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## DON'T BE AFRAID ABOUT VASCULAR EMERGENCIES ANYMORE

# Thombotic Complicatios during Peripheral Endovascular Intervention

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# Disclosure of Interest

**Disclosure**

Speaker name:

Maria Antonella Ruffino, MD, EBIR

- I have the following potential conflicts of interest to report:
- Consulting
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
- Other(s)
- X I do not have any potential conflict of interest on this topic

# *CASE PRESENTATION*

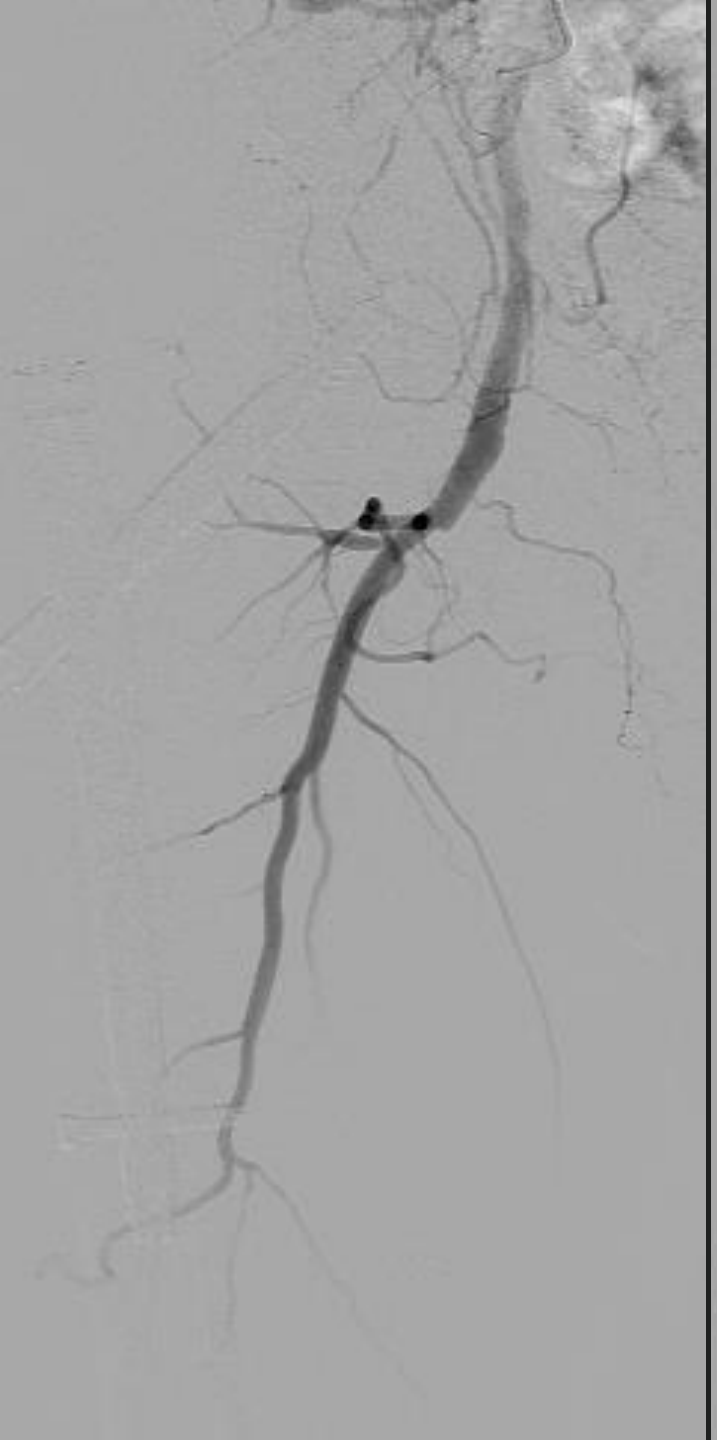
- 70 y.o. male
- Active smoker
- Hypertension
- 2000: bilateral SFA stenting
- 2014: right hip replacement
- 2016: left CEA
- 2017: right lower limb claudication <50 m (Ruth I, cat 3)

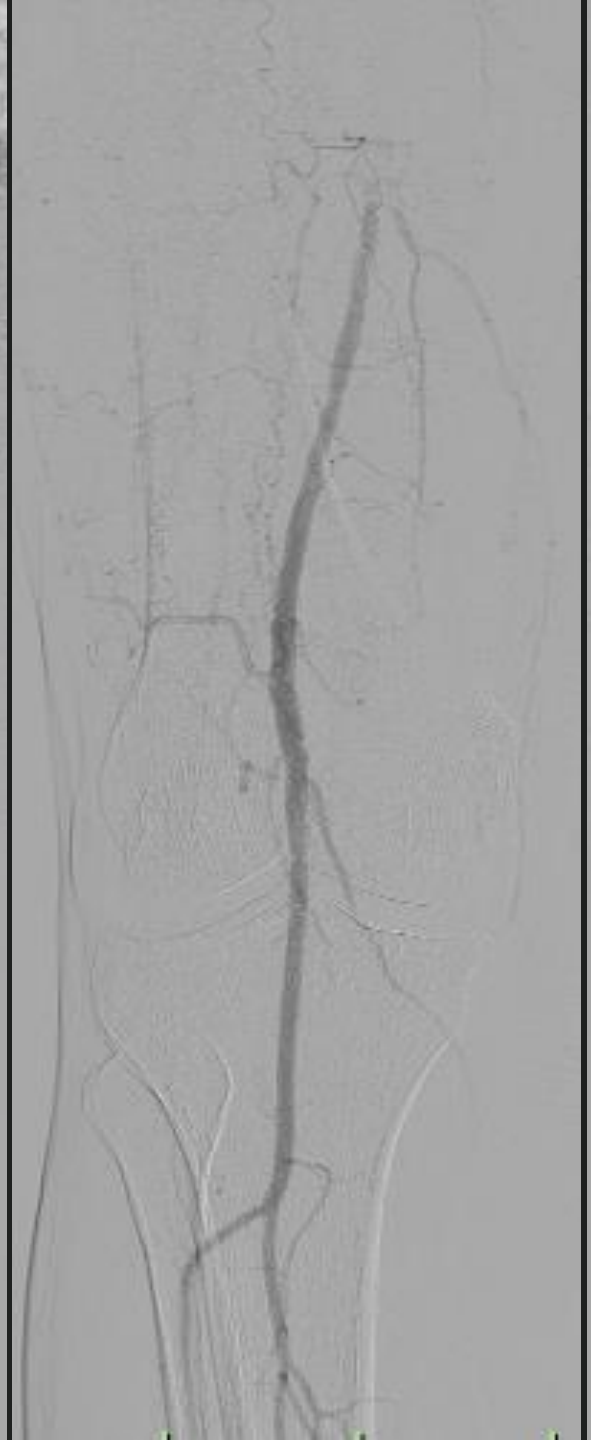
ONGOING THERAPY

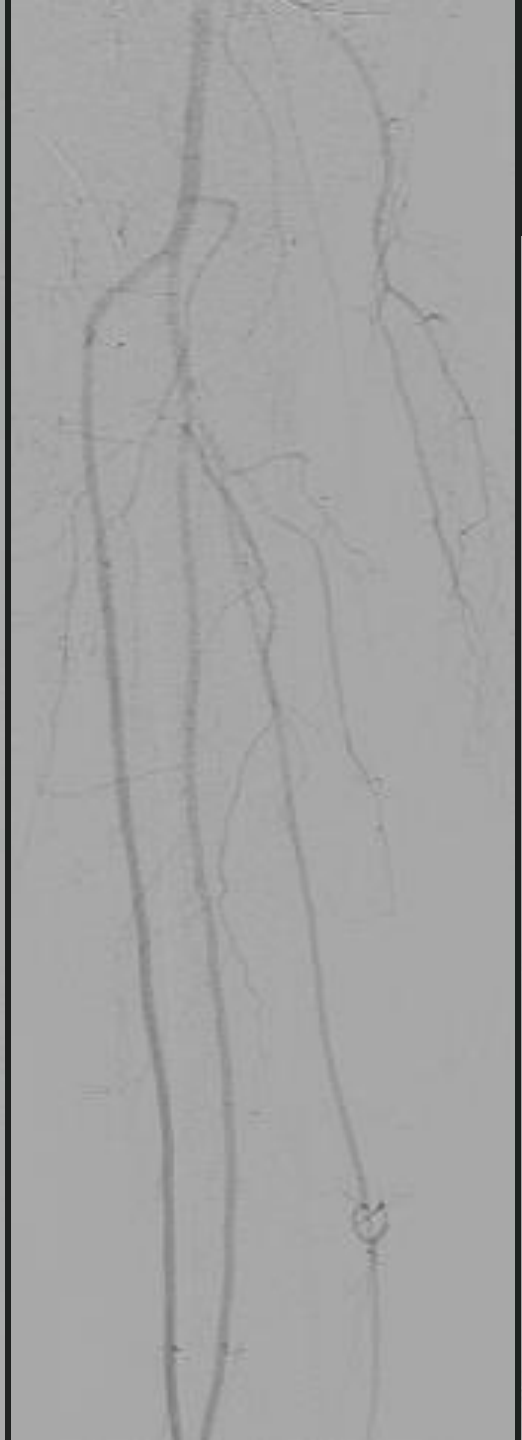
- ASA 100 mg
- Clopidogrel 75 mg
- Lisinopril 20 mg 1 tbl x2
- Esomeprazole 40 mg 1 tbl
- Nisoldipine 10 mg 1 tbl x2
- Atorvastatin 20 mg 1 tbl
- Bisoprolol 2.5 mg 1 tbl

