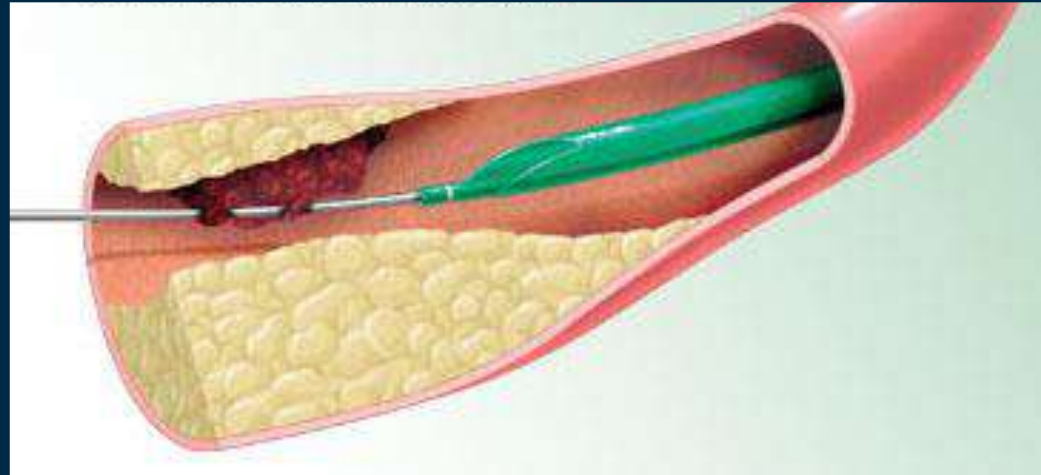


Thrombectomy During STEMI



Aaron WONG

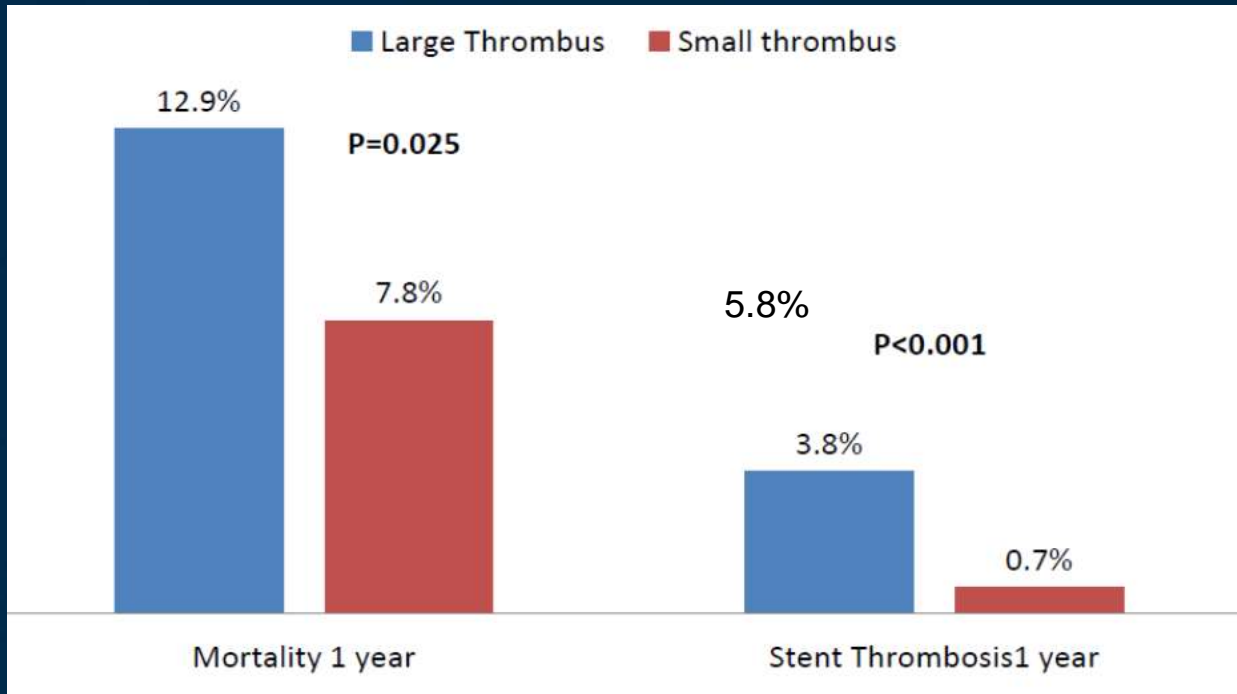
National Heart Centre SINGAPORE

Disclosure

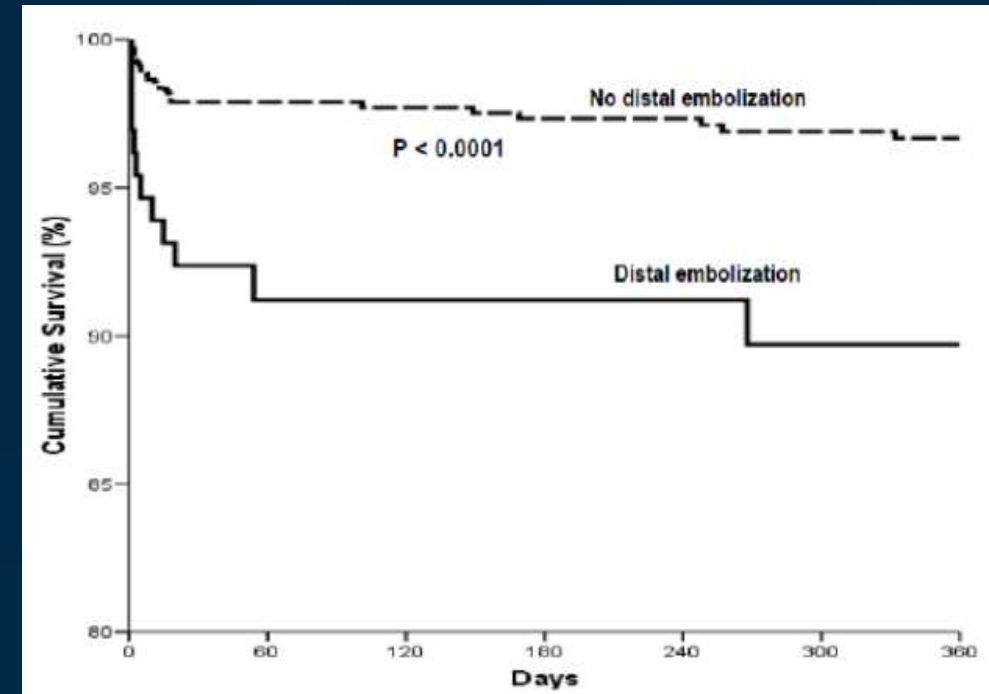
- I have NO conflict of interest to disclose

Thrombus in STEMI

- Over 70% of STEMI patients has angiographic evidence of thrombus
- Thrombus increases the risk of: **No reflow/Distal embolization and Stent thrombosis**
- Worse outcome in patients with high thrombus load and distal embolization



Sianos G et al. JACC 2007;50:573-83



De Luca et al. Journal of Thromb Thrombolysis 2009

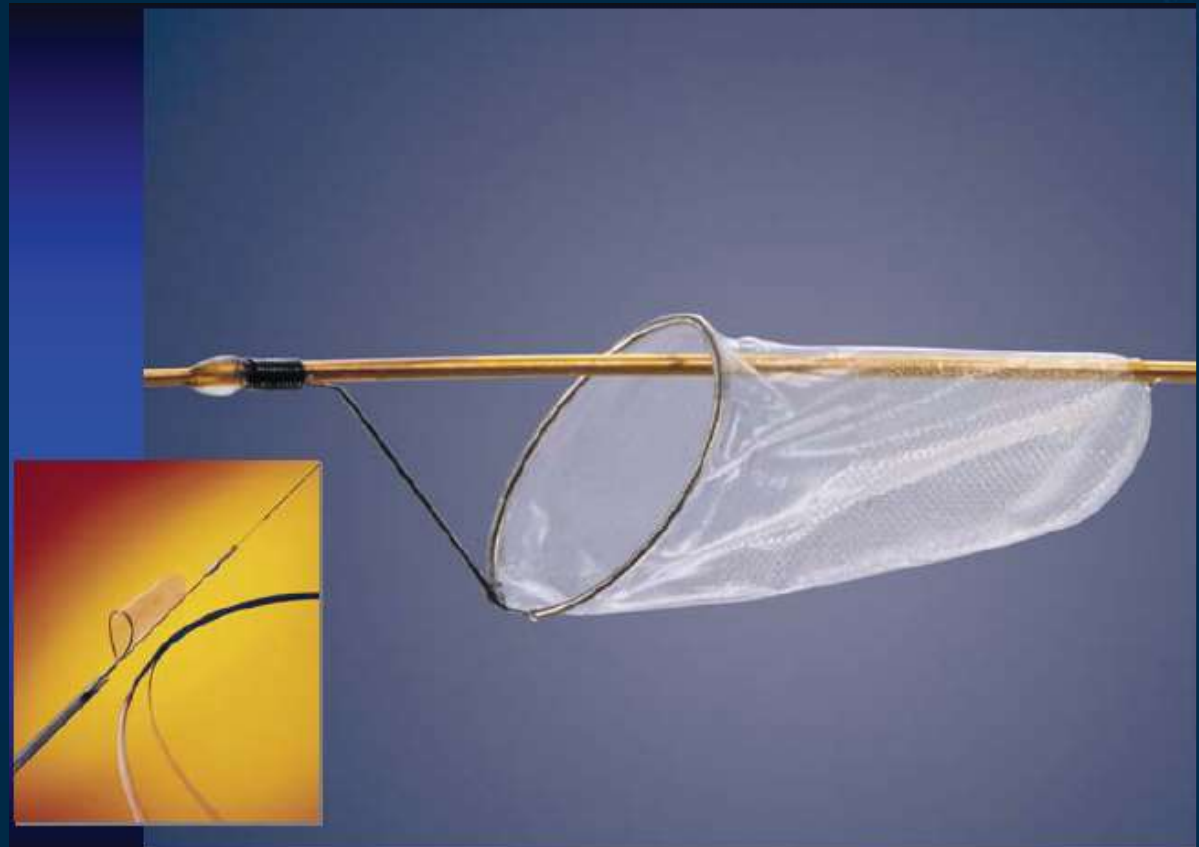
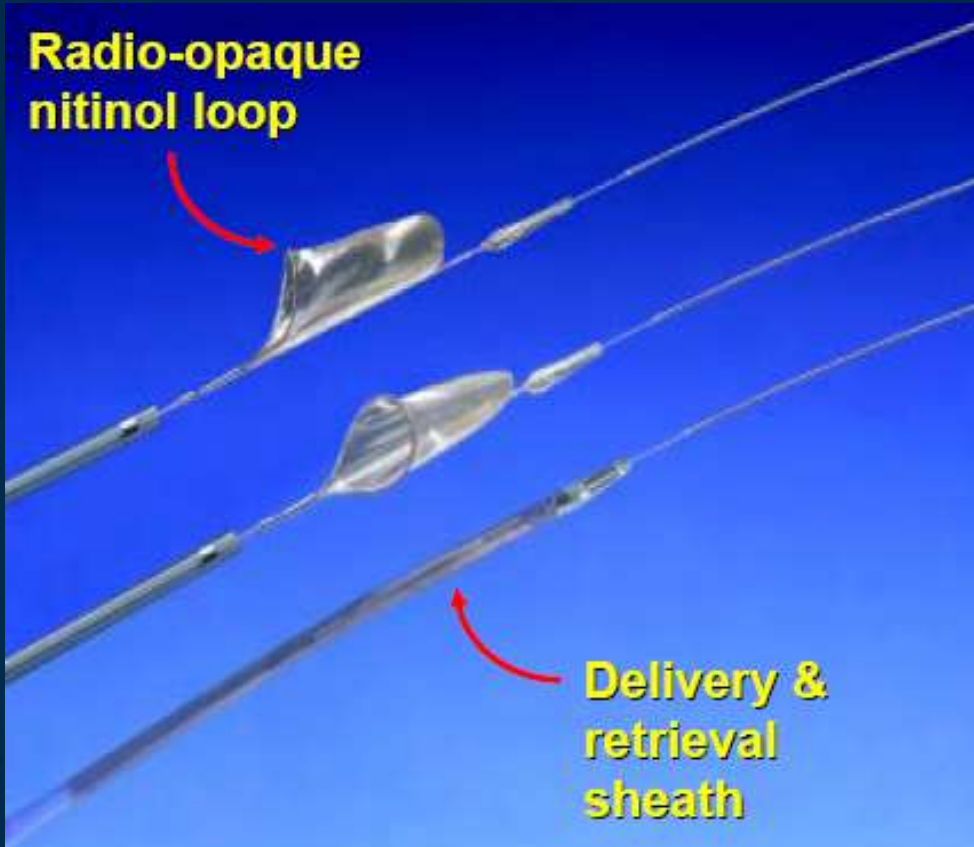
Distal Protection Devices

- Perc Surge GuardWire (Medtronic)



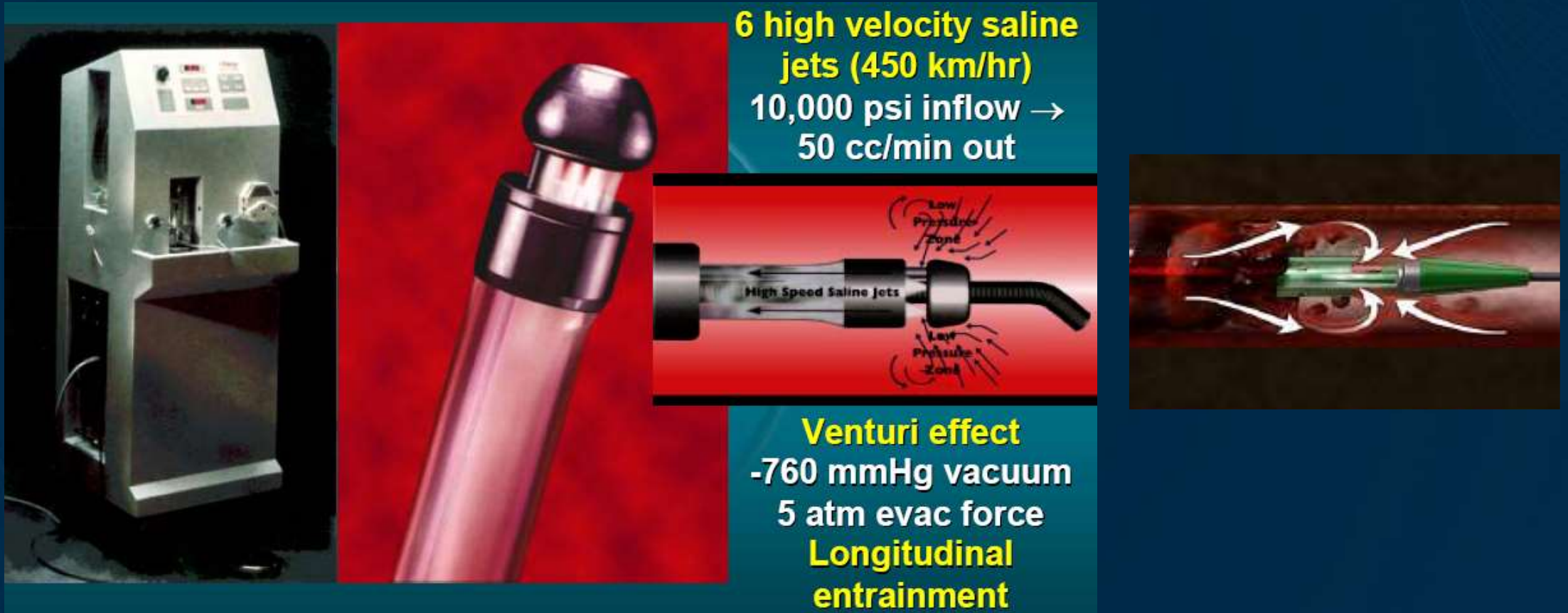
Distal Protection Devices

- EPI FilterWire EZ



Thrombectomy Devices

- Possis AngioJet



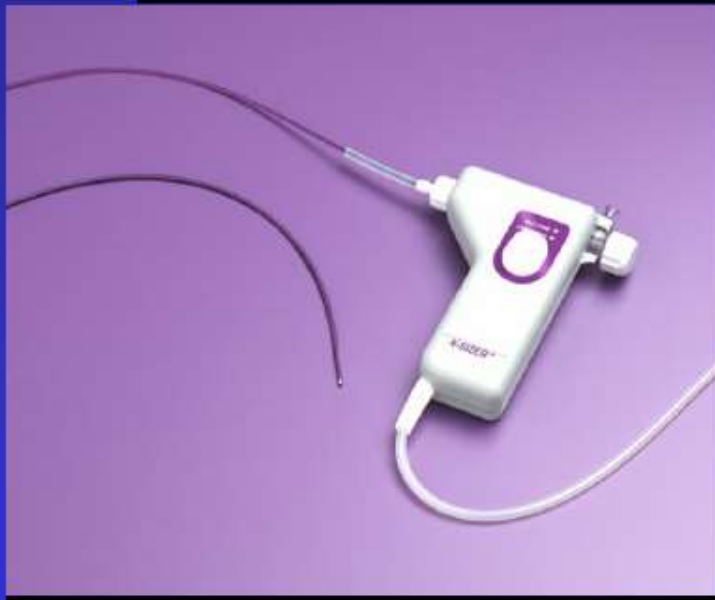
6 high velocity saline jets (450 km/hr)
10,000 psi inflow → 50 cc/min out

Venturi effect
-760 mmHg vacuum
5 atm evac force
Longitudinal entrainment

Thrombectomy Devices

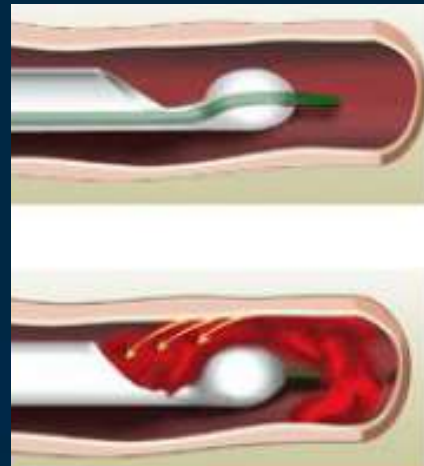
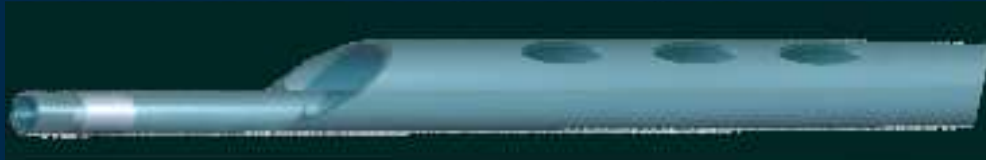
- eV3 (EndoCor) X-sizer

- Thrombo atherectomy device
- 1.5, 2.0 and 2.3 mm cutters
- 7-9F guide compatible



Aspiration Catheters

- Export®, TVAC®, Rescue®, Pronto®, Thrombuster®...



Aspiration Catheters

- Penumbra's Indigo® System CAT™ RX Catheter



Theoretical Advantages of Thrombectomy

- What do we expect thrombectomy devices to do?
 - Reduce thrombus load, or
 - Reduce distal embolization



Improves microvascular
perfusion



Reduce mortality
Reduce MACE events

- Facilitate PCI – assess lesion size and length
- Faster procedure

Distal Embolic Protection Devices

- Trials of distal protection devices

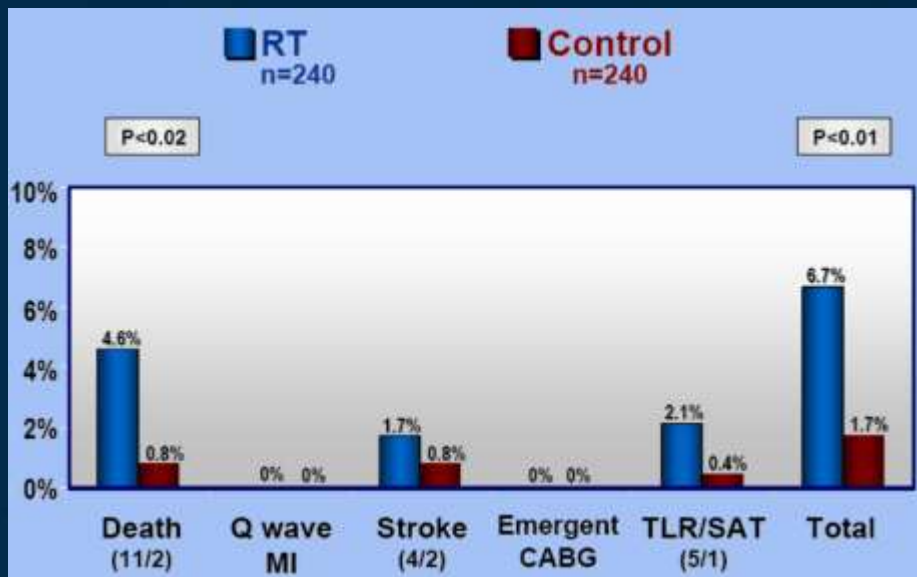


Trial	Design	Significant Particle rec	Outcome
Limbruno (Filterwire)	Case-controlled study	√	Improved cTFC Improved ST res Improved Grade 3 blush
DIPLOMAT (Angioguard)	60 pt RCT	√	No difference in cTFC or TIMI flow
EMERALD (PercuSurge)	427 pt RCT	√	No difference in infarct size No diff in CTFC, ST res or blush
PROMISE (Filterwire)	200 pt RCT	√	No difference in infarct size No difference in CFR or LVEF
ASPARAGUS (Filterwire)	200 pt RCT	√	No difference in CK, ST resolution, TIMI flow, or blush



Mechanical Thrombectomy Devices

AiMI Trial MACE at 30 days



Mortality at 6 months

JETSTENT Trial Surrogate Endpoints

Table 4 Surrogate End Points

	Rheolytic Thrombectomy	Direct Stenting	p Value
Early ST-segment resolution	n = 246 211 (85.8)	n = 240 189 (78.8)	0.043
Infarct size	n = 217 11.8 (3.15-23.70)	n = 208 12.75 (4.75-23.3)	0.398
TIMI flow grade 3	n = 252 203 (80.6)	n = 241 207 (85.9)	0.113
Corrected TIMI frame count	n = 228 20 (15-27.25)	n = 216 20 (14-25.75)	0.357
TIMI blush grade	n = 215	n = 211	0.207
Grade 0	7 (3.3)	2 (0.9)	
Grade 1	10 (4.7)	9 (4.3)	
Grade 2	43 (20.0)	33 (15.6)	
Grade 3	155 (72.1)	167 (79.1)	

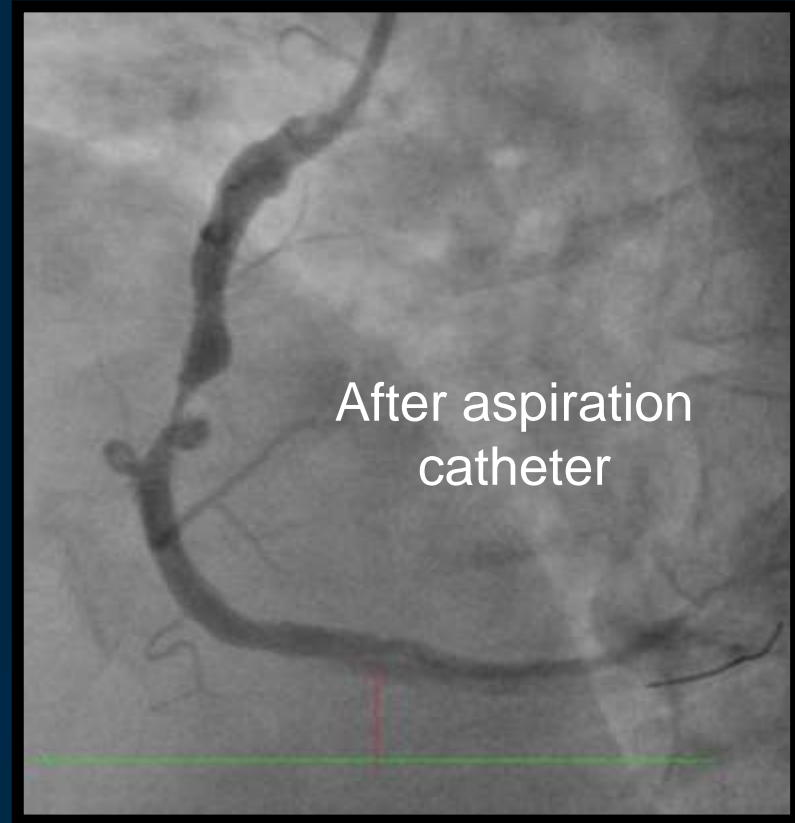
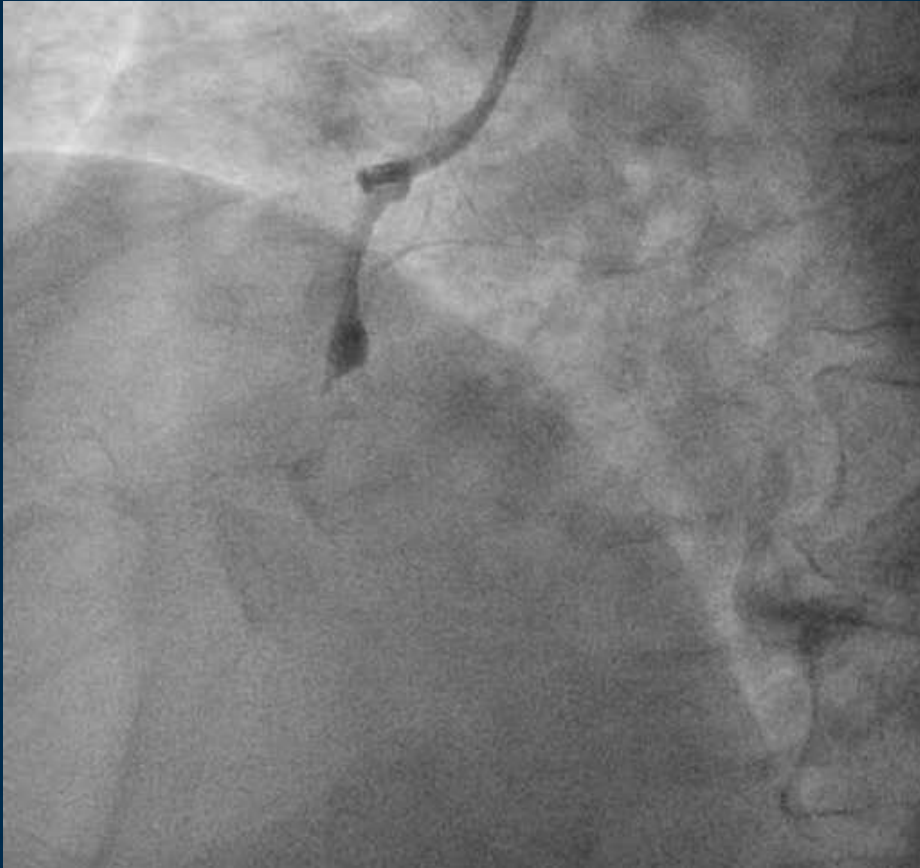
- 6-month MACE rate was 11.2% in the thrombectomy arm and 19.4% in the DS alone arm (p = 0.011)
- 1-year event-free survival rates were 85.2 vs. 75.0 % for (p = 0.009)

