
# Percutaneous access


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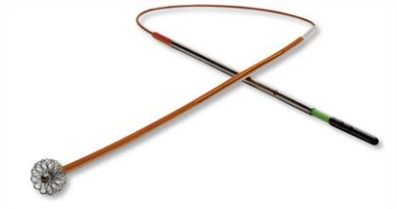
# Disclosures

- Illustrations of JVS paper 2018 paid by Abbott company

- Consultant for Abbott and Cook®

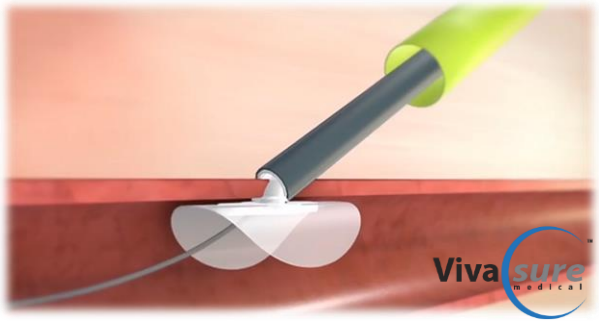
# Percutaneous Closure Devices (PCDs)

Different solutions proposed



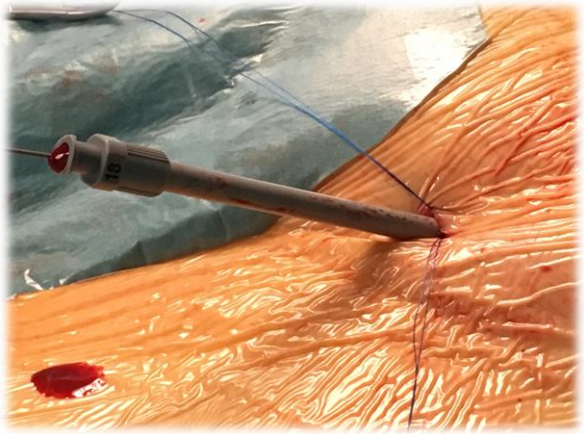




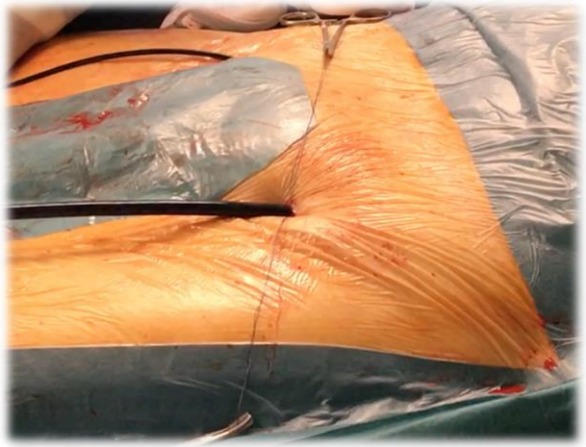


# PCD for aortic procedures

CE-marked approved suture devices (Abbott)



EVAR ≃ 14-18 F



TEVAR or F/BEVAR ≃ 18 – 26F

Prostar XL (<24 F)


Perclose Proglide (<21 F)

# Prostar XL *vs* Proglide

Data from OSR TAVI experience (mean size 18.5 ± 2.0 Fr.)

| | Prostar XL N=472 | Proglide N=472 |
|---|---|---|
| Rupture | 9 (1.9%) | 5 (1.1%) |
| Dissection | 12 (2.5%) | 14 (3.0%) |
| Stenosis | 3 (0.6%)* | 16 (3.4%) |
| Aneurysm | 20 (4.2%) | 23 (4.9%) |
| Haematoma | 45 (9.5%)* | 9 (1.9%) |
| PTA | 20 (4.2%) | 7 (1.5%) |
| Stenting | 23 (4.9%) | 23 (4.9%) |
| Urgent vascular surgery | 13 (2.8%)* | 5 (1.1%) |

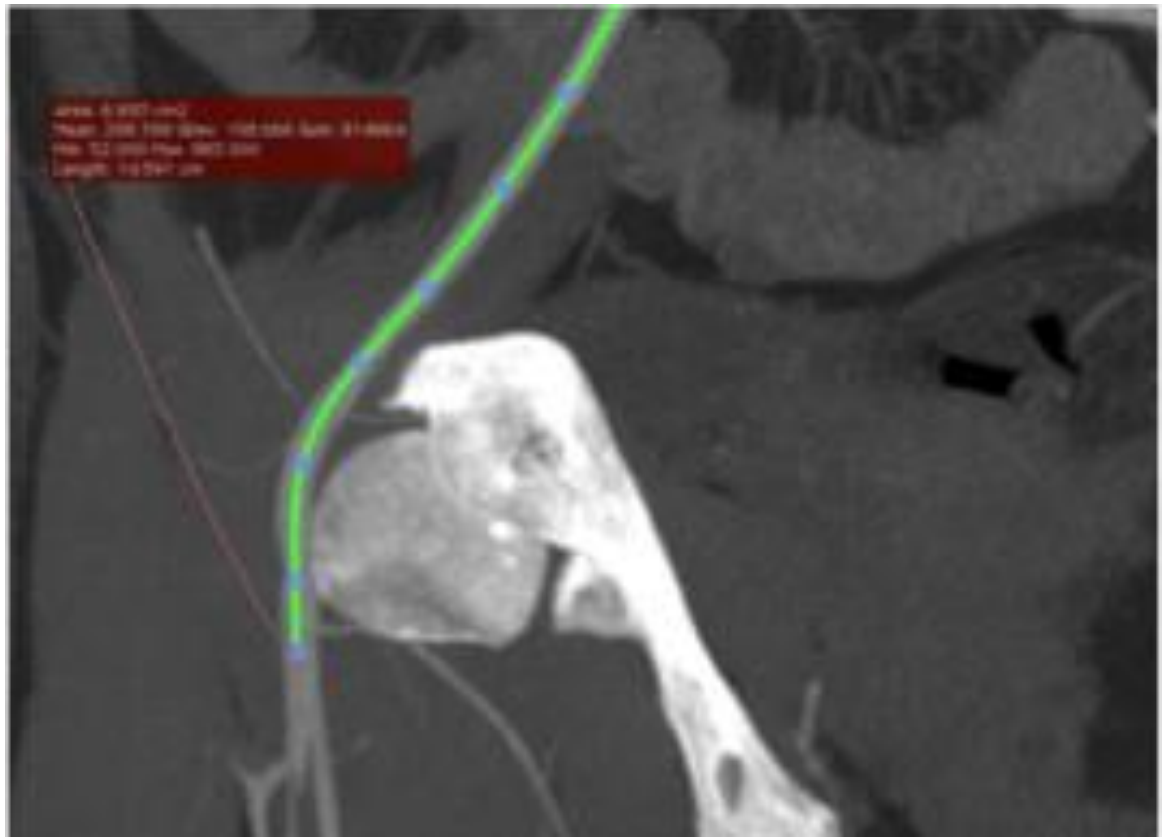
*. P< .05

”...a Perclose Proglide-based vascular closure strategy was associated with lower rates of major vascular complications and bleeding”


