Venøse interventioner
DVT trombektomi

DFIR Årsmøde 2023

Mikkel Taudorf

HTS 1302 – State-of-the-art: treatment of acute DVT

VENOUS INTERVENTION

Hot Topic Symposium | 11 Sep 2022 | 15:00–16:00 (Europe/Madrid) | Auditorium 1

Moderators: P. Haage, G. O'Sullivan

Add to my calendar

1302.1 / I would use pharmacomechanical

A. Wigham, T. MacKinnon

1302.2 / I would use mechanical only with no lytics

M. Taudorf

1302.3 / I would use catheter directed thrombolysis only

N. O'Halloran

1302.4 / I would use anticoagulation only

S. Konstantinides

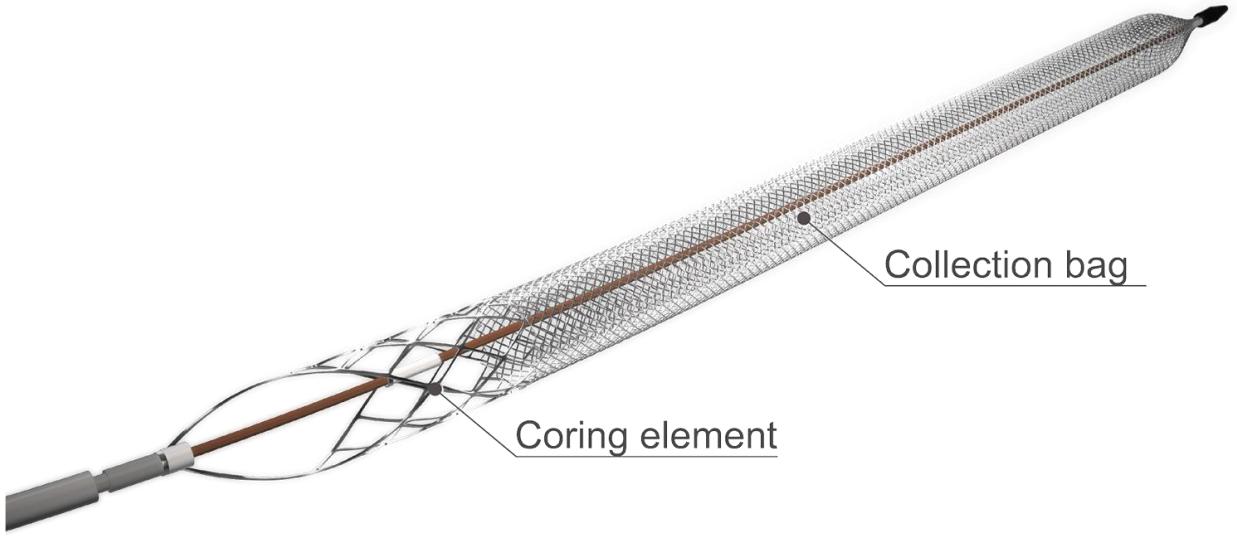
1302.5 / Round-table discussion, followed by conclusion and take-home points

Mechanical thrombectomy devices

Cardiac Interventions Today - EUROPEAN Device Guide Compare - Mechanical Thrombectomy/Thrombolysis (Peripheral/Venous)

Company Name	Invamed	Invamed	Penumbra, Inc. (Peripheral Vascular)	BD Interventional	Abbott	Teleflex	Inari Medical	Control Medical Technology	Argon Medical Devices, Inc.	Boston Scientific Corporation
Product Name	Mantis	Viper	Indigo System Catheter CAT8, CATD, CAT6, CAT5, and CAT3	Aspirex S	JETi Thrombectomy System	Arrow-Trerotola OTW PTD	ClotTriever Thrombectomy System	Control 10F Mechanical Thrombectomy System	Cleaner 15	AngioJet AVX Thrombectomy Set
Sheath Compatibility (F)	7	5	8 (CAT8, CATD) 6 (CAT6, CAT5) 5 (CAT3)	6	6, 8	7	13, 16	10	7	6
Guidewire Compatibility (inch)	–	0.035	0.014–0.038	0.018	0.014–0.035	0.025	0.035	0.035	–	0.035
Working Length (cm)	90	200	50–150	110, 135	100, 120	65, 120	80	90	65, 135	50
Mode of Operation	Battery-operated, handheld drive unit initiates the mechanical rotation of an atraumatic unique loop shape with aspiration	Designed for controlled infusion of tPA along with mechanical vibrations	Separator-assisted mechanical extraction of thrombus/ embolus with Penumbra ENGINE continuous aspiration	Aspirex S catheters in combination with the Straub Medical Drive System (REF SRS-Set/80300) are intended for the percutaneous transluminal removal of fresh thrombotic or thromboembolic material from blood vessels outside the cardiopulmonary, coronary, and cerebral circulations	Thrombus is aspirated into the catheter where a high-pressure saline jet breaks the clot up	Battery-operated handheld unit rotates unique 9-mm fragmentation basket at 3,000 rpm, macerating clot to < 2 mm; basket can be deployed/ withdrawn within catheter; deployed basket can be used to pull arterial plug	Mechanical coring, collection, and retrieval of emboli and thrombi	Mechanical thrombectomy with mechanical aspirator, OTW catheter, and dilator	Battery-operated, handheld drive unit initiates the mechanical rotation of an atraumatic, wall-contacting, 15-mm sinusoidal vortex wire for effective thrombus maceration	High-velocity water jets enclosed in catheter utilize the Bernoulli principle for capture, microfragmentation, and removal
CE Mark Indications	DVT pharmacomechanical declotting and controlled and selective infusion of physician-specified fluids,	Over the guidewire system and 200 cm catheter length	Intended for the removal of fresh, soft emboli and thrombi from vessels of the	Native blood vessels or vessels fitted with stents, stent grafts, or native or artificial bypasses outside	Peripheral vasculature excluding vessels < 4 mm, coronary, pulmonary, and	Permits mechanical declotting of native arterio/ venous fistula synthetic	The nonsurgical removal of thrombi and emboli from blood vessels; injection,	Mechanical thrombectomy to remove soft fresh emboli and thrombi from the	Indicated for mechanical declotting and controlled and selective infusion of	Breaking apart and removing thrombus from AV access conduits ≥ 3 mm in diameter

ClotTriever Inari Medical



The **ClotTriever** catheter features a nitinol coring element an
a braided collection bag, designed to core and collect clot for
extraction from **ClotTriever** sheath.

Penumbra

Litterature

- No RCT on mechanical thrombectomy

Objectives

- Normalize the situation
  - Reduce the pain
  - Reduce the edema
  - Reduce the risk of LE

- By restorering the blood flow as quickly as possible

- And correcting underlying triggering factors

Objectives

- To avoid long turn complications
  - Avoid rethrombosis
  - PTS, avoid venous hypertension
- Increase QOL

- By restorering optimal blood flow and valvular function

The aim of the treatment?

- To restore optimal blood flow as quickly as possible
- To avoid valvular damage

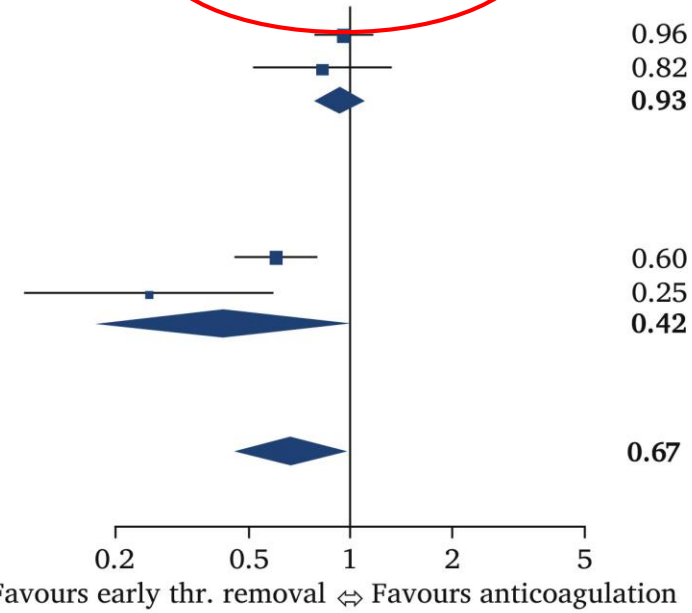
- To correct underlying triggering factors

Litterature

- No RCT on mechanical thrombectomy
- 4 RCT’s on early thrombus revoval compaired to anticoagulation alone

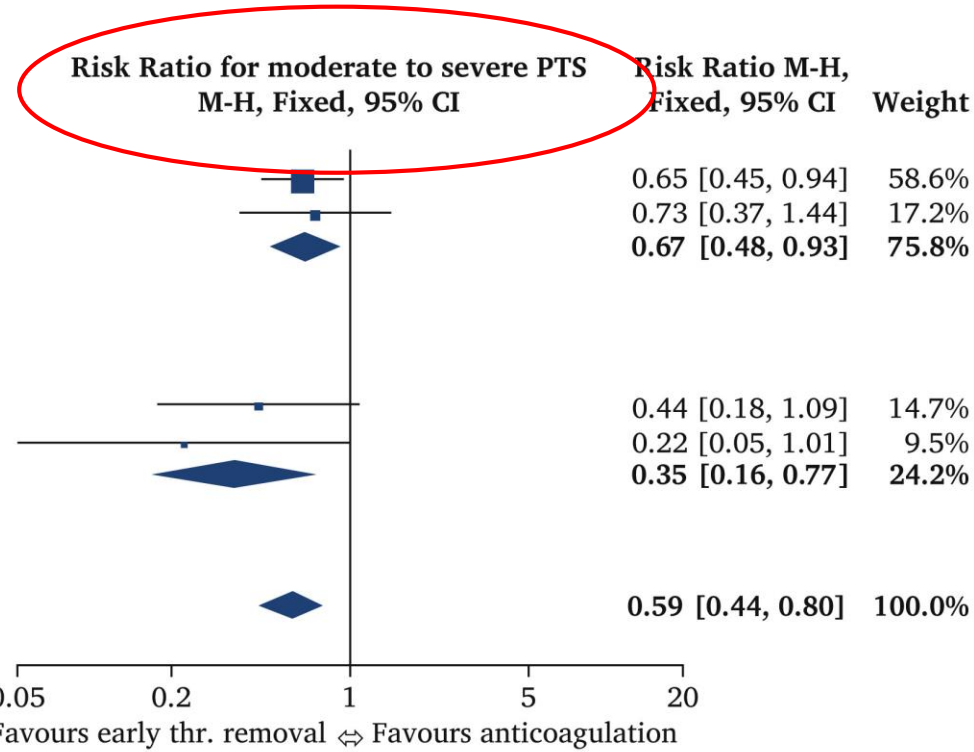
Lesson learnt from 4 RCT on early thrombus removal Meta-analysis results

	Early thrombus removal		Anticoagulation		Risk Ratio for any PTS M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI	Weight
Study or Subgroup	Events	Total	Events	Total			
A Iliofemoral DVT							
ATTRACT (Iliofemoral)	96	196	100	195		0.96 [0.78, 1.16]	32.5%
CAVA	22	77	26	75		0.82 [0.51, 1.32]	23.7%
Total	**118**	**273**	**126**	**270**		**0.93 [0.78, 1.12]**	**56.2%**
Heterogeneity: Tau² = 0.00; *Chi²* = 0.33, df = 1 (*p* = .57); *I²* = 0%							
Test for overall effect: Z = 0.73 (*p* = .46)							
B Any proximal DVT							
CaVenT	37	87	63	89		0.60 [0.45, 0.79]	30.1%
TORPEDO	6	91	24	92		0.25 [0.11, 0.59]	13.7%
Total	**43**	**178**	**87**	**181**		**0.42 [0.18, 1.03]**	**43.8%**
Heterogeneity: Tau² = 0.32; *Chi²* = 4.08, df = 1 (*p* = .04); *I²* = 75%							
Test for overall effect: Z = 1.90 (*p* = .06)							
Total (95% CI)	**161**	**451**	**213**	**451**		**0.67 [0.45, 1.00]**	**100.0%**
Heterogeneity: Tau² = 0.12; *Chi²* = 14.54, df = 3 (*p* = .002); *I²* = 79%							
Test for overall effect: Z = 1.97 (*p* = .05)							
Test for subgroup differences: *Chi²* = 2.95, df = 1 (*p* = .09); *I²* = 66.1%							



