Syndrome post-thrombotique - Traitement endovasculaire

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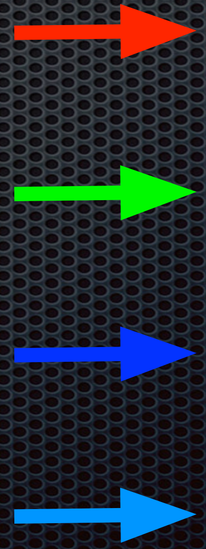
CHUM

Conflits d’intérêts/Codes

- Share holder - Abbott
- Présentateur - Consultant
  - BD
  - Cook

- Vaisseau atteint
- Vaisseau normal
- Collatérale



Objectifs

- Connaître les meilleures indications pour suggérer une intervention endovasculaire
- Minimiser le risque de complications
- Gérer le suivi d’une telle intervention

Meilleures indications

- Cliniques
- Radiologiques

Indications cliniques

- Patient jeune, actif, incommodé

  - Sx MI

  - Femme +/- homme : Sx congestion pelvienne
    - insuffisance veineuse pelvienne (SCP- IVP)

- Patient avec complications sévère: plaie veineuse

Indications cliniques

Table III. The 2020 revision of CEAP: Summary of clinical (C) classifications

C class	Description
C_0	No visible or palpable signs of venous disease
C_1	Telangiectasias or reticular veins
C_2	Varicose veins
C_{2r}	Recurrent varicose veins
C_3	Edema
C_4	Changes in skin and subcutaneous tissue secondary to CVD
C_{4a}	Pigmentation or eczema
C_{4b}	Lipodermatosclerosis or atrophie blanche
C_{4c}	Corona phlebectatica
C_5	Healed
C_6	Active venous ulcer
C_{6r}	Recurrent active venous ulcer

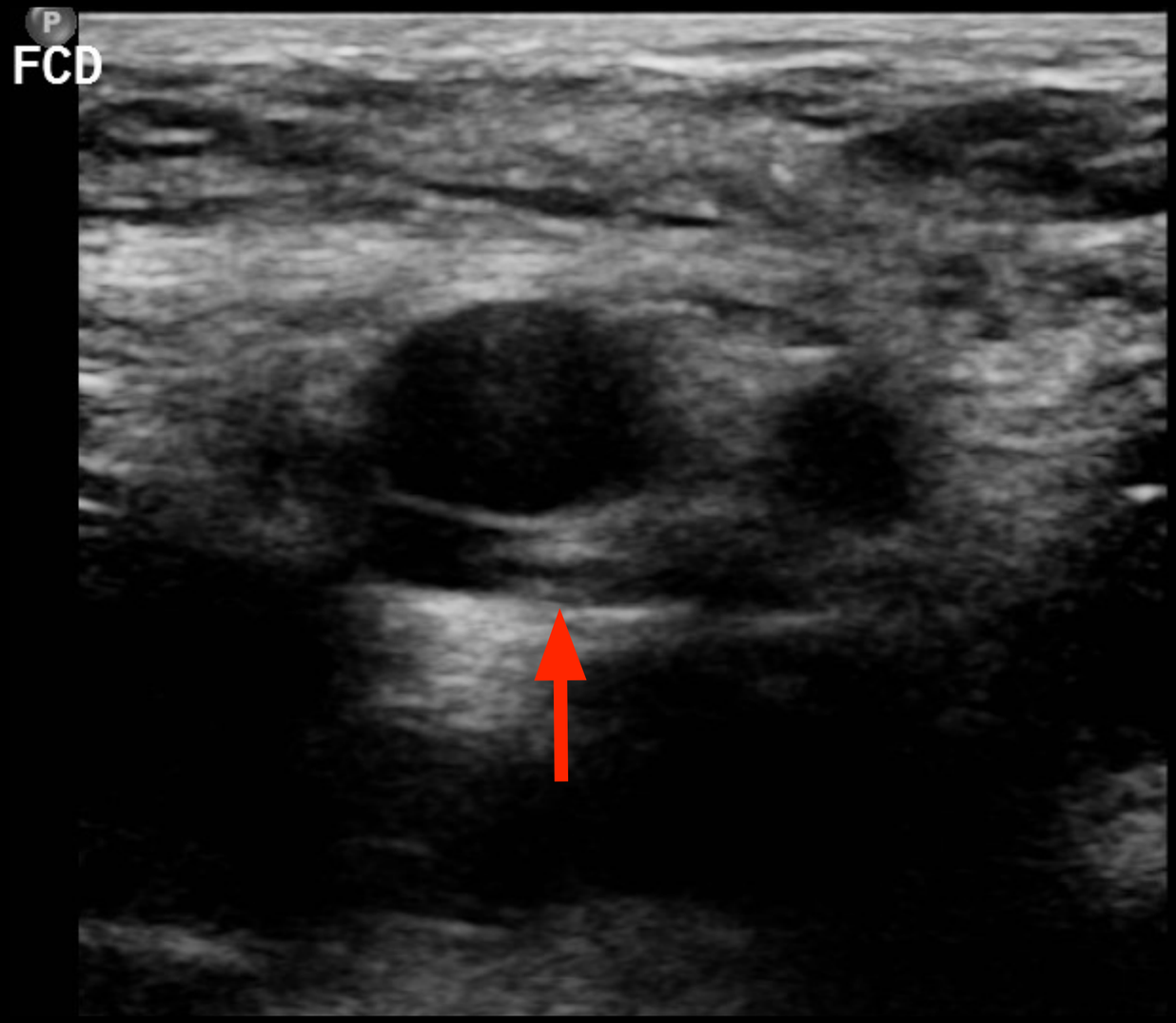
CVD, Chronic venous disease.
Each clinical class subcharacterized by a subscript indicating the presence (symptomatic, *s*) or absence (asymptomatic, *a*) of symptoms attributable to venous disease.

Score VCSS ≥ 2

Attribute	Absent (0)	Mild (1)	Moderate (2)	Se vere (3)
Pain	None	Occasional	Daily	Daily w/meds
Varicose Veins	None	Few	Multiple	Extensive
Venous Edema	None	Evening only	Afternoon	Morning
Skin Pigmentaton	None	Limited, old	Diffuse, more recent	Wider, recent
Inflammation	None	Mild celluitus	Mod cellulitus	Servere
Induration	None	Focal <5 cm	<1/3 gater	>1/3 gater
No. Active Ulcers	None	1	Moderate (2)	>2
Active Ulcer Size	None	<2 cm	2-6 cm	>6 cm
Ulcer Duration	None	<3 mo	3-12 mo	>1 yr
Compression Therapy	None	Intermittent	Most days	Fully comply

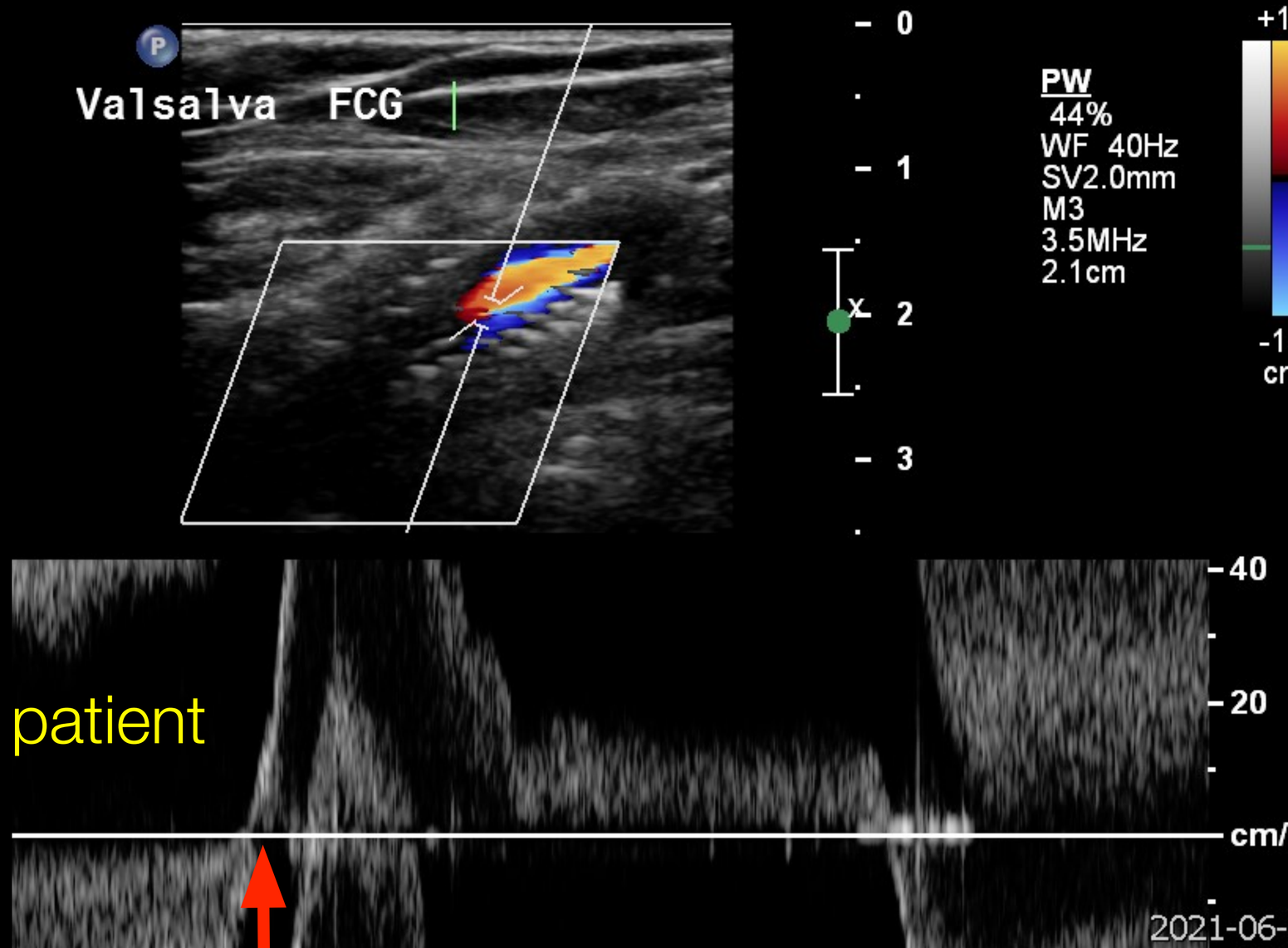
Évaluations radiologiques

- Extension d’atteinte
  - Supérieure
    - CTA veineux
  - Inférieure
    - Évaluation Doppler
- Bilan des collatérales
  - CTA veineux

