"Natural Coronary arteries gradually narrow (taper)": Biomime Morph, the first tapered DES

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Conflicts of Interest

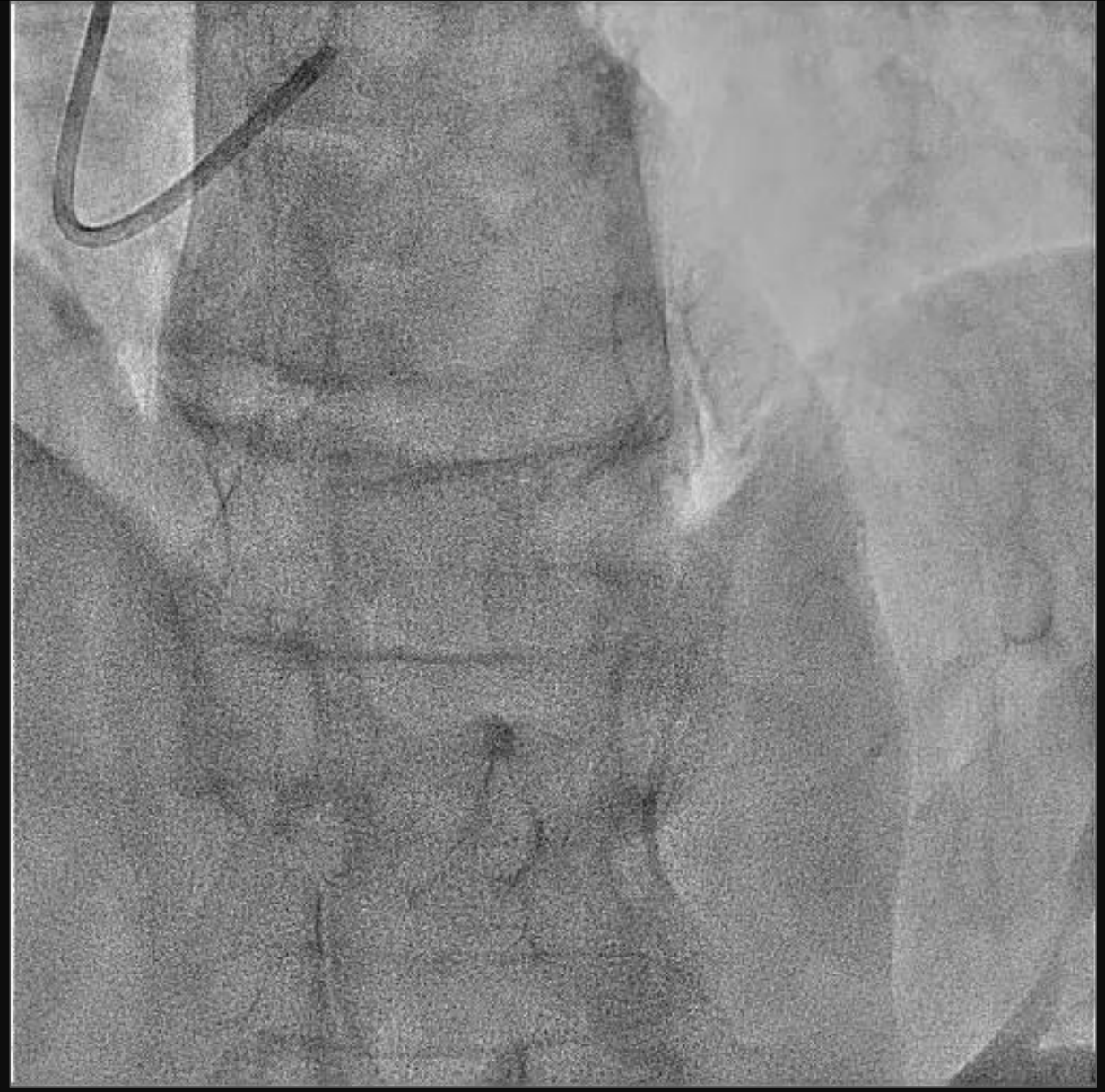
Personal Honoraria:	Abbott, Boston Sci, Medtronic, Edwards, Cardiolink, Cordis, Palex, Meril, Teleflex
Department Fees:	Medtronic, Abbott, Terumo, Boston Scientific, Palex.
Proctor:	Izasa, Biosensors, Meril

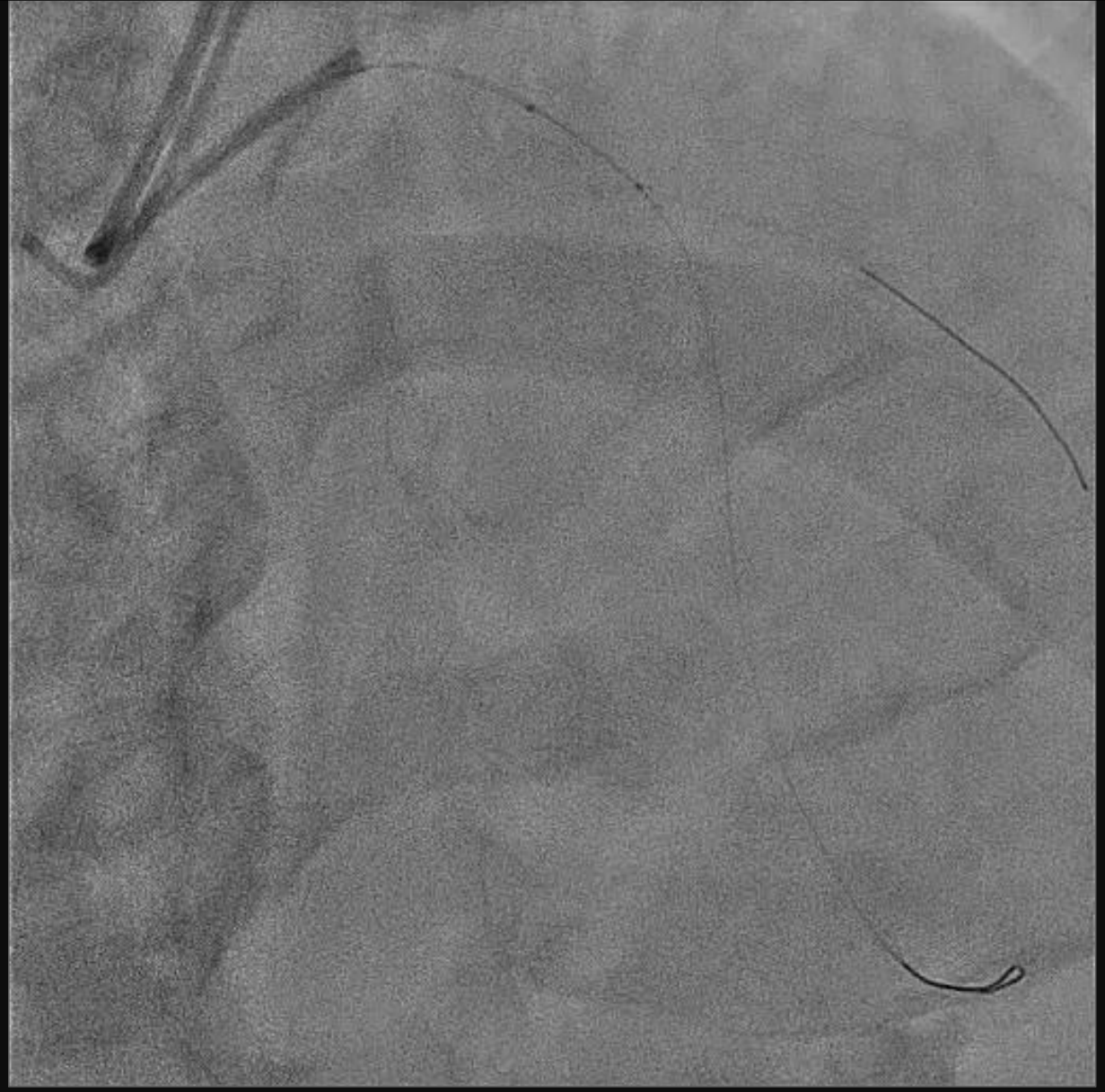
Management Concepts

Includes *Flip-Overs®* *2-sided circle 3/4" magnets* in red-green and yellow-medium blue to fit date spaces

SQDC applied to PCI procedures

S	SAFETY	Avoid Complications during PCI	• Radial Access • Be careful with the movements • Select appropriate material • Always be sure where is my guide-wire
Q	QUALITY	Check you Results	• Register your Success Rate • Register your Complications • Follow your patients
D	DELIVERY	Efficiency	• Early discharge • Send the patient to referral centres
C	COSTS	Decrease Costs	• Use cost-effective materials • Avoid bad material: requires increase in number of units • Long DES





Ultrathin Struts DES

	Orsiro	CoroFlex IsarNeo	Biomime	Biomime Morph	Evermine 50	MiStent	Supraflex Cruz
							
Company	Biotronik	B. Braun	Meril	Meril	Meril	Stentys	Sahajanand Medical Technologies (SMT)
Platform material and Strut thickness (µm)	2.5 to 3 mm: 60; 3.5 to 4 mm: 80	2 to 3 mm: 55; 3.5 to 4 mm: 65	65	65	50	64	60
Crossing Profile	0.95 mm	0.79 to 0.96 mm	0.83 to 1.19 mm	0.93 to 1.03	0.83 to 1.19	n.a.	0.95 mm
Available diameters (mm)	2.25, 2.5, 2.75, 3.0, 3.5, 4.0	2.0, 2.25, 2.5, 2.75, 3.0, 3.5, 4.0	2.0, 2.25, 2.75, 3.0, 3.5, 4.0, 4.5	2.75-2.25, 3.0-2.5, 3.5-3.0	2.0, 2.25, 2.50, 2.75, 3.0, 3.5, 4.0, 4.5	n.a.	2.0, 2.25, 2.5, 2.75, 3.0, 3.5, 4.0, 4.5
Lengths available (mm)	9 to 40	9 to 38	8 to 48	30 to 60	8 to 48	n.a.	8 to 48 mm
Polymer type	Biodegradable (proBIO®)	Polymer free	Biodegradable Biocompatible	Biodegradable Biocompatible	Biodegradable Biocompatible	Biodegradable	Biodegradable
Coating distribution	Circumferential	-	Circumferential	Circumferential	Circumferential	Circumferential	Circumferential
Polymer material and thickness	3,5 µm abluminal; 7.5 µm luminal	-	2 µm	2 µm	2 µm	5 µm/ 15 µm	4-5 µm
Polymer absorption	15 months	-	60 days	60 days	60 days	3 months	9-12 months
Eluted drug	Sirolimus	Sirolimus and Probucol	Sirolimus	Sirolimus	Everolimus	Sirolimus (microcrystals)	Sirolimus
Drug dose	1.4 µg/mm²	1.2 µg/mm²	1.25 µg/mm²	1.25 µg/mm²	1.25 µg/mm²	2.4 µg/mm²	1.4 µg/mm²
Drug release	50% by 1 month 80% by 3 months	80% by 28 days 100% by 90 days	30-40 days	30-40 days	30-40 days	9 months	70% by 1 week 100% by 3-4 months

Cobalt-Chromium · PLLA · PLLA and PLGA · PLLA + PCL + PVP

Morph. Key Features

Type: Sirolimus-Eluting Tapered Coronary Stent System
Purpose: Designed for **long, diffused coronary lesions**; eliminates need for multiple overlapping stents (reduces restenosis risk).
Material: **Cobalt Chromium L605** alloy for strength and flexibility.
Strut Thickness: **Ultra-thin 65 µm** for better deliverability and vessel healing.
Design:

- **Tapered structure** to match vessel anatomy (proximal to distal diameter).
- **Hybrid cell design**: Closed cells at ends, open cells in the middle for optimal expansion and side branch access.
- **Non-linear S-links & Y-connectors** for flexibility and conformability.

Lengths & Diameters:

- Lengths: **30, 40, 50, 60 mm**
- Diameters (proximal-distal): **2.75–2.25 mm**, **3.00–2.50 mm**, **3.50–2.75 mm**, **3.50–3.00 mm**

BioMime Morph. Key Features

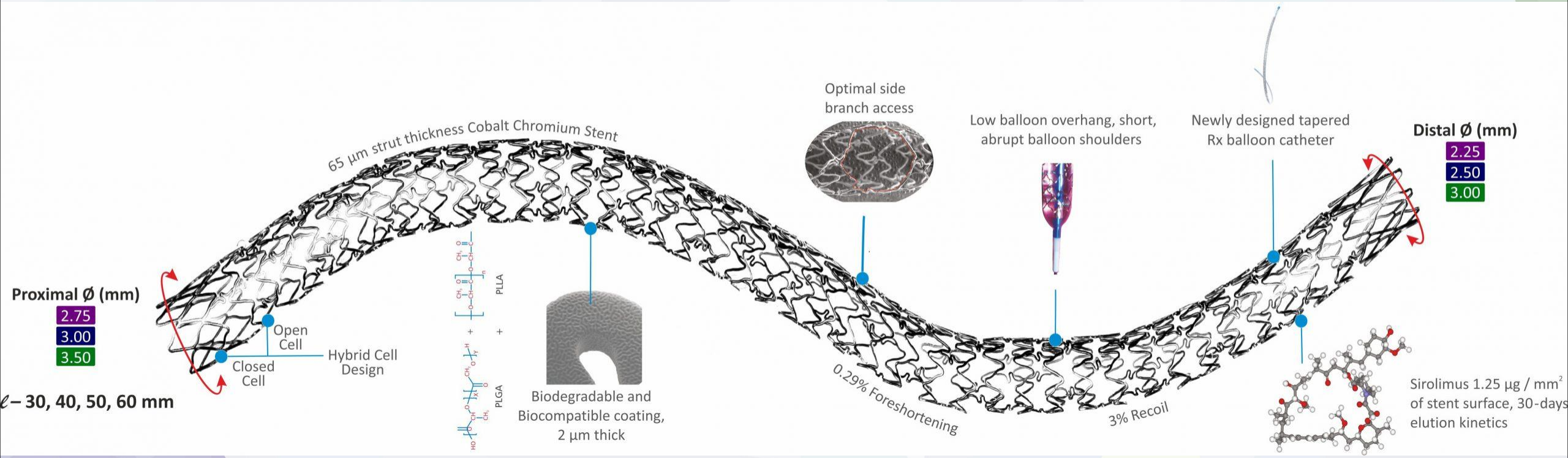
Sirolimus-Eluting Stent
Biodegradable Polymer

65 µm Cobalt chromium
Hybrid cell design

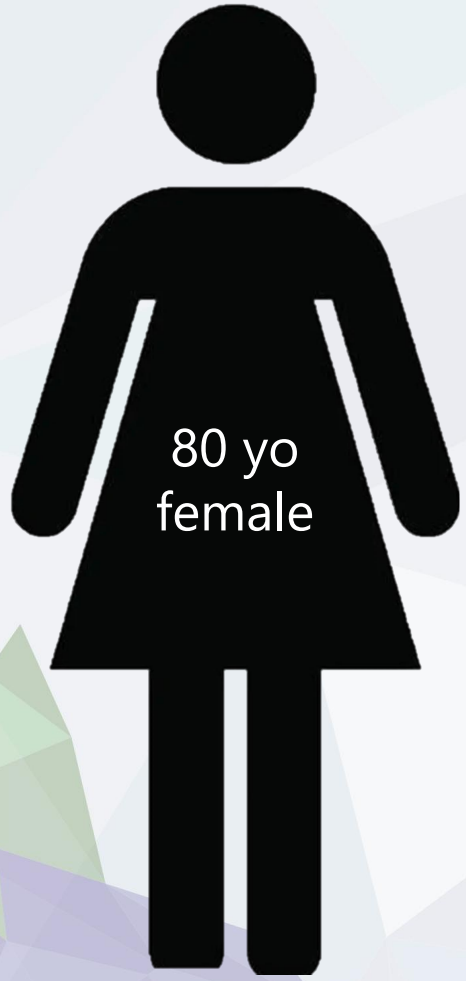
Longest length: up to 60 mm
Tapered for vessel adaptability

2,75 – 2,25	30
3,0 – 2,5	40
3,5 – 3,0	50
	60

Case 1:
Complex Lesion

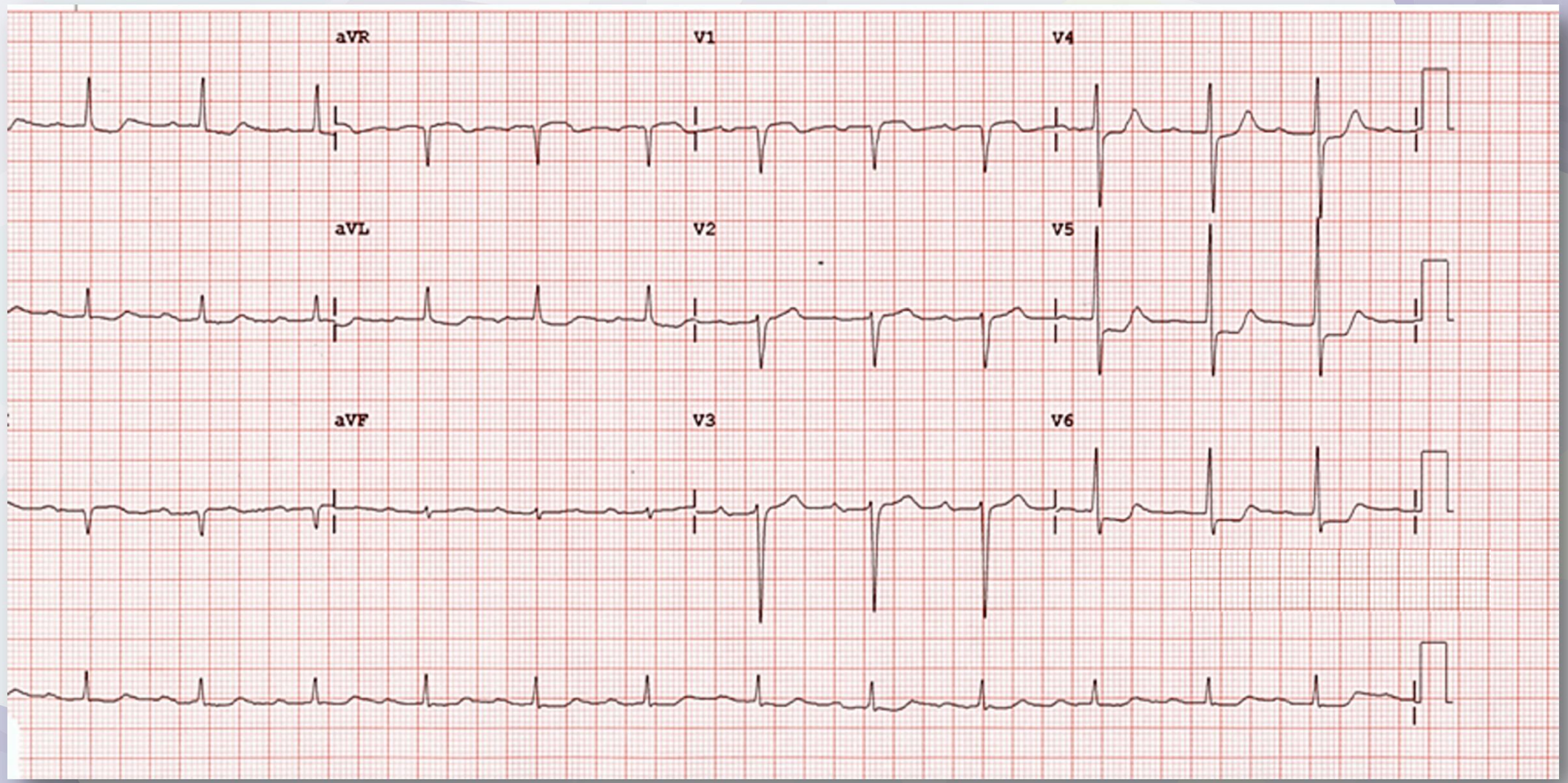


Clinical Case 1



CV Risk Factors	• Hypertension. • Hyperlipidaemia.
Cardiac Disease	• Chest pain episodes with normal Echo and negative Stress Test in 2021.
Comorbidities	• Bronchial asthma. • Colon Neoplasm: surgery in 2015. • Chronic Anaemia.
Present Admission (Referral Centre)	• Prolonged Chest pain at rest. • ST depression in lateral leads of ECG. • Moderate increase in Troponin value. • Echo: LVEF 51%. Anterior hipokinesia.

