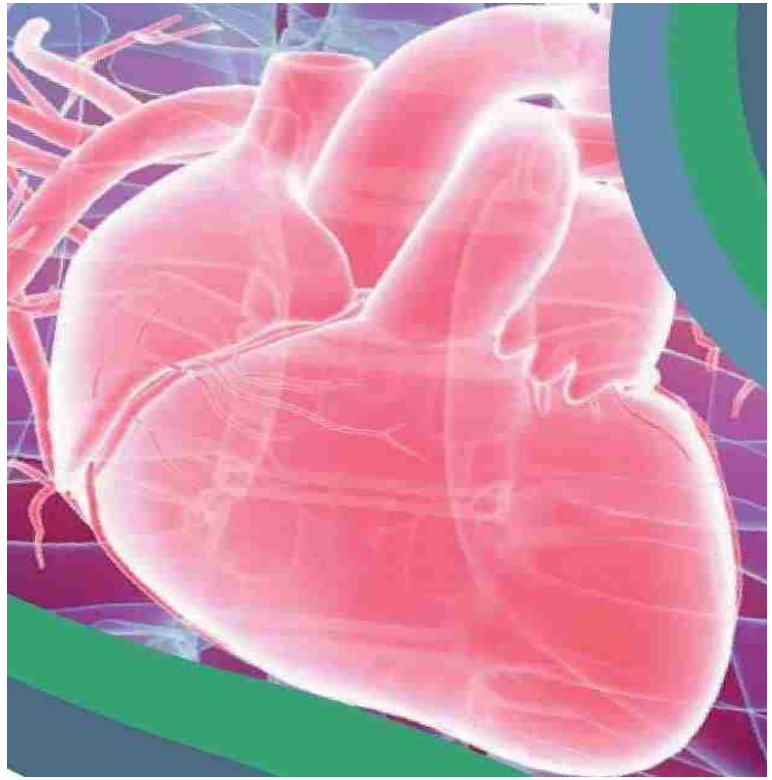
HOT TOPICS IN CARDIOLOGIA 2023



HOW TO MANAGE COMPLEX VASCULAR ACCESS

Angelo Cioppa, MD

Division of Invasive Cardiology
«Montevergine» Cinic
Mercogliano- Avellino - Italy

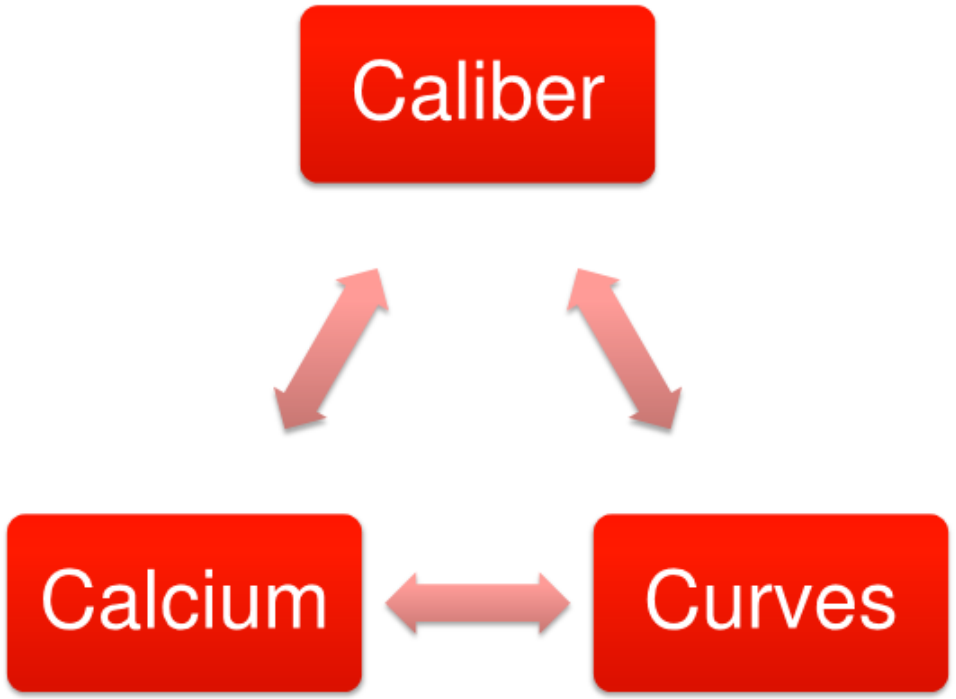
13 e 14 Novembre 2023

Villa Doria D'Angri - Via F. Petrarca 80,
Napoli

Presidente del congresso: Dr. Ciro Mauro

Direttore UOC di Cardiologia UTIC con emodinamica
AORN Cardarelli, Napoli

The 3C's of the TF access management



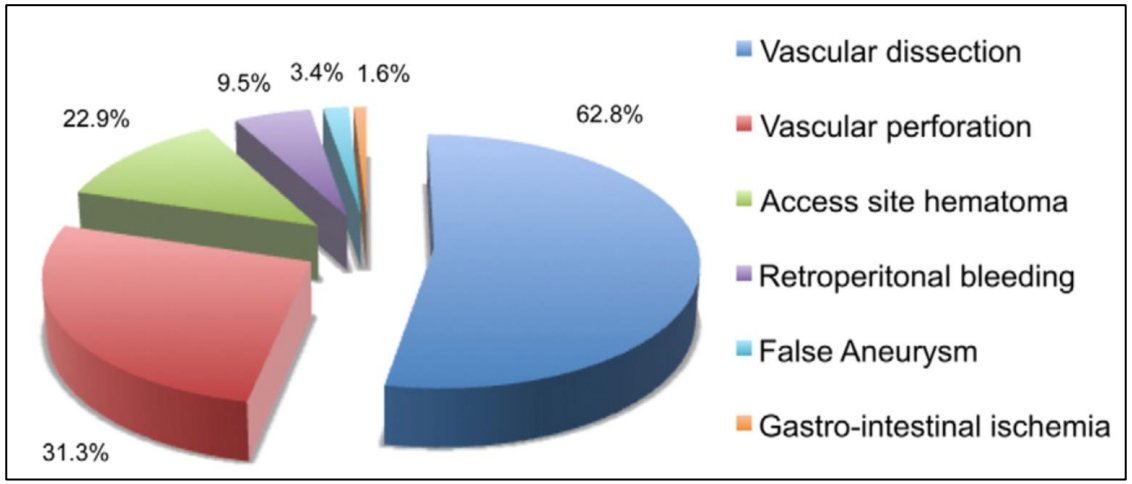
VASCULAR COMPLICATIONS

AORTIC COMPLICATIONS

ILIO-FEMORAL COMPLICATIONS

→ **RUPTURE**

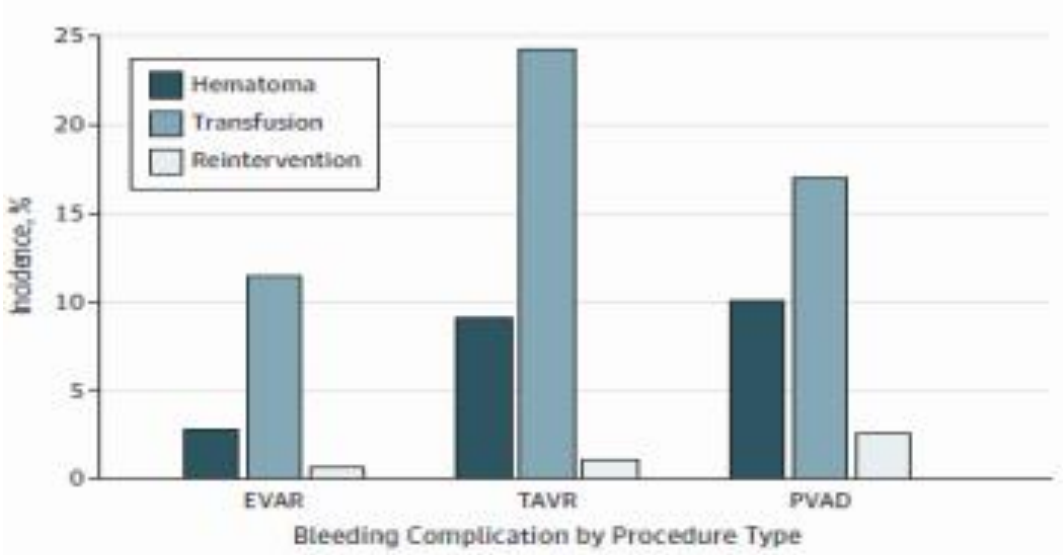
→ **DISSECTION**



CASA DI CURA MONTEVERGINE

Généreux et al. Vascular Complications After Transcatheter Aortic Valve Replacement Insights From the PARTNER Trial. *JACC 2012.* 1043–52.

INCIDENCE OF VASCULAR COMPLICATIONS



Among patients who had endovascular aneurysm repair (EVAR), the incidence of hematoma and/or hemorrhage without the need for blood transfusion or reintervention was 2.8%, the incidence of blood transfusion was 11.4%, and the incidence of reintervention was 0.6%. Among patients who underwent transcatheter aortic valve replacement (TAVR), the incidence rates were 9.1%, 24.3%, and 1.1%, respectively. The incidence rates for patients who had percutaneous ventricular assist device (PVAD) implant were 10.1%, 17%, and 2.6%, respectively.

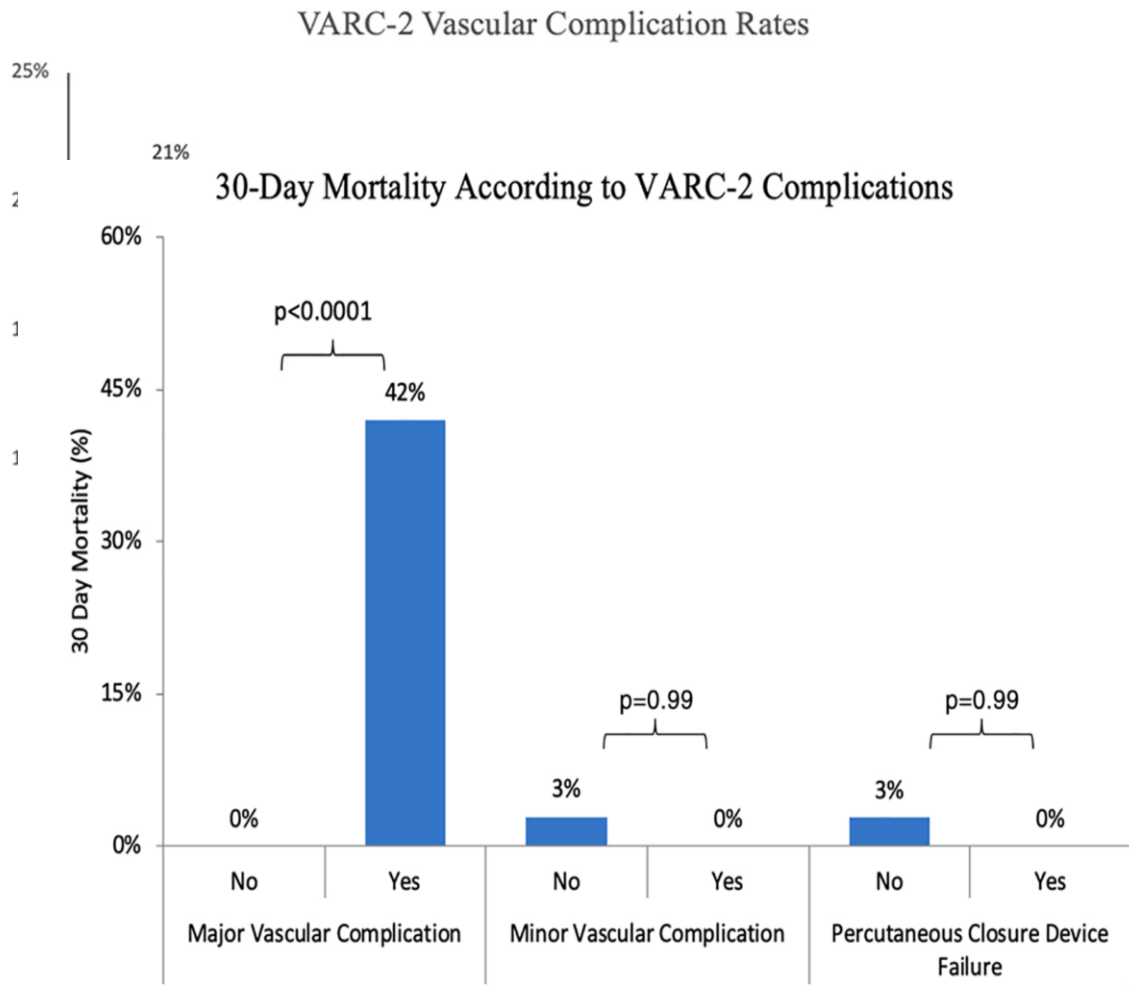
17,672 patients from national inpatient sample.

- **Overall bleeding complications occurred in 17.7% of patients**
- **Bleeding had higher:**
  - **Mortality**
  - **Cost**
  - **Longer Hospital Stay**

Redfors, B et al. Mortality, Length of Stay, and Cost Implications of Procedural Bleeding After Percutaneous Interventions Using Large-Bore Catheters. JAMA Cardiol. 2017 Mar 18

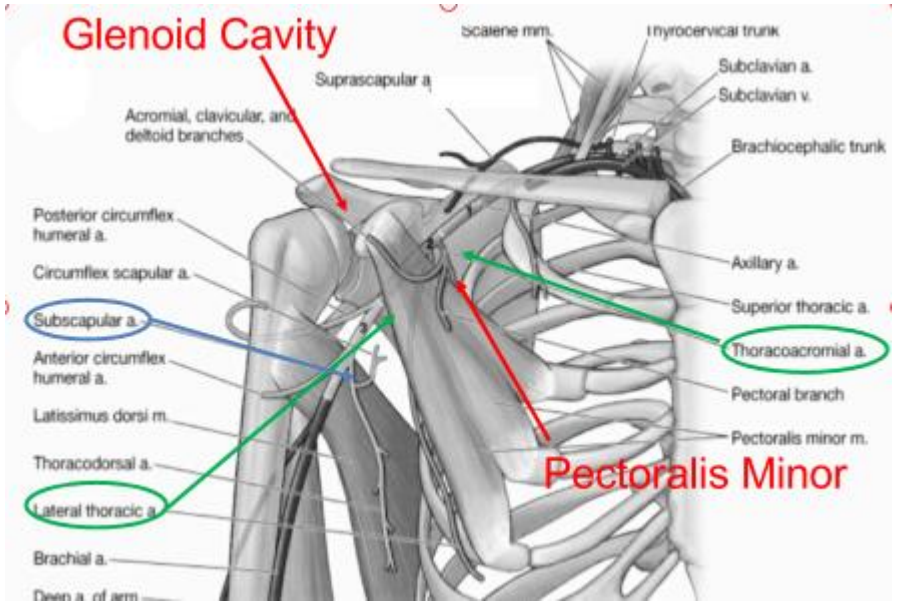
TRANSFEMORAL ACCESS

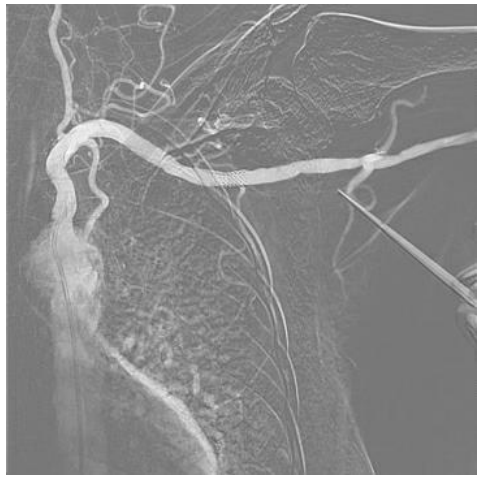
- Completely percutaneous TF-TAVR is an important advance in technique.
- The advantages of this minimally invasive technique include quicker recovery, shorter length of stay, lower procedural costs and lower rates of wound infection compared to TAVR performed with femoral artery surgical cutdown techniques
- Major VCs, but not minor VCs or PCDFs, are associated with increased mortality.
- PCDFs are associated with a longer median longer hospitalization.

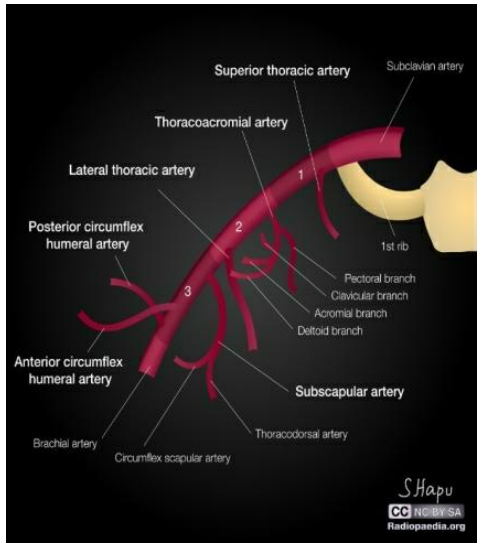


W. Batchelor et al. / Cardiovascular Revascularization Medicine (2020)

ALTERNATIVE ACCESS: Axillary Artery







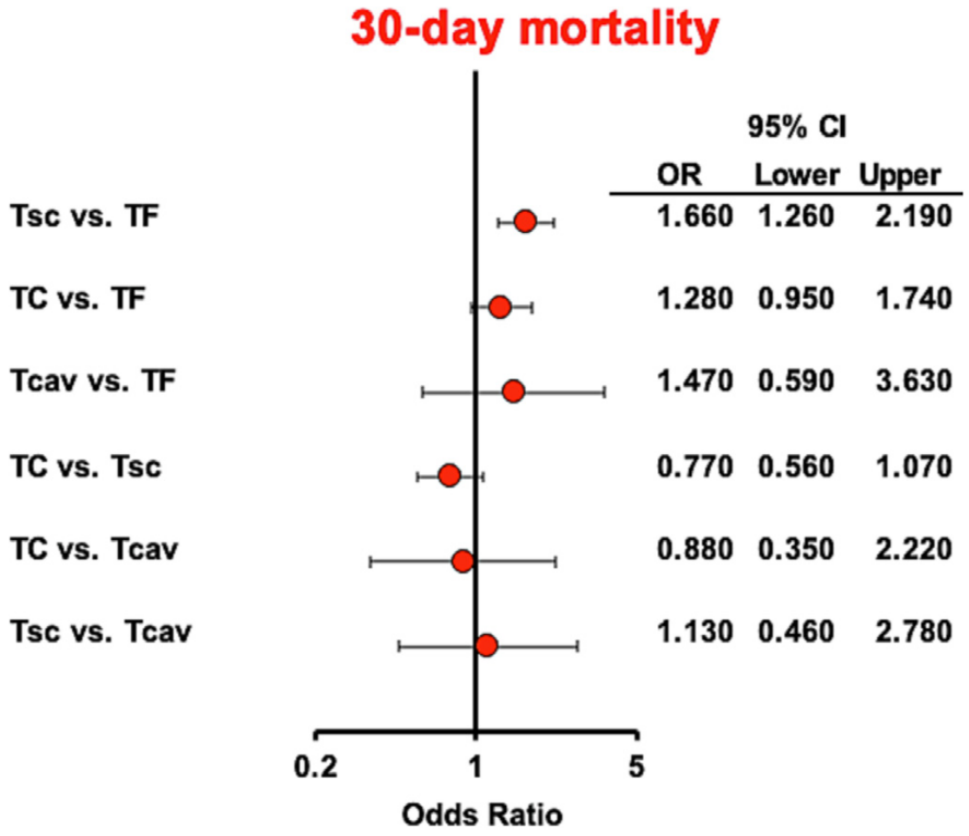
Axillary access
Registry to Monitor Safety (ARMS)

UW: James McCabe, Bill Lombardi
Newark Beth Israel: Raj Tayal
DMC: Ted Schreiber, Amir Kaki, Nimrod Blank
Tufts: Navin Kapur
Columbia: Ajay Kirtane, Jeff Moses, Amir Masoumi
Mid America Heart: Aaron Grantham, Patrick Goleski
Beth Israel Deaconess: Duane Pinto, Robert Yeh
WellspanYork: Bill Nicholson
University of Arizona: Kapil Lotun

- -97.5% implant success rate
- - Poor femoral access 66%
  - (*) 34% Primary choice
- - Anterior chest wall approach 76%
- -54% right sided access
- -Complication rates: 78% = none
- -4% access site hematoma, 0% death related, 3% transfusion rate, 0% PTX, 3% Neuro complaints
- -Average duration 4.5 days +/- 3.9 days, longest 21 days

COMPARISON BETWEEN VASCULAR ACCESS FOR TAVR

- The risk of major or life-threatening bleeding was higher via Tsc compared with TF
- The risk of stroke was higher via Tsc compared with TF and Tcav
- The risk of major vascular complications was lower via TF compared with Tsc, and Tcav and higher with Tcav compared with TF and Tsc.
- Tsc was associated with higher risk of major or life-threatening bleeding compared with TF, and higher risk of stroke compared to TF and Tcav.
- Tcav had the highest risk of major vascular complications
- 30-day mortality was higher via Tsc compared with TF.



