The Art of Angioplasty in SFA
- use of Chocolate balloon in different scenarios

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Disclosure

Speaker name: Mian Wang

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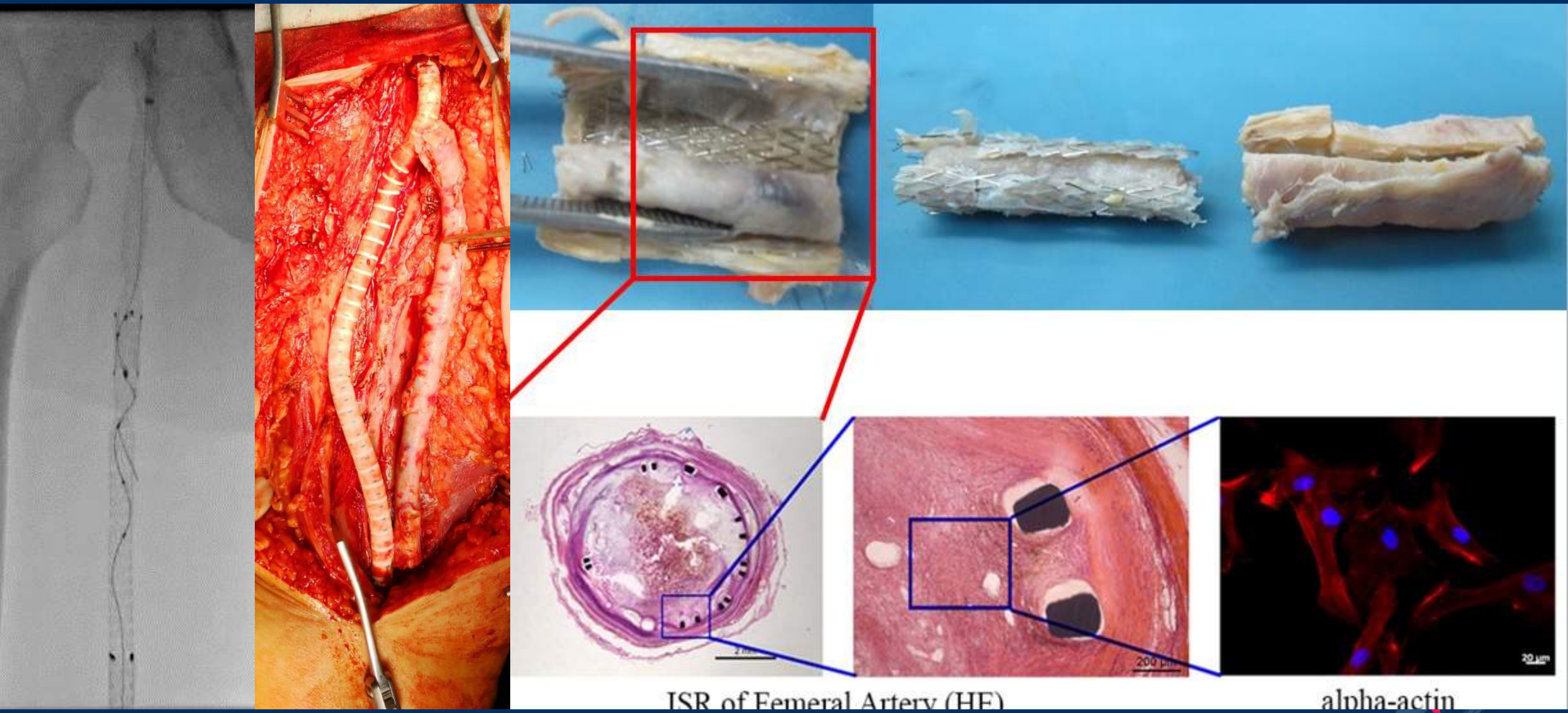
I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☑ I do not have any potential conflict of interest

What We Want

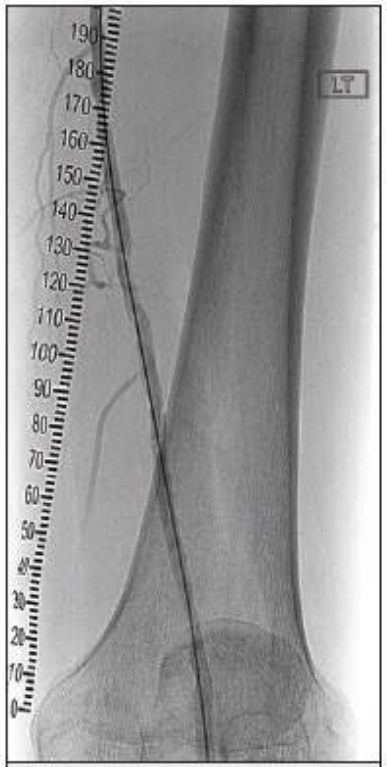
What We Meet



Mian Wang, et al. J Atheroscler Thromb. 2018 Nov 1;25(11):1168-1181.

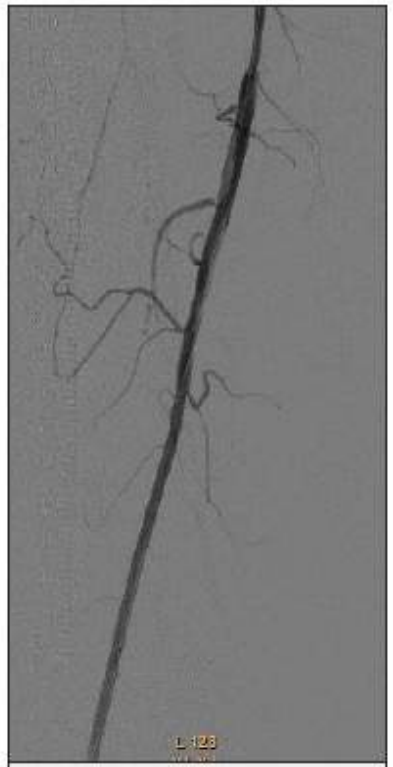
Drug Coated Balloon：Leave nothing behind？

