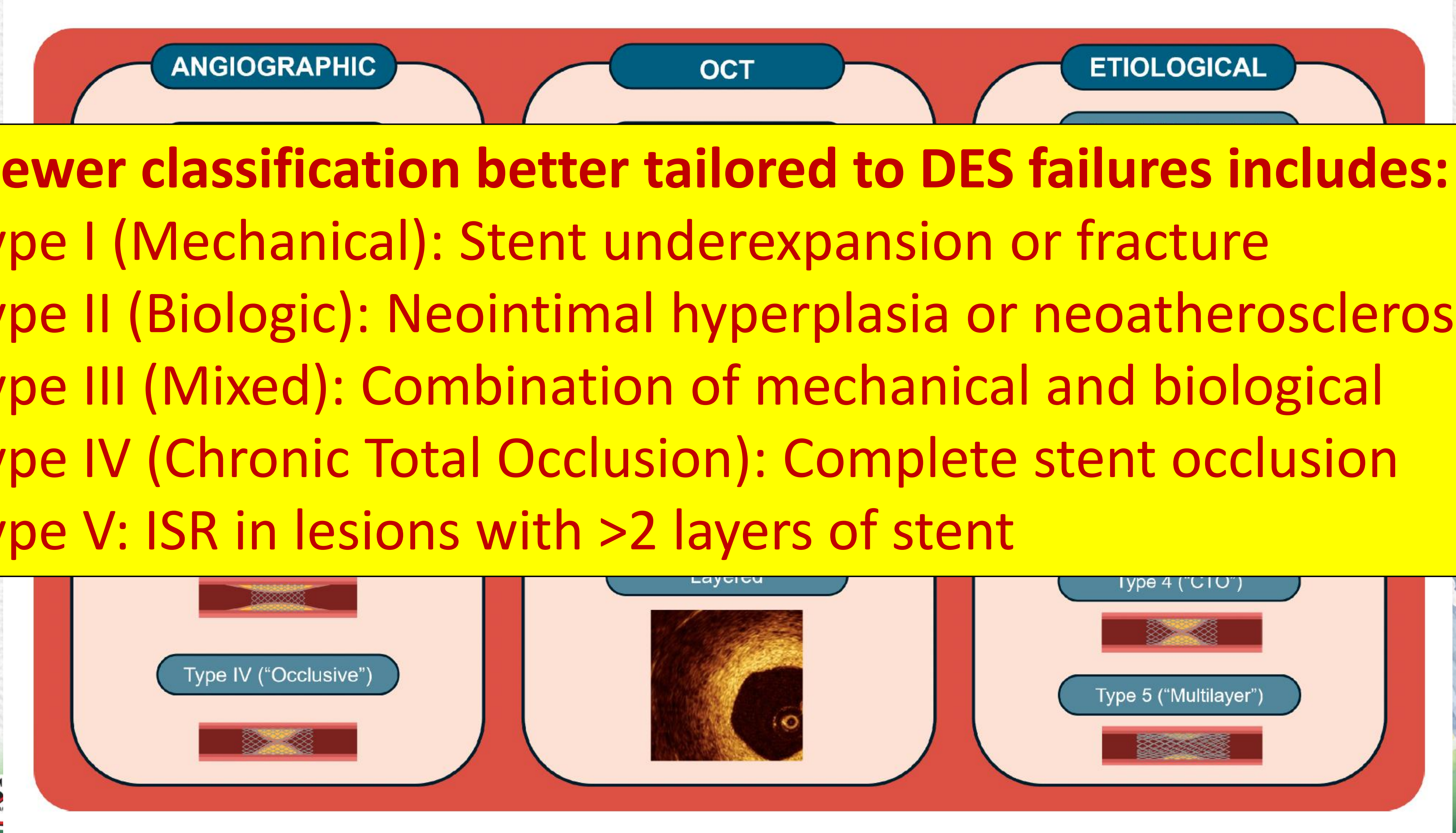
Predictors & High-Risk Subsets

- Long lesions
- Small vessels
- Diabetics
- Bifurcations (SB ostium)
- Calcified lesions
- Ostial location
- Stent underexpansion
- Stent length/number
- Multiple layers of metal
- Geographical miss
- Smoking, CKD
- CTO

Management of ISR

- Definition and types of recurrences
- Clinical impact in contemporaneous daily practice
- **Identifying mechanisms of (stent) failure**

Waksman Mechanistic Classification



A newer classification better tailored to DES failures includes:

- Type I (Mechanical): Stent underexpansion or fracture
- Type II (Biologic): Neointimal hyperplasia or neoatherosclerosis
- Type III (Mixed): Combination of mechanical and biological
- Type IV (Chronic Total Occlusion): Complete stent occlusion
- Type V: ISR in lesions with >2 layers of stent

Management of ISR

- Definition and types of recurrences
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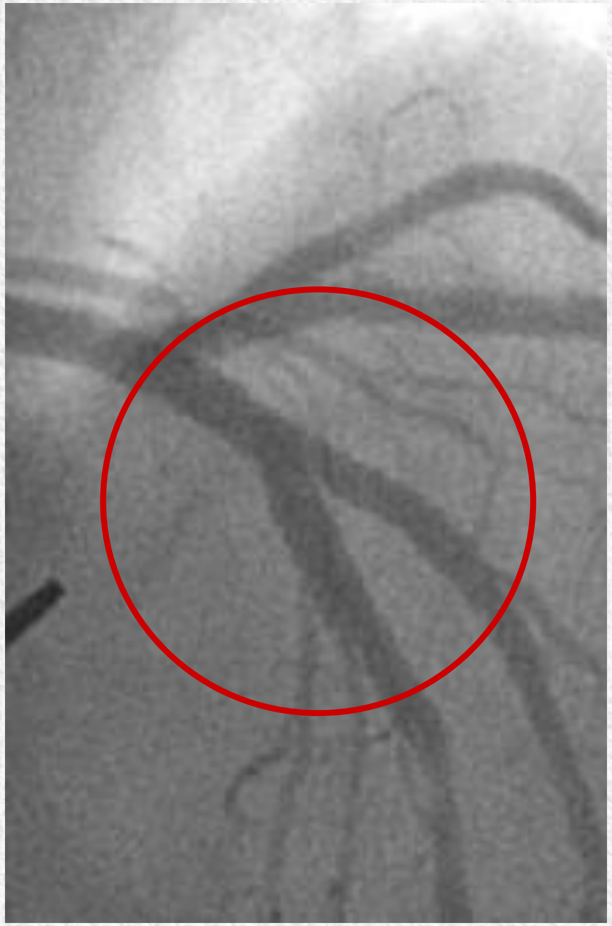
- Identifying mechanisms of (stent) failure
- **Role of intravascular imaging modalities**

Stent Underexpansion

Side Branch Ostium ISR

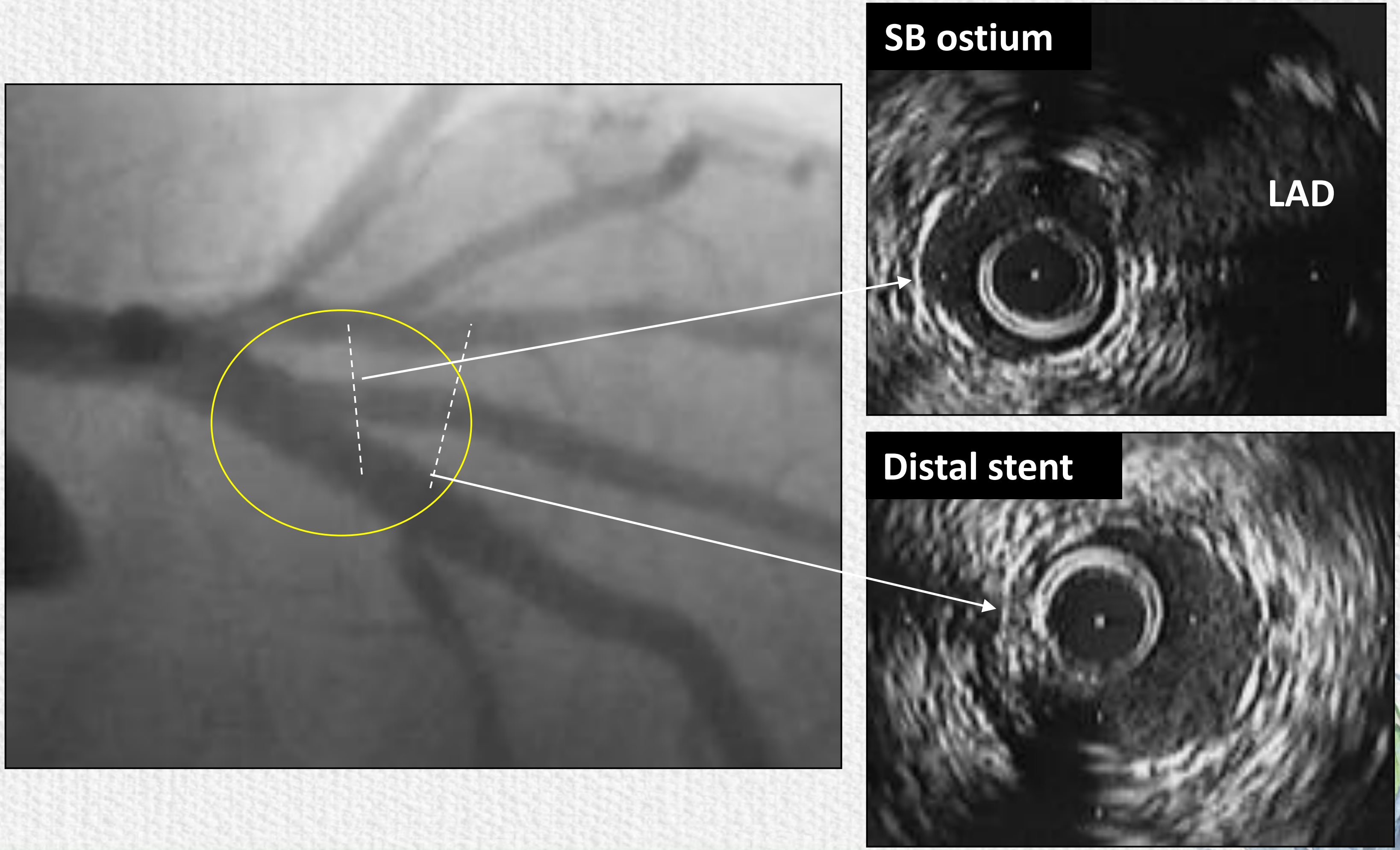
Preprocedure



Final

6 Months Follow-Up

Signficant Underexpansion



Management of ISR

- Definition and types of recurrences
- Clinical impact in contemporaneous daily practice
- Identifying mechanisms of (stent) failure
- Role of intravascular imaging modalities
- **Treatment alternatives**

Treatment with DES

Historical Perspective

Sirolimus-Eluting Stent for the Treatment of In-Stent Restenosis

A Quantitative Coronary Angiography and Three-Dimensional Intravascular Ultrasound Study

J. Eduardo Sousa, MD, PhD; Marco A. Costa, MD, PhD; Alexandre Abizaid, MD, PhD; Amanda G.M.R. Sousa, MD, PhD; Fausto Feres, MD, PhD; Luiz A. Mattos, MD, PhD; Marinella Centemero, MD; Galo Maldonado, MD; Andrea S. Abizaid, MD; Ibraim Pinto, MD; Robert Falotico, PhD; Judith Jaeger, BA; Jeffrey J. Popma, MD; Patrick W. Serruys, MD, PhD

Background—We have previously reported the safety and effectiveness of sirolimus-eluting stents for the treatment of de novo coronary lesions. The present investigation explored the potential of this technology to treat in-stent restenosis.

Methods and Results—Twenty-five patients with in-stent restenosis were successfully treated with the implantation of 1 or 2 sirolimus-eluting Bx VELOCITY stents in São Paulo, Brazil. Nine patients received 2 stents (1.4 stents per lesion). Angiographic and volumetric intravascular ultrasound (IVUS) images were obtained after the procedure and at 4 and 12 months. All vessels were patent at the time of 12-month angiography. Angiographic late loss averaged 0.07±0.2 mm in-stent and −0.05±0.3 mm in-lesion at 4 months, and 0.36±0.46 mm in-stent and 0.16±0.42 mm in-lesion after 12 months. No patient had in-stent or stent margin restenosis at 4 months, and only one patient developed in-stent restenosis at 1-year follow-up. Intimal hyperplasia by 3-dimensional IVUS was 0.92±1.9 mm^3 at 4 months and 2.55±4.9 mm^3 after 1 year. Percent volume obstruction was 0.81±1.7% and 1.76±3.4% at the 4- and 12-month follow-up, respectively. There was no evidence of stent malapposition either acutely or in the follow-up IVUS images, and there were no deaths, stent thromboses, or repeat revascularizations.

Conclusion—This study demonstrates the safety and the potential utility of sirolimus-eluting Bx VELOCITY stents for the treatment of in-stent restenosis. (***Circulation*. 2003;107:24-27.**)

Key Words: stents ■ restenosis ■ drugs ■ angiography ■ ultrasonics

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Restenosis Post New DES

Table 3 Quantitative angiographic analysis at baseline, post-procedure, and follow up*

	Preprocedure	Post-procedure	Follow up
Reference diameter (mm)	2.64 (0.56)	2.73 (0.54)	2.83 (0.50)
Minimum lumen diameter (mm)	0.90 (0.55)	2.33 (0.59)	2.20 (0.81)
Diameter stenosis (%)	66 (19)	16 (15)	23 (25)
Lesion length (mm)	17.5 (12.1)	NA	NA
Acute gain (mm)	NA	1.42 (0.70)	NA
Late loss (mm)	NA	NA	0.17 (0.76)
Late loss excluding occlusions (mm)	NA	NA	0.11 (0.67)
Binary post-SES restenosis†	NA	NA	14.6%

Data are mean (SD).
*Related to 41 lesions with angiographic follow up; †including one total reocclusion.
NA, not applicable; SES, sirolimus eluting stent.

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Saia et al. Heart. 2004;90(10):1183-8

New Recurrences in DES-ISR

Treatment Type	1-Year Recurrence	2–4 Year Recurrence
New-generation DES	~7–10%	20–28%
Drug-Coated Balloon	~8–13%	20–38%
Balloon Angioplasty	~13%	>20%

DCB versus POBA

AGENT IDE Study Design

Prospective, randomized, multicenter, superiority trial across 40 US sites (N=480 patients*)

- Key Inclusion Criteria: Patients with ISR of a lesion previously treated with BMS or DES; lesion length <26 mm, RVD >2.0 - ≤4.0 mm, and %DS >70 - <100% (asymptomatic) or %DS >50 - <100% (symptomatic)
- Key Exclusion Criteria: Recent STEMI, bifurcation, LM, SVG or arterial graft, thrombus in target vessel

2:1 randomization after successful pre-dilation of target lesion

AGENT DCB

Balloon Angioplasty

Primary Endpoint: Target Lesion Failure at 1-year (composite of TLR, TV-MI, or cardiac death)
Clinical follow-up: In-hospital, 30 days, 6 months, 1-year and annually between 2 and 5 years

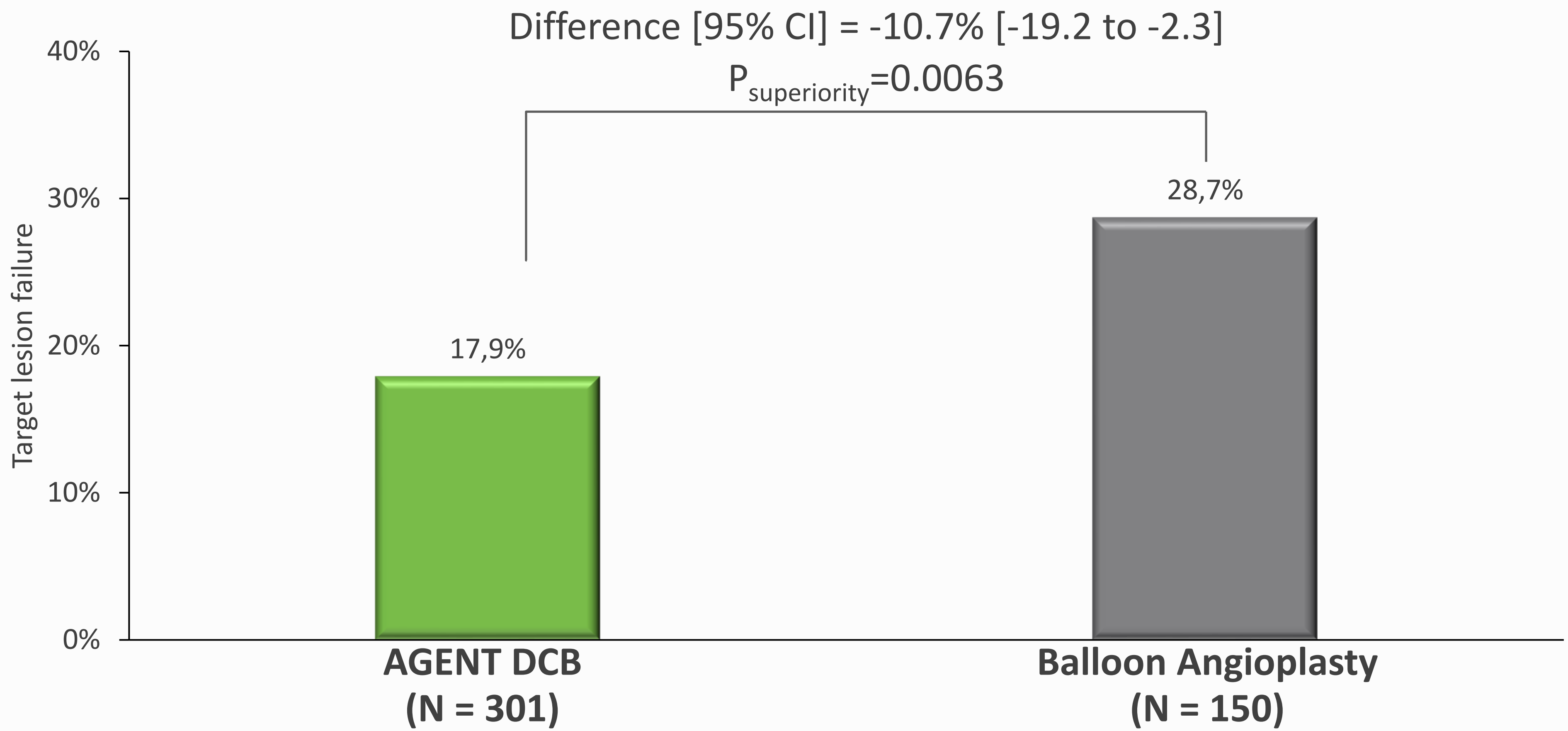
DAPT required for at least a month; Antiplatelet monotherapy through the duration of the study
*Based on an adaptive trial design (interim analysis with pre-specified sample size readjustment plan); Yeh et al. Am Heart J. 2021;241:101-107

Baseline Restenosis Pattern

	AGENT DCB N=321	Balloon Angioplasty N=159
Single stent layer	56.4%	56.6%
Multiple stent layers	43.6%	43.4%
Mehran ISR pattern*		
0	0.0%	0.0%
1A (articulation)	0.0%	0.0%
1B (margin)	1.3%	1.3%
1C (focal)	35.8%	44.2%
1D (multifocal)	0.3%	0.6%
2 (intrastent)	57.5%	48.1%
3 (proliferative)	4.4%	5.2%
4 (total occlusion)	0.6%	0.6%

*Quantified by the angiographic core laboratory

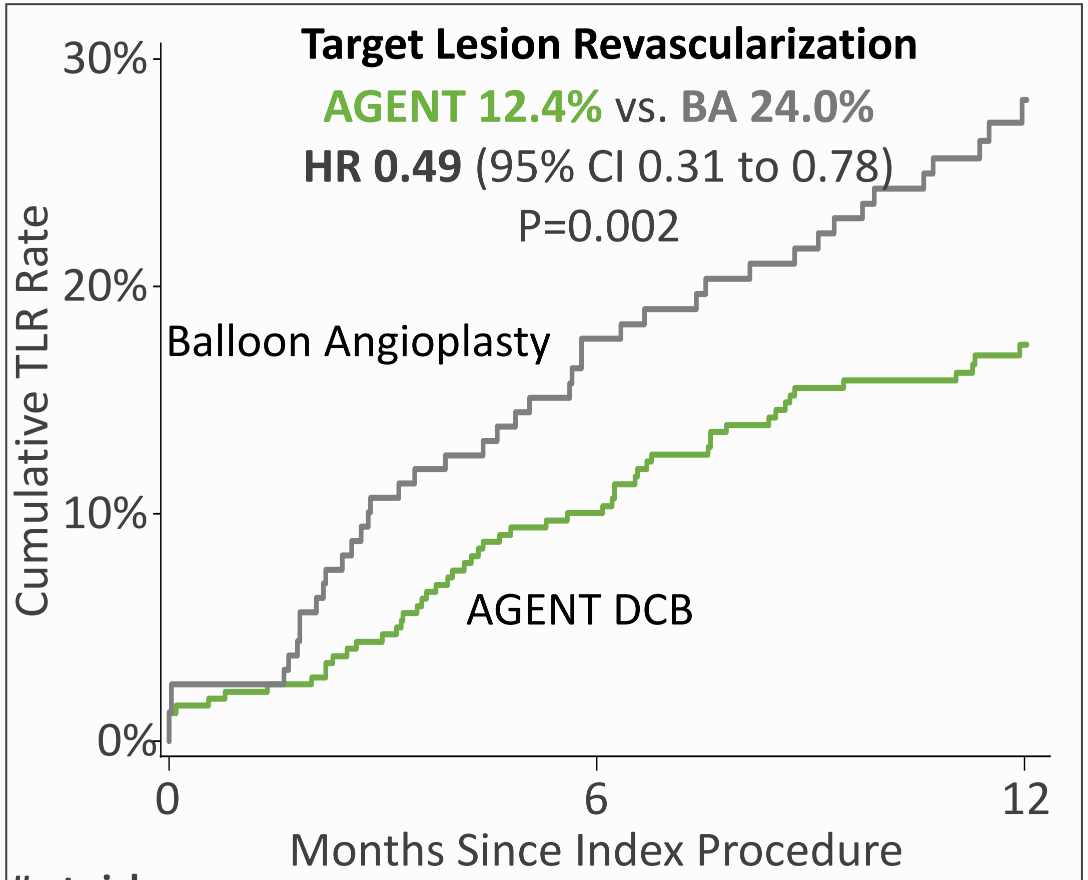
Primary Endpoint: TLF at 1-Year



AGENT DCB demonstrated superior outcomes compared to BA for 1-year TLF

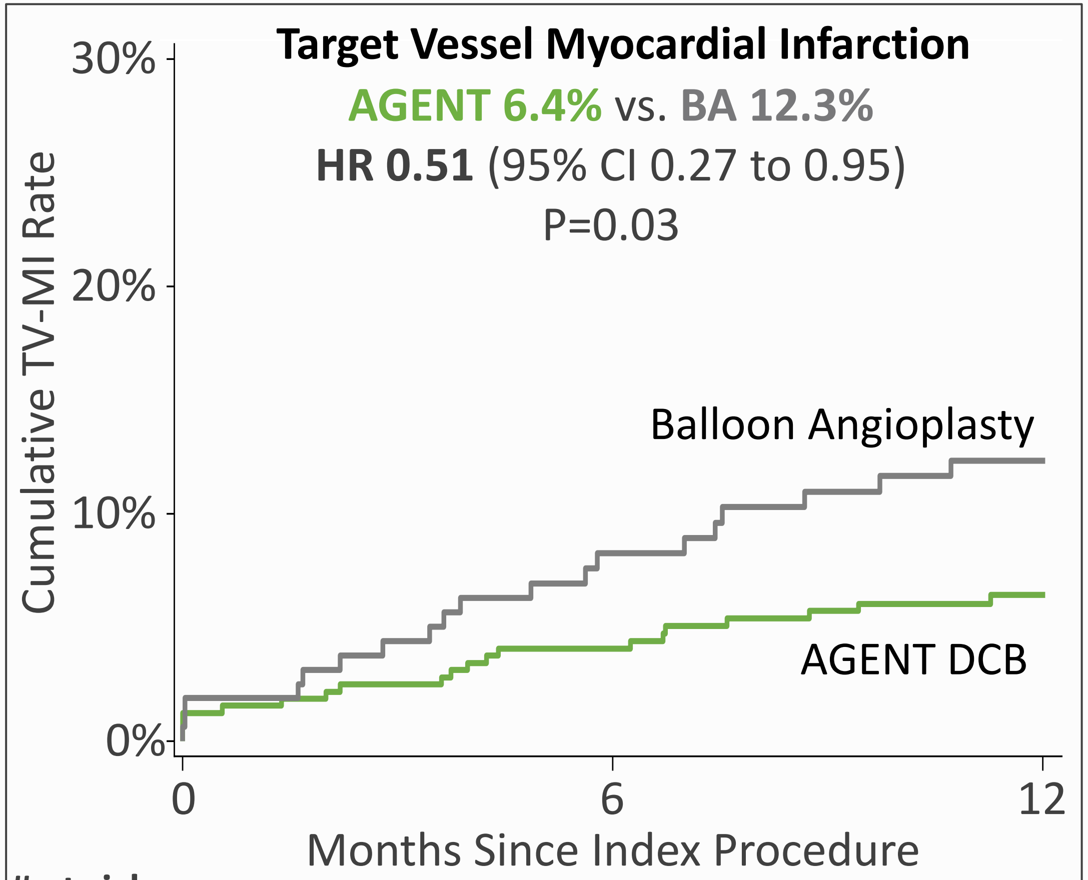
Binary event rates; A z-test with unpooled variance for the difference of two proportions was used