CASA DI CURA MONTEVERGINE

W. Batchelor et al. / J Cardiol. (2023)

Vascular Planning

Multidetector Computed Tomography Angiography

Structural Heart Disease

Transfemoral Access Assessment for Transcatheter Aortic Valve Replacement

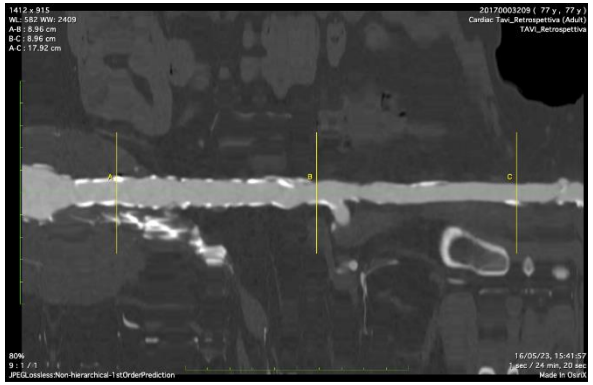
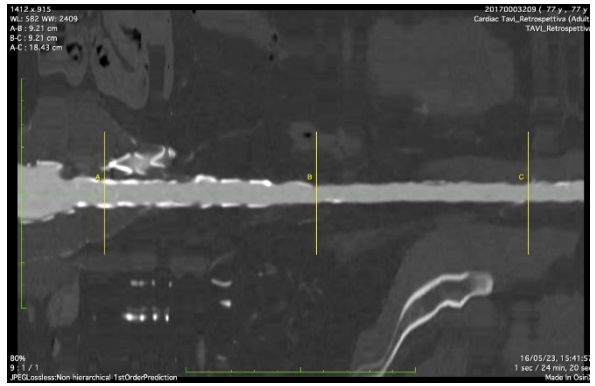
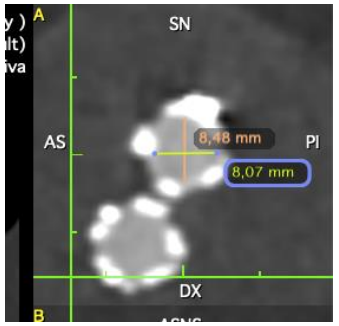
Evidence-Based Application of Computed Tomography Over Invasive Angiography

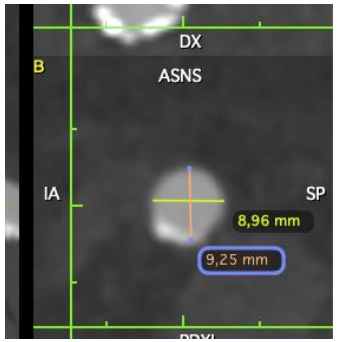
Kazuaki Okuyama, MD; Hasan Jilaihawi, MD; Mohammad Kashif, MD; Nobuyuki Takahashi, MD; Tarun Chakravarty, MD; Heera Pokhrel, MD; Jigar Patel, MD; James S. Forrester, MD; Mamoo Nakamura, MD; Wen Cheng, MD; Raj R. Makkar, MD

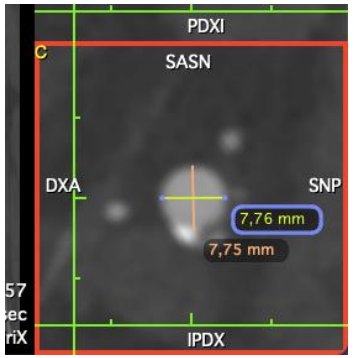
Conclusions—Contrast CT has a greater predictive value for post-transcatheter aortic valve replacement vascular complications than angiography. Because these complications increase mortality, an accurate assessment of the vasculature is a critical component of proper access selection. (*Circ Cardiovasc Imaging*. 2015;8:e001995. DOI: 10.1161/CIRCIMAGING.114.001995.)

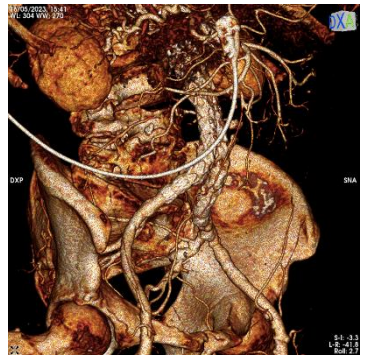
- Reliably examine vessel size
- Degree of calcification
- Minimal luminal diameter
- Plaque burden
- Vessel tortuosity
- High-risk features (including dissection and atheroma)
- You get to know the vessel really well before you even touch it…

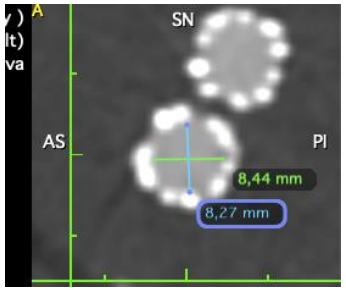
Multidetector Computed Tomography Angiography

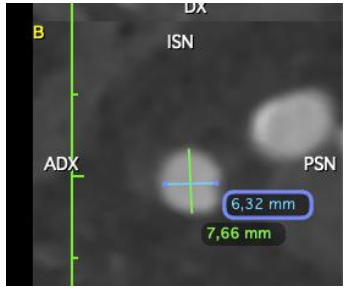




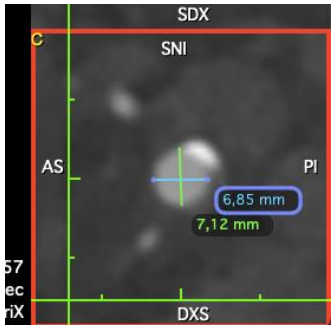










Negative attributes :

Contrast use

Vascular Complications in PARTNER It is all about Size(Caliber)

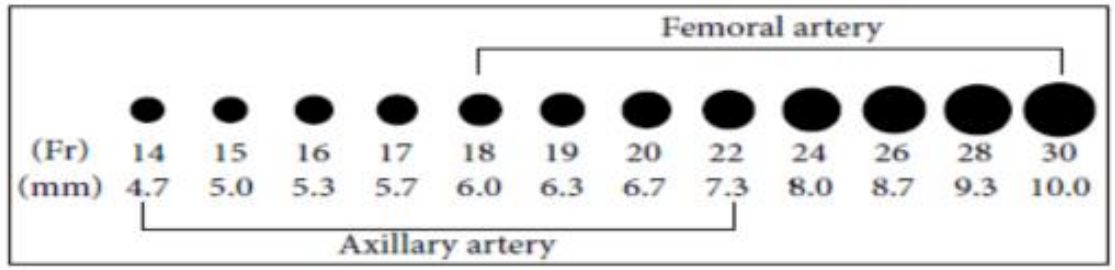
Table 2 Procedural Characteristics According to the Occurrence of VCs up to 30 Days

	Major Vascular Complications (n = 64)	No Major Vascular Complications (n = 355)	Combined (n = 419)	p Value
Valve size				
23 mm (22-F sheath introducer)	60.3% (38/63)	49.3% (169/343)	51.0% (207/406)	0.11
26 mm (24-F sheath introducer)	39.7% (25/63)	50.7% (174/343)	49.0% (199/406)	0.11
Femoral vessel diameter,* mm	7.94 ± 1.07 (49)	8.39 ± 1.28 (297)	8.32 ± 1.26 (346)	0.007
Ext Iliac vessel diameter,* mm	8.29 ± 1.46 (49)	8.71 ± 1.38 (298)	8.65 ± 1.40 (347)	0.02
Iliac vessel diameter,* mm	9.07 ± 1.94 (49)	9.70 ± 1.71 (298)	9.61 ± 1.75 (347)	0.009
SEIAR	1.08 ± 0.16 (49)	0.99 ± 0.23 (298)	1.00 ± 0.22 (347)	0.02
SFAR	1.11 ± 0.13 (49)	1.03 ± 0.24 (297)	1.04 ± 0.23 (346)	0.01
Severe tortuosity†	0.0% (0/53)	3.2% (10/315)	2.7% (10/368)	0.37
Severe calcification‡	5.7% (3/53)	5.7% (18/315)	5.7% (21/368)	1.00

Transparency for sheath outer diameters (in mm not French) is necessary to refine decision making

Genereux et al. JACC. 2012.1043-52

→Calcification, stenosis, or tortuosity
→ Vessel size
→ Vessel Depth (obesity)
→ Graft material
→ Duration of Implant



(a) Relative French sizes of the axillary artery compared to the femoral artery

CASA DI CURA MONTEVERGINE

CT pre operating planning

Ilio-femoral axis to choose

Biforcation of CFA

Diameter

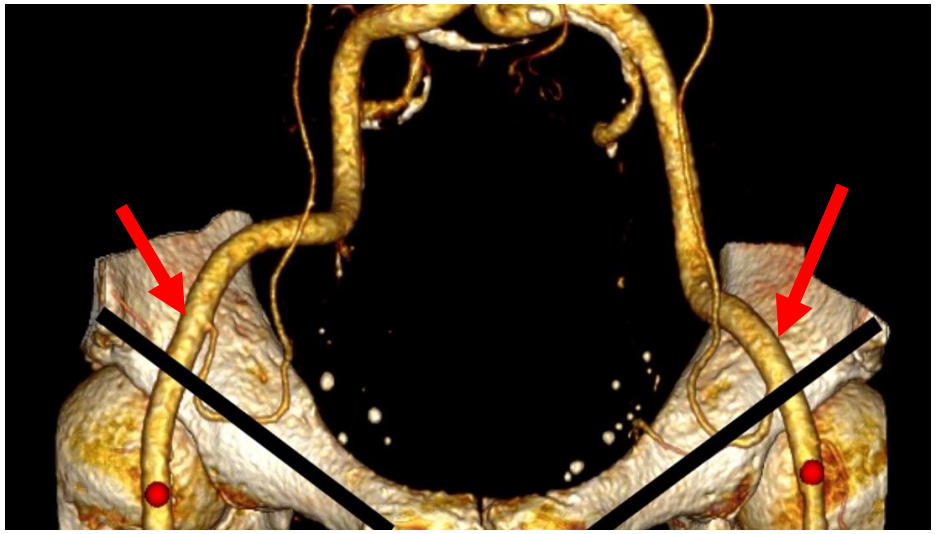
Tortuosity,

Calcifications

Distance skin to artery)

Pre-Localize the puncture site between

Inguinal Ligament (IL) and femoral biforcation (FB)

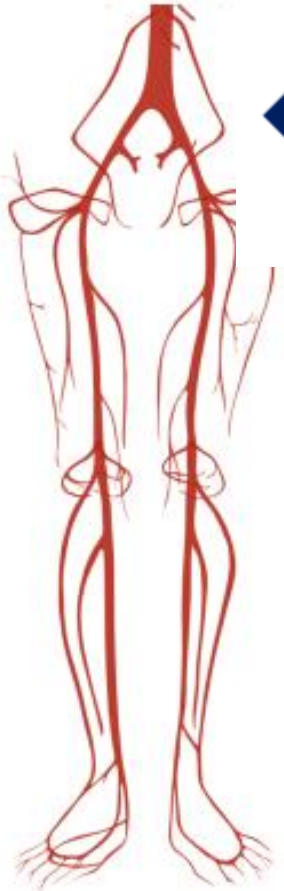


Inferior Epigastric Artery

NEVER erises below Inguinal Legament

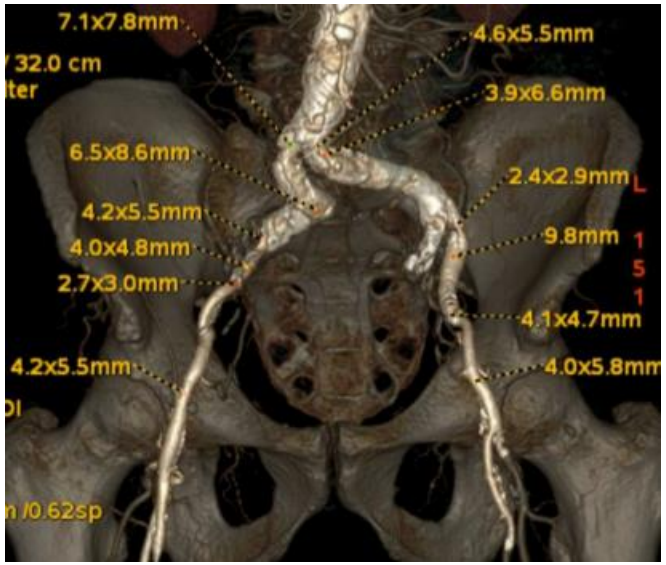
CASA DI CURA MONTEVERGINE

Two Areas of Concern in the Iliofemoral Tree

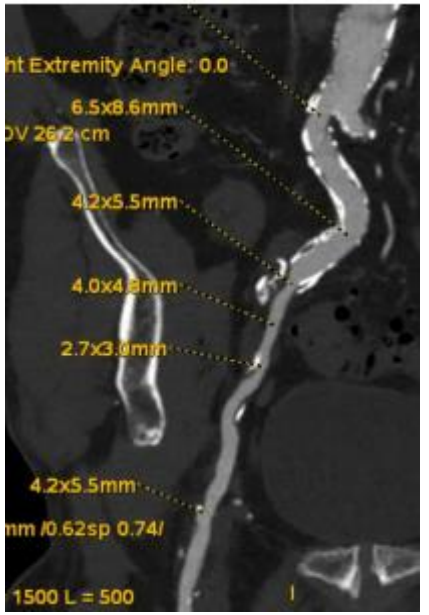


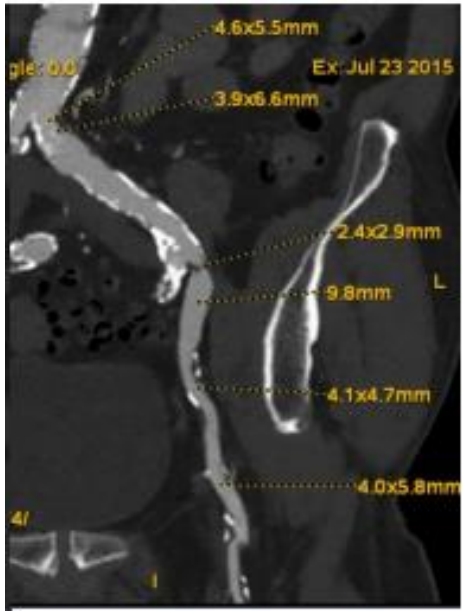
Ostial CIA

Puncture Site

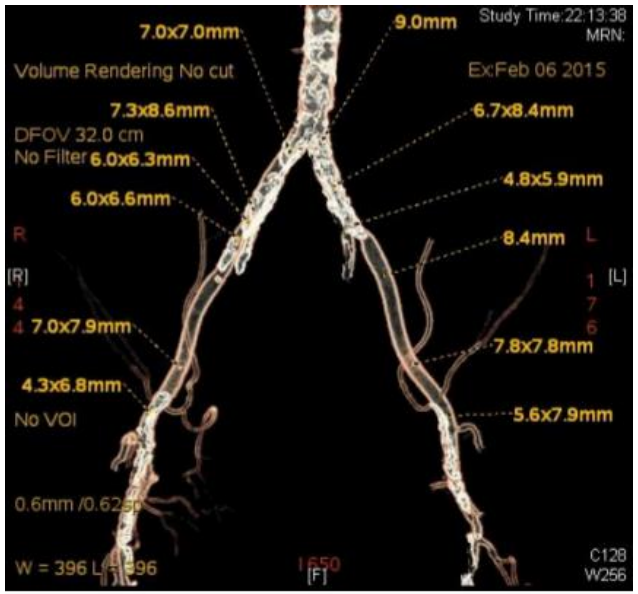


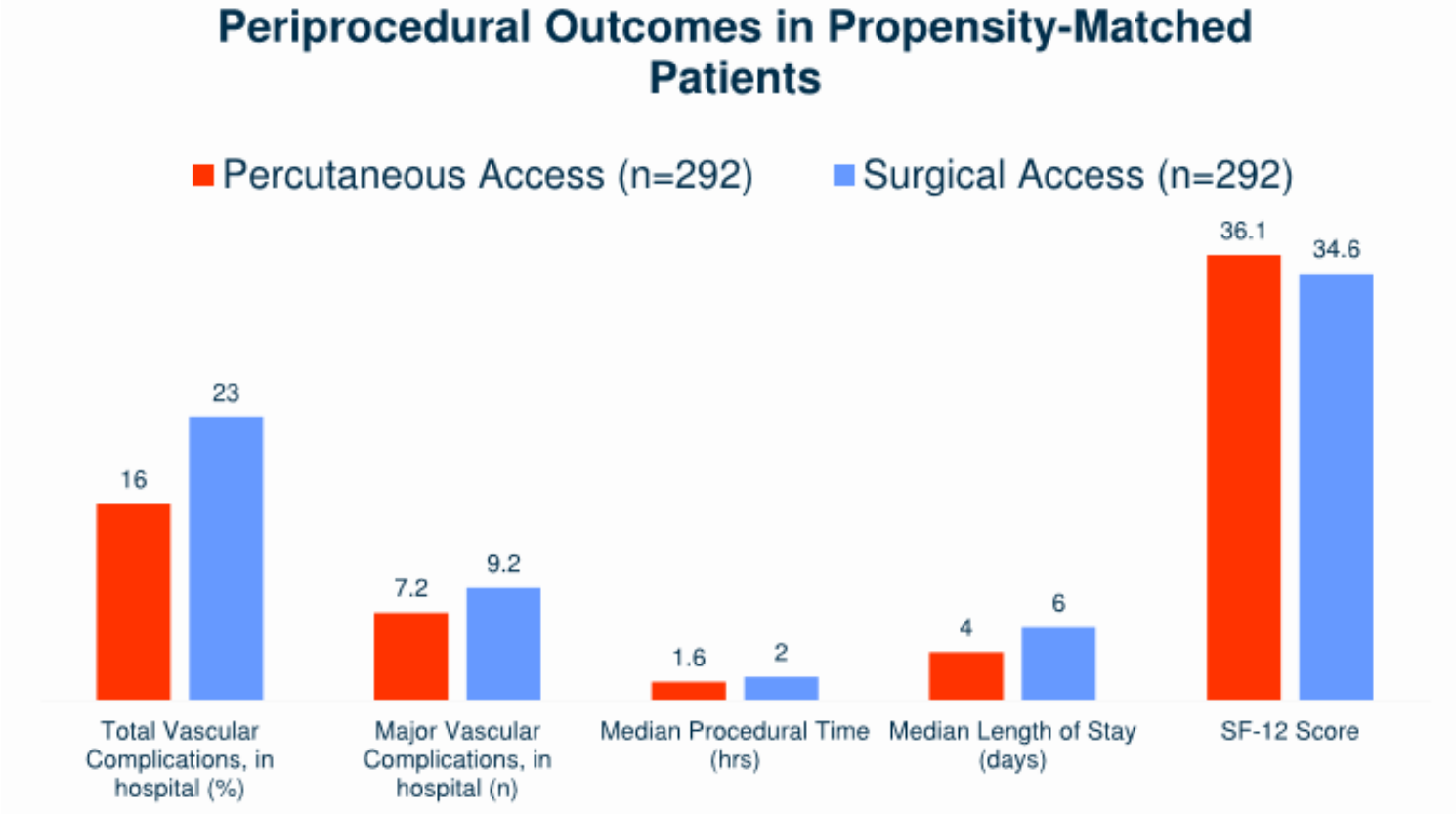
External Iliacs Generally Least Concerning