*I.M. Barbash et al. Eur HearT J 2015*

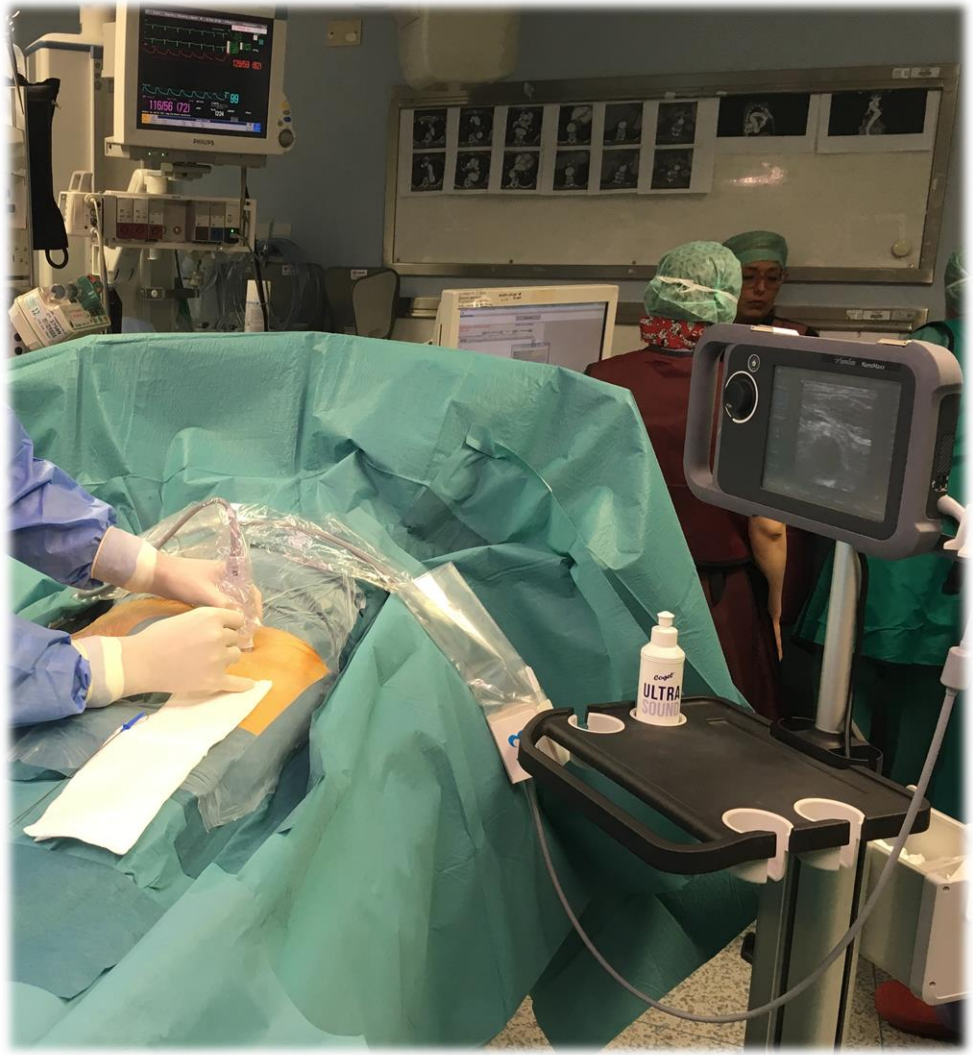
# Preoperative planning

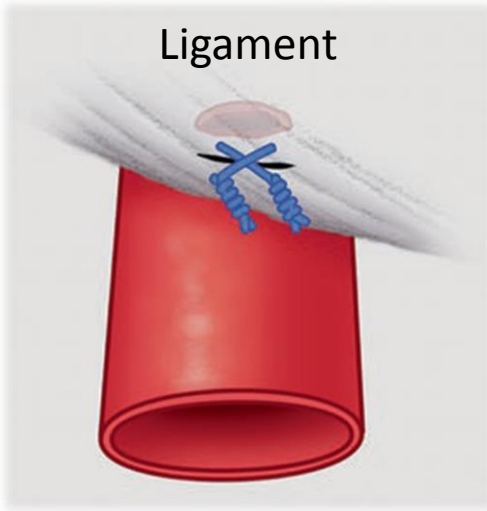
CT evaluation with Osirix

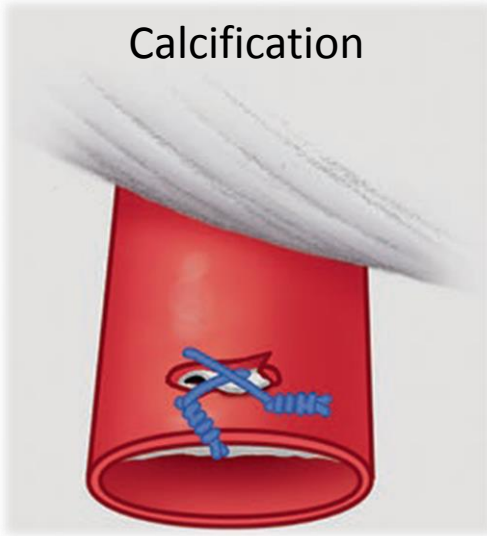


# OSR EVAR/TEVAR protocol

- US guided puncture

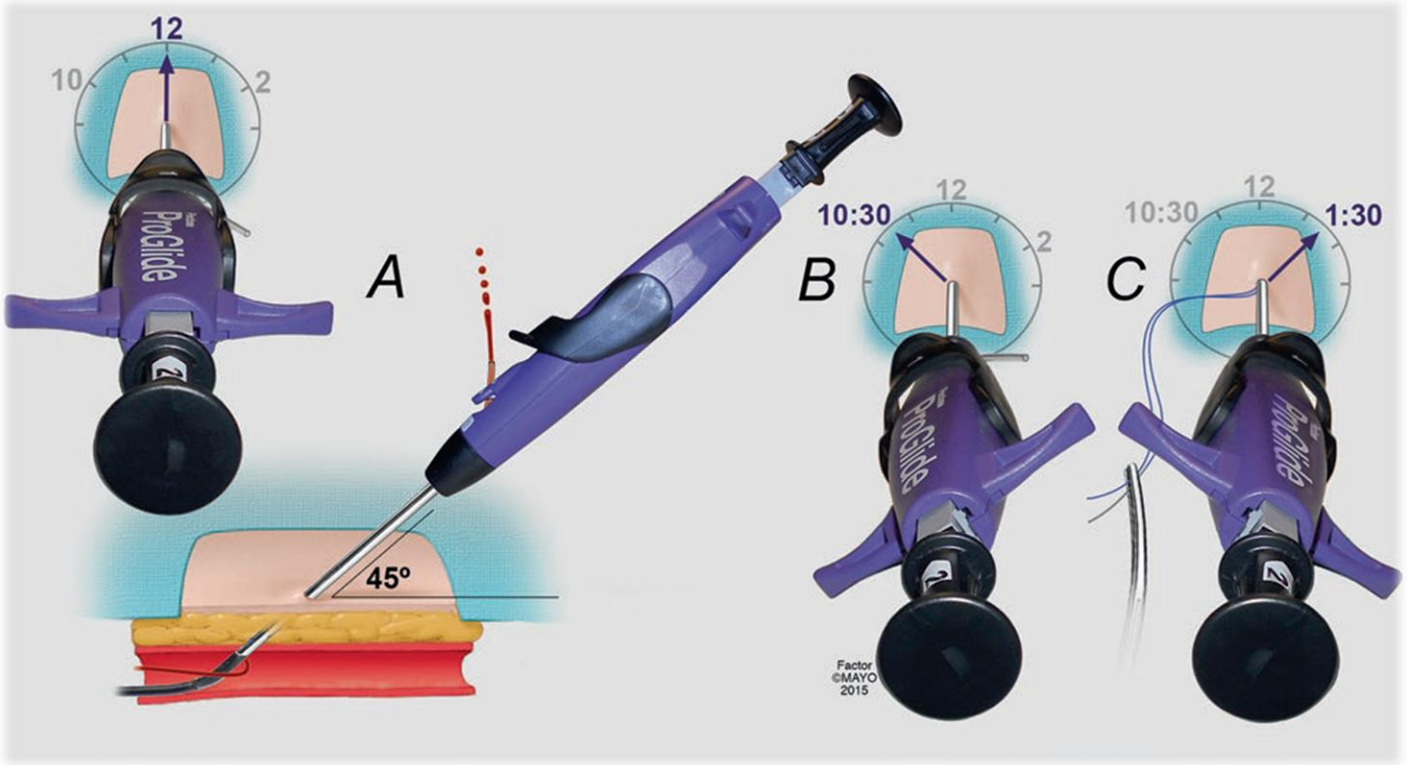




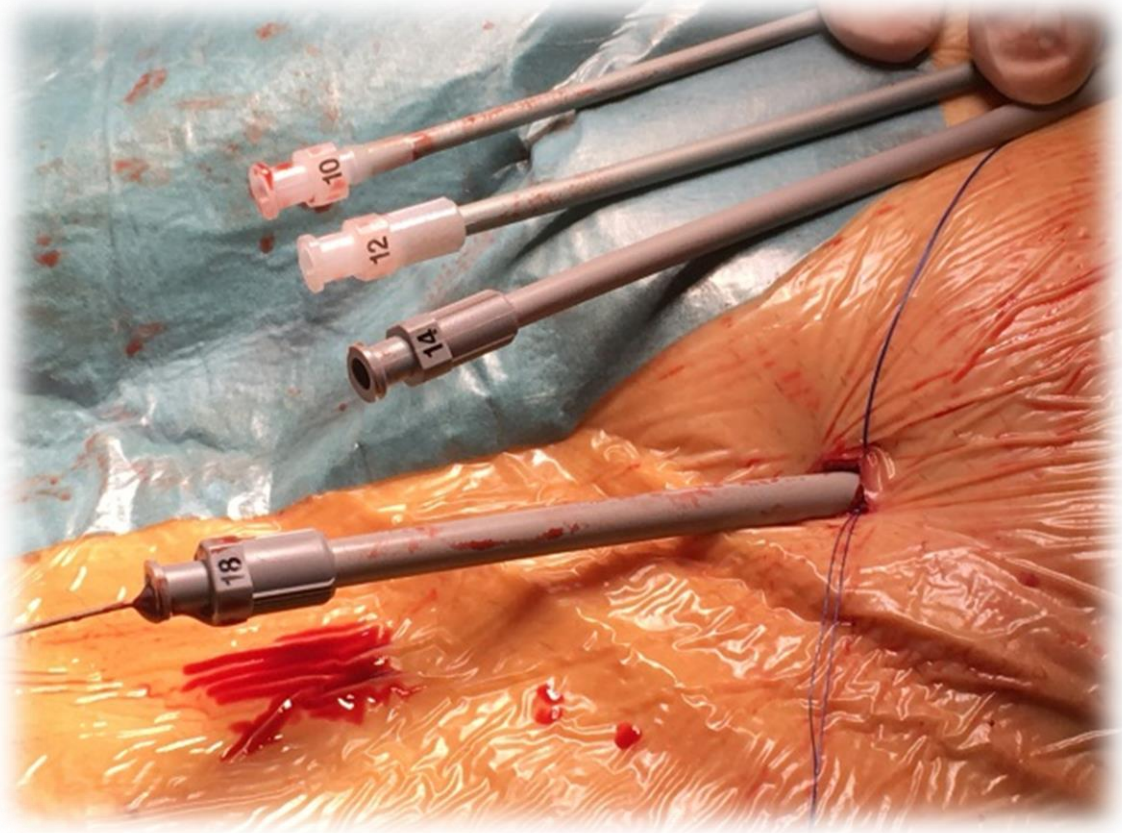
# OSR EVAR/TEVAR protocol

- US guided puncture
- Double Proglide technique



# OSR EVAR/TEVAR protocol

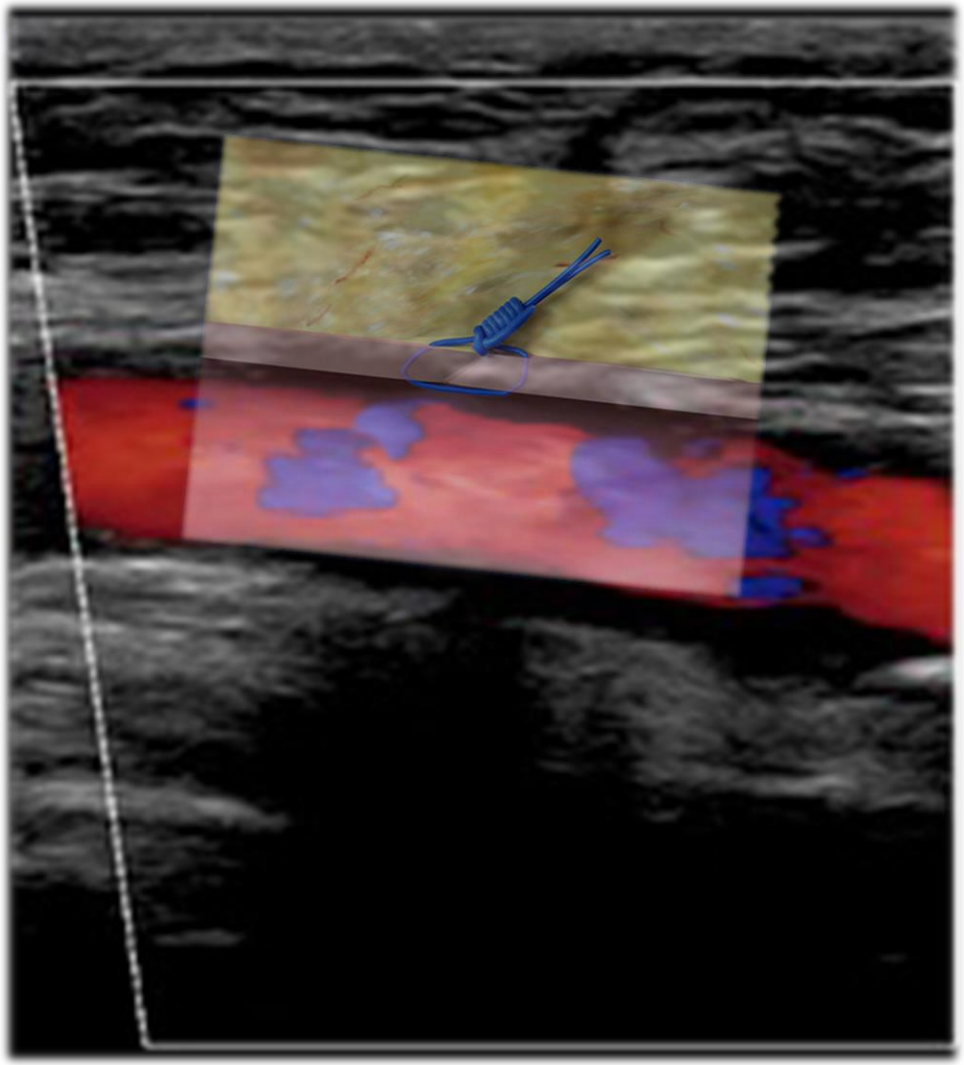
- US guided puncture
- Double Proglide technique
- Progressive dilatation



# Implant video

# OSR EVAR/TEVAR protocol

- US guided puncture
- Double Proglide technique
- Progressive dilatation
- Completion US check intraop.