Lesson learnt from 4 RCT on early thrombus removal Meta-analysis results

	Study or Subgroup	Early thrombus removal Events	Total	Anticoagulation Events	Total	Risk Ratio for moderate to severe PTS M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI	Weight
A	**Iliofemoral DVT**							
	ATTRACT (Iliofemoral)	36	196	55	195		0.65 [0.45, 0.94]	58.6%
	CAVA	12	77	16	75		0.73 [0.37, 1.44]	17.2%
	Total	**48**	**273**	**71**	**270**		**0.67 [0.48, 0.93]**	**75.8%**
	Heterogeneity: $Chi^2 = 0.09$, df = 1 ($p = .77$); $I^2 = 0\%$							
	Test for overall effect: Z = 2.42 ($p = .02$)							
B	**Any proximal DVT**							
	CaVenT	6	87	14	89		0.44 [0.18, 1.09]	14.7%
	TORPEDO	2	91	9	92		0.22 [0.05, 1.01]	9.5%
	Total	**8**	**178**	**23**	**181**		**0.35 [0.16, 0.77]**	**24.2%**
	Heterogeneity: $Chi^2 = 0.56$, df = 1 ($p = .45$); $I^2 = 0\%$							
	Test for overall effect: Z = 2.63 ($p = .009$)							
	Total (95% CI)	**56**	**451**	**94**	**451**		**0.59 [0.44, 0.80]**	**100.0%**
	Heterogeneity: $Chi^2 = 2.63$, df = 3 ($p = .45$); $I^2 = 0\%$							
	Test for overall effect: Z = 3.42 ($p = .0006$)							
	Test for subgroup differences: $Chi^2 = 2.20$, df = 1 ($p = .14$); $I^2 = 54.6\%$							



Post Hoc Analysis of the CAVA trial[1]

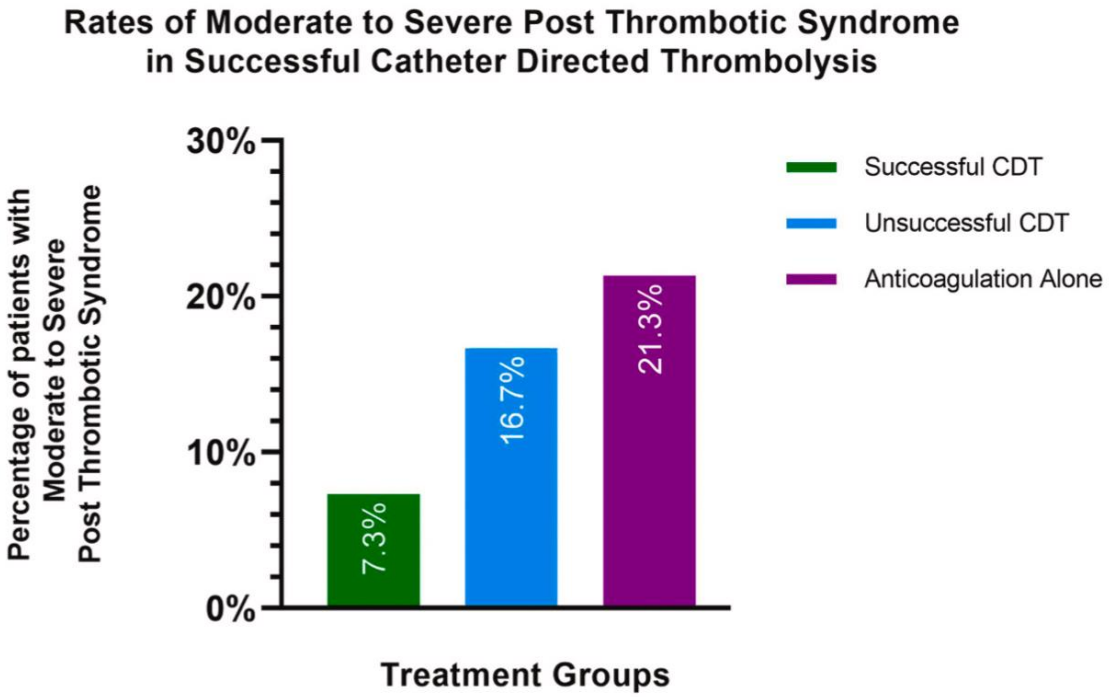
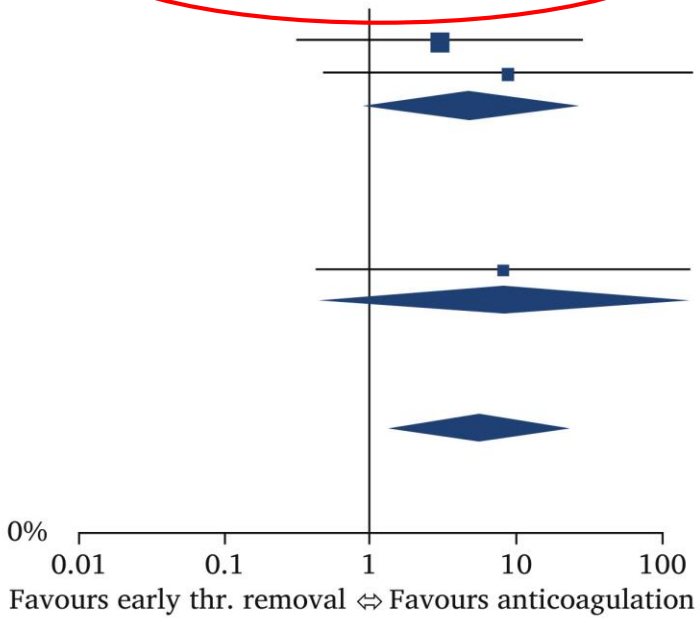


Illustration: Catheter directed thrombolysis for deep vein thrombosis in 2022: Rationale, evidence base and future direction, M. Khalid et al, International Journl of cardiology 2022

Lesson learnt from 4 RCT on early thrombus removal Meta-analysis results

	Study or Subgroup	Early thrombus removal Events	Total	Anticoagulation Events	Total	Risk Ratio for major bleeding M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI	Weight
A	**Iliofemoral DVT**							
	ATTRACT (Iliofemoral)	3	196	1	195		2.98 [0.31, 28.44]	50.8%
	CAVA	4	77	0	75		8.77 [0.48, 160.11]	25.7%
	Total	**7**	**273**	**1**	**270**		**4.93 [0.86, 28.26]**	**76.5%**
	Heterogeneity: $Chi^2 = 0.34$, df = 1 ($p = .56$); $I^2 = 0\%$							
	Test for overall effect: Z = 1.79 ($p = .07$)							
B	**Any proximal DVT**							
	CaVenT	3	93	0	108		8.12 [0.42, 155.13]	23.5%
	Total	**3**	**93**	**0**	**108**		**8.12 [0.42, 155.13]**	**23.5%**
	Heterogeneity: Not applicable							
	Test for overall effect: Z = 1.39 ($p = .16$)							
	Total (95% CI)	**10**	**366**	**1**	**378**		**5.68 [1.27, 25.33]**	**100.0%**
	Heterogeneity: $Chi^2 = 0.45$, df = 2 ($p = .80$); $I^2 = 0\%$							
	Test for overall effect: Z = 2.28 ($p = .02$)							
	Test for subgroup differences: $Chi^2 = 0.08$, df = 1 ($p = .78$); $I^2 = 0\%$							



Conclusion of the meta-analysis

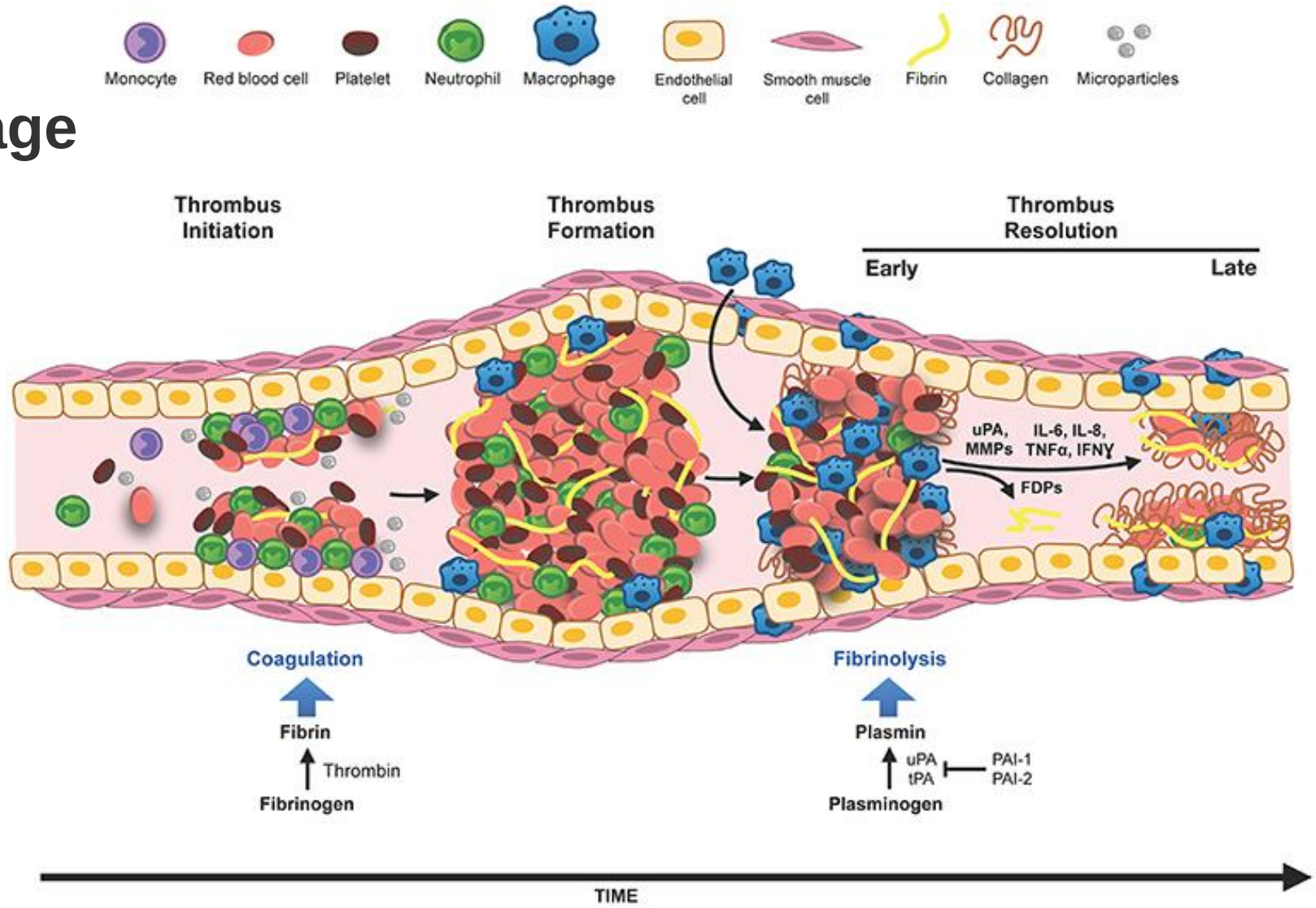
”It is evident that, although early thrombus removal techniques are more effective than anticoagulation alone in preventing PTS and, particularly, moderate to severe PTS, there is a significantly risk of major bleeding”

