New Support Catheter: CrossLock™

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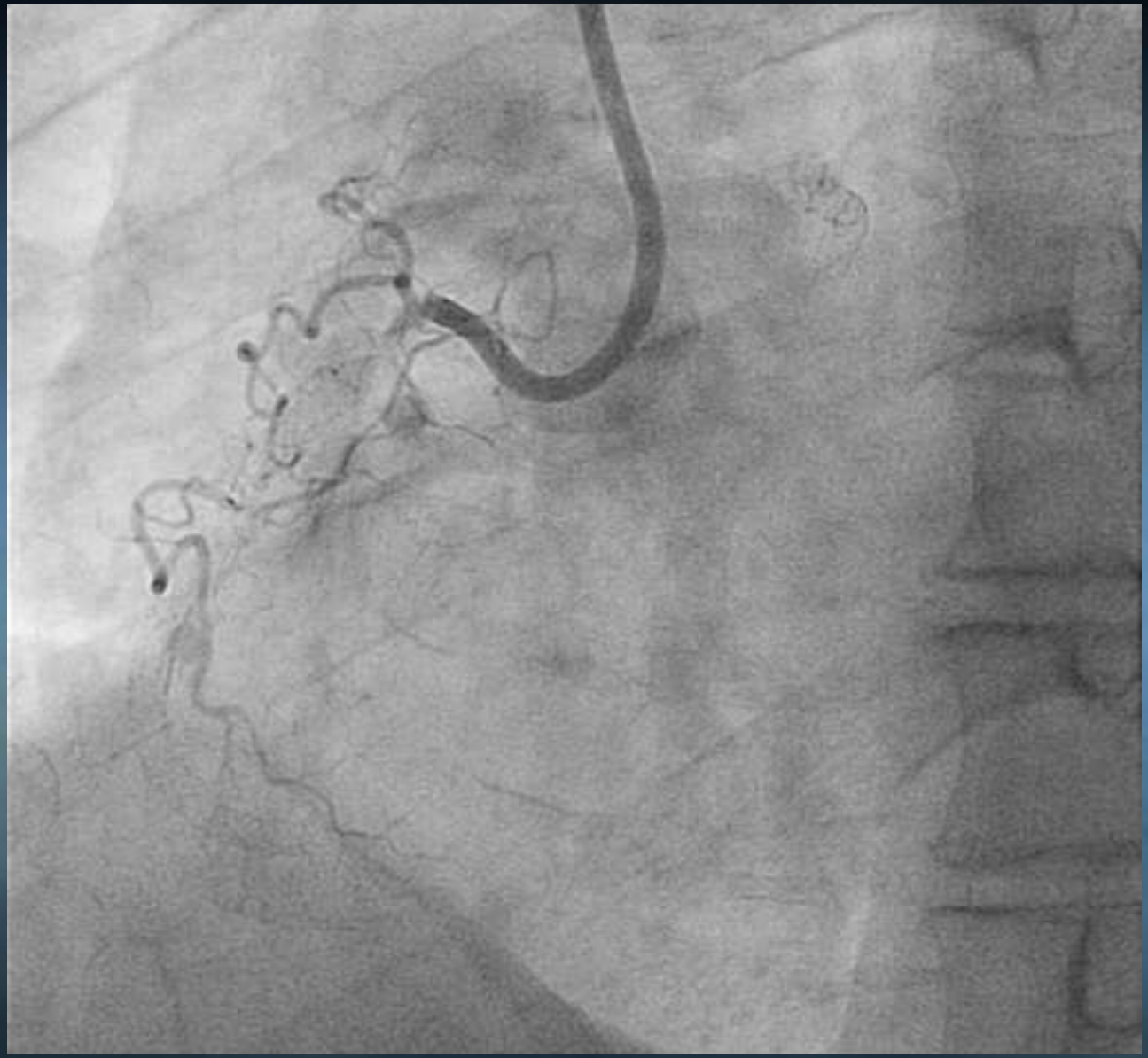
Presenter Disclosure Information

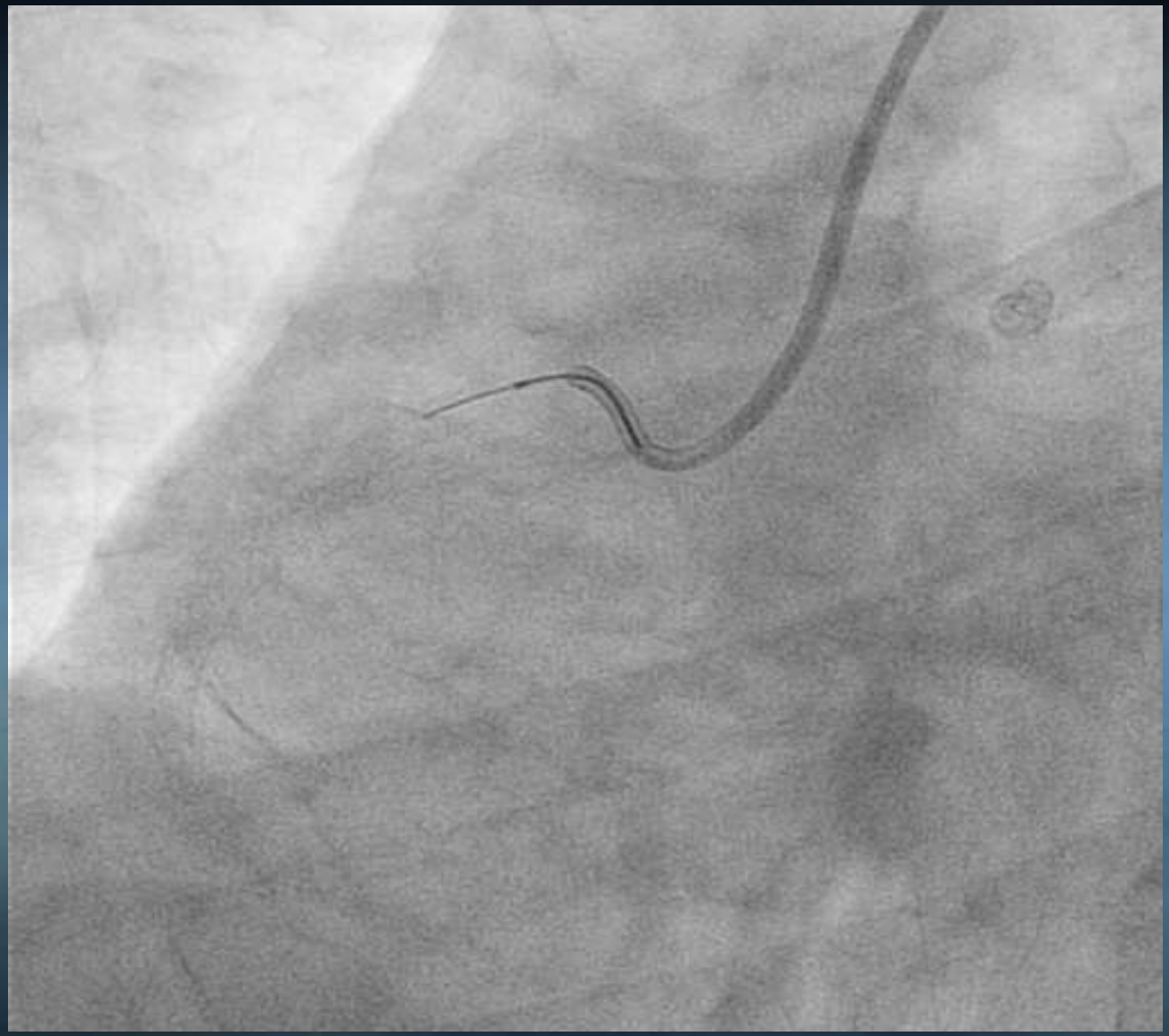
Name: ***RICHARD R. HEUSER M.D.***

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.

- ***QuantumCor, Major Stock Holder/Medical Director;***
- ***Radius Medical, Avinger and Claret Medical, Major Stock Holder;***
- ***PQ ByPass, Founder and Major Stock Holder;***
- ***CSI, Stockholder;***
- ***Spectranetics, Abbott, Medtronic, Bard, Abiomed, Honorarium;***
- ***Medtronic, Abbott, AngioScore, Speaker;***
- ***Acist Medical Systems Grant; and***
- ***Verve Medical, Inc., Major Stockholder***

Patents *-- RF, Snares, Wires, Balloon Catheters, Covered Stents, Devices for Arterial Venous Connection, Devices for LV and RV Closure*





Are there techniques that can be helpful using the Antegrade Approach?"

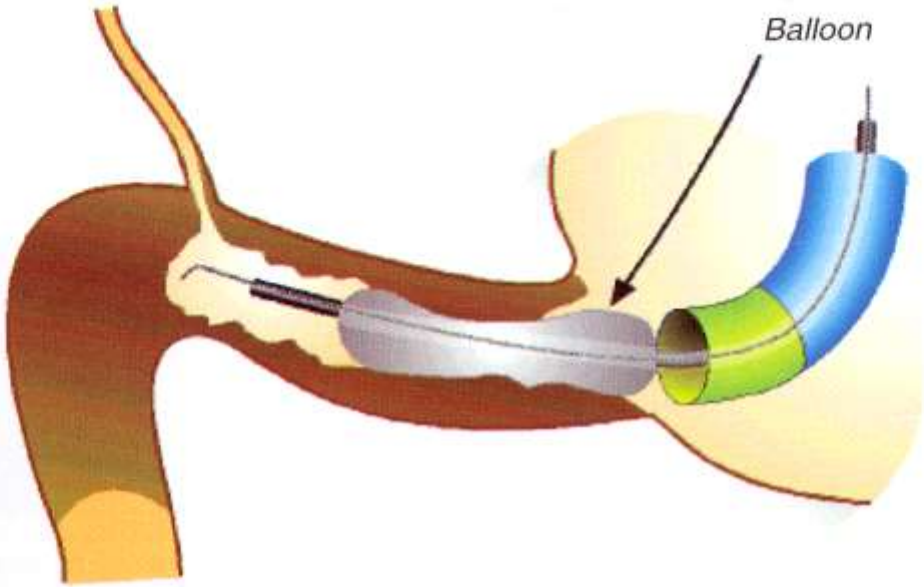


Figure 3.5 Another kind of anchoring balloon technique. This is a scheme of another type of anchoring technique by using an over-the-wire (OTW) balloon. When the proximal fibrous cap cannot be penetrated even by using a stiff wire, an OTW balloon may be dilated proximal to the occlusion as a support catheter. The inflated balloon makes an extra back-up force for the wire tip to break down the proximal cap.

G. Dangas, et al., Handbook of Chronic Total Occlusions, 2007 Informa UK Ltd

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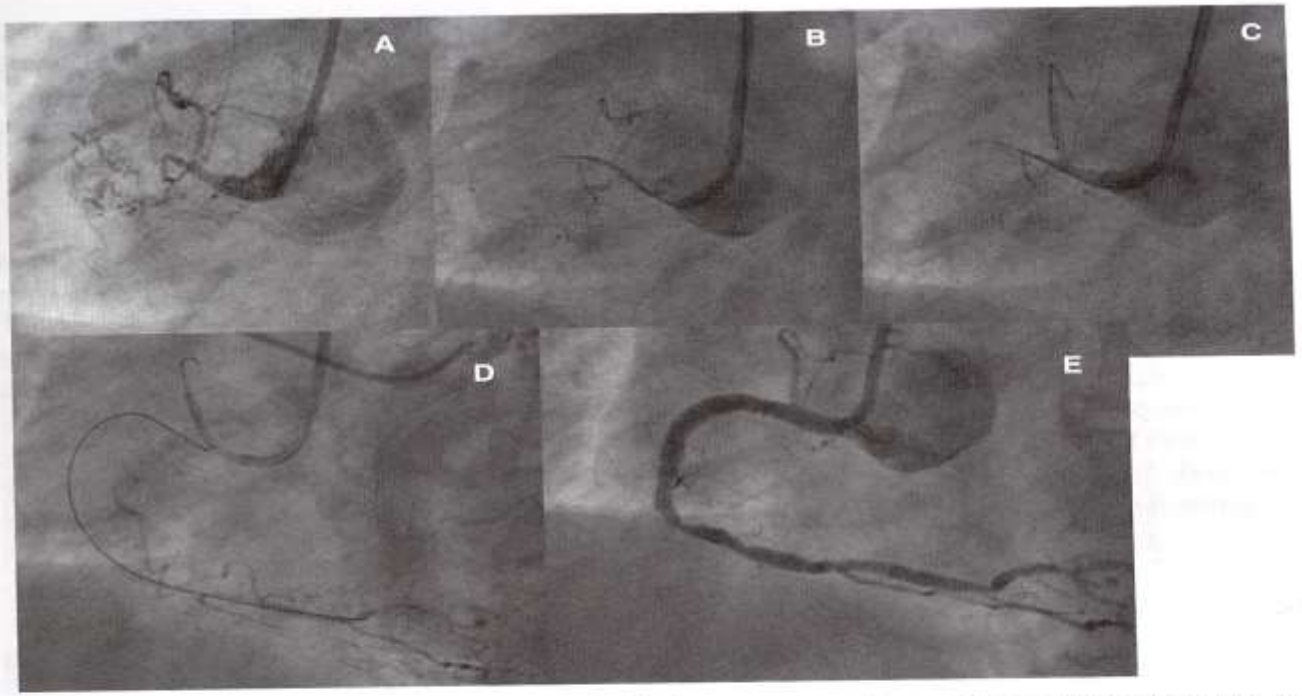
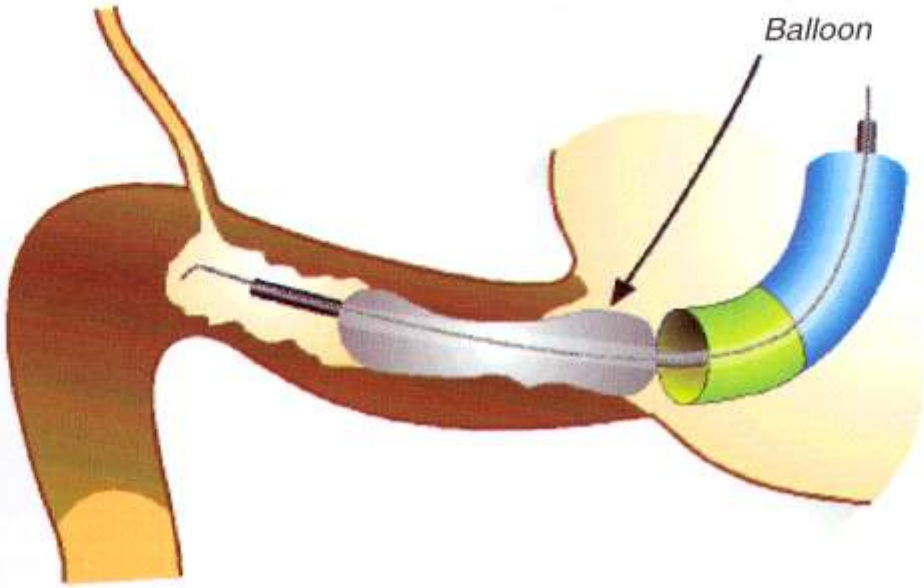


Figure 3.4 Case example of an RCA CTO (right coronary artery chronic total occlusion). A middle-aged male patient with stable angina. The proximal RCA was completely blocked with bridging collaterals (A). To prevent damage to the RCA ostium by the guiding catheter, a Judkins-type catheter was used. However, because of the tight plaque in the CTO, the guiding catheter was unstable during the wire handling so that the wire could not be advanced intentionally (B). Then, a 2.5 mm balloon was inserted and inflated with a low pressure in the conus branch to stabilize the guiding catheter (C). Under the use of this anchoring balloon, the wire control was improved, so that the occlusion was successfully negotiated (D). Final angiographic result after stenting (E).

G. Dangas, et al., Handbook of Chronic Total Occlusions, 2007 Informa UK Ltd



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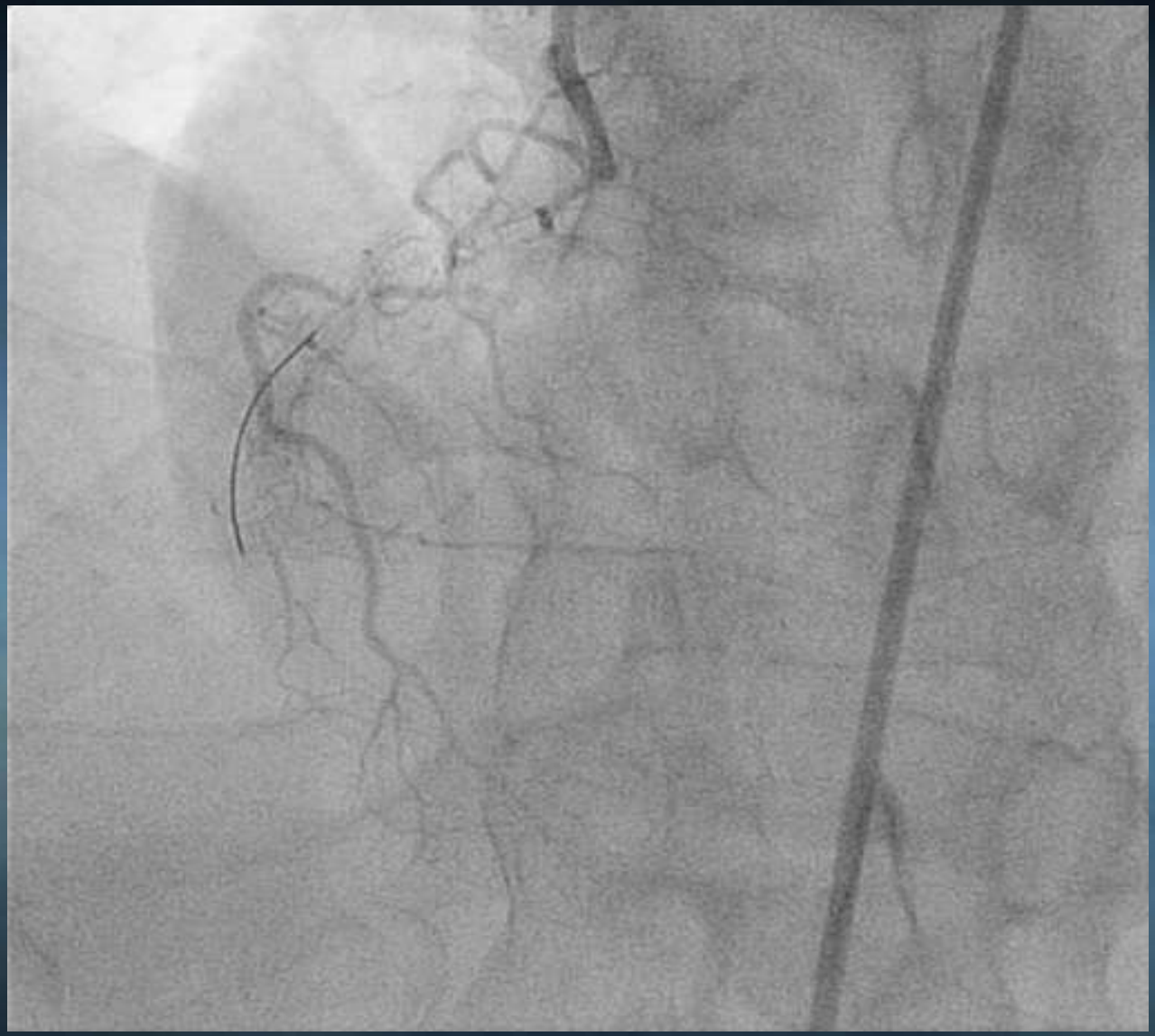
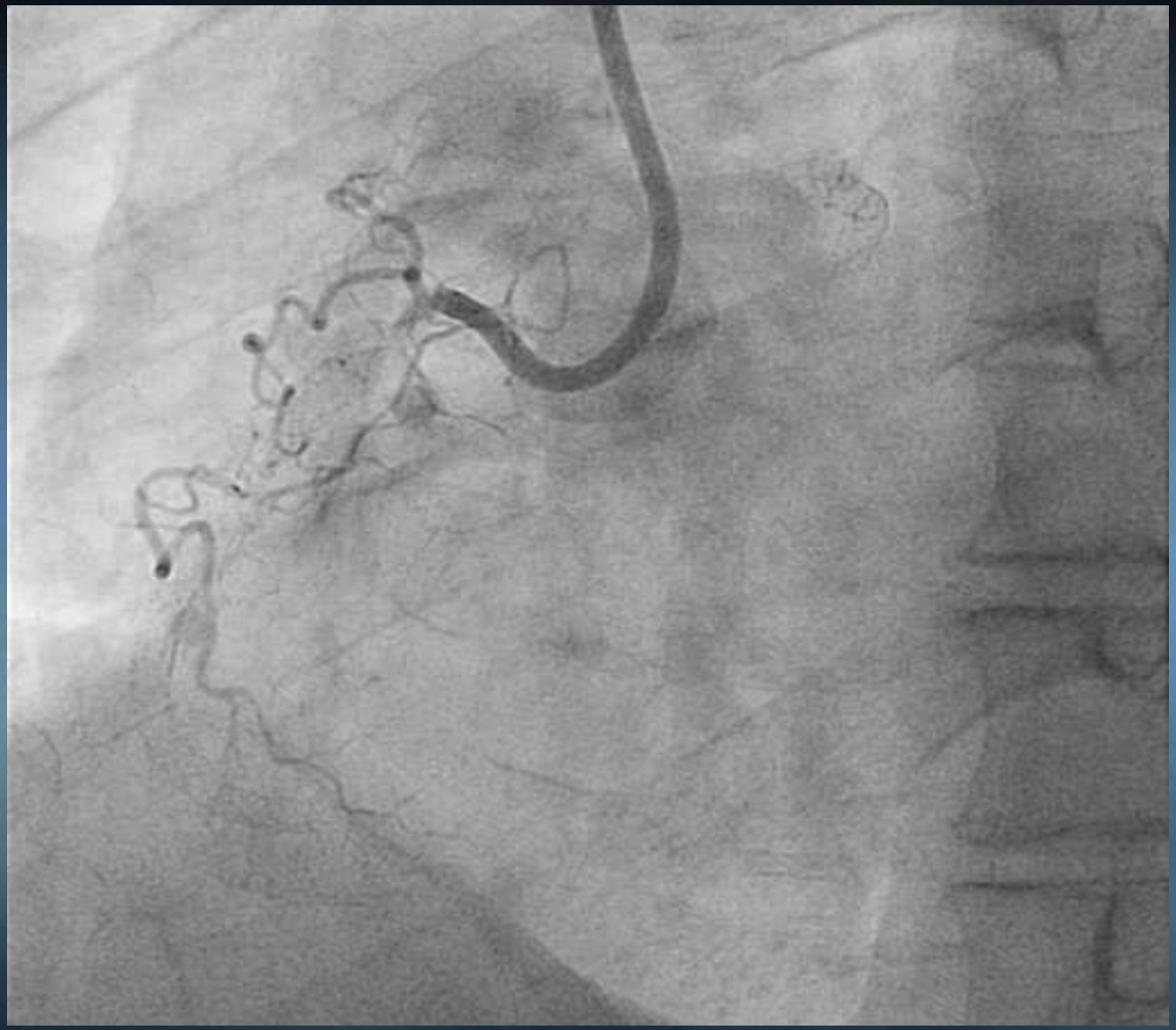
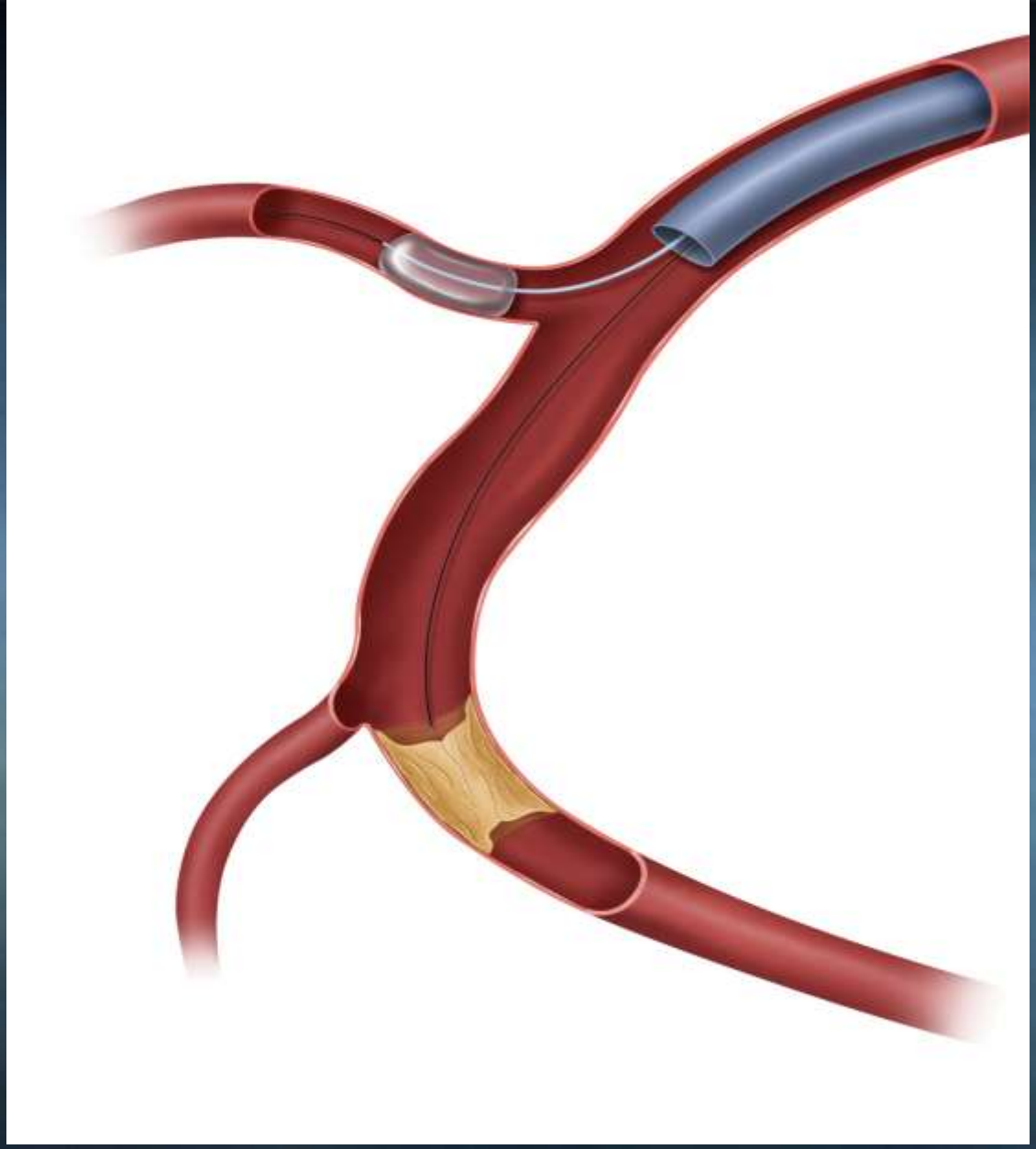
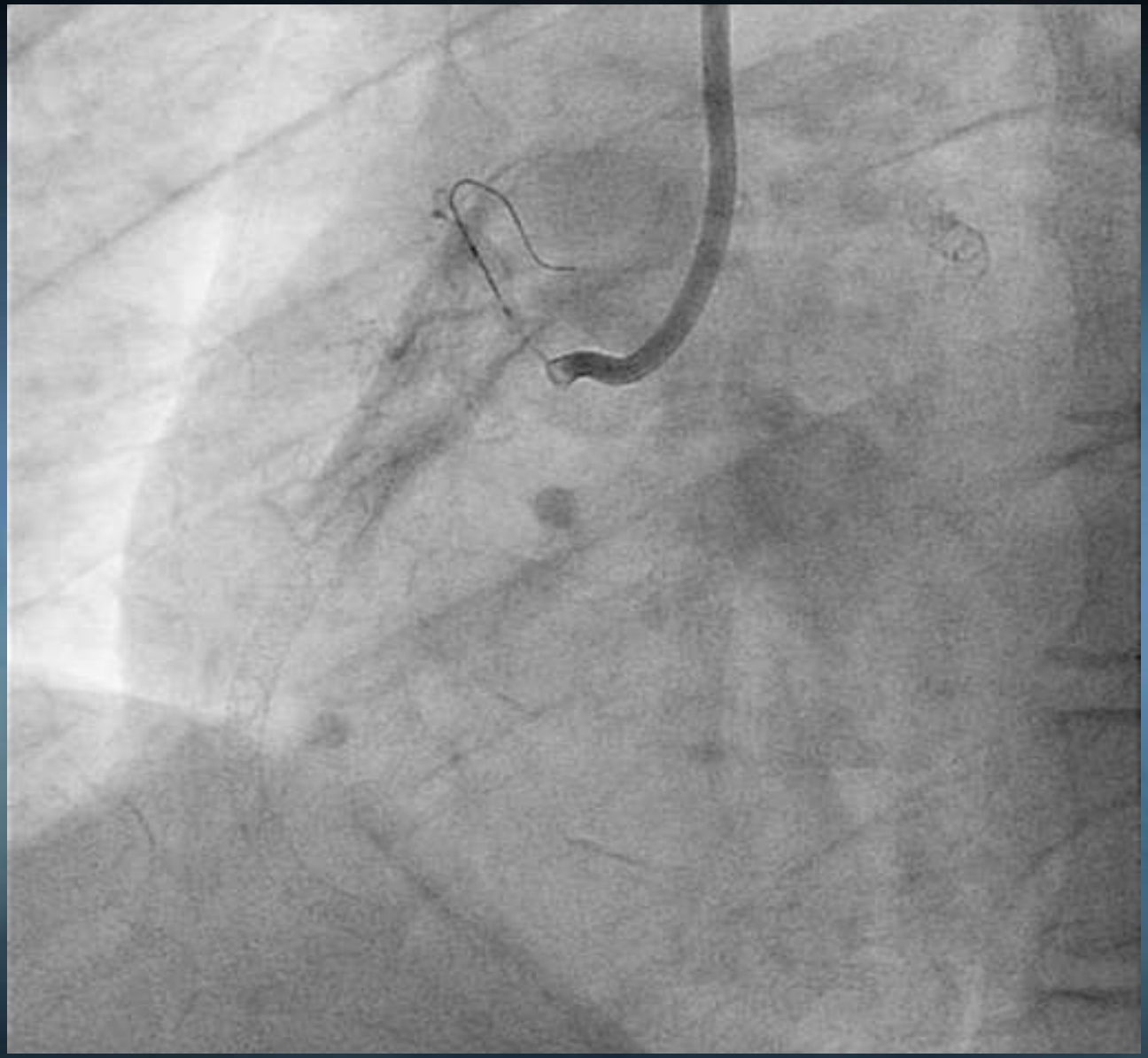
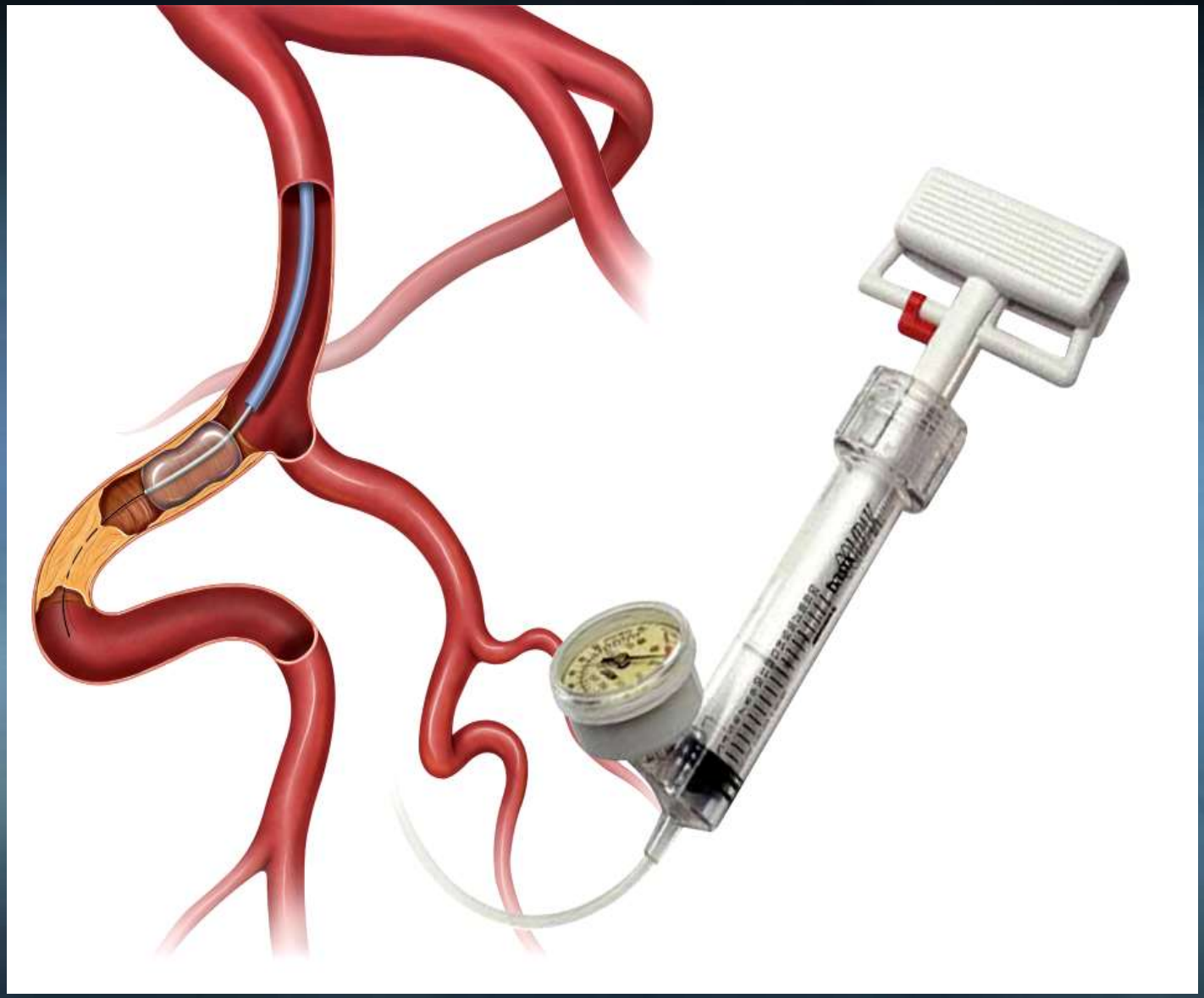
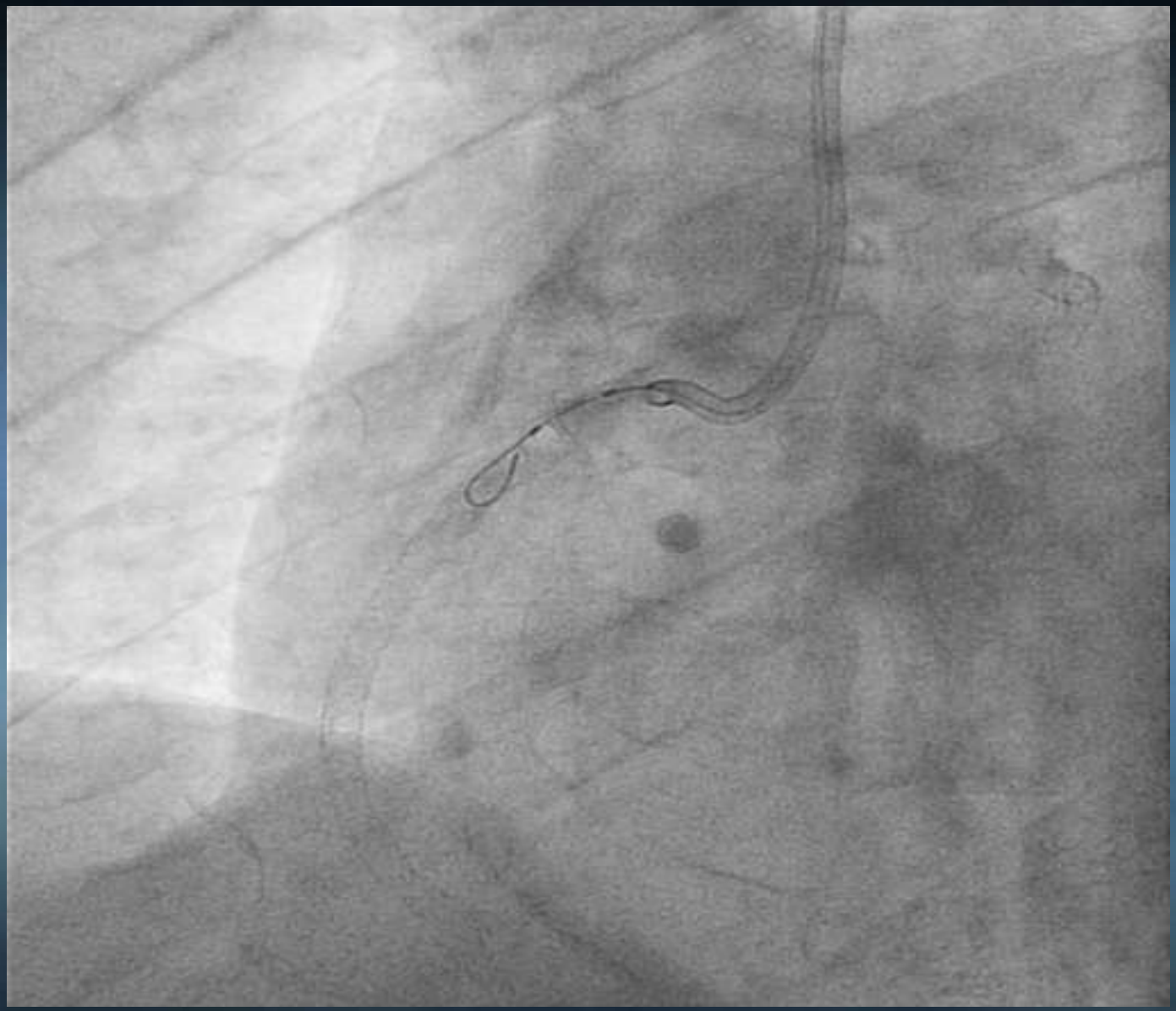