Aspiration Thrombectomy in Primary PCI

- Very appealing to interventionalists:
 - Simple concept
 - Easy to use
 - Faster procedure in some cases



Aspirate and Stent



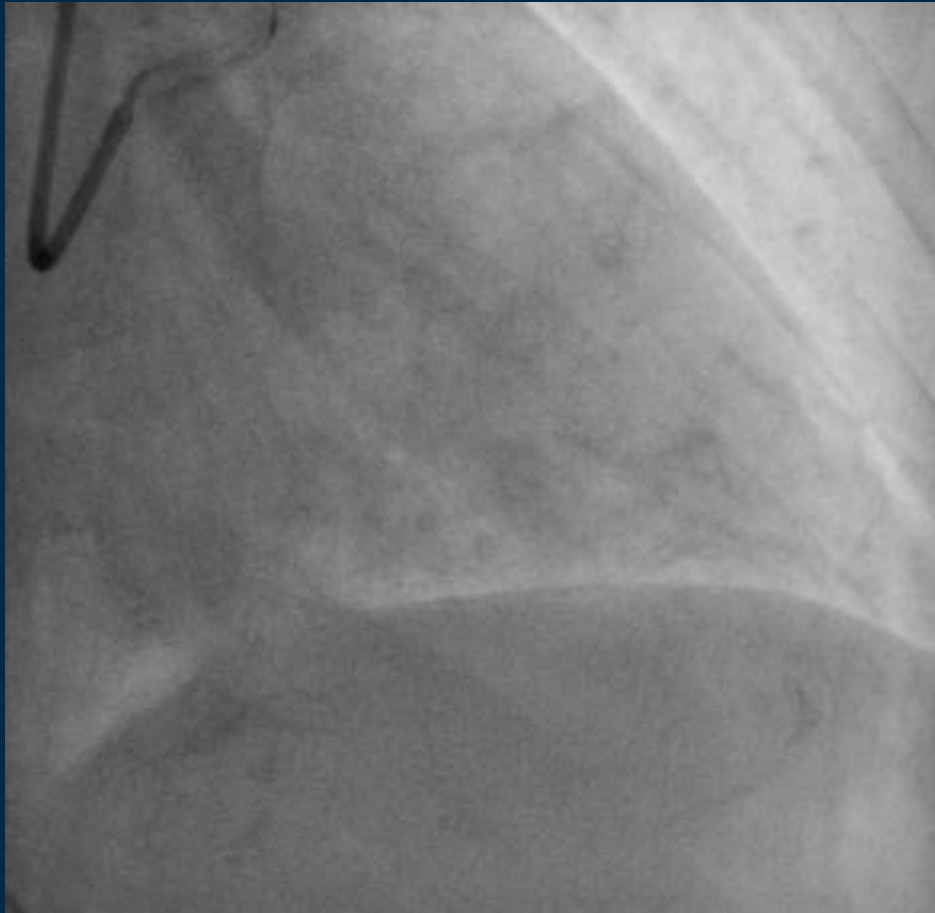
Advantages:

Removal of thrombus, establish flow and visualization of the vessel for sizing of stent

Aspirate and Stent



Aspirate and Stent

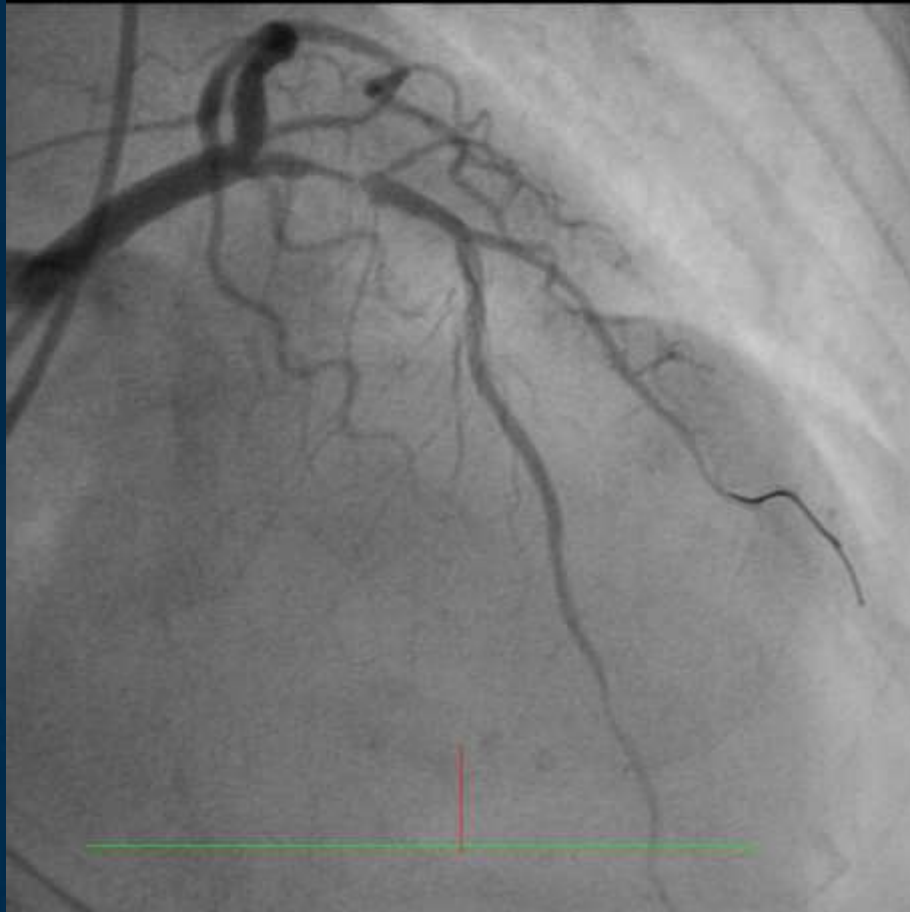


Initial angiography



Aspiration thrombectomy

Aspirate and Stent

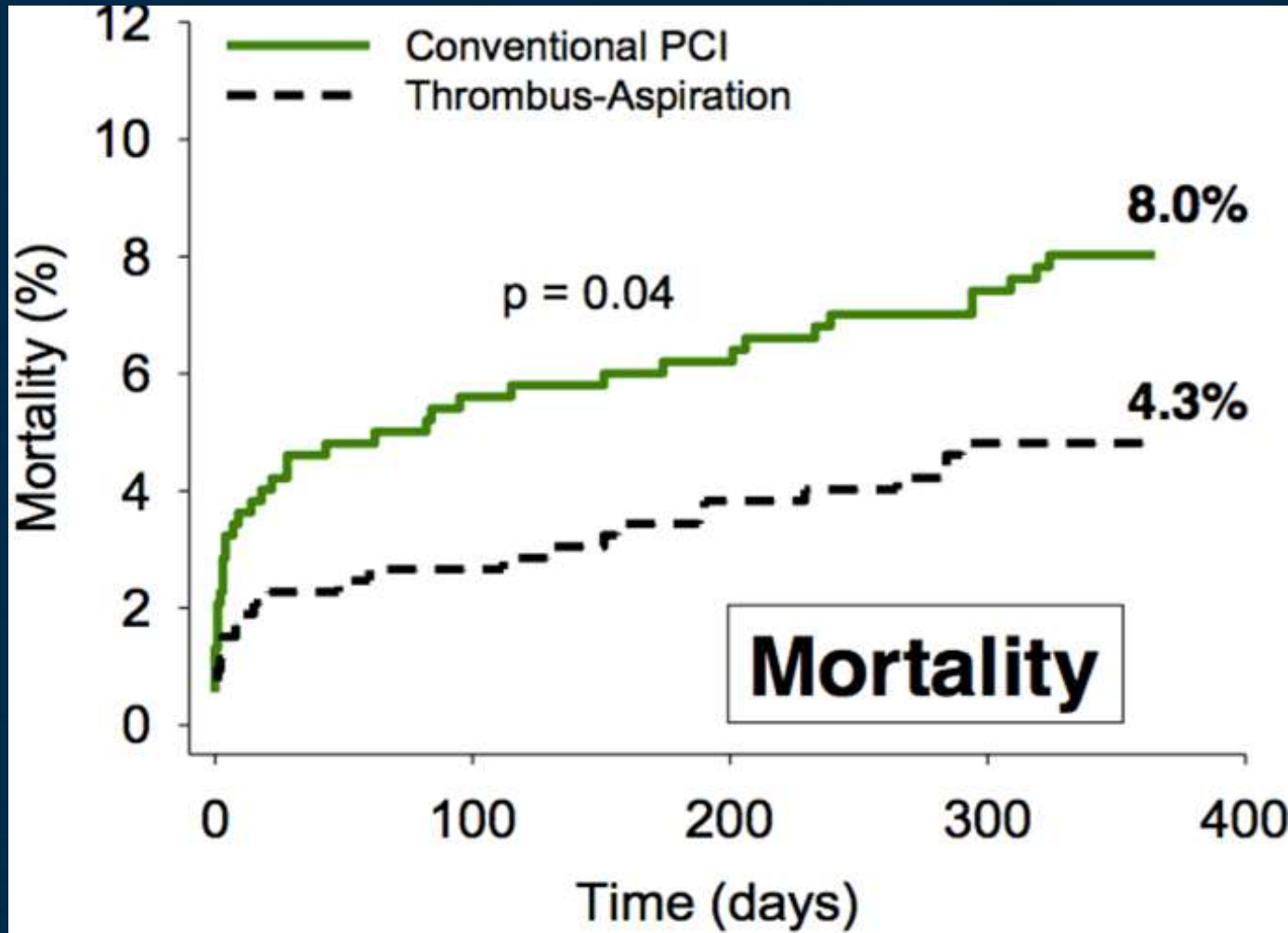


Post aspiration thrombectomy
Post aspiration thrombectomy



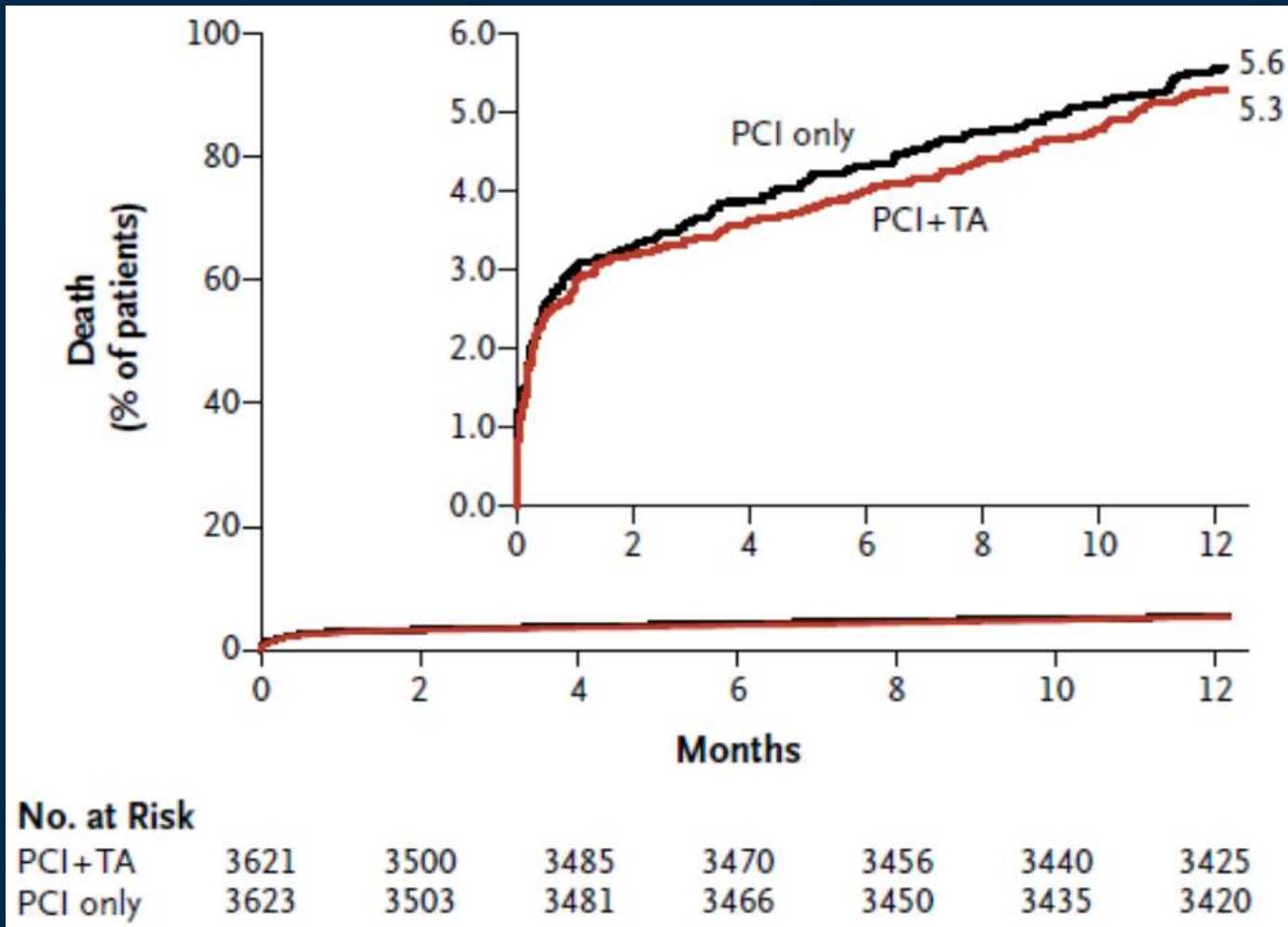
Stent placement
Final angiography

TAPAS Trial – Mortality at One year



Higher rate of:
1) ST segment resolution
2) Better MBG

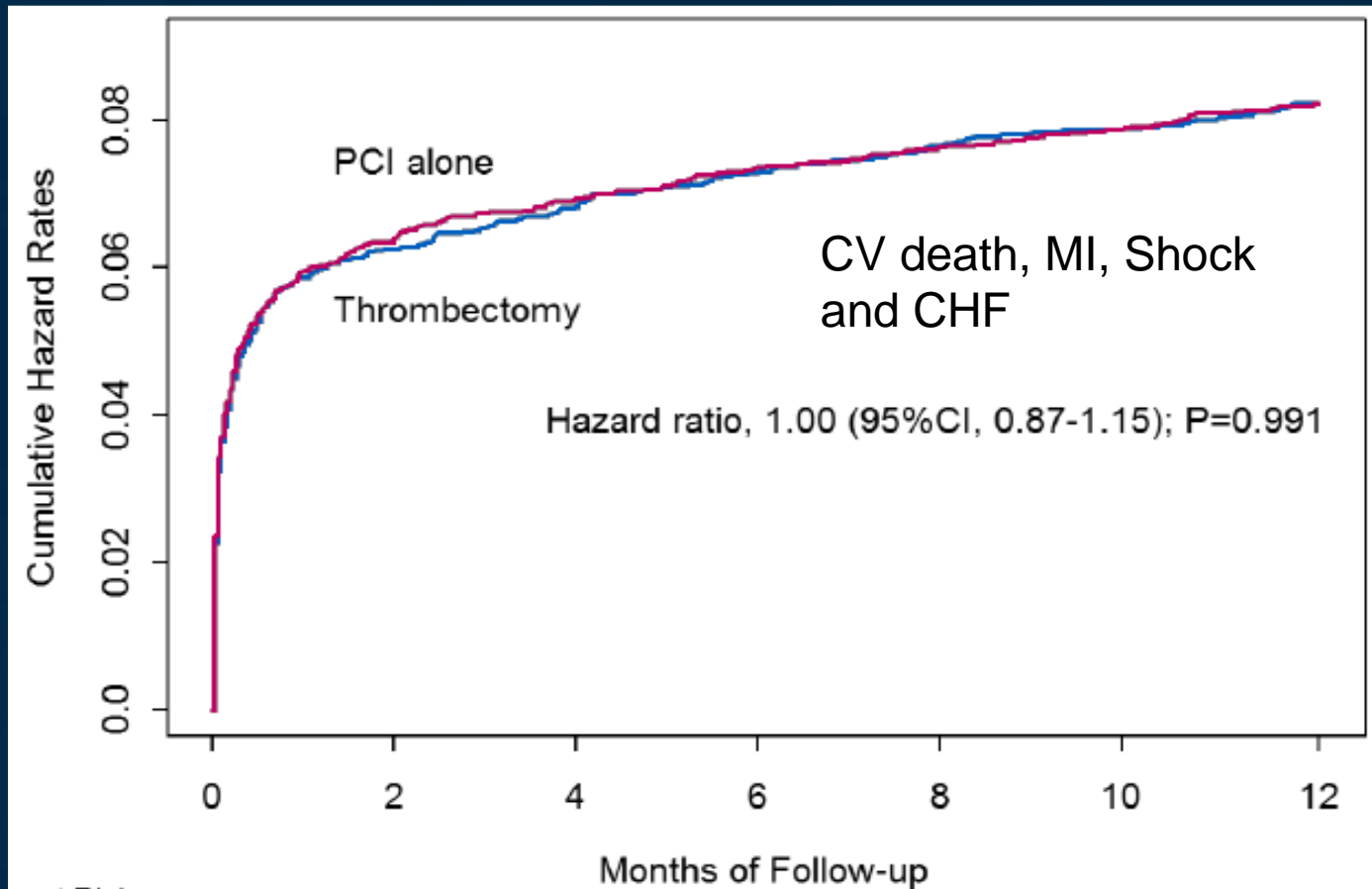
TASTE Trial – Mortality at One year



No difference in:

- 1) Re-hospitalization for MI
- 2) Stent thrombosis

TOTAL Trial – Primary Outcome at 1 year



- No difference in efficacy
- Worse outcome with increase risk of stroke

Recommendation of Aspiration Thrombectomy

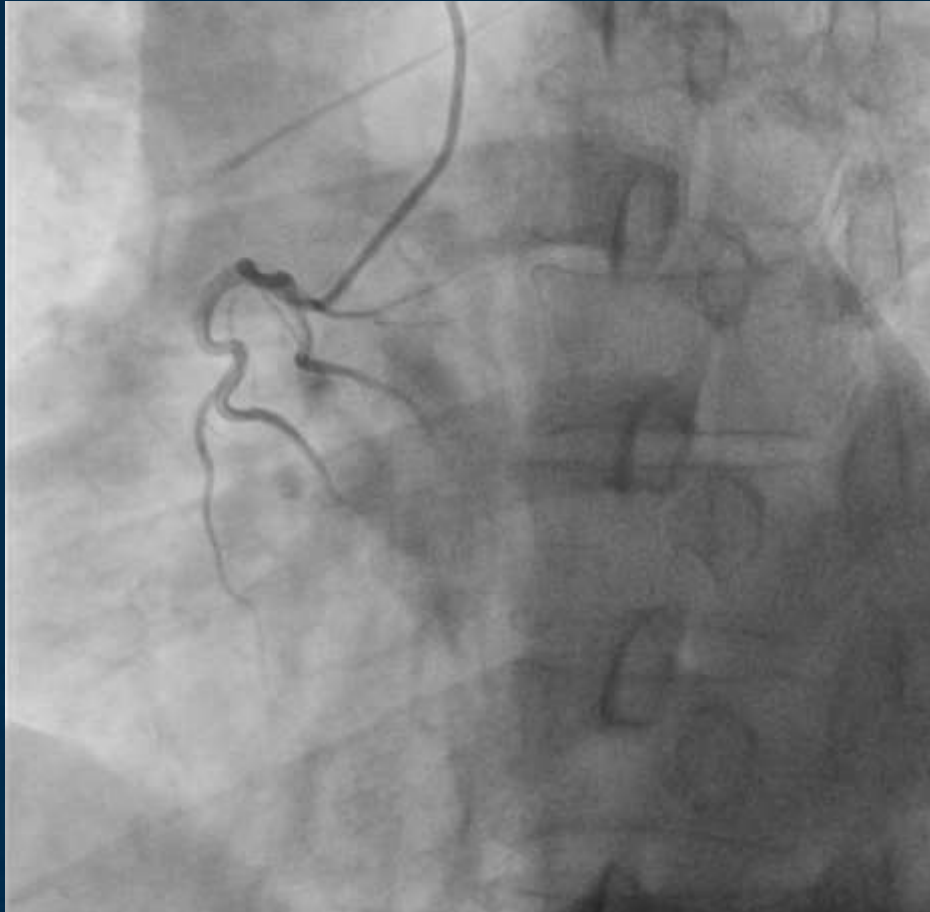
COR	LOE	Recommendations
IIb	C-LD	The usefulness of selective and bailout aspiration thrombectomy in patients undergoing primary PCI is not well established. ¹
III: No Benefit	A	<i>Routine</i> aspiration thrombectomy before primary PCI is not useful. ²

1. Modified recommendation from 2013 guideline (Class changed from IIa to IIb for selective and bailout aspiration thrombectomy before PCI)
2. New recommendation

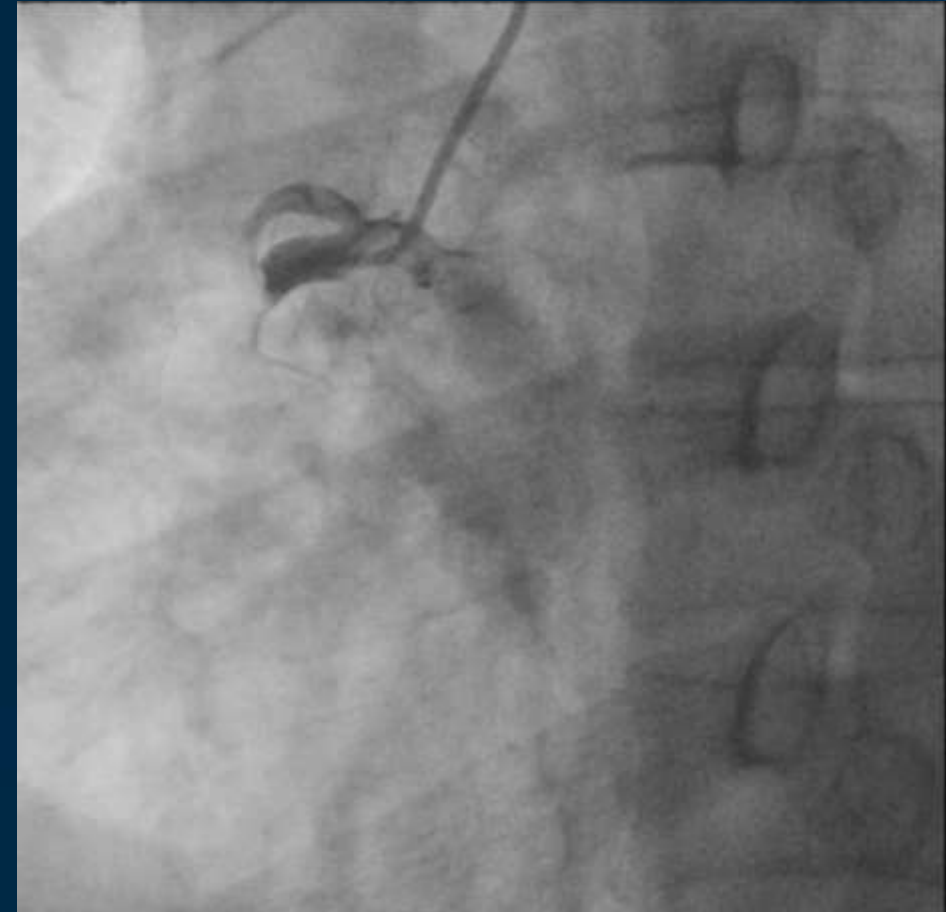
Reasons for failure of Thrombectomy

- Too little experience with device use
- Too little thrombus presence
- Too much thrombus
- Too little thrombus can be removed
- Too late to have a discernable effect against the large background of myocardial necrosis