Post balloon angioplasty dissections

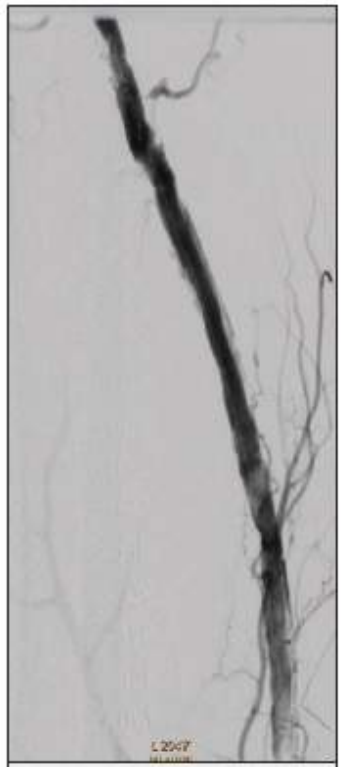


A
Minor radiolucent areas

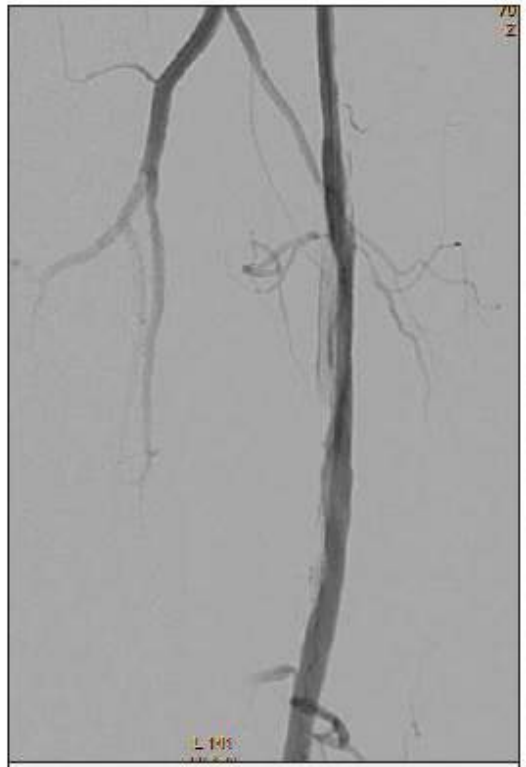
B
Linear dissection



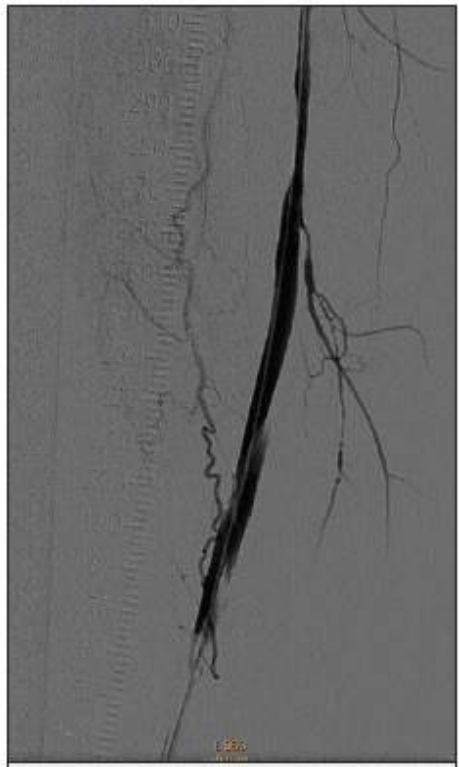
C
Contrast outside the lumen



D
Spiral dissection



E
Persistent filling defects



F
Total occlusion w/o distal antegrade flow

After balloon angioplasty of the SFA, the prevalence of any angiographic dissection has been reported to occur between 50% to 84%. Severe dissections (characterized as type C or greater) occurred 42% of the time and were associated with significantly increased rates of restenosis and target lesion revascularization (TLR)

1. Fujihara M, et al. J Endovasc Ther. 2017;24:367-375. 2. Kobayashi N, et al. J Vasc Surg. 2017;67:1151-1158. Picture courtesy of Prof. Marianne Brodmann.

Current data suggest that DCB angioplasty is associated with rates of dissection similar to those of standard PTA, but it is difficult to extrapolate the results of these studies to real-world practice, where lesions tend to be longer, calcified, and more often occluded. In real-world registries, the rates of bailout stenting range from 20% to 40%, suggesting higher rates of operator-determined severe dissections that necessitated stent implantation.

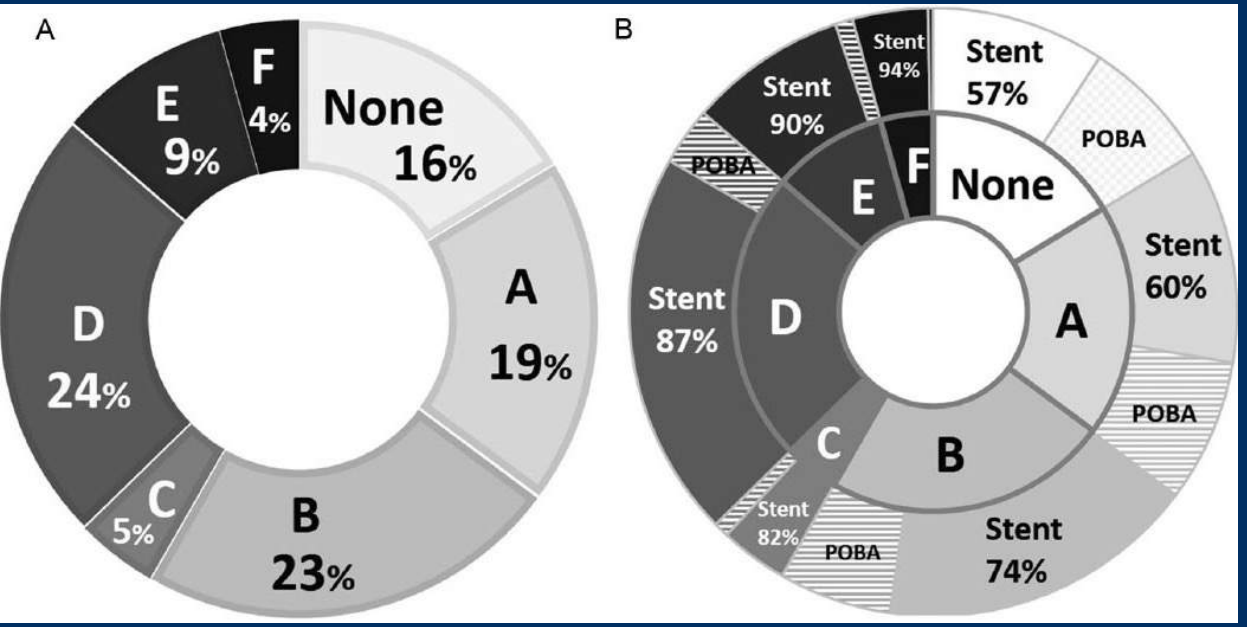
Project	Study	Dissection Rate	
Lutnoix TM	Global Registry	Grade D Grade E Grade F	5.5% (7/127) 2.4% (3/127) 1.6% (2/127)
	Global Registry Long Lesion	Grade D Grade E Grade F	8.3% (4/48) 4.2% (2/48) 4.2% (2/48)
	Global Registry ISR	Grade D	16.7% (2/12)
Stellarex TM	ILLUMENTE EU ILLUMENTE Global ILLUMENTE Pivotal	Flow limiting Grade D Flow limiting Flow limiting	0.4% (1/254) 19.7% (81/416) 0.3% 0.0%
IN.PACT TM Admiral TM	IN.PACT SFA IN.PACT Global ISR IN.PACT Global CTO IN.PACT Global long Lesion	Grade D-F Grade D-F Grade D-F Grade D-F	0.0% (0/221) 4.7% (7/149) 23.6% (30/127) 14.9% (24/161)