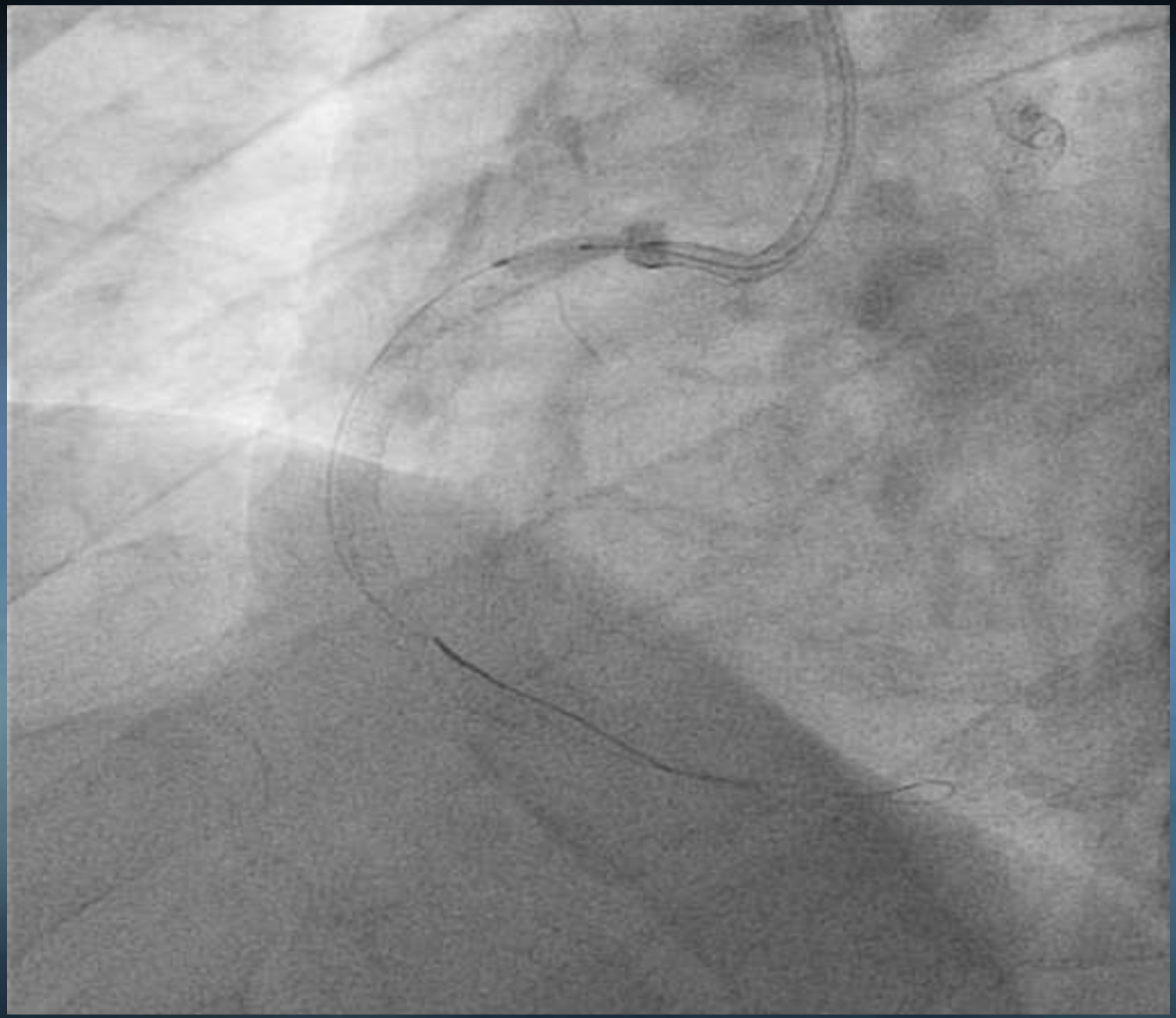


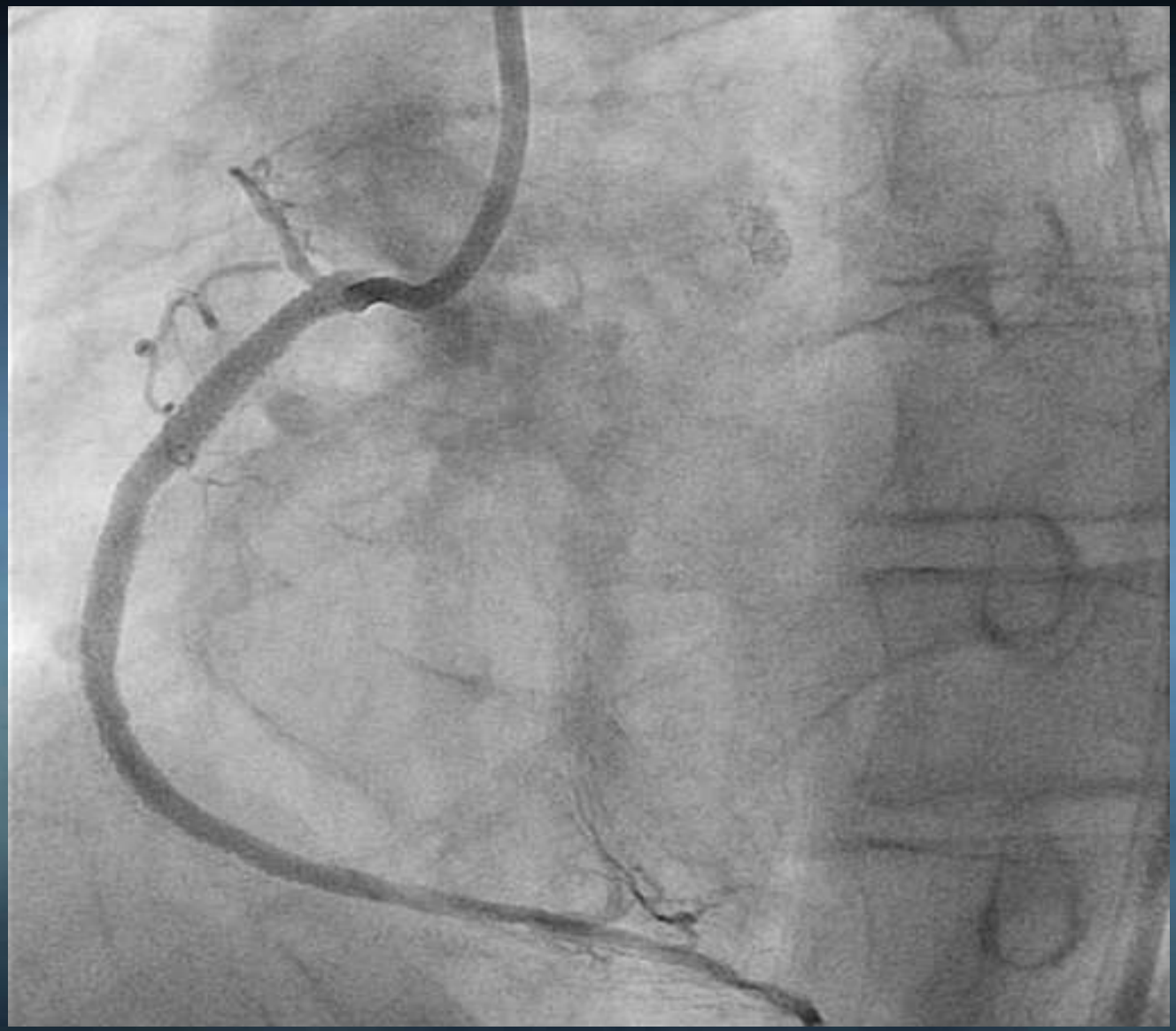


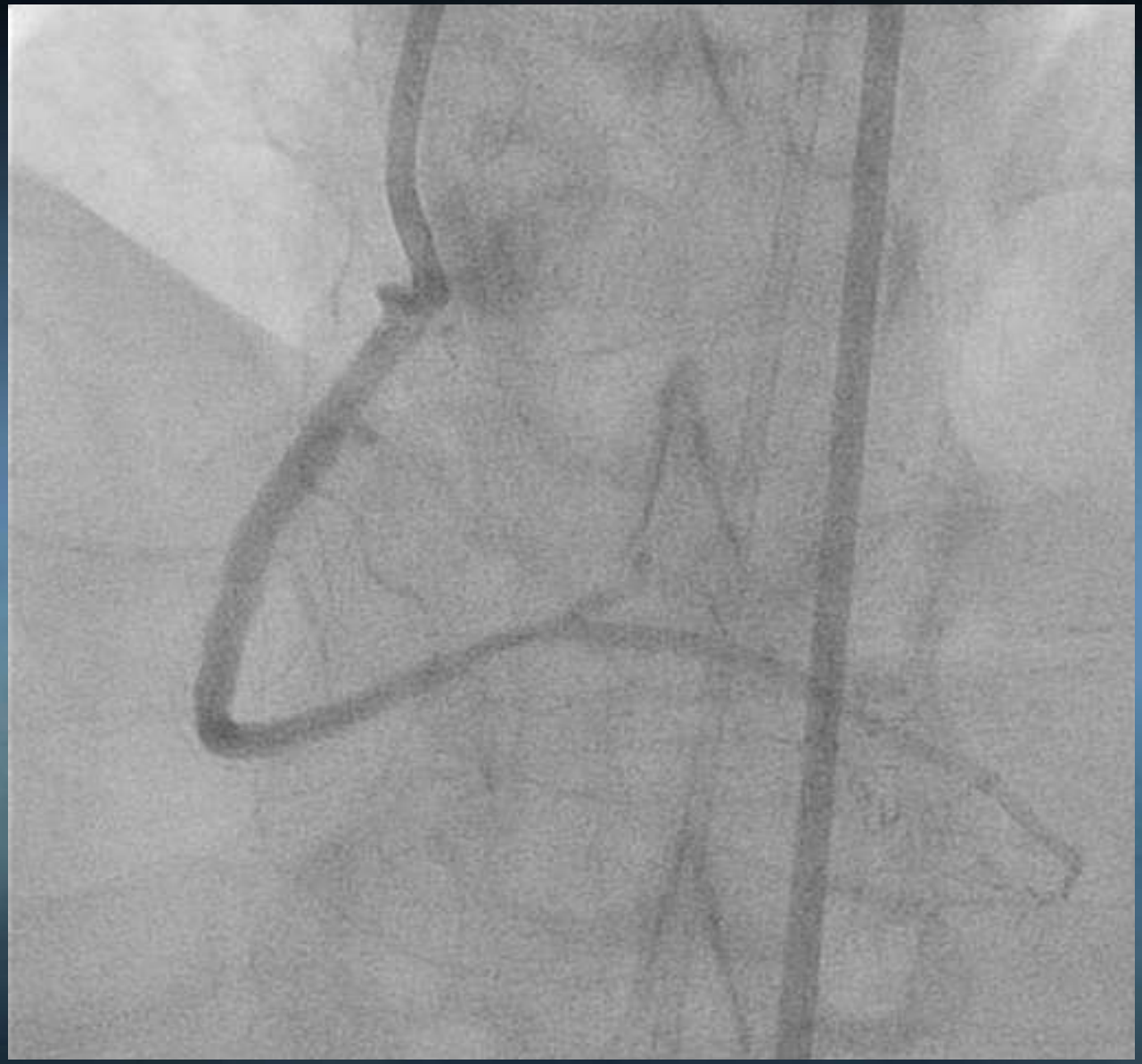






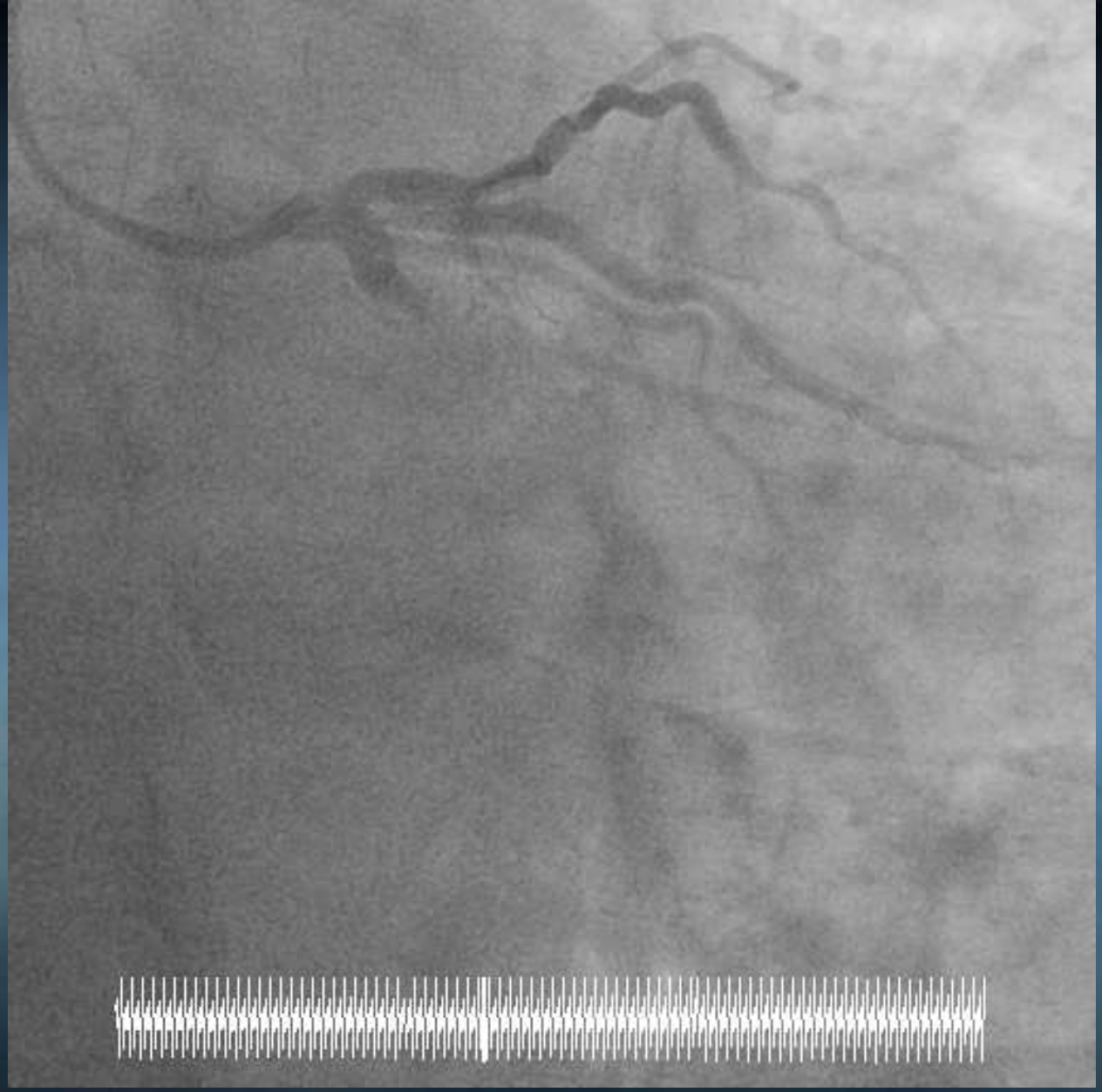


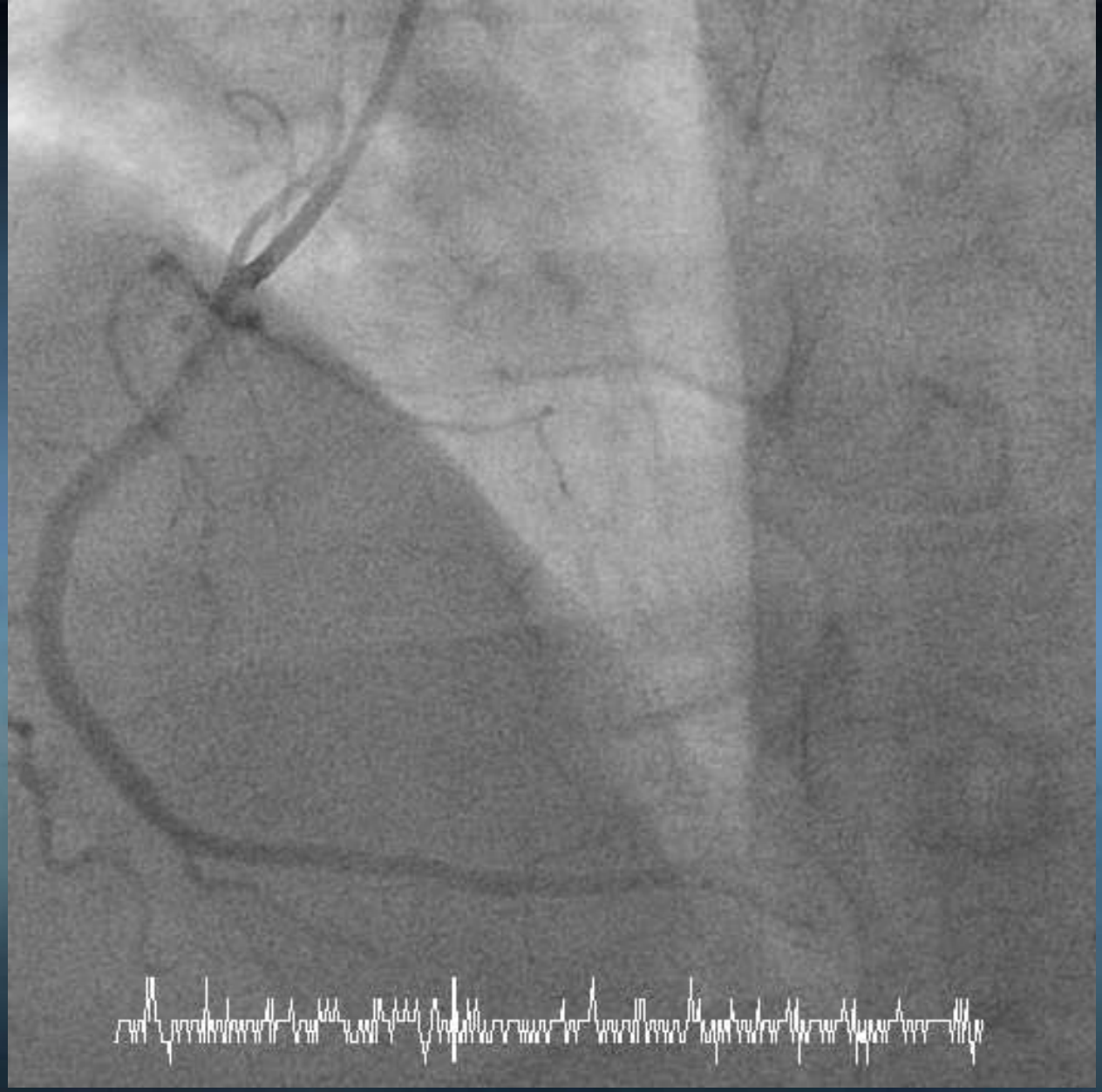


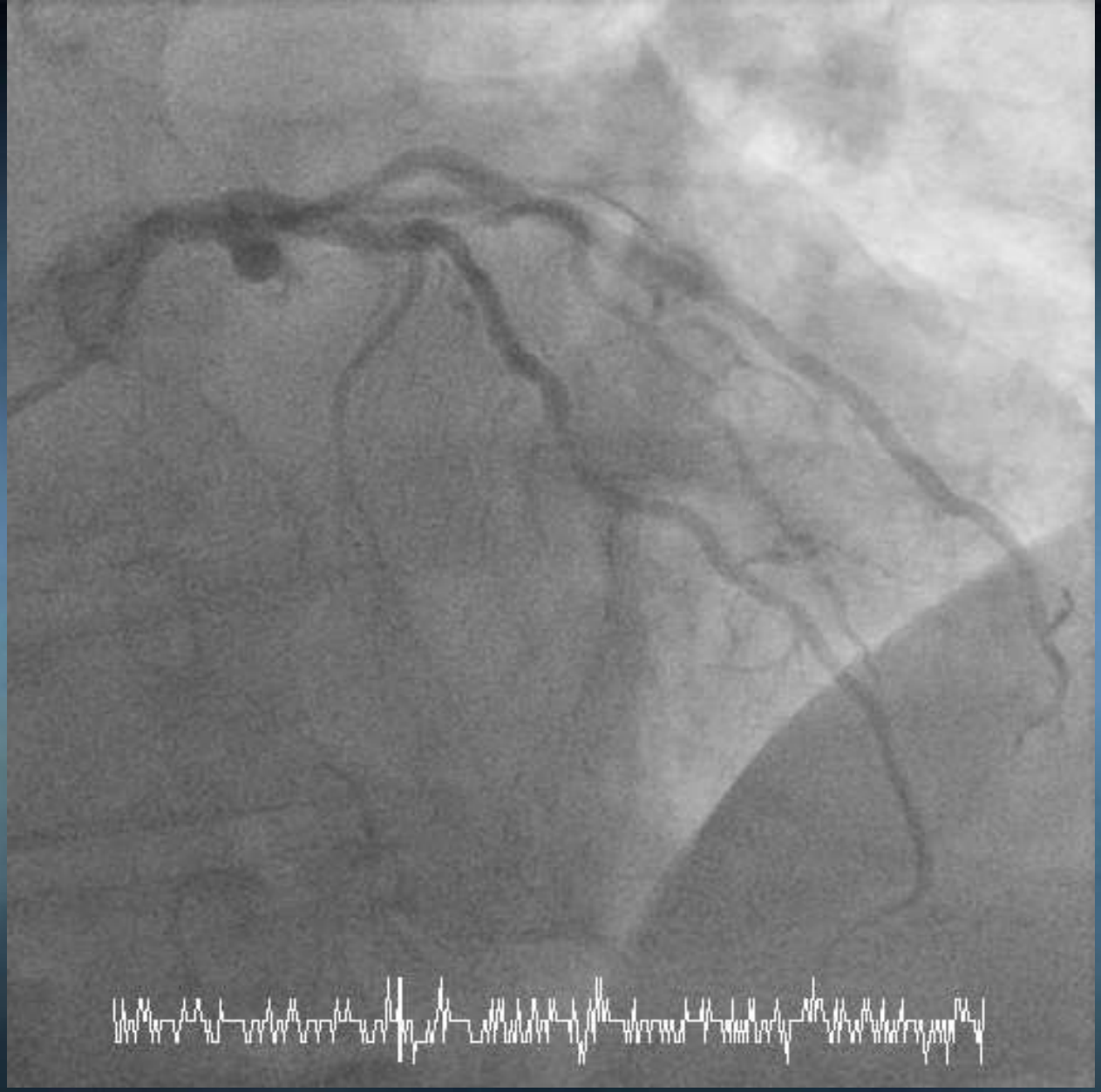


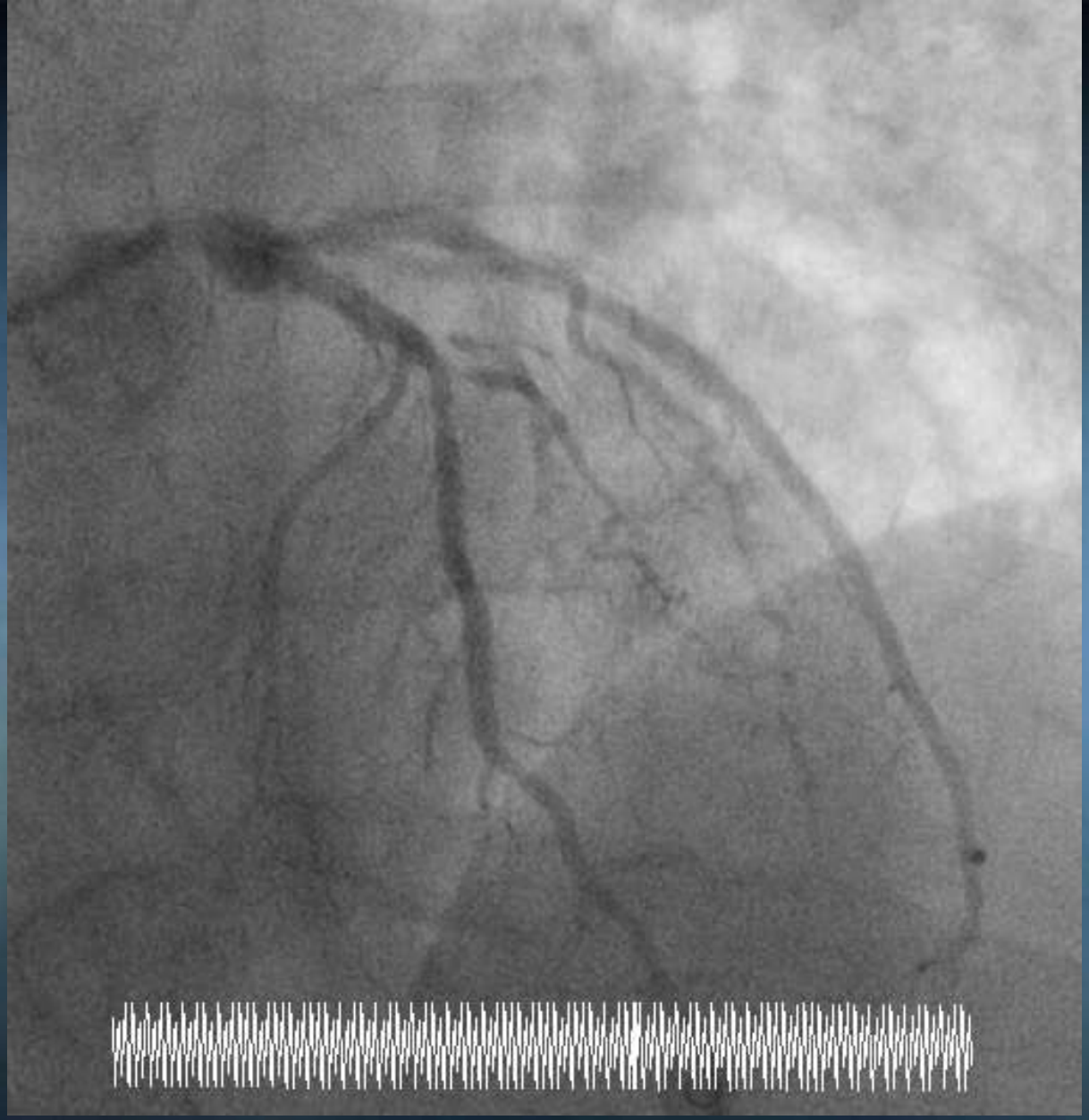
65 year old presents with a non ST elevation MI immediately post gastric bypass surgery

Patient is over 200 pounds over his ideal weight

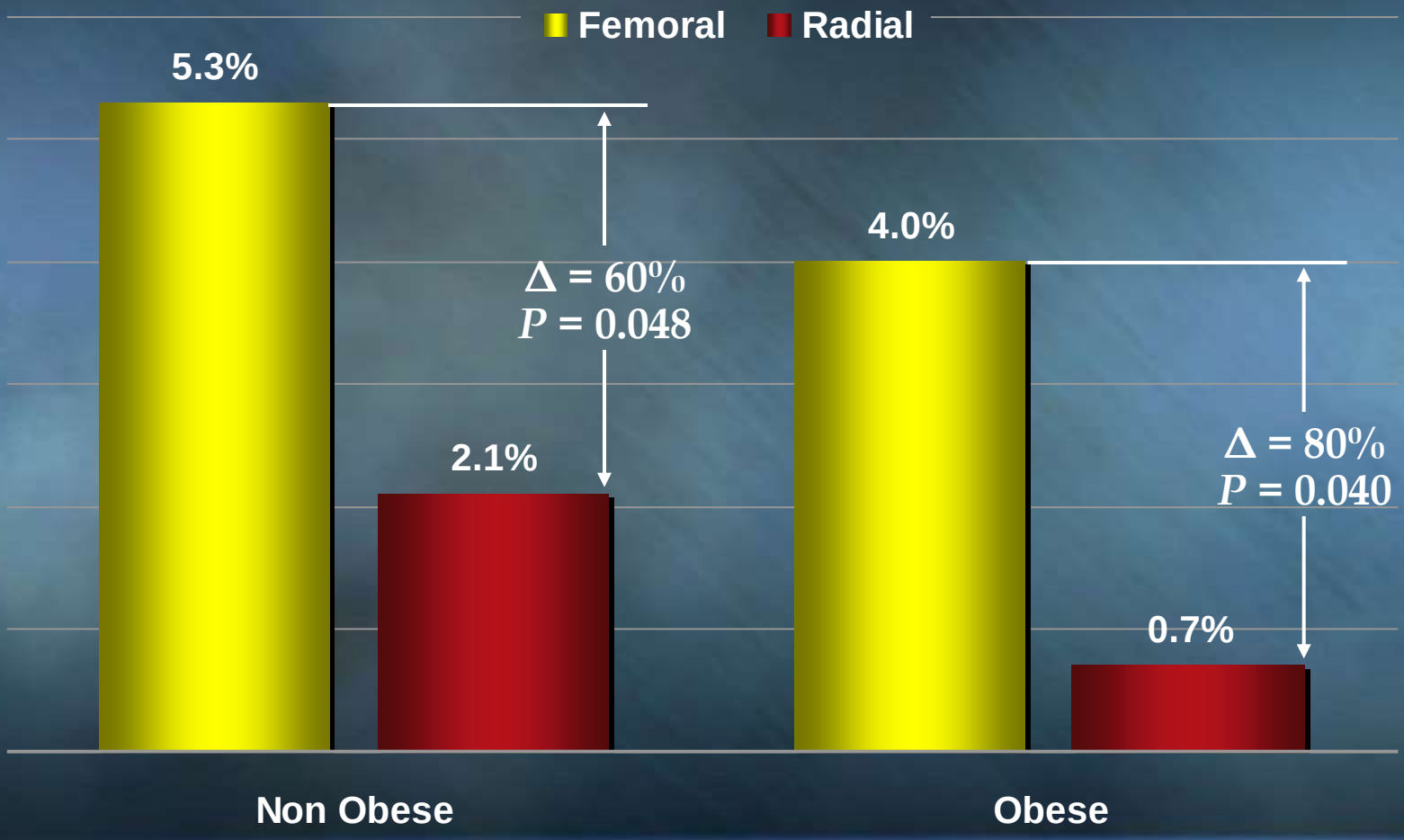








Obese Patients Have a Greater Relative Reduction in Vascular Complications



Cox N et al. *AJC* 2004; 94:1174.

