Severe Calcified Lesions

What strategy do you choose?

Rotablation? CABG?

There is an easier way!

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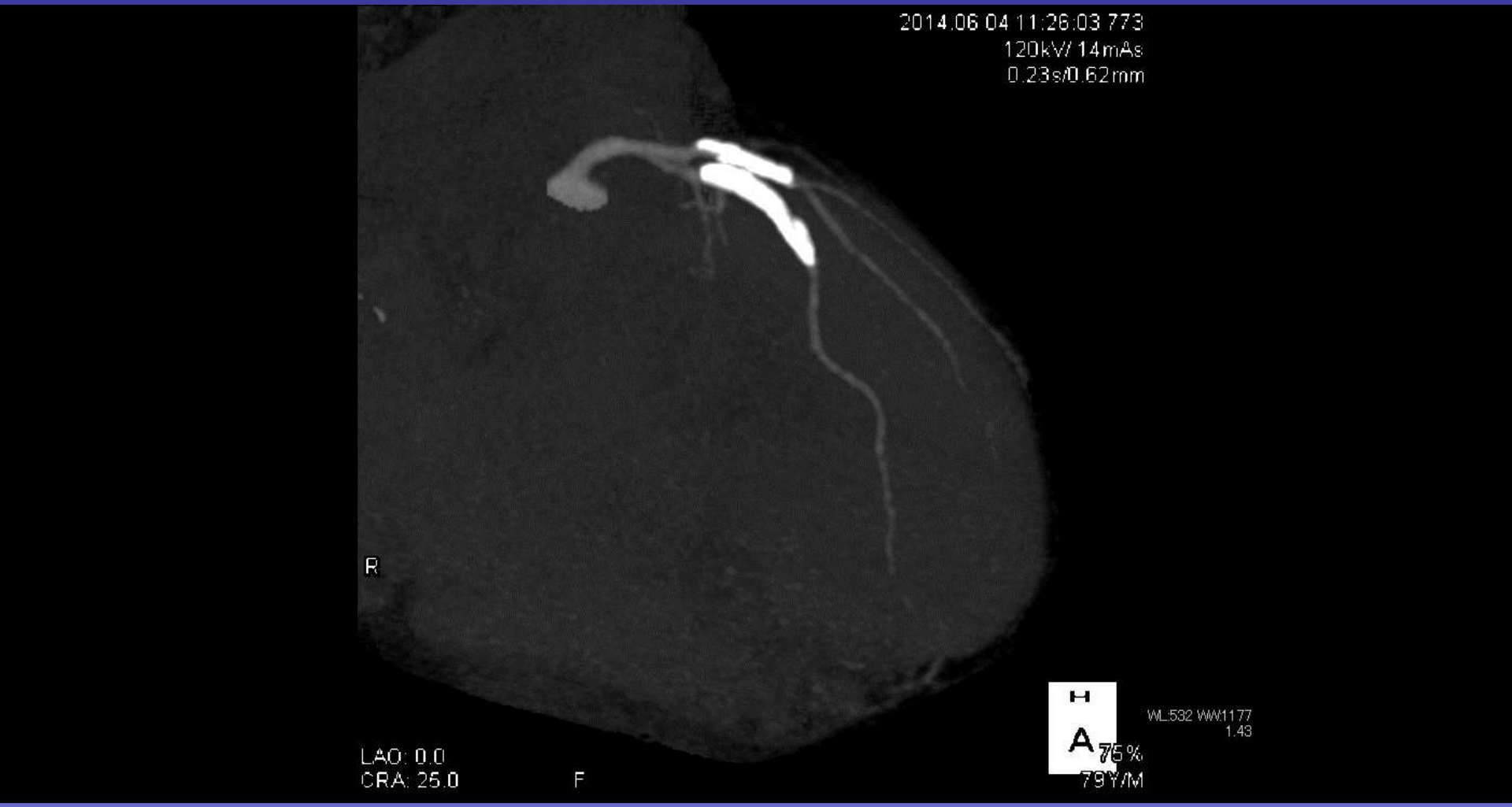
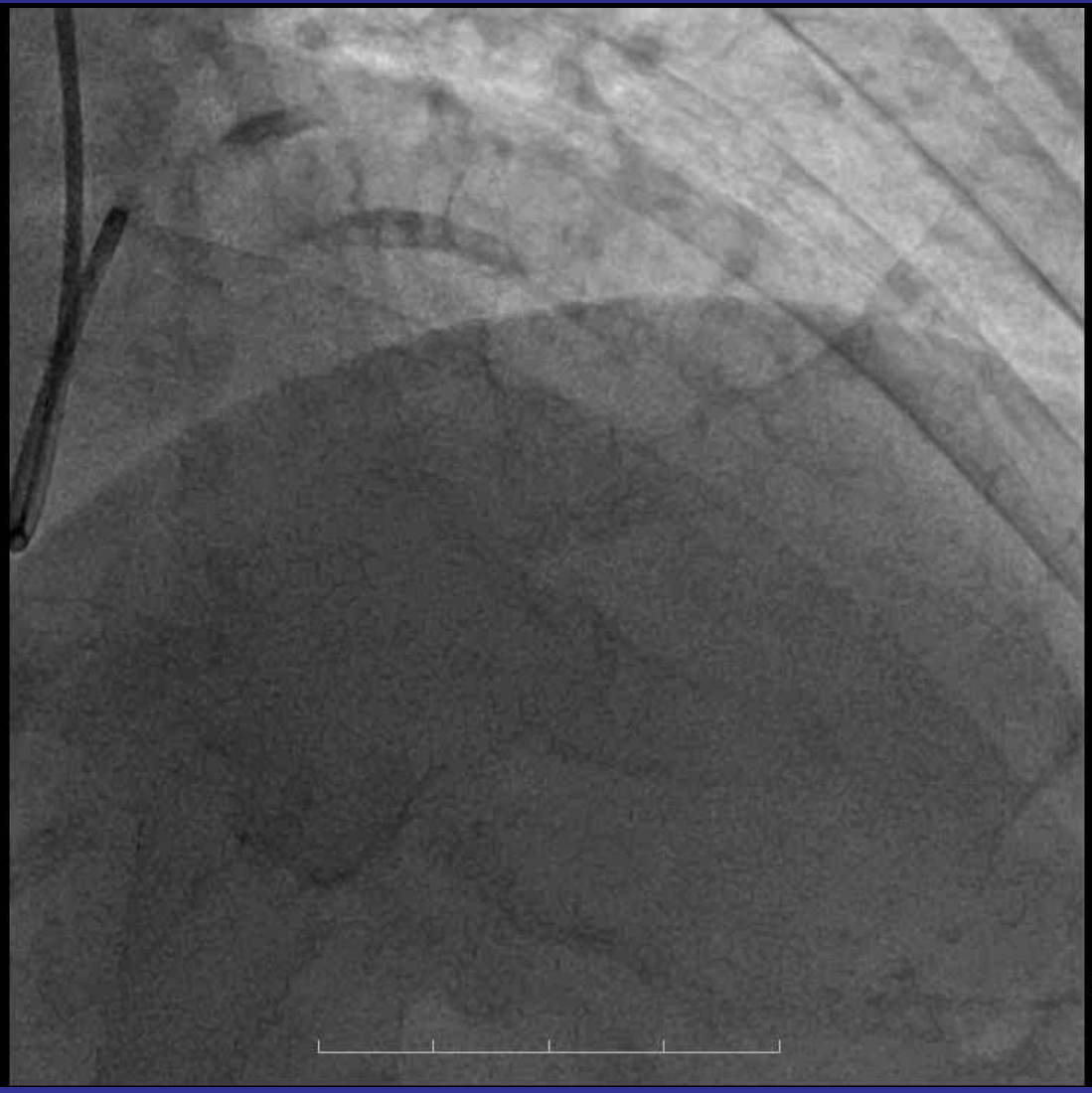
Disclosure Statement of Financial Interest

I, (Kazuhiro Ashida) DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

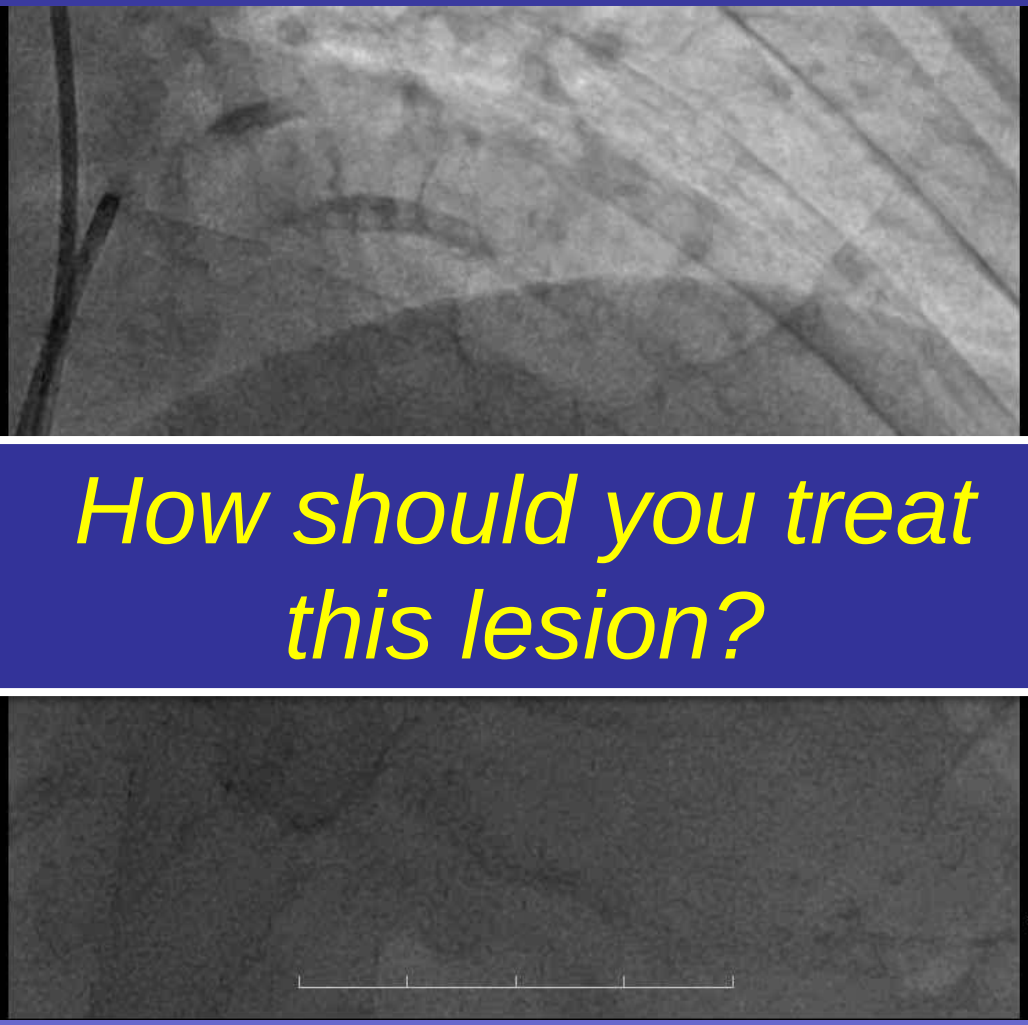
Case:
Severe calcification in LAD



Pre CAG



Pre CAG



How should you treat this lesion?

Severe calcification

✓Rotablator?

Good and reasonable option

Large guide catheter is needed.

Original complication; slow/no flow, bur stuck, high cost?

✓CABG?

Open surgery; might be performed CABG to the only one vessel lesion?

Severe calcification

✓Scoring balloon

Especially Lacrosse NSE; good option!!

Relatively easy, and low cost

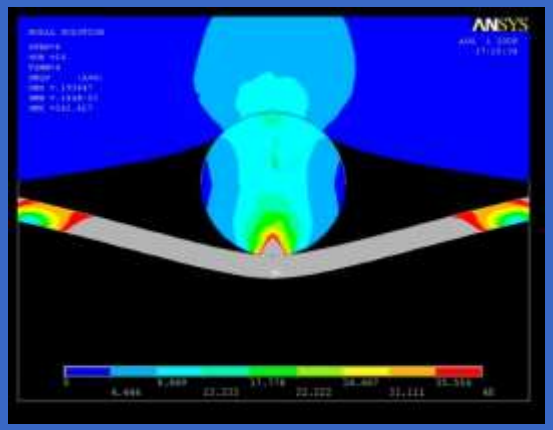
At our hospital, we treat *all* the severe calcification lesion by *Lacrosse NSE* with *Leopard Crawl technique*!!

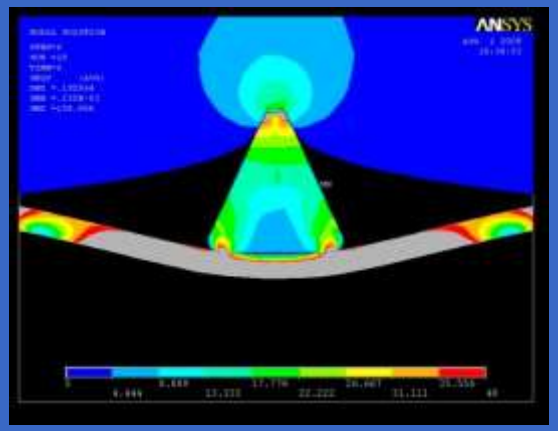
Lacrosse NSE : Element

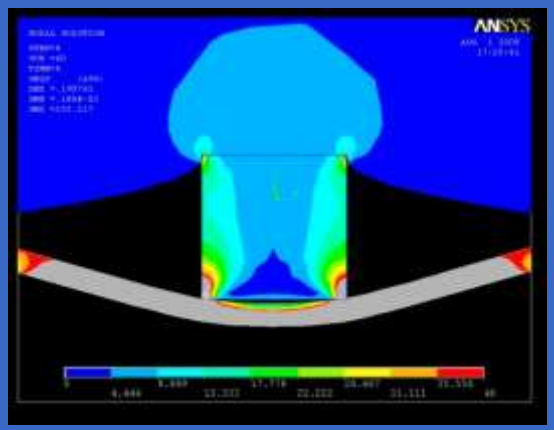
3 elements

The Elements are attached at the Distal and Proximal ends only

Lacrosse NSE : Element



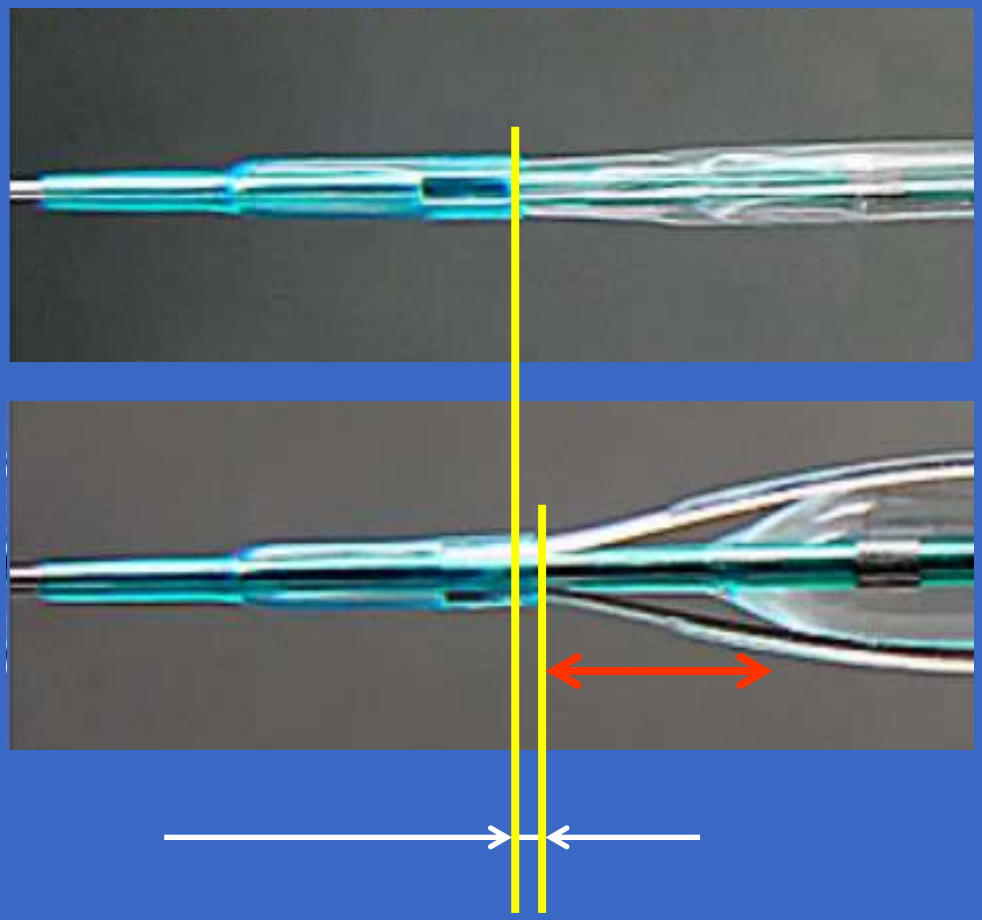




NSE

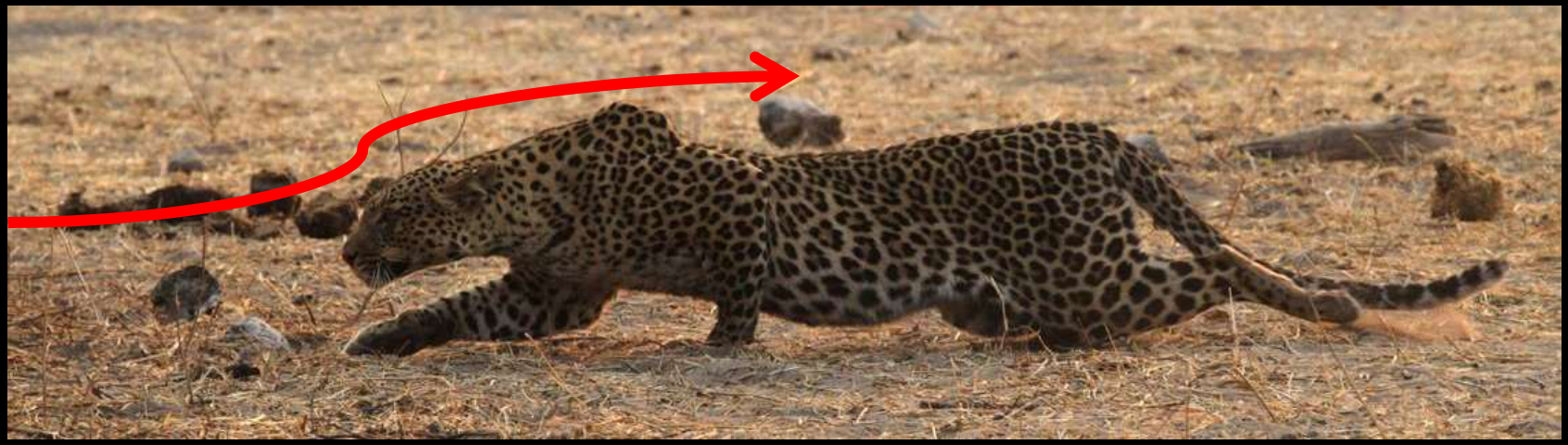
The triangular shape of the NSE element provides for the greatest concentration of force to create a cracking effect.

The elements are connected beyond the distal (and proximal location) of the balloon.

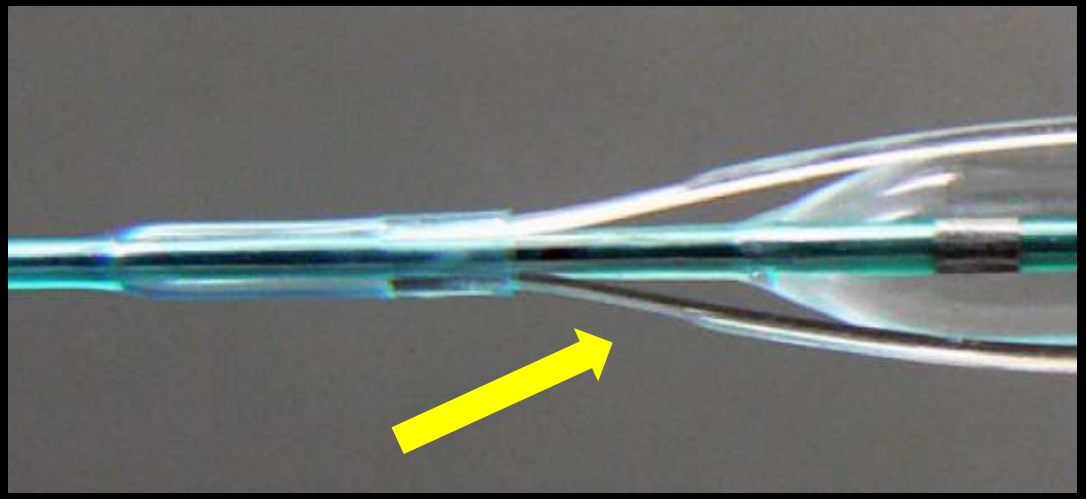


Even when the balloon is not able to advance to target lesion, it is considered that the elements provide a wedge that formulate a cracking effect.

