

Why Do I Love to Use DCB ?

Case-based story

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RIGHT CASE
RIGHT TIME
PREVAIL

Prevail™
Paclitaxel Coated PTCA
Balloon Catheter



RIGHT CASE RIGHT TIME

In-stent restenosis and small vessel treatment are prevalent clinical needs:

- **30–40%** of eligible PCIs involve small vessels <2.75 mm¹
- **5–12%** of eligible PCIs involve in-stent restenosis with a drug-eluting stent²

When stenting is not an option for your patient, a drug-coated balloon offers:

- An effective treatment³
- A safe alternative to a permanent implant⁴



¹ Siontis GCM, et al. *JACC Cardiovasc Interv.* 2016;9:1324-1334.
² Cassese S, et al. *Heart.* 2014;100:153-159.
³ Jeger RV, et al. *JACC Cardiovasc Interv.* 2020;13:1391-1402.
⁴ Latib A, et al. *J Am Coll Cardiol.* 2012;60:2473-2480.

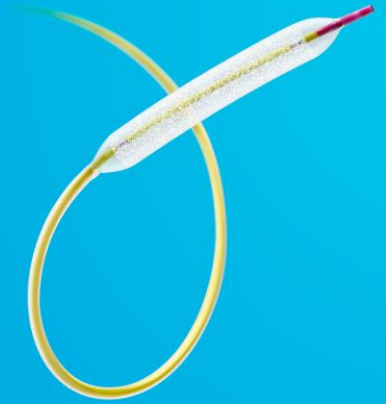
RIGHT CASE RIGHT TIME PREVAIL

Prevail™

Paclitaxel Coated PTCA Balloon Catheter

Prevail DCB offers the performance you want for treating complex lesions¹:

- **Superior deliverability²**
— deliberately designed to maximise pushability
- **Rapid absorption of paclitaxel¹**
— facilitated by biocompatible urea excipient³
- **Excellent safety and efficacy**
— demonstrated in the IN.PACT Falcon clinical program; confirmed by the PREVAIL Study⁴



¹Third-party brands are trademarks of their respective owners.

²Prevail Instructions for Use.

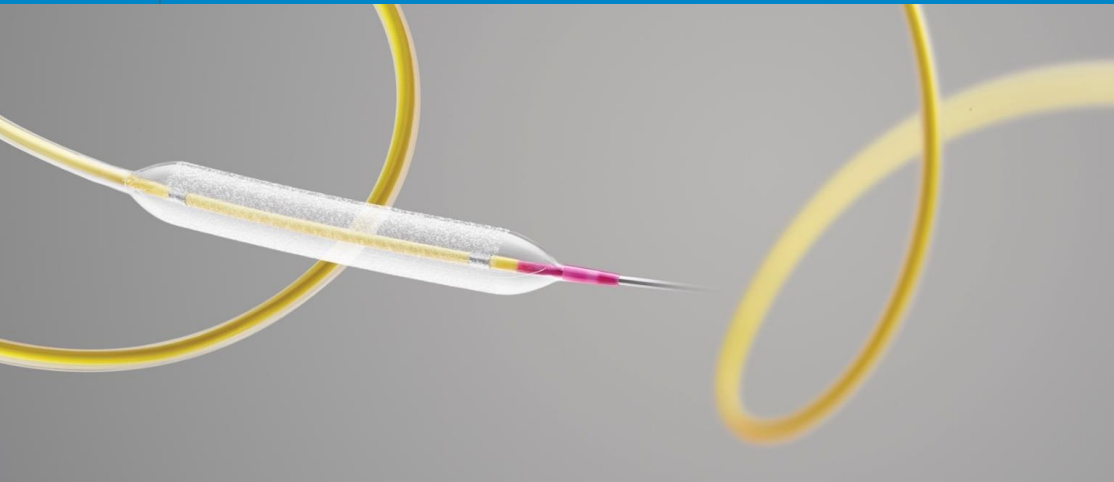
³Compared with IN.PACT Falcon™ DCB, SeQuent™ Please NEO DCB Agent™ DCB and MagicTouch™ DCB. Deliverability defined as pushability. Based on bench test data, 2020. Bench test data may not be indicative of clinical performance.

⁴Chang GH et al. *Scientific Reports*. May 2, 2019;9(1):6839.

⁵Latib A, et al. *J Invasive Cardiol*. Published online August 19, 2021. PREVAIL study did not have powered endpoints. Prevail DCB and IN.PACT Falcon DCB uses the same drug coating.

AN ADDITIONAL TOOL FOR COMPLEX PCI ENHANCED ENGINEERING PLUS PROVEN FREEPAC™ COATING¹

Enhanced delivery system† and hydrophilic coating



PowerTrac™ technology combined with a hydrophilic coating facilitates superior deliverability and device performance.²

* Third-party brands are trademarks of their respective owners.

† Compared to IN.PACT™ Falcon DCB.

¹ Virmani R. Arterial wall response to drug-coated balloons. *Confluence* September 2016; 13: 15–19.

² Compared with IN.PACT Falcon DCB, SeQuent™ Please NEO DCB, Agent™ DCB, and MagicTouch® DCB. Deliverability defined as a pushability. Based on bench test data, 2020. Bench test data may not be indicative of clinical performance.

³ PS762 preclinical study report: An Evaluation of the Medtronic Drug Coated Coronary Balloon Catheter in a Porcine Artery Model, 2016. On file at Medtronic.

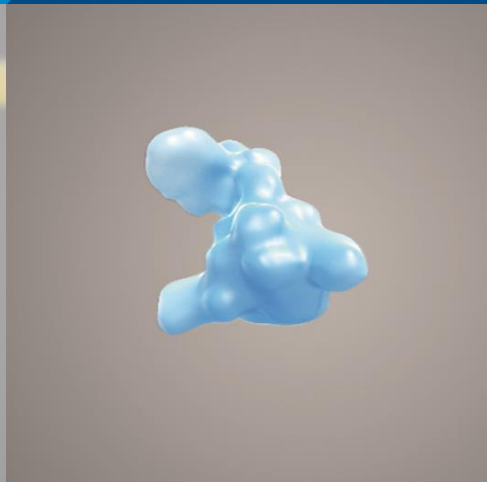
⁴ Cremers B, et al. *Minerva Cardioangiol* 2010; Oct;58(5):583–8.

⁵ Chang GH et al. *Scientific Reports*. May 2, 2019;9(1):6839.

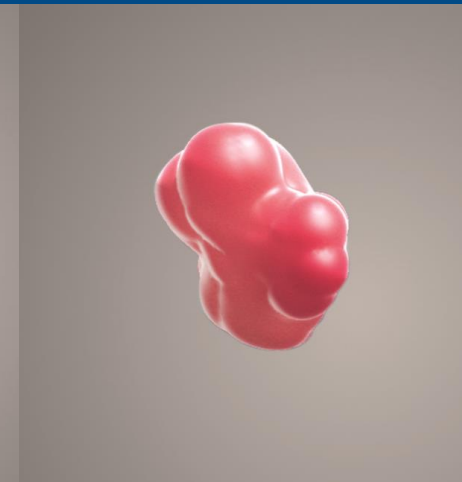
⁶ Prevail Instructions for Use

⁷ Latib A, et al. *J Invasive Cardiol*. Published online August 19, 2021. PREVAIL study did not have powered endpoints. UC202014514b ML

FreePac coating



Paclitaxel drug — potent antiproliferative drug persists in the tissue throughout the healing process.^{3,4}



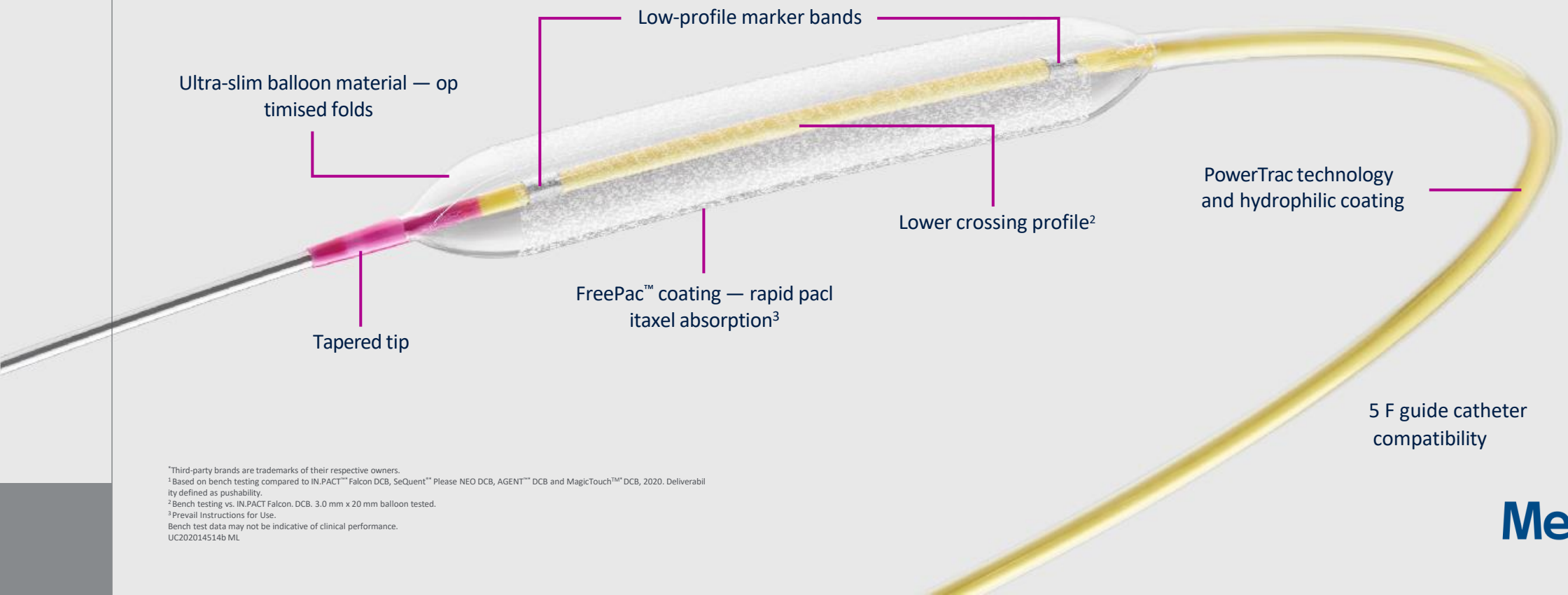
Urea excipient — highly biocompatible excipient enables rapid drug transfer to the vessel wall within 30–60 seconds.^{5,6}

Clinical benefits

At 6 months in PREVAIL clinical trial⁷:

- Very low angiographic late loss (**0.05 ± 0.44 mm**)⁷
- Low **4.0% TLR**⁷

POWERTRAC™ TECHNOLOGY AND HYDROPHILIC COATING ENABLE SUPERIOR DELIVERABILITY¹

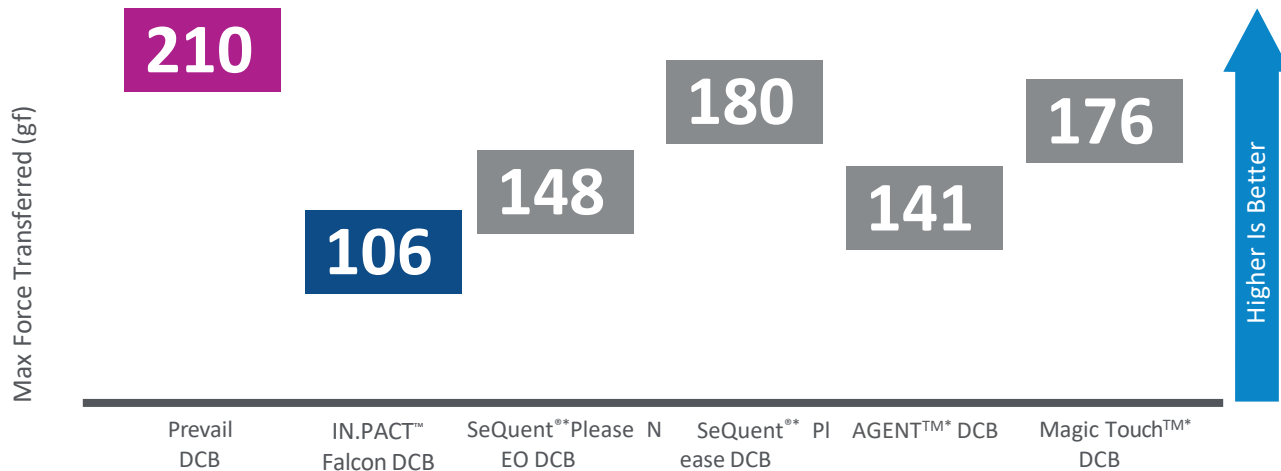


¹Third-party brands are trademarks of their respective owners.
²Based on bench testing compared to IN.PACT™ Falcon DCB, SeQuent™ Please NEO DCB, AGENT™ DCB and MagicTouch™ DCB, 2020. Deliverability defined as pushability.
³Bench testing vs. IN.PACT Falcon, DCB. 3.0 mm x 20 mm balloon tested.
⁴Prevail Instructions for Use.
Bench test data may not be indicative of clinical performance.
UC202014514b ML

Significantly greater pushability for tortuous anatomies

SUPERIOR DELIVERABILITY¹

PUSHABILITY¹



Prevail DCB is

2x

more pushable vs. IN.PACT Falcon DCB[†]

[†]Third-party brands are trademarks of their respective owners.

[†]99% improved push force compared to IN.PACT Falcon DCB.

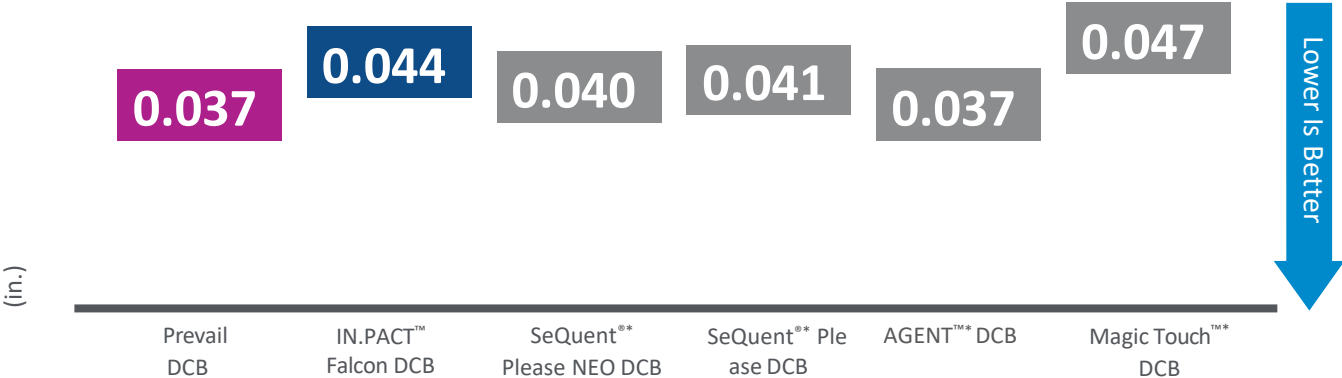
¹ Bench testing vs. IN.PACT Falcon DCB, SeQuent Please NEO DCB, SeQuent Please DCB, AGENT DCB, and Magic Touch™ DCB, 2020.

3.00 mm x 20 mm balloon tested. Bench test data may not be indicative of clinical performance.