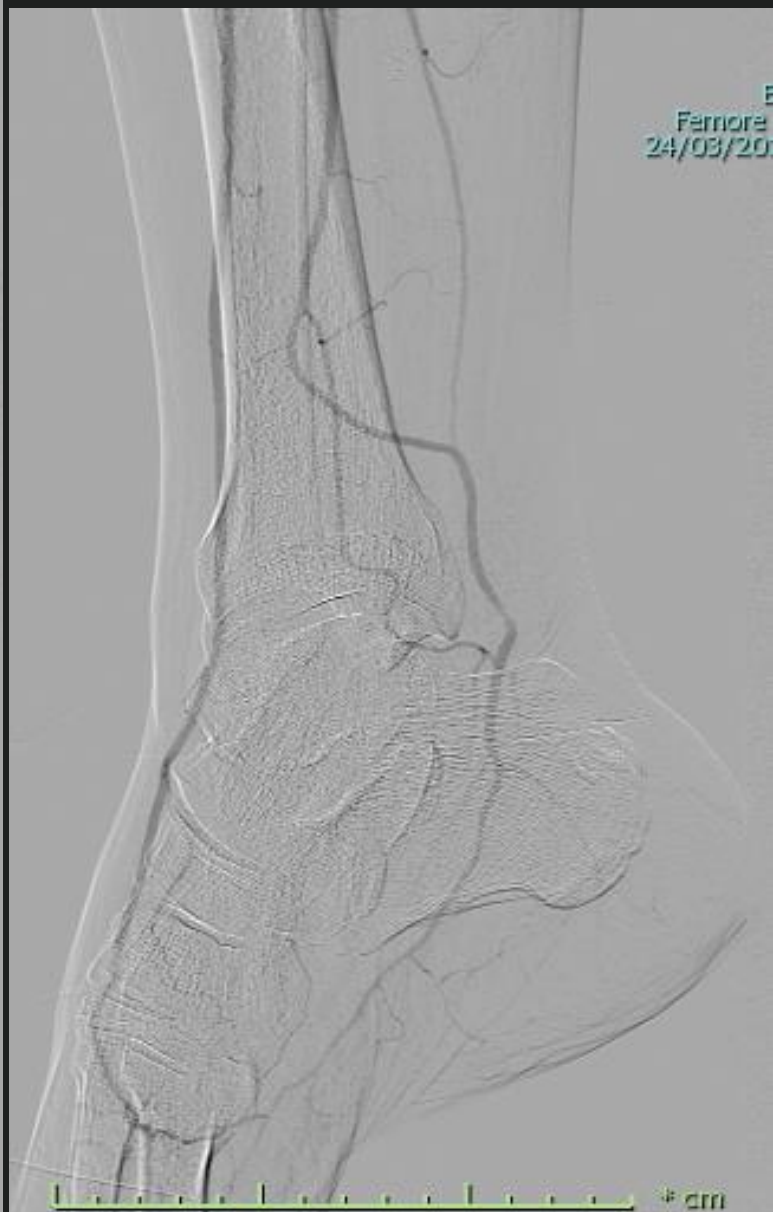
February 2017 DUS: SFA occlusion from the origin to the Hunter canal
out-flow: 3 vessels
no autologous saphenous vein

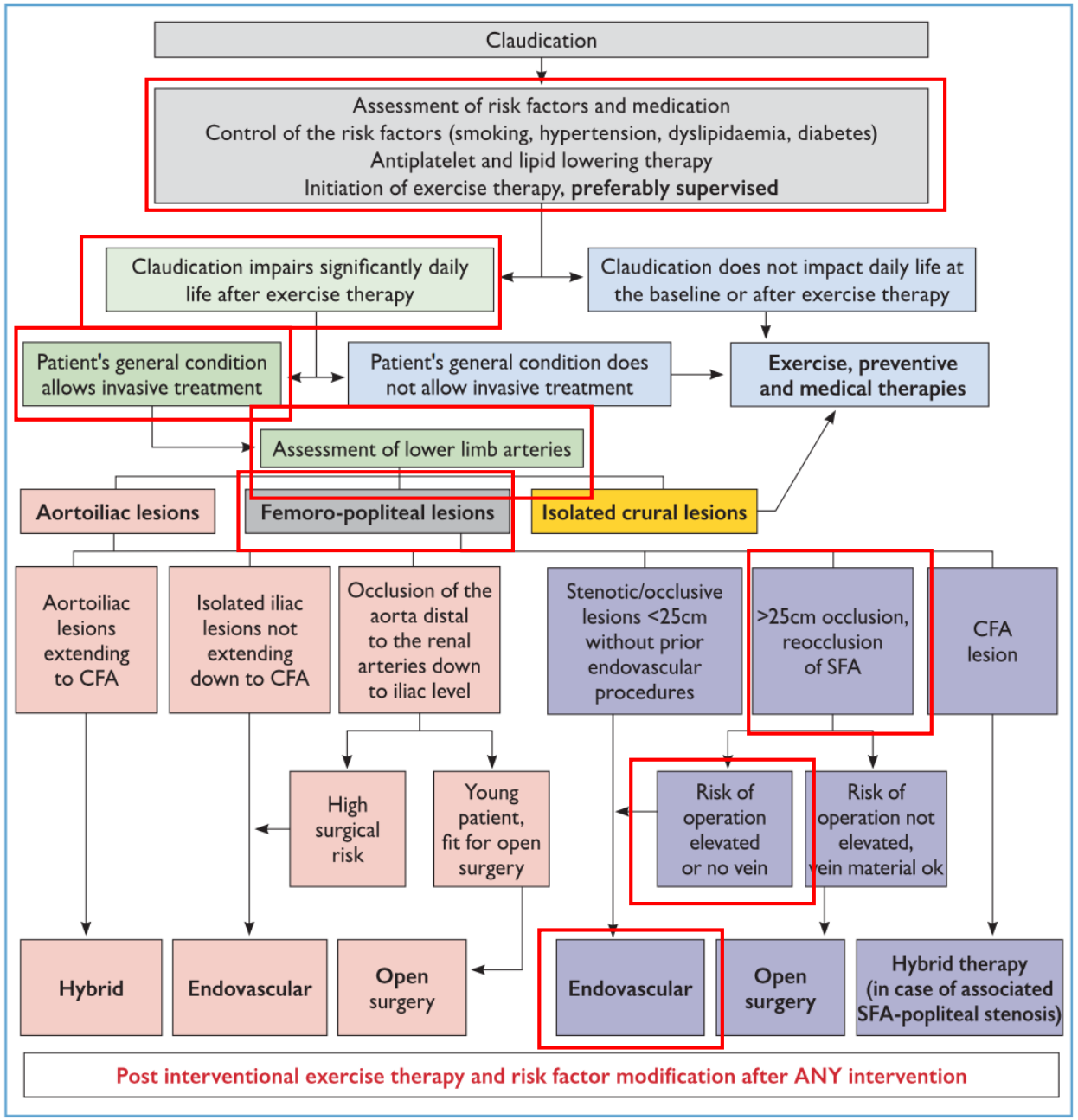
DSA 24.03.2017












CFA = common femoral artery; SFA = superficial femoral artery.
[a]Related to atherosclerotic lower extremity artery disease (LEAD).

**Figure 5.** Management of patients with intermittent claudication.[a]

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Eur J Vasc Endovasc Surg (2017) ■, 1–64

# 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS)

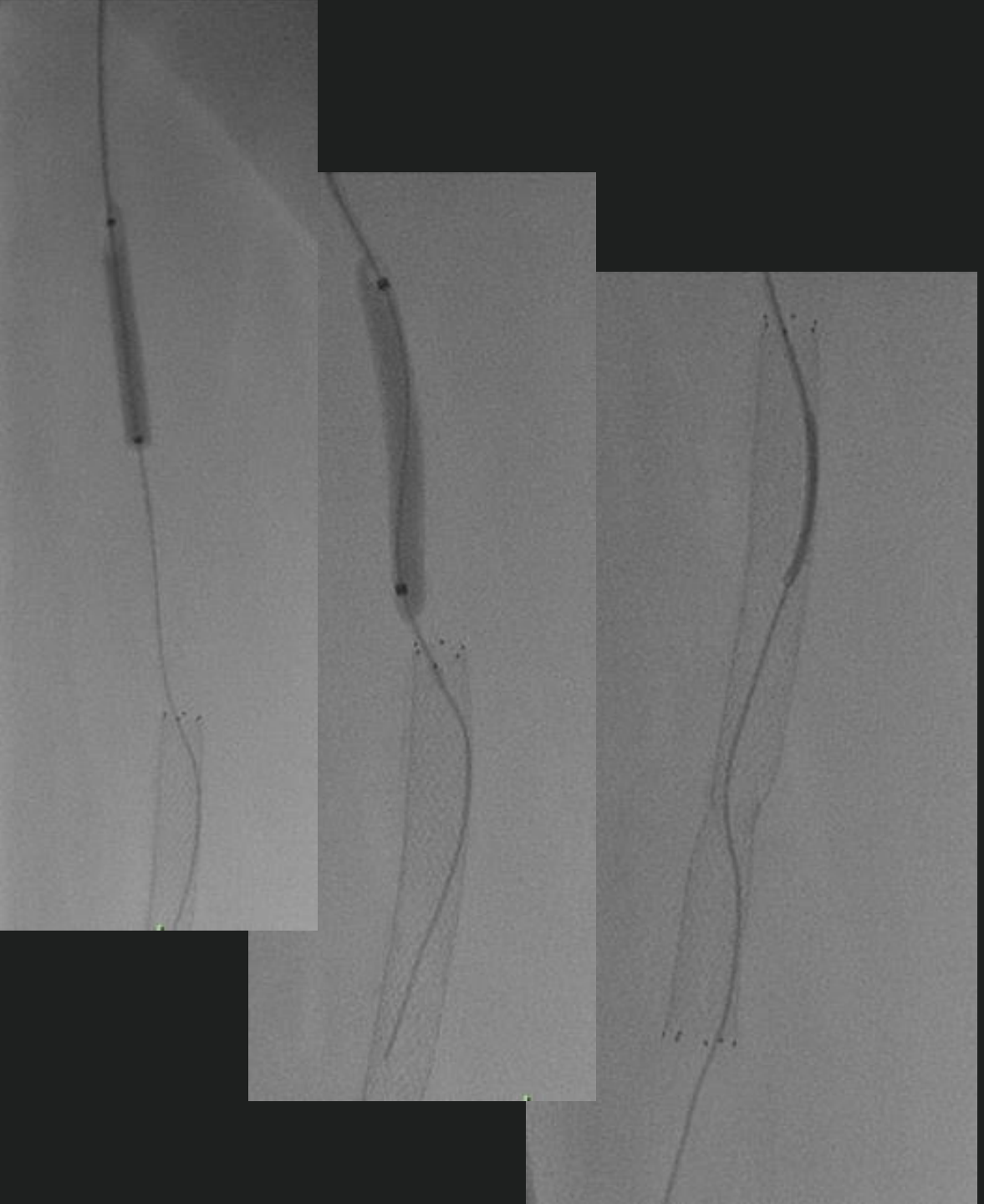
**Document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteries**