ECG with Chest Pain



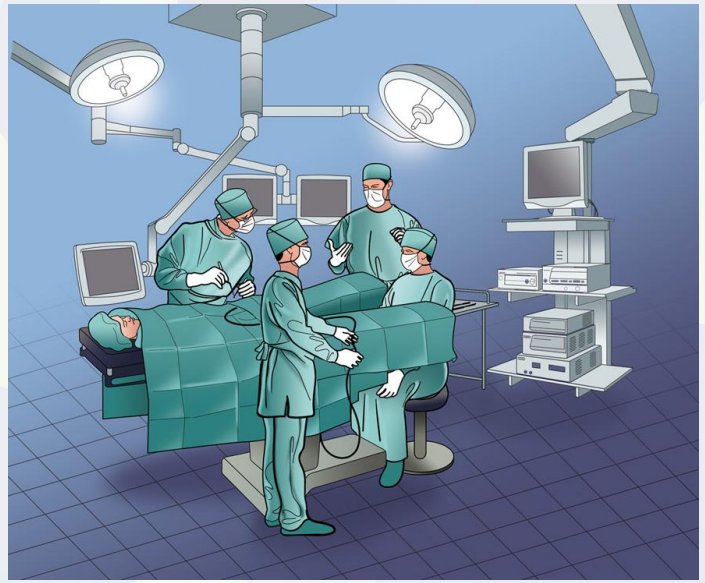
Acute Coronary Syndrome. Strategy:

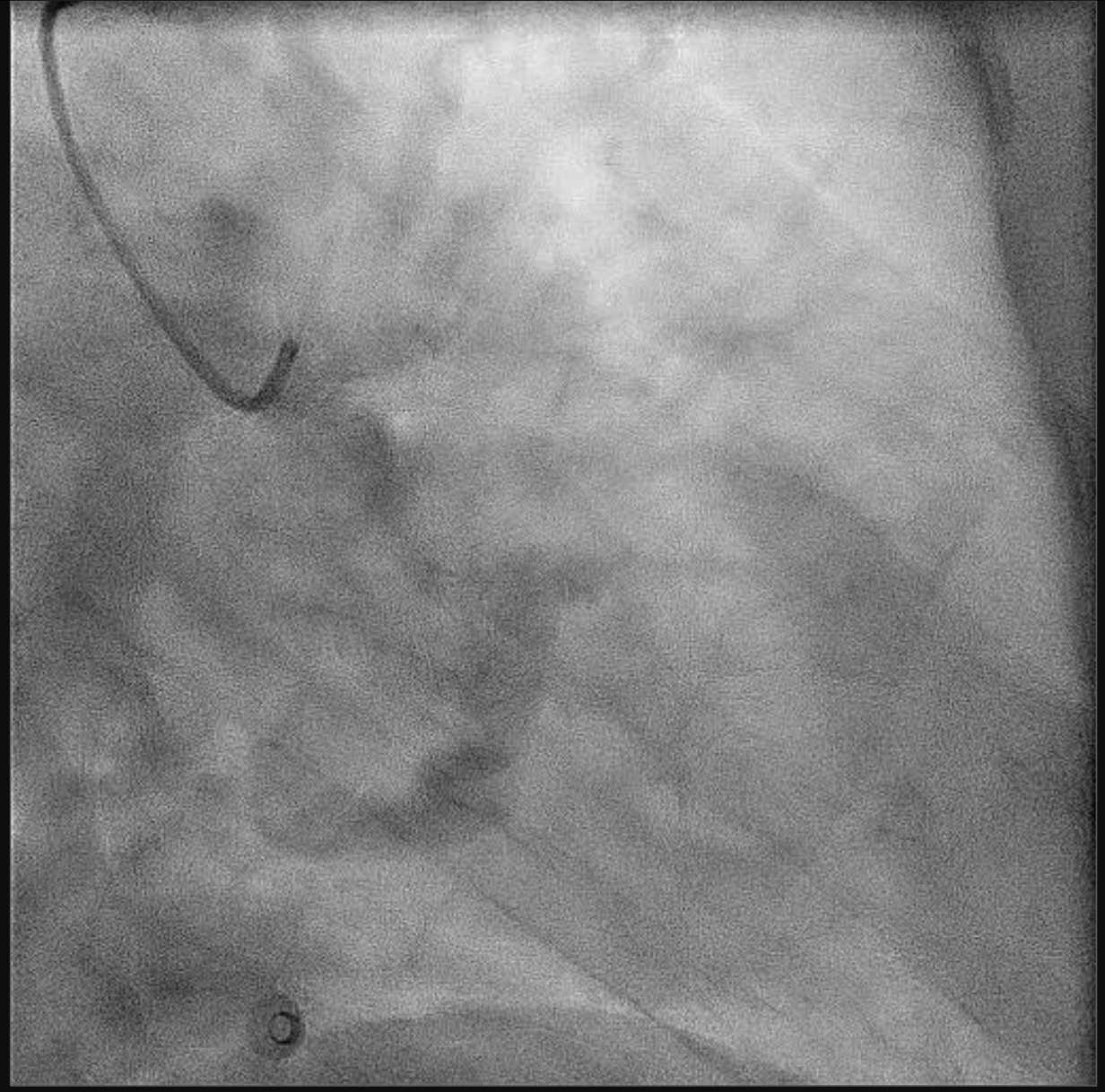
Medical Treatment

DAPT: ASA + Clopidogrel
Anticoagulation: Enoxaparin

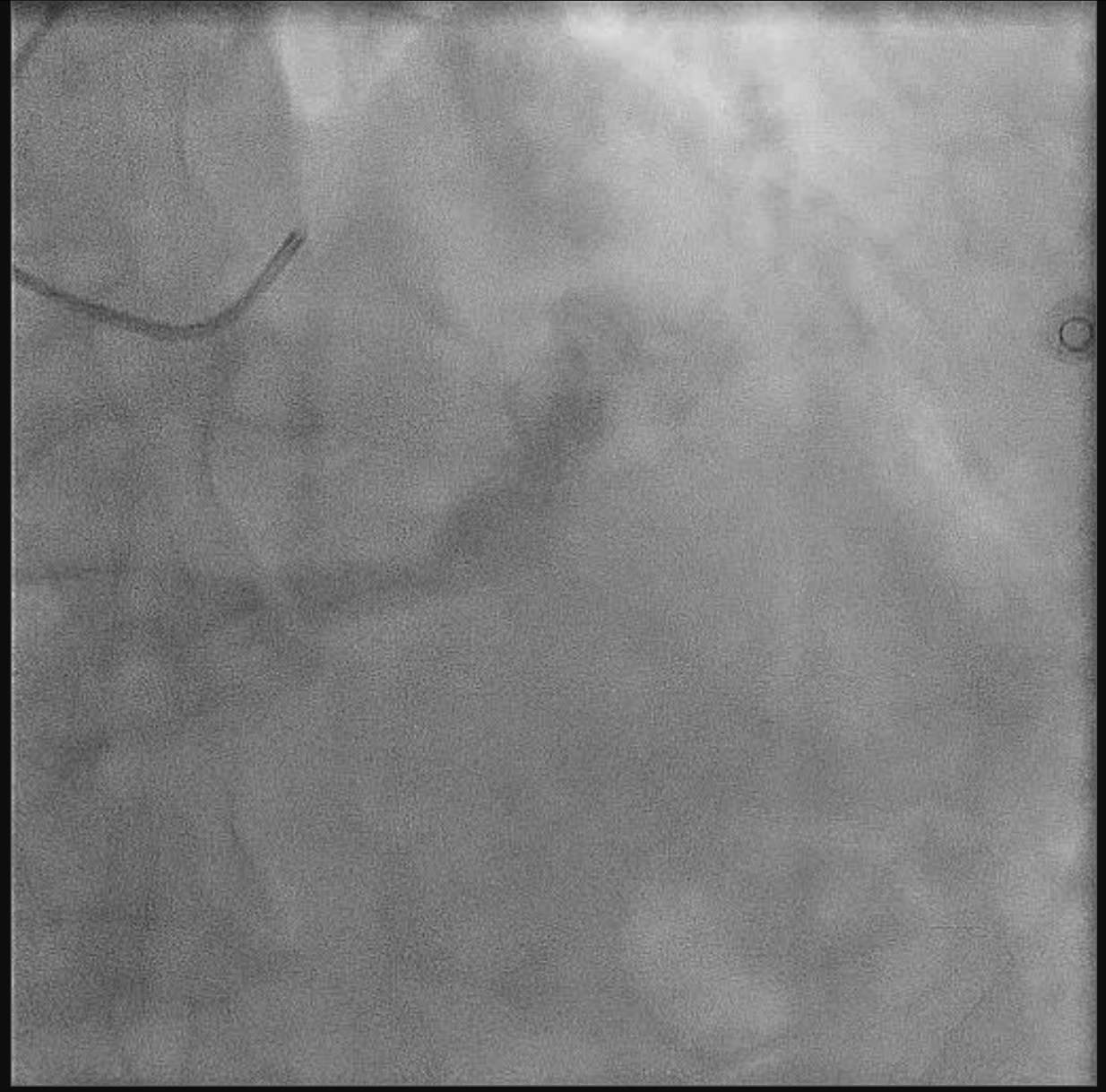
Invasive Strategy:

Scheduled Coronary Angio 48 h after the admission

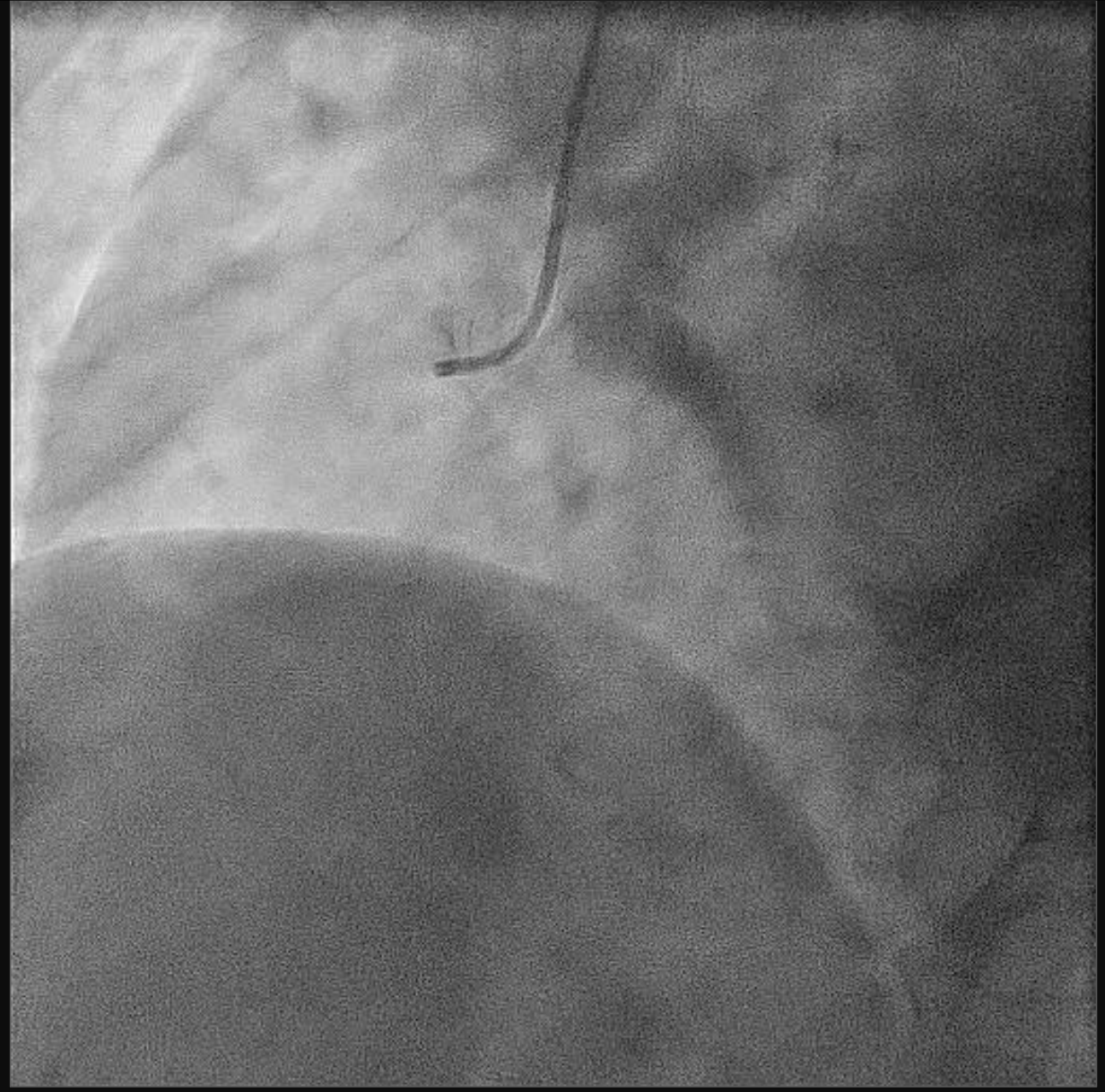




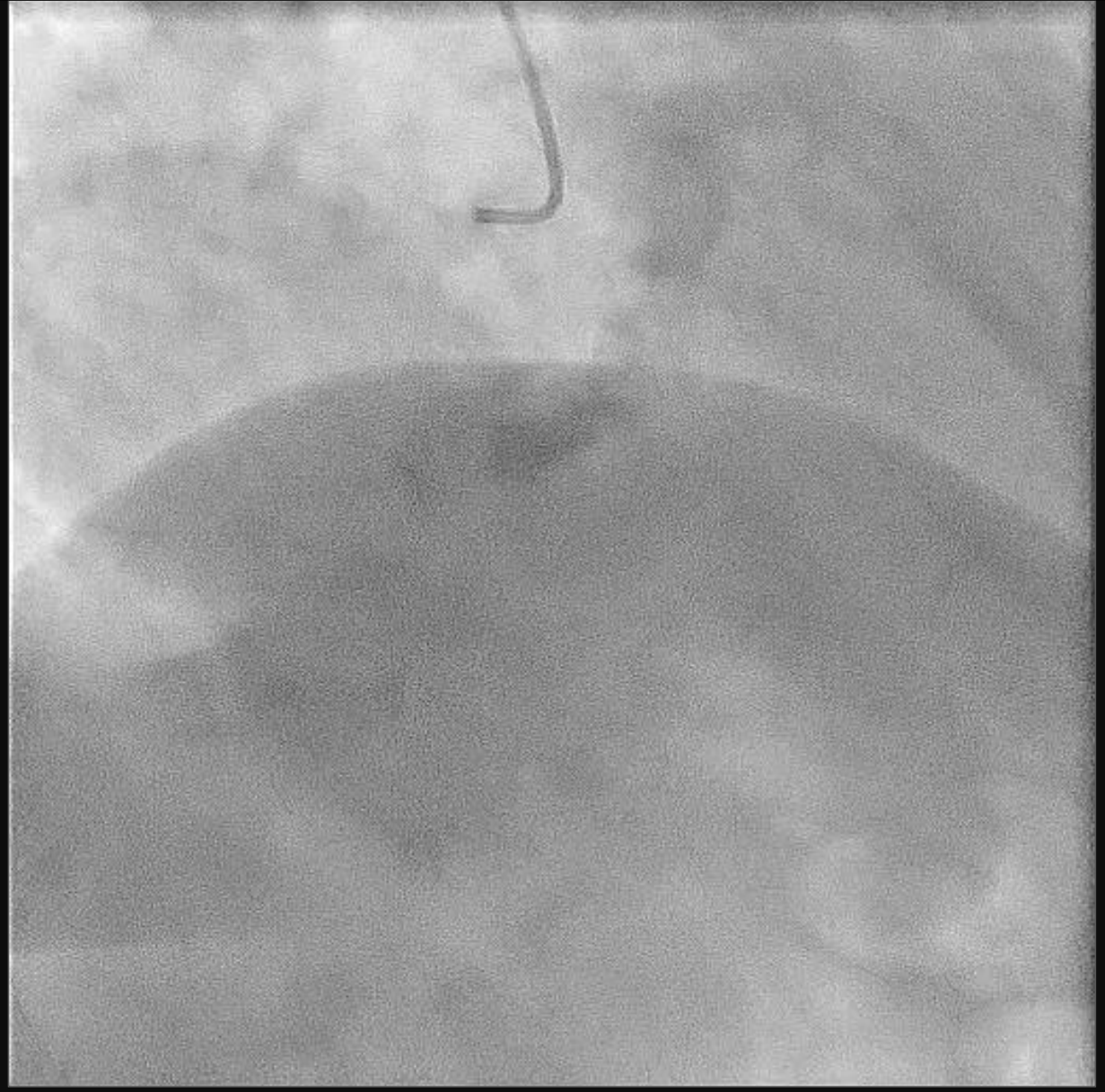
Radial Access: Left Coronary Angio: RAO Caudal view



AP cranial view



RCA: LAO view

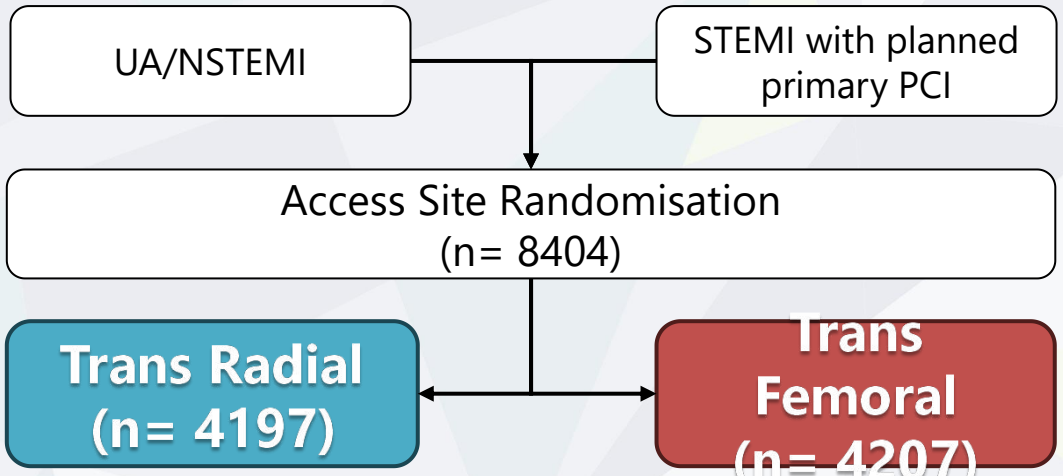


RCA: RAO view

Radial versus femoral access in patients with acute coronary syndromes undergoing invasive management: a randomised multicentre trial

Marco Valgimigli, Andrea Gagnor, Paolo Calabró, Enrico Frigoli, Sergio Leonardi, Tiziana Zaro, Paolo Rubartelli, Carlo Briguori, Giuseppe Andò,

SQDC



Primary Endpoints cohort for Access Site Selection

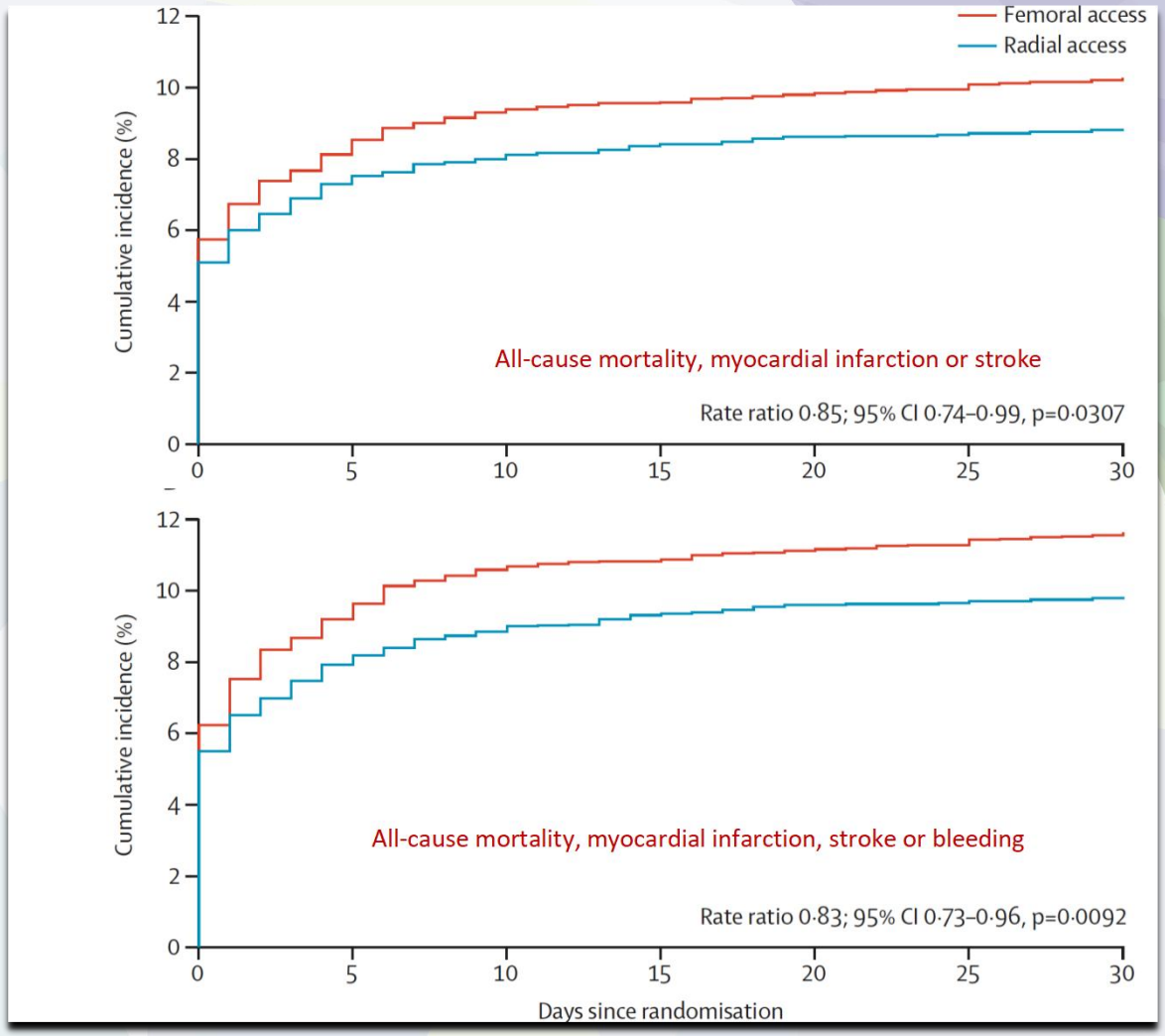
30 day:

All-Cause Mortality

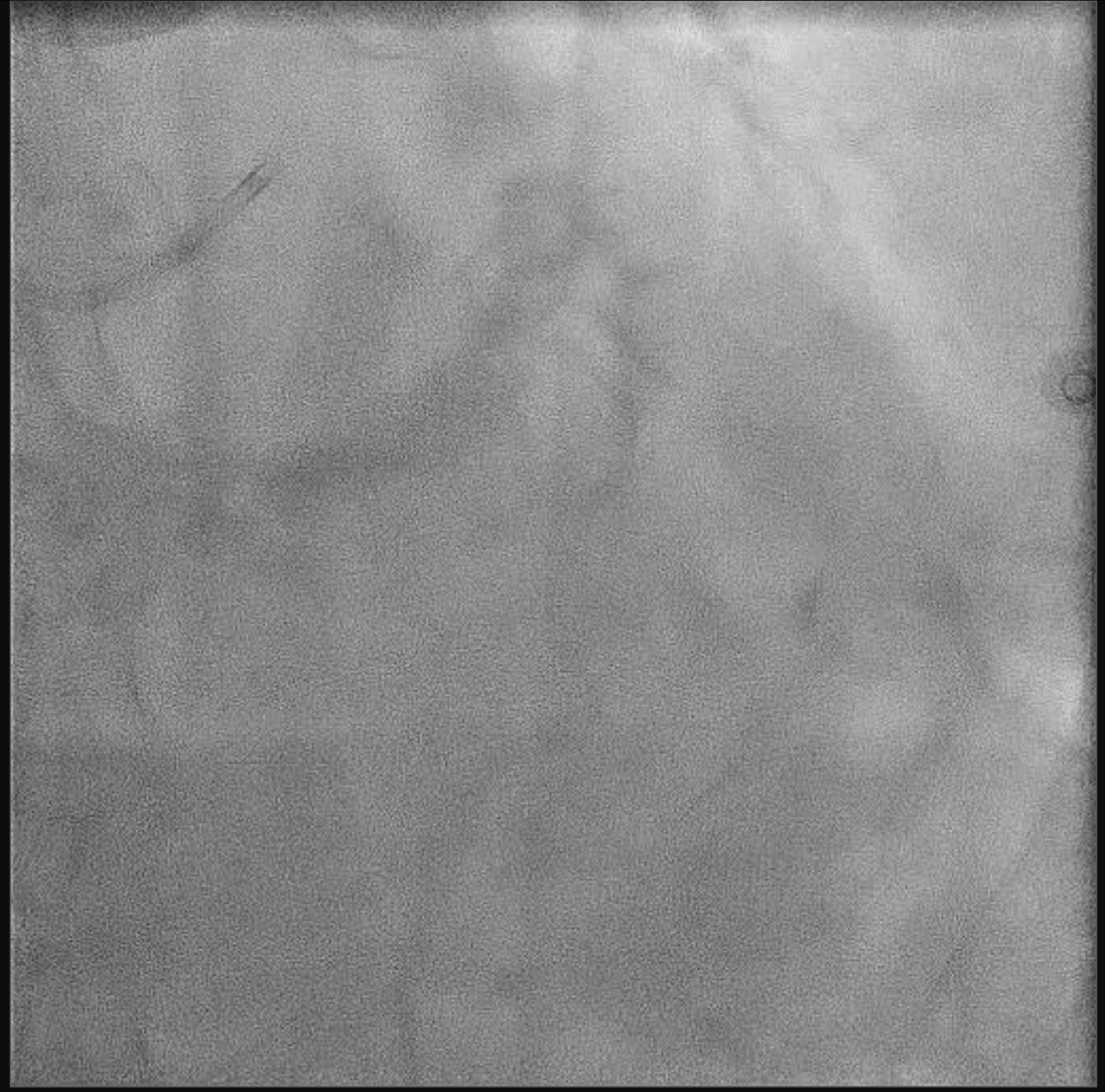
Myocardial Infarction

Stroke

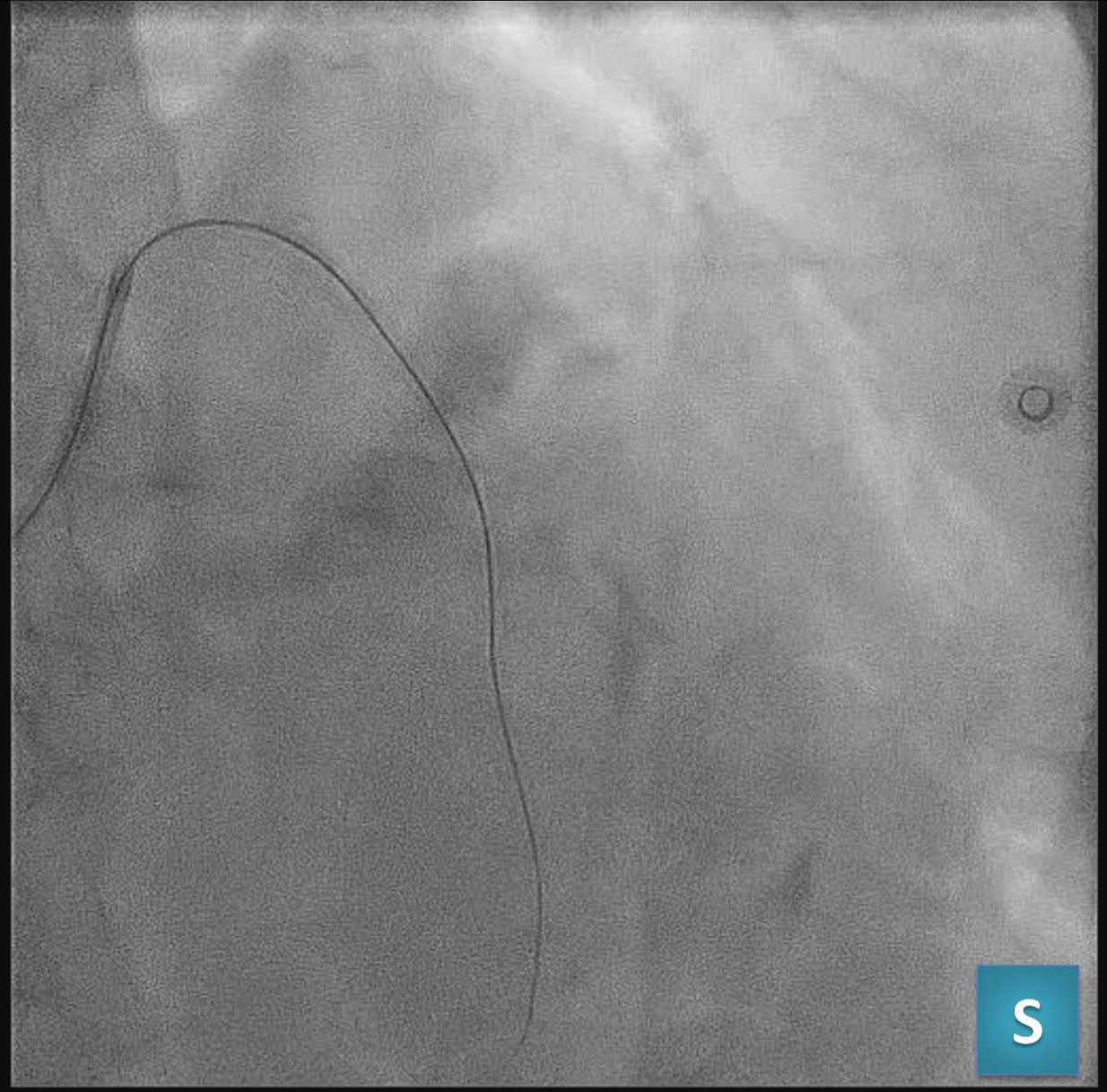
Bleeding



Valgimigli M et al. *Lancet* 2015; 385(9986): 2465.