TLR and Target Vessel Related MI at 1-Year



 # at risk

	0	6	12
AGENT	321	306	219
BA	159	142	98



 # at risk

	0	6	12
AGENT	321	306	233
BA	159	148	108

Log-rank P values; Periprocedural MI occurring within 48 hours of the index procedure adjudicated by the SCAI definition, and spontaneous MI occurring 48 hours after the index procedure was adjudicated according to the 4th Universal MI definition

New Sirolimus DEB

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Selution DEB FIM Trial

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

Sirolimus-coated balloon with a microsphere-based technology for the treatment of de novo or restenotic coronary lesions

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A R T I C L E   I N F O

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Keywords:
Drug-coated balloon
Sirolimus
Balloon angioplasty

A B S T R A C T

Background: Non stent-based local drug delivery with drug-coated balloon (DCB) is an alternative to drug-eluting stent with favorable clinical applicability in the treatment of selected coronary lesions. Our purpose was to report the initial performance, safety and efficacy evaluations of a novel sirolimus-coated balloon in the treatment of coronary lesions.
Methods: This was a phase I (first-in-man), prospective, multicenter, single-arm trial evaluating the novel SELUTION SLR™ DCB (M.A. Med Alliance SA, Nyon, Switzerland), which incorporates a polymeric microsphere-based technology for controlled and continuous release of sirolimus, in the treatment of de novo or restenotic lesions.

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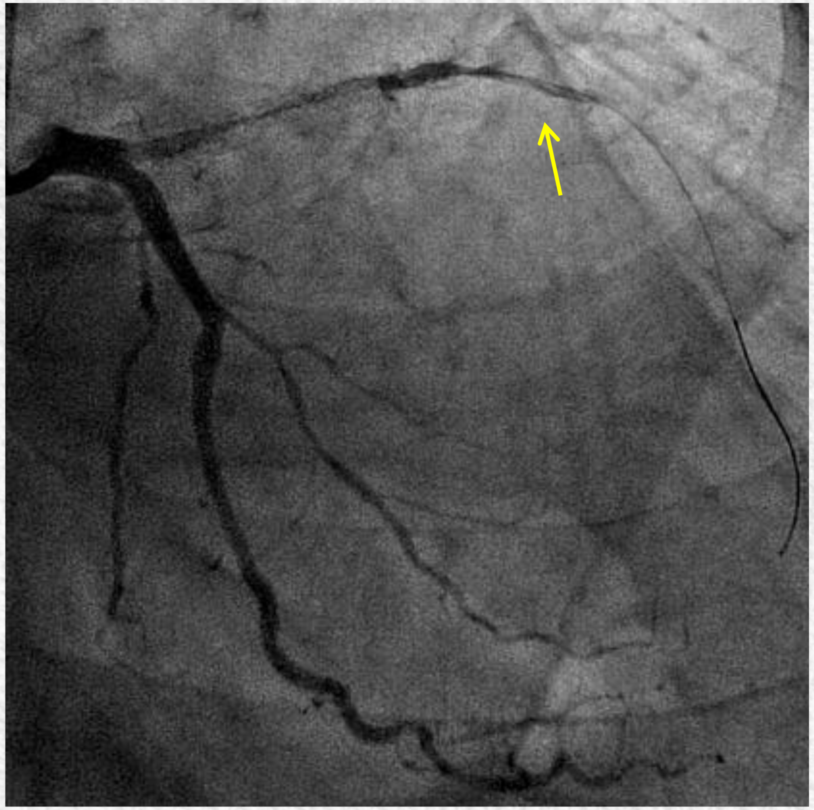
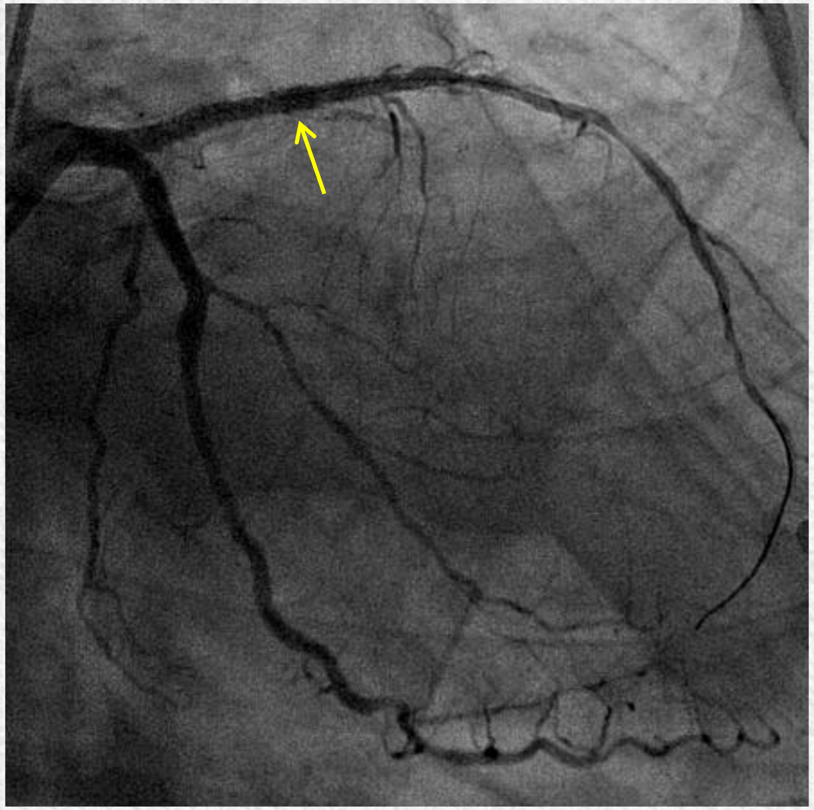
Selution FIM Trial

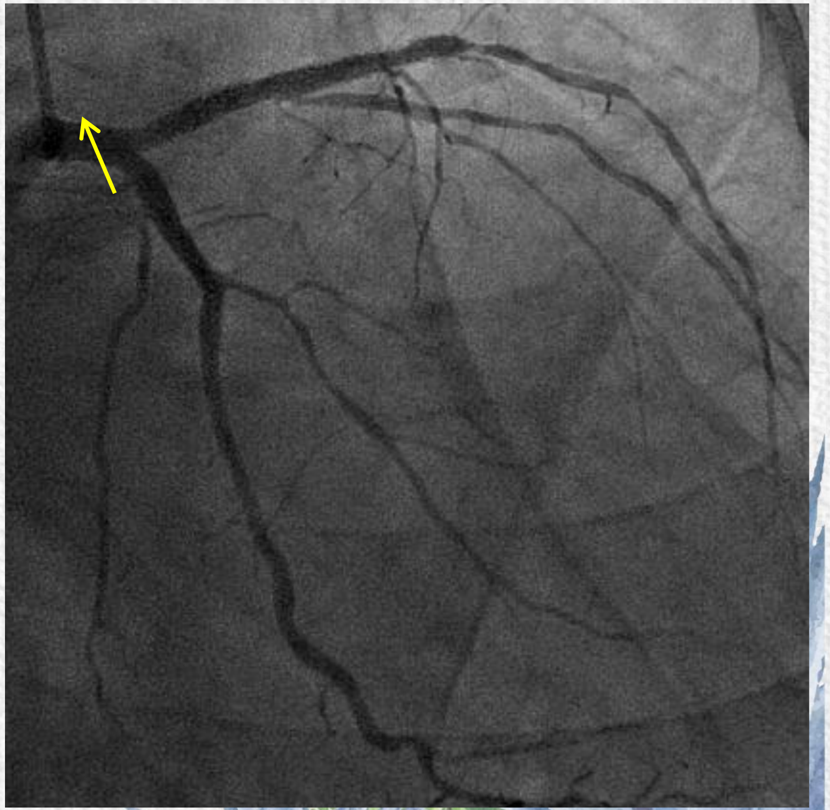
Pre-procedure



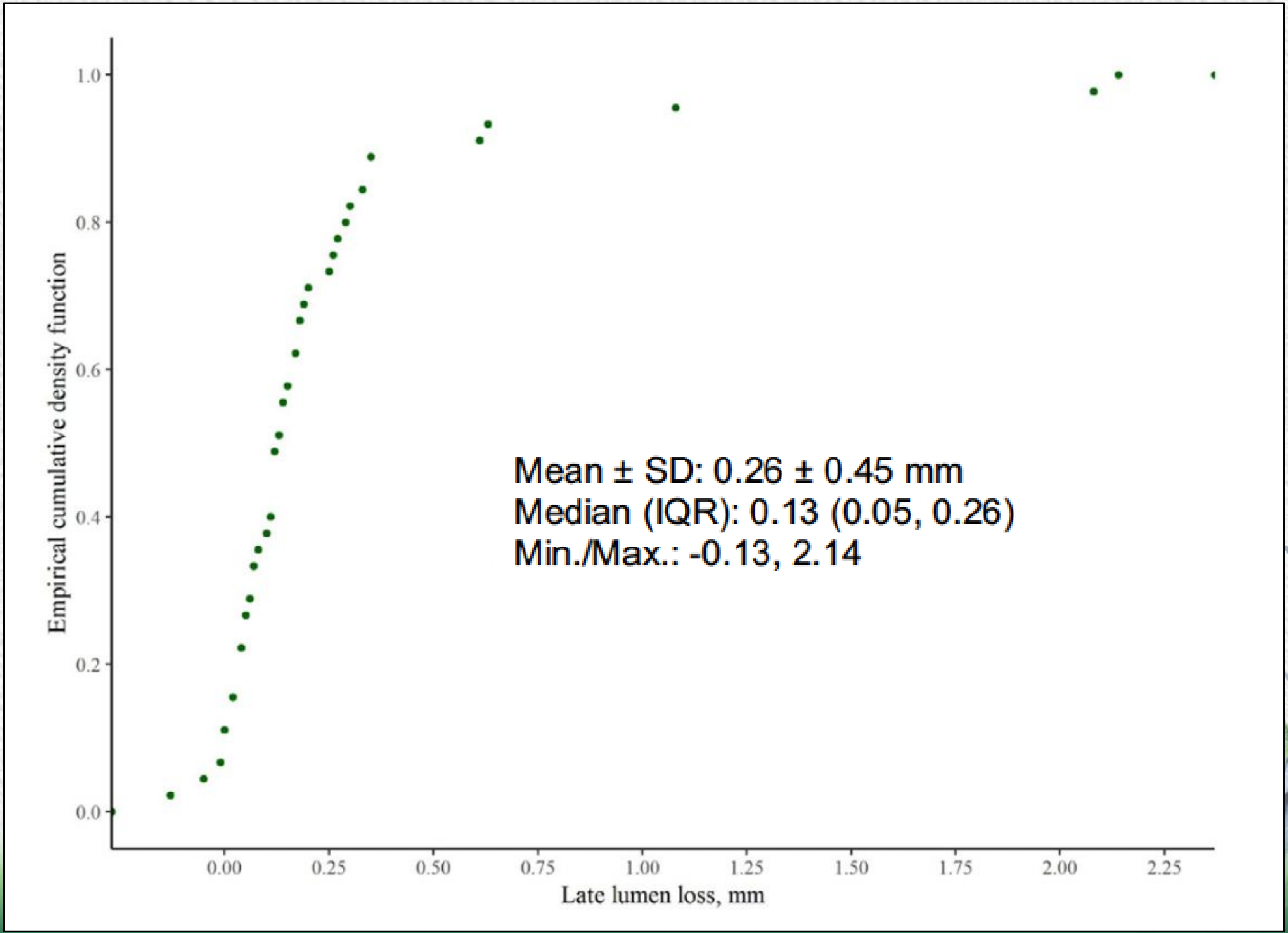
Post-procedure



Follow-up



Late Lumen Loss at 6 Months FU



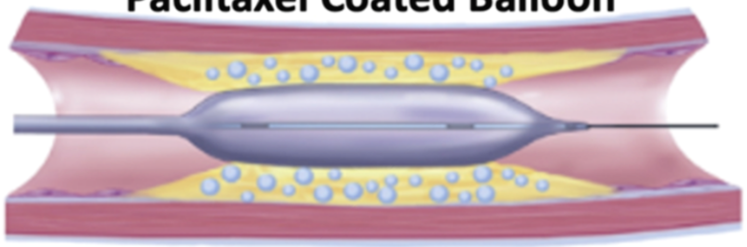
PCB versus SCB

Paclitaxel versus Sirolimus

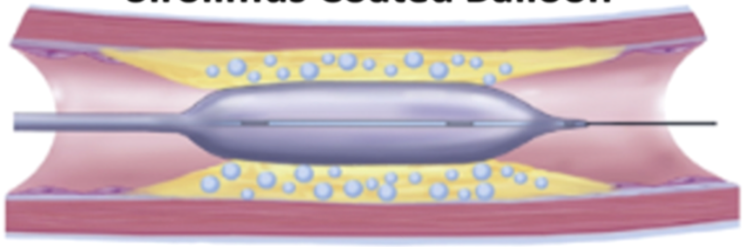
RCT to compare a novel SCB (SeQuent SCB, 4 µg/mm²) with a PCB (SeQuent Please, 3 µg/mm²) in coronary ISR
Primary endpoint: angiographic late lumen loss (LLL) at 6 months

One hundred and one patients with drug eluting stent (DES) ISR
Randomization ITT, lesion preparation mandatory

Paclitaxel Coated Balloon



Sirolimus Coated Balloon



0.25 ± 0.57 mm

Non-inferiority SCB vs PCB
Late lumen loss in-segment @ 6 months

0.26 ± 0.60 mm

Clinical events @ 12 months

Circ Cardiovasc Interv. 2022 Sep;15(9):e012305

DCB versus DES

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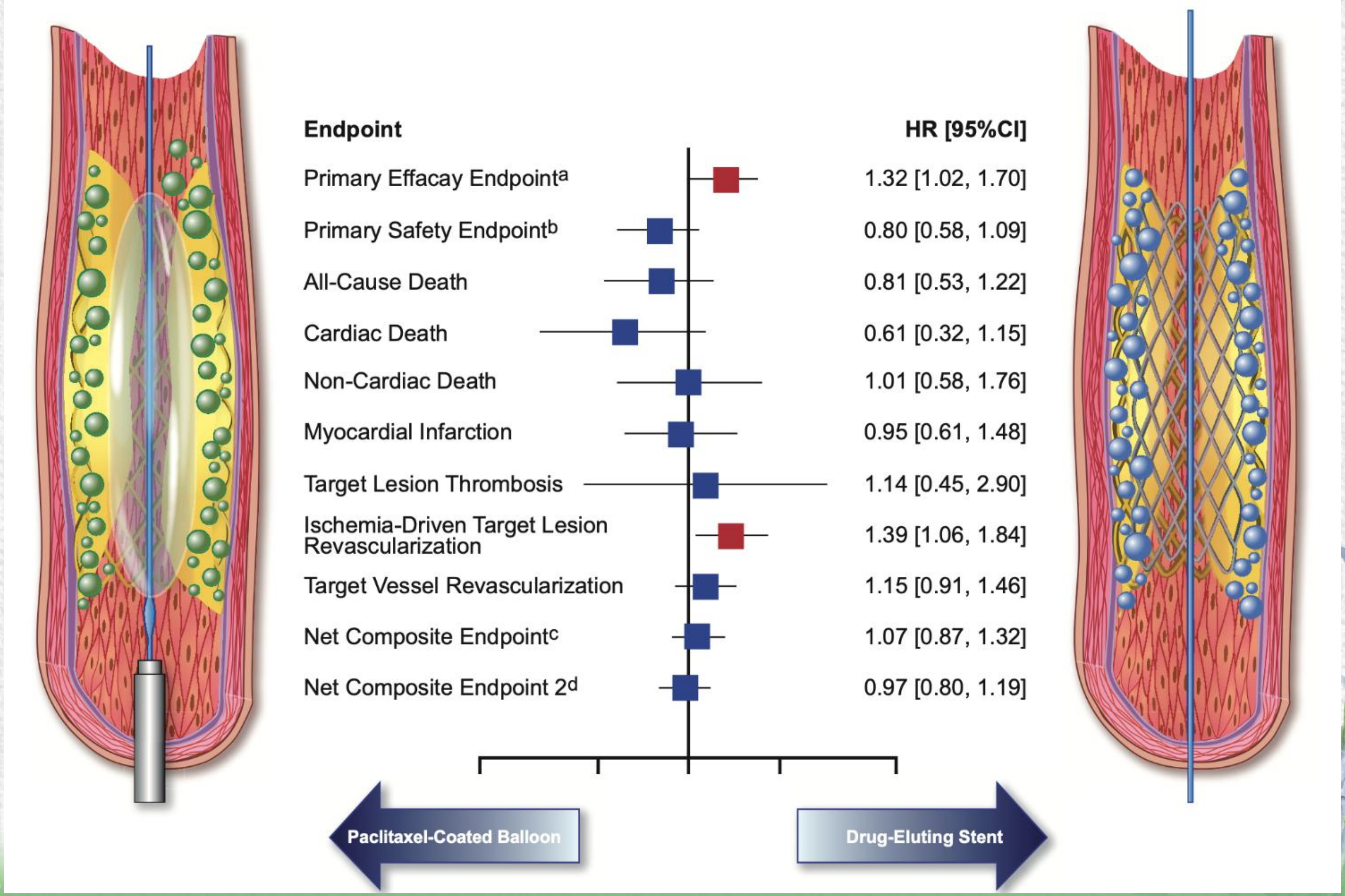
DCB versus DES in ISR



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European Heart Journal (2020) 41, 3715–3728

Can DCB Still Be Preferable?

- Avoid additional metallic scaffolding within the previously stented segment - The premise is to reduced long-term (>1 year) ischemic events related to permanent overlaying metal struts! To be proven!
- Avoid excessive number of stents and overall high stented length – both predictors of new failure
- Target locations where stents have already failed, including diffusely diseased segments and small vessels
- Avoid multiple layers of metal in critical locations and conditions (LM, proximal large epicardial vessels, anatomies unfavorable to stents that have already failed)
- Need to target mechanistic causes before!