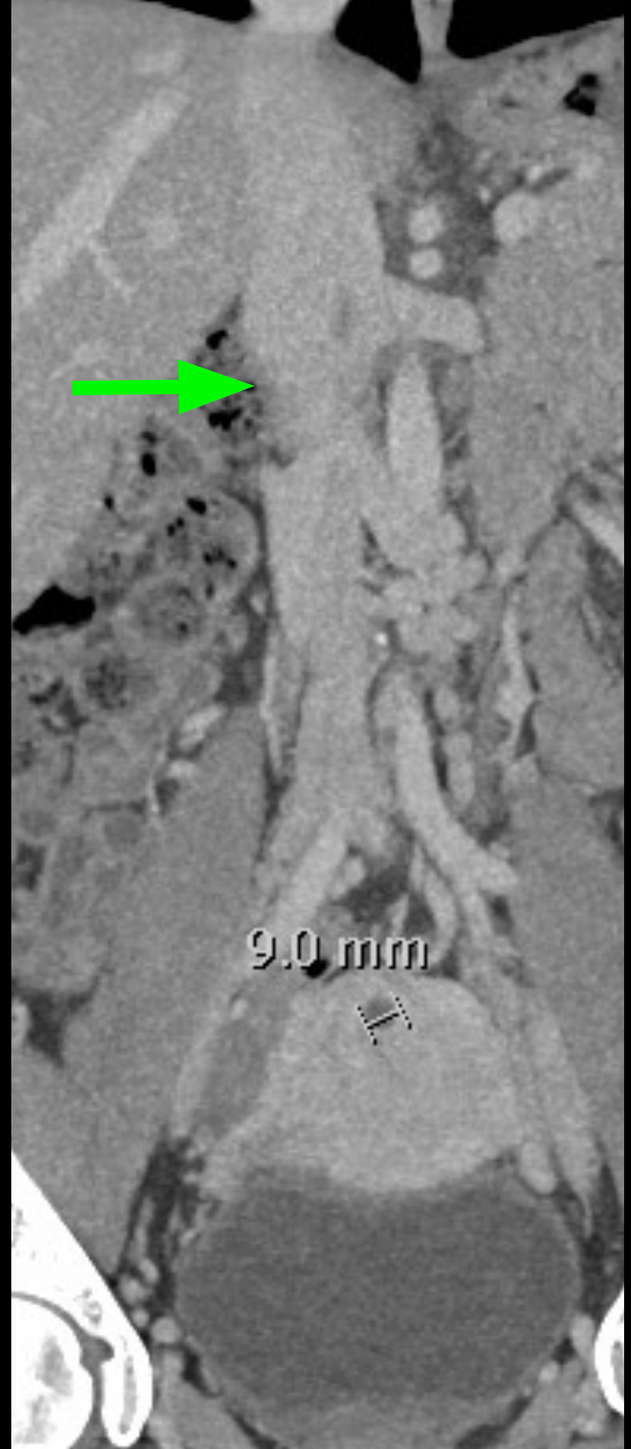


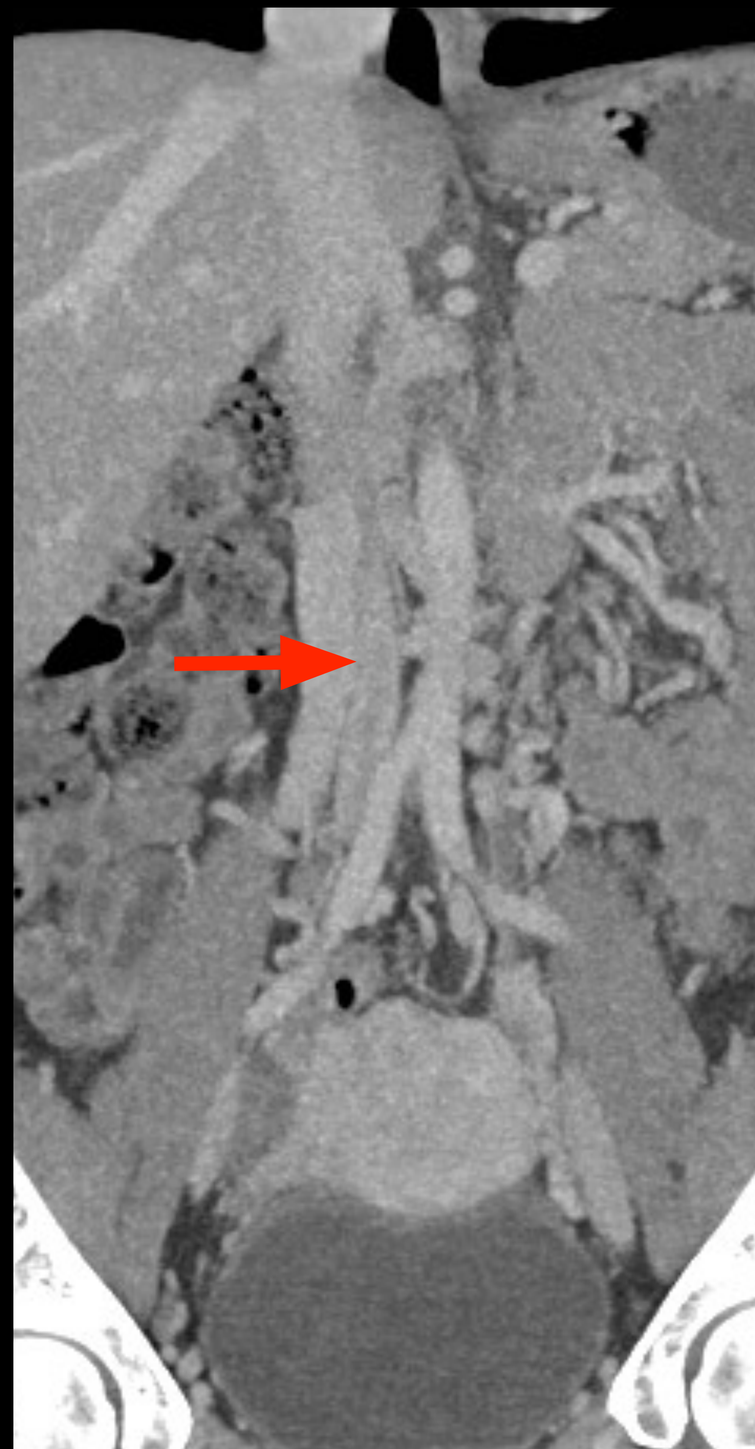
Évaluations radiologiques

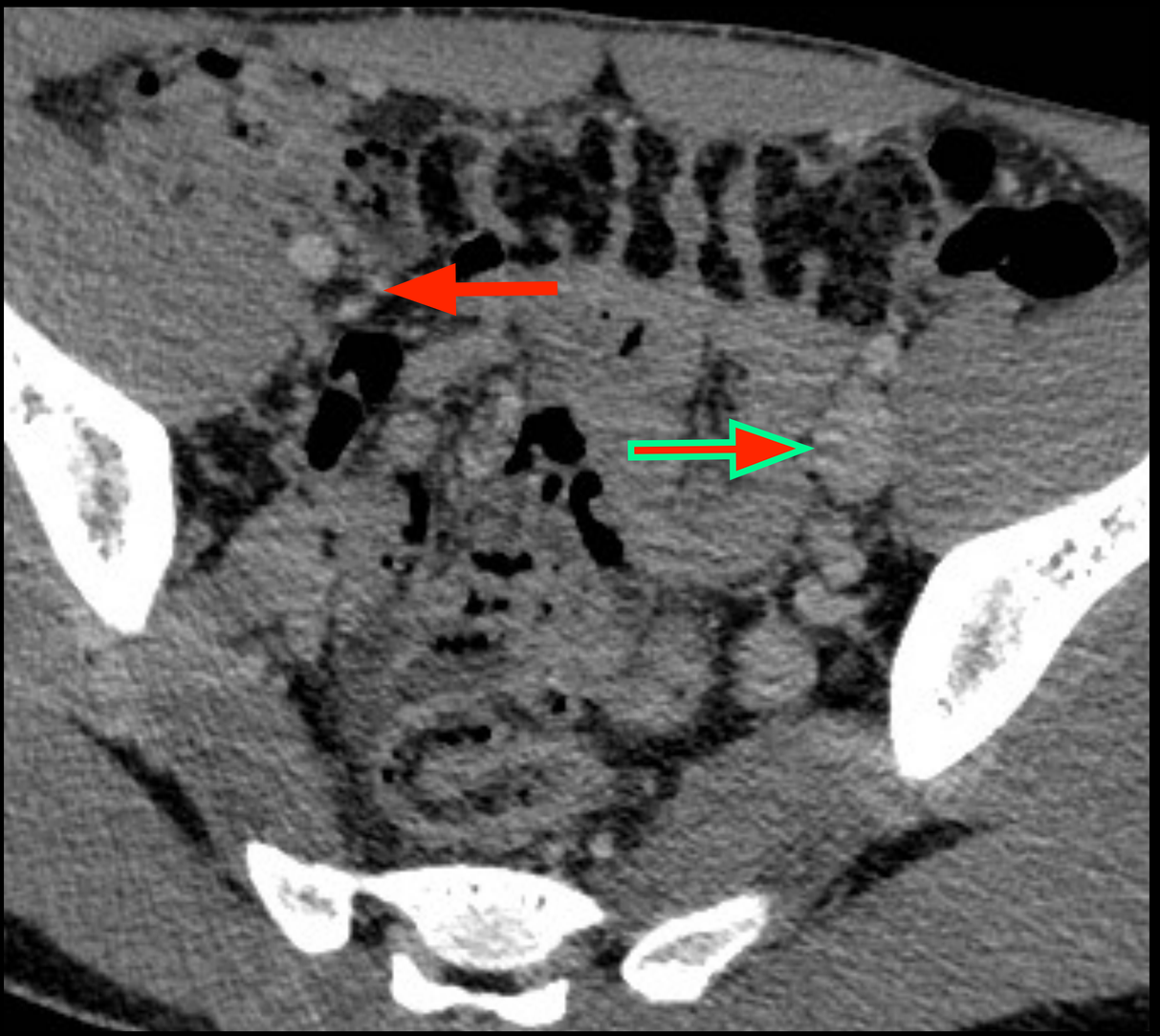
- Atteinte non-traitable
  - Extension inférieure
  - Valves
- Gestion des attentes du patient