R. Heuser

Bleeding Complications

Bleeding complications after PCI have been associated with higher rates of serious clinical events, including death.

Right groin hematoma at femoral puncture site.

Rao, Using Procedural Approaches to Reduce PCI Complications, Journal of Invasive Cardiology, Aug 2009 Vol 21/Suppl A pg. 2A

Impact of Chronic Total Occlusions on Markers of Reperfusion, Infarct Size, and Long-Term Mortality: A Substudy from the TAPAS-Trial

Chris P.H. Lexis,[1*] MD, Iwan C.C. van der Horst,[1] MD, PhD, Braim M. Rahel,[2] MD, PhD, Monique A.S. Lexis,[3] MSc, Marthe A. Kampinga,[1] MD, Youlan L. Gu,[1] MD, Bart J.G.L. de Smet,[1] MD, PhD, and Felix Zijlstra,[1] MD, PhD

Objectives: This study evaluated the impact of a chronic total occlusion (CTO) in a non-infarct related coronary artery (IRA) on markers of reperfusion, infarct size, and long-term cardiac mortality in patients with ST-elevation myocardial infarction (STEMI). Background: A concurrent CTO in STEMI patients has been associated with impaired left ventricular function and outcome. However, the impact on markers of reperfusion is unknown. Methods: All 1,071 STEMI patients included in the TAPAS-trial between January 2005 and December 2006 were used for this substudy. Endpoints were the association between a CTO in a non-IRA and myocardial blush grade (MBG) of the IRA, ST-segment elevation resolution (STR), enzymatic infarct size, and clinical outcome. Results: A total of 90 patients (8.4%) had a CTO. MBG 0 or 1 occurred more often in the CTO group (34.2% versus 20.6% (Odds Ratio [OR] 2.00, 95% confidence interval [CI]: 1.22–3.23, $P = 0.006$)). Incomplete STR occurred more often in the CTO group, (63.6% versus 48.2% [OR 1.96, 95% CI: 1.22–3.13, $P = 0.005$]). Median level of maximal myocardial-band of creatinin kinase (CK-MB) in the CTO group was 75 μg/l (IQR 28-136) and 51 μg/l (IQR 18–97) in the no-CTO group ($P = 0.021$). The presence of a CTO in a non-IRA in STEMI patients was an independent risk factor for cardiac mortality (HR 2.41, 95% CI: 1.26–4.61, $P = 0.008$) at 25 months follow-up. Conclusion: A CTO in a non-IRA is associated with impaired reperfusion markers and impaired long-term outcome in STEMI patients.

Conclusion: A CTO in a non-IRA is associated with impaired reperfusion markers and impaired long-term outcome in STEMI patients.

Catheter Cardiovasc Interv 77:484-491 (2011).

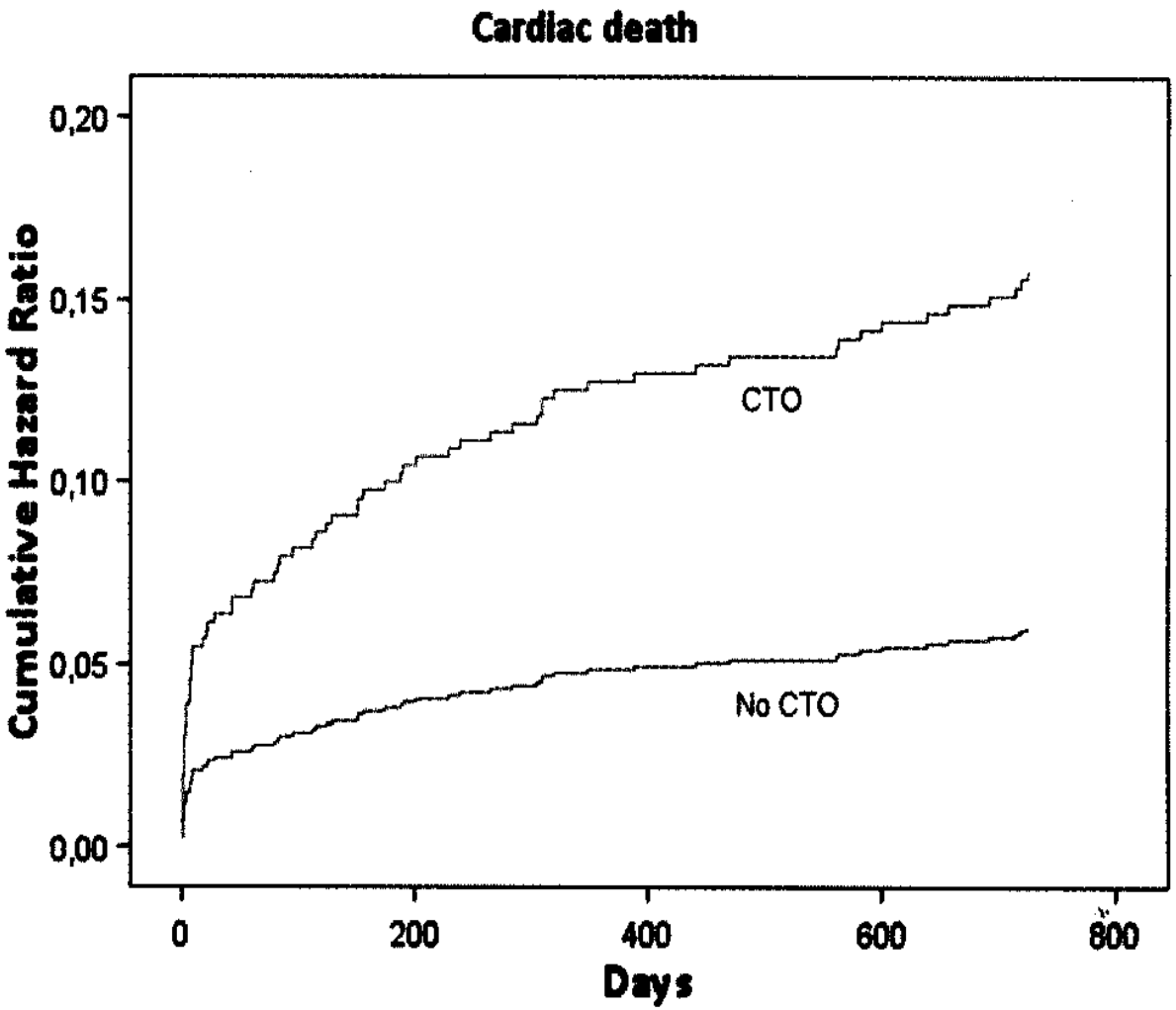
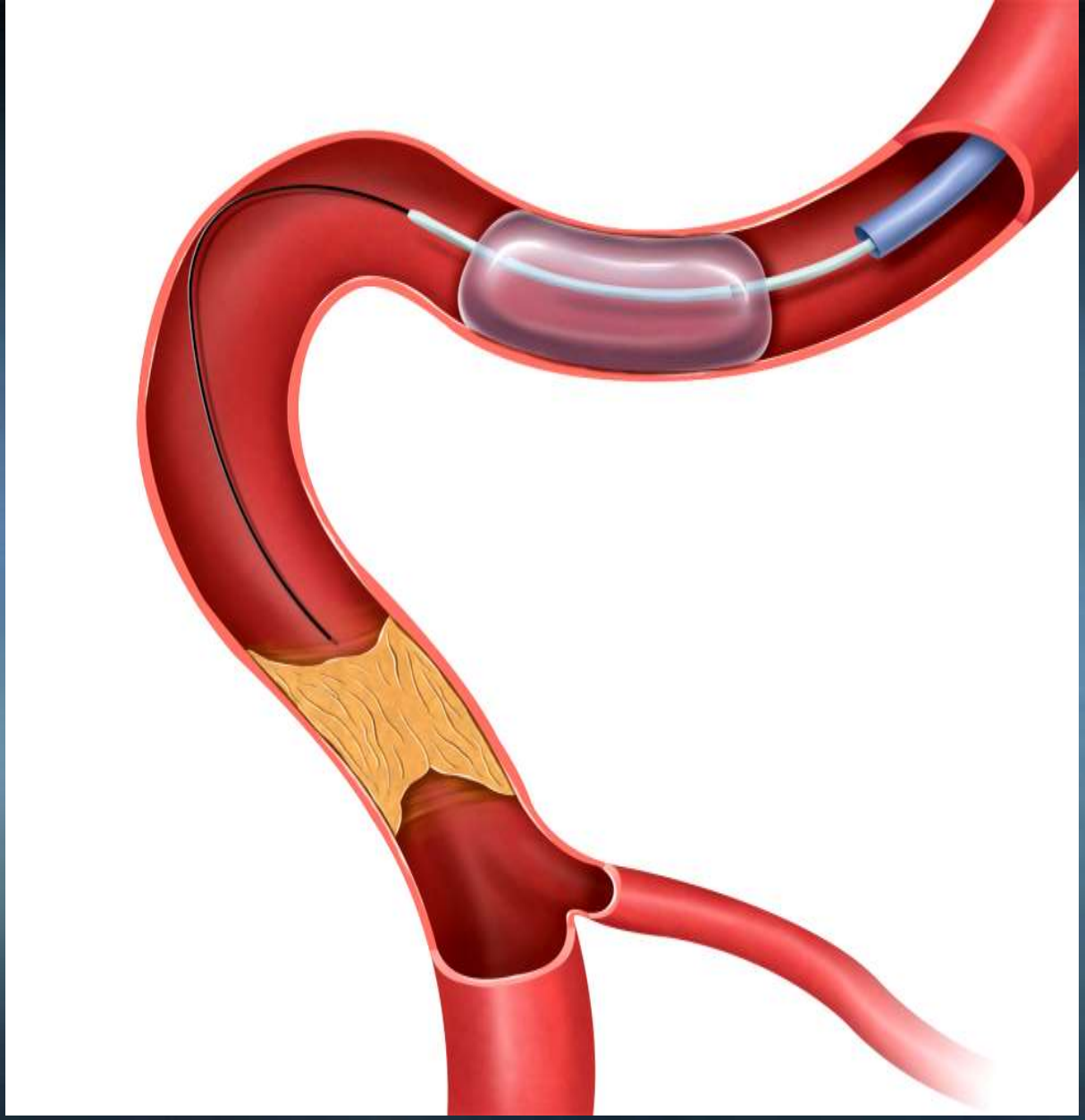


Fig. 2. Cumulative Hazard Rate for cardiac mortality in the patients with a CTO (blue line) and the patients without a CTO (red line).

Catheter Cardiovasc Interv 77:484-491 (2011).




POST

Single Center Experience in Radial Access for Treating Chronic Total Occlusions

Richard A. Heuser MD, FACC, FACP, FESC, FSCAI; John D. Lassetter, MD, FACC, FSCAI
Phoenix Heart Center, St. Luke's Medical Center, Phoenix AZ

93.3% of Radial Cases Successful

93% of Groin Cases Successful

BACKGROUND

The treatment of chronic total occlusion (CTO) is thought to be the final frontier in treating coronary artery disease percutaneously. Most chronic total occlusion patients are treated with the femoral route. Patients undergoing PCI via groin access experience a four fold increase in MACE compared to PCI via the radial approach.

METHODS

We became a radial first laboratory in April 2012. Since becoming a radial first laboratory we performed 17 radial CTO procedures amongst 60 consecutive chronic total occlusion procedures performed.

RESULTS

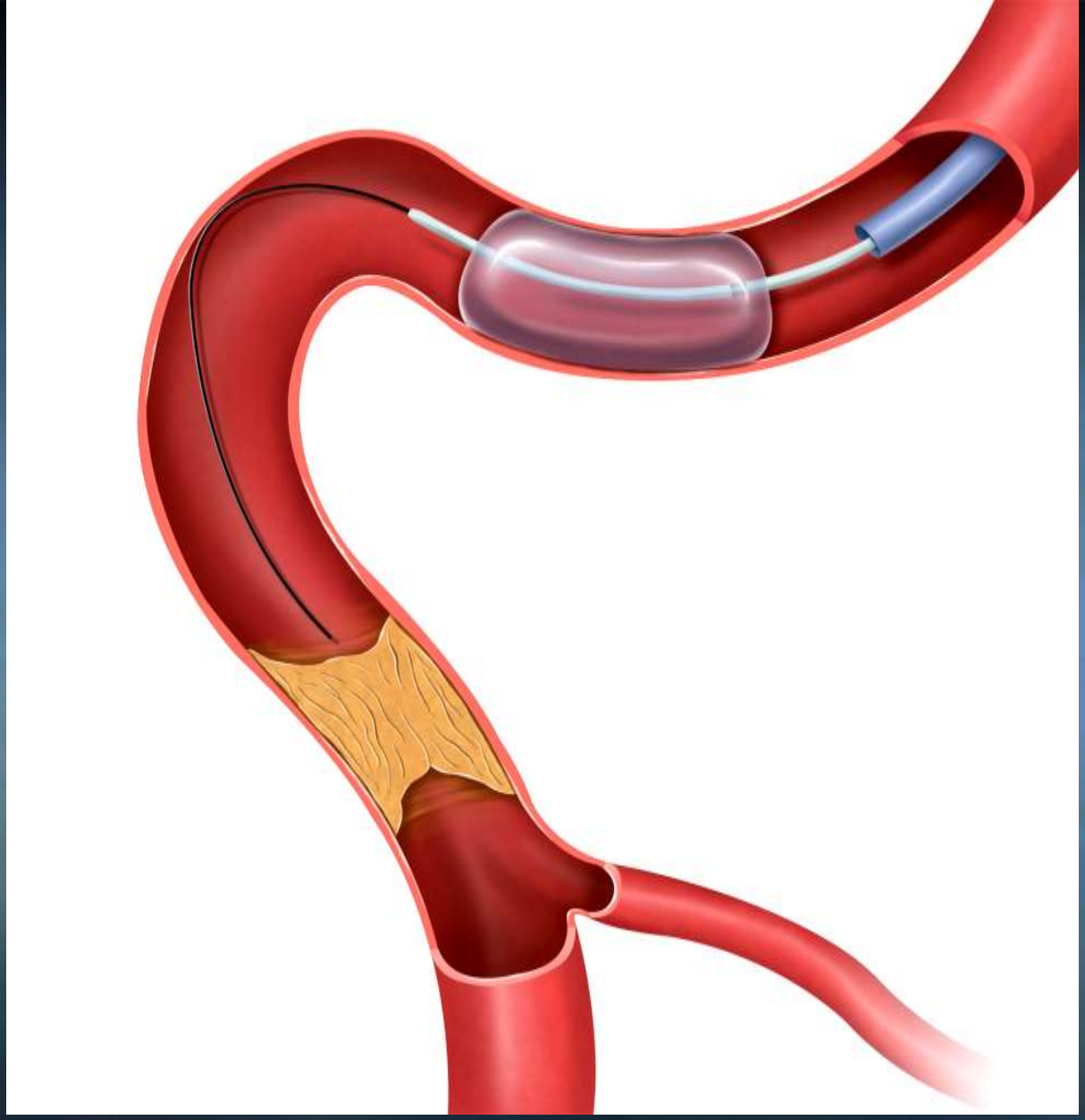
We treated patients at a mean age of 62.5 (48-77 range). Fourteen radial cases were male. One was female. Fourteen were RCA's. Two were circumflex CTO's, and one was in the LAD.

The primary reasons the patients were treated radially was difficult groin access in terms of visualizing the total occlusion in 3 patients. In 2 patients, radial access appeared feasible but in one patient the diagnostic and interventional procedure was performed at the same time. In almost all groin access cases, we used bilateral groin approaches to visualize collaterals. In one radial case, we used bilateral radial access to visualize collaterals. We were successful 94.1% (16 of 17) of the time in the radial cases. In patients treated by groin access since April, we were successful in 41 of 45 cases (91.1%). No patients in either group had any vascular complications or MACE during hospitalization.

CONCLUSION

With our small single center experience, we have been highly successful with radial CTO procedures with no significant major adverse cardiovascular events. The radial approach may show promise in treating this difficult patient subset.

R. Heuser



A Technique to Improve Success with CTO's using the Antegrade Approach and an Improvement in Current Design: The Support Balloon

Richard R. Heuser[1] Shishir Murarka[2]
[S] St. Luke's Medical Center, Phoenix AZ [2]Banner Estrella Medical Center, Phoenix AZ

BACKGROUND

Success rate treating CTO's has been improved by dedicated systems, excellent guiding support and physician experience. Most physicians feel more comfortable using the antegrade approach to treat CTO's.

METHODS

The anchoring balloon technique has been used for several years to allow guiding catheter support to be reinforced with the use of an over the wire (OTW) conventional balloon. We have used this technique over the last 18 months successfully in 35 of 36 (97.5%) consecutive patients, all but four cases were in the right coronary artery (four were circumflex CTO's) (Fig 1). The patient age ranged from 48 to 70 (mean years). All the patients were male and the total occlusions ranged in age from 8 months to 5 years (mean 2 years). This technique has potential for complications. Trauma to the proximal vessels often results from the routine use of the stiff Amplatz guiding catheters, and it sometimes is difficult to place an OTW balloon with a relatively long length and tip (Fig. 2) without the guiding catheter being displaced from the coronary ostium. There is also the potential of barotrauma from the balloon with resultant dissection.

RESULTS

We developed a new system to potentially reduce the trauma (Fig. 3). Our system has a shorter tip, as well as a much shorter elastomeric balloon length measuring 5mm in length and less than 2mm in tip length.

In a silastic tube model, it has been shown to be more effective as a support system for crossing a putty type total occlusion compared to a conventional balloon (Sprinter, Medtronic) (Fig. 4). The balloon size can be dilated to 6mm and able to be used in multiple diameter size silastic vessels.

(Fig 1.Top left) Standard Support Balloon System. (Fig 2.Top Right) Standard Over-the-Wire Balloon. (Fig 3.Bottom Left) New Support Balloon System. (Fig 4.Bottom Right) Sprinter Balloon Catheter.

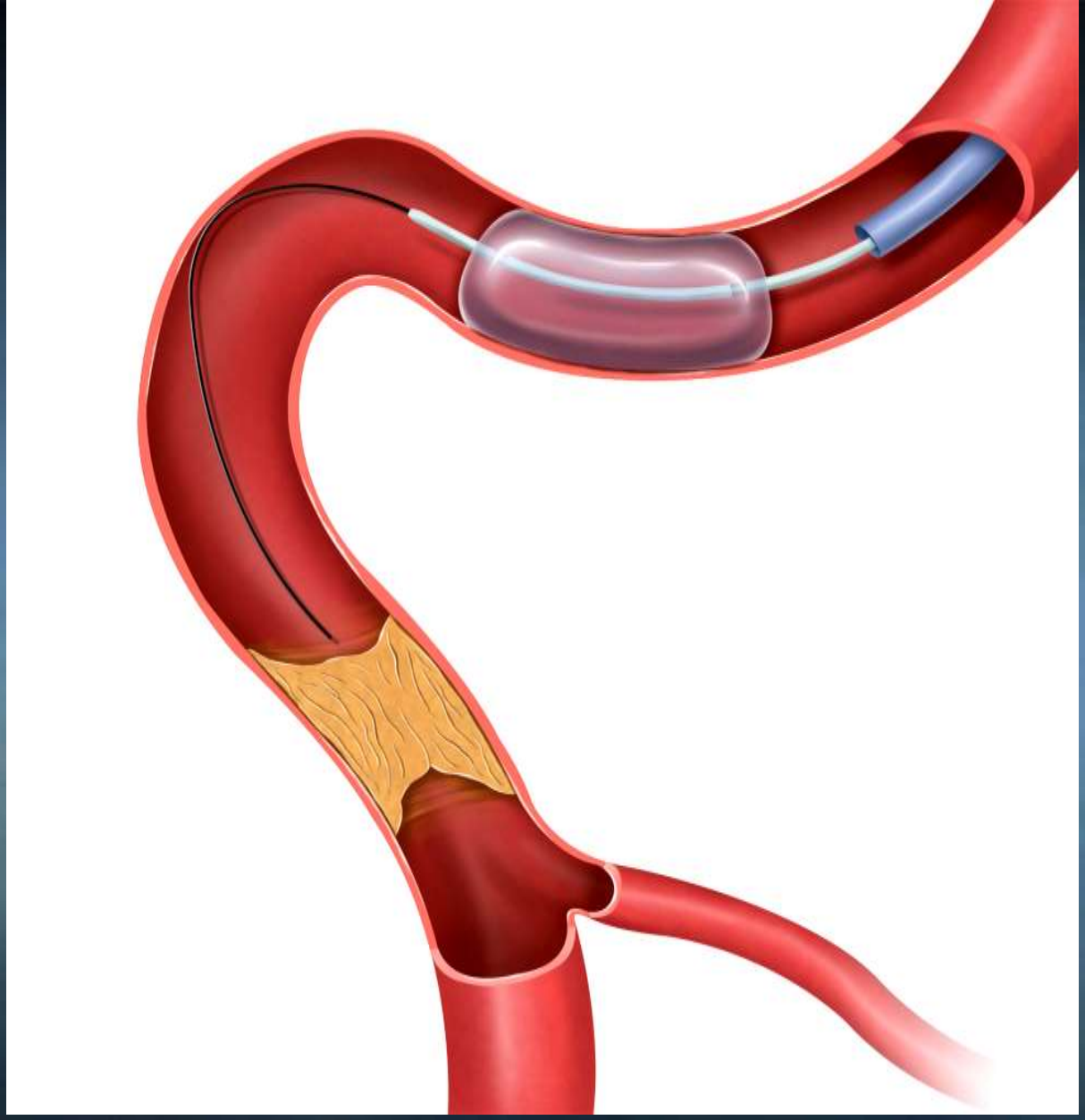
CONCLUSION

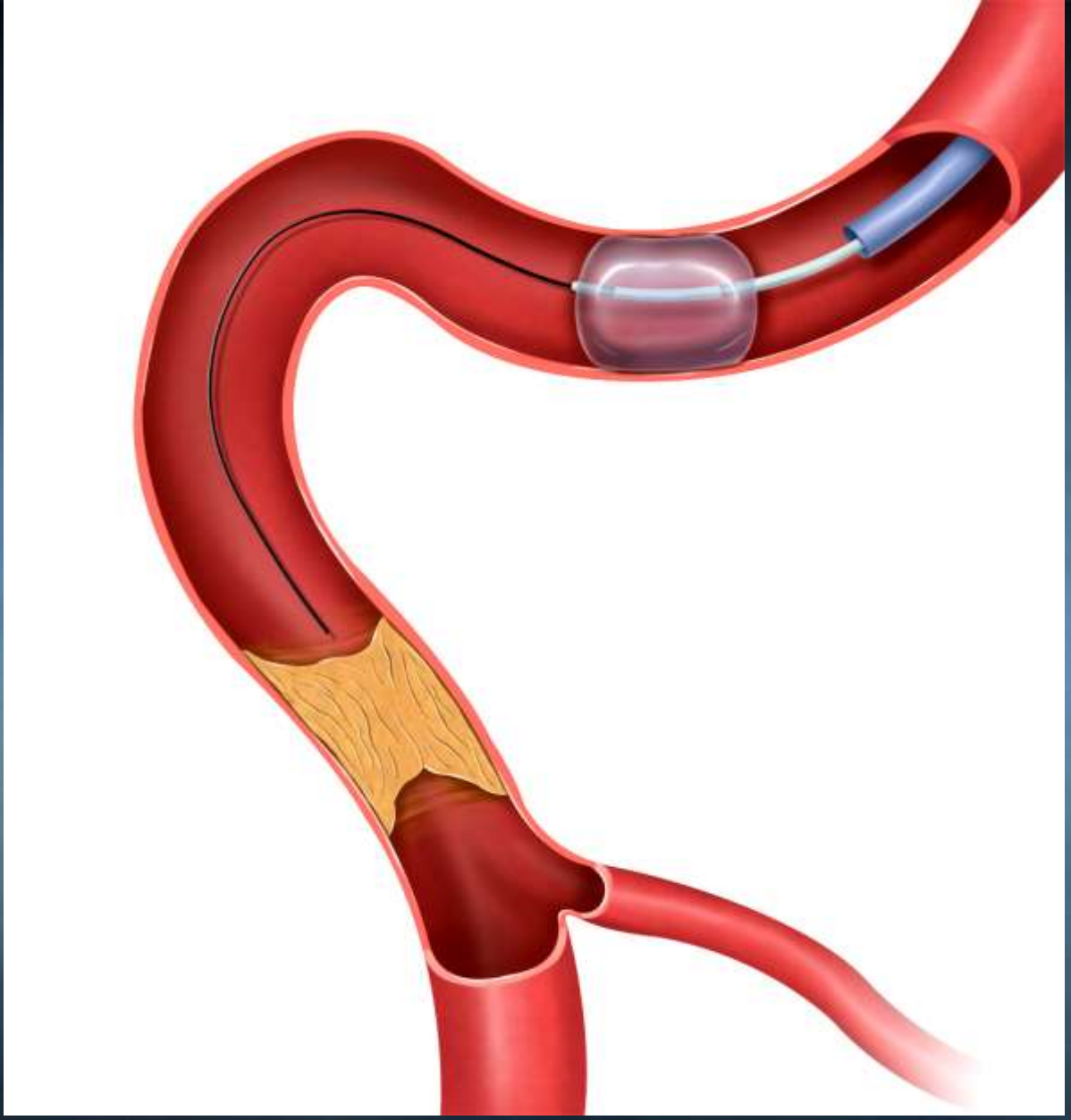
The support balloons have been effective in our small series; however, an improvement in the standard over the wire balloon may make it possible to safely treat larger numbers of patients with this technique. Improved antegrade approaches are essential in increasing rates in this difficult patient subset.