Management of ISR

- Definition and types of recurrences
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- Identifying mechanisms of (stent) failure
- Role of intravascular imaging modalities
- Treatment alternatives
- **Optimal technique**

Recurrent ISR

Patient demographics

50-years-old, male

Co-morbidities

Hypertension

Dyslipidemia

TTE – 04/2021

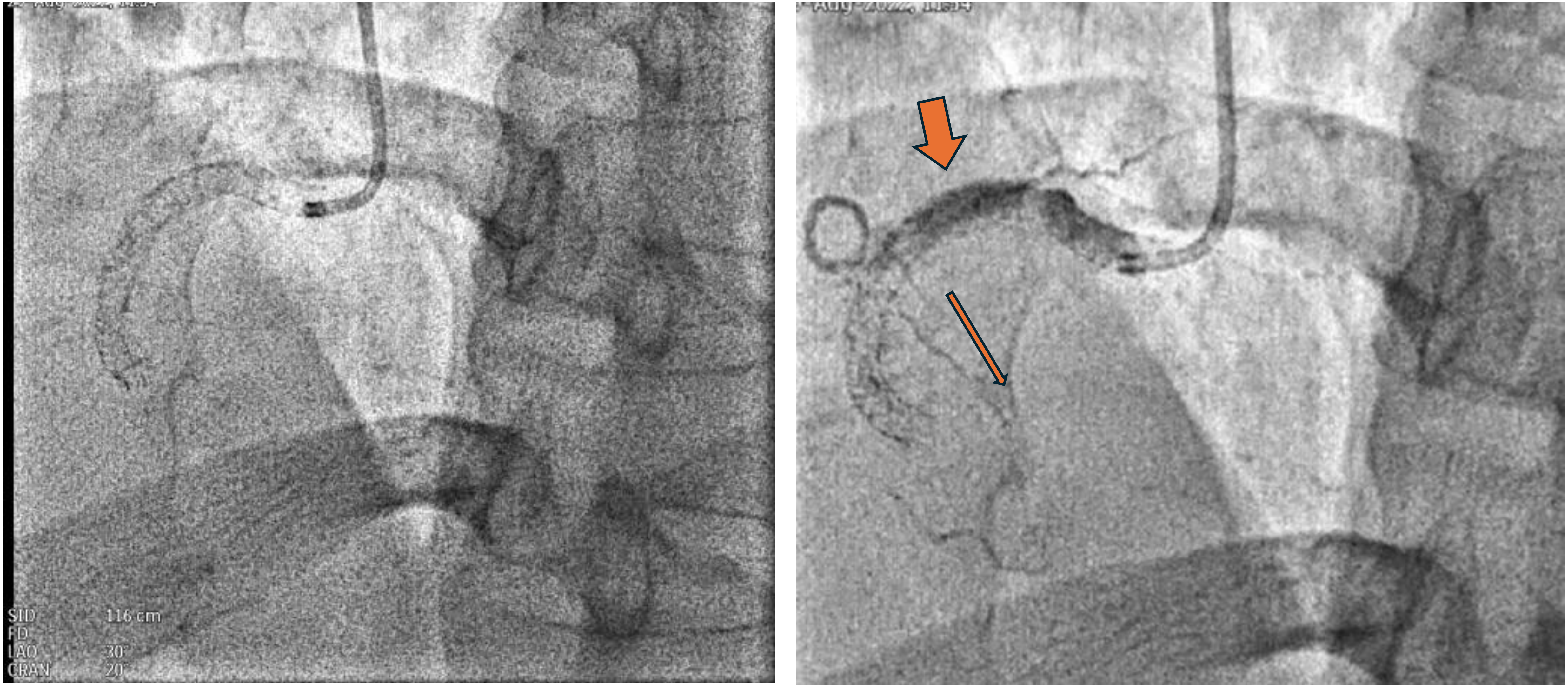
LVEF = 45%

Mild inferior hypokinesia

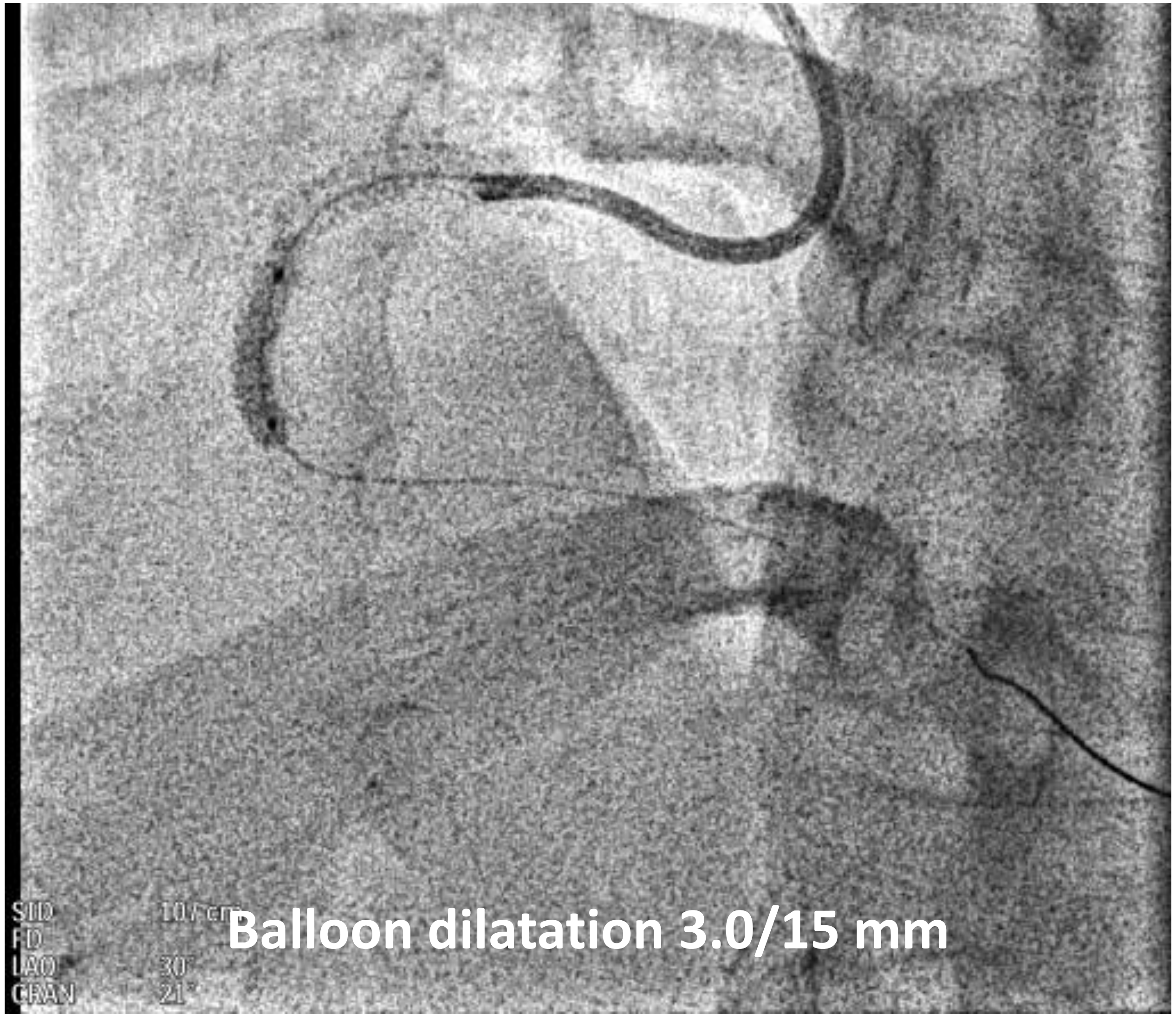
Clinical Hx

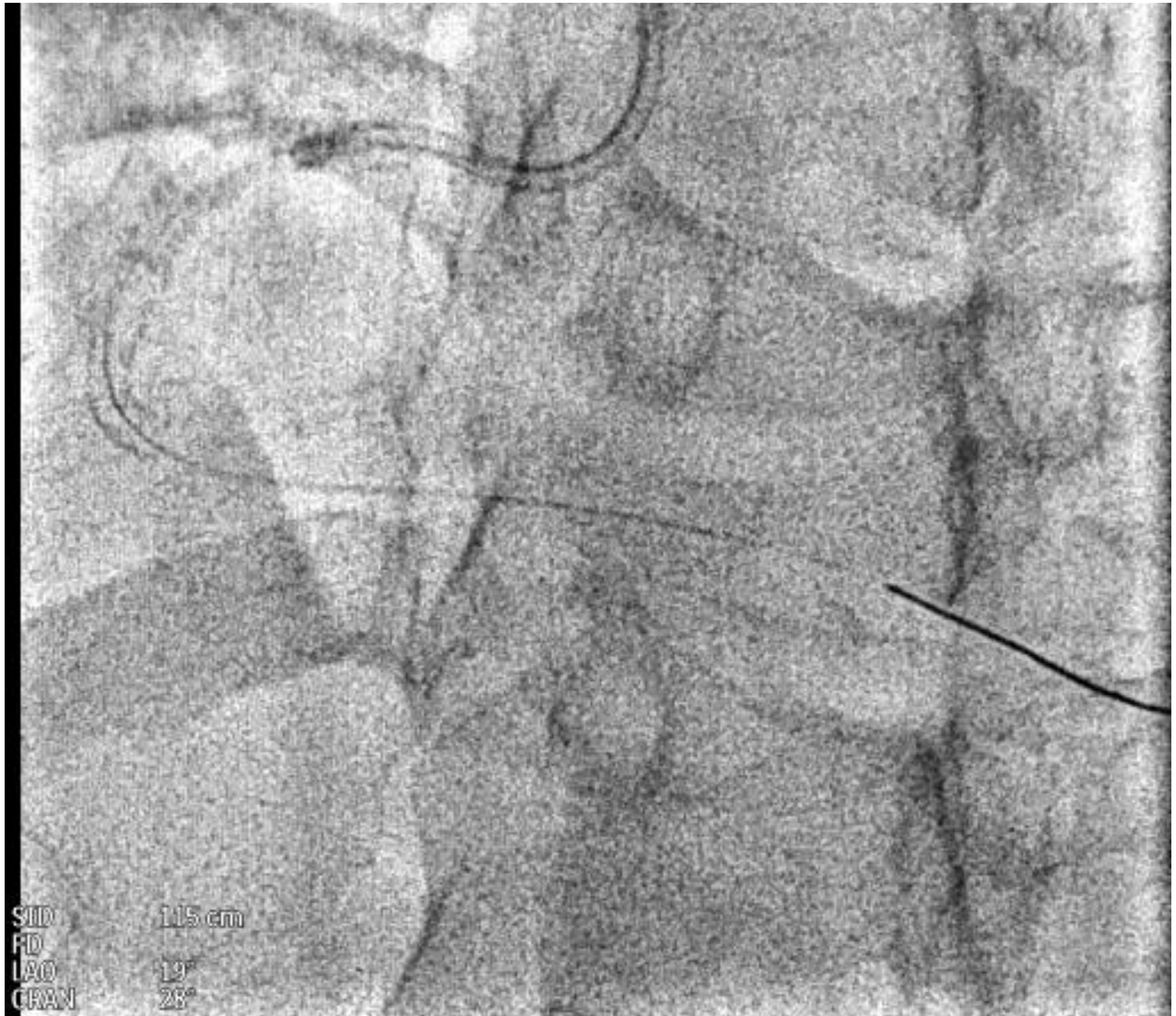
- **NSTEMI in 2021 with PCI to LAD, OM1 and RCA**
- **Unstable angina in Aug/22**