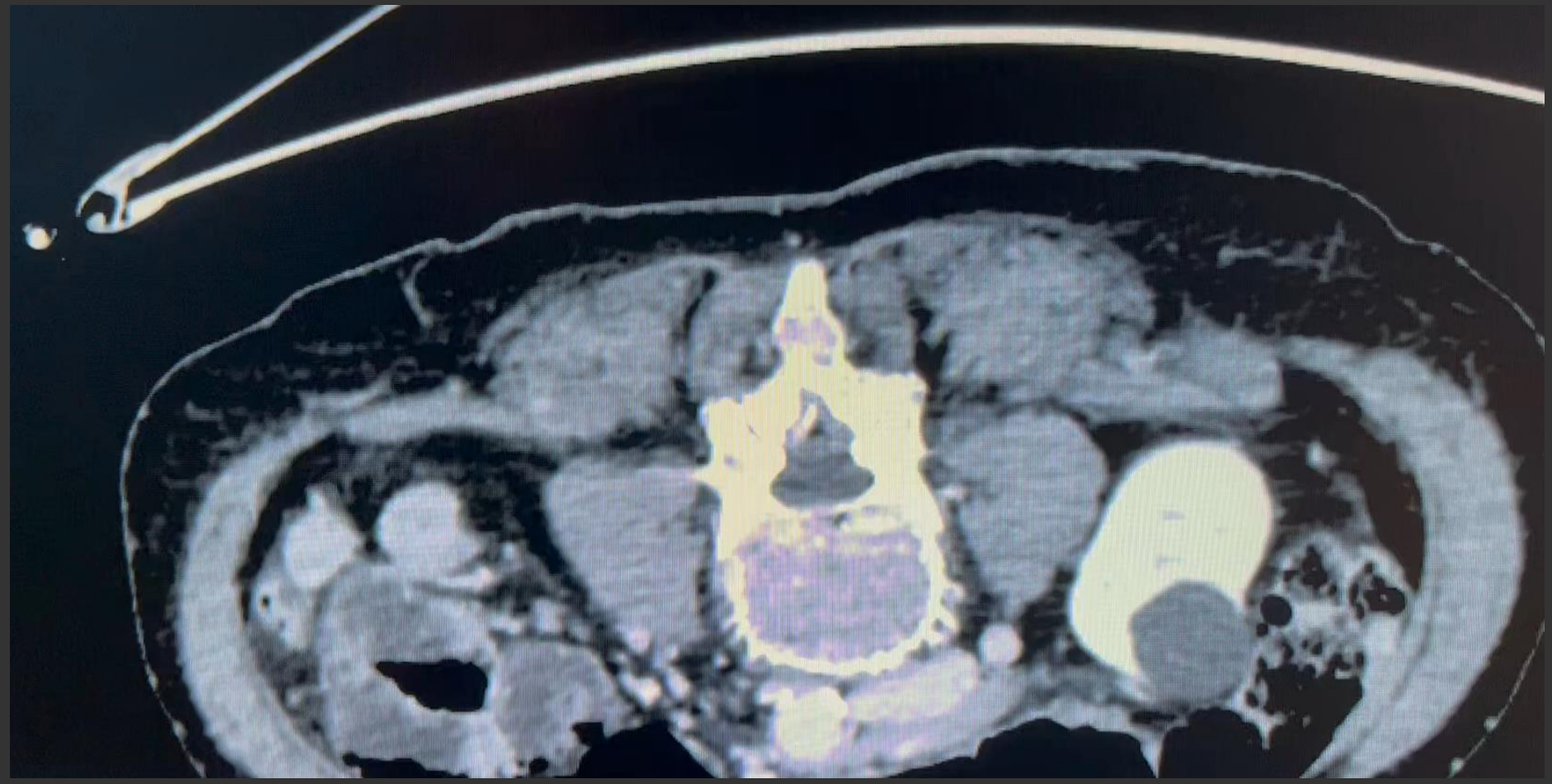
Thrombus age

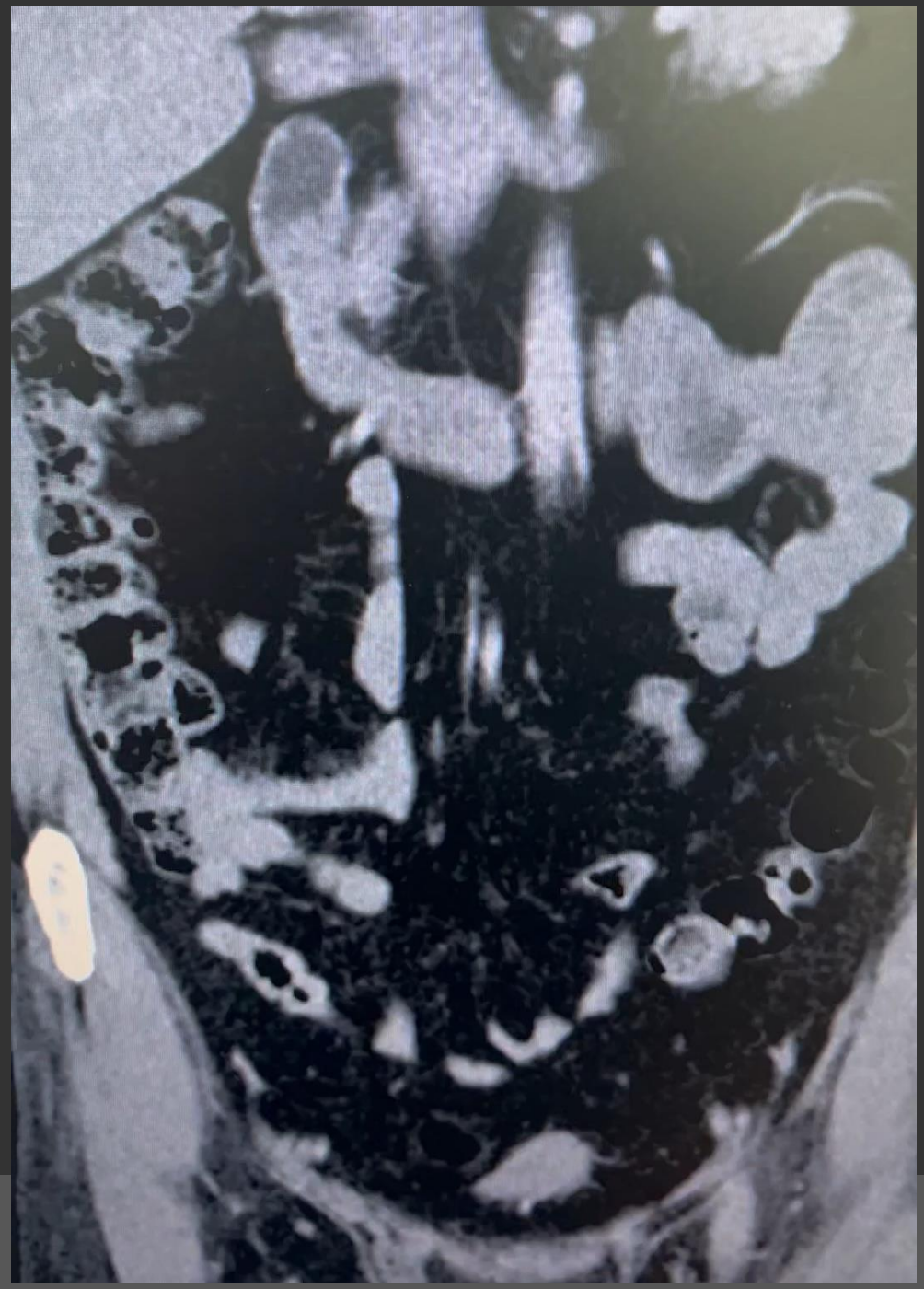
CDT started after few days of symptoms

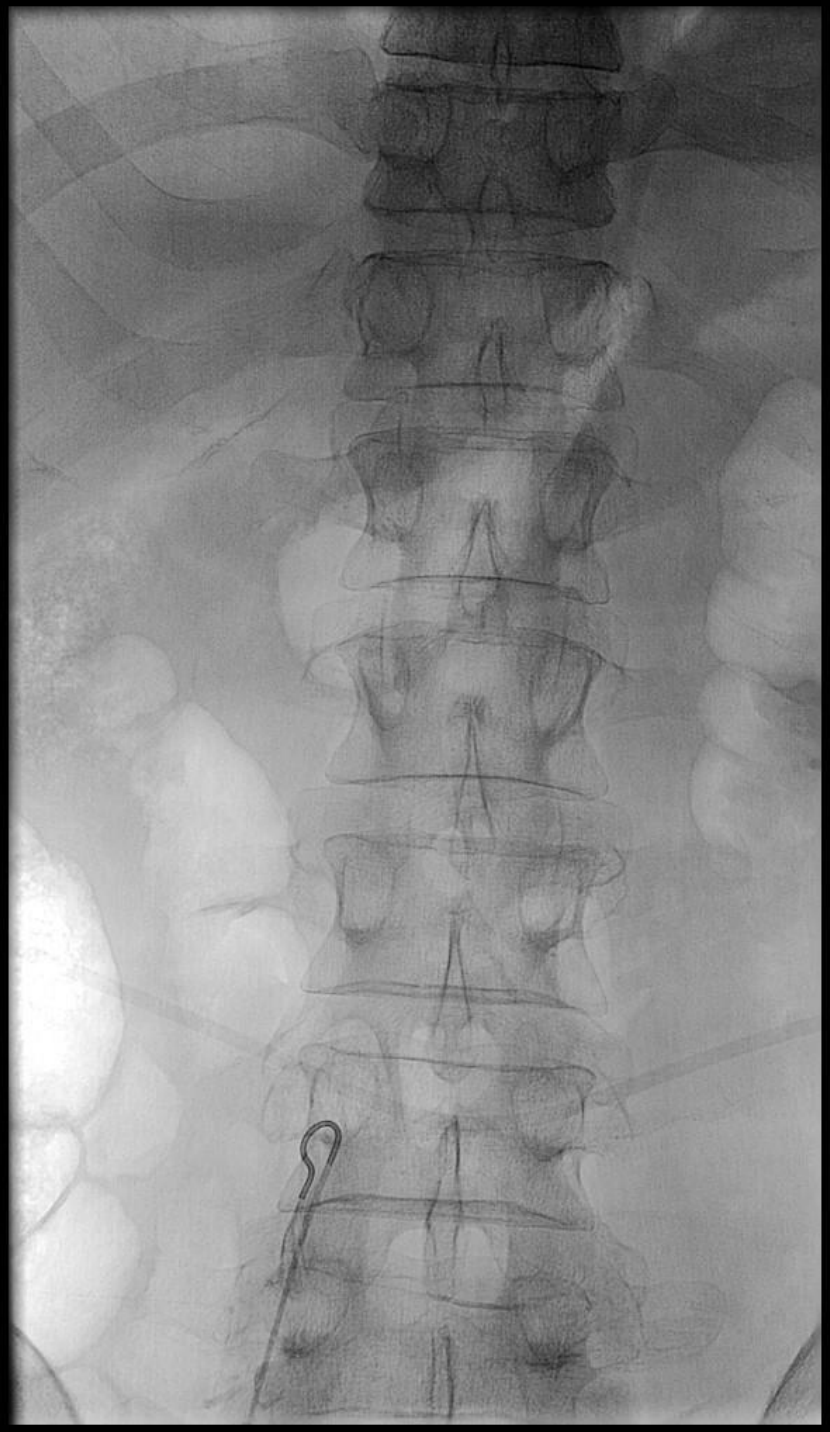
Result after 3 days of CDT

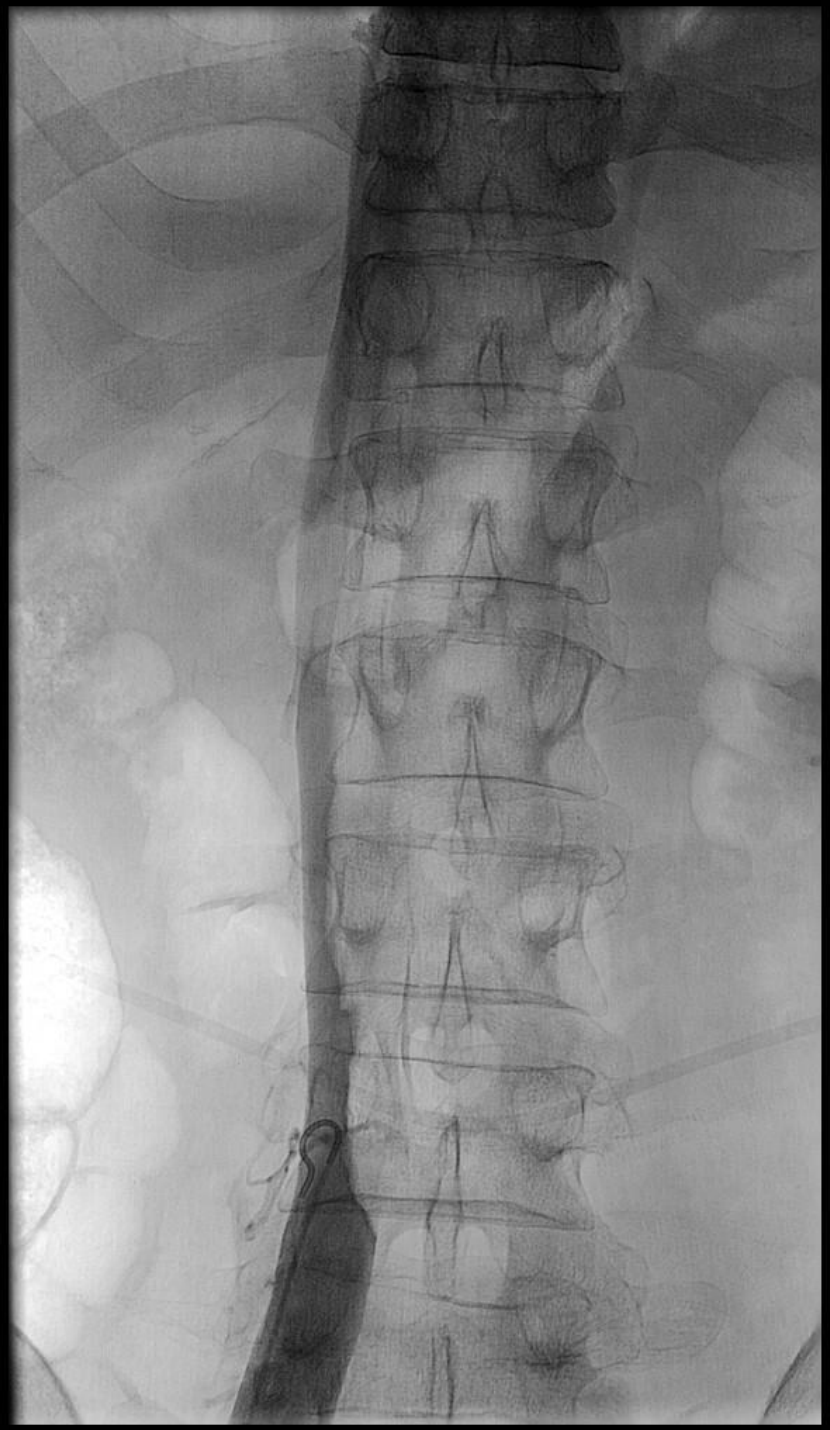
Thrombus age

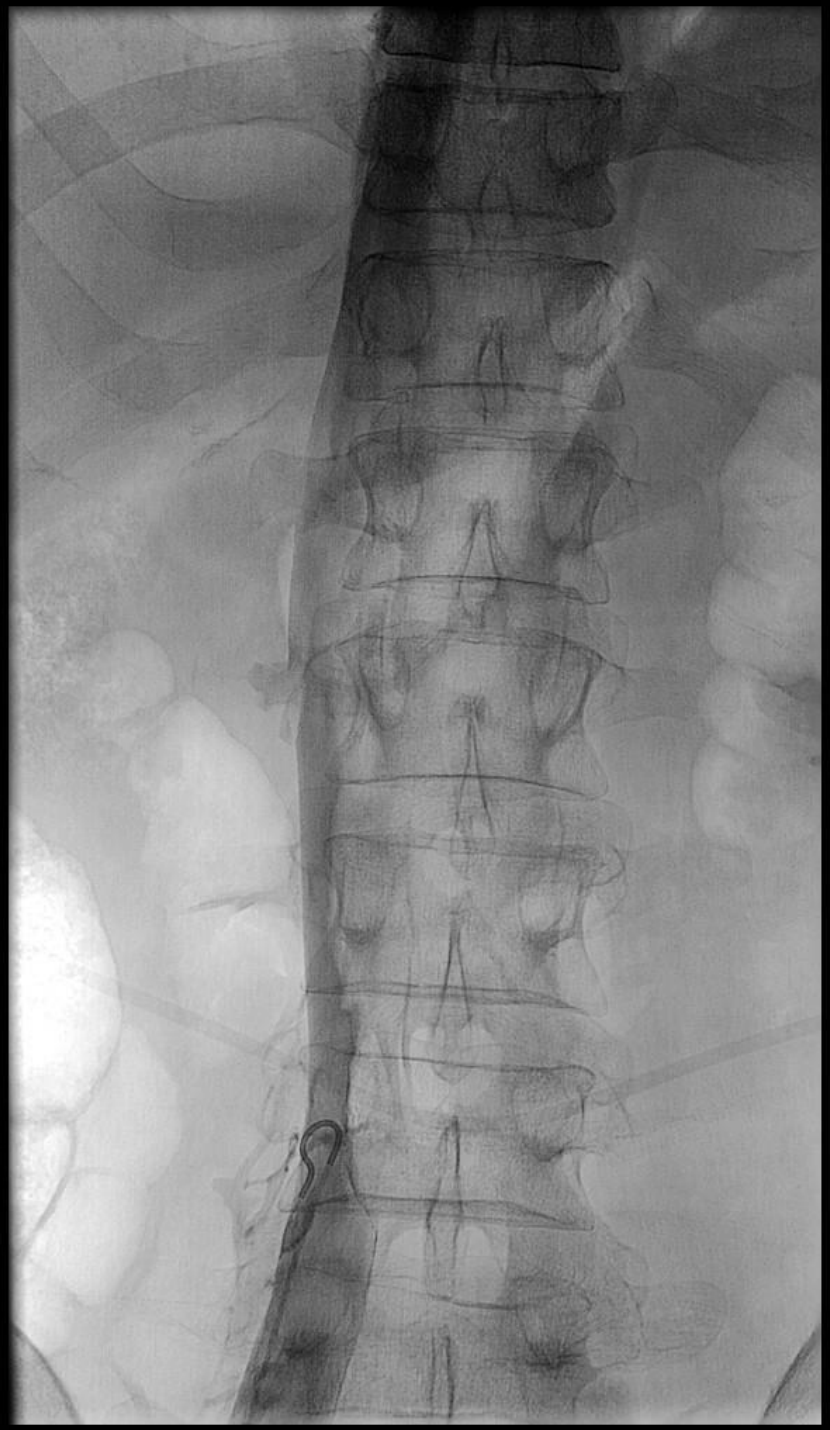


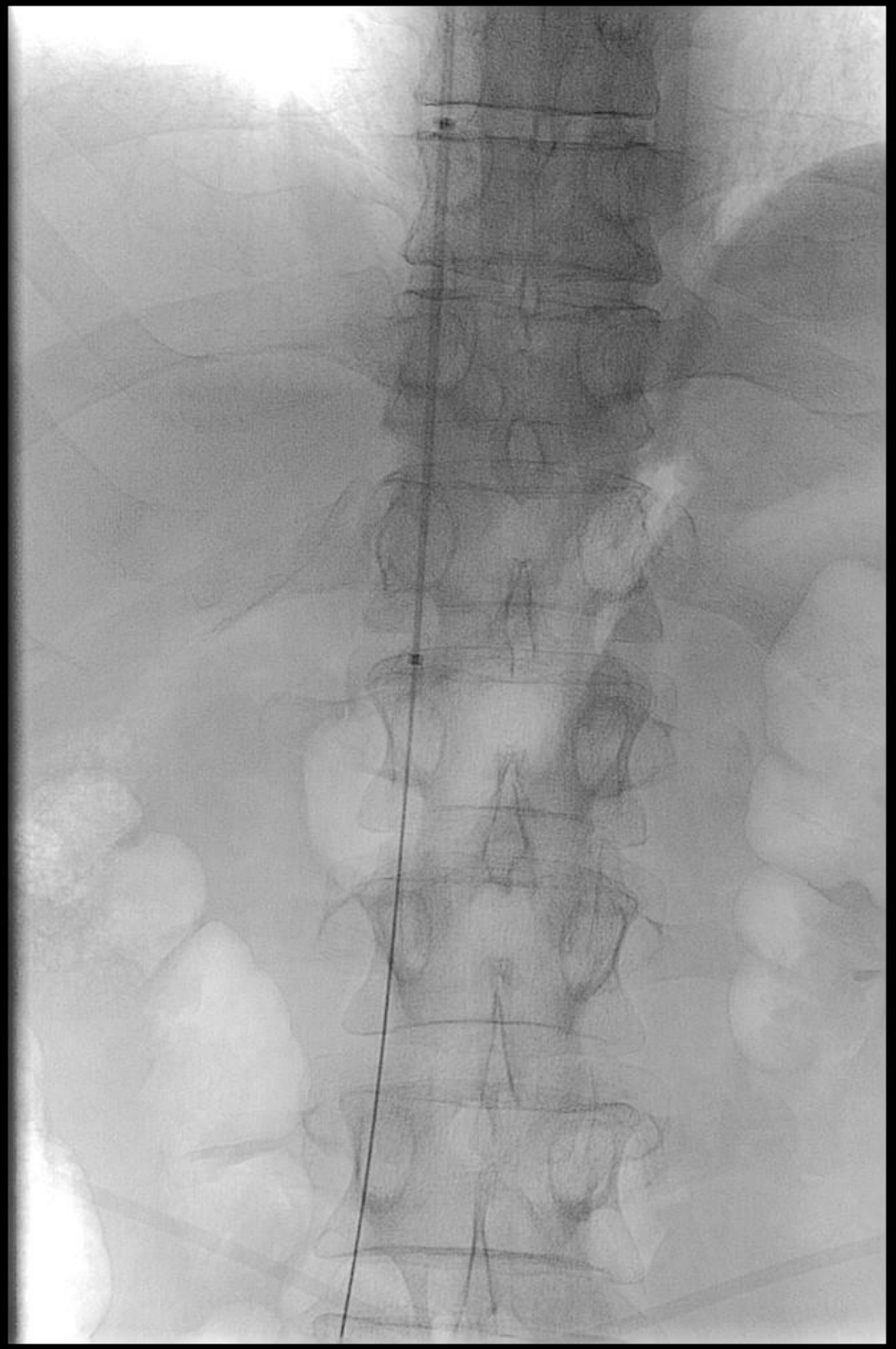


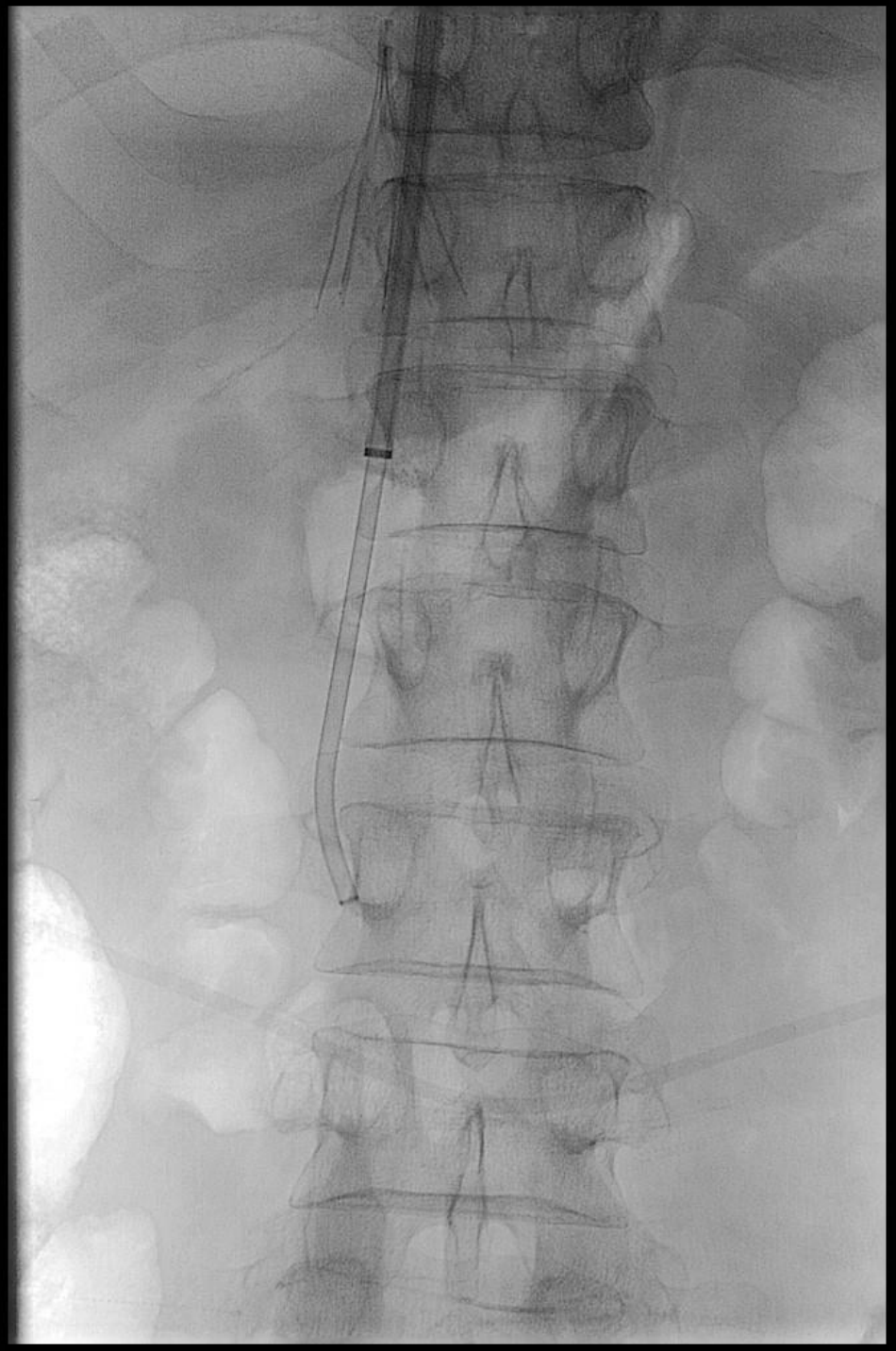


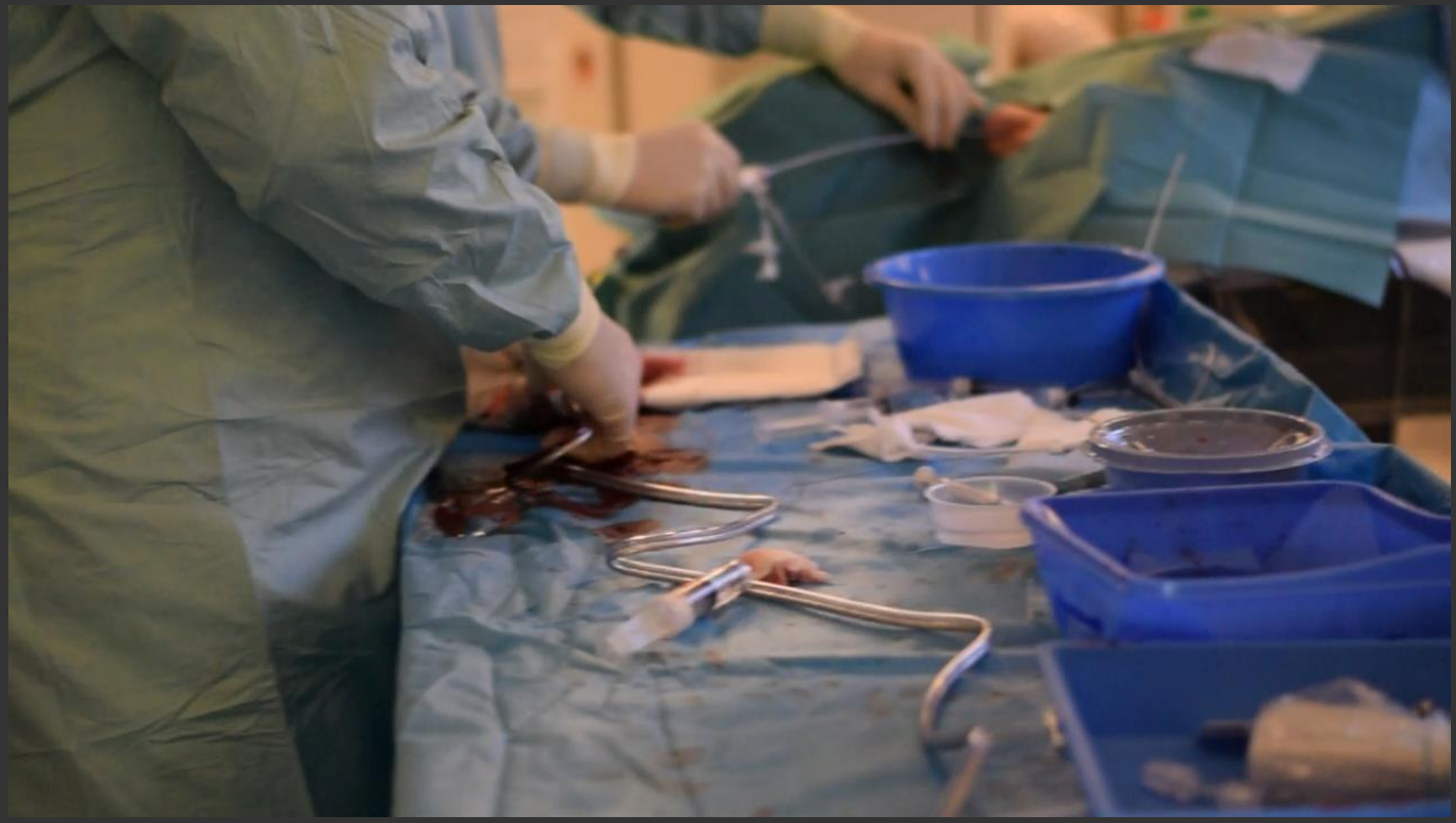


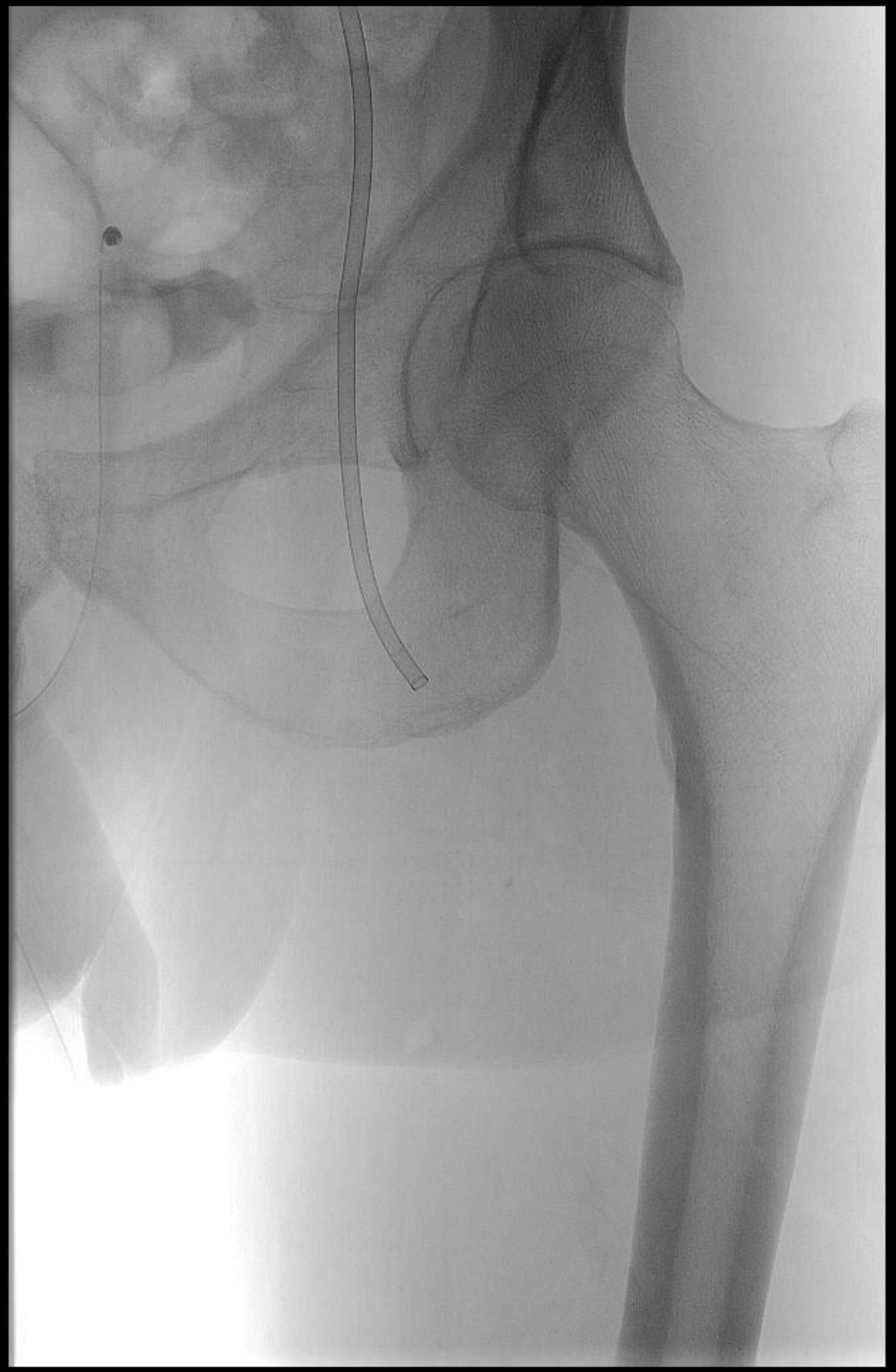


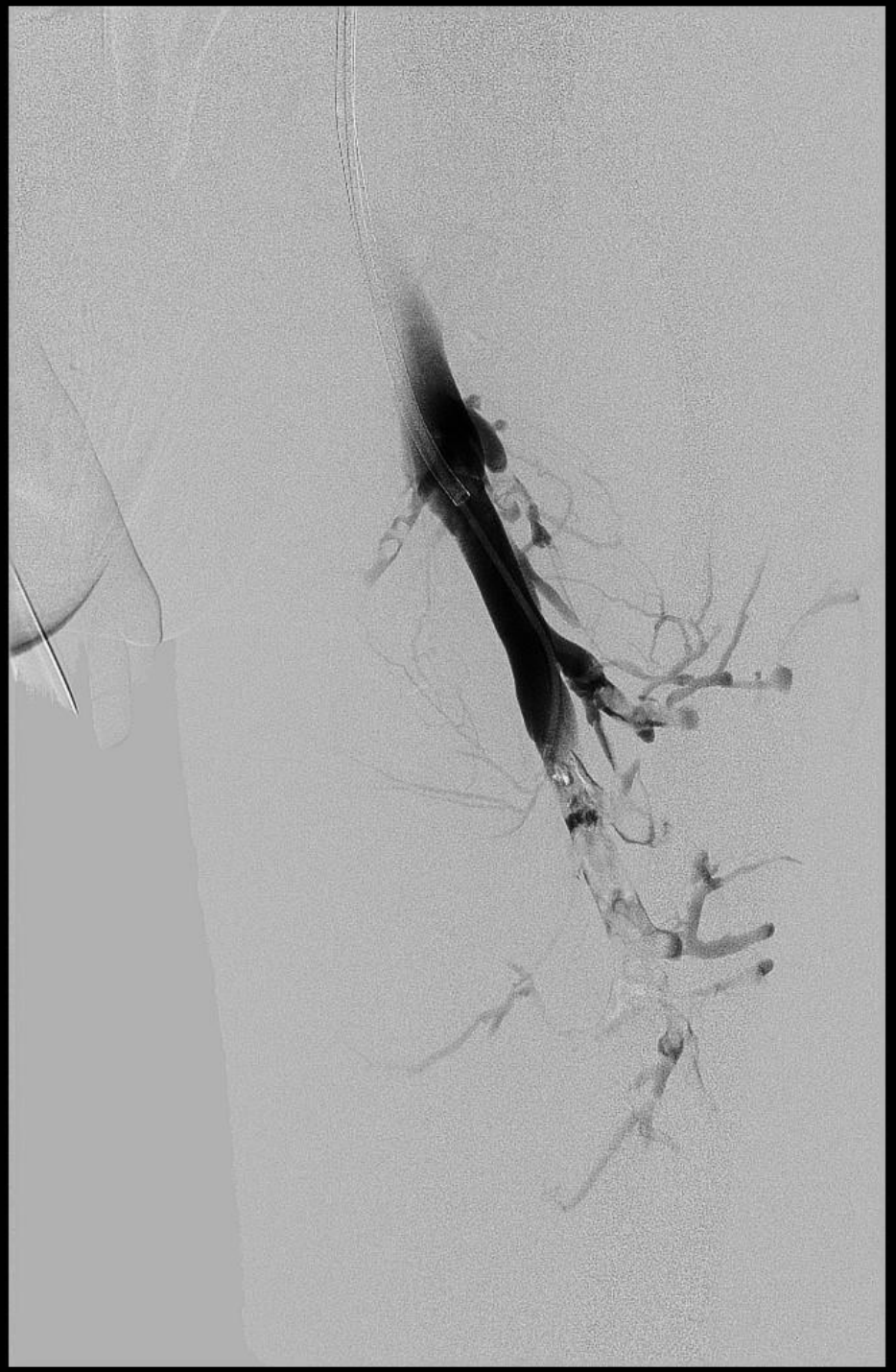


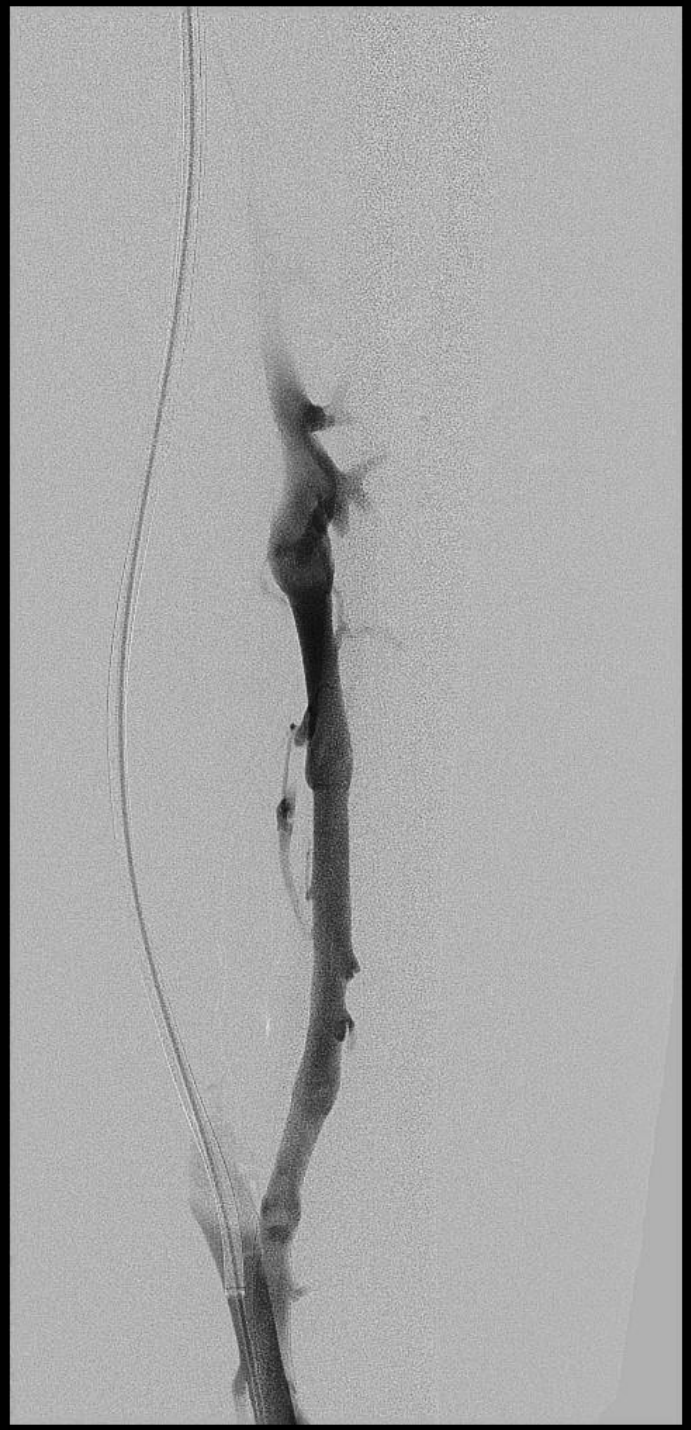


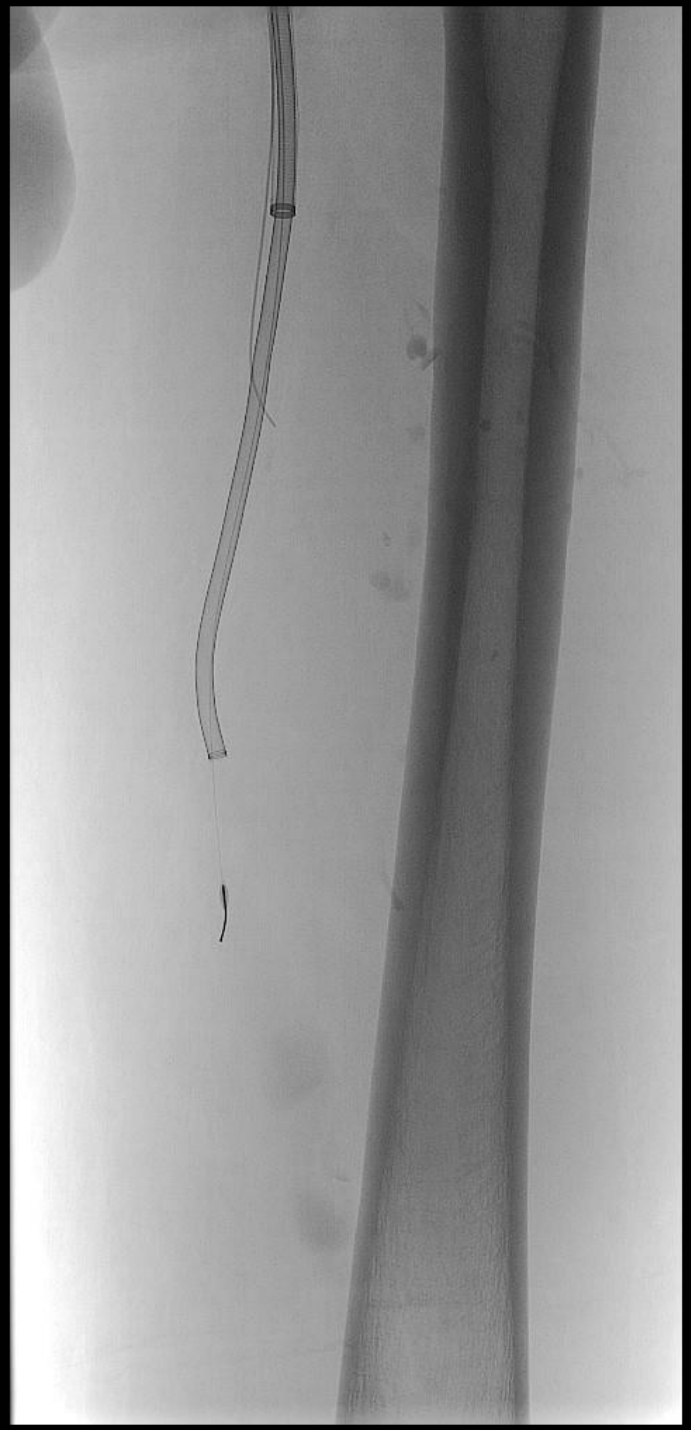


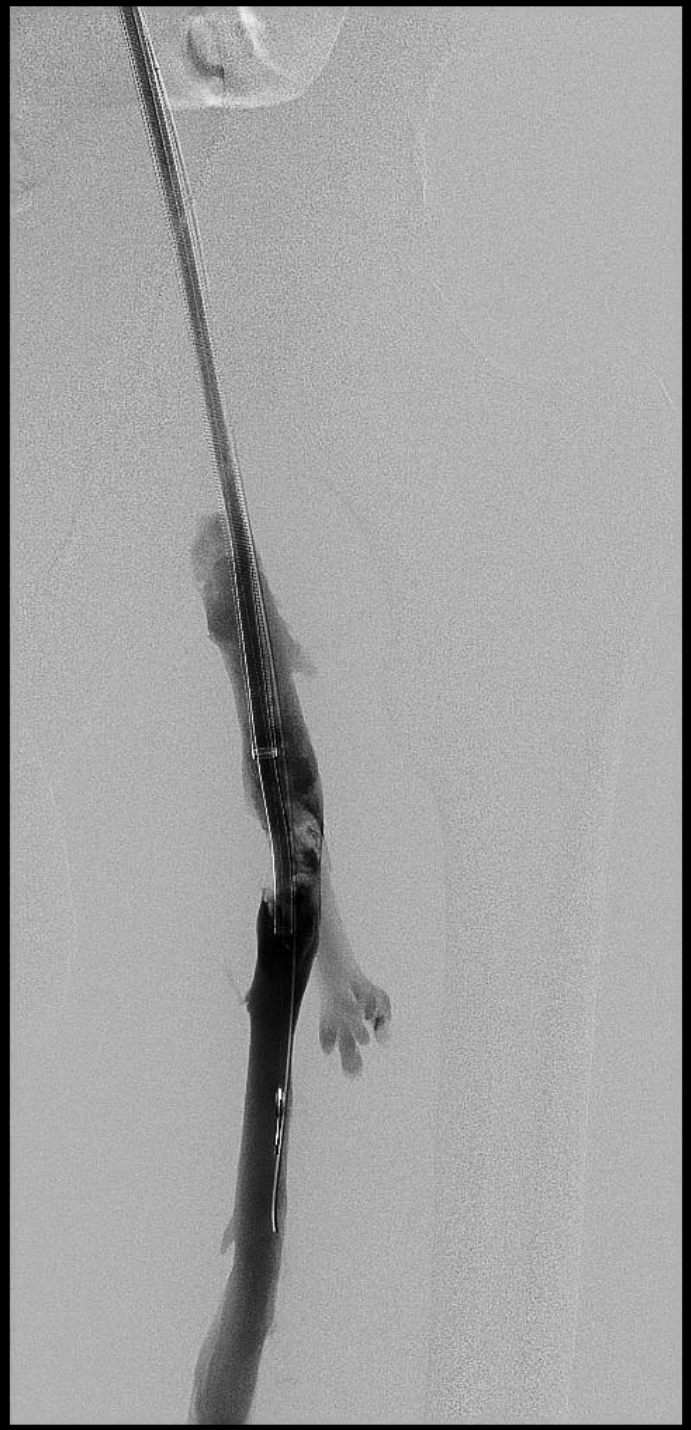


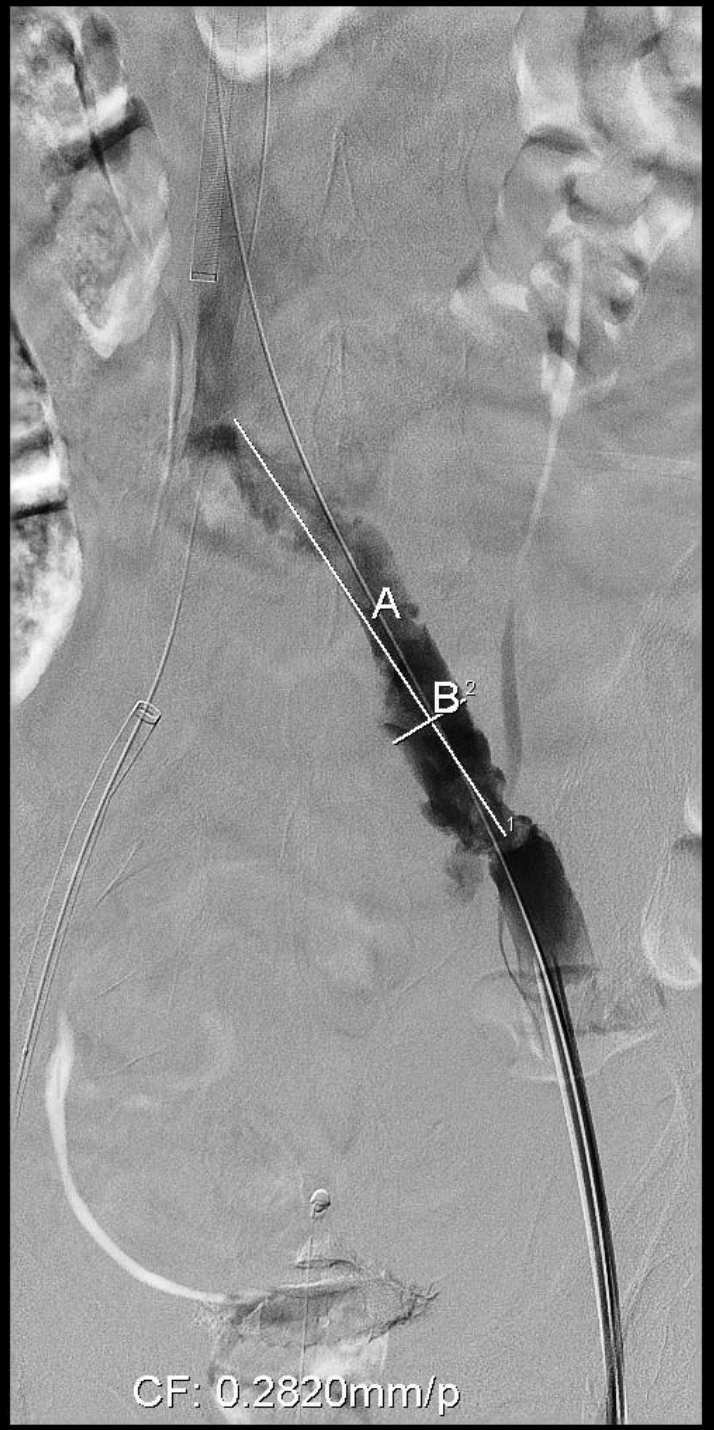




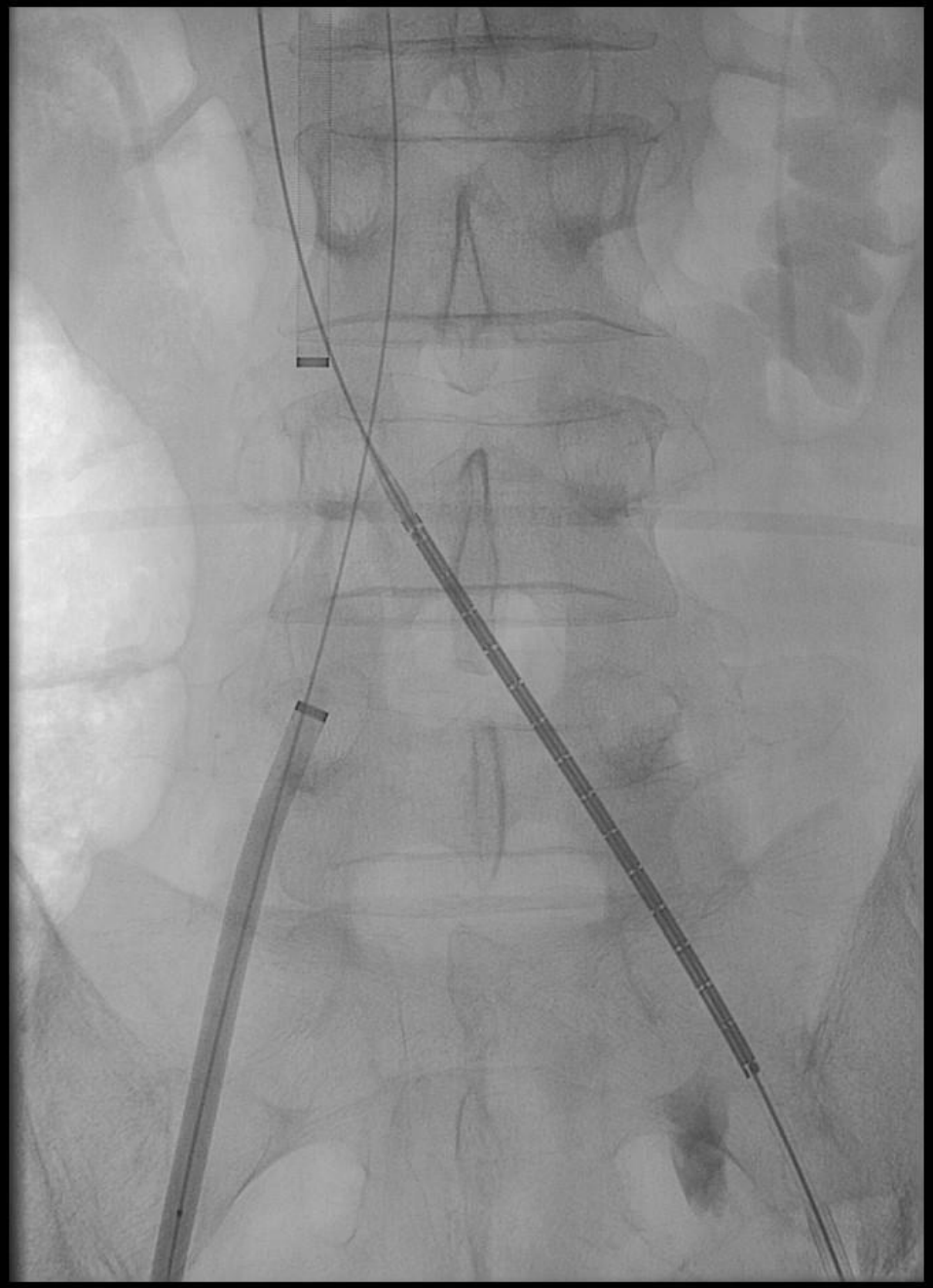


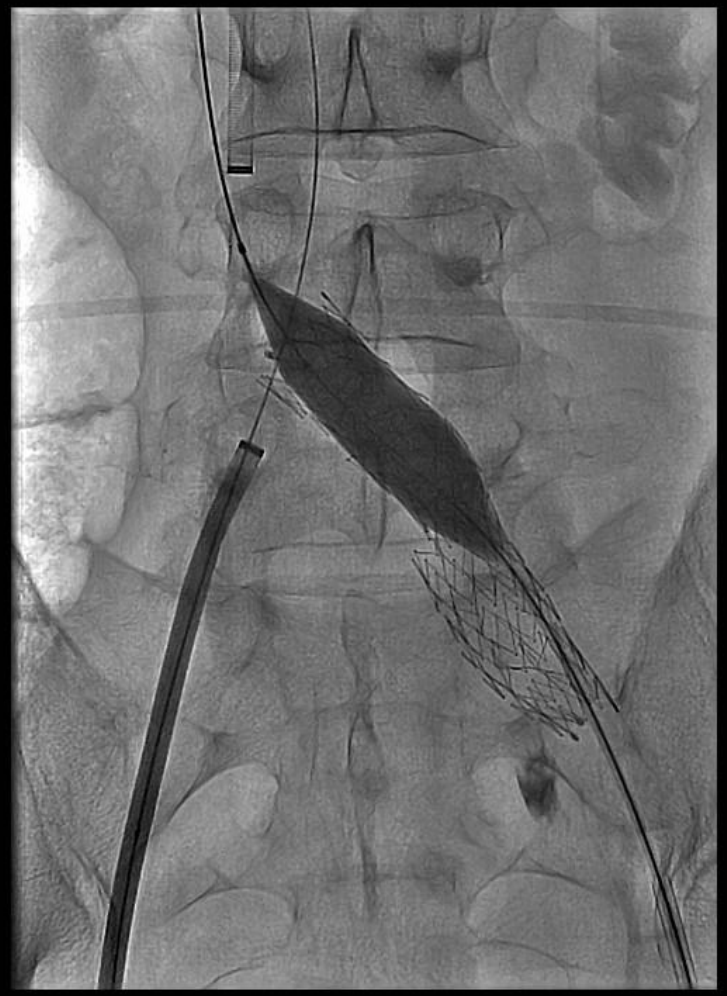


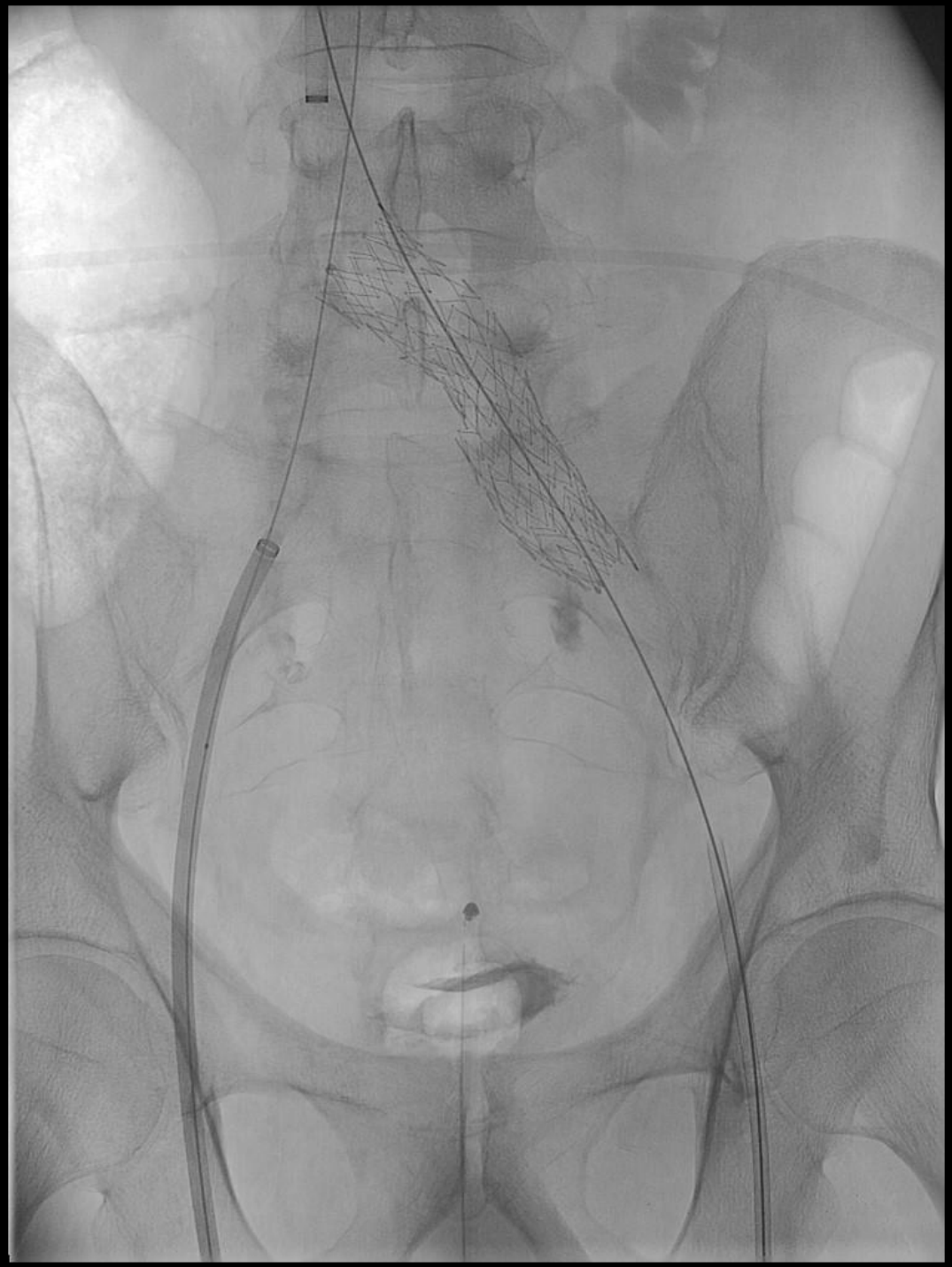


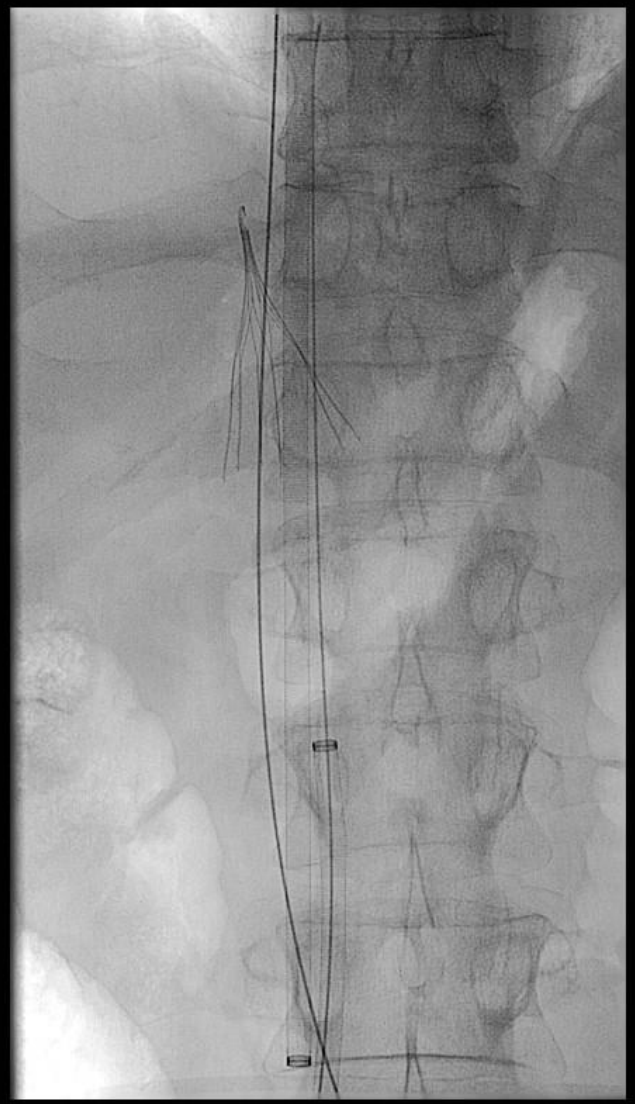


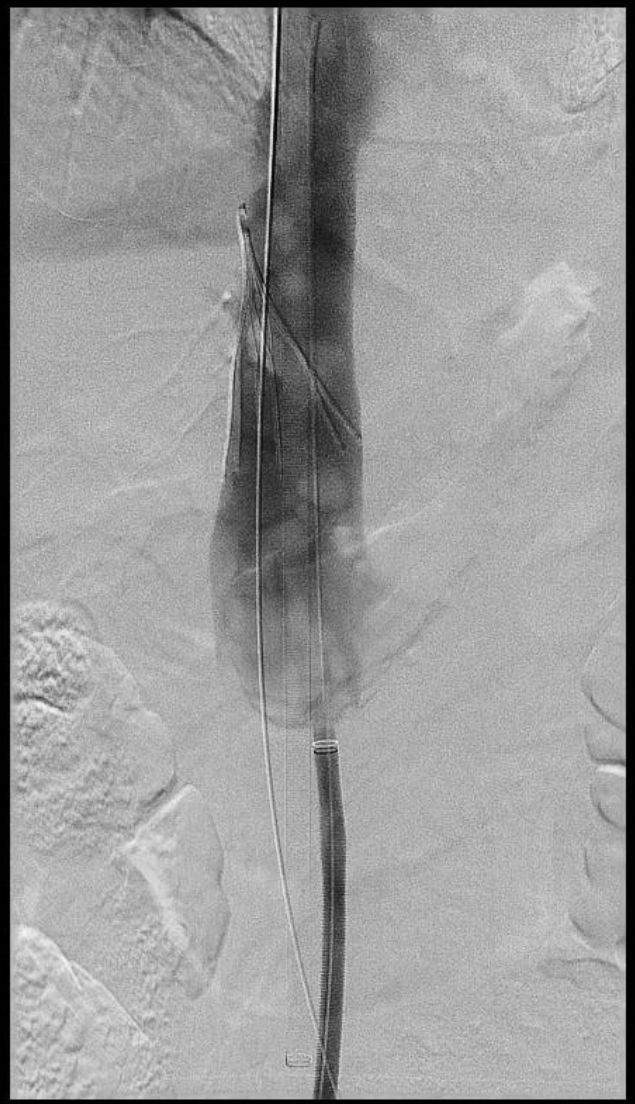
B:16.8mm
A:99.7mm












Penumbra

From the Eastern Vascular Society

Interim outcomes of mechanical thrombectomy for deep vein thrombosis from the All-Comer CLOUT Registry