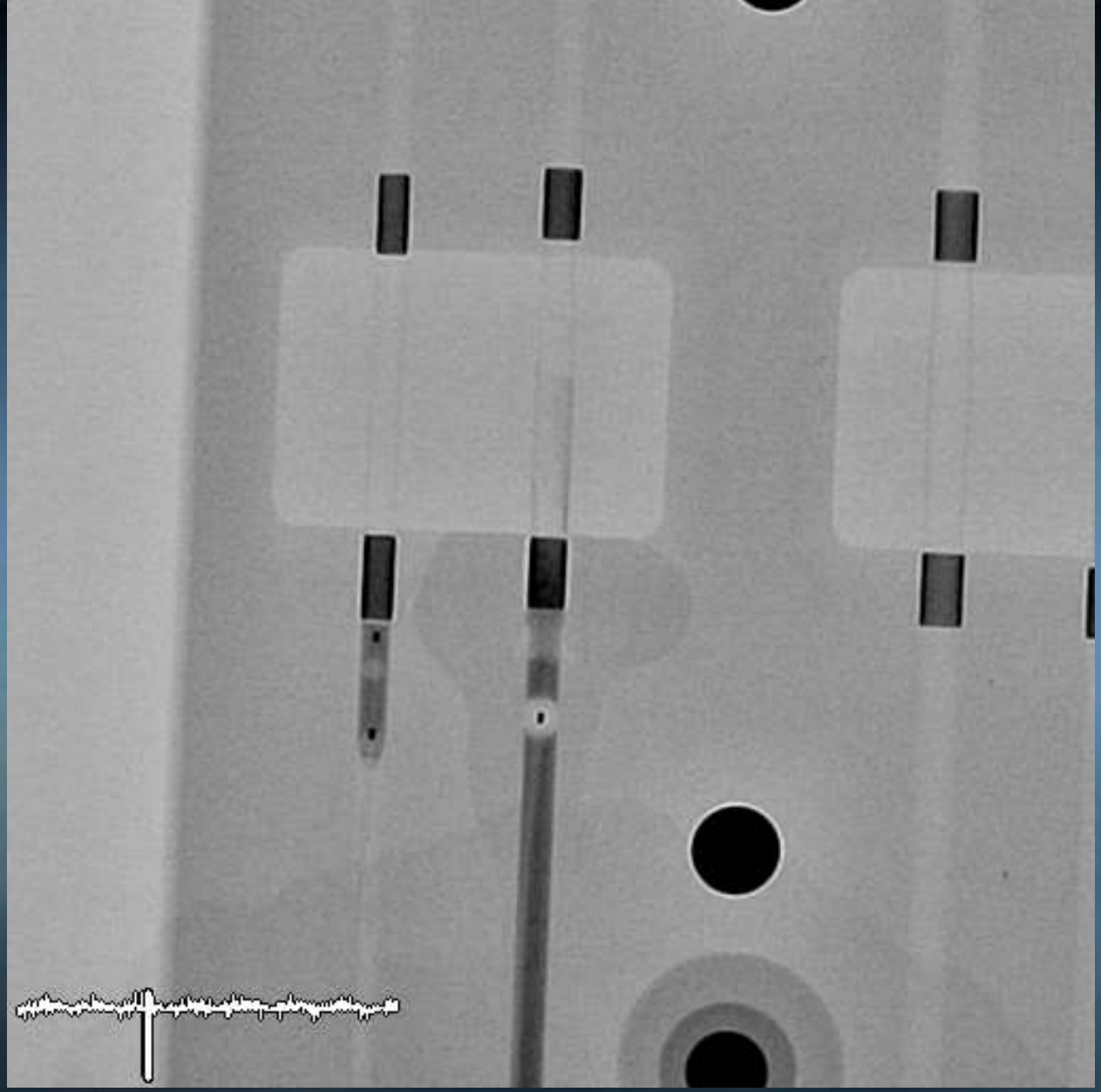
Disclosures: [1] Stockholder in QuantumCor and CSI, honorarium from CSI, holds patents for snares, wires, balloon catheters,

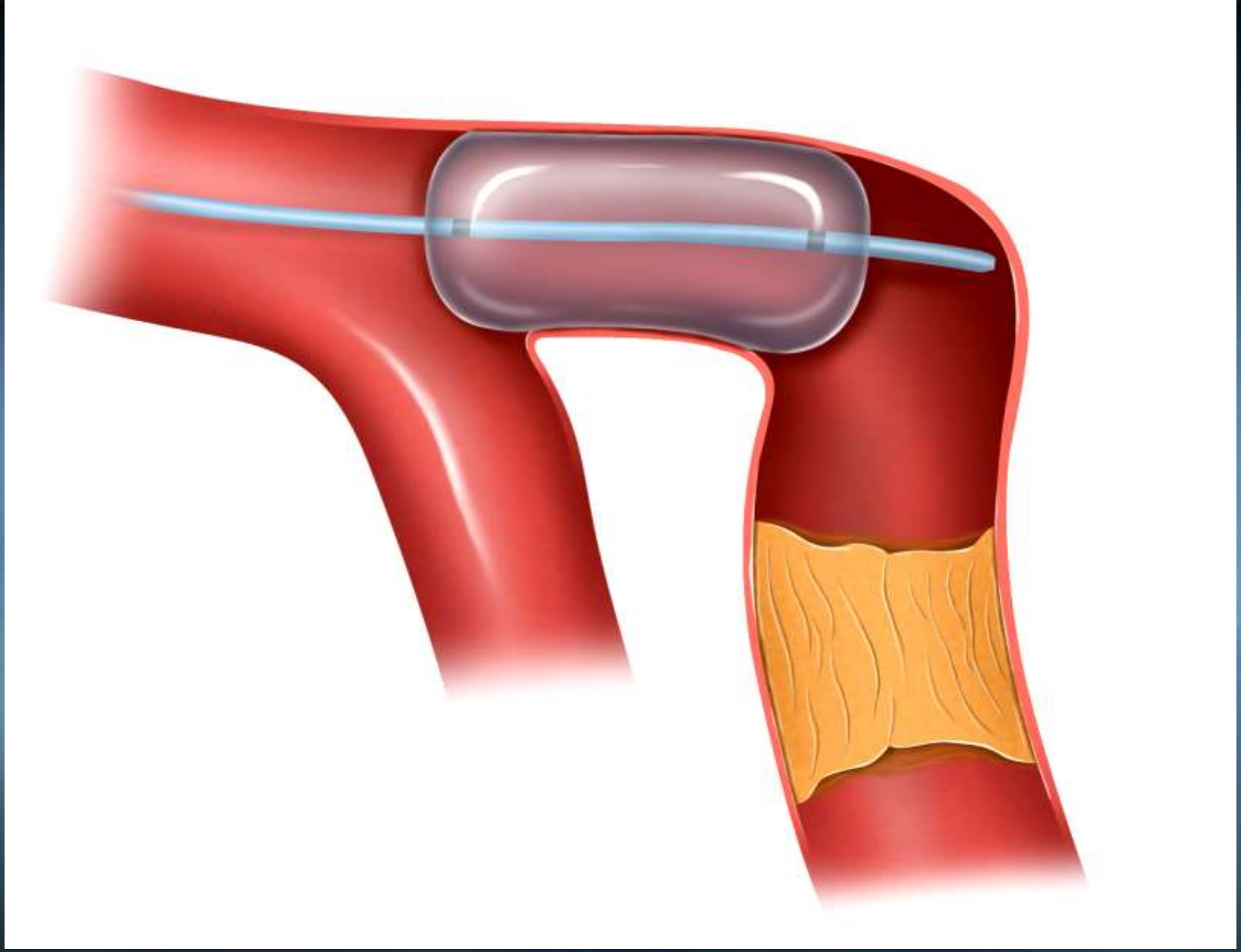
Optimal guiding catheter support is a prerequisite for successful angioplasty of CTO

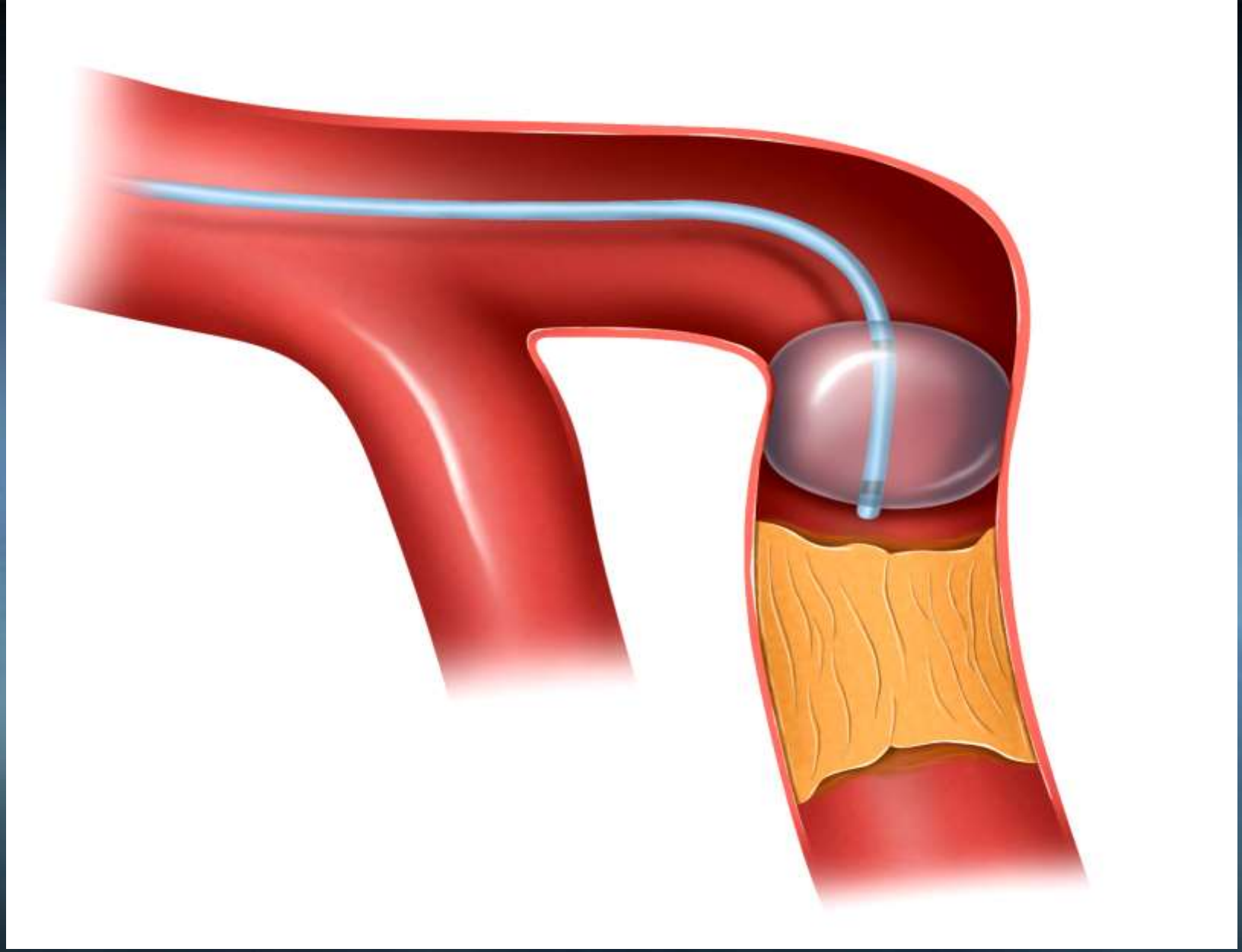
- Fixed stiff guide catheter
- Anchoring balloon in main vessel
- Anchoring balloon in side branch
- Fixed stiff catheter can result in dissection
- Side branch is difficult if the vessel is small
- Small balloons don’t always allow wire manipulation
- All commercially available balloons are too long, tips too long and can cause barotrauma

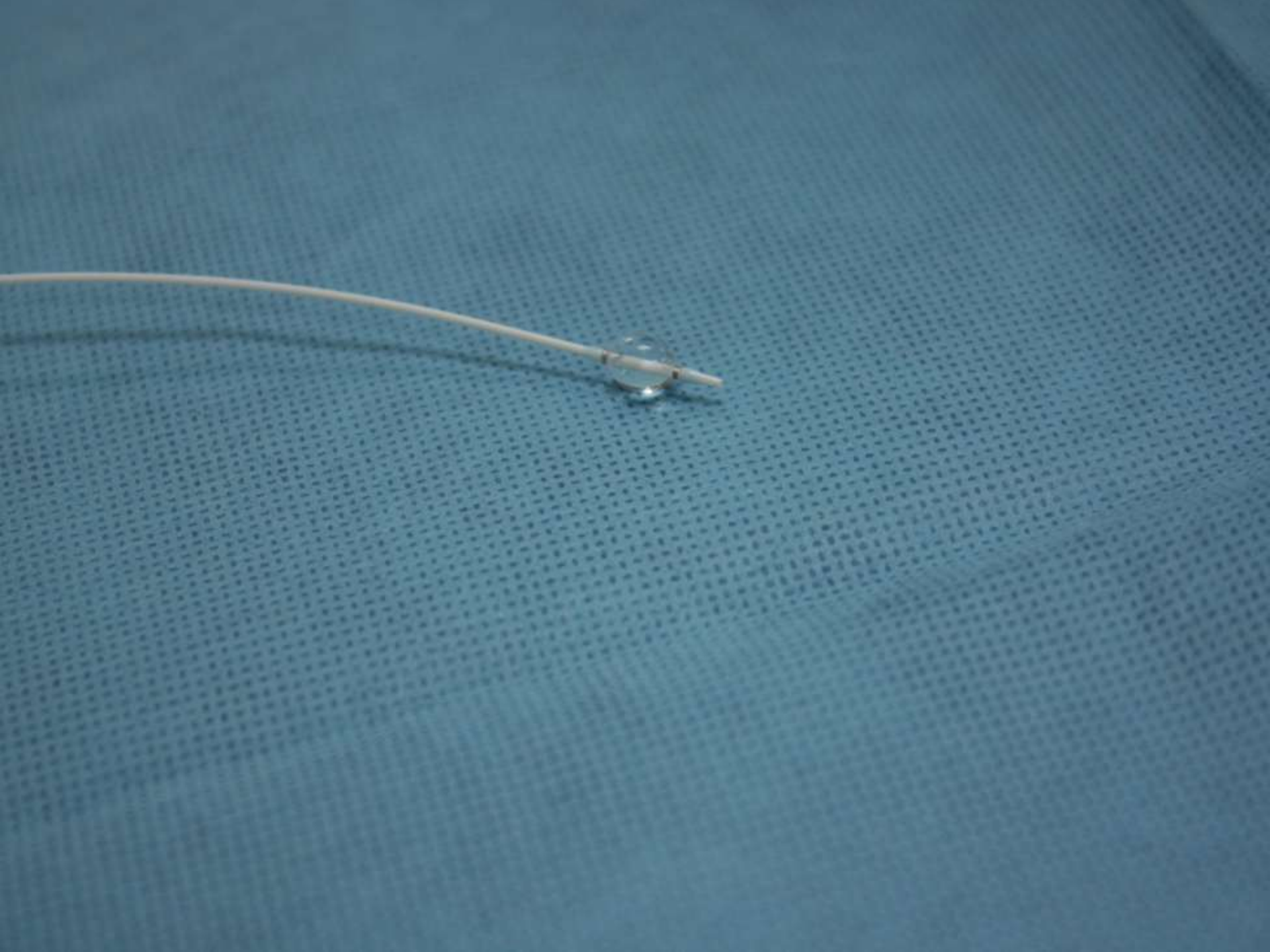




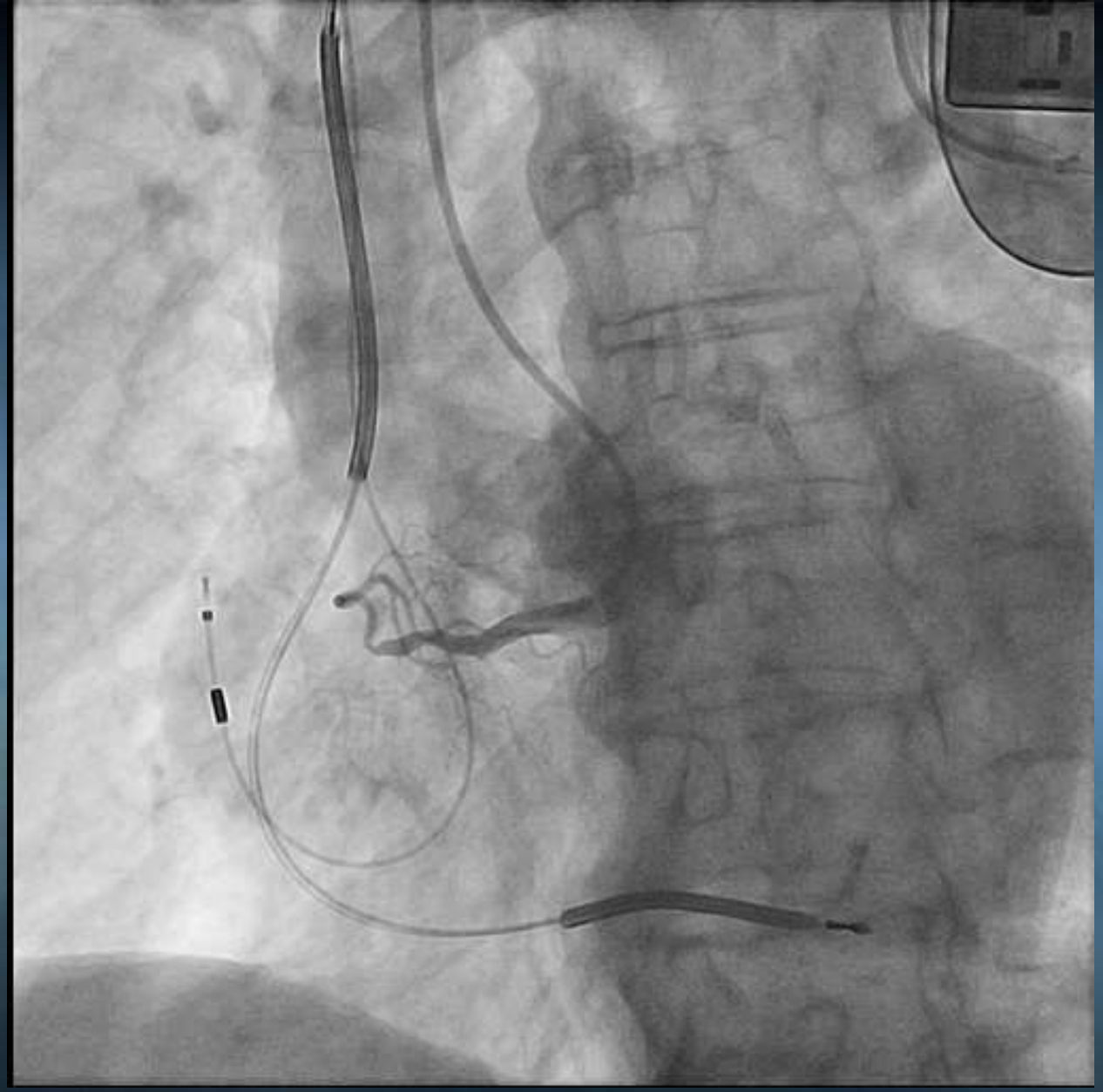


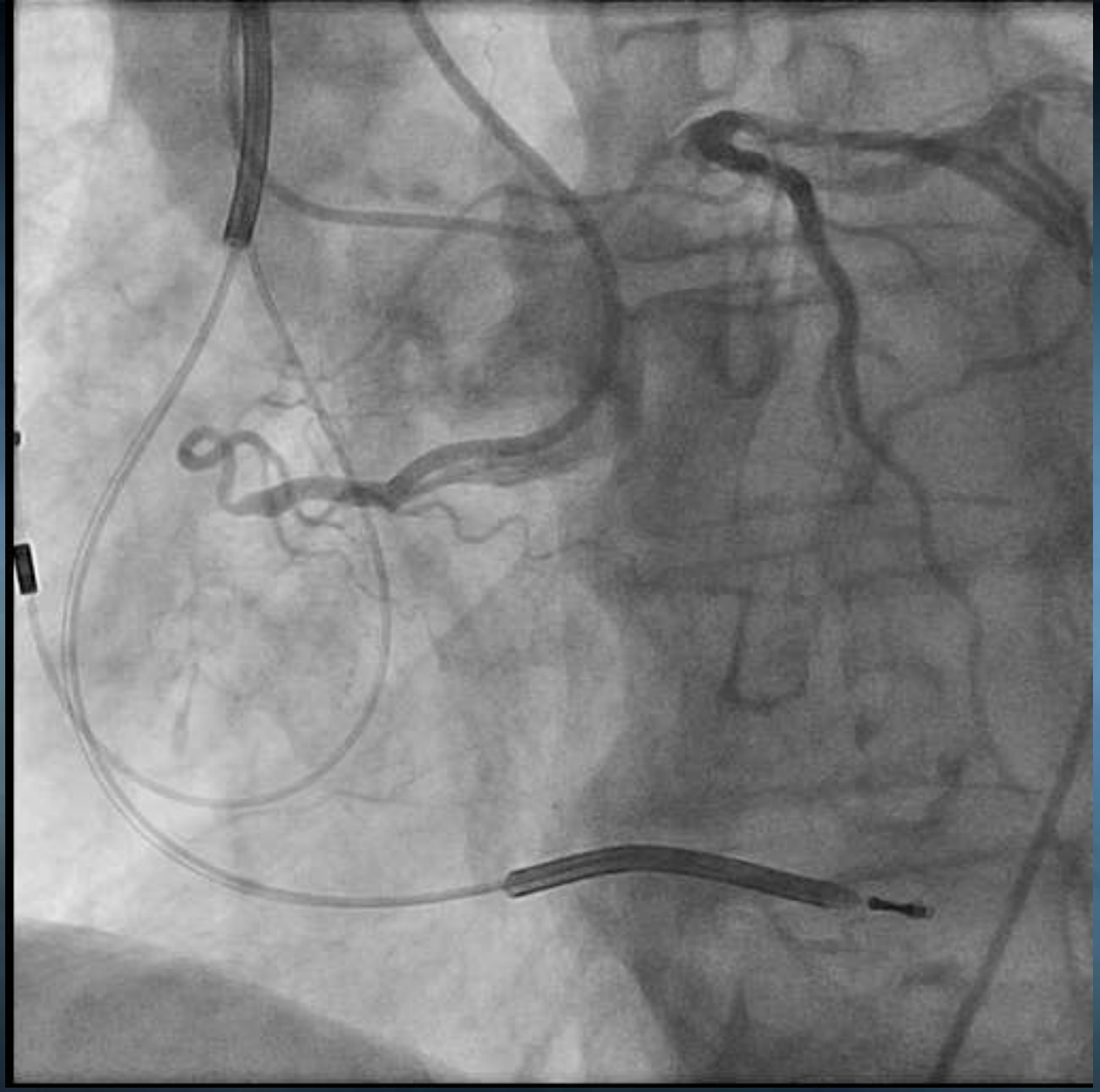


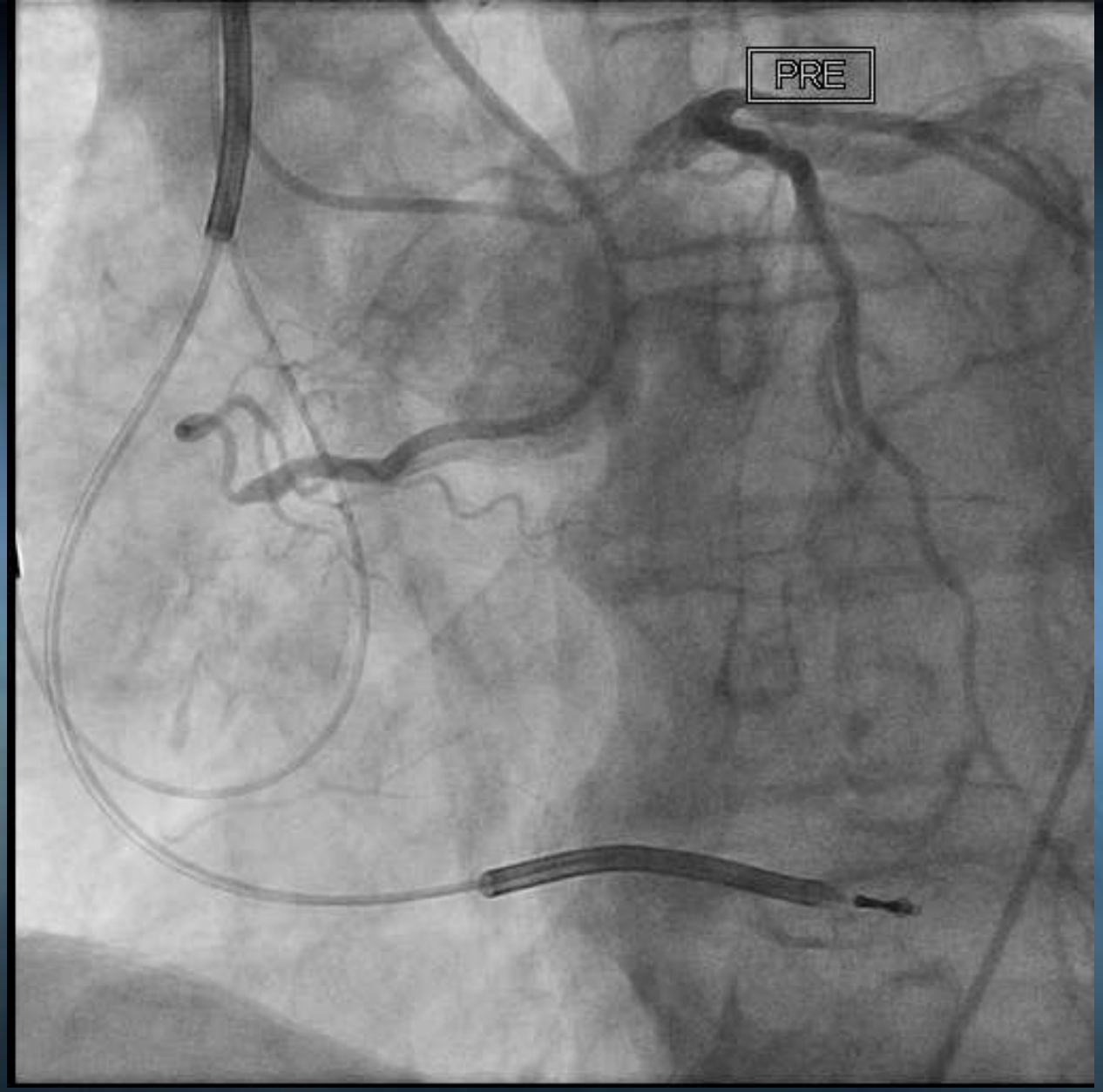




- 68 year old gentleman presents with new onset ischemic cardiomyopathy with inferior ischemia on stress myoview



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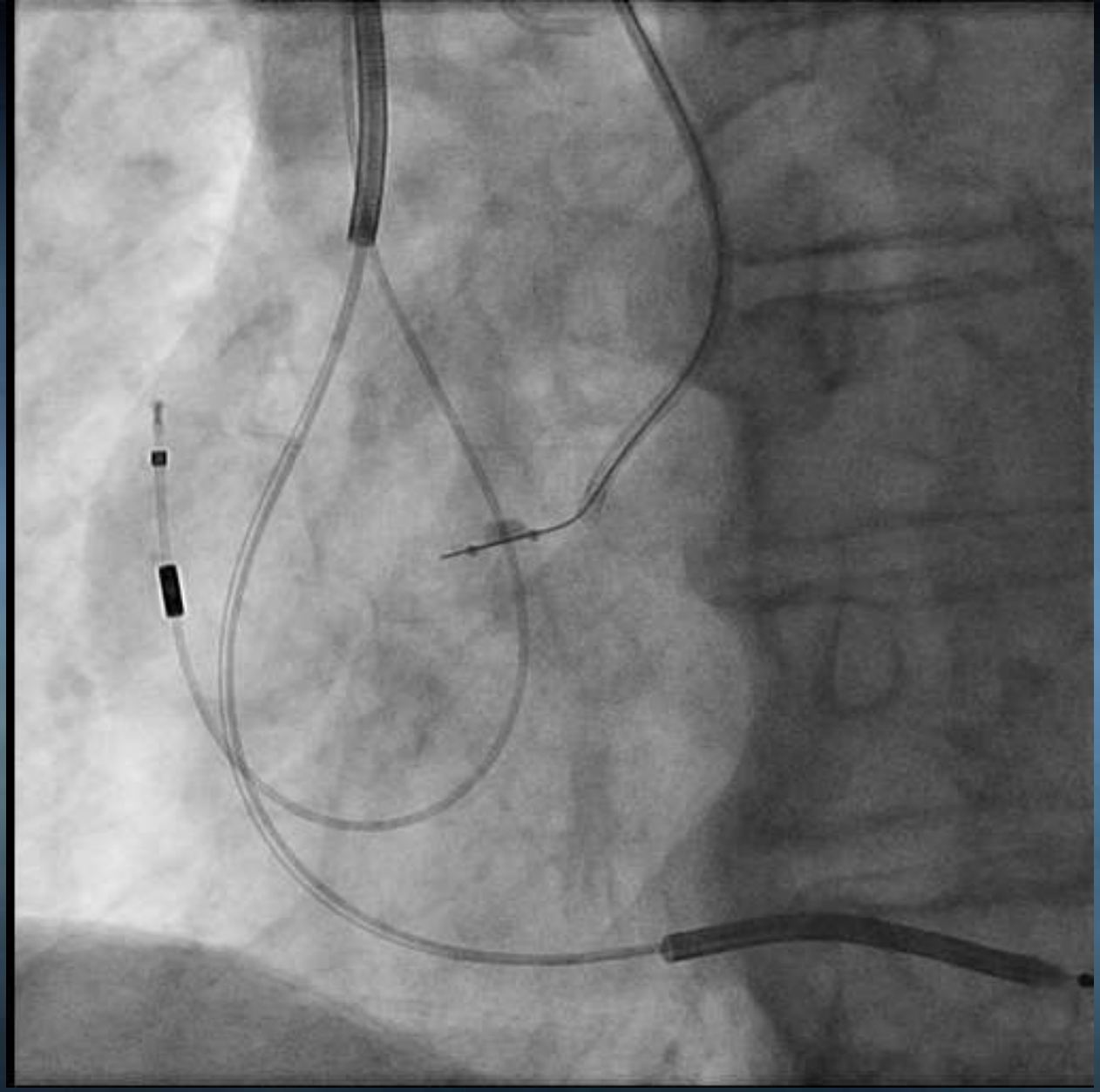