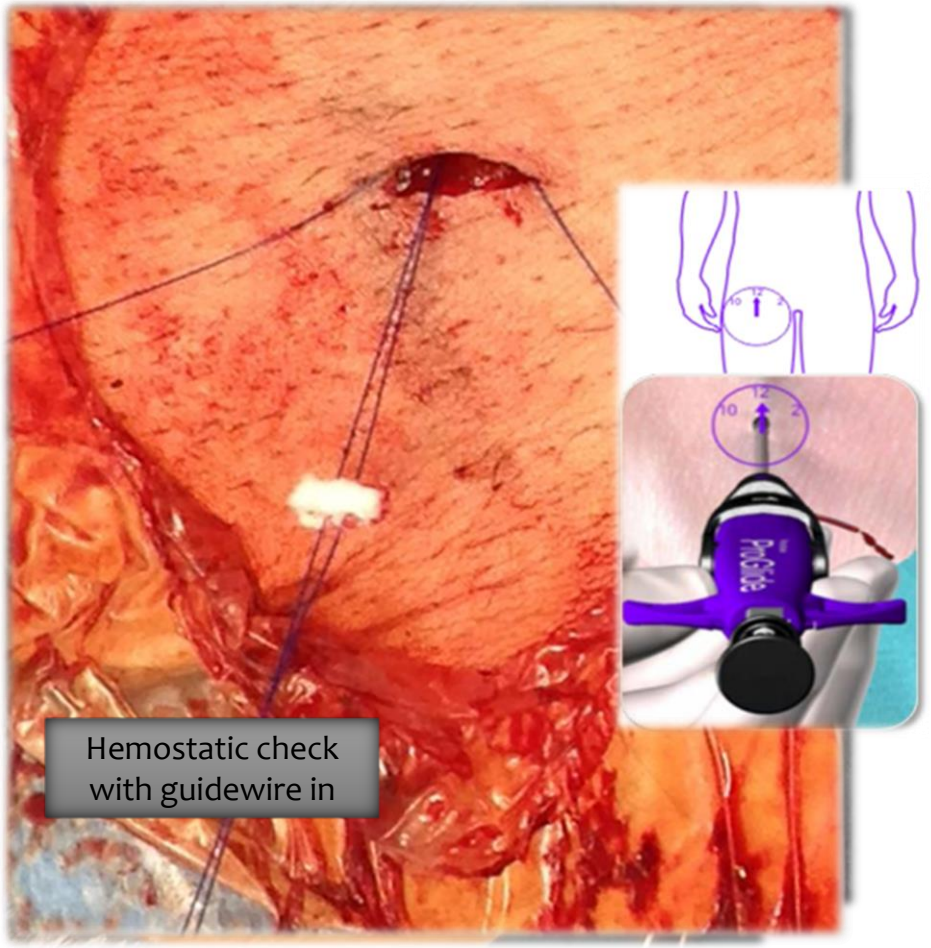


# OSR EVAR/TEVAR protocol

- US guided puncture
- Double Proglide technique
- Progressive dilatation
- Completion US check intraop.
- 24h US check

# Bailout manouvers

- 3rd PCD
- Felt interposition
- Balloon assisted  hemostasis

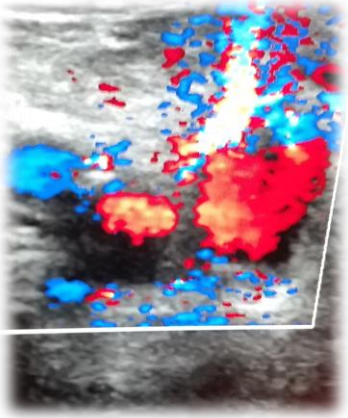
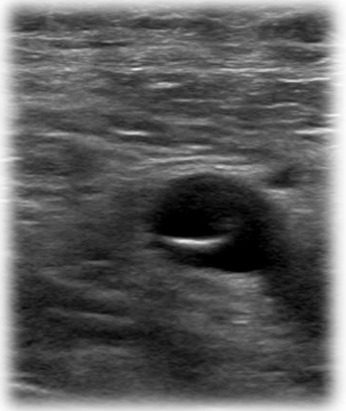


# Percutaneous femoral downsizing

Early limb reperfusion: often a third proglide is required (67%)

# San Raffaele Experience (all-comers)

PEVAR-PRO study (2016-2018) - *ClinicalTrials.gov Identifier: NCT03484013*

| | N (%) | RR |
|---|---|---|
| **Technical success** | 600/639 (93.9%) | |
| LS (> 21 Fr) | 174/191 (90.8%) | 1.81 (95% CI 0.98 to 3.34) |
| SS (≤ 21 Fr) | 426/448 (95.1%) | |
| **Complications** | | |
| Haemorrhagic | 19/39 (47.5%) |   |
| Occlusive | 20/39 (52.2%) | |

# San Raffaele Experience (2016-2018)

PEVAR-PRO study - *ClinicalTrials.gov Identifier: NCT03484013*

363 patients enrolled – 639 percutaneous femoral accesses

Univariate analysis: risk factors identification for failure

1:2 Propensity matching (**> 21 *vs* ≤ 21 Fr**)

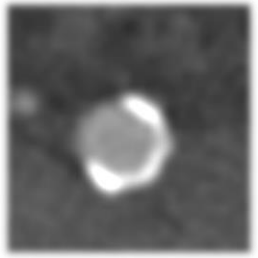
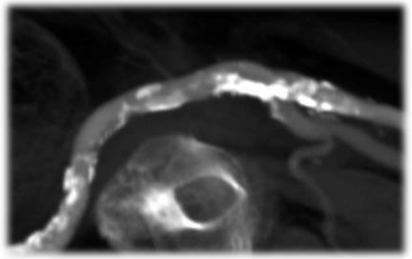
# Study univariate analysis

Technical success 93.9%

| | N (%) |
|---|---|
| **Technical success** | 600/639 (93.9%) |

| | RR | p |
|---|---|---|
| Diabetes mellitus | 3.4 | < 0.001 |
| SVS score > 12 | 2.3 | 0.017 |
| CFA stenosis > 50% | 6 | < 0.001 |
| CFA anterior calcifications | 2.3 | 0.031 |
| CFA calcifications > 1/3 vessel circumference | 2.6 | 0.002 |



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| CFA anterior calcifications | 2.3 | 0.031 |
| CFA calcifications > 1/3 vessel circumference | 2.6 | 0.002 |

| | | |
|---|---|---|
| **Introducer sheath diameter > 21 Fr** | **1.81**<br>**95% CI .98 - 3.34** | **0.054** |

# Study propensity score matching

173 accesses > 21F

**Propensity score matching 1:2**

| **173 accesses > 21F** | **346 accesses ≤ 21F** |
| --- | --- |
| Male 80% | Male 85% |
| Mean age 71 y (IQR 65 77) | Mean age 76 y (IQR 70-79) |

# Study propensity score matching

173 accesses > 21F

**Propensity score matching 1:2**

| **173 accesses > 21F** | **346 accesses ≤ 21F** |
| --- | --- |
| Technical success 90.8% | Technical success 94.2% |

# Study propensity score matching

173 accesses > 21F

RR 1.6

CI 95%: 0.85 – 3.01

**p=0.143**

Technical success
> 21F
90.8%

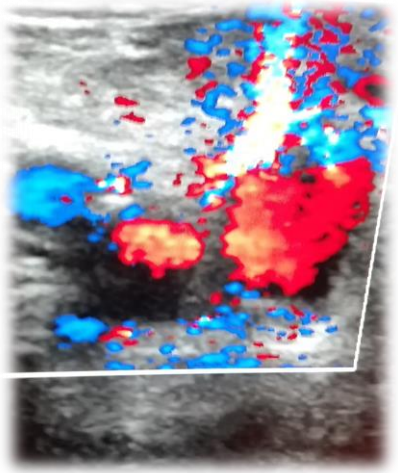
Technical success
≤ 21F
94.2%

# Large sheath (>21F)

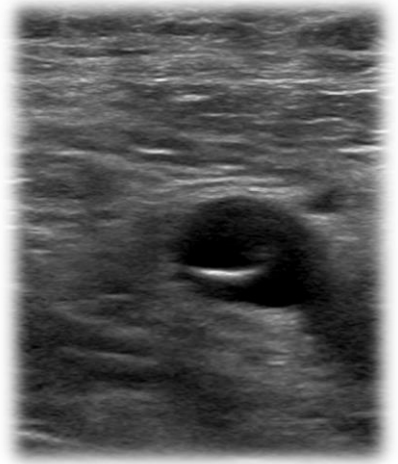
Failure (9.2%) analysis

**9.2% failure (17/173)**

Bleeding
6 cases



Occlusion
11 cases



# Previous cutdown / VCD

Failure (9.2%) analysis

**9.2% failure (17/173)**

| 173 patients | Success | p |
|---|---|---|
| **Previous cutdown** | | |
| - Yes (n=42, 24%) | 90.5% | ns |
| - No | 90.8% | |
| **Previous VCD** | | |
| - Yes (n=35, 20%) | 88.6% | ns |
| - No | 91.3% | |

# Previous cutdown / VCD

Failure (9.2%) analysis

**9.2% failure (17/173)**

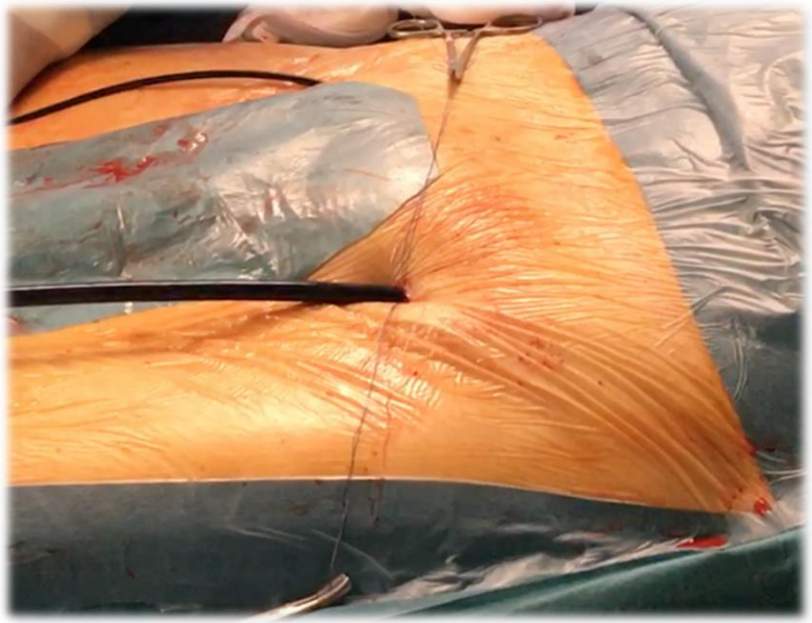
| 173 patients | Success (154) | Failure (17) | p |
|---|---|---|---|
| **Transfusion** | | | |
| - Any | 62 (40%) | 8 (47%) | ns |
| - >1 | 43 (28%) | 6 (35%) | ns |
| - >2 | 20 (13%) | 4 (23%) | ns |

| 173 patients | Length of stay (mean ± SD) | | p |
|---|---|---|---|
| **Success (n=154)** | 4.7 + 0.7 | } | ns |
| **Failure (n=17)** | 4.8 + 1.6 | | |