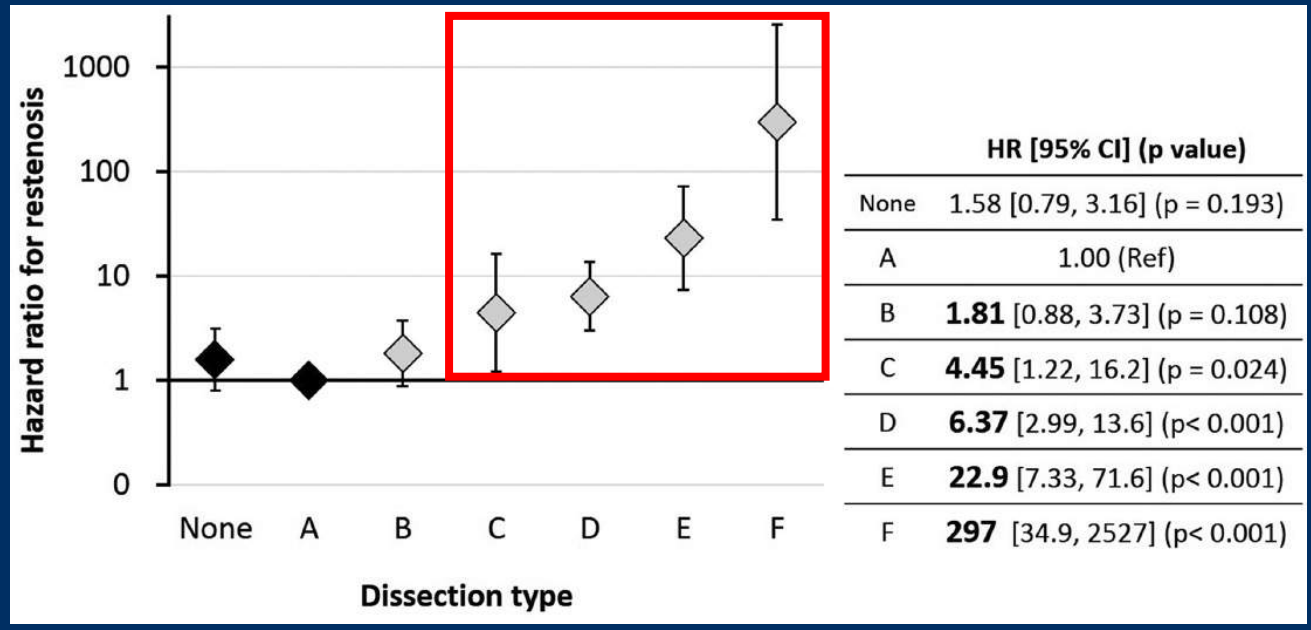
1. Thieme M., et al. JACC CI. 2017.
2. Schroeder, H., et al. Circulation. 2017.
3. Zeller T., LINC, 2017.
4. Shroë H., et al., CIR. 2018.
5. Krishnan P., et al. Circulation. 2017.
6. Tepe G., et al. Circulation. 2015.
7. Brodmann, M., et al. JACC CI. 2017.
8. Tepe, G. Charing Cross. 2016.
9. Scheinert, D. EuroPCR. 2015.

Dissection severity negatively influences patency

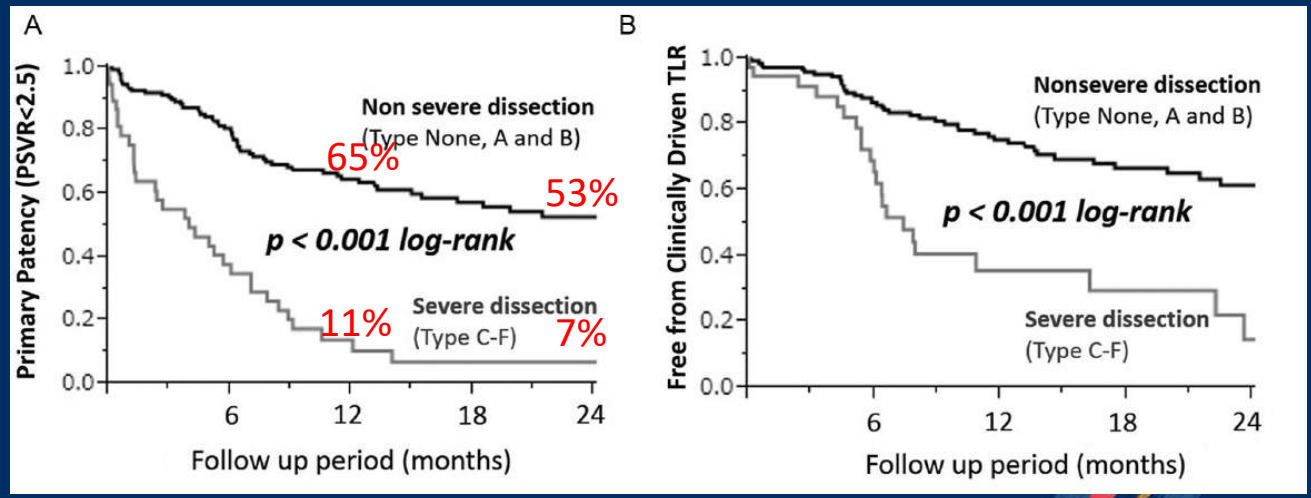
The bailout stent implantation rate increased according to dissection severity.

The severe dissection group (types C–F) showed a significantly lower patency rate (p<0.001) and higher clinically driven TLR (p<0.001) compared to the nonsevere group. Severe dissection is a significant risk factor for restenosis and TLR





	HR [95% CI] (p value)
None	1.58 [0.79, 3.16] (p = 0.193)
A	1.00 (Ref)
B	**1.81** [0.88, 3.73] (p = 0.108)
C	**4.45** [1.22, 16.2] (p = 0.024)
D	**6.37** [2.99, 13.6] (p< 0.001)
E	**22.9** [7.33, 71.6] (p< 0.001)
F	**297** [34.9, 2527] (p< 0.001)



Masahiko Fujihara, et al. J Endovasc Ther. 2017 Jun;24(3):367-375.

Dissection Decrease the Primary Patency Rate

AcoArt I DCB RCT: 144 patients, 24 months follow-up

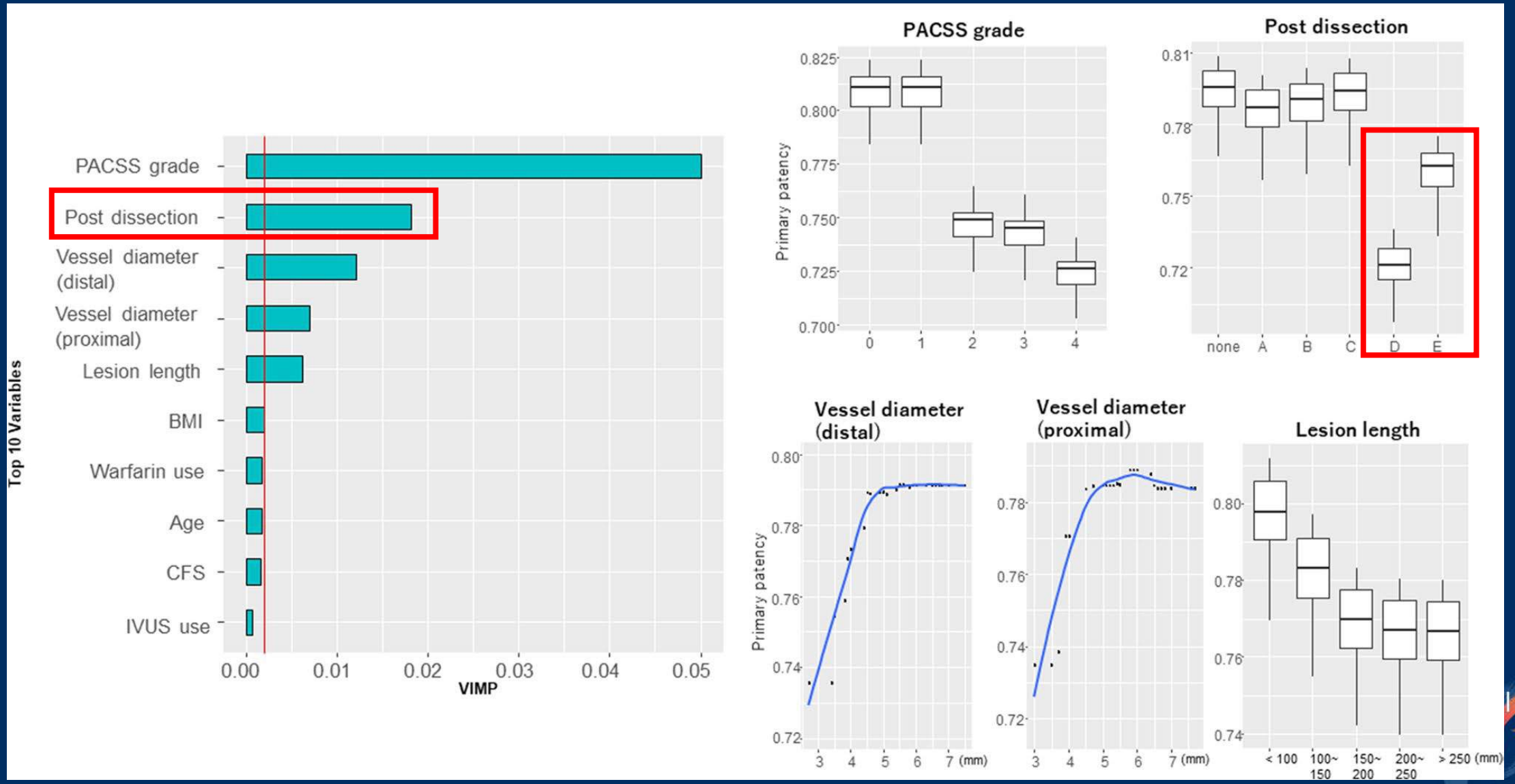
Mild dissection reduced the primary patency rate by 52% in PTA group and 19% in DCB group