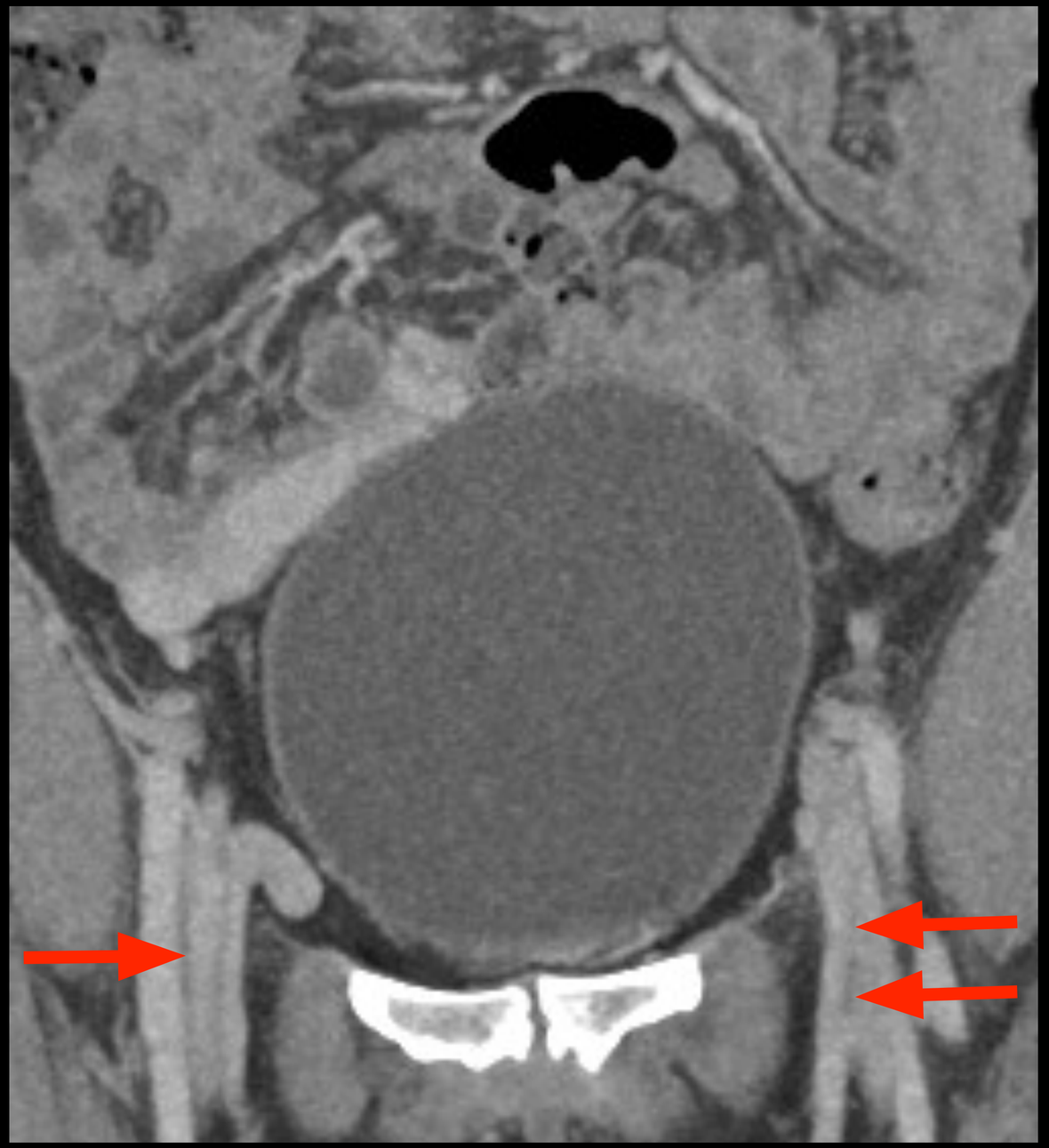


- Y a-t-il une VCI?
  - Atteinte p/r aux veines rénales
- Apparence des
  - axes iliaques veineux
  - FC