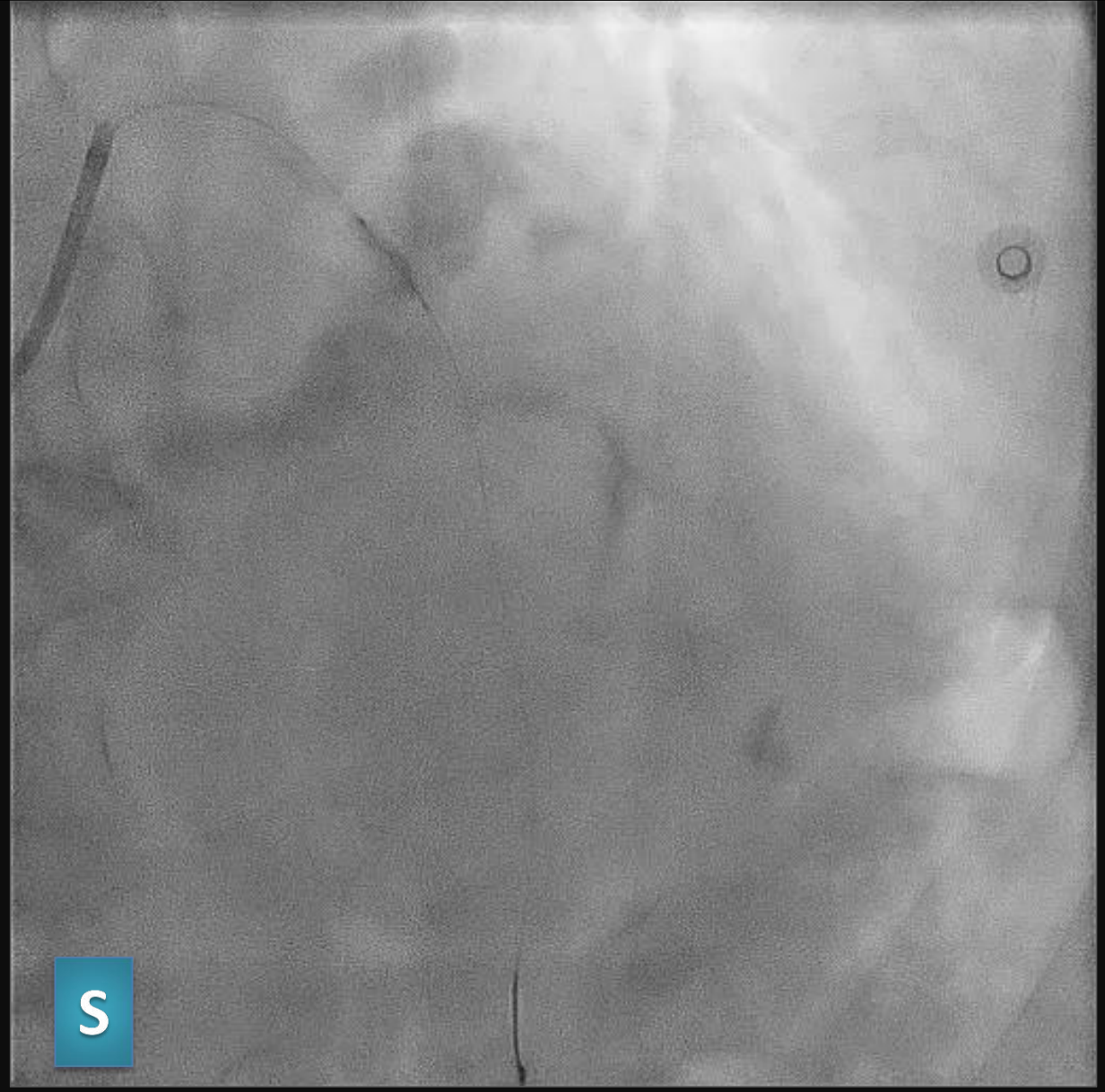


PCI: Extrasupport 3,5 Guiding Catheter

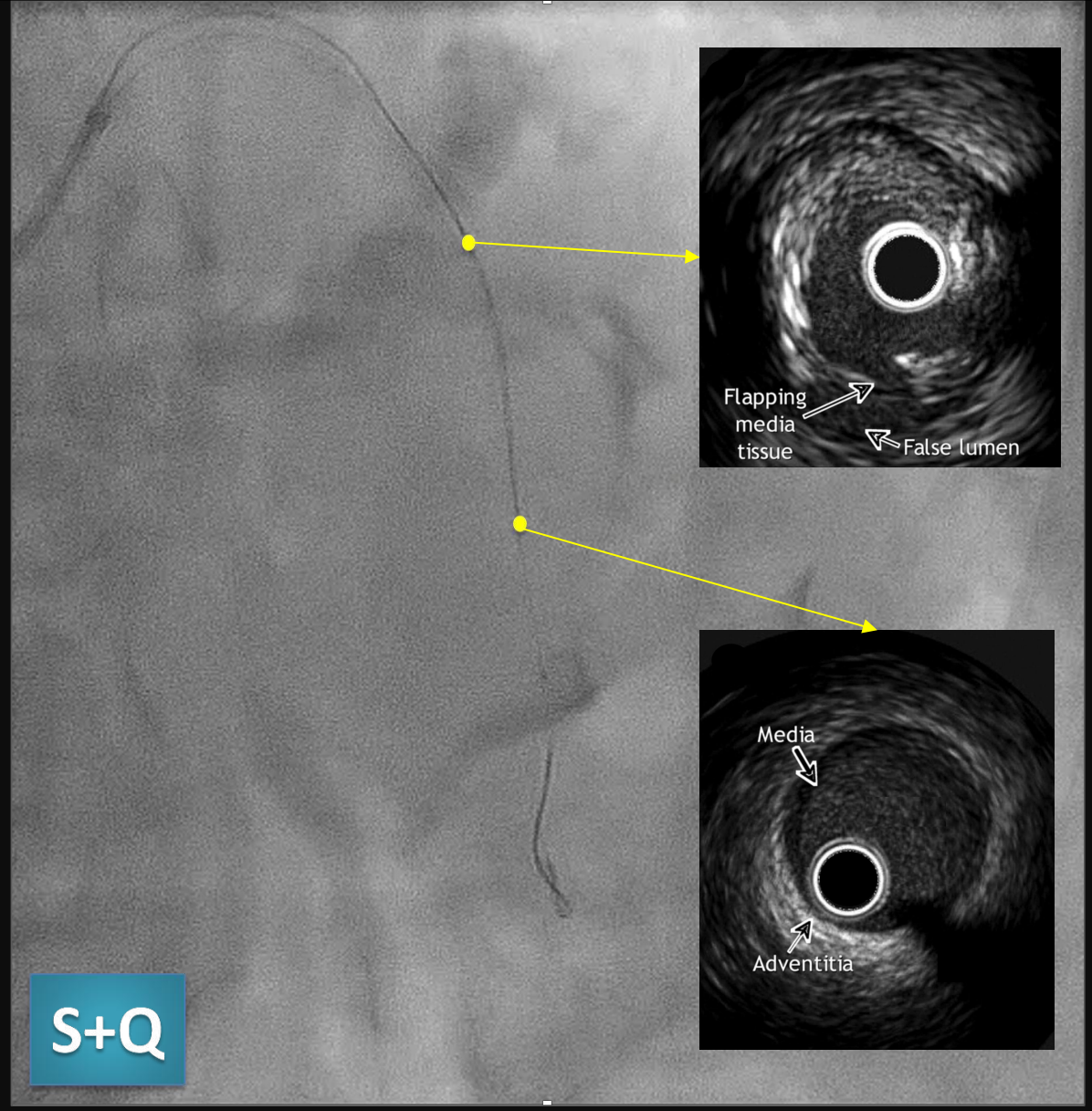


Microcatheter: CARAVEL.