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LOW CROSSING PROFILE FOR EXCEPTIONAL CROSSABILITY¹

CROSSING PROFILE[†]

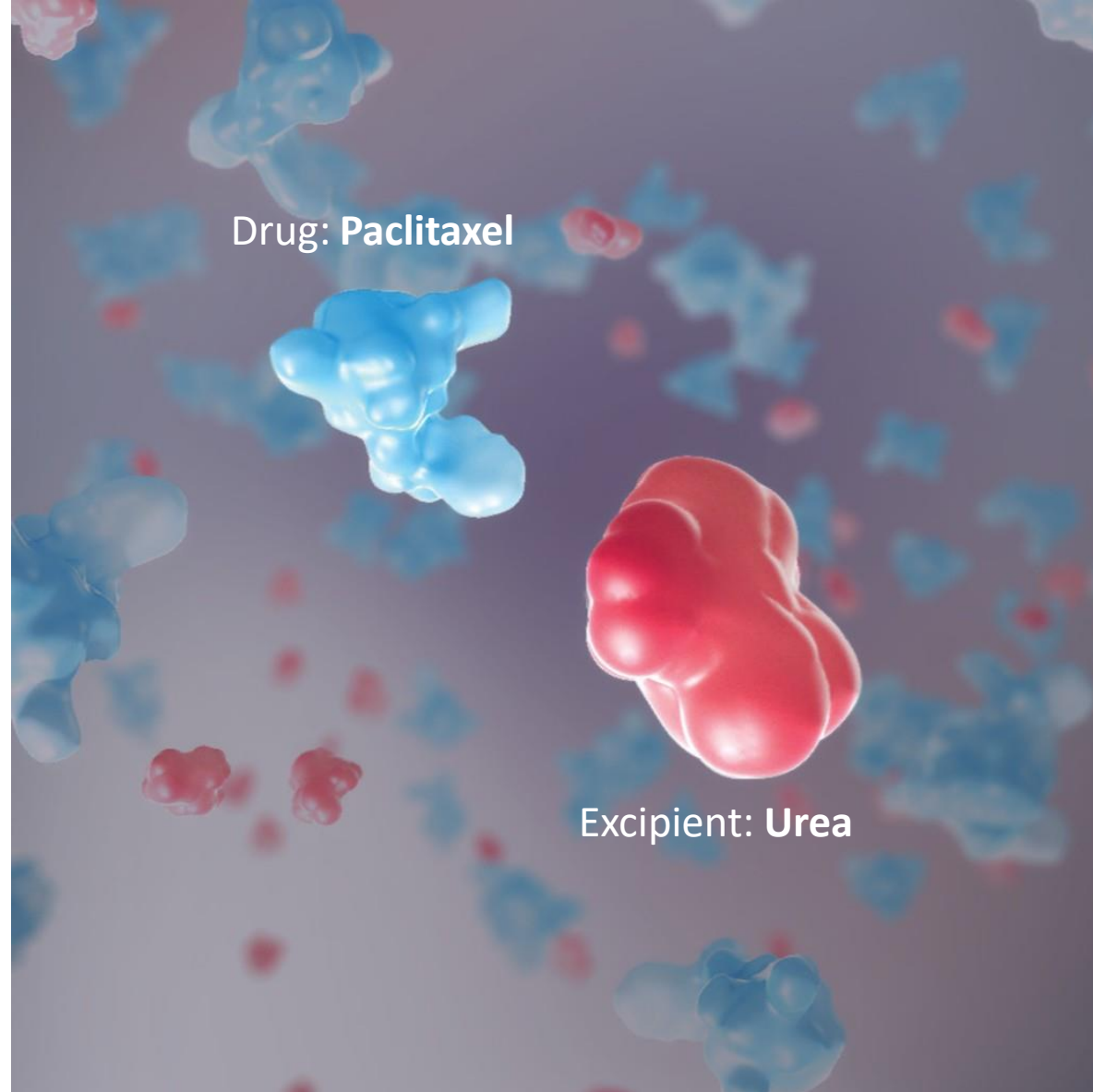


[†]Third-party brands are trademarks of their respective owners.
[†]Crossing profile is a measurement of five locations along balloon (distal bond, distal crossing profile, middle crossing profile, proximal crossing profile, and proximal bond).
[†]Bench testing vs. IN.PACT Falcon™ DCB, SeQuentPlease NEO DCB, SeQuentPlease DCB, AGENT DCB, and Magic Touch DCB, 2020. 3.00 mm x 20 mm balloon tested. Bench test data may not be indicative of clinical performance.
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AN OPTIMISED PARTNERSHIP

FreePac™ coating combines two proven¹ components that work together:

- **Paclitaxel** — potent antirestenotic drug²
- **Urea** — biocompatible excipient that enables rapid drug delivery^{3,4}



FreePac Coating

Medtronic

¹Virmani R. Arterial wall response to drug-coated balloons Confluence September 2016: 13: 15–19.

² Cremers B, et al. *Minerva Cardioangiol* 2010; Oct;58(5):583–538.

³ Prevail Instructions for Use.

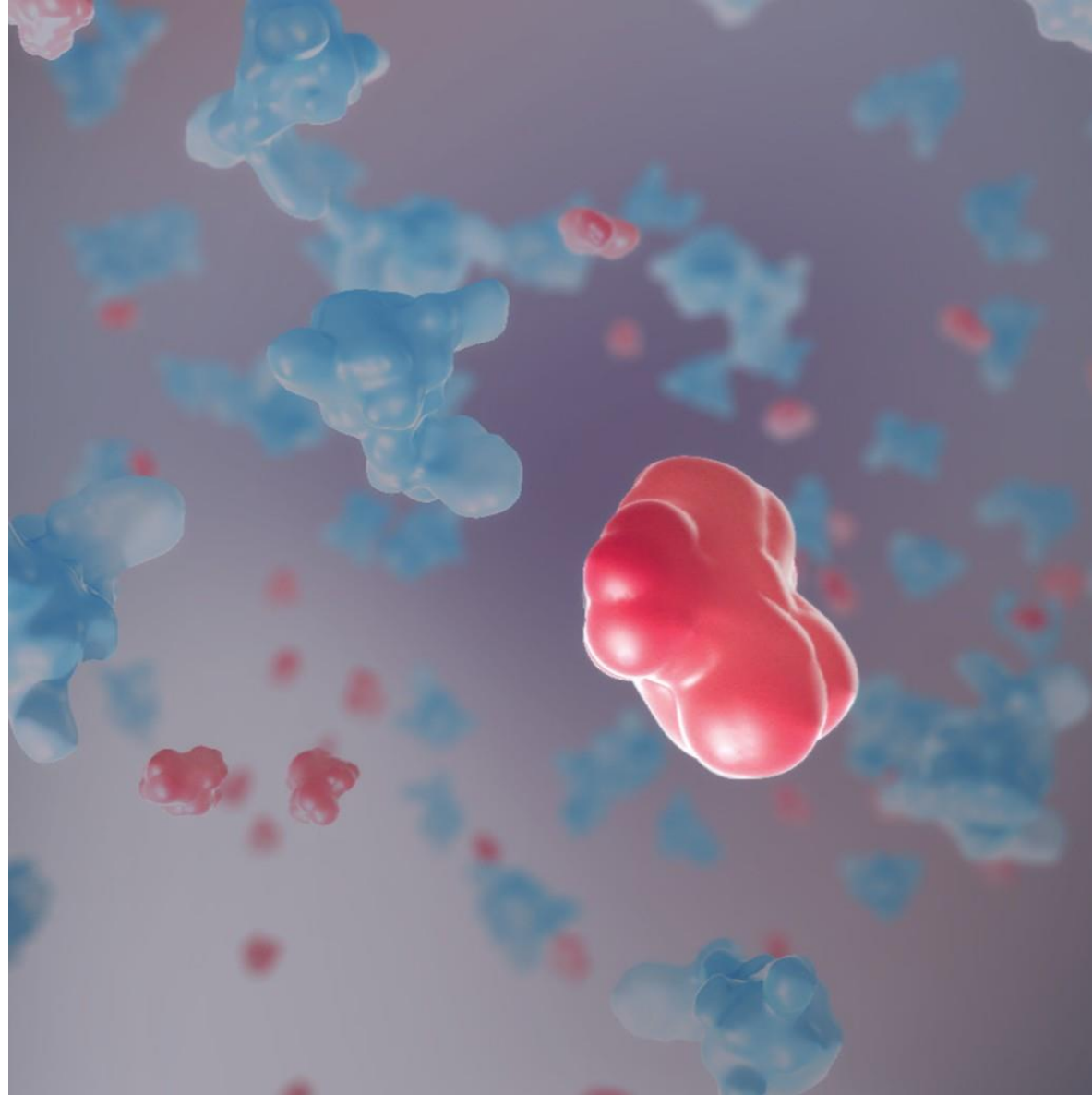
⁴ Chang GH et al. *Scientific Reports*. May 2, 2019;9(1):6839.

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THE ONLY DCB WITH UREA*¹

Urea excipient:

- Is a biocompatible naturally occurring molecule²
- Plays a critical role in delivering solid-phase drug to the tissue
- Enables rapid drug transfer to the vessel wall within 30–60 seconds³



Urea Excipient

Medtronic

*Refers to the Medtronic DCB family.

¹ Granada, J. *Cardiac Interventions Today*. May/June 2010: 35-40.

² Chang GH et al. *Scientific Reports*. May 2, 2019;9(1):6839.

³ Prevail Instructions for Use.

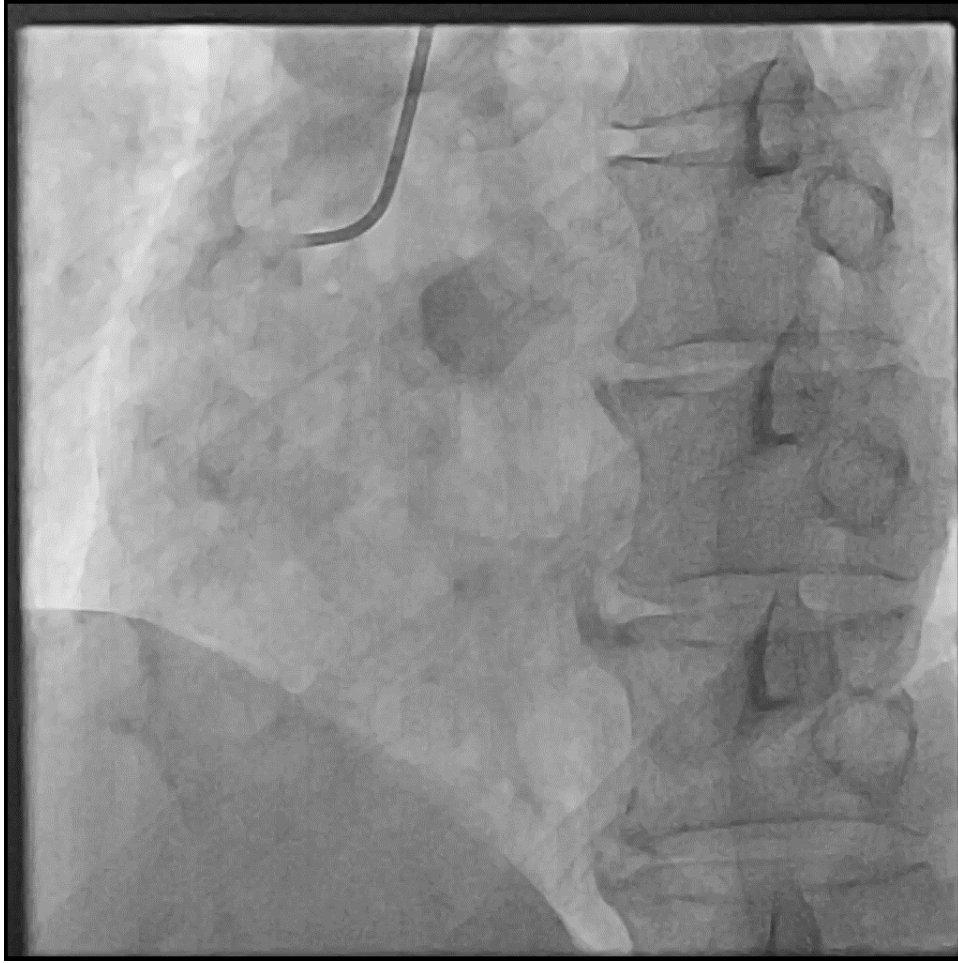
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My “DCB” recipe in my daily practice

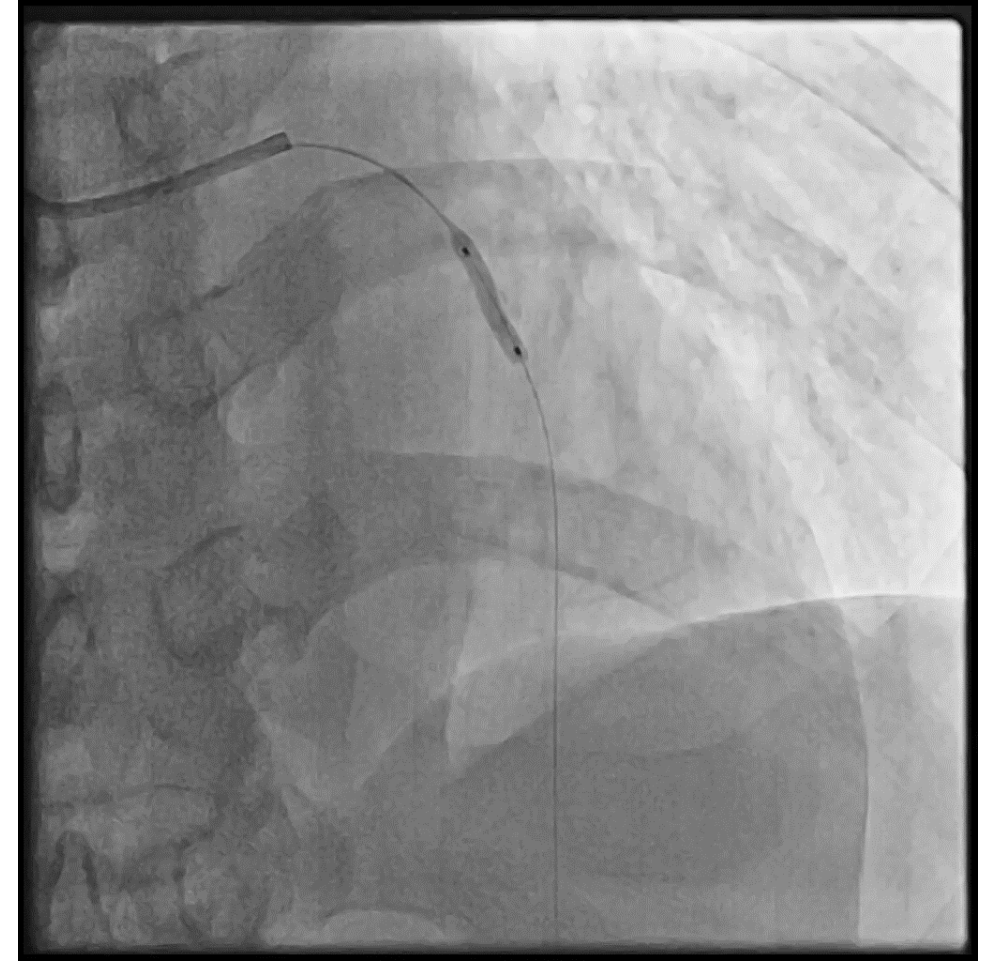
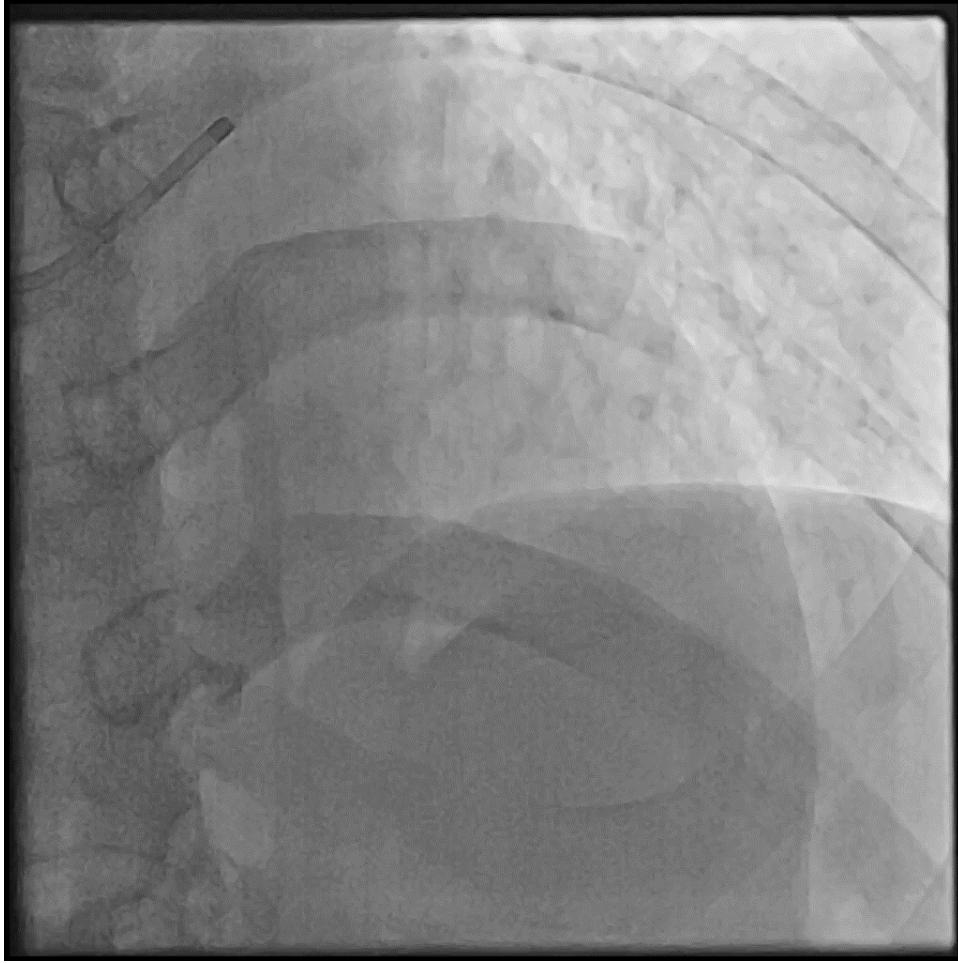
- Try to minimize stent burden.
- Perform IVUS/OCT guidance procedure, especially in complex lesion. (especially before DCB)
- Make a sufficient flow, which is meant to minimize ischemia.
- Prefer hybrid or DCB only strategy in, especially, small vessel, diffuse stenosis, bifurcation and/or CTO, sometimes MI culprit lesion.