Severe dissection (type D/E) reduced the primary patency rate by more than 70% in both the PTA and DCB groups

	PTA Group		DCB Group	
Overall	HR, 95% CI	P-value	HR, 95% CI	P-value
Non-dissection group	Ref	—	Ref	—
Dissection group	0.35 (0.12–1.01)	0.05	0.41 (0.12–1.38)	0.15
Dissection Grade				
Mild (type A/B/C)	0.48 (0.15–1.48)	0.20	0.81 (0.19–3.39)	0.77
Severe (type D/E)	0.25 (0.08–0.76)	0.01	0.27 (0.08–0.96)	0.04

Hao Ren, et al. J Int Med Res. 2021 Apr;49(4):3000605211006546.

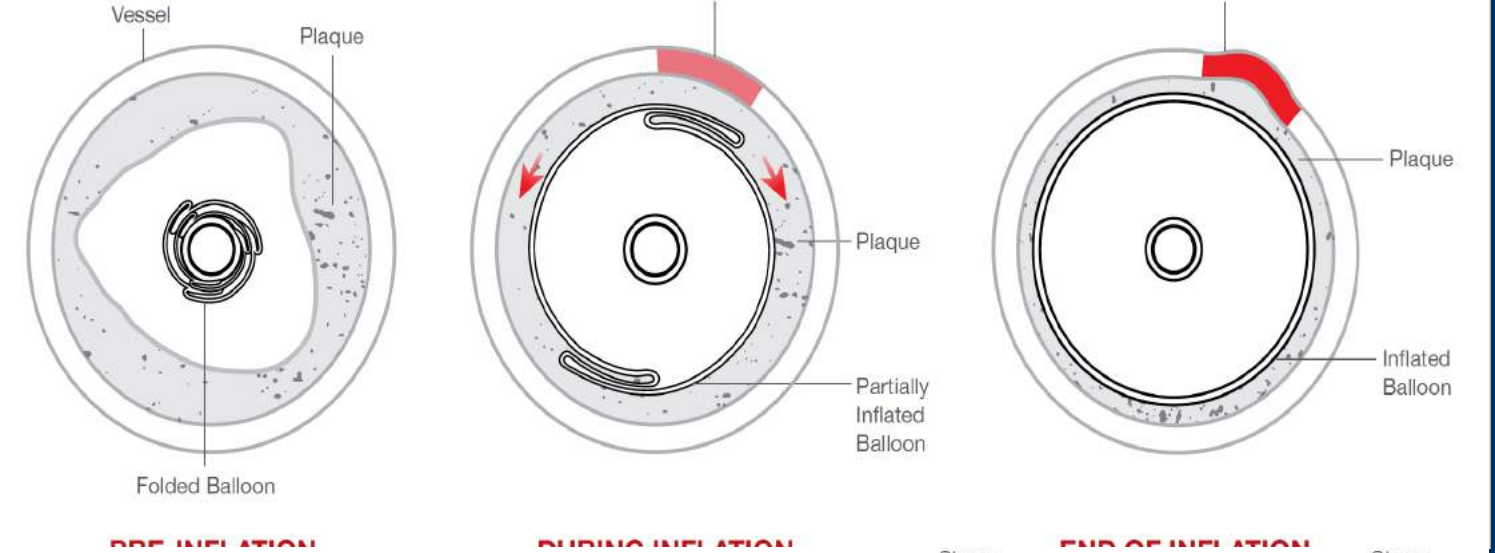
ASIGARU (reseArcherS In next GenerAtion of endovasculaR therapeUtics) PAD registry database from Japan: Post dissection pattern ≥ D is a predictive risk factor of restenosis in the DCB group



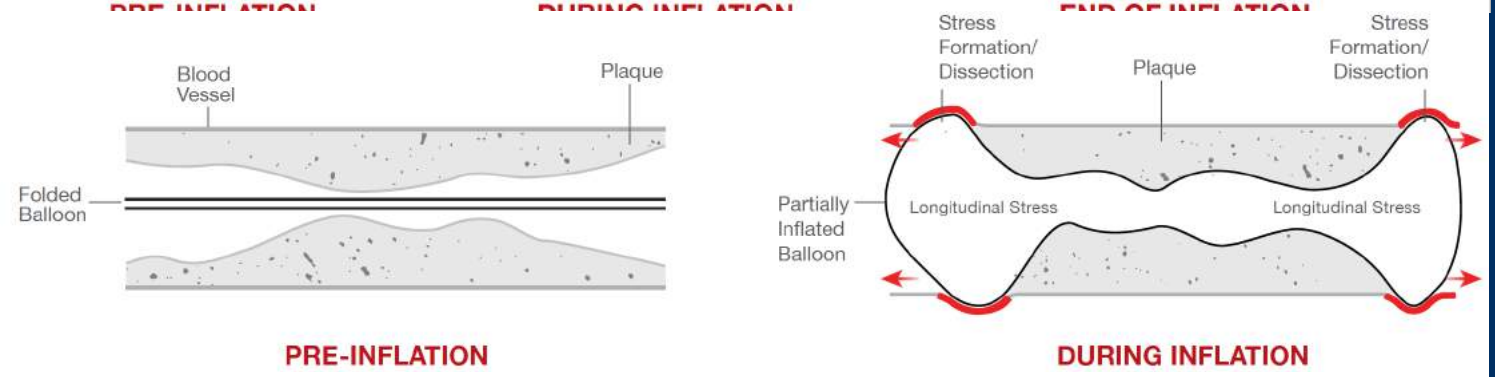
Naoki Yoshioka, et al. Heart Vessels. 2022 Apr;37(4):555-566.