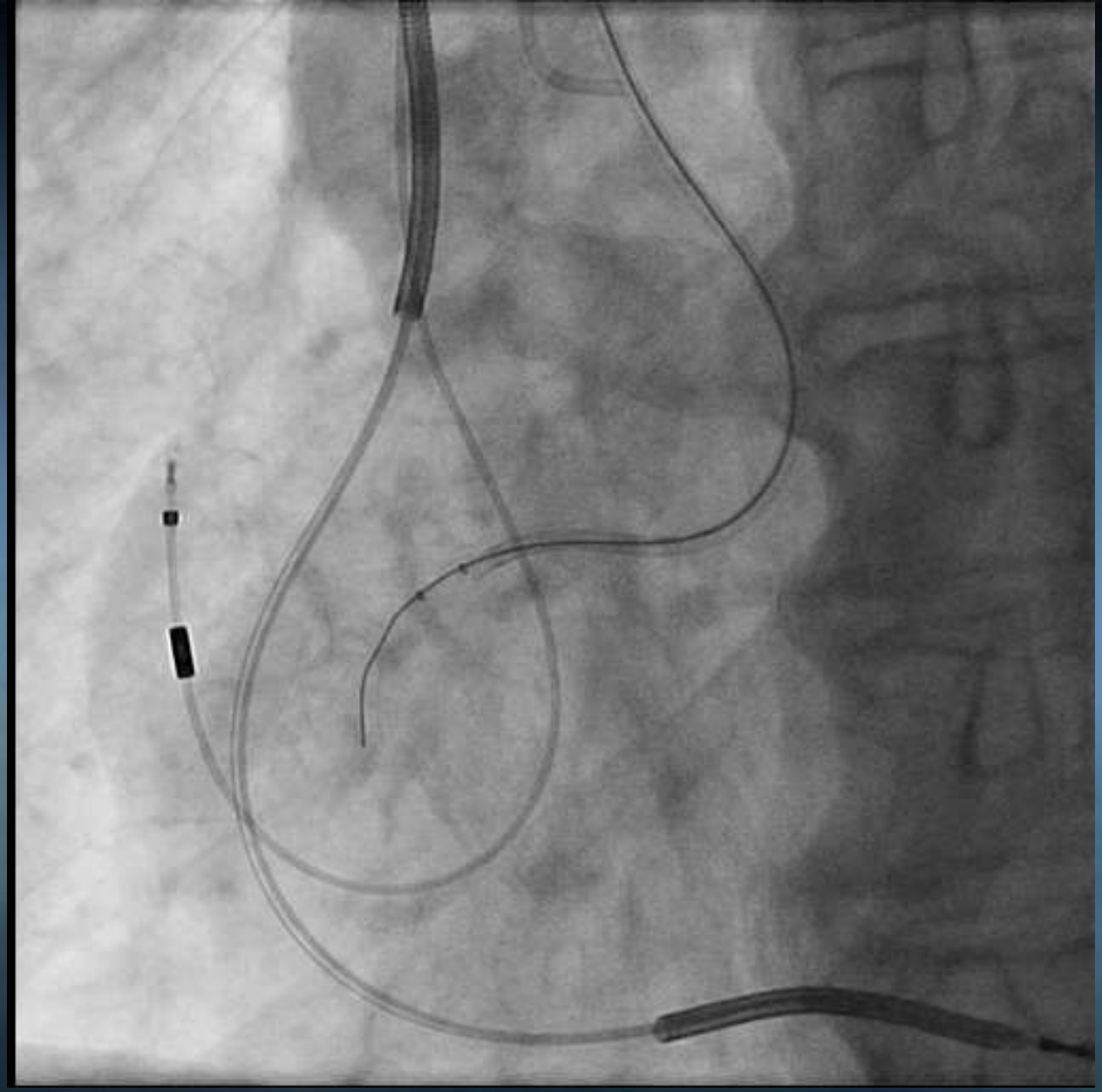

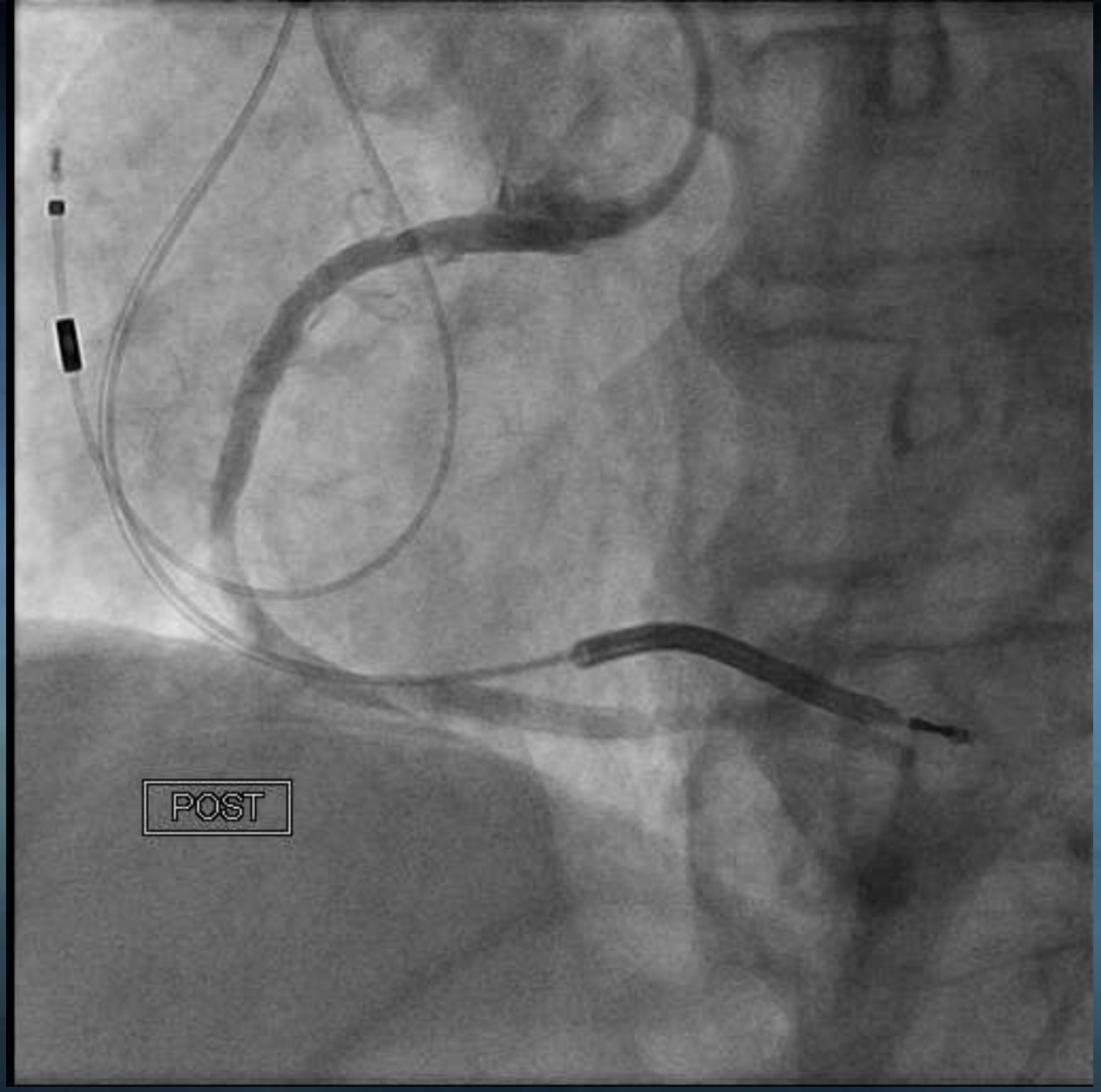
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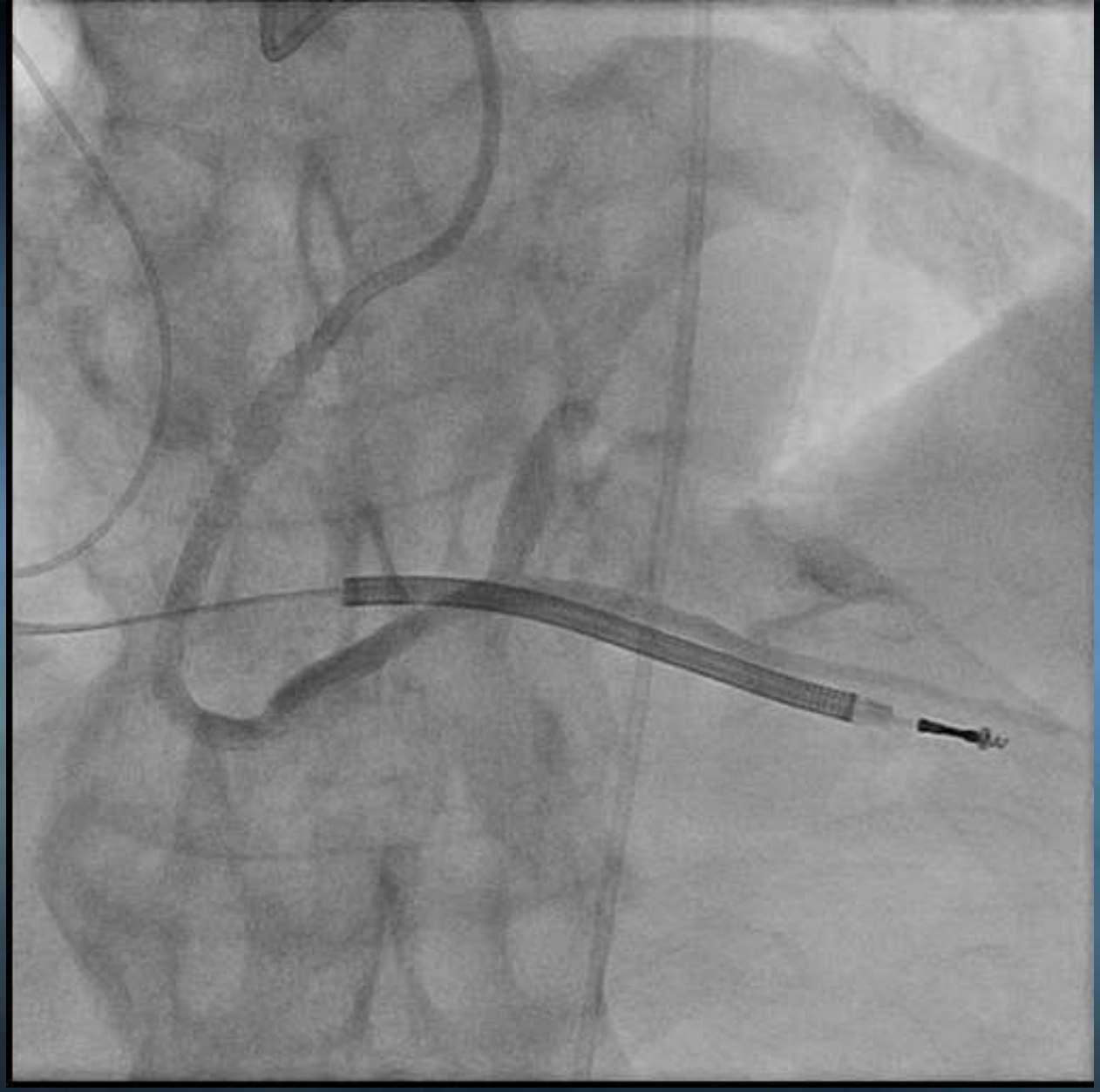
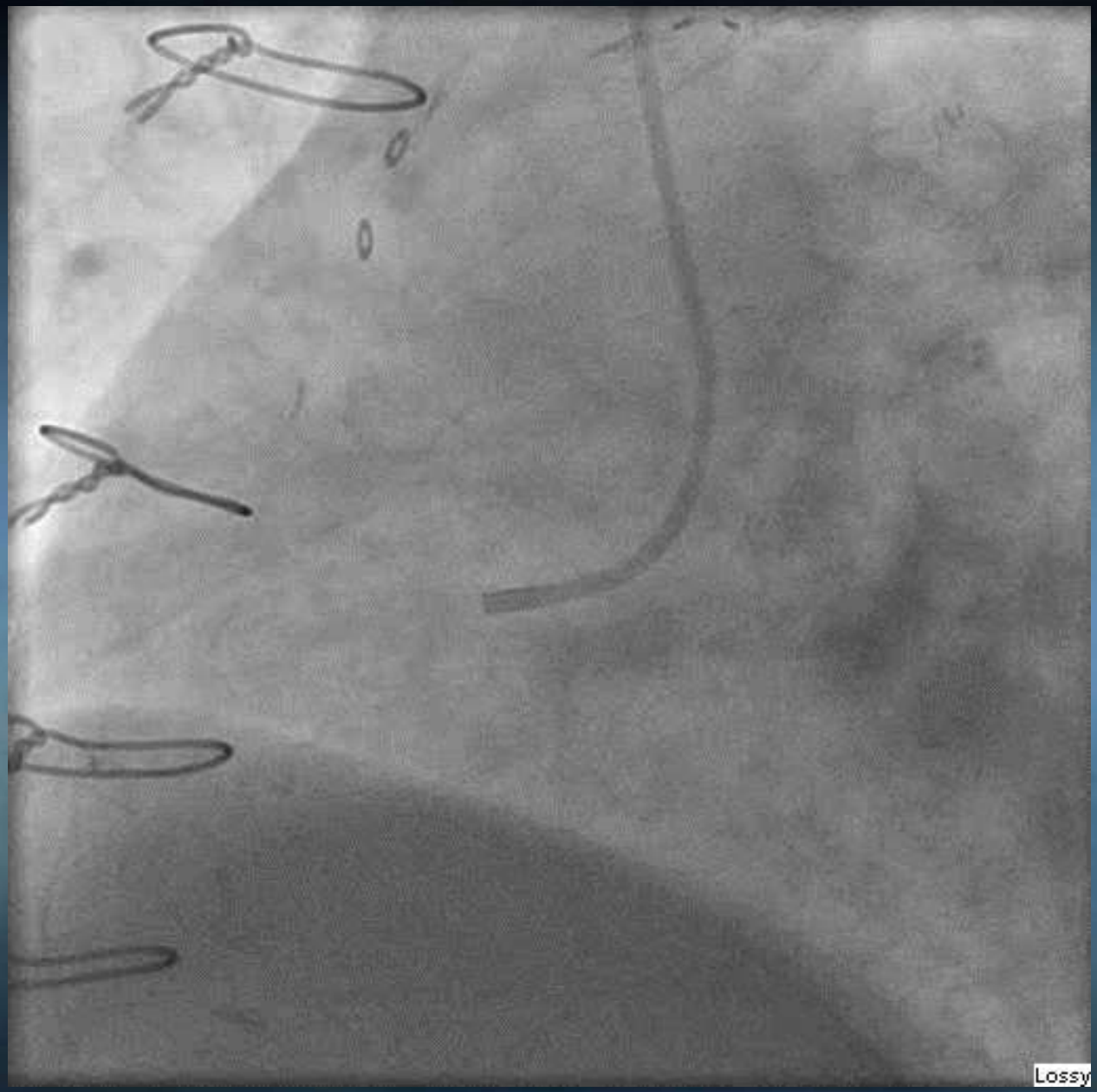


A 62 year old man presented with recurrence of angina and a RCA CTO with inferior ischemia. Attempted recanalization was unsuccessful at an outside center. He was status post CABG with an occluded RCA graft.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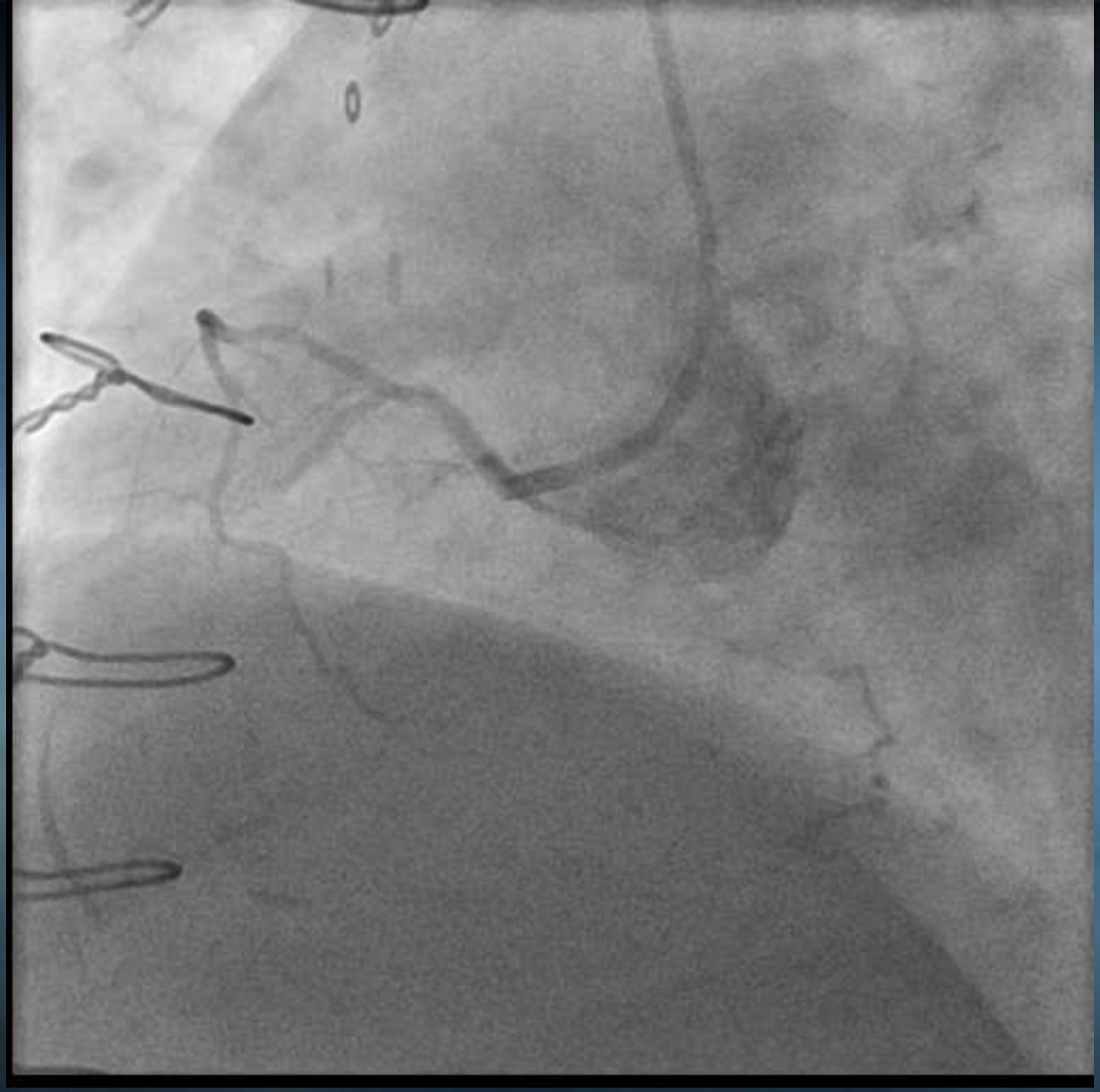