Stroke and Aspiration Thrombectomy



Inferior STEMI with large conus branch



Proximal RCA occlusion

Stroke and Aspiration Thrombectomy



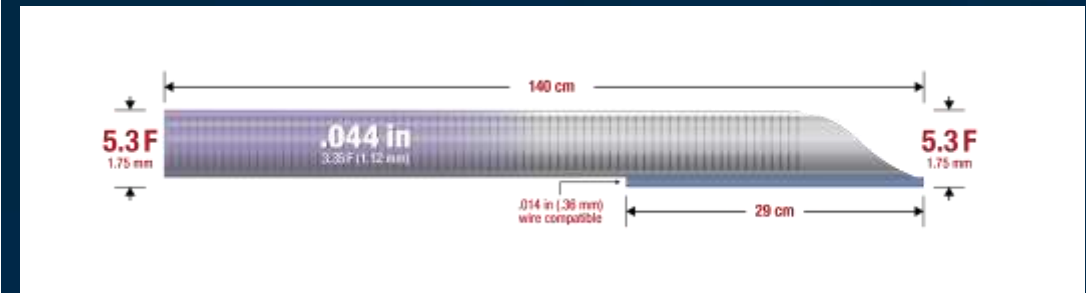
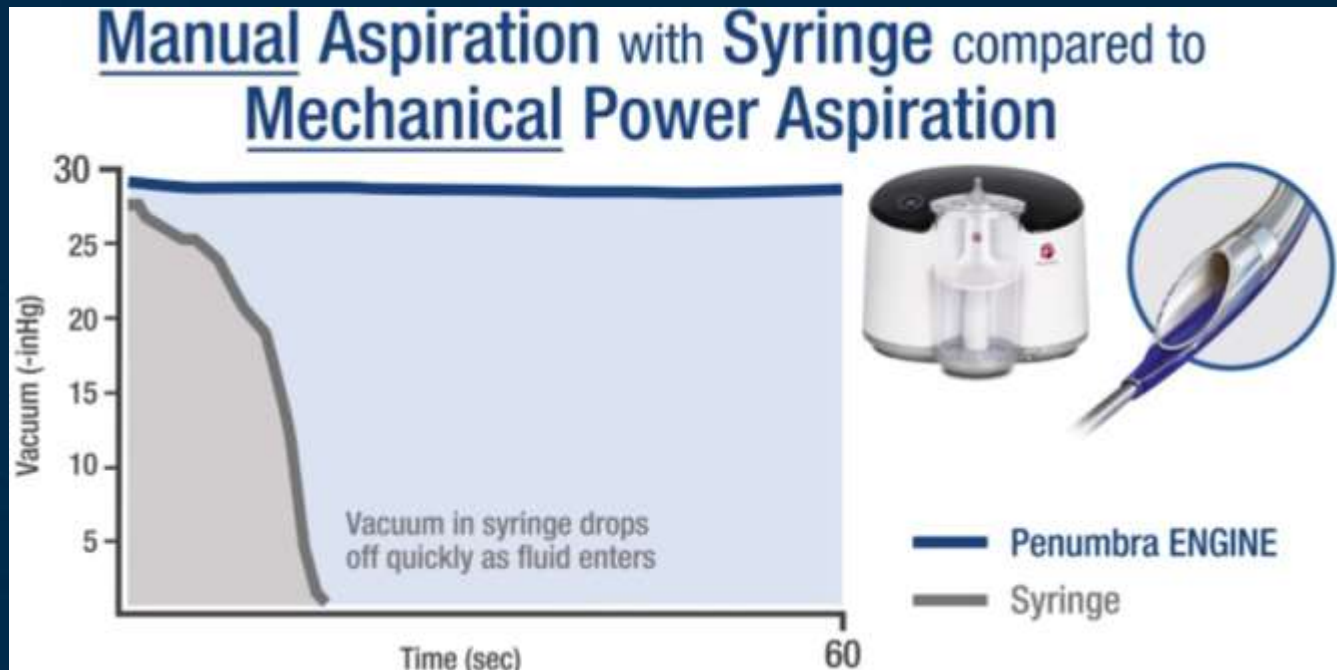
Trans-radial approach with difficult guiding
Attempted thrombus aspiration



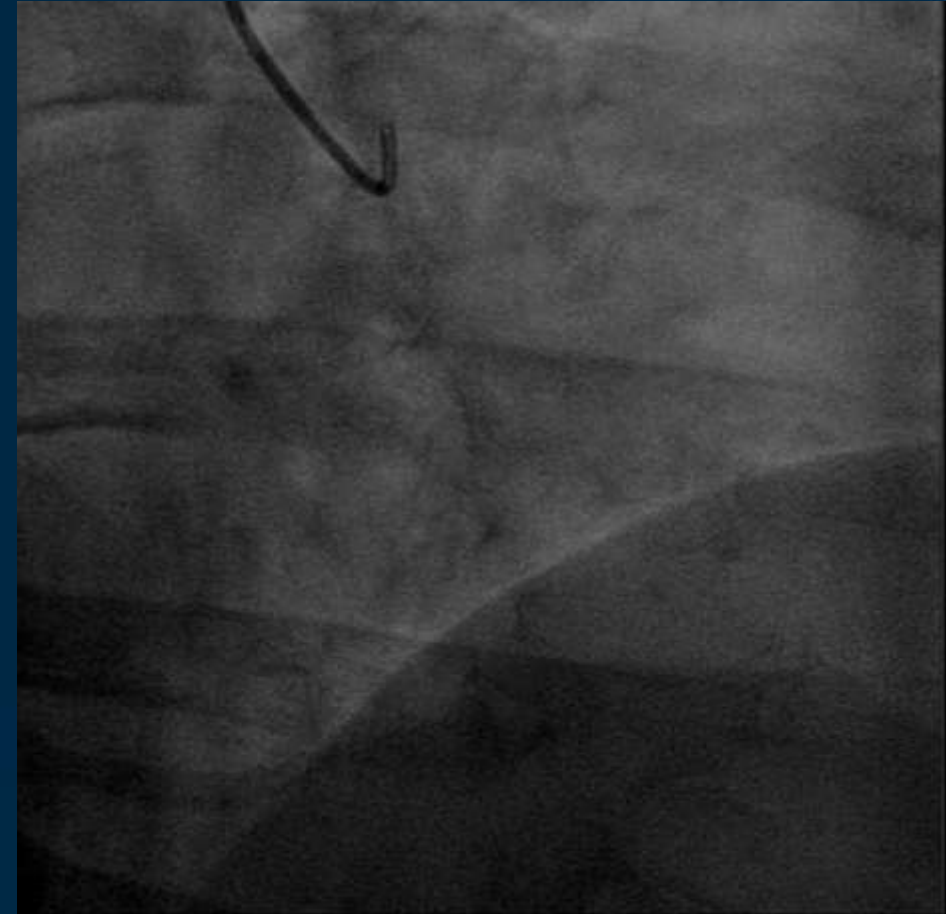
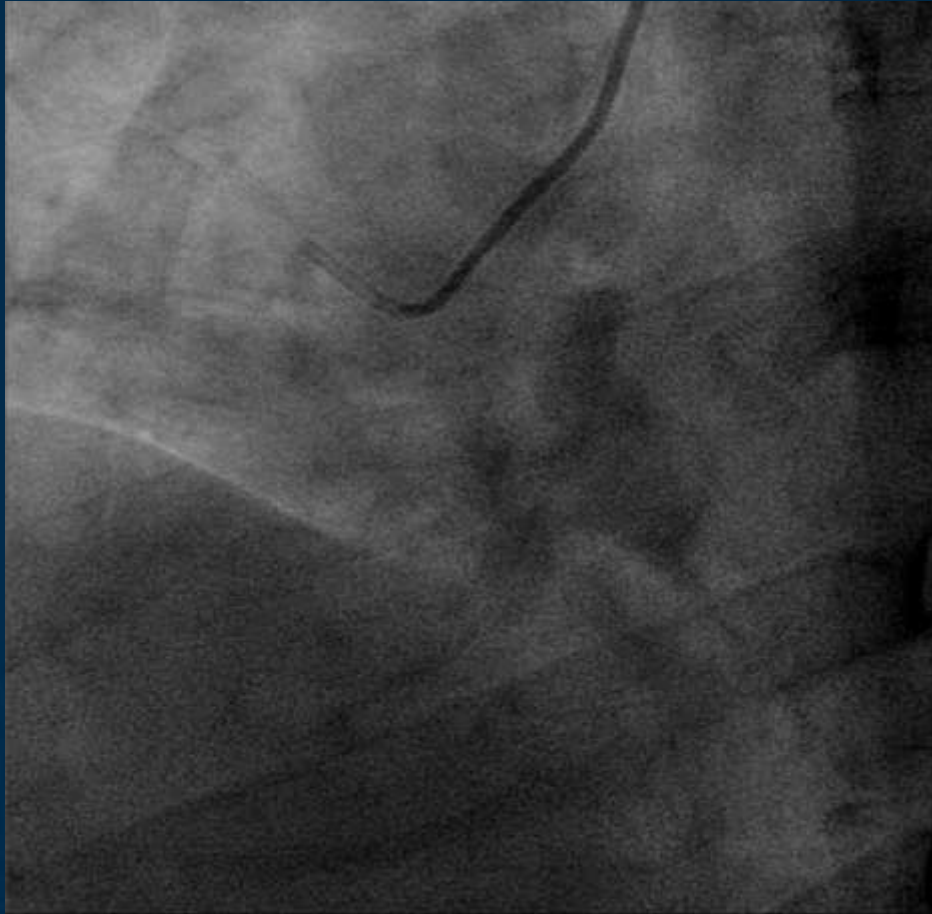
Proximal embolization to conus branch

Penumbra's CAT™ RX Mechanical Thrombectomy

- Mechanical aspiration device for continuous aspiration
- Consists of engine pump
- 6F compatible large lumen trackable catheter



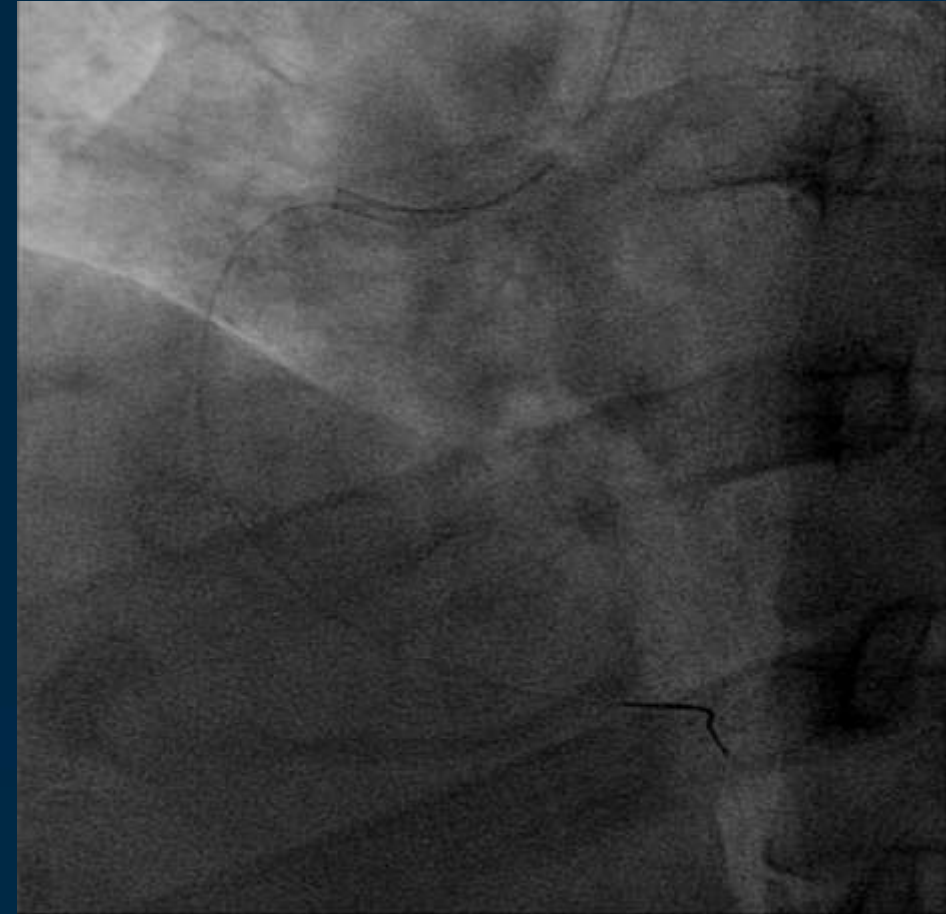
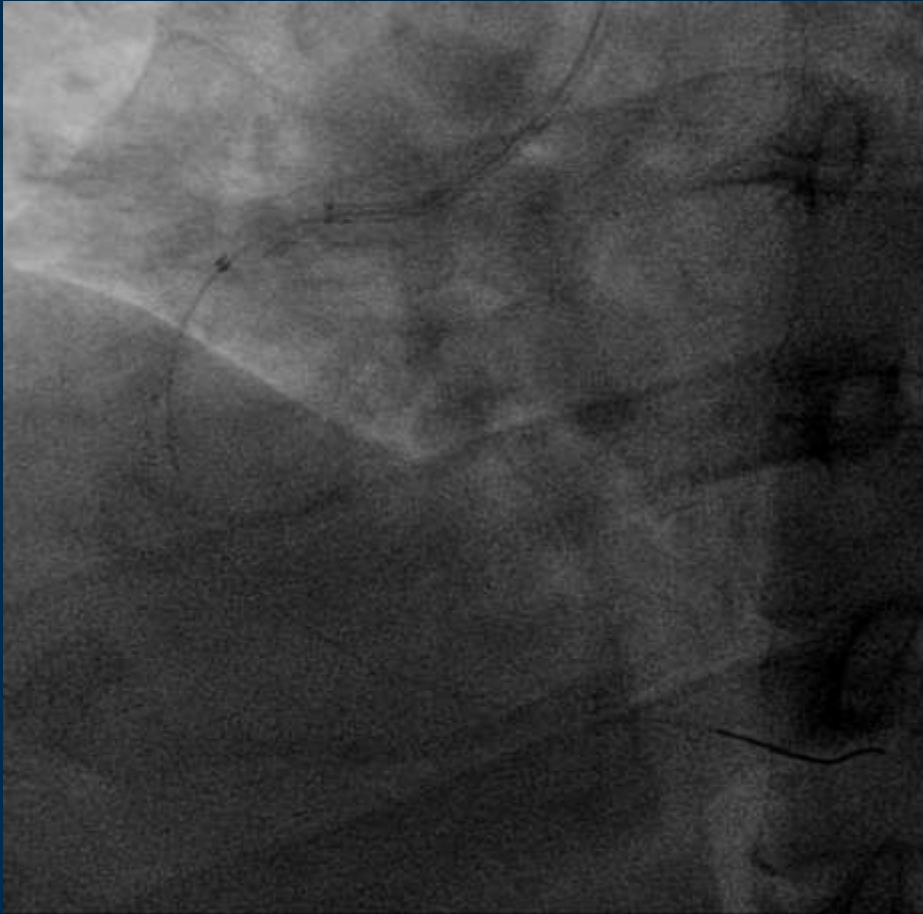
Penumbra Indigo® CAT™ RX Catheter



Few days post inferior STEMI

Courtesy of Lim ST

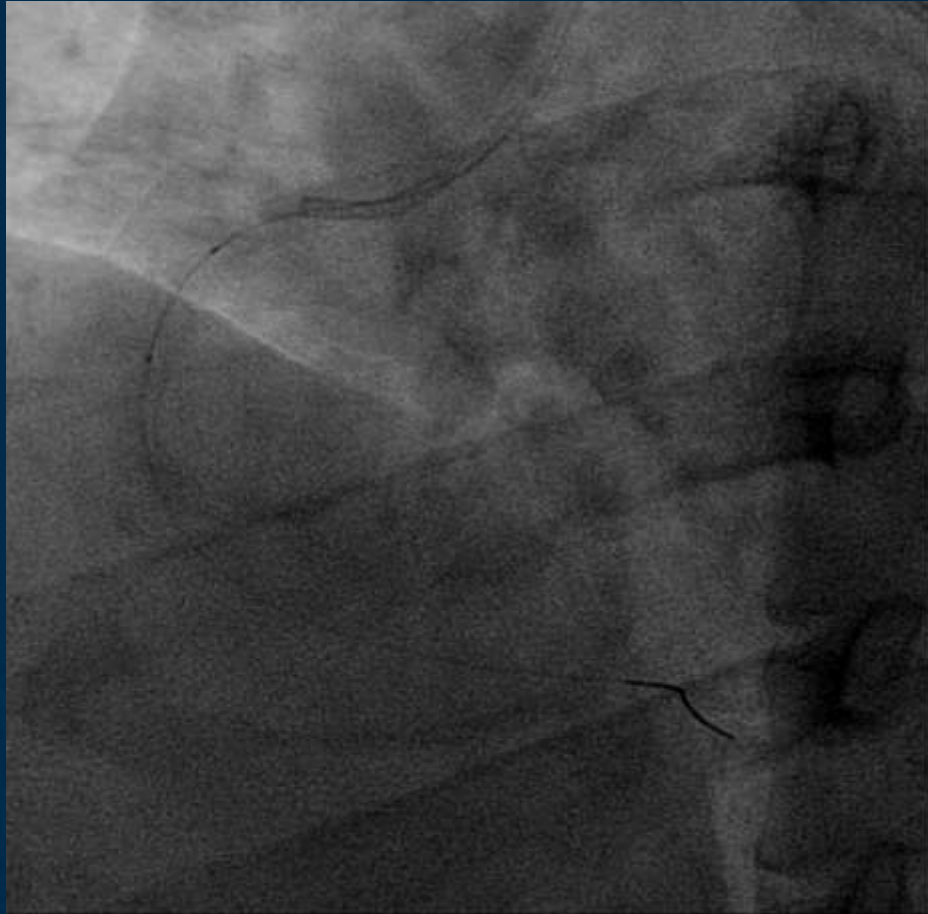
Indigo® CAT™ RX Catheter



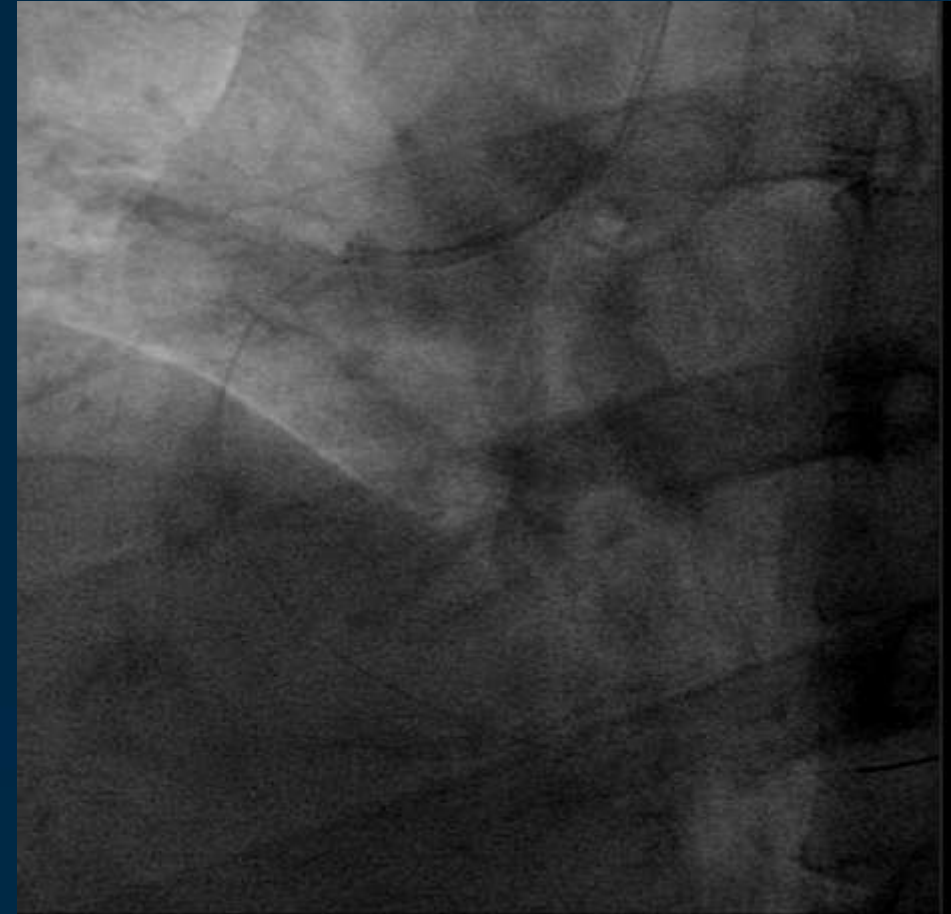
Penumbra's Indigo CAT RX aspiration catheter

Post aspiration

Indigo® CAT™ RX Catheter

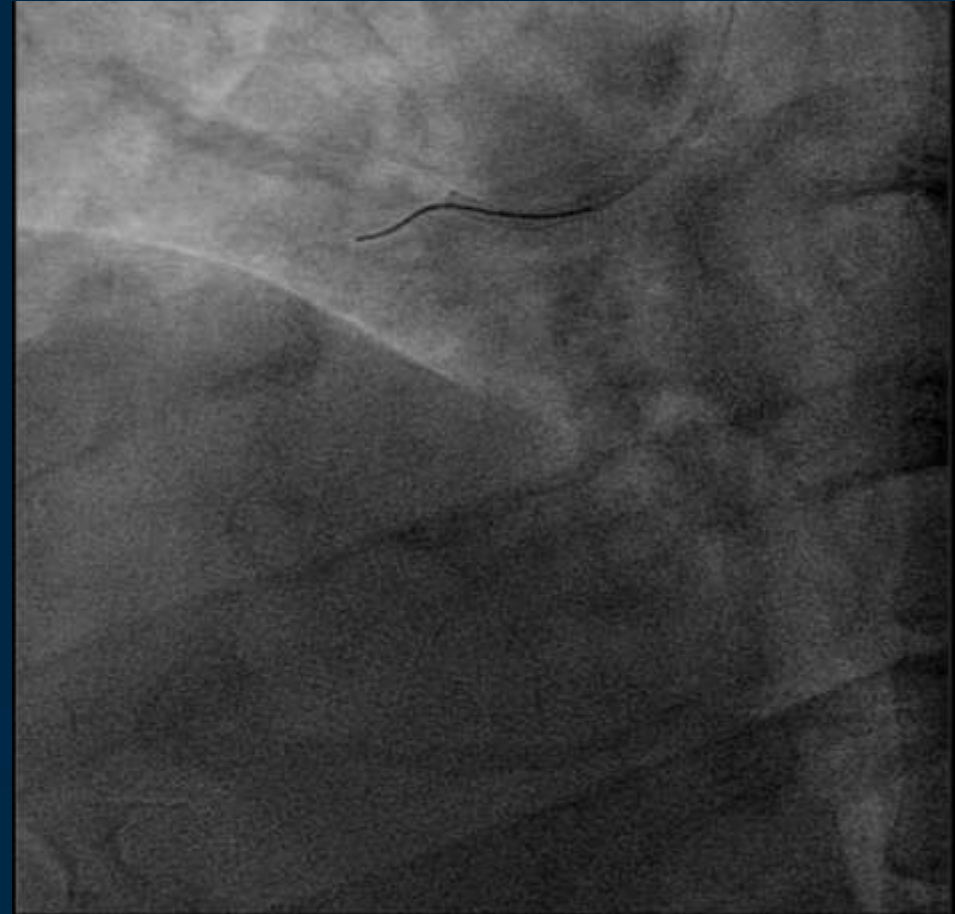
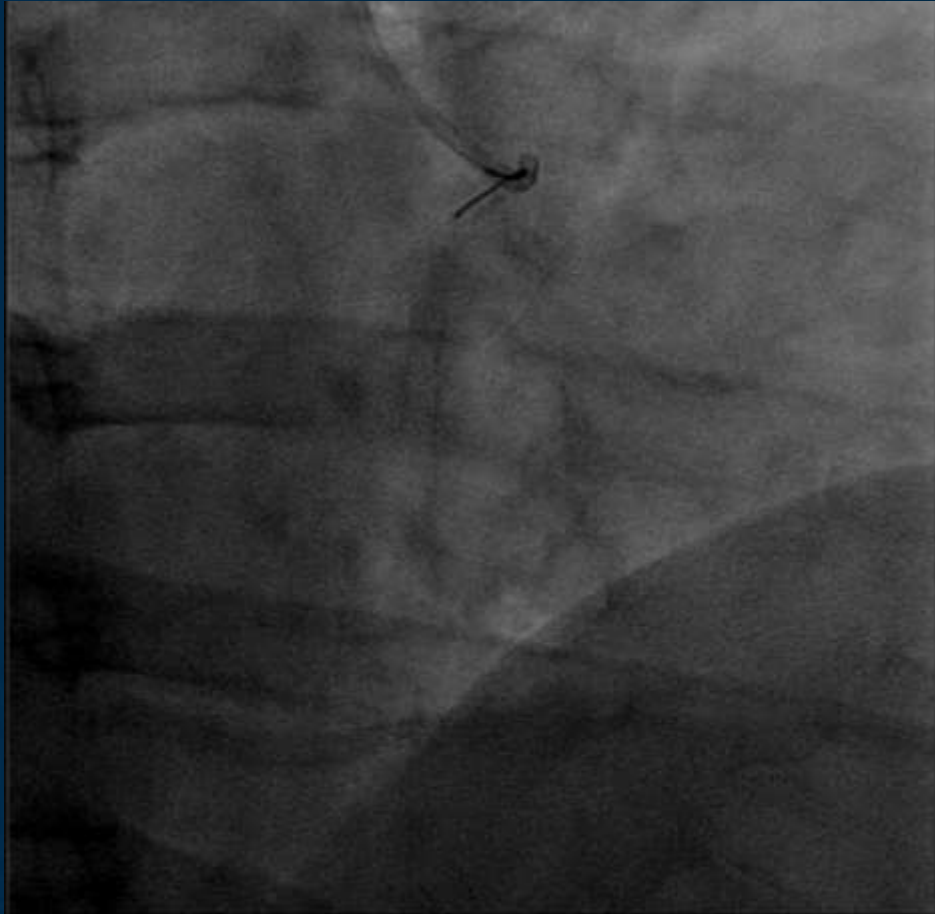