Prevent or minimize dissection is important

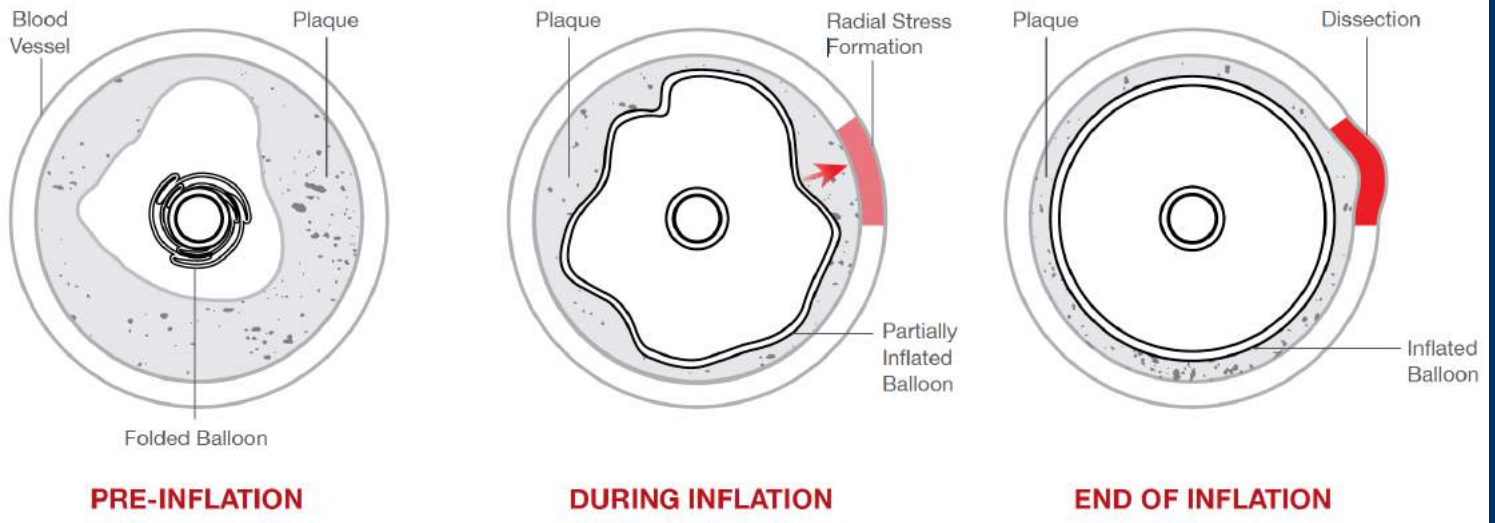
Uncontrolled Expansion during Balloon Angioplasty



Torsional stress can be imparted on the vessel wall through a twisting motion when a plain balloon unfolds during inflation



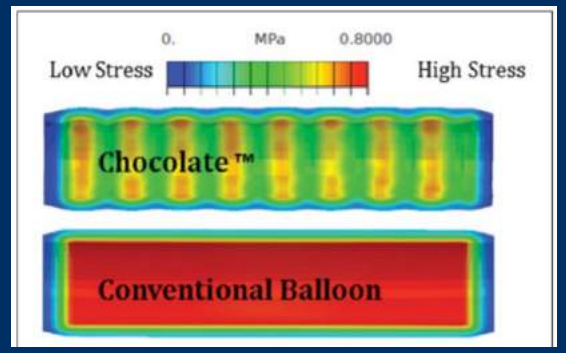
Longitudinal stress elongates the vessel wall when a plain balloon unfolds during inflation.



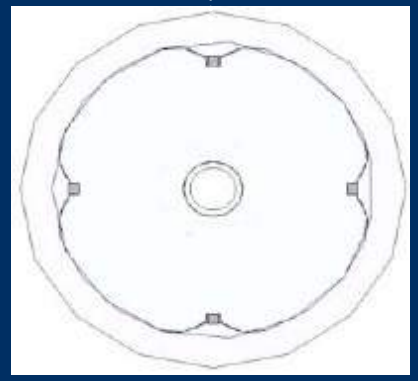
Radial stress outwardly expands the vessel wall when a plain balloon unfolds during inflation.

LINC

Basic concept of Chocolate Balloon: reduce wall stress and increase contact surface area



Nitinol Constraining Structure



Chocolate cross section

Cage (Nitinol Constraining Structure) :

- Shields vessel wall from shear (torsional) stress caused by balloon unfolding.
- Enables the even distribution of radial and longitudinal forces during balloon inflation.
- Allows for rapid deflation and uniform rewrap

Pillows :

- Provide predictable vessel dilatation without cutting or scoring

Grooves :

- Allow for plaque release, minimizing traumatic angioplasty effect.

LINC

Chocolate BAR registry

Prospective, multi-center, all-comers registry
A total of 262 patients (290 femoropopliteal lesions) were enrolled at 30 US centers between 2012 and 2014.

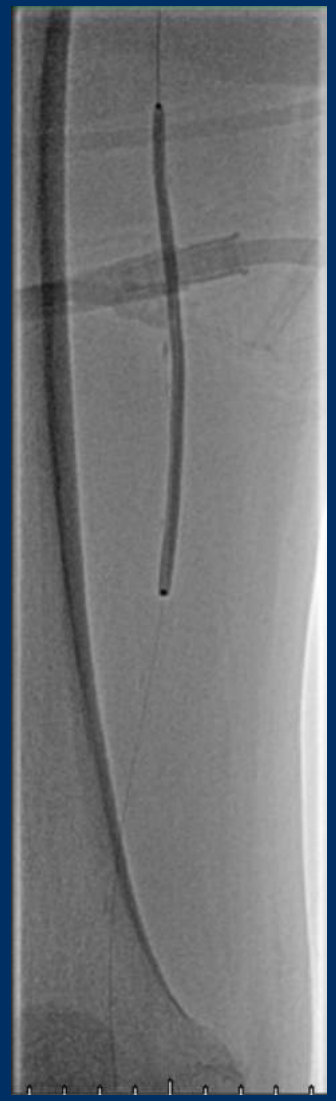
≤30% residual stenosis without flow-limiting dissection	85.1%
Flow limiting dissection Grade E Grade F	 0% 0%
Bail-out stenting	1.6%
Freedom from TLR	78.5%
Freedom from major amputation	97.2%
Freedom from all-cause mortality	93.3%

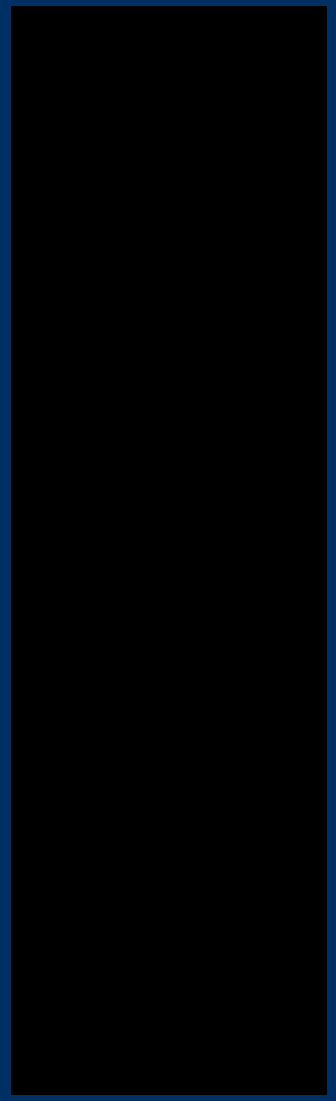
Jihad A Mustapha, et al. Catheter Cardiovasc Interv. 2018 May 1;91(6):1144-1148.