David J. Dexter, MD,[a] Herman Kado, MD,[b,c] Jonathan Schor, MD,[d] Suman Annambhotla, MD,[e] Brandon Olivieri, MD,[f] Hamid Mojibian, MD,[g] Thomas S. Maldonado, MD,[h] Sagar Gandhi, MD,[i] Joseph Paulisin, DO,[j] Matthew C. Bunte, MD, MS,[k] Wesley Angel, MD,[l] Jon Roberts, MD,[l] Kalyan Veerina, MD,[m] Steven Abramowitz, MD,[n] Fakhir Elmasri, MD,[o] Jeffrey Hnath, MD,[p] Matthew Jung, MD,[q] Daniel Long, MD,[r] Luis Sanchez, MD,[s] Octavio Cosme, MD,[t] Edvard Skripochnik, MD,[u] Ankur Lodha, MD,[v] Abdullah Shaikh, MD,[w] Christopher King, MD,[x] Mohannad Bisharat, MD,[y] *and* Robert E. Beasley, MD,[z] for the CLOUT Investigators, *Norfolk, VA; Farmington Hills and Royal Oak, MI; Staten Island, NY; Gainesville, GA; Miami, FL; New Haven, CT; New York, NY; Greenville, SC; Bay City, MI; Kansas City, MO; Germantown, TN; Opelousas, LA; Washington, DC; Lakeland, FL; Albany, NY; Louisville, KY; Cincinnati, OH; St. Louis, MO; Tampa, FL; Lafayette, LA; Pittsburgh, PA; Birmingham, AL; Jacksonville, FL; and Miami Beach, FL*

ABSTRACT