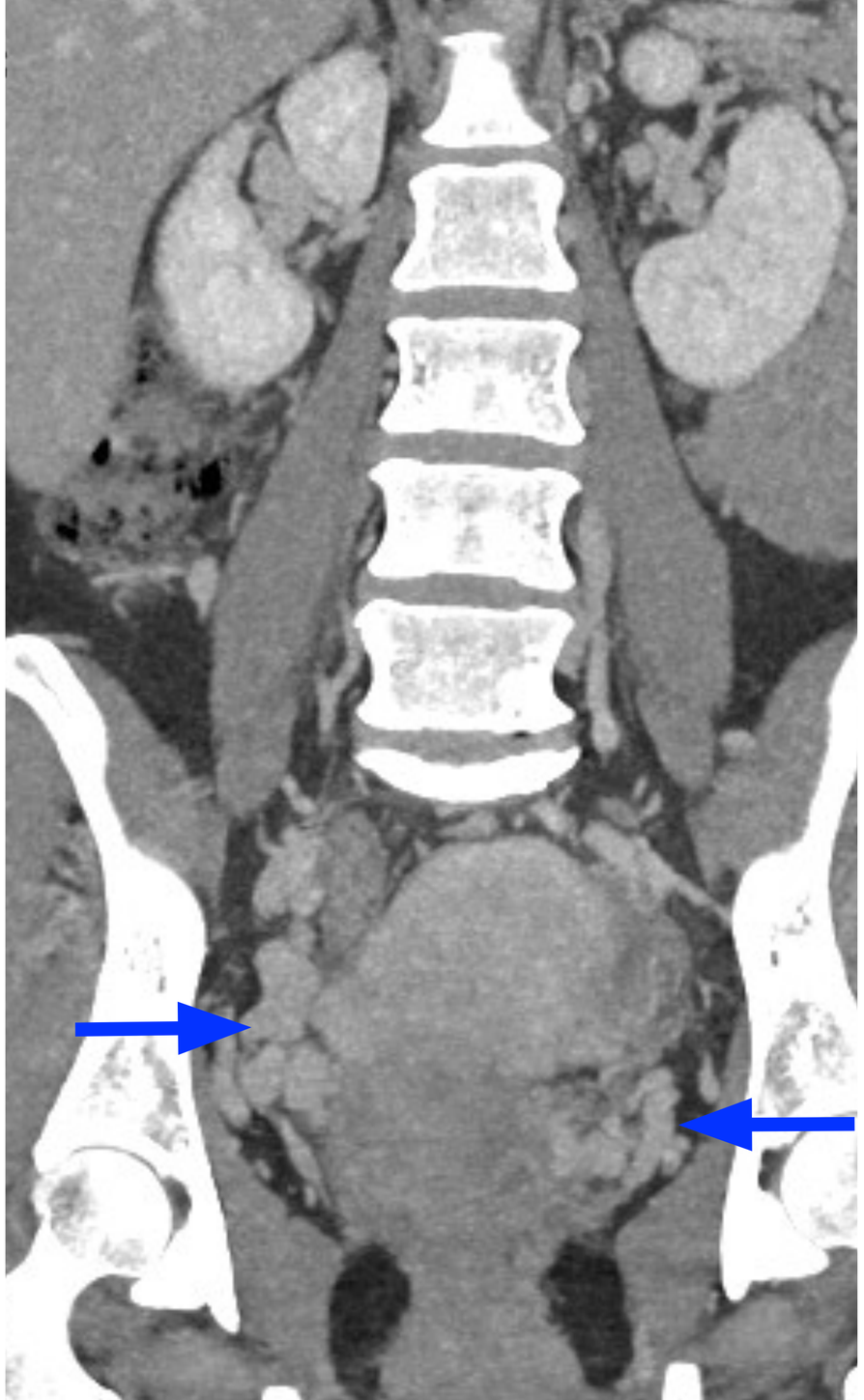


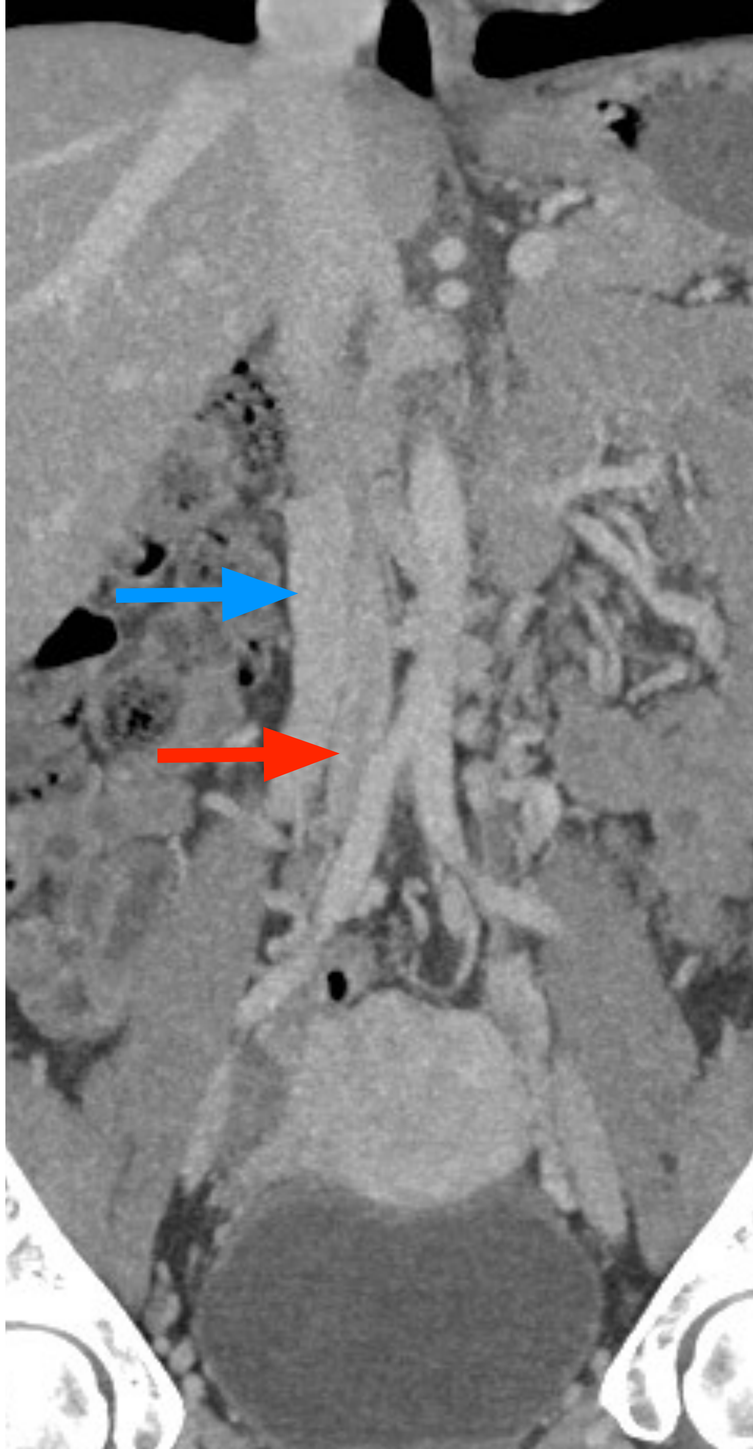




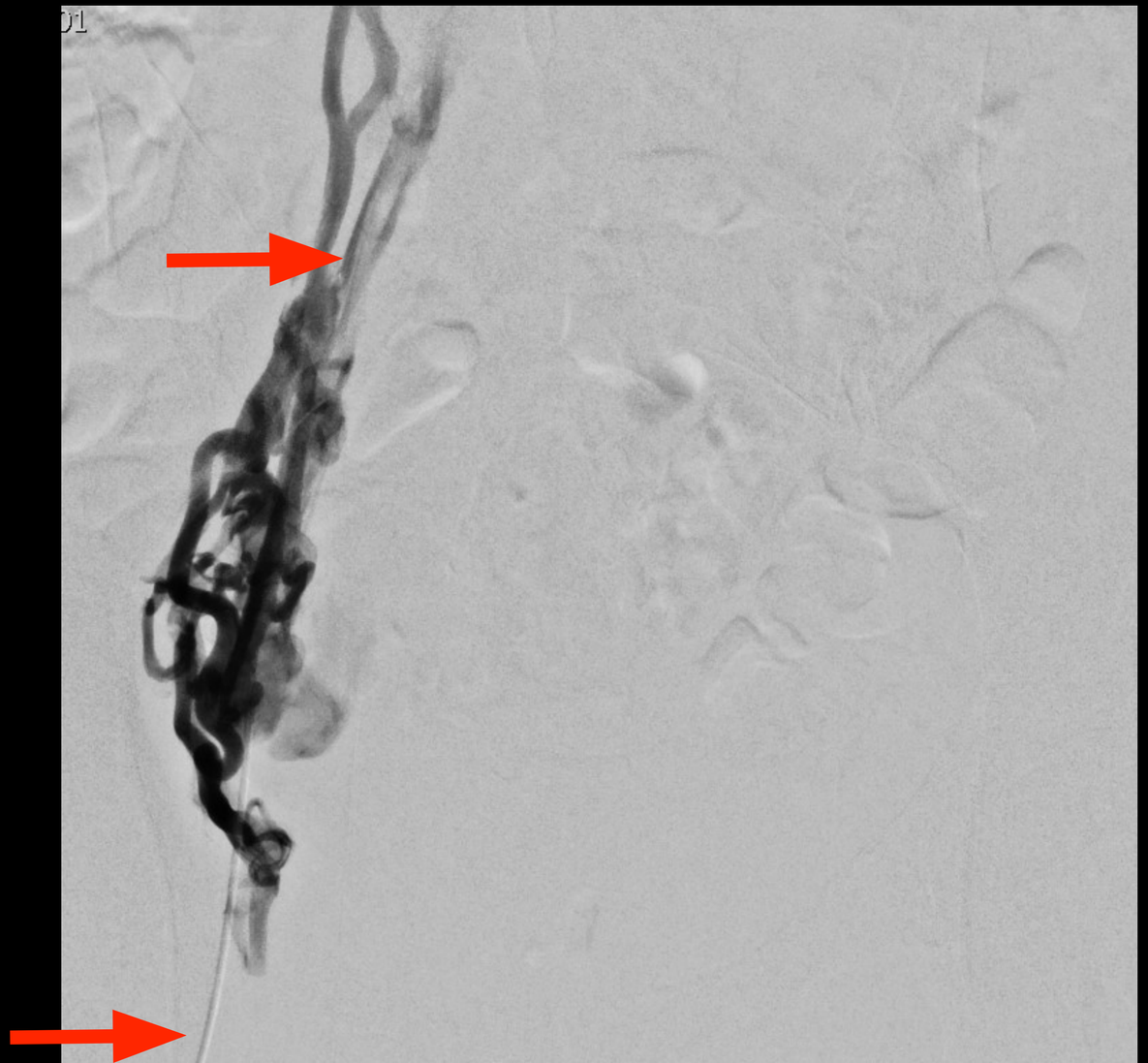


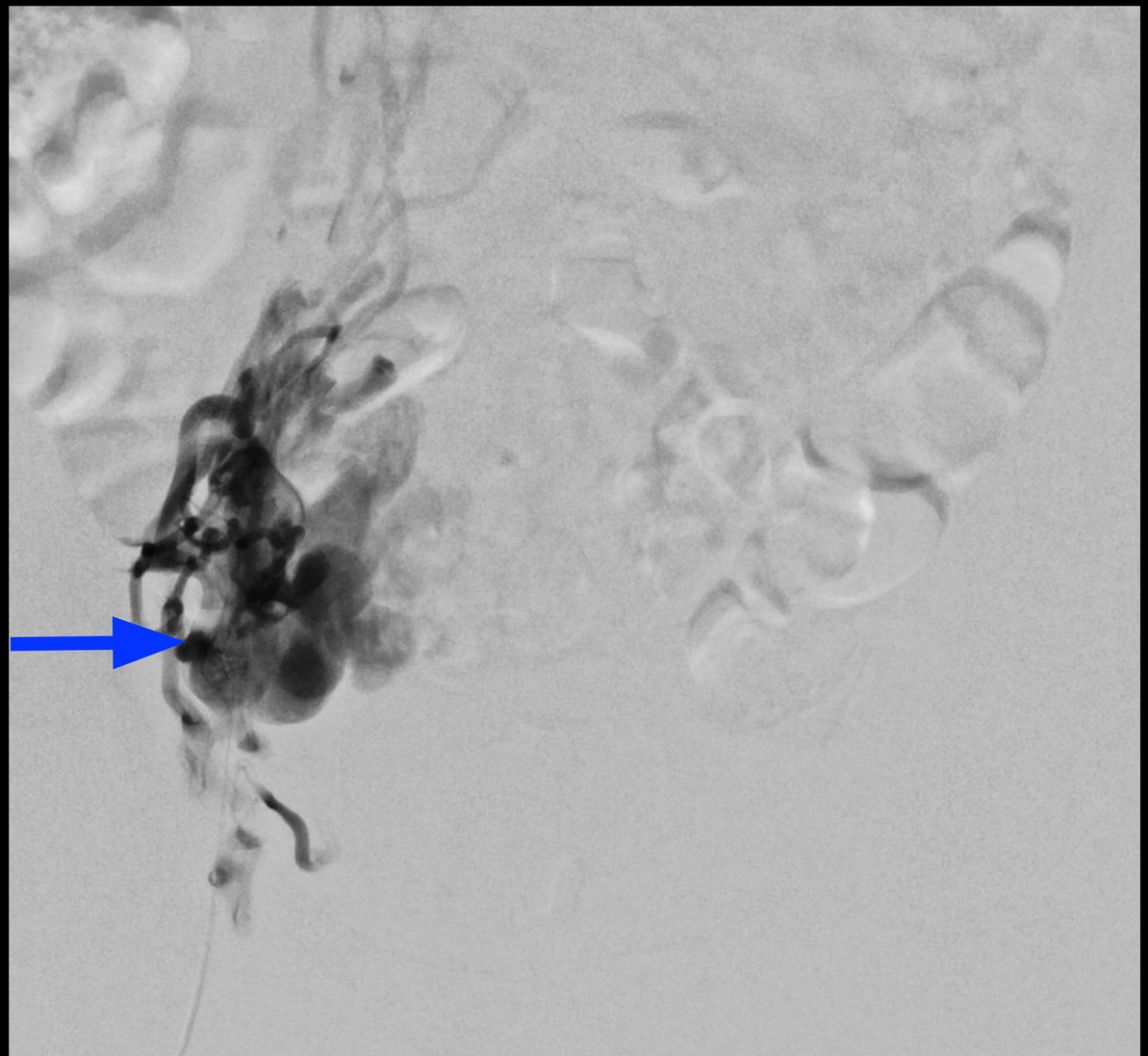
- Collatérales?
  - Explique SCP-IVP
  - Favorise les thromboses

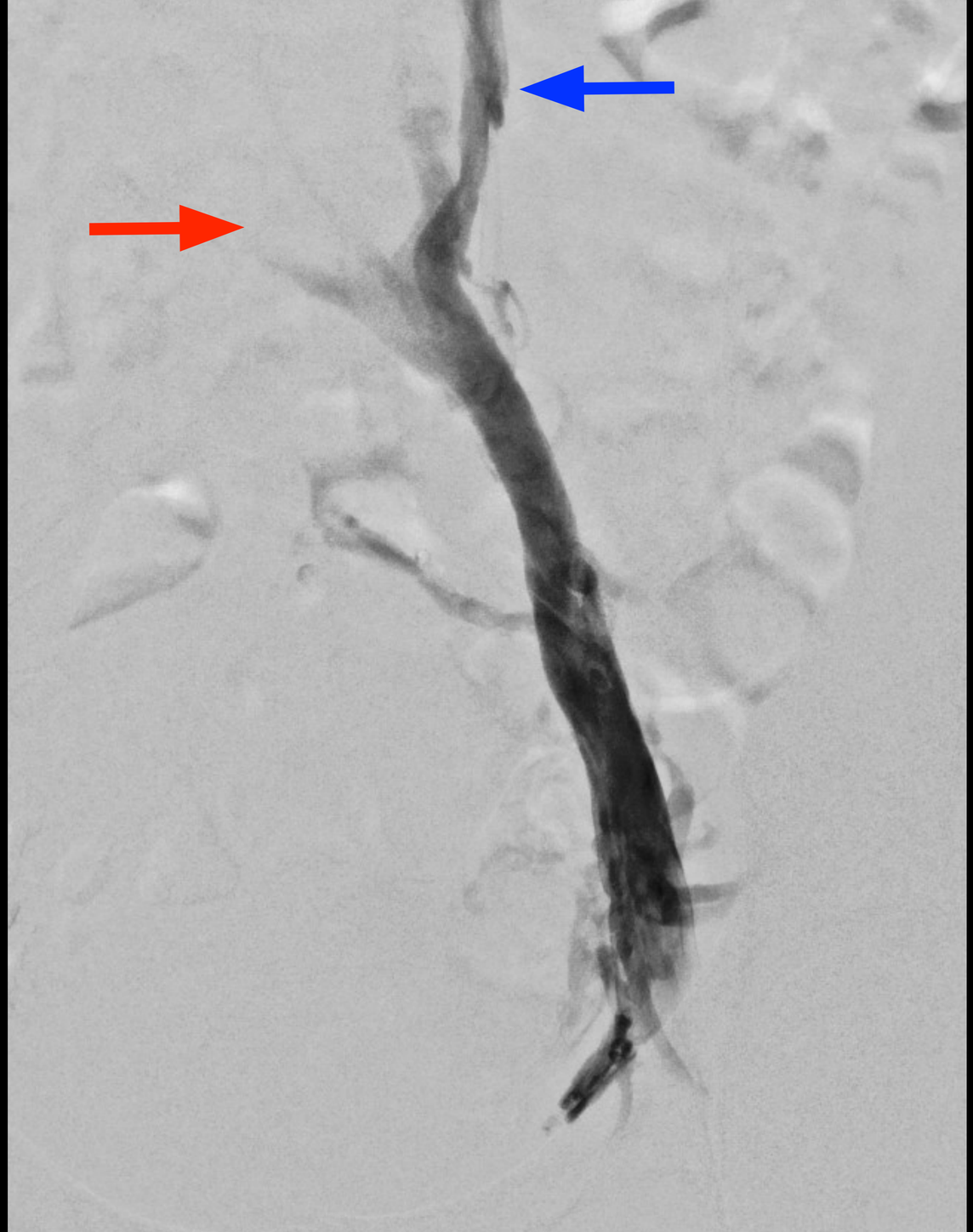
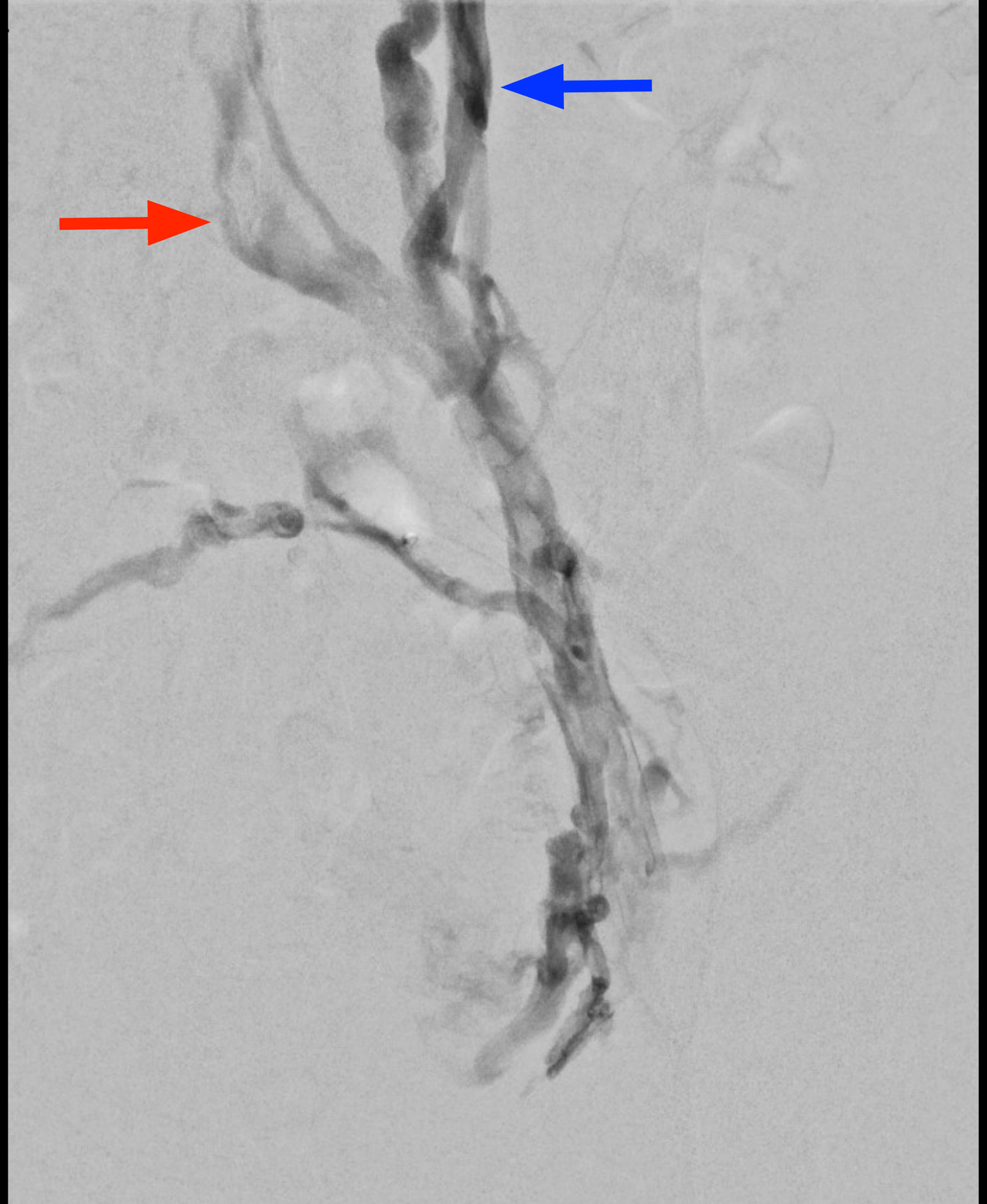


