

**EVENTI AVVERSI LEGATI ALLA PROCEDURA,
LINEE GUIDA E APPROPRIATEZZA DELLE
INDICAZIONI**

**CHIUSURA DEL PFO: UN RARO
CASO DI MIGAZIONE
DELL'AMPLATZER.**

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**Laboratorio di Emodinamica
Ospedale "Luigi Sacco" - Milano**

"...una procedura che deve essere intrapresa solo dopo una attenta analisi dell'indicazione clinica..."

POSITION PAPER

Documento di posizione multidisciplinare sulla gestione del forame ovale pervio in presenza di ischemia cerebrale criptogenica – versione 2013

Società Italiana di Cardiologia Invasiva (SICI-GISE), Associazione Italiana Ictus (ISA-AIS), Scienze Neurologiche Ospedaliere - Società dei Neurologi, Neurochirurghi e Neuroradiologi Ospedalieri (SNO), Gruppo di Studio sulle Cardiopatie Congenite della Società Italiana di Cardiologia (SIC), Associazione Nazionale Medici Cardiologi Ospedalieri (ANMCO), Società Italiana di Cardiologia Pediatrica (SICP), Società Italiana di Ecografia Cardiovascolare (SIEC), Società Italiana per lo Studio dell'Emostasi e della Trombosi (SISET)

LE INDICAZIONI



TIA criptogenico o Ictus criptogenico (sintomatico/asintomatico) associato a PFO con shunt destro-sinistro

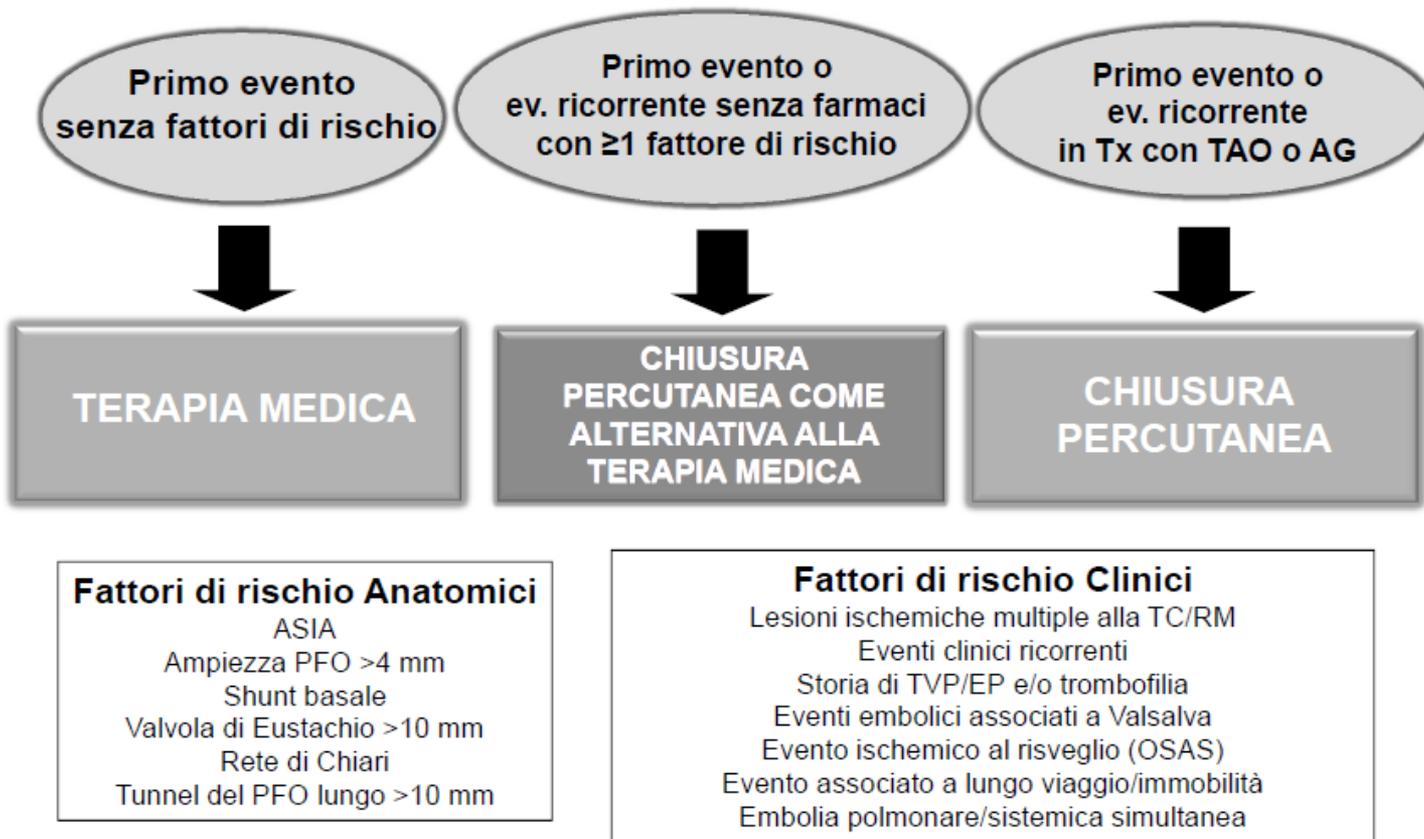


Figura 3. Schema delle raccomandazioni terapeutiche.

AG, antiaggreganti; ASIA, aneurisma del setto interatriale; EP, embolia polmonare; OSAS, sindrome delle apnee ostruttive del sonno; PFO, forame ovale pervio; RM, risonanza magnetica; TAO, terapia anticoagulante orale; TC, tomografia computerizzata; TIA, attacco ischemico transitorio; TVP, trombosi venosa profonda; Tx, terapia.

Modificata da Pristipino et al.⁴².

Ultima meta-analisi degli studi randomizzati (2013)

J.S.W. Kwong et al. / International Journal of Cardiology xxx (2013) xxx-xxx

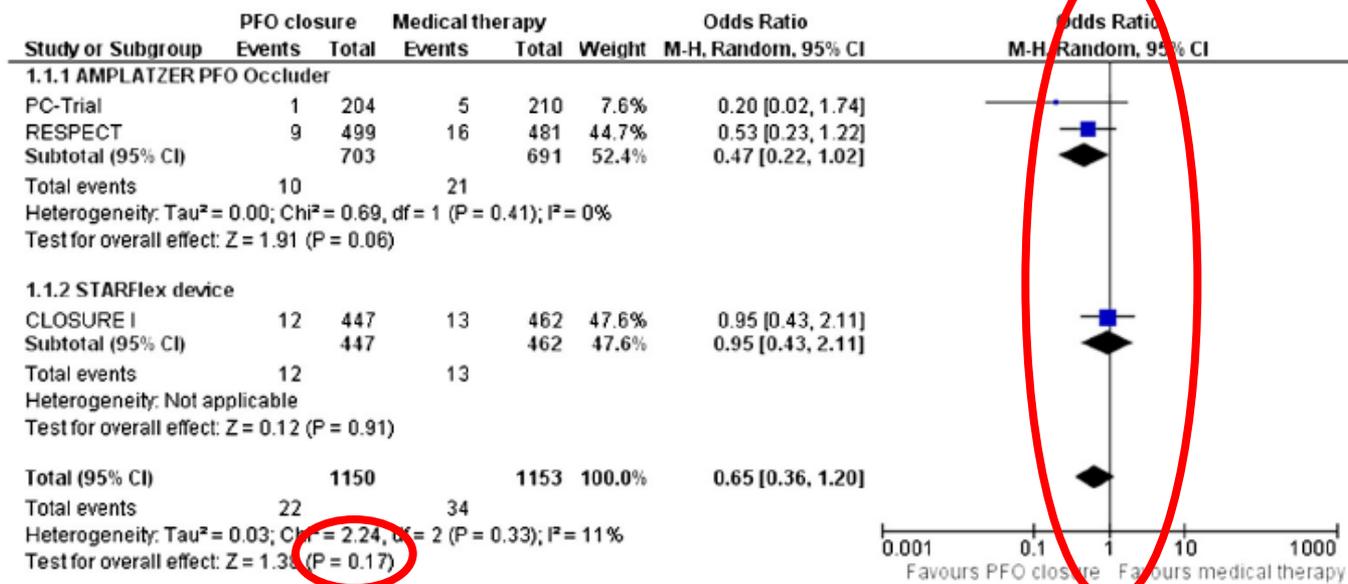
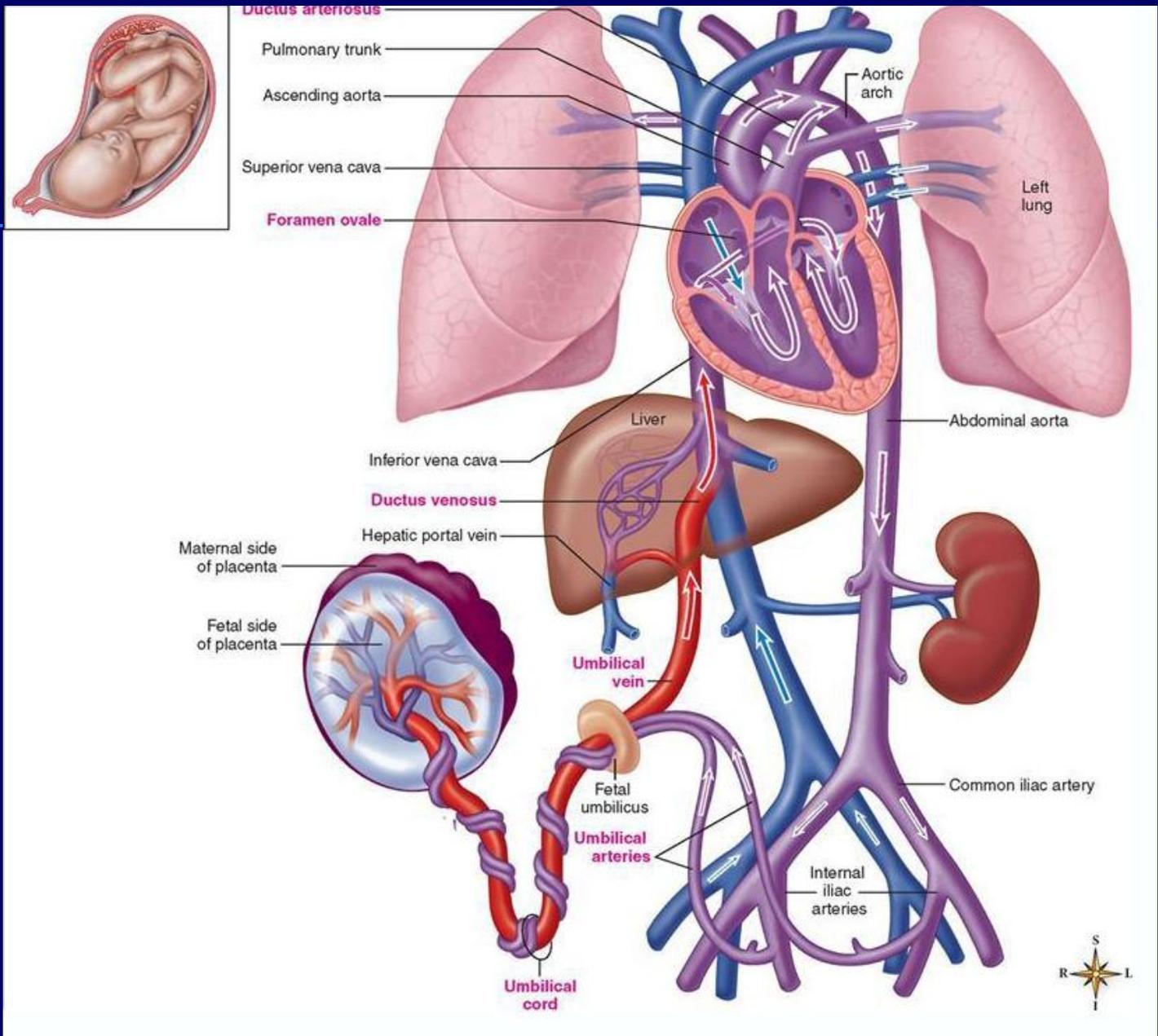
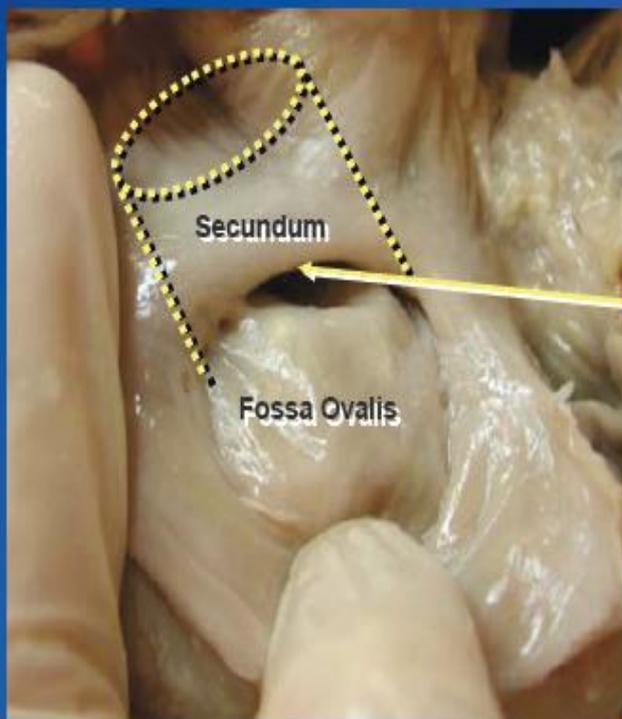


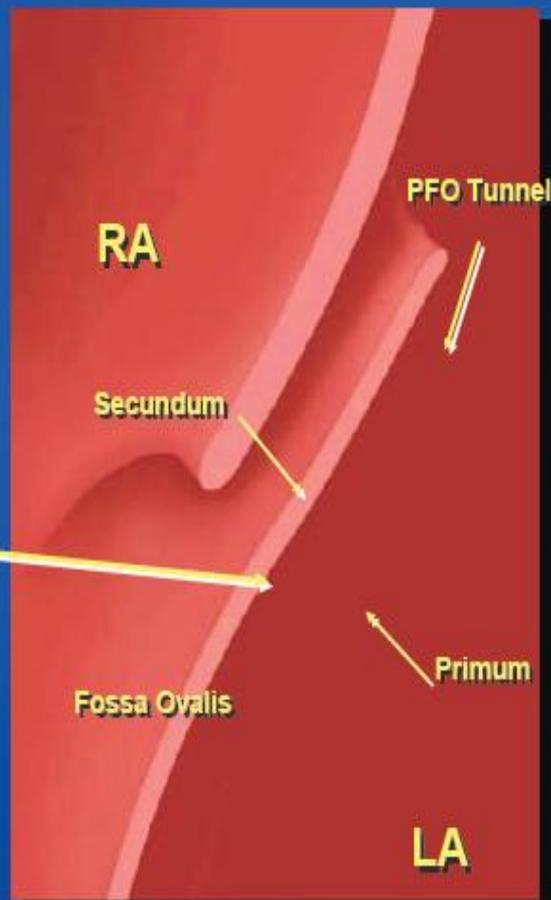
Fig. 3. Forest plot of stroke.