Post 2.0 mm balloon dilatation



After another pass of CAT RX

Indigo® CAT™ RX Catheter

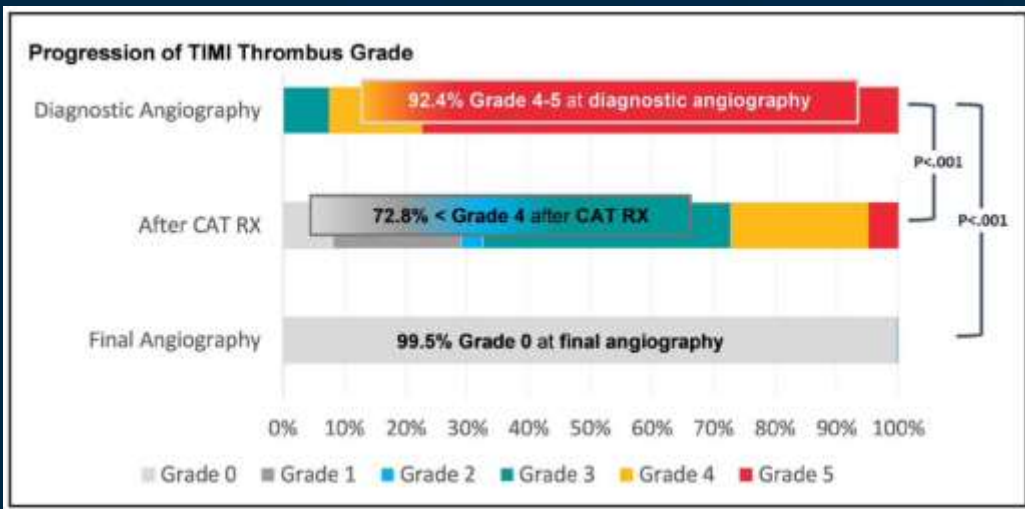
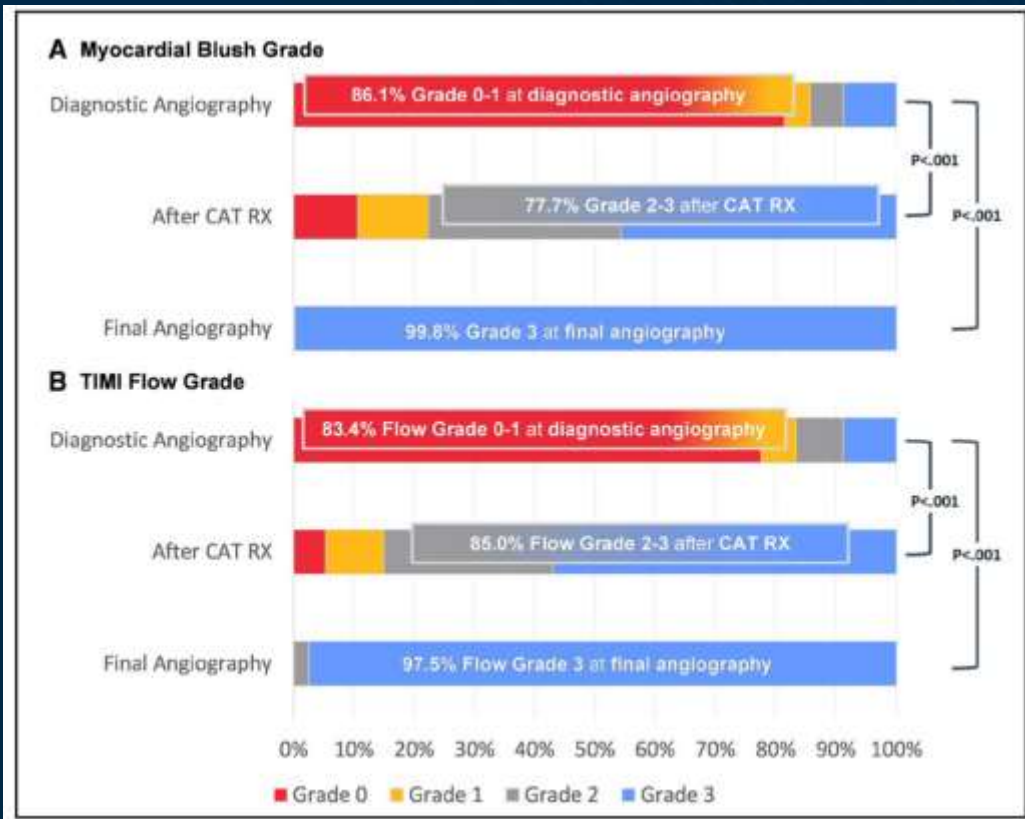


Final Angiography

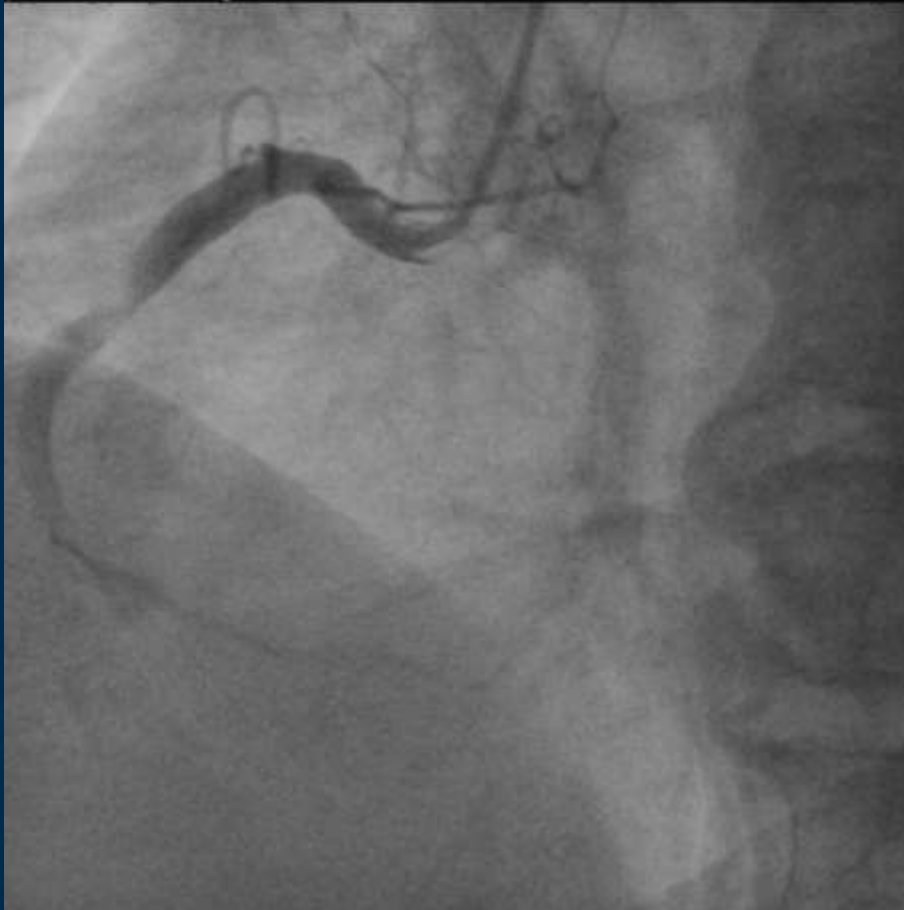
CHEETAH Trial

Table 3. End Points per IMR

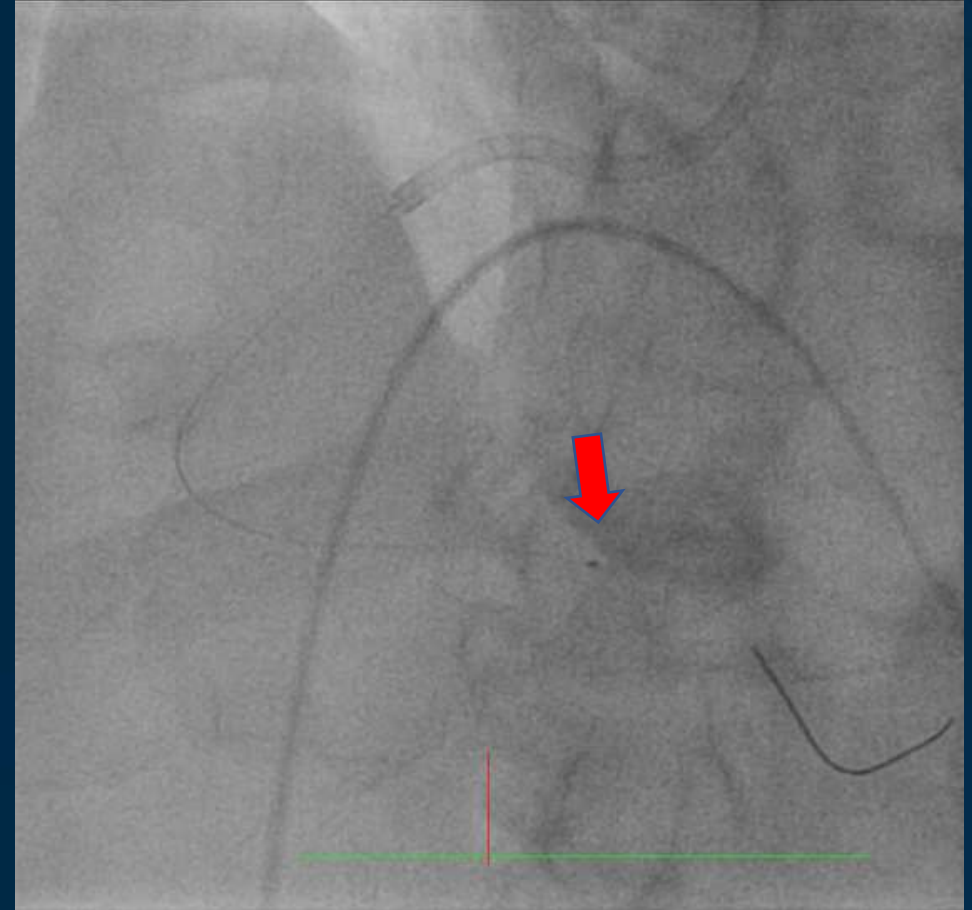
	All patients (N=400)
Primary composite end point (MACE); % (n/N; [95% CI])*	3.60% (14/389; 2.0%, 6.0%)
Cardiovascular death within 30 d	0.51% (2/389; 0.1%, 1.8%)
Recurrent MI within 30 d	1.80% (7/389; 0.7%, 3.7%)
Cardiogenic shock within 30 d	1.80% (7/389; 0.7%, 3.7%)
New or worsening NYHA class IV heart failure within 30 d	0.77% (3/389; 0.2%, 2.2%)
Secondary safety end points; % (n/N; [95% CI])	
Stroke within 30 d†	0.77% (3/389; 0.2%, 2.2%)
Major stroke within 30 d	0.51% (2/389; 0.1%, 1.8%)
Minor stroke within 30 d	0.26% (1/389; 0.0%, 1.4%)
Major bleeding within 30 d‡	1.03% (4/389; 0.3%, 2.6%)
All-cause mortality within 180 d	2.43% (9/370; 1.1%, 4.6%)
Cardiovascular death within 180 d	1.08% (4/370; 0.3%, 2.7%)
Recurrent MI within 180 d	2.70% (10/370; 1.3%, 4.9%)
Cardiogenic shock within 180 d	2.16% (8/370; 0.9%, 4.2%)
Class IV heart failure within 180 d	1.08% (4/370; 0.3%, 2.7%)
Incidence of device-related SAE(s)§	0.00% (0/389; N/A)
Distal embolization rate; % (n/N; [95% CI])	0.75% (3/400; 0.2%, 2.2%)
Stent thrombosis within 180 d; % (n/N; [95% CI])	2.43% (9/370; 1.1%, 4.6%)



A Case of Failure of Current Devices in STEMI

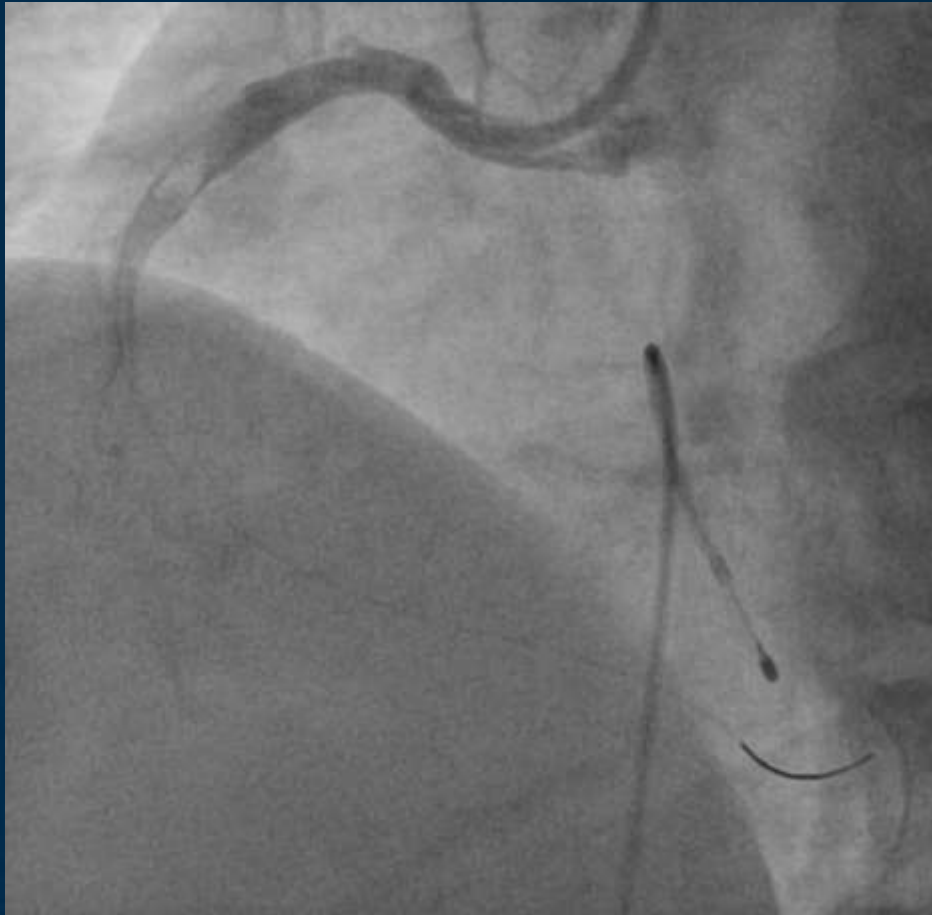


Inferior STEMI with RCA culprit



Aspiration thrombectomy

A Case of Failure of Current Devices in STEMI

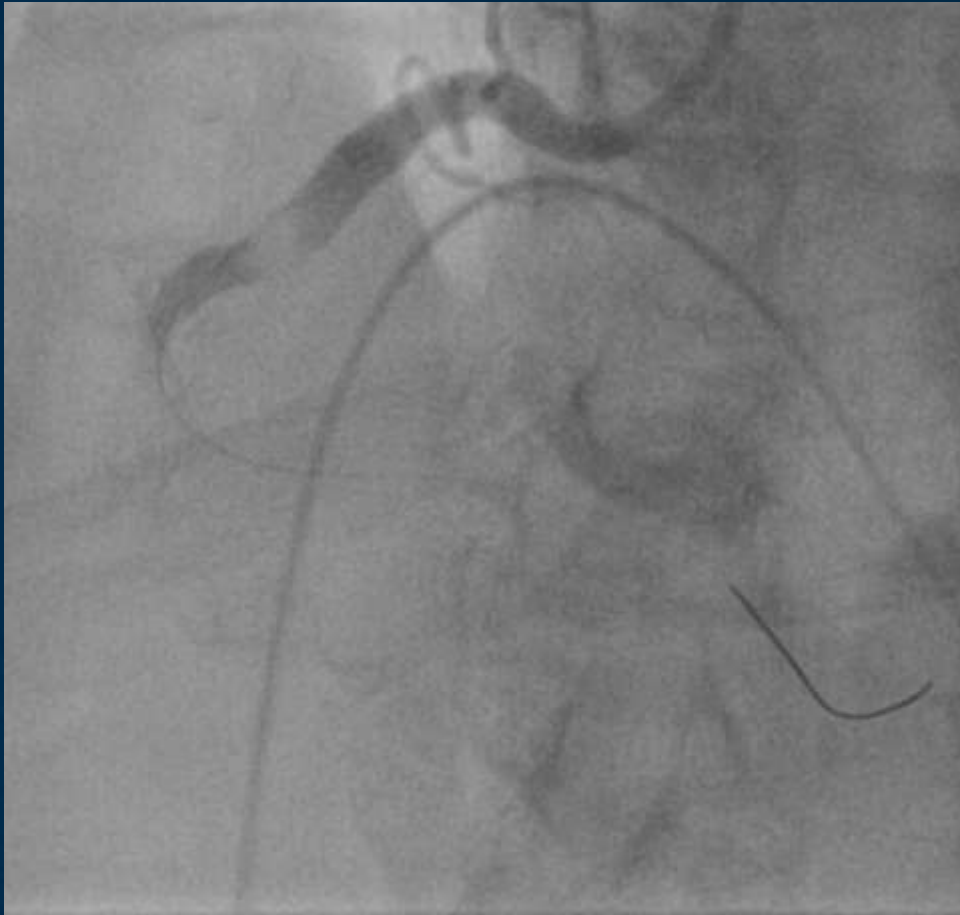


Post aspiration thrombectomy

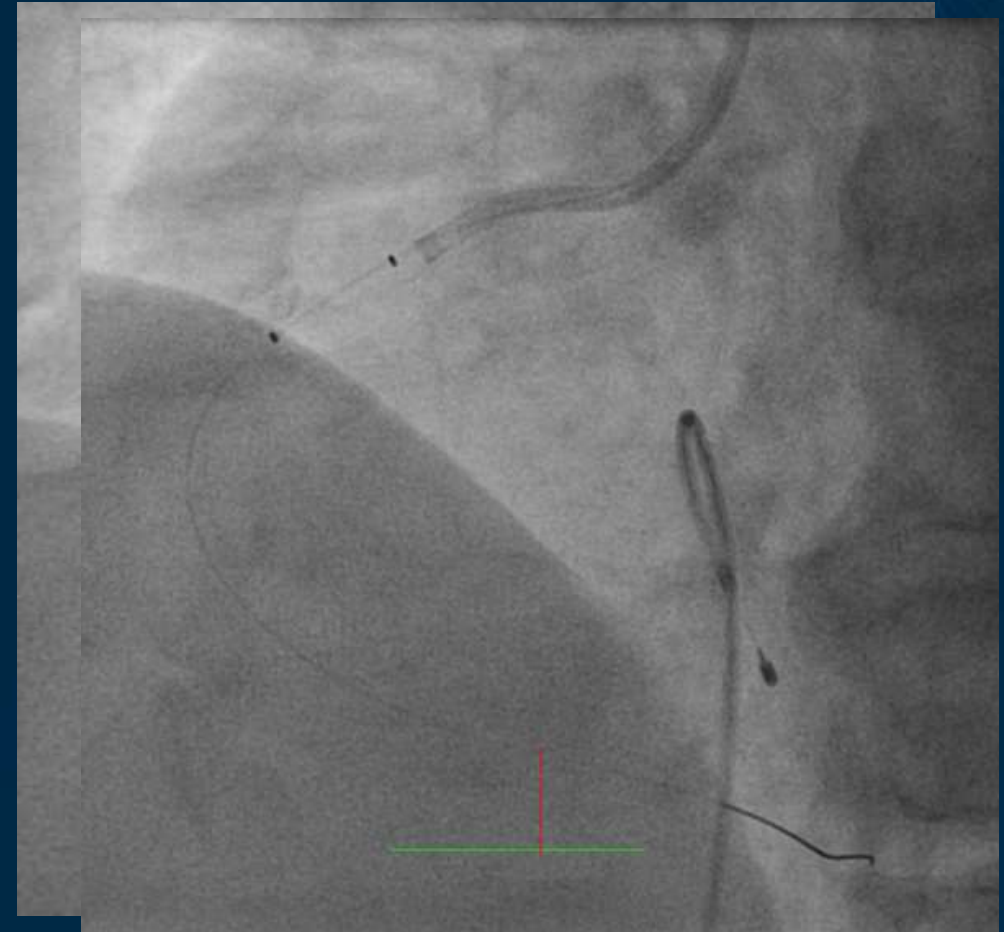


Balloon angioplasty with distal protection

A Case of Failure of Current Devices in STEMI



Post balloon angioplasty and distal protection

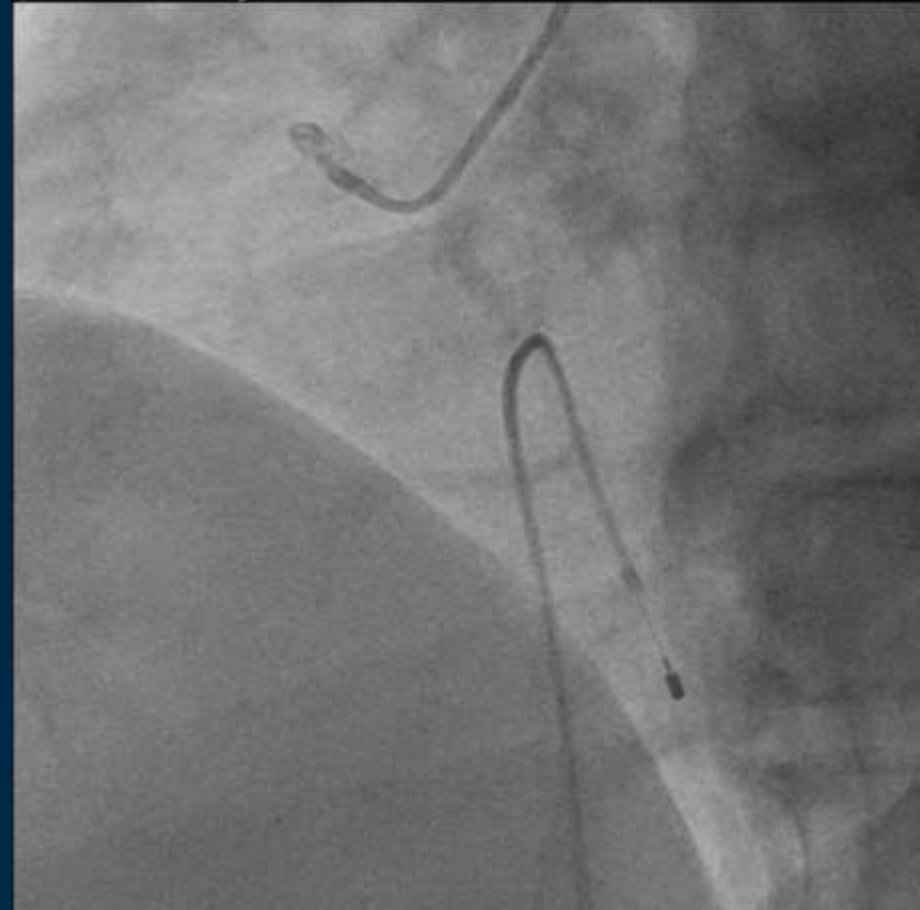


Possis AngioJet

A Case of Failure of Current Devices in STEMI



Post Pocsis Angiojet

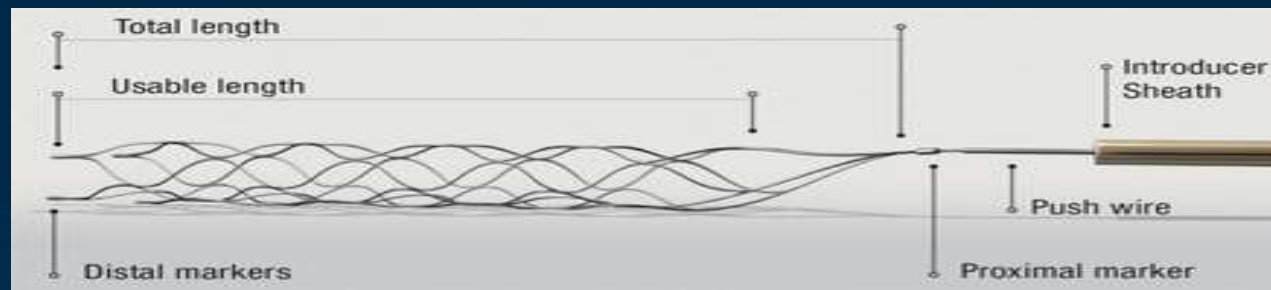


Re-look 4 days later

SOLITAIRE Trial

Feasibility trial evaluating efficacy and safety of Solitaire thrombus retrieval device in ACS

- Multi-centre study using Solitaire device in ACS patients as bail out Singapore
- Recruitment from: TTSH, NHCS, NUH, KTPH, CGH
- To investigate the **efficacy and safety** of Solitaire™ X thrombus retrieval device as an adjunctive interventional technique in ACS patients with **refractory thrombus** during percutaneous coronary intervention
- **Eligibility:** large thrombus burden of **TIMI thrombus grade 4 or above or TIMI flow grade of 1 or less** in at least one native infarct related artery following conventional methods of treatment for thrombus

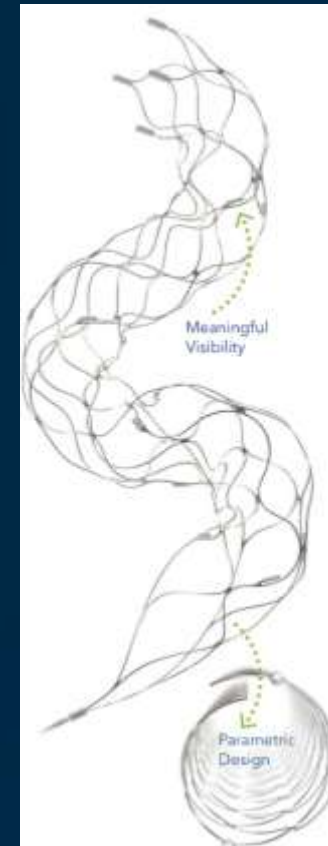


Courtesy of Deanna Khoo 

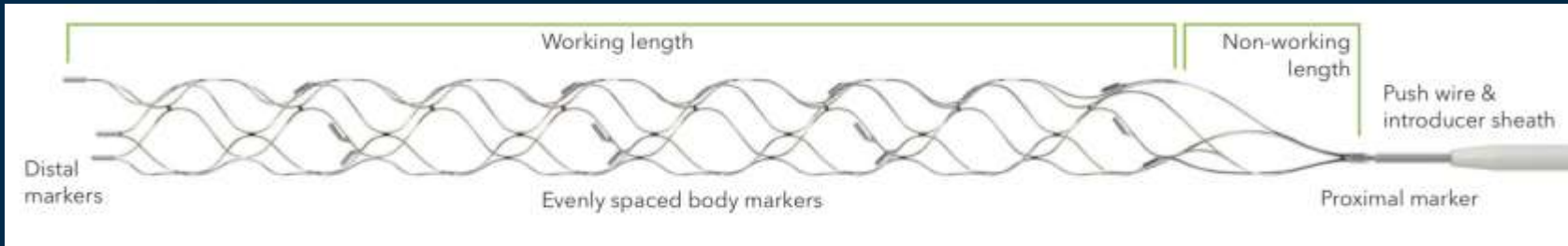
What is Solitaire X?