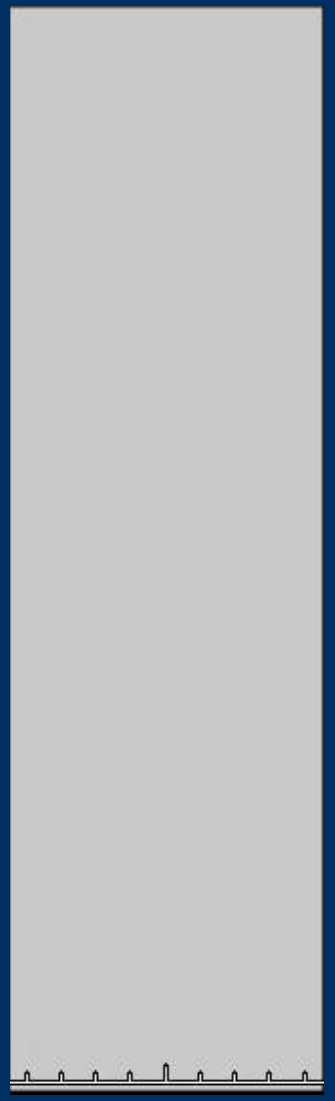
Case 1: Short SFA CTO lesion

Late 60s yo F

4-120mmChocolate Balloon + 4-150mmIN.PACT DCB



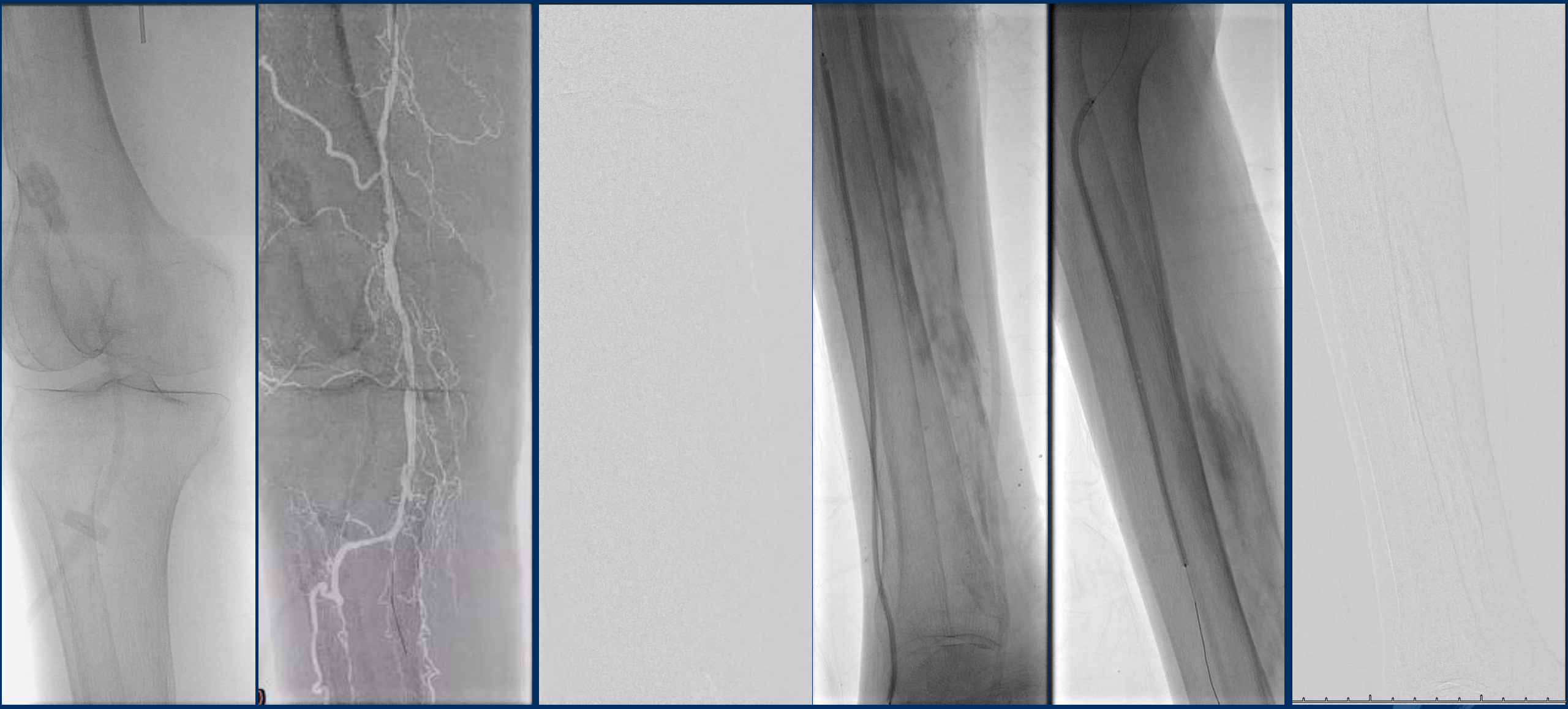




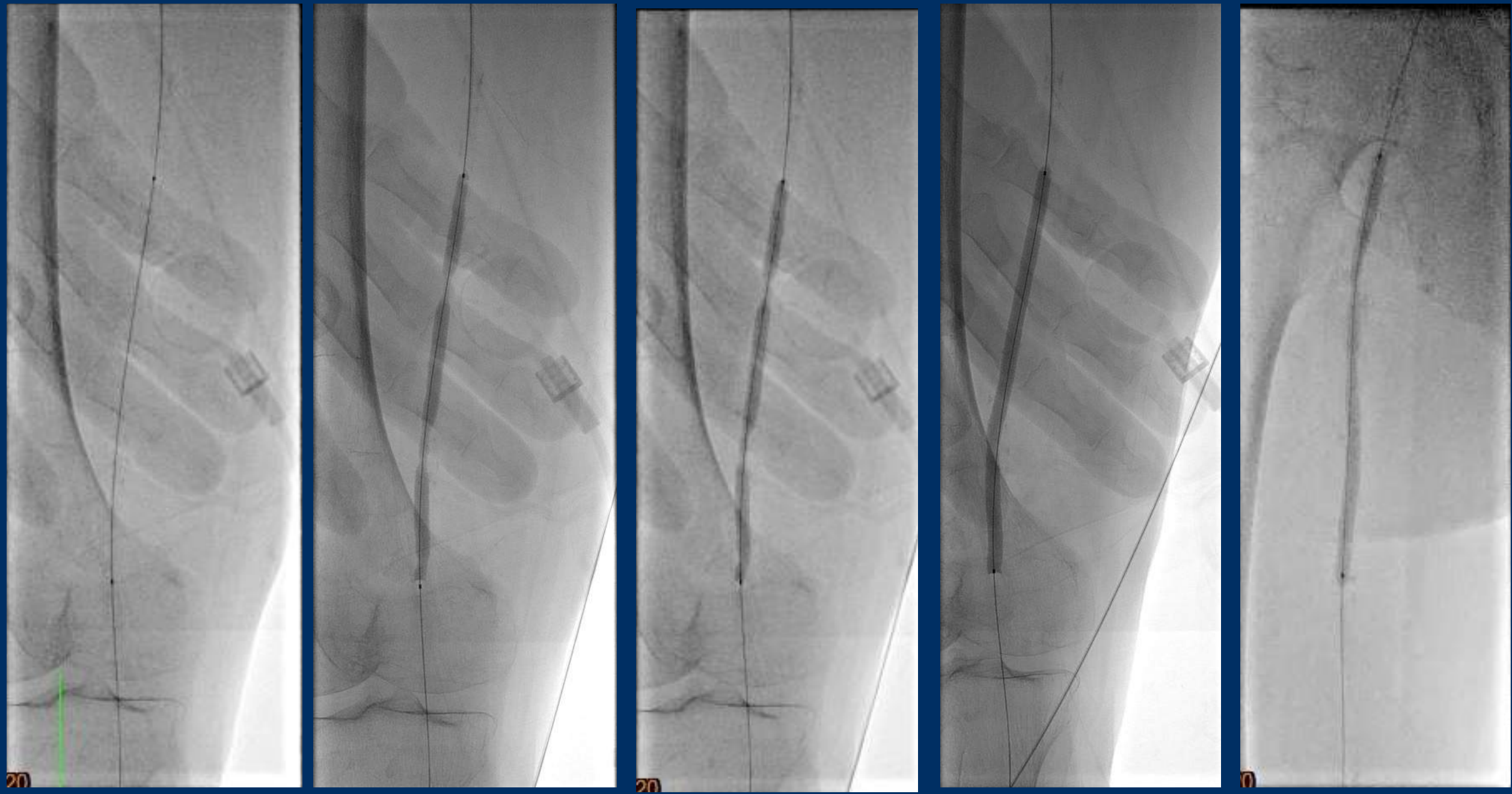
Case 2: Diffused stenosis with CTO

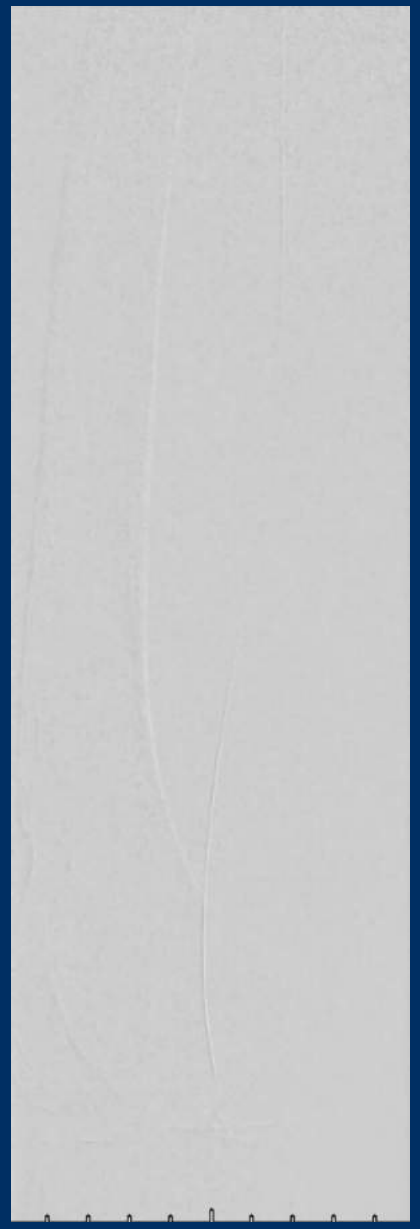
90s yo F

2.5-3-210mm Amphirion Deep Balloon

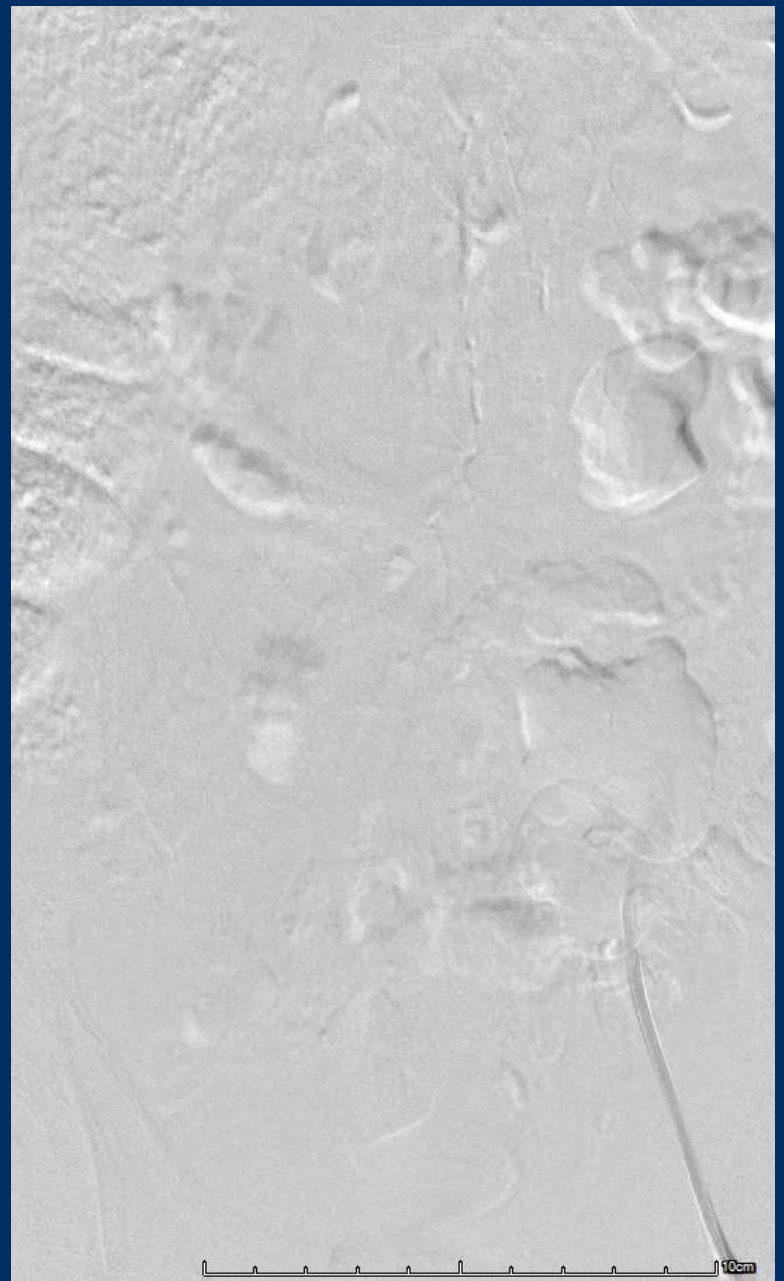