Anatomia



Limbus



RA

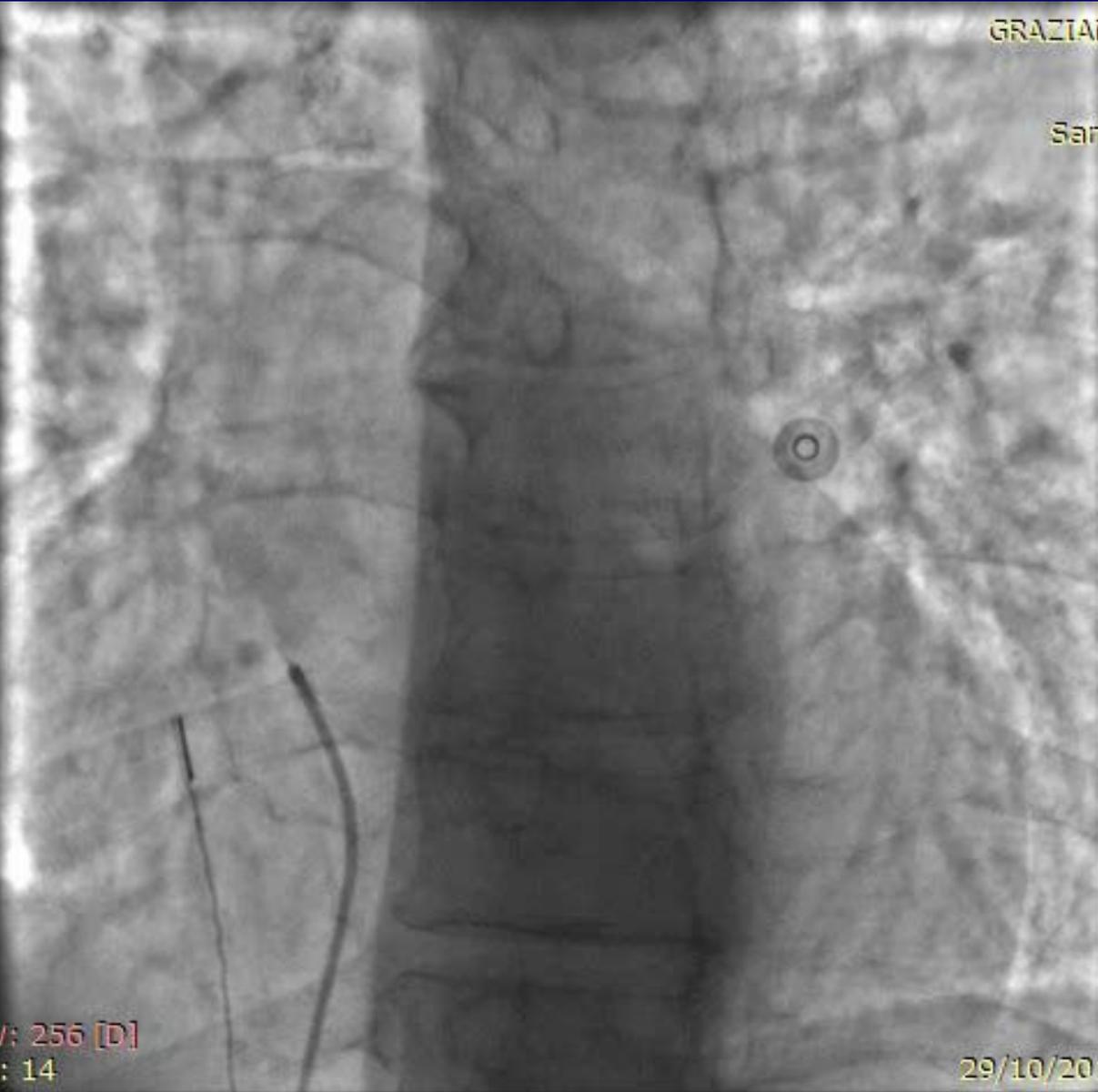
PFO Tunnel

Secundum

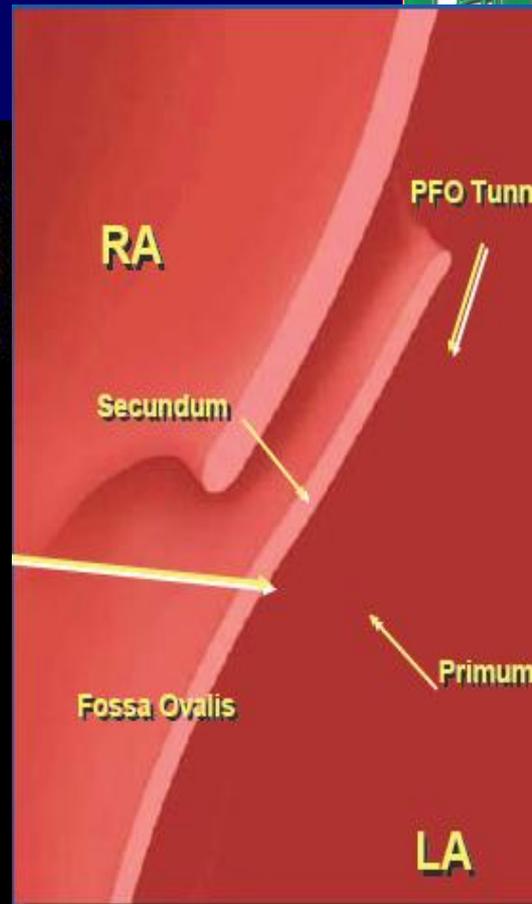
Fossa Ovalis

Primum

LA

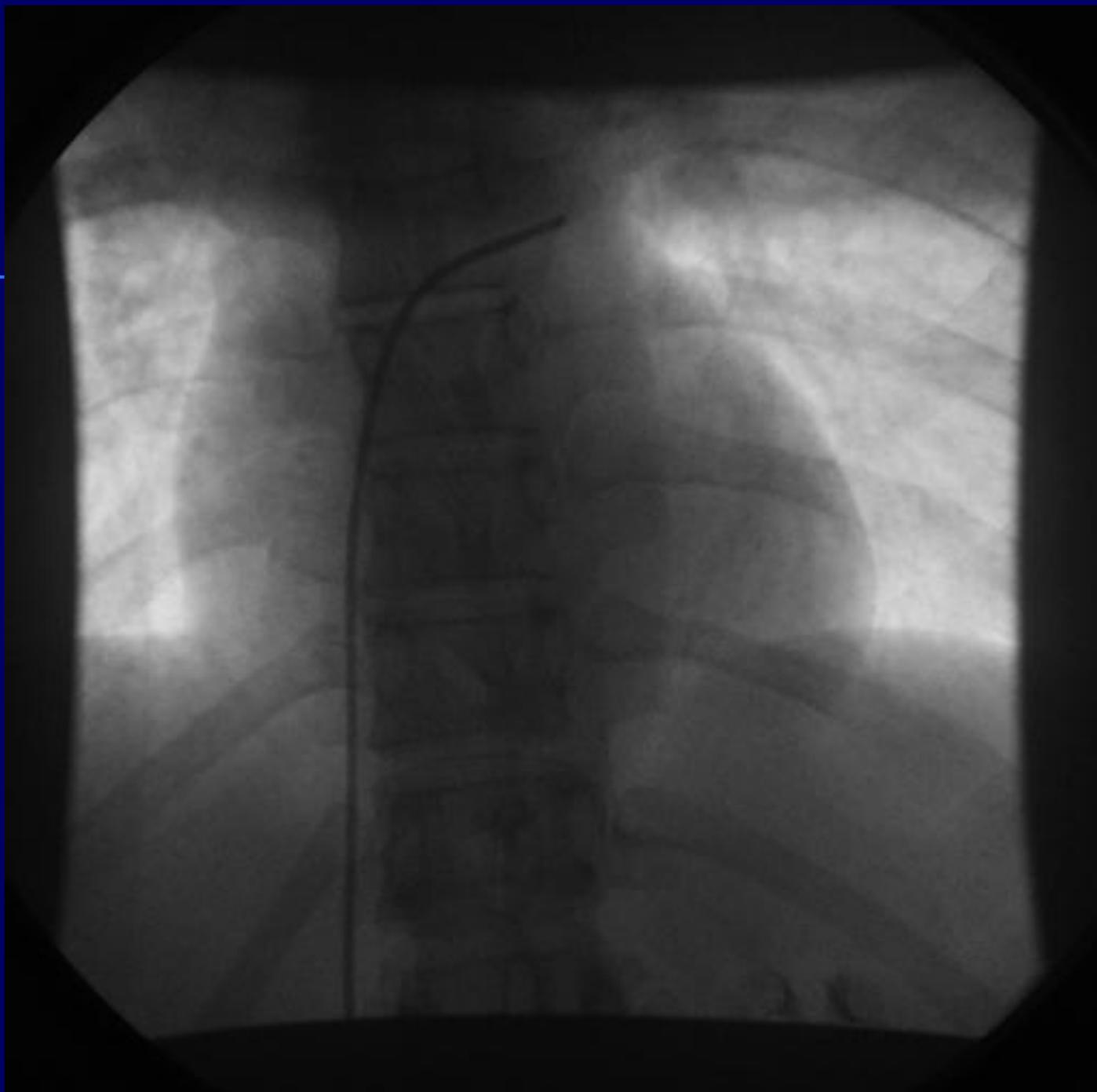


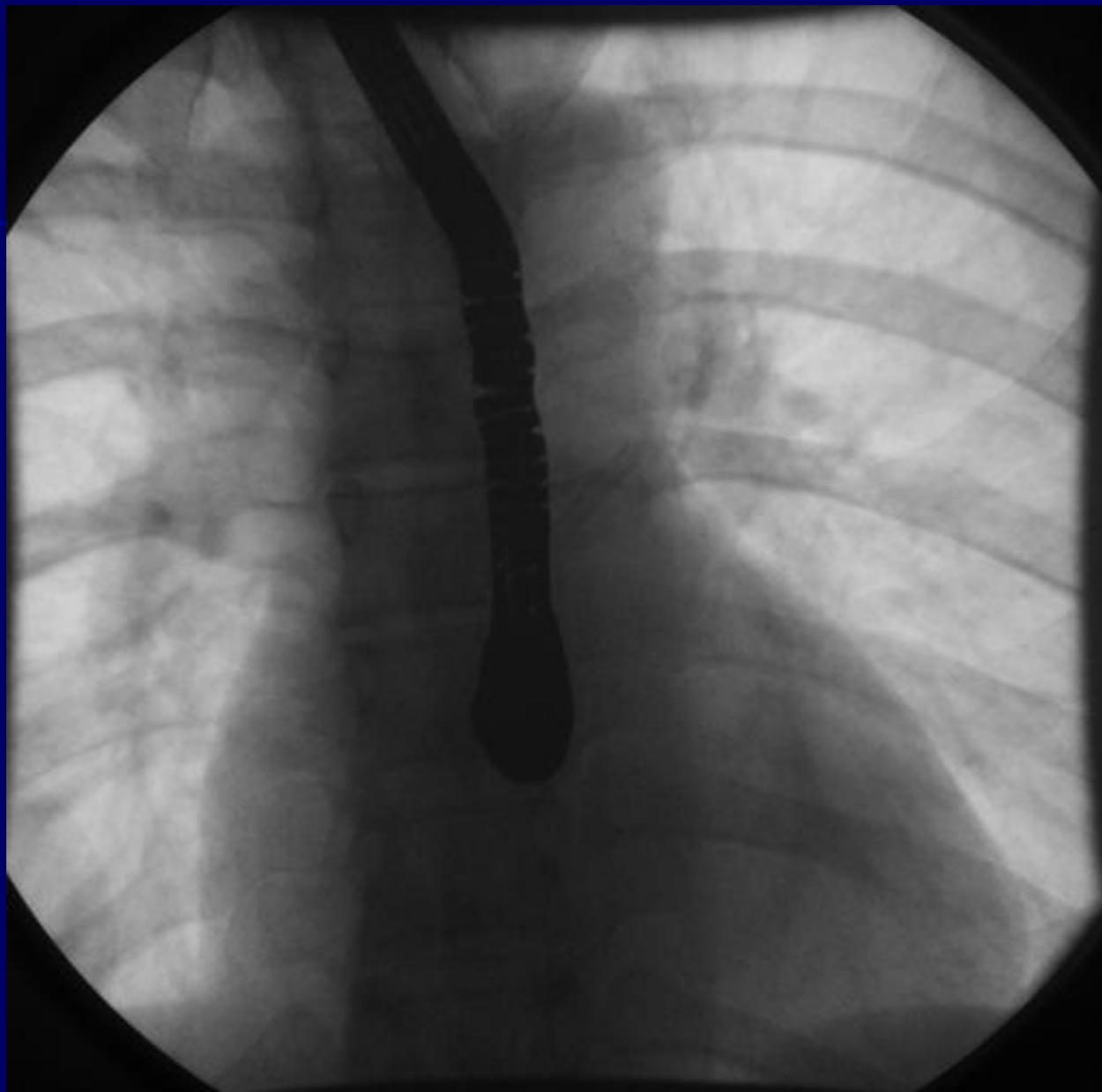
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43147
30/01/1952
San Filippo Neri
43147
P.F.O