**Endorsed by: the European Stroke Organization (ESO)**

**Recommendations on revascularization of femoro-popliteal occlusive lesions[c]**

| Recommendations | Class[a] | Level[b] |
|---|---|---|
| An endovascular-first strategy is recommended in short (i.e. <25 cm) lesions.[302,303] | I | C |
| Primary stent implantation should be considered in short (i.e. <25 cm) lesions.[304,305] | IIa | A |
| Drug-eluting balloons may be considered in short (i.e. <25 cm) lesions.[77,306–310] | IIb | A |
| Drug-eluting stents may be considered for short (i.e. <25 cm) lesions.[302,303,311] | IIb | B |
| Drug-eluting balloons may be considered for the treatment of in-stent restenosis.[312,313] | IIb | B |
| In patients who are not at high risk for surgery, bypass surgery is indicated for long (i.e. ≥25 cm) superficial femoral artery lesions when an autologous vein is available and life expectancy is >2 years.[314] | I | B |
| The autologous saphenous vein is the conduit of choice for femoro-popliteal bypass.[284,315] | I | A |
| When above-the-knee bypass is indicated, the use of a prosthetic conduit should be considered in the absence of any autologous saphenous vein.[284] | IIa | A |
| In patients unfit for surgery, endovascular therapy may be considered in long (i.e. ≥25 cm) femoro-popliteal lesions.[312] | IIb | C |

[a] Class of recommendation.
[b] Level of evidence.
[c] These recommendations apply for patients with intermittent claudication and severe chronic limb ischaemia.



## STEP 1: left femoral access

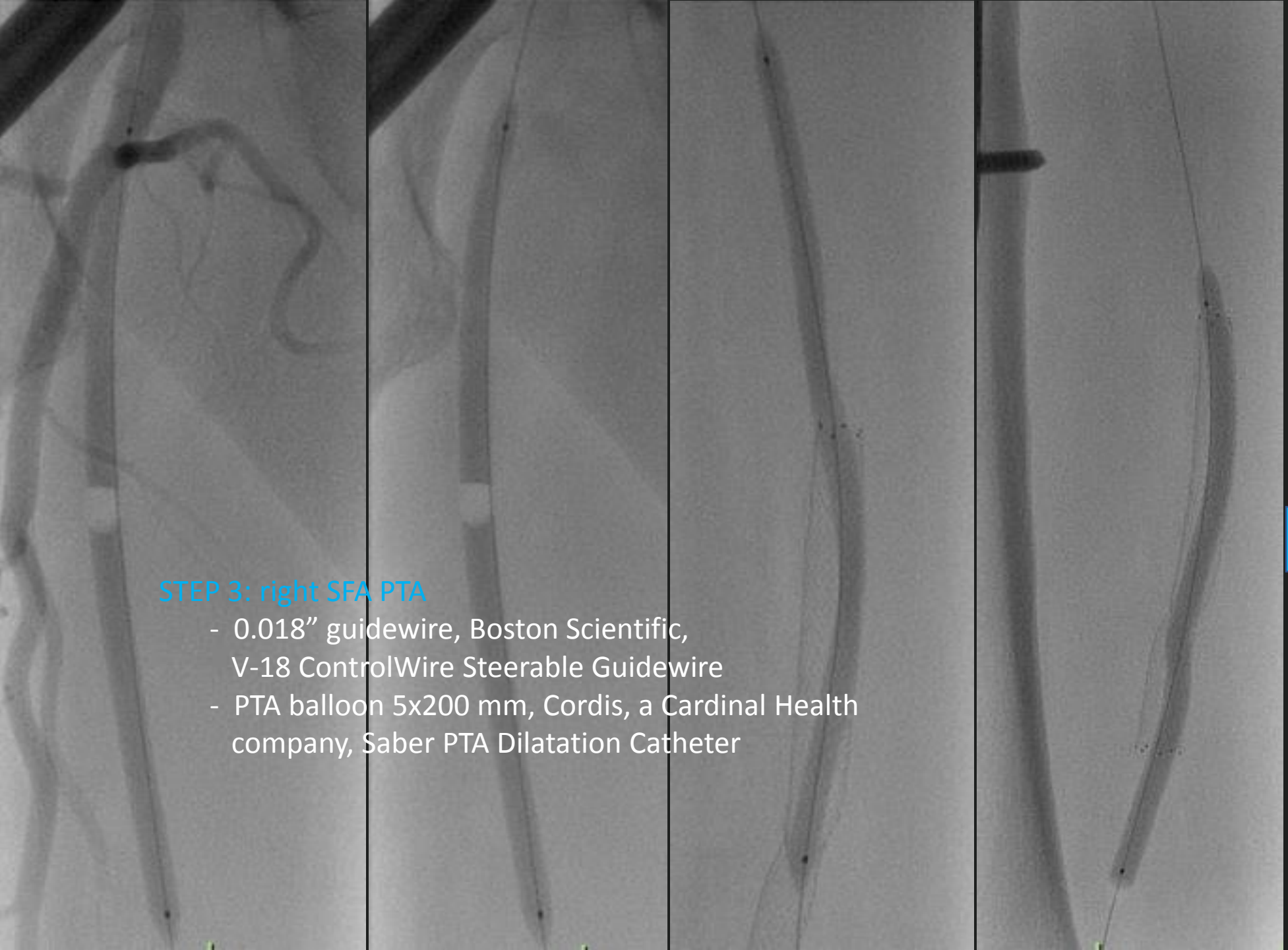
- 0.035’’ Terumo Radifocus® Guide Wire M
- 6 F – 45 cm Cook Flexor® Ansel Guiding Sheath

## STEP 2: right SFA rivascularization

- 0.035’’ Terumo Radifocus® Guide Wire straight
- PTA balloon 4x40 mm, Abbott Vascular Armada 35 PTA Catheter
- pig-tail catheter 5 F, Cordis, a Cardinal Health company, Tempo Flush Catheters