# Conclusions

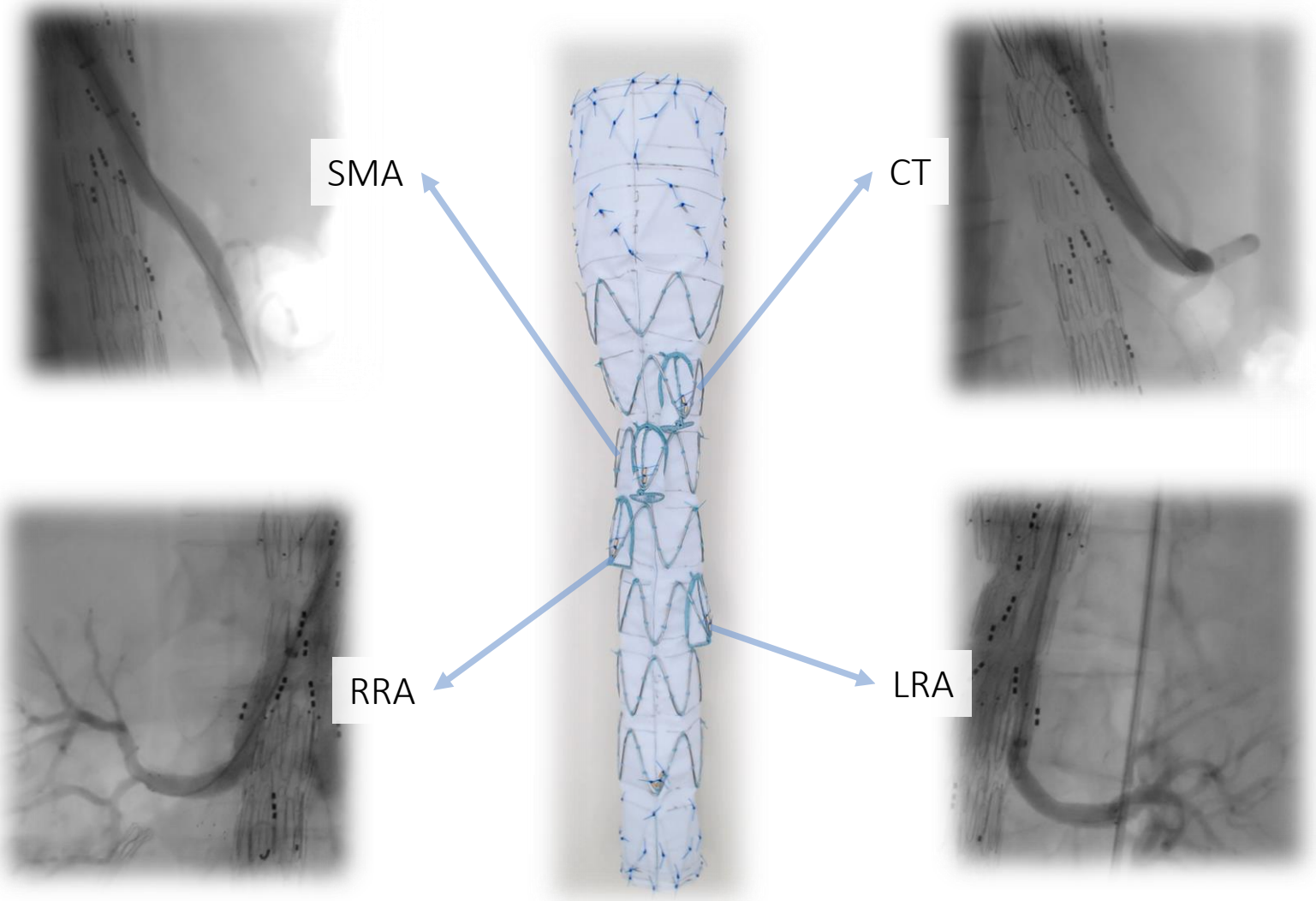
Percutaneous approach during EVAR / TEVAR

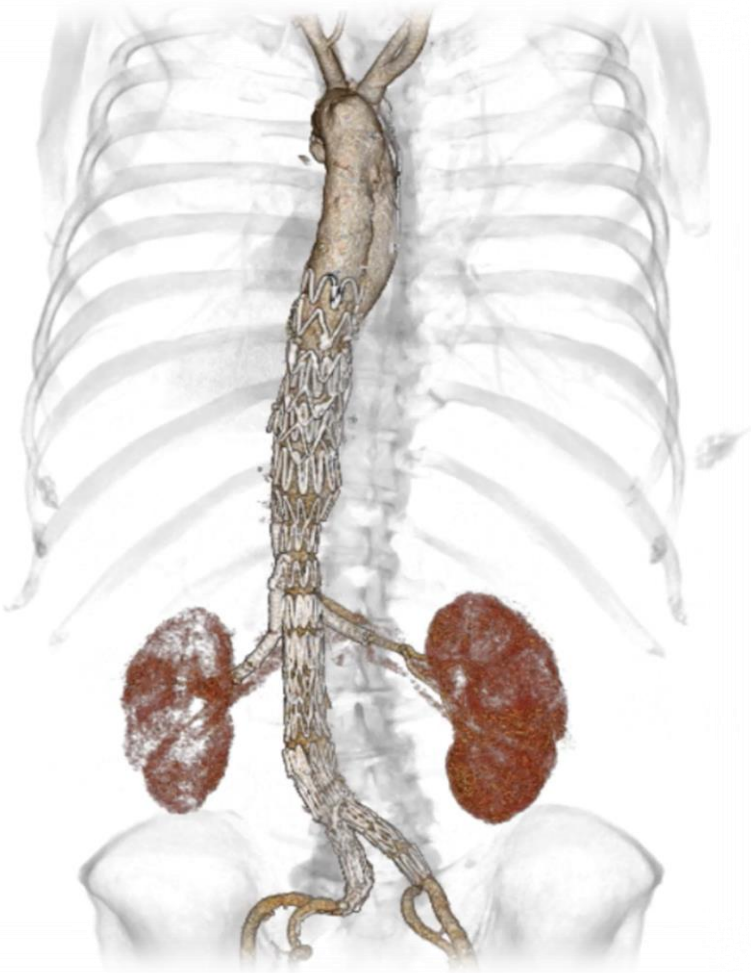
- PEVAR high technical success (≃95%) in an all-comers cohort
- Off-label use with large sheaths > 21Fr is feasible and safe
- Redo access: no higher rate of complications
- Failed access: no increase in transfusions or LOS
- Selective use in heavily calcified femoral arteries and diabetic patients



# UEA for BEVAR /FEVAR

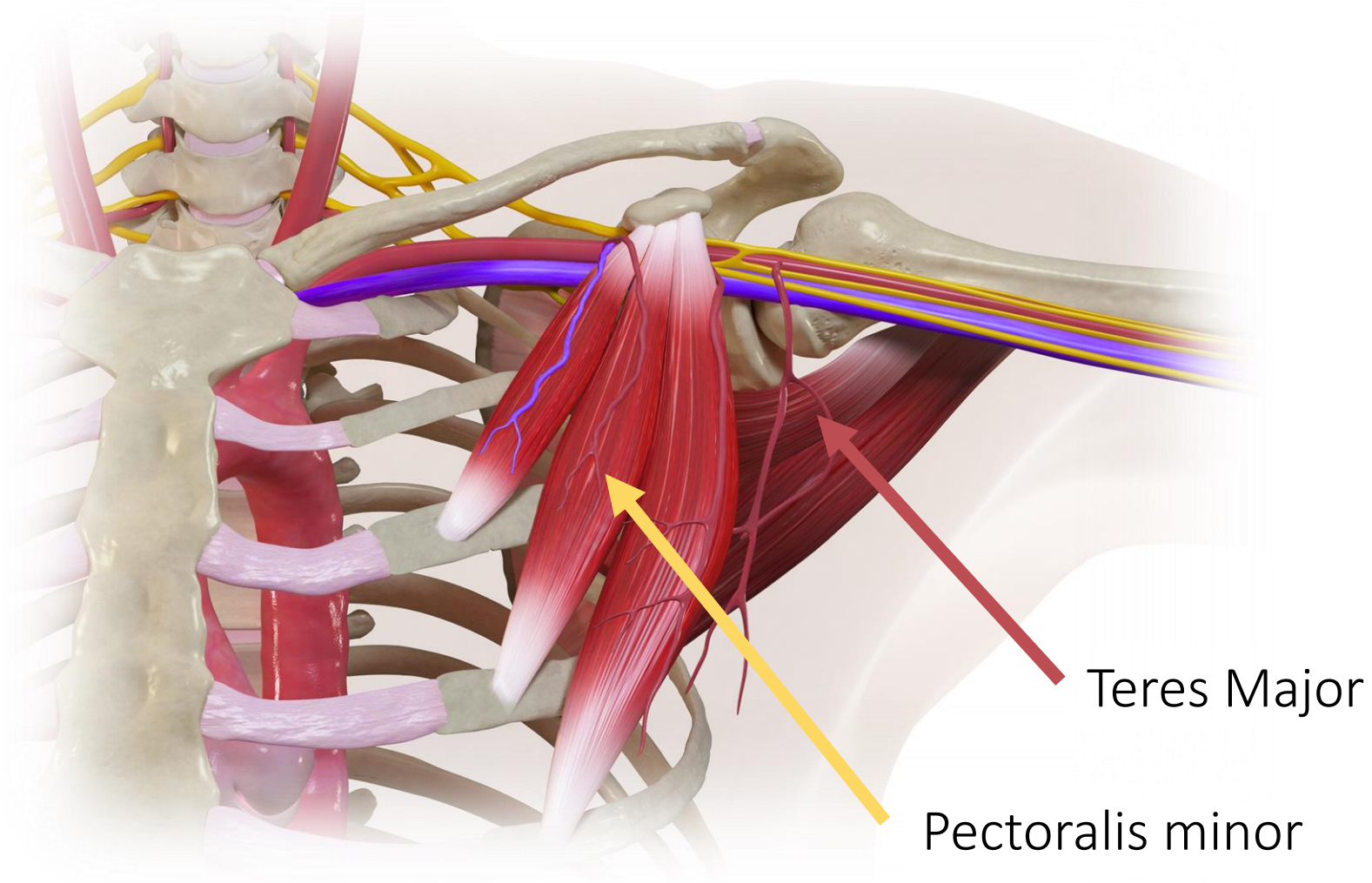
Open / percutaneous access



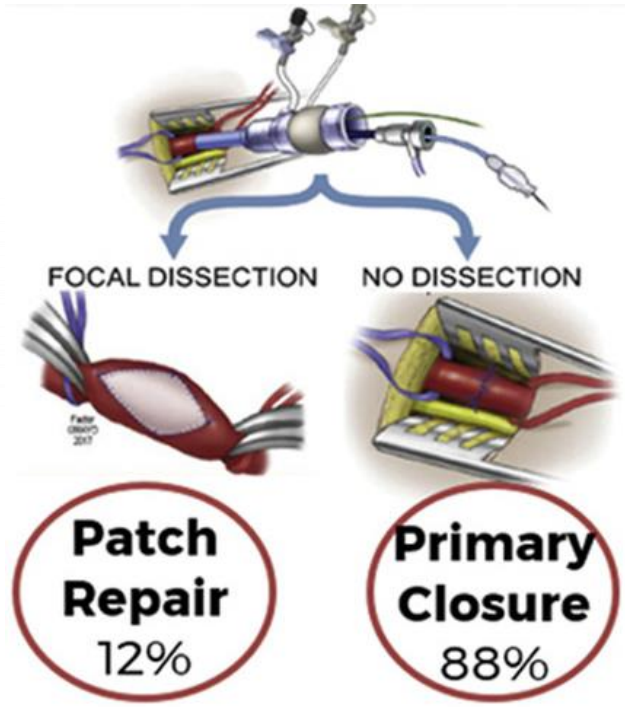
# Upper extremities access (UEA) for aortic procedure

Axillary / Brachial artery



# Open UEA for B/FEVAR

Mayo clinic (2007-2016): 243 (73%) with UEA




**UE ACCESS RELATED COMPLICATIONS**

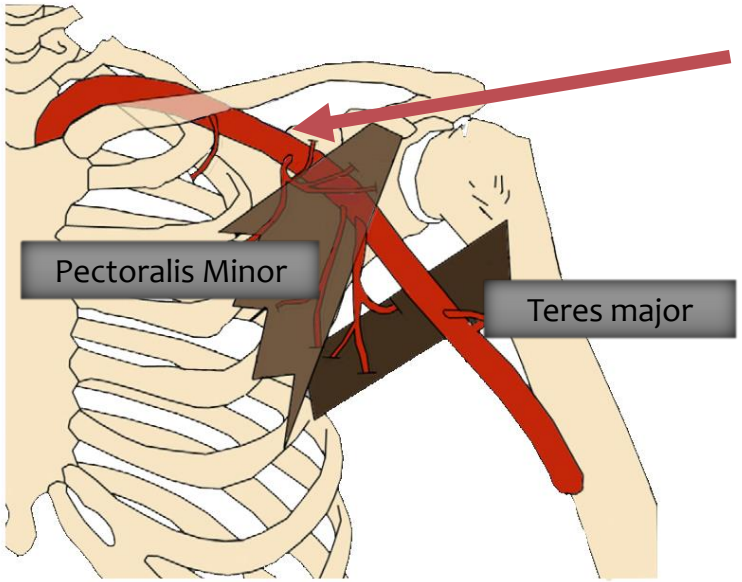
- **2%** Stroke
- **1%** Transient median nerve neuropraxia
- **0.5%** Access site hematoma requiring evacuation
- **0%** Pseudoaneurysm, distal embolus, secondary intervention