Leopard crawl



The wedge shape provides a gap to allow the catheter to advance



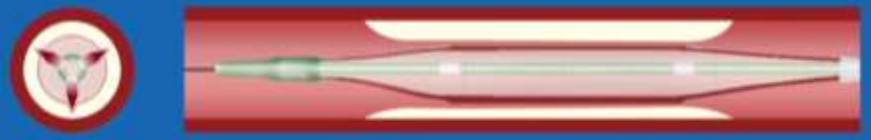
Flow chart of Leopard Crawl Technique

1. Calcified lesion

2. Advance NSE catheter to lesion location

3. Dilate NSE at calcified lesion.
   Repeat Step 2 and 3 until catheter is advanced distally

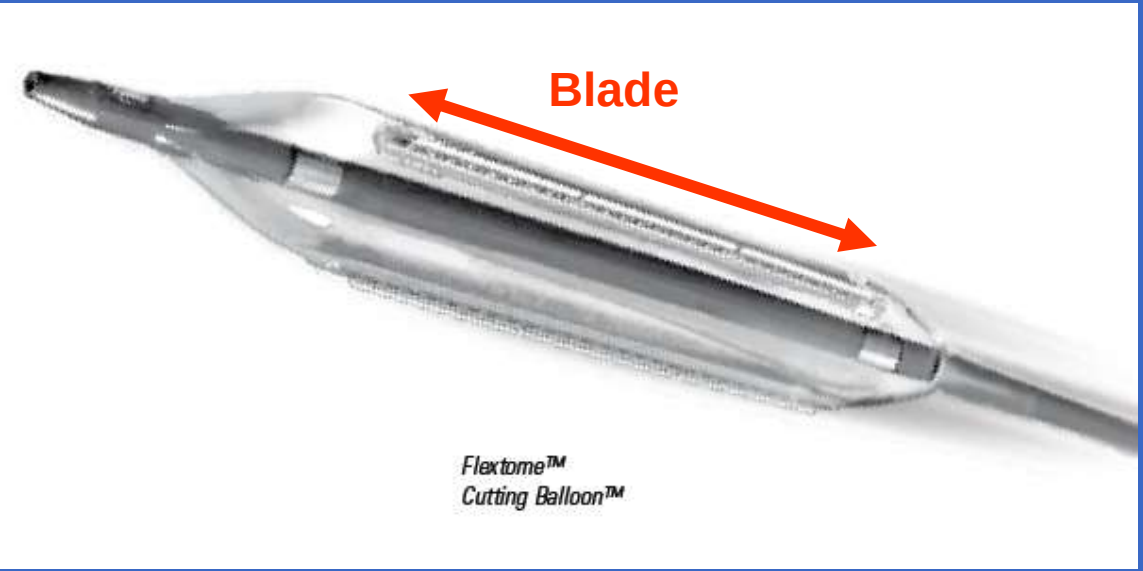
4. Scoring of calcification facilitates catheter advancement



5. Fully dilate lesion with NSE

6. Scoring effect throughout full length of calcified lesion

Cutting balloon



Whether leopard crawl can be utilized relies on the re-wrapping of the balloon

The blade component is shorter than the balloon

Post-deflation of various balloons

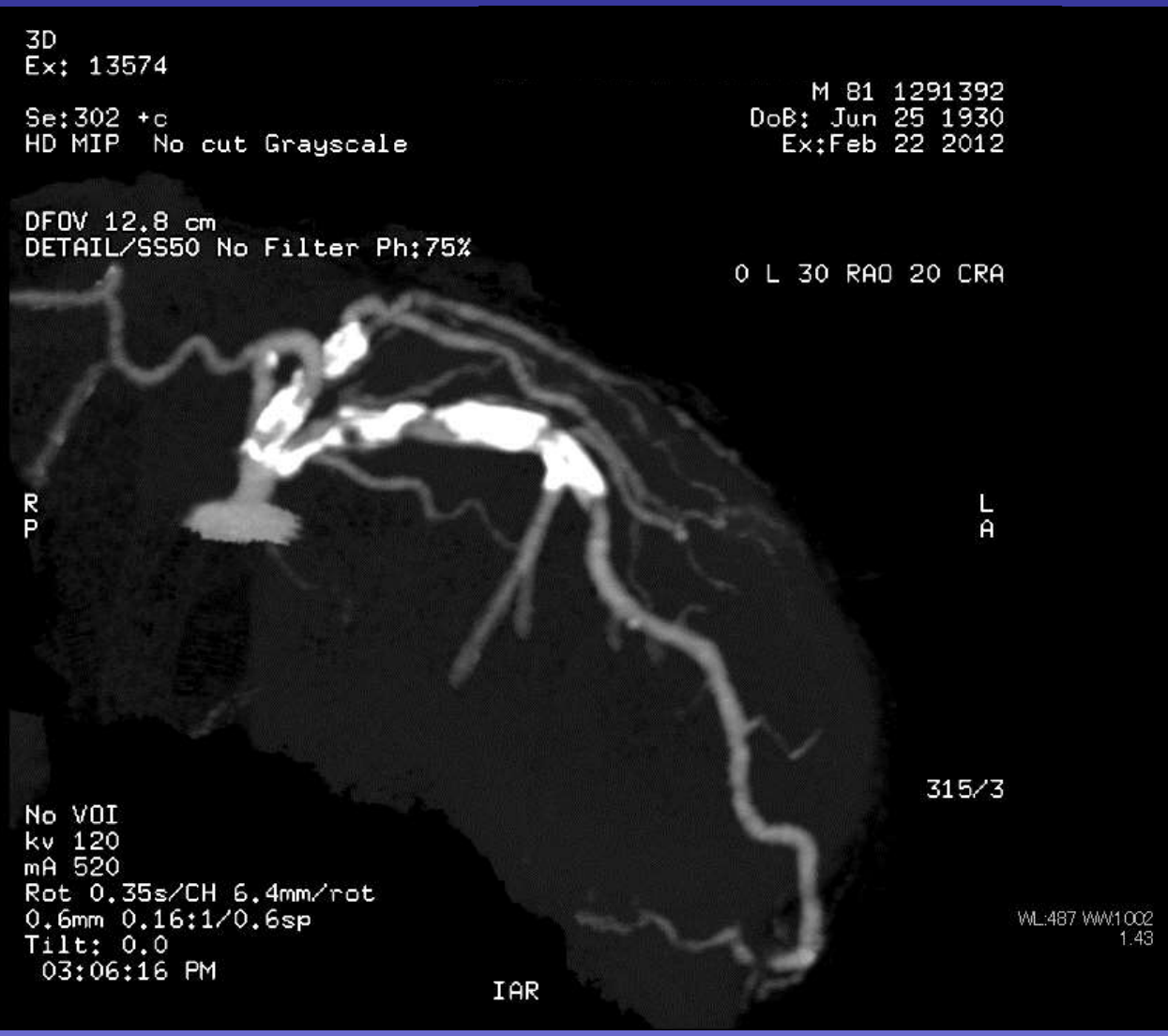
The design of Lacrosse NSE provides for the easiest catheter advancement through calcified lesions as well as having the greatest cracking functionality.

Pre Lacrosse NSE

Post Lacrosse NSE

Case 1:

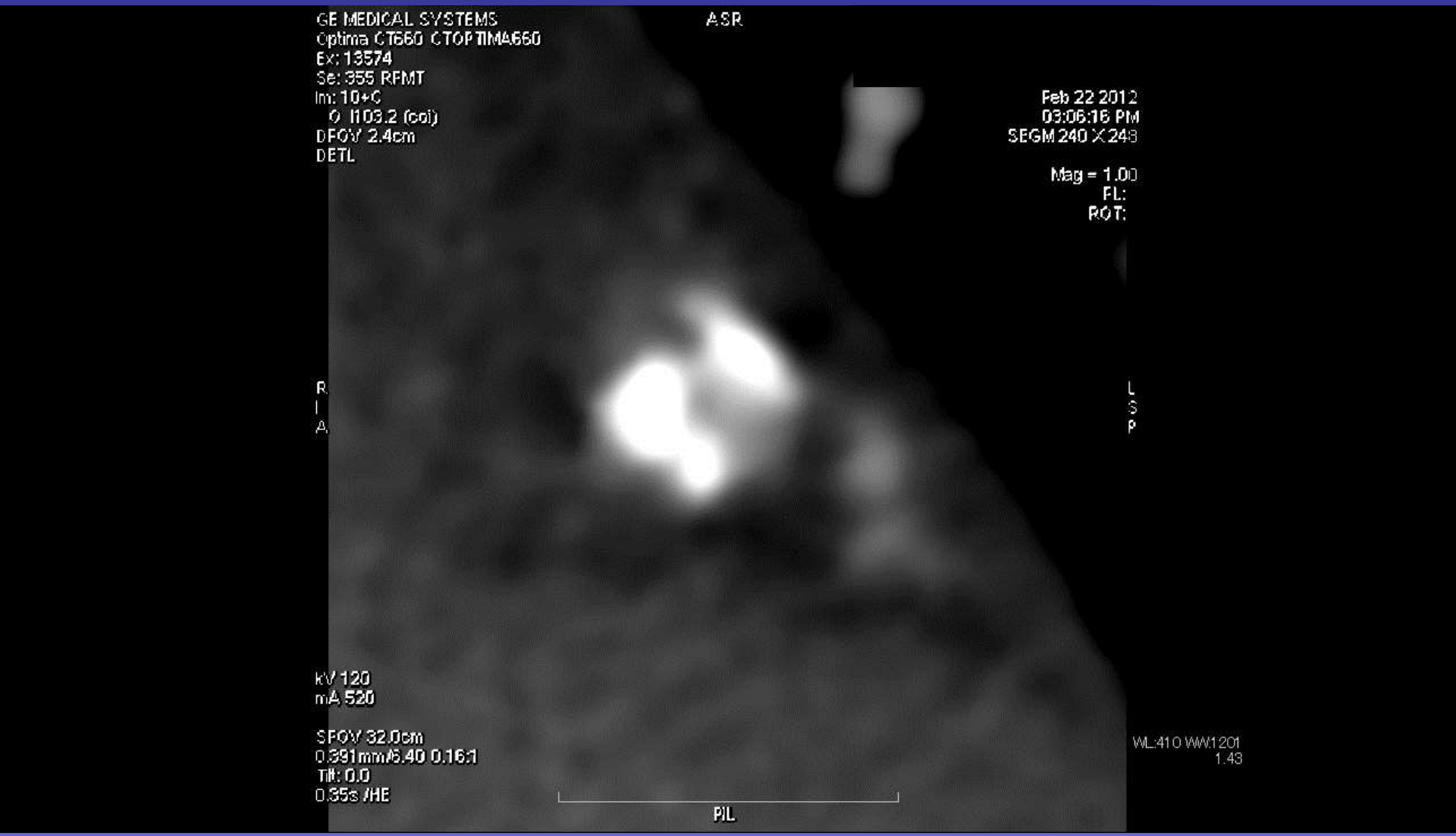
Diffuse, severely calcified lesion


3D
Ex: 13574
Se:302 +c
HD MIP No cut Grayscale
M 81 1291392
DoB: Jun 25 1930
Ex:Feb 22 2012
DFOV 12.8 cm
DETAIL/SS50 No Filter Ph:75%
0 L 30 RAO 20 CRA
R
P
L
A
315/3
No VOI
kv 120
mA 520
Rot 0.35s/CH 6.4mm/rot
0.6mm 0.16:1/0.6sp
Tilt: 0.0
03:06:16 PM
IAR
WL:487 WW:1002
1.43


Curved
Ex: 13574
I
M 81 1291392
DoB: Jun 25 1930
Ex:Feb 22 2012
Se:302 +c
LAD Angle: 60.0
DFOV 17.7 cm
DETAIL/SS50 Ph:75% No Filter
R
L
318/5
kv 120
mA 520
Rot 0.35s/CH 6.4mm/rot
0.6mm 0.16:1/0.6sp 0.4/
Tilt: 0.0
03:06:16 PM
S
WL:410 WW:1201
1.43


Curved
Ex: 13574
P
M 81 1291392
DoB: Jun 25 1930
Ex:Feb 22 2012
Se:302 +c
LAD Angle: 135.0
DFOV 17.7 cm
DETAIL/SS50 Ph:75% No Filter
R
L
318/10
kv 120
mA 520
Rot 0.35s/CH 6.4mm/rot
0.6mm 0.16:1/0.6sp 0.4/
Tilt: 0.0
03:06:16 PM
A
WL:410 WW:1201
1.43


GE MEDICAL SYSTEMS
Optima CT660 CTOPTIMA660
Ex: 13574
Se: 355 RFMT
Im: 3+C
0 A33.4 (coi)
DFOV 2.4cm
DETL
SPL
Feb 22 2012
03:06:16 PM
SEGM 240 X 248
Mag = 1.00
FL:
ROT:
R
A
S
L
P
I
kV 120
mA 520
SFOV 32.0cm
0.391mm/3.40 0.16:1
Tilt: 0.0
0.35s /HE
WL:410 WW:1201
1.43
IAR


GE MEDICAL SYSTEMS
Optima CT660 CTOPTIMA660
Ex: 13574
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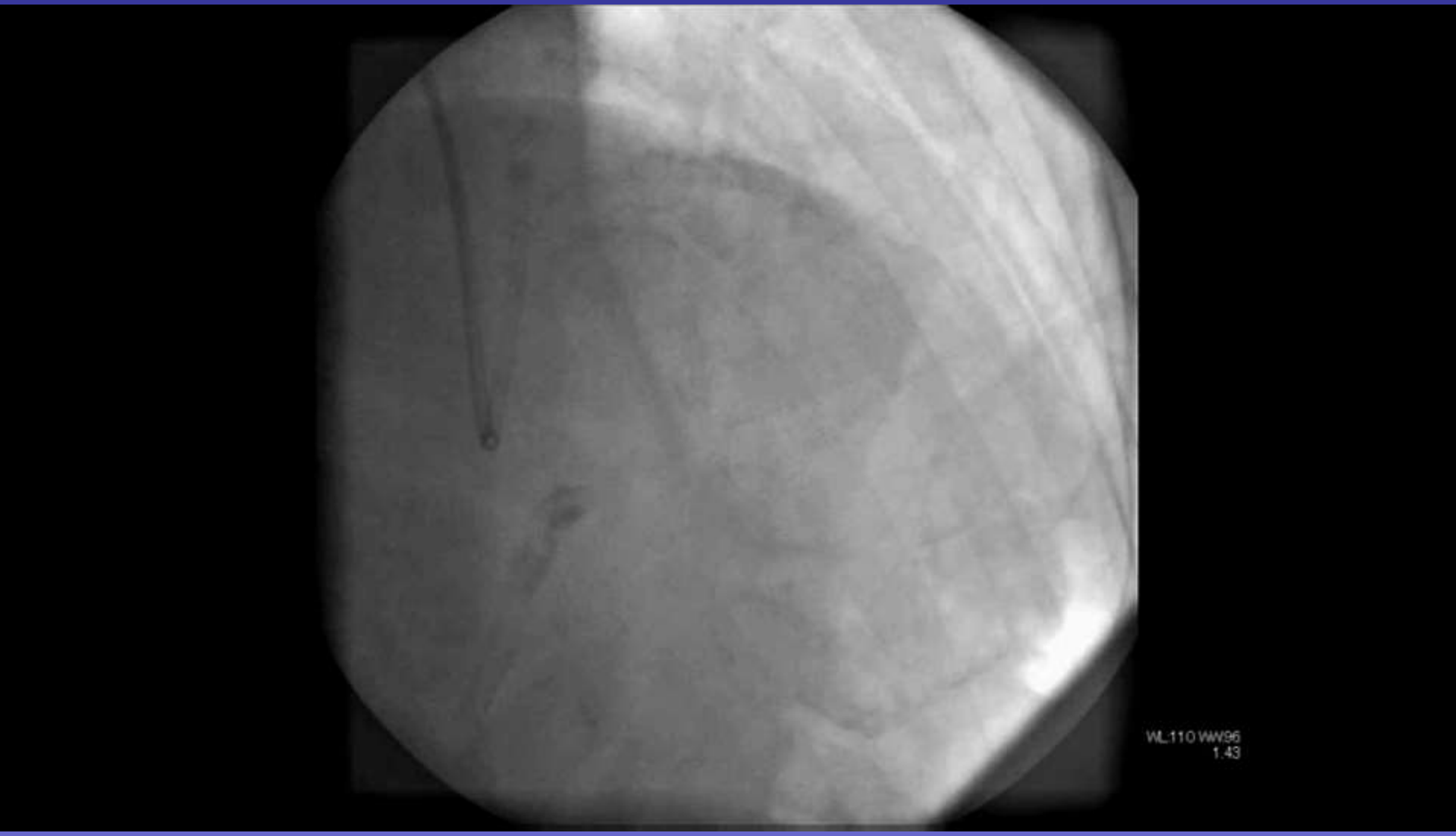
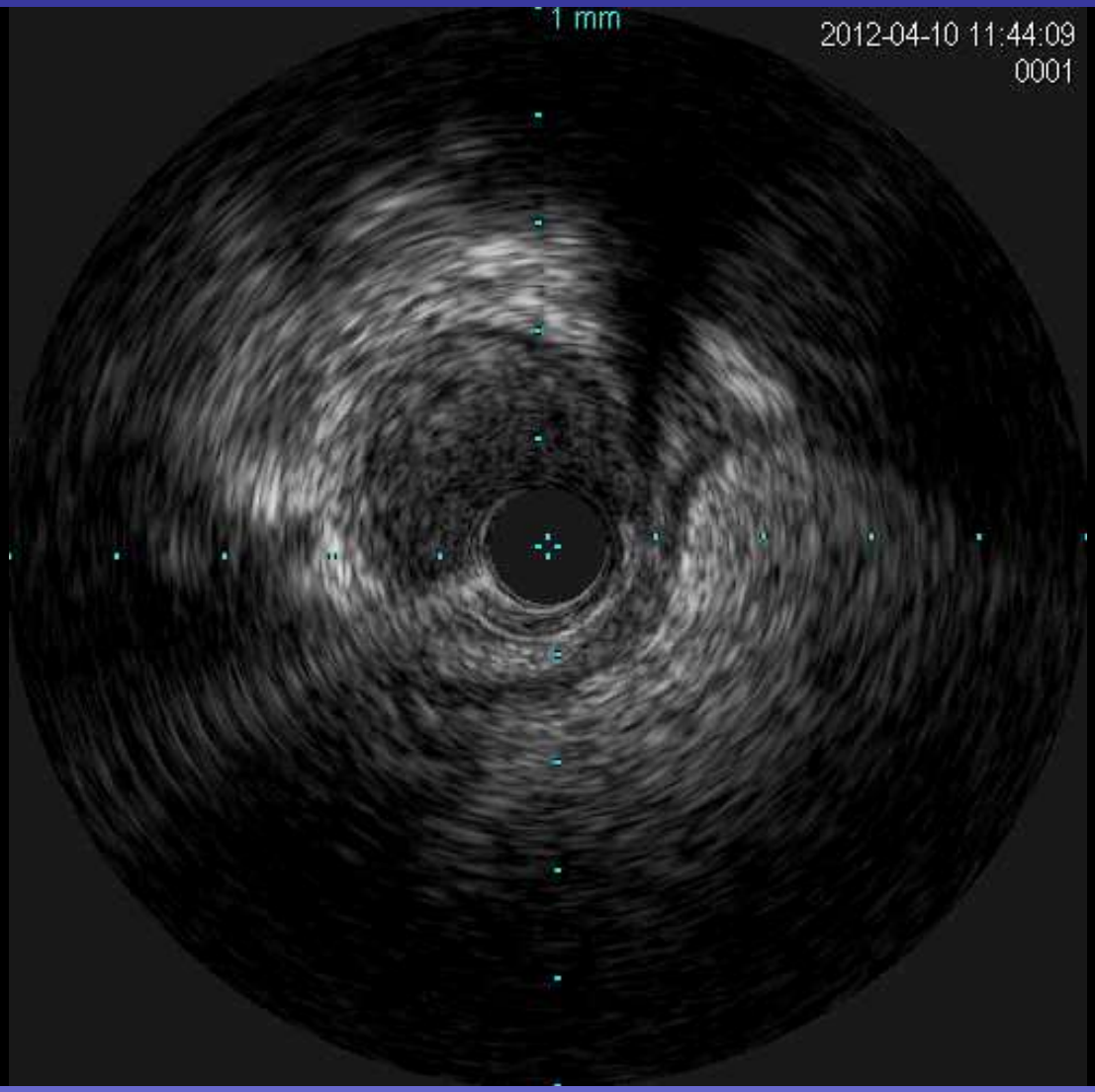
Im: 10+C
0 1103.2 (coi)
DFOV 2.4cm
DETL
ASR
Feb 22 2012
03:06:16 PM
SEGM 240 X 248
Mag = 1.00
FL:
ROT:
R
I
A
L
S
P
kV 120
mA 520
SFOV 32.0cm
0.391mm/6.40 0.16:1
Tilt: 0.0
0.35s /HE
WL:410 WW:1201
1.43
PIL