Objectives: The multicenter, prospective, single arm CLOUT registry assesses the safety and effectiveness of the Clot-Triever System (Inari Medical, Irvine, CA) for the treatment of acute and nonacute lower extremity deep vein thrombosis (DVT) in all-comer patients. Reported here are the outcomes of the first 250 patients.

Methods: All-comer patients with lower extremity DVT were enrolled, including those with bilateral DVT, those with previously failed DVT treatment, and regardless of symptom duration. The primary effectiveness end point is complete or near-complete (≥75%) thrombus removal determined by independent core laboratory-adjudicated Marder scores. Safety outcomes include serious adverse events through 30 days and clinical outcomes include post-thrombotic syndrome severity, symptoms, pain, and quality of life through 6 months.

Results: The median age was 62 years and 40% of patients had contraindications to thrombolytics. A range of thrombus chronicity (33% acute, 35% subacute, 32% chronic) was observed. No patients received thrombolytics and 99.6% were treated in a single session. The median thrombectomy time was 28 minutes. The primary effectiveness end point was achieved in 86% of limbs. Through 30 days, one device-related serious adverse event occurred. At 6 months, 24% of patients had post-thrombotic syndrome. Significant and sustained improvements were observed in all clinical outcomes, including the Revised Venous Clinical Severity Score, the numeric pain rating scale, and the EuroQol Group 5-Dimension Self-Report Questionnaire.

Conclusions: The 6-month outcomes from the all-comer CLOUT registry with a range of thrombus chronicities demonstrate favorable effectiveness, safety, and sustained clinical improvements. (J Vasc Surg Venous Lymphat Disord 2022;10:832-40.)

Keywords: Deep vein thrombosis; Mechanical thrombectomy; Post-thrombotic syndrome

Table II. Adjudicated serious adverse events (*SAEs*) through 30 days

SAE	Total	Device-related
DVT[a]	10 (4.5%)	0 (0)
PE	4 (1.8)	1 (0.4)
Hemoglobin decreased	1 (0.4)	0 (0)
Non-small cell lung cancer stage IV	1 (0.4)	0 (0)
Pulseless electrical activity	1 (0.4)	0 (0)