- Stent retriever – recoverable self-expanding nitinol stent based device
- Clot retrieval thrombectomy device for acute ischemic stroke
- Manufacturer: Medtronic

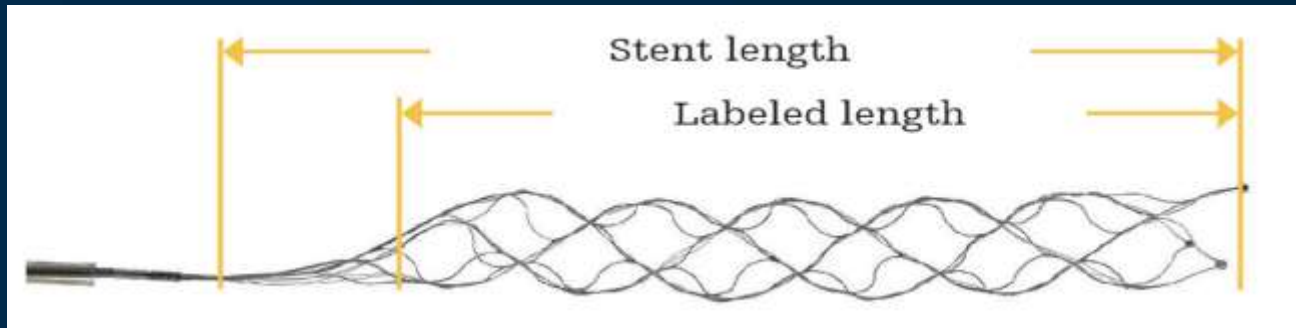
Solitaire™ X Revascularization Device Portfolio Information ³³											
Model	Recommended Vessel Diameter ^A (mm)		Microcatheter ID Range (min - max)	Push Wire Length (cm)	Stent Diameter (mm)	Usable Length ^B (mm)	Stent Length (mm)	Length from Distal Tip to Fluorosafe Marker (cm)	Radiopaque Markers		Radiopaque Stent Markers Spacing (mm)
	(min)	(max)							Distal	Prox.	
SFR4-3-20-10	1.5	3.0	0.017" - 0.027" 0.43mm - 0.69mm	200	3.0	20.0	30.6	< 150	3	1	10
SFR4-3-40-10	1.5	3.0	0.017" - 0.027" 0.43mm - 0.69mm	200	3.0	40.0	51.6	<150	3	1	10
SFR4-4-20-05	1.5	4.0	0.021" - 0.027" 0.53mm - 0.69mm	200	4.0	20.0	31.0	<130	3	1	5
SFR4-4-20-10	1.5	4.0	0.021" - 0.027" 0.53mm - 0.69mm	200	4.0	20.0	31.0	<130	3	1	10
SFR4-4-40-10	1.5	4.0	0.021" - 0.027" 0.53mm - 0.69mm	200	4.0	40.0	50.0	<130	3	1	10
SFR4-6-20-10	2.0	5.5	0.021" - 0.027" 0.53mm - 0.69mm	200	6.0	20.0	31.0	<130	4	1	10
SFR4-6-24-06	2.0	5.5	0.021" - 0.027" 0.53mm - 0.69mm	200	6.0	24.0	37.0	<130	4	1	6
SFR4-6-40-10	2.0	5.5	0.021" - 0.027" 0.53mm - 0.69mm	200	6.0	40.0	47.0	<130	4	1	10



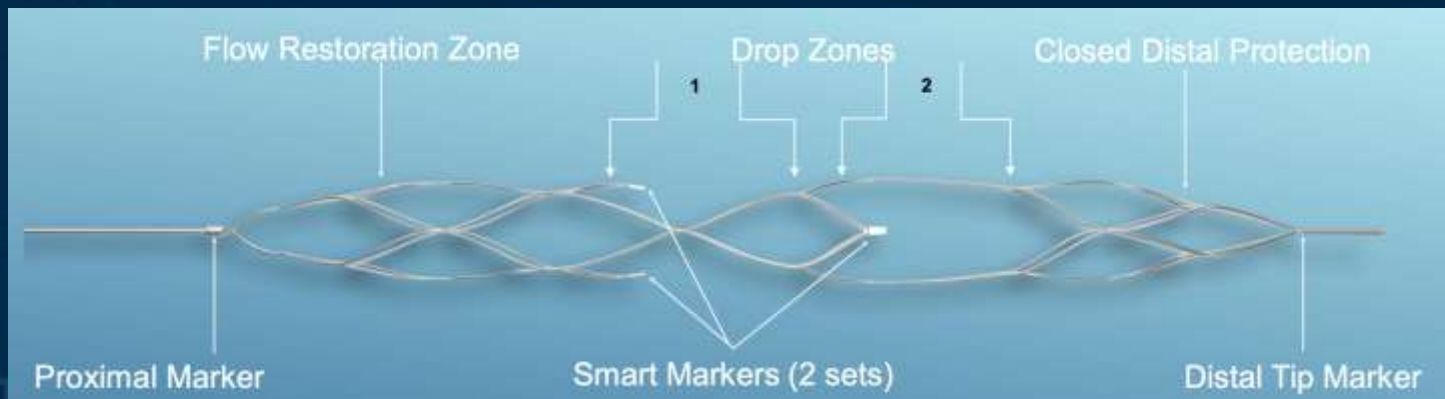
Stent retrievers



Solitaire X
Medtronic



Trevo NXT
Stryker



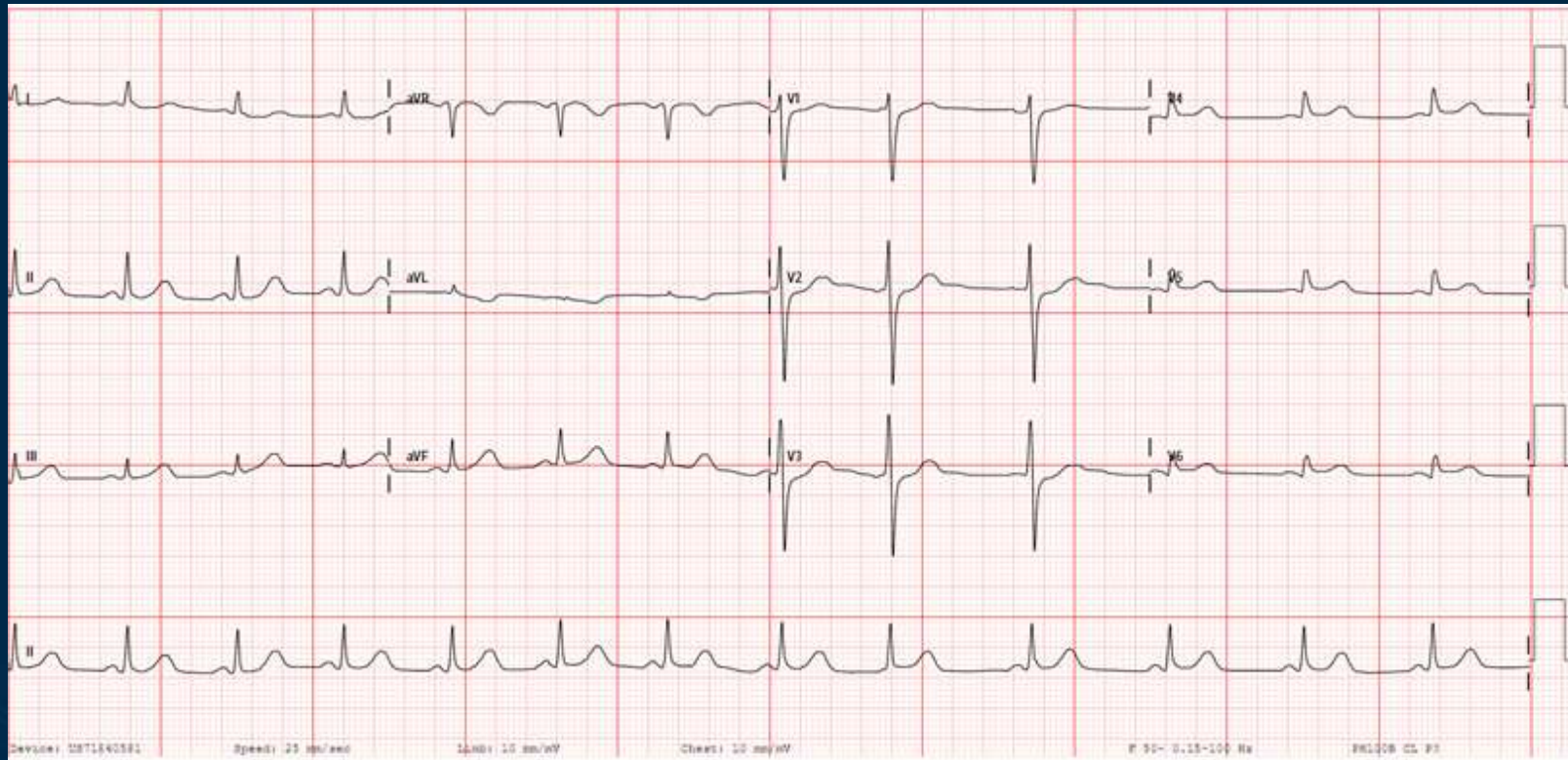
Neva
Vesalio

A prospective, first-in-human use of the NeVa mechanical thrombectomy device for patients with acute coronary syndromes

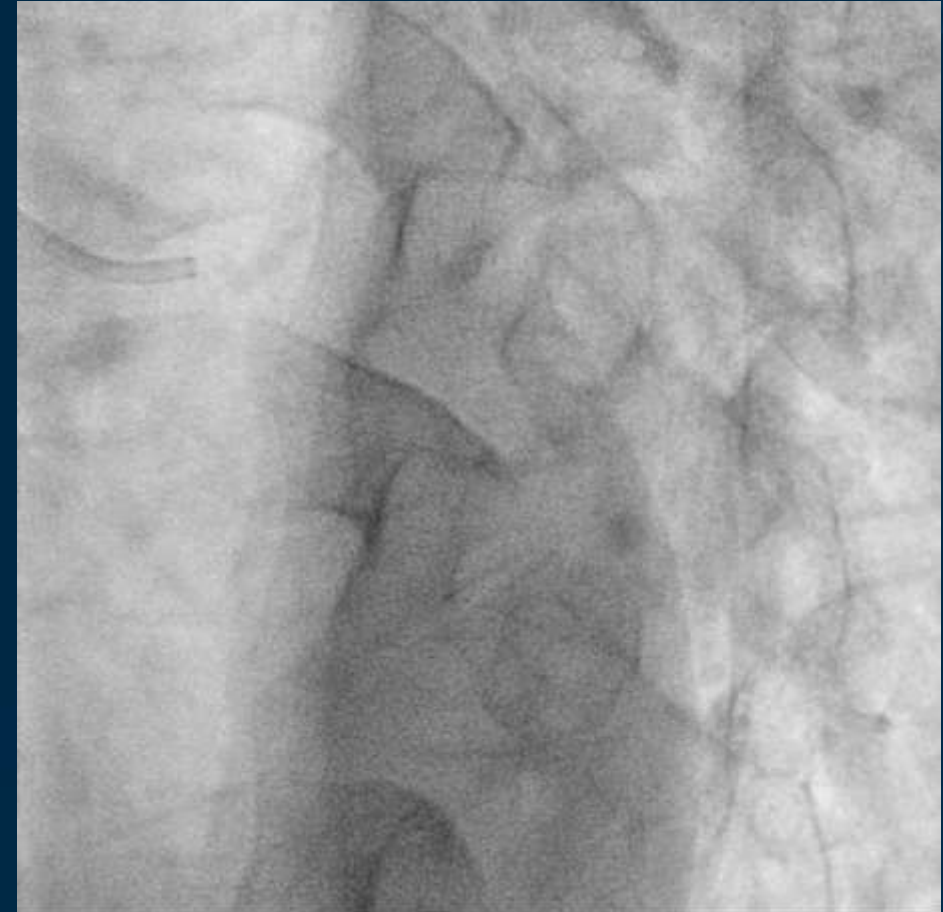
Alessandro Spirito¹, MD; Angelo Quagliana², MD; Marco Coiro¹, MD; Gebremedhin D. Melaku³, MD; Stijn Vandenberghe^{2,4}, MD; Gregor Leibundgut⁵, MD, PhD; Jonas Häner¹, MD; Marco Moccetti², MD; Marco Araco², MD; Hector M. Garcia Garcia³, MD; Marco Valgimigli^{2*}

CASE 1 – Solitaire X

- 47 year-old smoker
- 6 hours history of chest pain

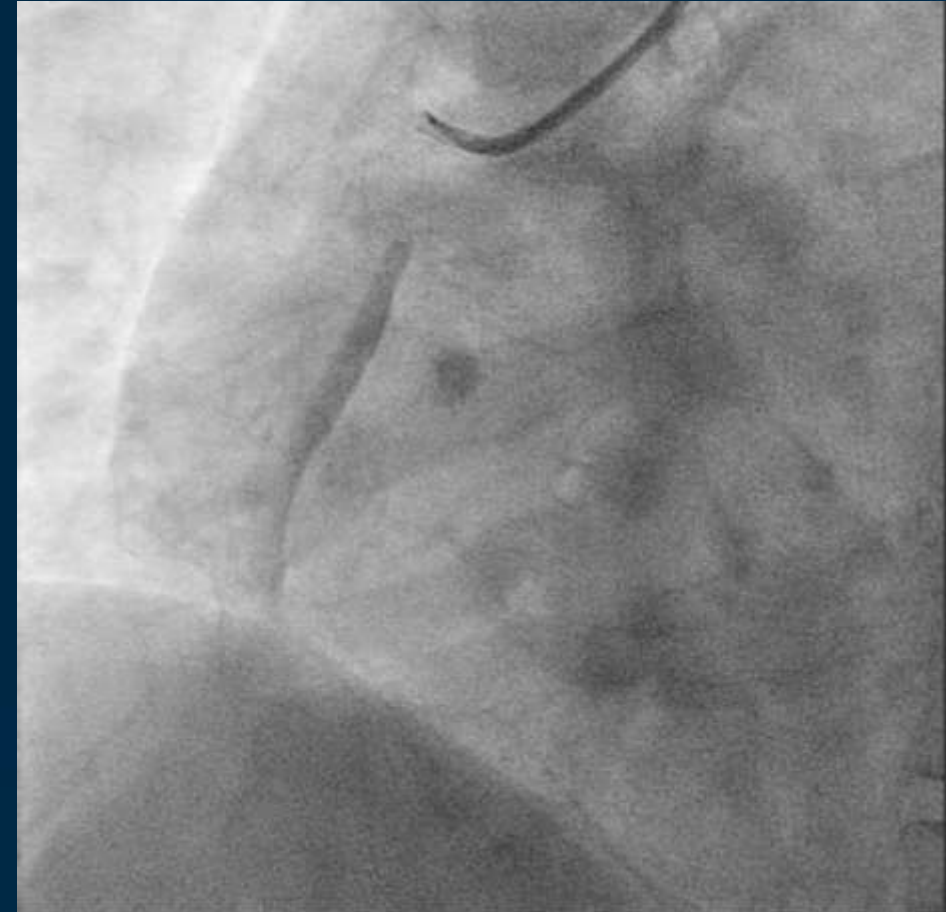
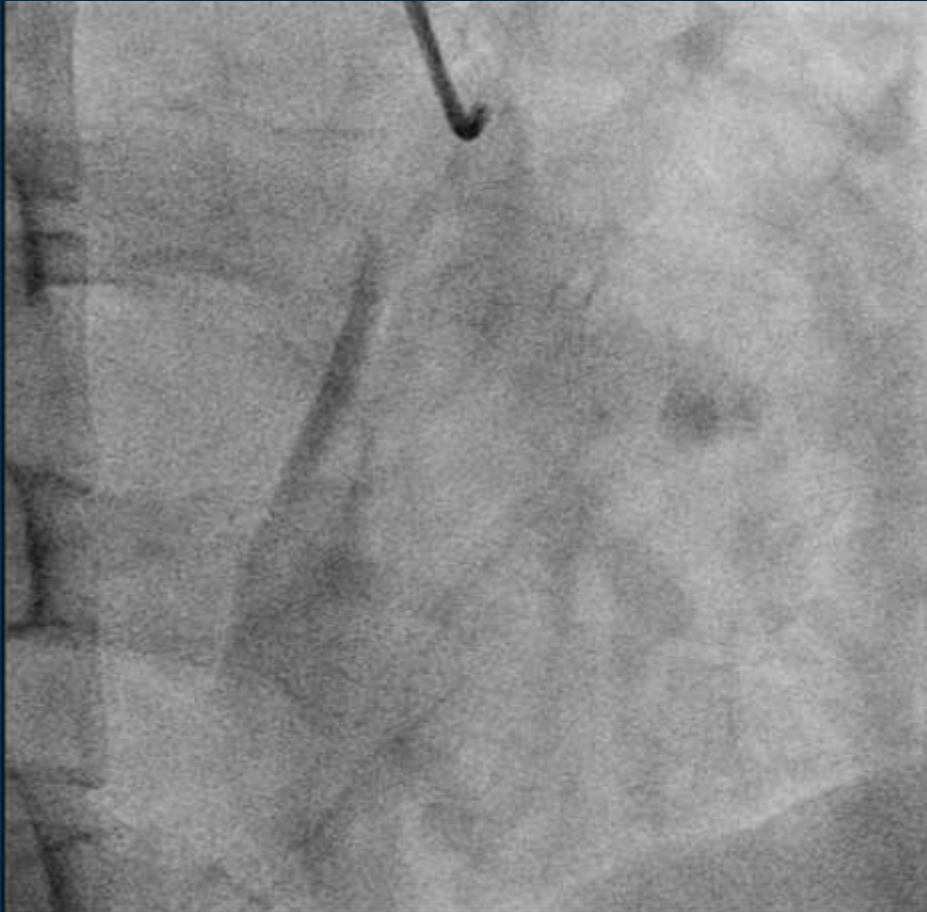


CASE 1 – Solitaire X



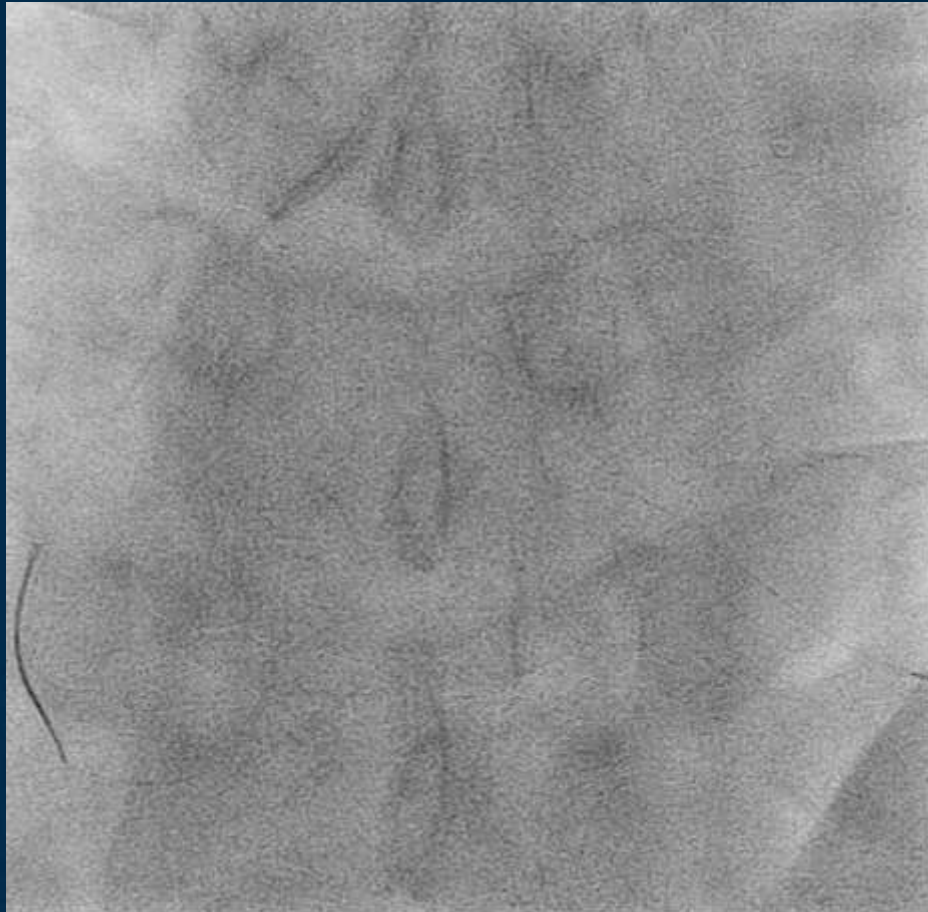
Normal LCA with ectatic LAD

CASE 1 – Solitaire X

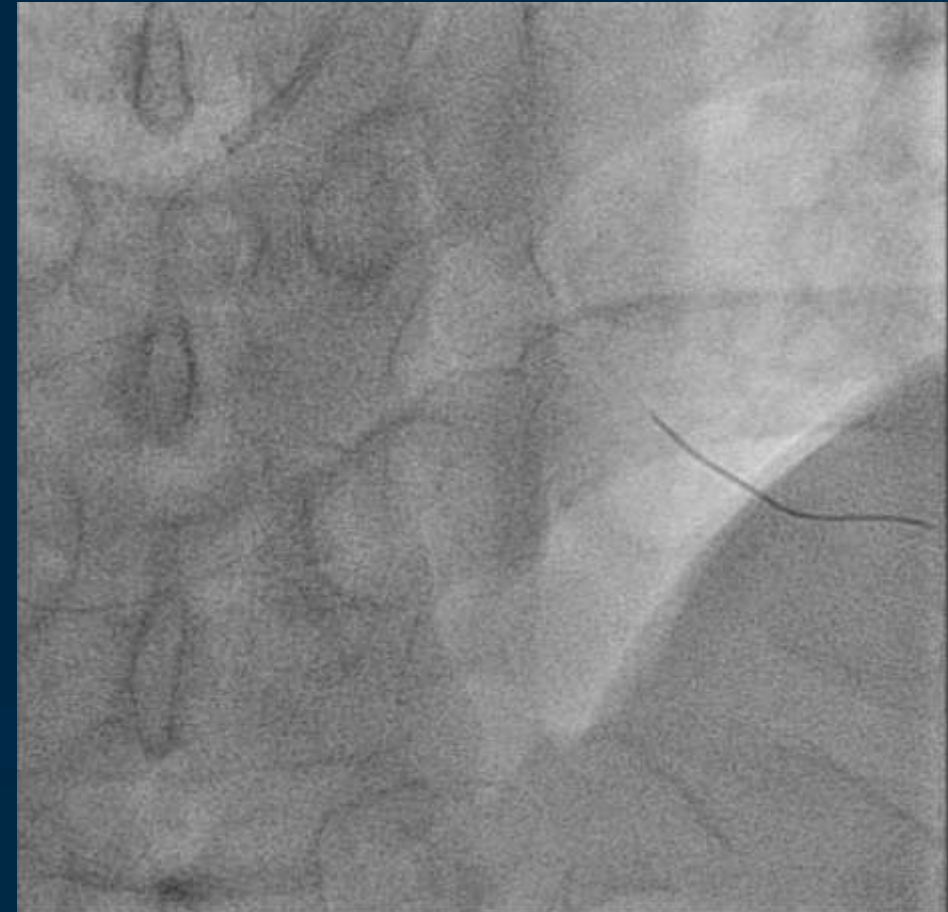


Occluded ectatic RCA with high thrombus load

CASE 1 – Solitaire X

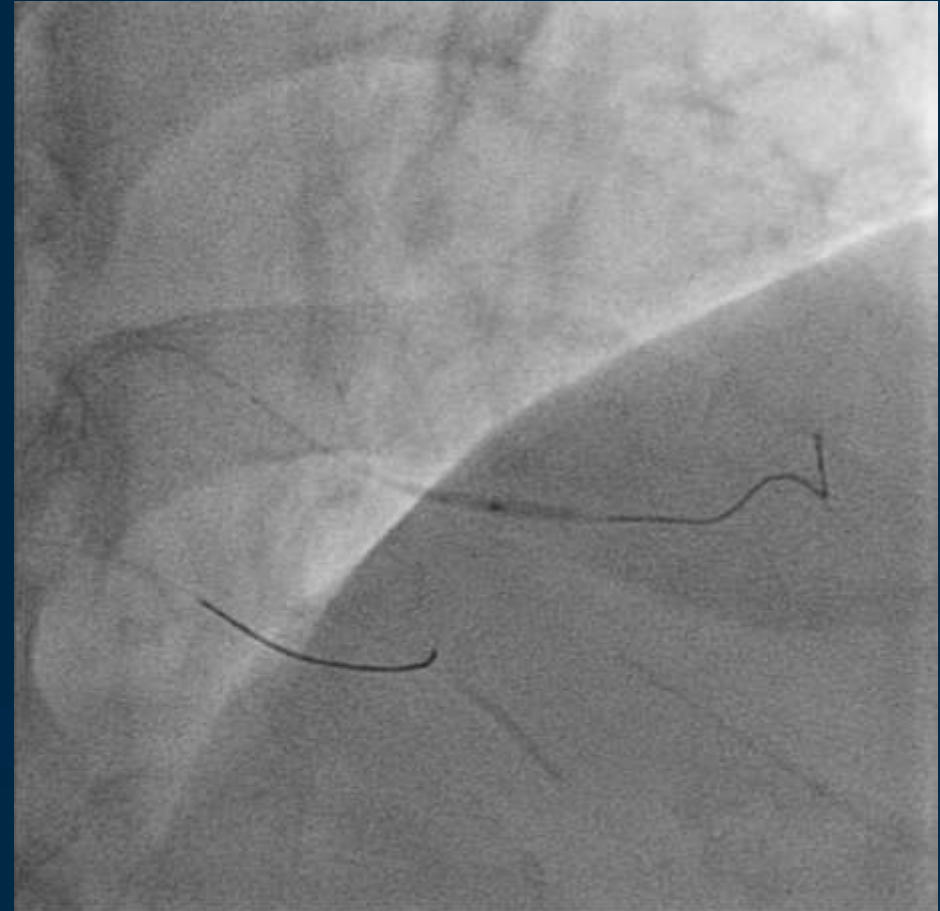


Aspiration thrombectomy – multiple passes



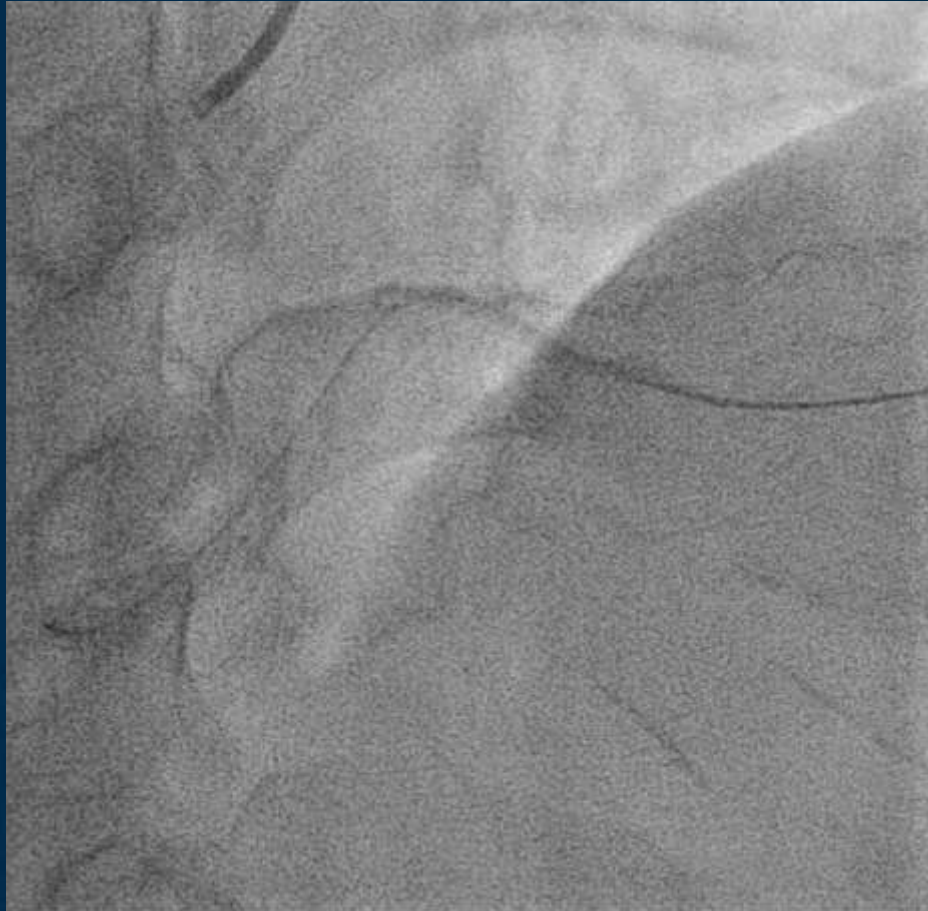
Residual thrombus and embolization to RPL