Diffuse stenosis

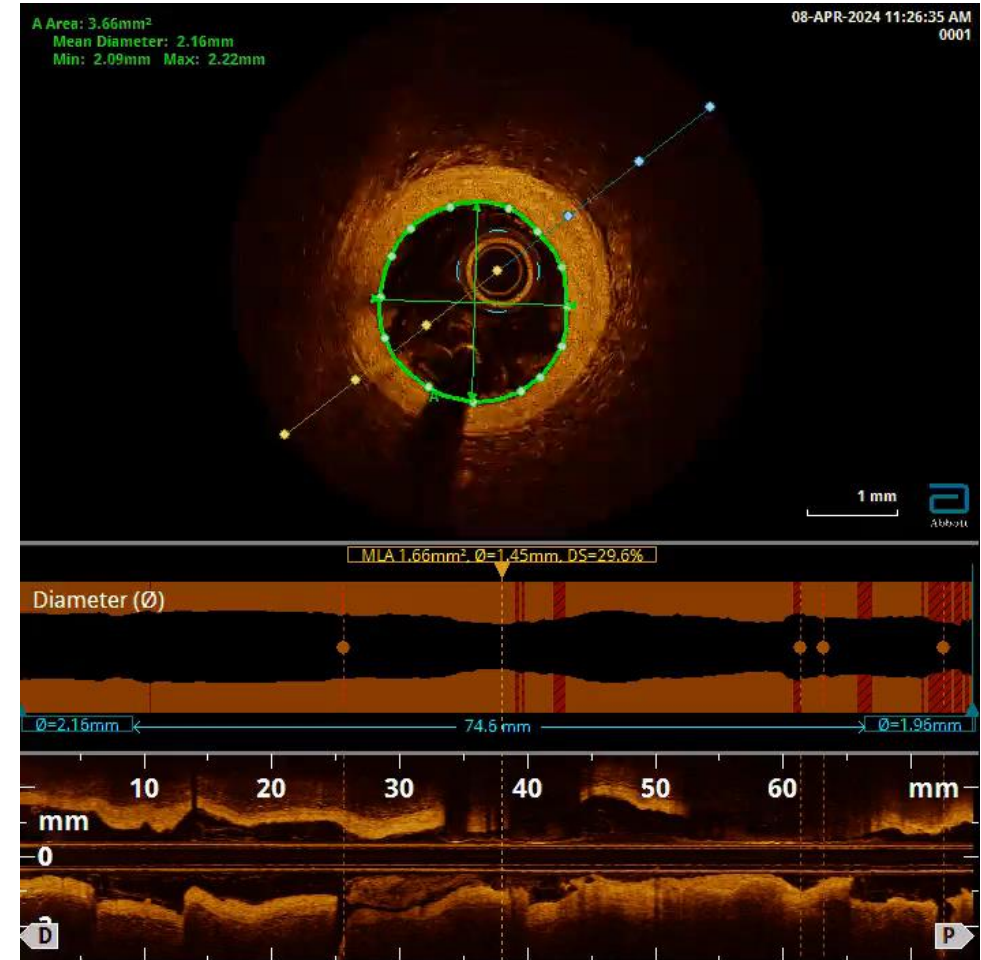
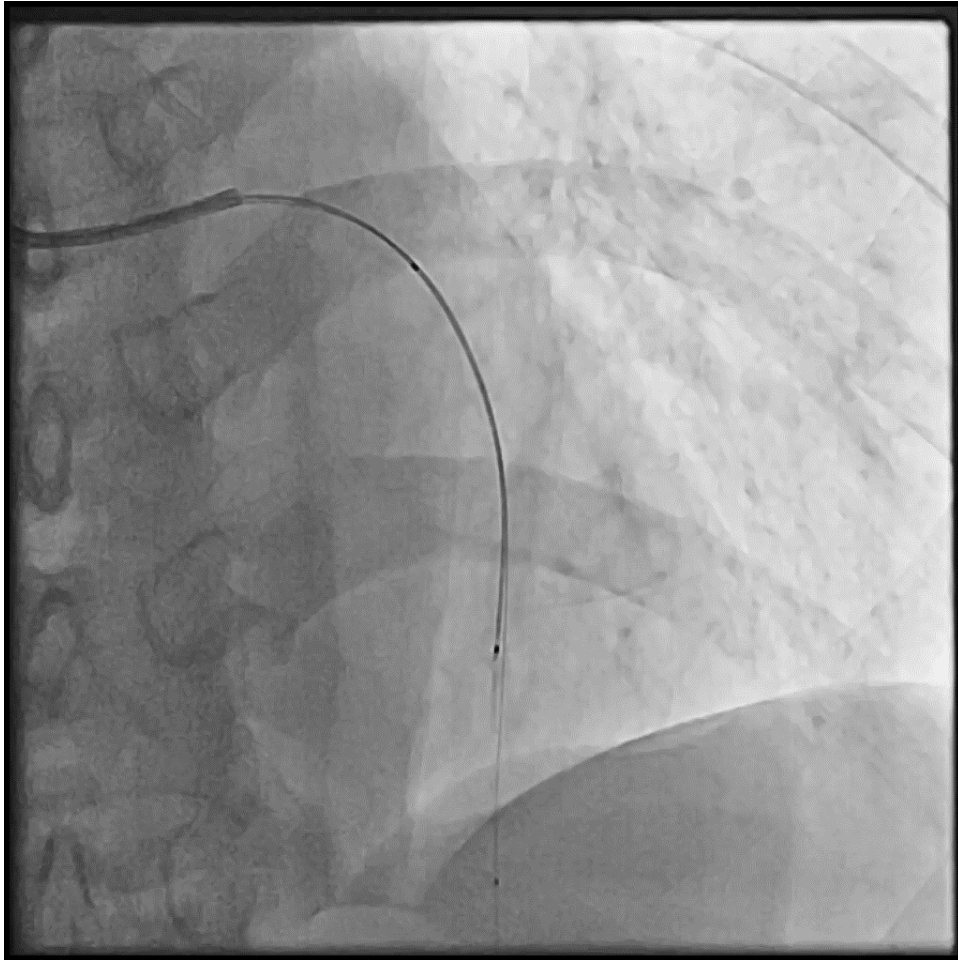
51/M, chest pain, graded exercise test: + at stage 2
Preferred DCB to DES, "no metal remnant"



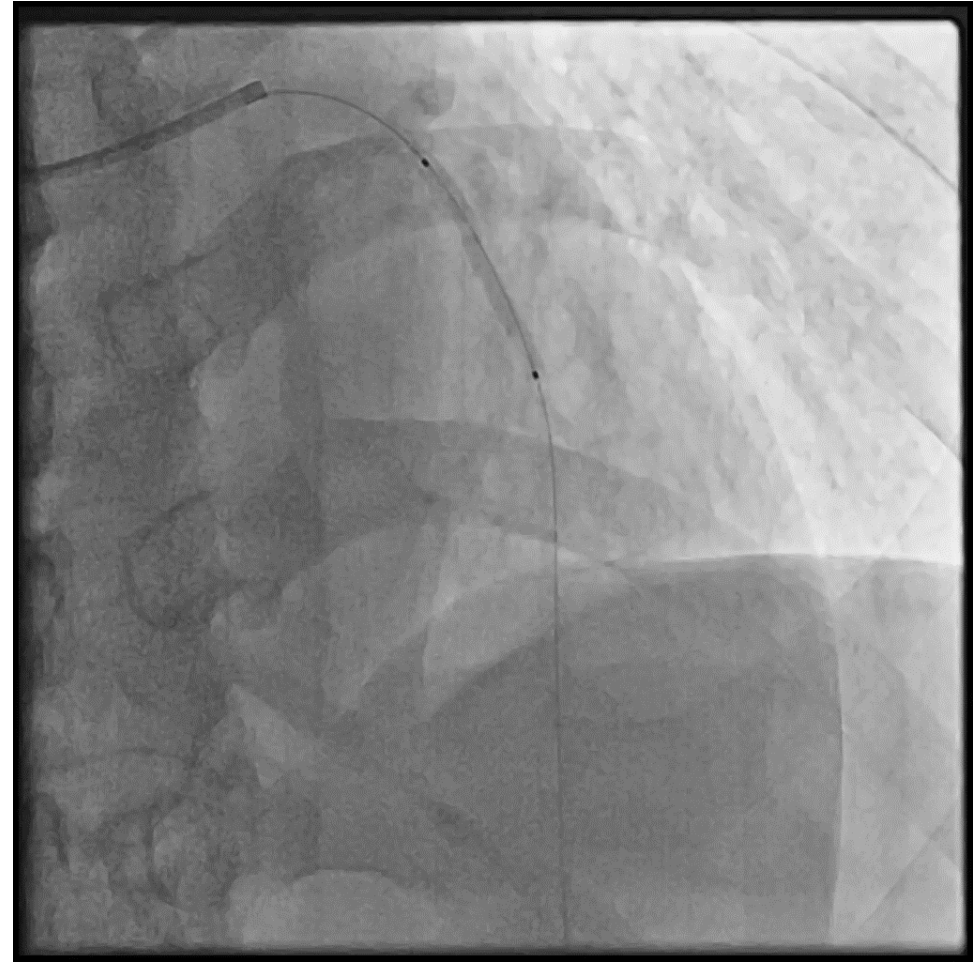
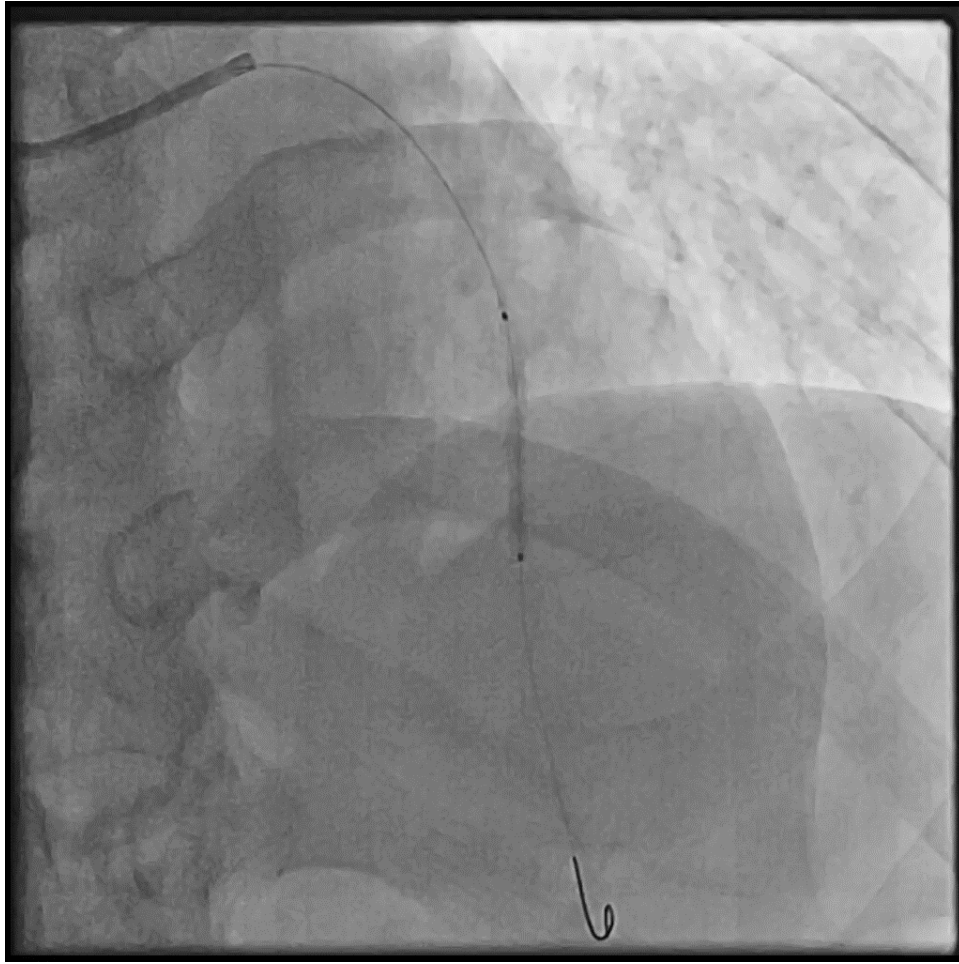
LAD diffuse stenosis, lesion length about 60 mm