Aug/2022

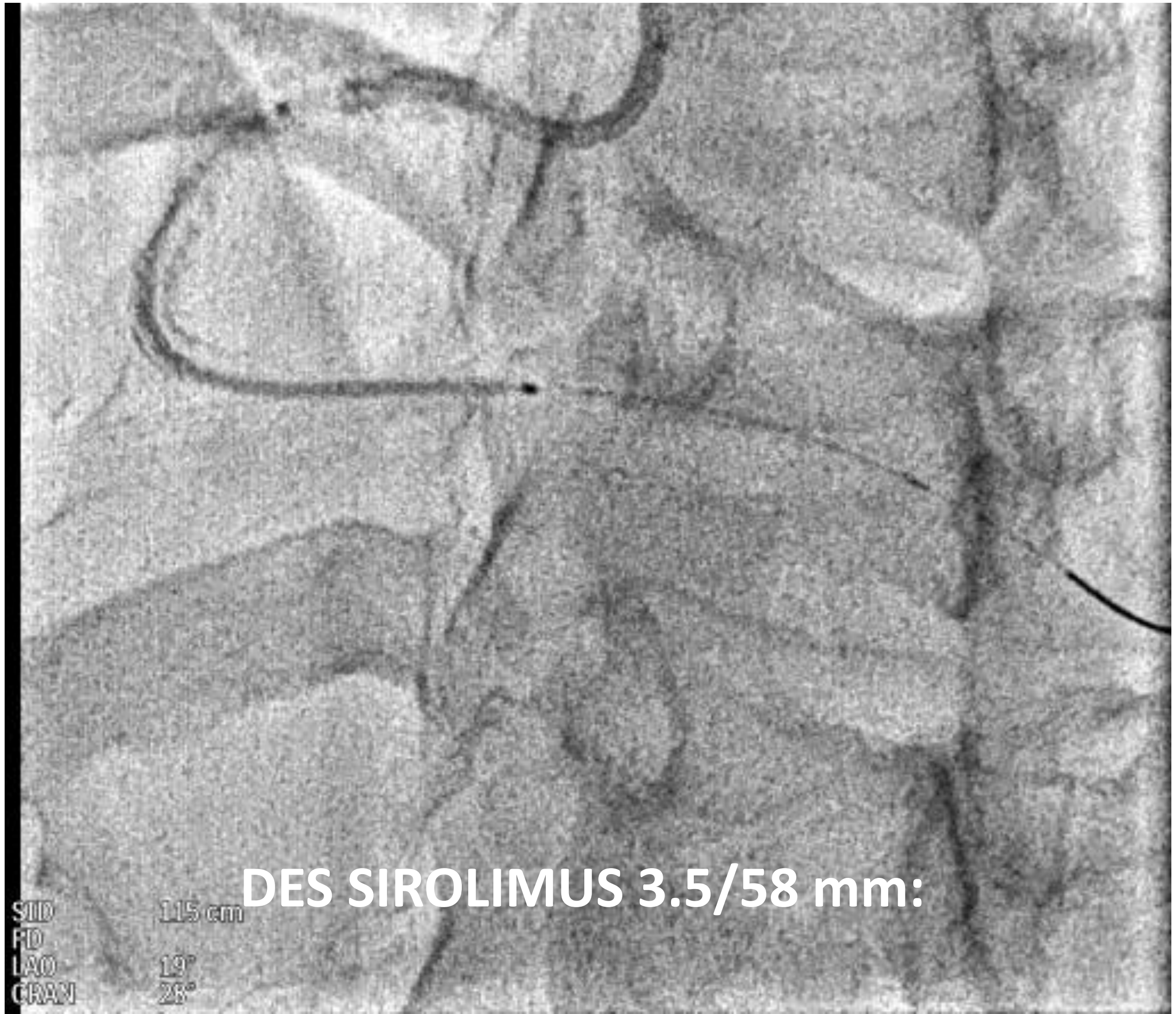


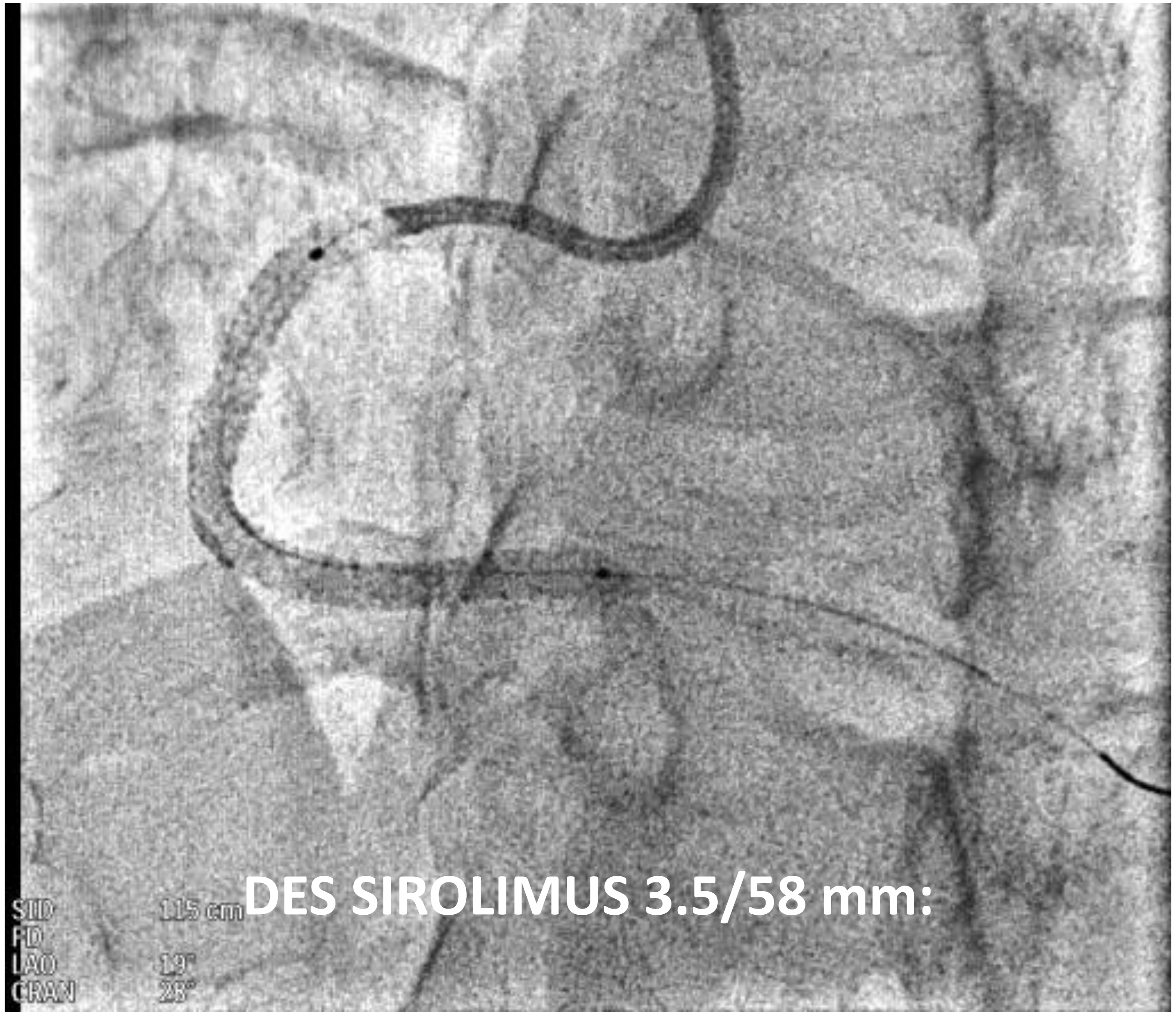
PCI for Occlusive ISR



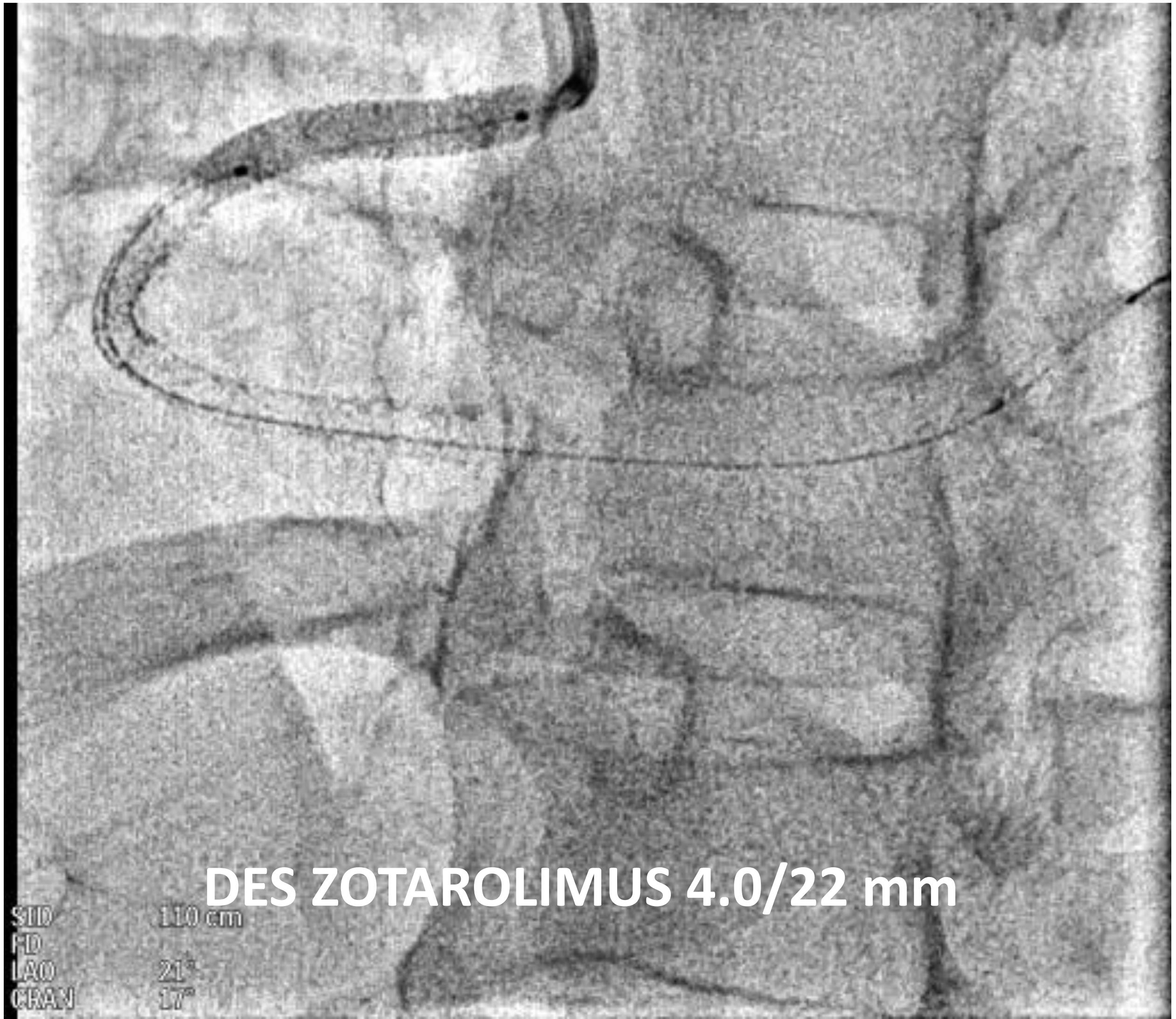


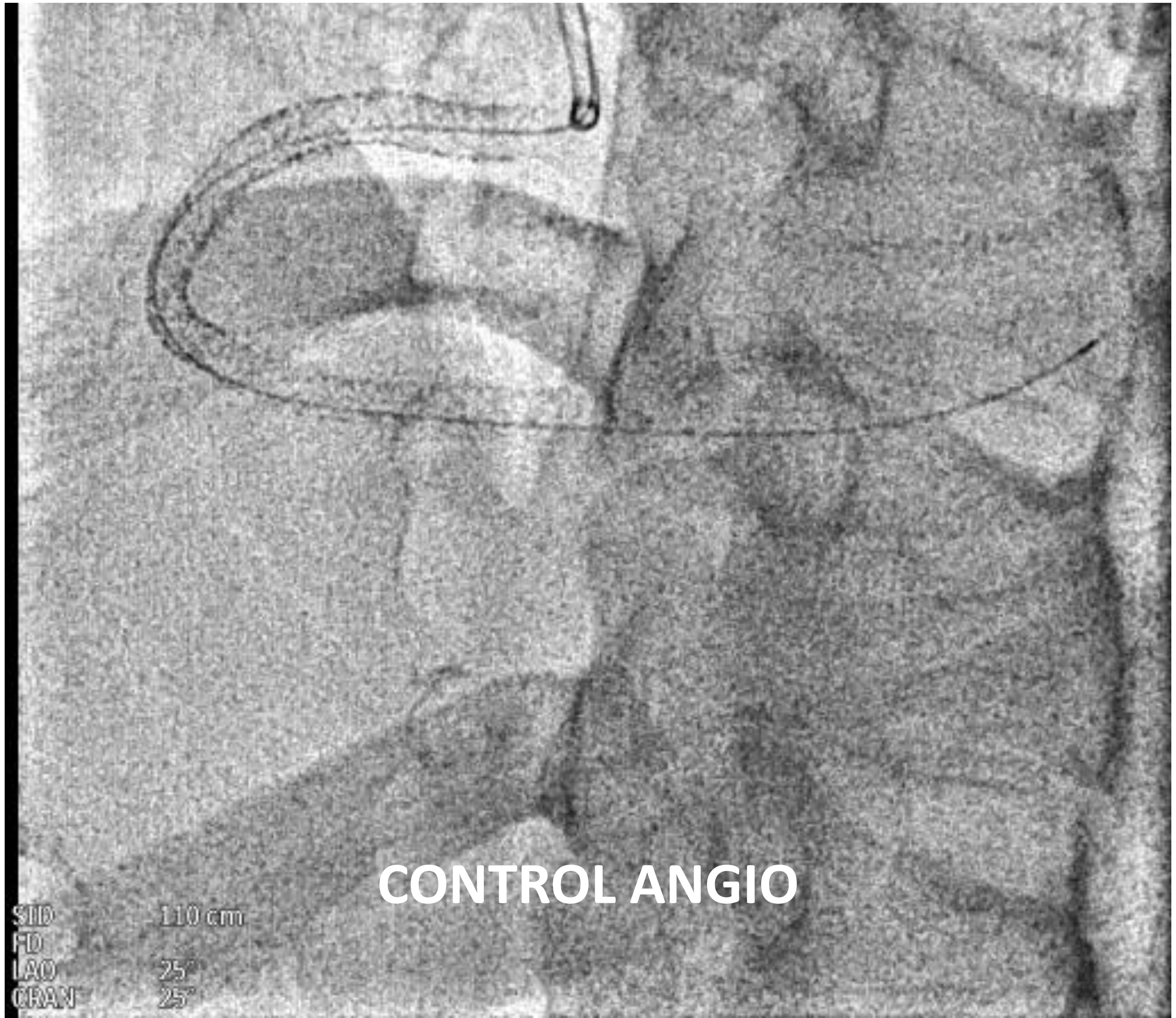
New Stents Implanted



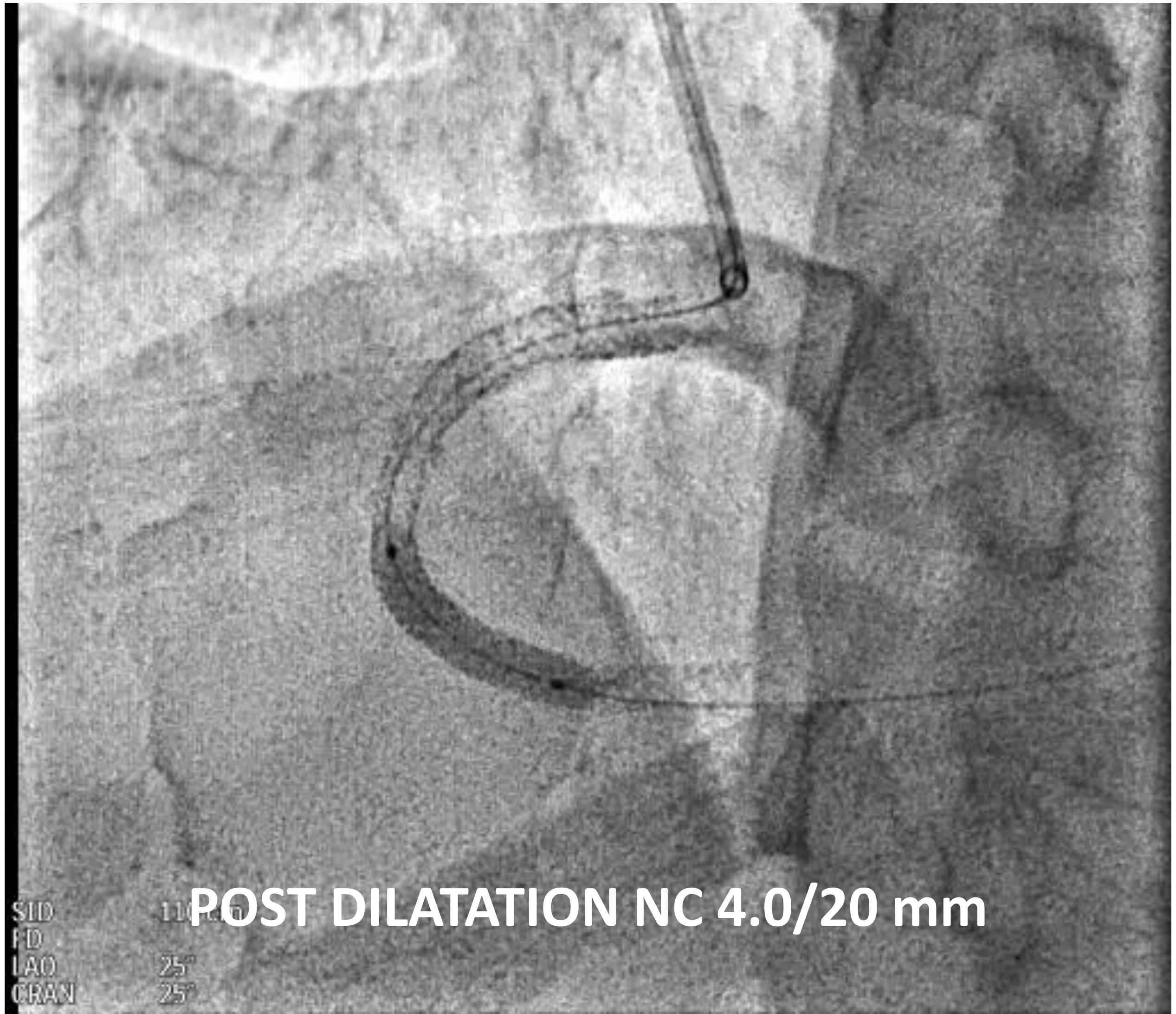


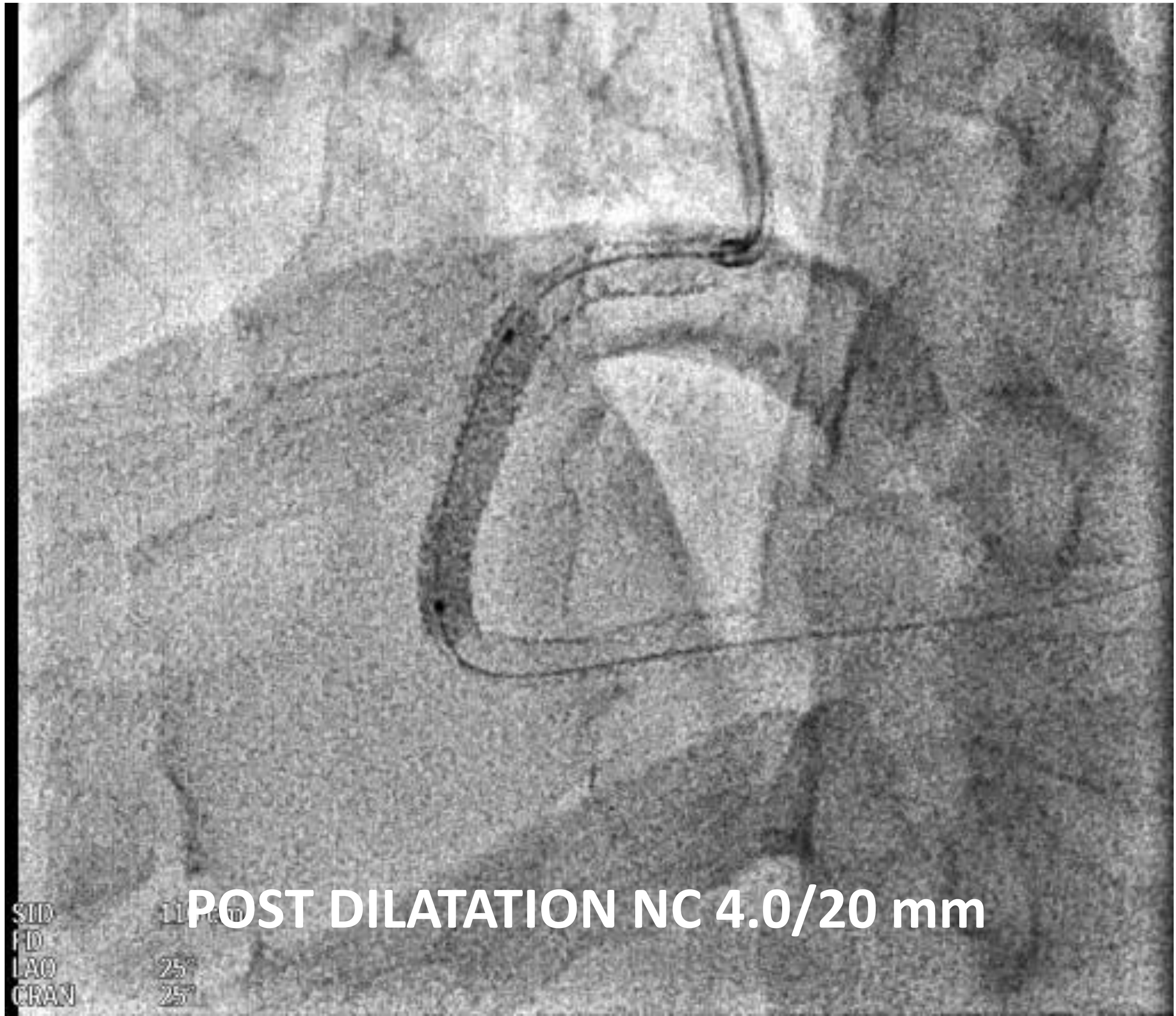
Proximal New Stent



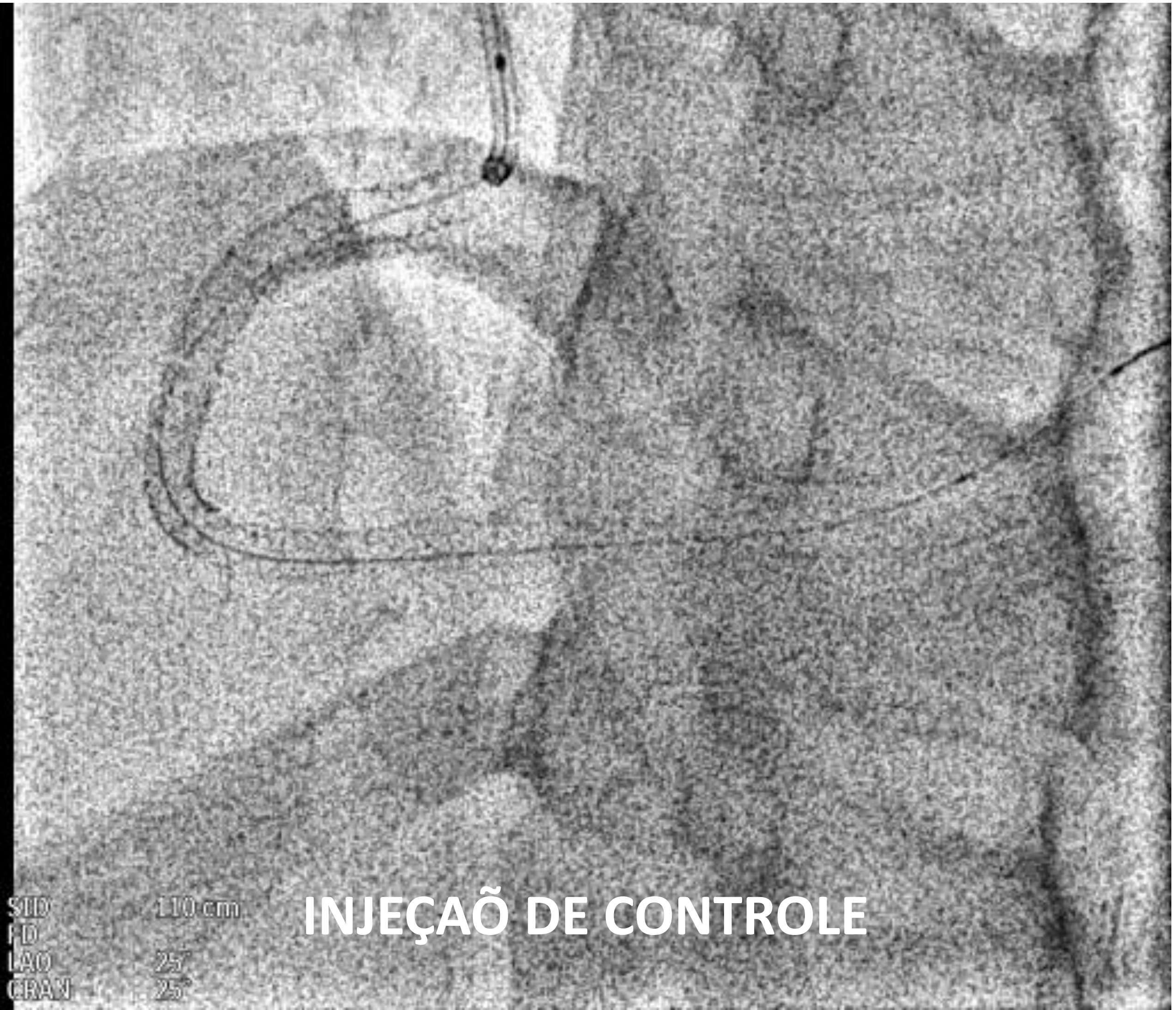


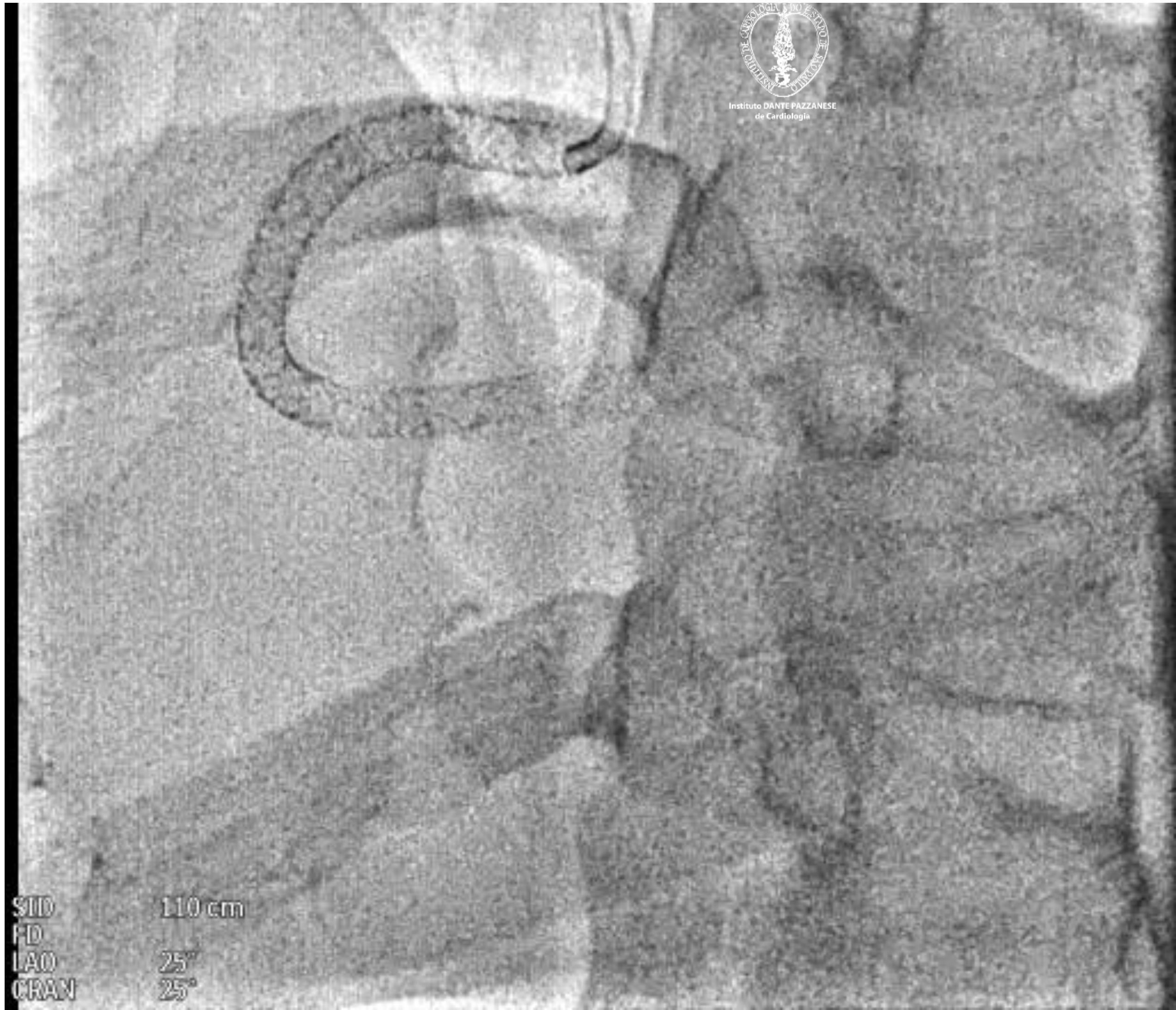
Balloon Postdilatation





Control Angios





Jul/2022

Clinical presentation

- **Angina CCS III**

Medication

AAS 100mg/dia;

Clopidogrel 75 mg/dia;

Ezetimibe 10 mg/dia;

Atorvastatin 80 mg/dia;

Anlodipin 5mg/dia;

Enalapril 10 mg 2x/dia;

Carvedilol 25 mg 2x/dia;

Lab

Jul/23

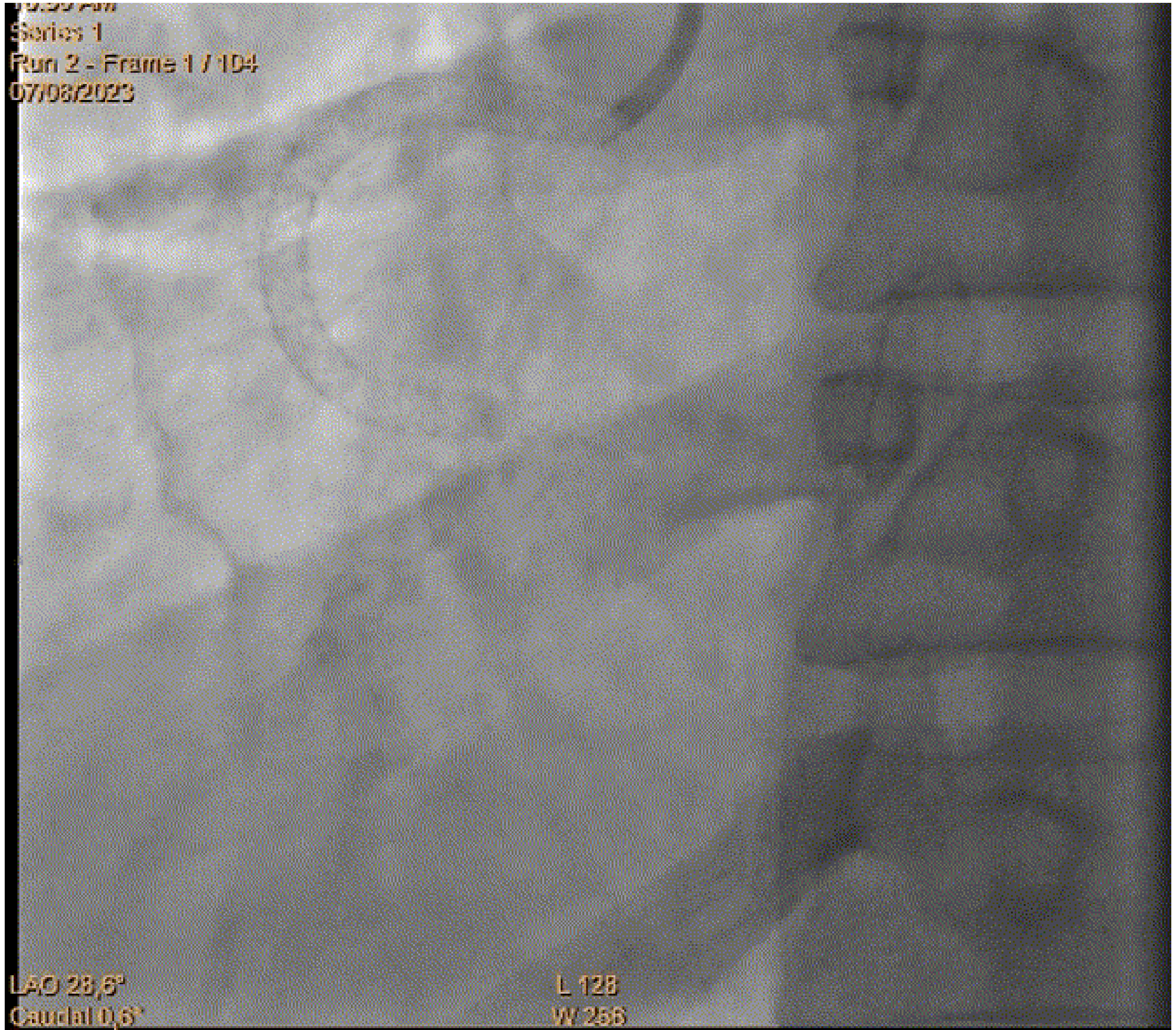
Hb: 14 g/dL; Ht: 41,1%;