Pre PCI



IVUS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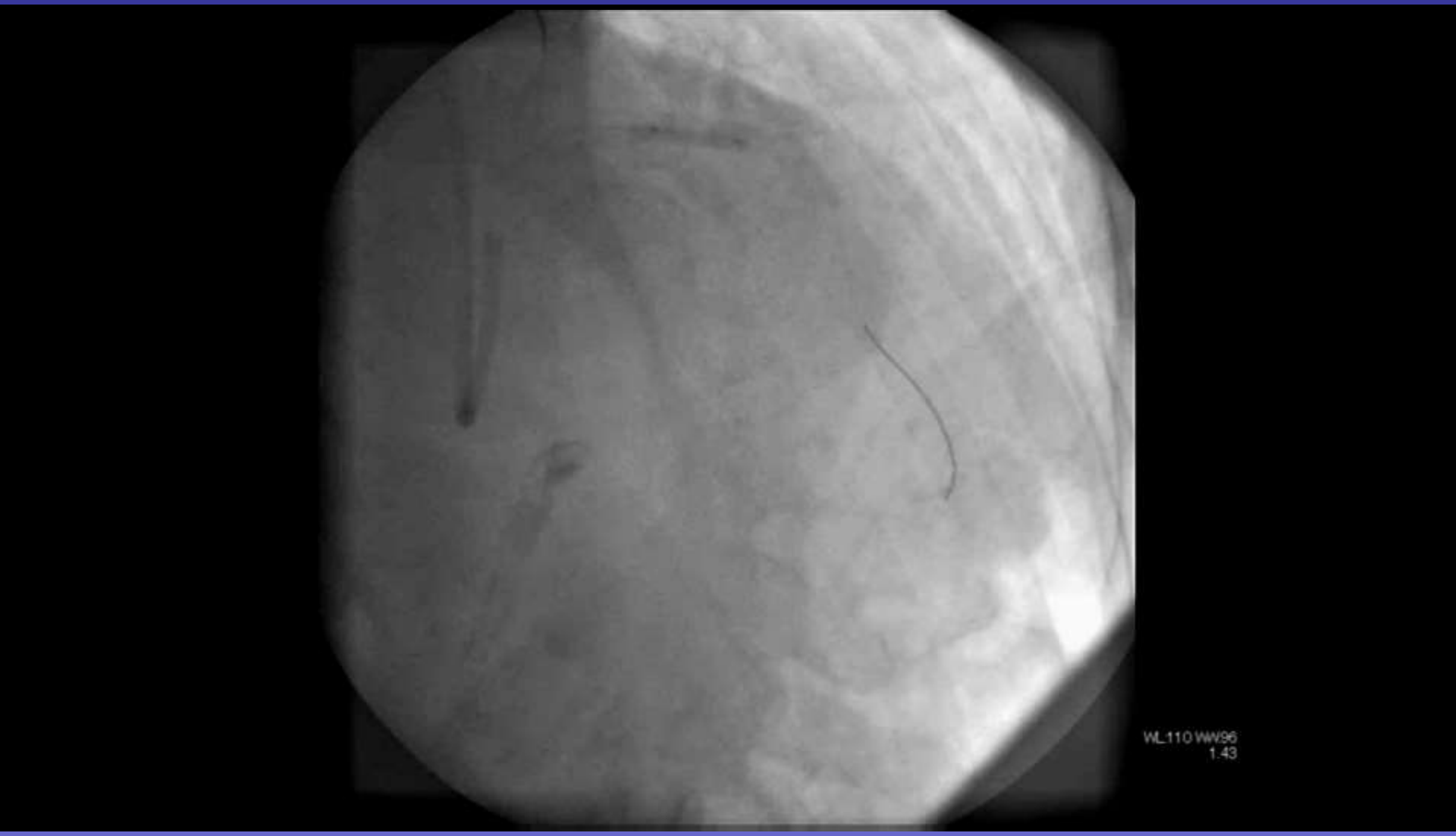
NSE leopard crawl ①; 2.25mm@4-6atm

NSE leopard crawl ②

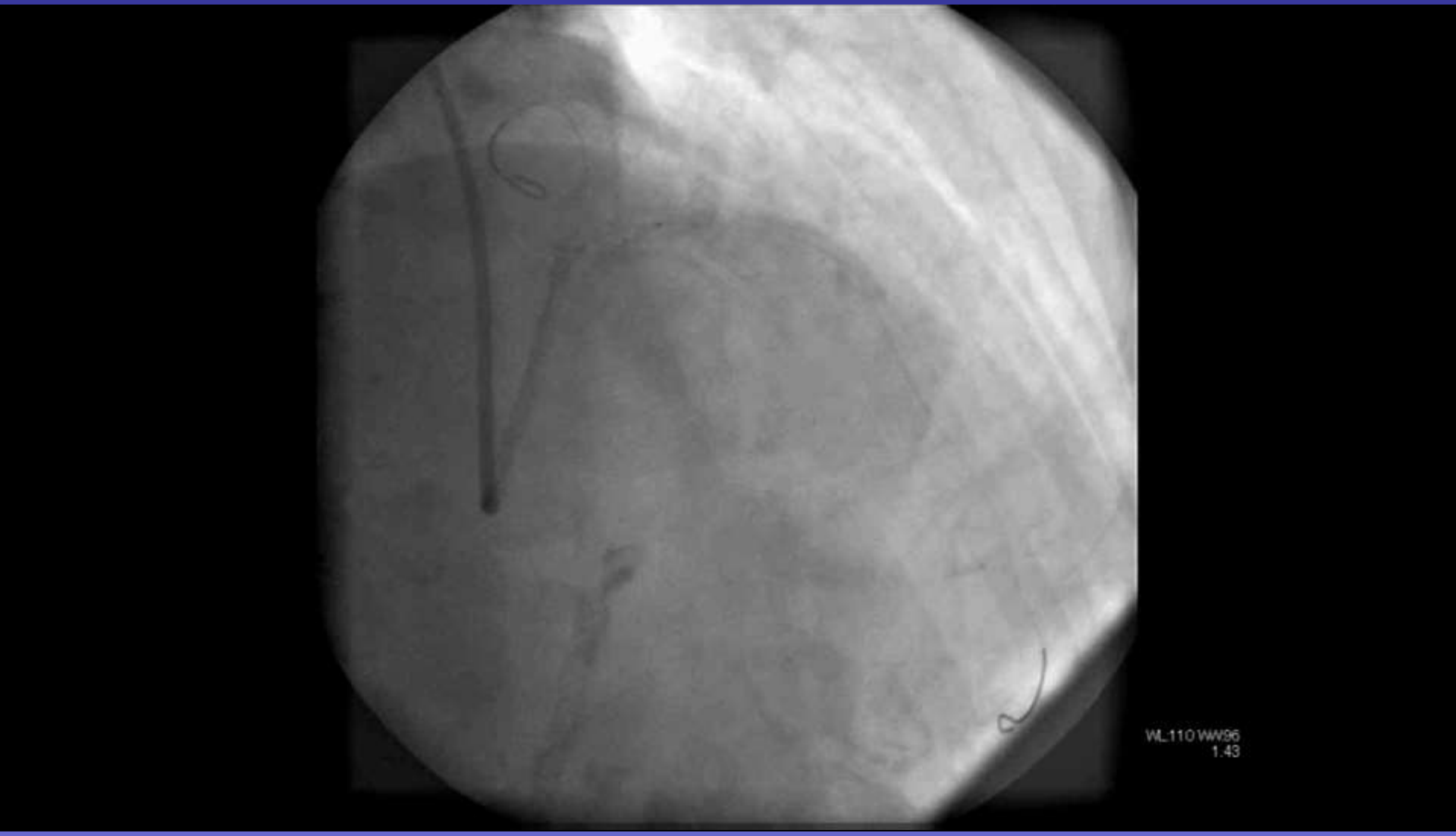


NSE leopard crawl ③

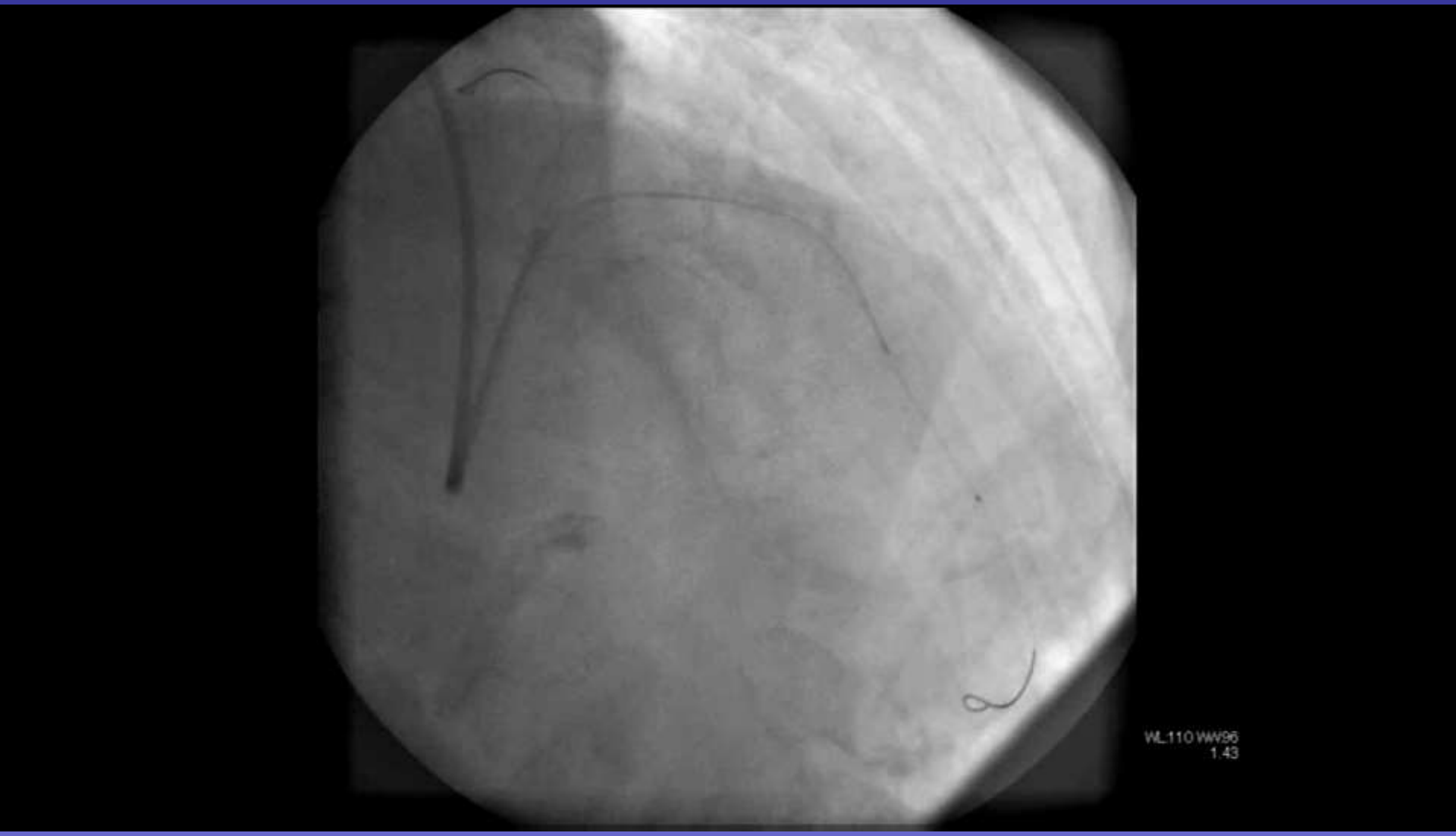
NSE leopard crawl ④

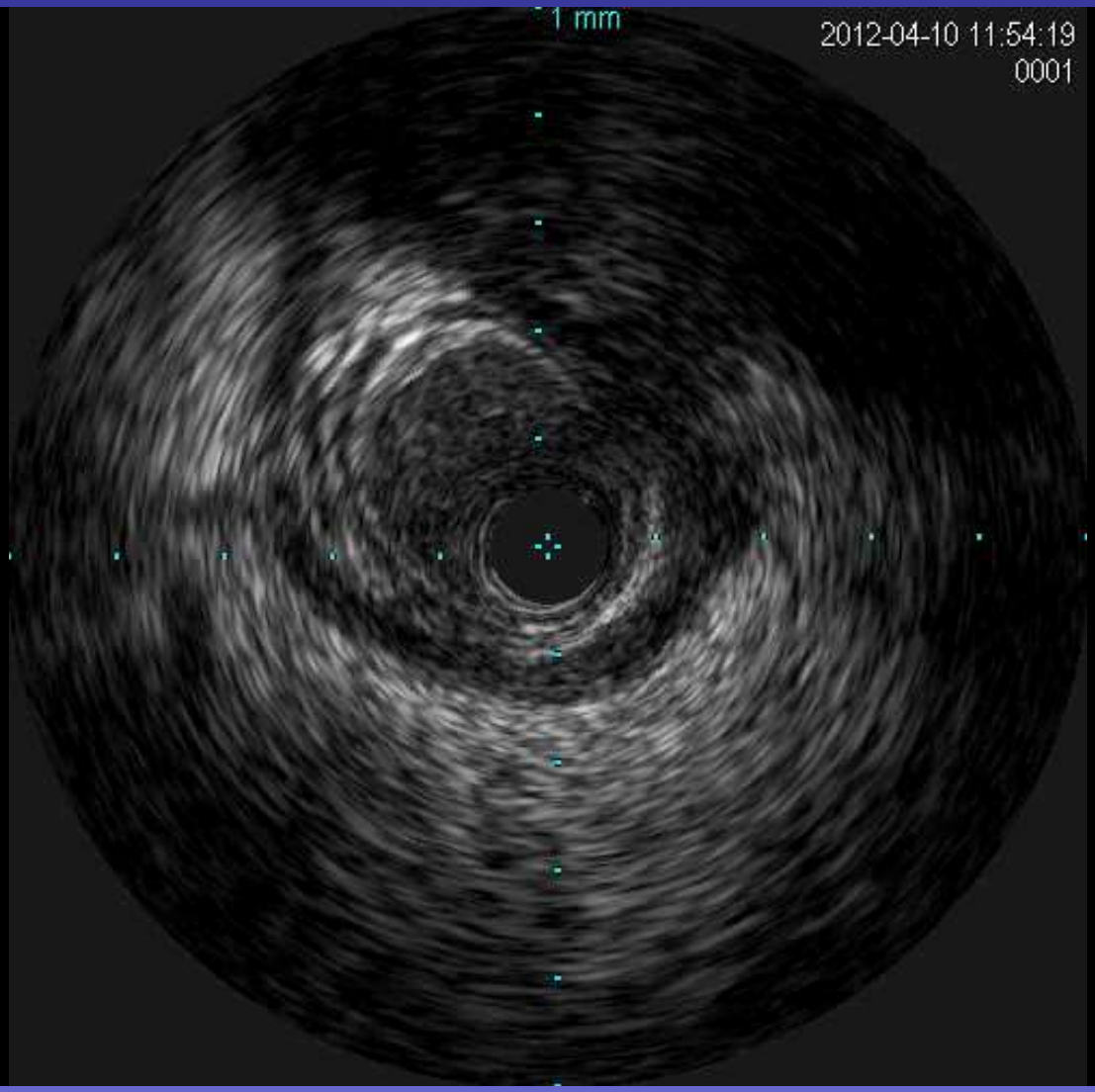
NSE leopard crawl ⑤

NSE post inflation push test



NSE post inflation IVUS




1 mm
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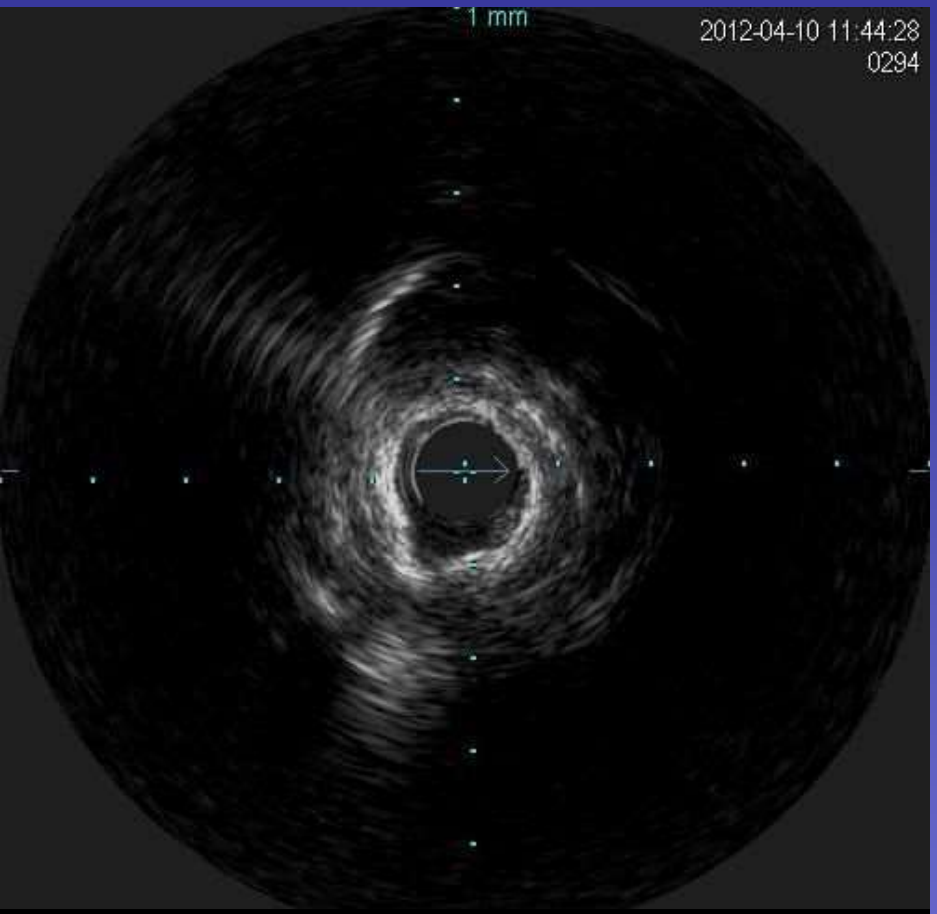
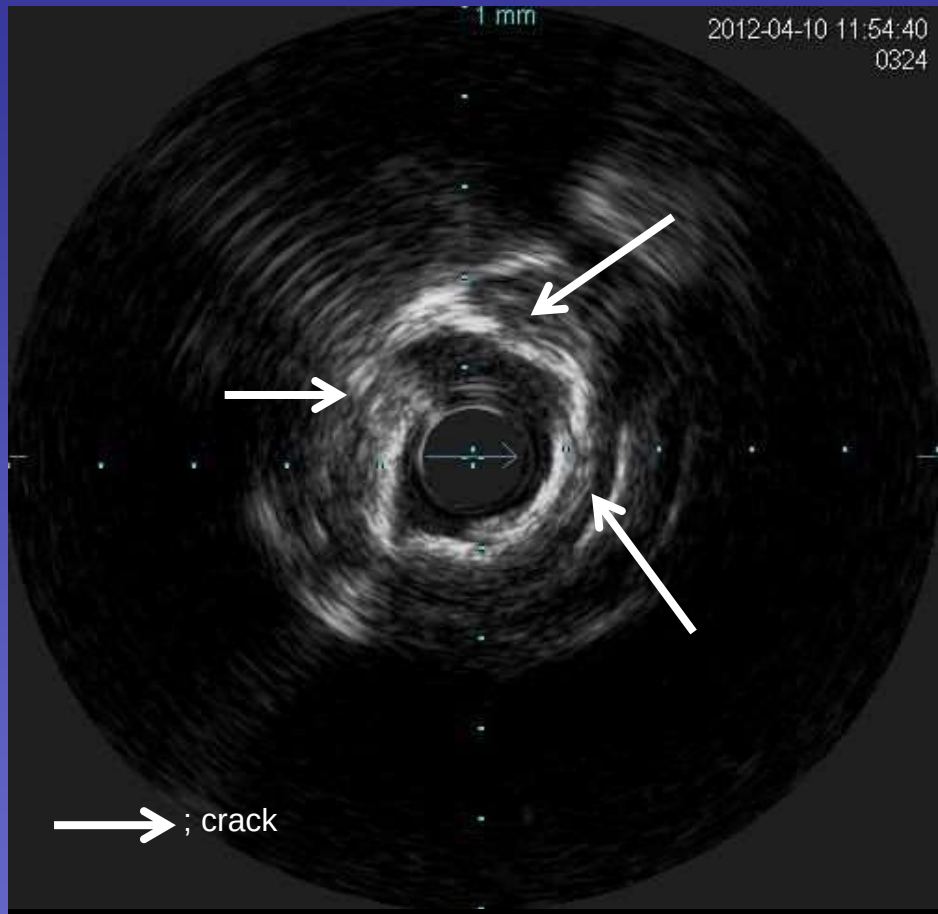
0001