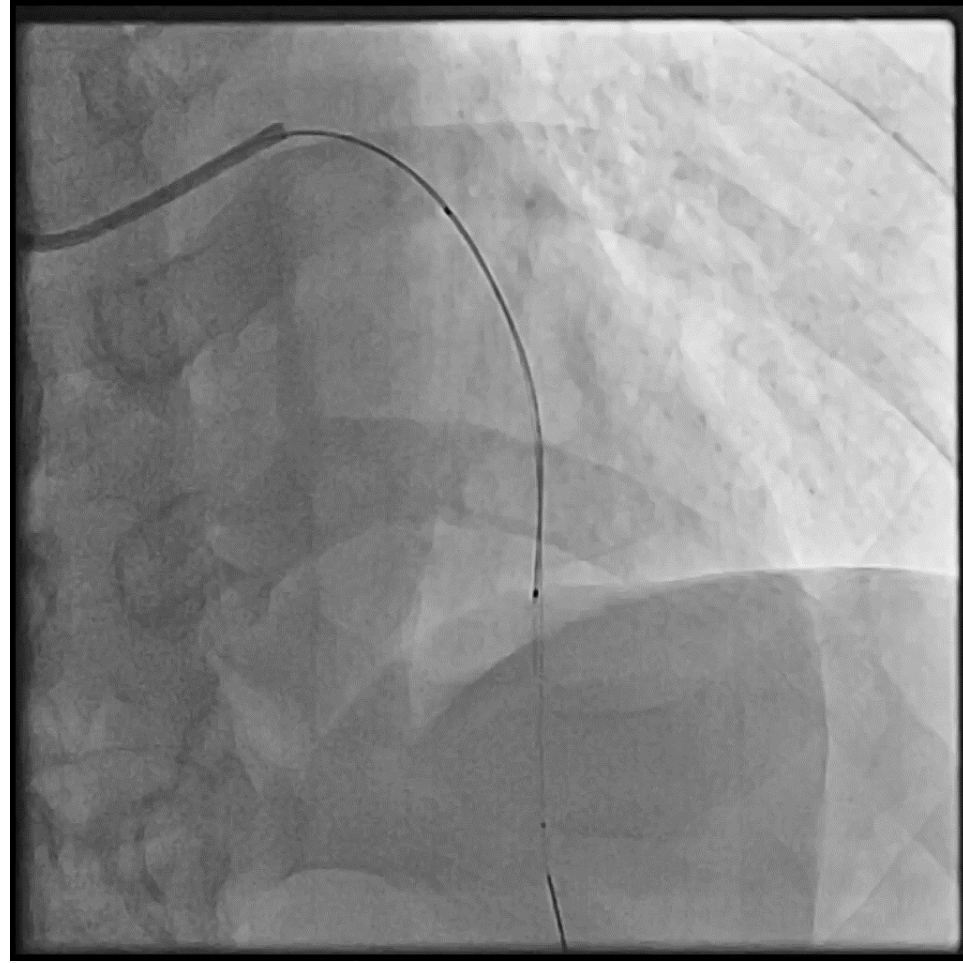
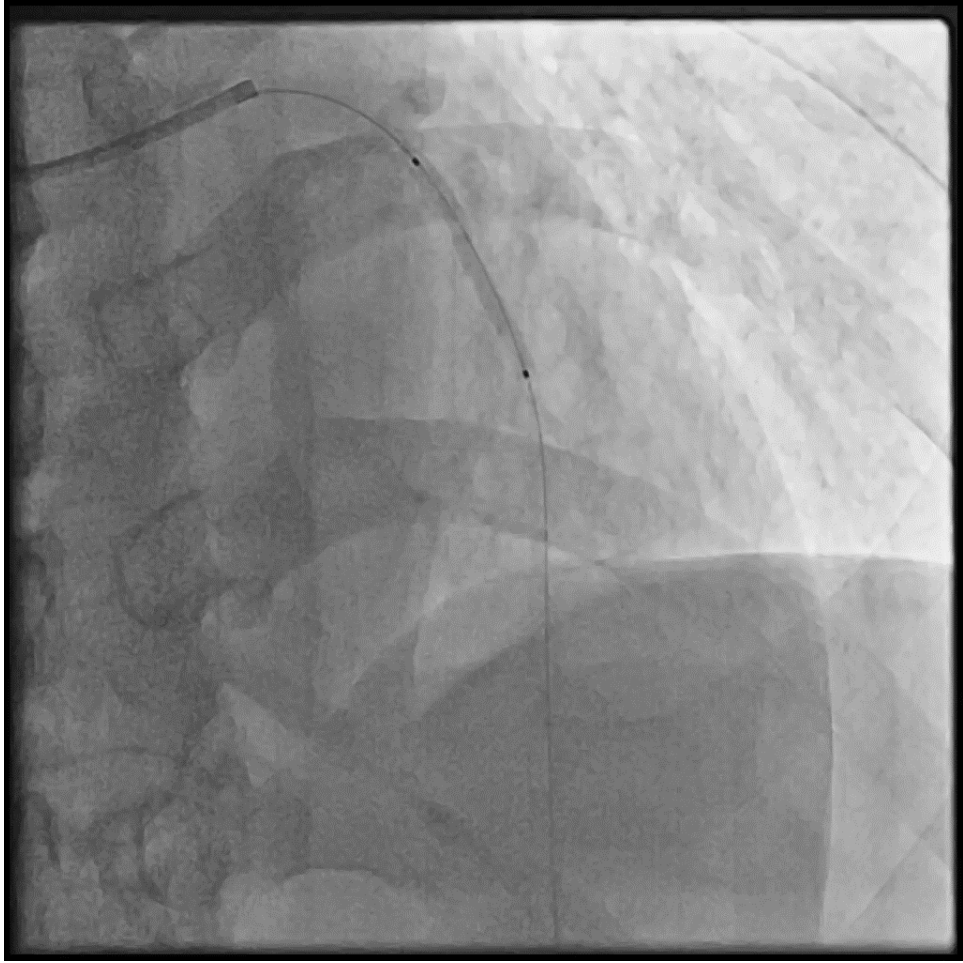


After OCT imaging, applied Prevail 2.75x30 mm

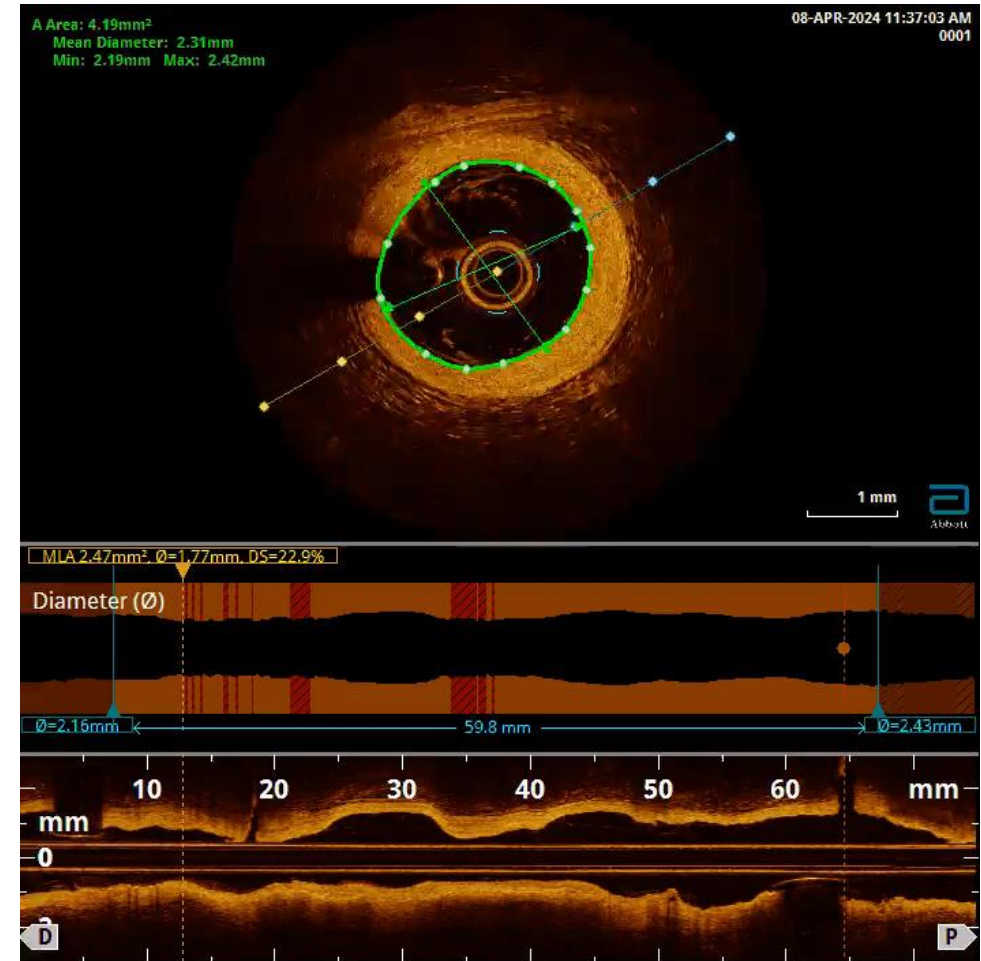
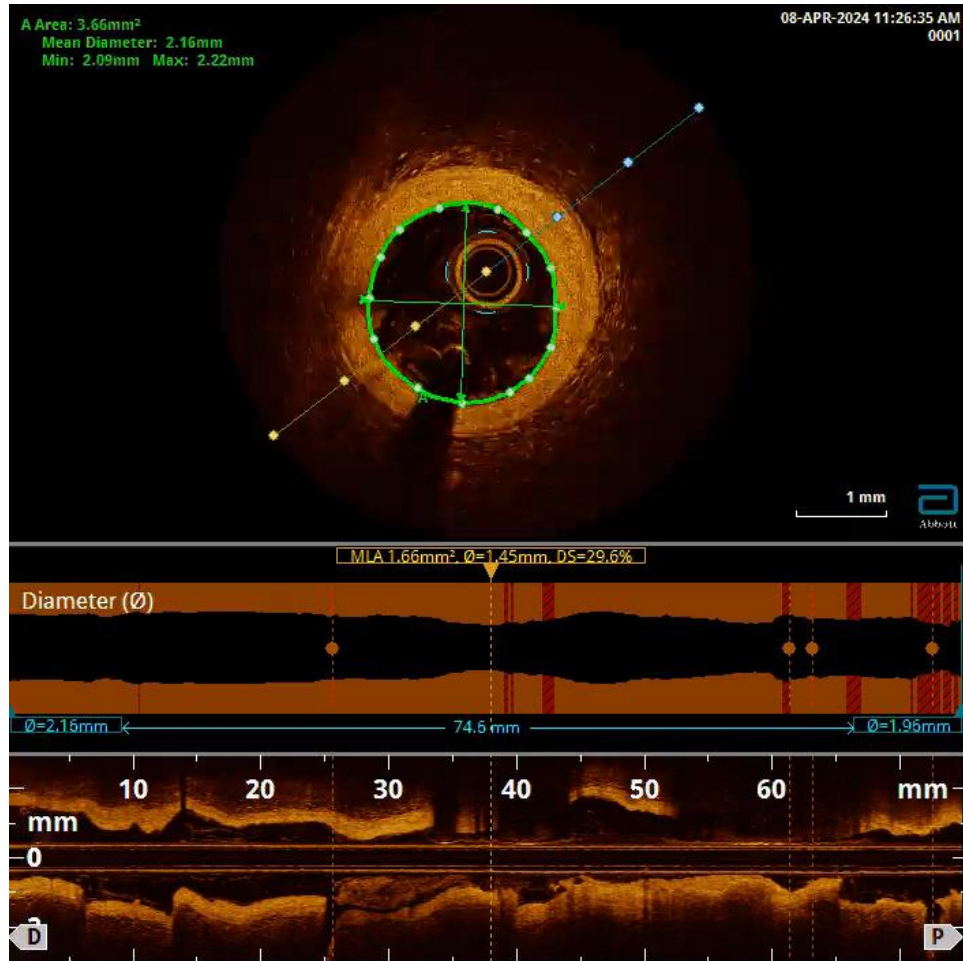


After OCT imaging, applied 2 Prevail 2.75x30 mm

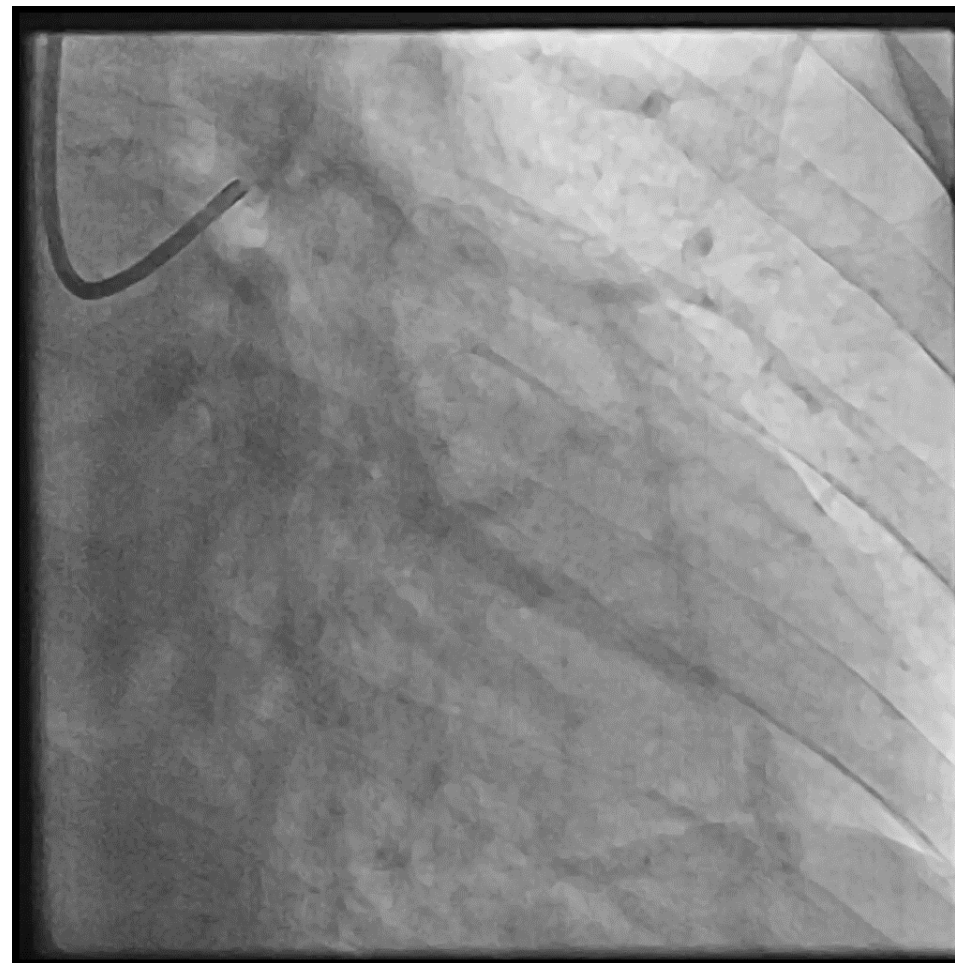
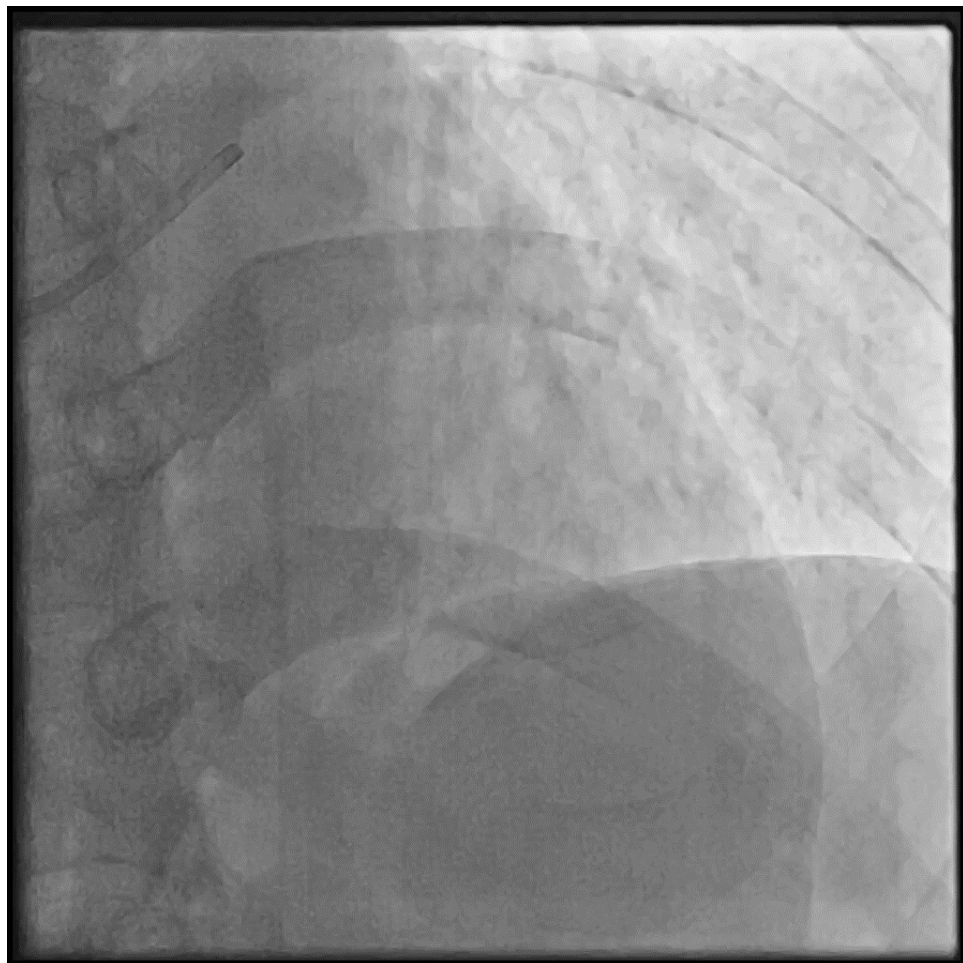