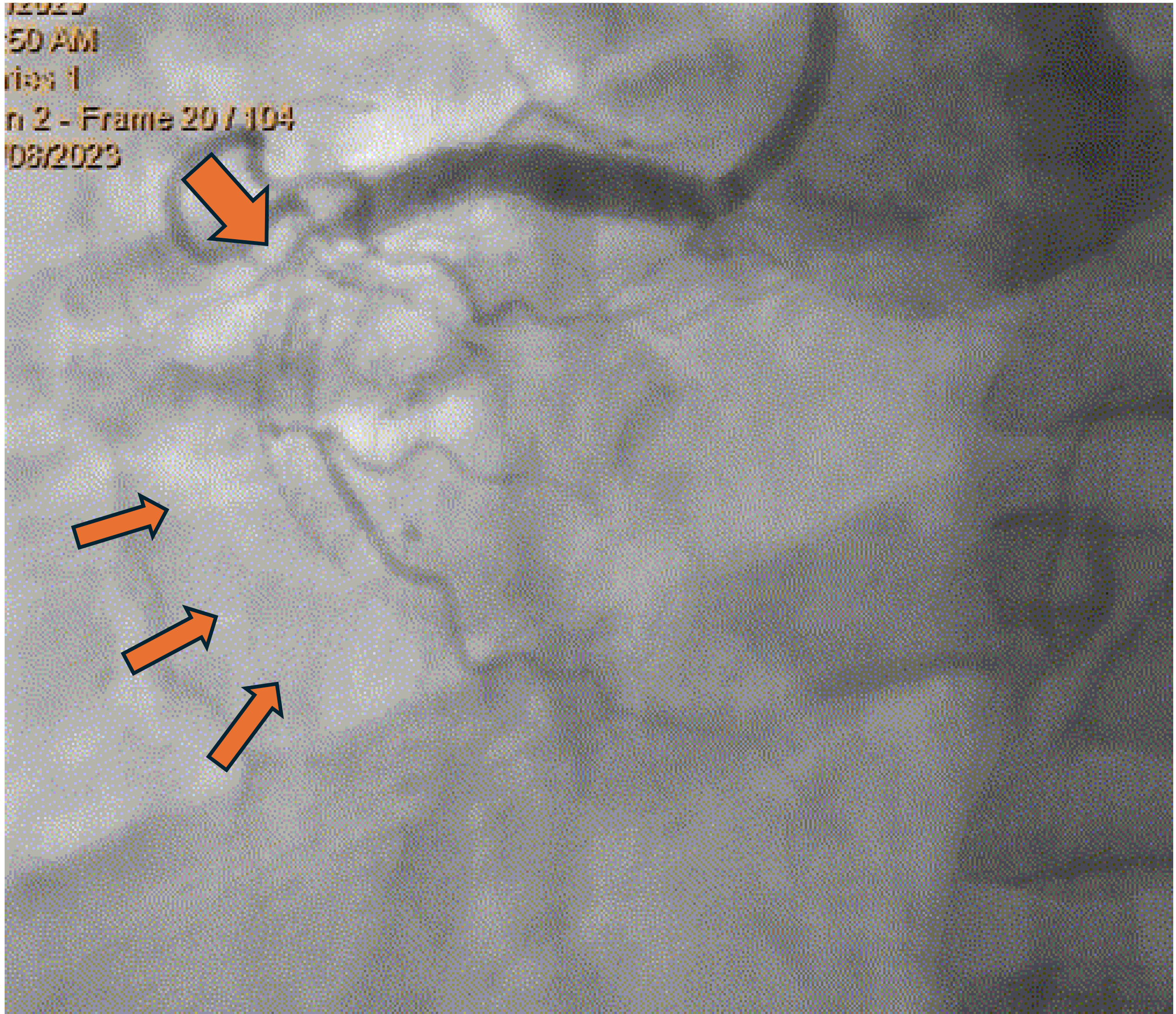
Platelets: 186.000

Serum creatinine = 0,9 mg/dl

CC: 104 mL/min/1.73m^2

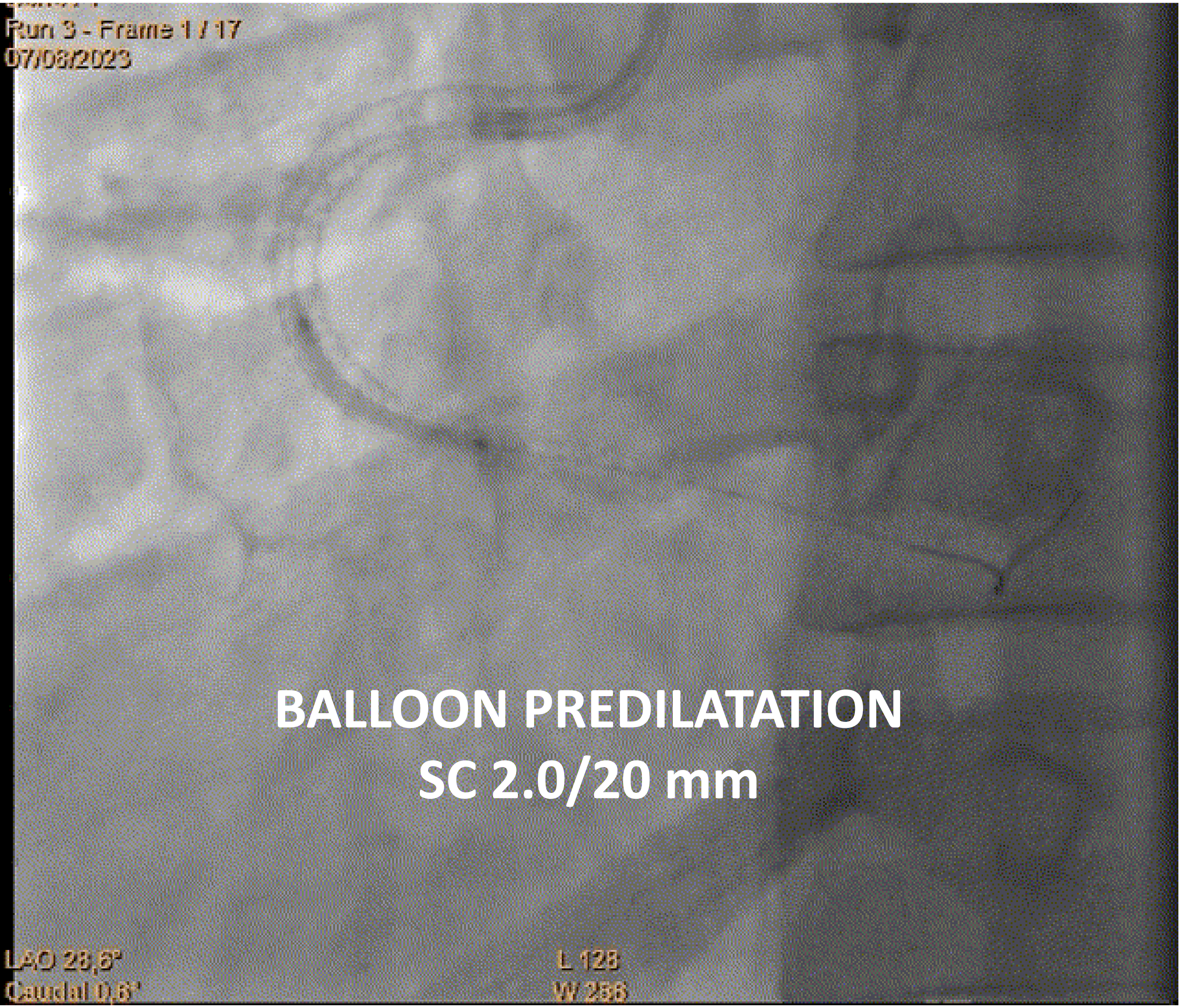
RCA re-Occlusive ISR – Aug/2023

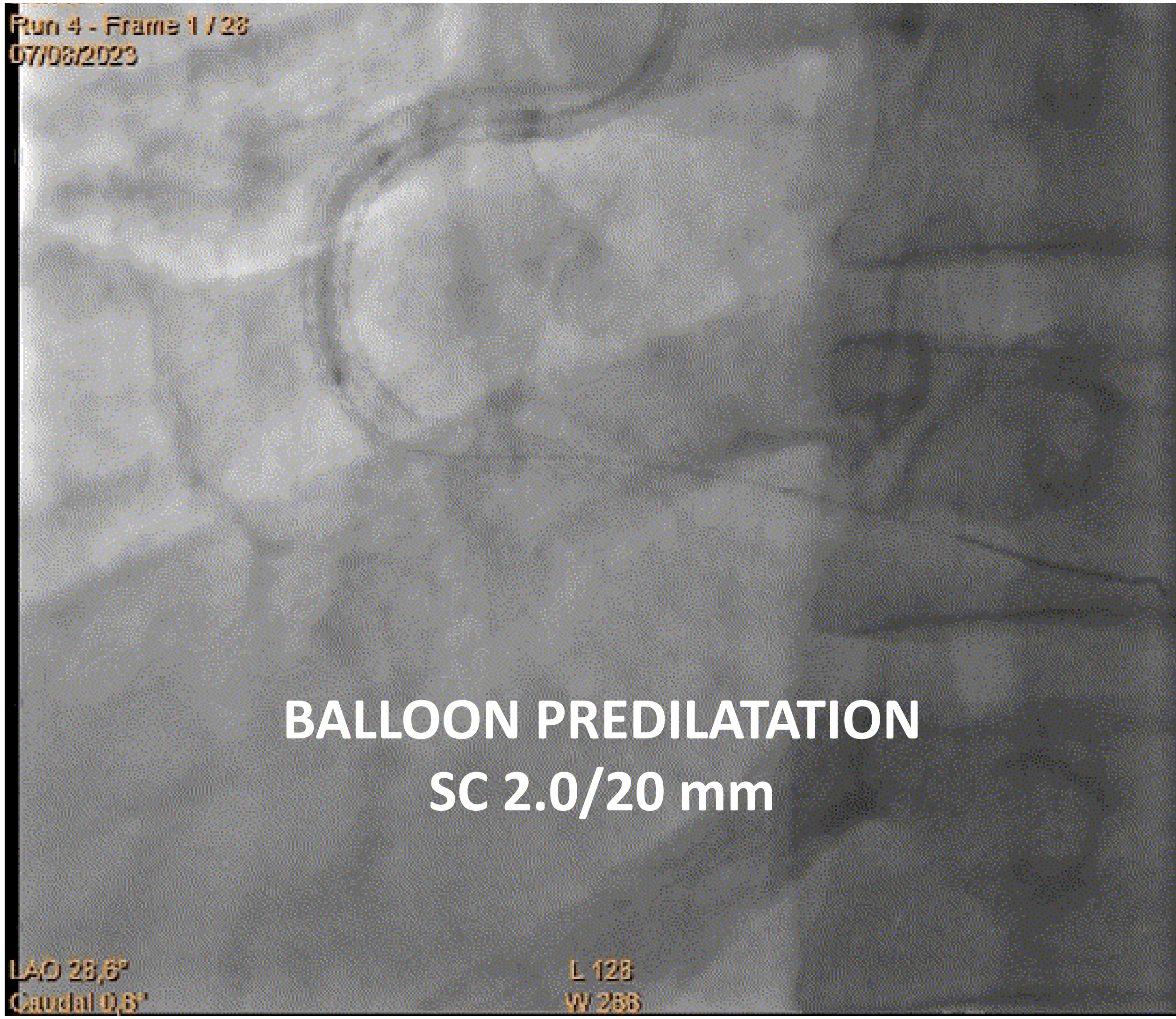




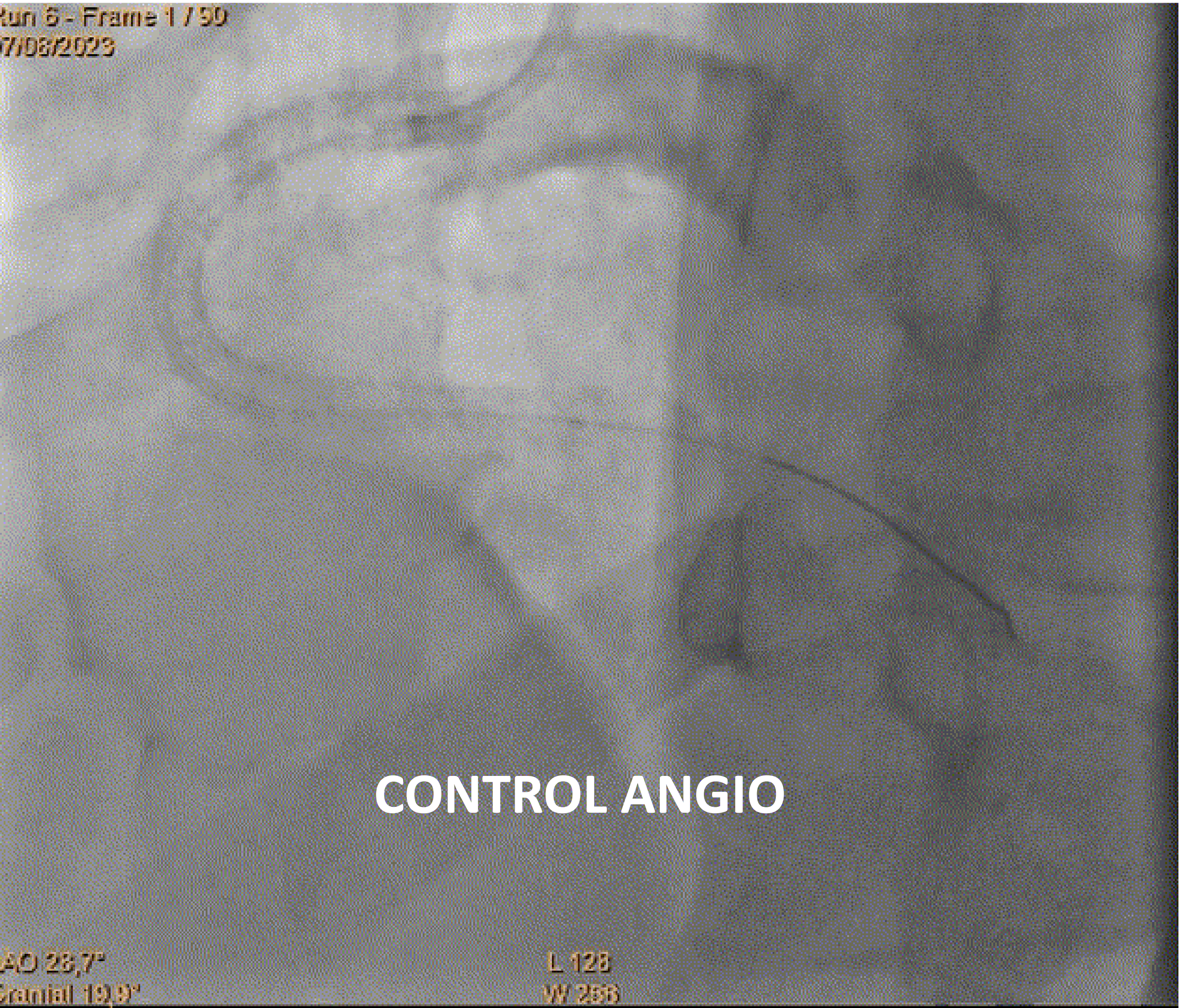
HOW TO APPROACH?