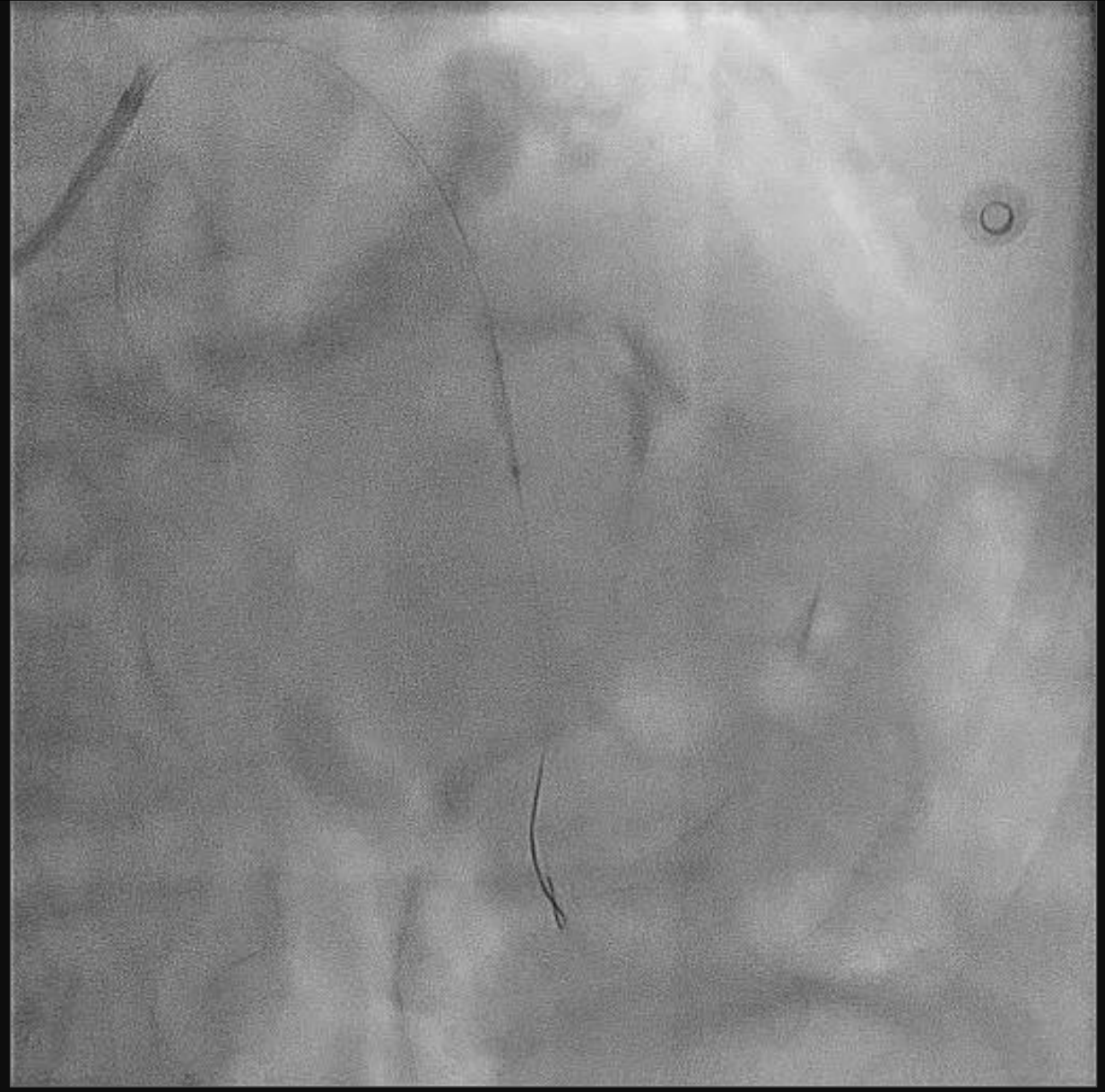
GUIDE-WIRE: Fielder XTA



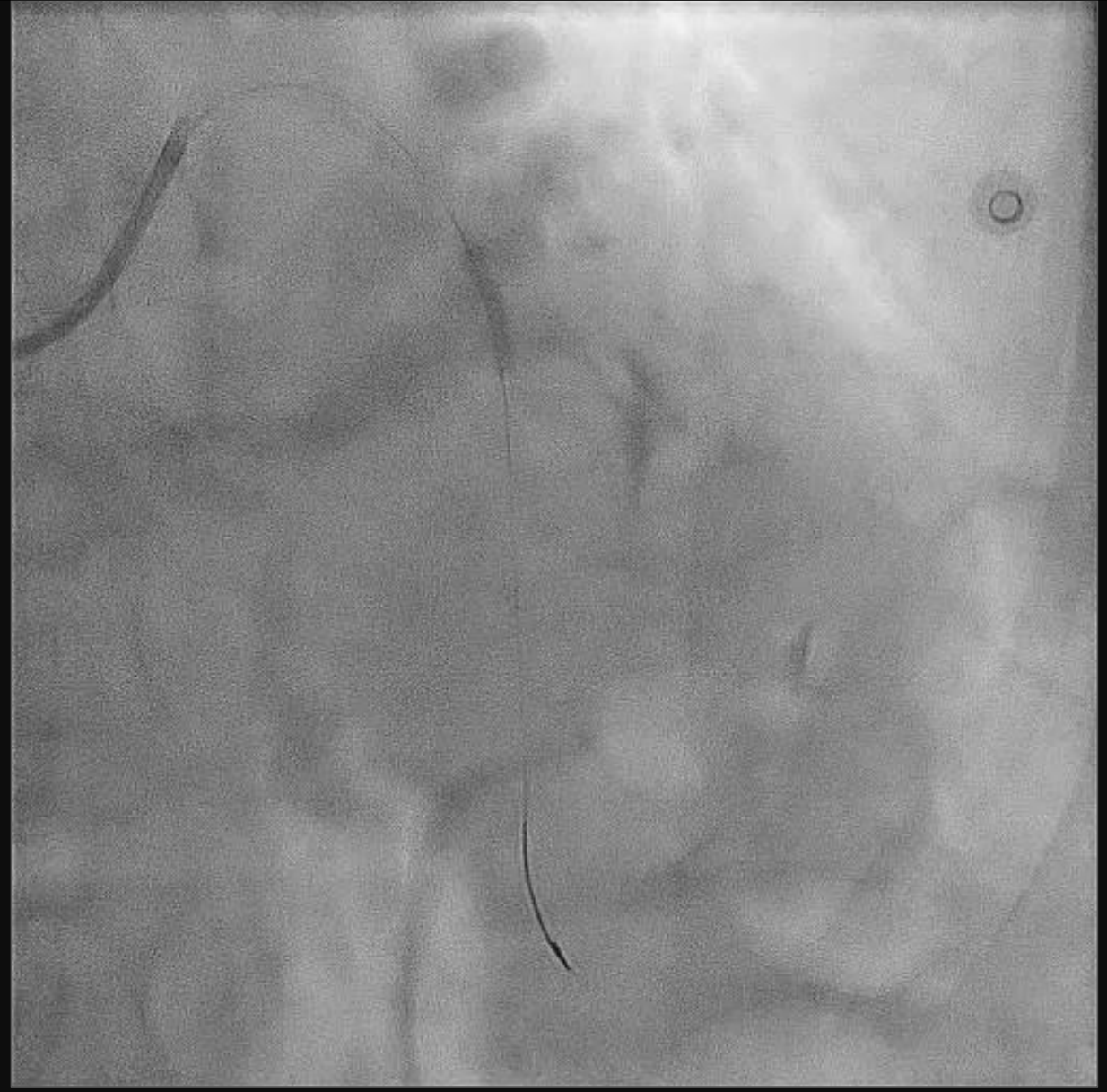
BMW wire and Balloon 1,5x15 mm



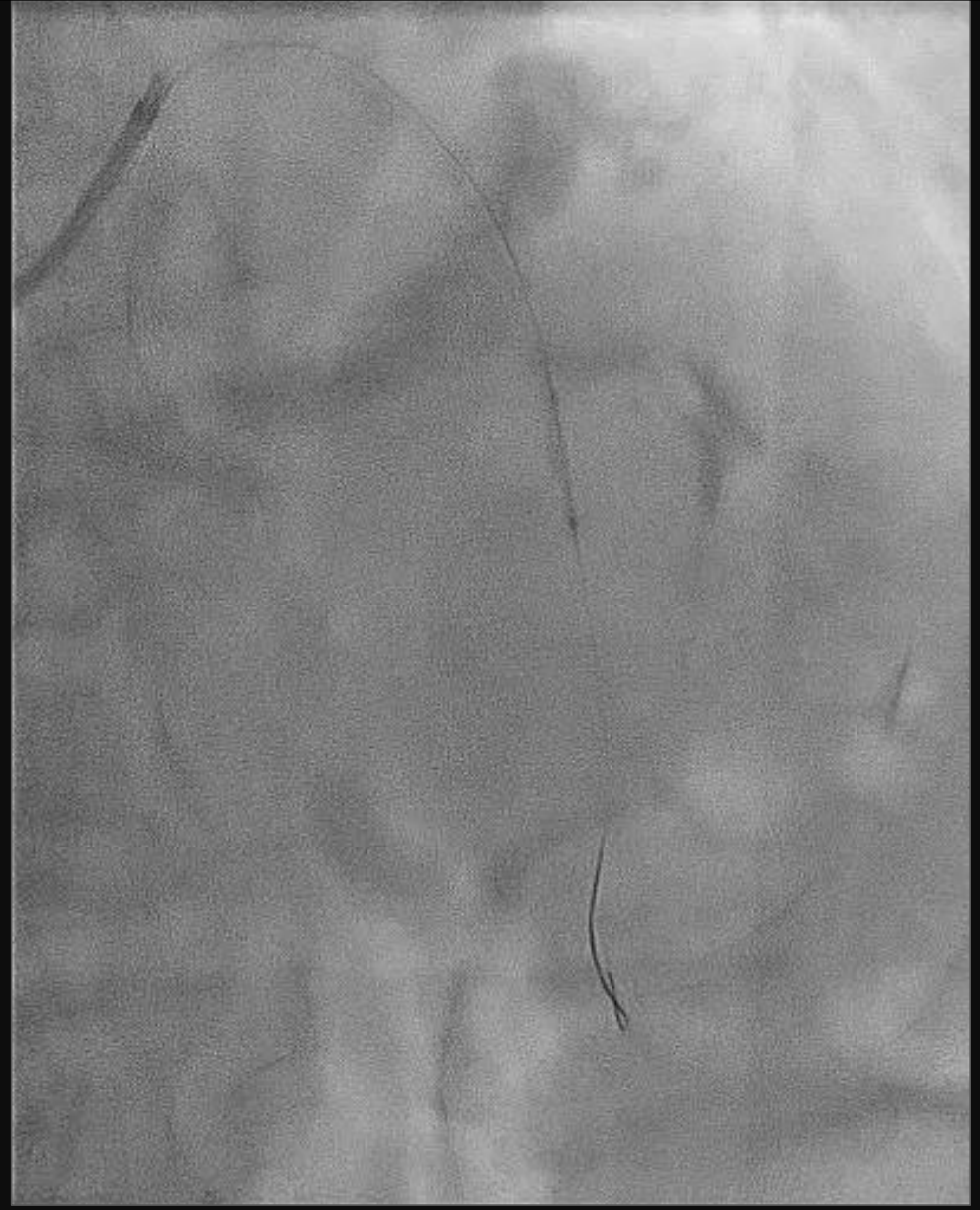
IVUS study



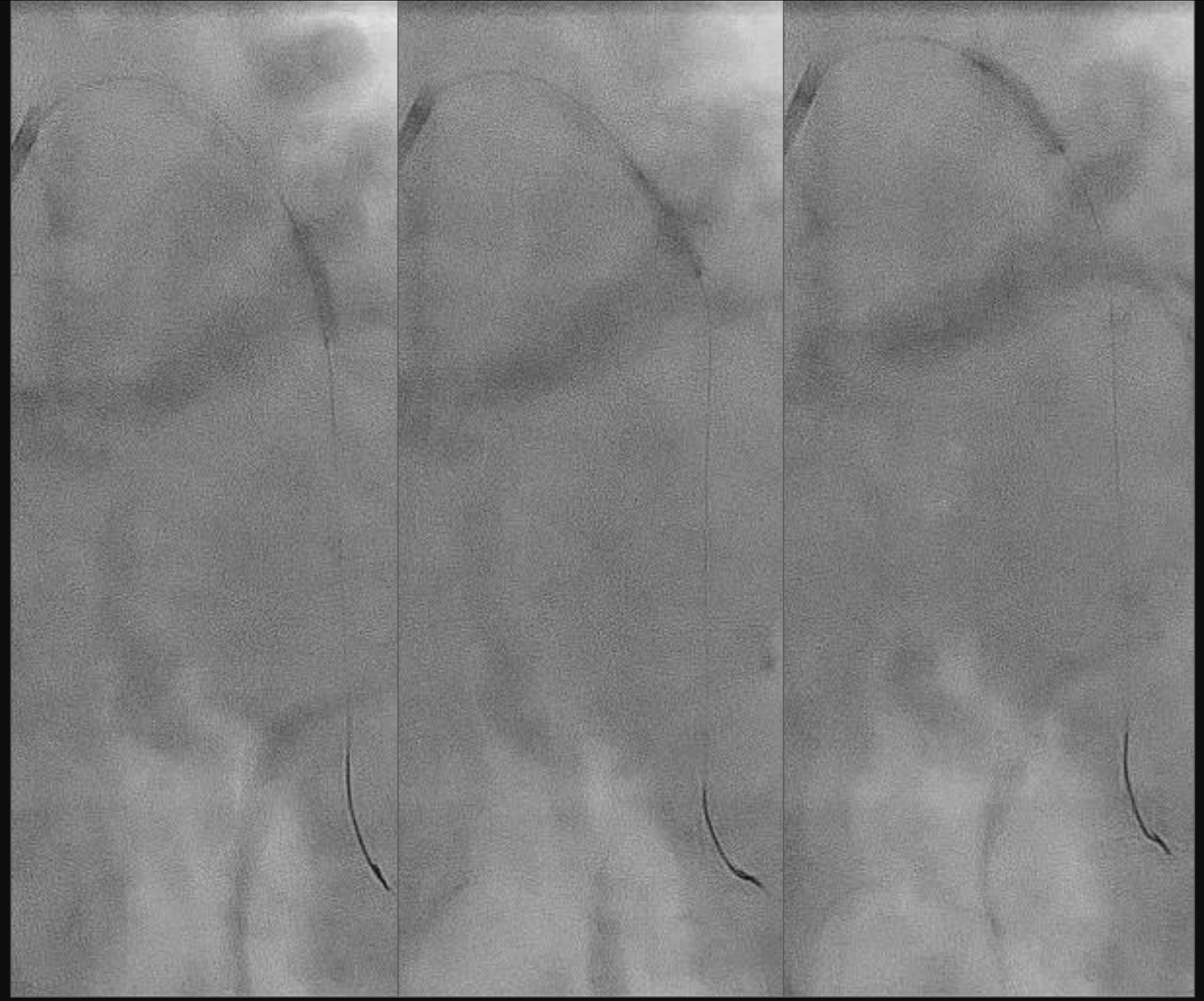
Balloon 2,0x12 mm



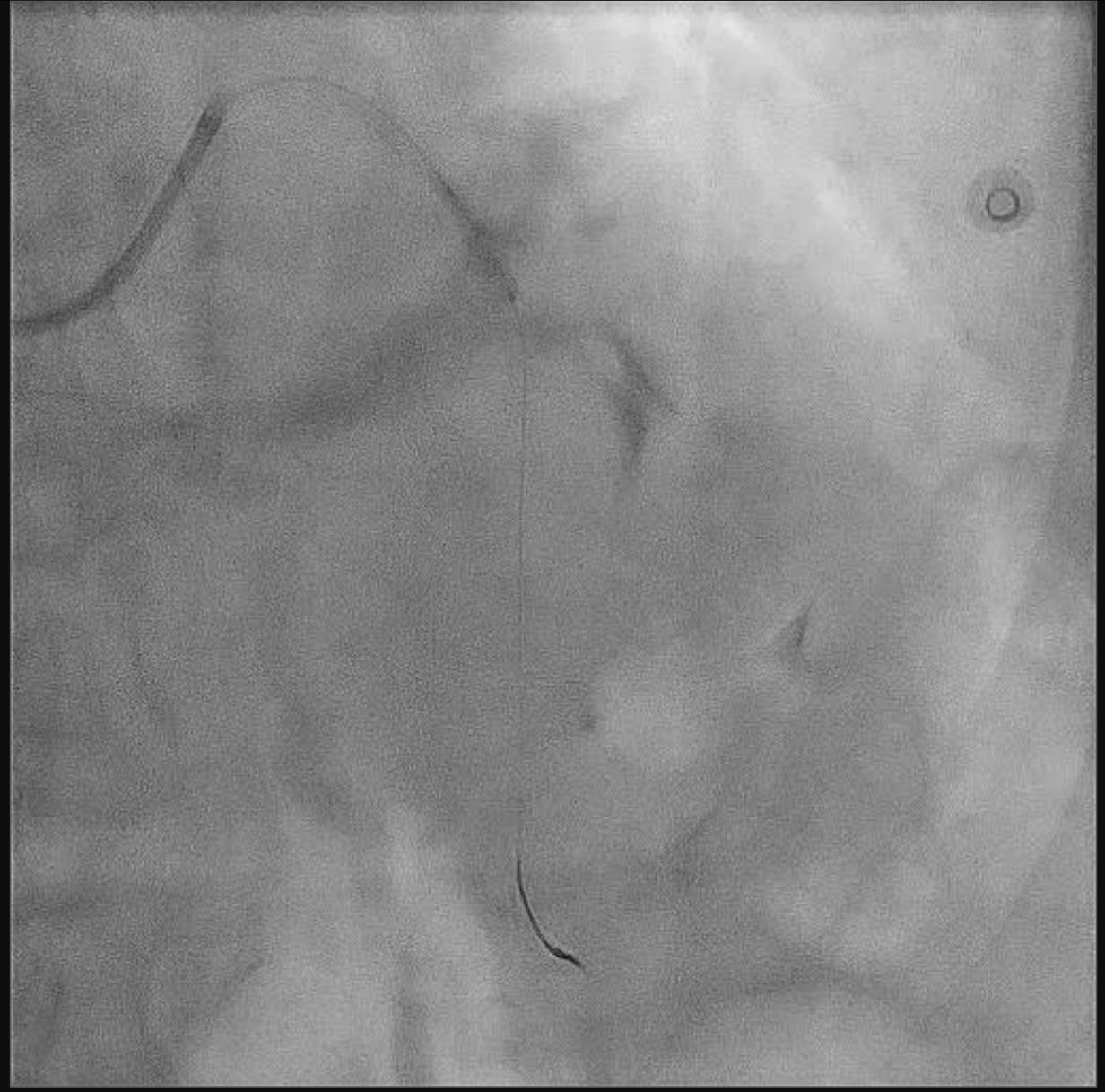
Balloon 2,5x15 mm



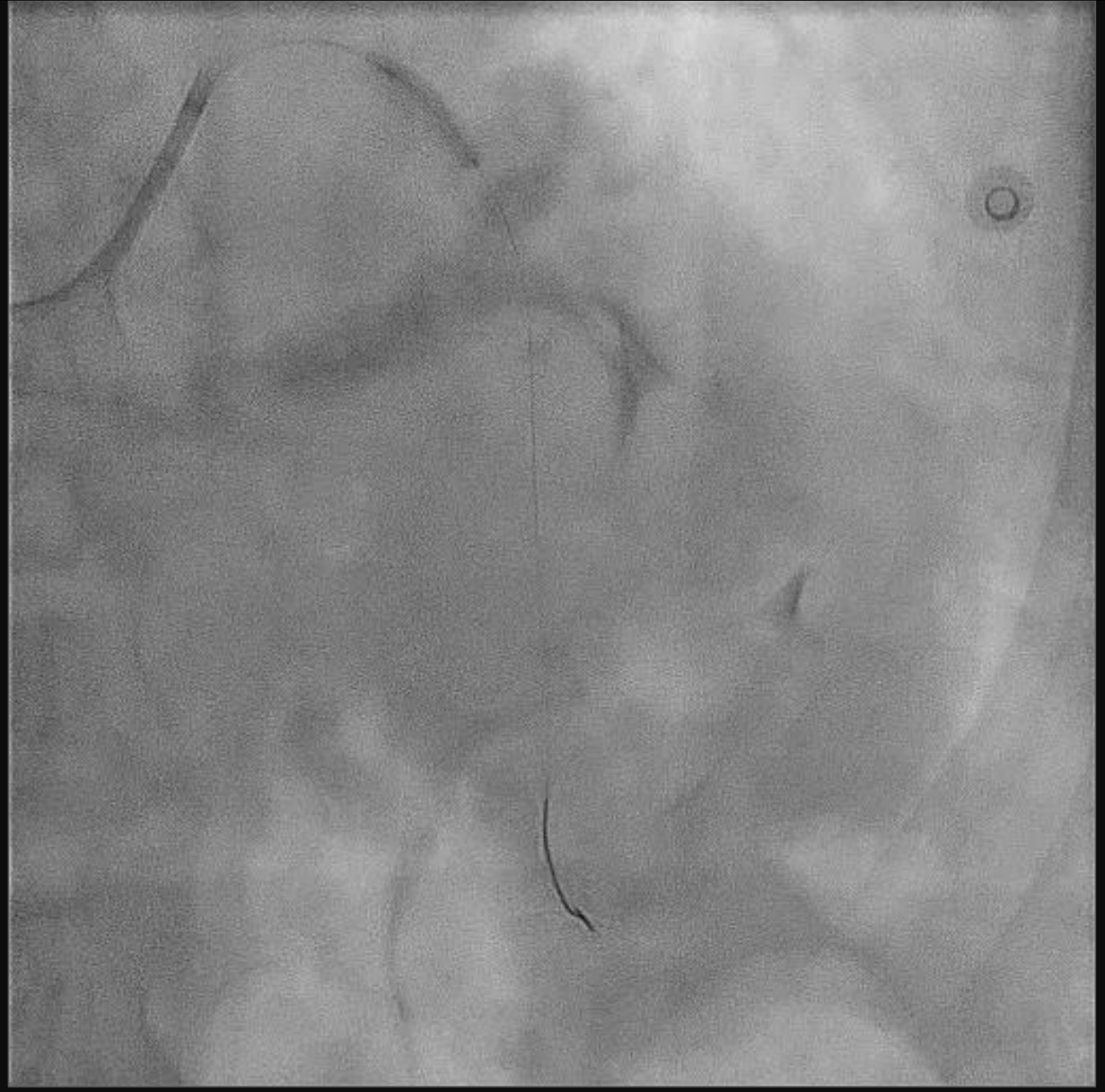
Balloon 2,0x12 mm



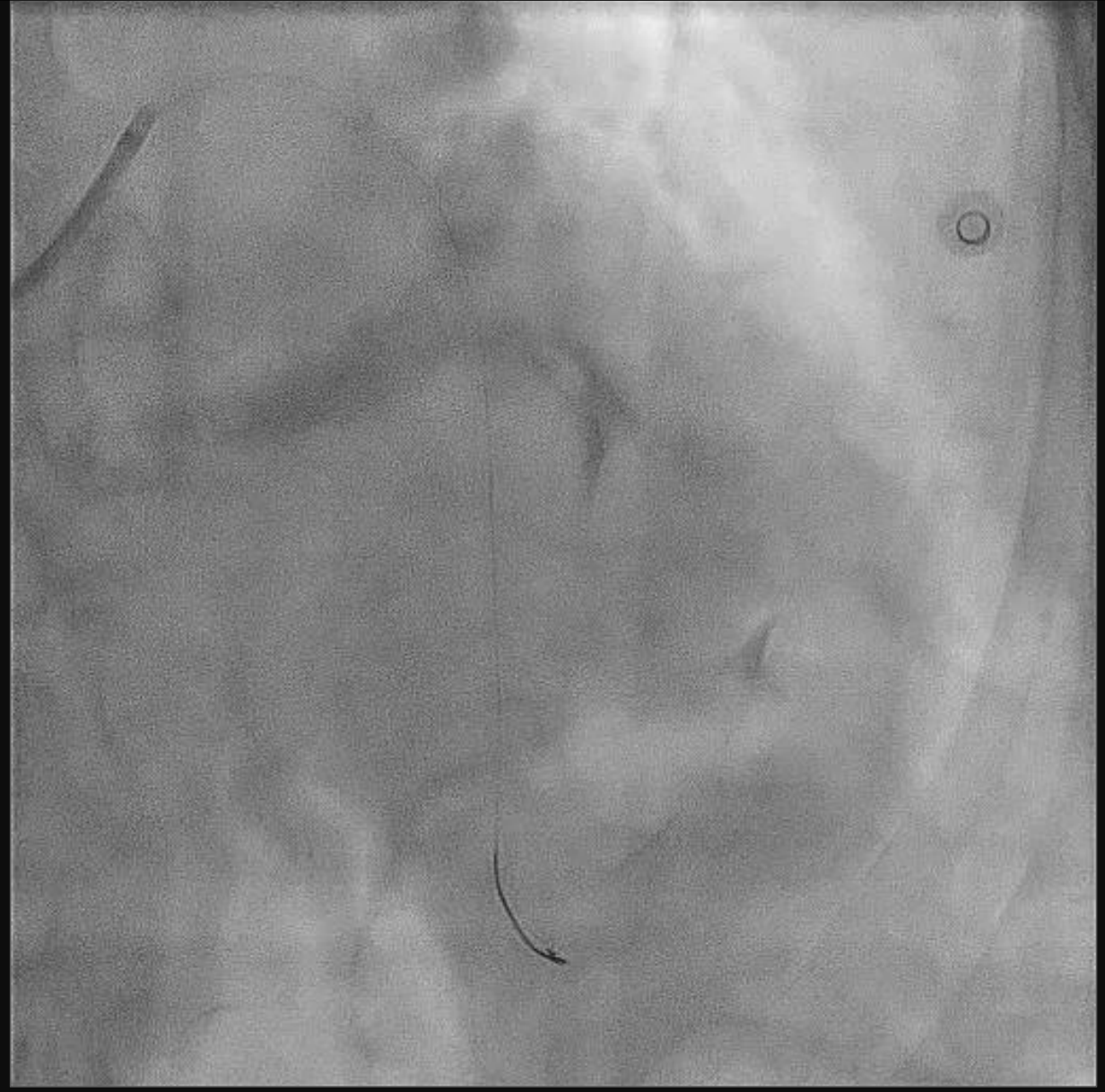
Balloon 2,5x15 mm



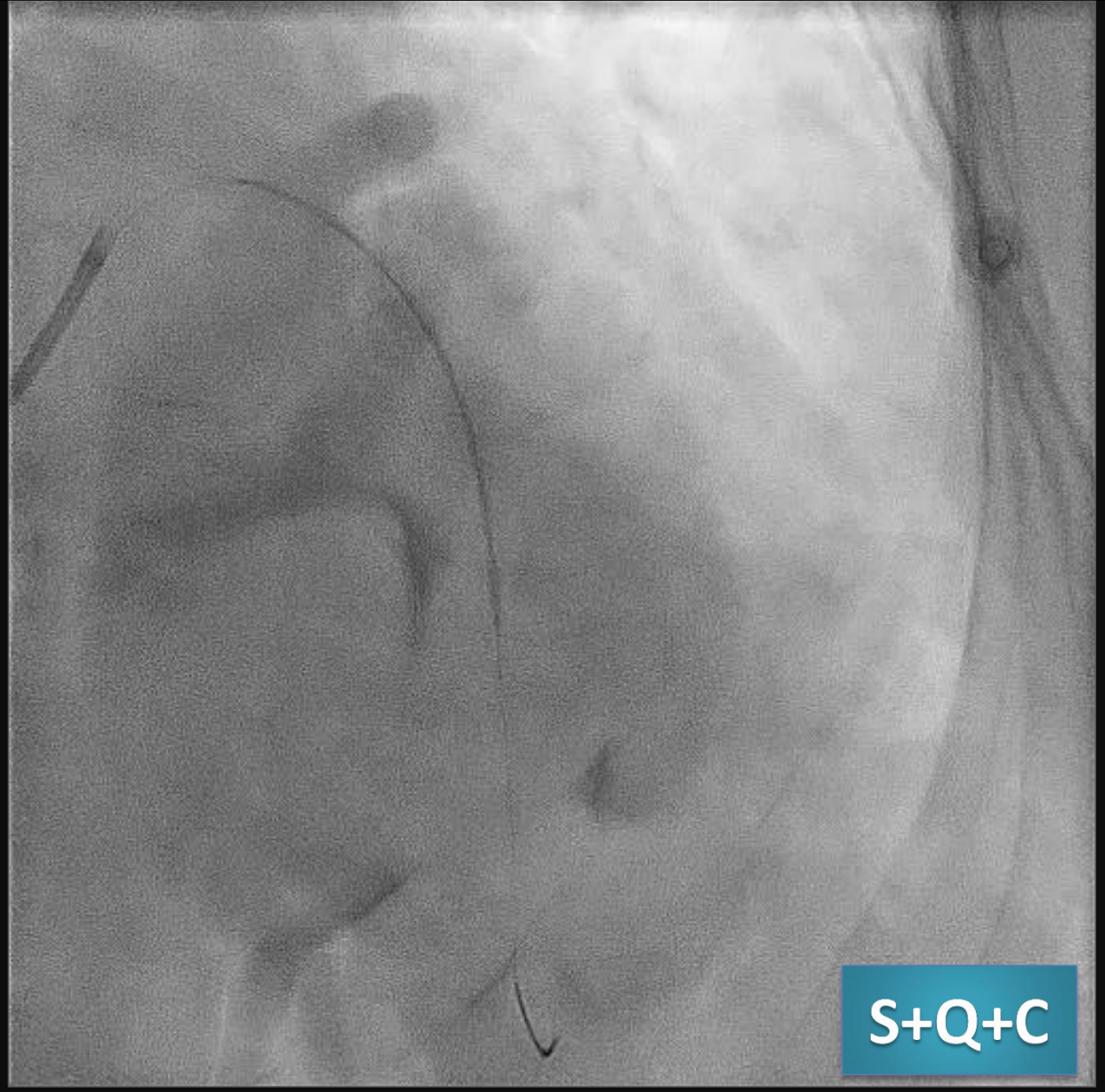
Balloon 2,5x15 mm



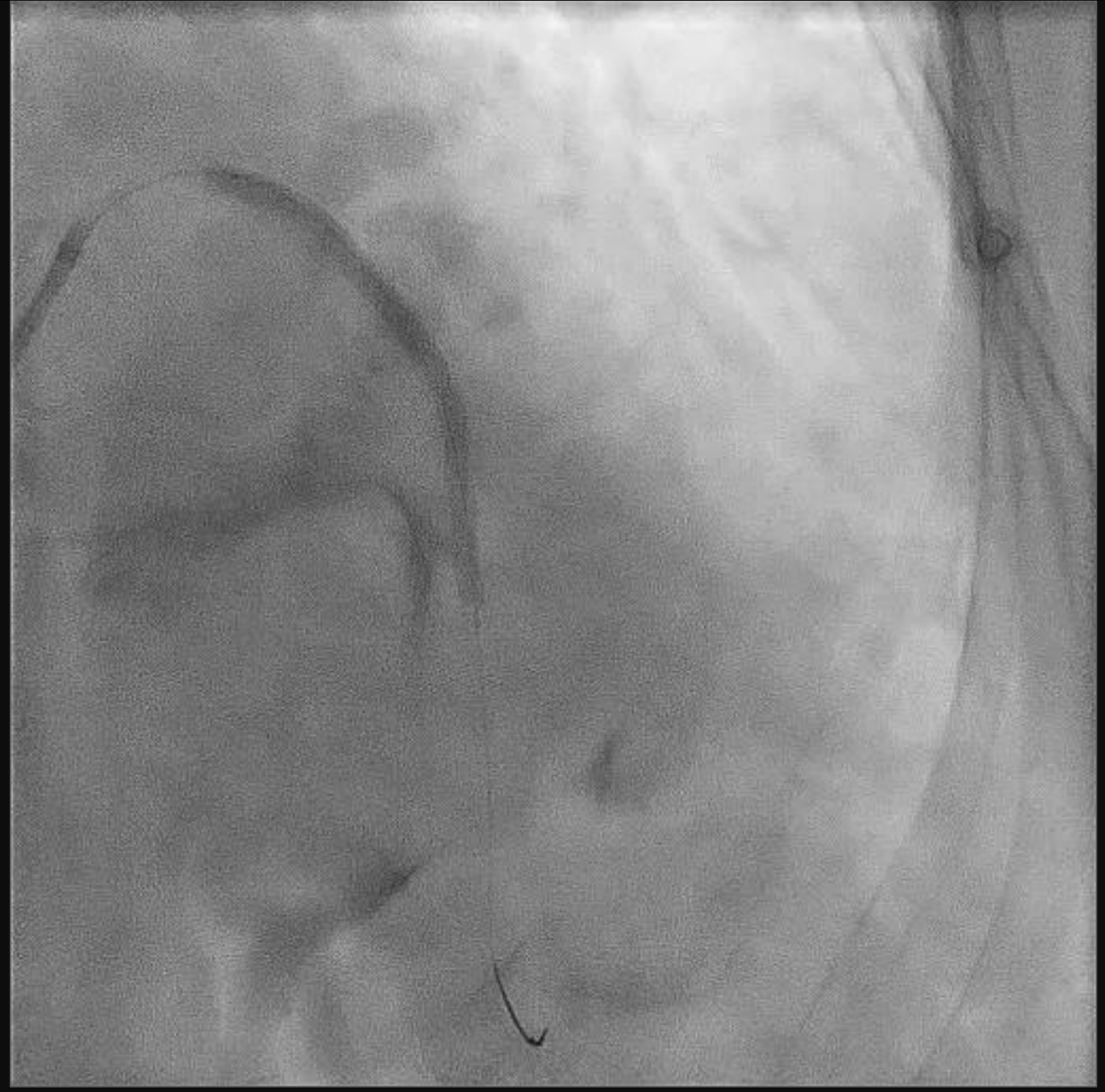
Balloon 2,5x15 mm



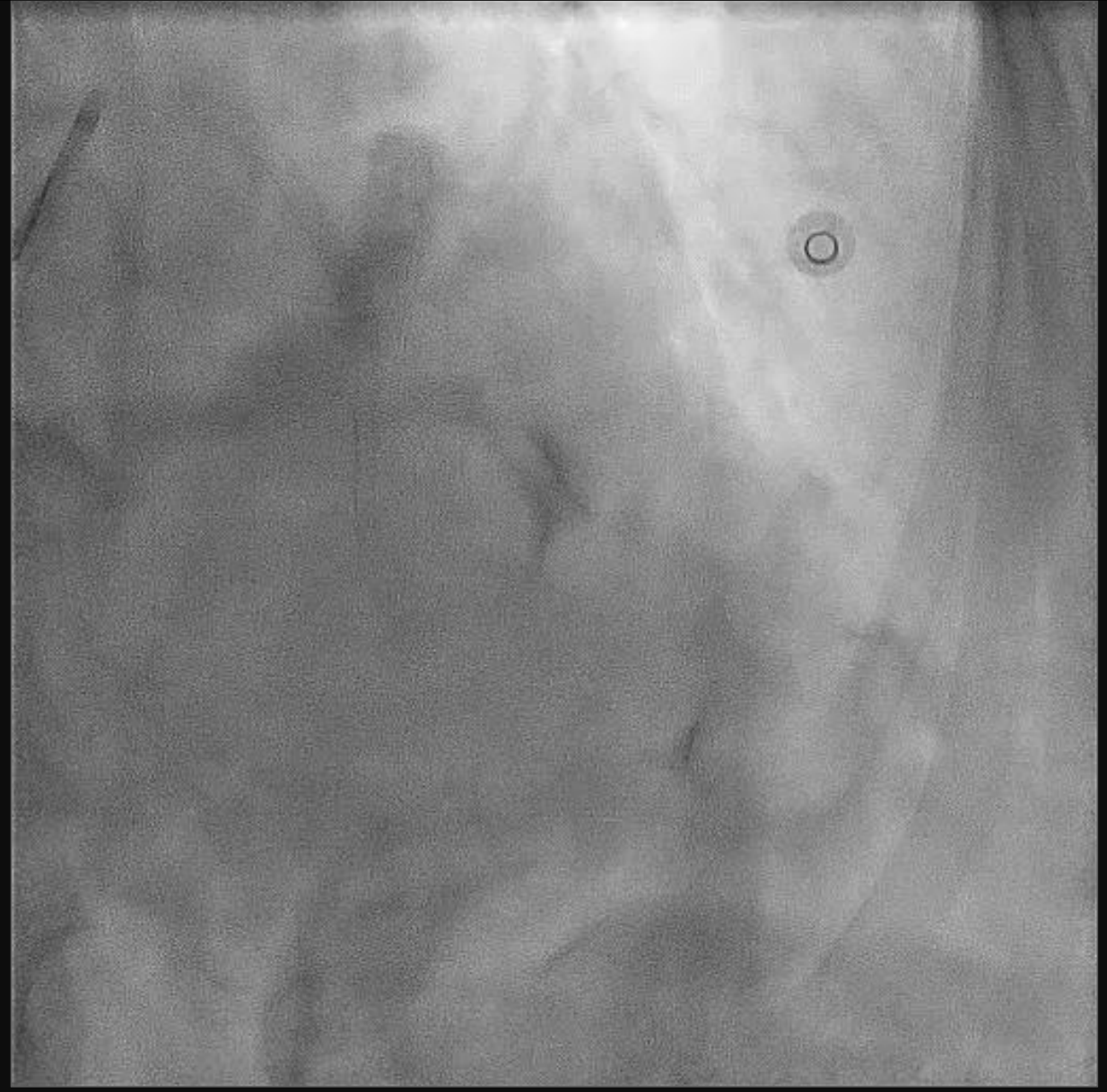
Result after ballooning



Biomime Morph Stent 3,0-2,5x60 mm



Stent deployment

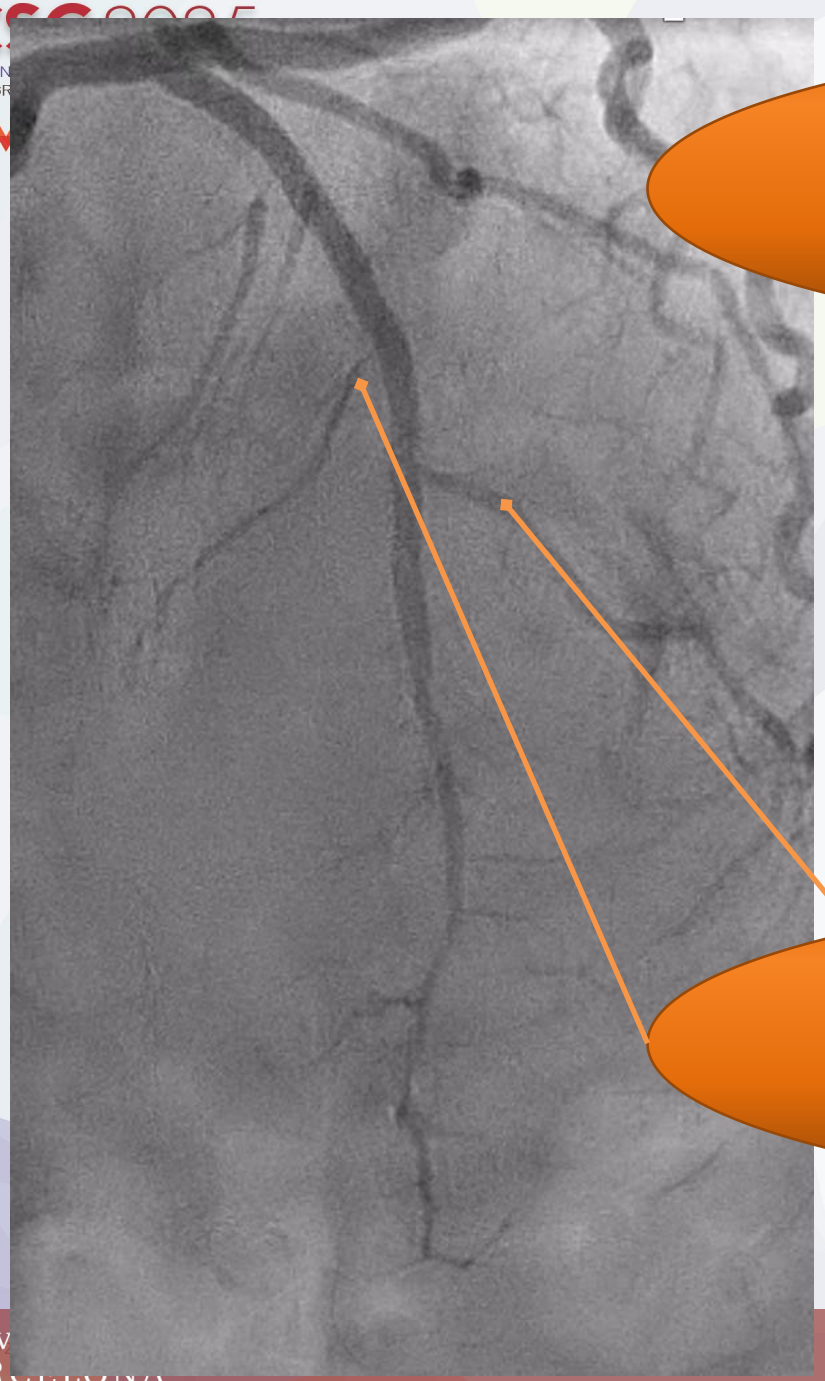


Final Result

Follow up: 15 months