CASE 1 – Solitaire X

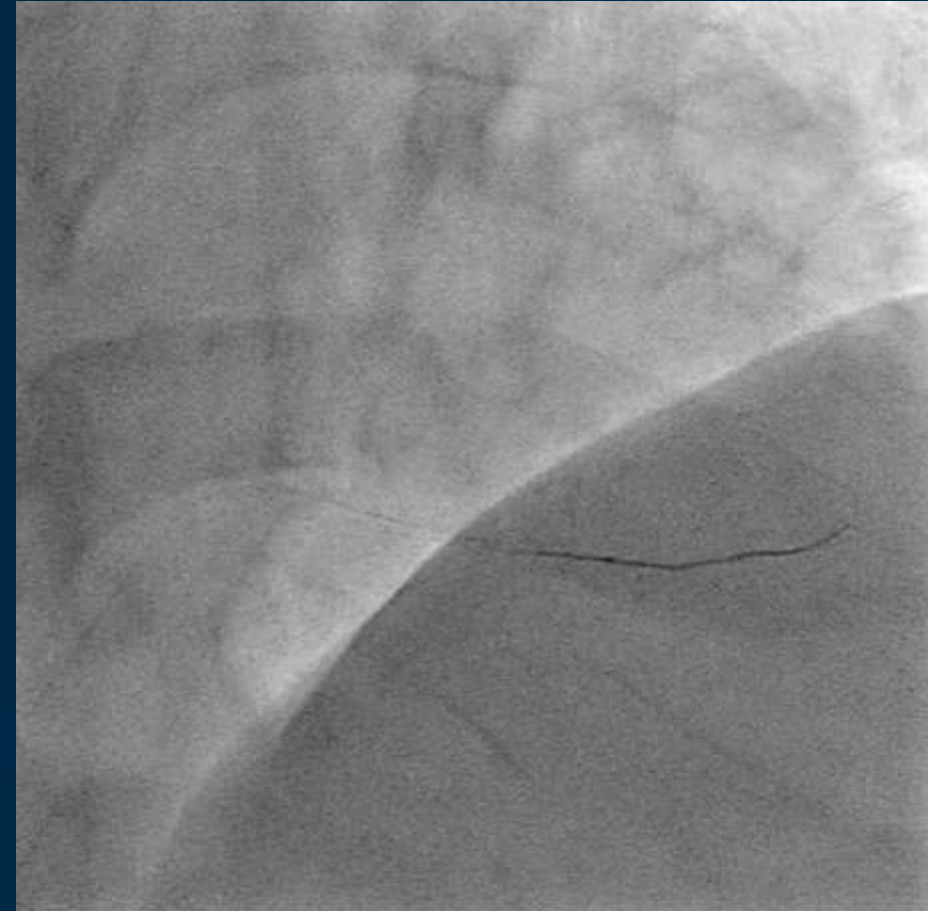


Balloon angioplasty

CASE 1 – Solitaire X

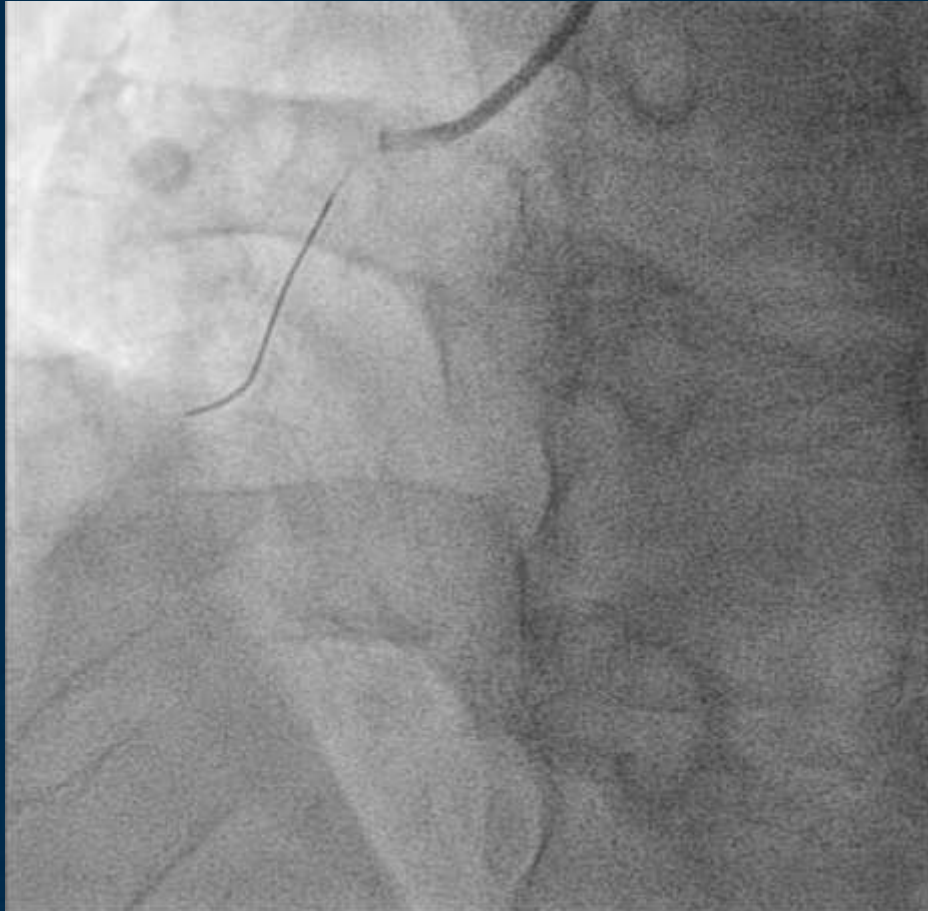


Post balloon angioplasty

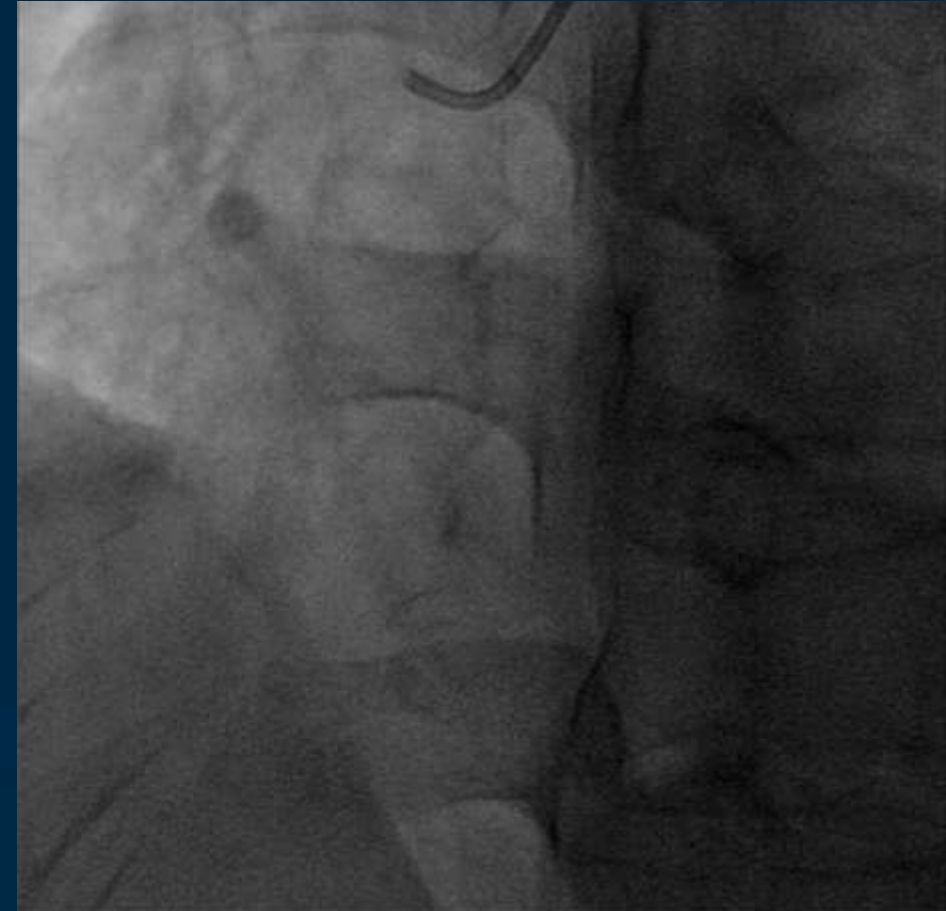


Aspiration thrombectomy

CASE 1 – Solitaire X

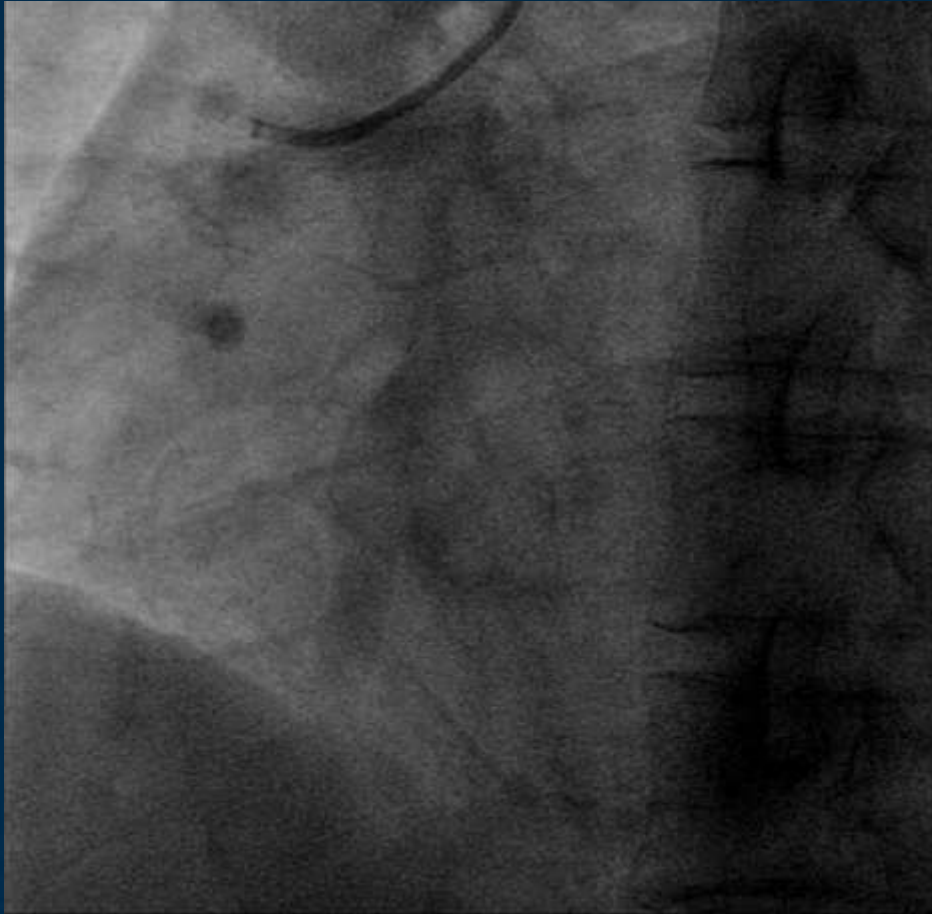


Final result with residual thrombus



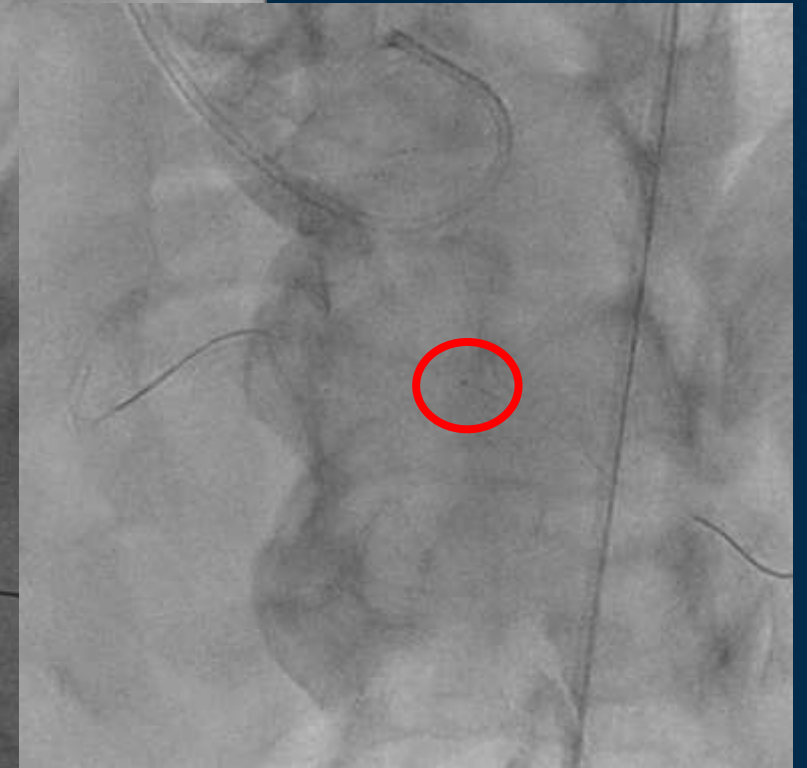
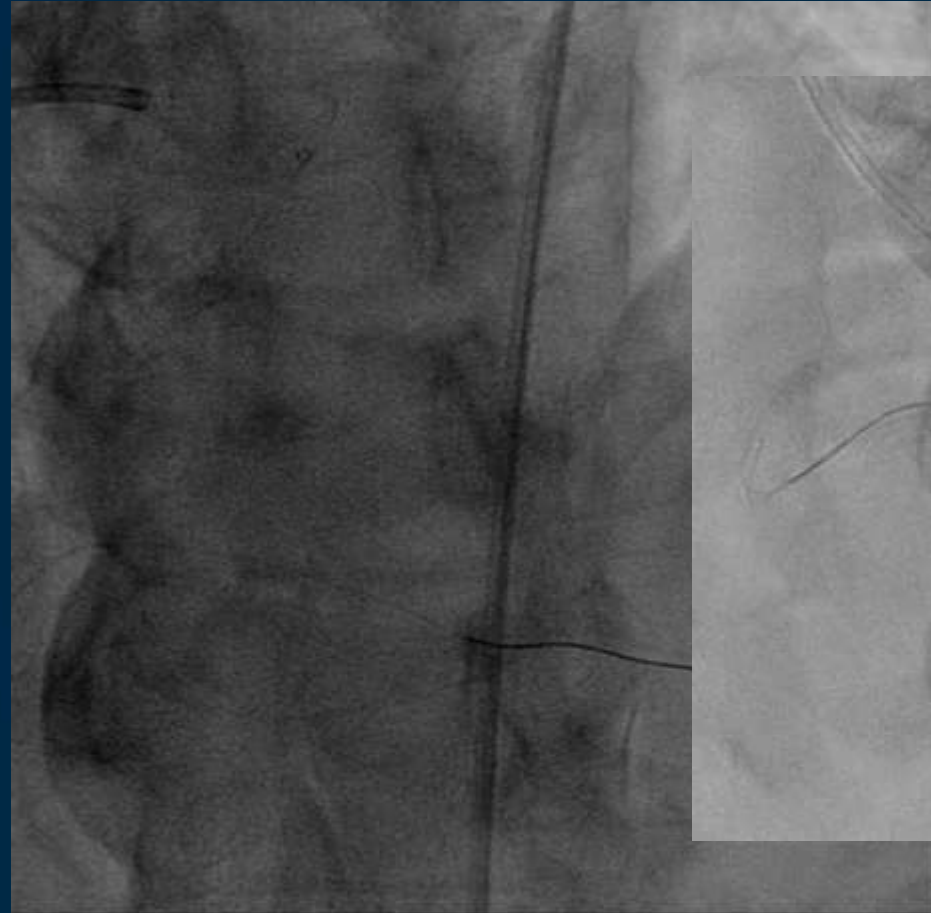
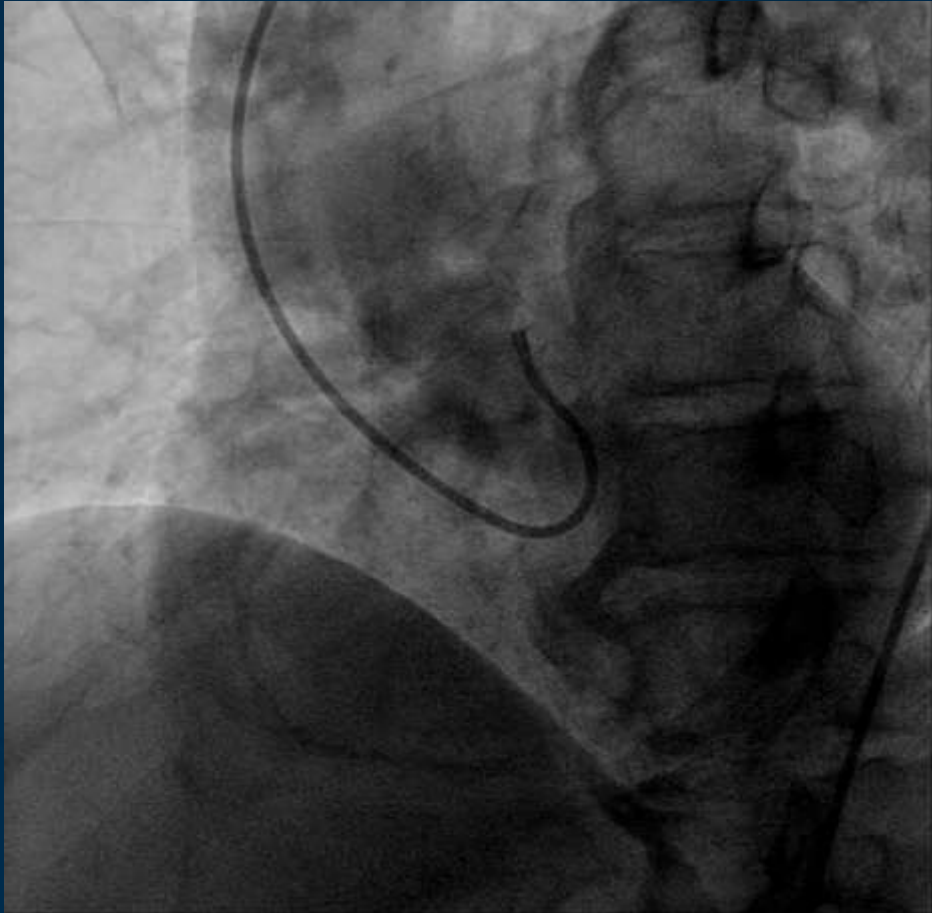
1 days later

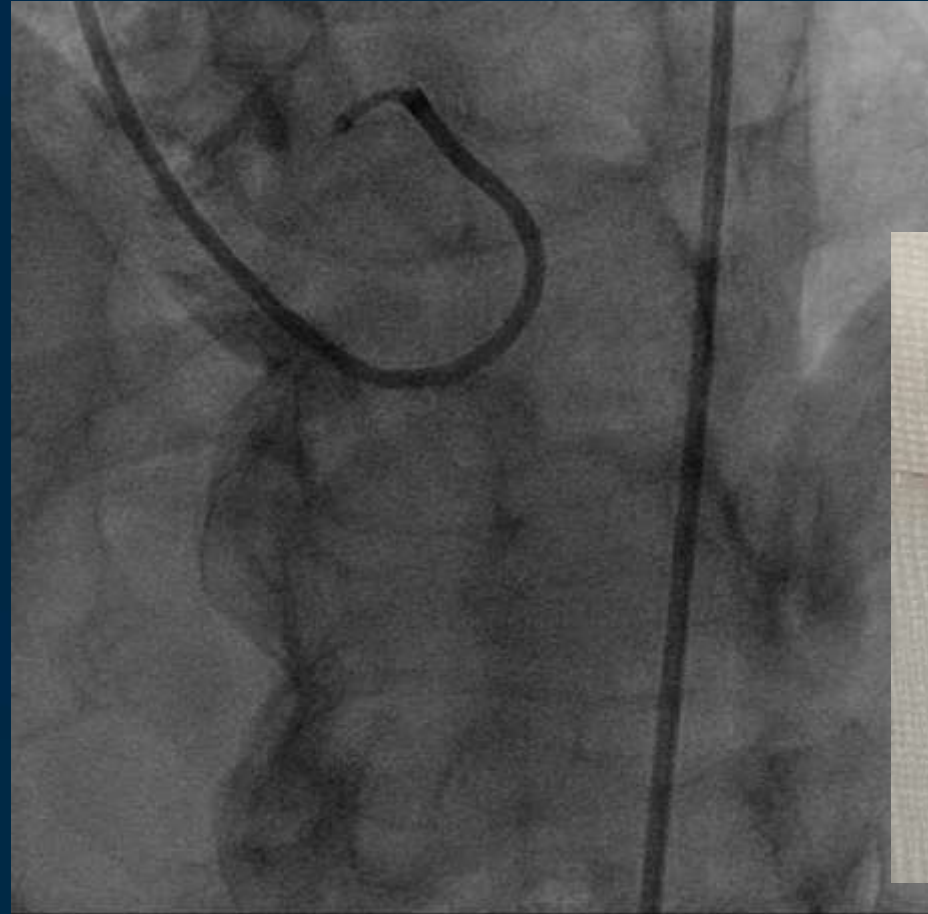
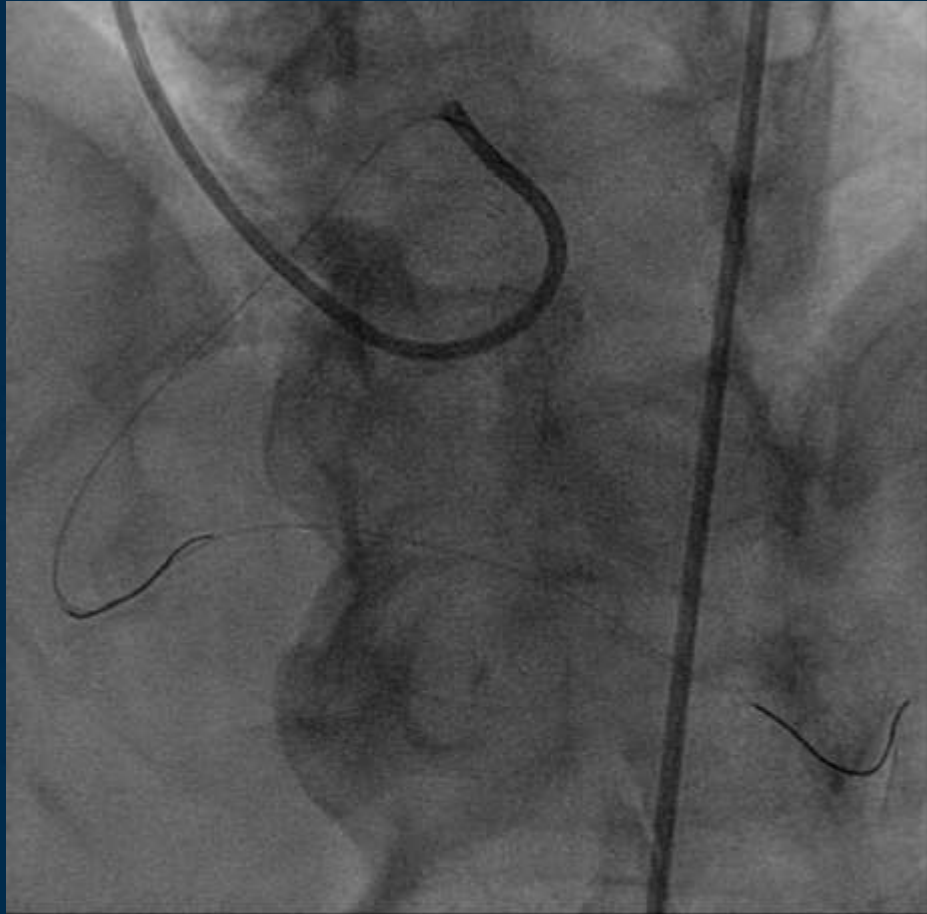
CASE 1 – Solitaire X