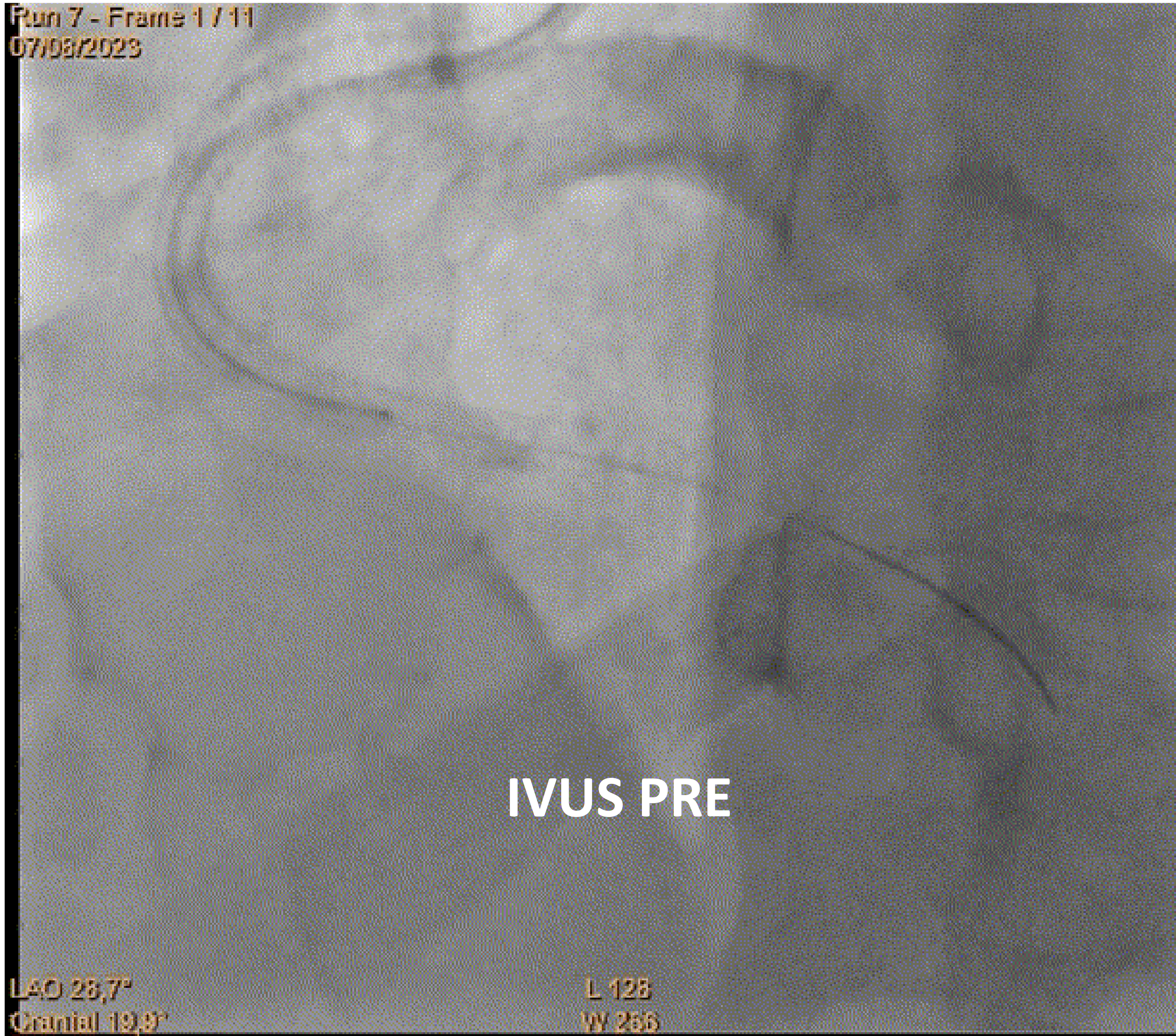
VESSEL RECANALIZATION



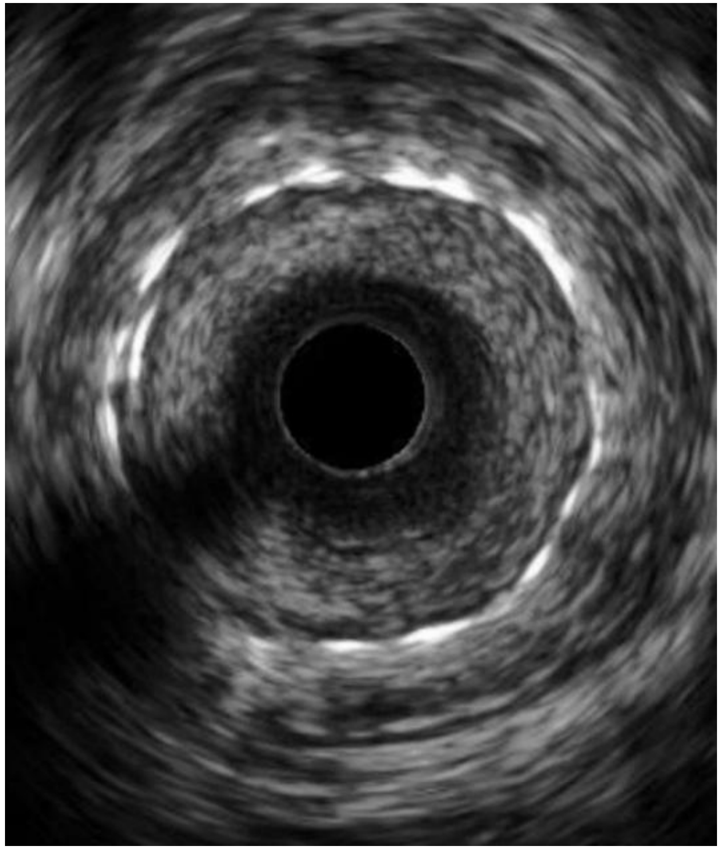


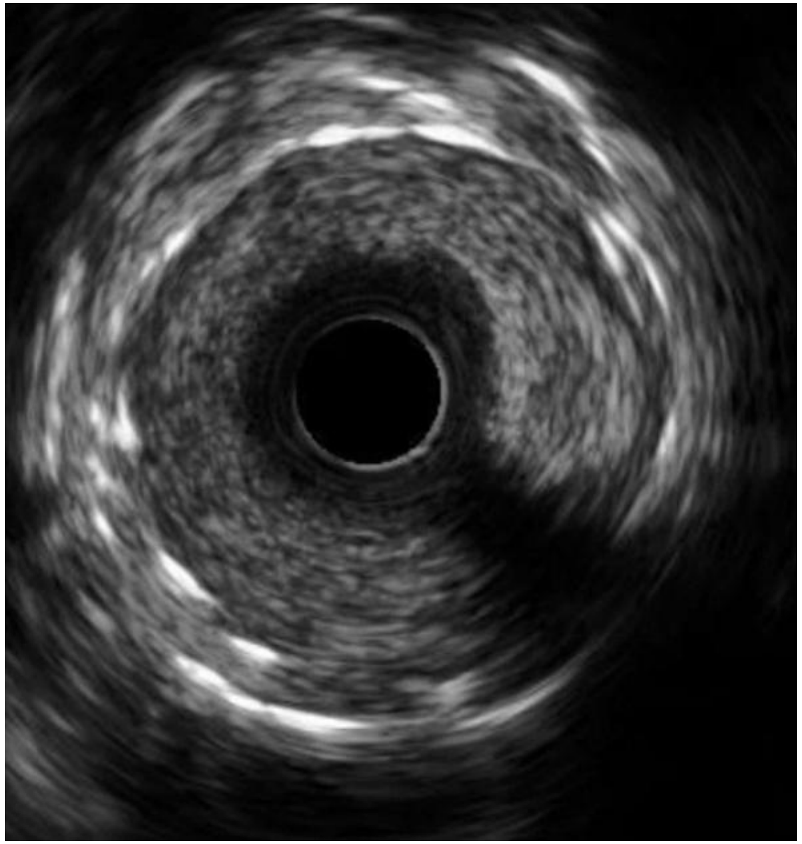
CONTROL ANGIO

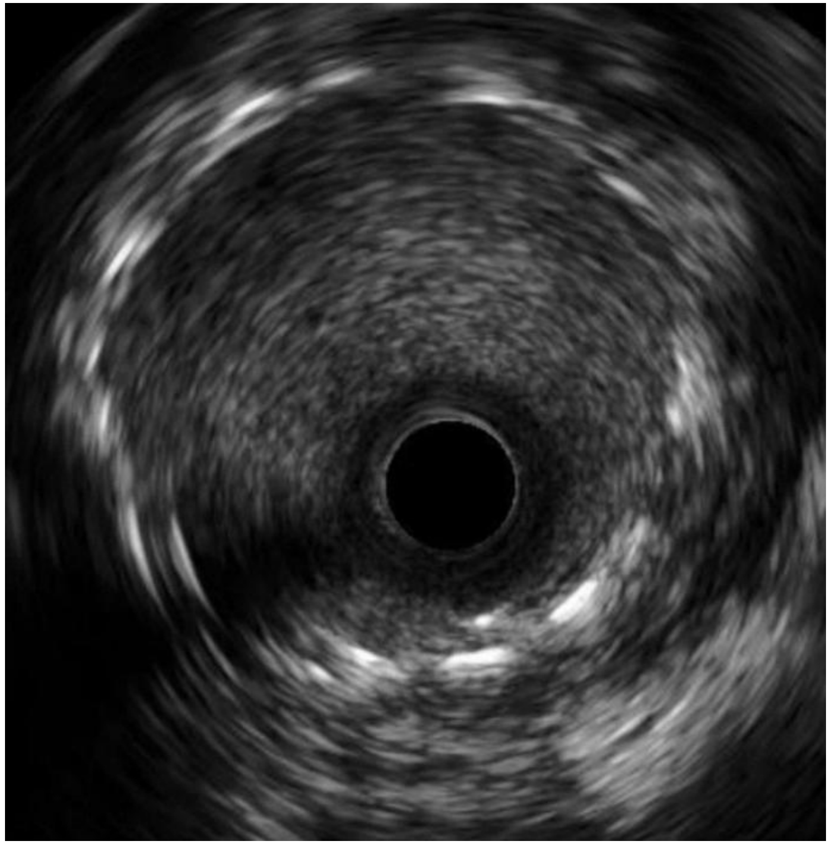




IVUS Analysis





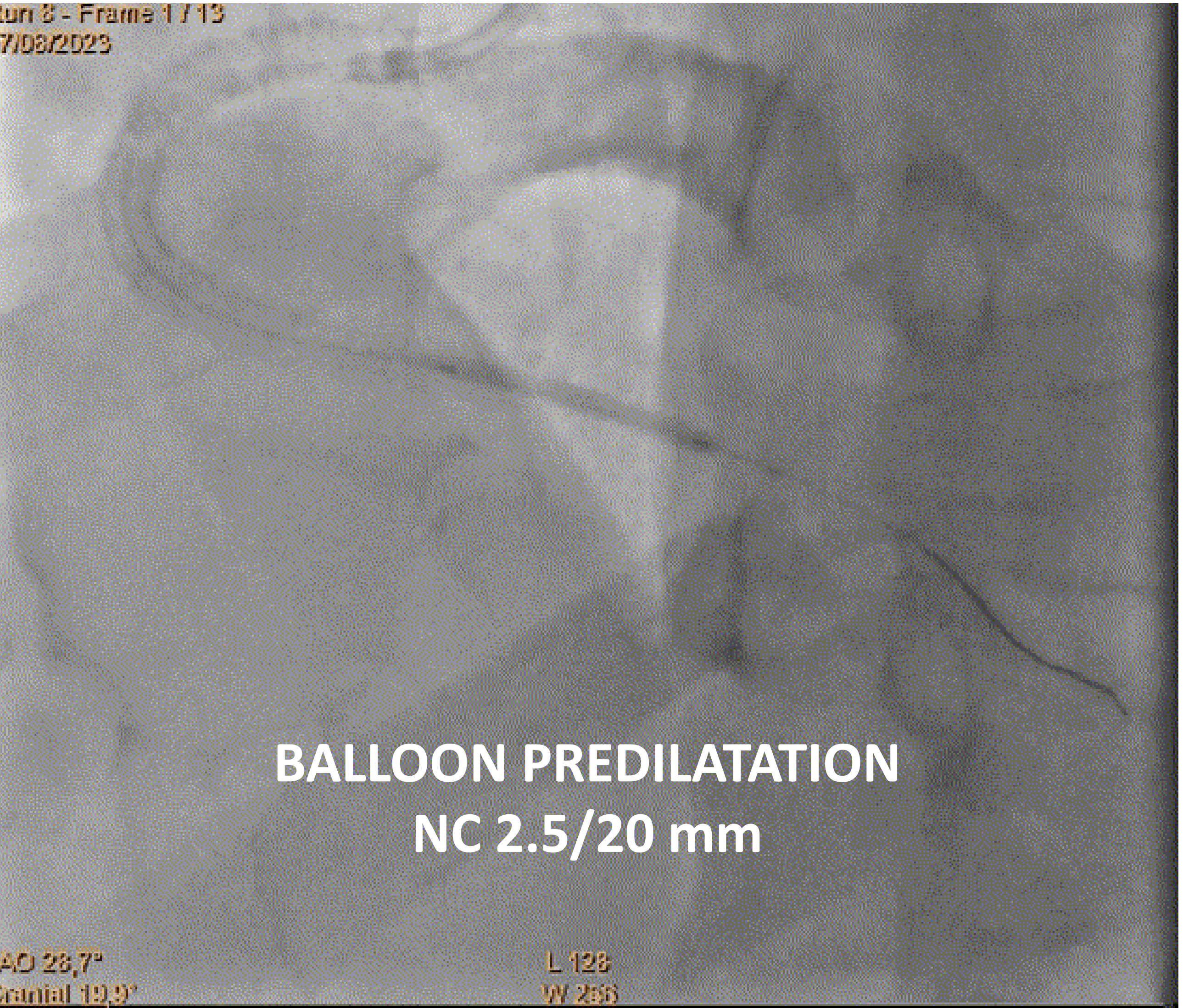


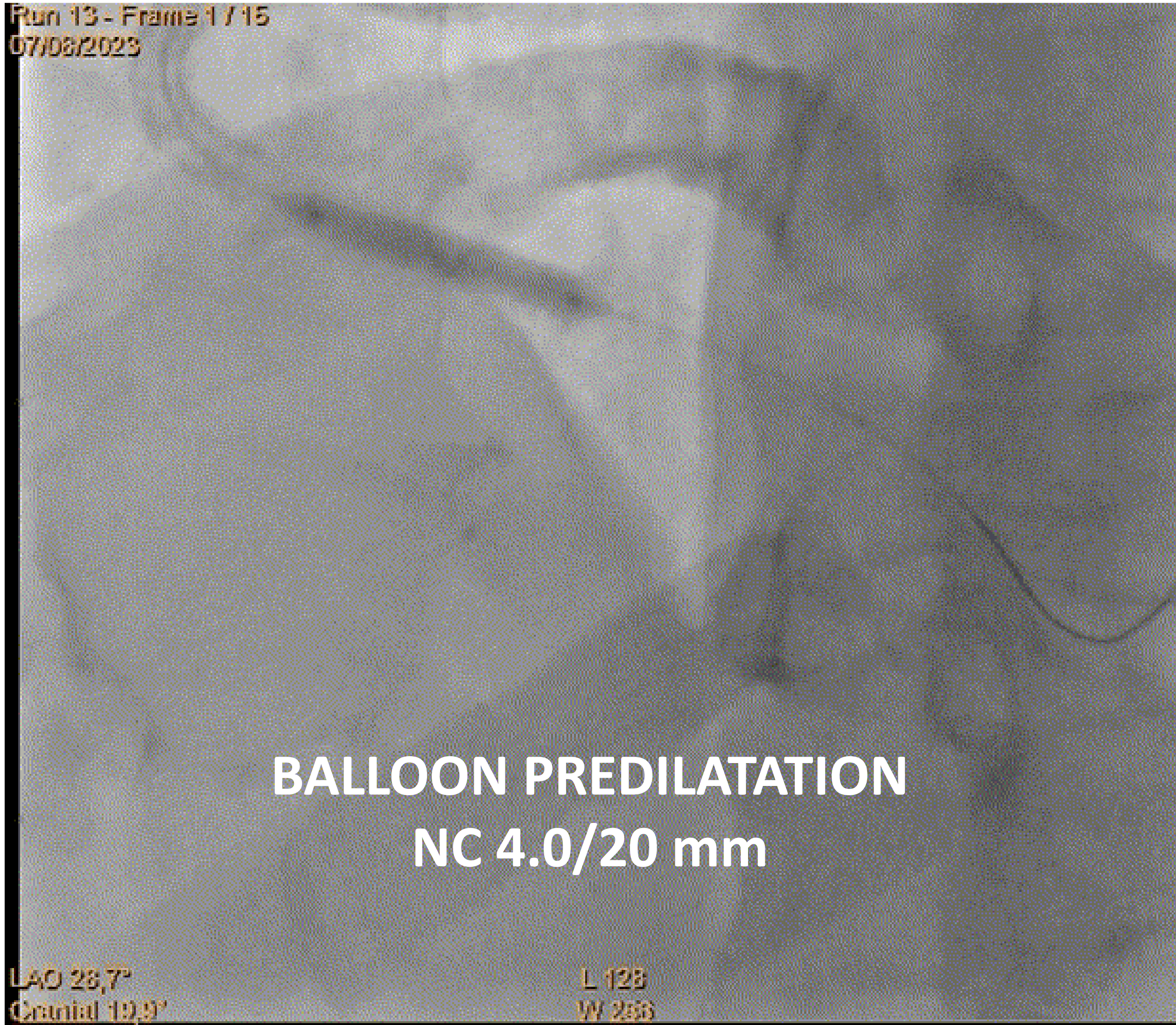
Distal stent

Mid stent

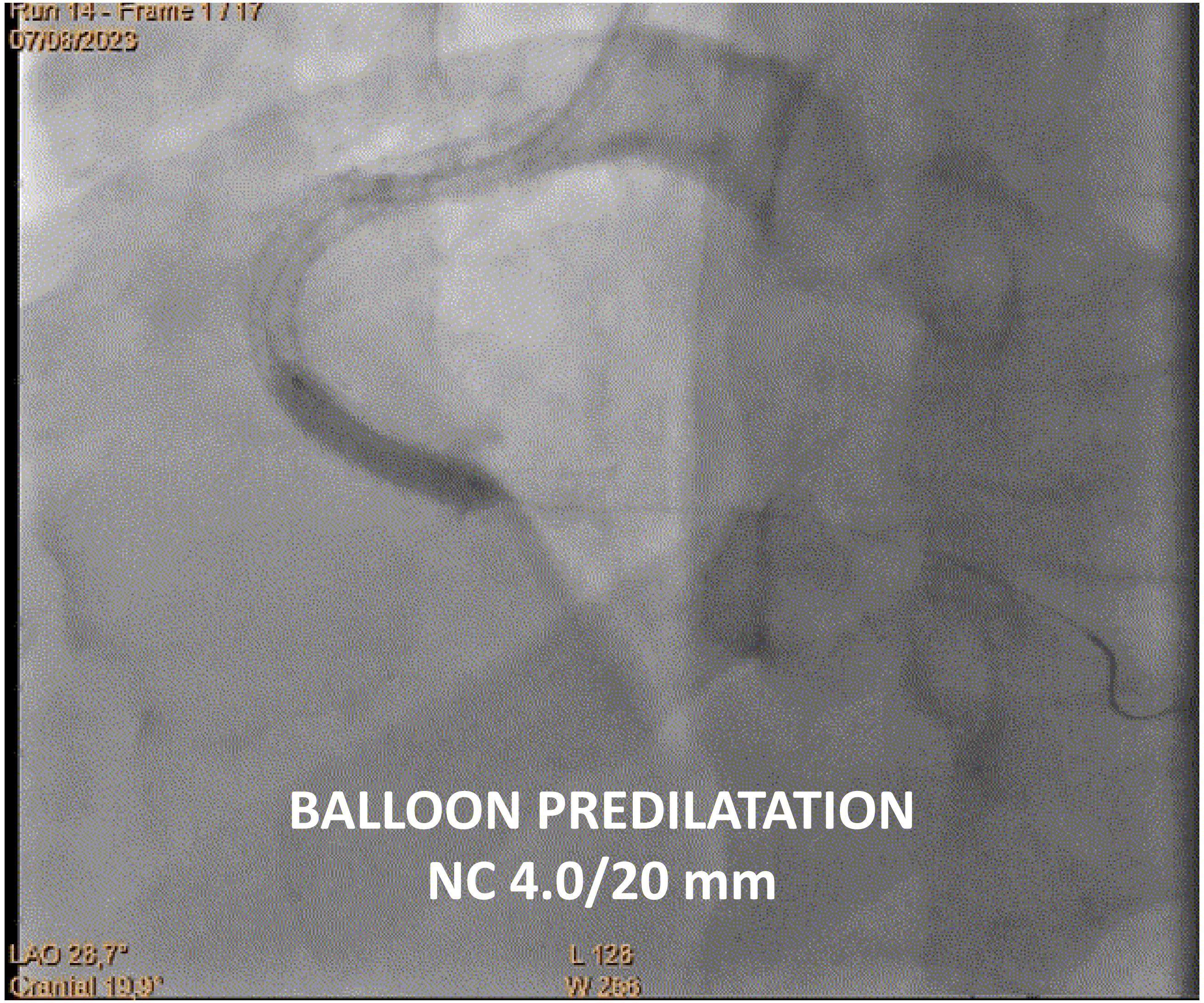
Proximal stent

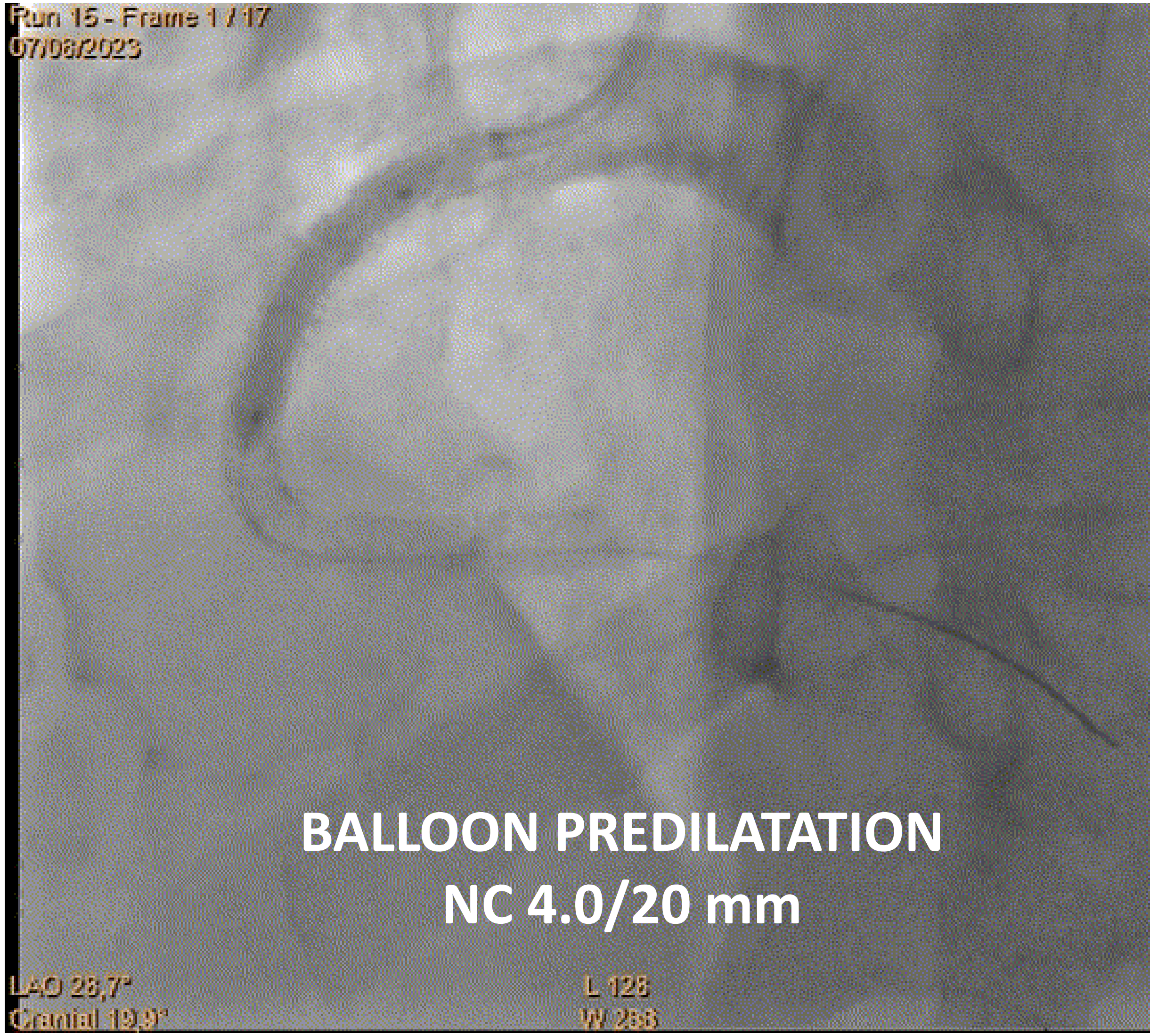
PCI


BALLOON PREDILATATION
NC 2.5/20 mm

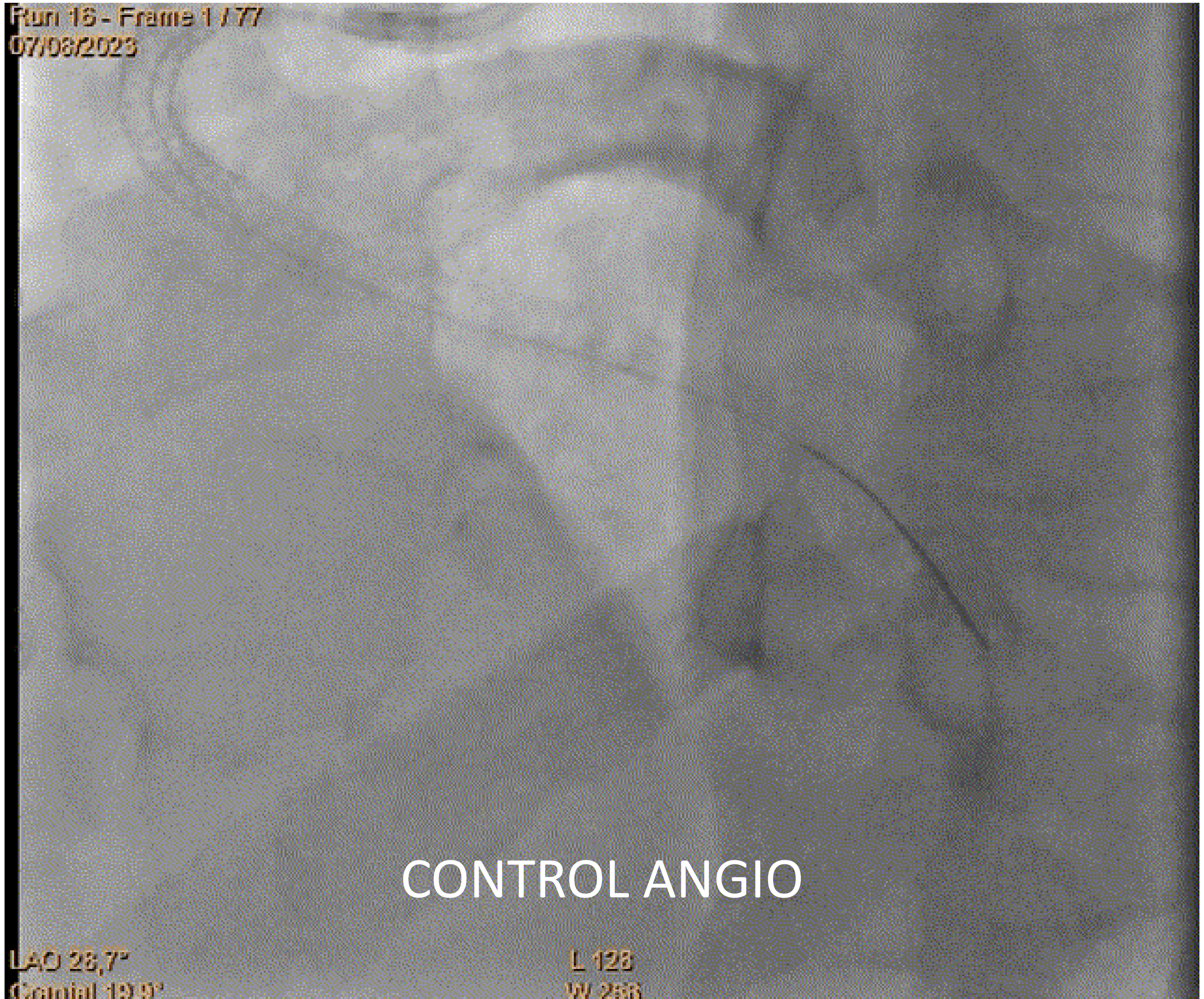

BALLOON PREDILATATION
NC 4.0/20 mm

PCI

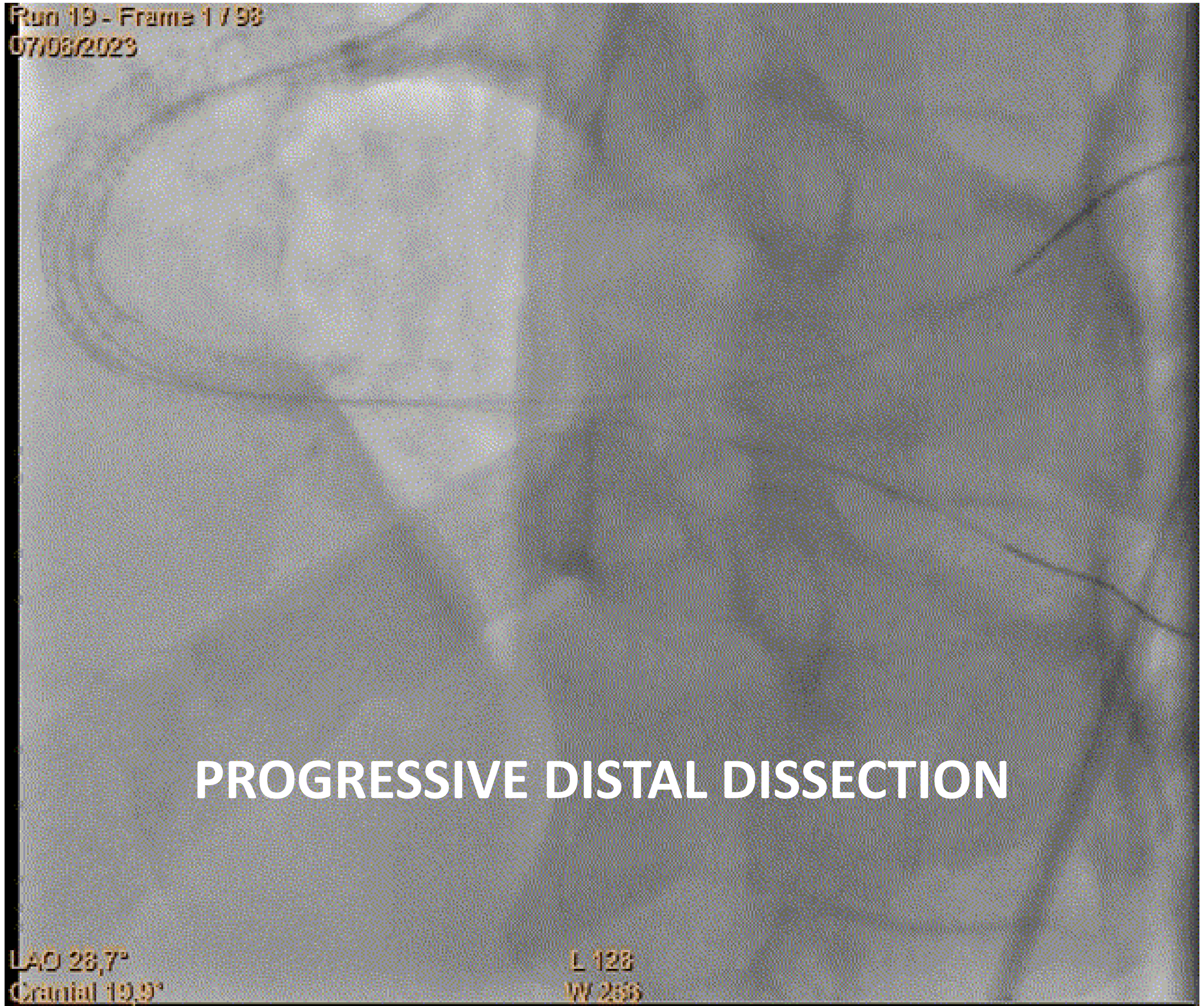

Run 14 - Frame 1 / 17
07/08/2023
BALLOON PREDILATATION
NC 4.0/20 mm
LAO 28,7°
Cranial 19,9°
L 128
W 256