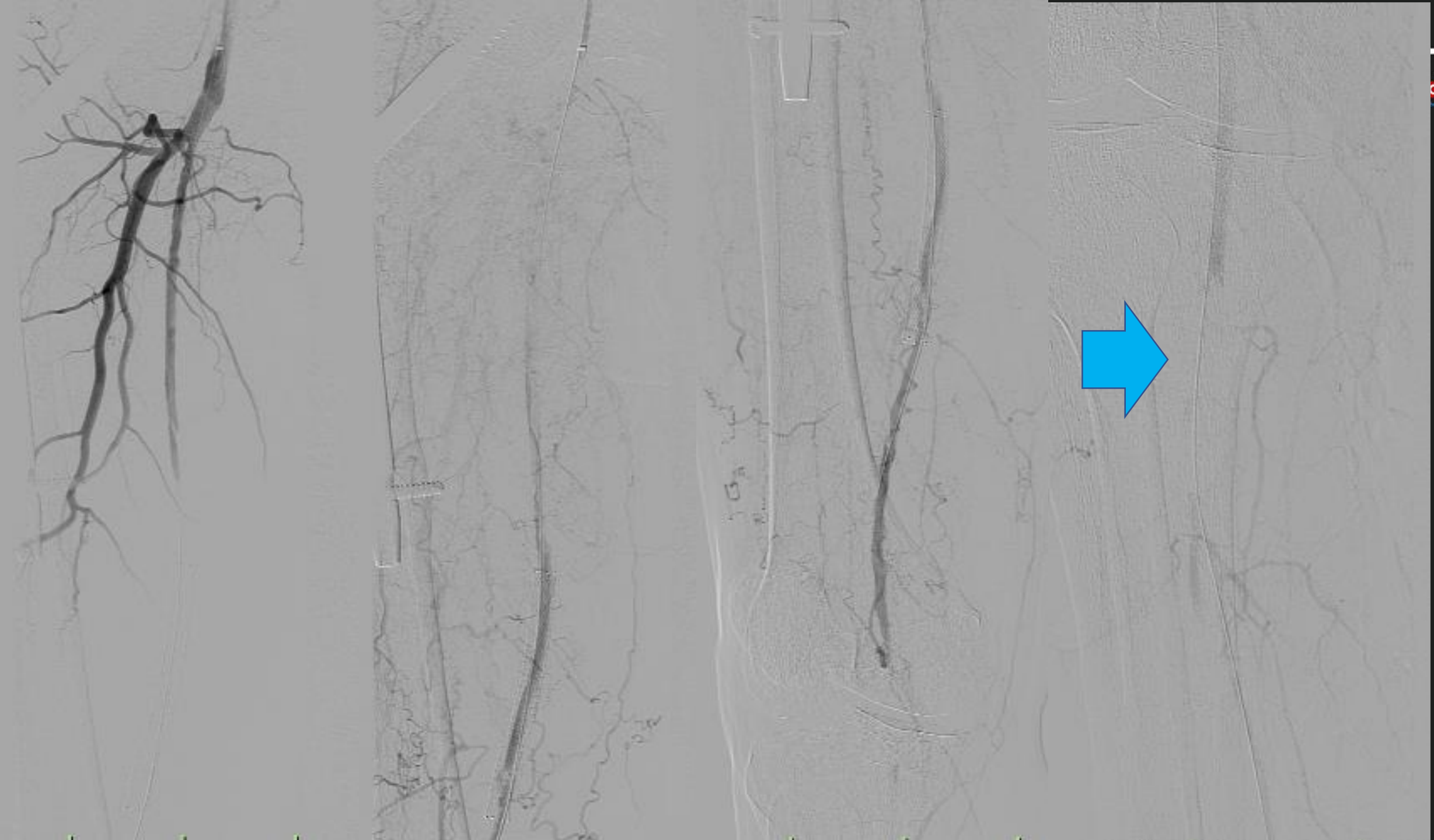
## INTRAPROCEDURAL THERAPY

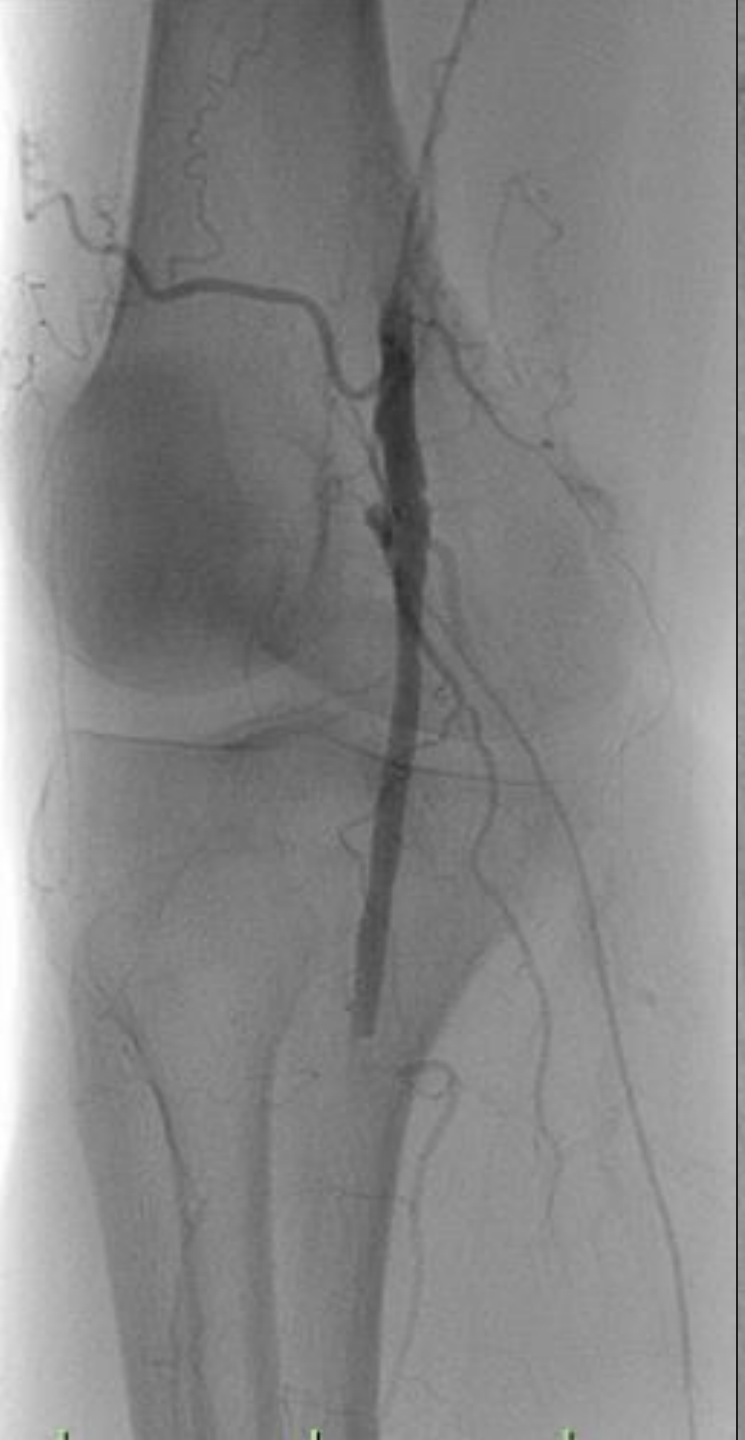
- 5000 UI Heparin
- ACT was kept within the 275-300 sec range with following injection of 1000 UI of heparin/hour with anticoagulation time control

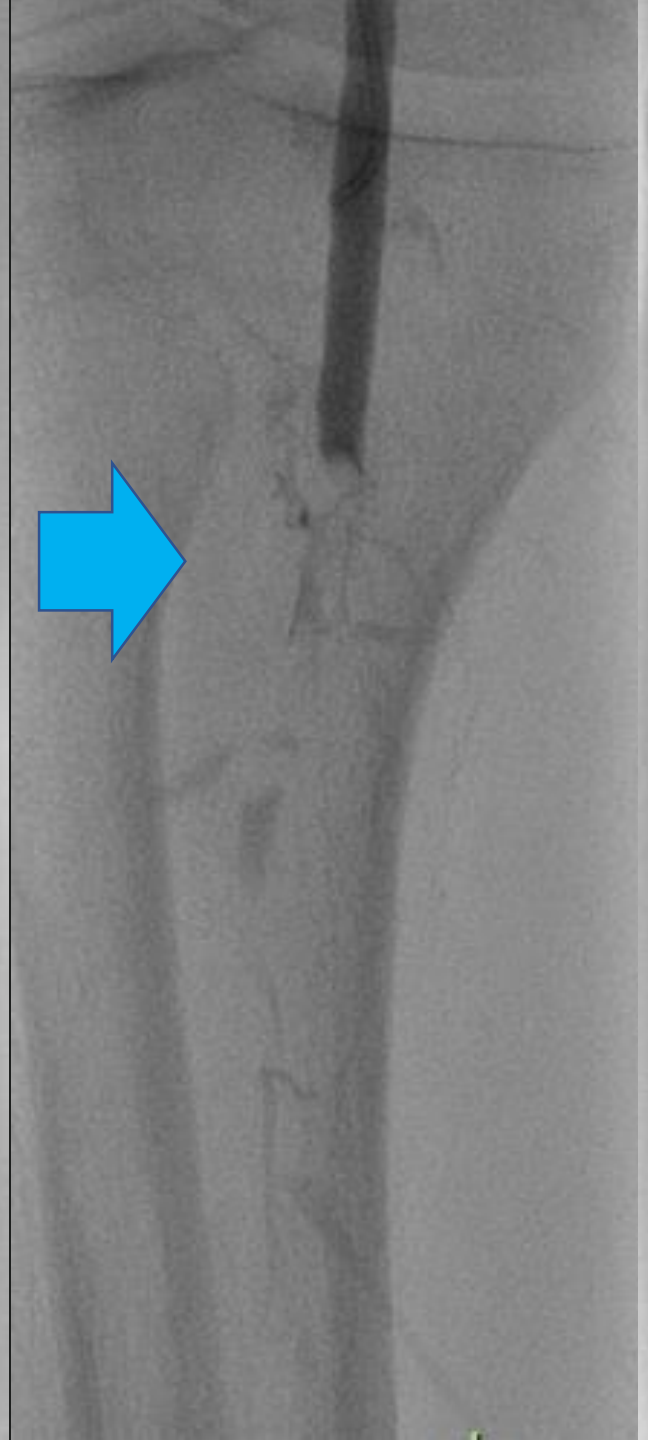


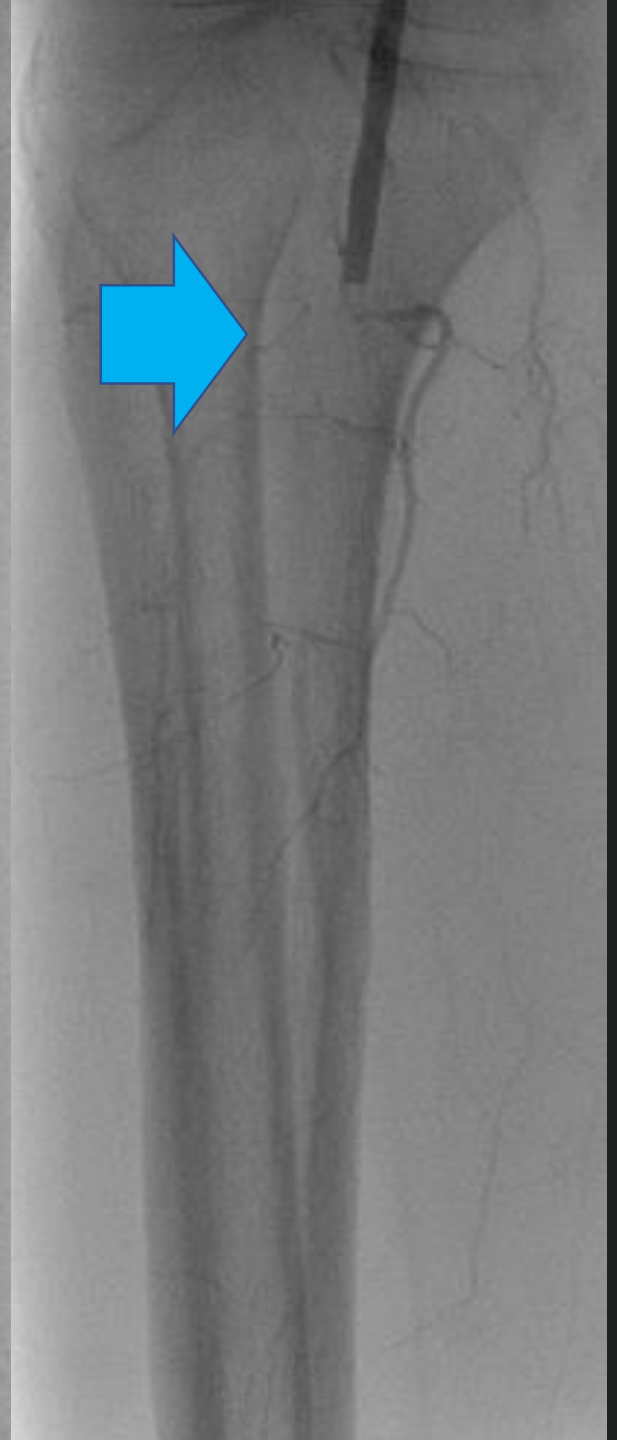
STEP 3: right SFA PTA

- 0.018” guidewire, Boston Scientific, V-18 ControlWire Steerable Guidewire
- PTA balloon 5x200 mm, Cordis, a Cardinal Health company, Saber PTA Dilatation Catheter