Final result with no stenting

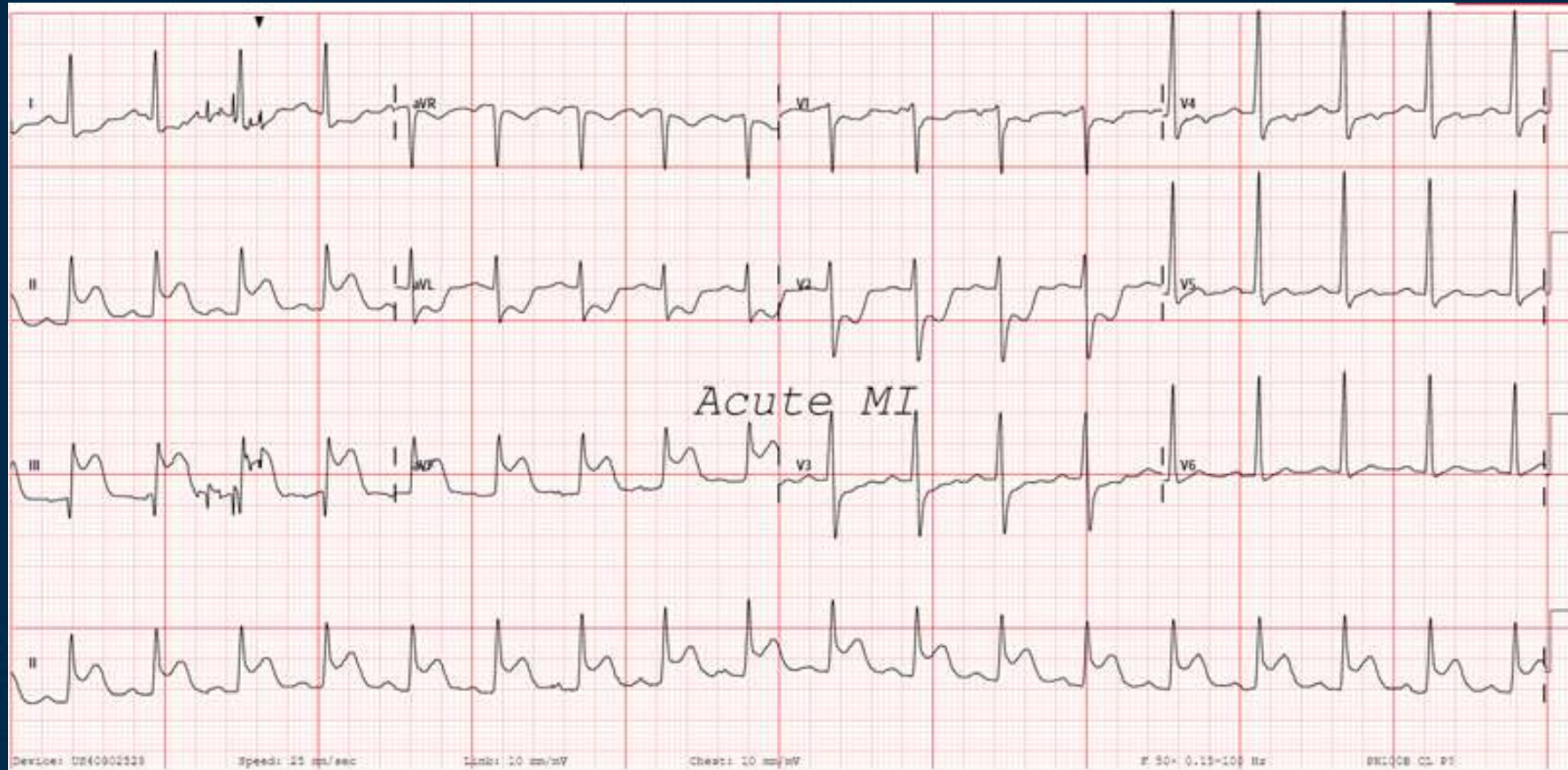
Aspiration Thrombectomy is Best for Terminal Branches Embolization



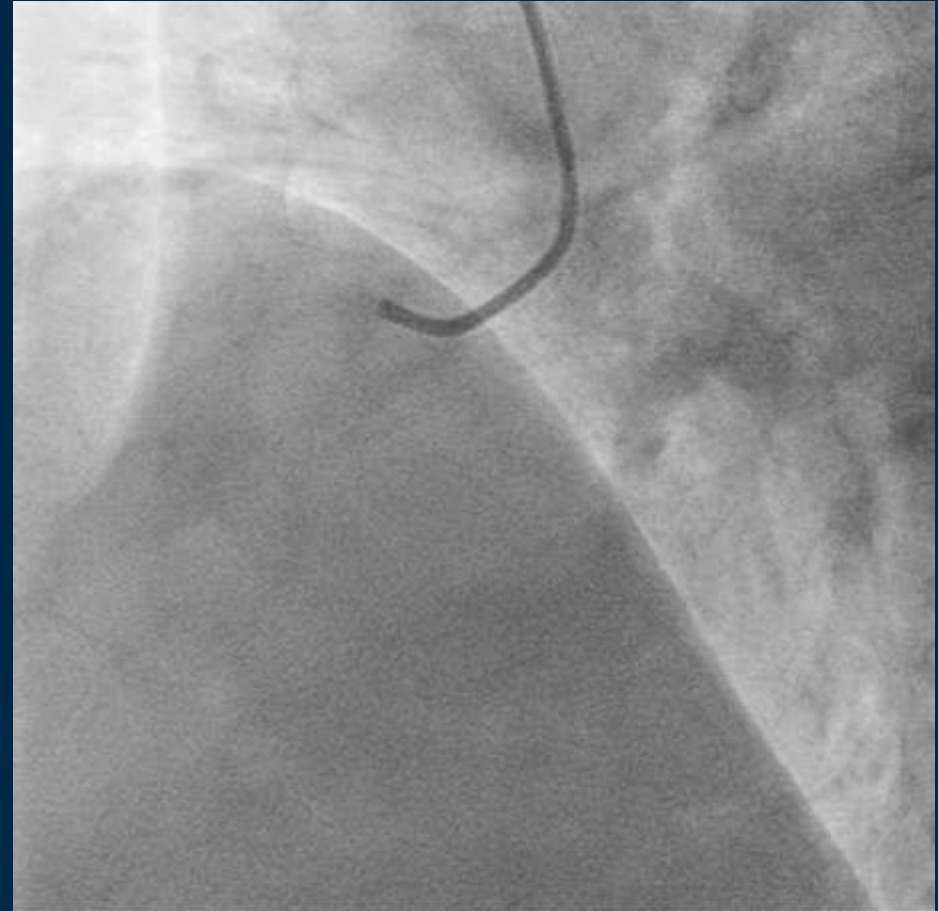
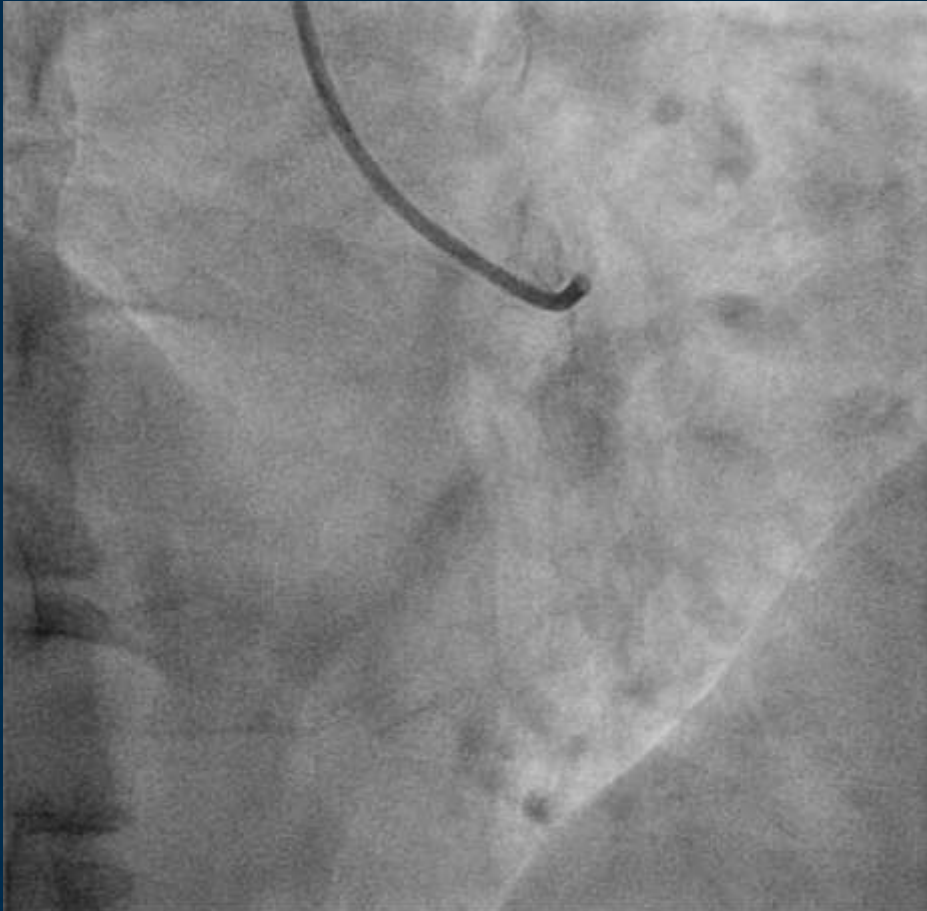


CASE 2 – Solitaire X

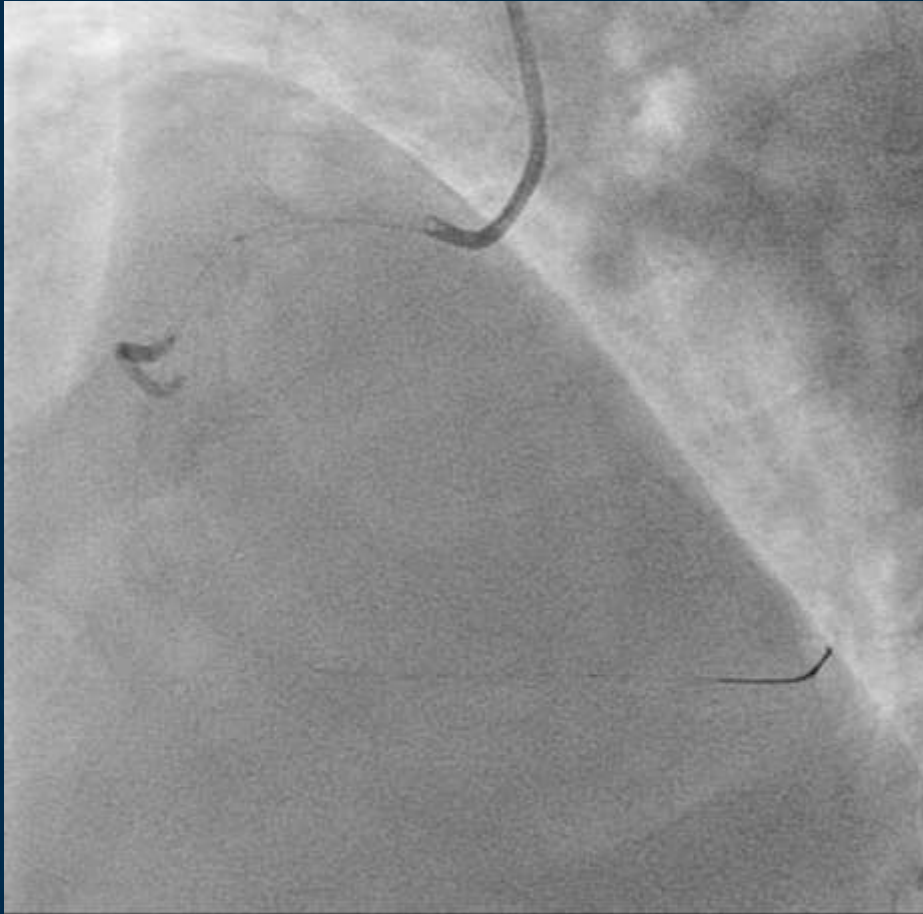
- 56 year-old man
- Chest pain while jogging



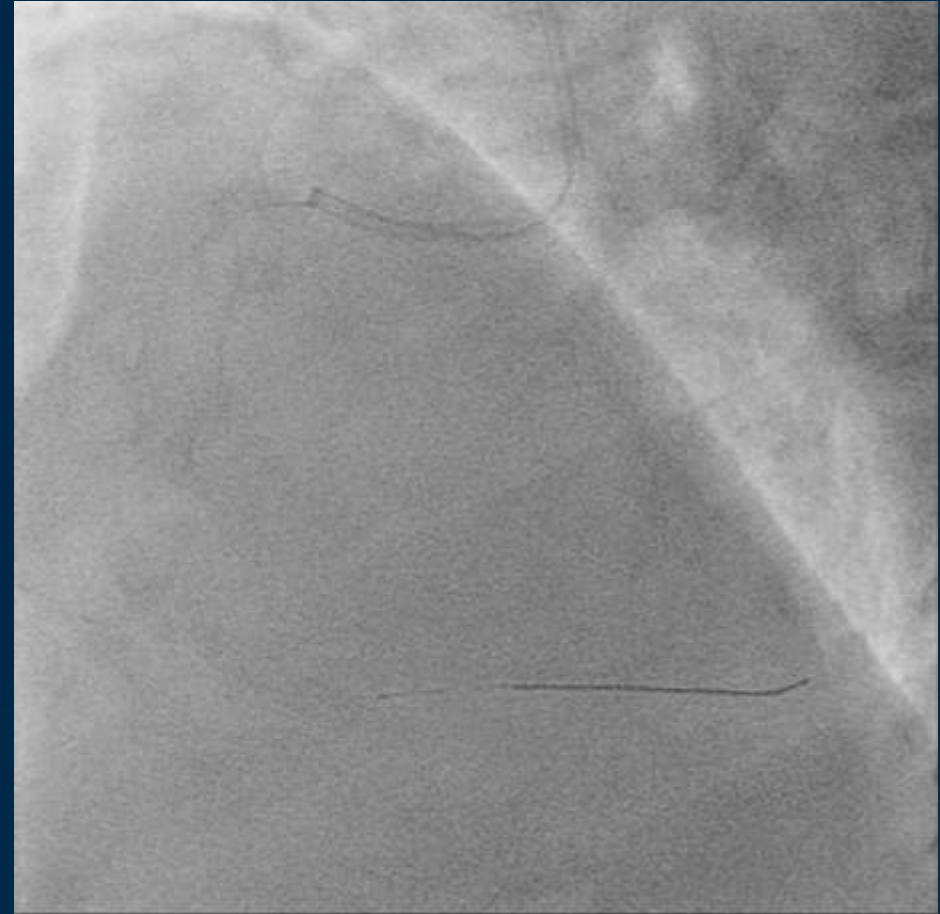
CASE 2 – Solitaire X



CASE 2 – Solitaire X

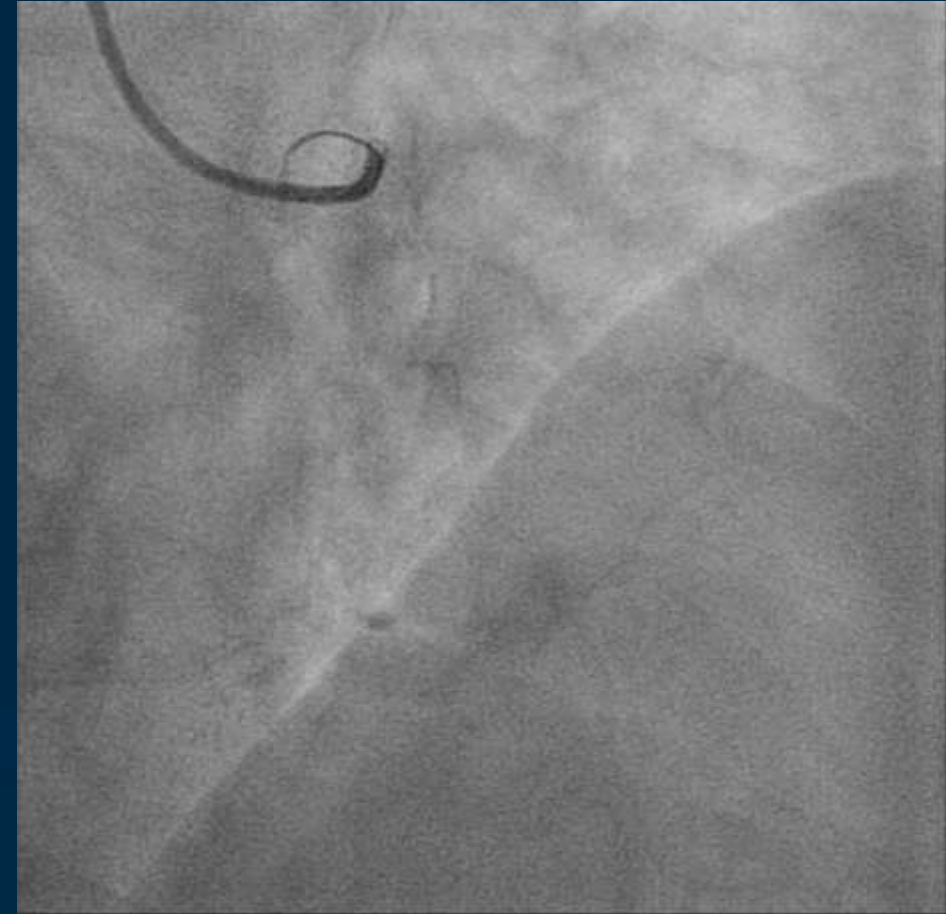
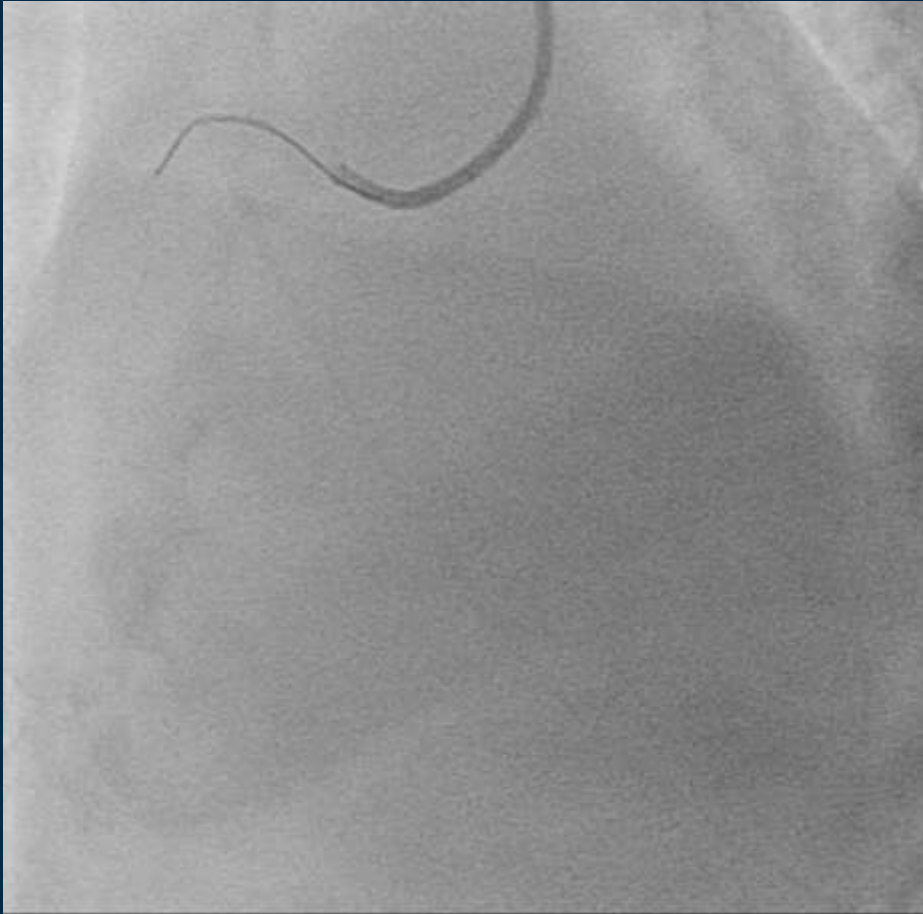


Post balloon dilatation



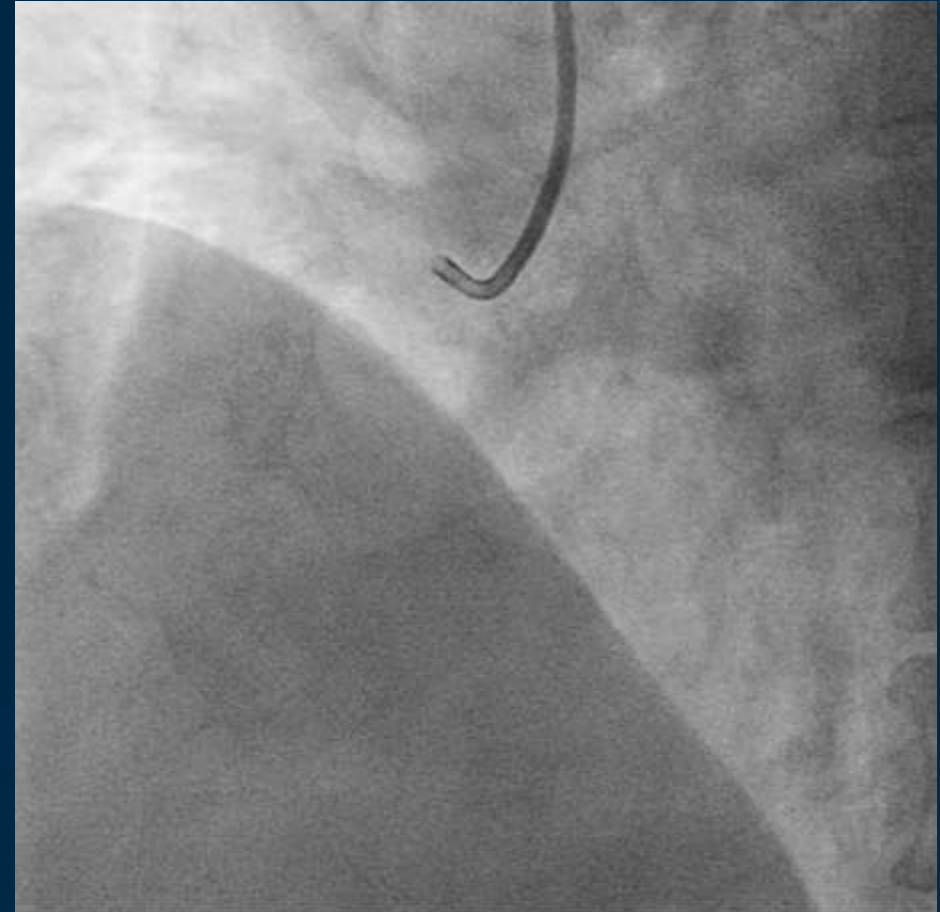
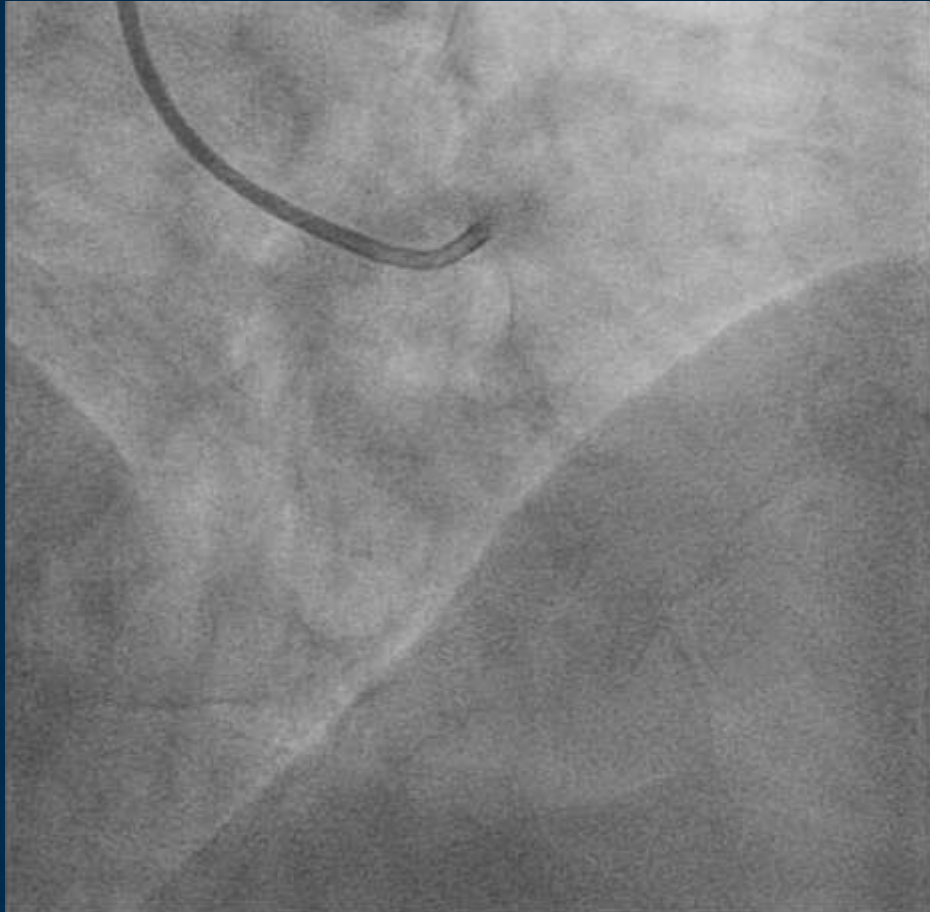
Post Aspiration thrombectomy