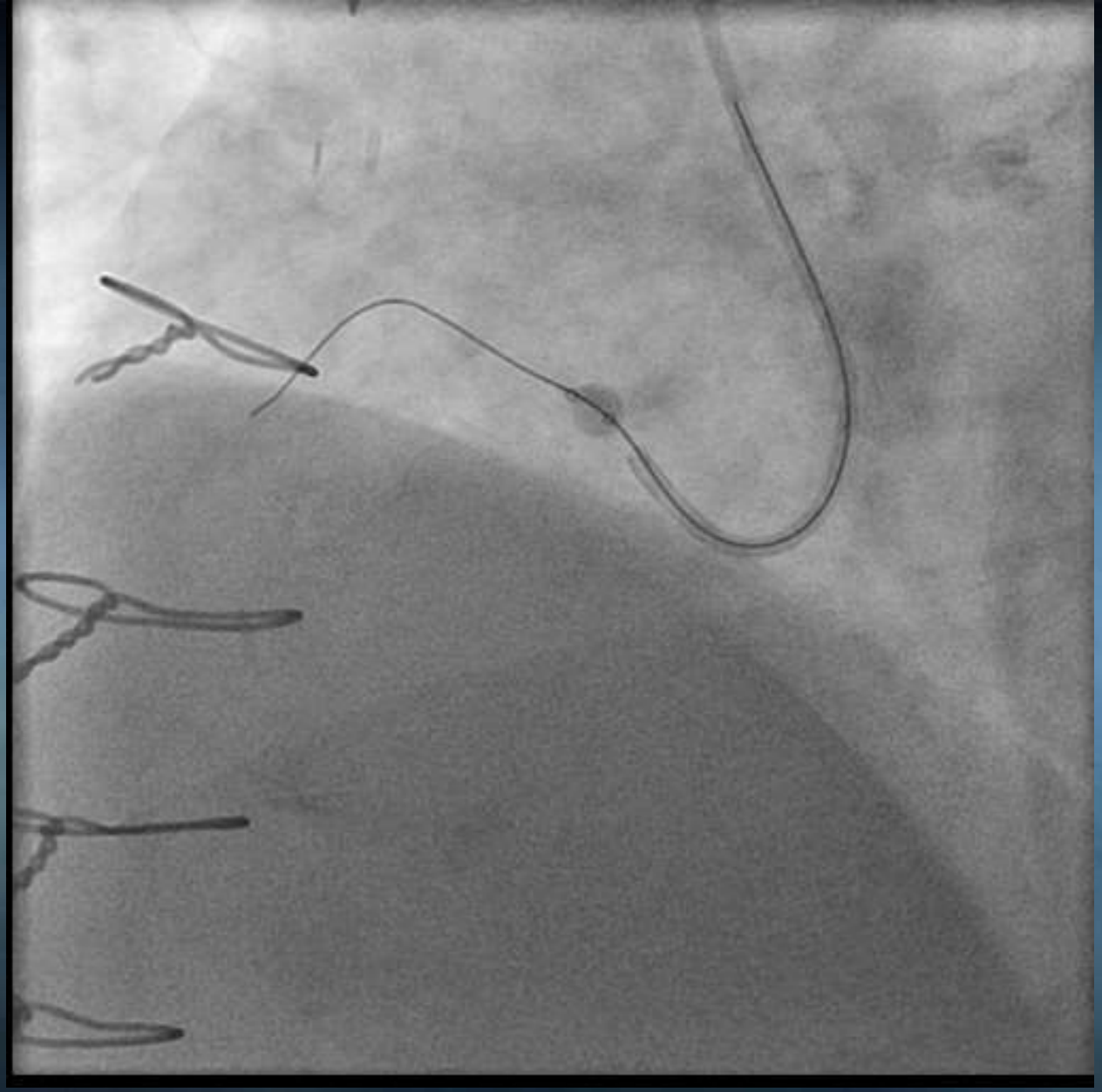

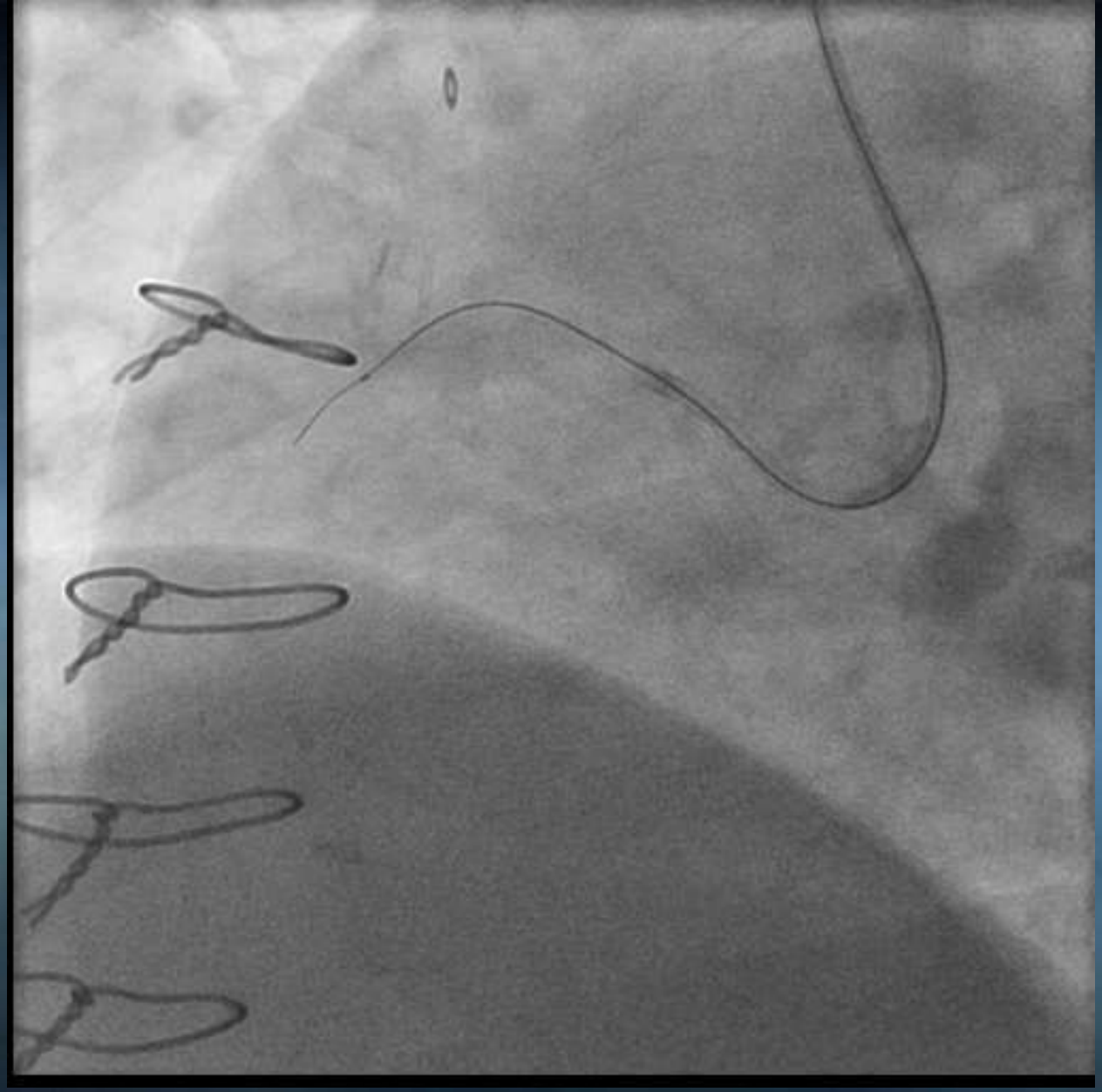

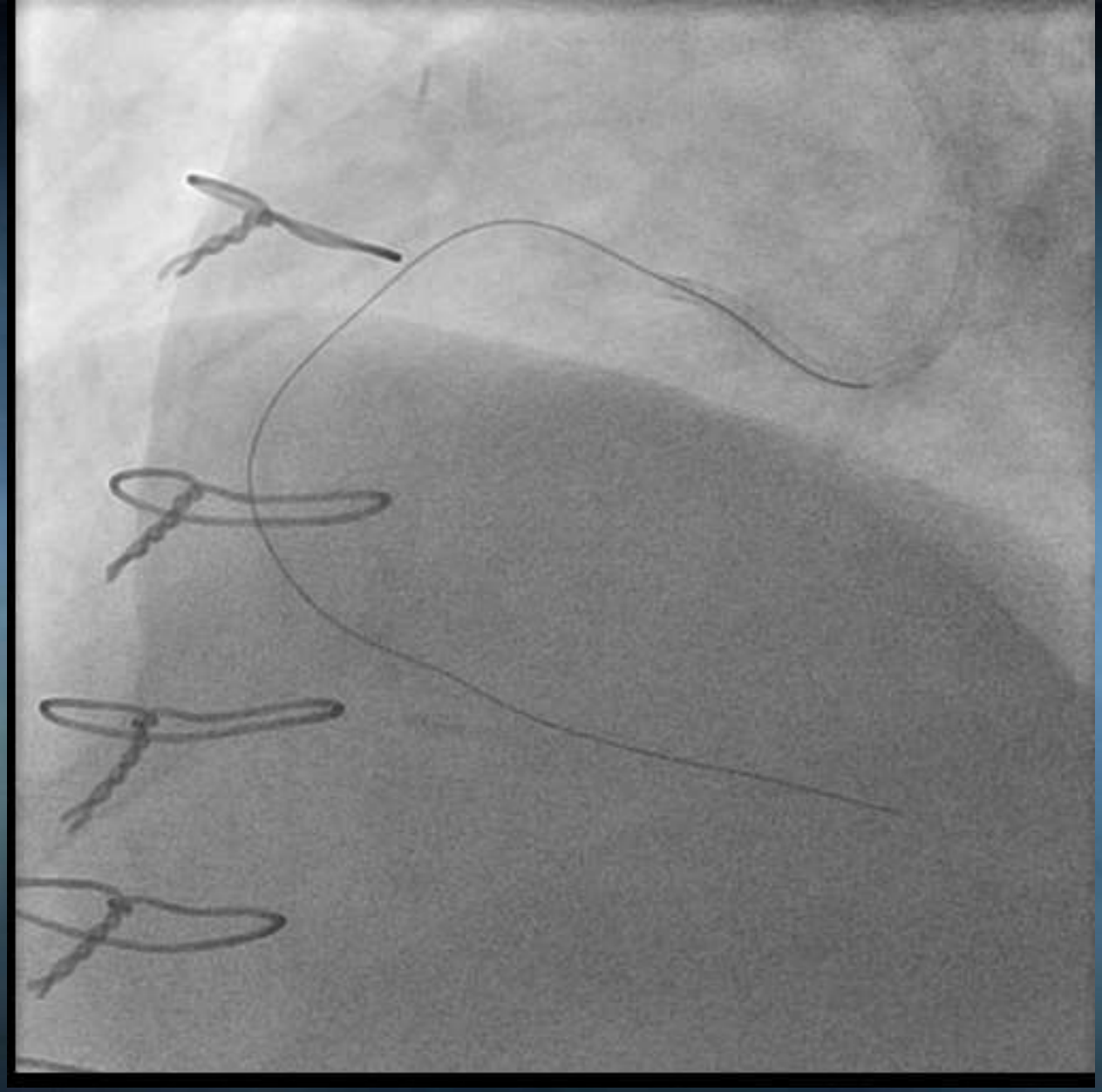

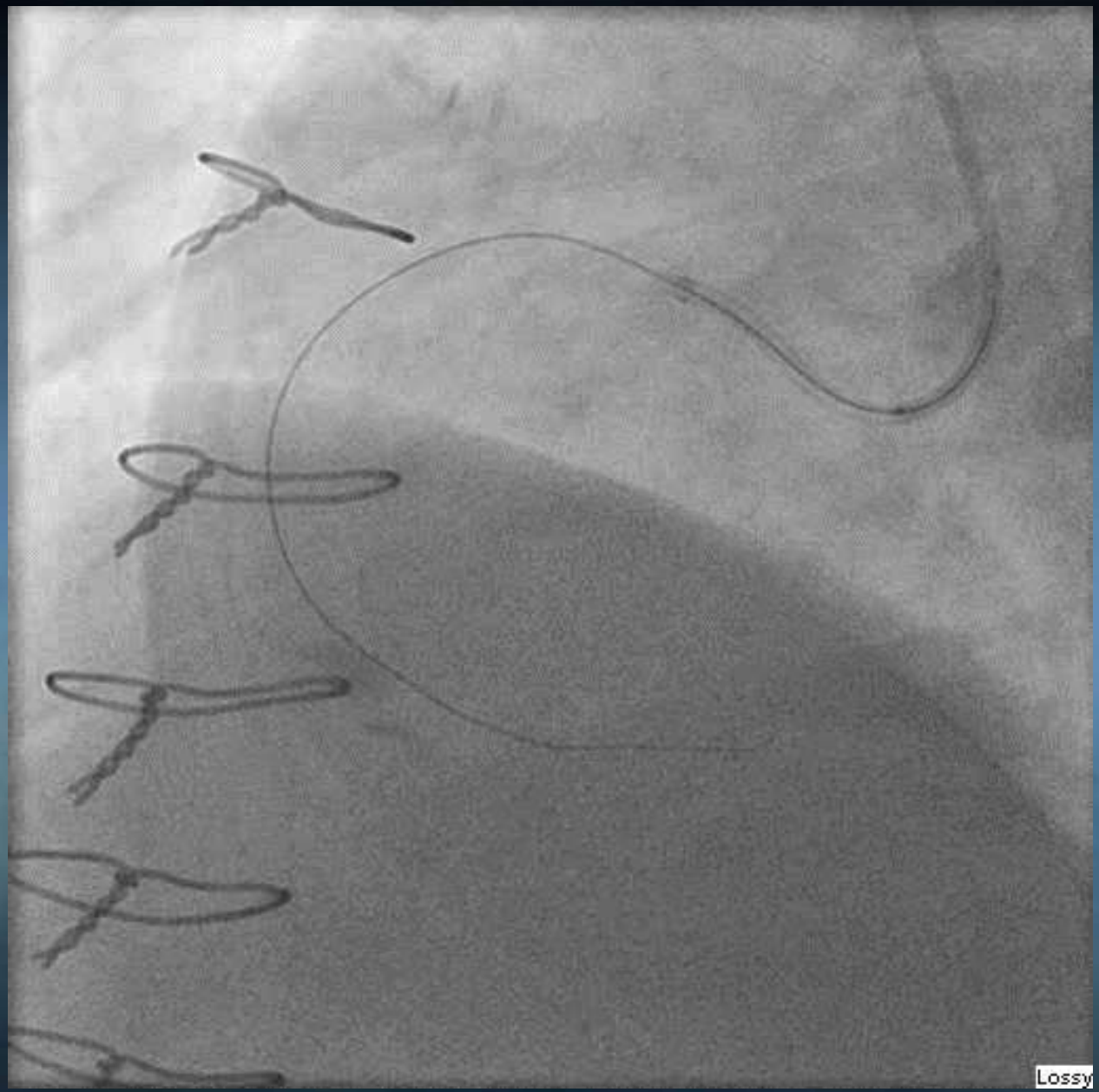
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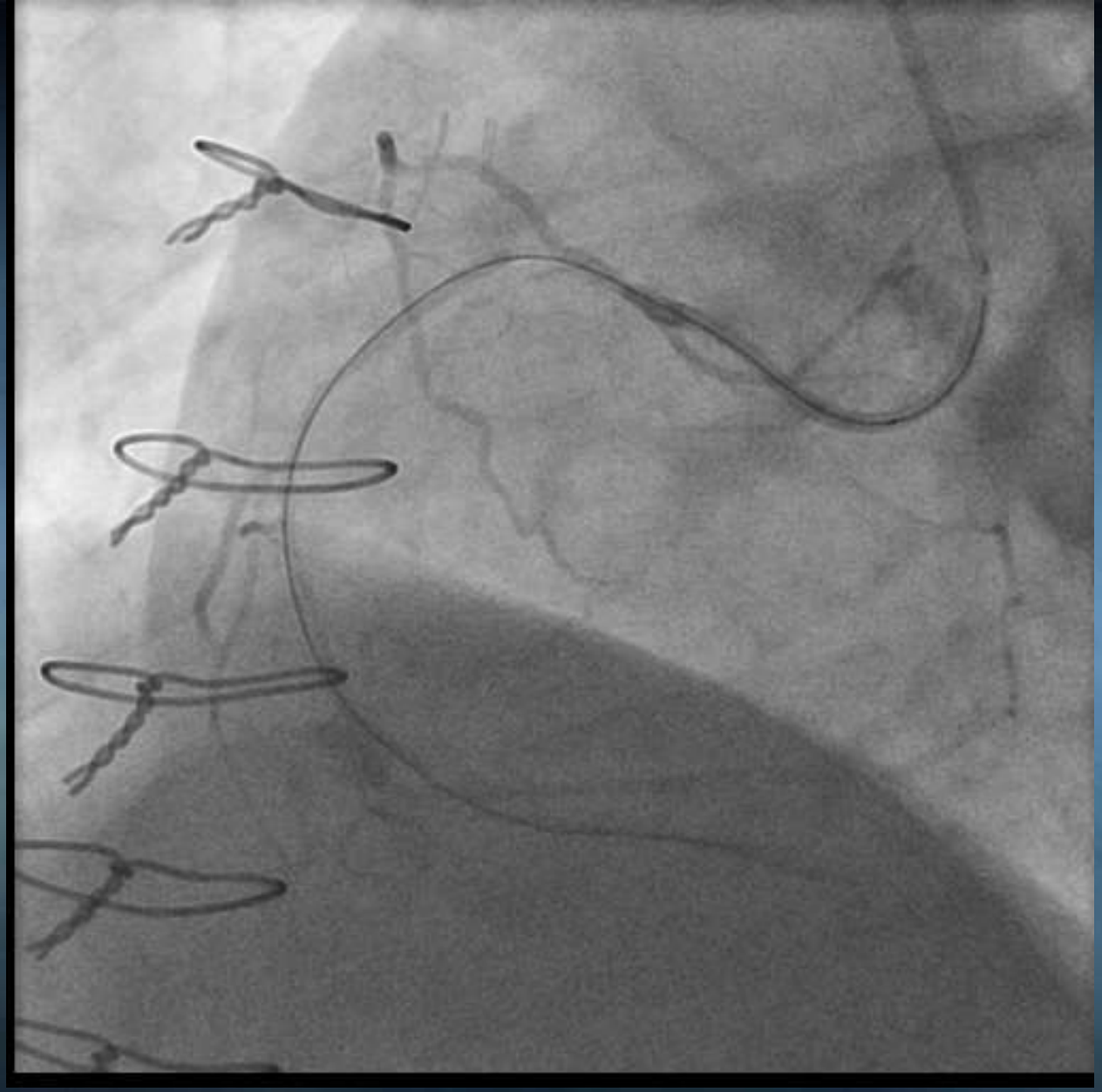
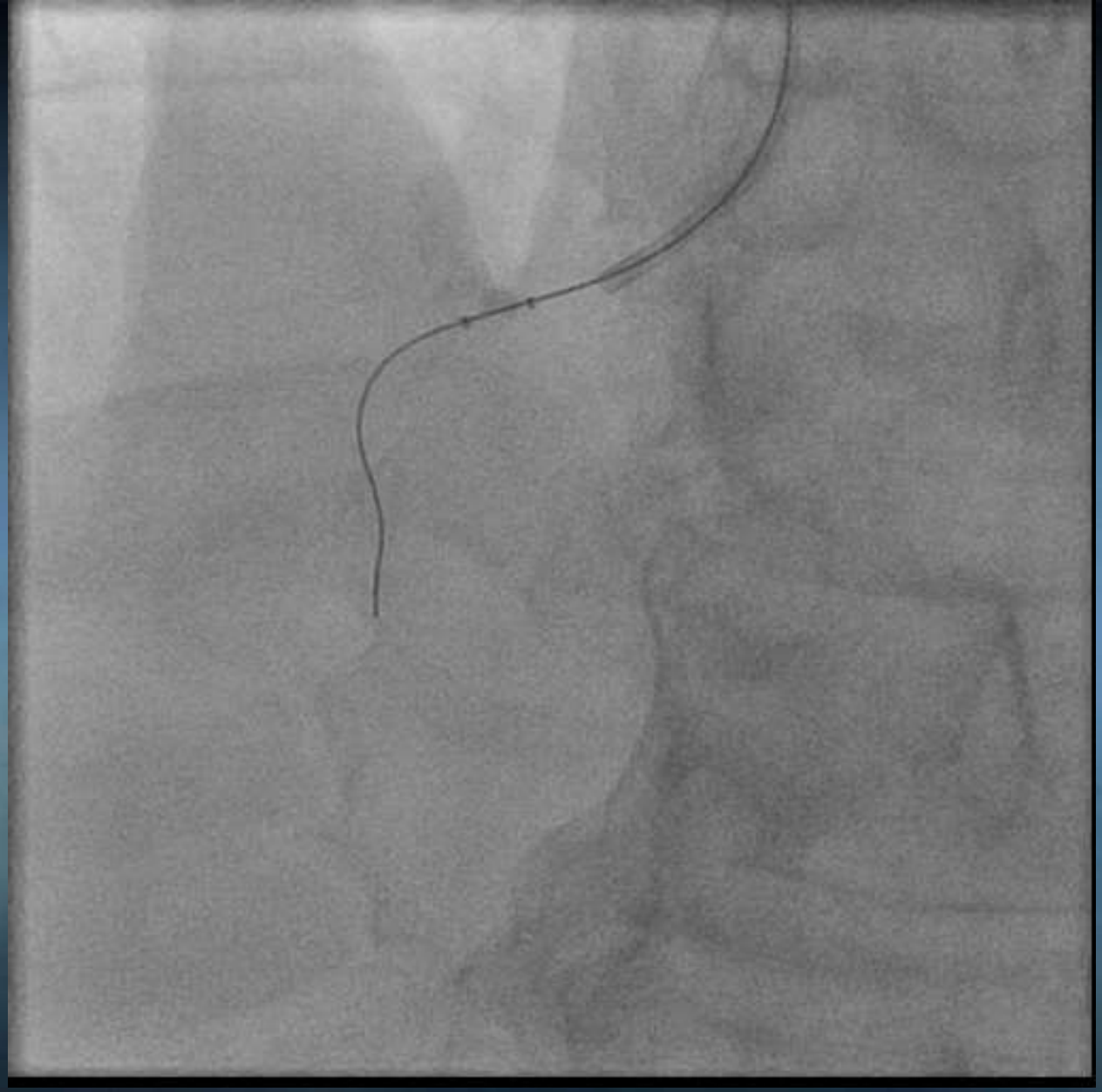
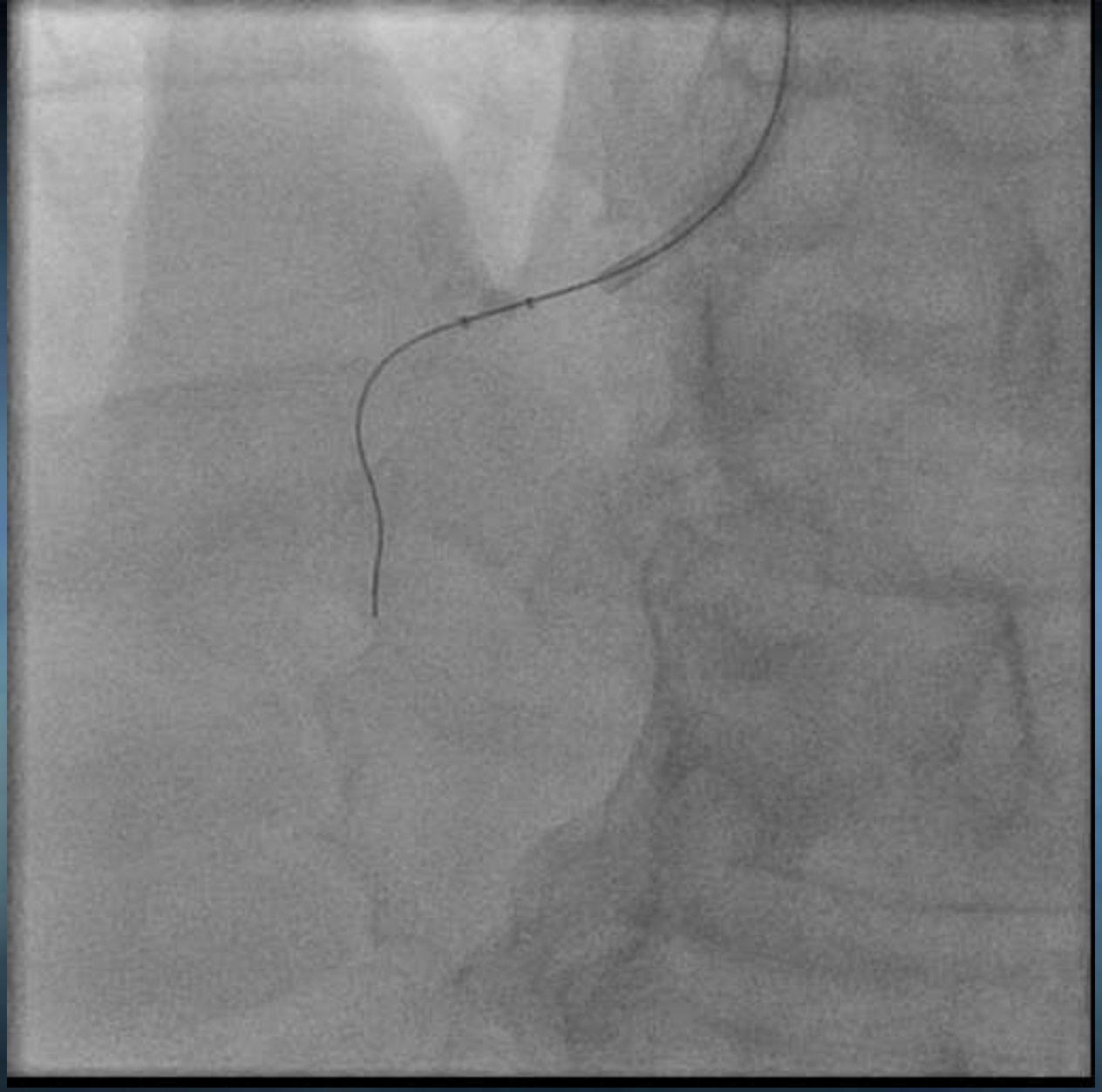
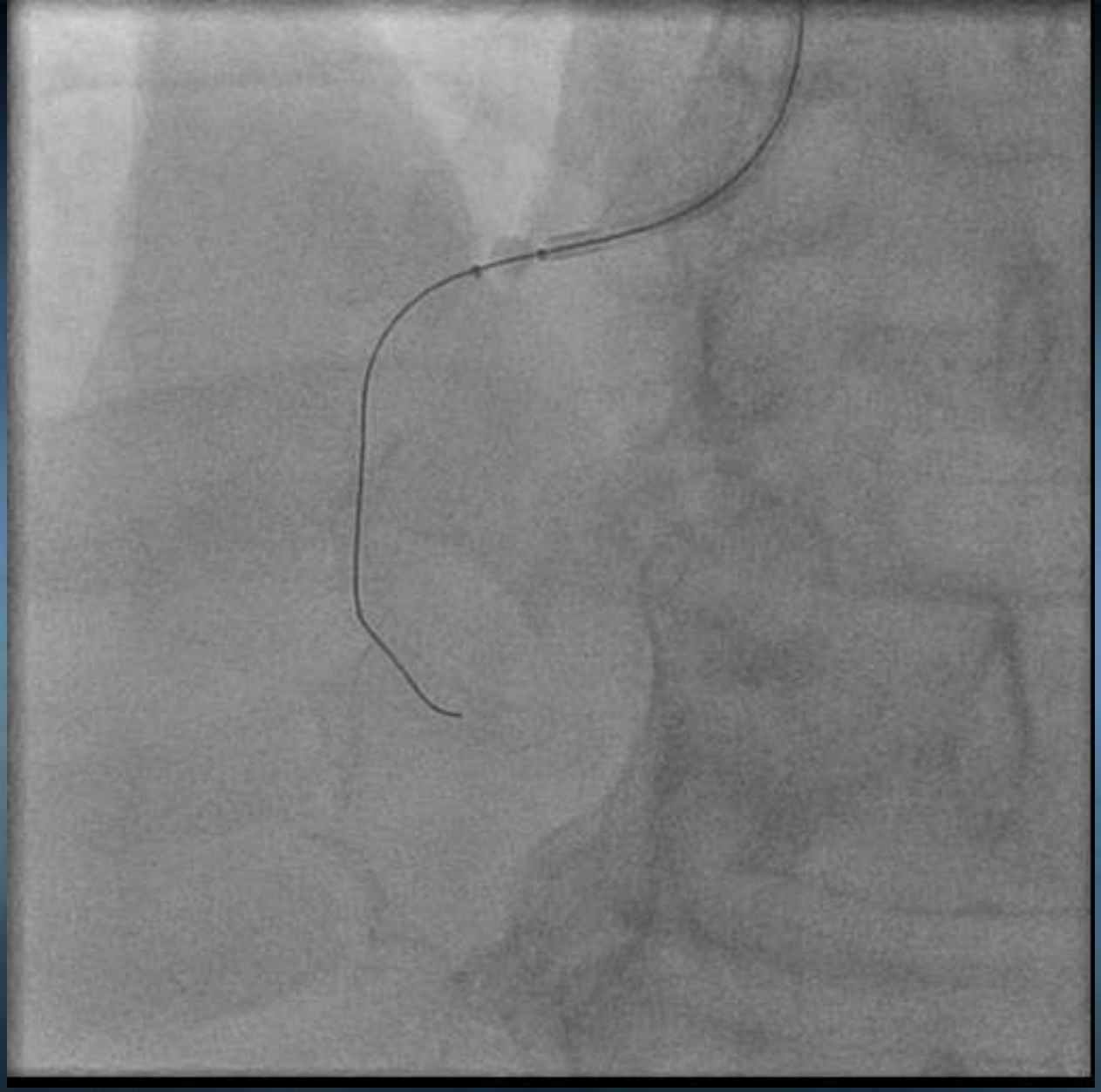


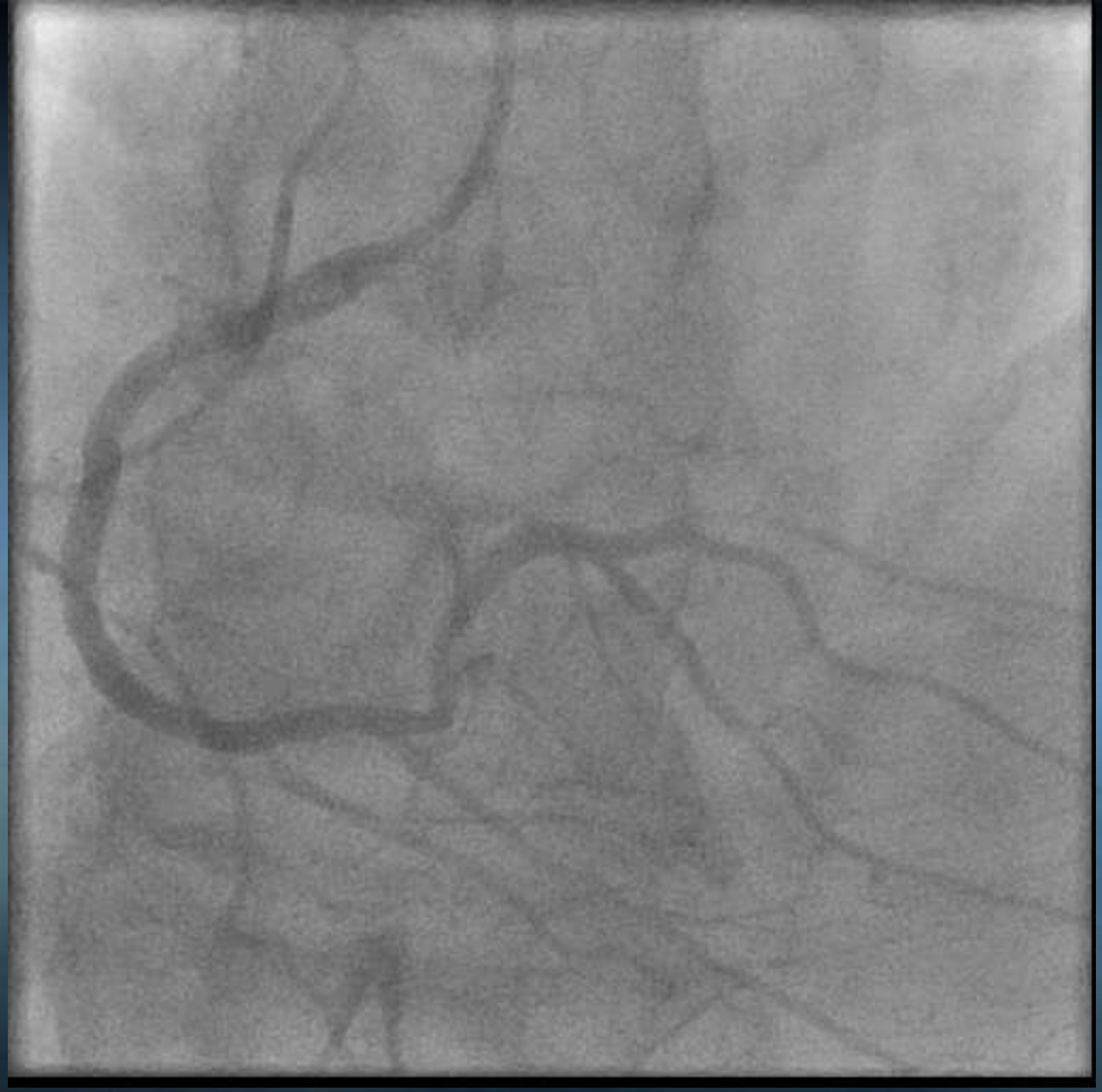

Lossy

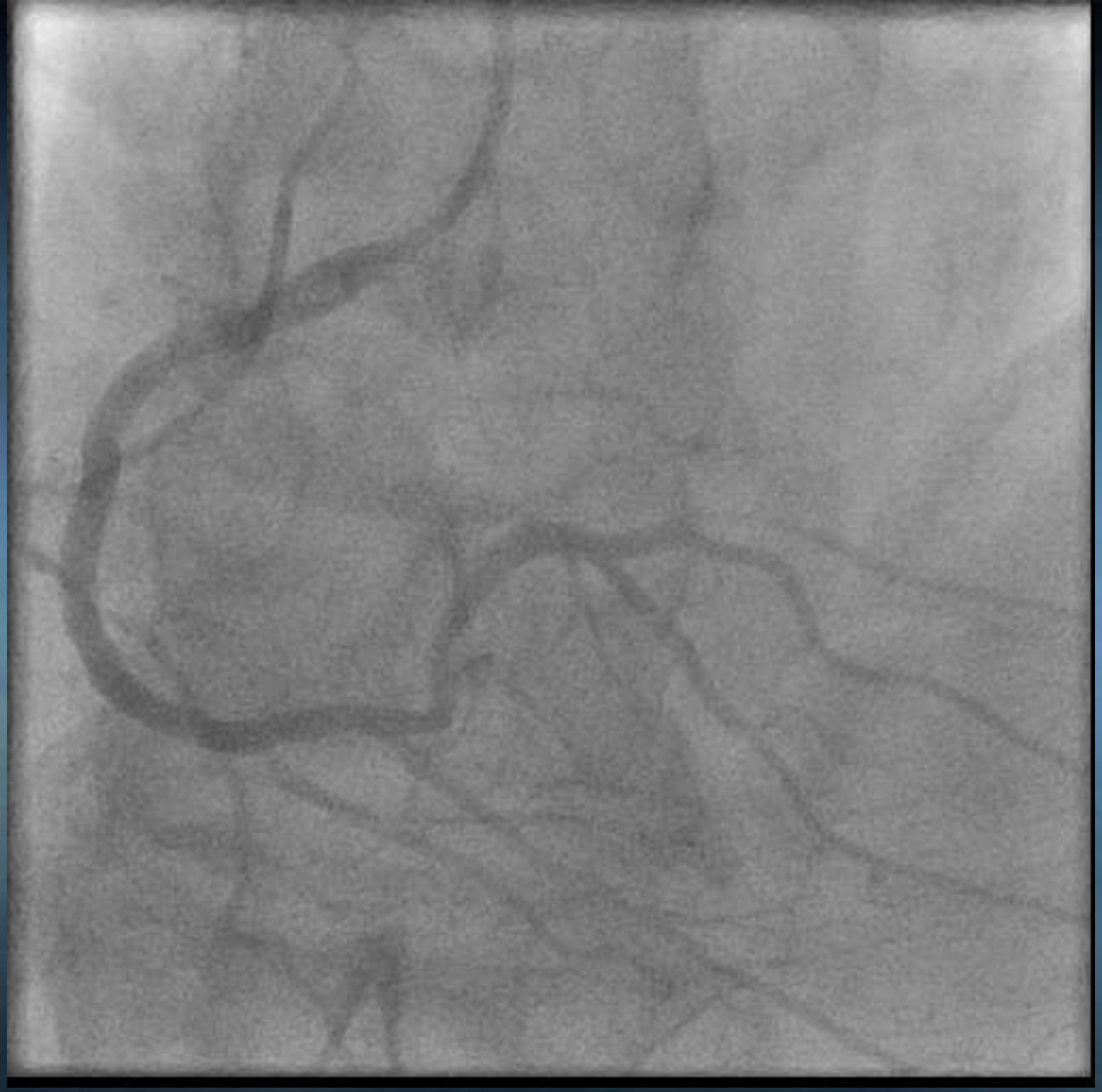
A 51 year old male presented with chronic angina and inferior ischemia. Outside angio revealed a CTO of the RCA.



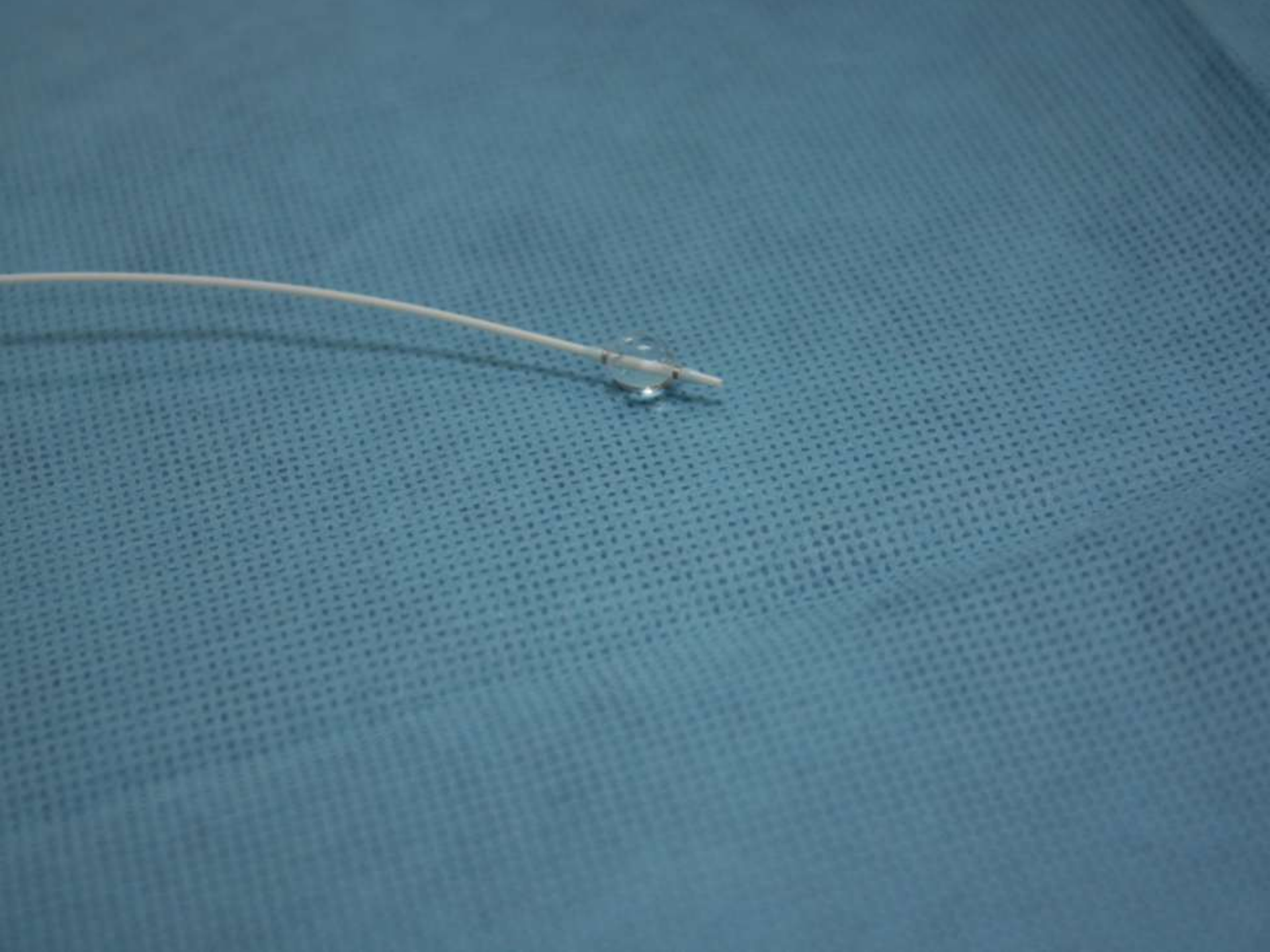








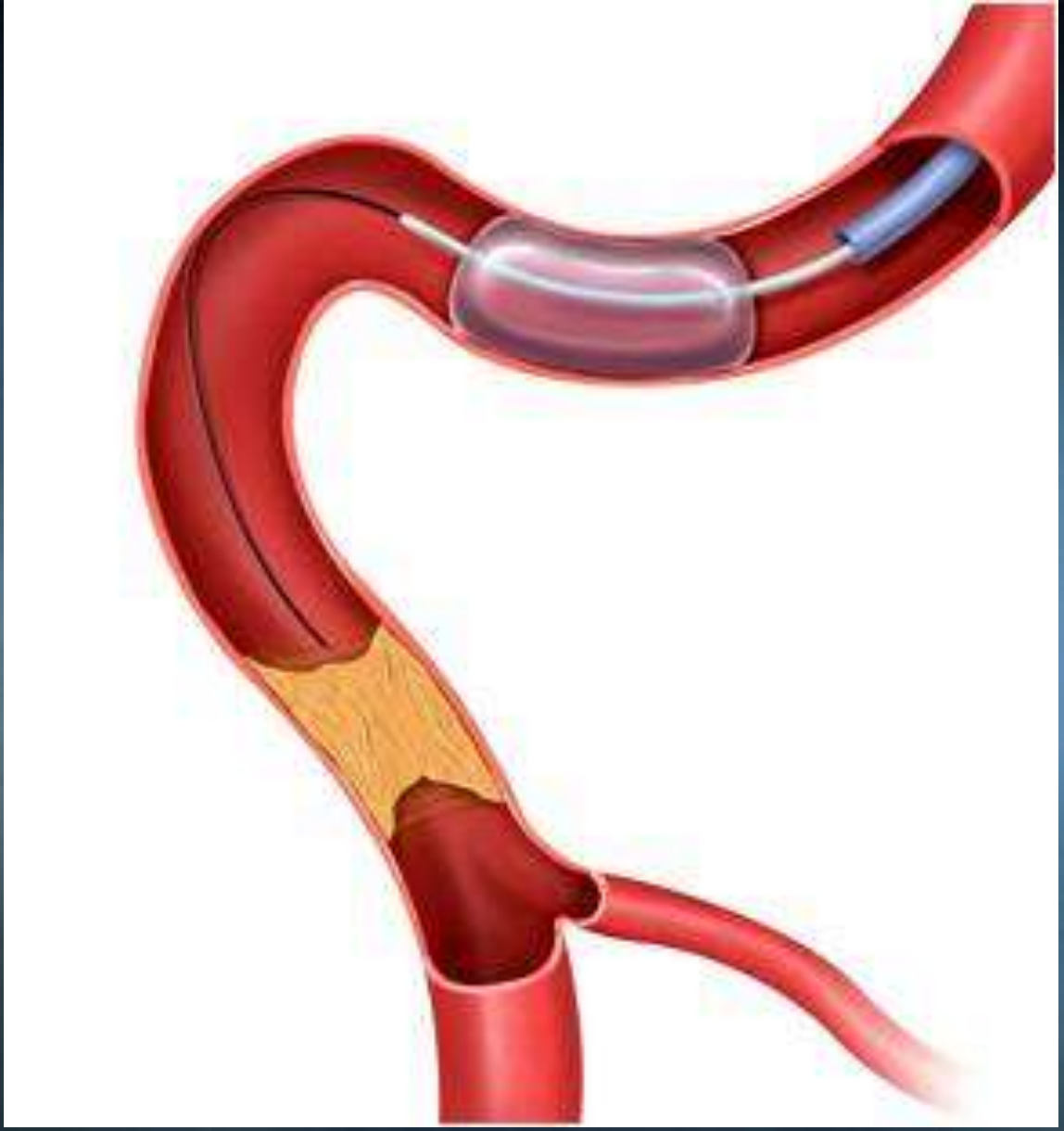
In CTO's It's a Brand New Ballgame

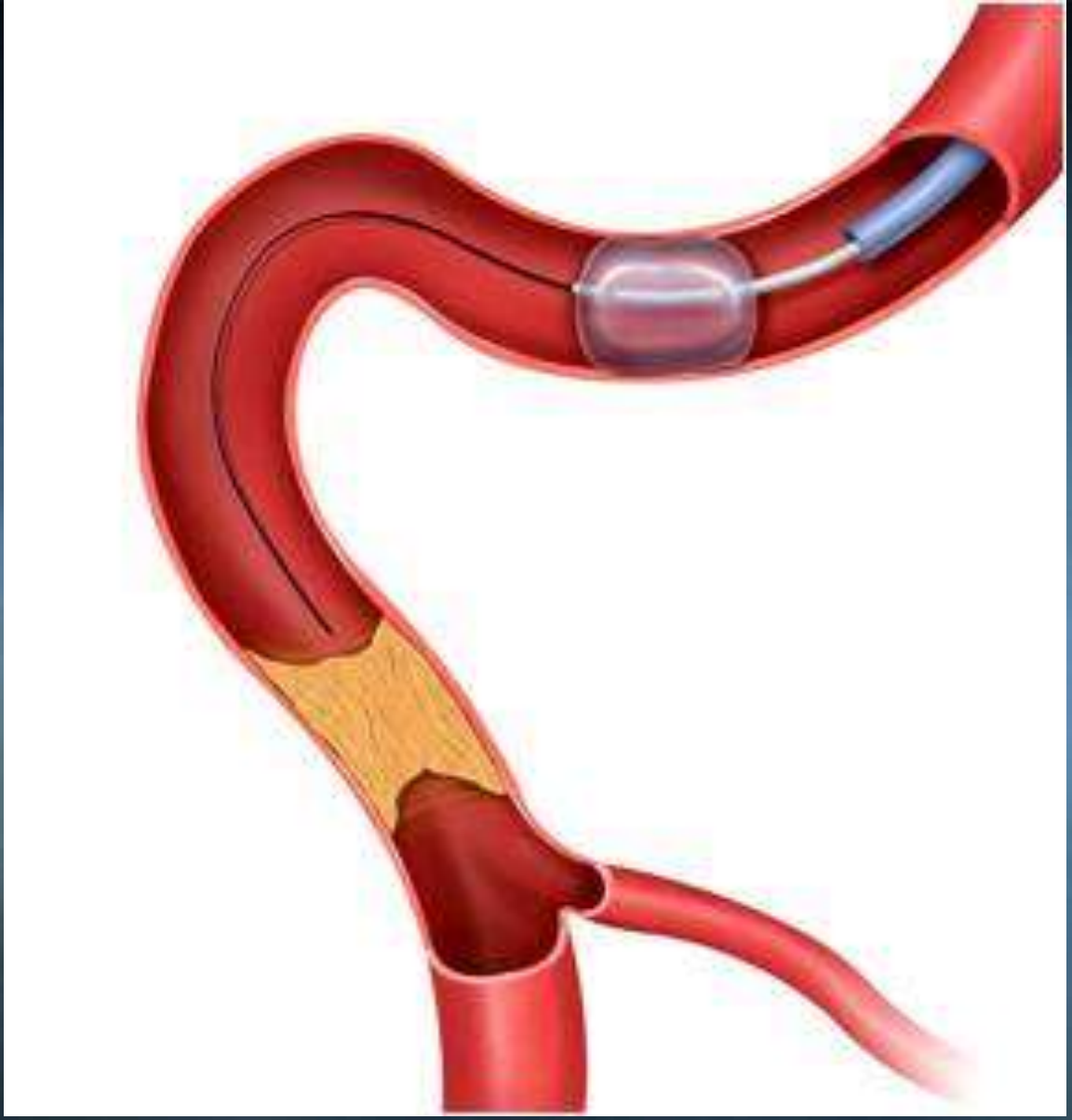


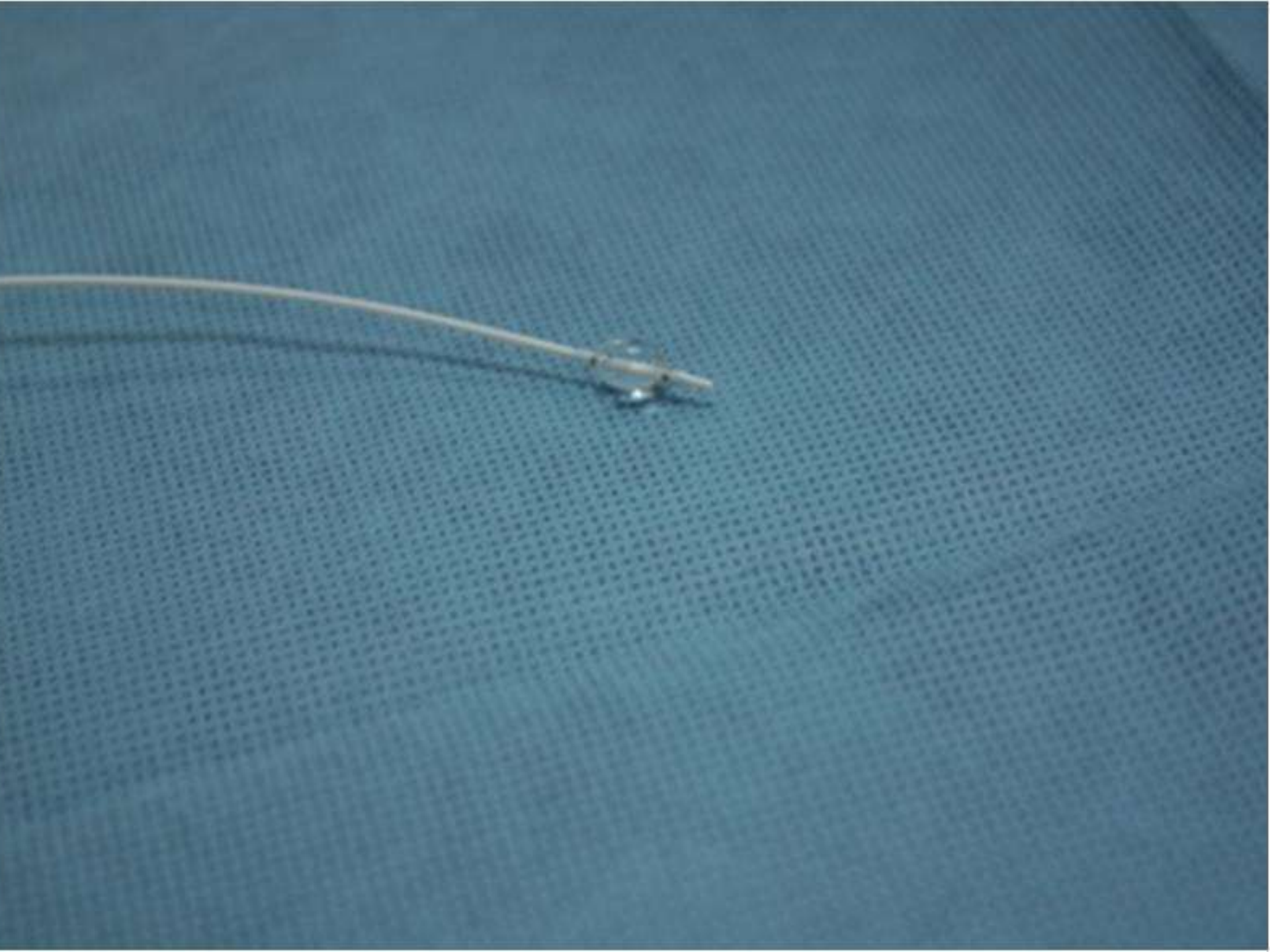
9 Cases

- 7 RCA
- 1 Cx
- 1 LAD
- All successful
- All radial
- 7 outpatients

The Prodigy catheter makes the antegrade procedure go more quickly and you can accelerate wire usage to easily cross most lesions. This approach has significantly reduced our procedures times and necessity to use the retrograde approach in CTOs.