Run 15 - Frame 1 / 17
07/08/2023
BALLOON PREDILATATION
NC 4.0/20 mm
LAO 28,7°
Cranial 19,9°
L 128
W 256

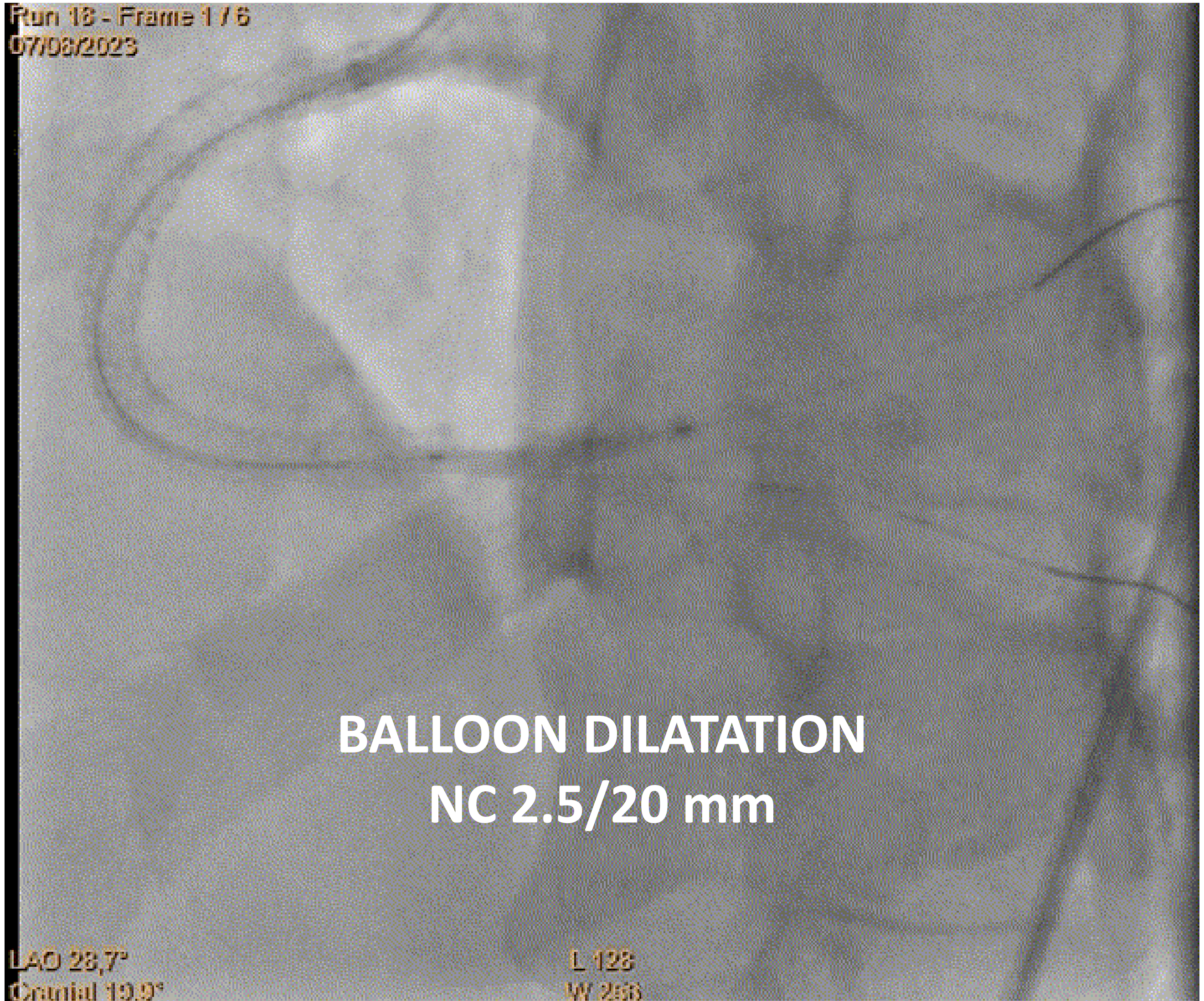
CONTROL ANGIO



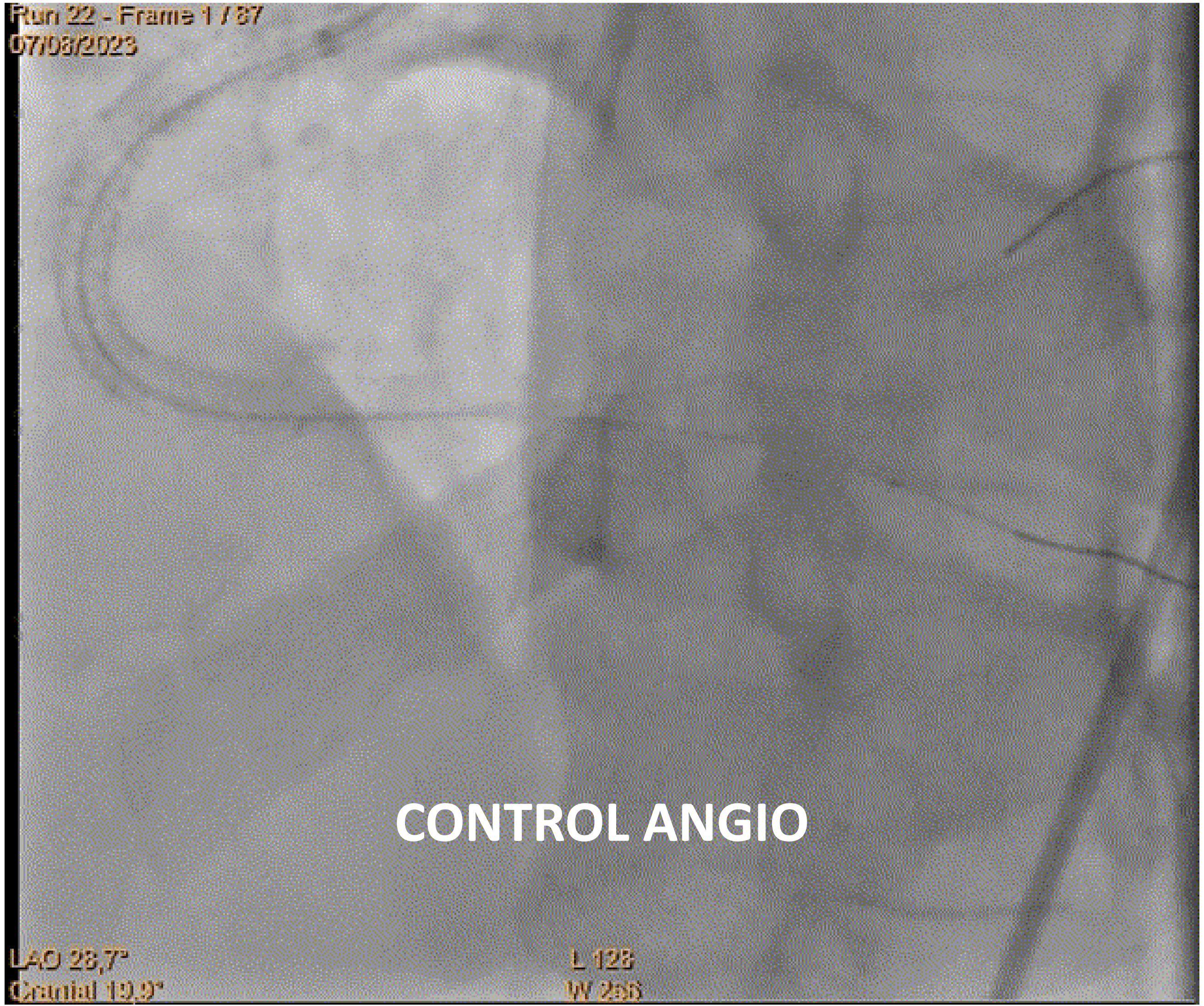
PLSA OCCLUSION



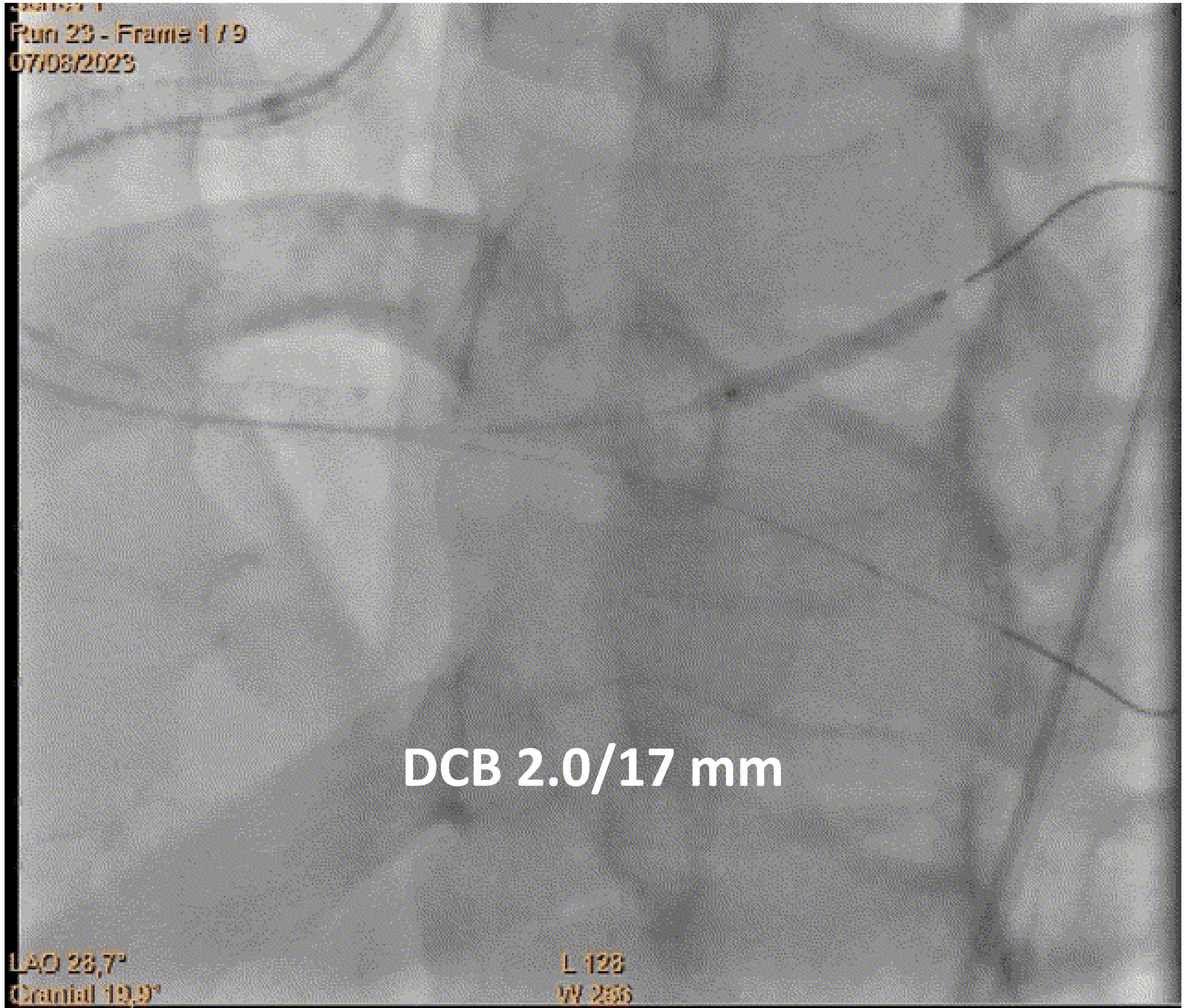
LONG-DURATION BALLOON DILATATION

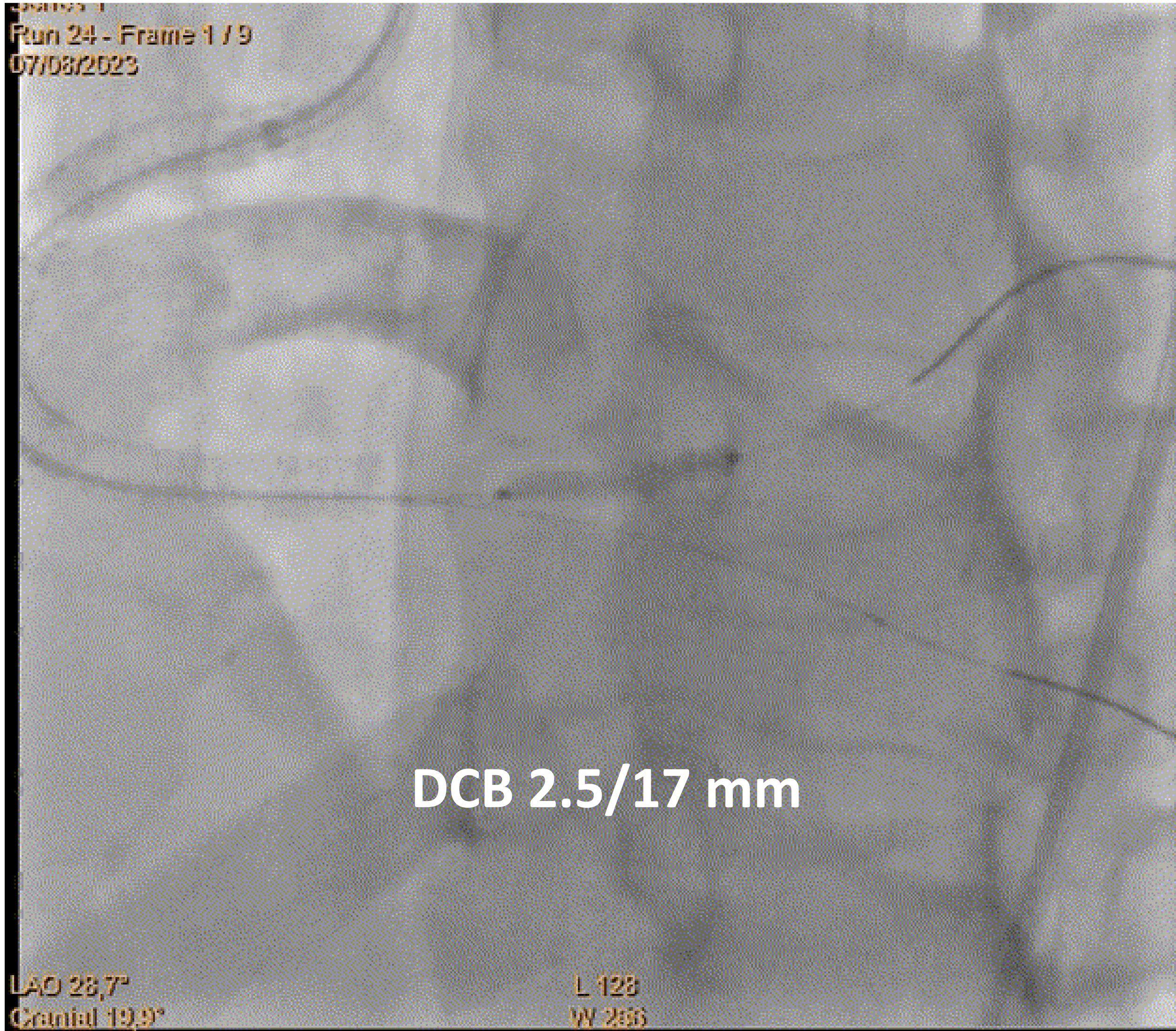


CONTROL ANGIO

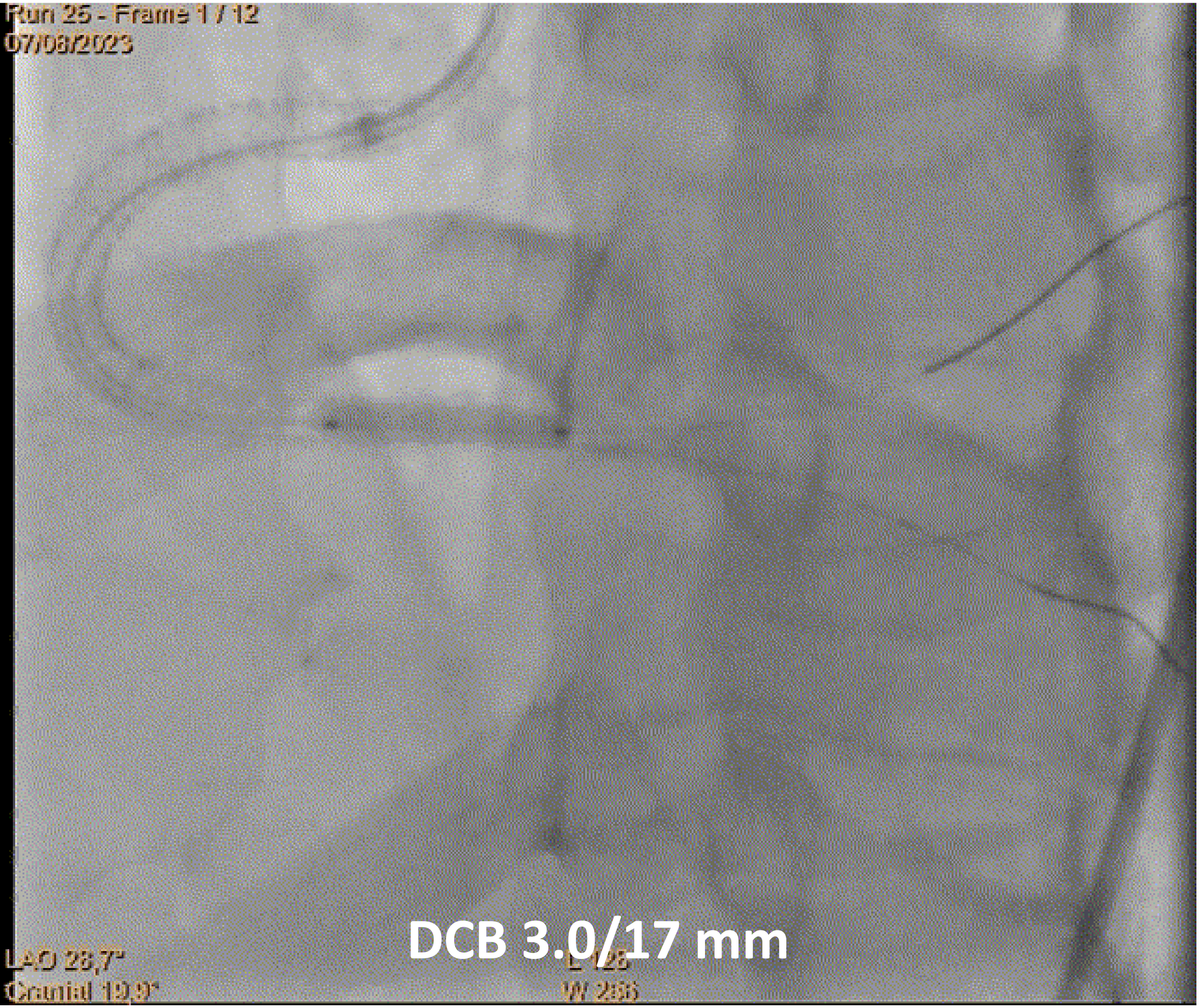


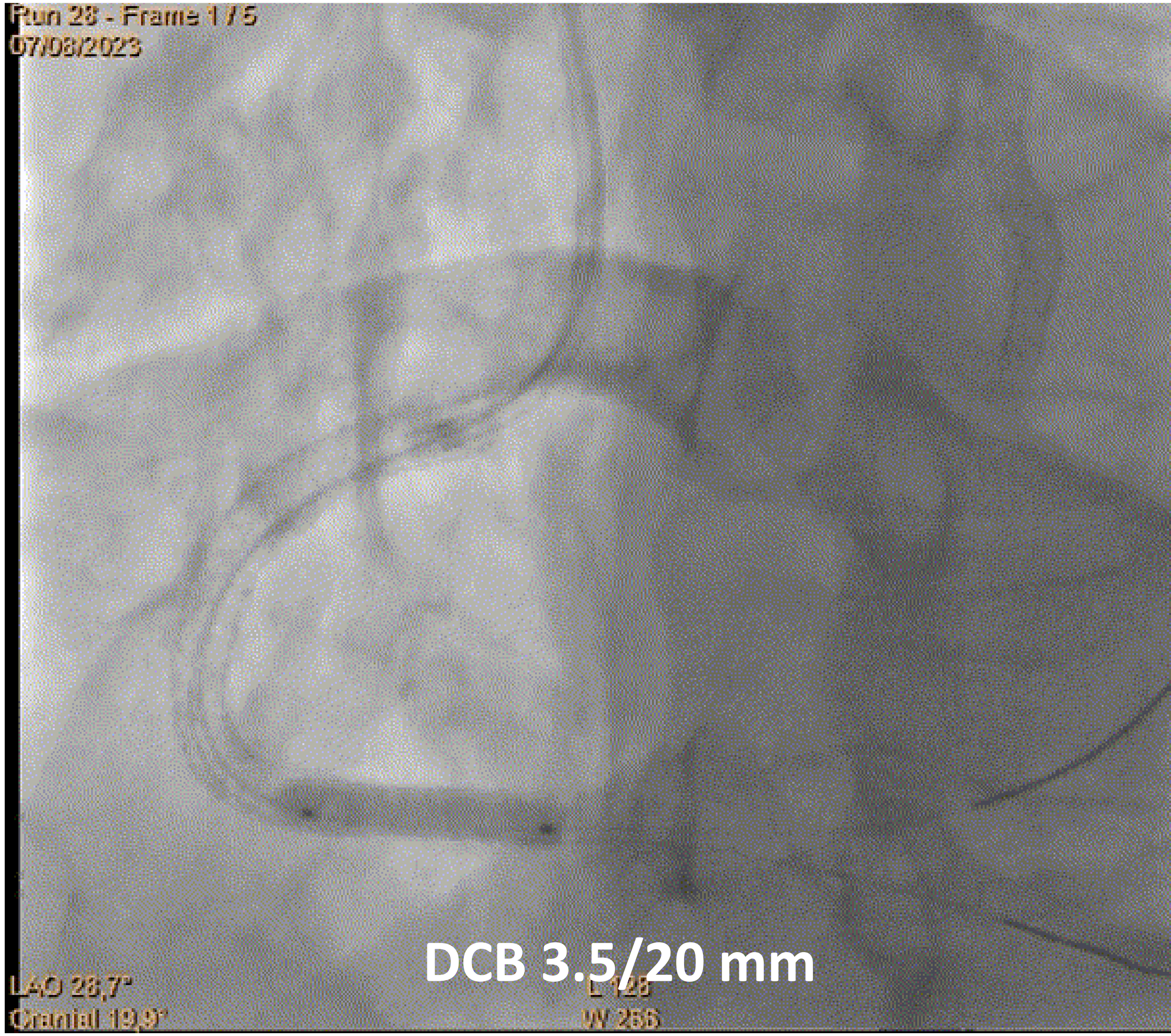
Drug-Coated Balloon INFLATIONS



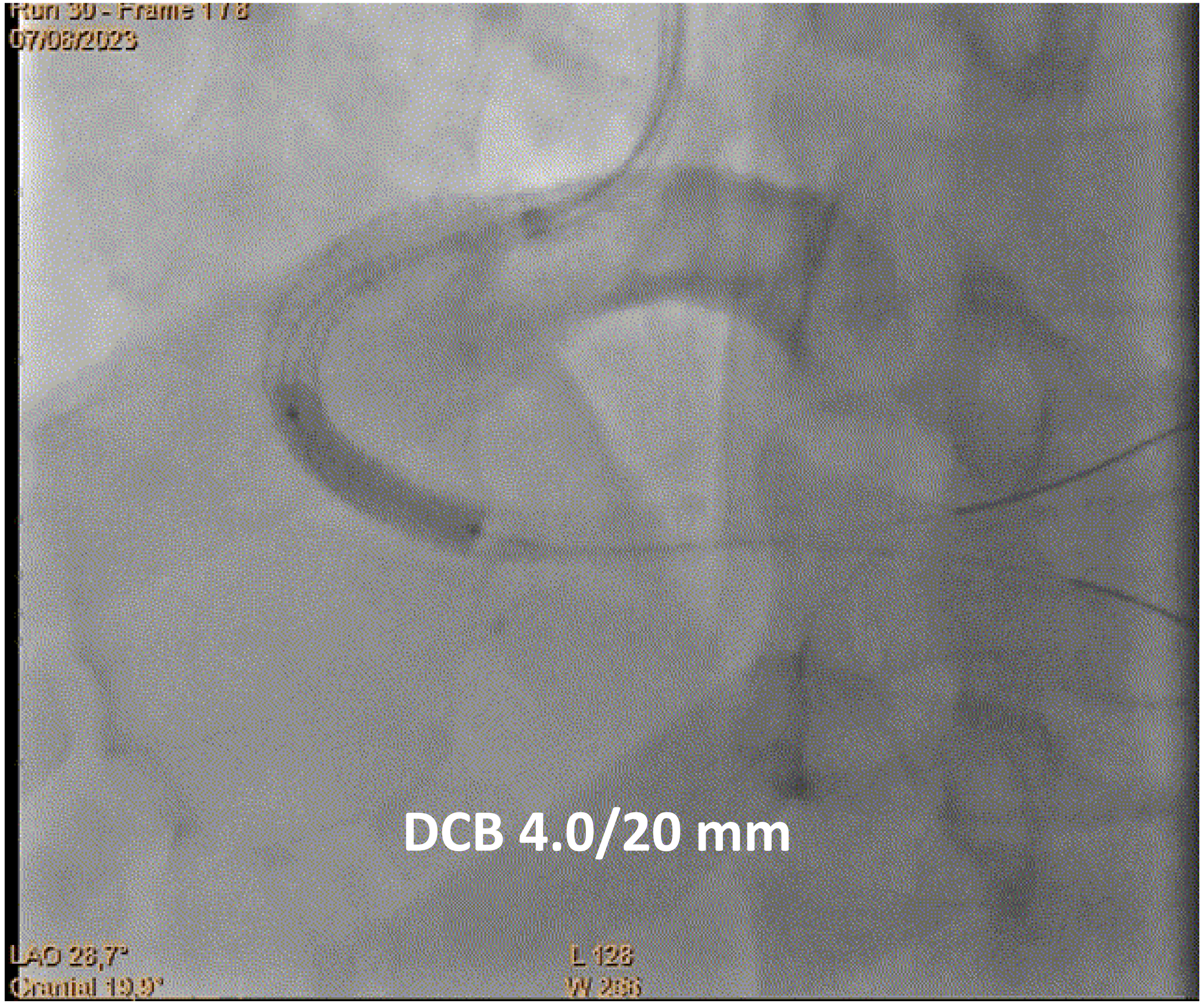


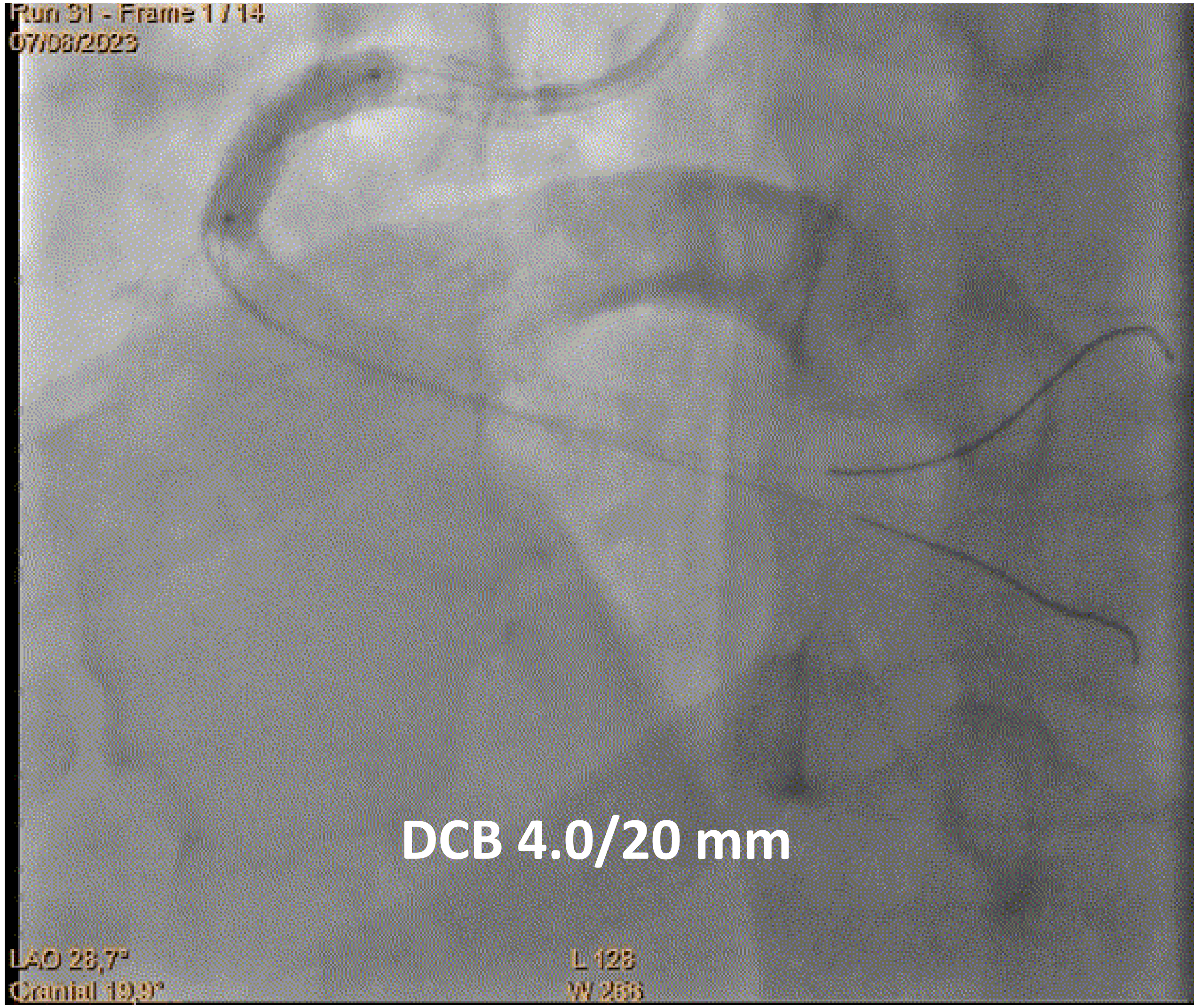
DCB INFLATIONS



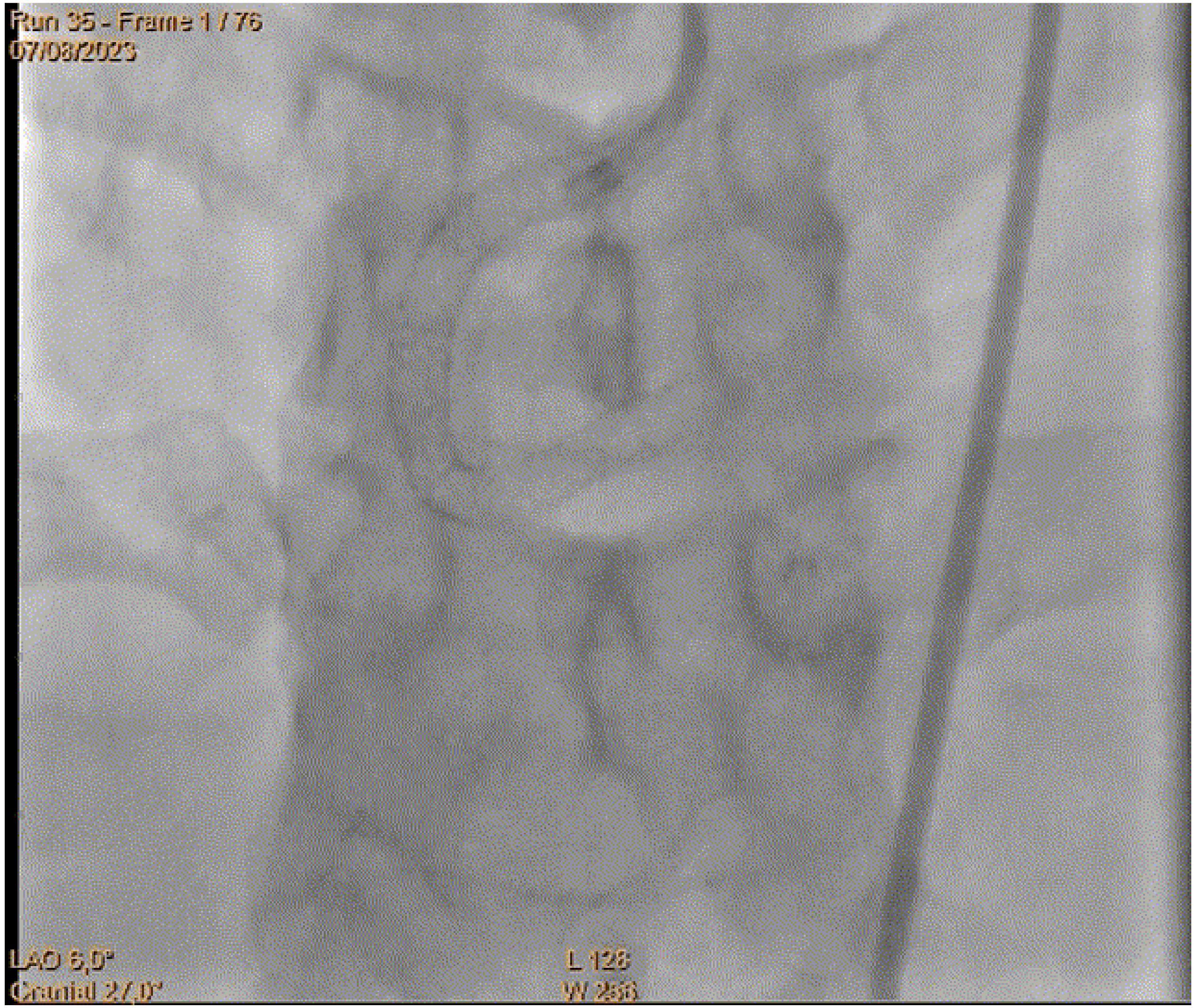


DCB INFLATIONS





CONTROL ANGIOS



CLINICAL OUTCOME

- No in-hospital events
- Discharge in the next day
- Asymptomatic since
- Intense physical exercise practice
- MIBI = absence of ischemia

Management of ISR

- Definition and types of recurrences
- Clinical impact in contemporaneous daily practice
- Identifying mechanisms of (stent) failure
- Role of intravascular imaging modalities
- Treatment alternatives
- Optimal (preventive) technique
- **Current recommendations**

How to Manage ISR?

- Identify mechanism of failure – intravascular imaging highly recommended!
- Tailored approach according to mechanism
- Mechanistic causes must be fixed before implanting new DES or applying DCB
- Biological failure may be addressed with different drug class
- DCB may be an attractive alternative in selected cases to avoid excessive metal scaffolding in unfavorable conditions
- Apply preventive mindset at index PCI to optimize technique and stent implant!

Recent Imaging Evidence

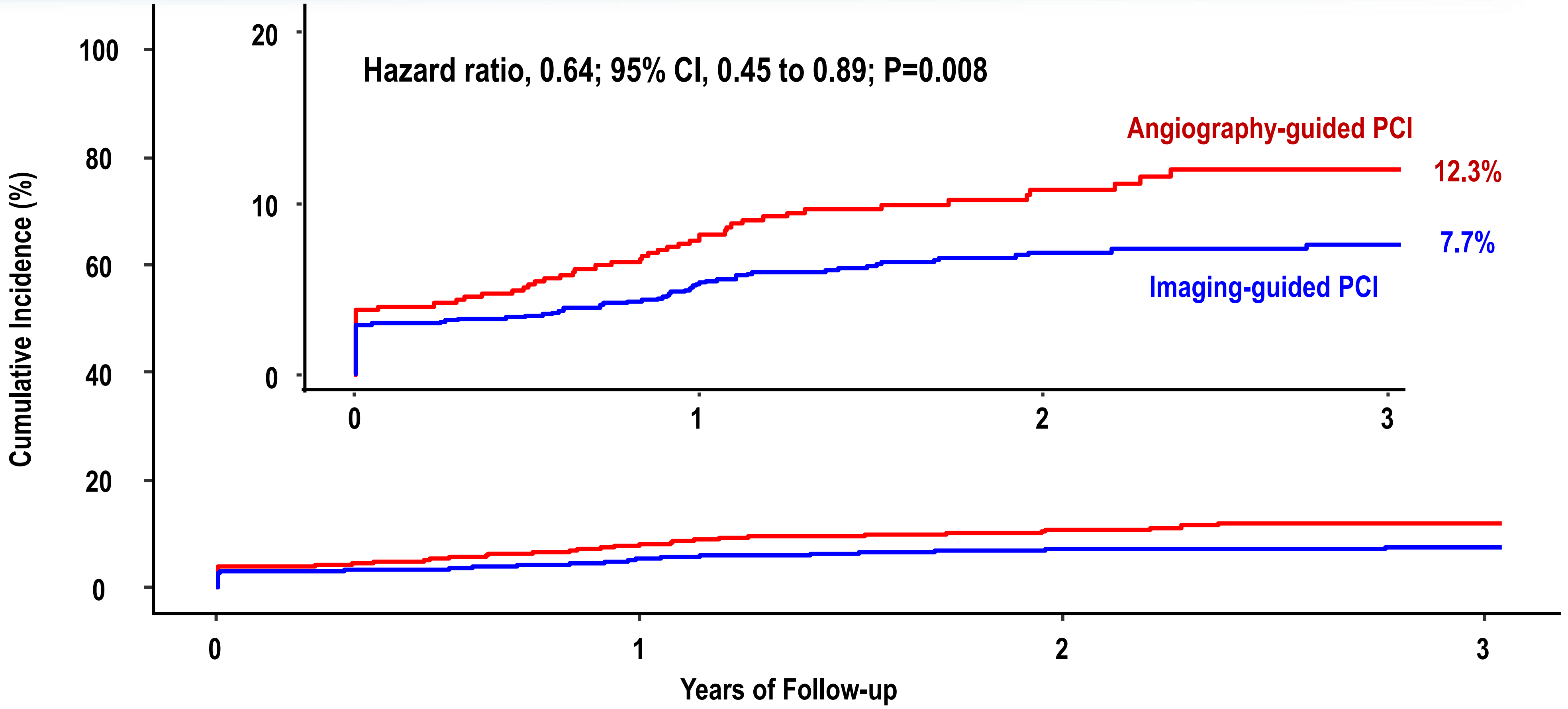
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Intravascular Imaging–Guided or Angiography-Guided Complex PCI

J.M. Lee, K.H. Choi, Y.B. Song, J.-Y. Lee, S.-J. Lee, S.Y. Lee, S.M. Kim, K.H. Yun, J.Y. Cho, C.J. Kim, H.-S. Ahn, C.-W. Nam, H.-J. Yoon, Y.H. Park, W.S. Lee, J.-O. Jeong, P.S. Song, J.-H. Doh, S.-H. Jo, C.-H. Yoon, M.G. Kang, J.-S. Koh, K.Y. Lee, Y.-H. Lim, Y.-H. Cho, J.-M. Cho, W.J. Jang, K.-J. Chun, D. Hong, T.K. Park, J.H. Yang, S.-H. Choi, H.-C. Gwon, and J.-Y. Hahn, for the RENOVATE-COMPLEX-PCI Investigators*