Cutdown Offers No Clear Upfront Advantage to Large Bore Access





CASA DI CURA MONTEVERGINE

McCabe et al. AJC. 2016; 117(10):1643-50

A good femoral puncture

Puncture Site is crucial

ANATOMY

Size ≥ **5.0 mm (or SFAR < 1.05)**

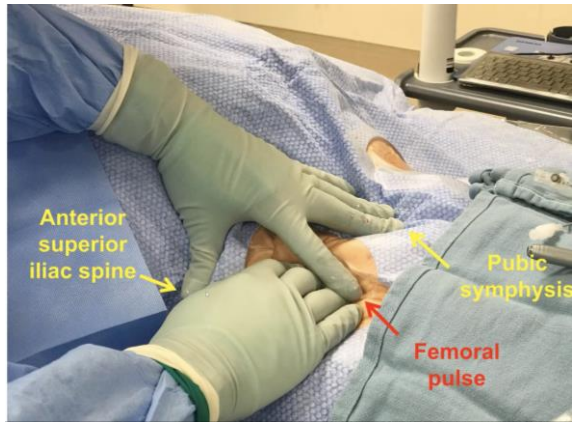
No anterior calcium at puncture site

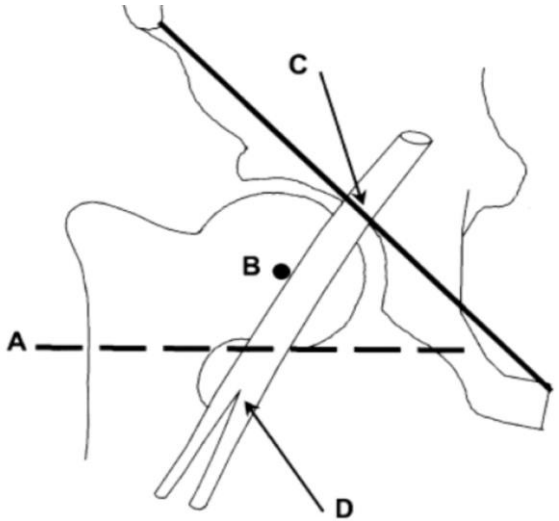
LOCATION

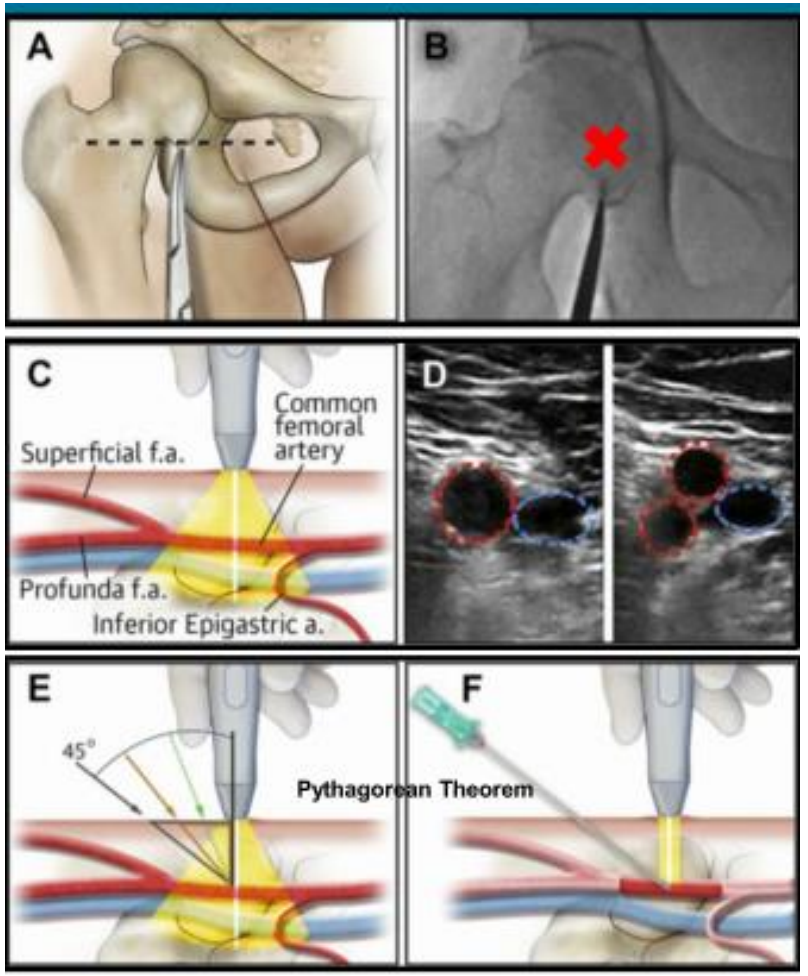
Below inguinal ligament (inferior epigastric artery)

≥ 1 cm above femoral bifurcation

Centre of anterior wall





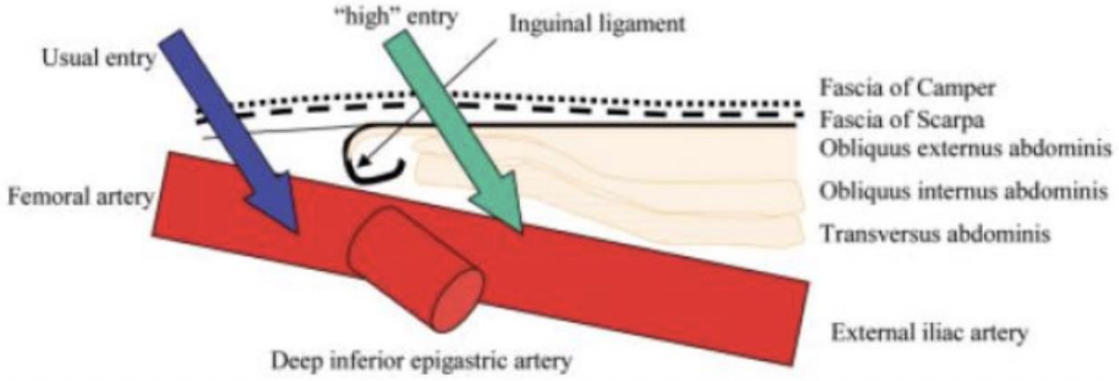


-- Sandoval et al *JACC Interv* 2017

How to have a good femoral puncture

Evoid Puncture too high!!!

Puncture above IL = high risk of retroperitoneal bleeding



Accidental Inferior Epigastric Cannulation /injury
Bleeding retroperitoneal hematoma)
Pseudoaneurysm

Catheterization and Cardiovascular Interventions 67:541–545 (2006)

CORONARY ARTERY DISEASE

Original Studies

Correlates and Outcomes of Retroperitoneal Hemorrhage Complicating Percutaneous Coronary Intervention

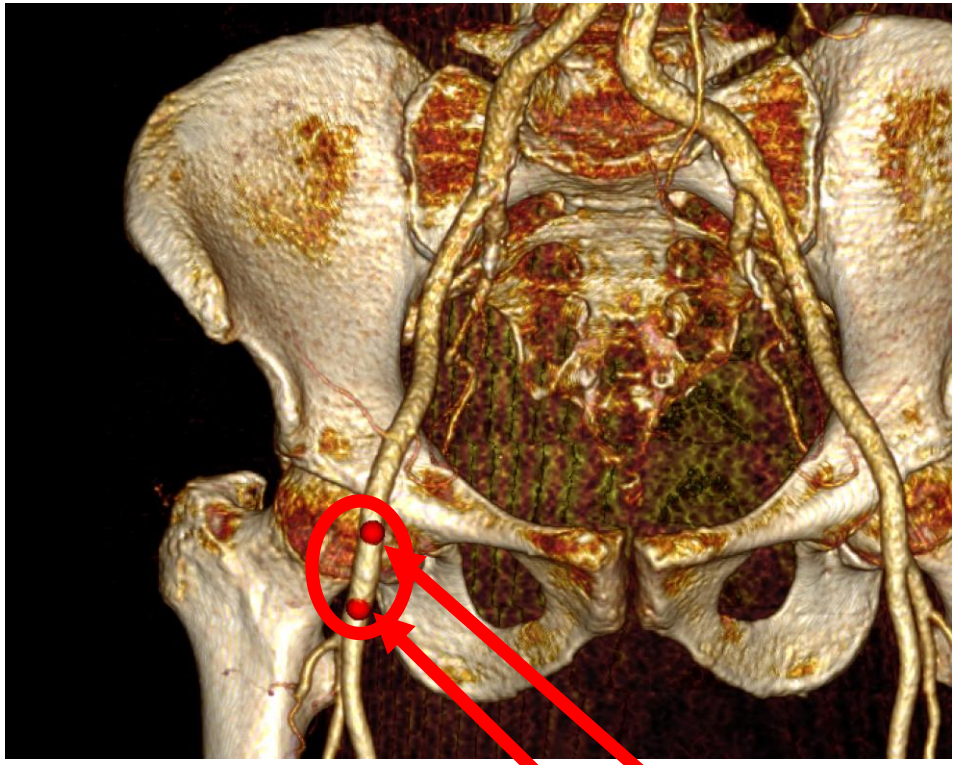
Stephen G. Ellis,* MD, Deepak Bhatt, MD, Samir Kapadia, MD, David Lee, MD, Michael Yen, MD, and Patrick, L. Whitlow, MD

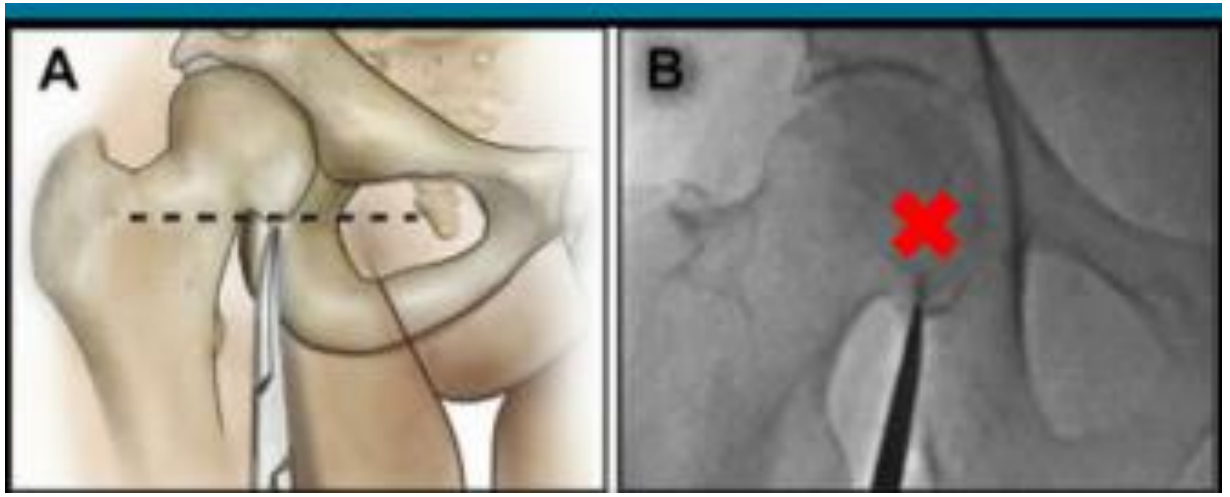
TABLE II. Independent Correlates of Retroperitoneal Bleeding

	OR	95% CI	*P*-value
Sheath placement superior to inferior epigastric artery[a]	17.6	2.21–141.63	<0.001
Female sex	3.73	2.55–5.43	<0.001
Angioseal™	2.80	1.95–4.00	<0.001
GP IIb/IIIa inhibitor	1.92	1.31–2.82	0.001
Weight (per kg)	0.987	0.976–0.997	0.014
Acute MI	1.82	1.05–3.17	0.035

Evoid Puncture too low!!!

Femoral Head is a compressible site





Bifurcation injury

Bleeding (groin)

Arteriovenous fistula

VCDs failure

CASA DI CURA MONTEVERGINE

Evoid Fluoroscopic Puncture!!!

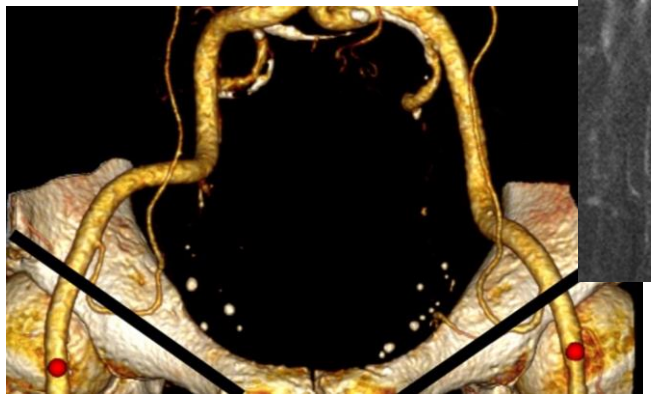
Even if you know the CT-Scan derived puncture site, could be unreliable

EuroIntervention 2017;12:1667-1673

CLINICAL RESEARCH

Impact of femoral artery puncture using digital subtraction angiography and road mapping on vascular and bleeding complications after transfemoral transcatheter aortic valve implantation

Mohamed El-Mawardy[1,2], MD; Bettina Schwarz[1], MD; Martin Landt[1], MD; Dmitriy Sulimov[1], MD; Julia Kebernik[1], MD; Abdelhakim Allali[1], MD; Bjoern Becker[1], MD; Ralph Toelg[1], MD; Gert Richardt[1], MD; Mohamed Abdel-Wahab[1]*, MD, FESC



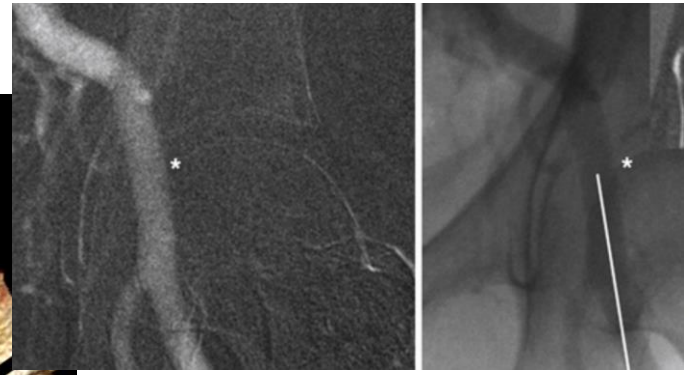


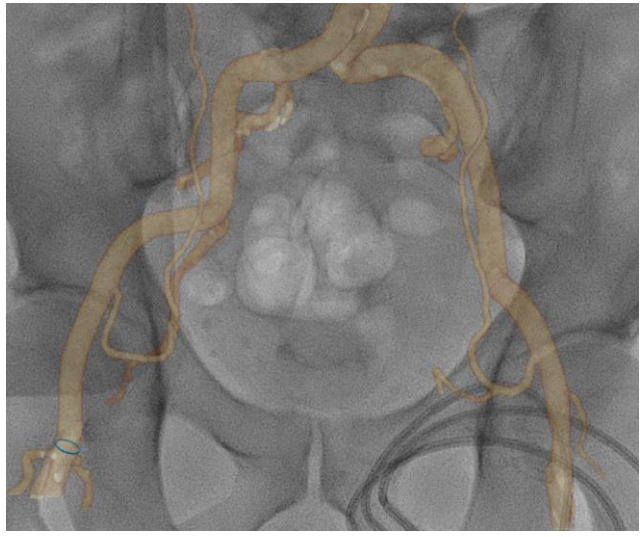
Table 5. Thirty-day outcome.