- Asymptomatic
- Stress Echo:
  - Normal baseline LVEF (67%).
  - Response to the Dobutamine + Atropine:
    - No chest pain
    - Atrial fibrillation induced, that reverts at the end of the test
    - Normal LV contractility

Case Remarks

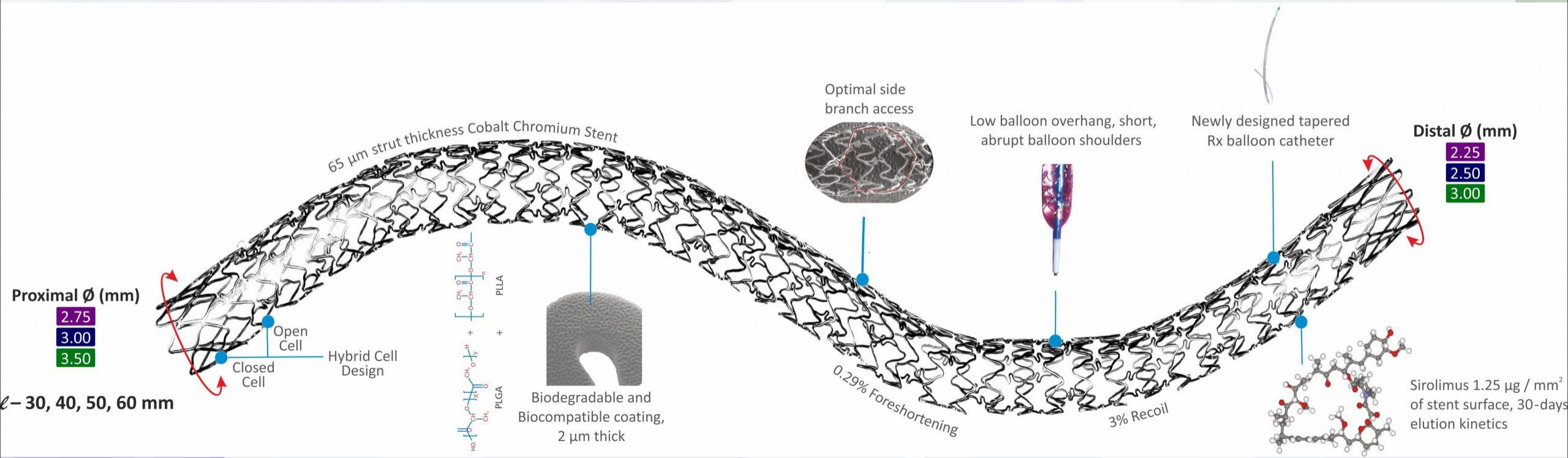


Navigation

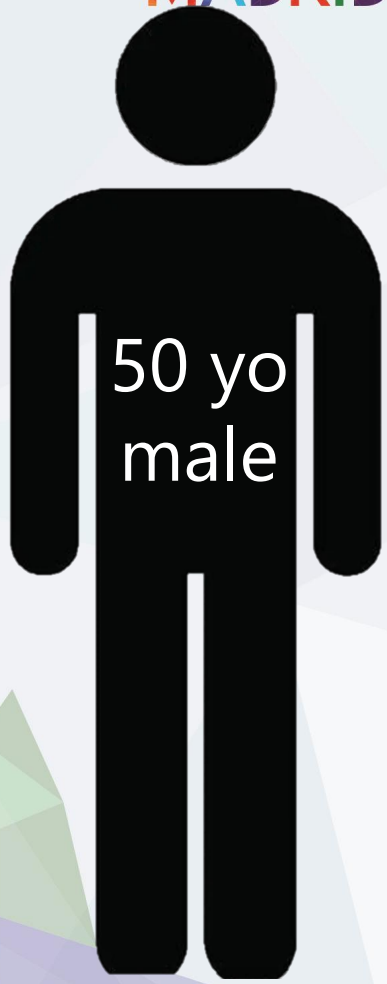
Adaptation to the vessel

Side Branch Preservation

Case 2:
Complex Lesion



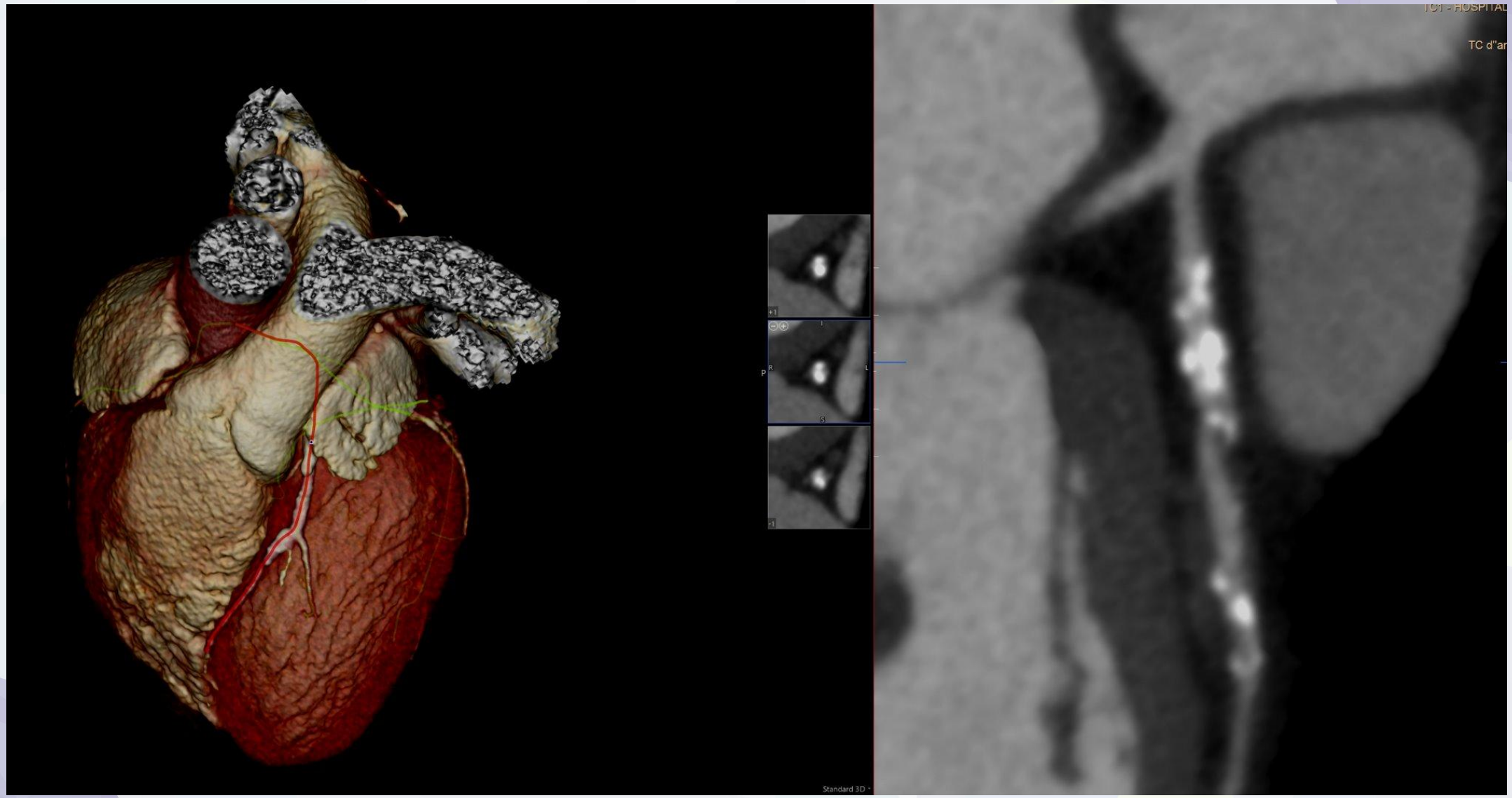
Clinical Presentation Case 2

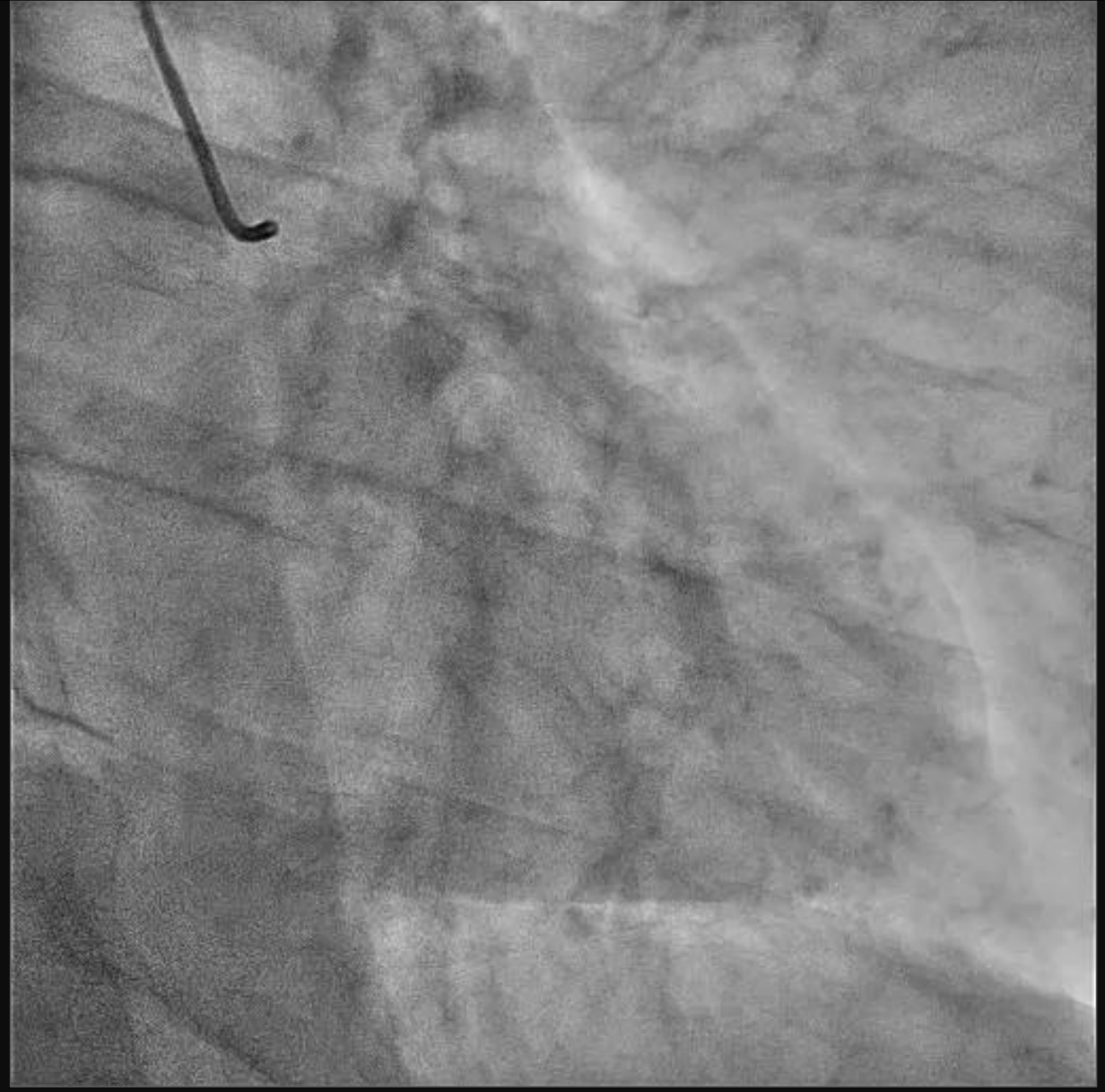


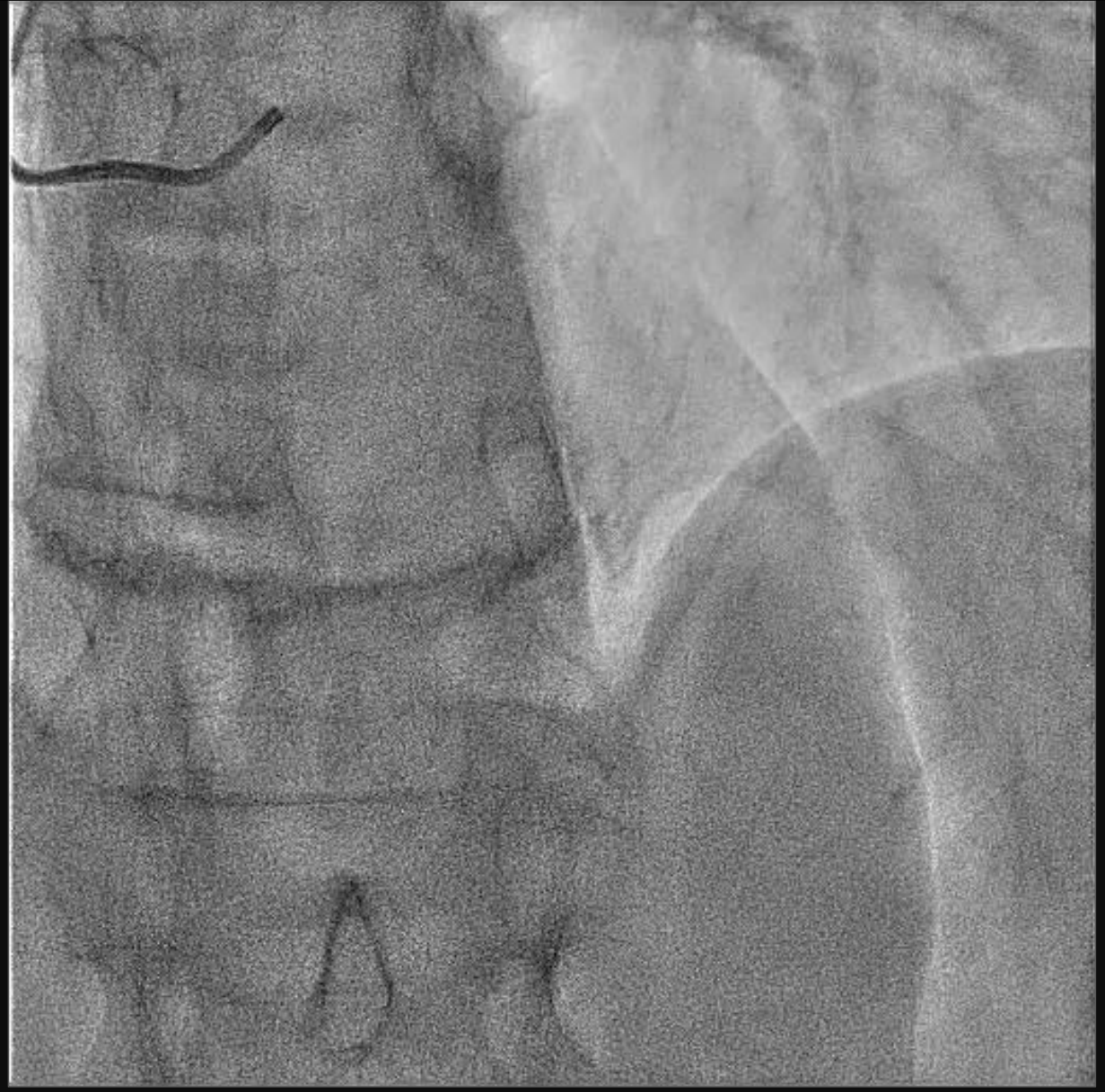
CV Risk Factors	• Smoker • Hyperlipidaemia • Familiar history of AMI
Symptoms	• Some episodes of chest pain • Repetitive syncope
Ambulatory Tests	• CT: Calcified LAD lesion • RNM: small subendocardial infarction