OCTs immediately after balloon and after DCB (MLA 2.5)

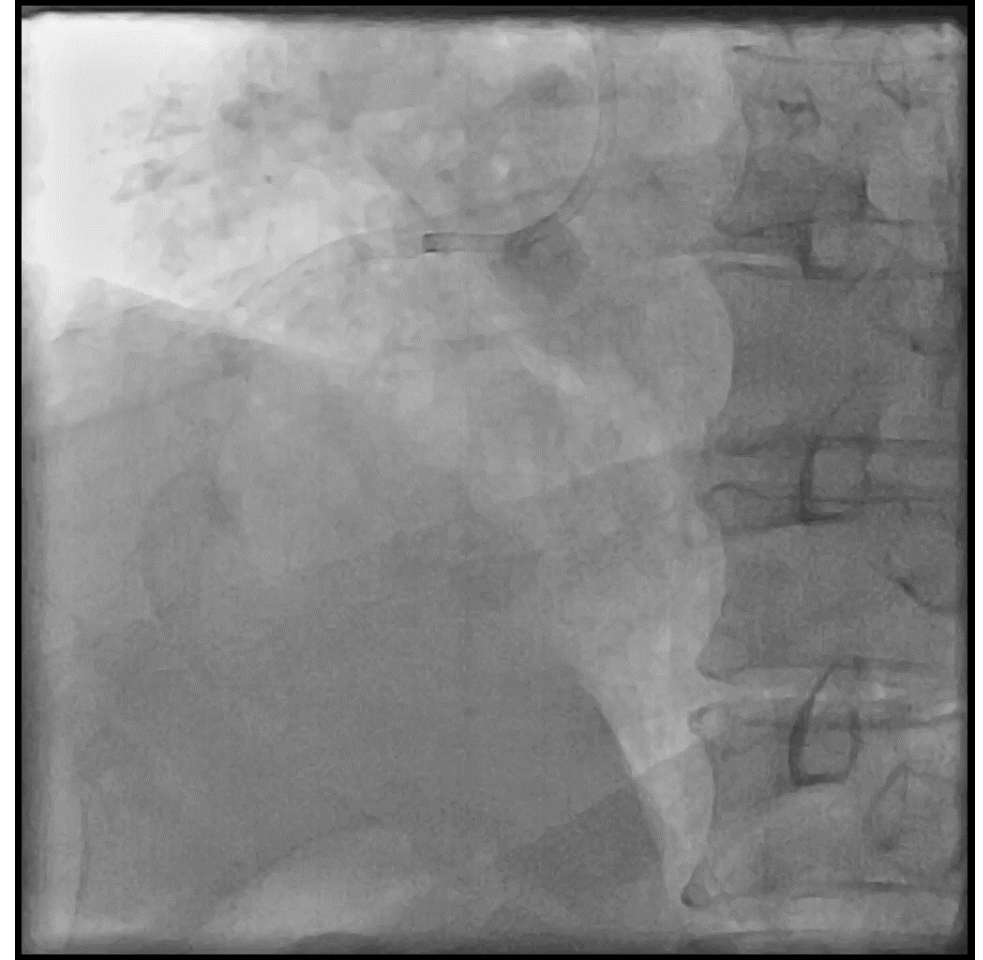
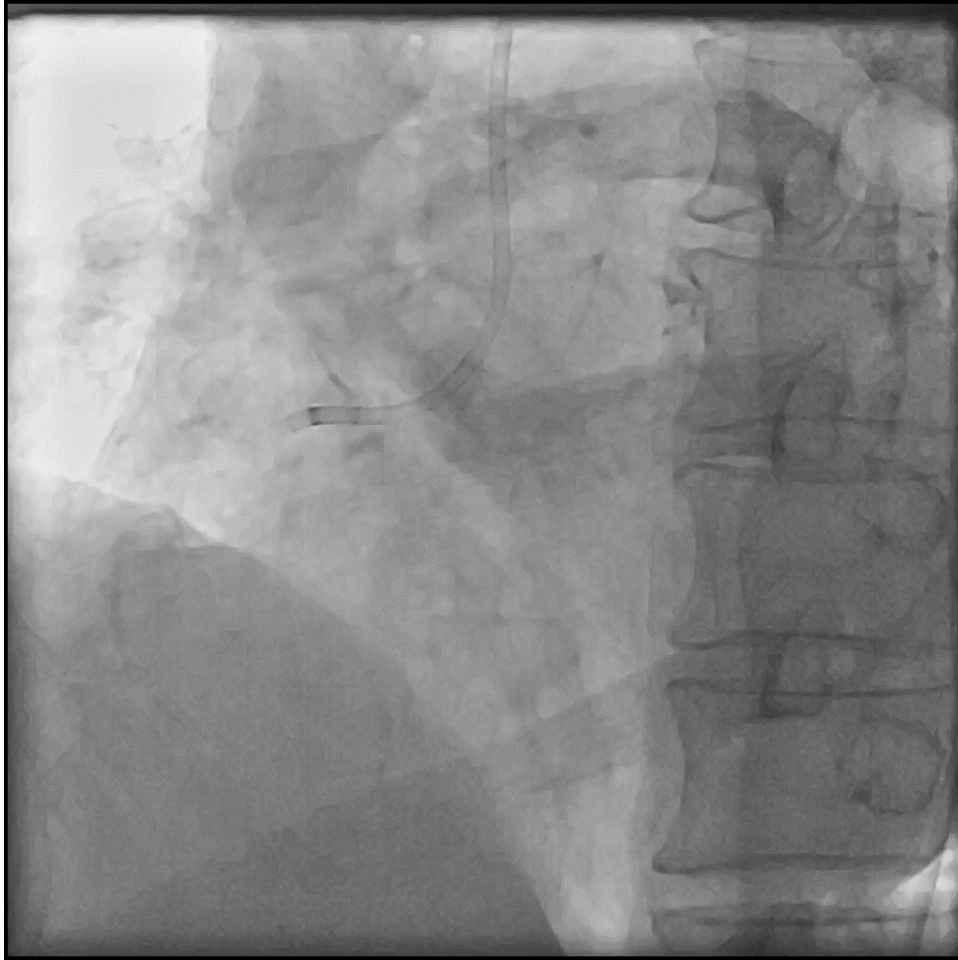


Post DCB, FFR 0.84, Graded exercise test: negative upto stage4



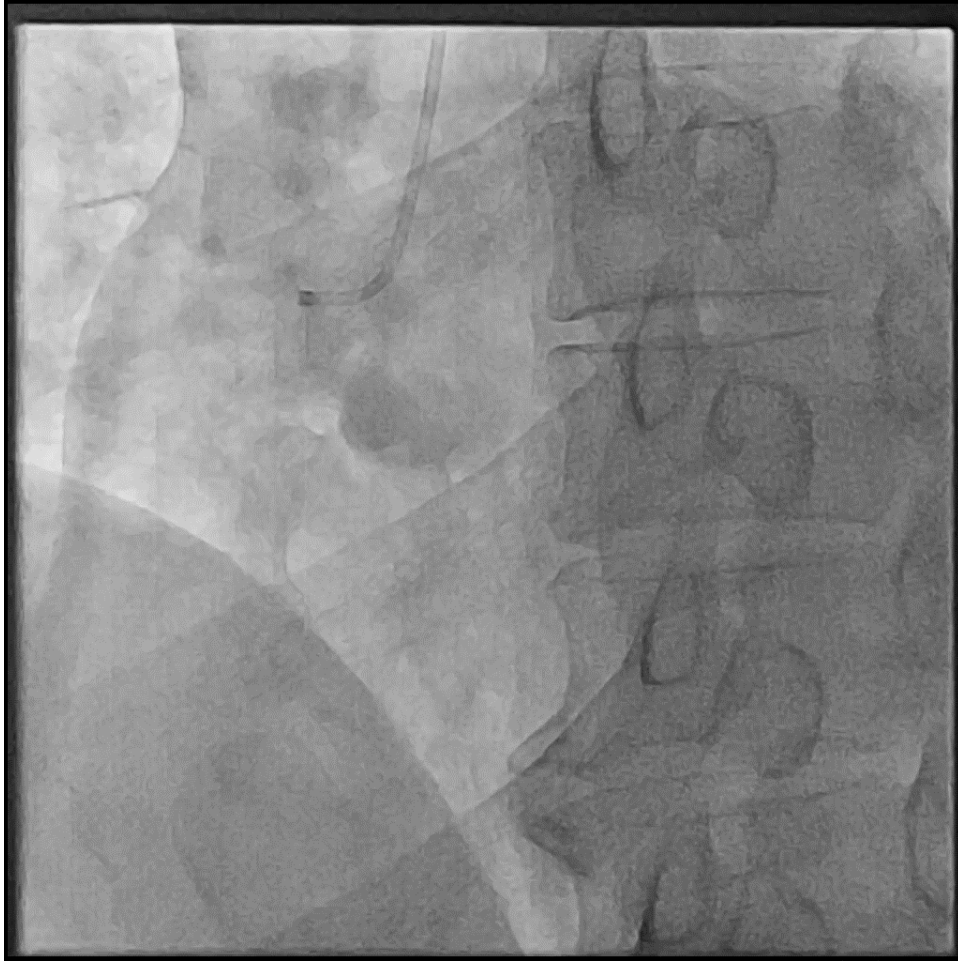
Reduce stent burden

Hybrid strategy (proximal with DES+ distal with Prevail)

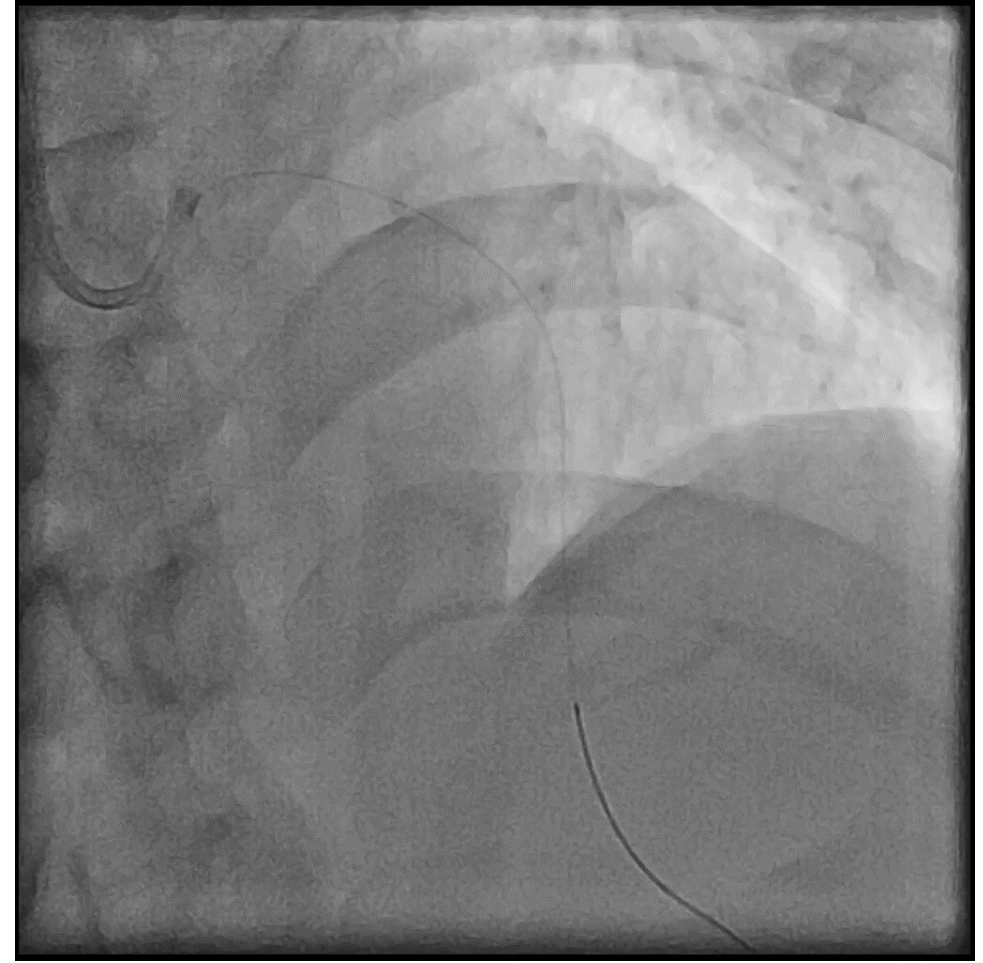
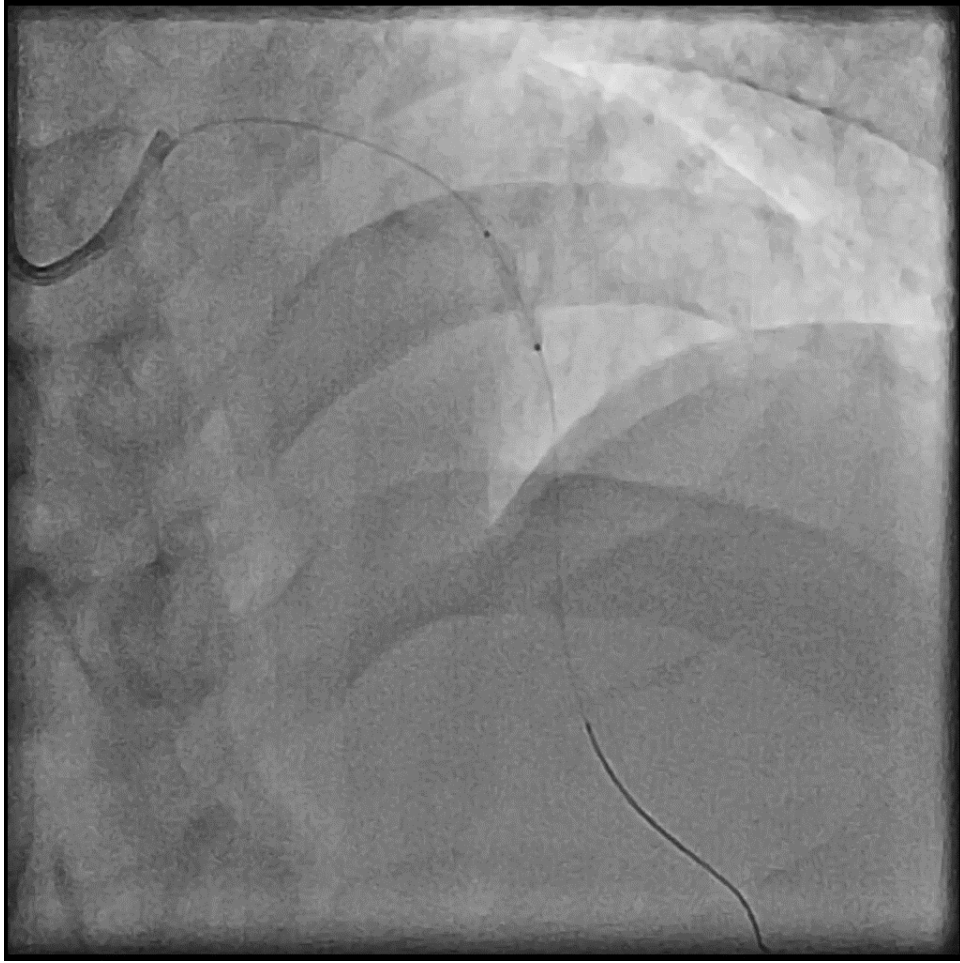