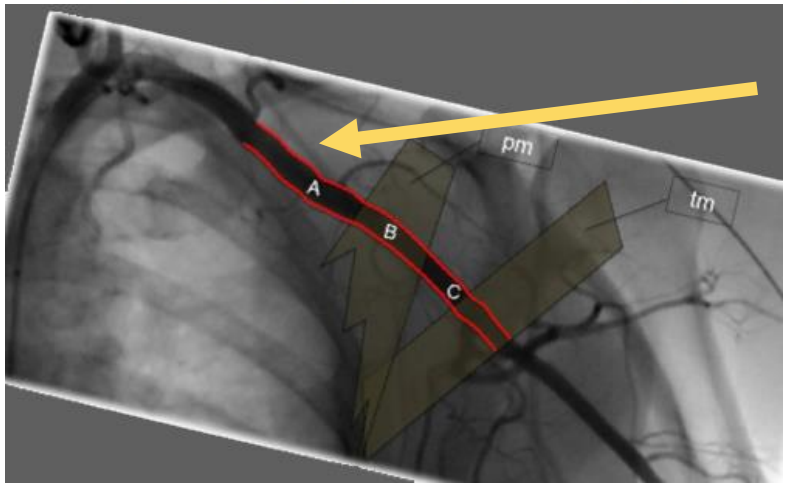


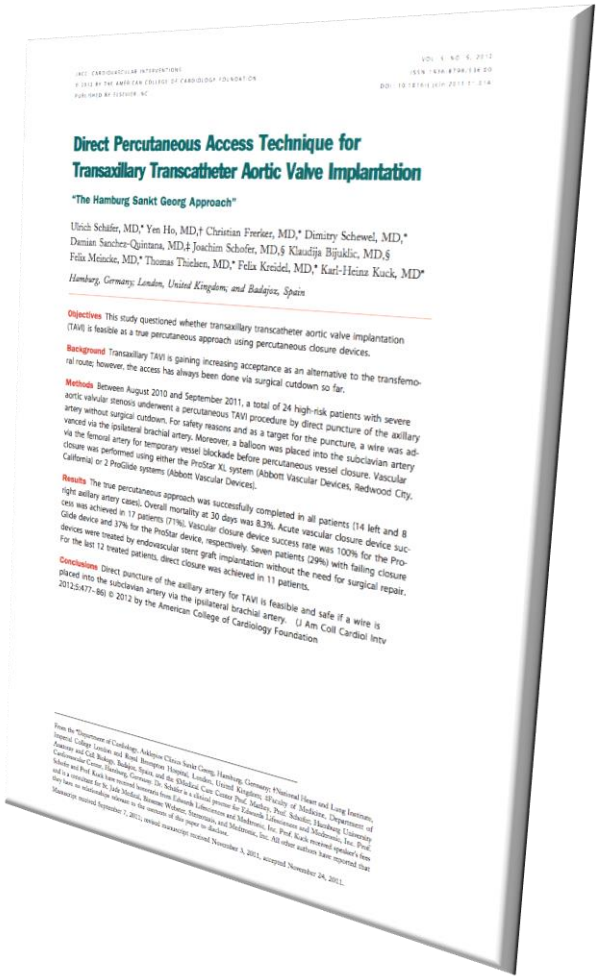
Mirza AK et al. J Vasc Surg 2019

# Percutaneous 1st segment AXA TAVI's approach

The Hamburg Sankt-Georg approach (2012)



**Direct Percutaneous Access Technique for Transaxillary Transcatheter Aortic Valve Implantation**

"The Hamburg Sankt Georg Approach"

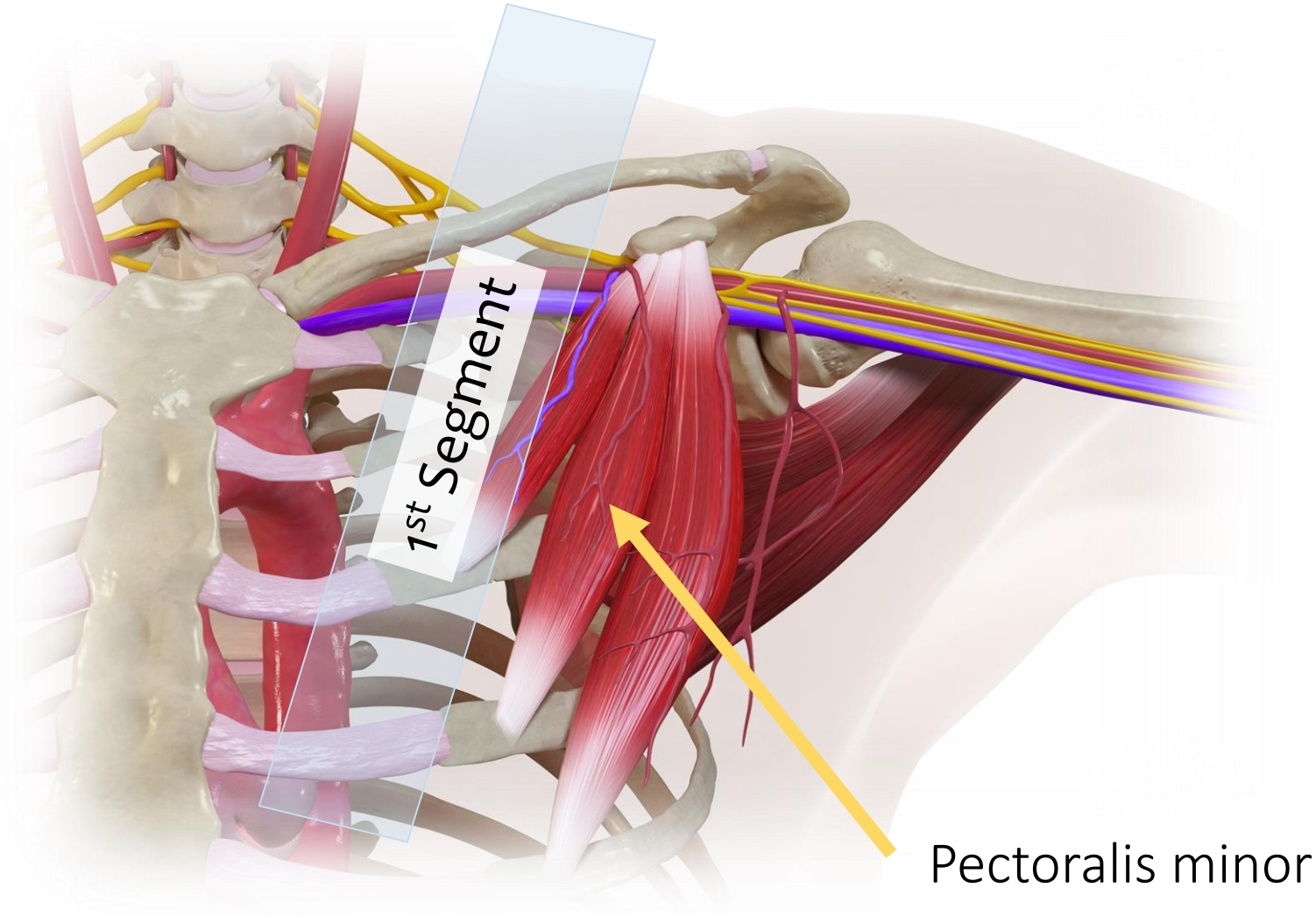
Ulrich Schäfer, MD,* Yen Ho, MD,† Christian Frerker, MD,* Dimitry Schewel, MD,* Damian Sanchez-Quintana, MD,‡ Joachim Schofer, MD,§ Klaudija Bijuklic, MD,§ Felix Meincke, MD,* Thomas Thielsen, MD,* Felix Kreidel, MD,* Karl-Heinz Kuck, MD*