Variable	Road map group (n=160)	Control group (n=160)	*p*-value
All-cause mortality	6 (3.7%)	5 (3.1%)	0.76
Cardiovascular mortality	6 (3.7%)	5 (3.1%)	0.76
Any stroke	6 (3.7%)	11 (6.8%)	0.21
Life-threatening bleeding	11 (6.8%)	18 (11.3%)	0.17
Major bleeding	23 (14.4%)	41 (25.6%)	0.01
Minor bleeding	7 (4.3%)	3 (1.8%)	0.19
Major vascular complications	7 (4.3%)	19 (11.8%)	0.01
Minor vascular complications	7 (4.3%)	5 (3.1%)	0.50
Access site-related complications	13 (8.1%)	22 (13.8%)	0.1

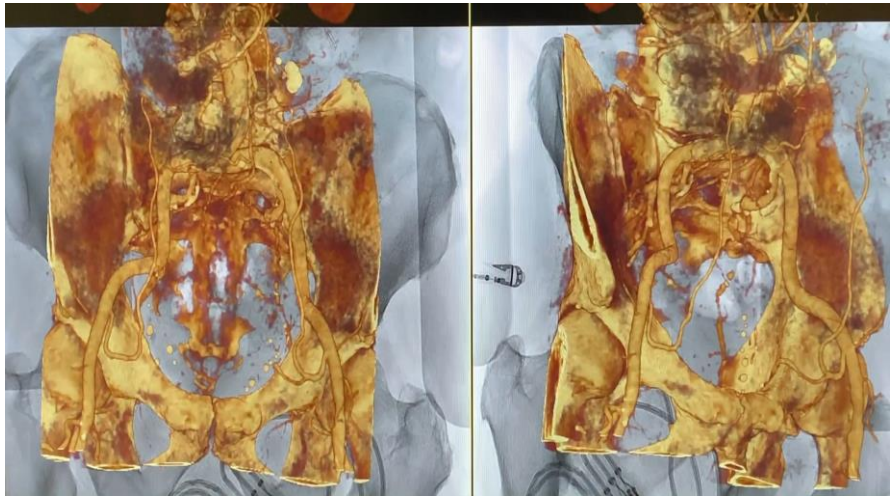
CASA DI CURA MONTEVERGINE

Angio-Guided Puncture

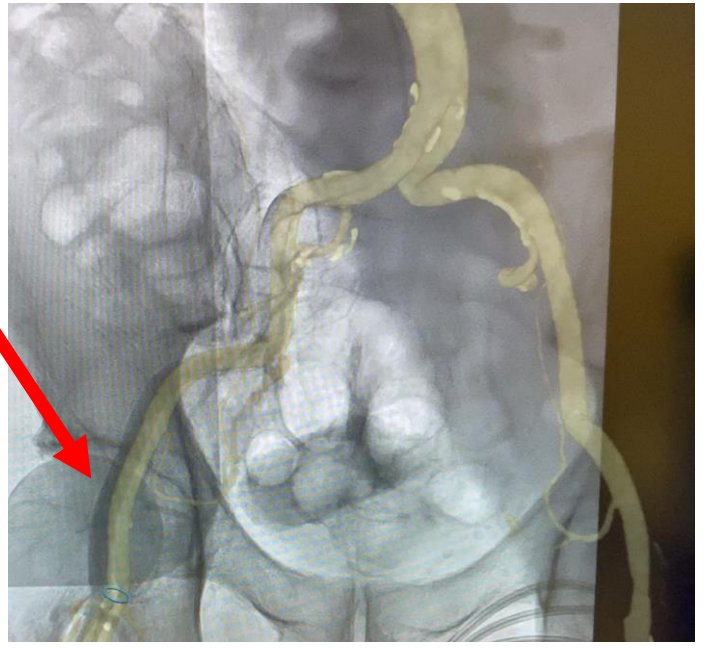
Vessel Navigator



Very useful to reduce CM volume (avoid CT-Scan double bolus) Only 25 ml
Volume Rendering and Centerline
Precise puncture similar to conventional Angio-guided Puncture



Vessel Navigator Pitfalls

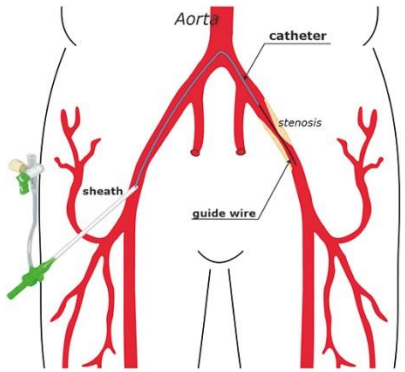


CASA DI CURA MONTEVERGINE

Angio-Guided Puncture

To reduce vascular access complications

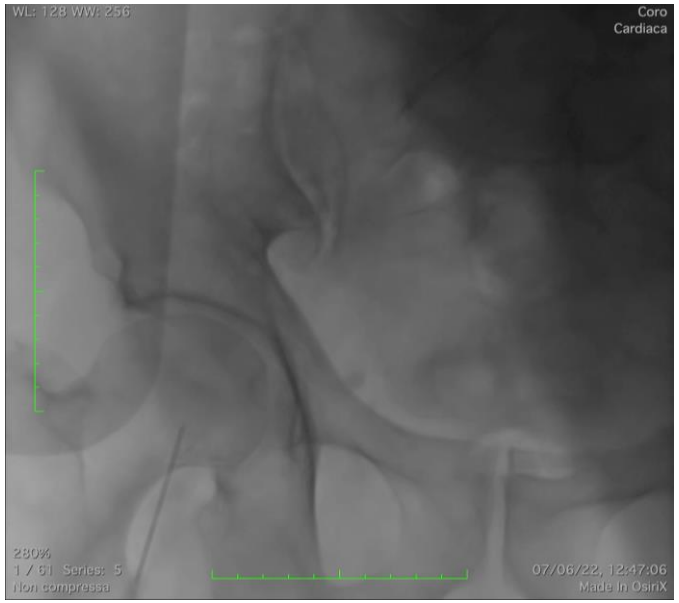
CONTRAL COMMON FEMORAL ARTERY CROSSOVER TECHNIQUE



- Not feasible in occluded femoral arteries
- Challenging in diffusely diseased, tortuous vessel or narrow iliac bifurcation

RADIAL ANTEGRADE TECHNIQUE

- No need for bilateral femoral punctures
- No negotiation with ilio-femoral tortuosity
- More direct route and efficient wiring of the therapeutic access site



CASA DI CURA MONTEVERGINE

A Comparison of the Femoral and Radial Crossover Techniques for Vascular Access Management in Transcatheter Aortic Valve Implantation: The Milan Experience

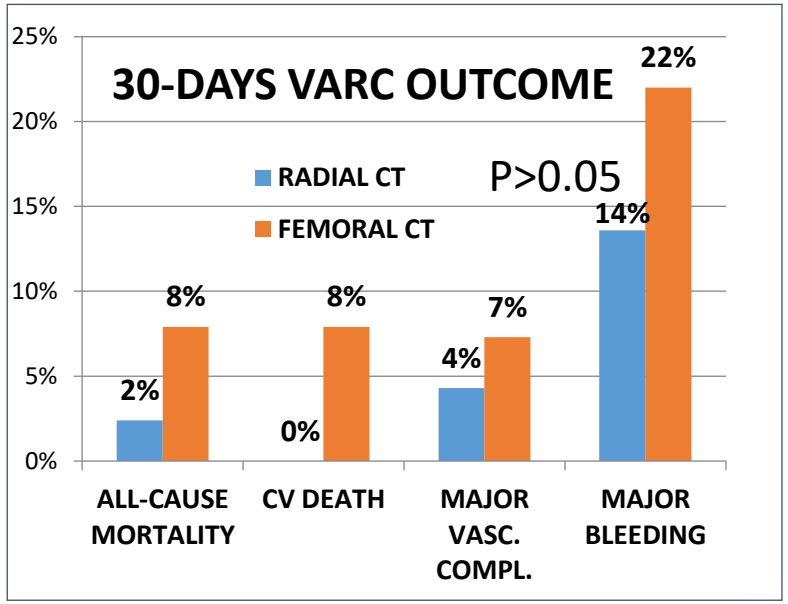
TRANSFEMORAL TAVI PATIENTS RECEIVING FEMORAL CT (n= 41)

VS

TRANSFEMORAL TAVI PATIENTS RECEIVING RADIAL CT (n= 46)

Thirty-day outcomes, overall and according to the secondary access

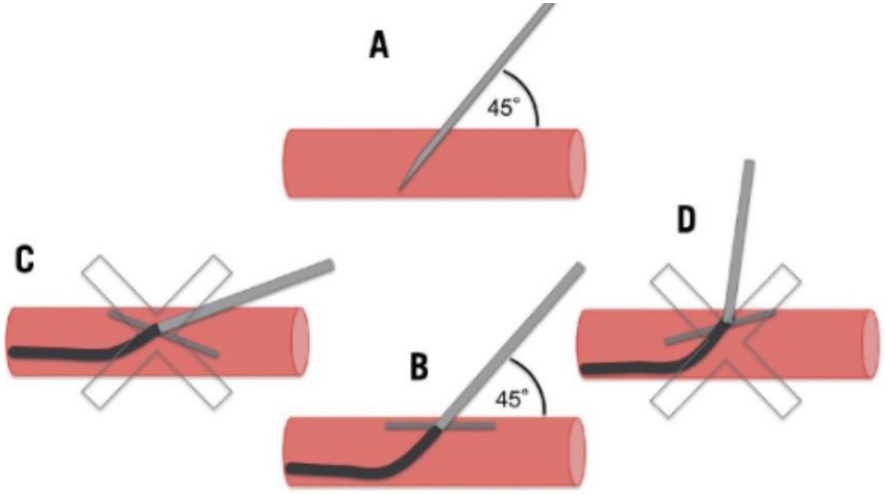
Variable	Study Population (n=462)	Secondary Access		p value	Adjusted p value*
		Femoral	Radial		
Major vascular complications	46 (10%)	37 (11%)	9 (7%)	0.228	0.285
Related to access	31 (7%)	28 (8%)	3 (2%)	0.021	0.046
Related to primary access	20 (4%)	17 (5%)	3 (2%)	0.305	0.266
Related to secondary access	11 (2%)	11 (3%)	0	0.040	0.049
Non-related to access	15 (3%)	9 (3%)	6 (5%)	0.256	0.272



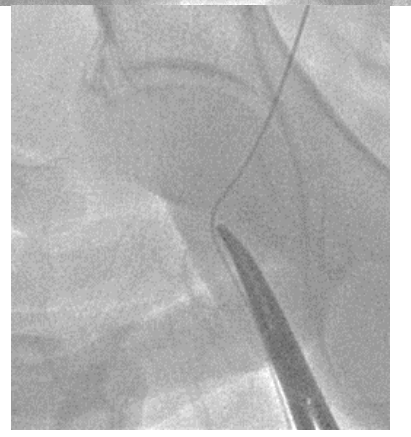
Curran H et al, Catheterization and Cardiovascular Interventions, 2013

Evoid vertical or too tangenzial puncture!!!

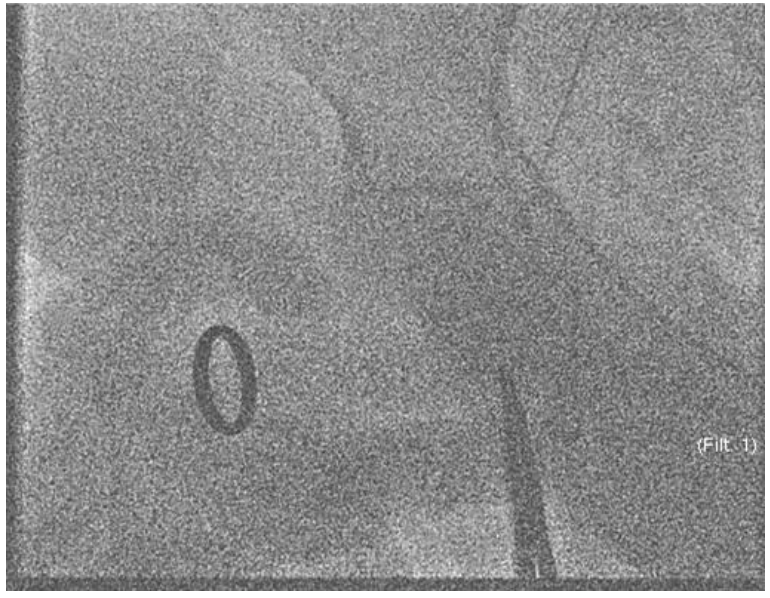
The angle of puncture influences Proglide results



How to improve the Pro-Glide performance

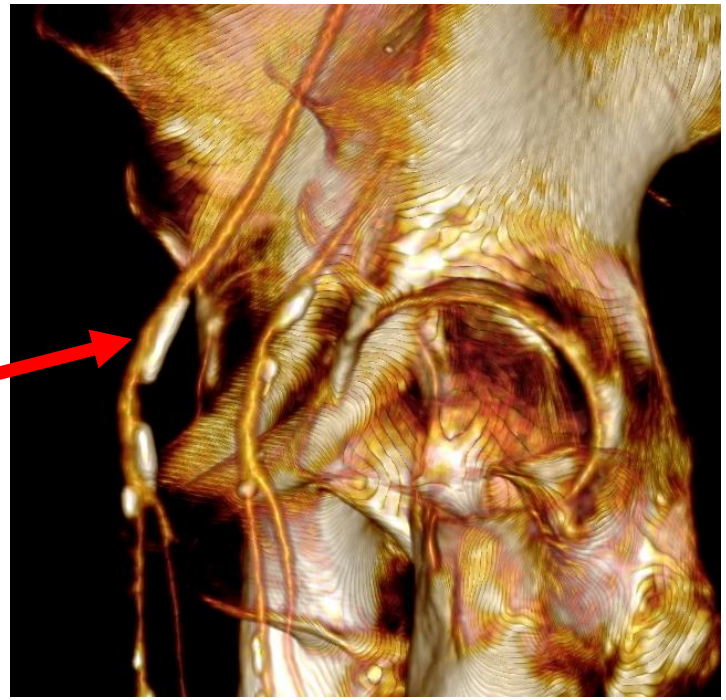


Meticulous tunneling of the skin and subcutaneous tissues separates the skin surface and artery



Evoid Anterior Calcification Puncture!!!

Posterior



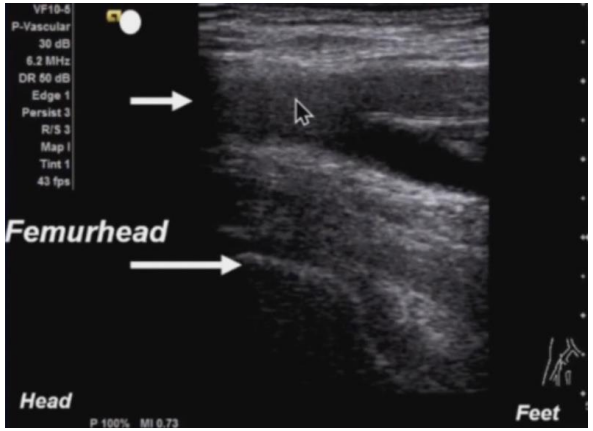
Most of hemostasis devices doesn't work properly

← Anterior

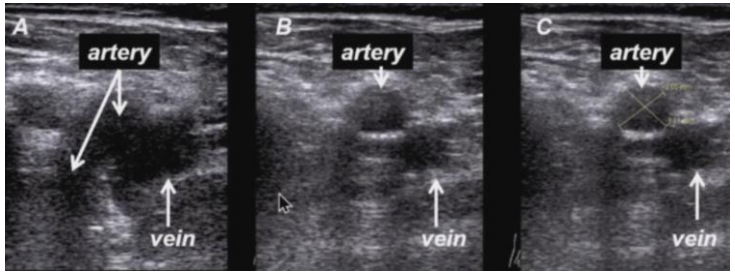
CASA DI CURA MONTEVERGINE

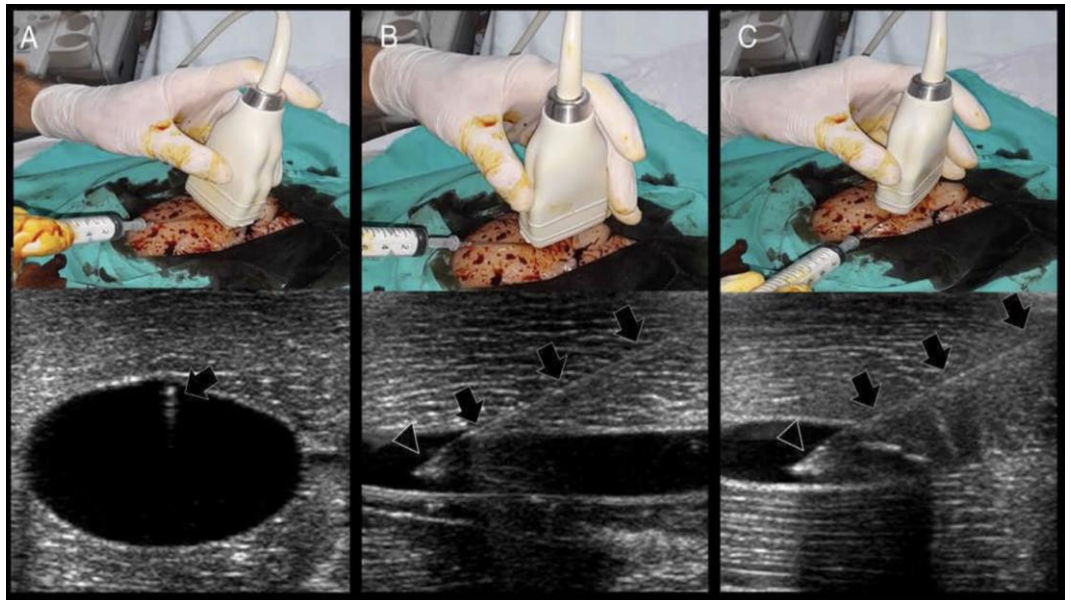
Echo-Guided Puncture

Longitudinal View



Cross-Sectional View (distal to proximal)





- No x-rays
- No CM
- Avoidance of posterior wall puncture
- Identification of plaques/calcium
- Avoidance of venopuncture

CASA DI CURA MONTEVERGINE

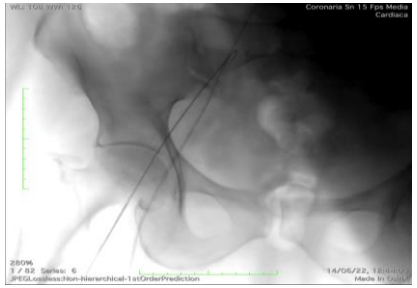
Echo-Guided Puncture

JACC: CARDIOVASCULAR INTERVENTIONS
© 2010 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
PUBLISHED BY ELSEVIER INC.
VOL. 3, NO. 7, 2010
ISSN 1936-8798/$36.00
DOI: 10.1016/j.jcin.2010.04.015

Real-Time Ultrasound Guidance Facilitates Femoral Arterial Access and Reduces Vascular Complications

FAUST (Femoral Arterial Access With Ultrasound Trial)

Arnold H. Seto, MD, MPA,* Mazen S. Abu-Fadel, MD,† Jeffrey M. Sparling, MD,† Soni J. Zacharias, MD,† Timothy S. Daly, MD,† Alexander T. Harrison, MD,* William M. Suh, MD,* Jesus A. Vera, MD,* Christopher E. Aston, PHD,‡ Rex J. Winters, MD,§ Pranav M. Patel, MD,* Thomas A. Hennebry, MB, BCH, BAO,† Morton J. Kern, MD*



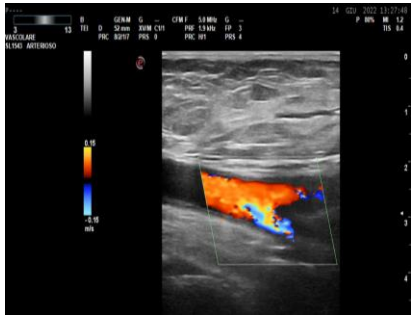


Table 3. Intraprocedural Outcomes

Characteristic	Fluoroscopy (n = 500)	Ultrasound (n = 502)	p Value
Number of attempts	3.0 ± 3.2	1.3 ± 0.9	<0.000001
First pass success	232 (46.4%)	415 (82.7%)	<0.000001
Venipuncture	79 (15.8%)	12 (2.4%)	<0.000001
Number of arterial punctures	1.14 ± 0.43	1.09 ± 0.36	0.076
Mean time to insertion, s	213 ± 194	185 ± 175	0.016
Median time to insertion, s	148 (102–242)	136 (90–212)	0.003

Values are mean ± SD, n (%), or median (interquartile range).