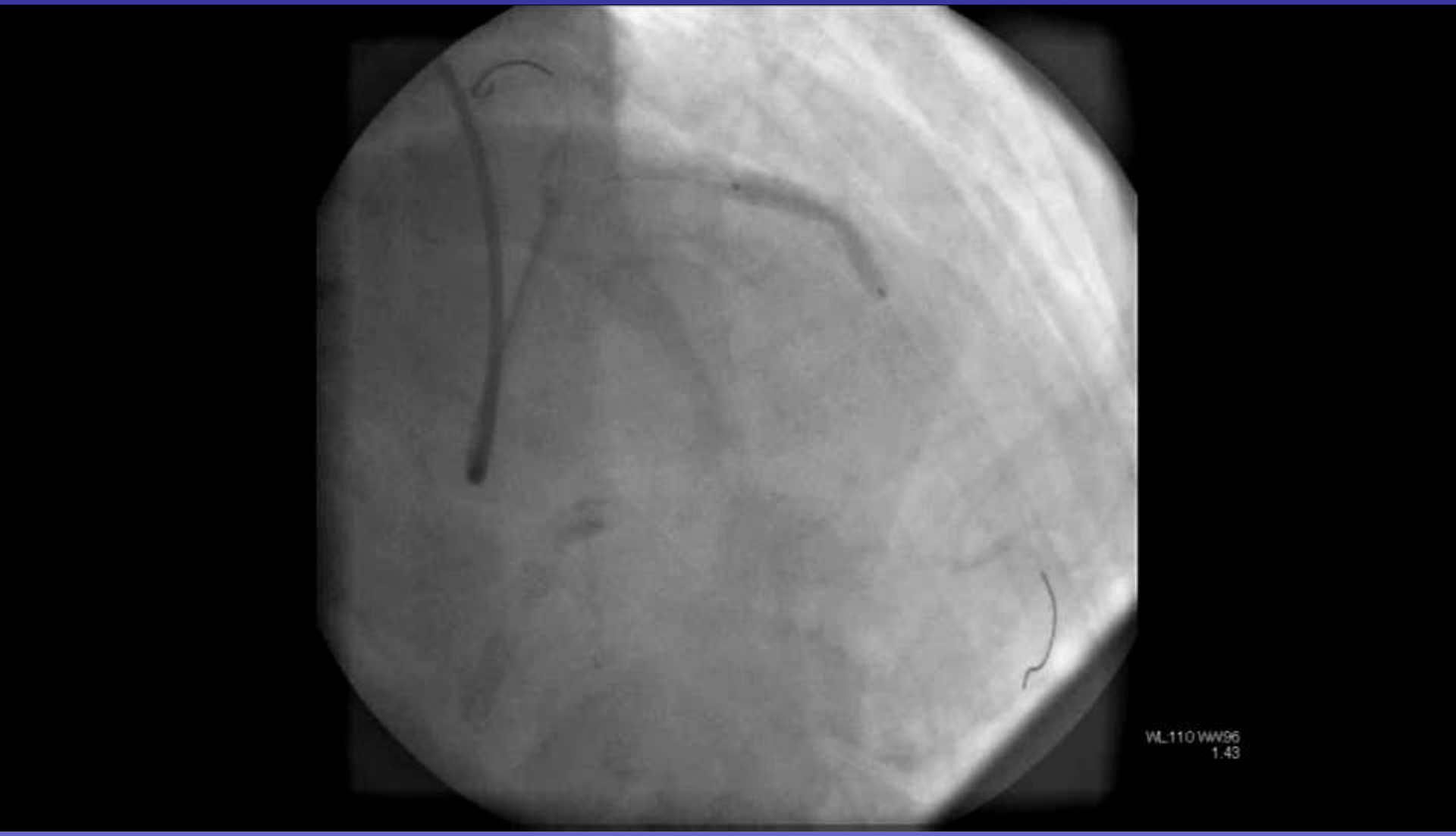


Pre NSE

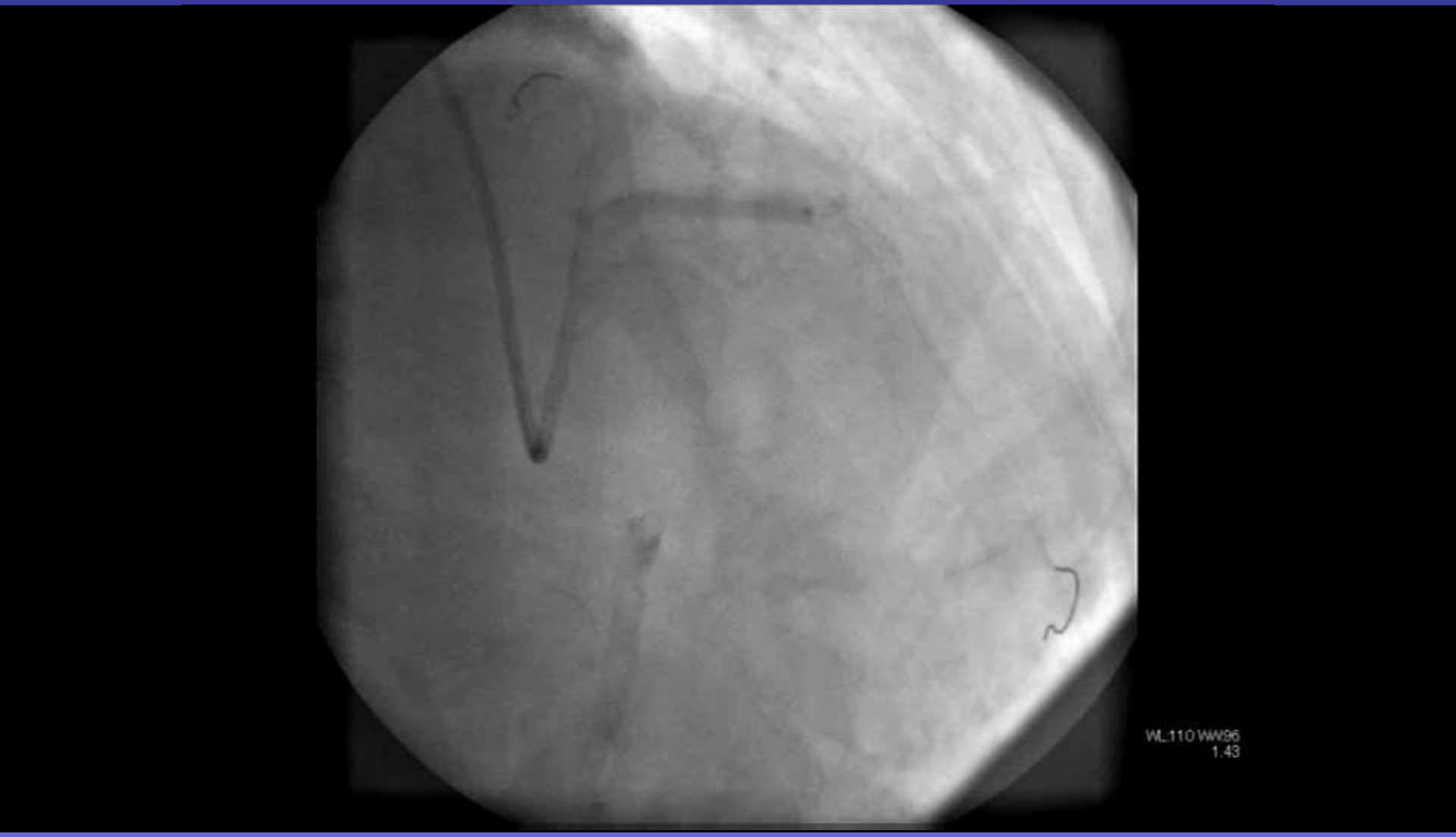


Post NSE

Stent（Xience V 3.5*28mm)

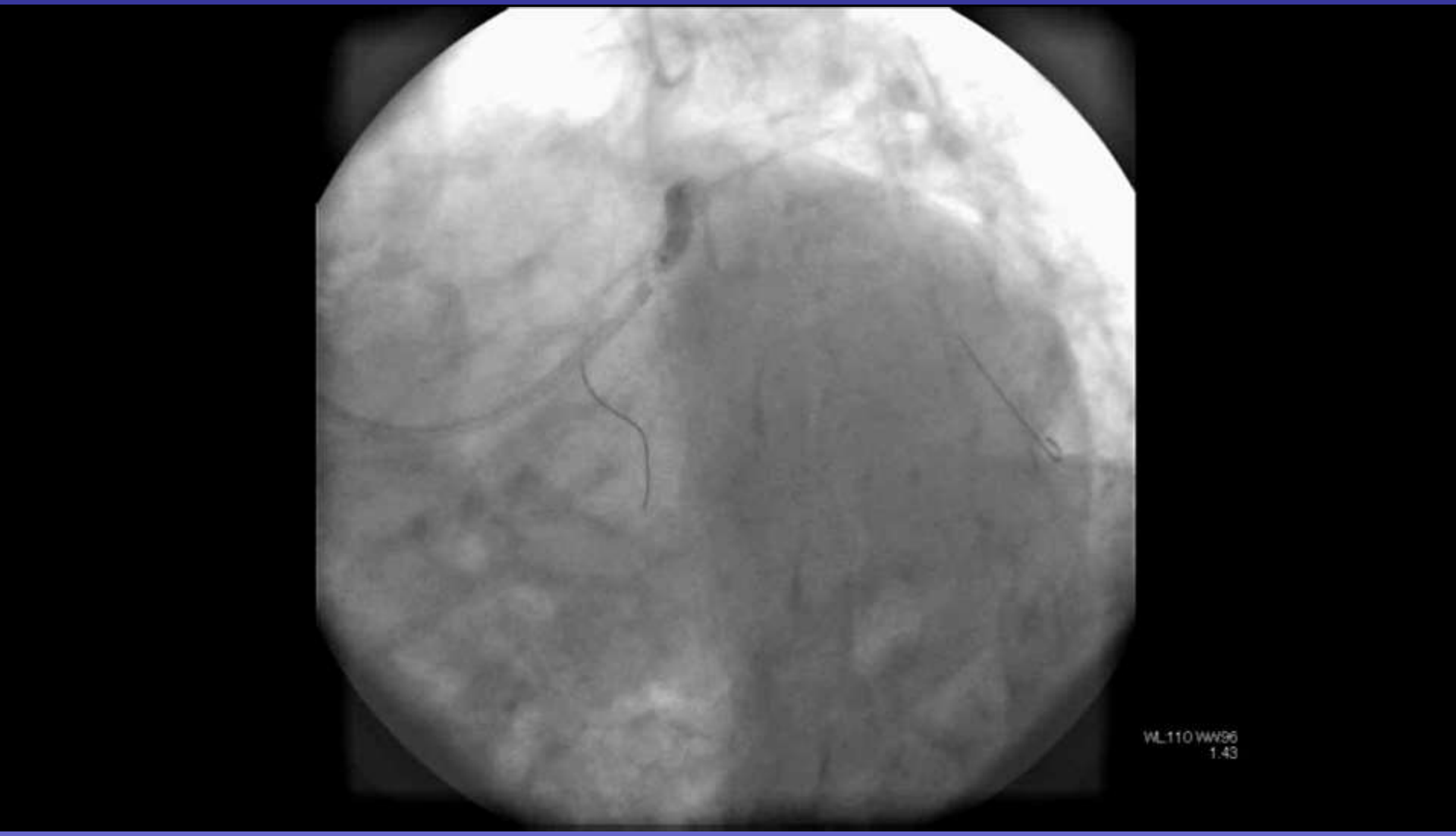


Stent（Xience 3.5*28mm)