Bifurcation

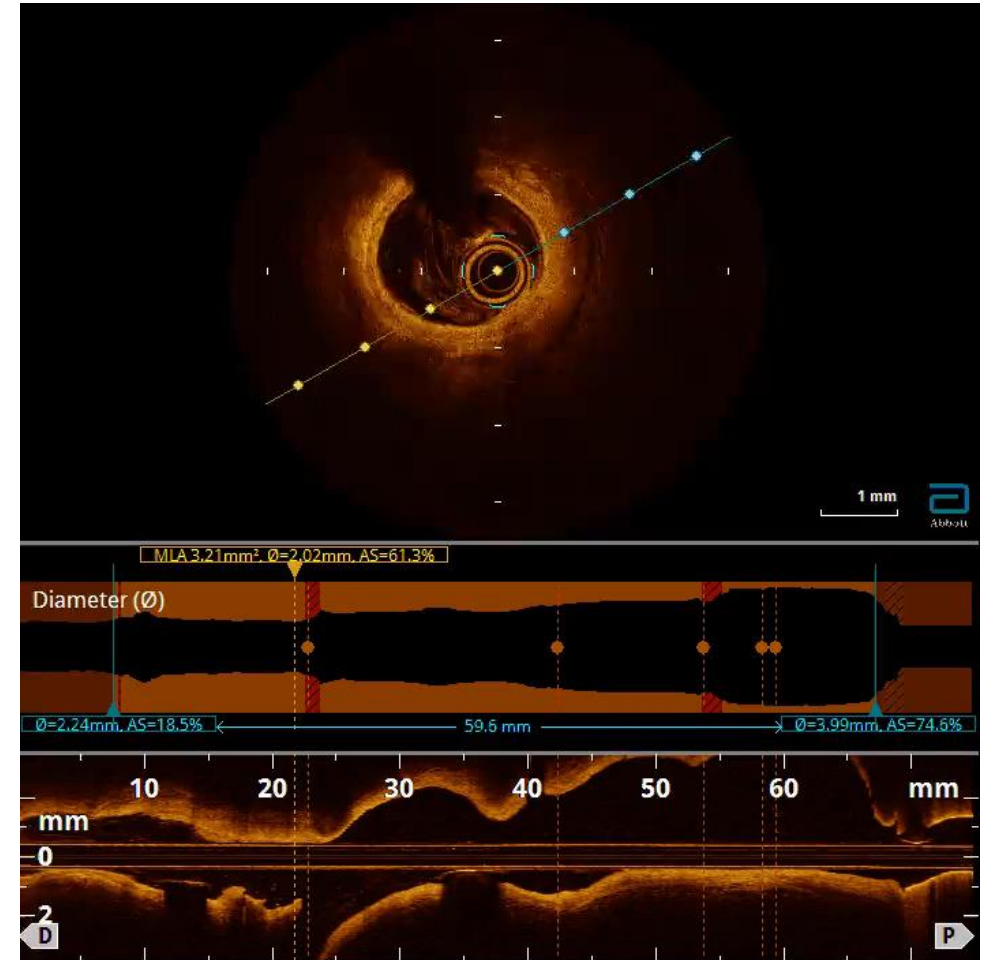
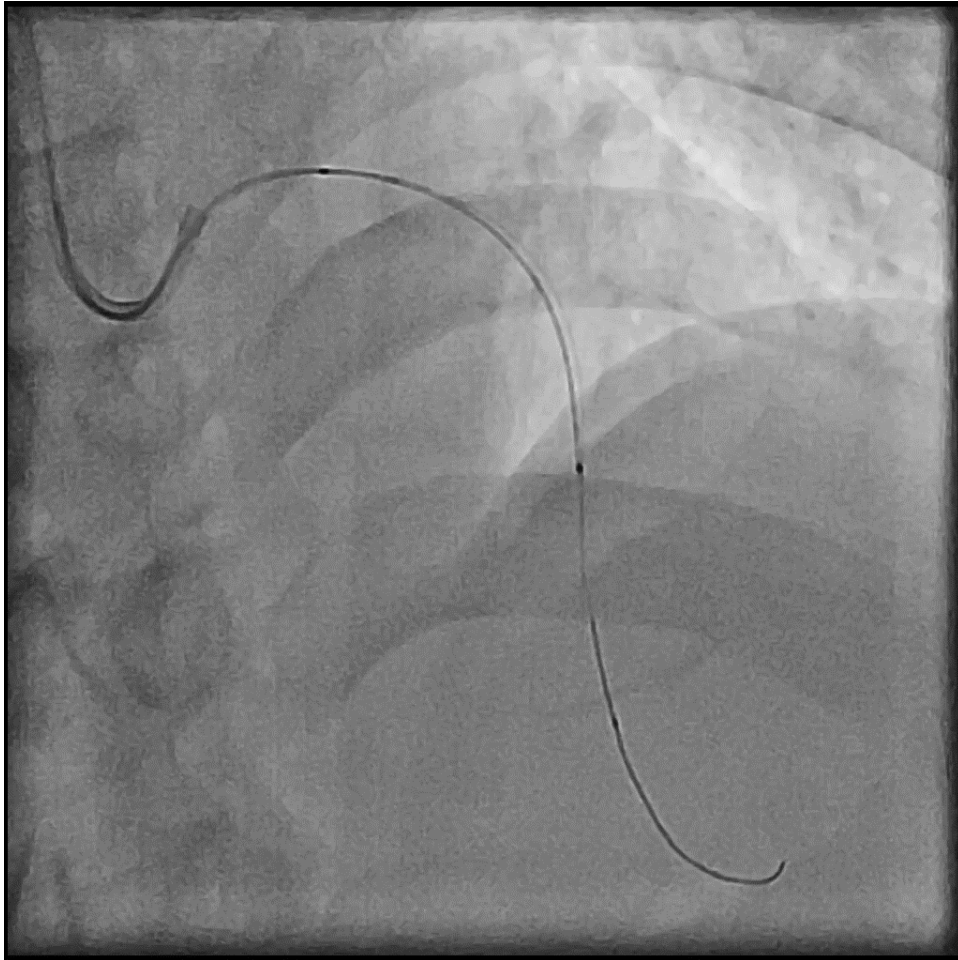
Mid portion of LAD lesion, bifurcation



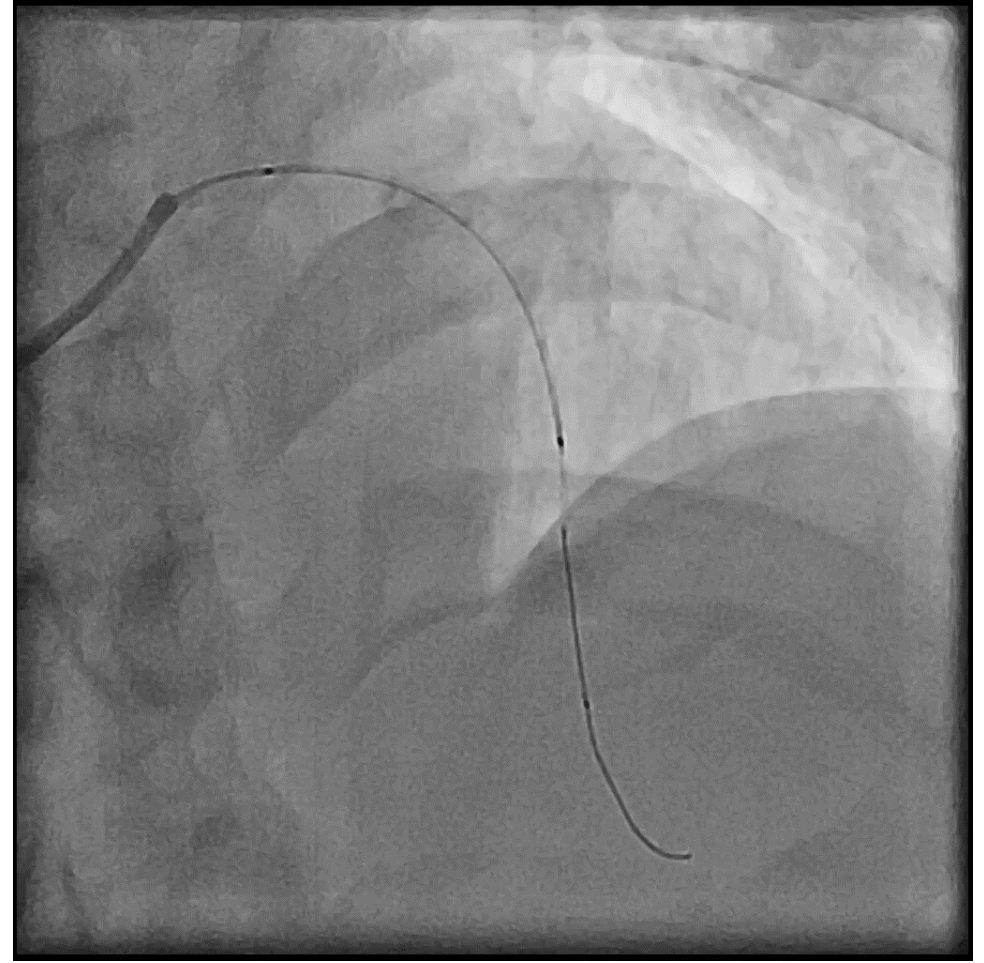
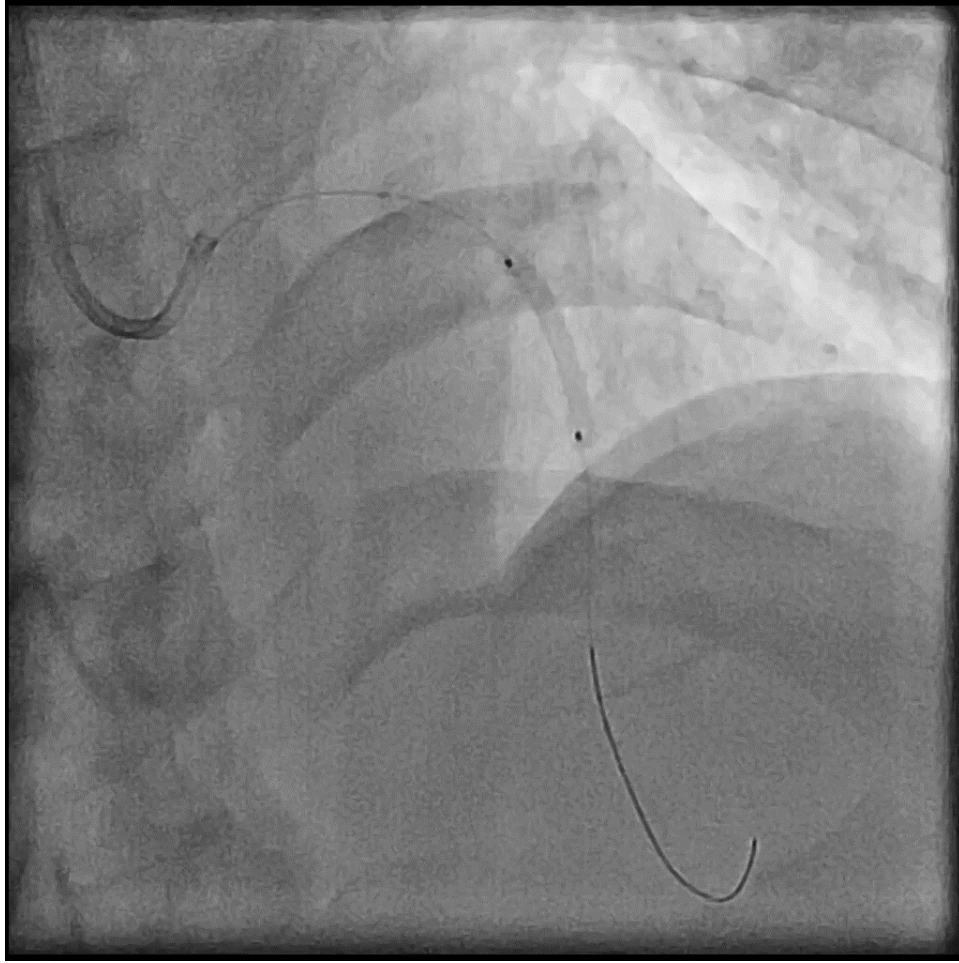
Intentionally prepared for DCB



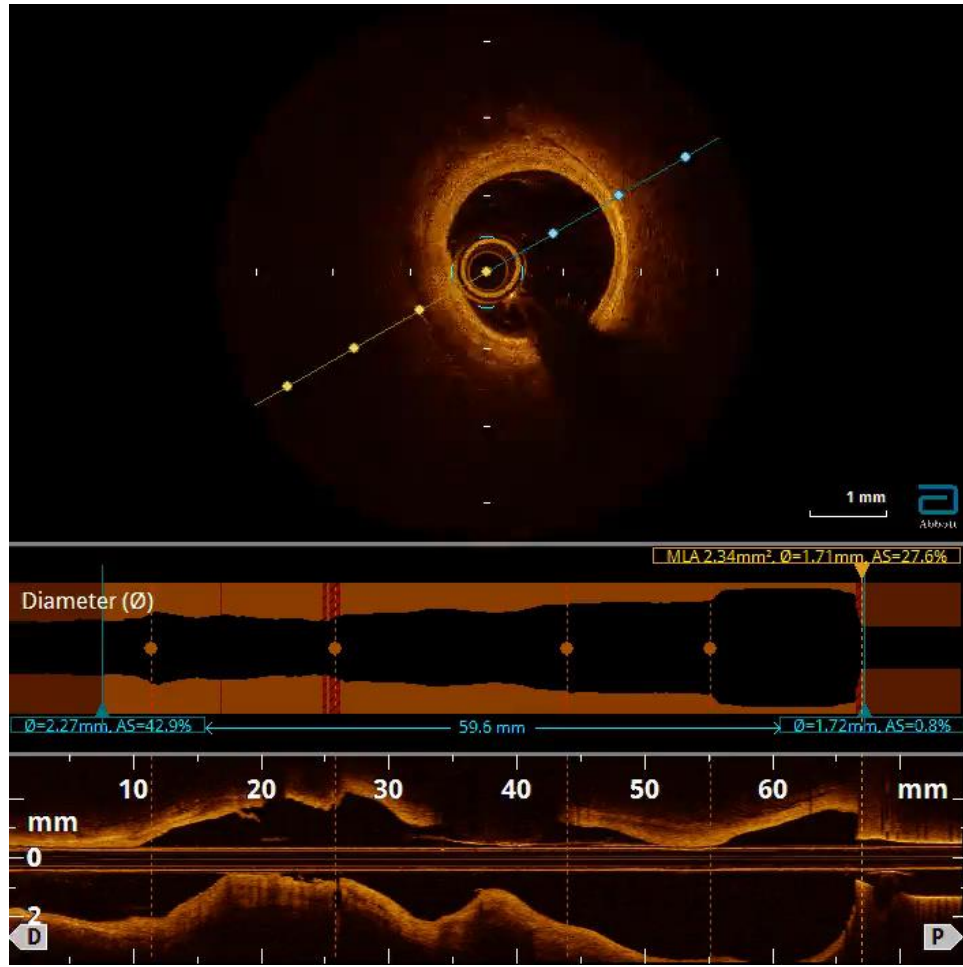
OCT and angiogram: Immediate after ballooning