*Hamburg, Germany; London, United Kingdom; and Badajoz, Spain*

Schäfer et al. JACC 2012
Schäfer et al. Int J Cardiol. 2017

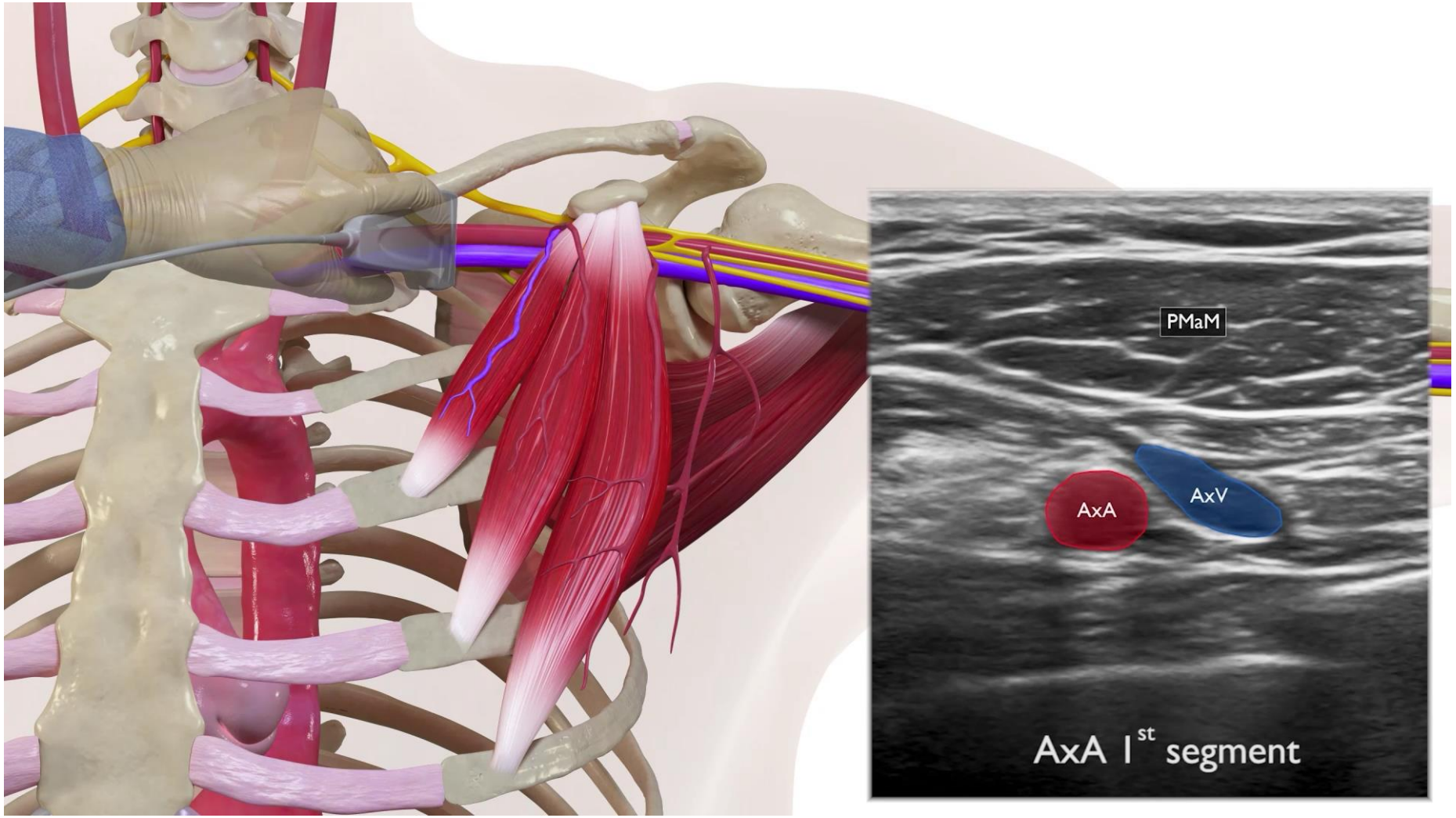
# Large sheaths puncture site

1st Segment



# Axillary ecoguided puncture

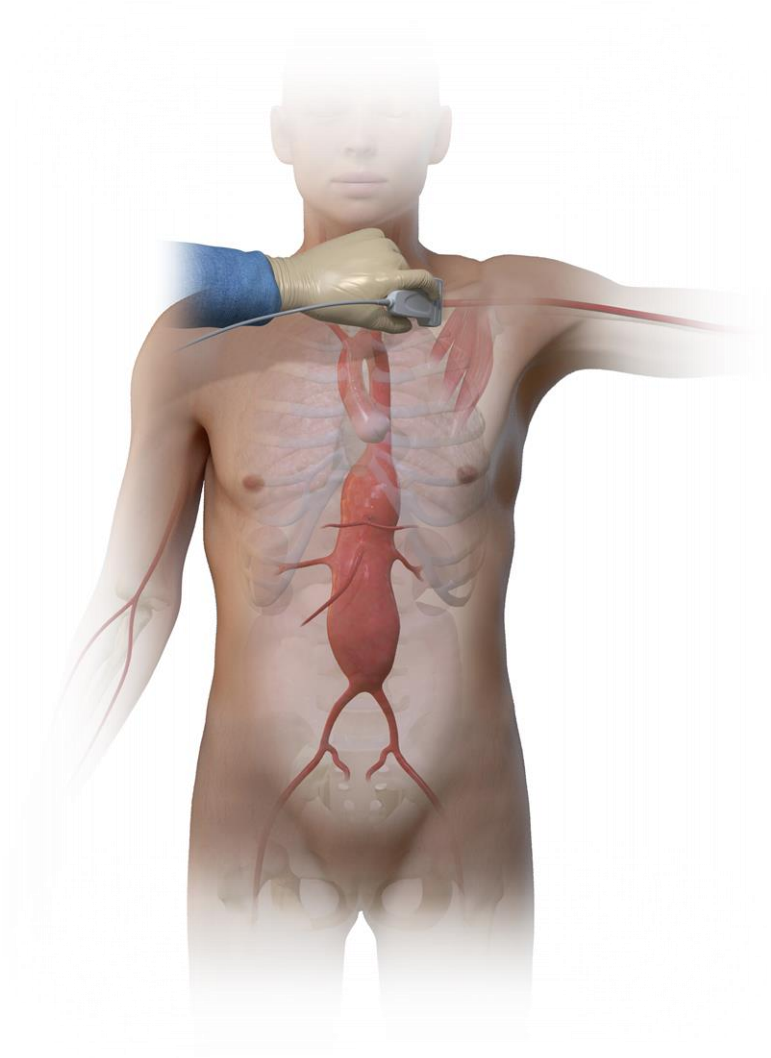
All cases




Bertoglio et al. J Vasc Surg 2018
Online video

# Standard double Proglide implant

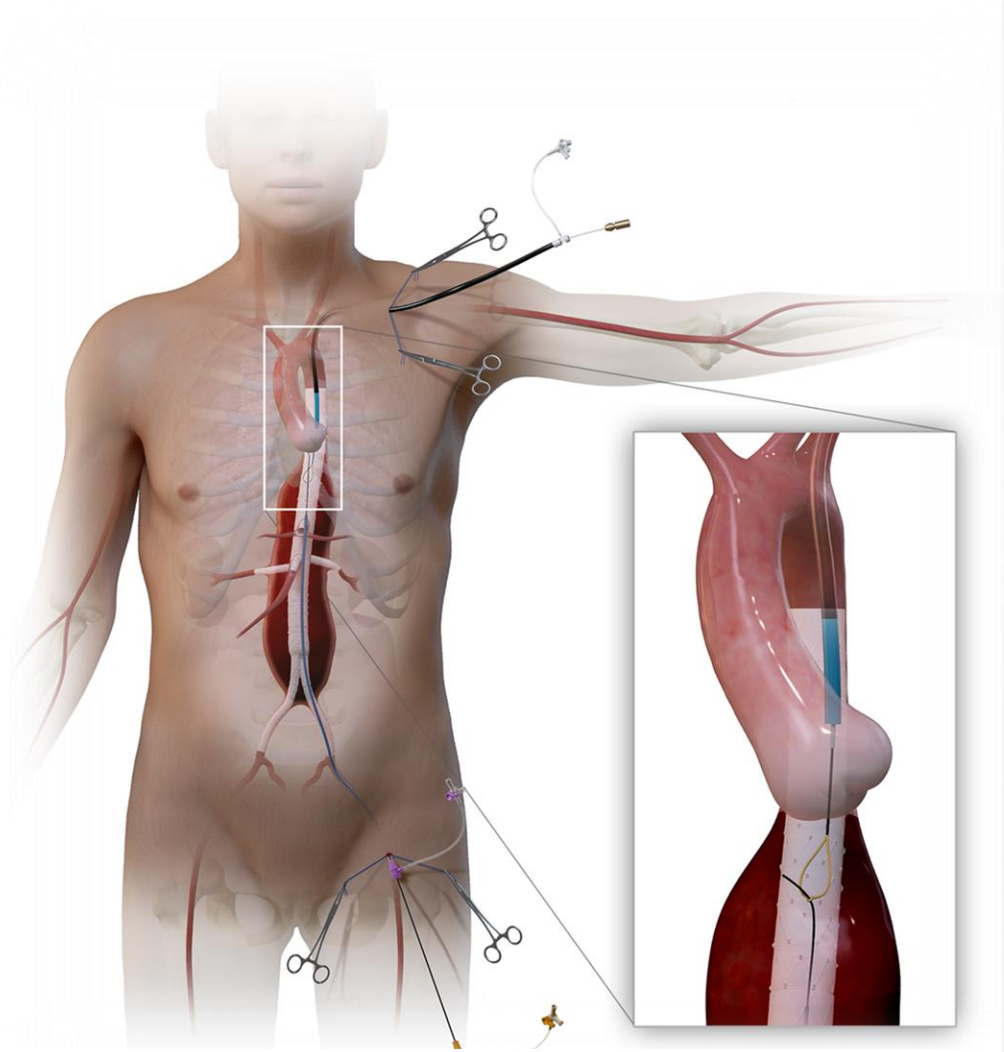
According to IFU

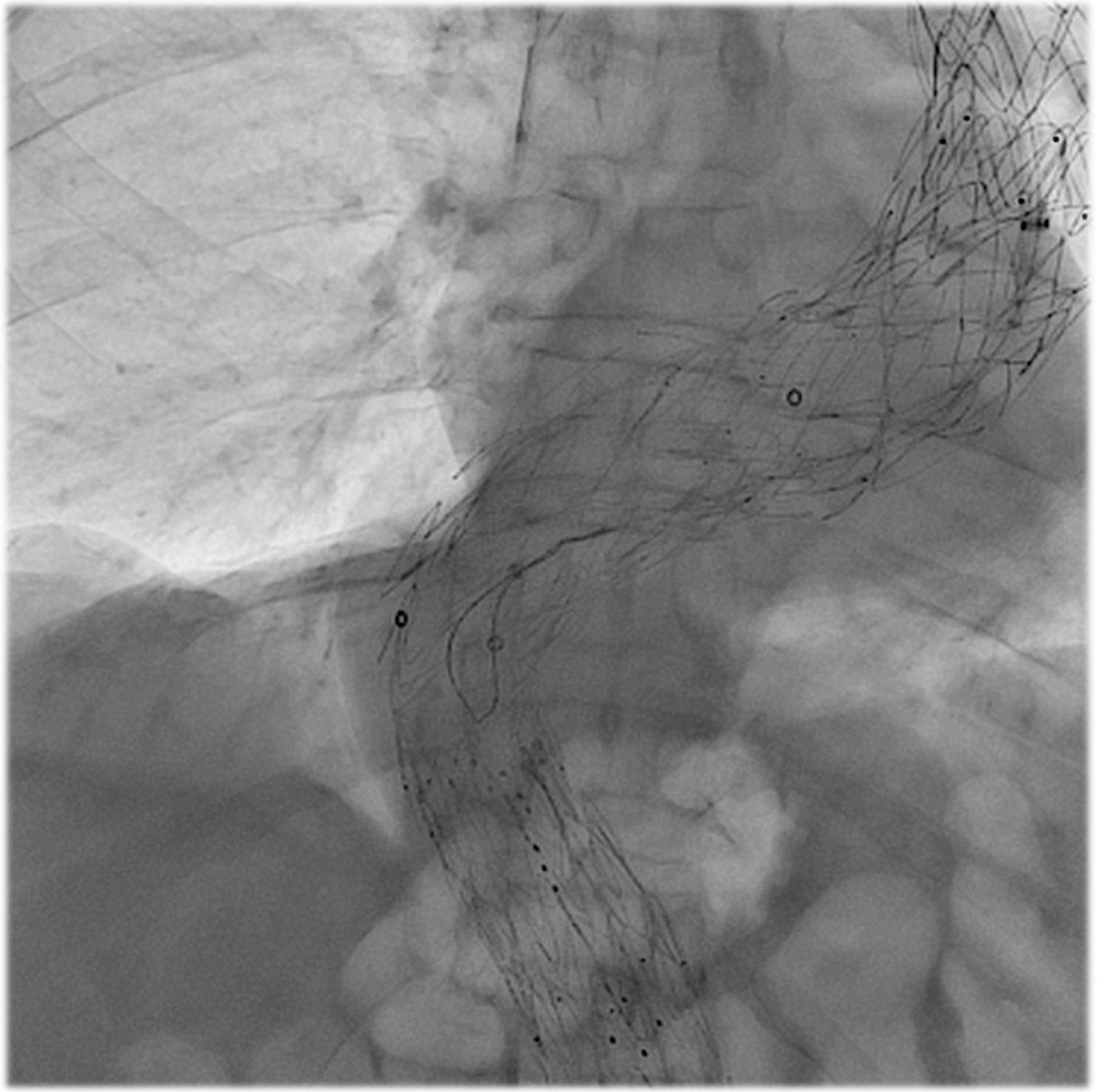


Bertoglio et al. J Vasc Surg 2018
Online video

# AXA closure 1st step

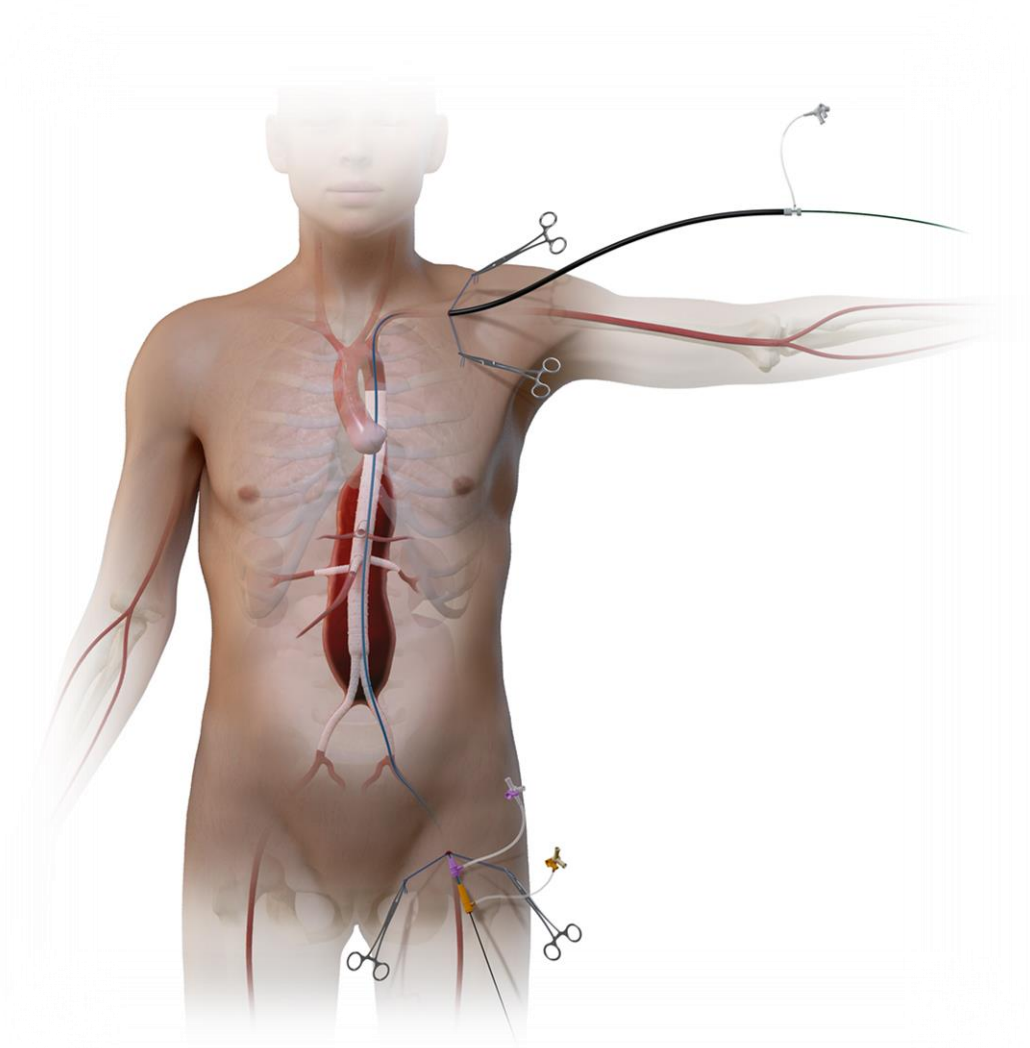
In-graft through-and-through wire and sheath rendez-vous