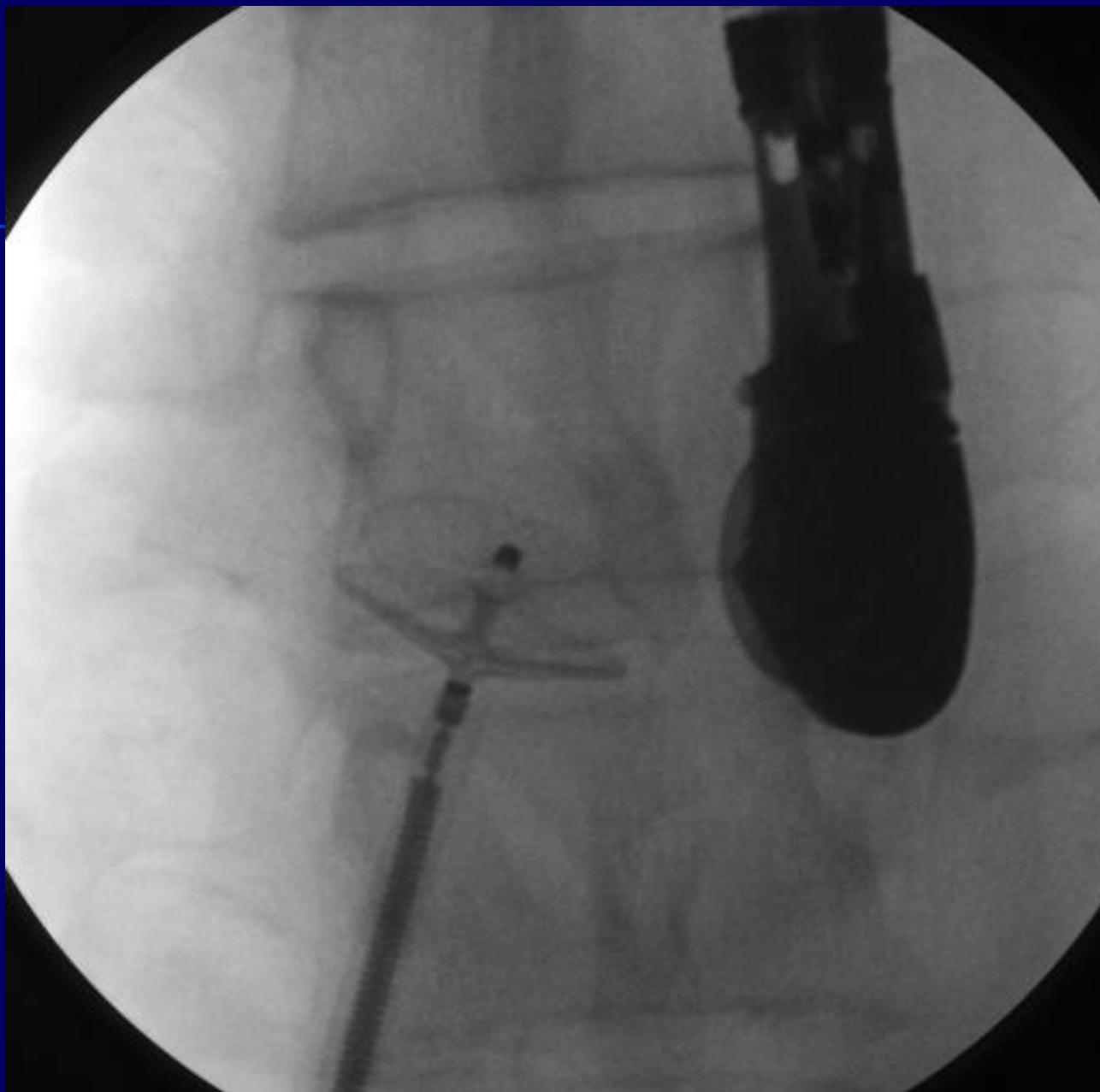


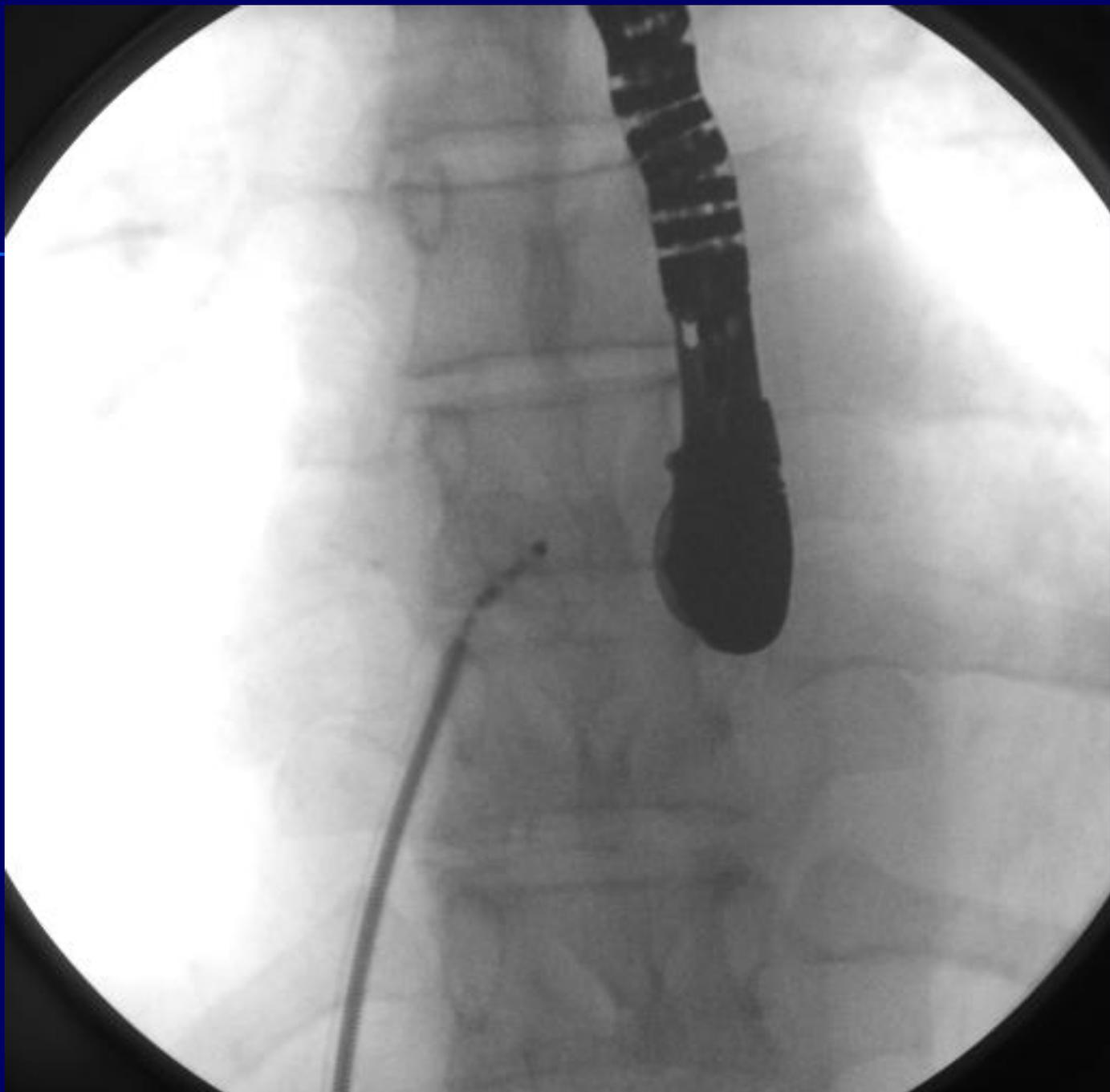
La chiusura percutanea
del PFO:

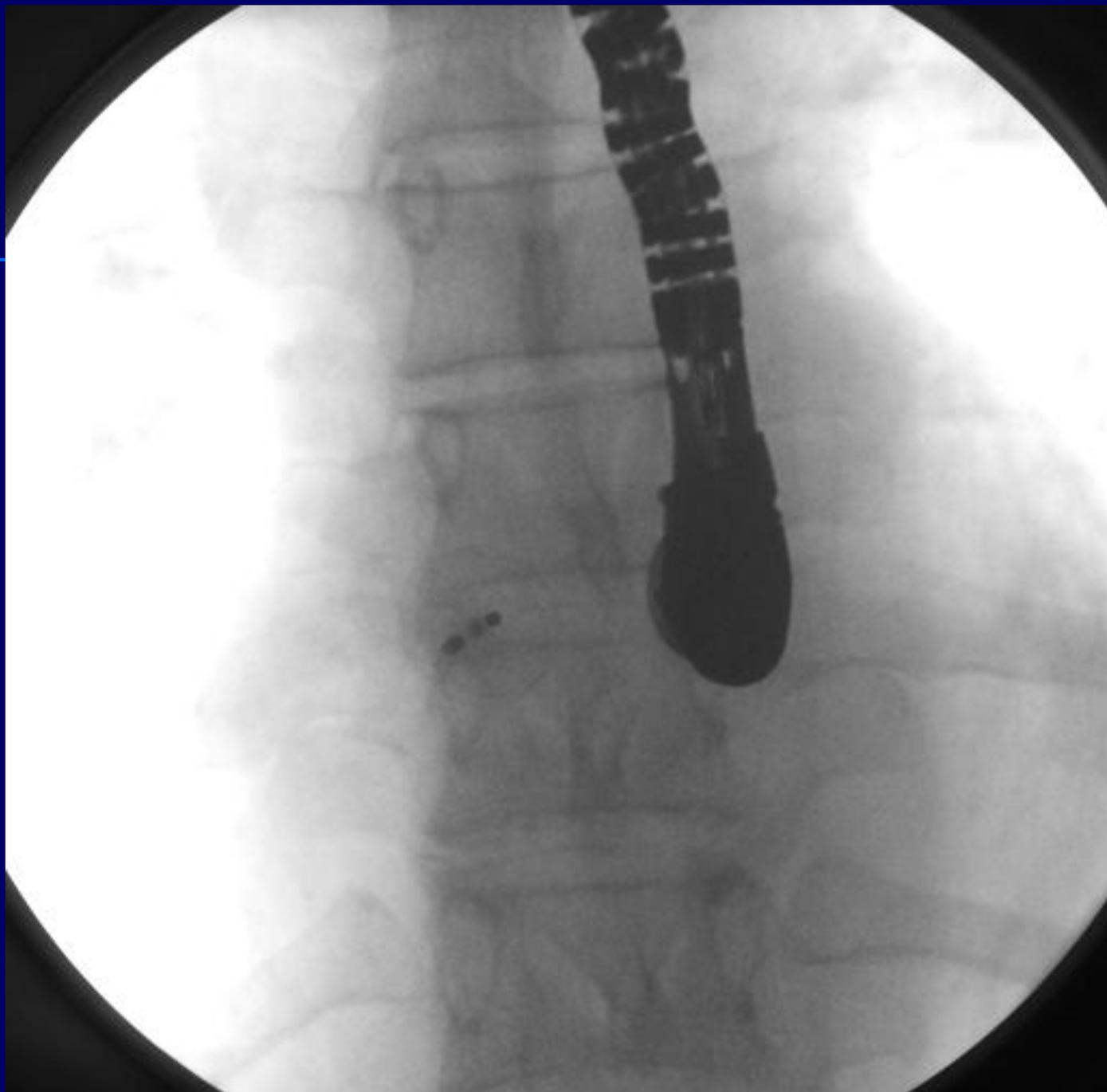
Fluoroscopia

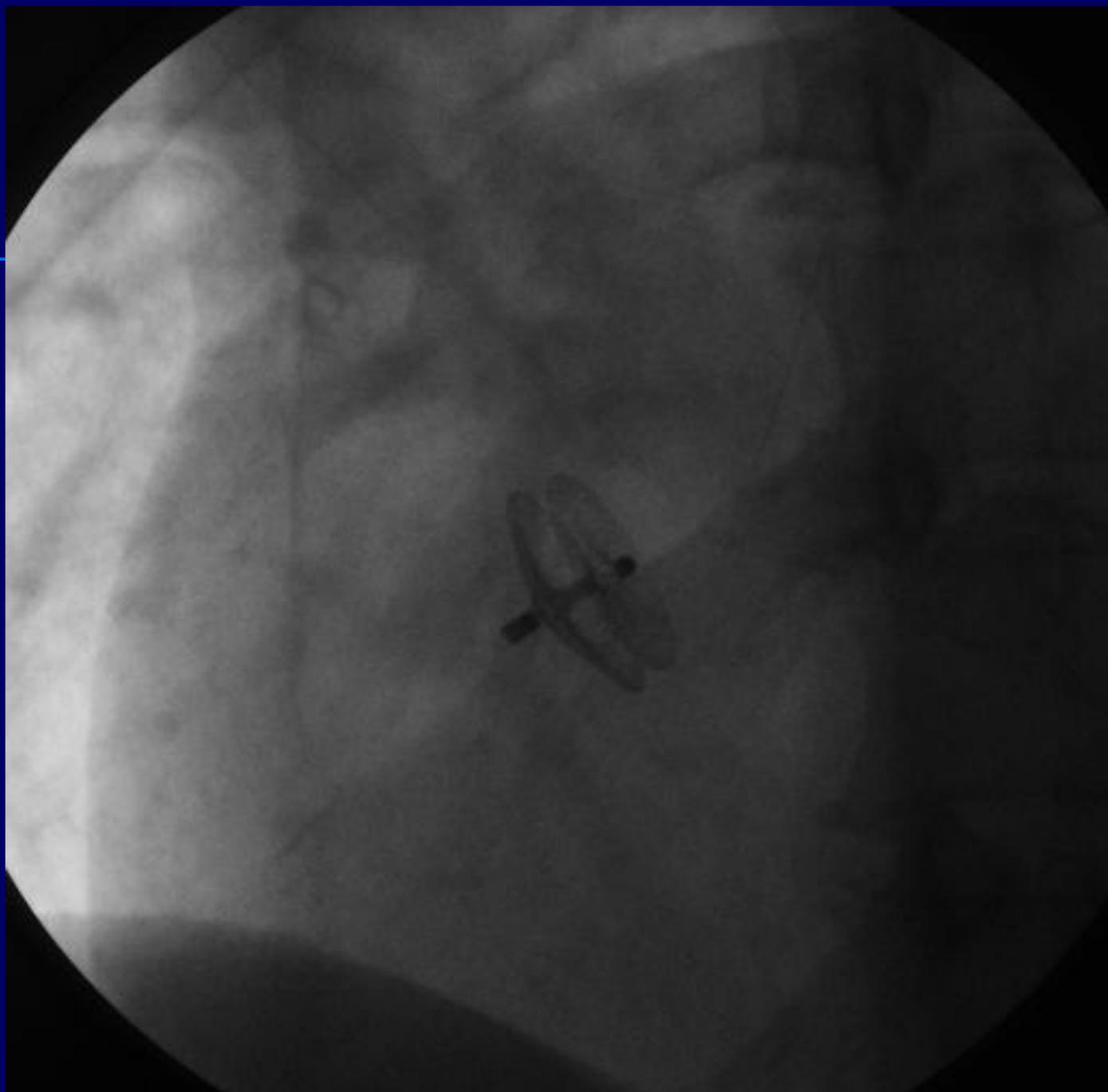












La chiusura percutanea del PFO:

Eco TEE



08/07/04:221301
5/7/2008
Map3
150 dB/C 3
Persistenza Basso
Ott. 2D:Gen
Freq Imm:Med



17:1

Clip

42



EMM TARABELLONI, ANNA M 08/07/04:221301 08 Lug 08 ITI 0.7 IM 0.48
TARABELLONI, ANNA M CARDIOLOGIA MPT7-4 CardA/TEE 09:24:29 48 Hz 10.7cm
08/07/04:221301

8/7/2008
Map3
150 dB/C 3
Persistenza Basso
Ott. 2D:Gen
Freq Imm:Med



12:1

Clip



TARABELLONI ANNA M 08/07/04:221301 09 Lug 08 ITI 0.7 IM 0.48
TARABELLONI ANNA M CARDIOLOGIA MPT7-4 CardA/TEE 09:25:01 48 Hz 10.7cm

08/07/04:221301
8/7/2008
Map3
150 dB/C 3
Persistenza Basso
Ott. 2D:Gen
Freq Imm:Med

13:1

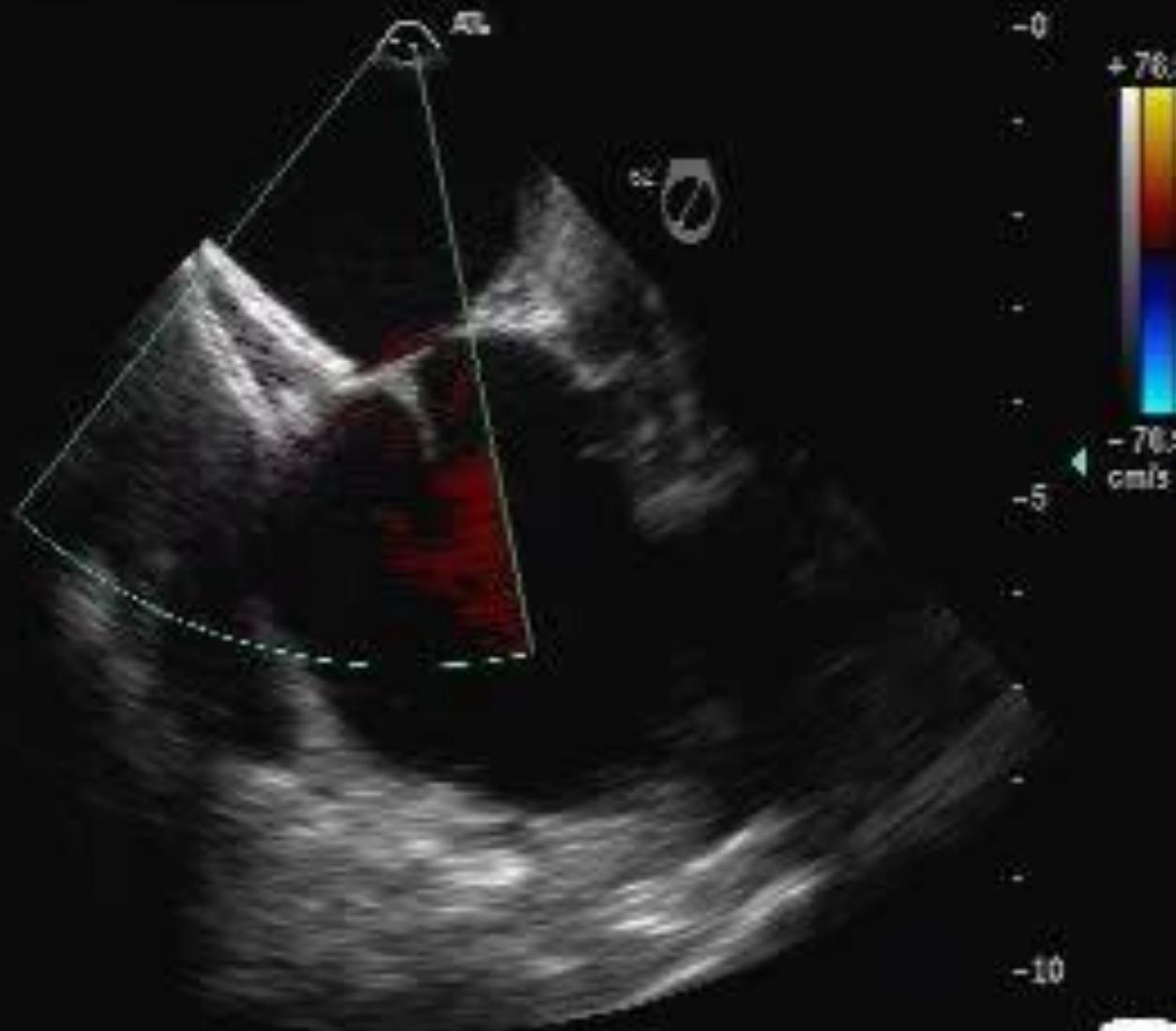
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48