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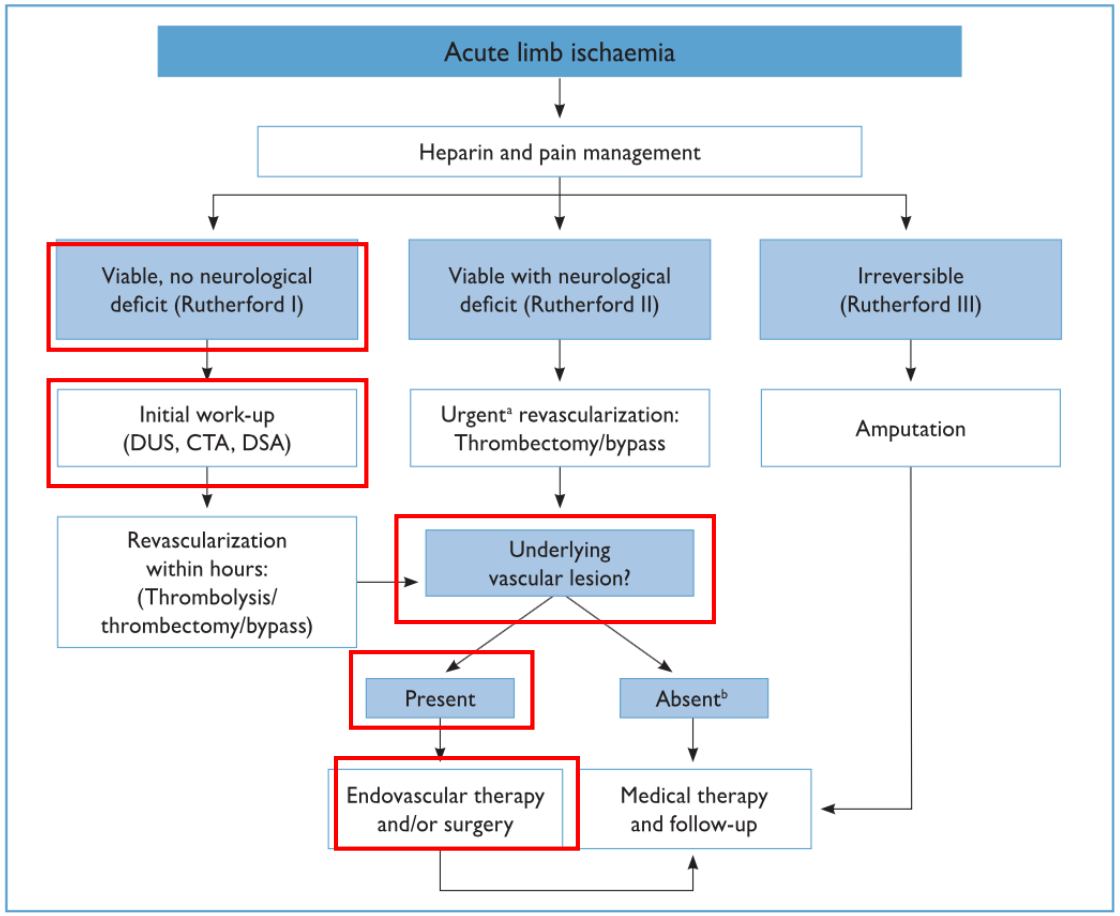


CTA = computed tomography angiography; DSA = digital subtraction ultrasound; DUS = duplex ultrasound.
[a]Imaging should not delay revascularization.
[b]Specific etiological work-up is necessary (cardiac, aorta).

**Figure 7.** Management of acute limb ischaemia.

Eur J Vasc Endovasc Surg (2017) ■, 1—64

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**Document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteries**

**Endorsed by: the European Stroke Organization (ESO)**

**Recommendations for the management of patients presenting with acute limb ischaemia**

| Recommendations | Class[a] | Level[b] |
|---|---|---|
| In the case of neurological deficit, urgent revascularization is indicated.[246,331,c] | I | C |
| In the absence of neurological deficit, revascularization is indicated within hours after initial imaging in a case-by-case decision.[246,331] | I | C |
| Heparin and analgesics are indicated as soon as possible.[246,331] | I | C |

[a] Class of recommendation.
[b] Level of evidence.
[c] In this case, imaging should not delay intervention.

SYSTEMATIC REVIEW

# Catheter Directed Thrombolysis Protocols for Peripheral Arterial Occlusions: a Systematic Review

**Harm P. Ebben, Vincent Jongkind, Willem Wisselink, Arjan W.J. Hoksbergen, Kak K. Yeung** *

Department of Vascular Surgery, Amsterdam UMC, Amsterdam, the Netherlands

**WHAT THIS PAPER ADDS**

Current thrombolysis protocols for peripheral arterial occlusions are based on evidence from randomised controlled trials performed >20 years ago. To this day, there is no consensus on the optimum fibrinolytic agent or dose regimens to use. Numerous devices and techniques, such as mechanical thrombectomy and ultrasound assisted thrombolysis, have been proposed and investigated to improve the results of thrombolysis. Major bleeding complications remain a substantial clinical problem of thrombolytic therapy. The present systematic review of the literature provides an update of all reported patient cohorts with peripheral arterial occlusions treated by catheter directed thrombolysis.

**Objective:** Catheter directed thrombolysis (CDT) for peripheral arterial occlusions is a well established alternative to thrombo-embolectomy in patients with (sub)acute limb ischaemia. However, protocols are heterogeneous and need optimisation to improve results and lower bleeding risks. The objective was to review the results and outcomes of different CDT protocols for patients with peripheral arterial occlusions.

**Data sources:** Electronic information sources (MEDLINE, Embase, Cochrane) and reference lists were searched to identify studies reporting results of CDT of peripheral arterial occlusions.

**Methods:** Two independent observers performed study selection, quality assessment and data extraction. Primary outcomes were treatment duration, success rates, and bleeding complications. Secondary outcomes were mortality and amputation rates.

**Results:** One hundred and six studies were included: 19 randomised controlled trials (RCTs), 38 prospective studies, 48 retrospective studies, and one mixed cohort study. The studies comprised a total number of 10,643 cases of which 9877 received CDT for lower extremity arterial occlusion, with a mean treatment duration of 21.4 h (95% confidence interval [CI] 21.0—21.8), an angiographic patency of 75% (95% CI 74.6—75.1), and freedom from amputation rate of 91% (95% CI 90.3—90.7). Pooled results showed a thrombolysis duration with high dose protocols of 21.9 h (95% CI 21.4—22.5) and 32.7 h with low dose protocols, with bleeding rates of 16.7% (95% CI 16.3—17.1) and 13.4% (95% CI 12.8—14.0), respectively. Weighted mean results for all RCTs and prospective cohorts of >100 cases analysed separately, showed comparable results to all observational cohorts pooled. Bleeding complications occurred in 18% (95% CI 17.8—18.3) of patients and remain an important risk of CDT.

**Conclusion:** CDT is an effective treatment for peripheral arterial occlusions, the main concern is bleeding complications. Although no formal meta-analysis could be performed, the pooled results suggest that lower doses of fibrinolytics lead to similar success rates at a cost of longer treatment duration but with less bleeding. There is large variation in treatment protocols and the available literature suffers from absence of reporting standards and high heterogeneity.

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## CONCLUSIONS

CDT is an effective treatment for peripheral arterial occlusion with an angiographic patency rate of 75% and freedom from amputation rate of 91%. The main concern is bleeding complications, which occur in 18% of patients. Although no formal meta-analysis could be performed, the pooled results suggest lower doses of fibrinolytics lead to similar success rates at the cost of longer treatment duration but with fewer bleeding complications. There is a large variety in treatment protocols and the available literature suffers from the absence of reporting standards and from high heterogeneity; therefore, there is a need for prospective data from large series.

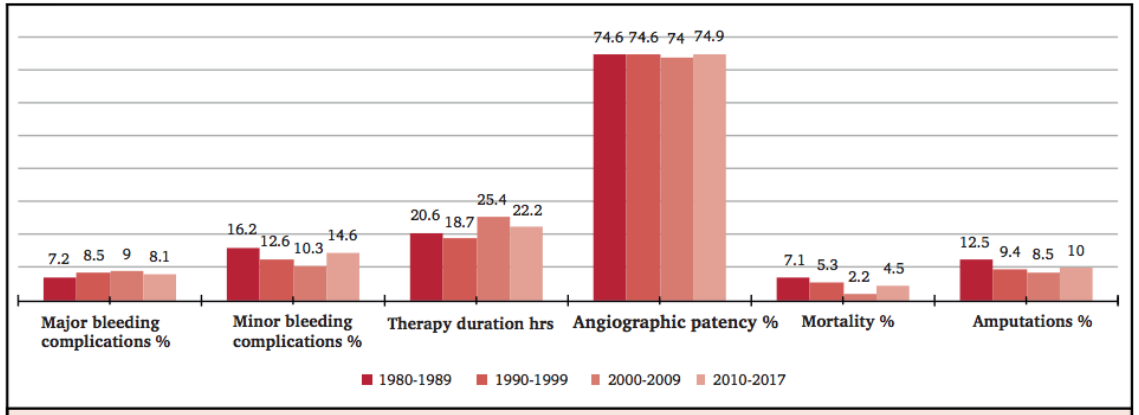


**Figure 2.** In hospital treatment outcomes of catheter directed thrombolysis through the years. Bleeding complications were recorded as major or minor as reported by the treating physician. If possible the definition by Mehran et al[6] was followed: type III/IV bleedings (need for transfusion or intervention, or intracranial or fatal bleeding) were classified major, and all others minor. Angiographic patency was defined as the reported success of thrombolysis at final angiography, and amputations included all reported amputations.