Primary End Point: TVF



Number at risk

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

ACC.24

Intravascular Ultrasound-guided *vs* Angiography-guided PCI in Acute Coronary Syndromes:

The randomized IVUS-ACS trial

Shao-Liang Chen, MD

Nanjing First Hospital, Nanjing Medical University

on behalf of Gregg W. Stone MD and the IVUS-ACS Investigators

Twitter: @Shao_Liang Chen

ClinicalTrials.gov number: NCT03971500

AMERICAN COLLEGE of CARDIOLOGY

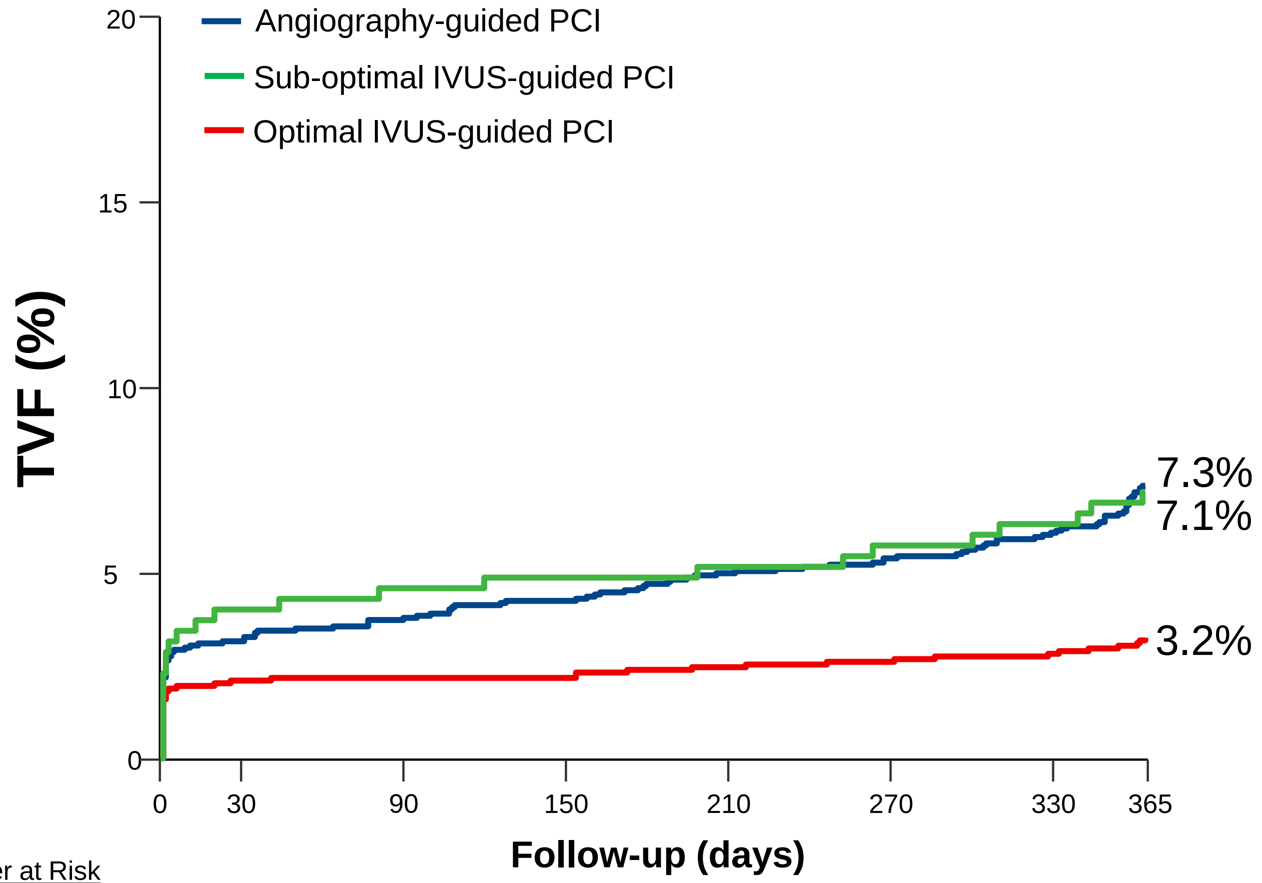
TVF according to pre-specified optimal IVUS criteria

Target criteria for optimal IVUS

Non-left main lesions:
(1) MSA >5.0 mm² or >90% of the MLA at the distal reference segment; and (2) plaque burden <55% within 5 mm proximal or distal to the stent edge; and (3) absence of medial dissection >3 mm in length.

Left main lesions:
MSA >10 mm² for the left main segment, >7 mm² for the ostial/proximal LAD and >6 mm² for the ostial/proximal LCX (if stented).

In the IVUS group, optimal post-PCI IVUS criteria were met in 1392 of 1743 (79.9%) patients



Number at Risk								
Angiography-guided PCI	1752	1697	1687	1677	1664	1655	1642	1625
Optimal IVUS-guided PCI	1392	1363	1361	1361	1357	1353	1350	1347
Sub=optimal IVUS-guided PCI	351	336	334	333	1330	328	326	324

Conclusions

- ISR is still present in daily practice of contemporaneous PCI (up to 10%)
- Rate of new recurrences after PCI in DES-ISR is still relatively high and still increases overtime
- Mechanistic factors are often present in PCI failure
- Optimal treatment is related to identification and correction of mechanisms of failure
- Intravascular Imaging may help optimize PCI outcomes and avoid re-interventions if optimal criteria is achieved
- The impact of new DCB technologies is still to be determined