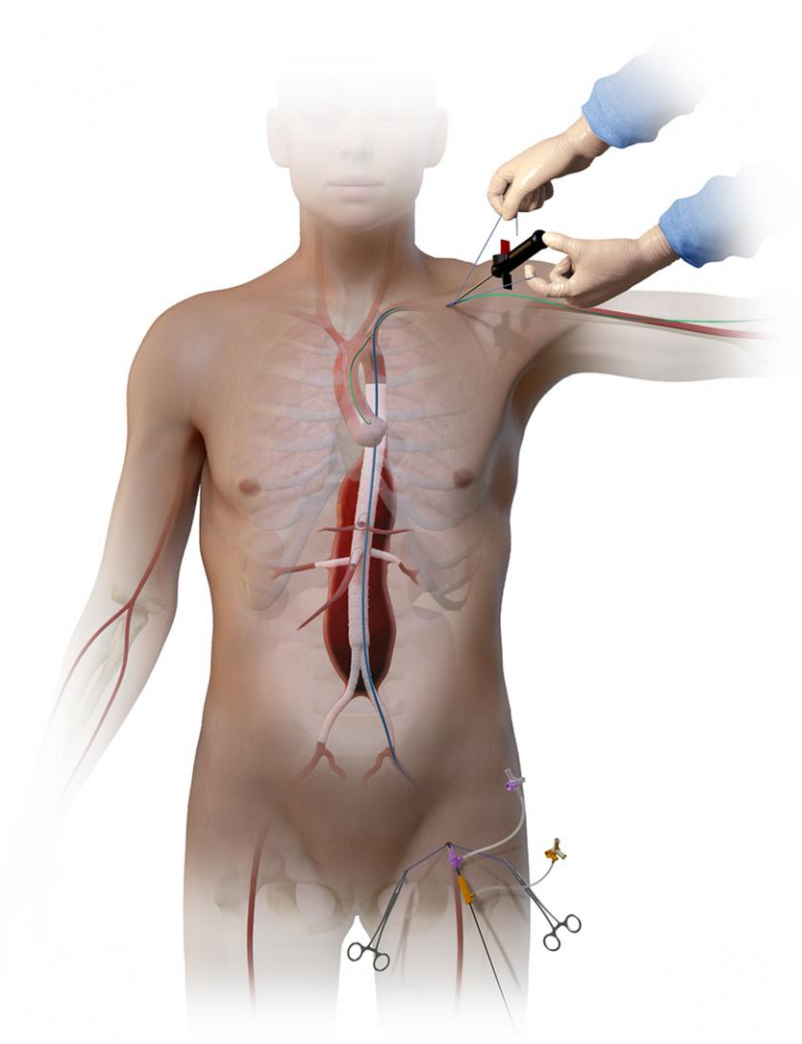
# AXA closure 2nd step

Sheaths unlink and disassemble the through-and-through



# AXA closure 3rd step

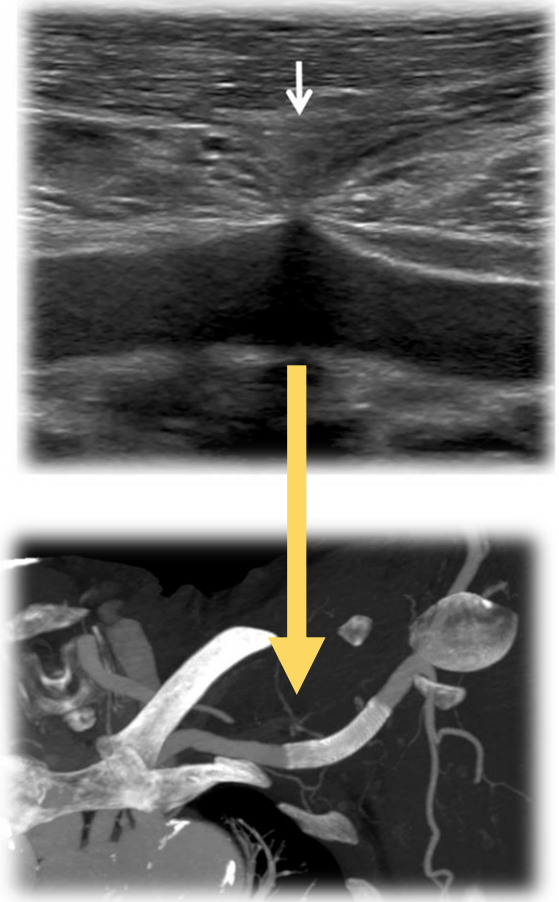
Sheaths unlink and balloon-assisted sheath removal



# pAXA study: 30-day outcomes

Technical success: 56 cases (93%) - Stroke: 1 case (1.7%)

| | |
|---|---|
| **Primary technical success** | **56 (93%)** |
| Any 30-day open conversion | 0 |
| **Assisted technical success** | **60 (100%)** |
| Need for bare stents for dissection | 1 (2%) |
| Need for covered stents for bleeding | 3 (5%) |
| Access site hematoma (any) | |
| Clinically evident | 2 (3%) |
| Radiological (US or CT assessment) | 5 (8%) |
| Access site false aneurysm (any) | 0 |
| Access artery thrombosis (any) | 0 |
| Peripheral neurological complications | |
| Permanent | 0 |
| Temporary paraesthesia < 48 hours | 3 (5%) |

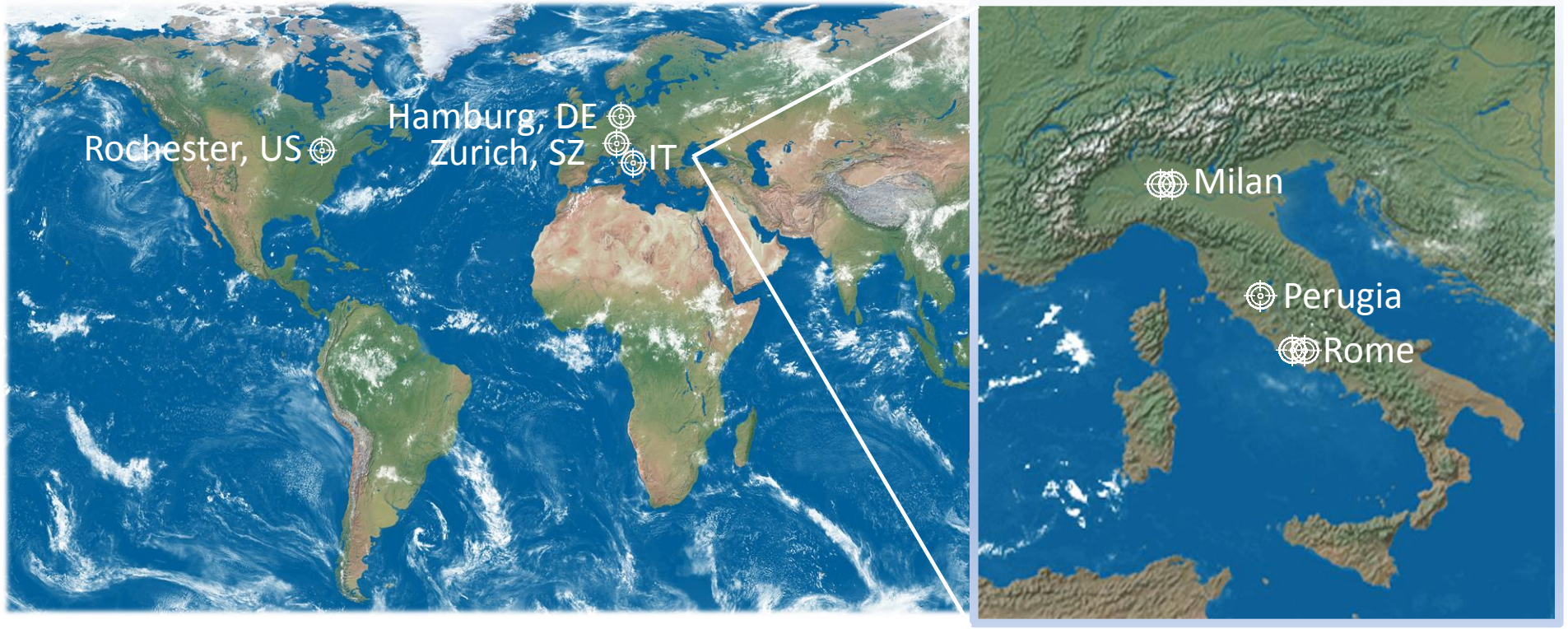


# d) Total percutaneous approach (univariate analysis)

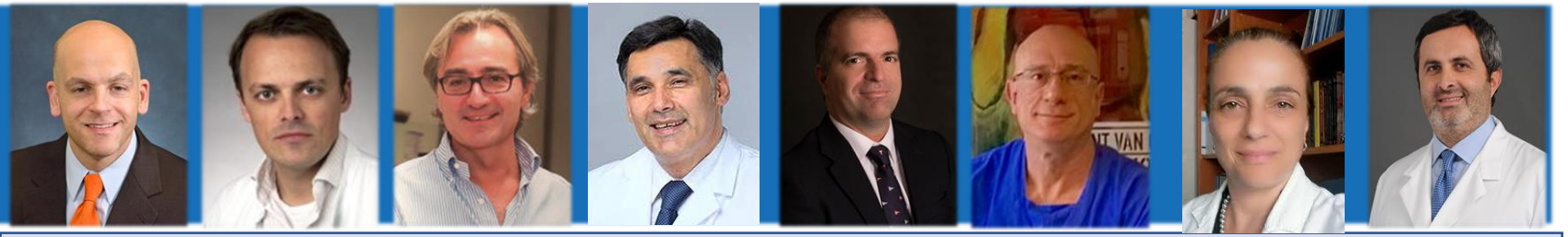
| | Total PF/BEVAR (n=51) | Cutdown F/BEVAR (n=29) | *p* value |
|---|---|---|---|
| **Local anaesthesia** | **31 (62%)** | **11 (38%)** | **.039** |
| **Procedural time (min)** | **260 (210-350)** | **333 (280-385)** | **.013** |
| **OR occupation time (min)** | **330 (297-450)** | **431 (345-492)** | **.008** |
| Fluroscopy time (min) | 78 (63-96) | 90 (66-114) | ns |
| DAP (cGycm$^2$) | 505 (233-789) | 480 (305-1049) | ns |
| Contrast media (mL) | 250 (180-360) | 295 (220-450) | ns |
| Estimated blood loss (mL) | 200 (100-500) | 450 (0-600) | ns |
| Mean n. of RBC transfusions | 2 (0-4) | 3 (1-5) | ns |