# Utility of a Power Aspiration–Based Extraction Technique as an Initial and Secondary Approach in the Treatment of Peripheral Arterial Thromboembolism: Results of the Multicenter PRISM Trial

Richard R. Saxon, MD, James F. Benenati, MD, Corey Teigen, MD, George L. Adams, MD, MHS, and Luke E. Sewall, MD, for the PRISM Trialists

**ABSTRACT**

**Purpose:** To investigate the safety and initial efficacy of XTRACT, a power aspiration–based extraction technique for treatment of peripheral arterial thromboembolism with the use of the Penumbra/Indigo system.

**Materials and Methods:** A total of 79 patients were enrolled: 39 (49.4%) underwent XTRACT as the initial therapy and 40 (50.6%) underwent XTRACT after failed catheter-directed thrombolysis or other mechanical intervention or for removal of distal emboli that occurred during an intervention. Occlusion locations were as follows: 36.7% (n = 29) in the profunda, common, or superficial femoral artery; 35.4% (n = 28) in the popliteal artery; 15.2% (n = 12) in the tibial artery; 7.6% (n = 6) in the peroneal artery; and the remainder in the common iliac (n = 1), external iliac (n = 1), sciatic (n = 1), and brachial (n = 1) arteries.

**Results:** Complete or near-complete revascularization (Thrombolysis In Myocardial Infarction [TIMI] grade 2/3 flow) was achieved in 87.2% of patients (68 of 78) immediately after the XTRACT procedure and before any other intervention. Successful revascularization was achieved in 79.5% of patients (31 of 39) as an initial treatment and in 92.5% (37 of 40) as salvage or secondary therapy. After additional adjunctive endovascular interventions, TIMI grade 2/3 flow was achieved in 96.2% of patients (76 of 79). Complete thrombus removal and restoration of normal flow (TIMI grade 3) was achieved in 77.2% of patients (61 of 79) after all endovascular treatment was completed. No patients required surgical revascularization. No device-related adverse events occurred.

**Conclusions:** XTRACT was safe and effective for revascularization of acute or subacute peripheral arterial occlusions as a primary therapy or as a secondary therapy after other endovascular techniques had failed.

Indigo System

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The Indigo catheters:

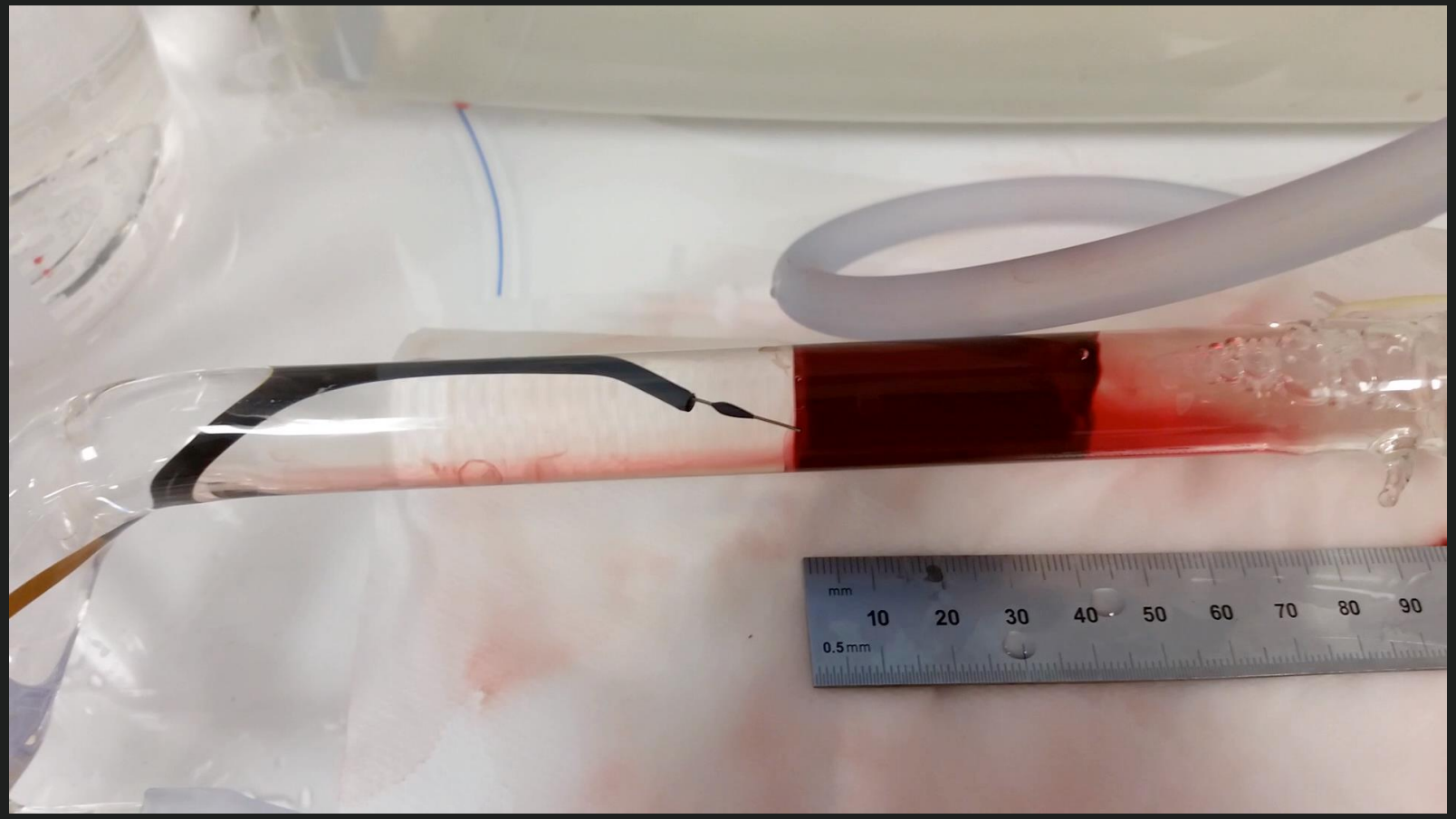
- dedicated, last generation system
- designed specifically to address the limitations of conventional technology:
  - trackability,
  - risk of vessel injury,
  - incomplete revascularization