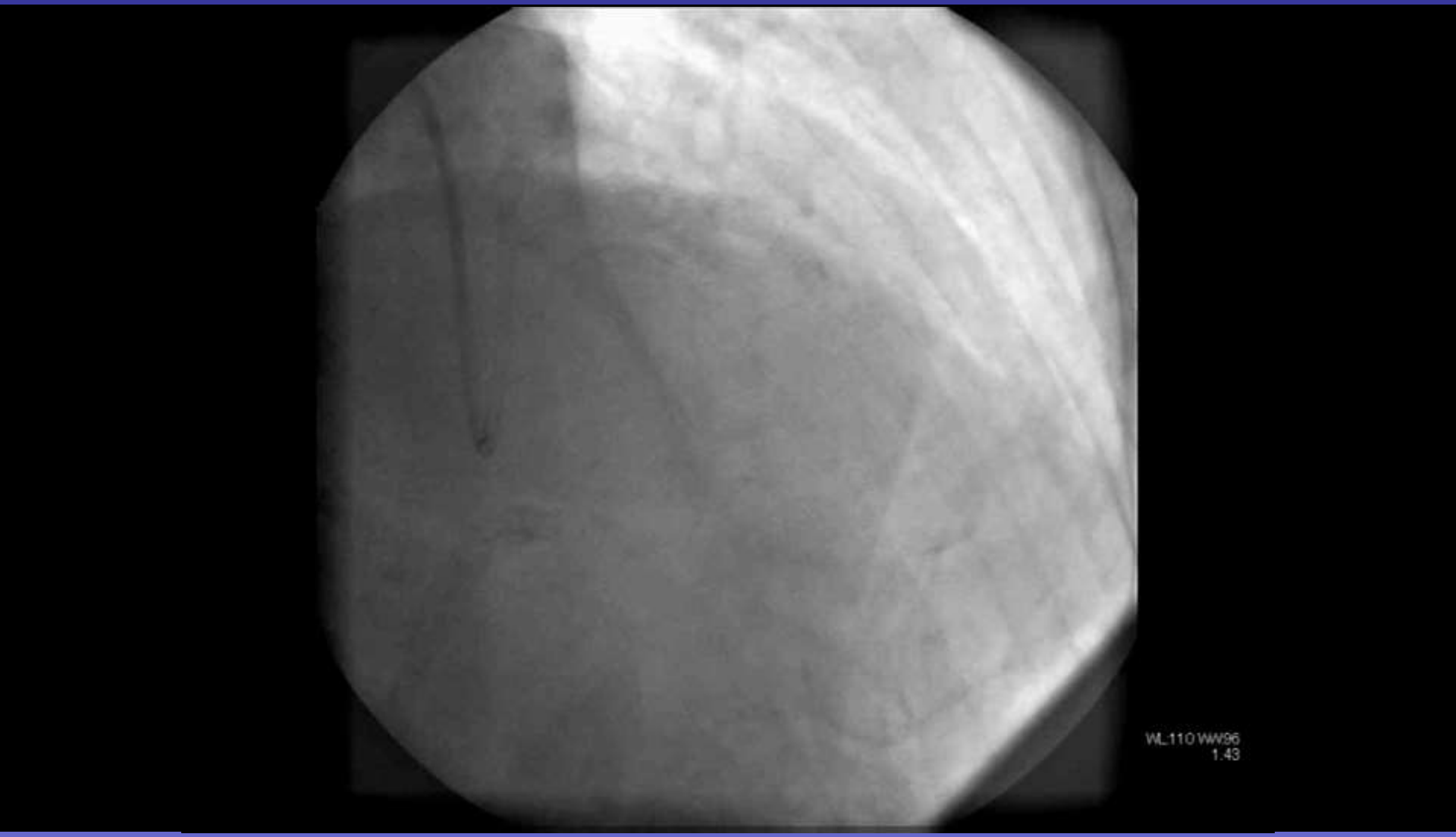


Stent②; LAO caudal

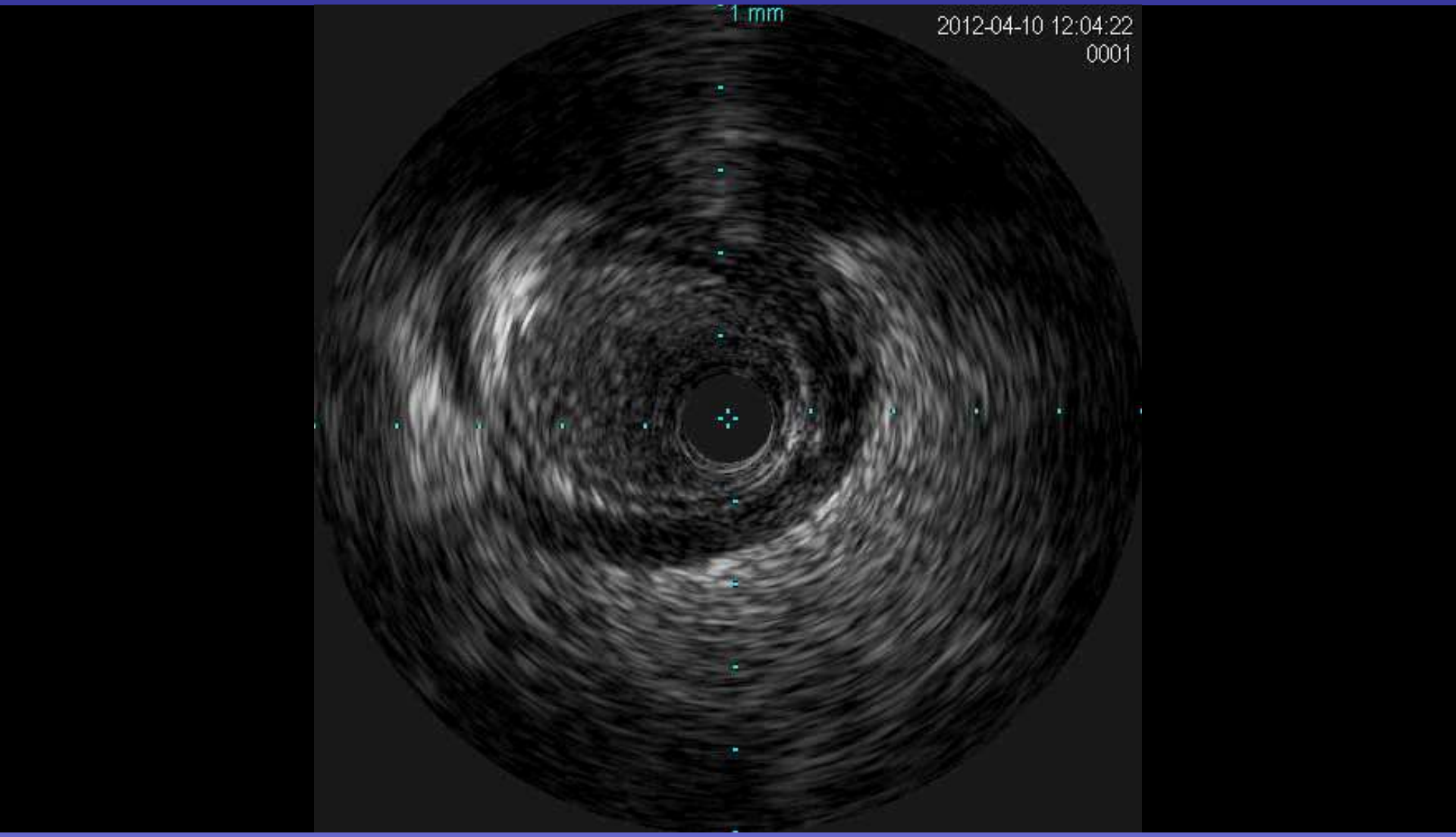
Additional post NSE inflation



Final CAG



Final IVUS



Case 4:
Late 80’s yr old female

LAD mid (#6-7) with severe calcified

Approach: 6F TRI

GC: Heart-rail2 BL3.5 GW: Sion blue

Diagnosis: dyspnea on exertion

Risk factors: hypertension

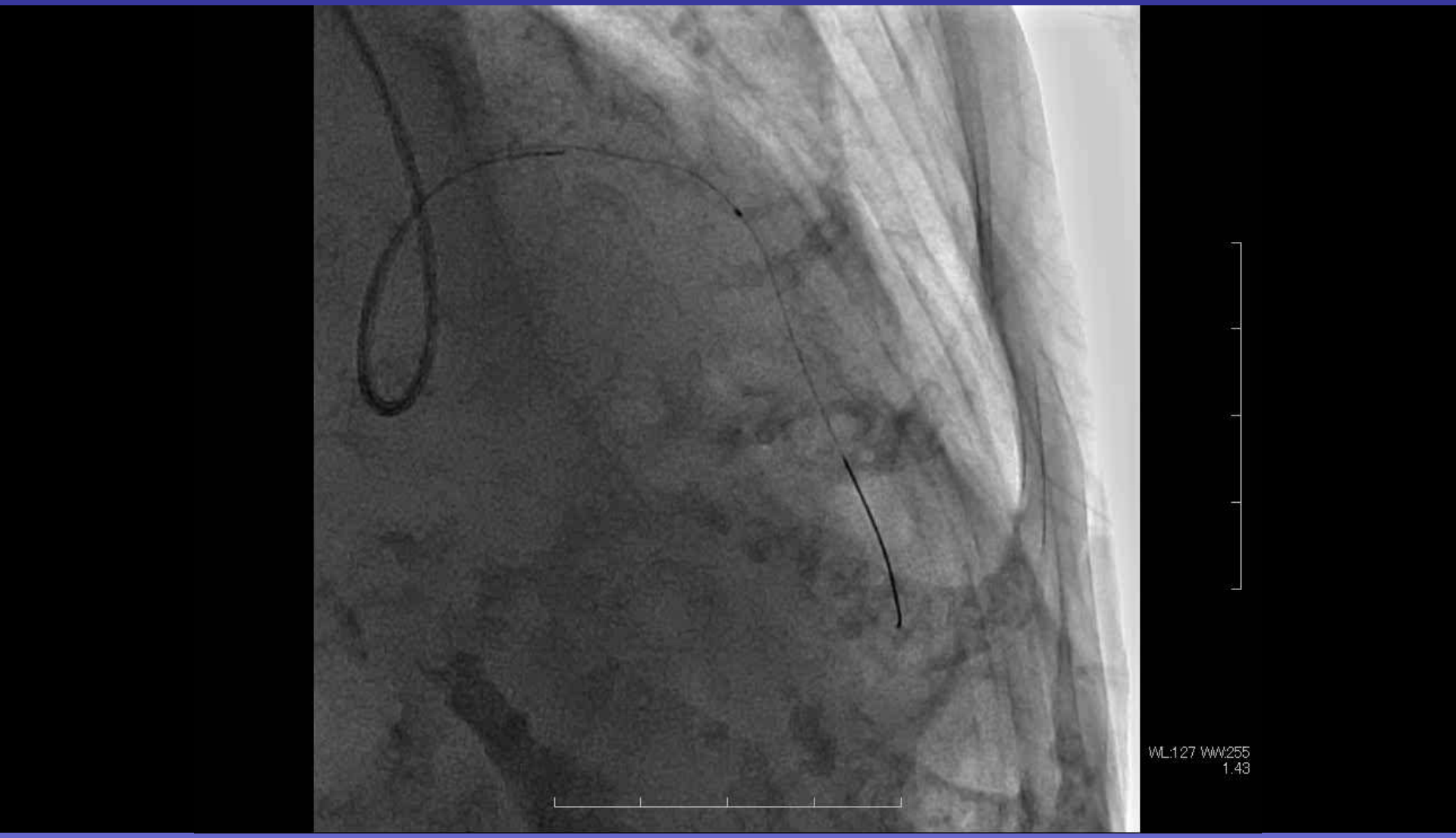
Previous history: stroke

MDCT

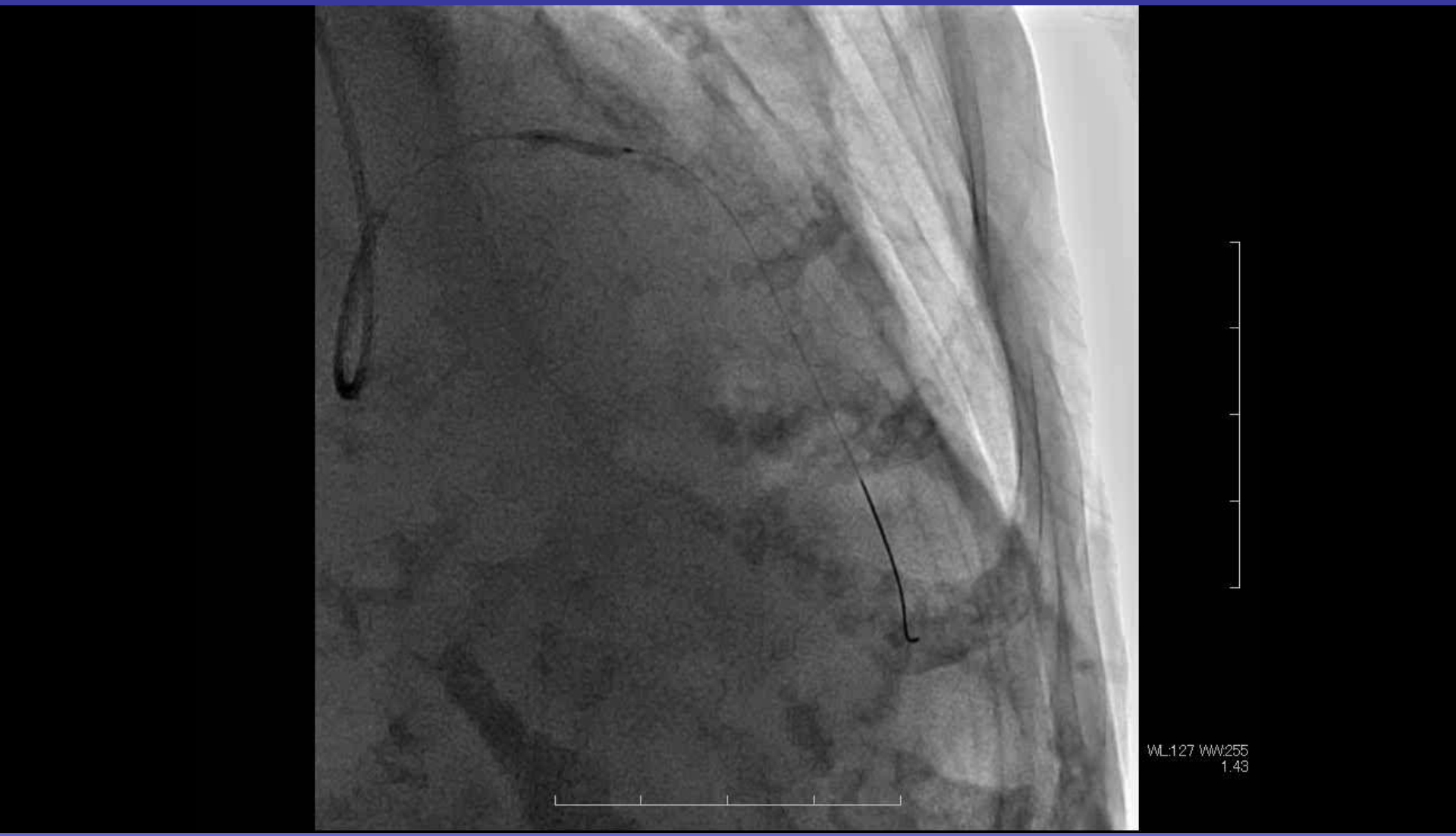

Vessel Direction Based
Depth: 0.0 mm
Angle: 105.2 deg
LAD
2325207
000
WL:332 WW:1132
1.41
CPR-A

Pre CAG: RAO cranial

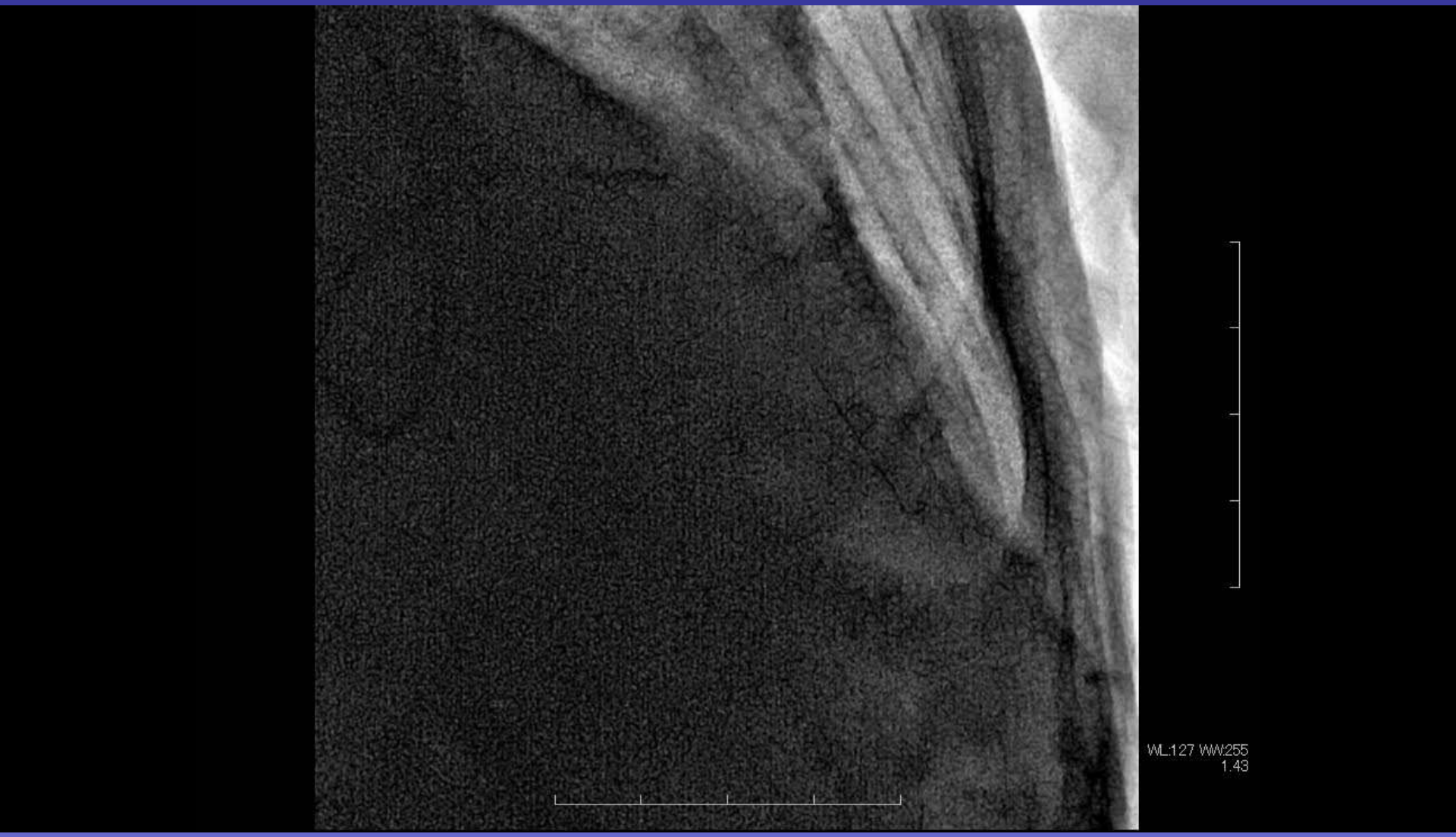
Pre IVUS; unable to cross



Lacrosse NSEα 2.25mm@4-6atm

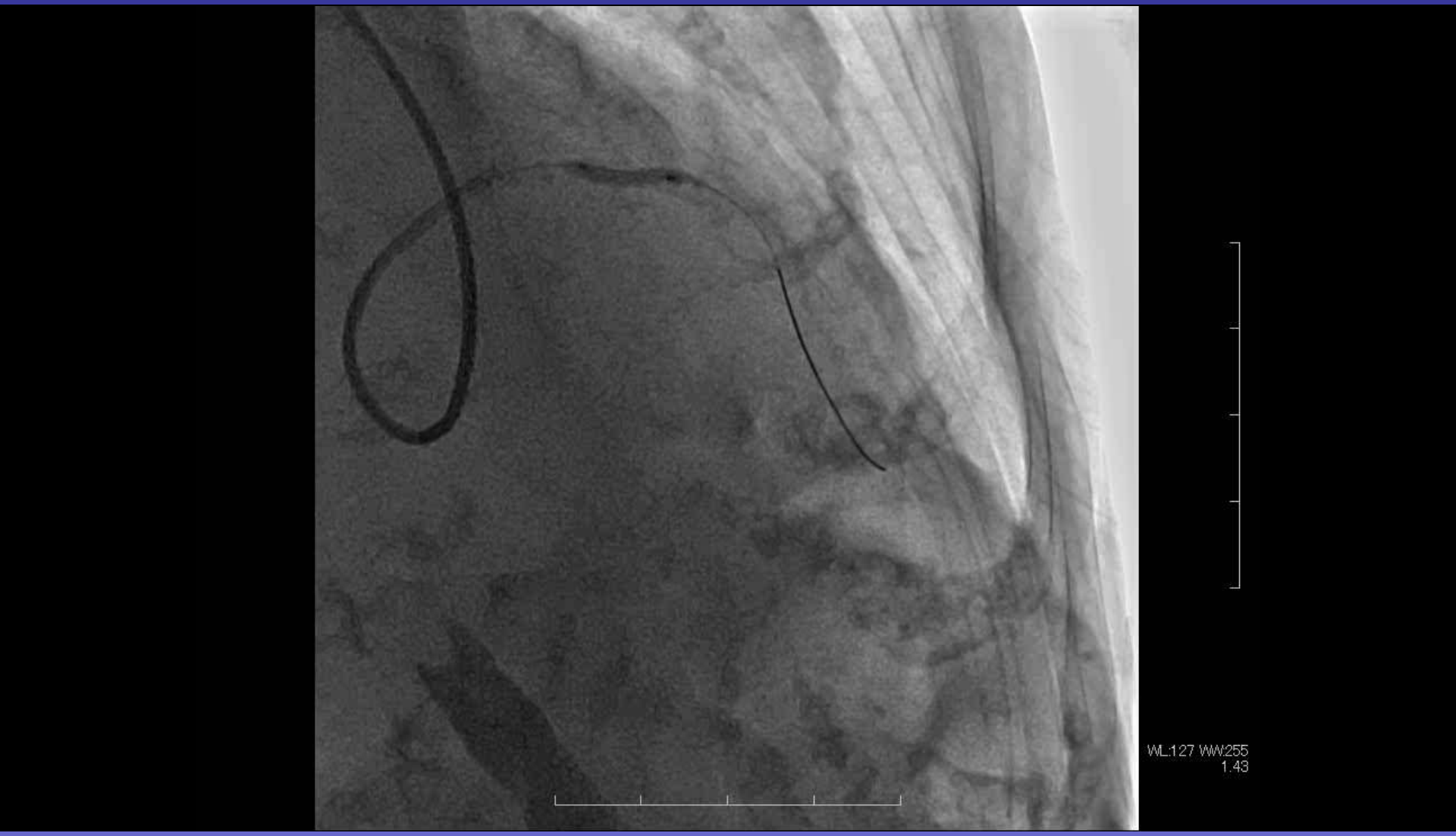


Lacrosse NSE; leopard crawl



Lacrosse NSEα; distal

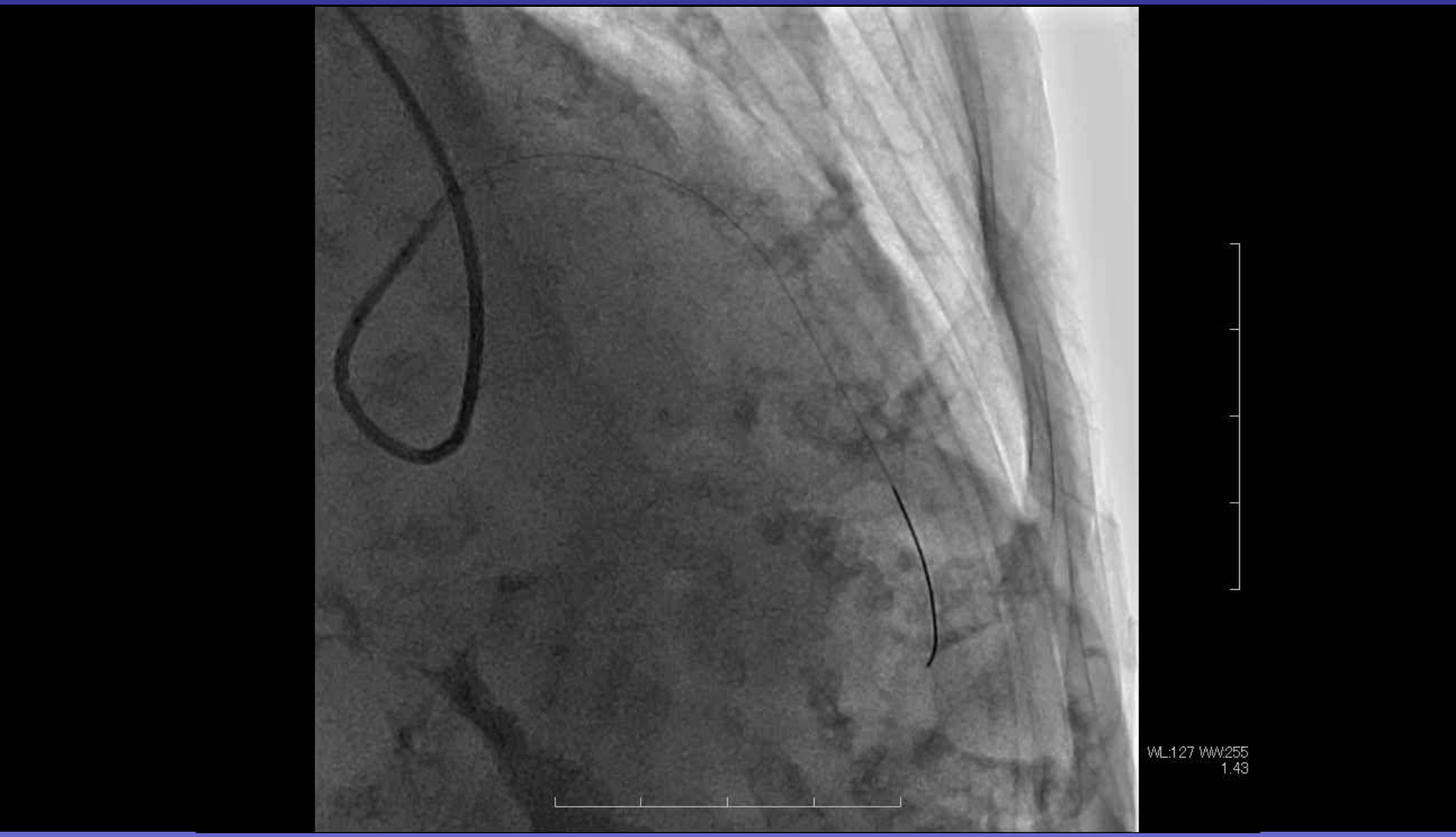
Lacrosse NSE: high pressure inflation at proximal @14atm