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08/07/04:221301
8/7/2008
Map3

150 dB/C 3
Persistenza Basso
Ott. 2D:Gen
Freq Imm:Max
Col 79% Map3
FP Media
FRI 8000 Hz
Ott. flusso: V Med



11:1

Clip

47



TARABELLONI, ANNA M 08/07/04:221301 09 Lug 08 ITI 0.7 IM 0.48
TARABELLONI, ANNA M CARDIOLOGIA MPT7-4 CardA/TEE 09:25:57 48 Hz 10.7cm
08/07/04:221301

8/7/2008
Map3
150 dB/C 3
Persistenza Basso
Ott. 2D:Gen
Freq Imm:Med



10 : 1

Clip

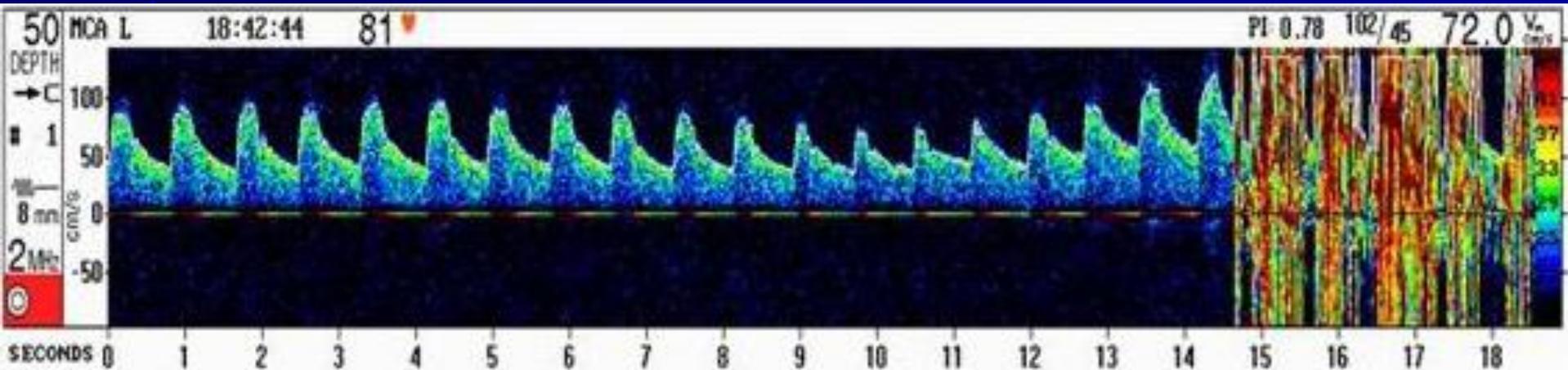
48



Paziente di 54 a con recente ictus ischemico nel territorio dell'arteria cerebrale media destra

- Ipertesa ben controllata - non altri fattori di rischio – pregresso “TIA” in terapia con ASA
- TSA - Normali
- Holter 24 ore – normale
- Screening coagulativo – normale
- Ecocardio – normale ad eccezione di ridondanza del setto interatriale senza segni doppler di shunt.
- Eco transcranico – positivo a riposo, “effetto tendina” dopo Valsalva
- Eco TEE – PFO ampio (10 mm), shunt confermato, ampia valvola di Eustachio, non placche aorta asc.
- RMN encefalo – lesione recente parietale destra, piccola lesione pregressa frontale sinistra

Doppler transcranico



PHILIPS

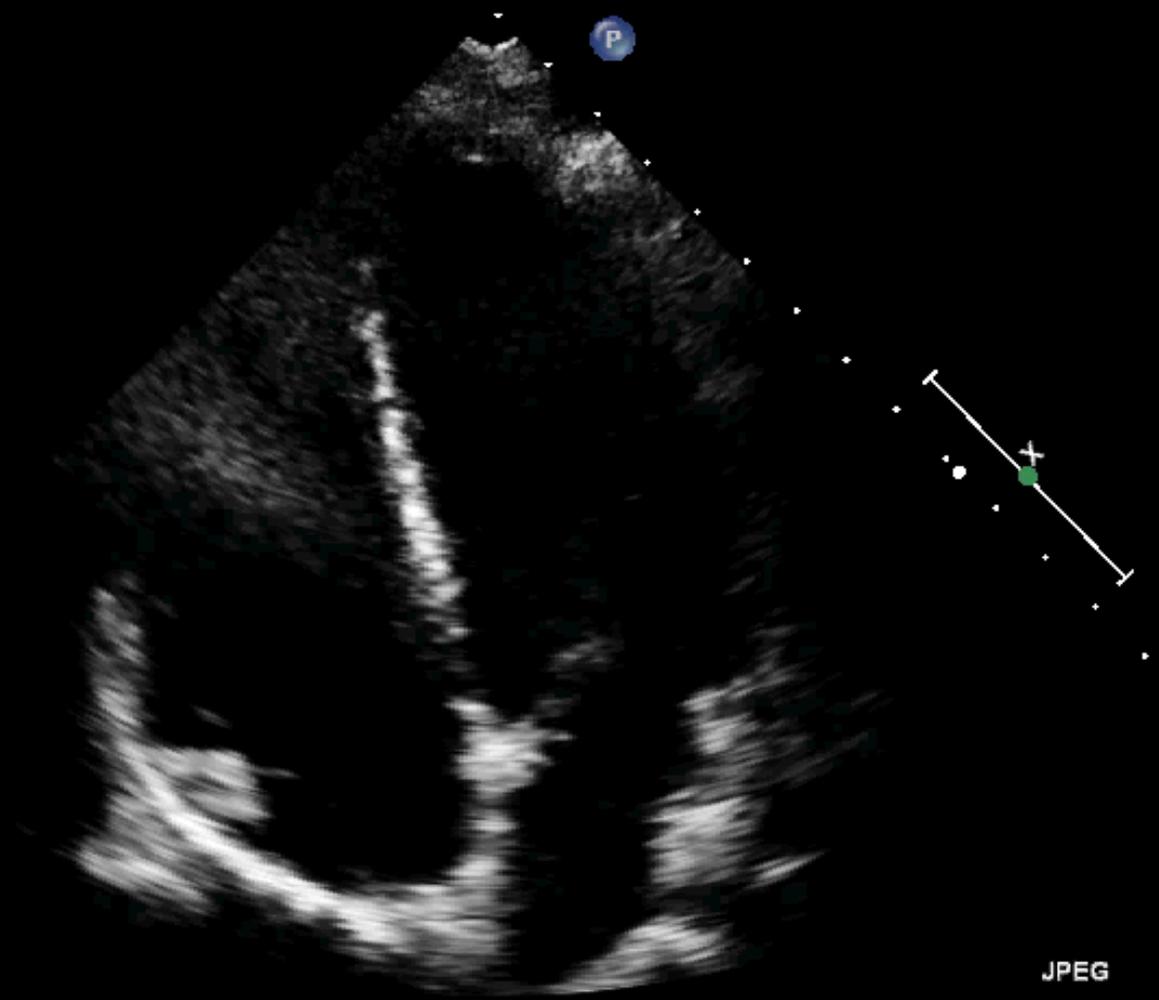
TISO.9 MI 1.4

S5-1/Adulti

FR 53Hz
14cm

M3

2D
53%
C 49
P Bassa
AGen



JPEG

54 bpm

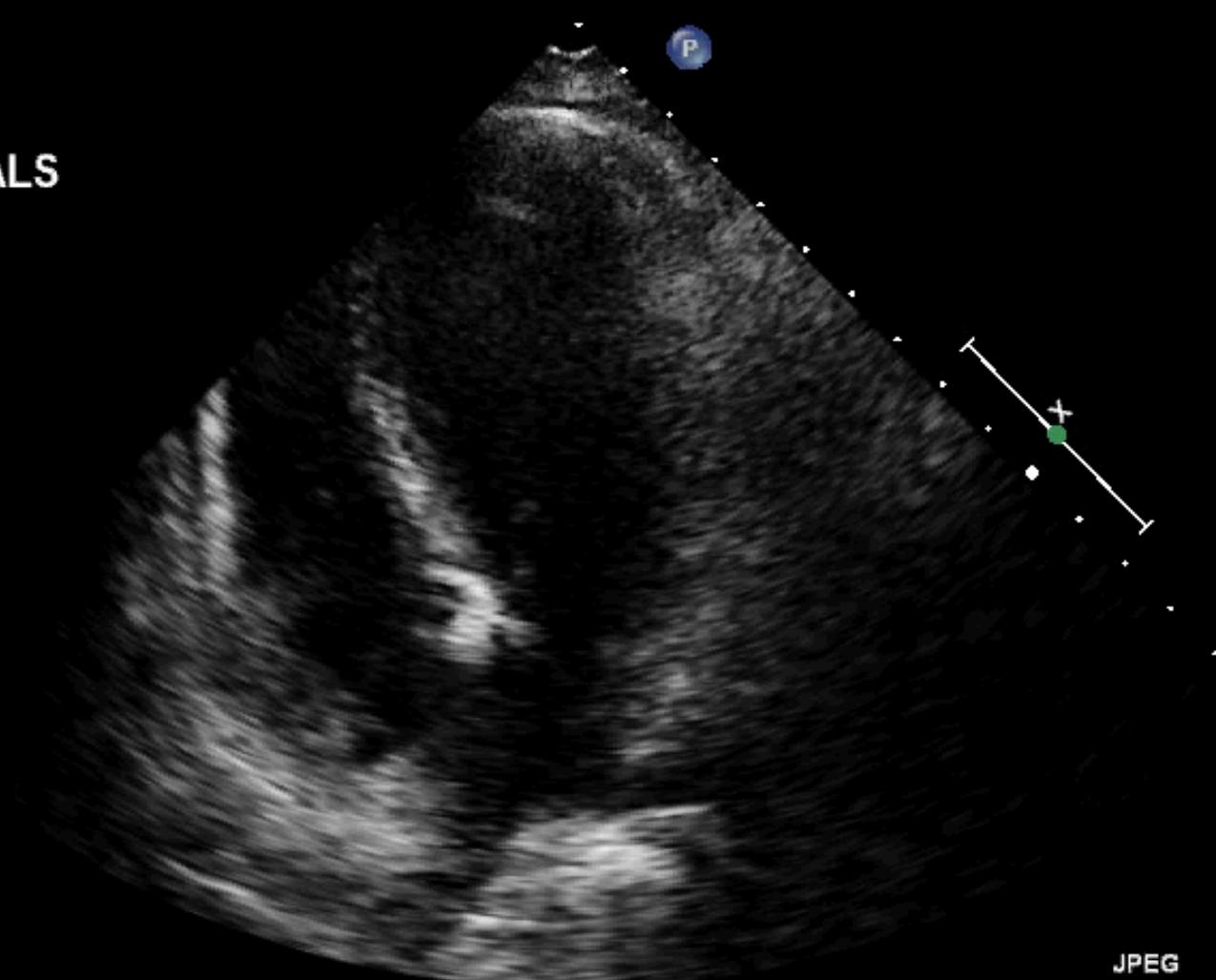
PHILIPS D'AMBROSIO, ANTONELLA 54 13/11/2012 16:55:29 TIS0.8 MI 1.4
48531620121113 S5-1/Adulti