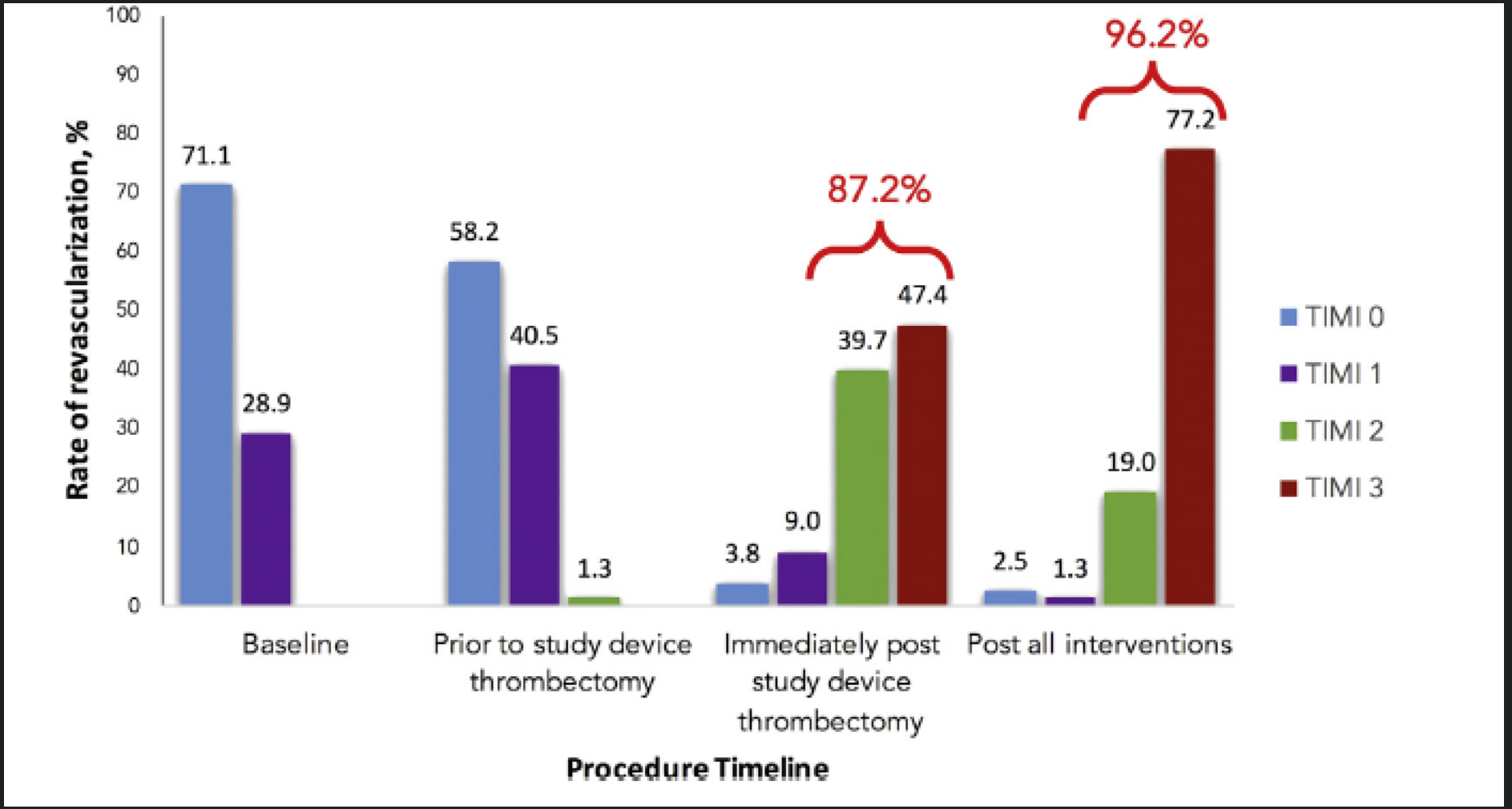


The aspiration thrombectomy system designed for peripheral intervention

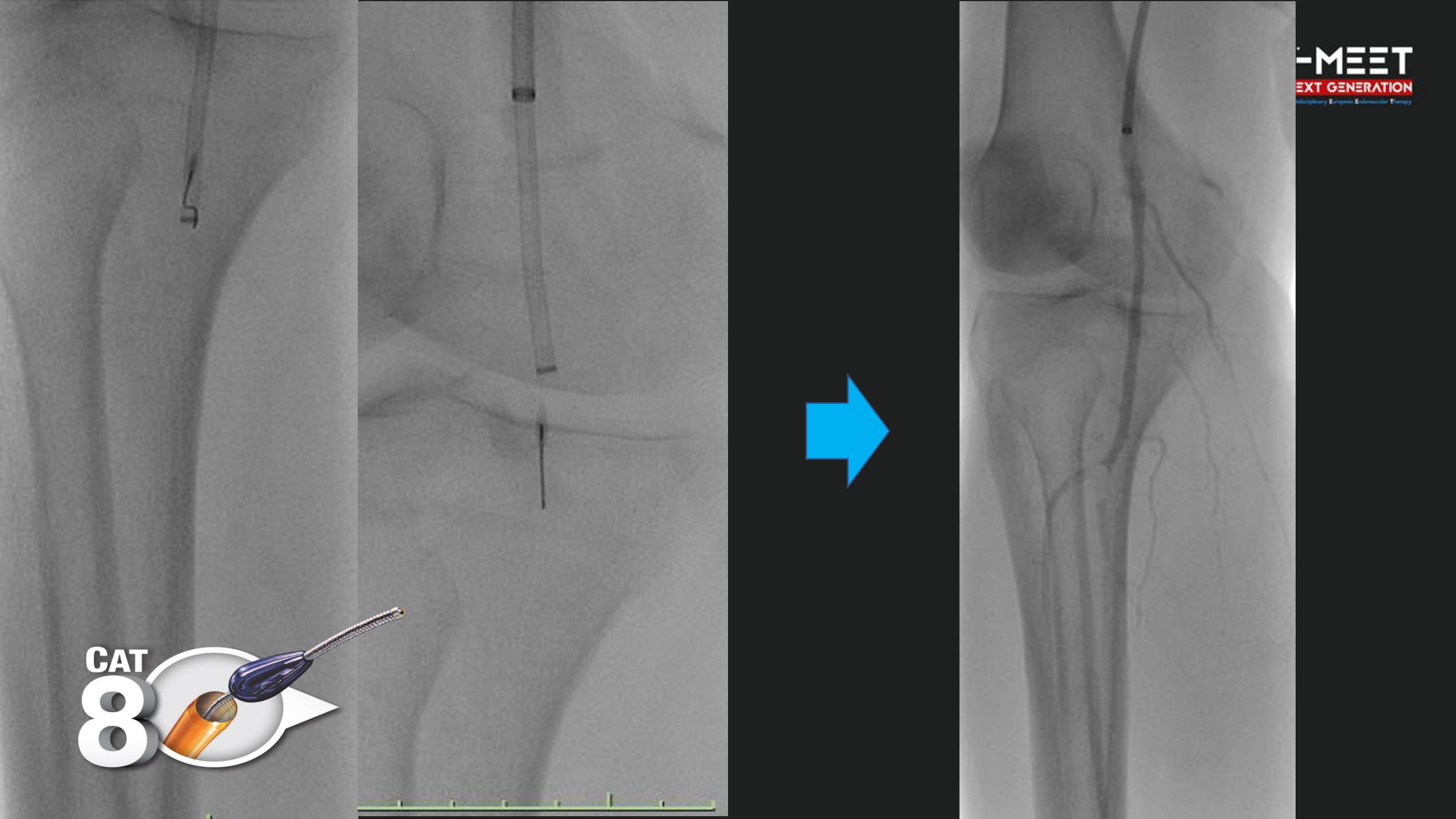
# INDIGO CAT8 XTORQ with SEP



# Results – PRISM (total pts 79)




Saxon RR, J Vasc Interv Radiol. 2018;29:92-100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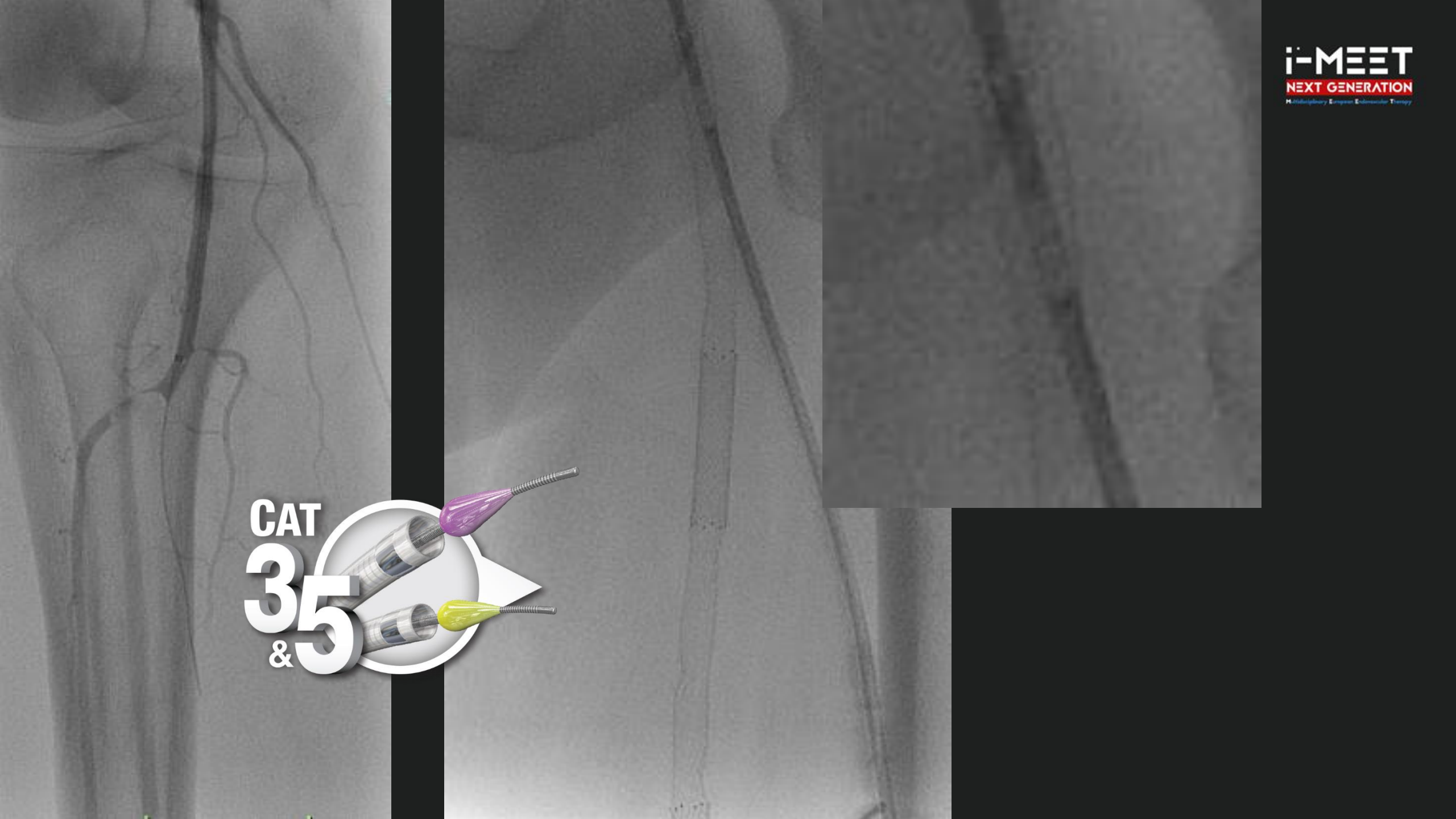
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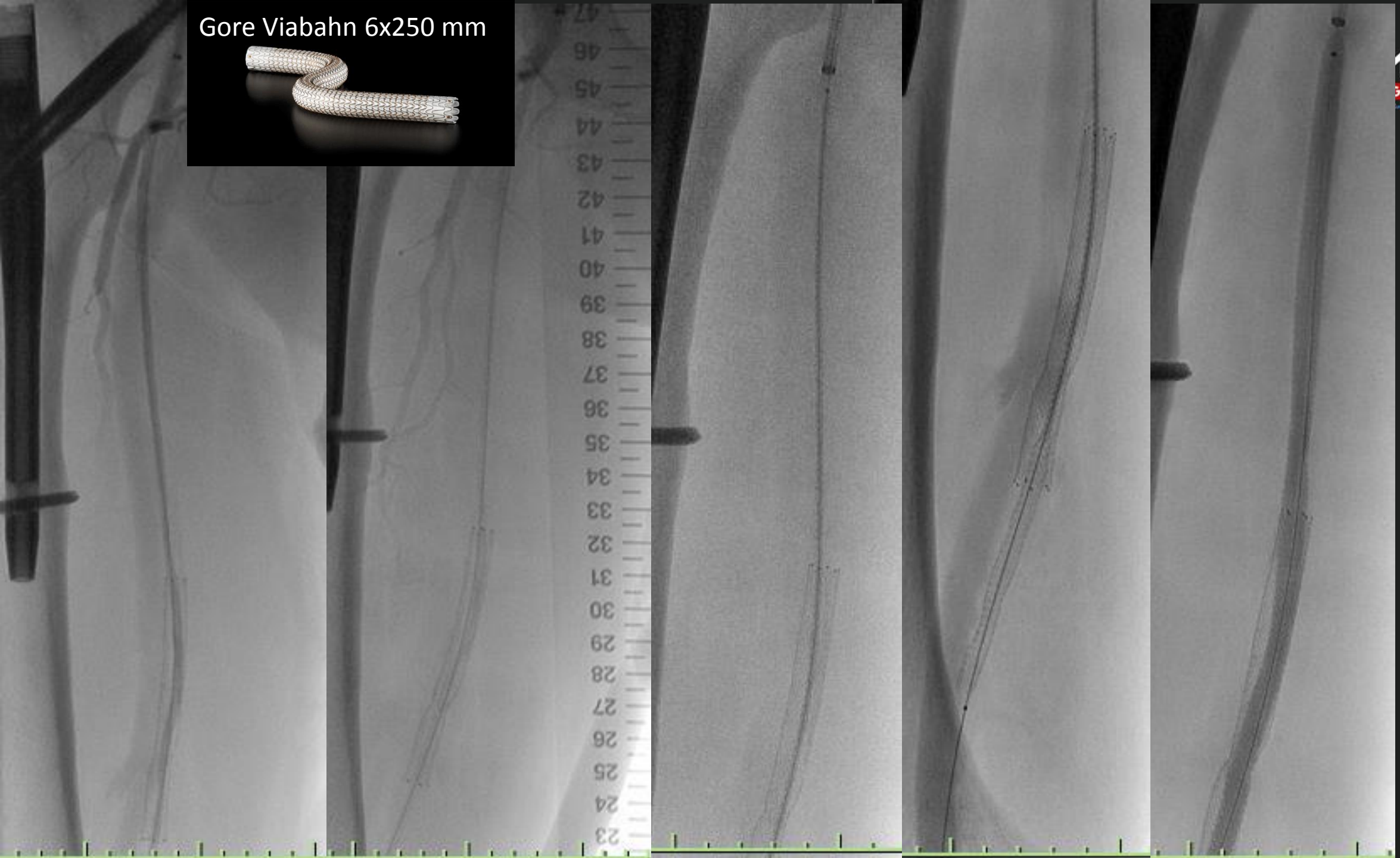
INTRAPROCEDURAL THERAPY