Prevail 2.75x20 mm upto 14 atm

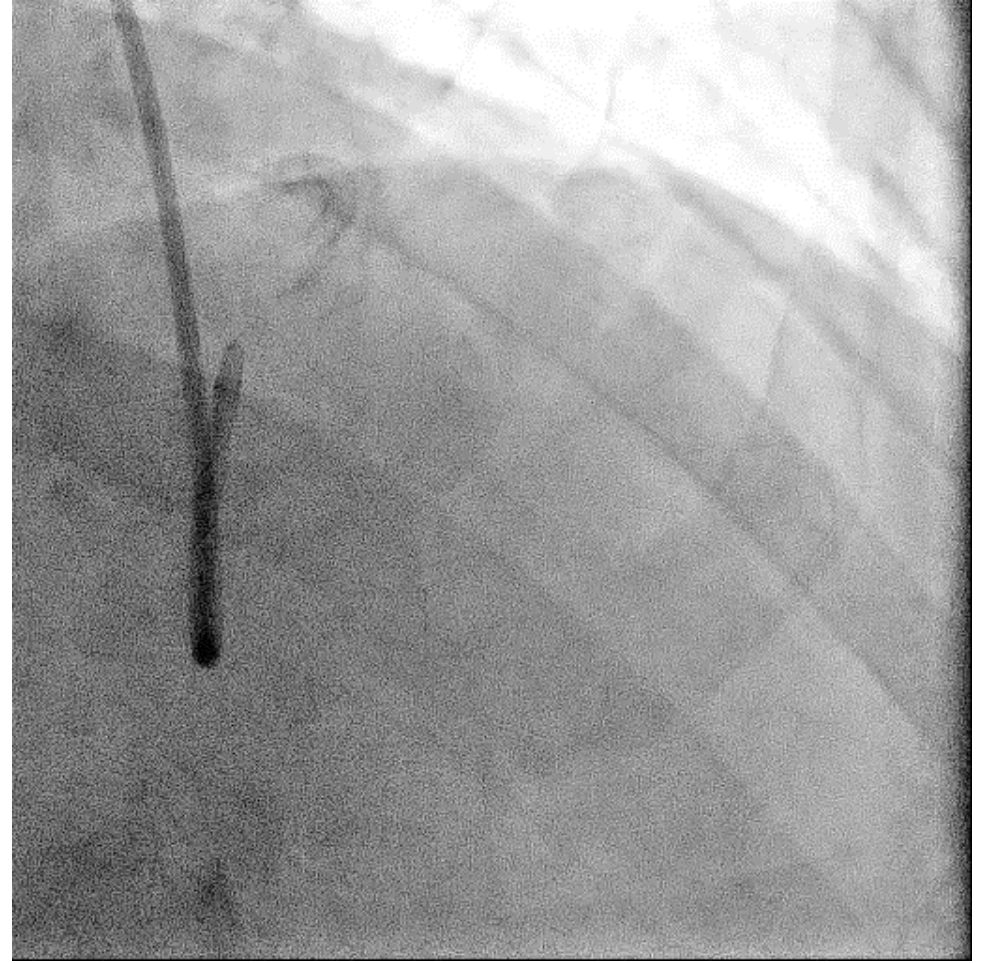


Final angiogram after DCB and OCT

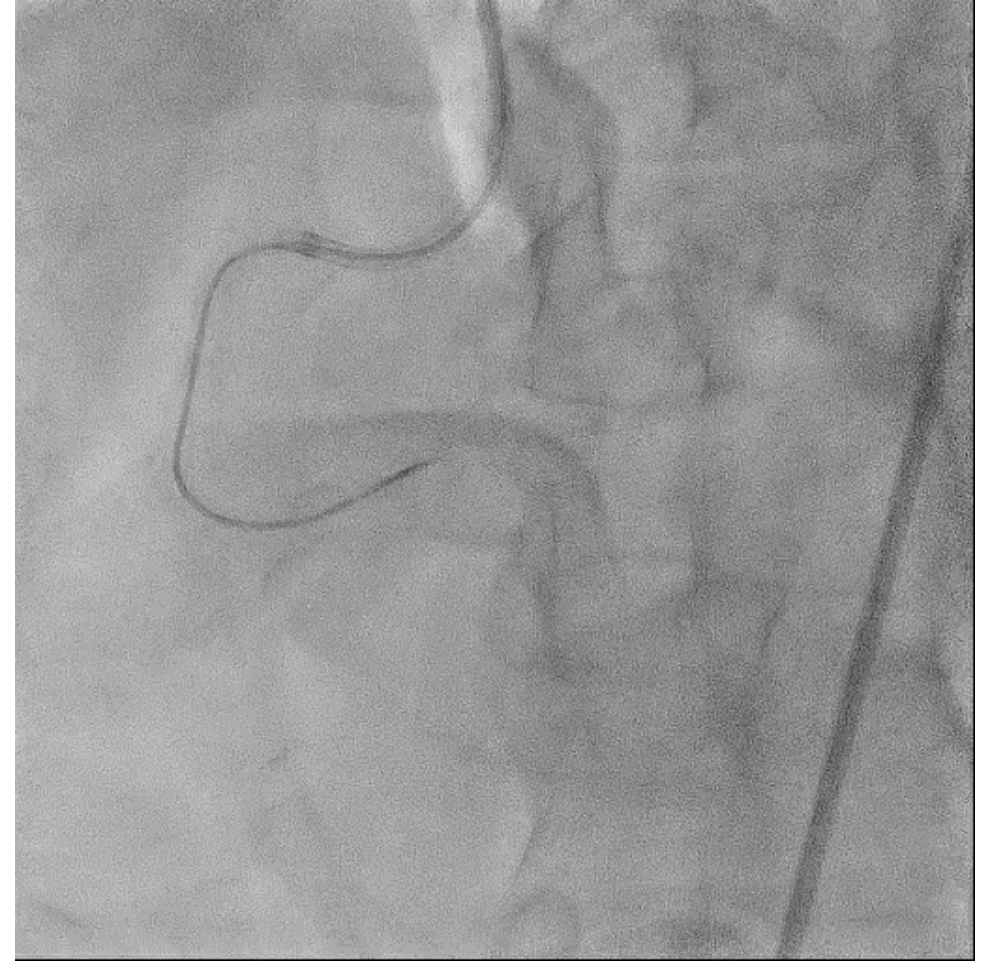
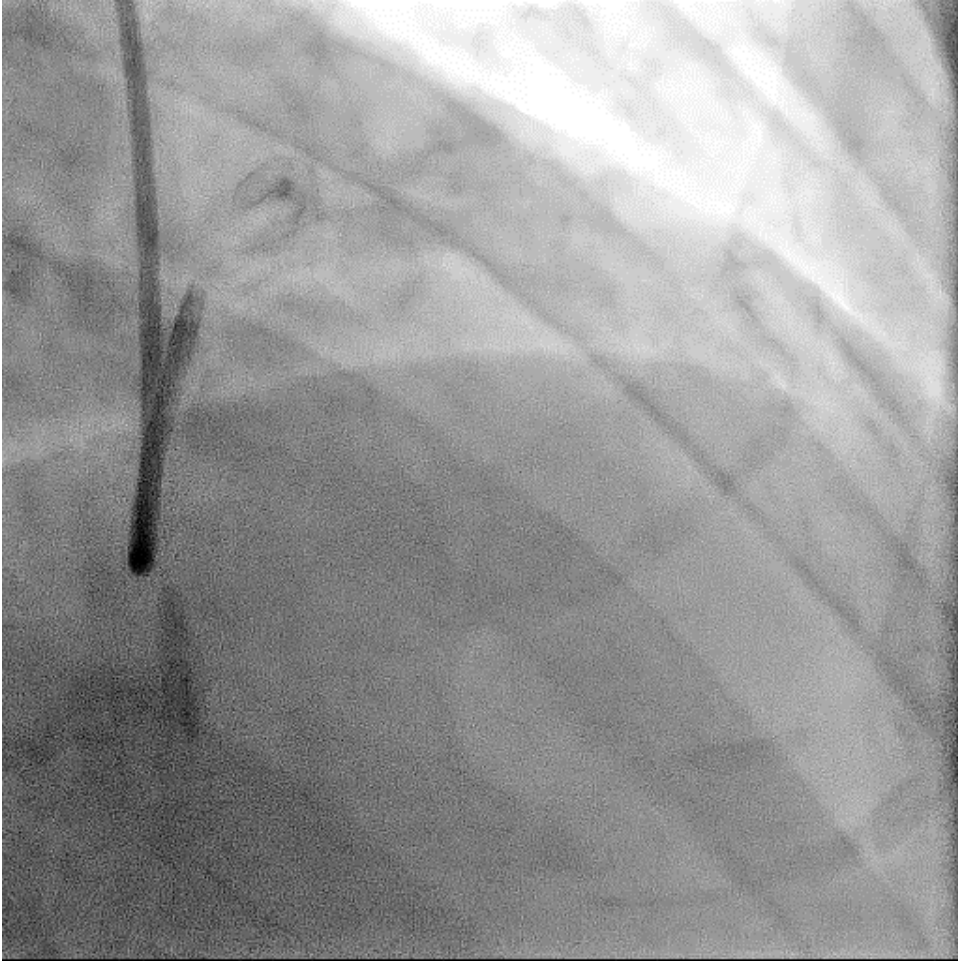


Adequate Lesion Preparation
With excellent deliverability

M/70, 4-years ago

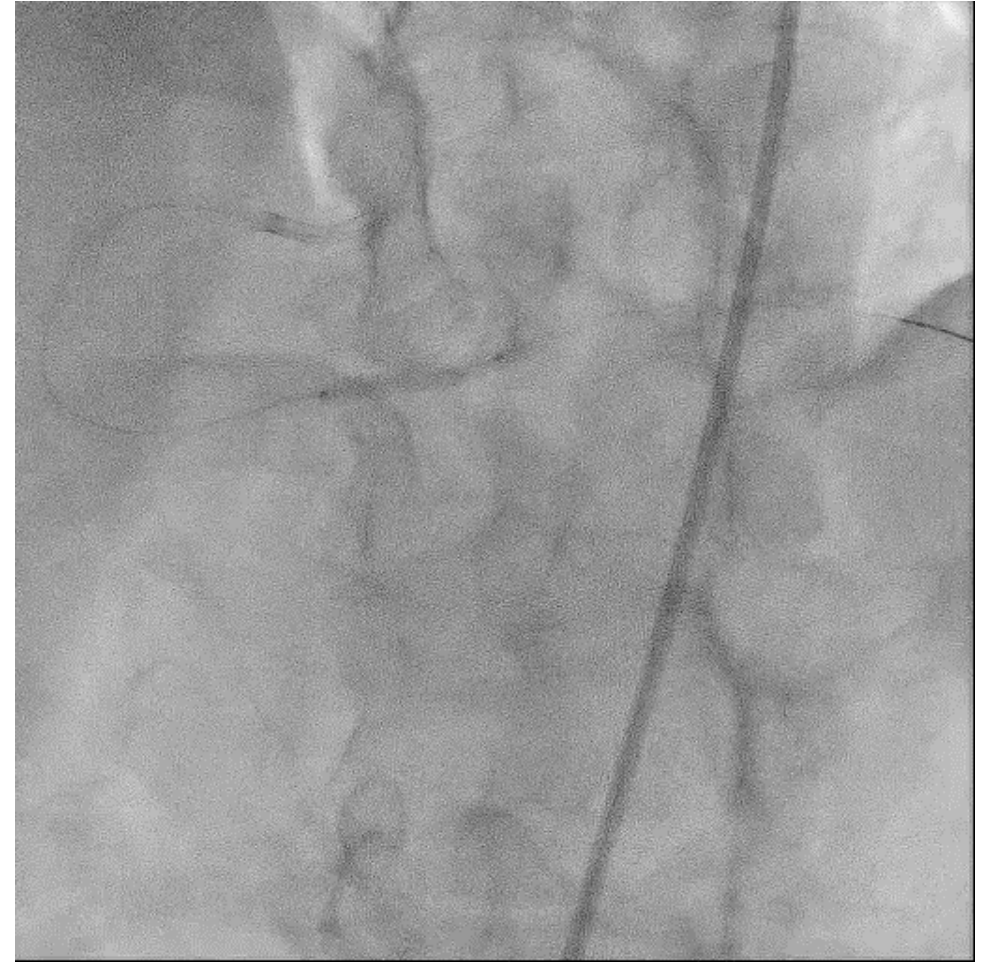
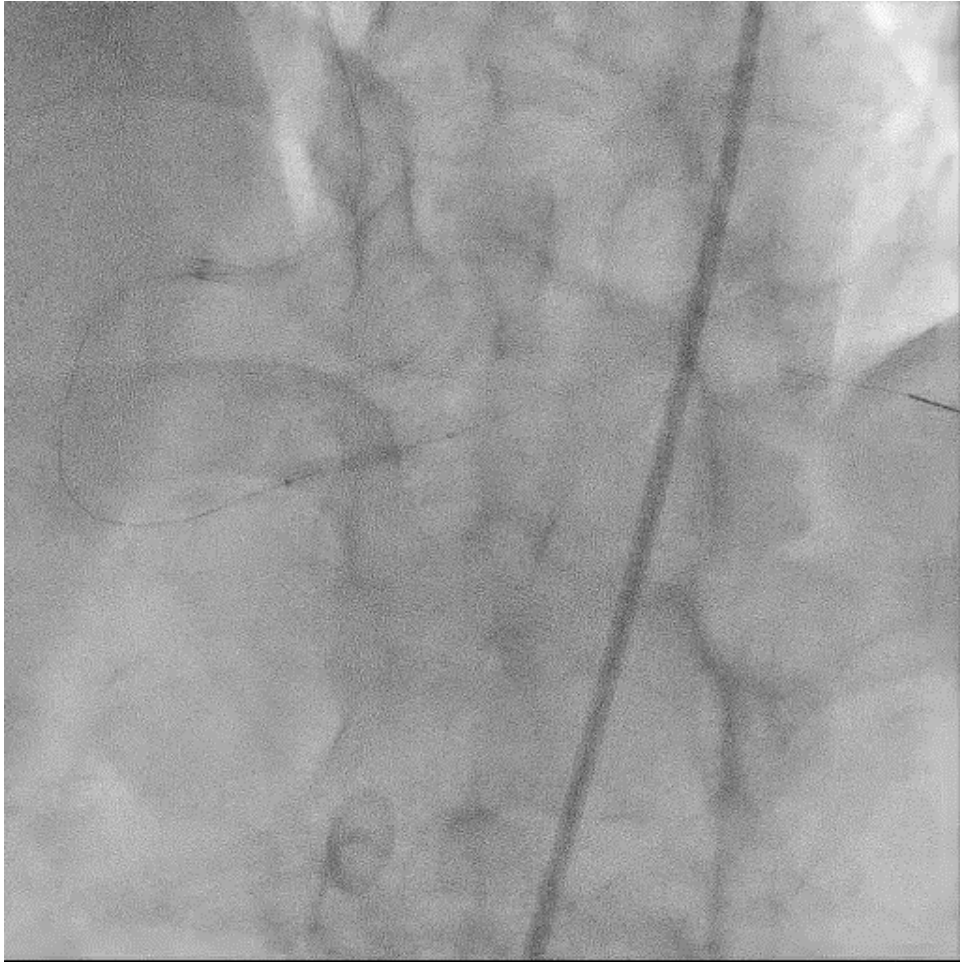