Minor Number of attempts
Better First Time Access
Less Venopuncture
Less time of inserction

Table 4. Vascular Access Complications

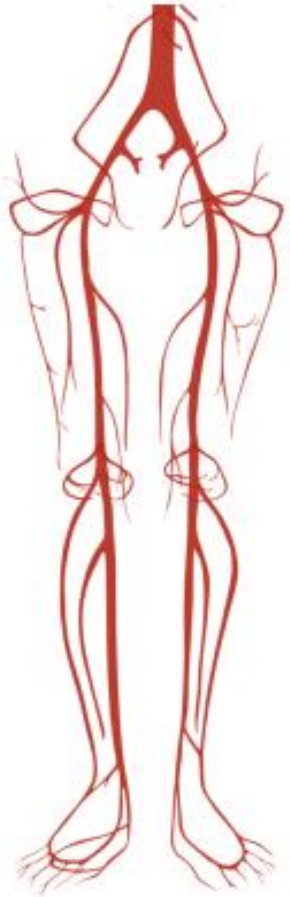
Complication	Fluoroscopy (n = 501)	Ultrasound (n = 503)	p Value
Hematoma ≥5 cm	11 (2.2%)	3 (0.6%)	0.034
Pseudoaneurysm	0	1	NS
Dissection	3	2	NS
Access bleeding, transfusion	2	1	NS
Hematoma with DVT	1	0	NS
Any complication	17 (3.4%)	7 (1.4%)	0.041

Values are n (%) or n.
DVT = deep venous thrombosis.

NO Differences in
Vascular Access
Complications

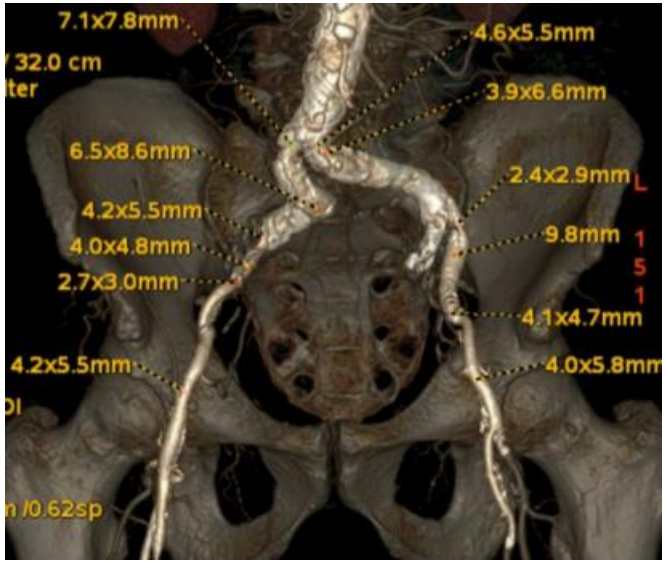
CASA DI CURA MONTEVERGINE

Two Areas of Concern in the Iliofemoral Tree

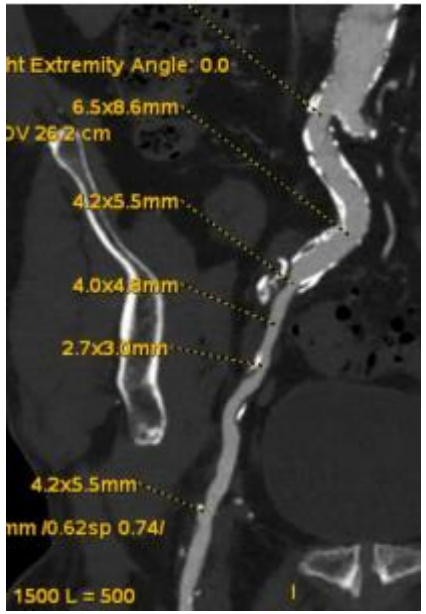


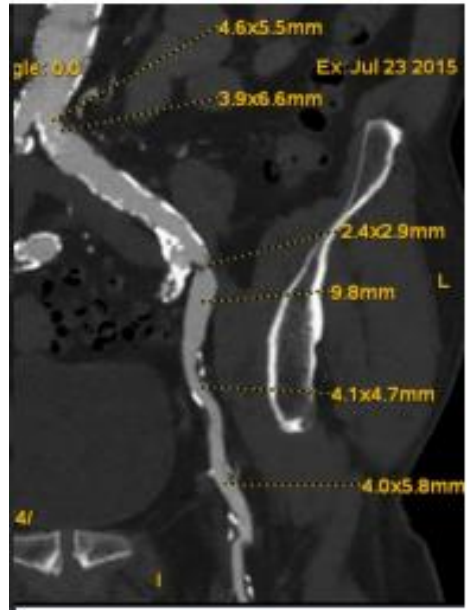
Ostial CIA

Puncture Site



External Iliacs Generally Least Concerning

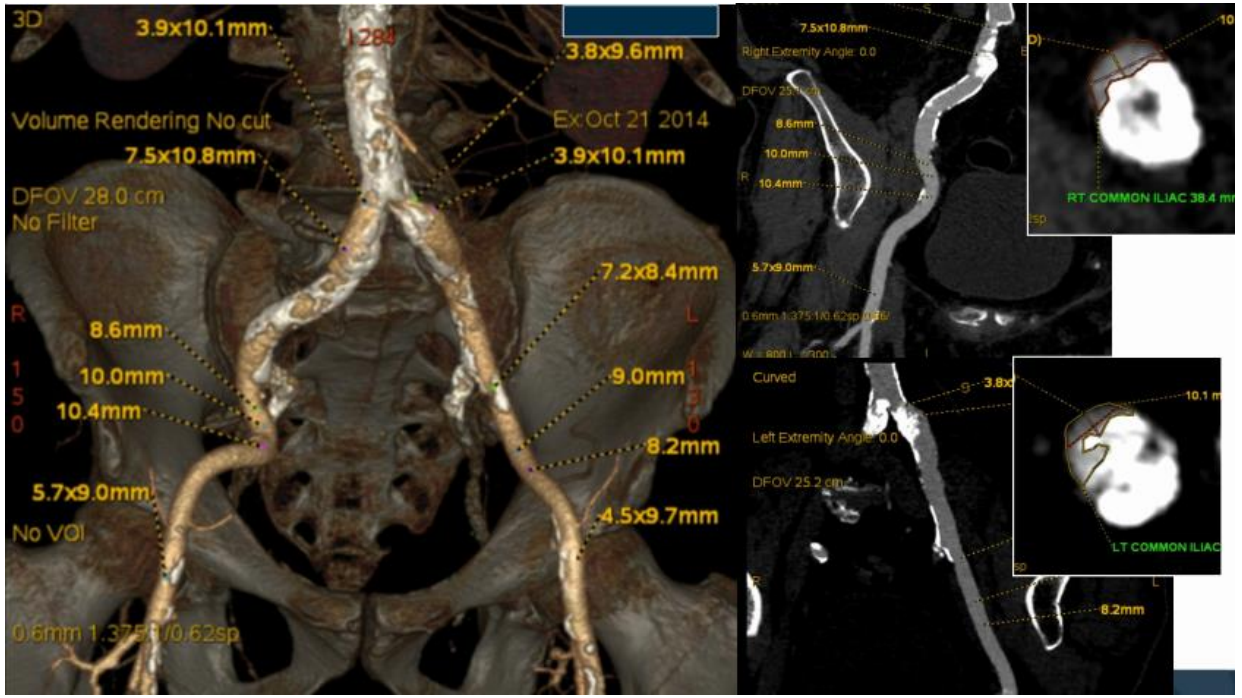




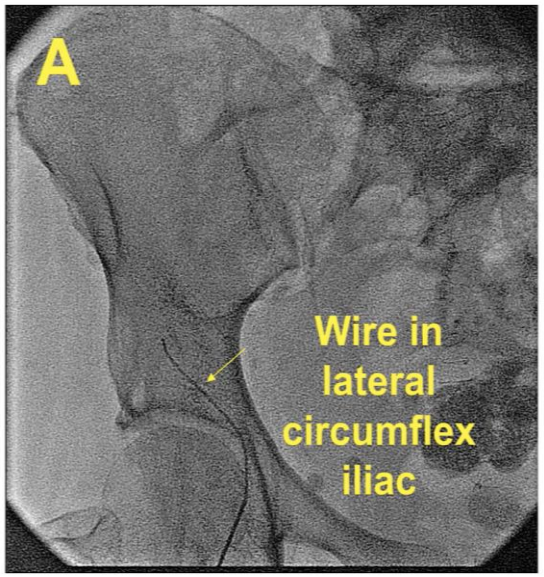
CASA DI CURA MONTEVERGINE

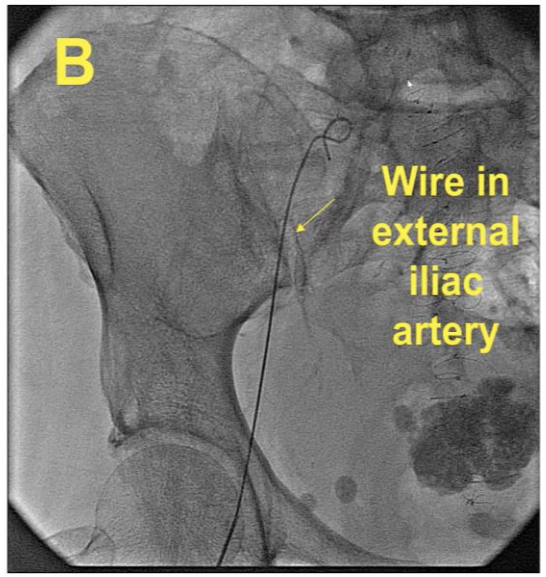
Ostial Common Iliac

Concern with Ostial CIA is Disruption of the Aorta



If resistance:
DO NOT PUSH!!!



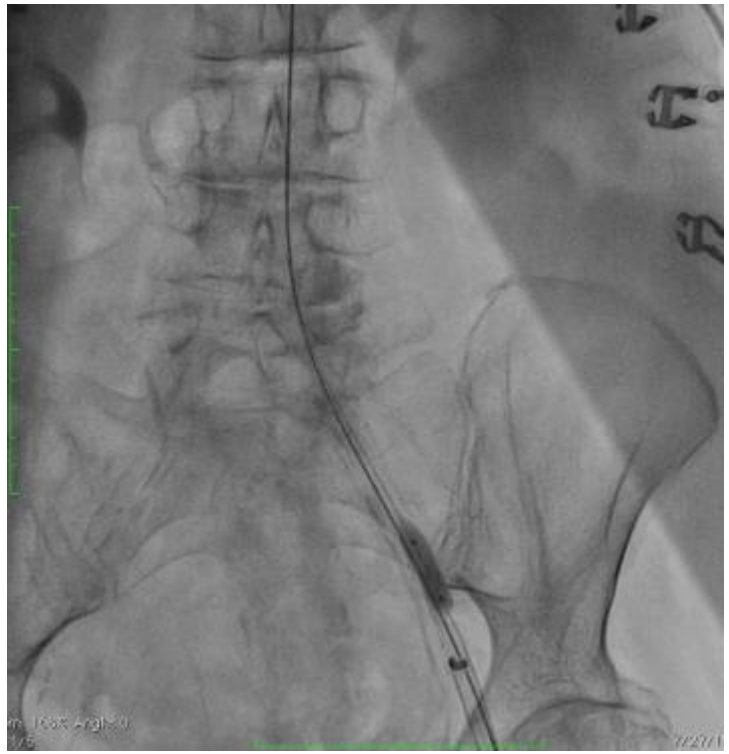


Why you should
have wire in during
femoral
angiography

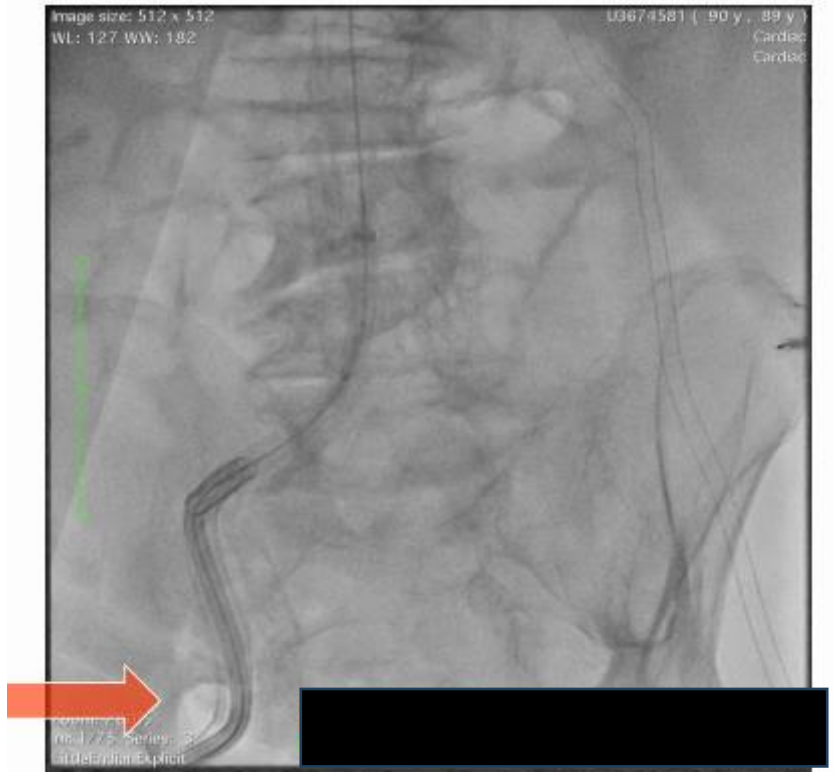
Tortuosity (Curves)

Consider Secondary Access from the radial Shallow Angle Stick Important

Straight down can be easier than up & over



Shallow Angle Stick Prevents Creating an Additional Flex Point



CASA DI CURA MONTEVERGINE

GUIDEWIRES

Diameter (inch)	Product Name	Length (cm)	Tip Type
0.035”	Hi-Torque Supracore	145-190-300	Straight
	Boston Sch. Safary XS S M	**180-260**	**Curved Pig-Tail shape**
	Radifocus Guidewire Stiff M	180-300	Straight, 45° angle
0.018”	**V18**	**110-300**	**Straight**
	Radifocus Guidewire Advantage	180-300	Straight, 45° angle
	HT Command	210-300	Shapeable nitinol

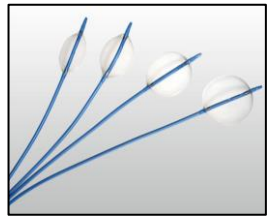
AORTIC COMPLICATIONS

RUPTURE | **DISSECTION**

Trauma from valve delivery system on atheromasic and tortuous aorta

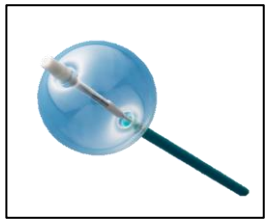
↓

ENDOVASCULAR OCCLUSION WITH OCCLUSION BALLONS
EMERGENCY SURGERY/COVERED STENT

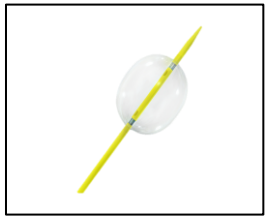


Reliant

Sheath Size	Catheter	Guidewire	Inflated Diameter
12 Fr	Reliant Stent Graft Balloon Catheter	0.038”	12-46 mm
	Coda LP	0.035”	32 mm
14 Fr	Equalizer Balloon Catheter	0.038”	20-27 mm
	Coda	0.035”	46 mm
16 Fr	Equalizer Balloon Catheter	0.038”	33-40 mm



Equalizer



Coda

CASA DI CURA MONTEVERGINE

ILIO-FEMORAL COMPLICATIONS

DISSECTION

- HIGH-PROFILE DEVICE THROUGH CALCIFED OR FRAGILE VESSEL
- PRE-EXISTING INTIMAL DAMAGE
- NOT CO-AXIAL PUSHING OF THE DEVICE

If extensive or flow-limiting can be associated with vessel occlusion (due to superimposed acute thrombosis or obstructive flaps) and may cause acute limb ischemia

Armada PTA Cath
Powerflex
Passeo
Sterling
Admiral
Ultraverse
Micro PBX

- PERIPHERAL BALLON INFLATION (6-9 mm)
- SELF EXPANDABLE STENT
- BALLOON EXPANDABLE STENT *(ostial lesion)*

ILIO-FEMORAL COMPLICATIONS

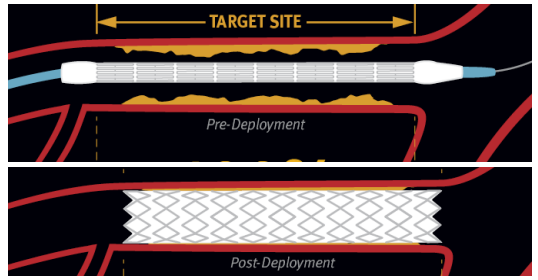
RUPTURE

SMALL PERFORATION	MAJOR PERFORATION
PERIPHERAL BALLON INFLATION *ispilateral or controlateral access (5-10')* COVERED STENT *(persisting laceration)* SURGICAL REPAIR	ENDOVASCULAR CLAMPING WITH OCCLUSIVE BALLOON

COVERED STENT

- *Fluency (SE)*
- *Gore Viabahn (SE)*
- *Endoprosthesis (SE)*
- *Advanta V12 (BE)*

- *BeGraft (BE)*
- *Viabahn VBX(BE)*
- *I-Cover(BE)*



CASA DI CURA MONTEVERGINE

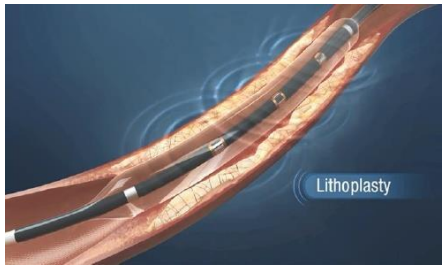
OTHER USEFUL DEVICES:

Shockwave:Peripheral Lithoplasty System

MINIMIZE TRAUMA - Minimize trauma to soft tissue by safely selecting and fracturing intimal and medial calcium