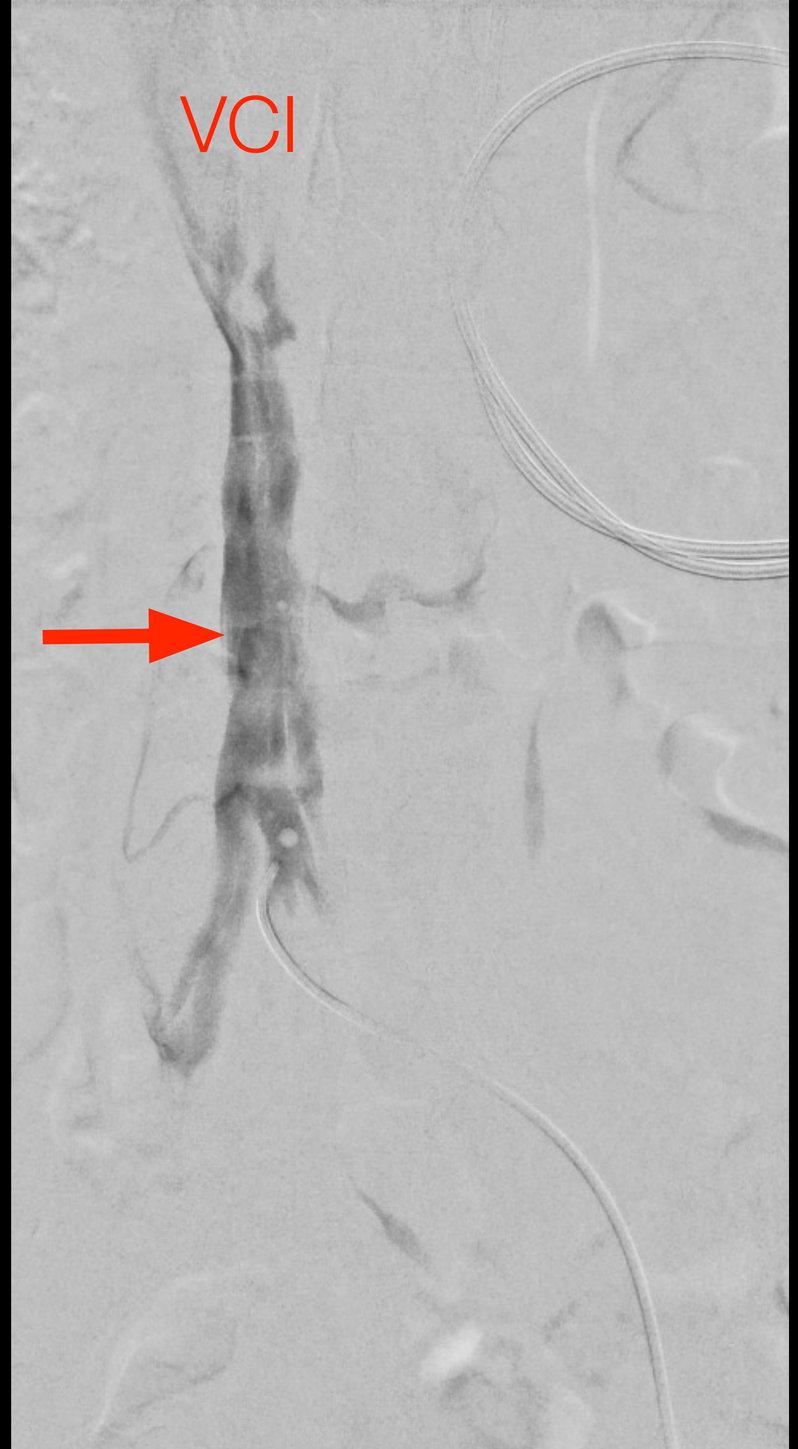


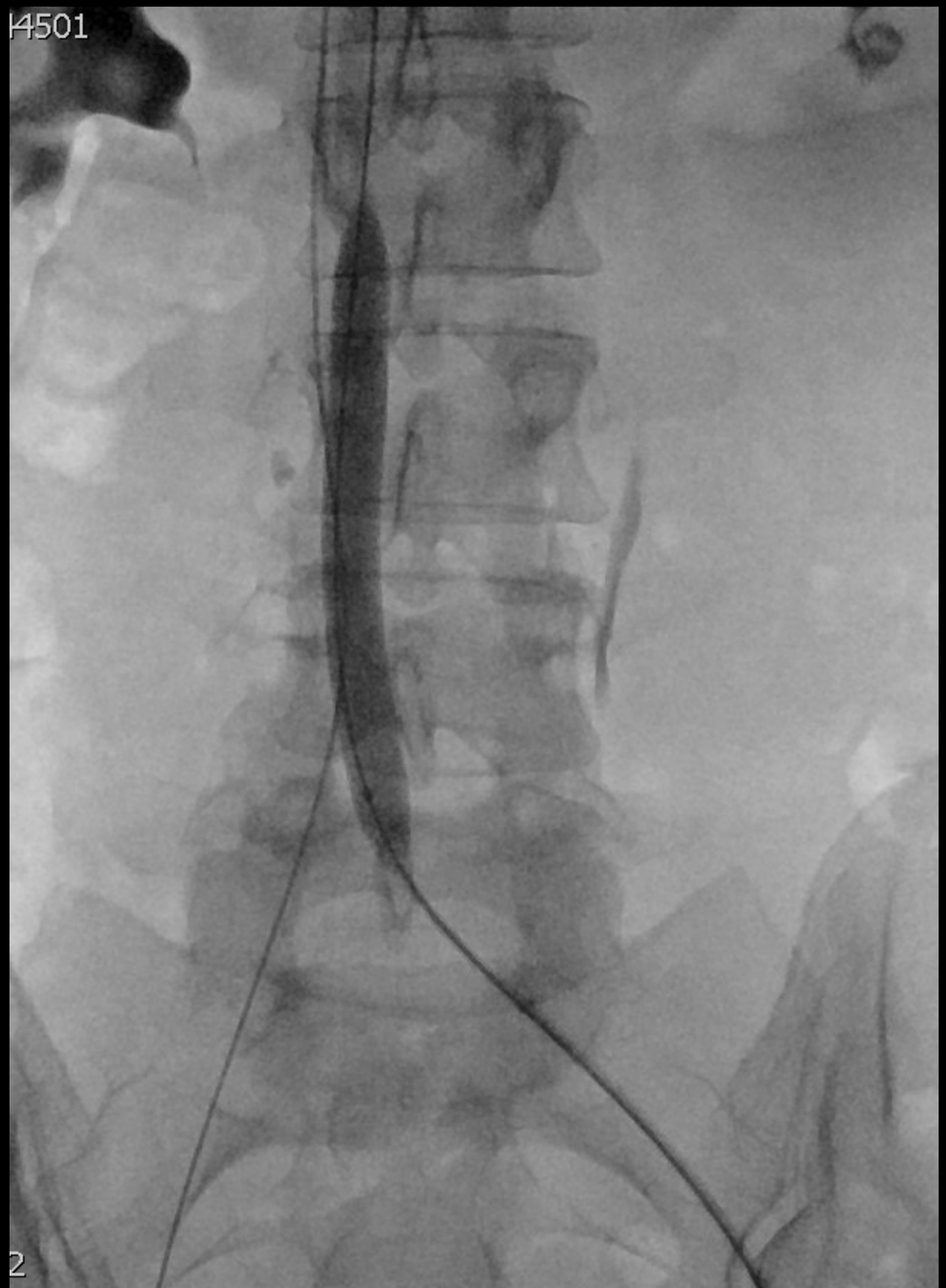
Phlébographie +/- Tx






VCI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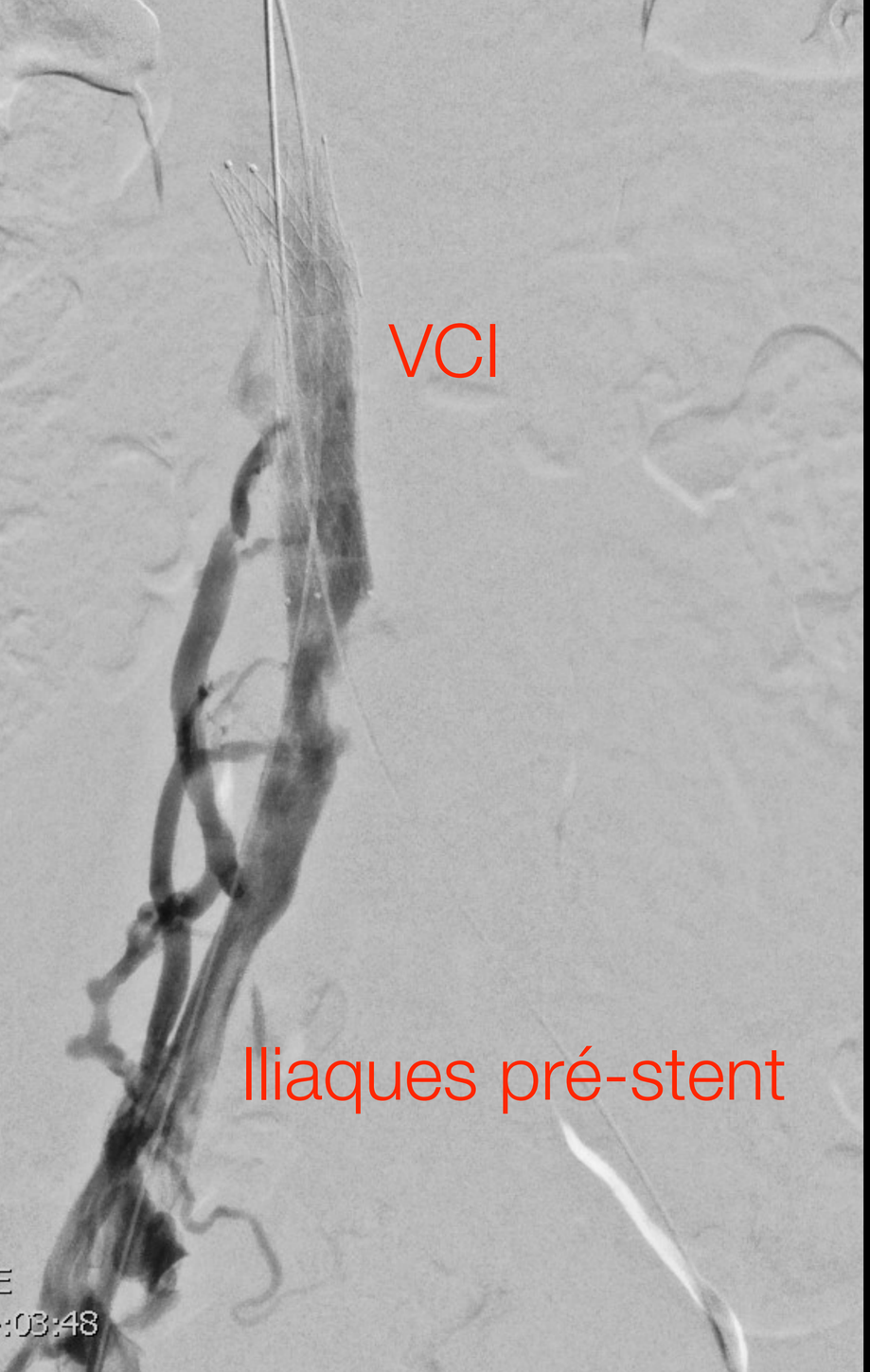