FR 50Hz
15cm

2D
60%
C 50
P Bassa
AGen

1 VALS

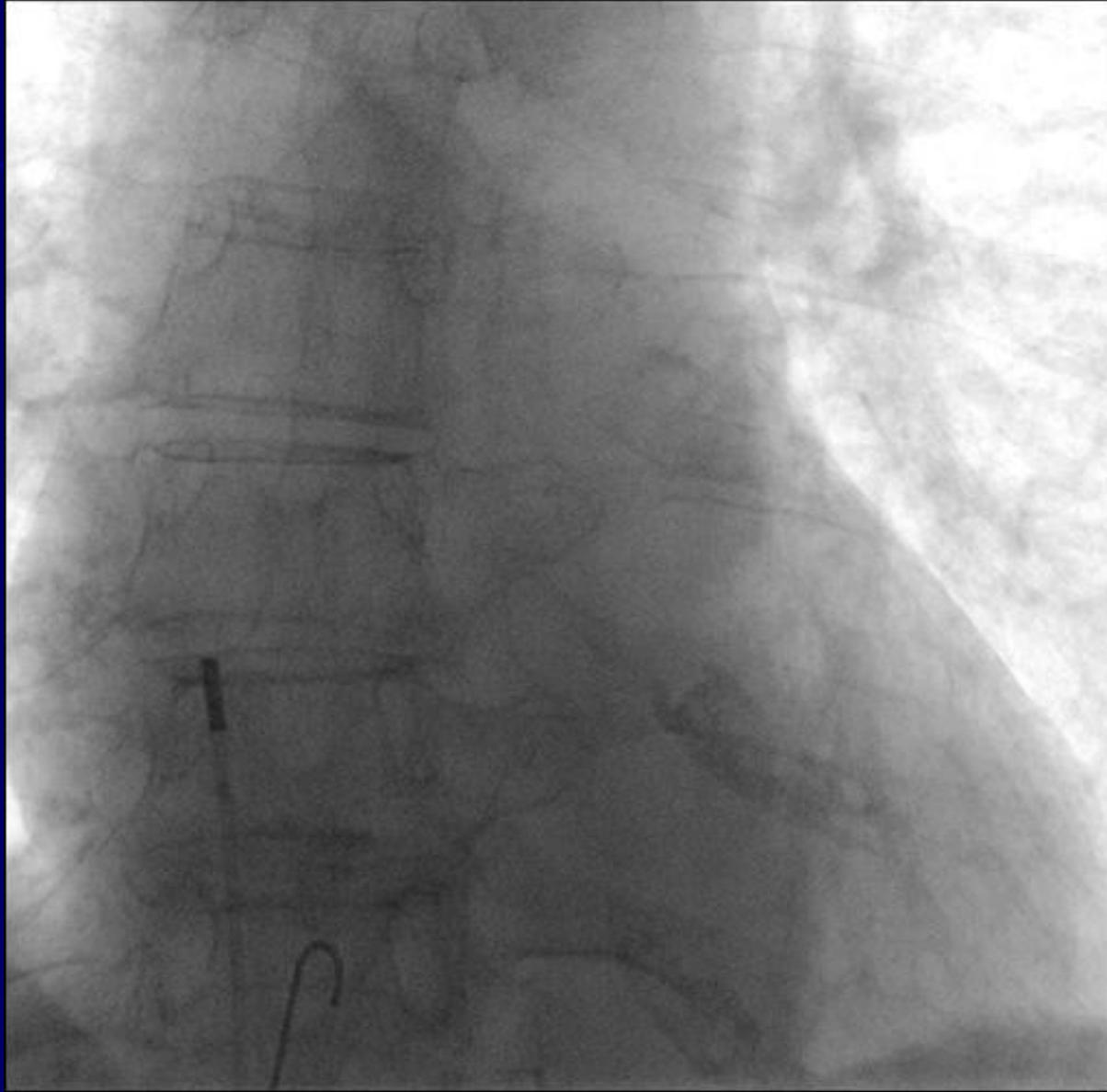
M3

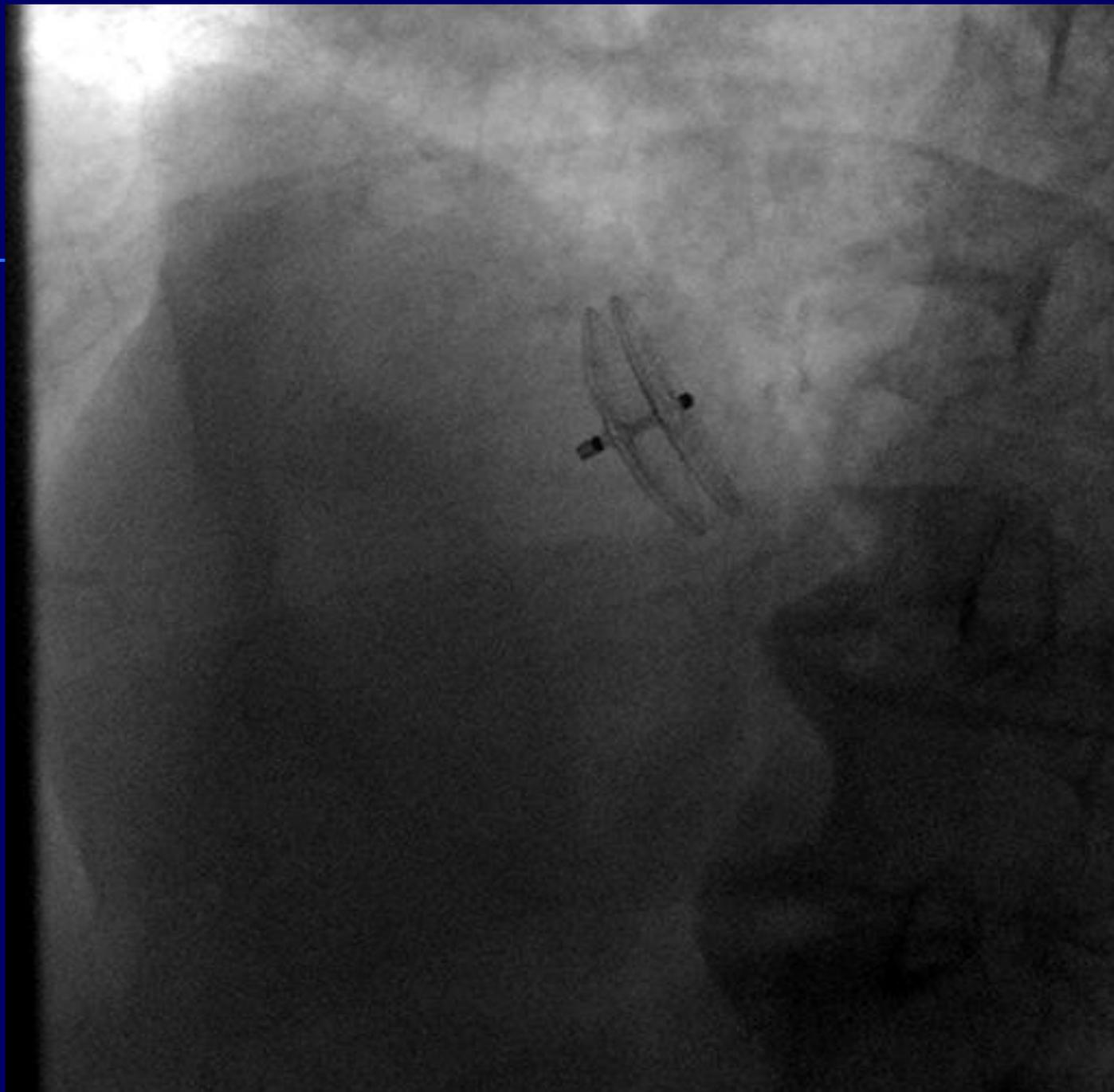


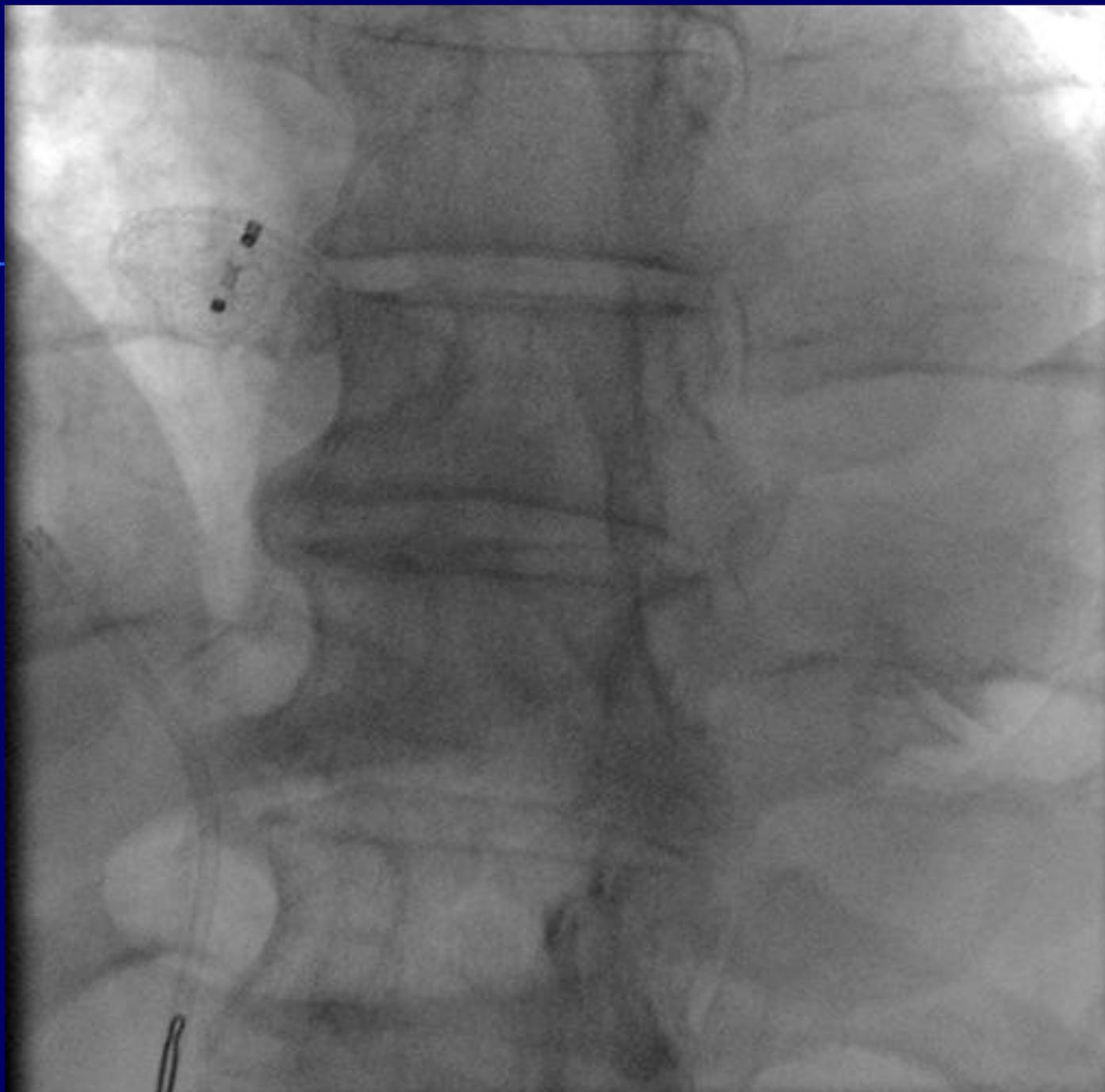
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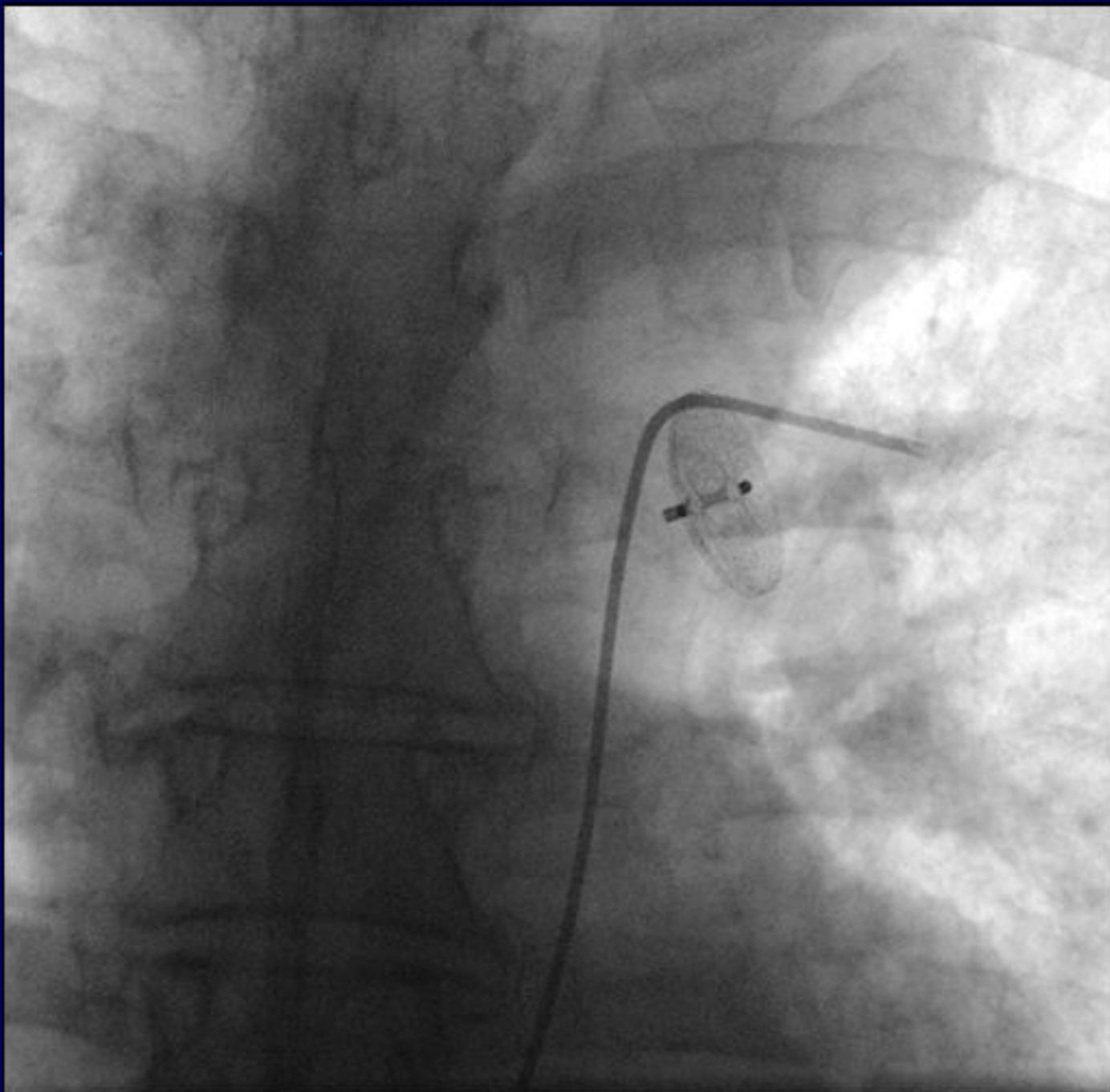
100 bpm