OPTIMIZE OUTCOMES - Optimize outcomes while reducing complications and cost escalation

SIMPLIFY PROCEDURES - Simple and intuitive system that makes complex calcified procedures more predictable



Size: Select Balloon using 1:1 (catheter to vessel RVD) sizing protocol

DIAMETER (mm)	LENGTH (mm)	Max Pulse Count	GUIDEWIRE COMPATIBILITY (in)	SHEATH COMPATIBILITY	WORKING LENGTH (cm)
3.5	60	180	0.014	6F	110
4	60	180	0.014	6F	110
4.5	60	180	0.014	6F	110
5	60	180	0.014	6F	110
5.5	60	180	0.014	6F	110
6	60	180	0.014	6F	110
6.5	60	180	0.014	7F	110
7	60	180	0.014	7F	110

Femoral access complications

- Lower extremity ischemia
- Bleeding (groin/retroperitoneal hematoma)
- Pseudoaneurysm
- Arteriovenous fistula
- Infection
- Nerve injury

Lower extremity ischemia

Causes

- Dissection
- Thrombosis
- Distal embolization
- Vascular closure device complications
- Occlusive sheath
- Prolunged sheath dwelling time
- Poor sheath management tecnique
- Prolonged femoral artery compression
- Suboptimal anticoagulation

Treatment

- Controlateral femoral access and angiography
- Endovascular RX
- Surgery

Femoral access bleeding

Causes

- High puncture
- Back wall puncture
- Anticoagulation/GP IIb/IIIa inhibitors/cangrelor
- Hypertension
- Inadvertent perforation of renal or lumbar arteries

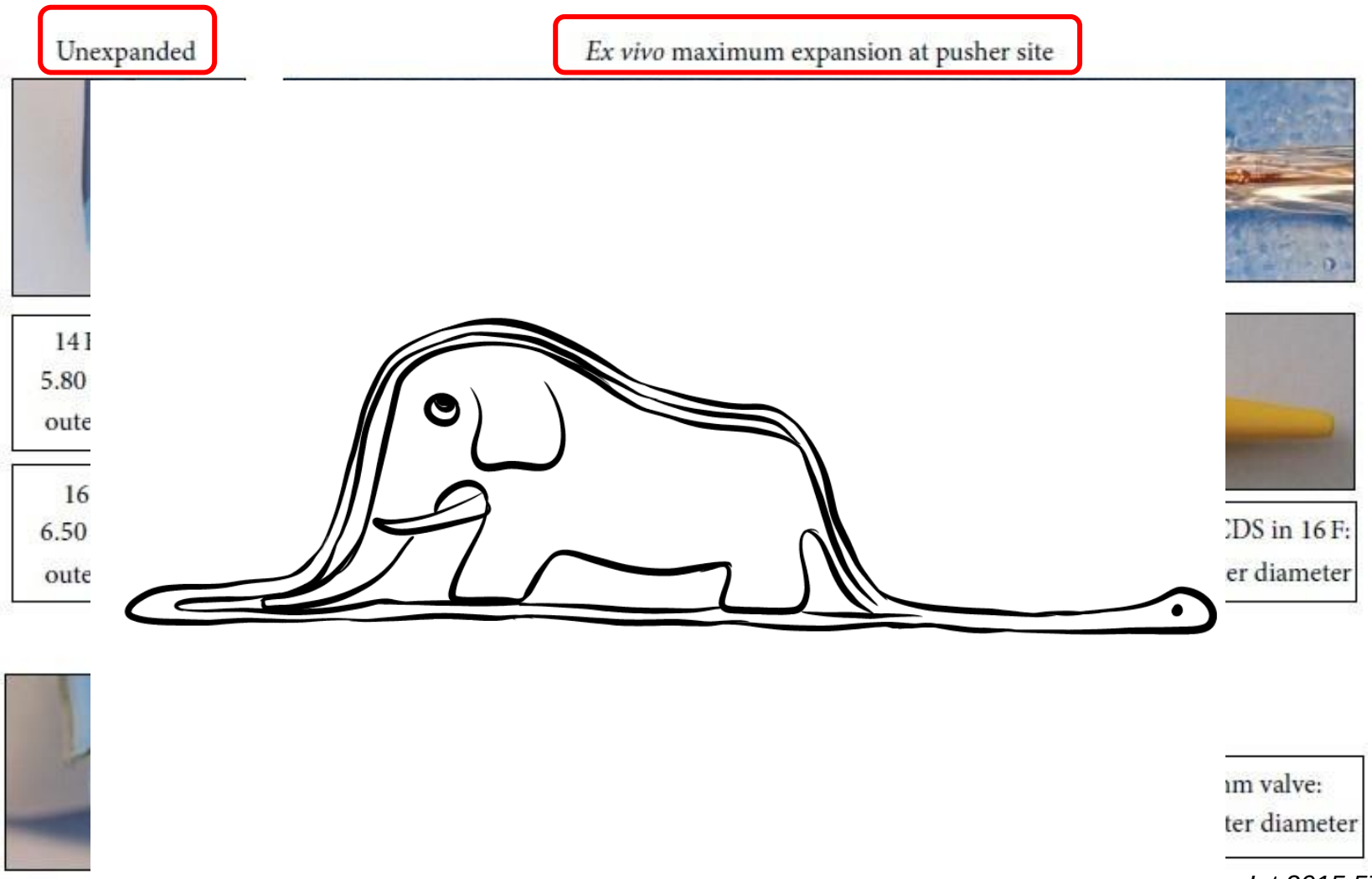
Prevention

- Meticulous access technique (fluoroscopy, US, femoral angiography)
- Advance guidewires with fluoroscopic guidance
- Control hypertension
- Attention to therapy

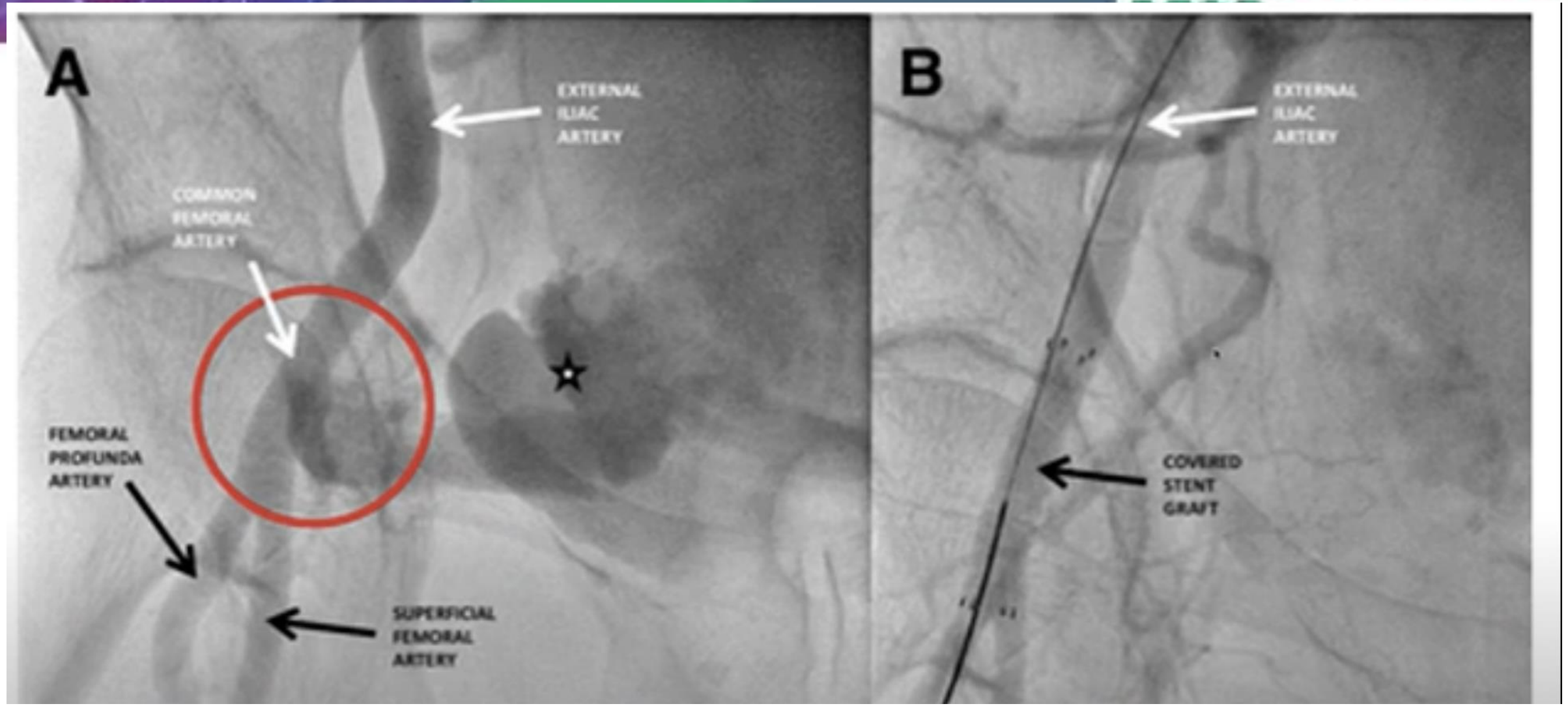
Treatment

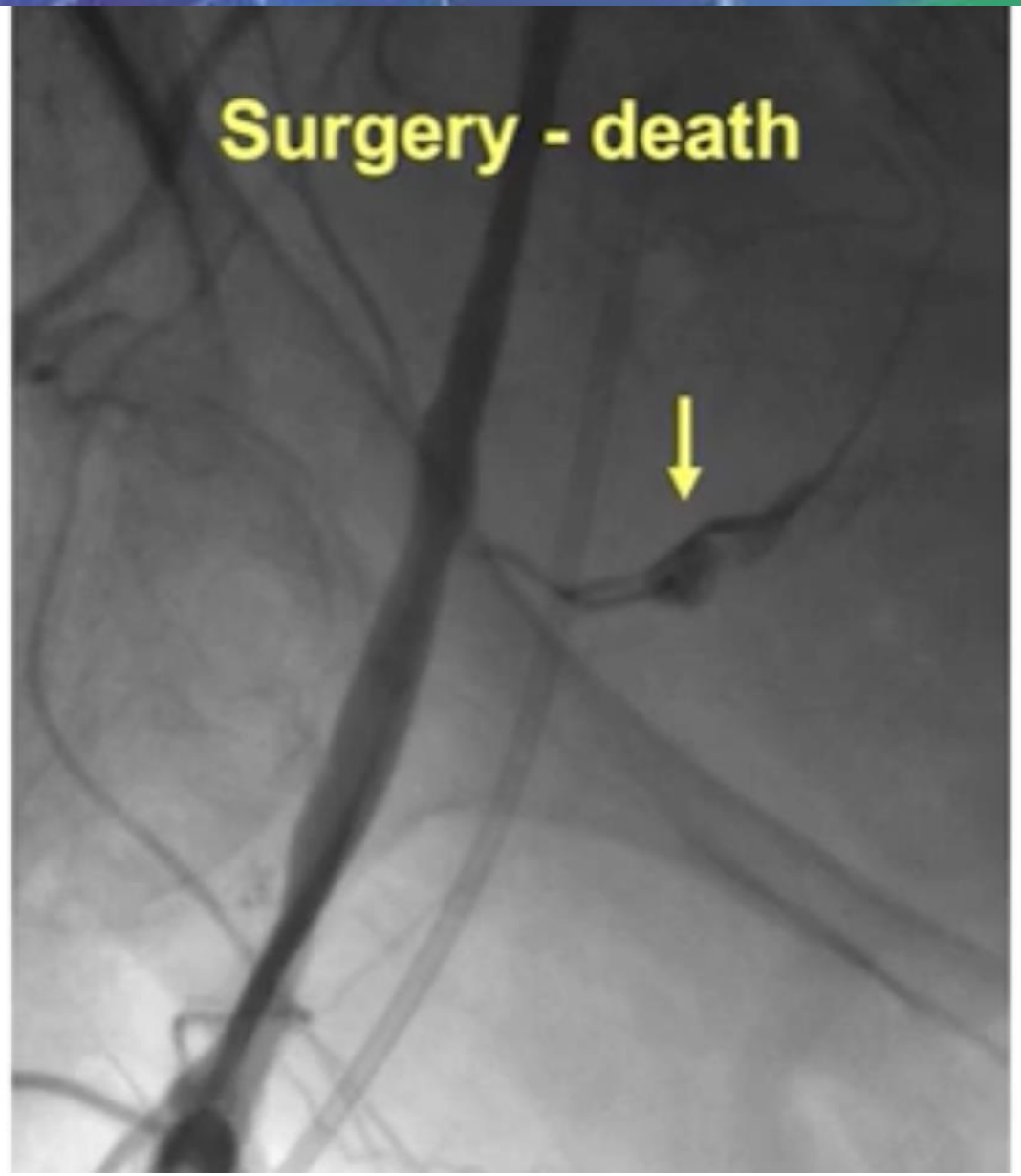
- *Groin hematoma: manual pressure/endovascular, surgery (rare cases)*
- *Retroperitoneal hematoma: conservative, endovascular, surgery*

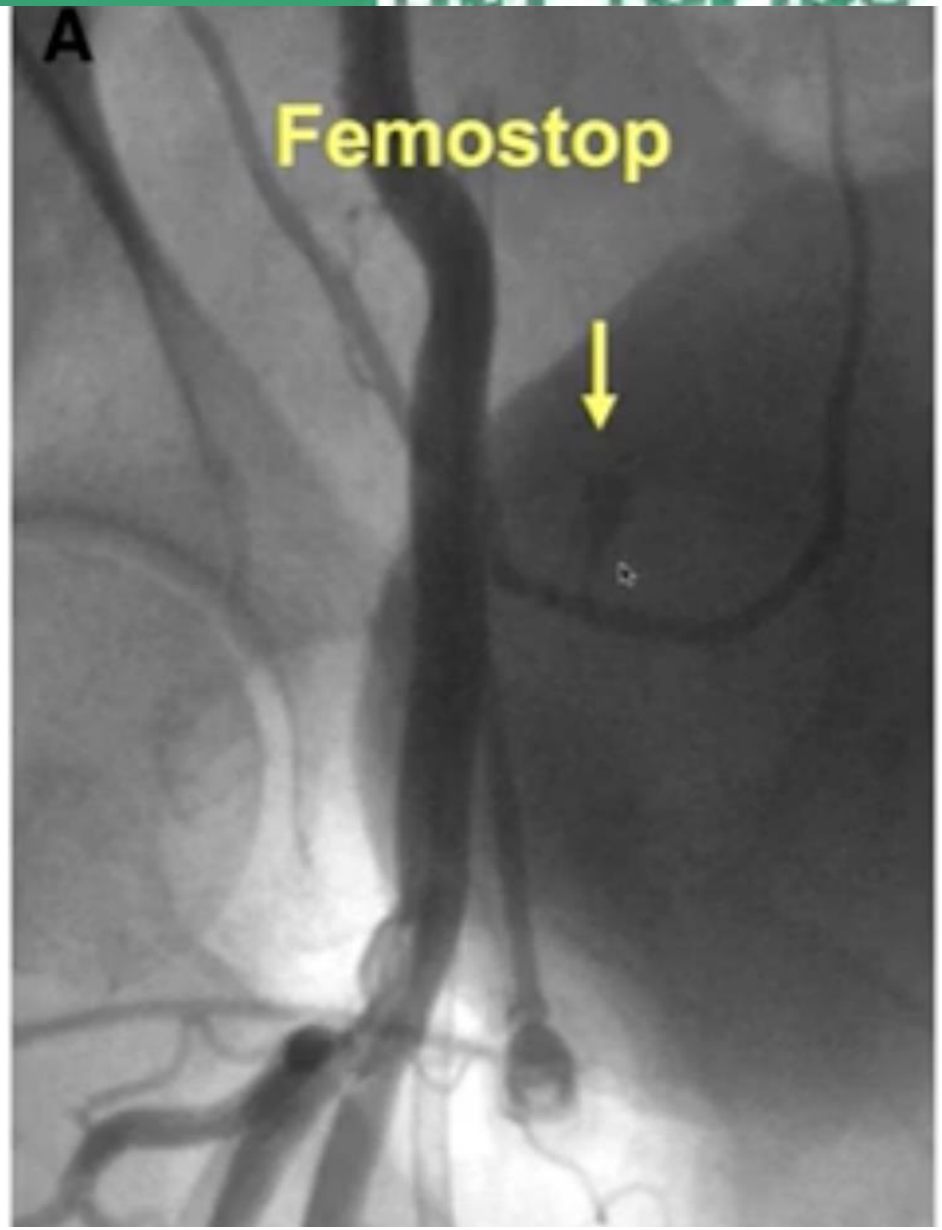
What about expandable sheaths?