Spinal cord infection	1 (0.4)	0 (0)
Acute renal injury	0 (0)	0 (0)
Vessel/valve damage	0 (0)	0 (0)

DVT, Deep vein thrombosis; *PE,* pulmonary embolism.
Values are number (%). Serious adverse events (SAEs) through 30 days were adjudicated by an independent medical safety monitor. SAEs are defined as events that are fatal or life-threatening, result in persistent or significant disability or incapacity, result in permanent impairment of a body function or permanent damage to a body structure, result in hospitalization or prolongs a hospitalization and necessitates medical or surgical intervention.
[a]Deep vein thromboses found incidentally at follow-up were recorded as SAEs if they met the SAE definition, regardless of whether they were symptomatic, and may have included those due to residual thrombus from the index procedure. The denominator is 223.

The aim of the treatment?

- To restore optimal blood flow as quickly as possible
- To avoid valvular damage

- To correct underlying triggering factors

The aim of the treatment?

✓To restore optimal blood flow as quickly as possible

- To avoid valvular damage

- To correct underlying triggering factors

The aim of the treatment?

✓To restore optimal blood flow as quickly as possible

✓To avoid valvular damage

- To correct underlying triggering factors

The aim of the treatment?

- ✓ To restore optimal blood flow as quickly as possible
- ✓ To avoid valvular damage

- ✓ To correct underlying triggering factors

HTS 1302 – State-of-the-art: treatment of acute DVT

VENOUS INTERVENTION

Hot Topic Symposium | 11 Sep 2022 | 15:00–16:00 (Europe/Madrid) | Auditorium 1

Moderators: P. Haage, G. O'Sullivan

Add to my calendar

1302.1 / ~~I would use pharmacomechanical~~

A. Wigham, T. MacKinnon

Risk of bleeding

I would use mechanical only with no lytics

1302.3 / ~~I would use catheter directed thrombolysis only~~

N. O'Halloran

Risk of bleeding and only partially succesful

1302.4 / ~~I would use anticoagulation only~~

S. Konstantinides

Not effectful in large thrombus

1302.5 / Round-table discussion, followed by conclusion and take-home points