VCI
Iliaques pré-stent


VCI
Iliaques
post-stent

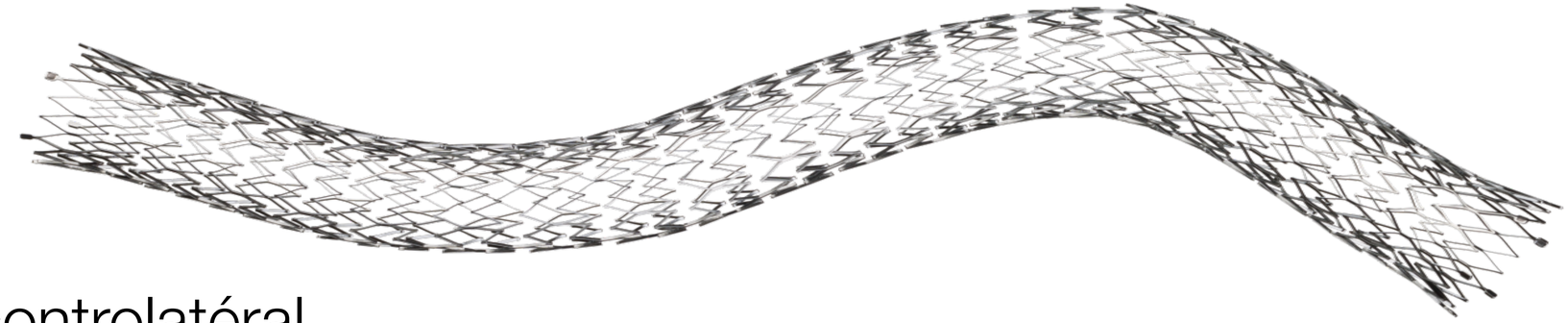

VCI
Iliaques
post-stent

Minimiser les complications

- Choix des patients
- Choix lors des procédures
  - Approche(s)
  - Matériel

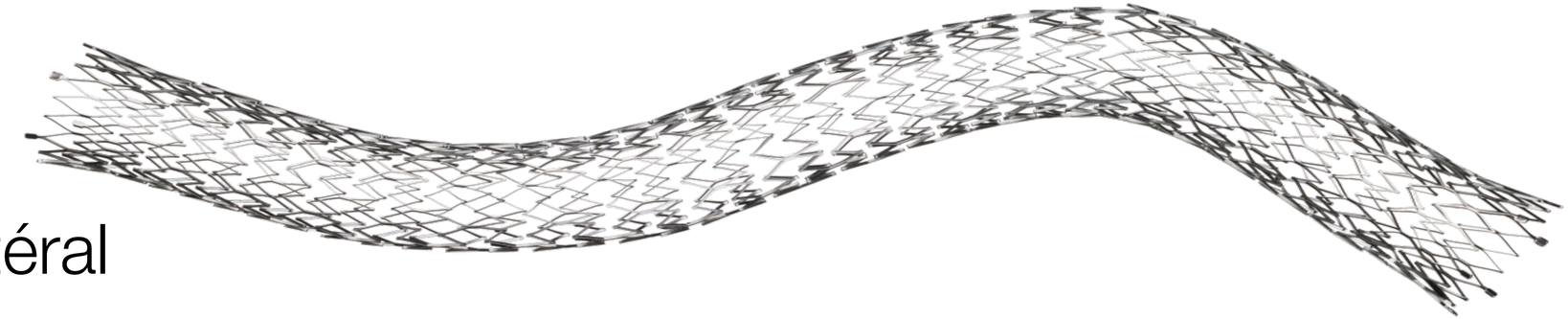
Considérations pour stents veineux

- Tailles
  - Largeur: 10 - 20 mm
  - Longueur: 40 -160 mm voire plus longs
- Longueurs de travail vu les différents accès
  - MS
  - Jugulaire
  - Fémoral ipsi & controlatéral
  - Poplité/saphène externe



Considérations pour stents veineux

- Haute force radiale/“crush resistance”
  - Prévenir compression
  - Prévenir migration
- Flexibilité
  - accès controlatéral
  - pour se conformer à la veine



Stents approuvés

- Cook Silver Vena
- BD Venovo: “temporairement” non-disponible

Stents utilisés “off-label"

- Rares autres stents auto-expansibles de bonne taille approuvés pour d’autres indications (artériel, biliaire, etc.)
- Rares stents “balloon expandible” dans certains endroits spécifiques
- Rares stents avec accès spécial

Complications péri-procédure

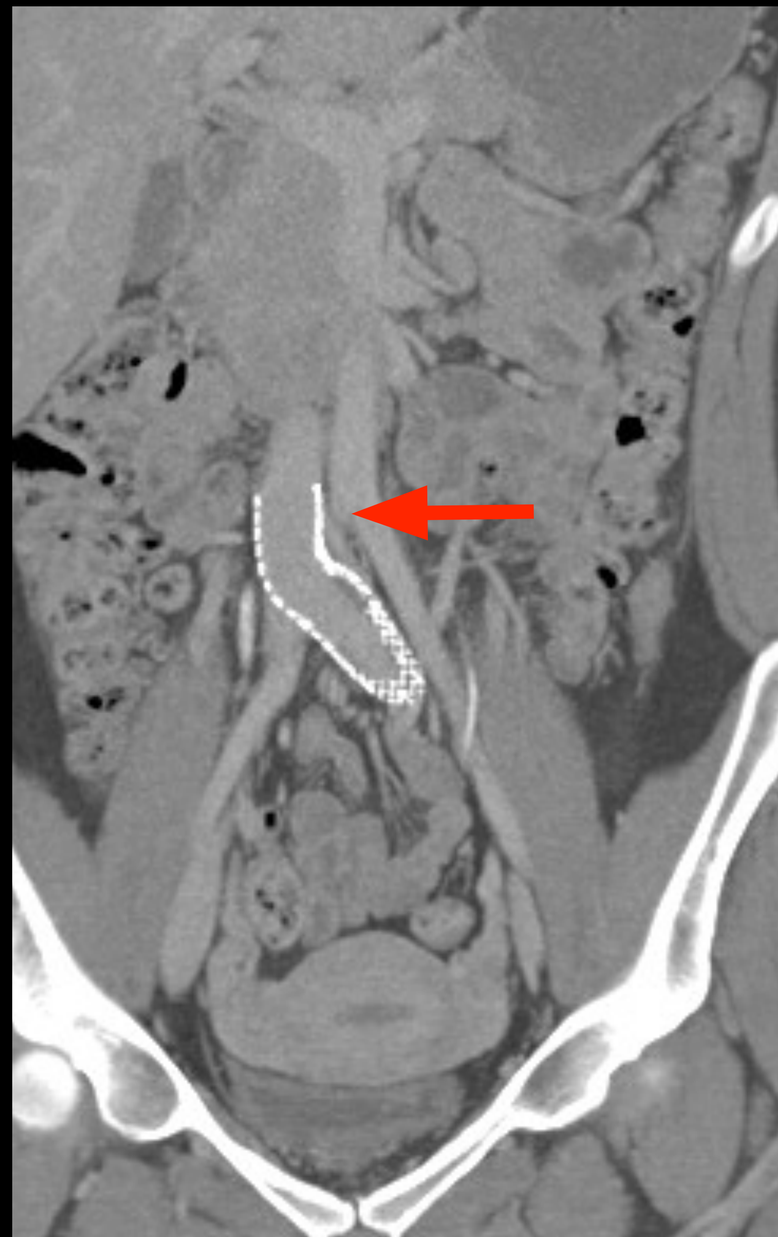
- Au site d’accès
  - Saignement
  - Thrombose
- Rupture veineuse
- Embolie pulmonaire

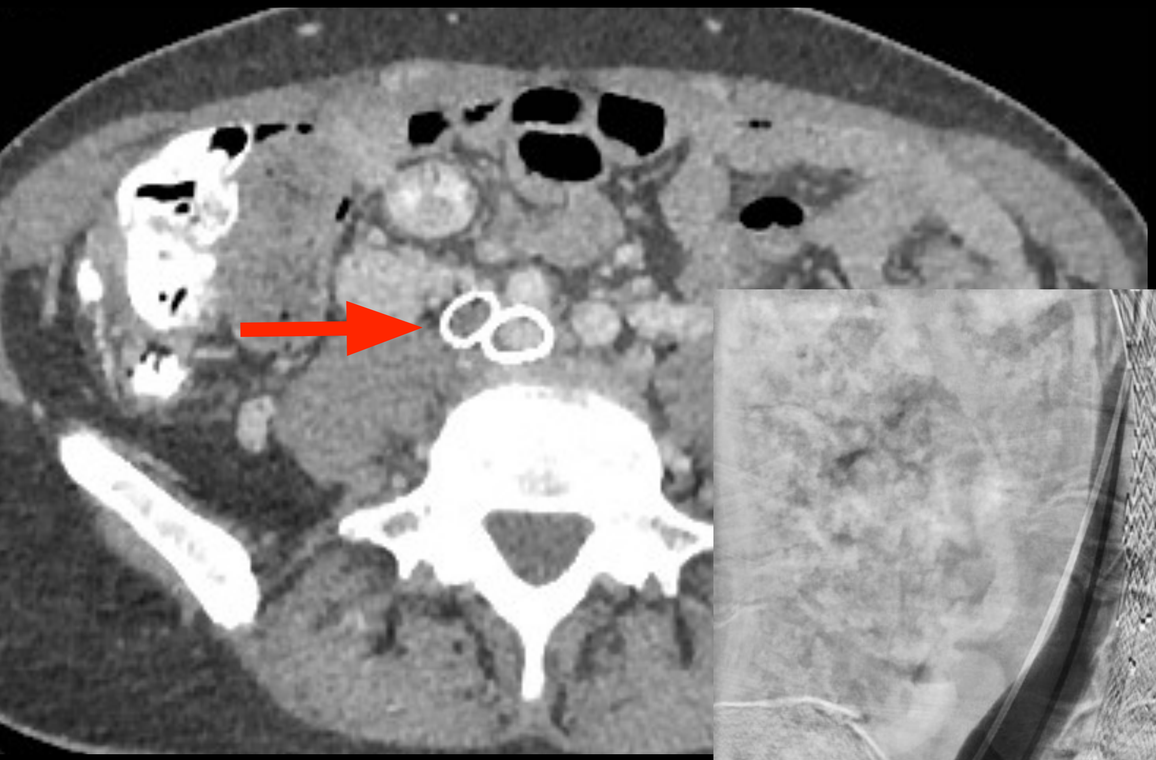
Complications “tardives”