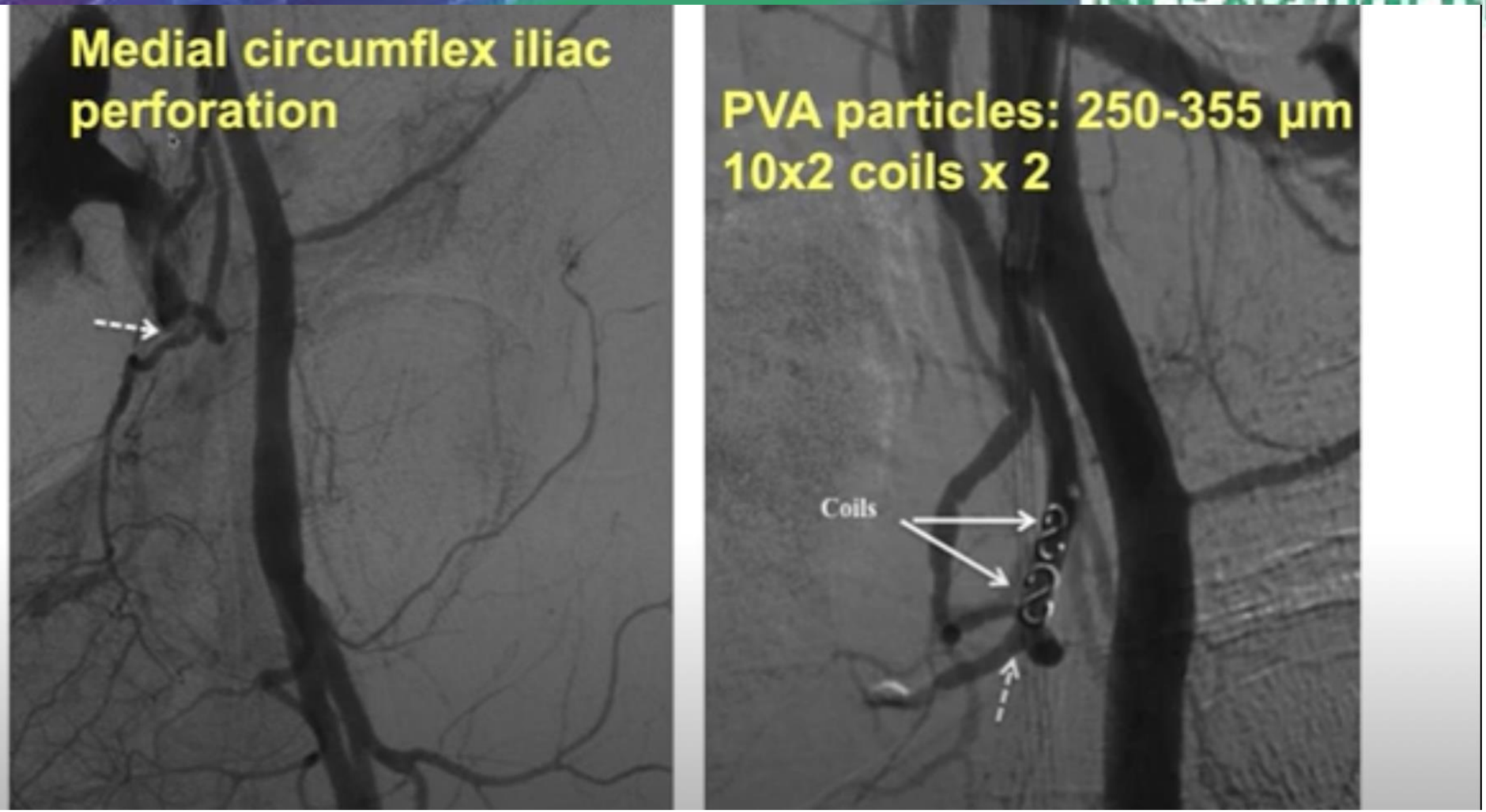
Kochiadakis et al. Biomed Res Int 2015;572681


A
EXTERNAL ILIAC ARTERY
COMMON FEMORAL ARTERY
FEMORAL PROFUNDA ARTERY
SUPERFICIAL FEMORAL ARTERY
B
EXTERNAL ILIAC ARTERY
COVERED STENT GRAFT





CASA DI CURA MONTEVERGINE


Medial circumflex iliac perforation
PVA particles: 250-355 µm
10x2 coils x 2
Coils

AV-fistula

Causes

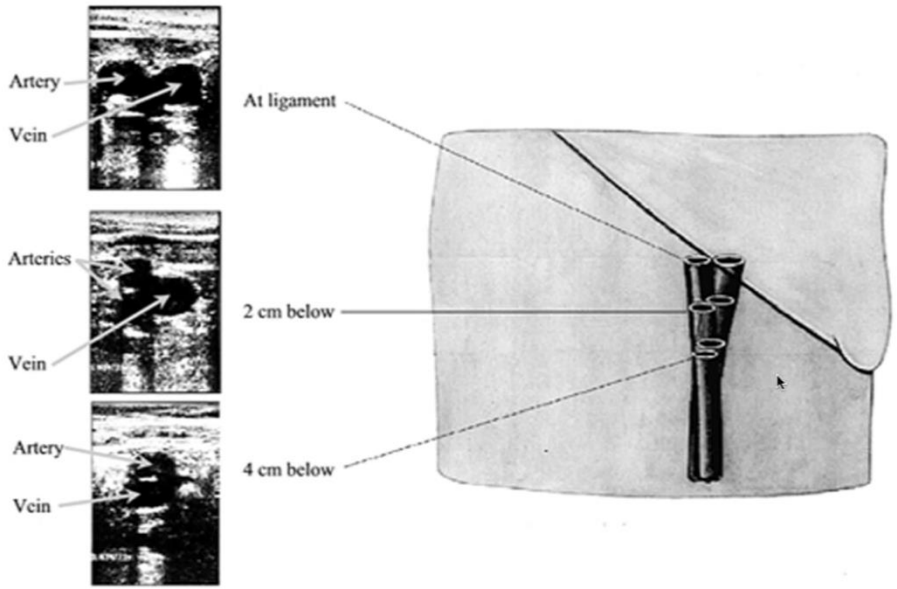
1. Low puncture
2. Multiple arterial punctures
3. Access to both artery and vein

Prevention

1. Optimal access technique
2. Remove arterial sheath first, then venous sheath

Treatment

1. Usually not needed
2. Covered stent - surgery



Hughes. Anaesthesia 2000;55: 1198-1202

Pseudoaneurysm

Causes

1. Low stick
2. Suboptimal compression
3. Challenging access
4. Access of both artery+vein
5. Intensive anticoagulation
6. Vascular closure device failure

Treatment

<2 cm: conservative

≥2 cm:

- US-guided thrombin injection
- US compression
- Surgery (>6 cm, synthetic graft, infection, limb ischemia, skin necrosis)

Meralgia paresthetica

Causes

1. Direct injury from needle
2. Nerve compression from hematoma or pseudoaneurysm

Prevention

1. State-of-the-art access technique

Treatment

1. Conservative

Access site infection

Causes

1. Groin hematoma
2. Pseudoaneurysm
3. Immunocompromised
4. Poor access site hygiene
5. Use of closure devices

Treatment

1. Antibiotics
2. Surgery

Prevention

1. Sterile technique
2. Repeat antiseptic prep before closure
3. Avoid closure devices in pts at high risk for infection
4. State-of-the-art access technique
5. Sheath removal asap post procedure
6. Prophylactic antibiotics
7. Prevent hematomas

Femoral artery manual compression steps

1. Telemetry with noninvasive BP monitoring.
2. Personnel available to administer atropine or fluids if needed
3. Sterile gloves
4. Operator's hands are placed above the femoral puncture site.
5. Sheath is removed while applying gentle pressure with small back bleed.
6. Firm pressure is applied confirming hemostasis.
7. Duration: 2–3 minutes × the sheath size

   6 Fr: 12–18 min 8 Fr: 16–24 min
8. Check access site for hematoma.
9. Check distal pulses
10. Clear sterile dressing (Tegaderm)

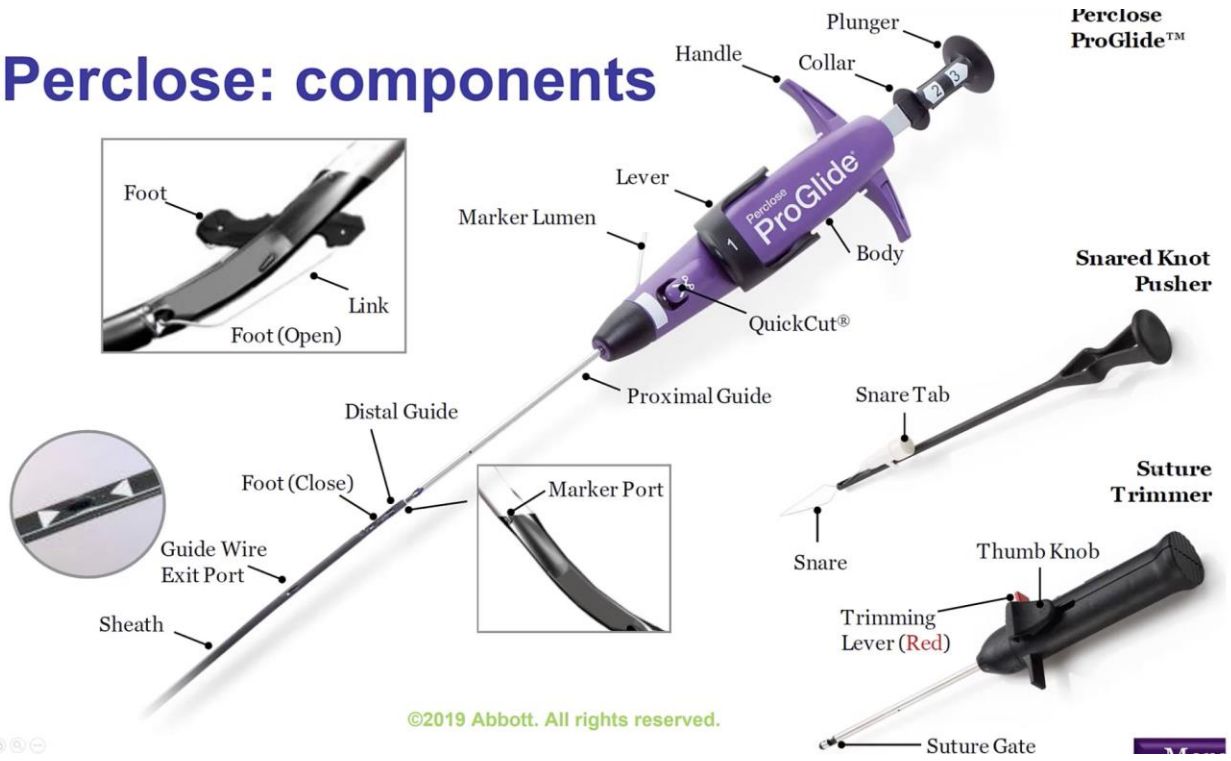
	Angio-Seal	**Perclose**	**Starclose**
Active Approximation Devices			
	Duett	**Exoseal**	**Mynx**
Passive Approximation Devices			
	Arstasis Axera	**Boomerang Catalyst III**	**FISH**
Unique Devices			

Perclose steps

Groin antiseptic preparation

1. Prepare device
2. Advance 0.035 inch guidewire + remove femoral sheath
3. Tissue track preparation
4. Insert Perclose device
5. Perclose foot deployment
6. Perclose suture deployment
7. Perclose foot retraction
8. Perclose device retraction
9. Perclose device removal and suture tightening
10. Suture cutting

Perclose: components



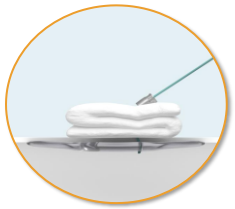
What is a MANTA device?

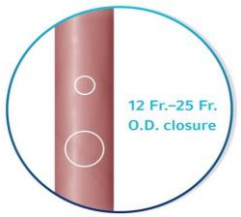
- The MANTA™ device (Teleflex, Wayne, Pennsylvania, U.S.A.) is the first commercially available biomechanical vascular closure device designed specifically for large bore femoral arterial access site closure.

The 14F MANTA Vascular Closure Device is for access sites in the femoral artery following the use of 10-14F devices or sheaths (maximum OD of 18F).

- Applicable procedures:
  - transcatheter aortic valve implantation (TAVI)
  - endovascular aneurysm repair (EVAR)
  - ventricular assist device (VAD)

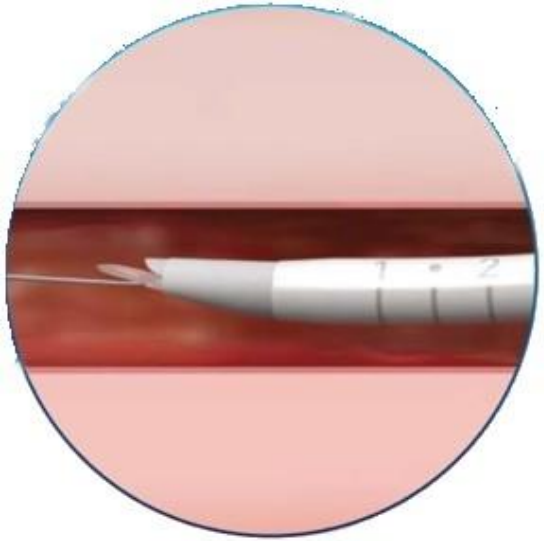
The 18F MANTA Vascular Closure Device is for access sites in the femoral artery following the use of 15-18F devices or sheaths (maximum OD of 25F).



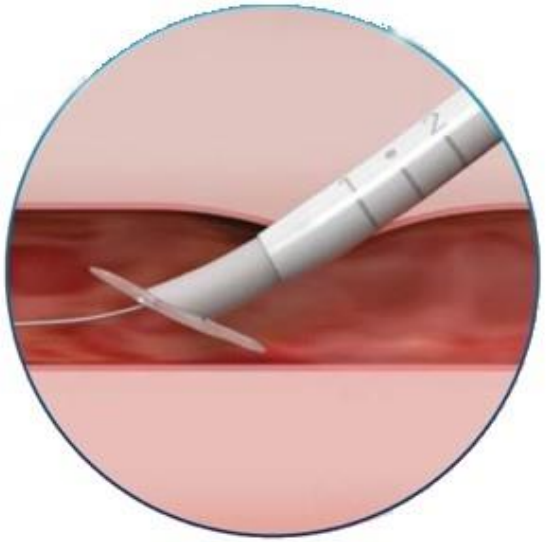


Mechanism of action

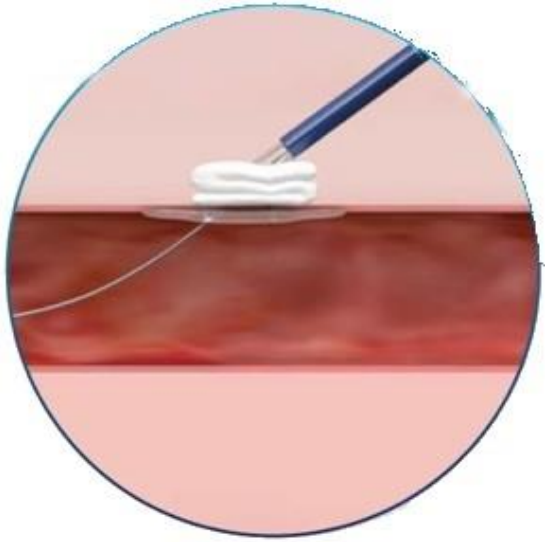
- Single (no safety wire) easy-to-use device;
- No pre-closure;
- Hemostasis is achieved primarily by the mechanical means of the anchor-arteriotomy-collagen sandwich, which is supplemented by the coagulation-inducing properties of the collagen;



1. Insert the MANTA™ Device



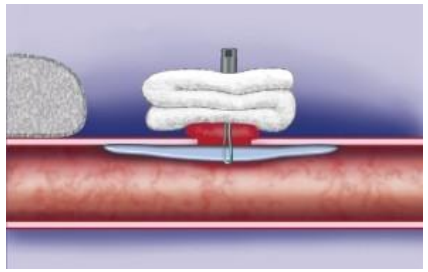
2. Position and release anchor



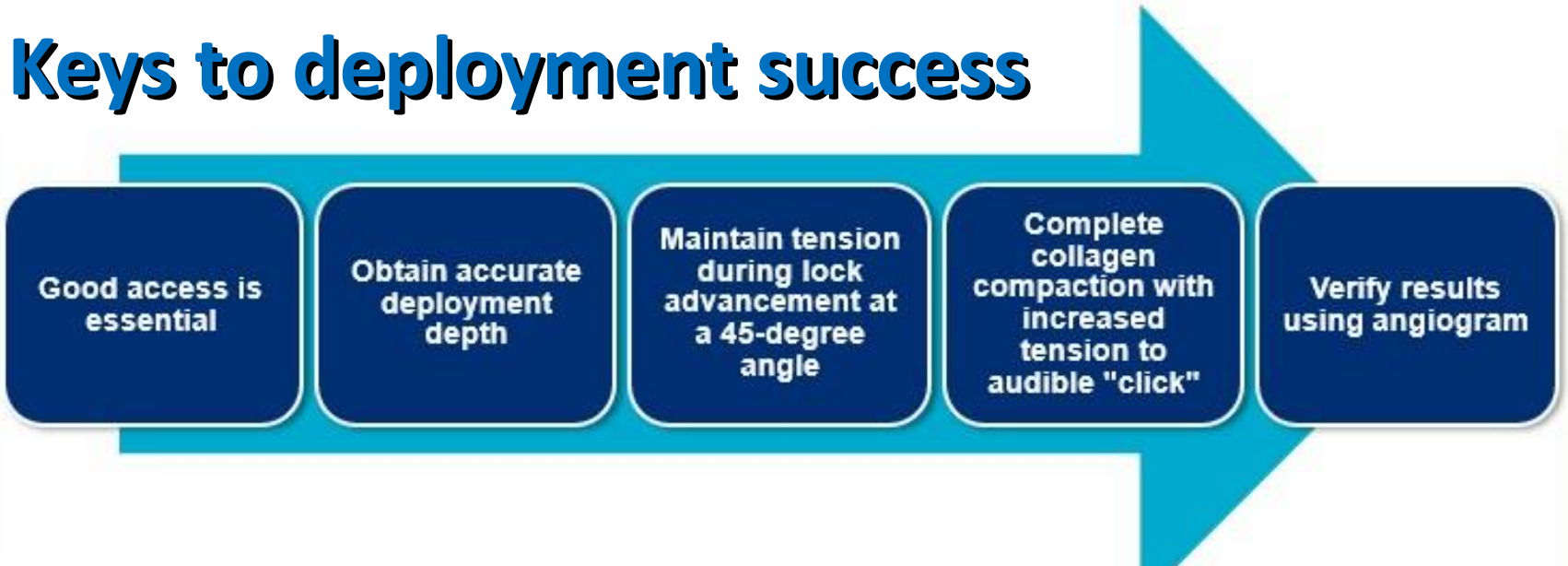
3. Withdraw and seal

Mechanism of action

- The polyester suture holds the components together and the extra-arterial radiopaque lock secures it in place.