Push test of NSE

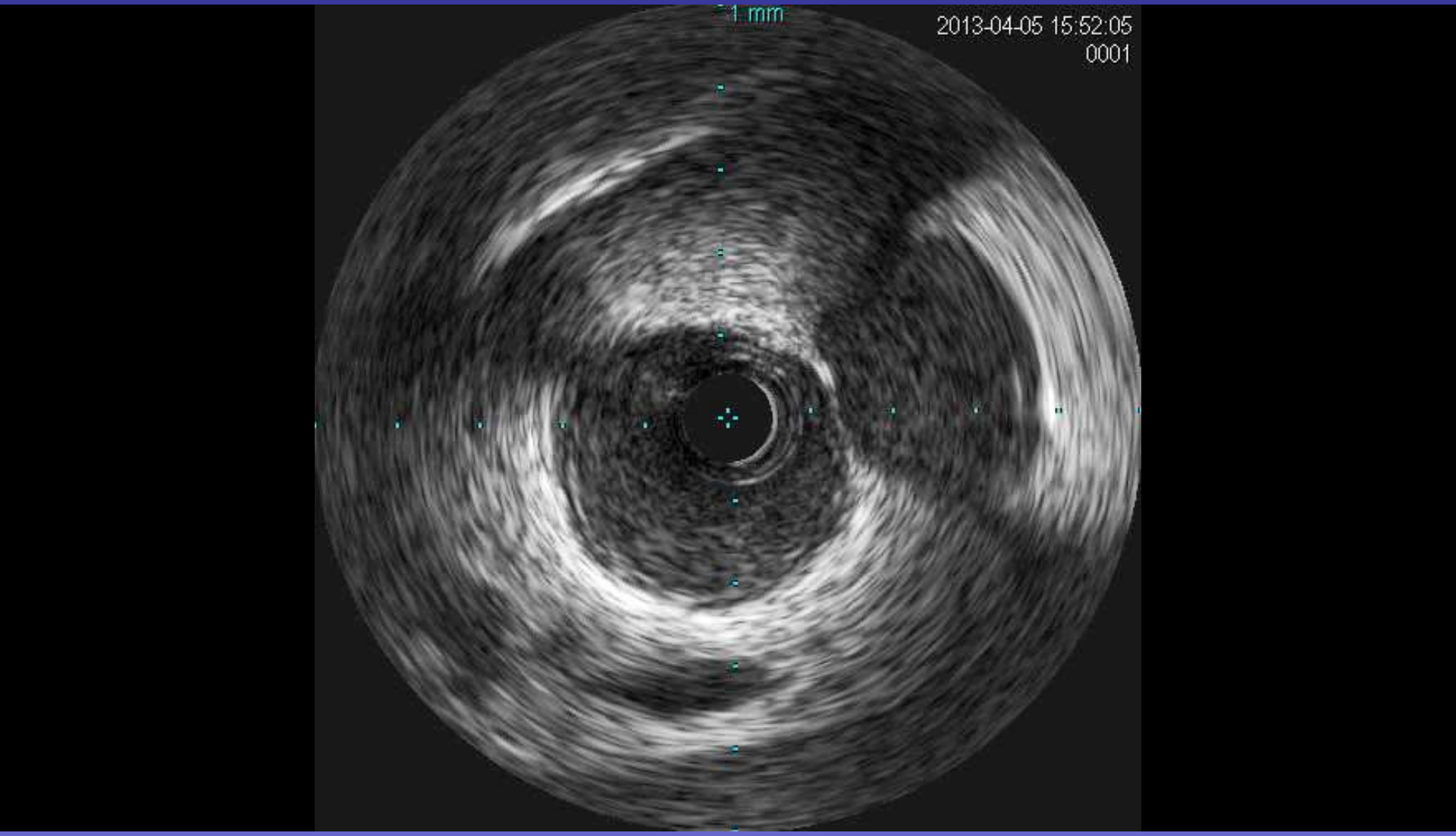
Re-inflation of location that had resistance @16atm