A 75 year old woman presents with resting left foot pain. Her ABI on the left is .5

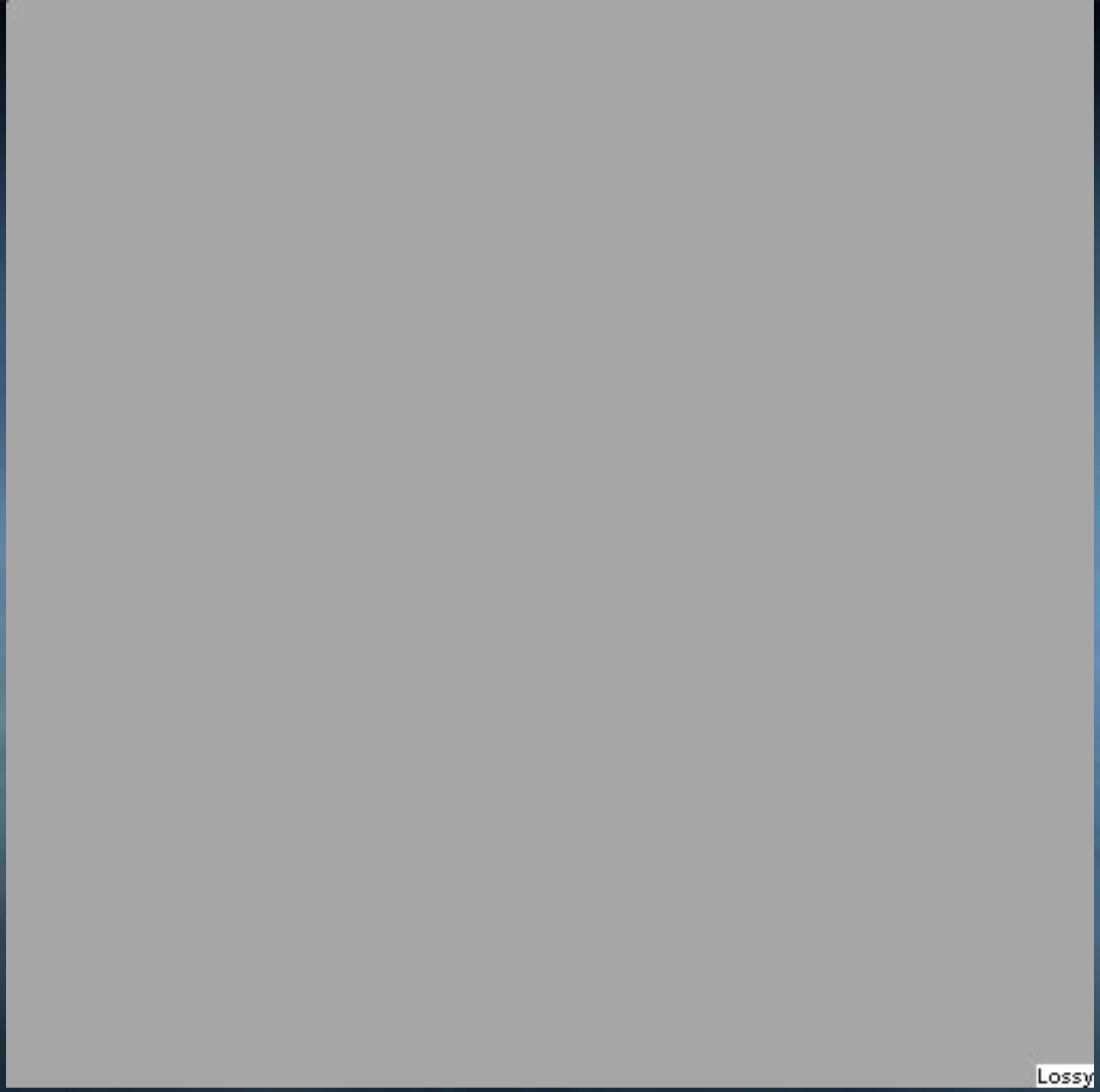

Lossy


POKIPALA, MARY
02312549
3/23/1939 F
2/11/2015
3:03 PM
Run 6 - Frame 1 / 17
Phoenix St. Lukes
63kV, - mAs, 244mA, 3ms
Zoom 100%
ViperTrack™ 50
100
RAO -9.0°
Cranial 0.1°
L 128
W 256

R. Heuser

ViperTrack™
50
100
150
Lossy

Fibertrack
50
100
Lossy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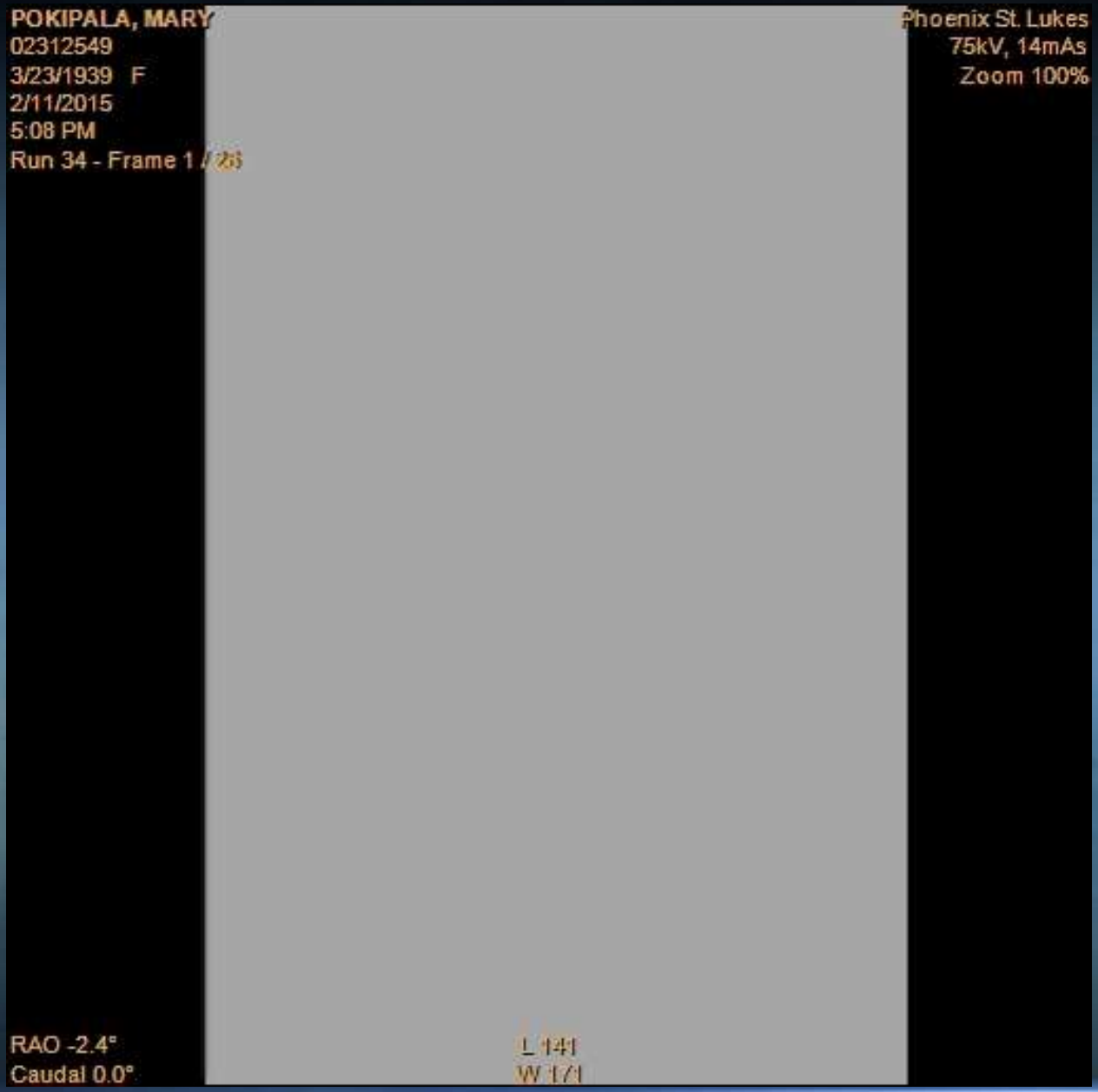
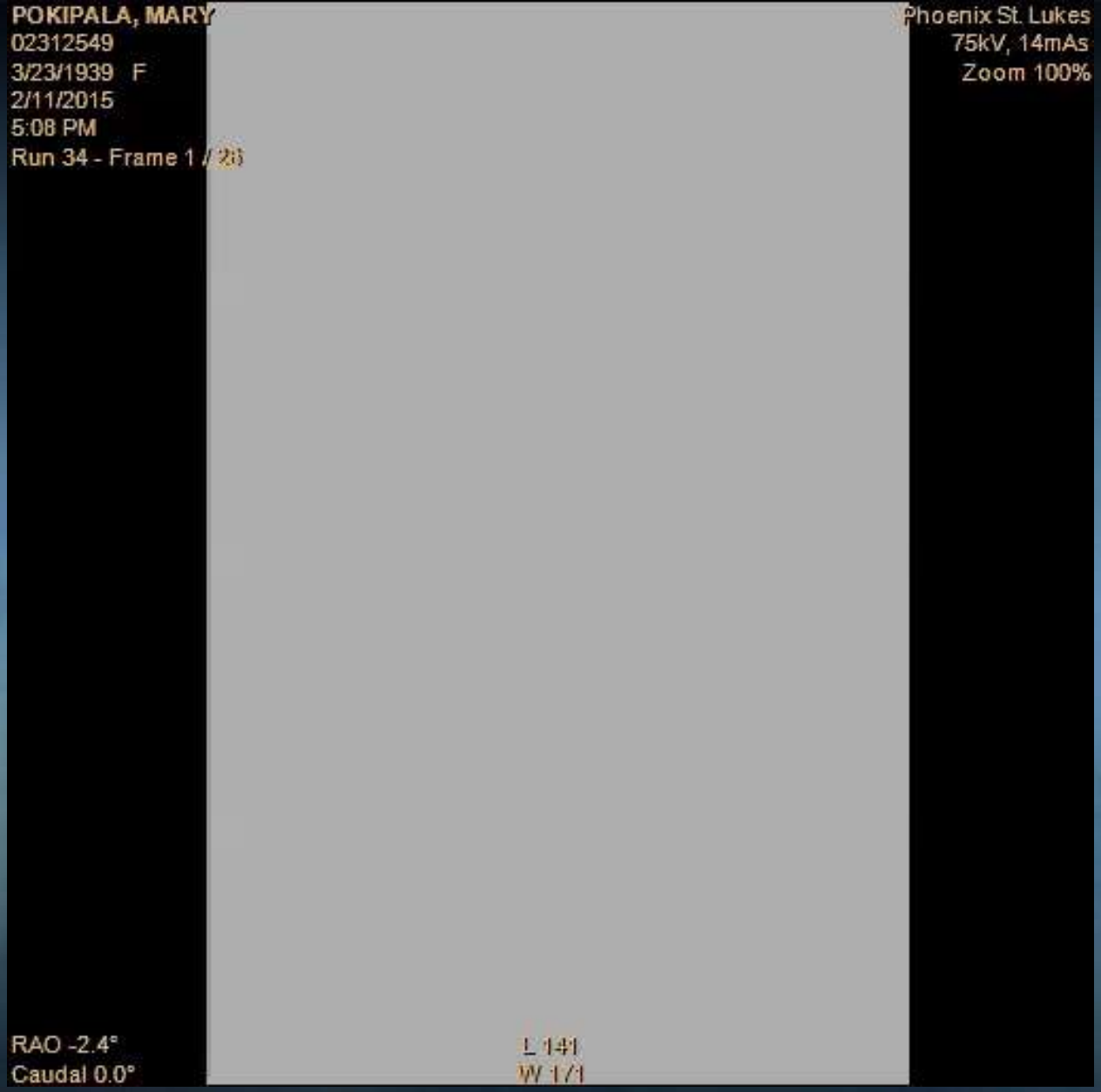

POKIPALA, MARY
02312549
3/23/1939 F
2/11/2015
5:08 PM
Run 34 - Frame 1 / 26
Phoenix St. Lukes
75kV, 14mAs
Zoom 100%
RAO -2.4°
Caudal 0.0°
L 141
W 171

R. Heuser


POKIPALA, MARY
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5:08 PM
Run 34 - Frame 1 / 26
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75kV, 14mAs
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RAO -2.4°
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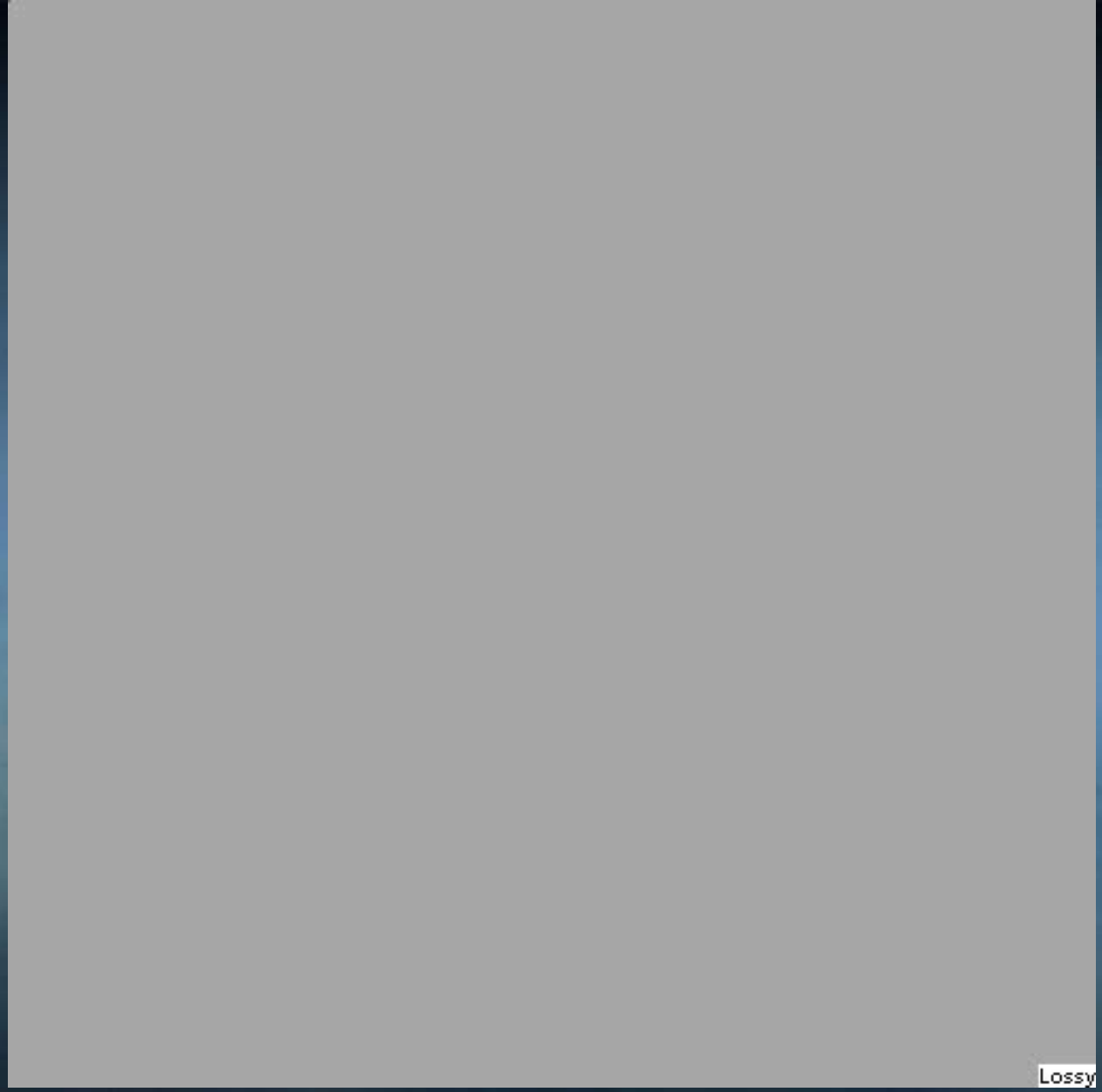
L 141
W 171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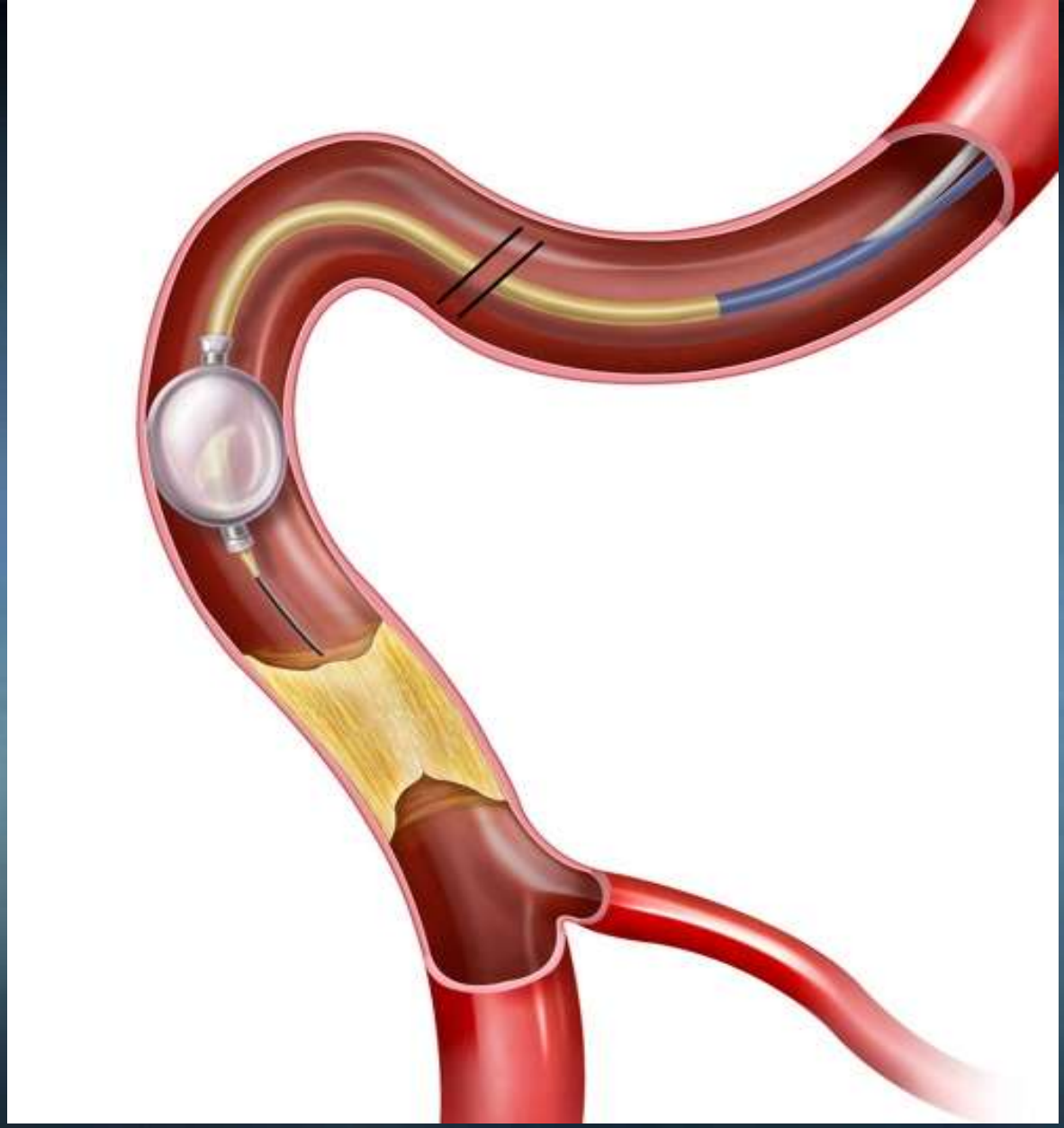
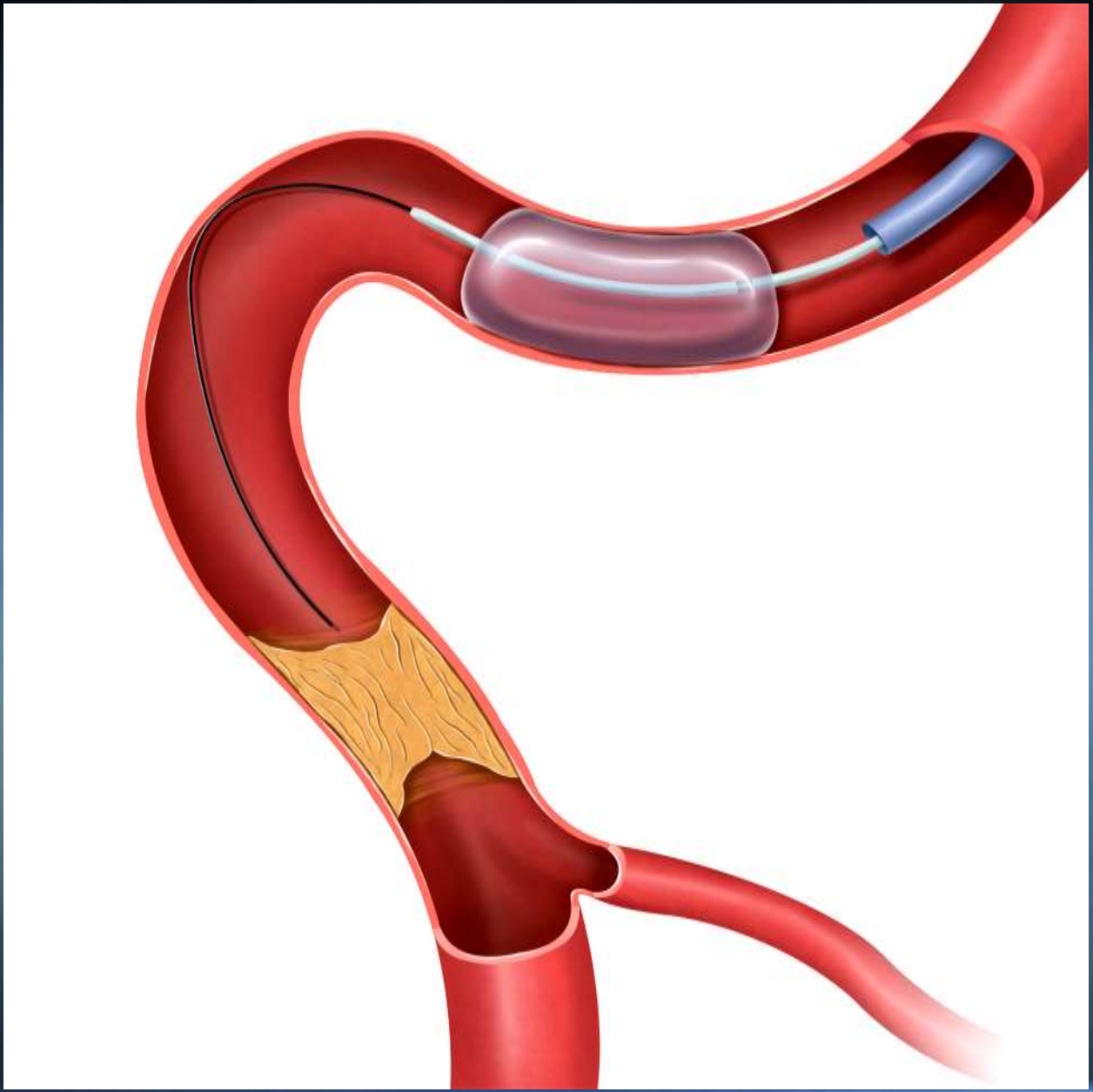
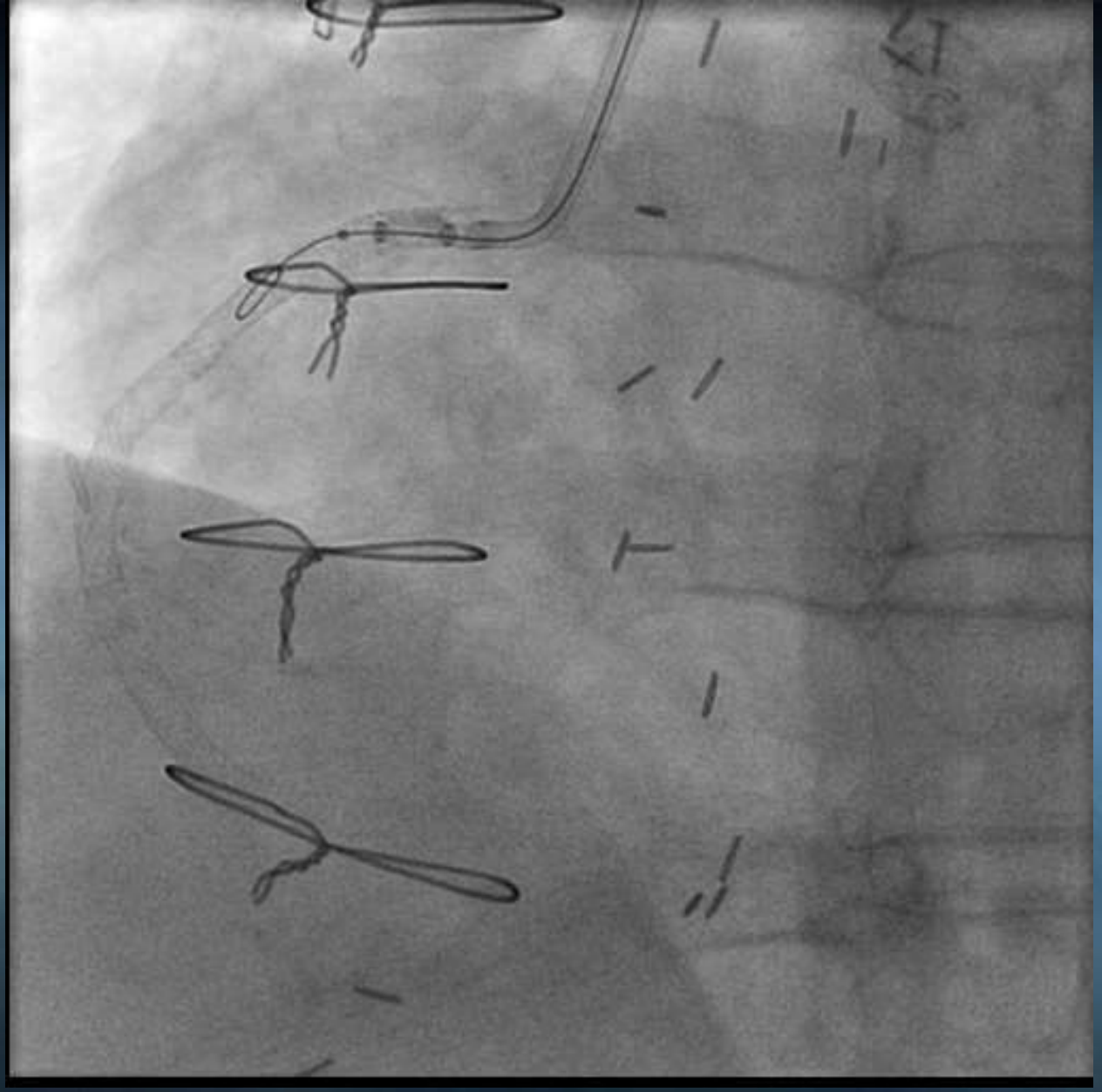
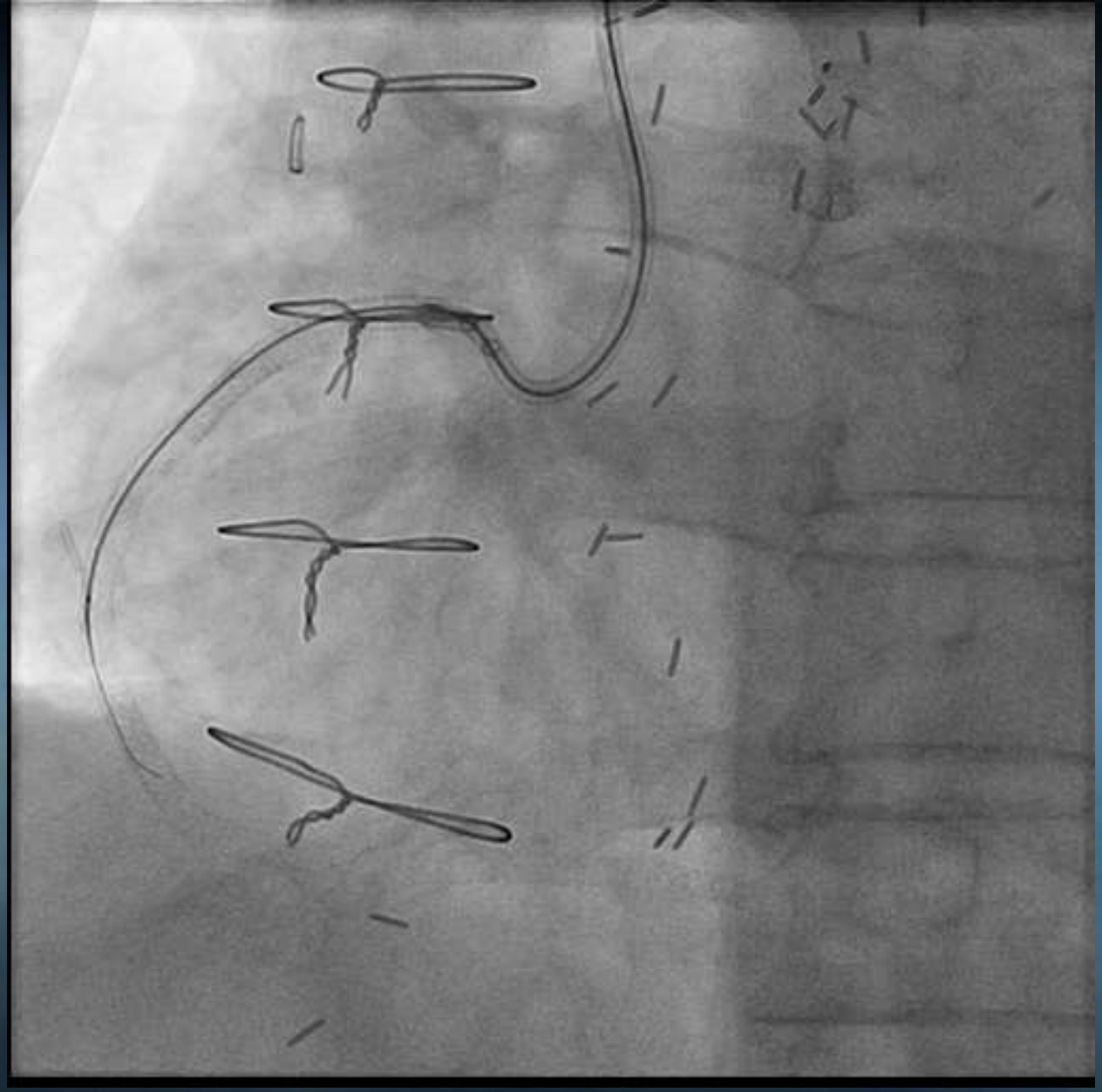