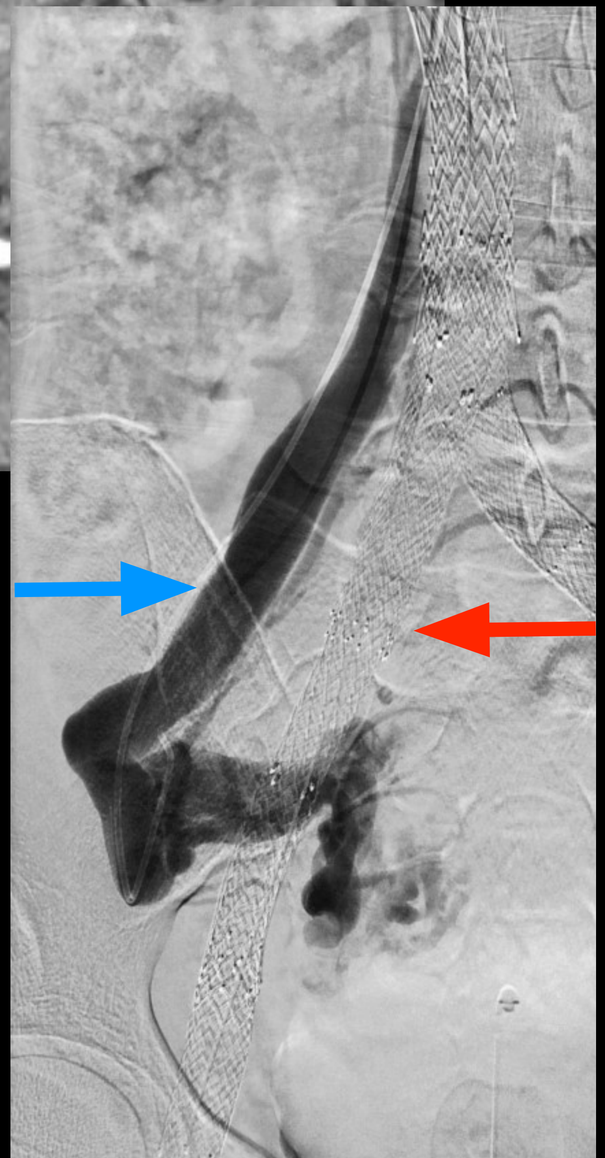
- Embolie pulmonaire
- Ré-occlusion
- Bris de stent
- (Infection)

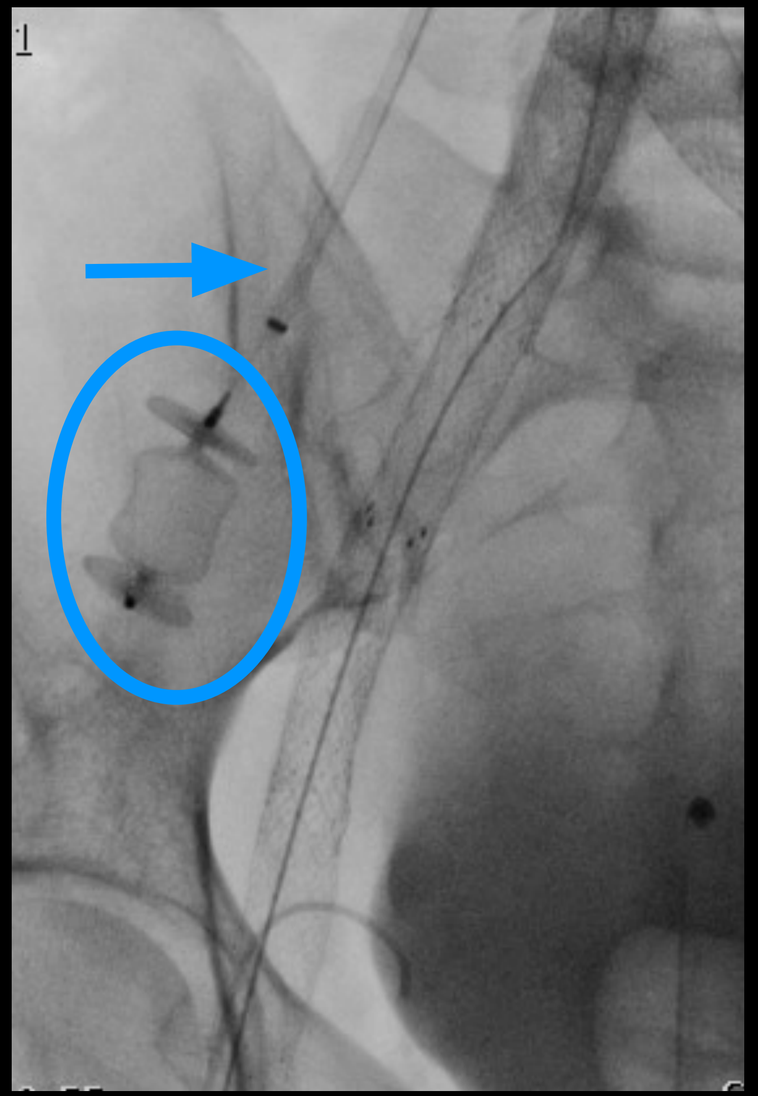
Facteurs de risques pour ré-occlusion

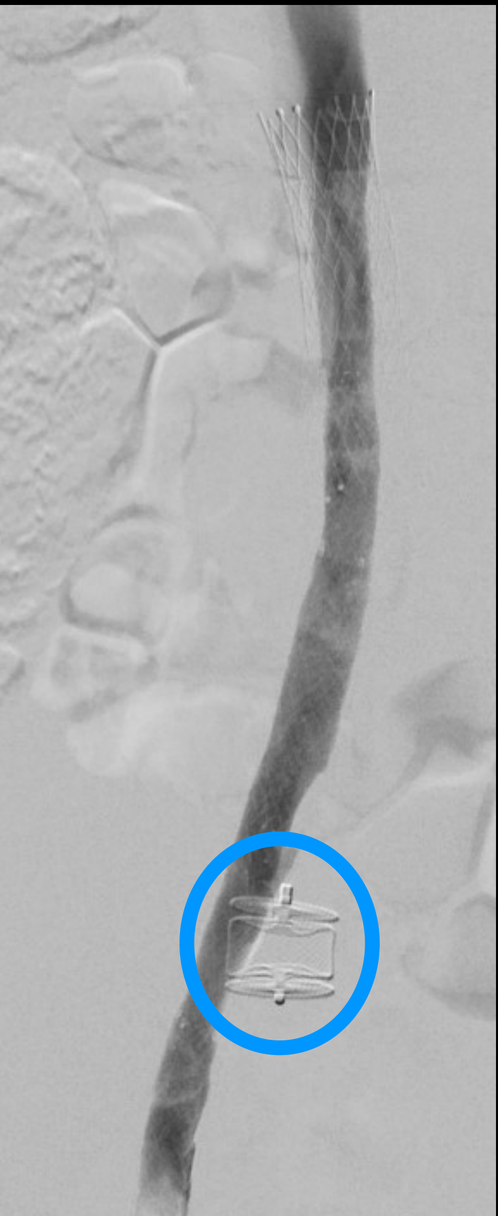
- Mauvais “inflow” dans les stents
- Mauvais débit dans les stents à cause de
  - Sténose résiduelle dans les stents ou en aval
  - Grosses collatérales
- Bris de stent











Étude Vernacular

- Prospective, non-randomisée, “single-arm”
- Internationale: 22 sites / É-U, Europe, Australie
- Objectif: Étude de la performance du stent Venovo dans l’obstruction veineuse ili-fémorale

Démographie

ITT Population

Subgroups

Demographic Criteria	Total (N=170)	PTS[1] (N=93)	NIVL[2] (N=77)
Mean Age, years ± SD	52.1 ± 15.3	49.8 ± 15.0	55.0 ± 15.4
Male/Female, %/%	37.2/62.9	45.2/54.8	27.3/72.7
Mean BMI, kg/m^2 ± SD	28.8 ± 7.0	28.6 ± 6.4	29.1 ± 7.7
Co-Morbidities/Medical History, % (n)			
Varicosis	78.2 (133)	76.3 (71)	80.5 (62)
May-Thurner Syndrome	60.0 (102)	37.6 (35)	87.0 (67)
Smoker (Current & Former)	34.1 (58)	30.1 (28)	39.0 (30)
Hypertension	32.4 (55)	29.0 (27)	36.4 (28)
Dyslipidemia	27.6 (47)	21.5 (29)	35.1 (27)
Diabetes (Type 2)	10.6 (18)	5.4 (5)	16.9 (13)
Peripheral Artery Disease	10.6 (18)	6.5 (6)	15.6 (12)

55% 45%

1 Post-Thrombotic Syndrome
2 Non-Thrombotic Iliac Vein Lesion

Charactéristiques des lésions & procédure

Lesion Criteria	Total (N=170) [1]	PTS (N=93)
Lesion Location[2], %		
Common Iliac Vein		92.1
External Iliac Vein		58.4
Common Femoral Vein		14.6
Lesion Morphology		
Mean Lesion Length, mm ± SD		80.5 ± 42.8
Thrombus Present, % (n/N)		14.8 (13/88)
No Blood Flow (Occluded), % (n/N)		38.6 (34/88)
Number of Stents, N		134
Number of Stents per Patient		1.4
Mean Stented Length, mm ± SD		109.2 ± 49.8
Acute Technical Success[3], % (n/N)		100 (93/93)
Acute Procedure Success[4], % (n/N)		97.8 (91/93)

1 One-hundred and sixty-three (163) patients had images evaluable by the core lab
2 Lesions could occur in more than one vein per patient
3 Successful stent deployment to the intended location with adequate lesion coverage (investigator assessment)
4 Technical success plus no MAEs through discharge. Two patients in the PTS group had revascularization following a DVT (investigator assessment)

Issues primaires

Safety: Freedom from MAEs (30 Days)

	ITT (N=170)
Freedom from MAEs % (n/N)	93.5% (159/170)

4 TPP reliées à procédure
6 ré-interventions
1EP pas reliée

Efficacy: 12-Month Primary Patency*

	ITT (N=170)	90% CI	Performance Goal	p-value[2]
Primary Patency% (n/N)	88.3% (128/145)	(82.4%, 94.2%)	74%	<0.0001

PTS:81.3% NIVL:96.9%

MAEs/Événements majeurs indésirables

Primary Safety Endpoint	PTS N = 93 n/N (%)		Total N = 170 n/N (%)
Freedom Composite Safety Events (MAE) through 30 Days	82/93 (88.2)		159/170 (93.5)
Had Failure	11/93 (11.8)		11/170 (6.5)
TVR	6/93 (6.5)		6/170 (3.5)
Pulmonary Embolism (not device or procedure related)	1/93 (1.1)		1/170 (0.6)
Device or procedure-related acute DVT	10/93 (10.8)	←	10/170 (5.9)