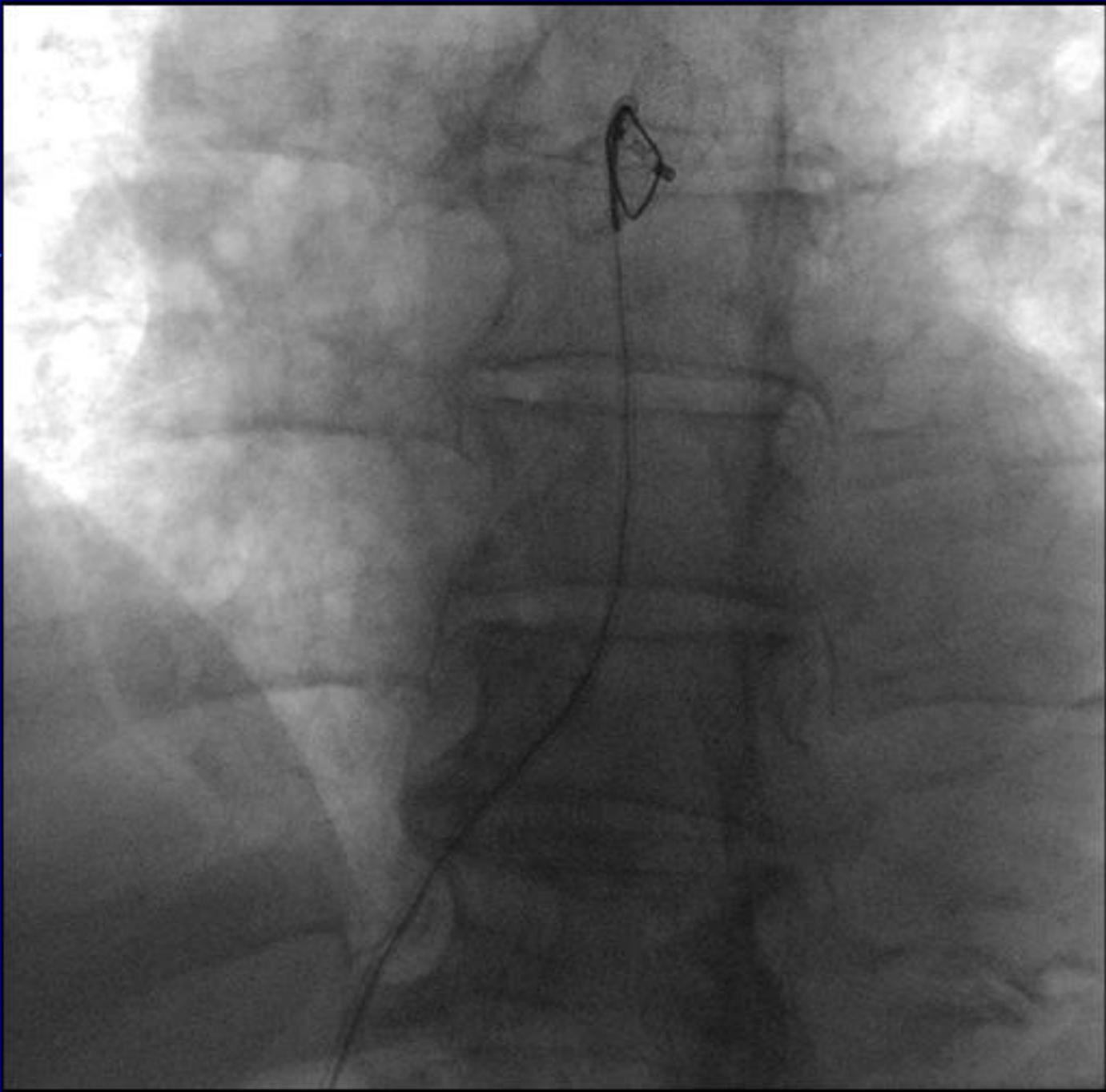
Passaggio spontaneo della guida



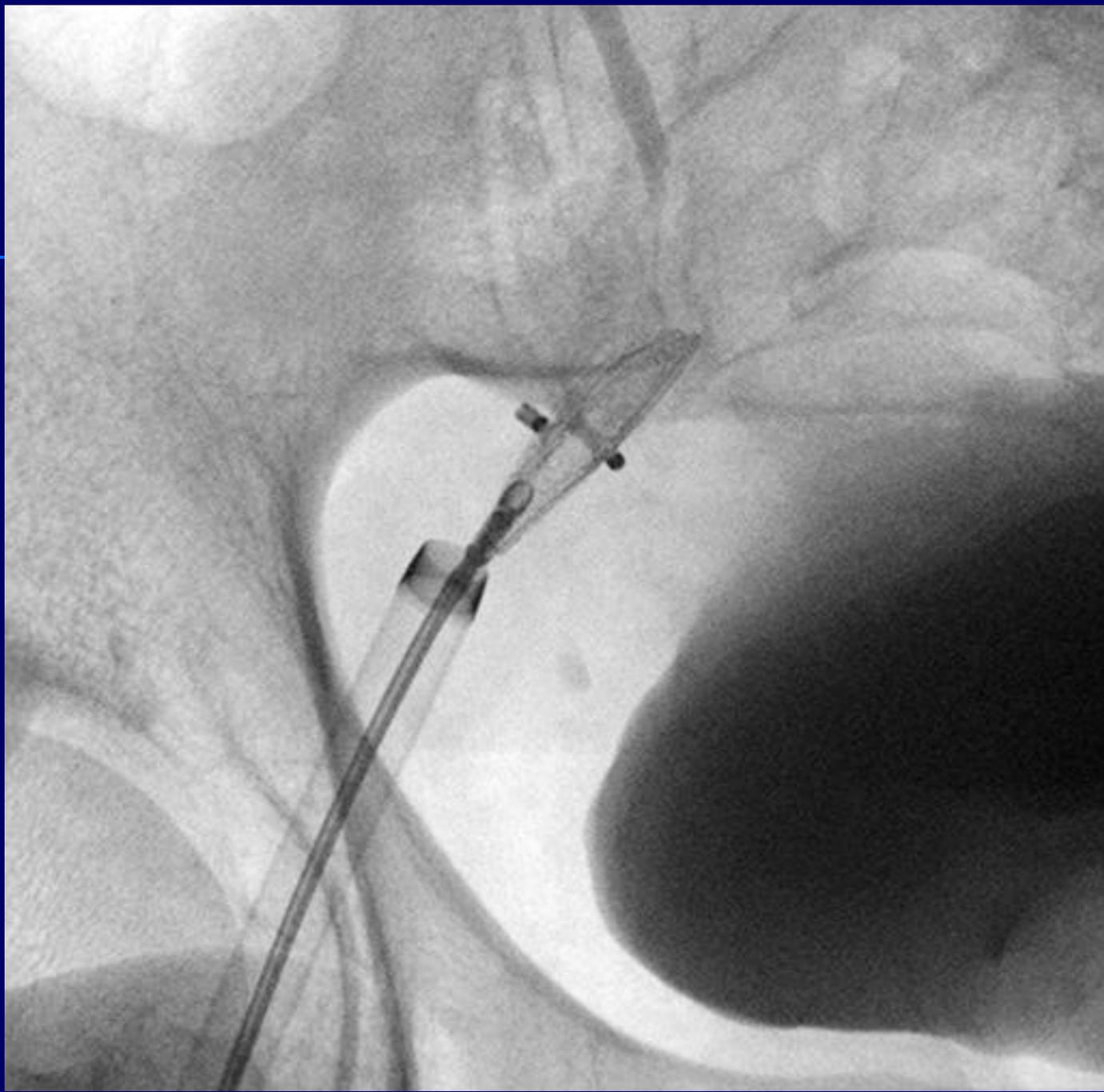


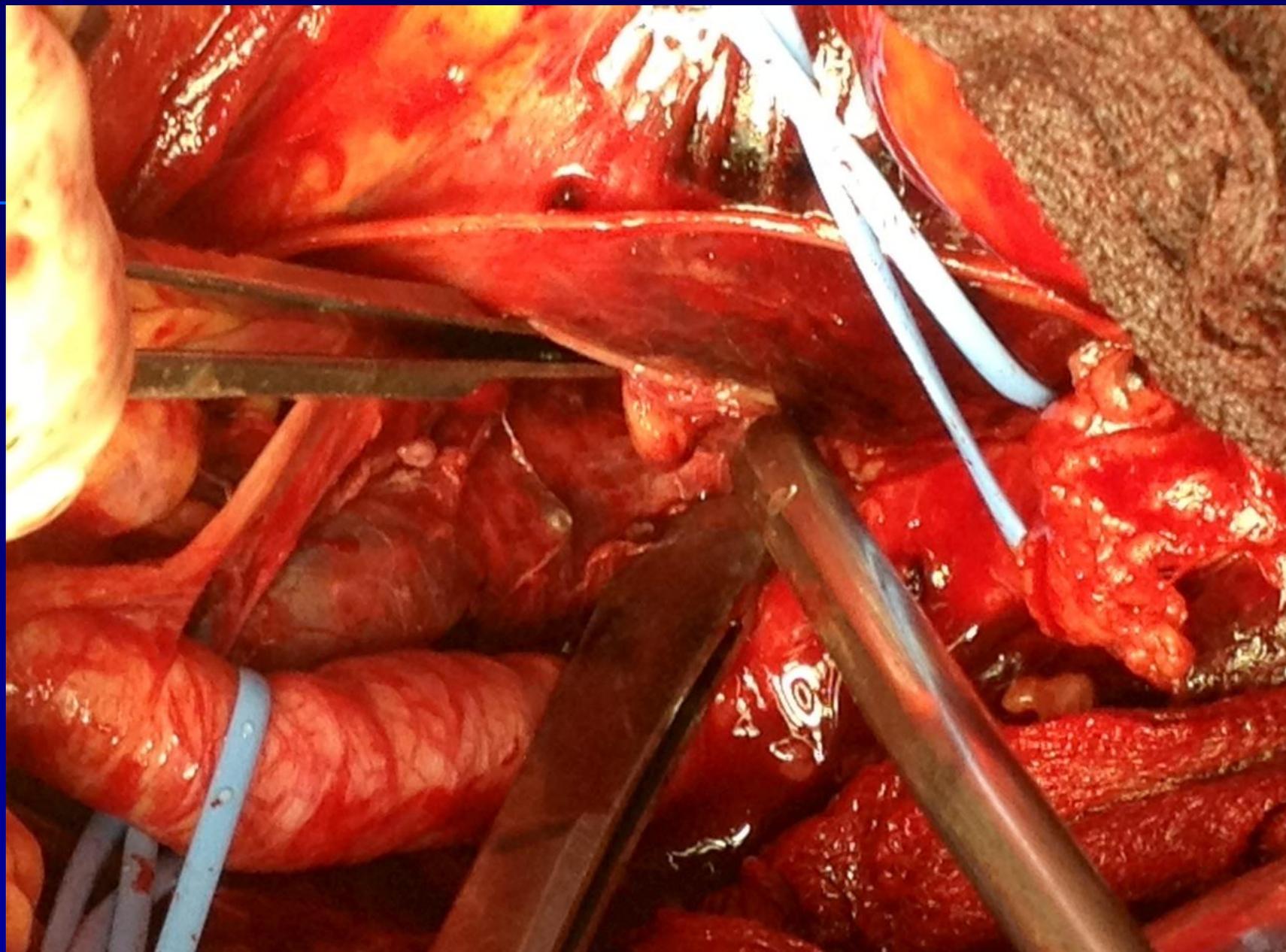






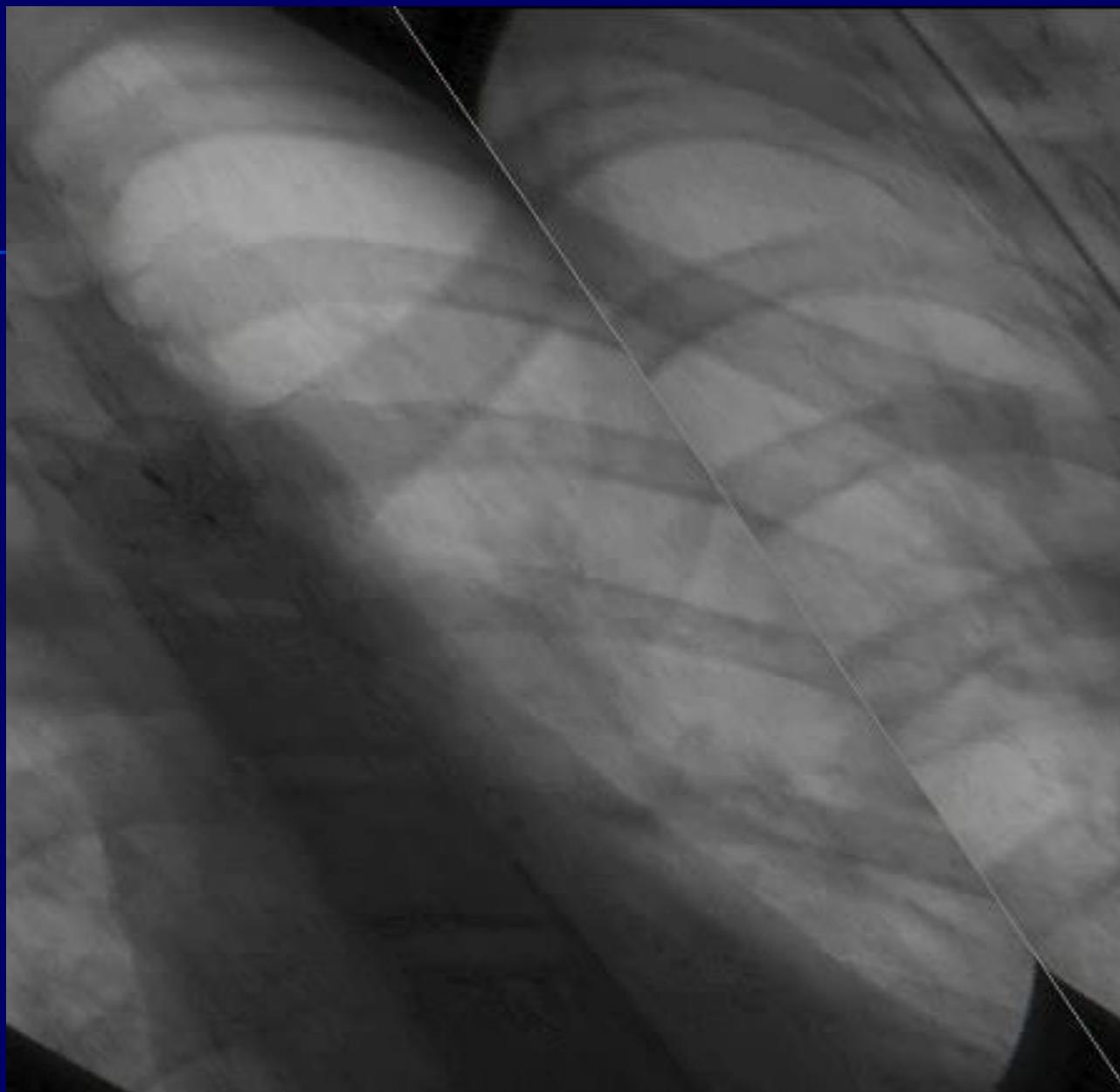