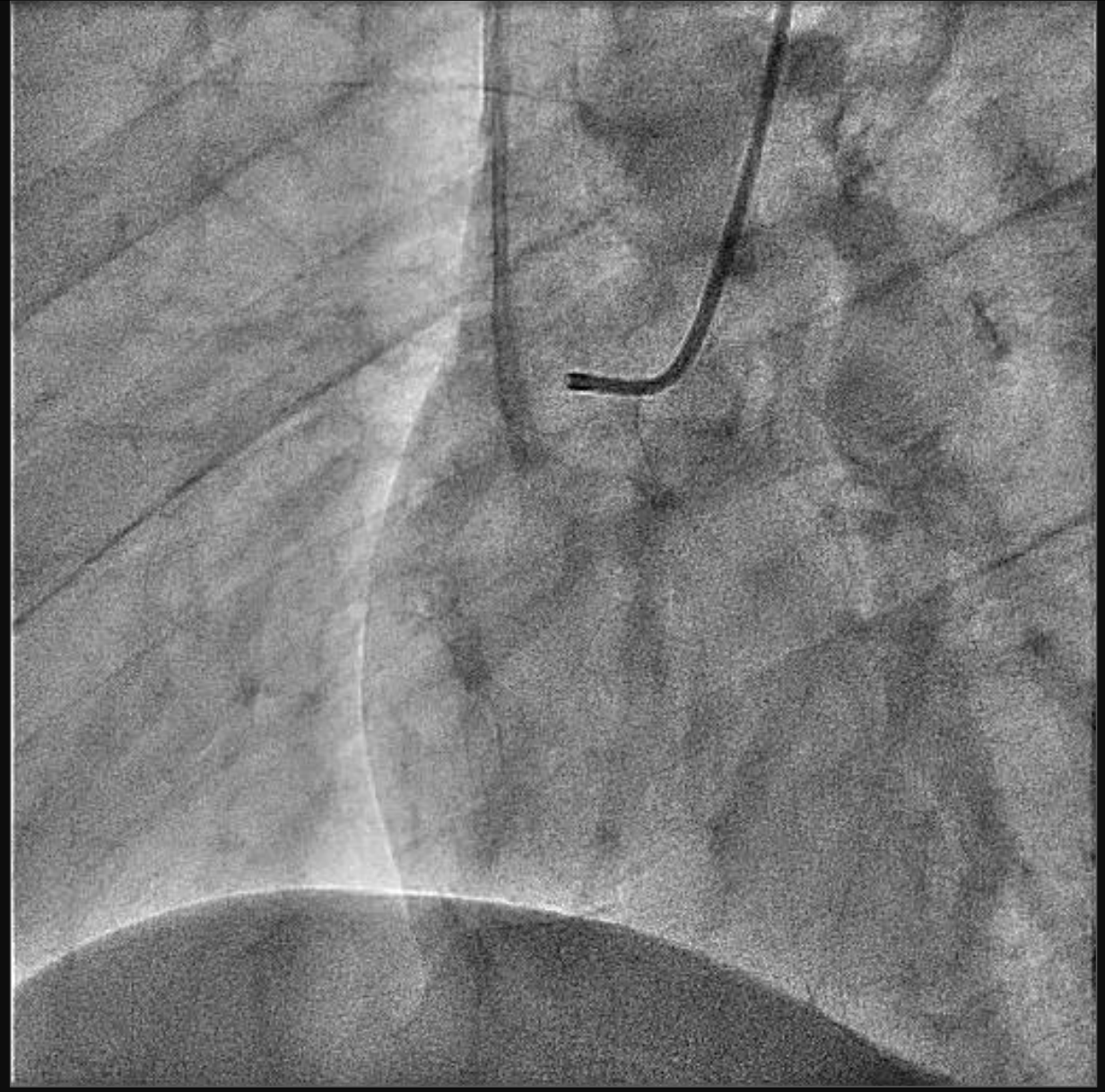
Stable Coronary Artery Disease

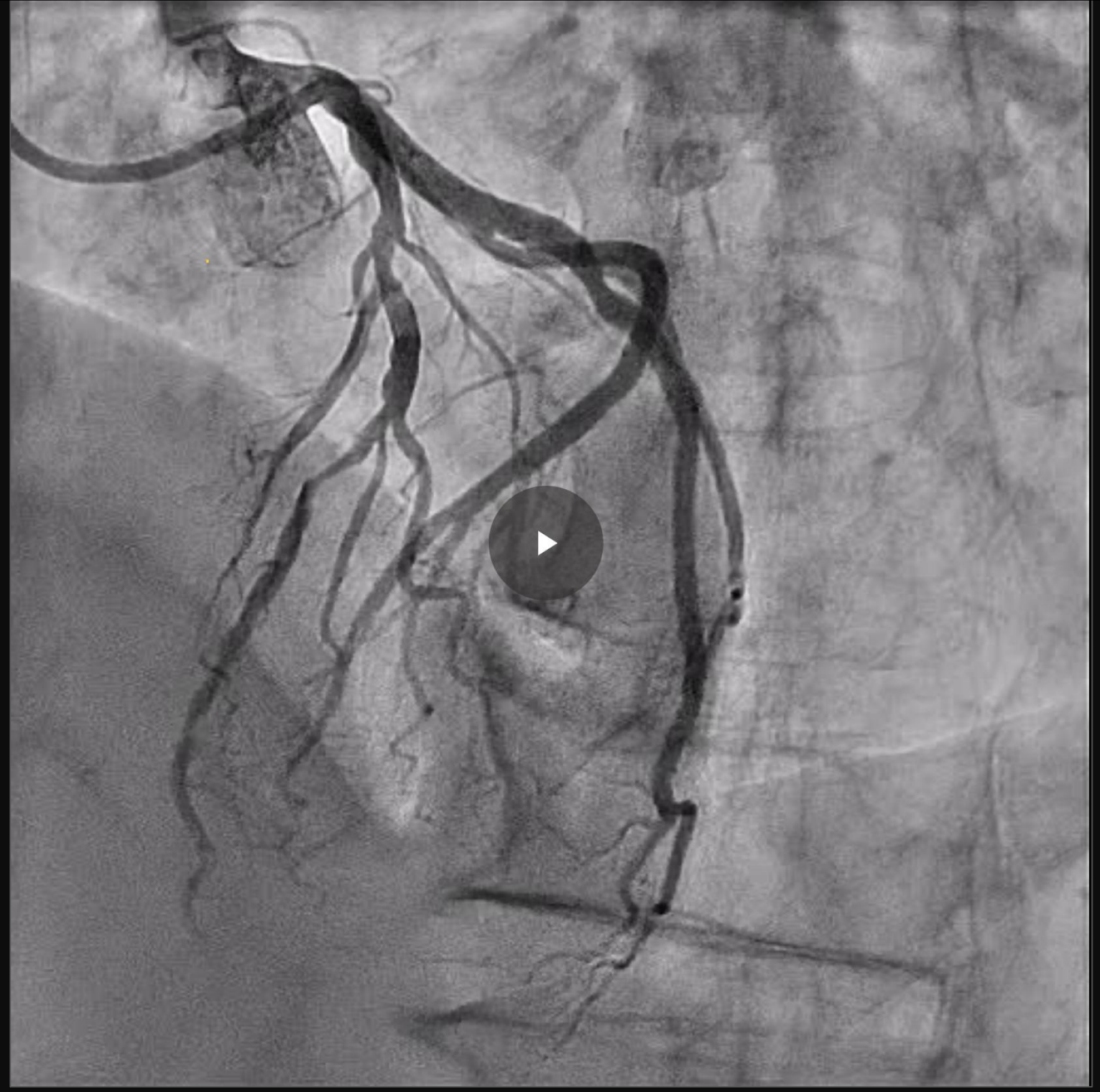
CT study

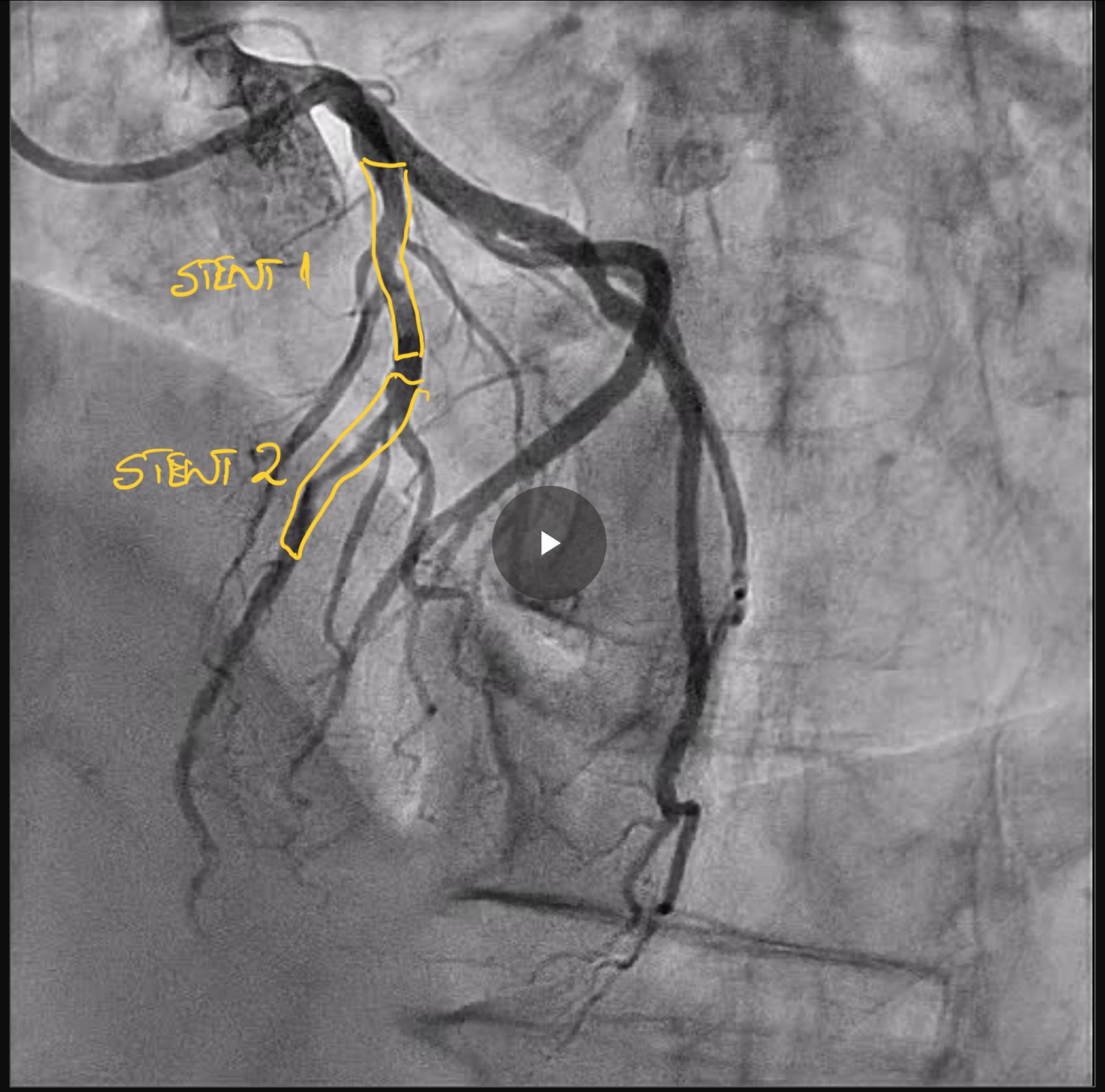


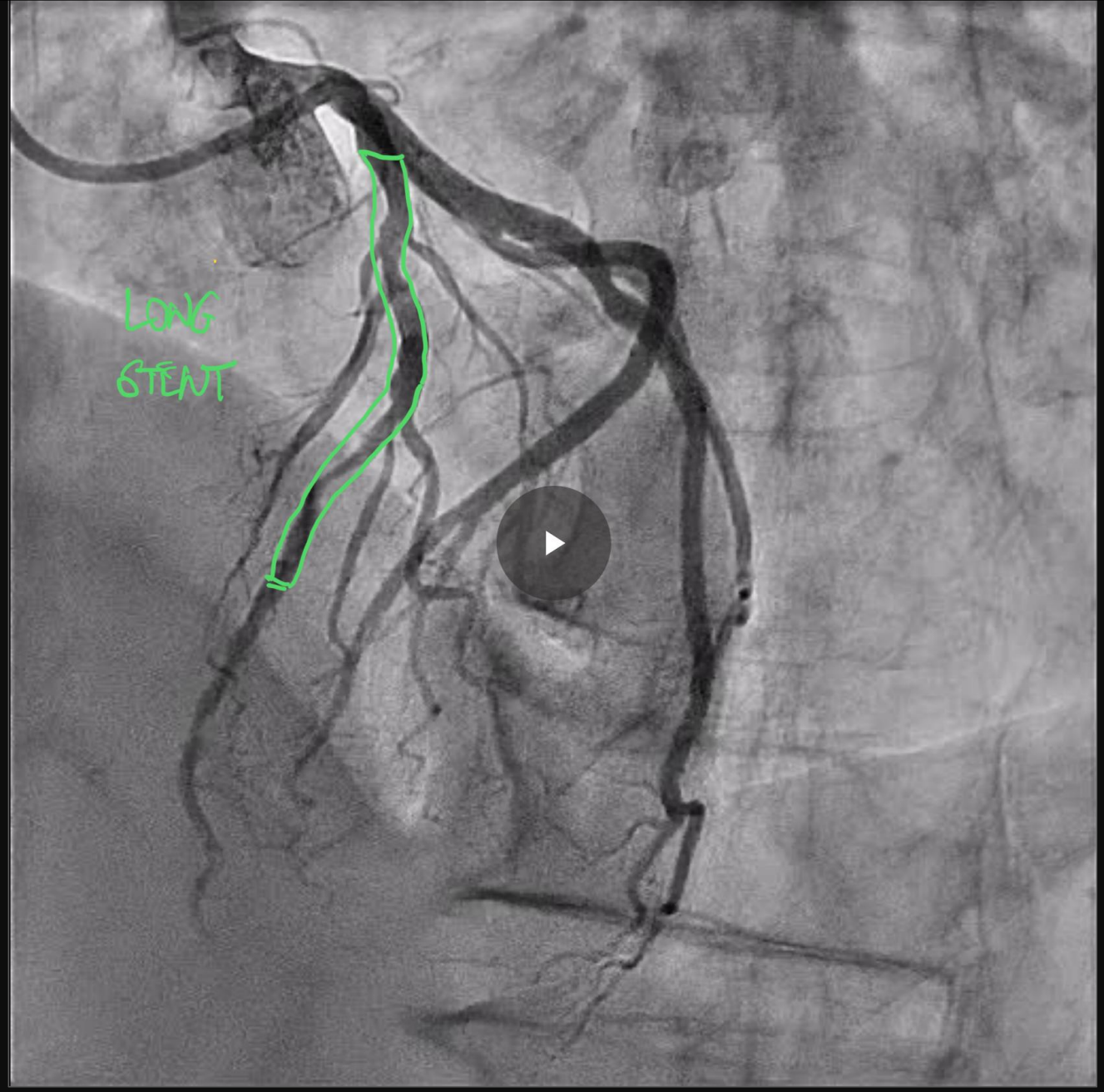


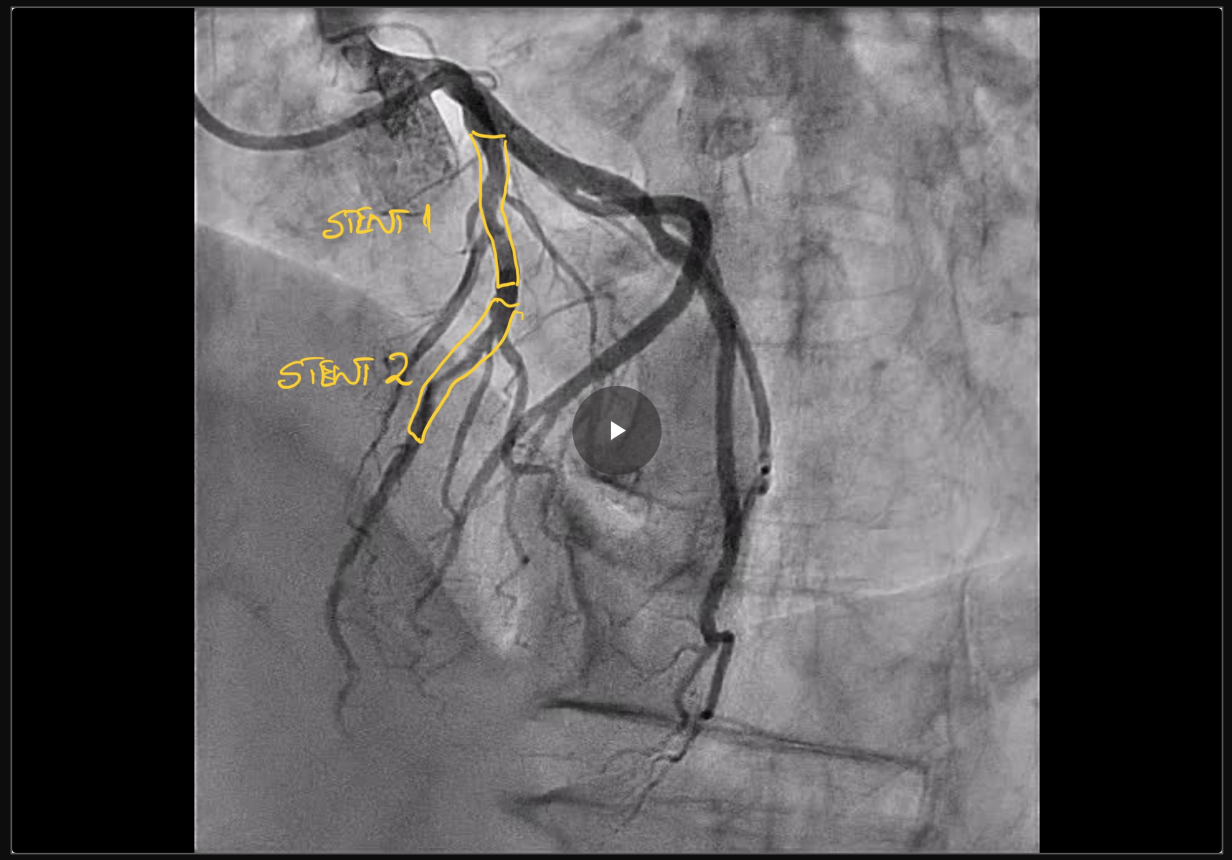


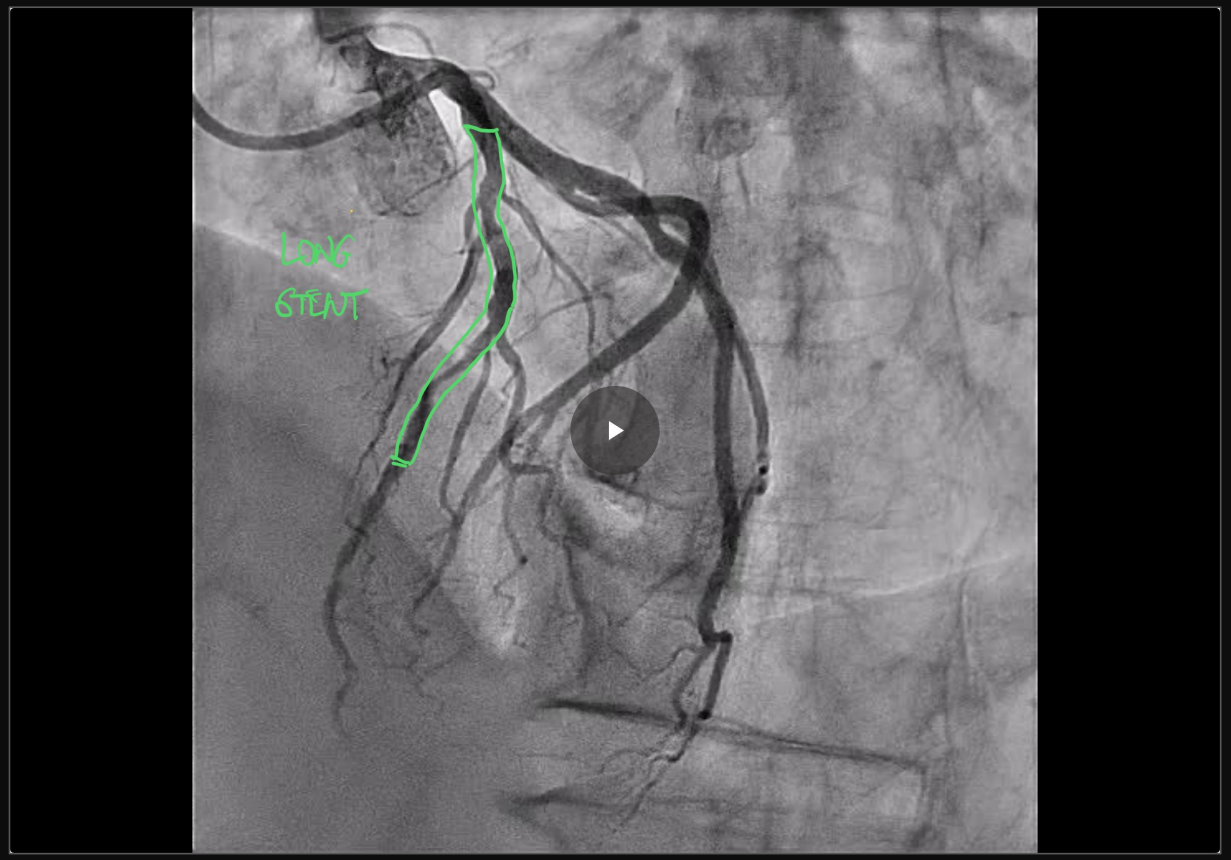


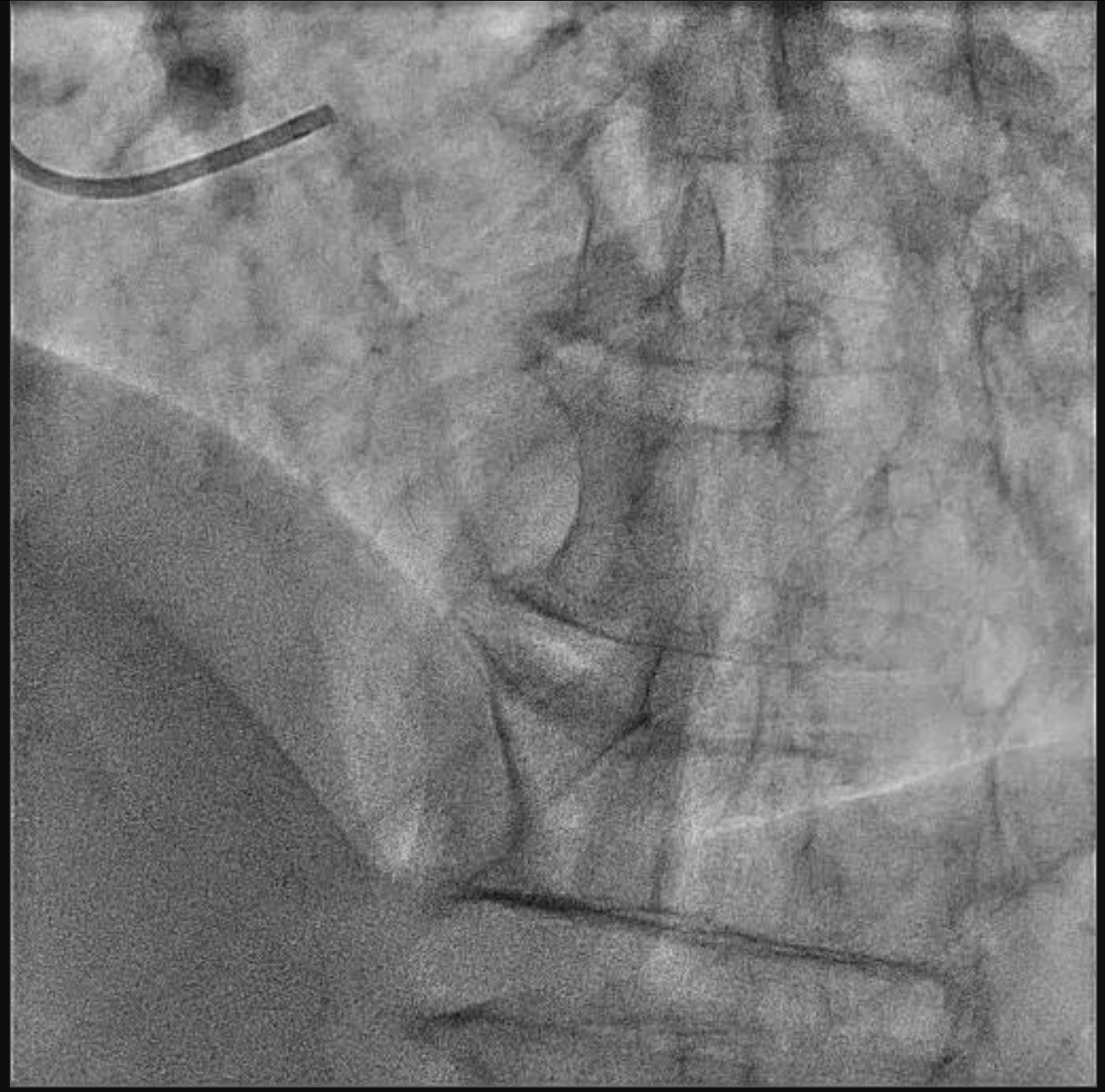


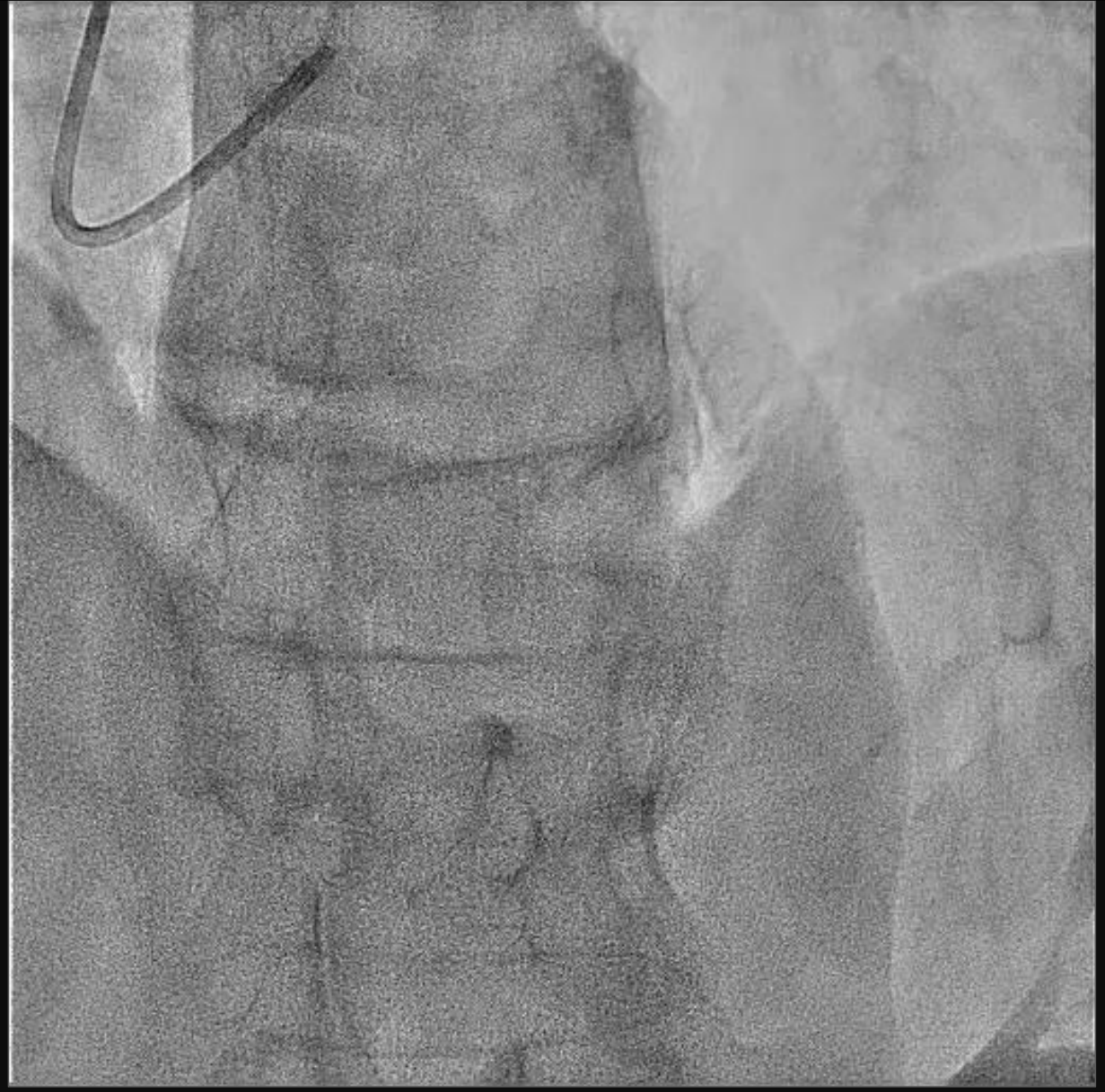