M/70, 4-years ago

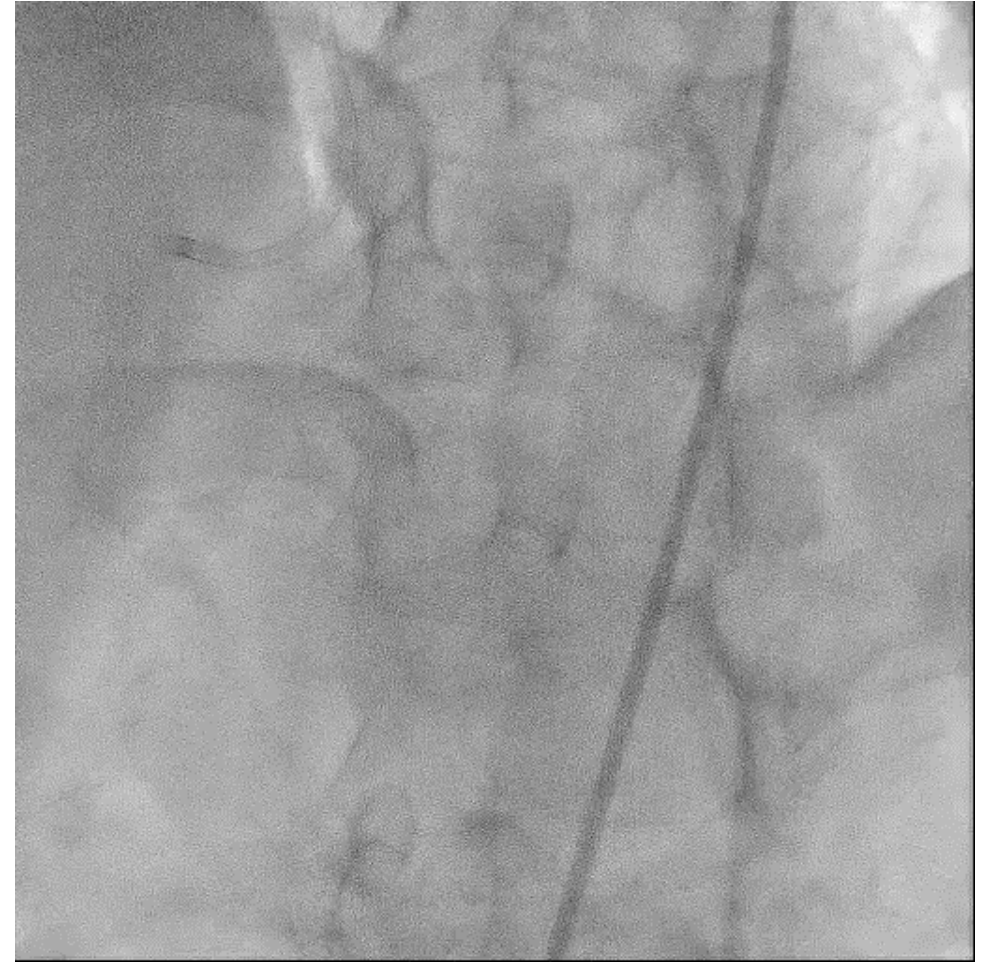
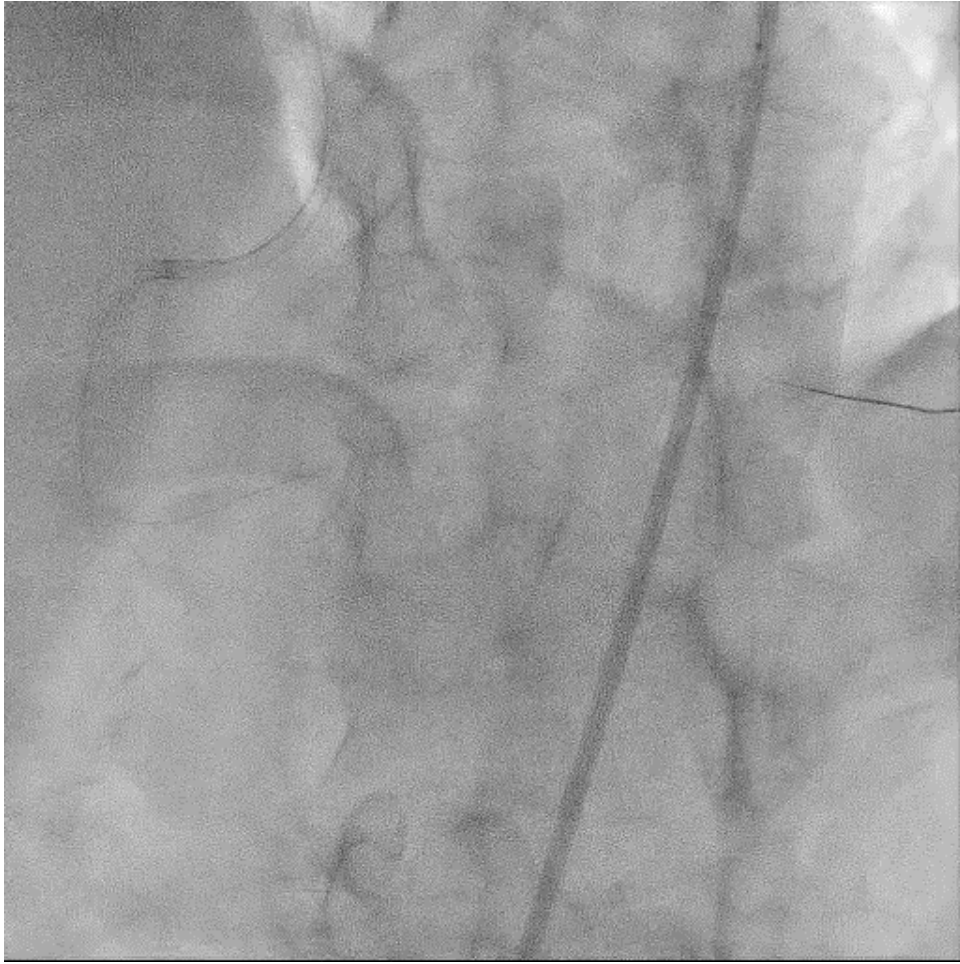


Physiology guided stent implantation

M/70, 4-years ago (DCB only after POBA)



M/70, 4-years ago (only after POBA, DCB applied)



M/70, this year (lesion progression and patent stent)



M/70, calcium obstacle

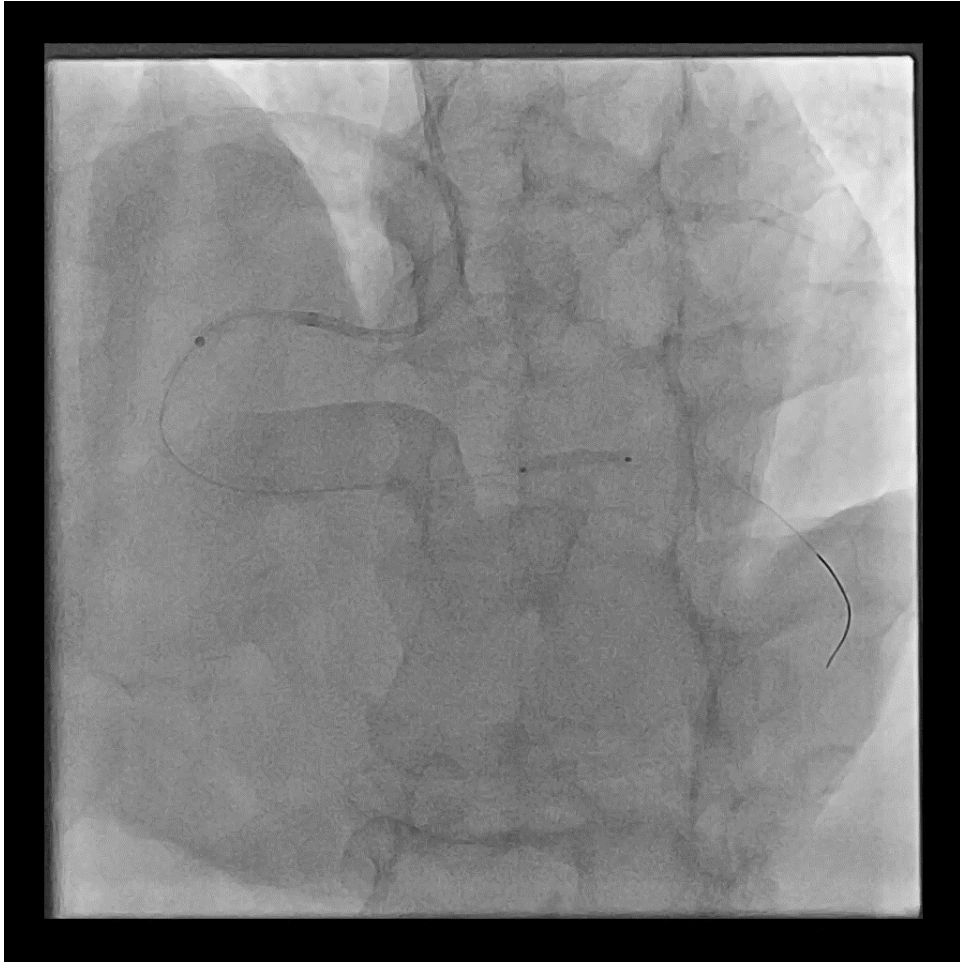


M/70, Rotablation for adequate lesion preparation

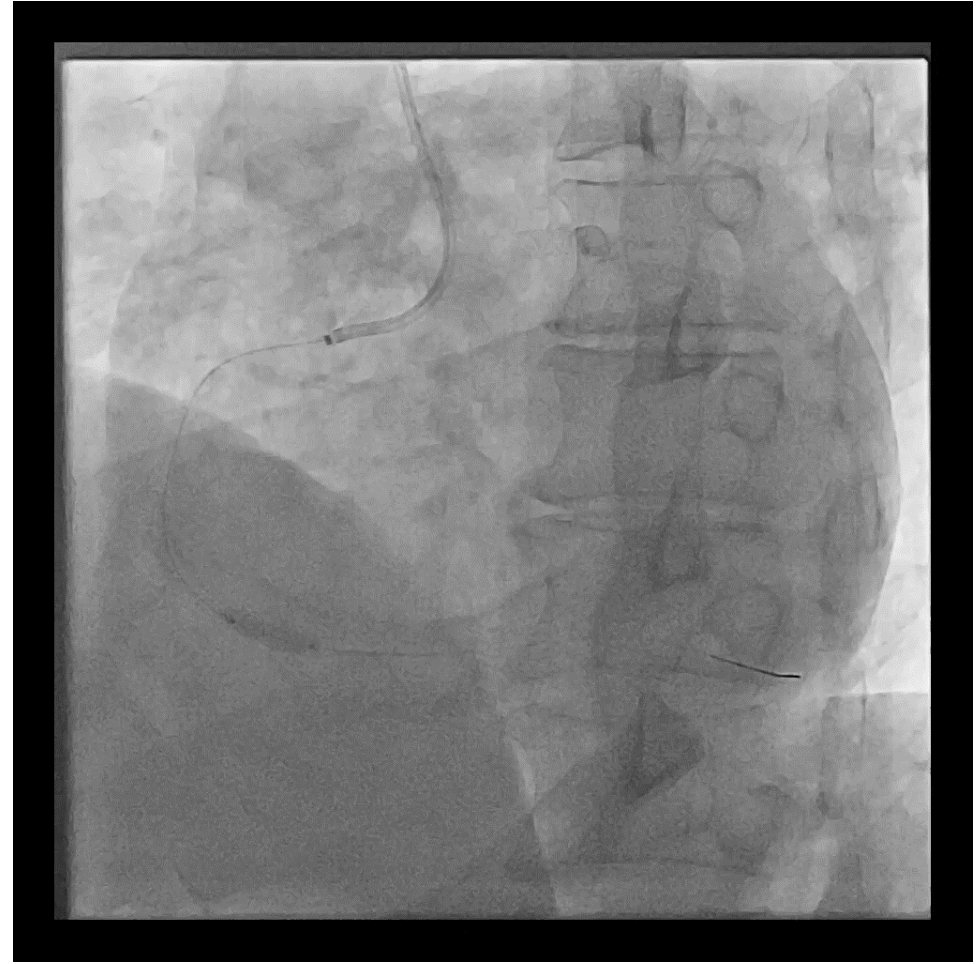
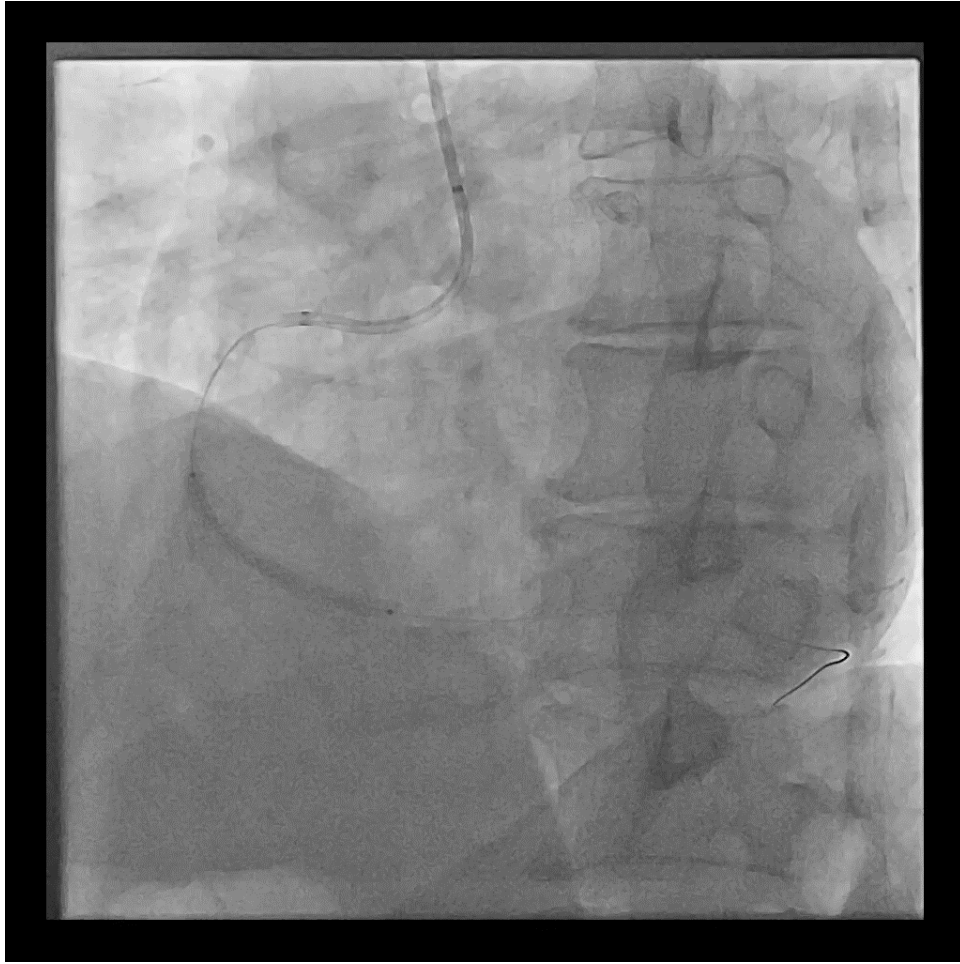


Rotablation using 1.25 and 1.75 mm sized burr

Prevail DCBs for far distal_wonderful deliverability



One stent for mid ~ distal lesion



After Rota + DCB and DES (Hybrid strategy)



Summary (Prevail must be prevalent !!)

- Take DCB as a viable option in your daily practice.
- Save the stent and save the life using DCBs.
 - shorten DAPT, even stop blood thinners
 - rare risk of stent thrombosis or restenosis
 - second chance for next procedure
- Lesion preparation is very crucial before DCBs.