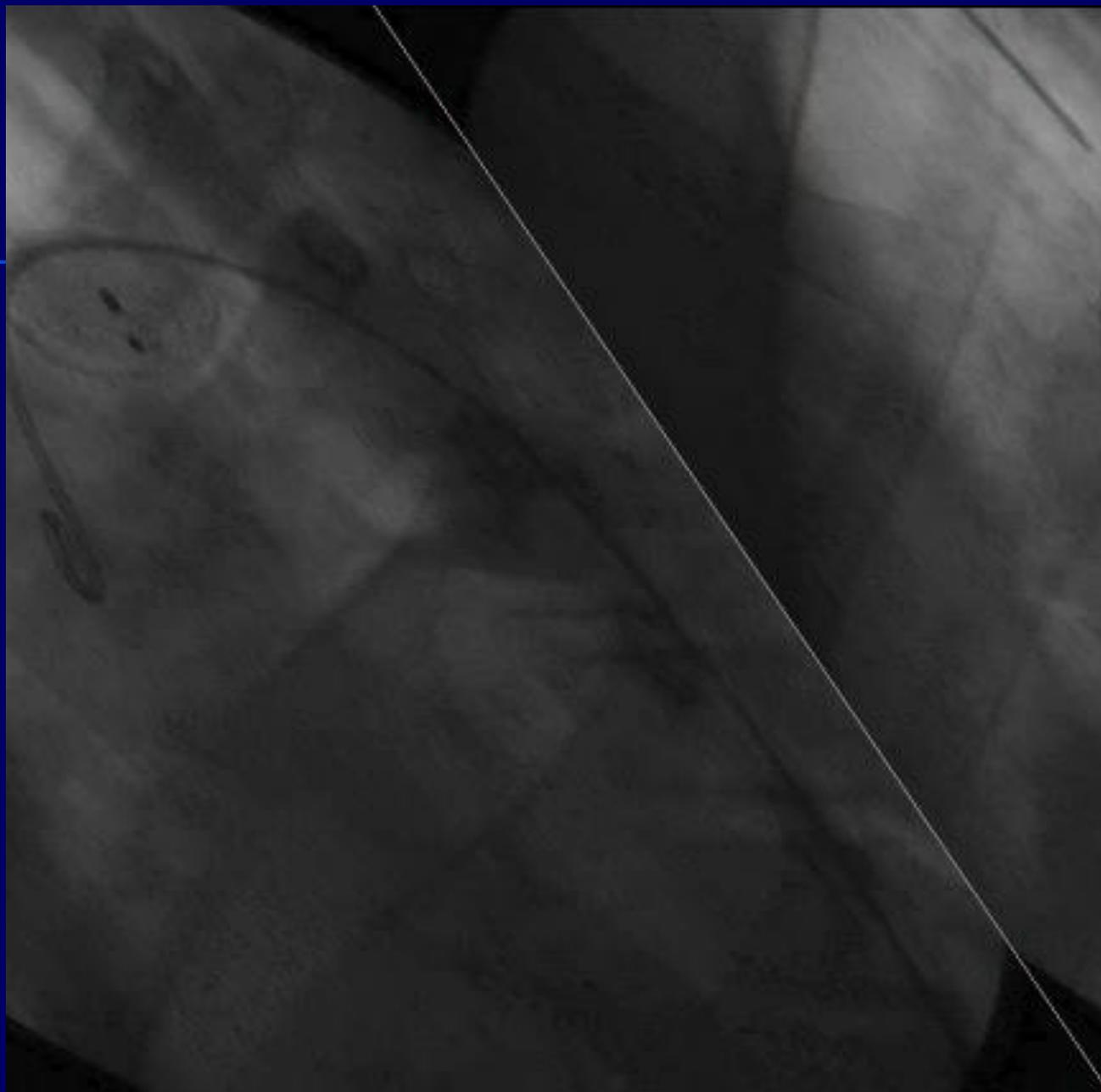


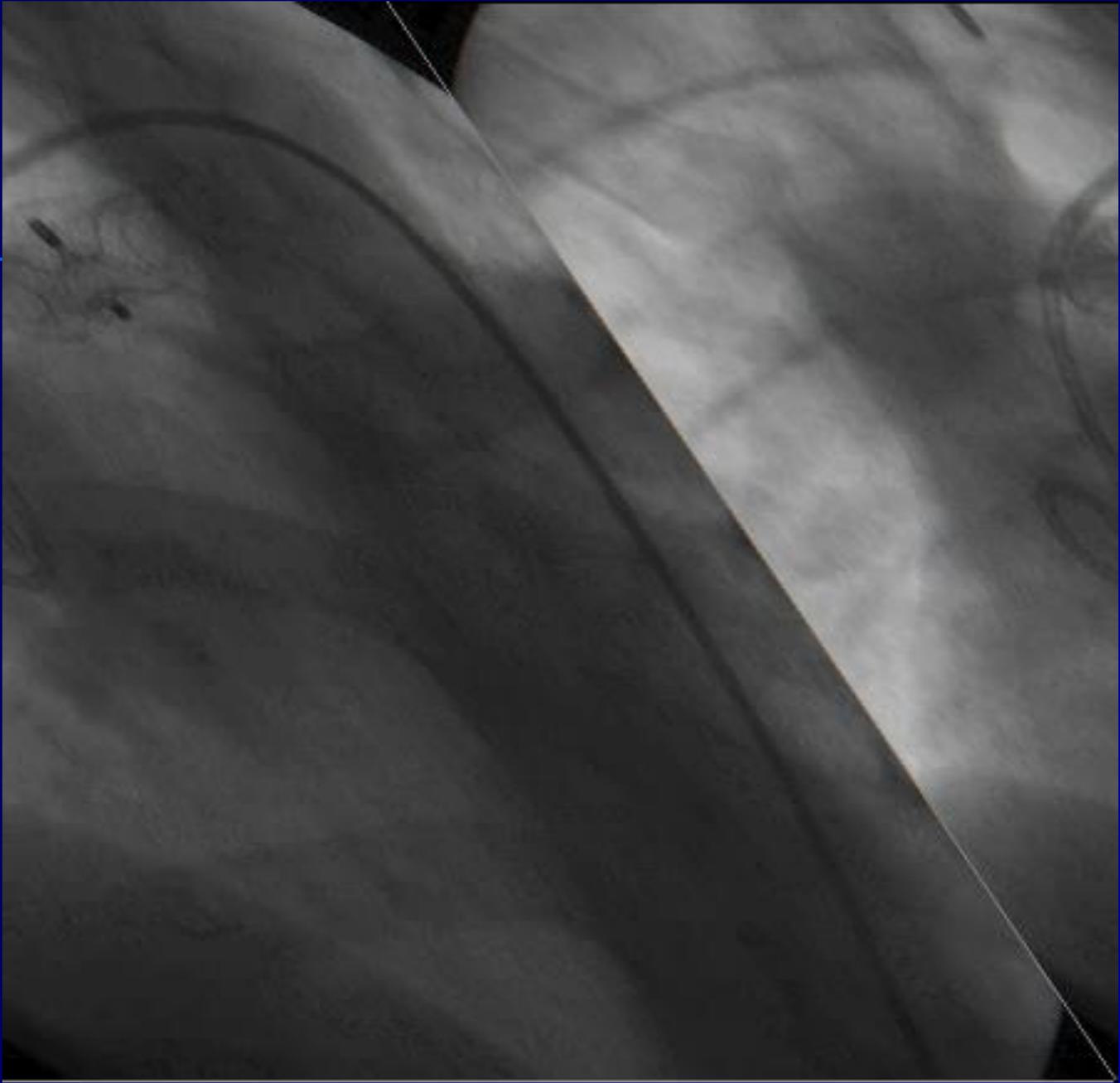


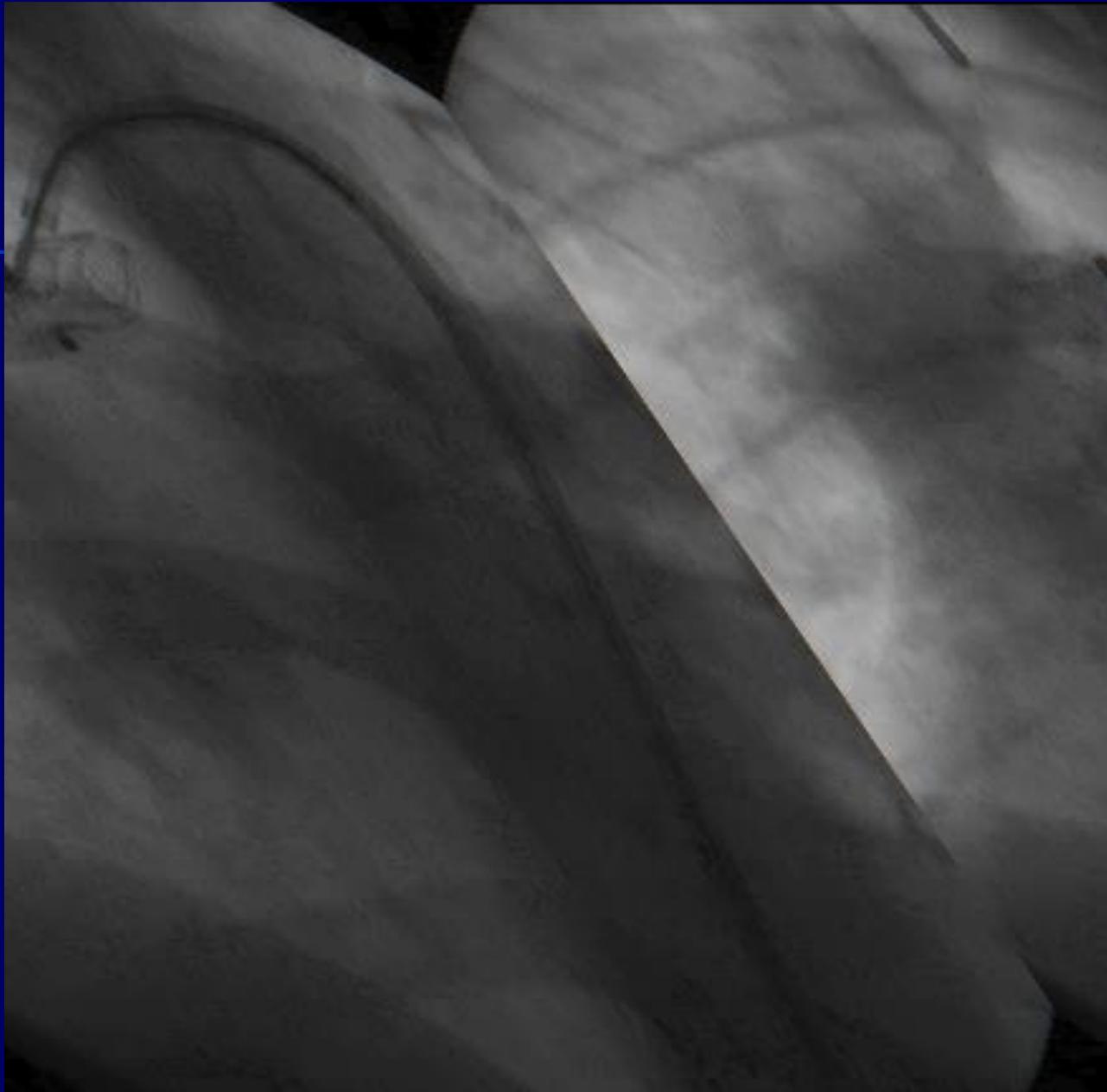


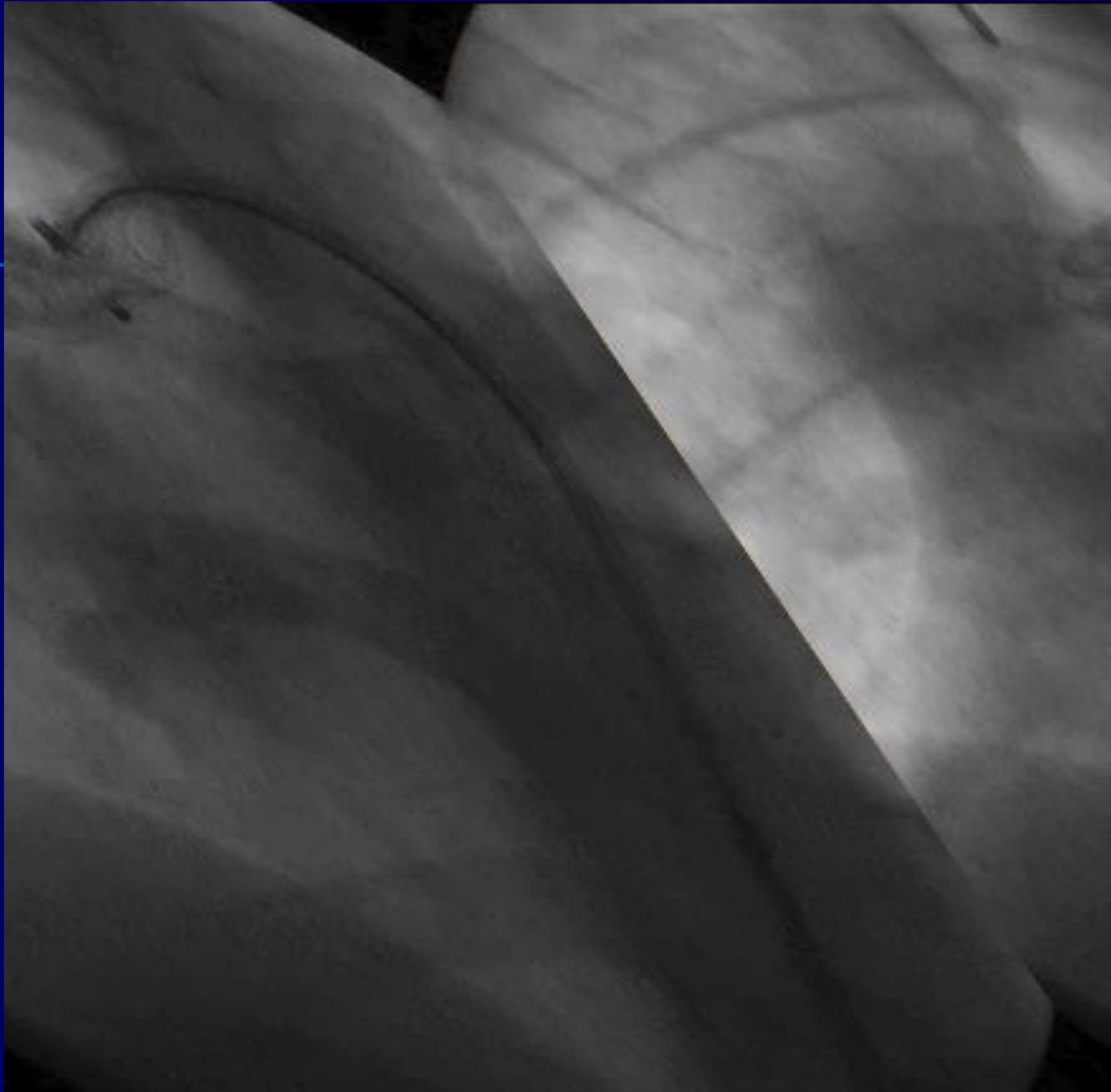
ANCORA UN CASO!
(gentilmente fornito da un
Collega)