Repeated push test

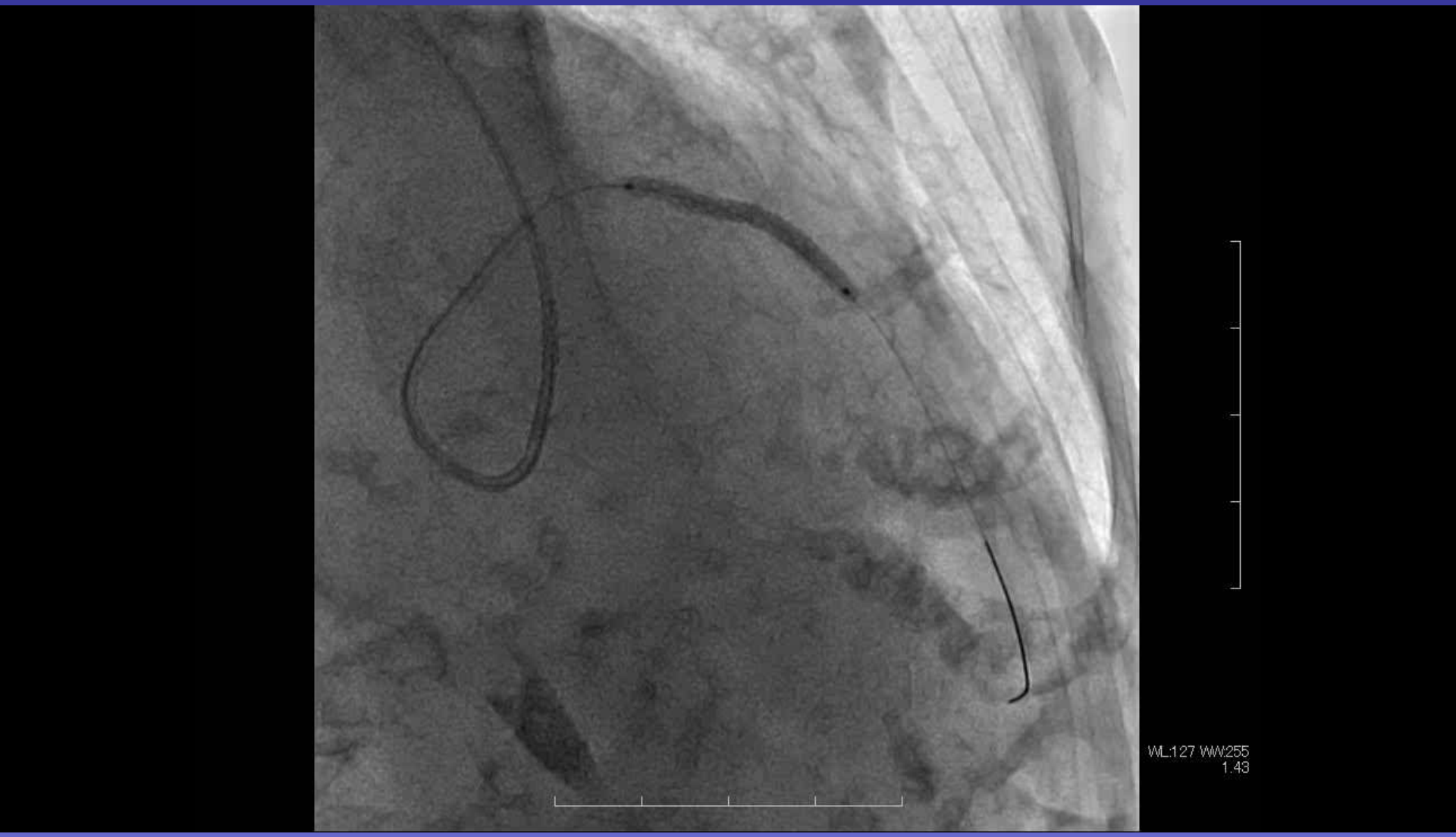


IVUS

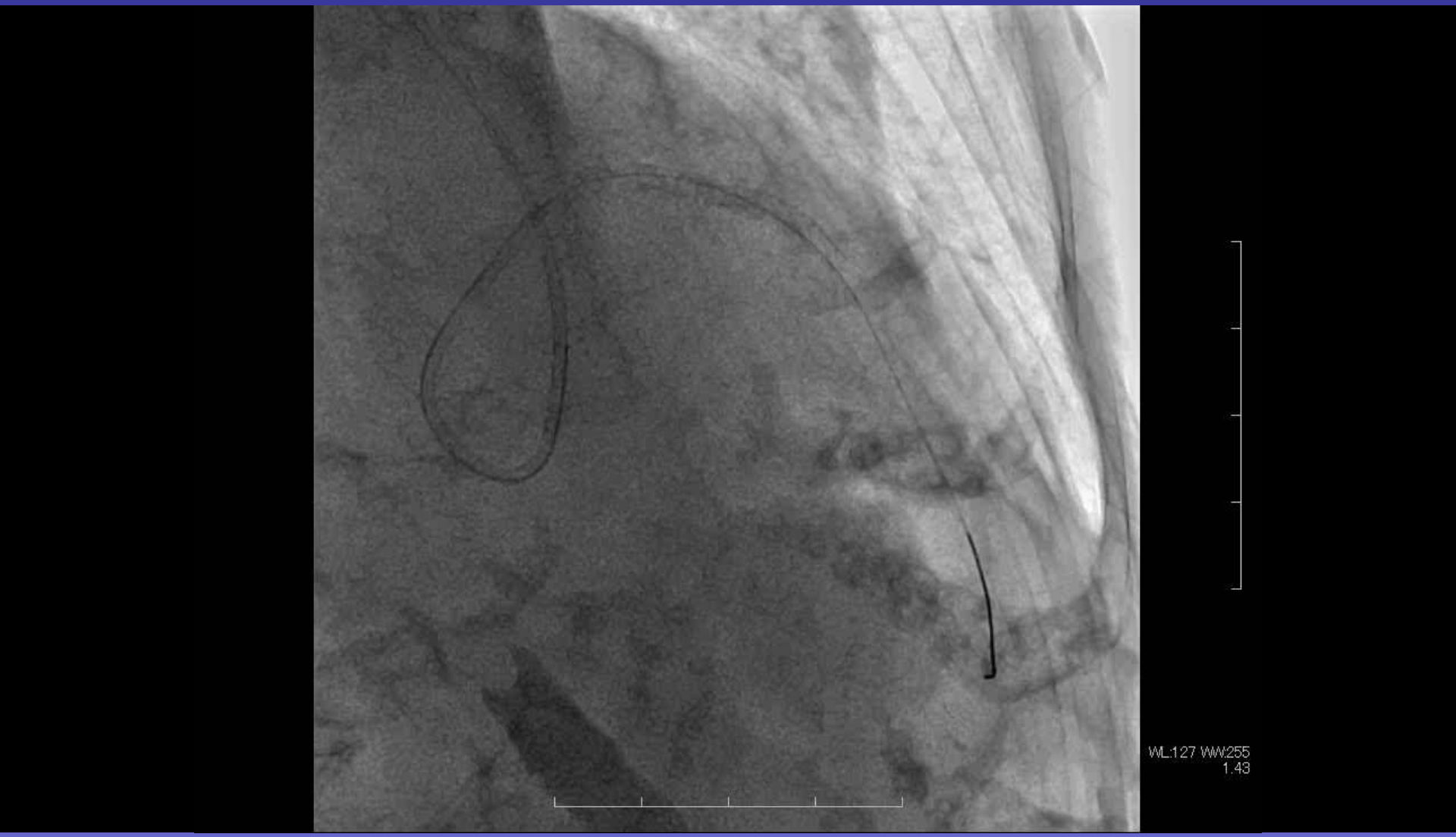
IVUS post NSE dilatation



NOBORI implantation 2.5*28mm @12atm

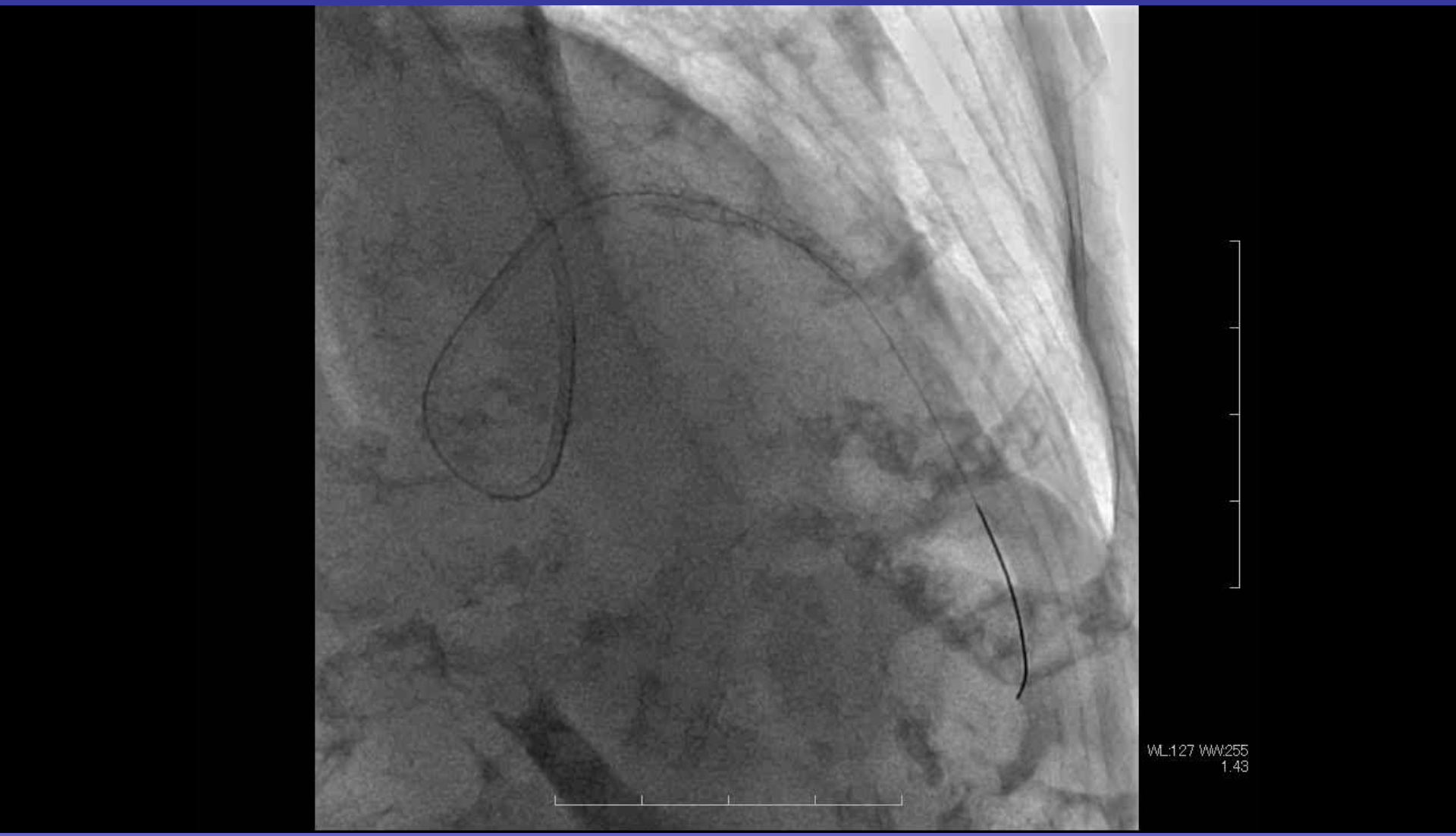


Angiogram post implantation

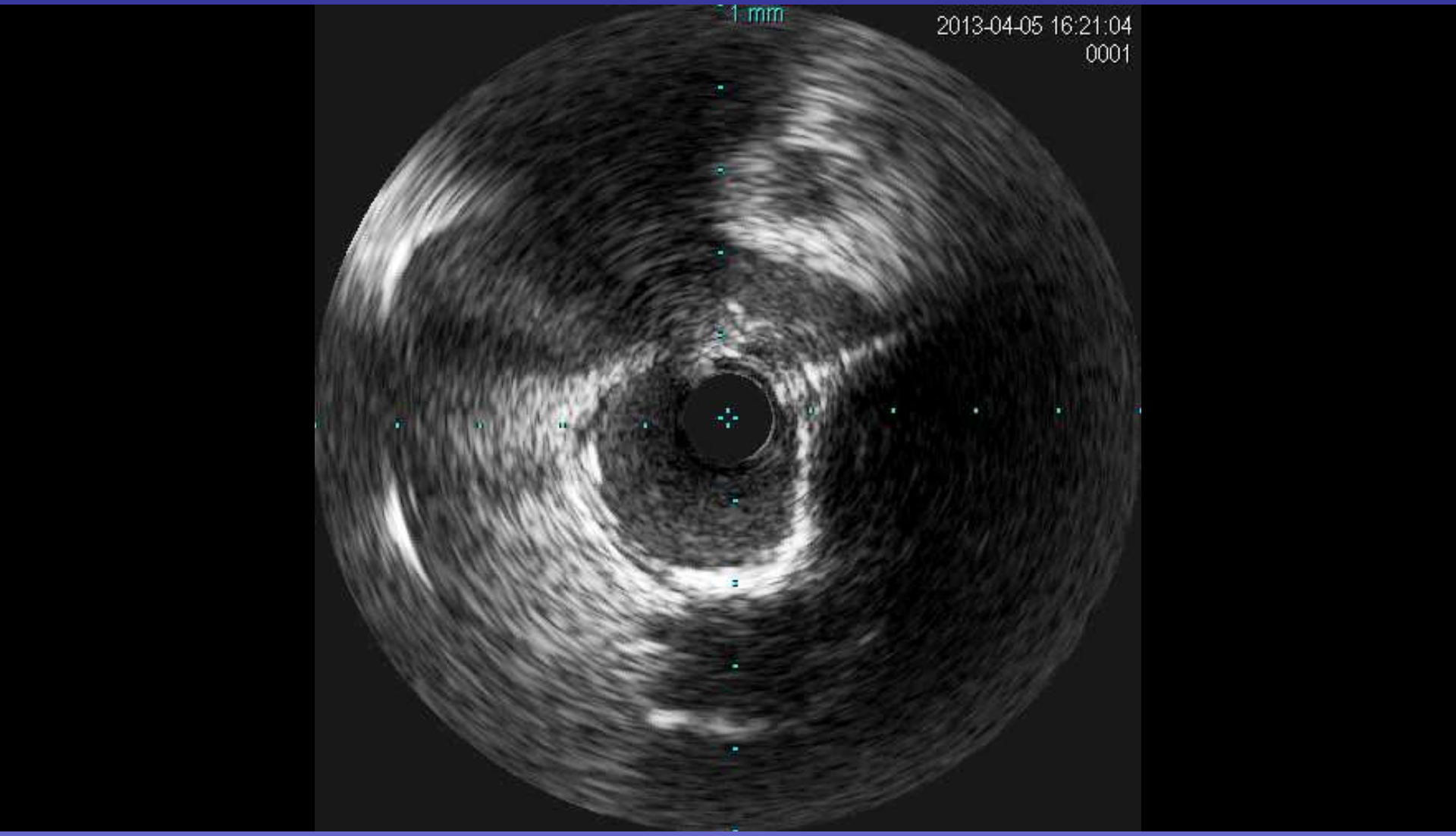


Post dilatation Hiryu 2.75@18atm

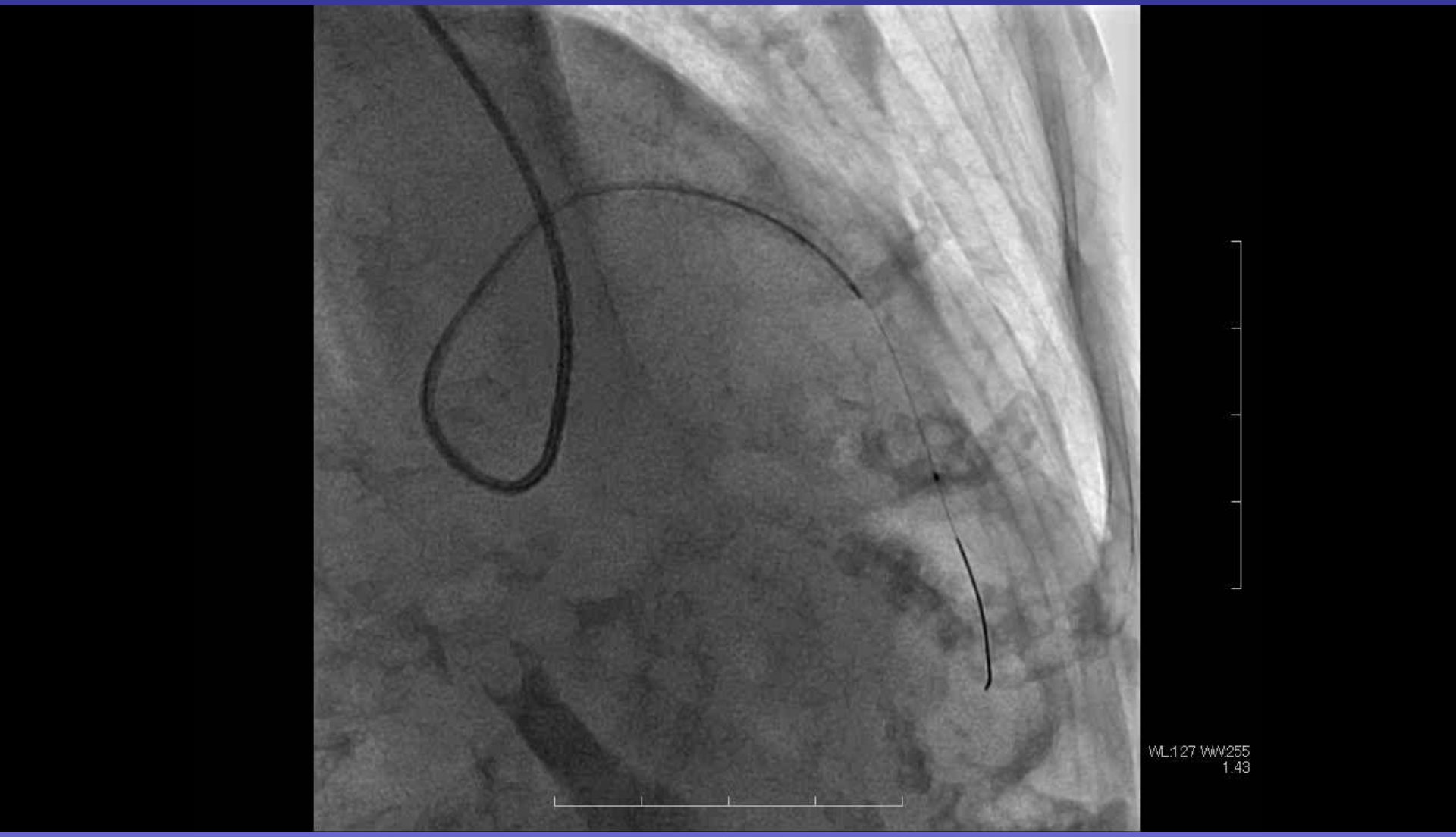
CAG post POBA inflation



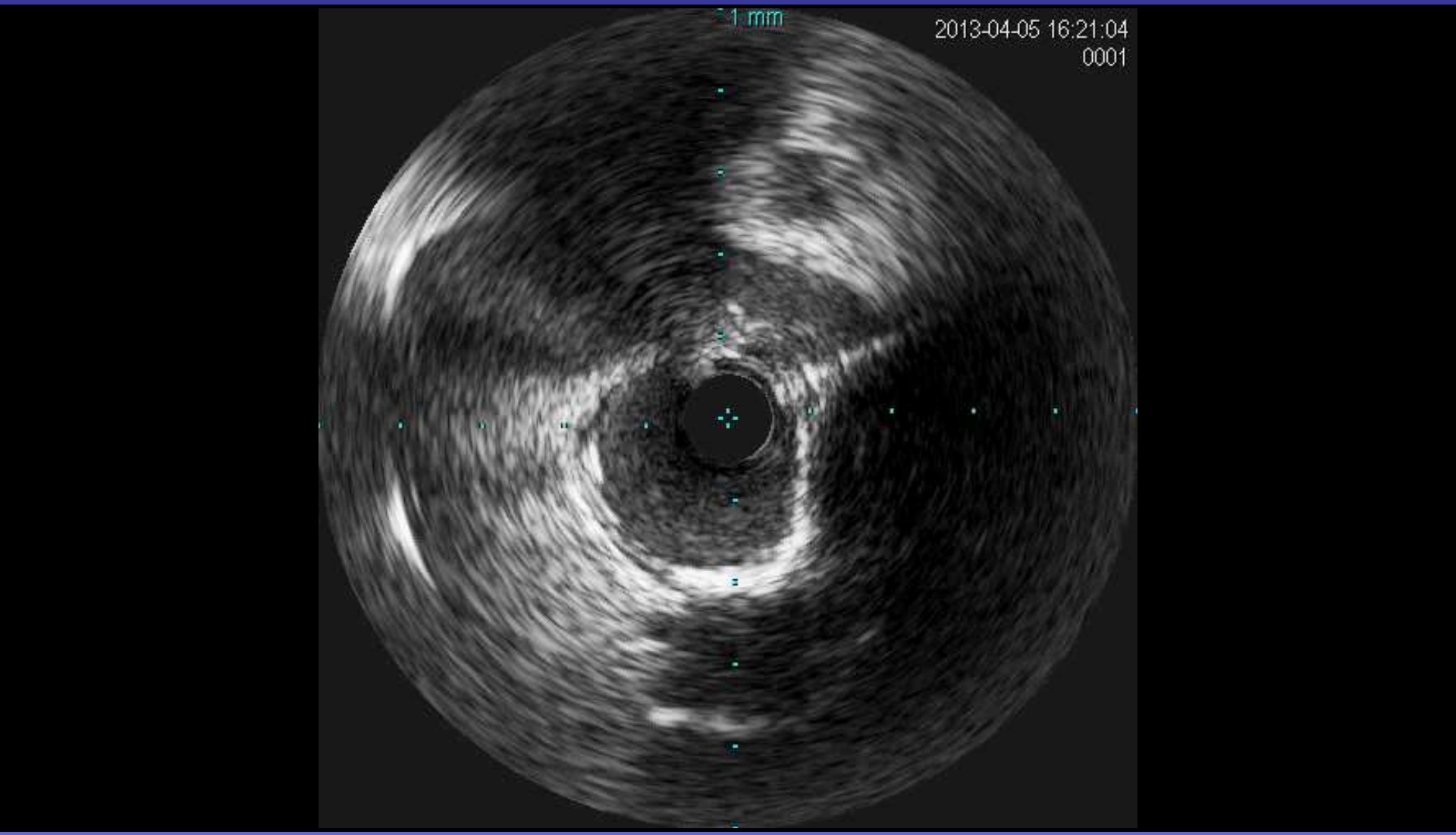
IVUS 2: post NSE



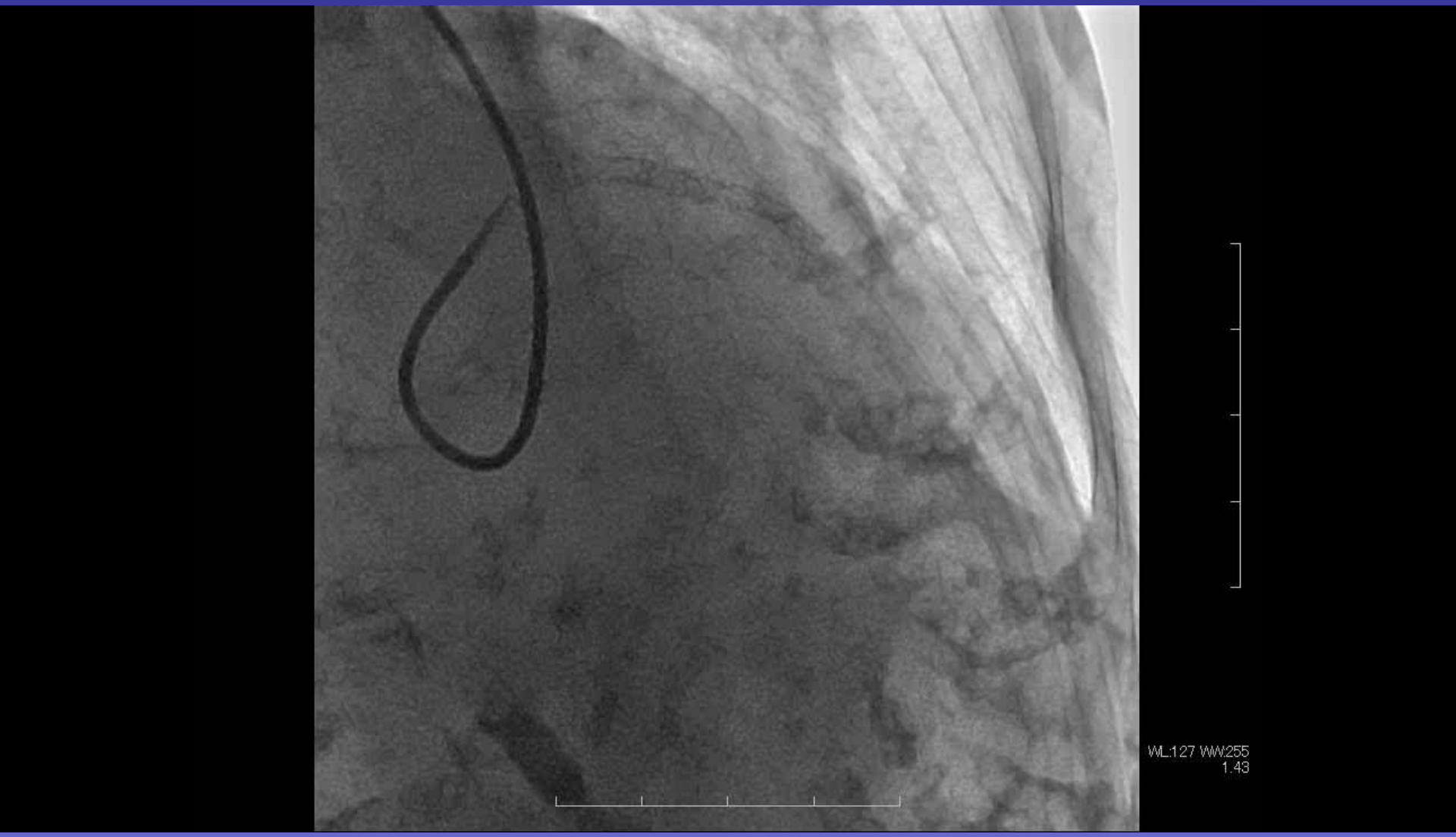
Final IVUS



Final IVUS



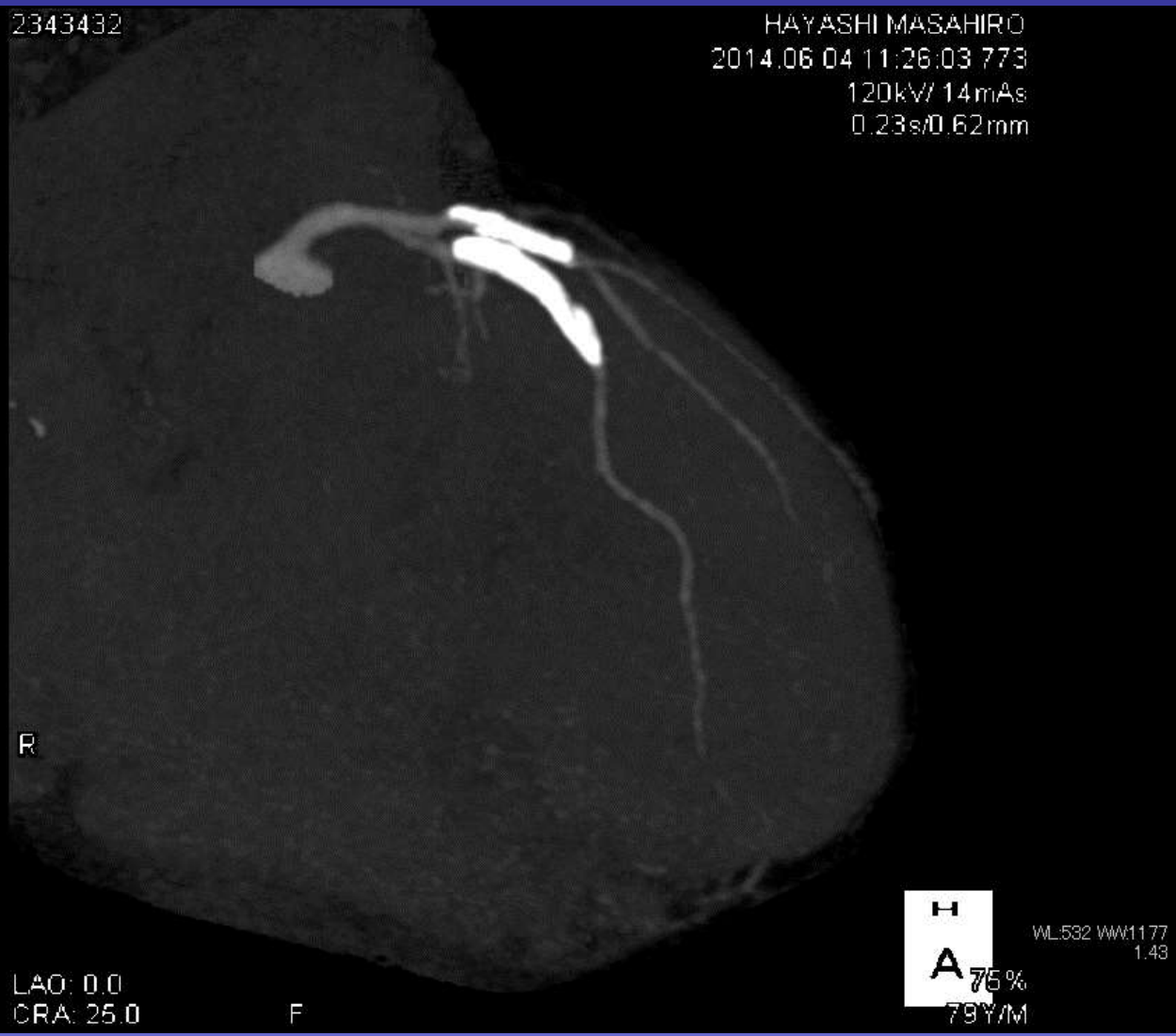
Final CAG; RAO cranial



Case 7:

How effective is NSE for calcified lesions?

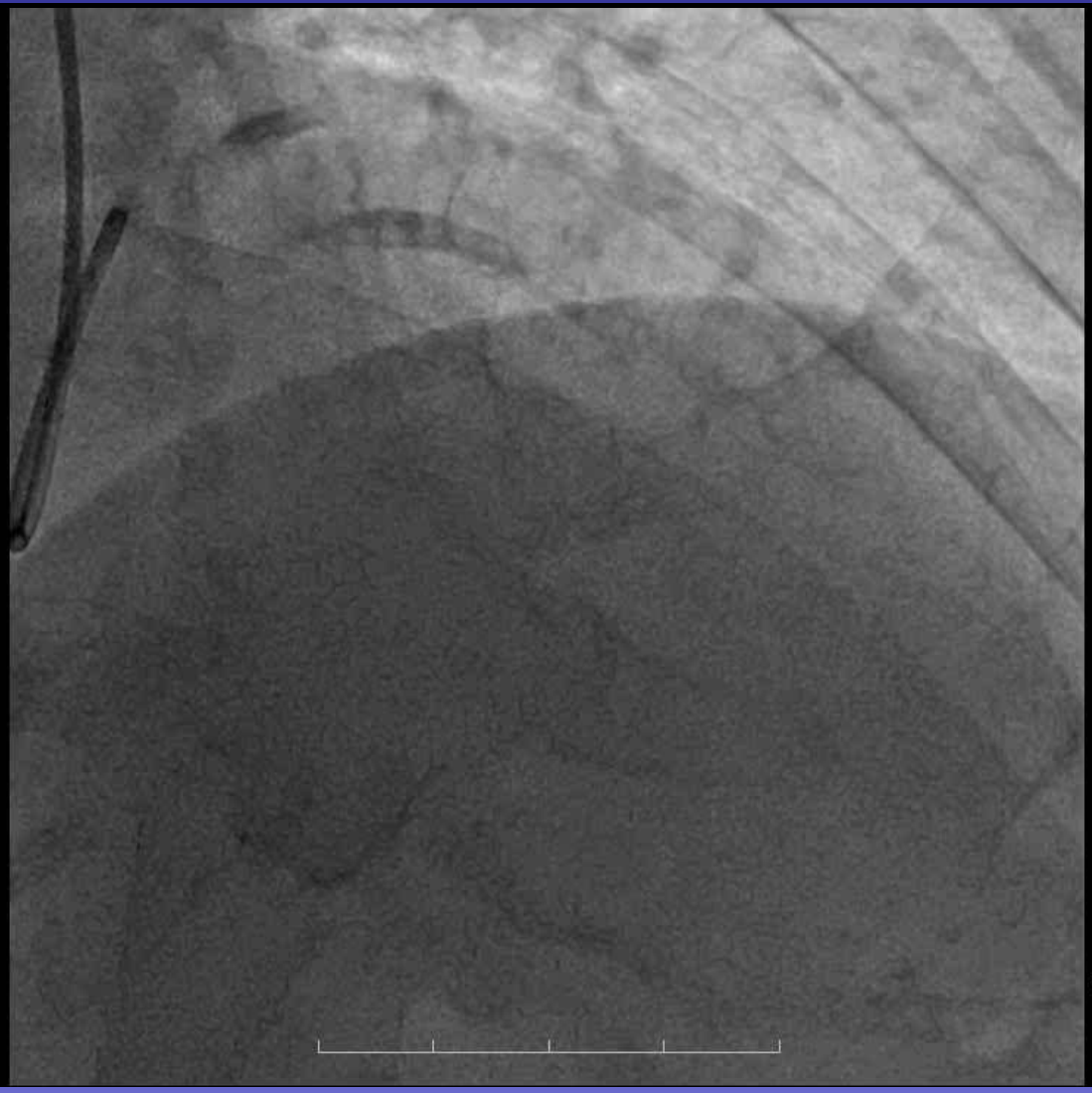
MDCT


2343432
HAYASHI MASAHIRO
2014.06 04 11:26:03 773
120kV/ 14mAs
0.23s/0.62mm
R
LAO: 0.0
CRA: 25.0
F
H
A
75%
79Y/M
WL:532 WW1177
1.43

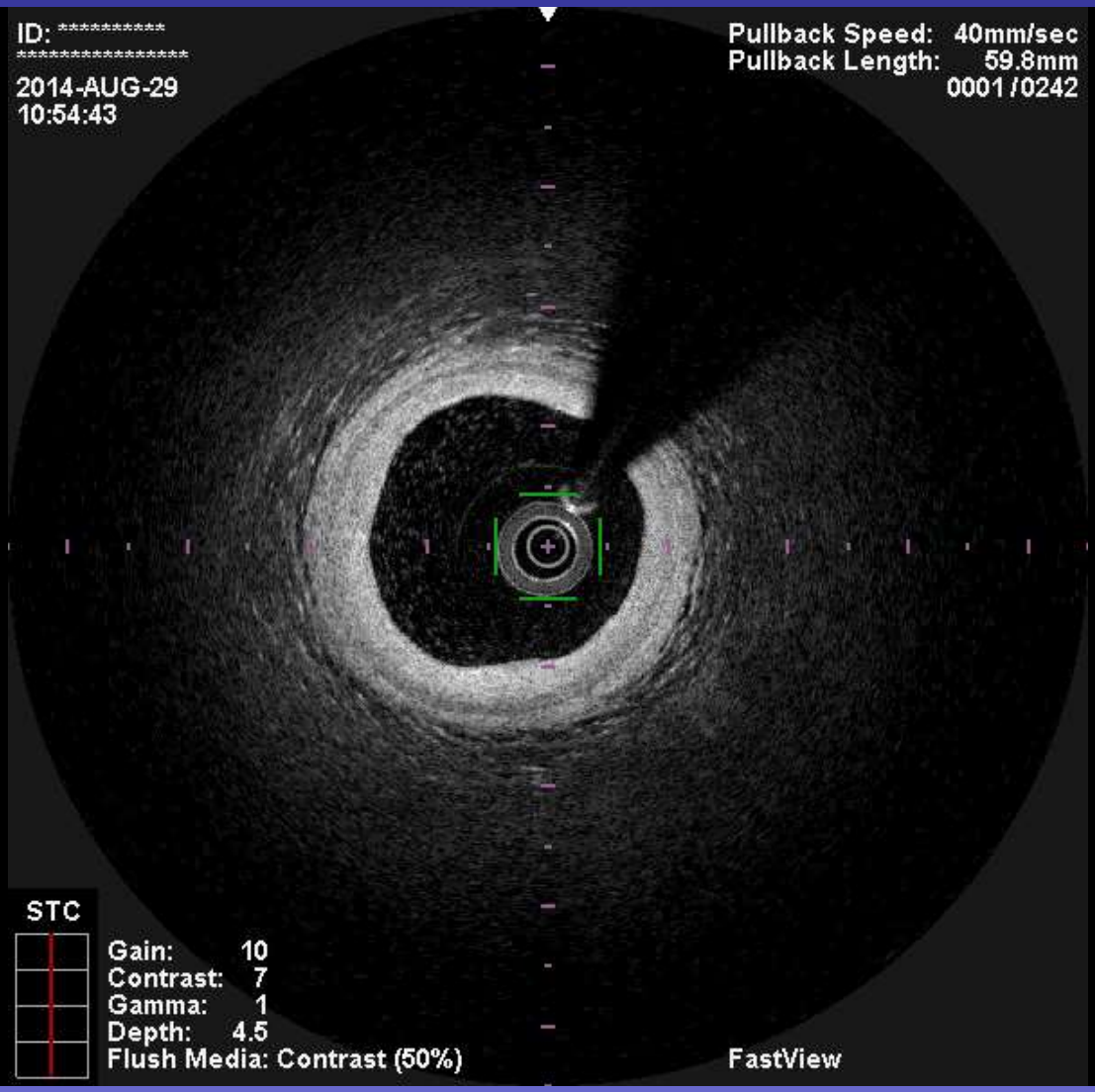
MDCT2


Vessel Direction Based
Depth: 0.0 mm
Angle: 0.0 deg
LAD
YOKOHAMA SHINTOSHI HOSPITAL
HAYASHI MASAHIRO 79Y M
2343432
2014/6/4
11:02:08.000
WL:673 WW:2258
1.43
CPR-A