STENT 1
STENT 2

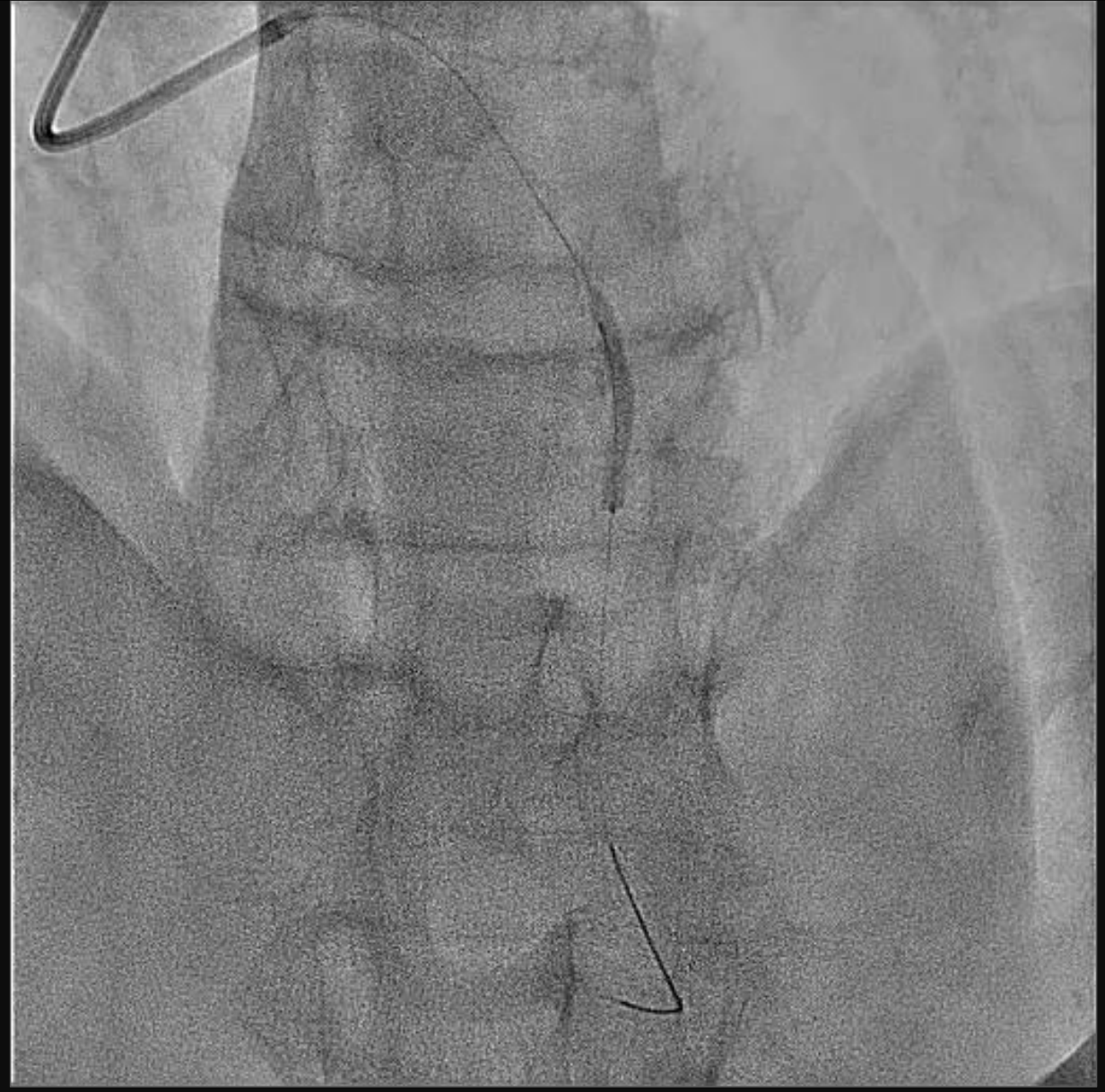

LONG
STENT


STENT 1
STENT 2

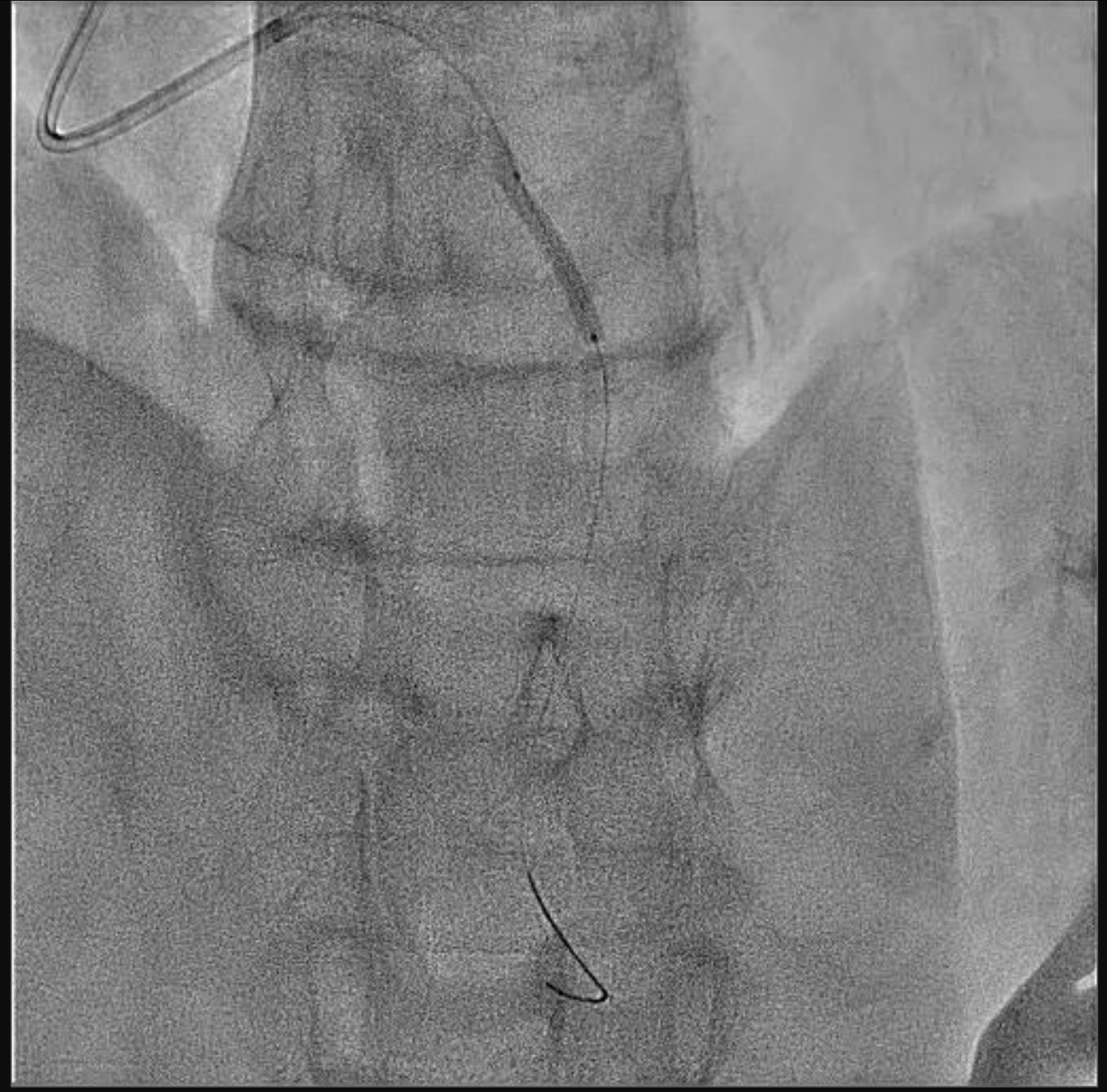

LONG
STENT



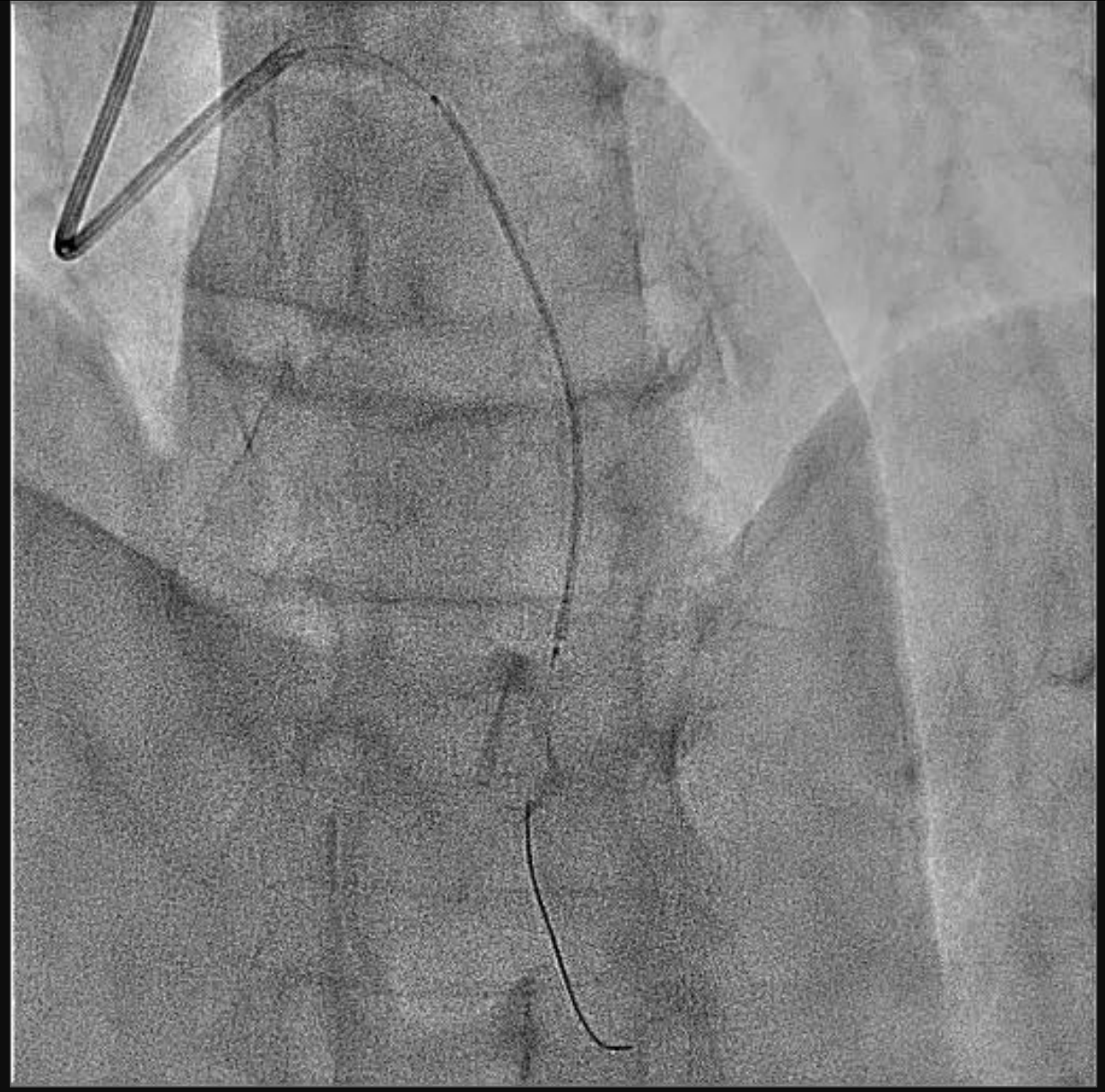




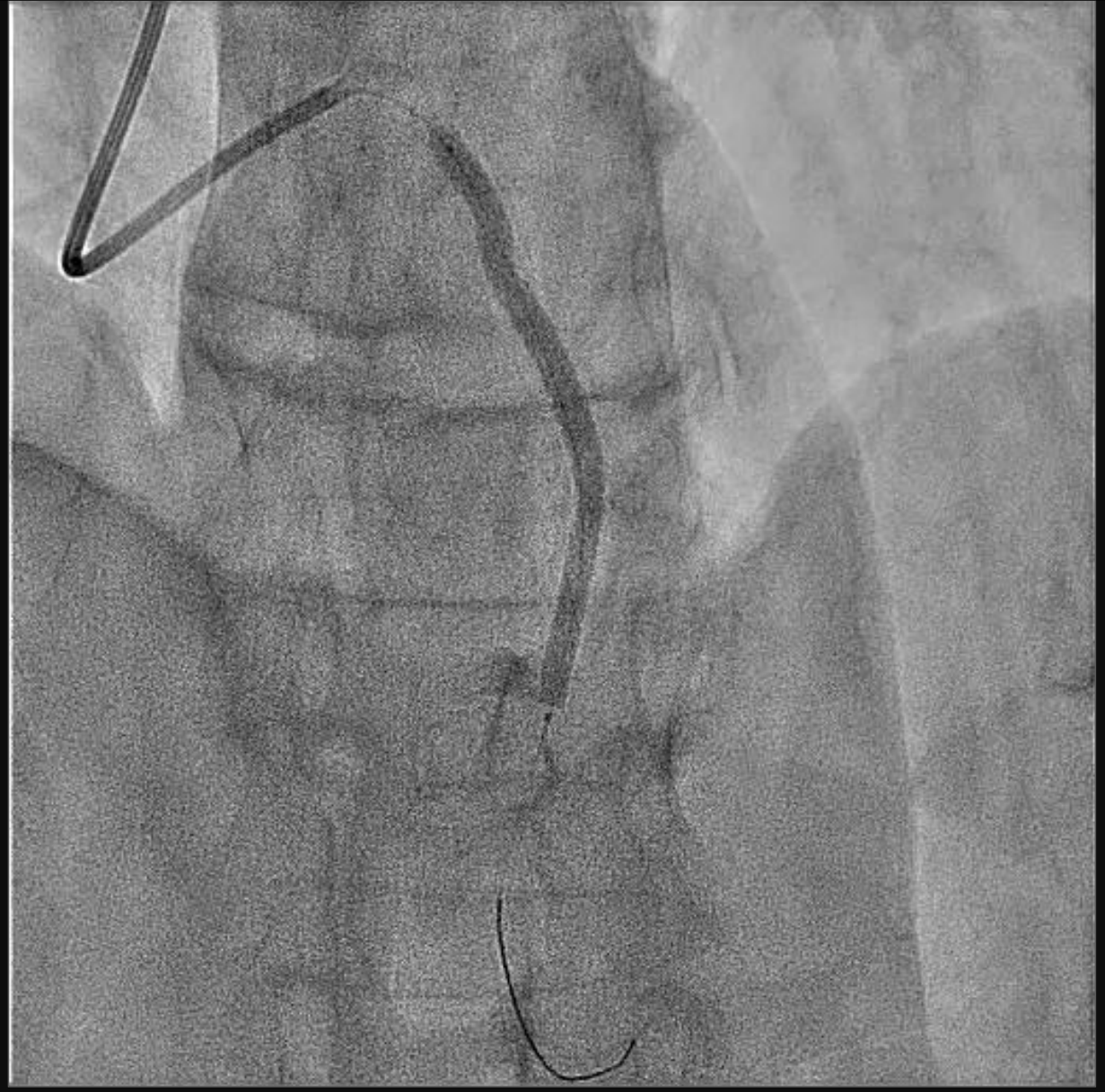
Predilation: Balloon 2,5x20 mm, medial



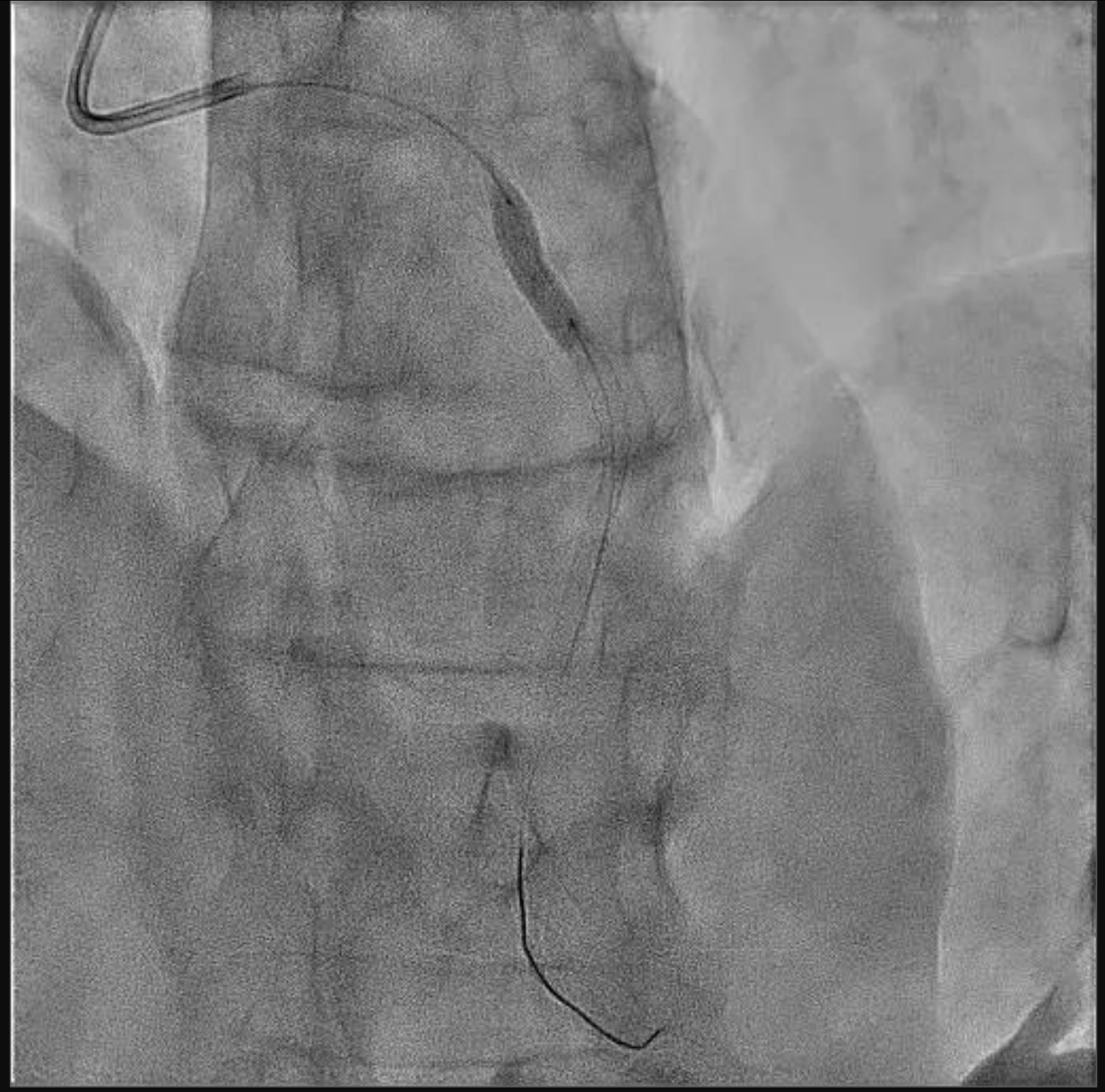
Predilation: Balloon 2,5x20 mm, proximal