Pas d'événement majeur indésirable relié au matériel à12 mois

Scores à 12 mois

- score VCSS amélioré: -1.7 ($p < 0.0001$)
- score CIVIQ-20 amélioré: -15.7 ($p < 0.0001$)

Dimension	Item
Pain	Pain in the legs Impairment at work Sleeping poorly Standing for long periods of time
Physical	Climbing several floors Squatting / kneeling Walking at a good pace Doing the housework
Psychological	Feeling nervous Having the impression of being a burden Being embarrassed to show legs Becoming irritable easily Having the impression of being disabled Having no desire to go out Having to take precautions Getting tired easily Difficulty in getting going
Social	Going to parties Performing athletic activity Traveling by car, plane, etc

Résultats à 24 mois

ITT Population

Observations	12 Month (n= 170)	24 Months (n=147)
Freedom from TLR, (95% CI)	92.6% (87.5, 96.1)	89.4% (83.6, 93.7)
Freedom from TVR, (95% CI)	92.6% (87.5, 96.1)	89.4% (83.6, 93.7)
Primary Patency[1], (90% CI)	88.3% (82.4, 94.2)	83.2% (77.3, 89.1)
Stent Fractures, (n/N)	0% (0/137)	0% (0/128)[2]

Subgroups (24 Months)

PTS (n=79)
82.8%
82.8%
81.3% → 73.4%
0%

Peu d'extension dans FC: 9.2%

Résultats à 36 mois

Résultats à 36 mois

- Pas de nouvel événement indésirable majeur
- Perméabilité primaire: PTS: 70%
  - 12 mois: 81.3%/ 24 mois: 73.4%
- 0% fracture de stent
- Amélioration moyenne des scores cliniques
  - VCSS: - 1.8
  - CIVIQ-20: -16.8

→ Stables à légèrement améliorés x 12 & 24 mois

Arnsberg registry-Venovo™

Study	Assess safety and effectiveness of venous stent placement through 36 months in patients with non-thrombotic iliac vein lesions (NIVL) and post-thrombotic (PTS) iliac vein lesions
Design	Investigator-initiated, ongoing prospective, single arm, single center, non-randomized registry
Endpoints	Primary patency at 12 months; Clinical outcome at 12 months
Primary Investigators	Dr. Michael Lichtenberg Dr. Rick de Graaf
Subjects	80 subjects; 50 (63%) PTS and 30 (37%) NIVL

Complications

- 4 complications aux site d’accès (5%)
- 3 réocclusions précoce de stent (3.8%)
- 0% stent migration/EP/rupture veineuse
  - 1/4 extension dans FC

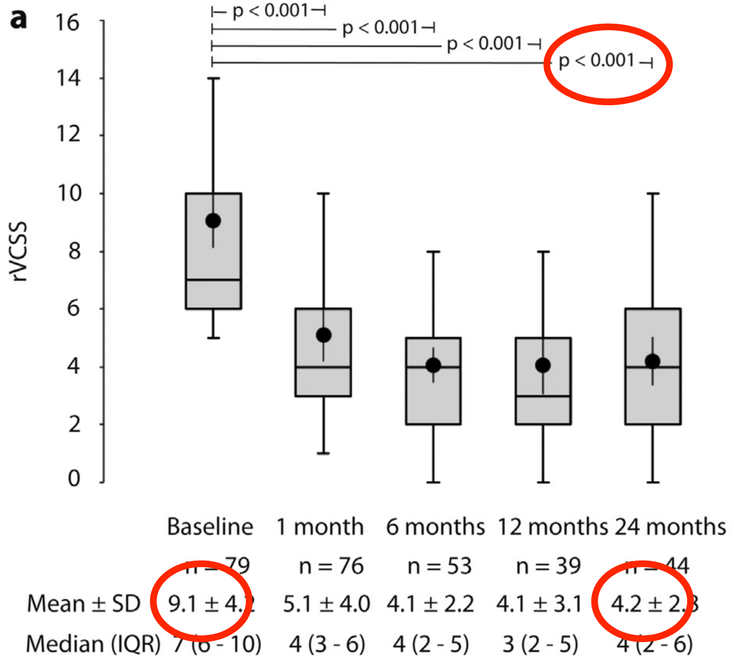
Résultats à 24 mois

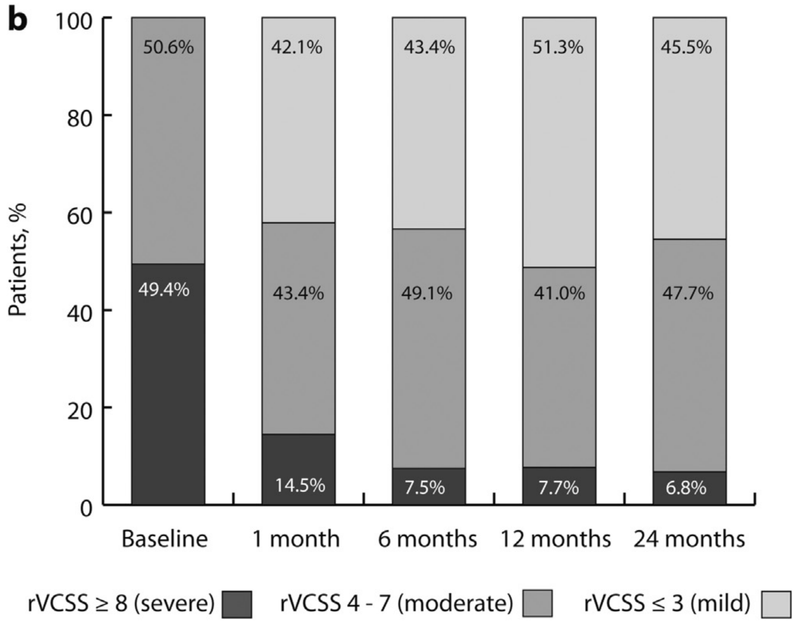
- 79 pts; 55.7% ont complété F/U
- Perméabilité primaire 95.5%
- Perméabilité secondaire: 100%
- Pas de différence entre PTS & NIVL pour perméabilité & amélioration clinique
- Pas de nouvelle complication p/r à 12 mois

Vasa (2021),50(1), 52–58

Revised VCSS Descriptor

Descriptor	Absent (0)	Mild (1)	Moderate (2)	Severe (3)
Pain	None	Occasional	Daily	Daily limiting
Varicose veins	None	Few	Calf or thigh	Calf and thigh
Venous edema	None	Foot and ankle	Above ankle, below knee	To knee or above
Skin Pigmentation	None	Perimalleolar	Diffuse, lower 1/3 calf	Wider, above lower 1/3 calf
Inflammation	None	Perimalleolar	Diffuse, lower 1/3 calf	Wider, above lower 1/3 calf
Induration	None	Perimalleolar	Diffuse, lower 1/3 calf	Wider, above lower 1/3 calf
No. active ulcers	None	1	2	≥ 3
Active ulcer size	None	< 2 cm	2 – 6 cm	> 6 cm
Ulcer duration	None	< 3 mo	3 – 12 mo	> 1 yr
Compression Therapy	None	Intermittent	Most days	Fully comply





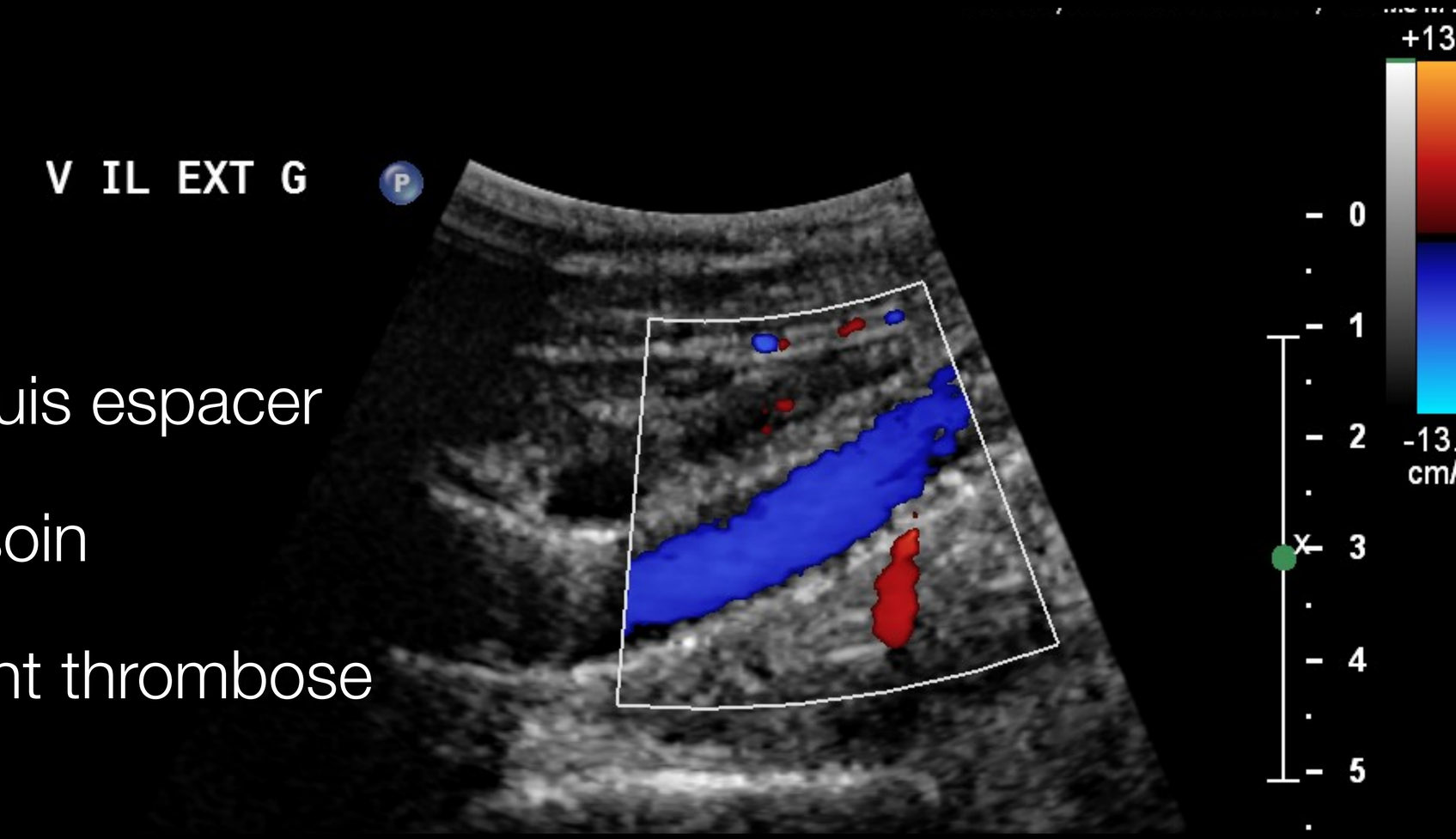
- CEAP amélioré 3.4 → 3.0 p<0.001
- 100% ulcères guéris
- Pas de récidive ou nouvel ulcère

Suivi Post-Tx

- Apixaban (Eliquis™)
  - 10 mg po BID x 10 jours
  - 5 mg po BID au moins 3 mois

Suivi

- Clinique
- Radiologique
  - Doppler 1-3 mois puis espacer
  - CTA veineux au besoin
  - Ré-intervention avant thrombose idéalement



Conclusion

- Choix du bon patient
  - Clinique
  - Radiologique
- Développement du matériel angiographique
- Suivi clinique et radiologique