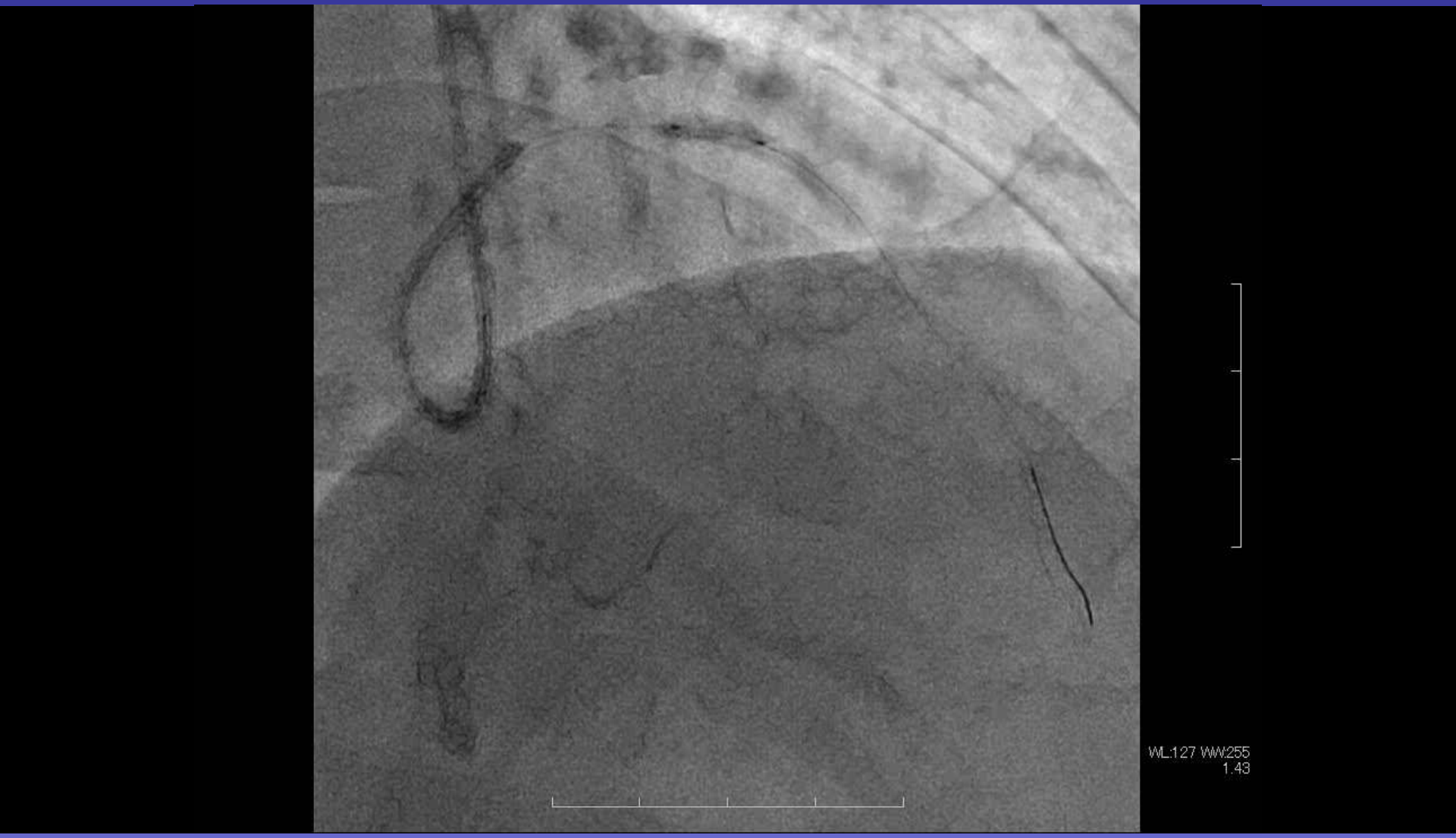
Pre CAG



Pre OFDI

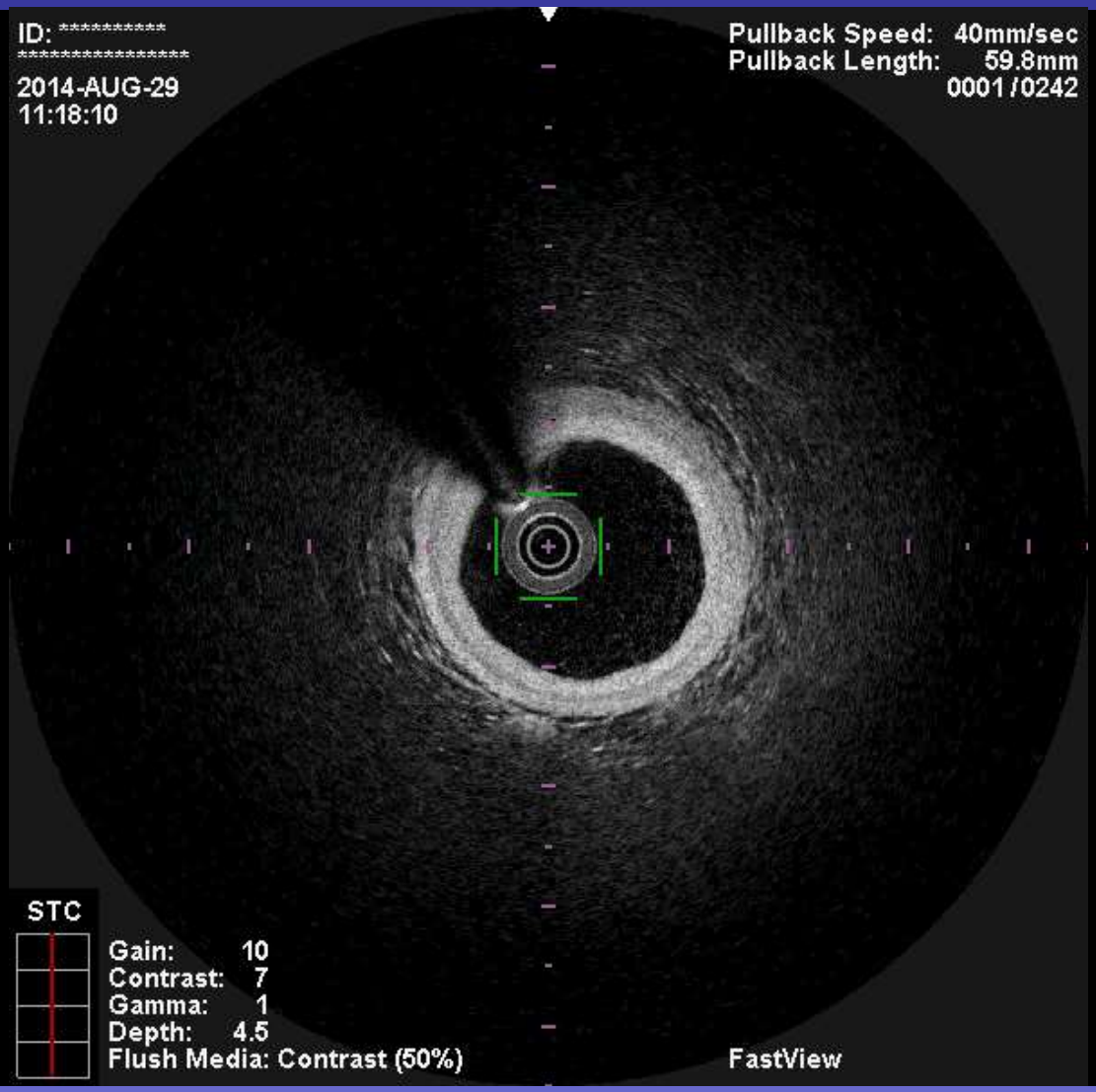

ID: **********
****
2014-AUG-29
10:54:43
Pullback Speed: 40mm/sec
Pullback Length: 59.8mm
0001/0242
STC
Gain: 10
Contrast: 7
Gamma: 1
Depth: 4.5
Flush Media: Contrast (50%)
FastView

NSE 2.25mm leopard crawl 1



NSE 2.25mm leopard crawl 2

Post NSE


ID: **********
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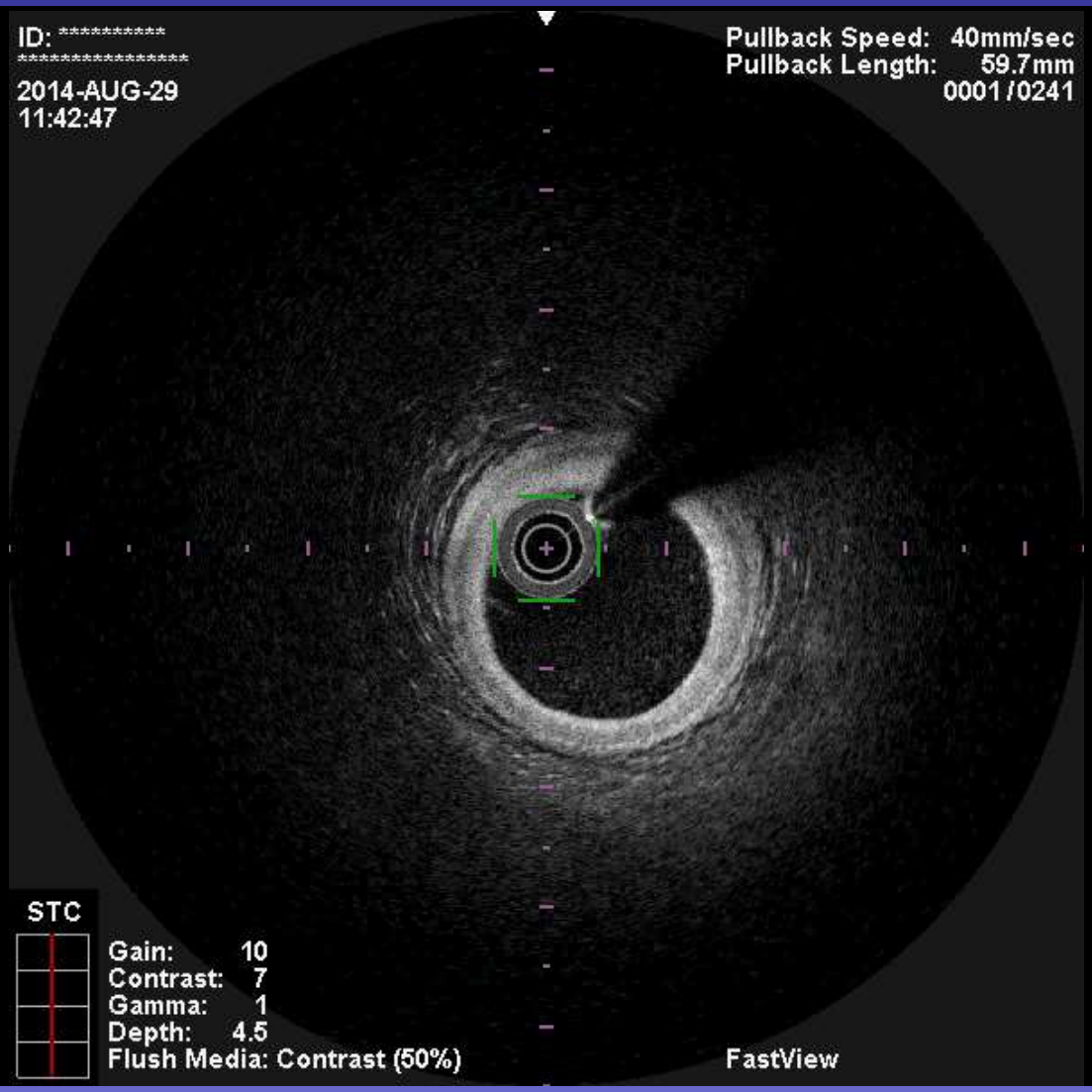
2014-AUG-29
11:18:10
Pullback Speed: 40mm/sec
Pullback Length: 59.8mm
0001 /0242
STC
Gain: 10
Contrast: 7
Gamma: 1
Depth: 4.5
Flush Media: Contrast (50%)
FastView

Post Stent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2014-AUG-29
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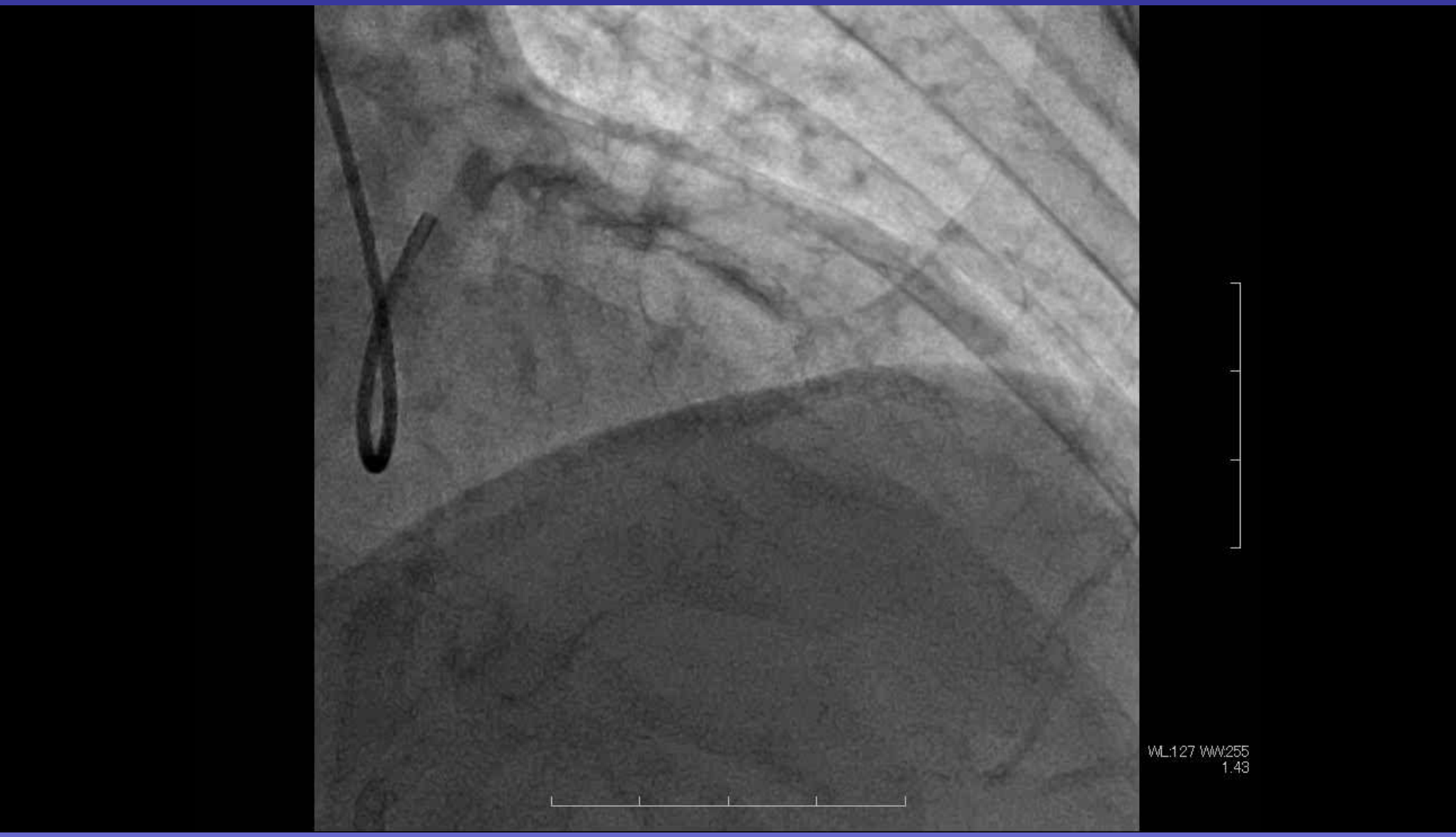
Depth: 4.5
Flush Media: Contrast (50%)
FastView

Final CAG



Leopard crawl using Lacrosse NSE.
Pre-dilatation of a calcified lesion

Efficacy of Lacrosse NSE Using the "Leopard-Crawl" Technique on Severely Calcified Lesions

Kazuhiro Ashida, MD, PhD, Taichiro Hayase, MD, Takayuki Shinmura, MD

ABSTRACT: Calcified lesions often encounter difficulties associated with stent delivery and underexpansion. Lesion preparation of calcified lesions prior to stent implantation is important to facilitate stent delivery and provide concentric stent expansion. The Lacrosse NSE, a balloon catheter with 3 nylon elements, provides an efficacious scoring effect when used for predilatation of calcified lesions. Although bench testing on a calcified model verified that Lacrosse NSE and other scoring catheters provide a greater scoring effect compared to conventional plain old balloon angioplasty, delivery to target lesion location using standard delivery techniques for severely calcified lesions is typically more problematic. One method for overcoming the obstacles faced by difficult delivery is use of the "leopard-crawl" technique. This technique uses a low inflation pressure to create a wedge into the calcification and then subsequently advances the catheter during balloon deflation to facilitate catheter delivery across the stenosis. This technique is well suited for the Lacrosse NSE due to the unique catheter design. We hereby report on the initial clinical use of the leopard-crawl technique for facilitating catheter delivery in cases of severely calcified lesions in which standard delivery was unsuccessful, while creating an efficacious scoring effect into the calcified lesion that reflects the results of bench testing.

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Key words: calcified lesion, leopard-crawl technique, intravascular ultrasonic imaging, CT angiography

Abbreviations
CAG – coronary angiography
IVUS – intravascular ultrasound
LAD – left anterior descending artery
LAO – left anterior oblique
LCX – left circumflex coronary artery
OCT – optical coherence tomography
PCI – percutaneous coronary intervention
POBA – plain old balloon angioplasty
RCA – right coronary artery

The scope of cases treated with PCI has increased with further advances in medical devices and techniques. However, treatment of calcified lesions by PCI remains problematic,[1-3] with difficulties associated with stent delivery, underexpansion, and asymmetric expansion resulting in worse patient prognosis. Therefore, it is considered that predilatation to create multiple scoring effects into the lesion prior to stenting leads to better stent expansion.[4,5]

Recently, the novel Lacrosse NSE catheter (Goodman Co, Ltd) has become commercially available. The catheter contains three triangular nylon elements (width, 0.014"; height, 0.015") that are free floating on the outside of the balloon surface, and attached proximal and distal to a 13 mm balloon length. Dilatation using a Lacrosse NSE creates a scoring effect into calcified tissue through a focused transmission of force through the elements. An investigation was performed into the dilative effect of various types of commercially available scoring balloons on fully circumferential calcified models.

Unfortunately, current designs of scoring balloons result in reduced functionality in regard to delivery in comparison to conventional balloons, and difficulties associated with delivery and lesion crossability of scoring catheters occur in a clinical setting.[6] The Lacrosse NSE elements are attached distal to the balloon location, and for instances whereby the catheter is unable to cross lesion location, a "leopard-crawl" technique can assist in facilitating device delivery. The efficacy of the leopard-crawl technique in crossing calcified lesions in a clinical setting is also further addressed.

Methods

Testing method for identifying scoring effect. Twelve cylindrical tubes (inner diameter, 3.0 mm; thickness, 0.7 mm; approximate length, 7.1 mm) comprised of New Diastone Yellow (dental stone; Morita Co, Ltd) (Figure 1) and covered by silicone tubing (thickness, 1.0 mm) were used to represent a calcified lesion (Figure 2) (calcified models were provided by Goodman Co, Ltd). Three catheters of each of the following devices were dilated within the calcified models: 3.5 x 10 mm Powered Lacrosse non-compliant balloon (Goodman Co, Ltd); 3.5 x 13 mm Lacrosse NSE scoring balloon; 3.5 x 10 mm Flextome cutting balloon; and 3.5 x 10 mm Scoreflex (Orbus Neich Medical). Inflation pressure, total number of cracks, and dimensions (longitudinal length) were recorded (Figure 3).

Results

A cracking effect was observed for the various scoring balloons during inflation from nominal burst pressure (NBP) to rated burst pressure (RBP), with multiple cracks observed for two of the scoring devices. For the scoring balloons, both Lacrosse NSE and the Flextome cutting balloon incurred cracking in at least 2 locations and throughout the entire calcified

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Conclusion

- ✓ Severely calcified lesions: issues with problematic stent delivery and under-expansion occur often.
- ✓ Given the mechanism of stent expansion, it is considered that creating a cracking effect in at least 2 locations is important.
- ✓ Create a creating effect with a scoring balloon catheter (Rotablator thins out the calcification).
- ✓ The design of Lacrosse NSE provides for distal inflation that facilitates the leopard crawl technique. The profile of cutting balloon, similar to conventional balloons, becomes enlarged upon inflation.
- ✓ Use of other scoring balloons is less effective in generating multiple cracking effects.
- ✓ Double wire technique is feasible: various delivery techniques can be utilized.
- ✓ Considering the distribution of calcification by using MDCT as well as wire bias, cracking can be created safely (process of sizing and inflation method).

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