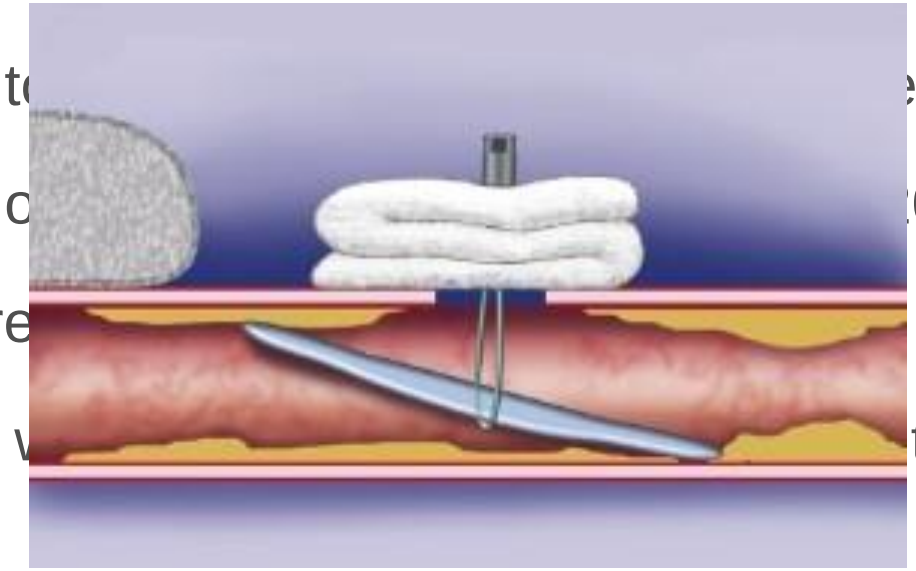


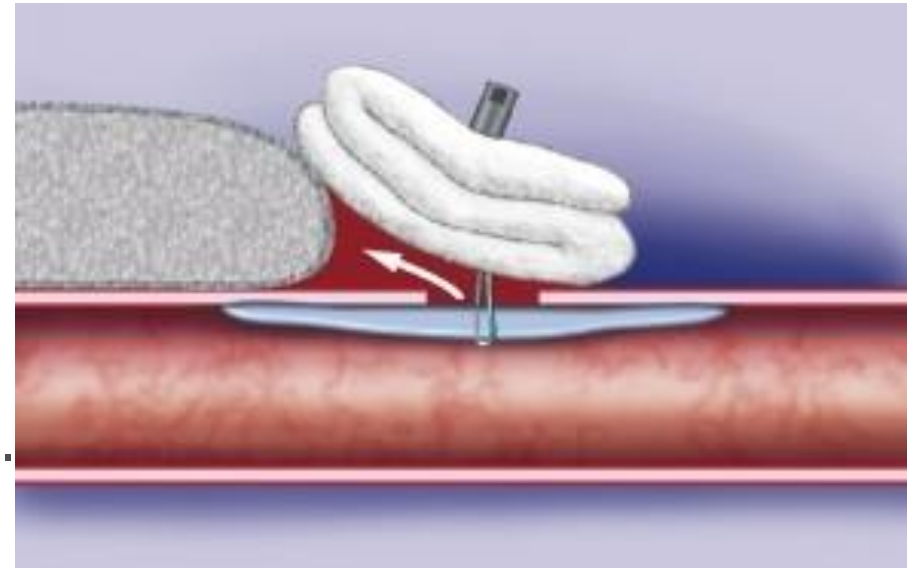
Keys to deployment success



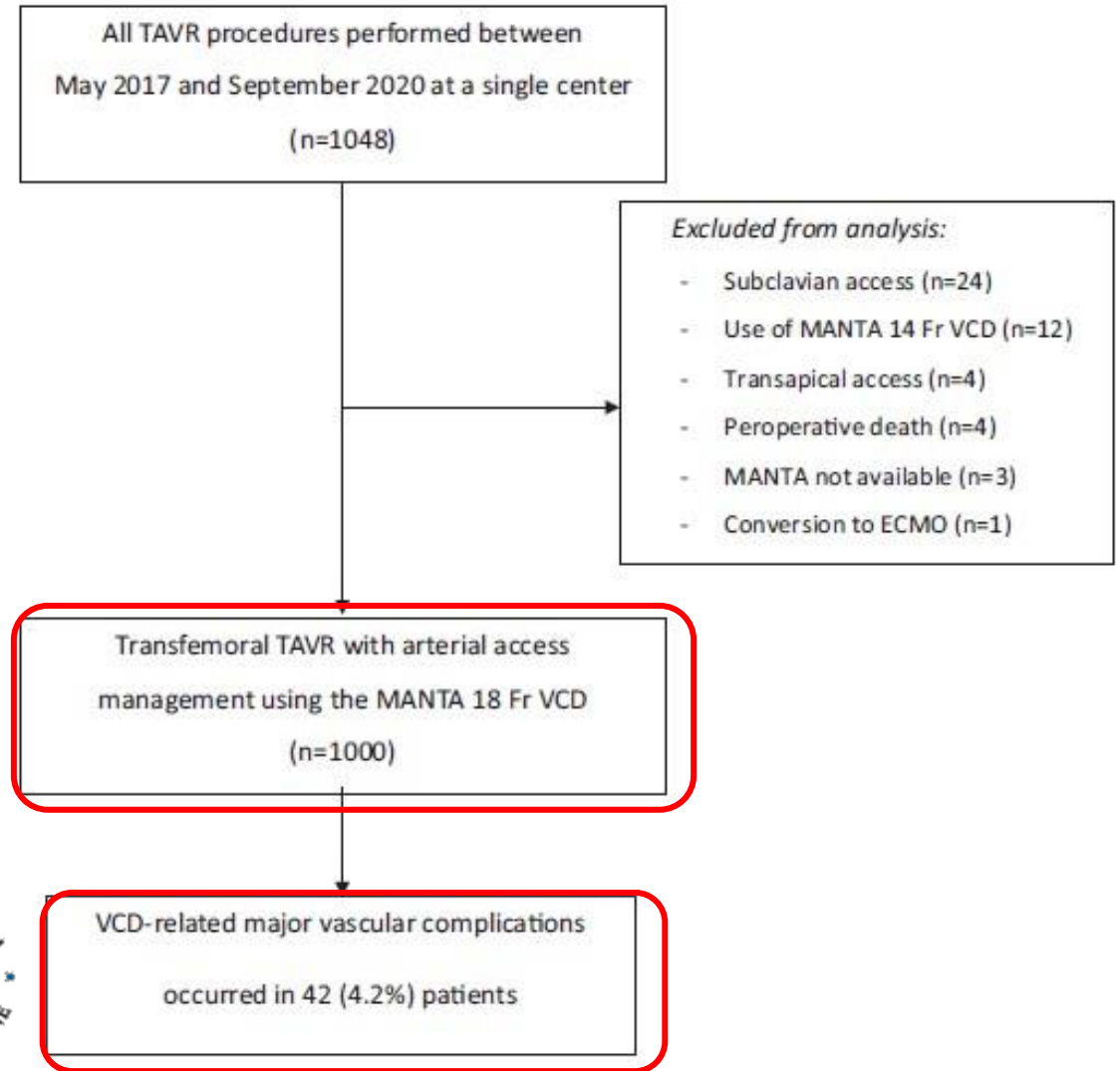
Contraindications

- severe calcification of the access vessel;
- severe peripheral artery disease (CFA <5.0 mm if 14F, <6.0 mm if 18F MANTA planned);
- puncture in the origin of the profundal femoral artery, above the inguinal ligament, or above the most inferior border of the epigastric artery (IEA);
- sheath insertion in vessel other than the femoral artery;
- marked t ery;
- marked c 0 kg/m^2);
- blood pre
- patients v the procedure.





What about the literature? The largest ever real-world observational study



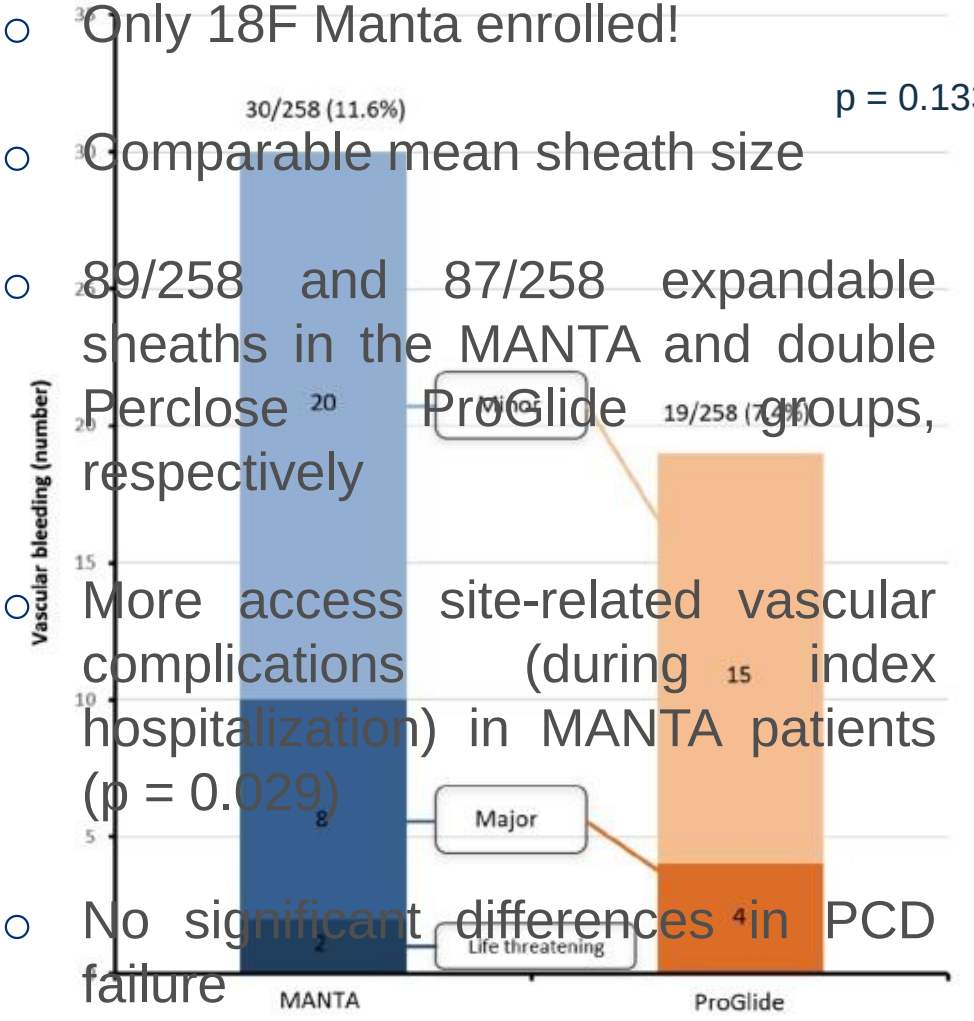
- 166/1000 expandable sheaths
- no significant differences in major complications were seen between individual interventionists irrespective of experience with the device
- a larger sheath (outer diameter) to femoral artery (inner diameter) ratio was the only factor associated with a significant increase of PCD-related major vascular complications

Kastengren M et al. Int J Cardiol 2022;359:7-13

What about the literature? CHOICE-CLOSURE randomized clinical trial

Variable	MANTA-based technique n=258	ProGlide-based technique n=258	*P* value
Use of protamine, n/N (%)			0.481
None	4/256 (1.6)	2/258 (0.8)	
Half-dose*	202/256 (78.9)	197/258 (76.4)	
Full dose†	50/256 (19.5)	59/258 (22.9)	
Manual compression, n/N (%)			<0.001
<3 min	190/253 (75.1)	81/251 (32.3)	
3–10 min	42/253 (16.6)	157/251 (62.5)	
>10 min	21/253 (8.3)	13/251 (5.2)	
Additional vascular closure device, n/N (%)	0/258 (0.0)	151/258 (58.5)	<0.001
Number of additional vascular closure devices	0.0±0.0	0.6±0.5	<0.001
Type of additional vascular closure device, n/N (%)			
Manta	–	6/151 (4.1)	–
ProGlide	–	3/151 (2.1)	–
Angio-Seal 6F	–	84/151 (57.9)	–
Angio-Seal 8F	–	51/151 (35.2)	–
Femoseal	–	1/151 (0.7)	–
Endovascular ballooning, n/N (%)	20/258 (7.8)	14/258 (5.4)	0.375
Stent or stent-graft, n/N (%)	11/258 (4.3)	4/258 (1.6)	0.116
Time to hemostasis, seconds, median (interquartile range)	80 (32–180)	240 (174–316)	<0.001
Residual stenosis ≥50%, n/N (%)	0/258 (0.0	4/258 (1.6)	0.132
Vascular closure device failure, n/N (%)	12/258 (4.7)	14 (5.4)	0.841

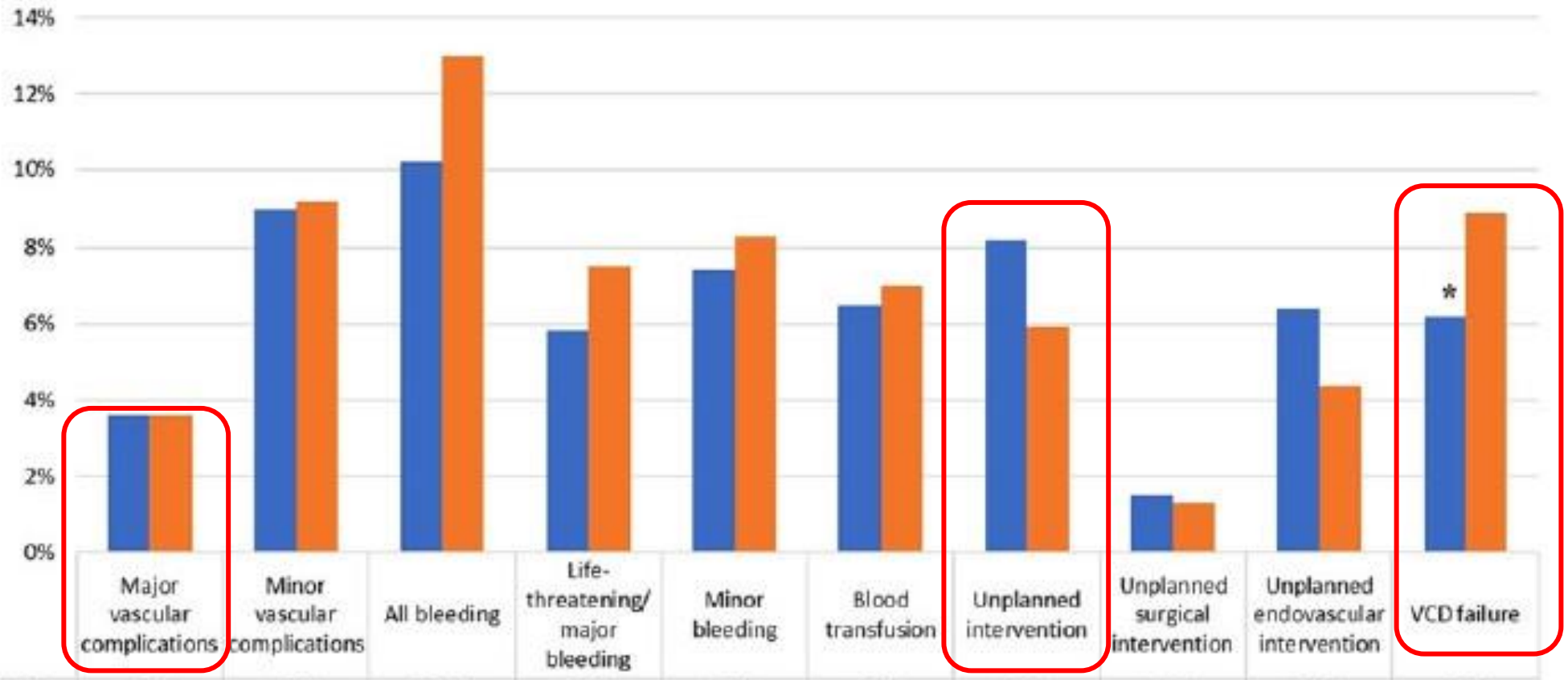
- Only 18F Manta enrolled!
- Comparable mean sheath size
- 89/258 and 87/258 expandable sheaths in the MANTA and double Perclose ProGlide groups, respectively
- More access site-related vascular complications (during index hospitalization) in MANTA patients (p = 0.029)
- No significant differences in PCD failure



Abdel-Wahab M et al. Circulation 2022;145:170-83

What about the literature? MANTA vs. suture-based PCDs: a meta-analysis

No discrimination according to sheath technology!!!

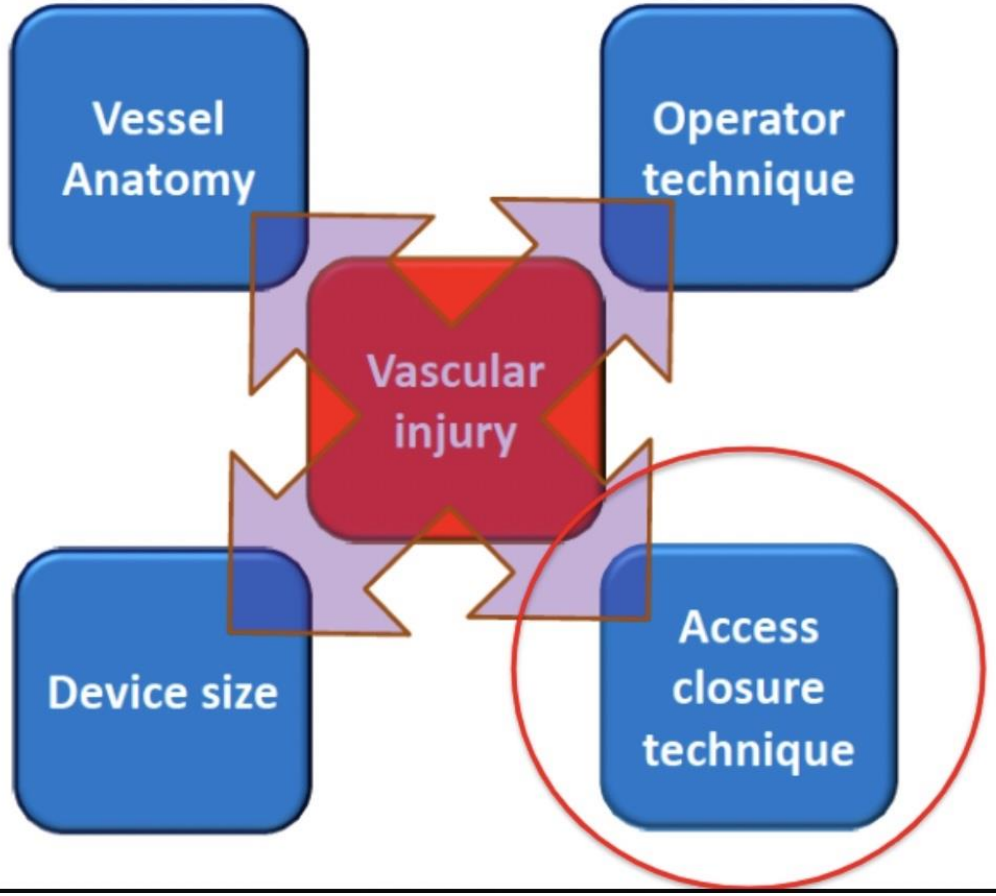


	Major vascular complications	Minor vascular complications	All bleeding	Life-threatening/ major bleeding	Minor bleeding	Blood transfusion	Unplanned intervention	Unplanned surgical intervention	Unplanned endovascular intervention	VCD failure
Plug-based VCD	3.6%	9.0%	10.2%	5.8%	7.4%	6.5%	8.2%	1.5%	6.4%	6.2%
Suture-based VCD	3.6%	9.2%	13.0%	7.5%	8.3%	7.0%	5.9%	1.3%	4.4%	8.9%

Sedhom R et al. Catheter Cardiovasc Interv 2023;101:817-27

Vascular Access and/or Complications

Multifactorial



CASA DI CURA MONTEVERGINE

Final Considerations

CONCLUSIONS (Vascular Access)

- **Femoral access 1st Choice**
- **Angio-Guided punture by left transradial approach is not time-consuming (choice left or right), if anatomy is unknown**
- **Not too high-not low femoral punture always avoids Retroperitoneal Hematoma**
- **Axillary Access possibile but… time consuming, more complications difficult to manage and less favourable to VCD**
- **VCD 1st Choice: Proglide**
- **Always be prepared to failure by a balloon dry closure**

CASA DI CURA MONTEVERGINE

CONCLUSIONS (Complications)

- *Percutaneous treatment of vascular complications occuring during TAVI is safe and effective.*
- *Radial artery crossover technique for the treatment of vascular complications is as safe as femoral approach.*
- *It is important to be familiar with peripheral techniques and devices for a safe and effective percutaneous management of vascular complications and the appropriate choosing of the right equipement.*
- *Choose you're strategy on the bases of your cath-lab capability.*
- *Be ready to use sliding strategies.*