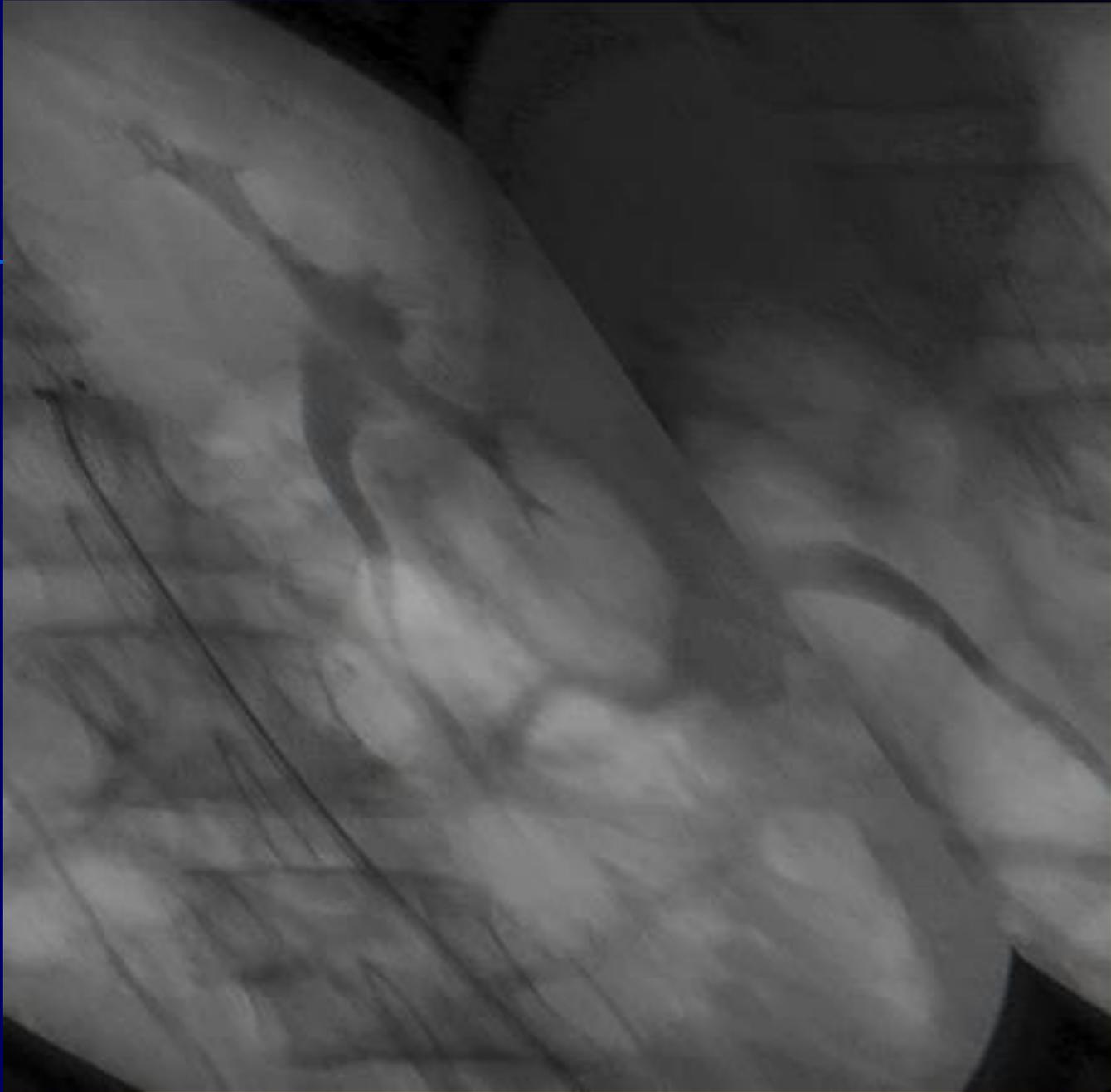




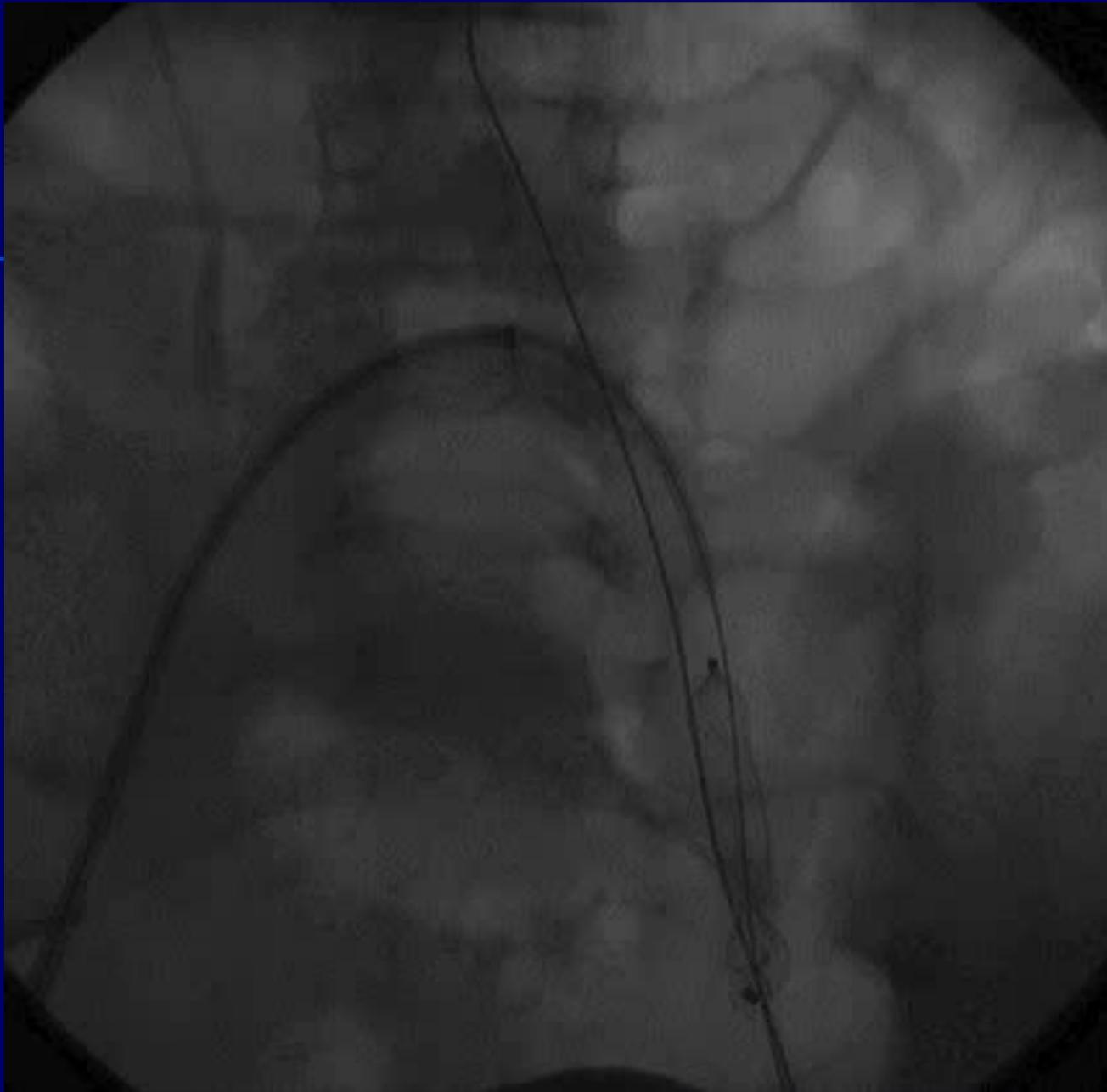


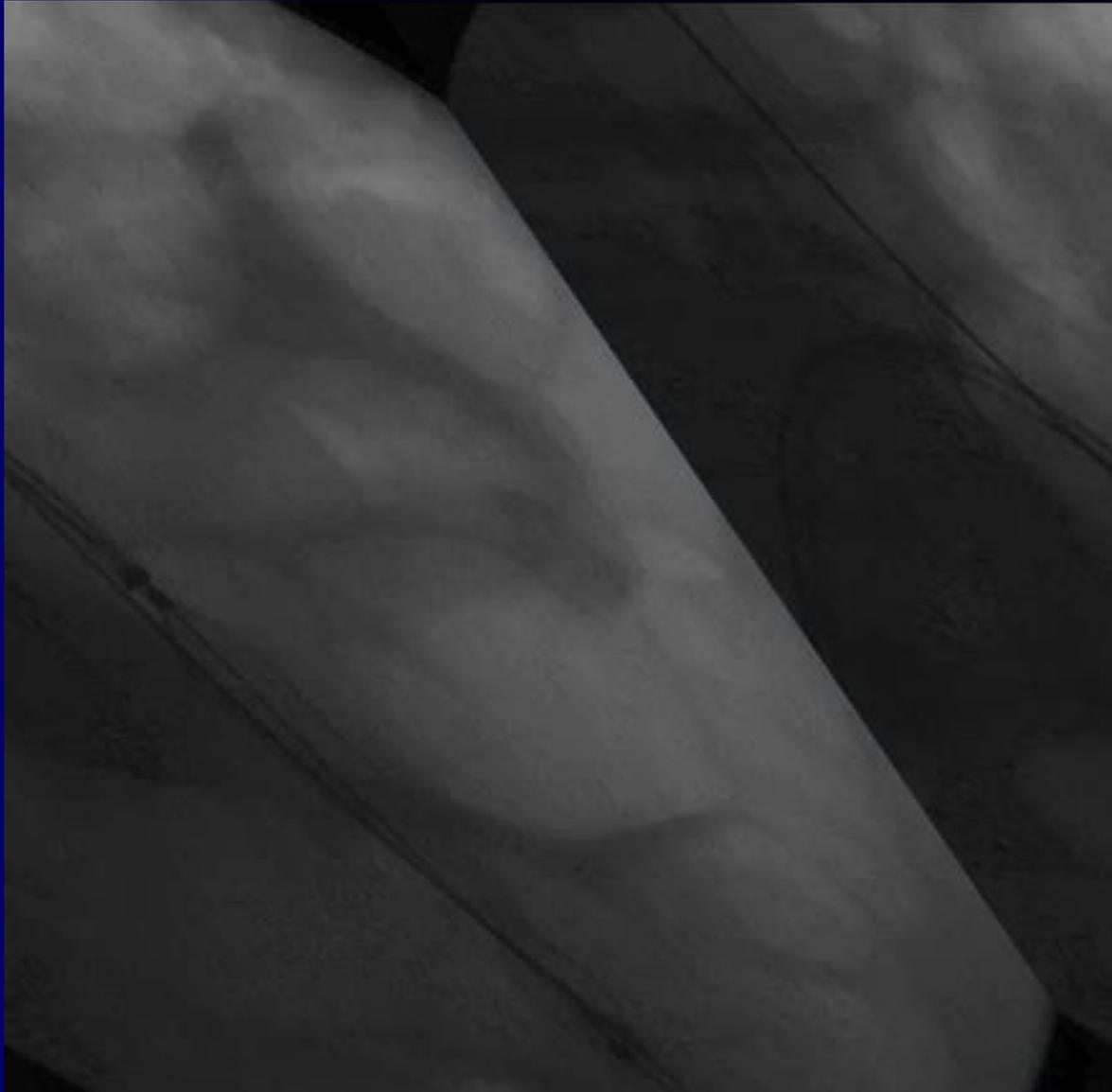


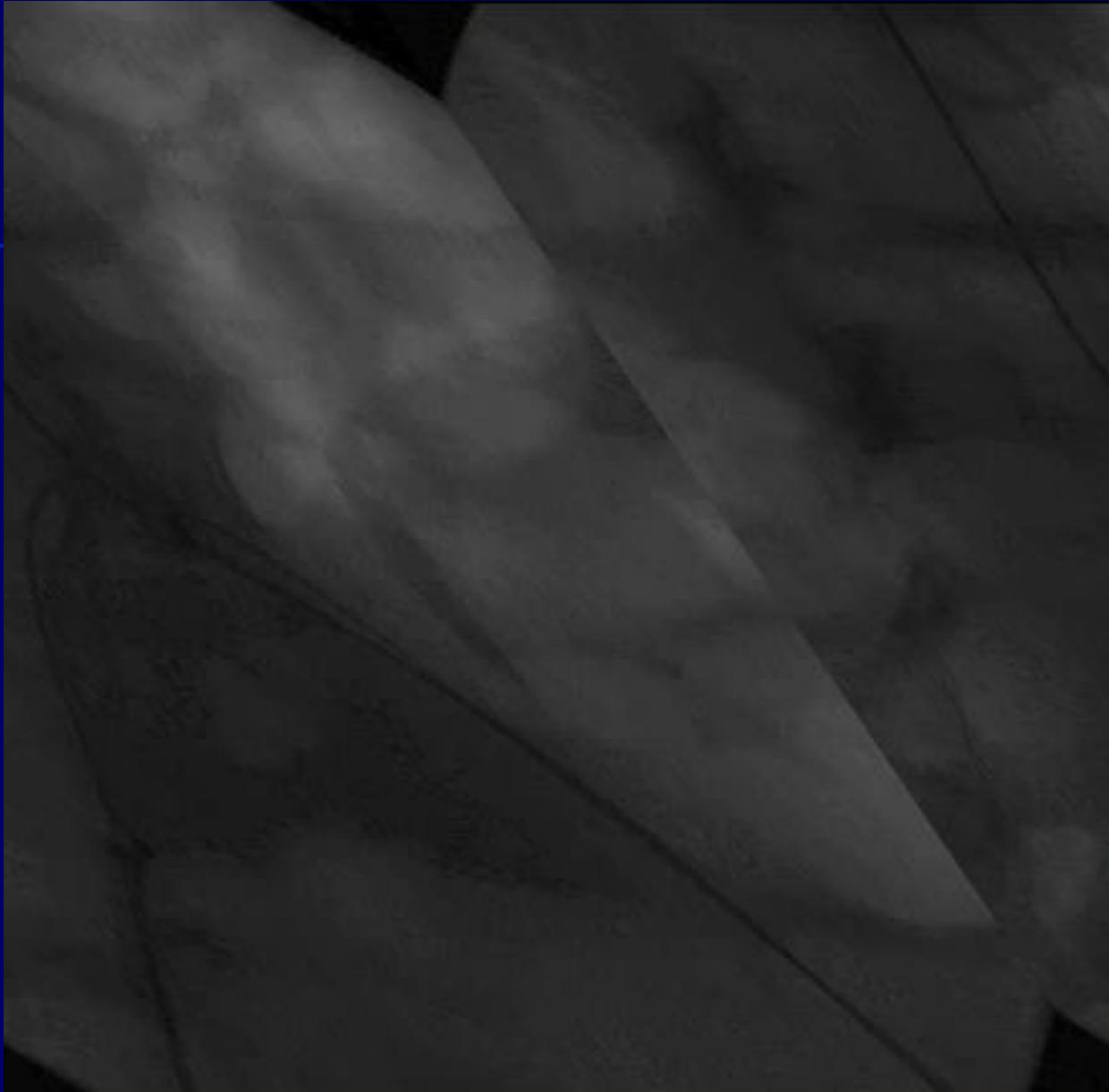
















Complicanze Precoci

Table 4 Adverse events for included trials

Trial	Events	Intervention group (%)	Medical therapy (%)	Hazard ratio	Confidence interval (95% CI)	P-value
PC trial	New-onset atrial fibrillation	6 (2.9) Two transient, 2 required pharmacological cardioversion, 1 required electrical cardioversion, and 1 sustained AF	2 (1)	3.15	0.64–15.6	0.16
	Myocardial infarction	2 (1)	1 (0.5)	2.04	0.19–22.5	0.62
	Hospital admission related to patent foramen ovale	13 (6.4)	13 (6.3)	1.02	0.48–2.21	0.95
	Bleeding	8 (3.9)	12 (5.7)	0.66	0.27–1.62	0.40
	Vascular procedural complication	2 (1)	N/A	N/A	N/A	N/A
CLOSURE 1	New-onset atrial fibrillation	23 (5.7) Only 14 during the initial 30 days of follow-up, it was transient in 17 patients and persistent in 6 patients	3 (0.7)	N/A	N/A	<0.001
	Major bleeding episode	10/378 (2.6)	4/374 (1.1)	N/A	N/A	0.11
	Death other than endpoint	2 (0.5)	4 (0.9)	N/A	N/A	0.51
	Nervous system disorder	6 (1.5)	16 (3.5)	N/A	N/A	0.15
	Vascular procedural complication	8 (1.7)	N/A	N/A	N/A	N/A
	Cardiac perforation	1 (0.2)	0	N/A		
RESPECT	New-onset atrial fibrillation	(3)	(1.5)	N/A	N/A	N/A
	Pulmonary embolism	6 (1.2)	1 (0.2)	N/A	N/A	0.12
	Major bleeding episode	8 (1.6)	9 (1.9)	N/A	N/A	0.81
	Vascular procedural complication	3 (0.6)	0	N/A	N/A	0.124
	Cardiac perforation	1 (0.2)	0	N/A	N/A	0.124

TABLE I. Peri-Procedural Major and Minor Complications

	All patients	
	No. of complications/ No. of patients	Complication rate (95% CI)
Major complications (95% CI)	216/28,142	0.8 (0.6–0.9)
Device embolization requiring surgery	121/28,142	0.4 (0.3–0.6)
Pericardial tamponade	42/28,142	0.1 (0.1–0.2)
Cerebrovascular events	22/28,142	0.1 (0.0–0.1)
Retroperitoneal hematoma	12/28,142	0.0 (0.0–0.1)
Device thrombosis	7/28,142	0.0 (0.0–0.1)
Malposition requiring surgery	6/28,142	0.0 (0.0–0.0)
Device erosion	5/28,142	0.0 (0.0–0.0)
Permanent pace maker implantation	1/28,142	0.0 (0.0–0.0)
Minor complications	271/26,267	1.0 (0.7–1.3)
Transient ST elevation	110/26,267	0.4 (0.2–0.6)
Percutaneously retrieved device embolization	83/26,267	0.3 (0.2–0.4)
Pericardial effusion	34/26,267	0.1 (0.1–0.2)
Malposition not requiring surgery	32/26,267	0.1 (0.0–0.3)
Pulmonary edema	12/26,267	0.0 (0.0–0.1)
Vascular complications	209/17,492	1.2 (0.9–1.5)
Arrhythmias	395/20,136	2.0 (1.5–2.5)
Heart Block	35/20,136	0.2 (0.1–0.3)

^aASD vs. PFO, $P = 0.027$.

^bASD vs. PFO $P < 0.001$, ASD vs. ASD/PFO, $P = 0.006$.

^cASD vs. PFO $P = 0.003$.



Grazie per l'attenzione!