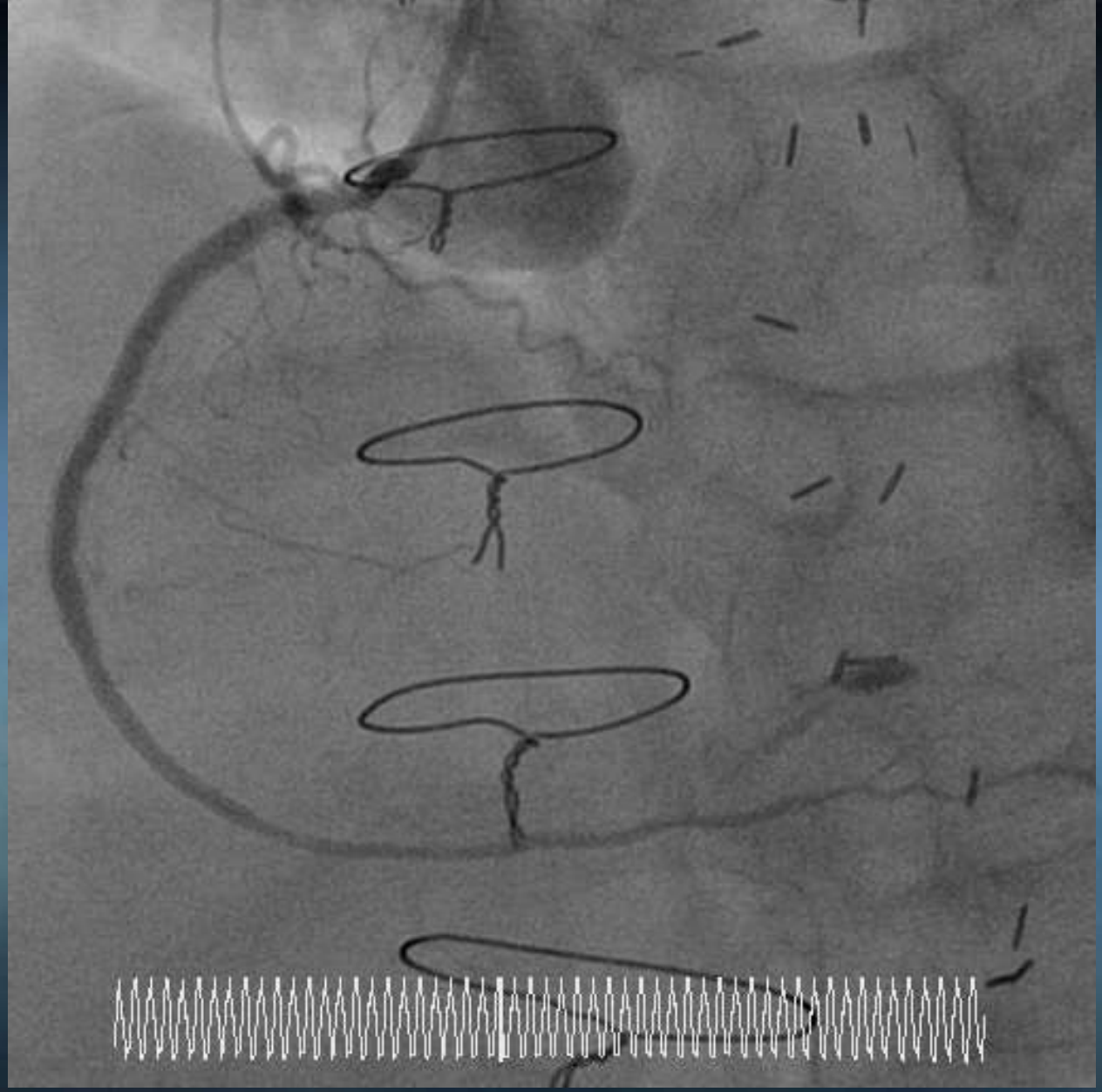


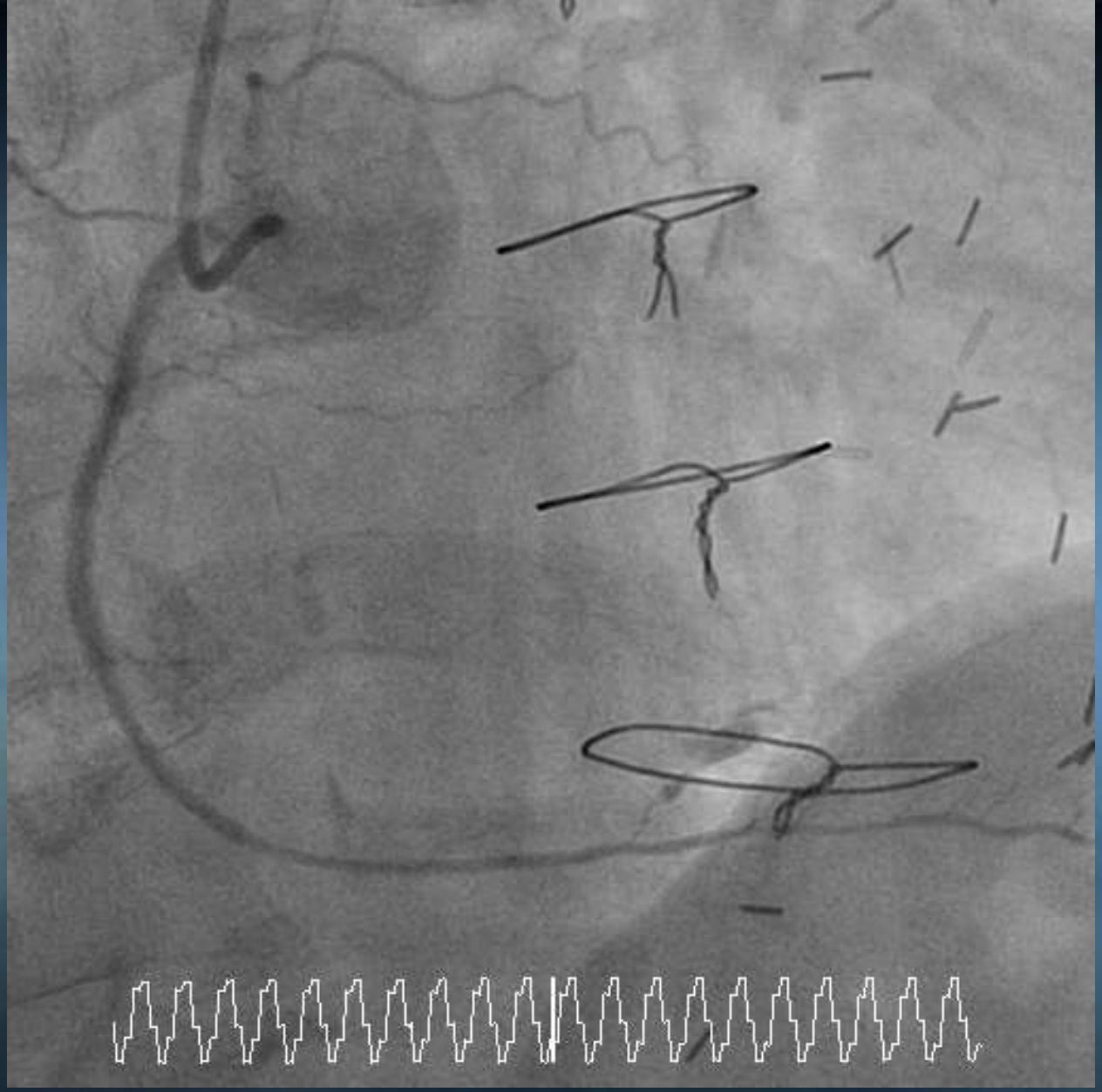
R. Heuser



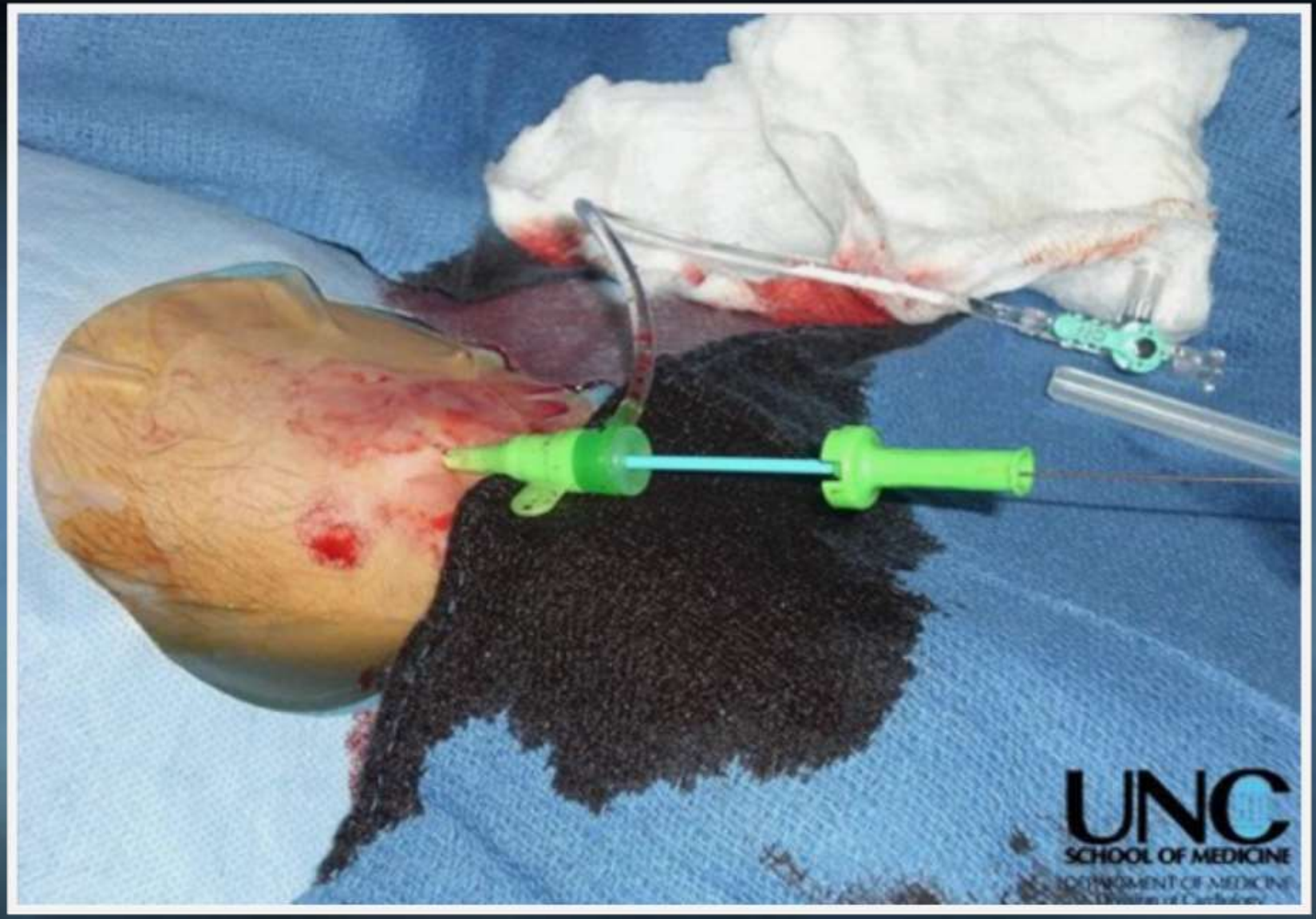


"LASERS"





In all of our successful CTO cases, the patients have had complete angina relief…which is always our primary goal.



R. Heuser

CTO: An Outpatient Procedure

- 9 cases
- Age 51-78
- 8 males
- 1 female
- 6 RCAs; 2 circumflex; 1 LAD
- All radial…discharged within 3 hours
- All discharged on Brilinta

Conclusion

- With CTOs, we preferentially try to approach with the radial approach particularly in RCA CTOs
- If there are no collaterals, we don't use contralateral injections
- If contralateral injection is needed, we prep the right groin and/or use 5F catheters or use the contralateral radial
- We sometimes discharge the same day

Continued…

…Conclusion

- We feel that the radial first approach should be considered even in CTOs
- With patients who require the an LV support device because of bad LV function, we usually go from the groin
- Collateral injections can still be performed biradially if necessary

To be an interventionalist, you should be able to safety treat multivessel disease in selected patients…including CTOs

With Proper Case Selection and Experience, There is No Reason That Most (80%-90%) of CTOs Cannot Be Successfully Opened

In select cases, we are now performing interventional CTO procedures on an outpatient basis.

Cardiovascular Disease Management:
A Case-Based Approach

October 1-2, 2015 • Arizona Biltmore Hotel, Phoenix, Arizona

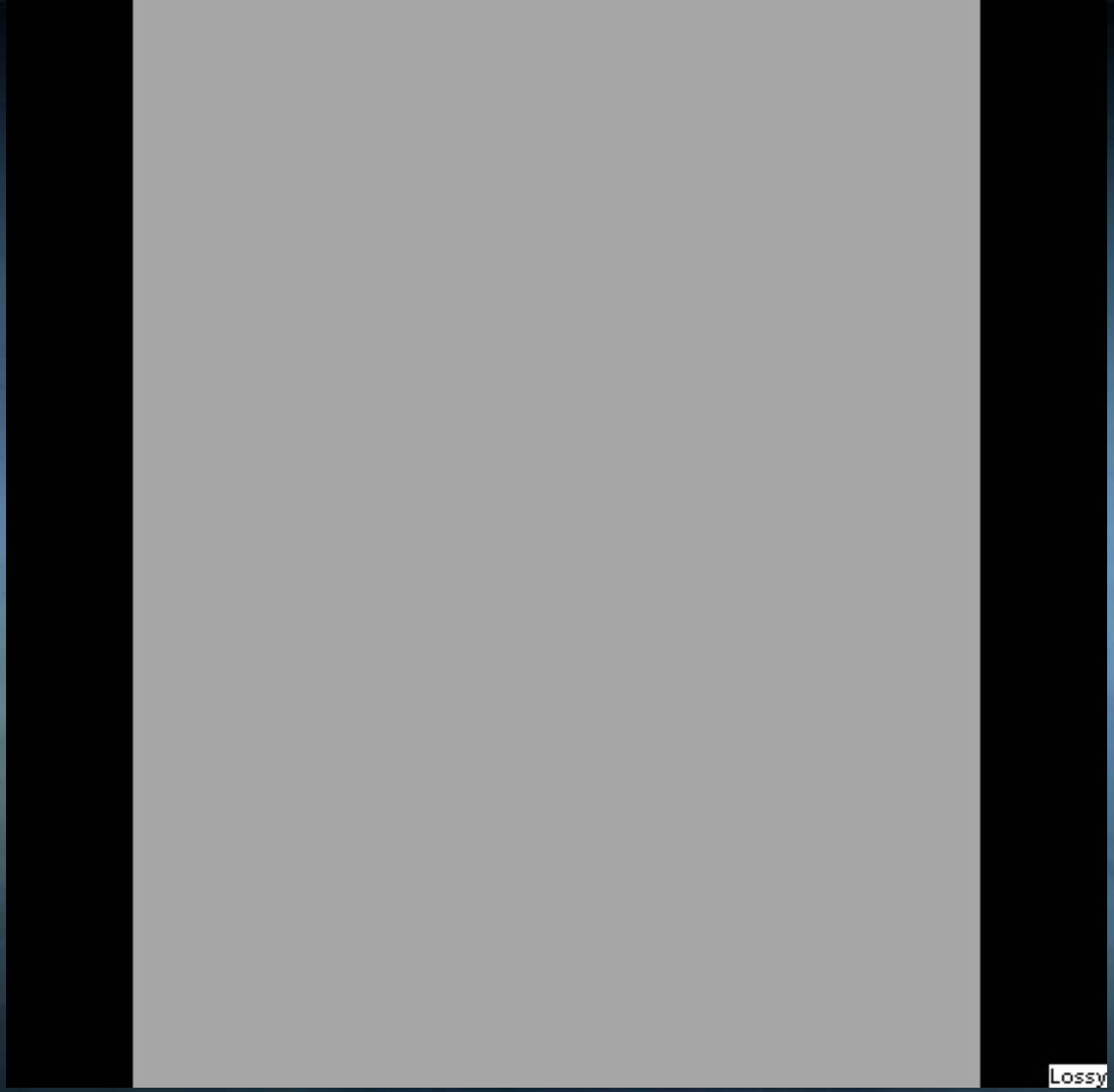
American College of Cardiology | California Chapter

American College of Cardiology | Arizona Chapter


R. Heuser


R. Heuser

Seventy-eight year old gentleman presents with left leg resting claudication. His past history includes Type I diabetes mellitus, as well as known coronary artery disease. Six months prior to this procedure, he underwent right leg intervention for similar symptoms. He has never had any non-healing ulcers. He also has been extremely compliant both in his diet, cholesterol management and diabetes treatment.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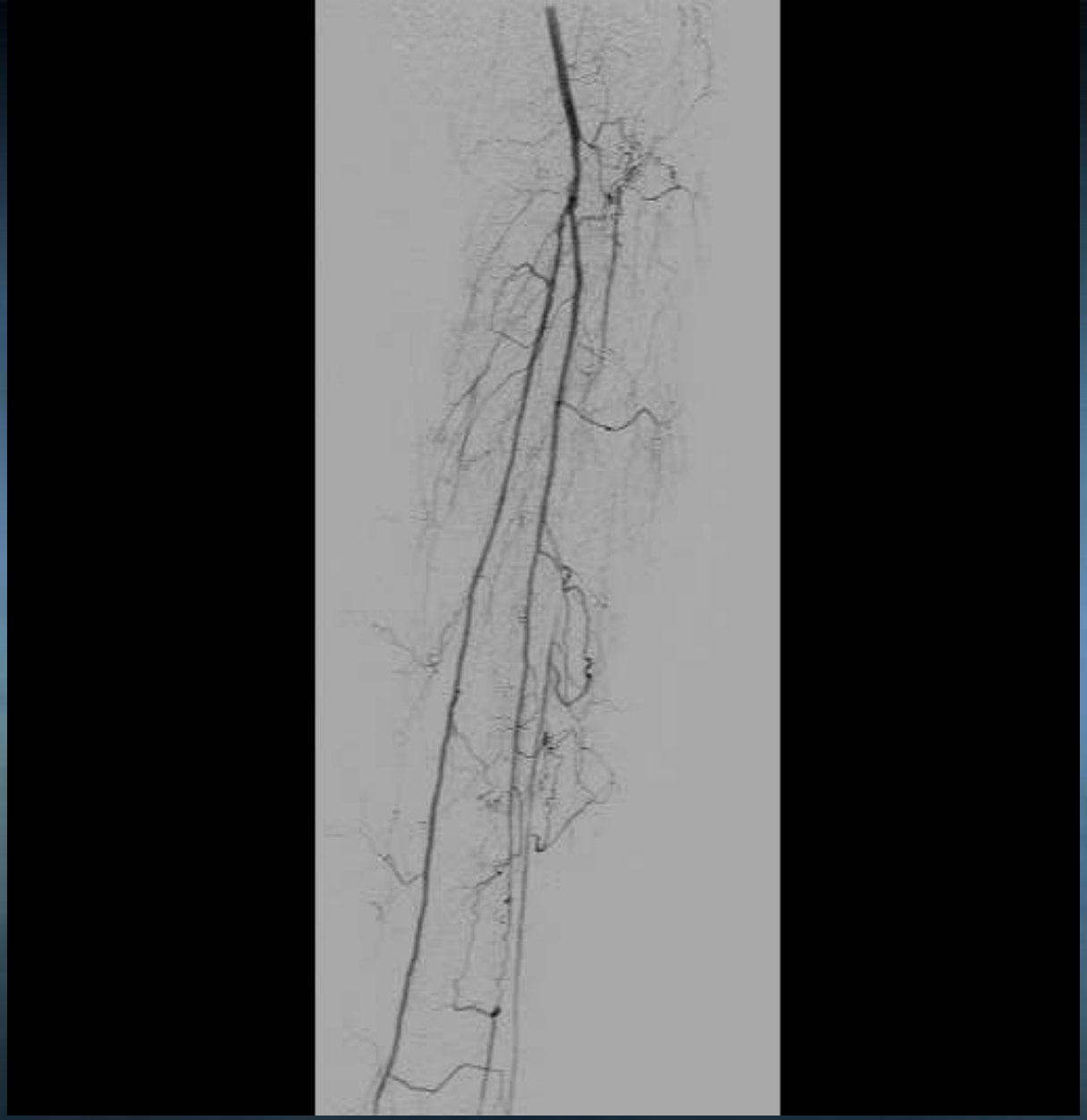

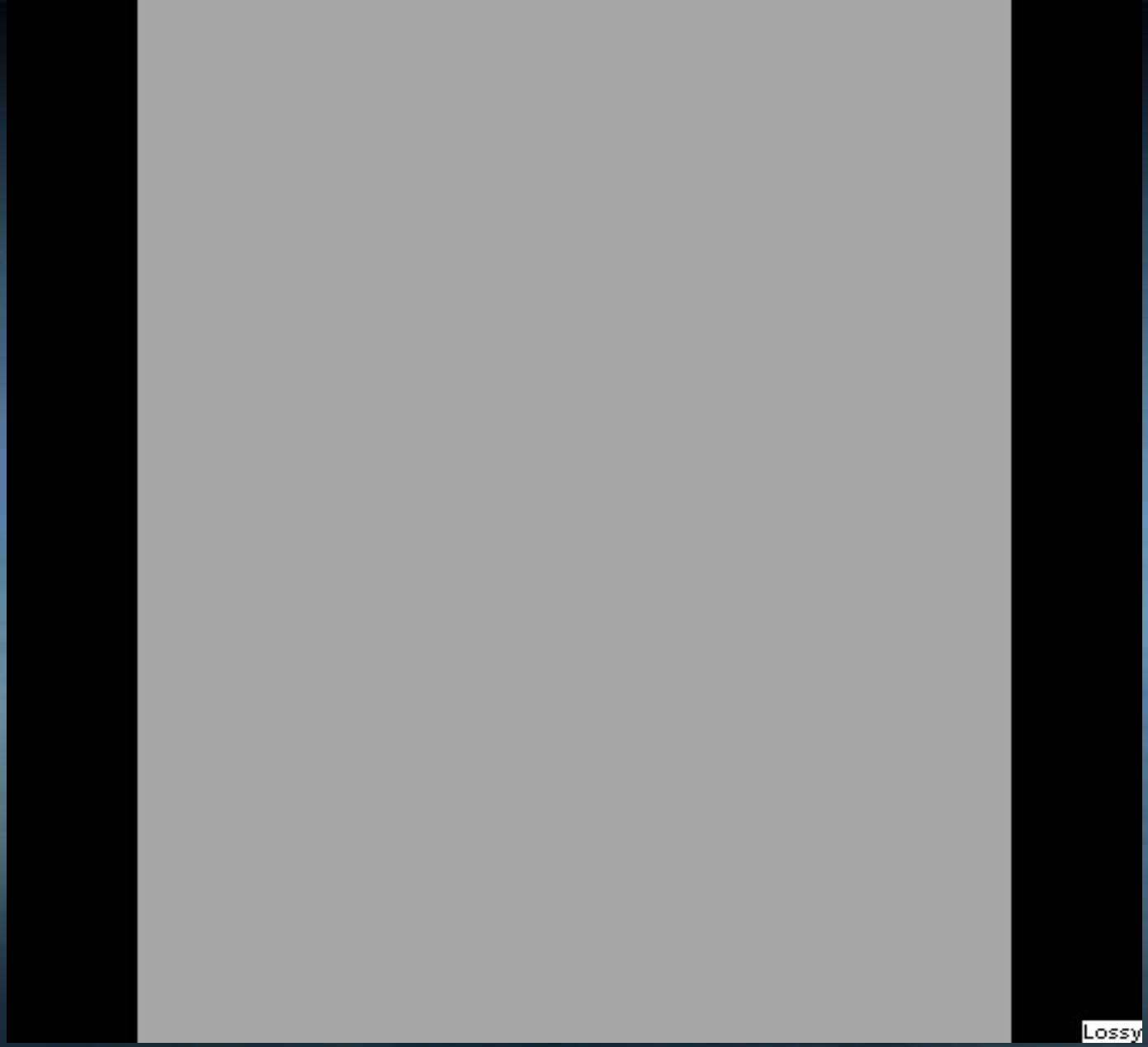
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R. Heuser

50
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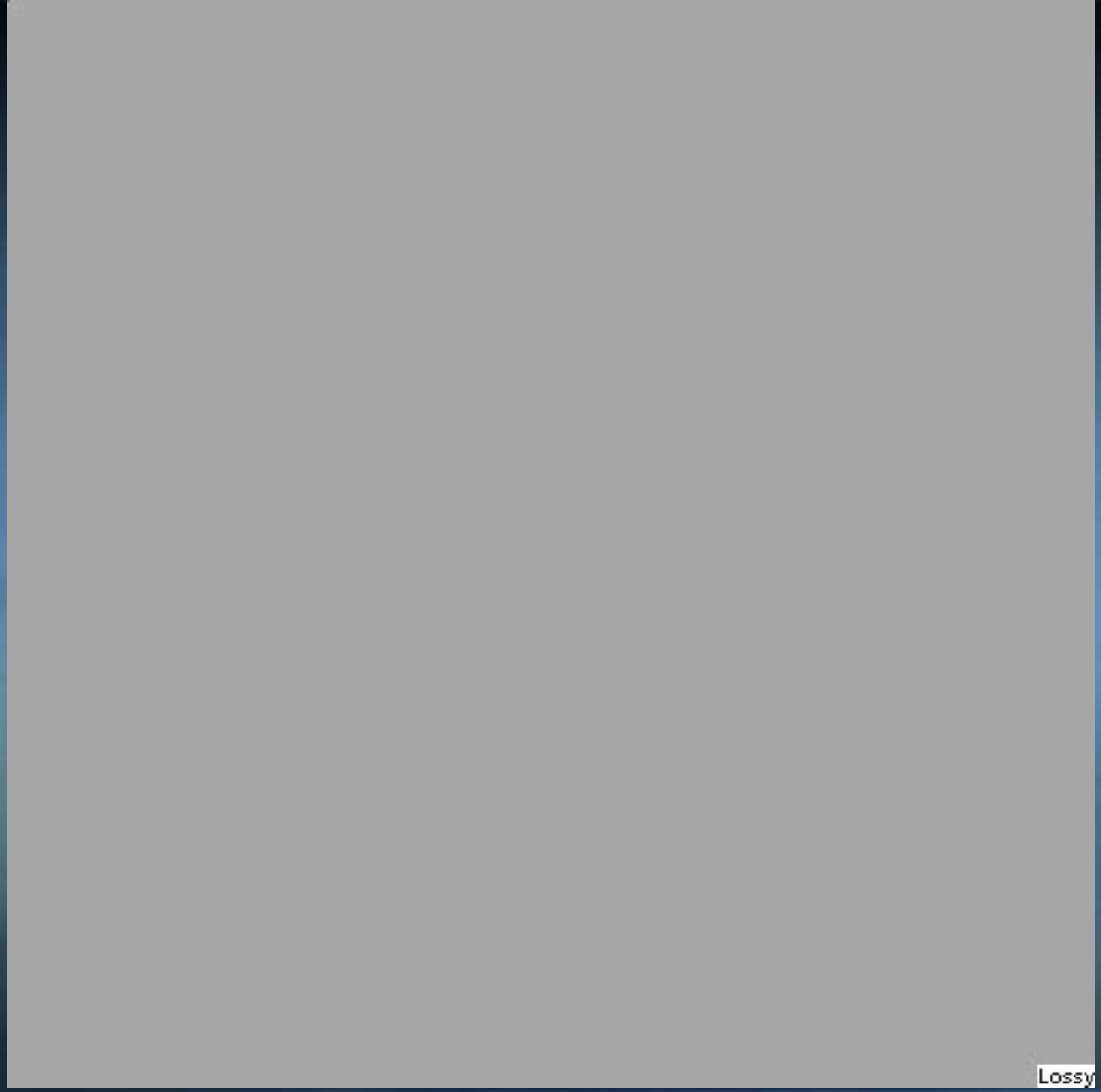
Lossy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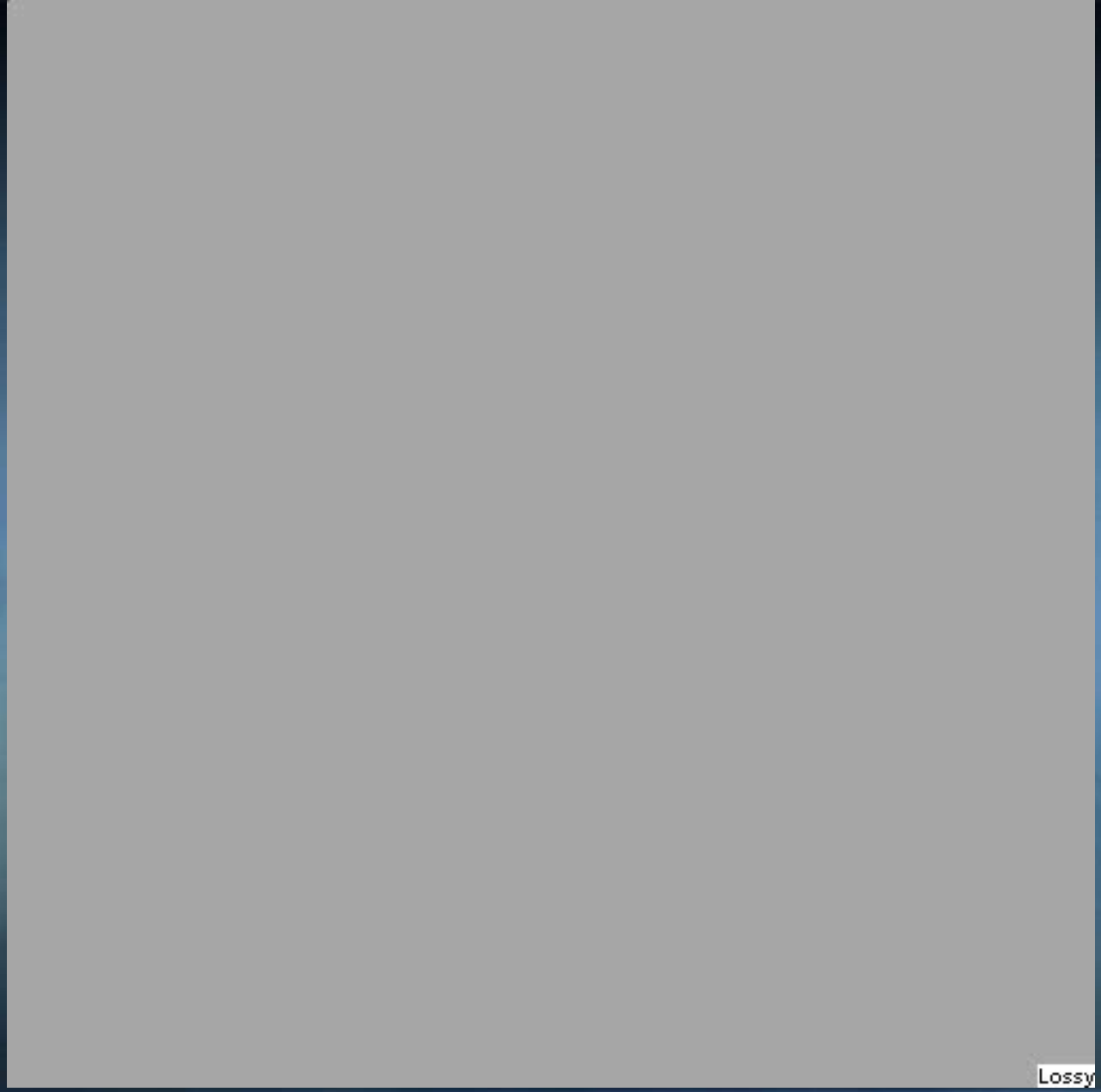
Lossy

R. Heuser

150
200
250

50
100
150
200


200

50
100
150
200
250

…Conclusion

- In spite of our Herculean efforts, CMS may go after us if we re-admit these patients because of vascular complications

Continued…