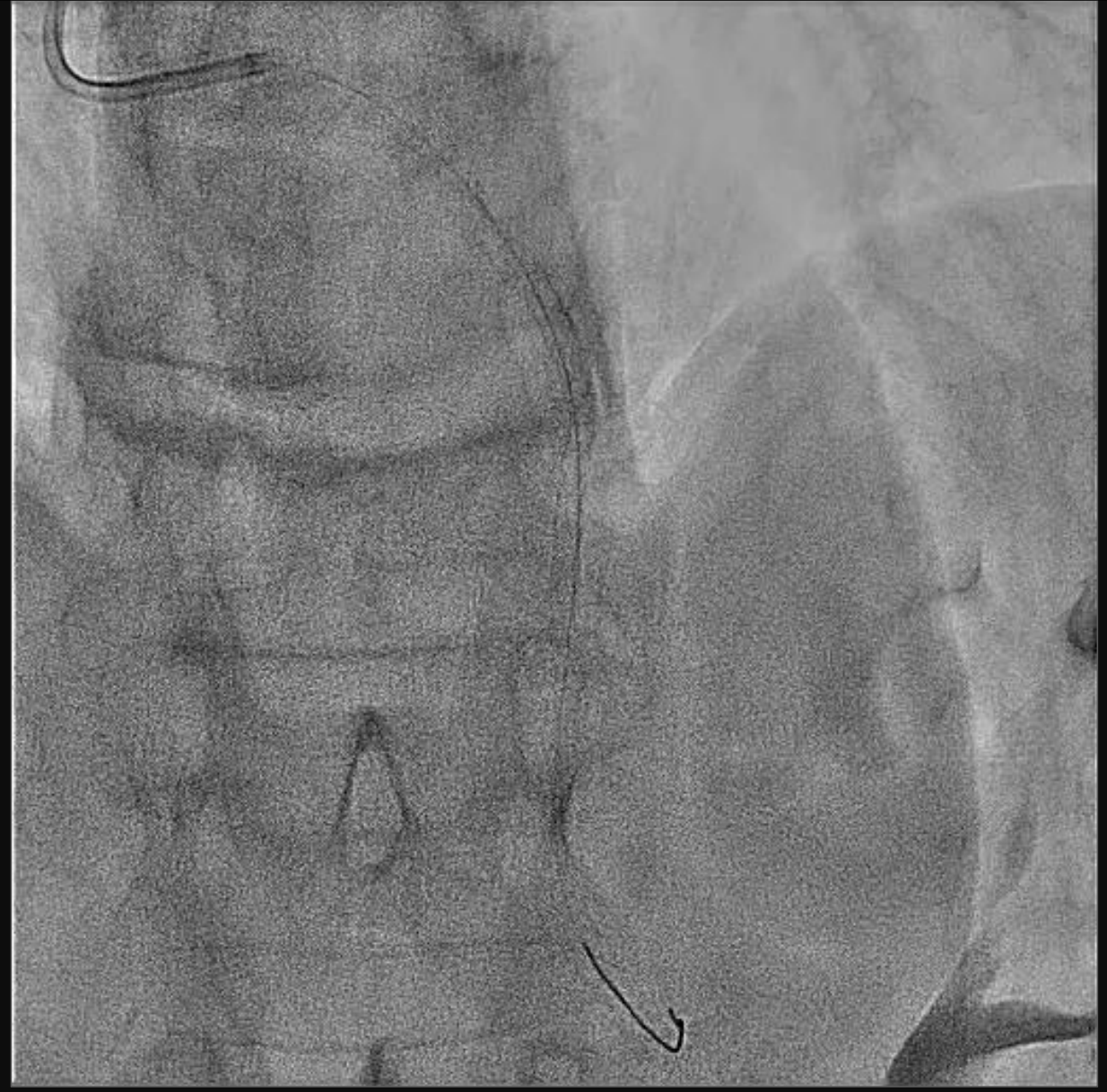
Biomime Morph 3,5-3,0 x 60 mm



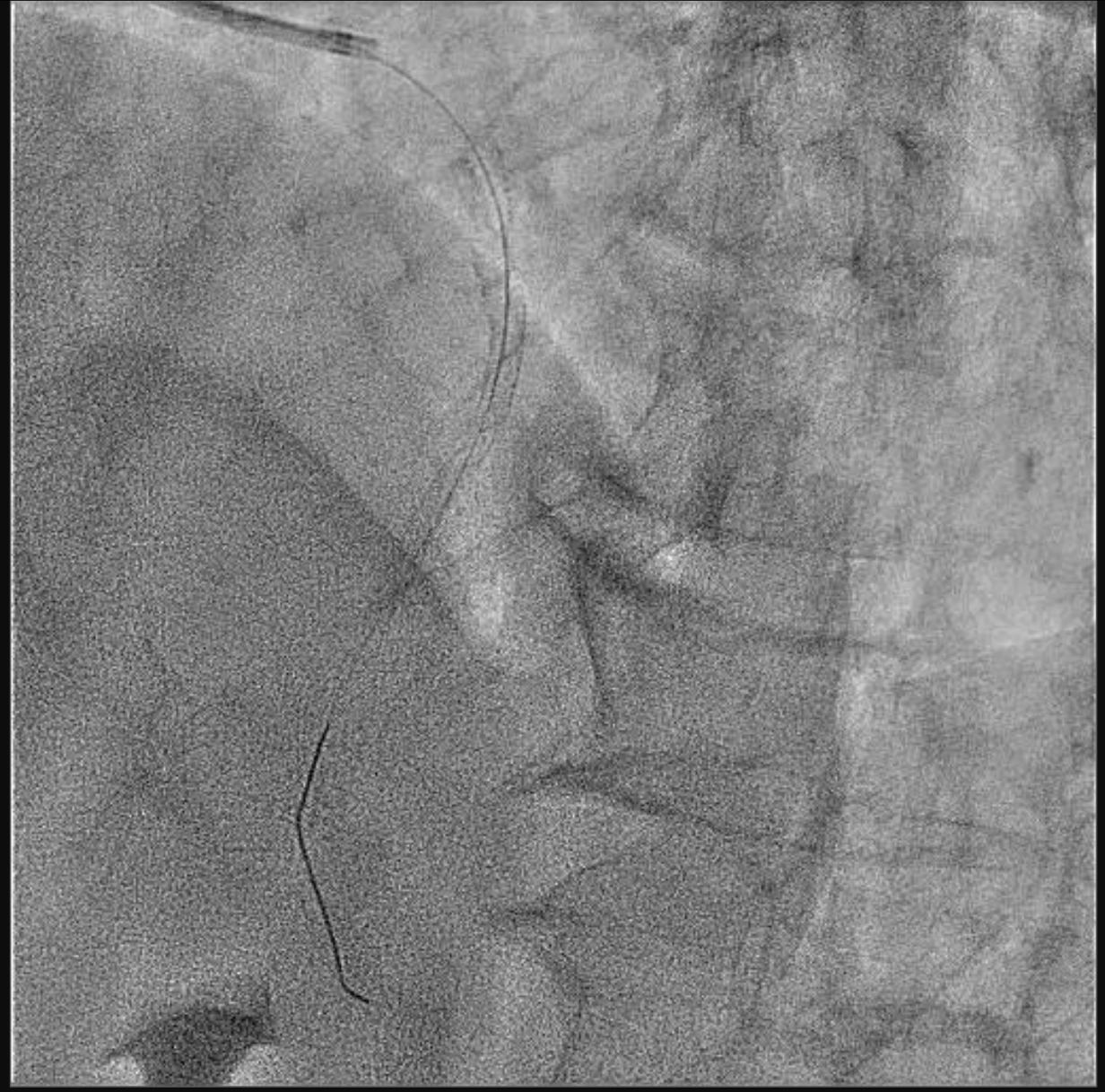
Deployment



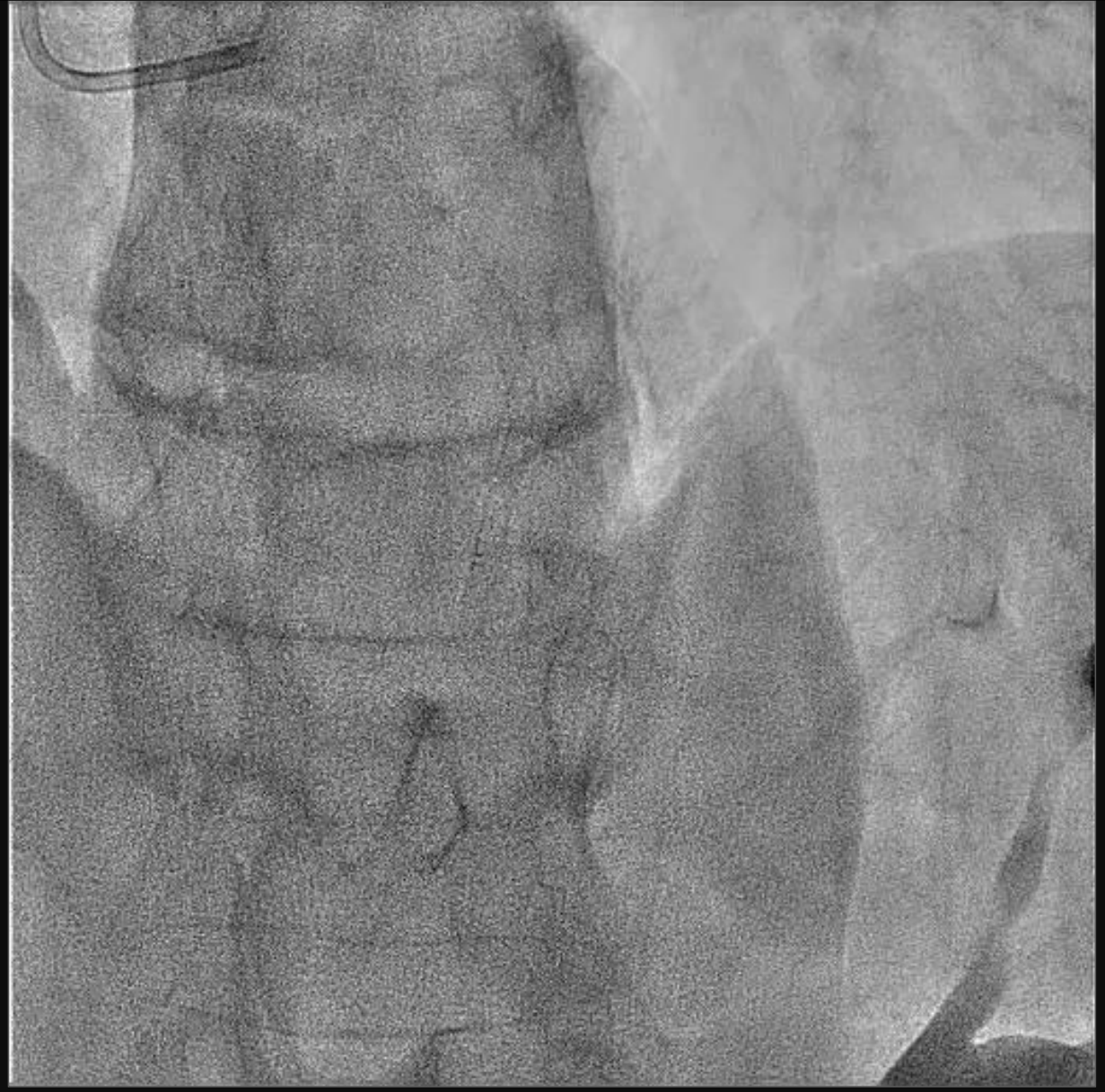
Post-dilation: NC balloon 4,0 x 15 mm



Result



Result



Final Result

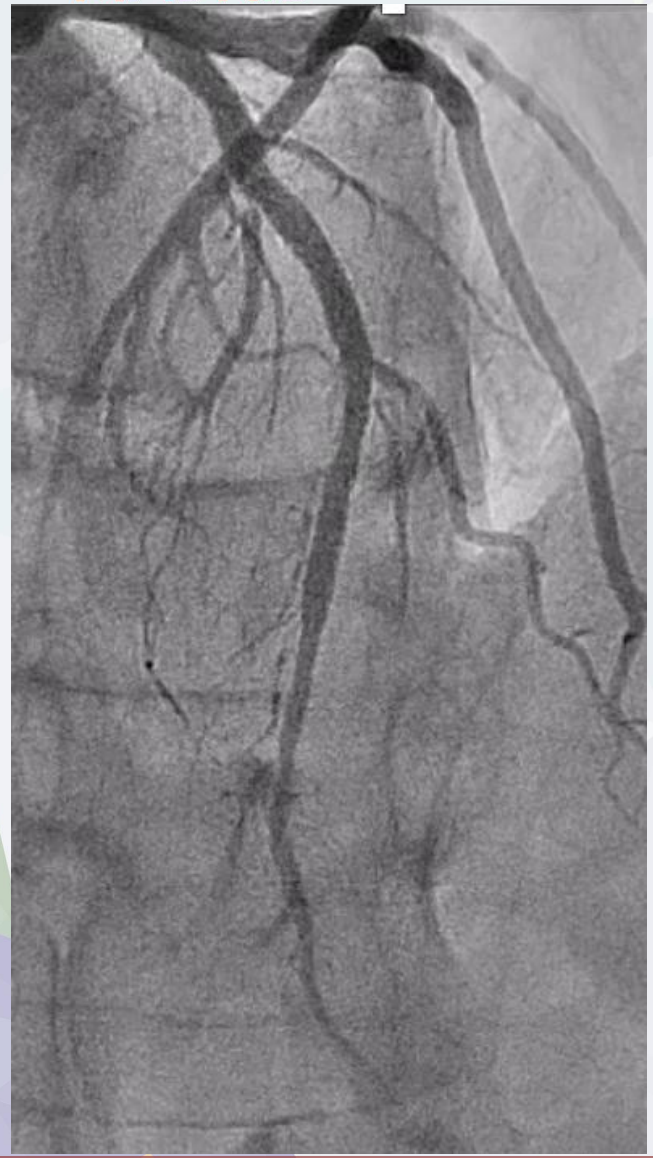
Follow-up: 4 months

Asymptomatic

Included in a Rehabilitation Program

Negative baseline Exercise Test.

Characteristics:



- Navigation
- Adaptation to the vessel
- Side Branch Preservation

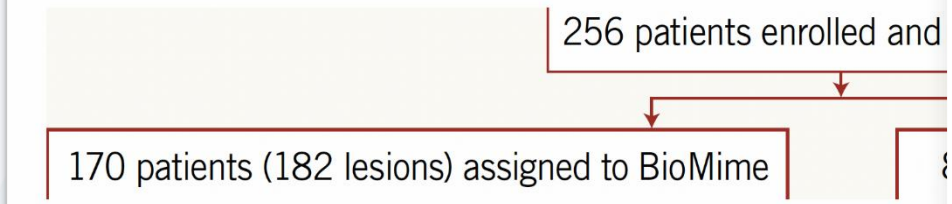
CLINICAL DATA:

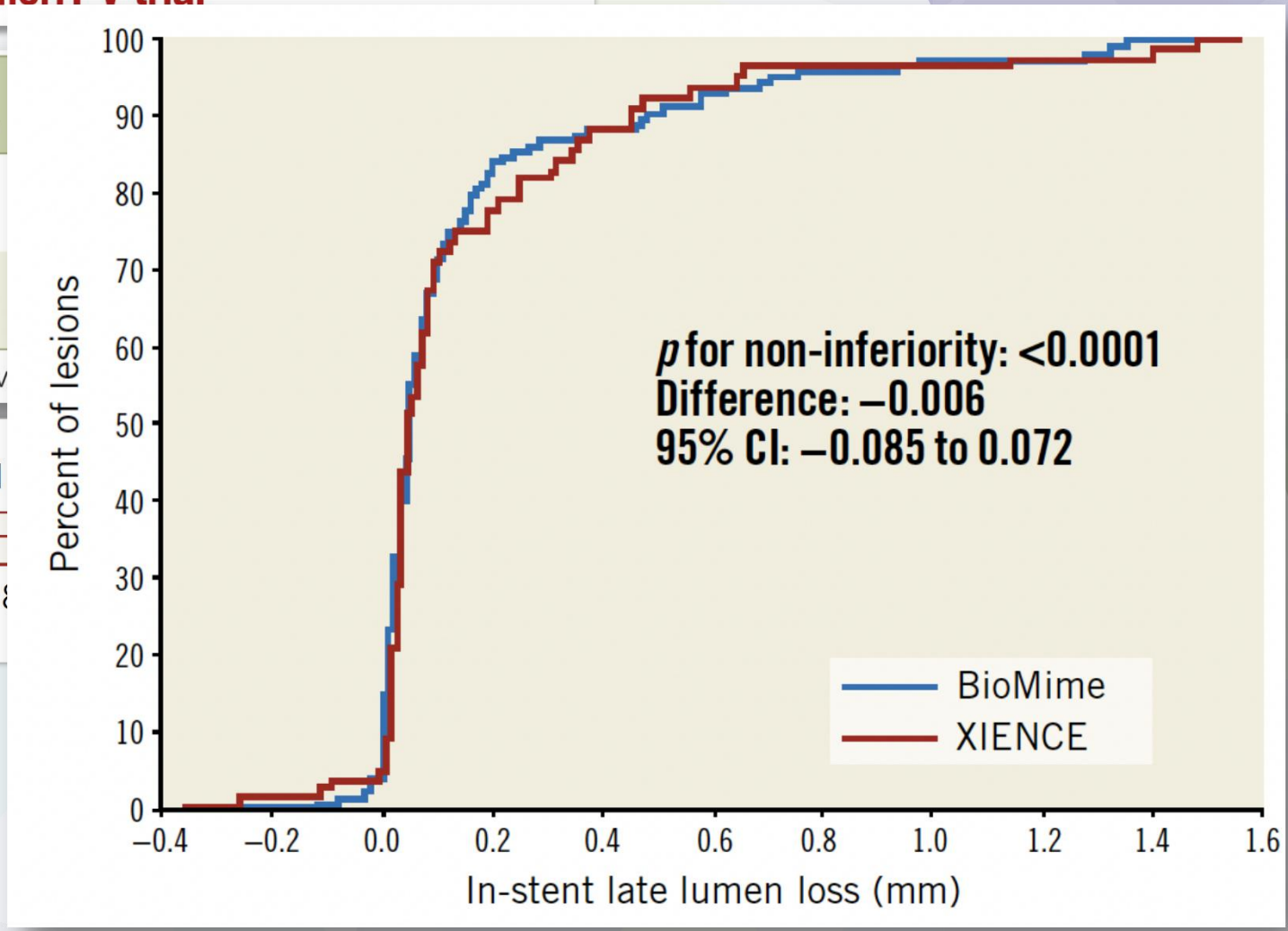
Randomised comparison of a biodegradable polymer ultra-thin sirolimus-eluting stent versus a durable polymer everolimus-eluting stent in patients with de novo native coronary artery lesions: the meriT-V trial

Why Biomime

Stent	Alloy	Strut thickness	Drug (dose density)	Polymer	Coating thickness
XIENCE V (Abbott Vascular)	L605 CoCr	81 µm	Everolimus (1.0 µg/mm^2)	Permanent fluorinated PVDF polymer	7.6 µm
BioMime (Meril Life Science)	L605 CoCr	65 µm	Sirolimus (1.25 µg/mm^2)	PLLA-PLGA	2 µm

DES: drug-eluting stent; PLLA: poly-L-lactic acid; PLGA: poly-lactic co-glycolic acid; PV





Abizaid A et al. *EuroIntervention2018;14*:e1207-e1214

Why Biomime

A Randomized Controlled Trial Comparing BioMime Sirolimus-Eluting Stent With Everolimus-Eluting Stent: Two-Year Outcomes of the meriT-V Trial

Alexandre Abizaid[a, q], Ricardo Costa[b], Sasko Kedev[c], Elvin Kedhi[d], Suneel Talwar[e], Andrejs Erglis[f], Ota Hlinomaz[g], Monica Masotti[h], Farzin Fath-Ordoubadi[i], Krzysztof Milewski[j], Pedro Lemos[a], Roberto Botelho[k], Alexander Ijsselmuiden[l], Jacques Koolen[m], Petr Kala[n], Luc Janssens[o], Udita Chandra[p]

Table 4. Cumulative Clinical Outcomes of Both Study Arms Through the 2-Year Follow-Up

Clinical events	Follow-up						
	In-hospital (N = 256)		1 year (N = 252)		2 years (N = 252)		P-value (at 2 years)
	BioMime (N = 170)	XIENCE (N = 86)	BioMime (N = 168)	XIENCE (N = 84)	BioMime (N = 168)	XIENCE (N = 84)	BioMime vs. XIENCE
Death, n (%)							
Cardiac death	0	0	0	0	0	0	NA
Non-cardiac death	0	0	1 (0.6%)	0	2 (1.19%)	0	0.32
Myocardial infarction	1 (0.59%)	1 (1.16%)	2 (1.19 %)	4 (4.76%)	3 (1.79%)	5 (5.95%)	0.17
ID-TLR	0	0	10 (5.95%)	3 (3.57%)	10 (5.95%)	3 (3.57%)	0.45
ID-TVR (including TLR)	0	0	10 (5.95%)	3 (3.57%)	10 (5.95%)	3 (3.57%)	0.45
ID-TVR (non-TLR)	0	0	4 (2.38%)	2 (2.38%)	4 (2.38%)	2 (2.38%)	0.99
Stent thrombosis, n (%)							
Definite or probable/probable	0	0	0	1 (1.19%)	0	1 (1.19%)	0.16
Total of three-point MACE	1 (0.59%)	1 (1.16%)	11 (6.55%)	7 (8.33%)	13 (7.74%)	8 (9.52%)	0.6170

Values are presented as n (%). ID-TLR: ischemia-driven target lesion revascularization; ID-TVR: ischemia-driven target vessel revascularization; MACE: major adverse cardiac event; N: number of patients.

Original Article Cardiol Res. 2023;14(5):360-369

Long-Term Assessment of Thin-Strut BioMime Coronary Stent System in Real-World Population at Single-Center: A Retrospective Observational Study

Girish Meennahalli Palleda[a, b], Mohit Gupta[a, b, c], Ankit Bansal[a], Vishal Batra[a], Sanjay Tyagi[a], Shekhar Kunal[a]

Stent Length & Events at 4 y

Table 3. Cumulative Major Adverse Cardiac Events at 1-Year to 4-Year Follow-Up

BioMime stent length	1-year		2-year		3-year		4-year	
	≥ 35 mm (n = 393)	< 35 mm (n = 761)	≥ 35 mm (n = 393)	< 35 mm (n = 761)	≥ 35 mm (n = 393)	< 35 mm[a] (n = 760)	≥ 35 mm (n = 393)	< 35 mm[a] (n = 755)
All-death	12 (3.0)	13 (1.7)	21 (5.3)	26 (3.4)	20 (5.1)	33 (4.3)	26 (6.6)	43 (5.7)
Cardiac	3 (7.6)	4 (0.5)	5 (1.3)	8 (1.0)	5 (1.3)	9 (1.2)	7 (1.8)	14 (1.9)
Non-cardiac	9 (2.3)	9 (1.2)	16 (4.1)	18 (2.4)	15 (3.8)	24 (3.1)	19 (4.8)	29 (3.8)
MI								
TVMI	0	0	0	0	0	0	0	0
Non-TVMI	0	1 (0.1)	0	1 (0.1)	0	1 (0.1)	0	1 (0.1)
TLR	0	0	2 (0.5)	2 (0.3)	2 (0.5)	8 (1.0)	2 (0.5)	16 (2.1)
TVR	0	0	4 (1.0)	3 (0.4)	4 (1.0)	13 (1.7)	4 (1.0)	23 (3.0)
ST	1 (0.3)	2 (0.3)	1 (0.3)	2 (0.3)	1 (0.3)	2 (0.3)	1 (0.3)	2 (0.3)
MACE	3 (0.8)	4 (0.5)	8 (2.0)	9 (1.2)	8 (2.0)	17 (2.2)	10 (2.5)	23 (3.0)

[a]Lo ves car

Comparison of clinical outcomes between very long stents and overlapping stents for the treatment of diffuse coronary disease in real clinical practice☆

Alfonso Jurado-Román [a,*], José Abellán-Huerta [a], Juan Antonio Requena [b], Ignacio Sánchez-Pérez [a],

Morph & Safety

	Single very long stent n = 232 lesions (224 patients)	Overlapping stents n = 343 lesions (341 patients)	p
Treated vessel			
LM	2 (0.9%)	8 (2.3%)	0.49
LAD	99 (42.7%)	137 (39.9%)	
LCx	27 (11.6%)	60 (17.5%)	
RCA	102 (43.9%)	135 (39.4%)	
Other	2 (0.9%)	3 (0.9%)	
Predilatation	180 (77.6%)	280 (81.6%)	0.5
Postdilatation	85 (36.6%)	124 (36.1%)	0.2
Duration of procedure (min)	38.8 ± 19	47 ± 22	<0.0001
FT (min)	16.2 ± 8.8	20.4 ± 13.4	<0.0001
Contrast volume (ml)	273 ± 127	309 ± 115	0.002
Angiographic success	228 (98.3%)	340 (99.1)	0.45

	Single very long stent n = 232 lesions (224 patients)	Overlapping stents n = 343 lesions (341 patients)	p
Duration of procedure (min)	38.8 ± 19	47 ± 22	<0.0001
FT (min)	16.2 ± 8.8	20.4 ± 13.4	<0.0001
Contrast volume (ml)	273 ± 127	309 ± 115	0.002

CONCLUSION:

SQDC applied to PCI procedures

S	SAFETY	Avoid Complications during PCI	• Decrease in fluoroscopic time • Decrease in Contrast amount • Decrease in Procedural Time
Q	QUALITY	Check you Results	• Good experience in our centre • Clinical results comparable with gold standard (clinical studies)
D	DELIVERY	Efficiency	• More safety: early discharge • Send the patient to referral centres
C	COSTS	Decrease Costs	• Decrease in number of stent implanted

Thank you very much

CSC 2025

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