- 5 micrograms rt-PA
- 10 micrograms nitroglycerin


Gore Viabahn 6x250 mm
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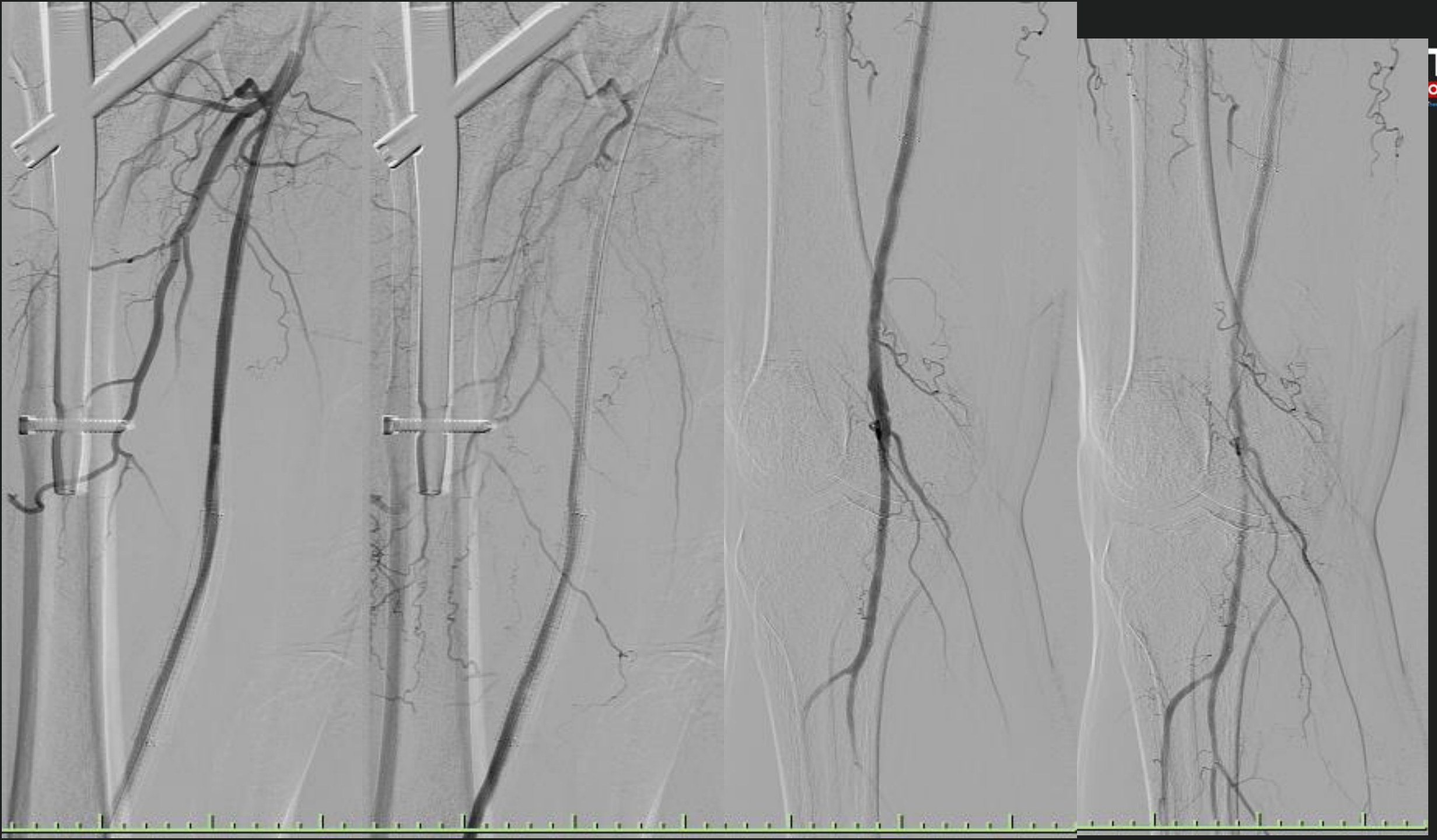

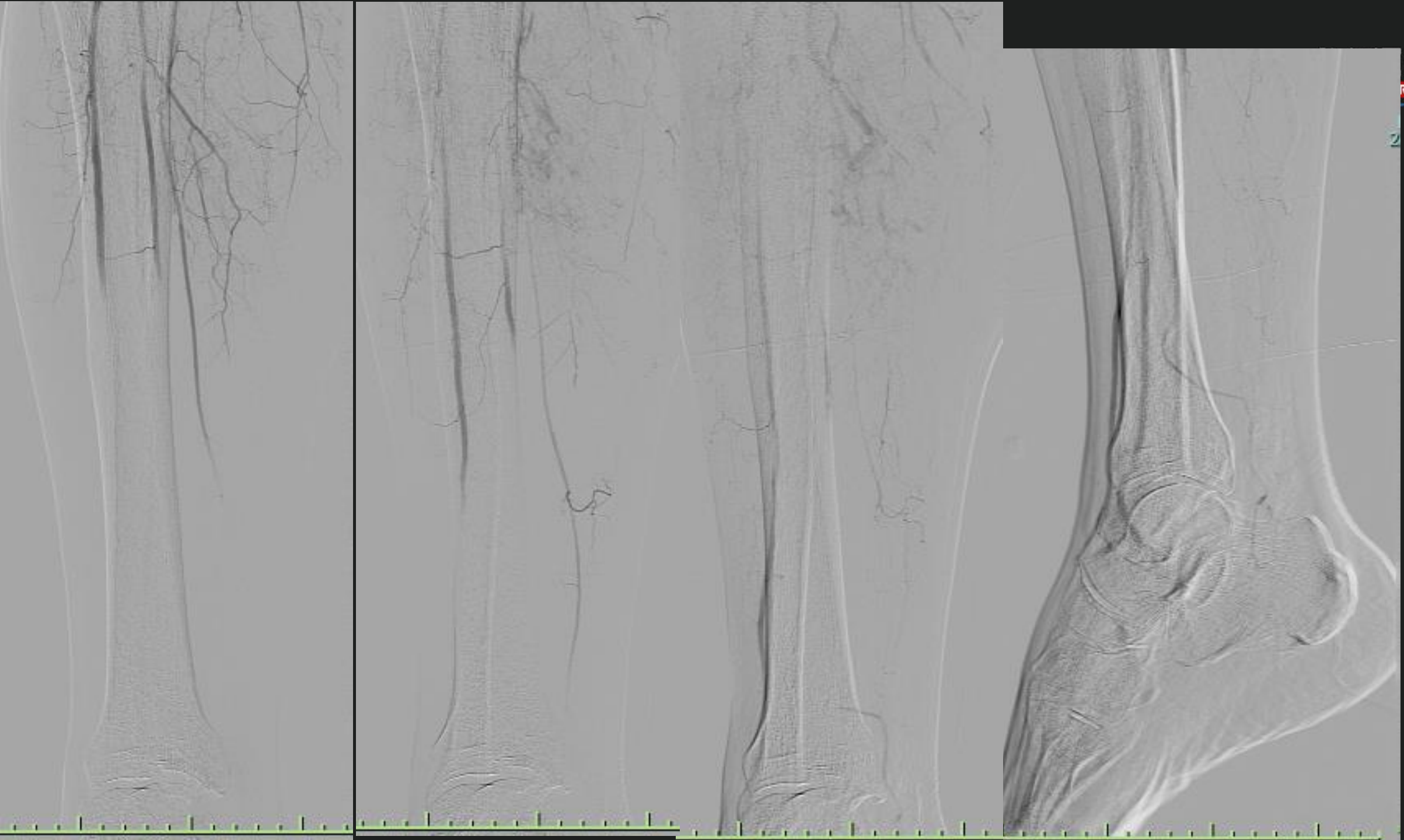

# CONCLUSIONS

- Distal embolization during  peripheral endovascular interventions is a serious complication

- Thomboaspiration with Indigo catheter is a reliable alternative option to surgical embolectomy and thrombolysis to restore quickly the flow to the foot in particular in case of BTK embolization