5-120mm Chocolate Balloon +5-300mm DCB

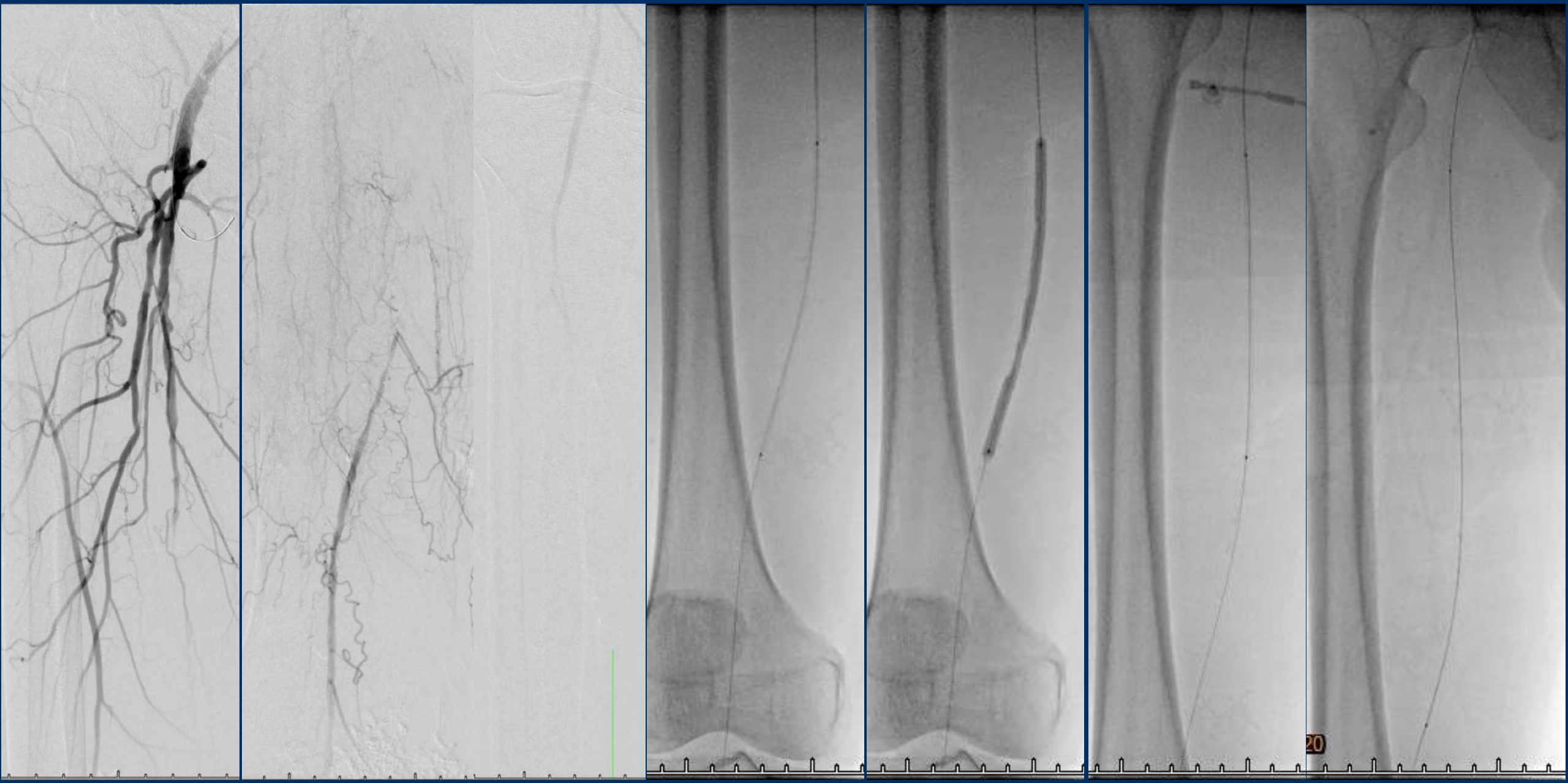


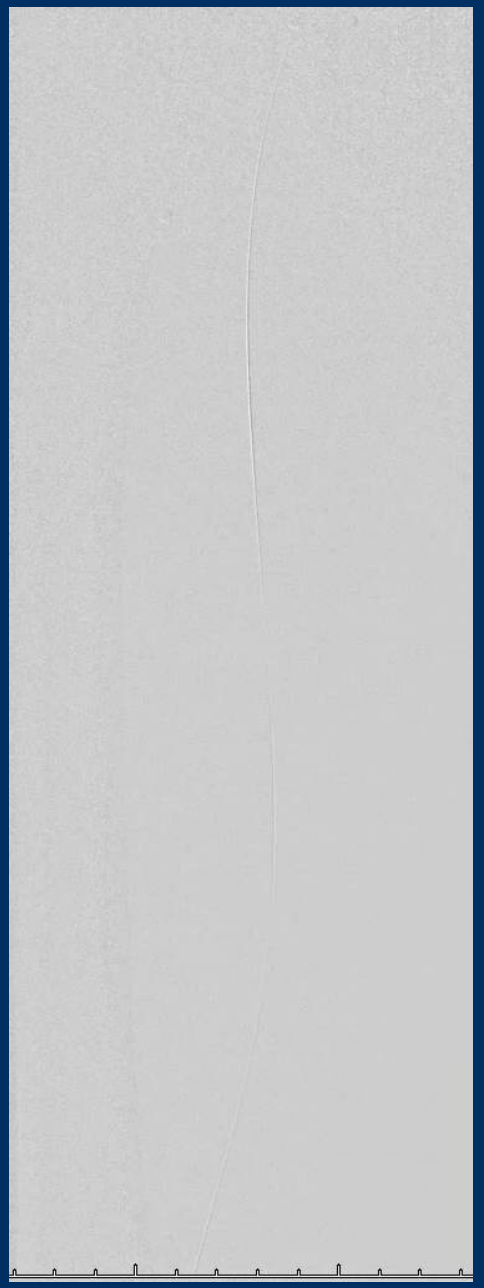
Case 3 late 70s yo M. Right external iliac artery occlusion, Right SFA long CTO lesion

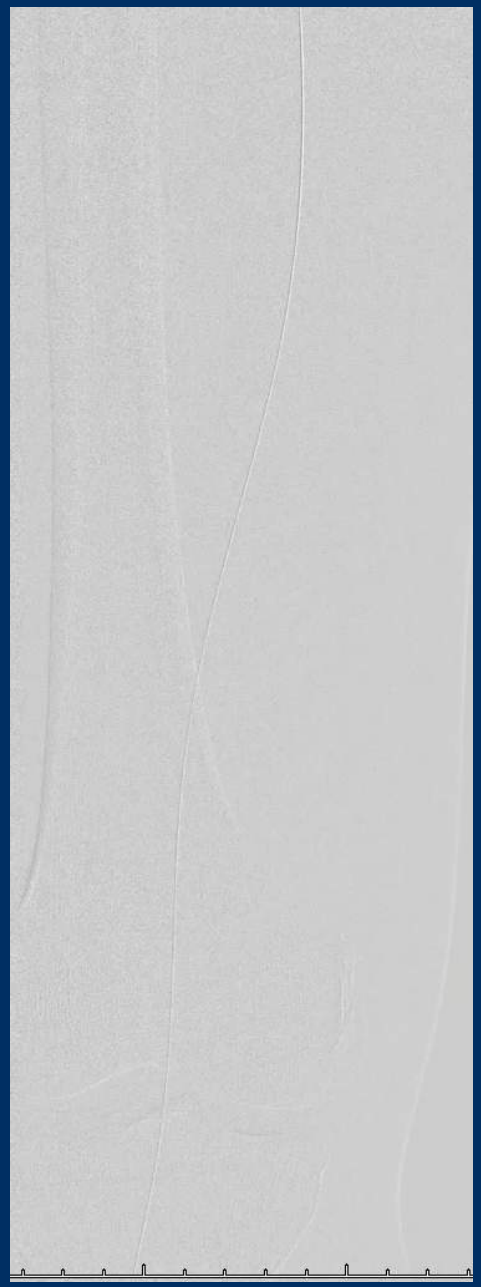


5-120mm Chocolate Balloon + 5-220mm DCB

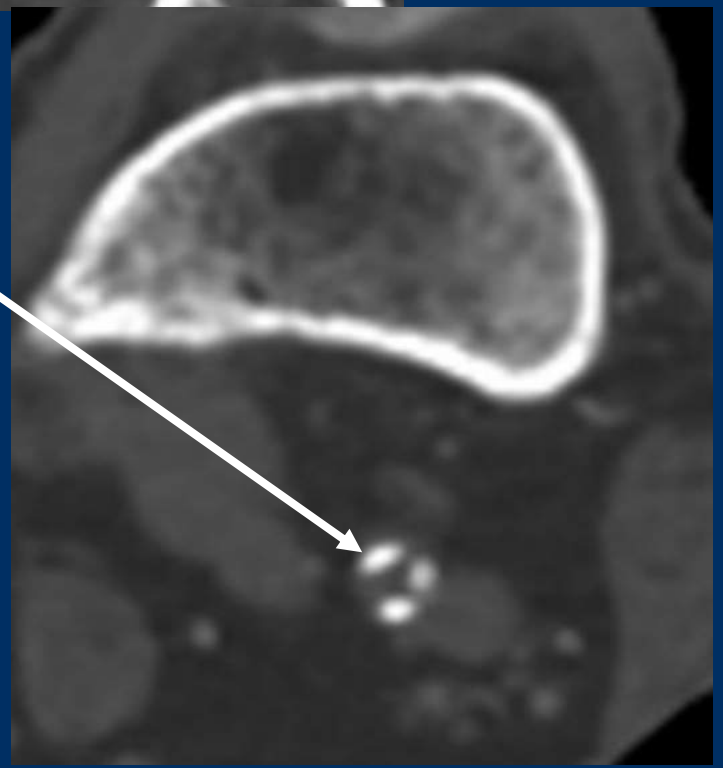


7-150mm stent





Case 4
80s yo F
Short occlusion with Grade 3 calcification



Grade 3 calcification

5-120mm Chocolate Balloon + 5-300mm DCB

Conclusion

- Prevent / Minimize dissection is important to improve the clinical outcomes
- Chocolate balloon is effective in minimizing dissections
- True lumen is essential, keep calm and control the inflate/deflate time

Thank You