CASE 2 – Solitaire X



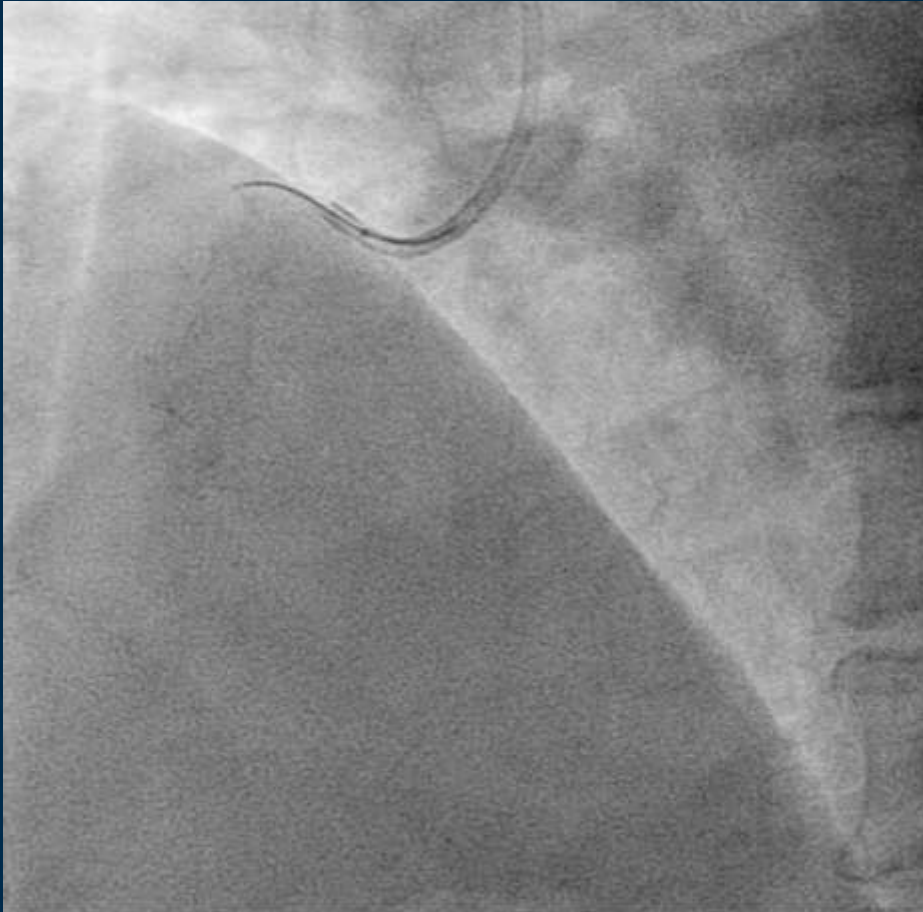
Final angiography

CASE 2 – Solitaire X

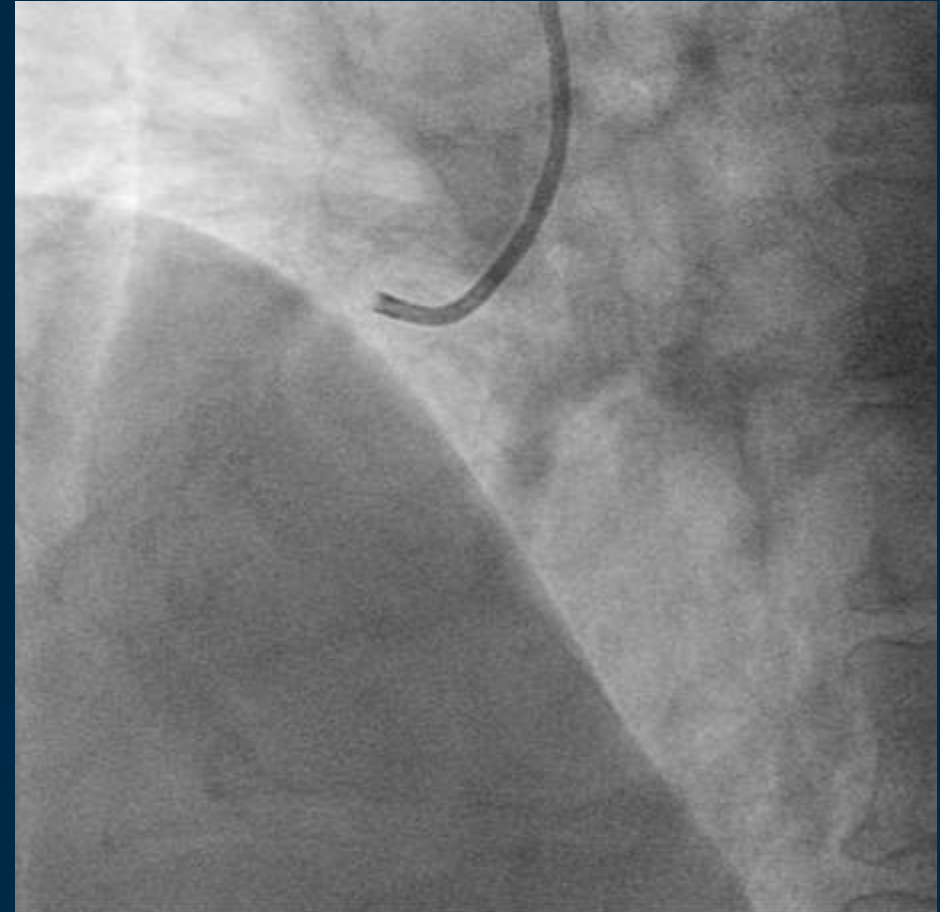


3 days later after LMWH and DAPT

CASE 2 – Solitaire X

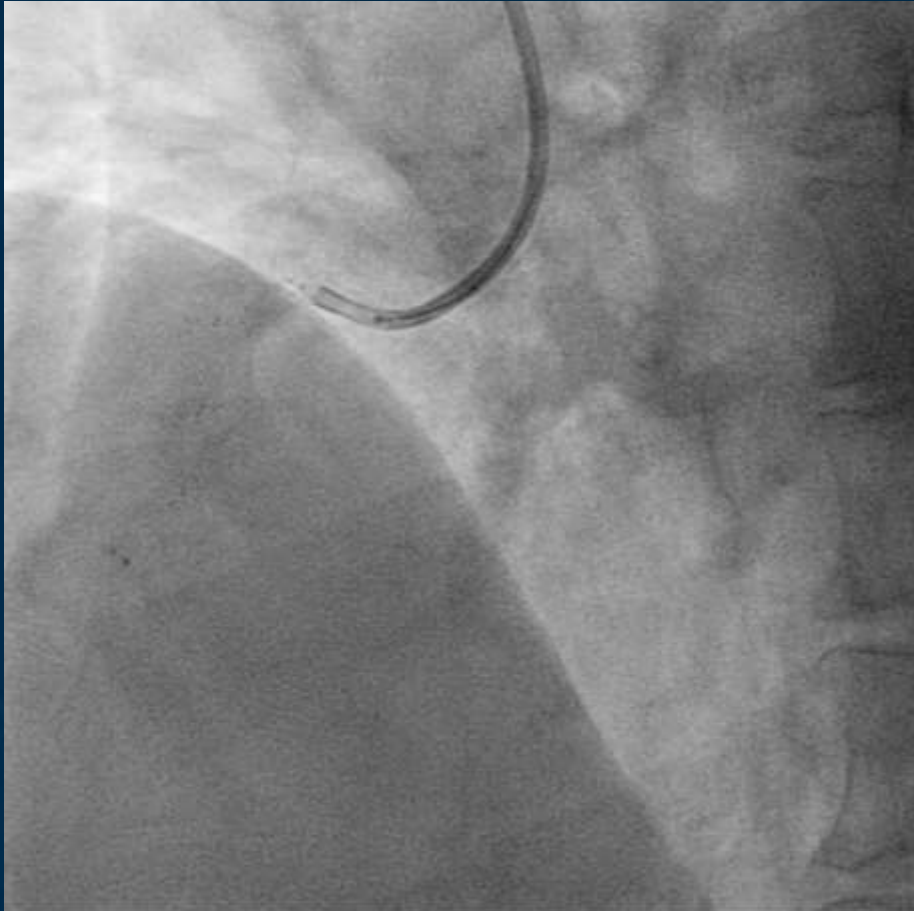


Solitaire placement

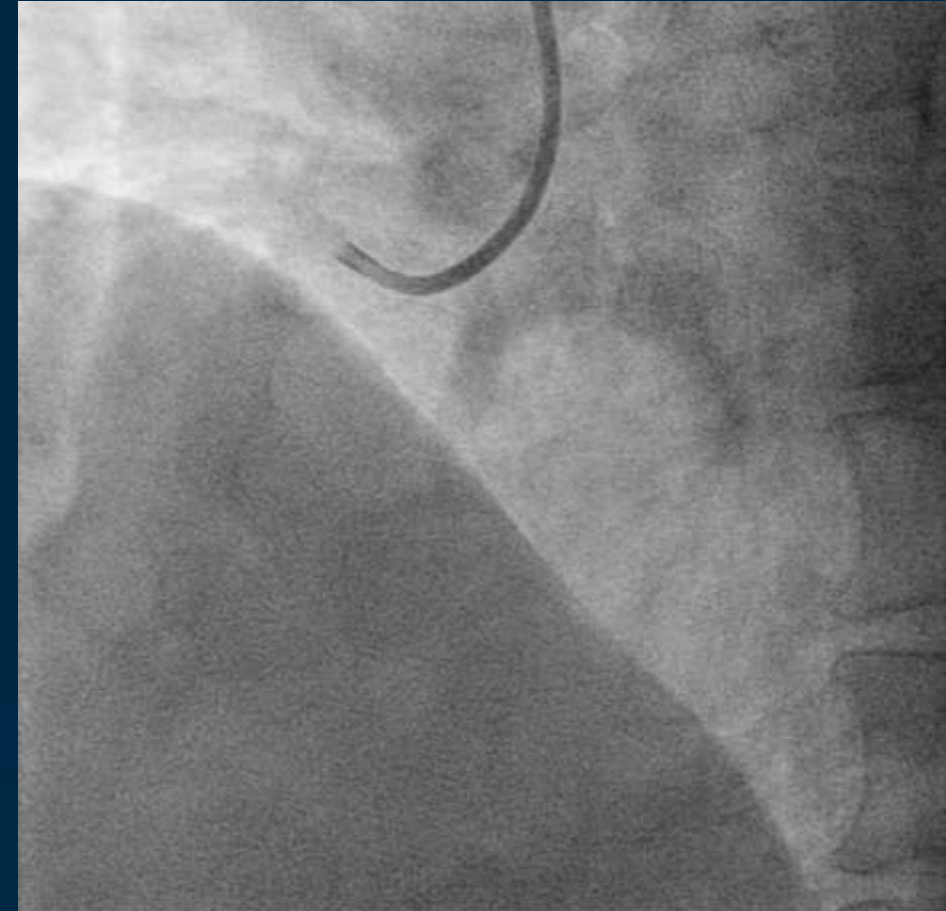


Post Solitaire

CASE 2 – Solitaire X

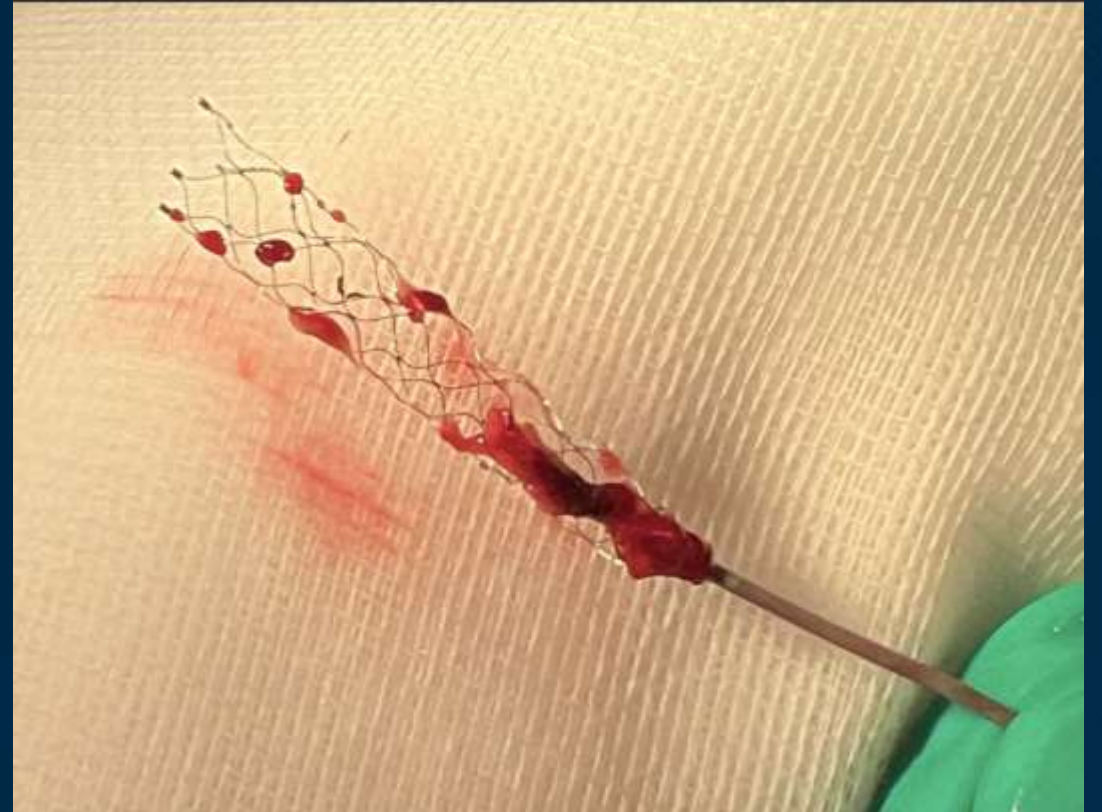
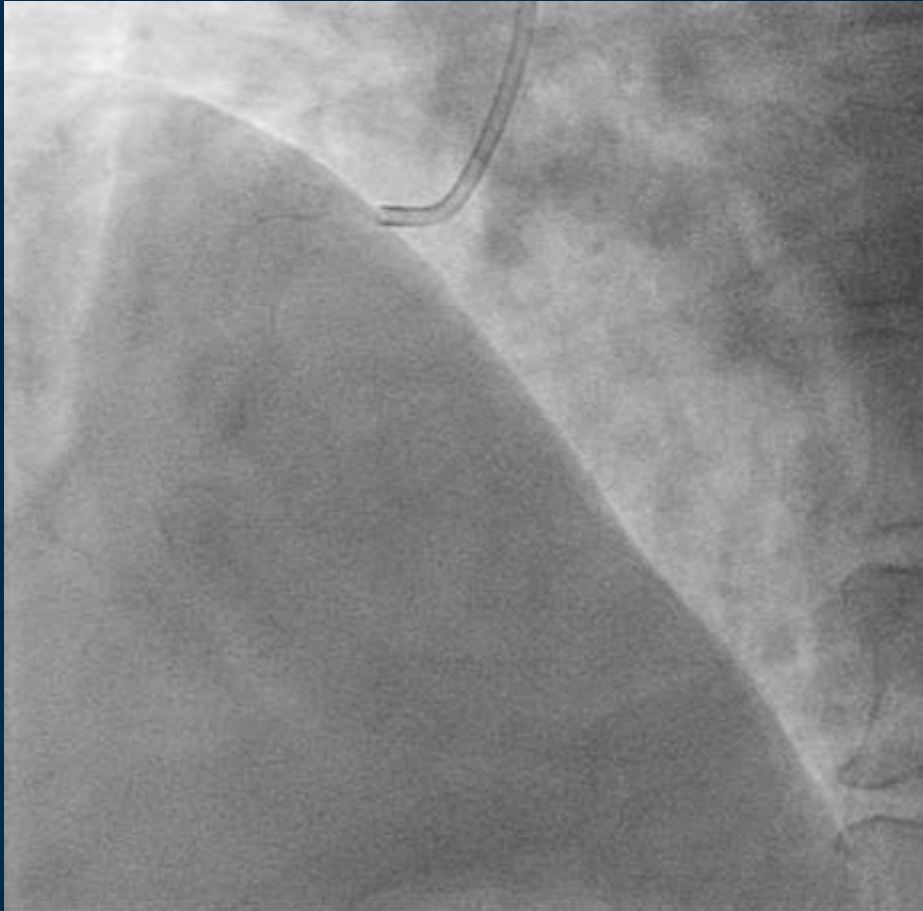


2nd Solitaire placement



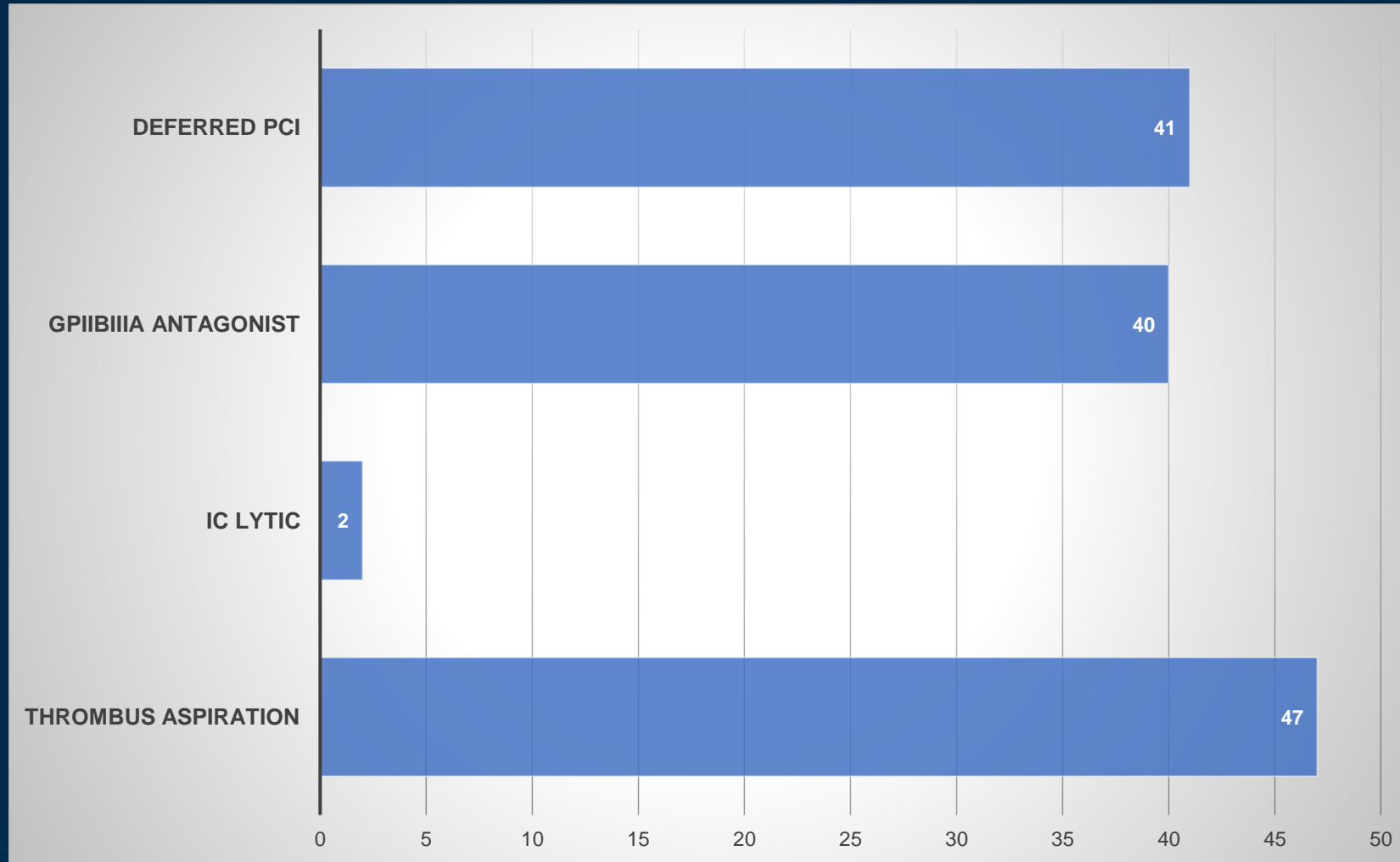
Post 2nd Solitaire

CASE 2 – Solitaire X

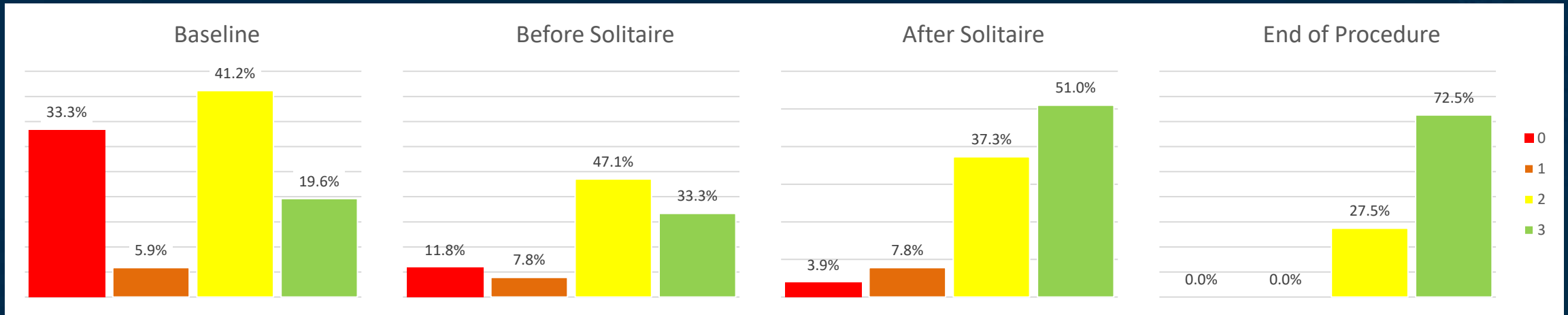


Final result after prox RCA stent

Thrombus Management prior to Solitaire

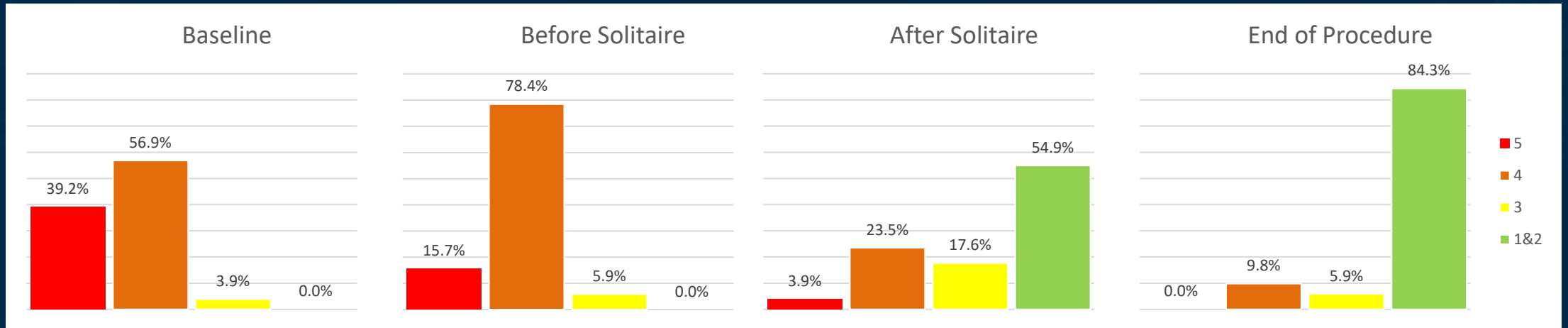


TIMI Flow (n=51)



TIMI Flow	Start of procedure	Before Solitaire	After Solitaire	End procedure
0	17	6	2	0
1	3	4	4	0
2	21	24	19	14
3	10	17	26	37

TIMI Thrombus Grade



Thrombus grade	Start of procedure	Before Solitaire	After Solitaire	End procedure
5	20	8	2	0
4	29	40	12	5
3	2	3	9	3
≤ 2	0	0	28	43

Safety

- No occurrence of stroke 24 hours post procedure, during index admission and at 30 days post discharge
- Intraprocedural complications
 - Distal embolization in 3 patients with improvement in flow after aspiration
 - Embolization to different branch in 1 patient
- 100% successful delivery and retrieval of Solitaire device
- 7 re-admissions to hospital within 30 days discharge
 - 1 MI requiring TVR
 - 3 CCF
 - 1 Atypical chest pain
 - 1 Lupus flare
 - 1 Food/drug allergy

Conclusion

- Routine thrombectomy is not recommendation for primary PCI in STEM
- However, it may be beneficial in selected patients, e.g. high thrombus load, or in bailout situation
- Aspiration thrombectomy is still commonly used as it is cheap, simple to use, facilitates stent selections and probably shorten the time of procedure
- Operators need to pay careful attention to the techniques of thrombectomy devices to prevent complications
- Application of stent retriever in the coronary artery in STEMI could be a game changer for recalcitrant thrombus as bailout or primary device