# Future

## pAXA International registry - EC submission




PARTICIPATING PHYSICIANS



| M. Stoner | L. Conradi | M. Montorfano | G. Rancic | L. Bertoglio | M. Lenti | S. Ronchey | G. Pratesi |
|---|---|---|---|---|---|---|---|
| Rochester Univerity | Heart Center | San Raffaele H. | Univeristy Hospital | San Raffaele H. | S. Maria Misericordia H. | S. Filippo Neri H. | Tor Vergata |
| ROCHESTER | HAMBURG | MILAN | ZURICH | MILAN | PERUGIA | ROME | ROME |

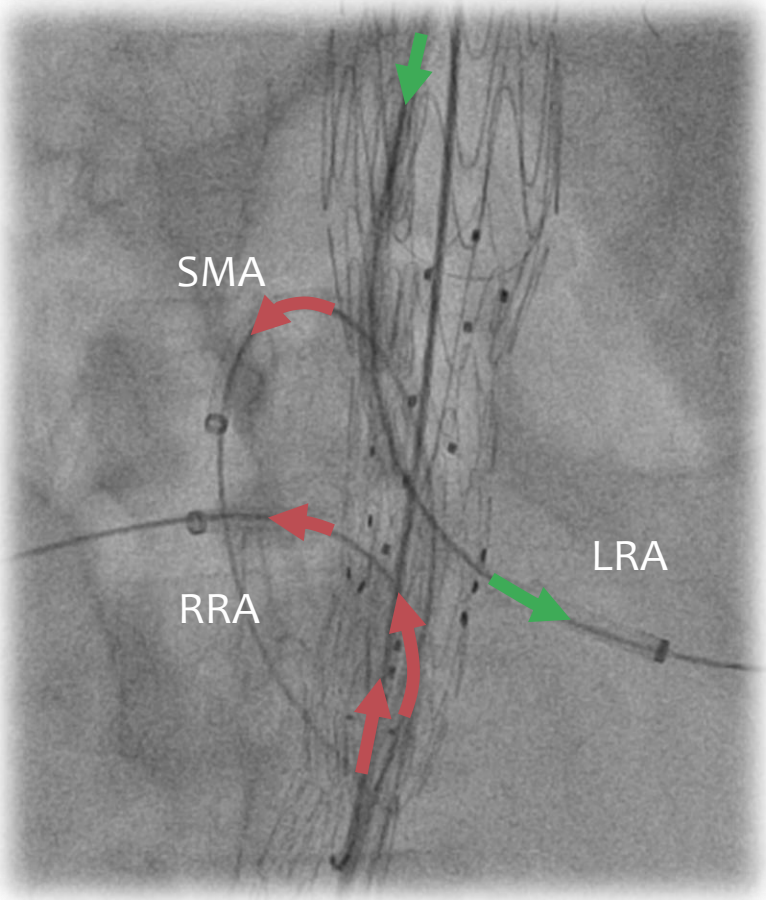
# Call for registry patecipants

e-mail: bertoglio.luca@hsr.it

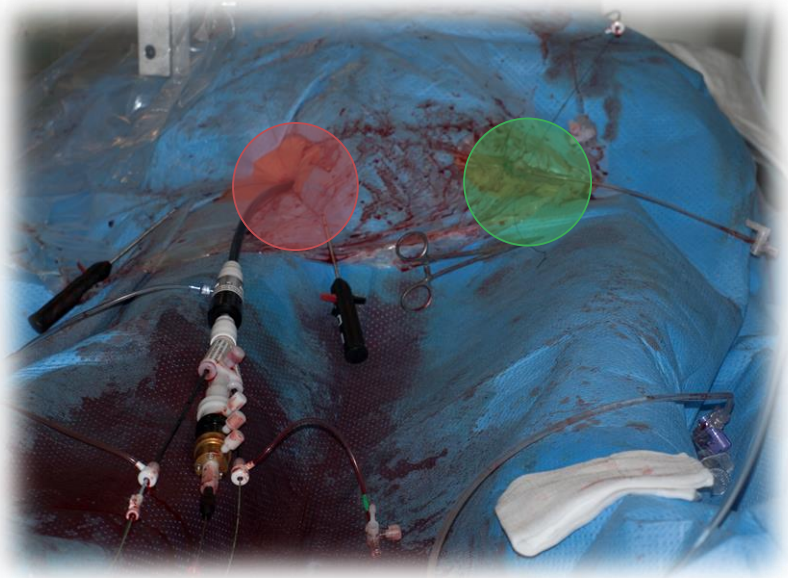
# Discussion

## D) More Extensive use of upper extremities access


Preloaded graft
(2 vessels from below)




one vessel from above

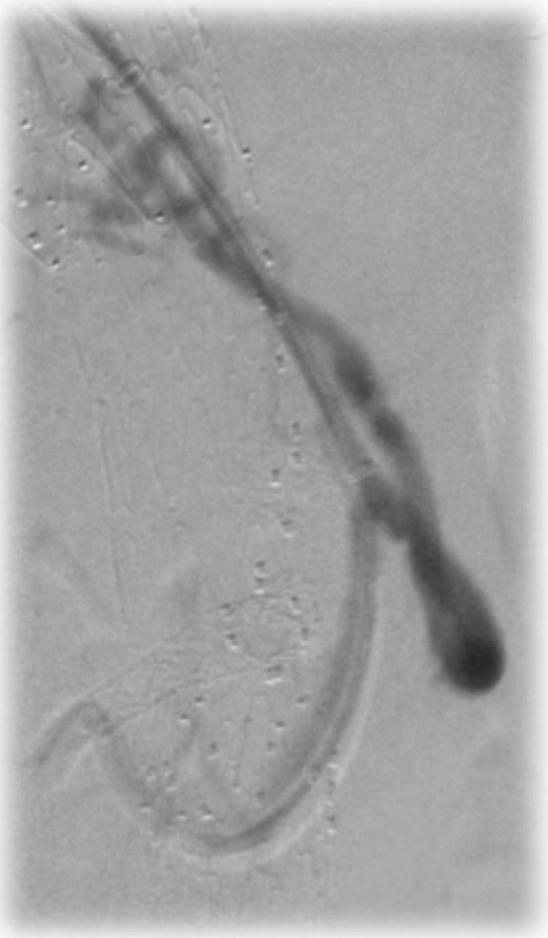


No contralateral femoral access

# FEVAR and upper extremities access

Down-looking target vessels

Acute down-looking orientation

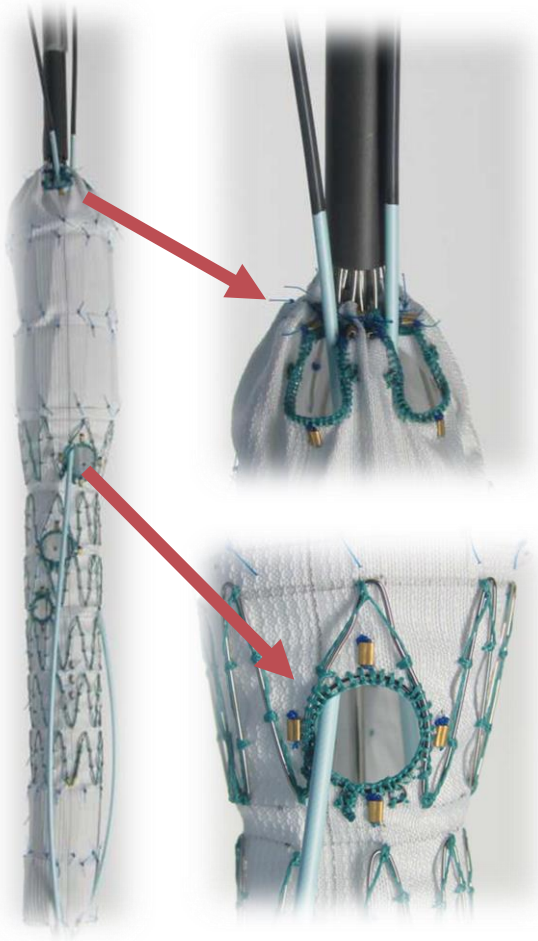


Stenting from above

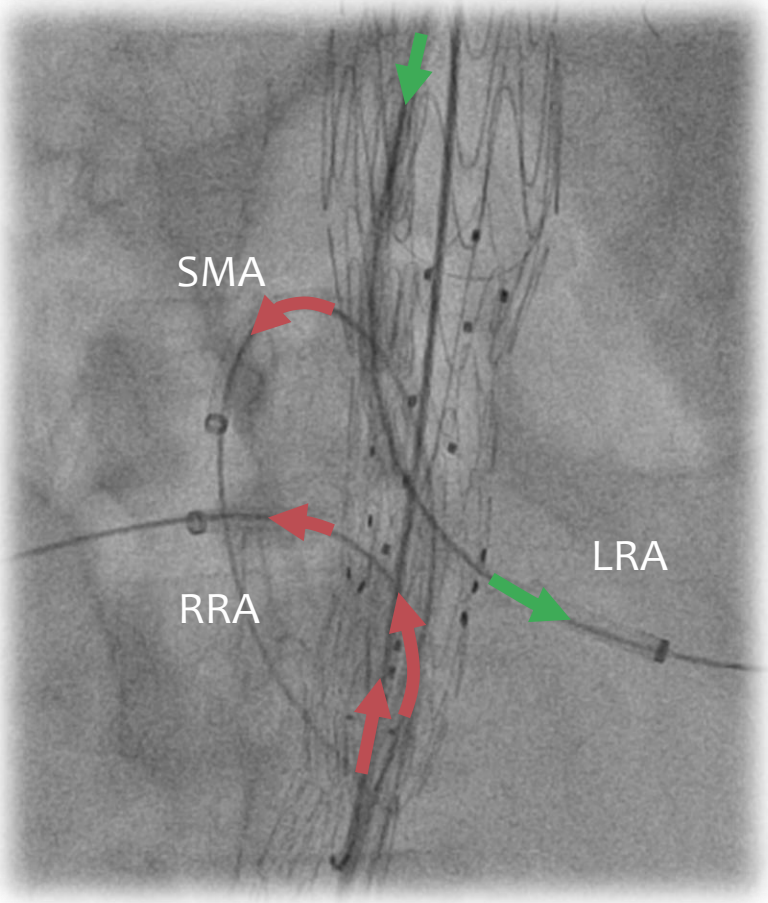
Completion CT scan

# Discussion

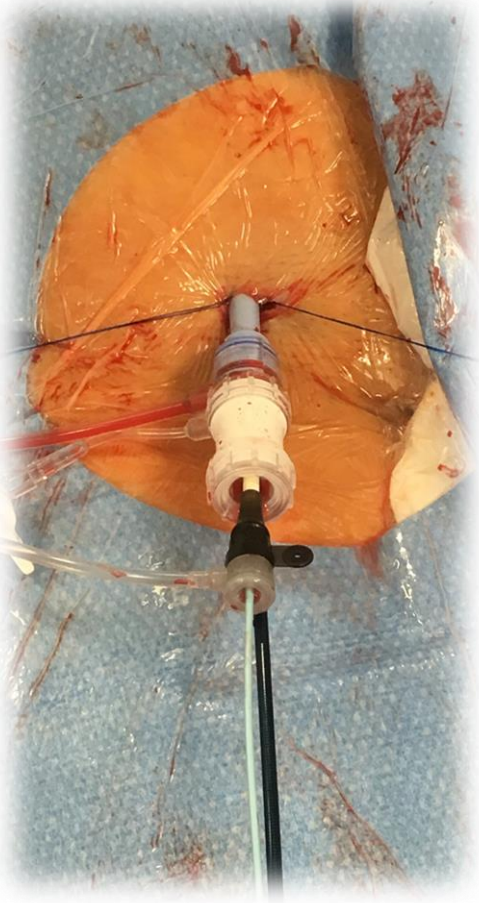
D) More Extensive use of upper extremities access



Indwelling catheter



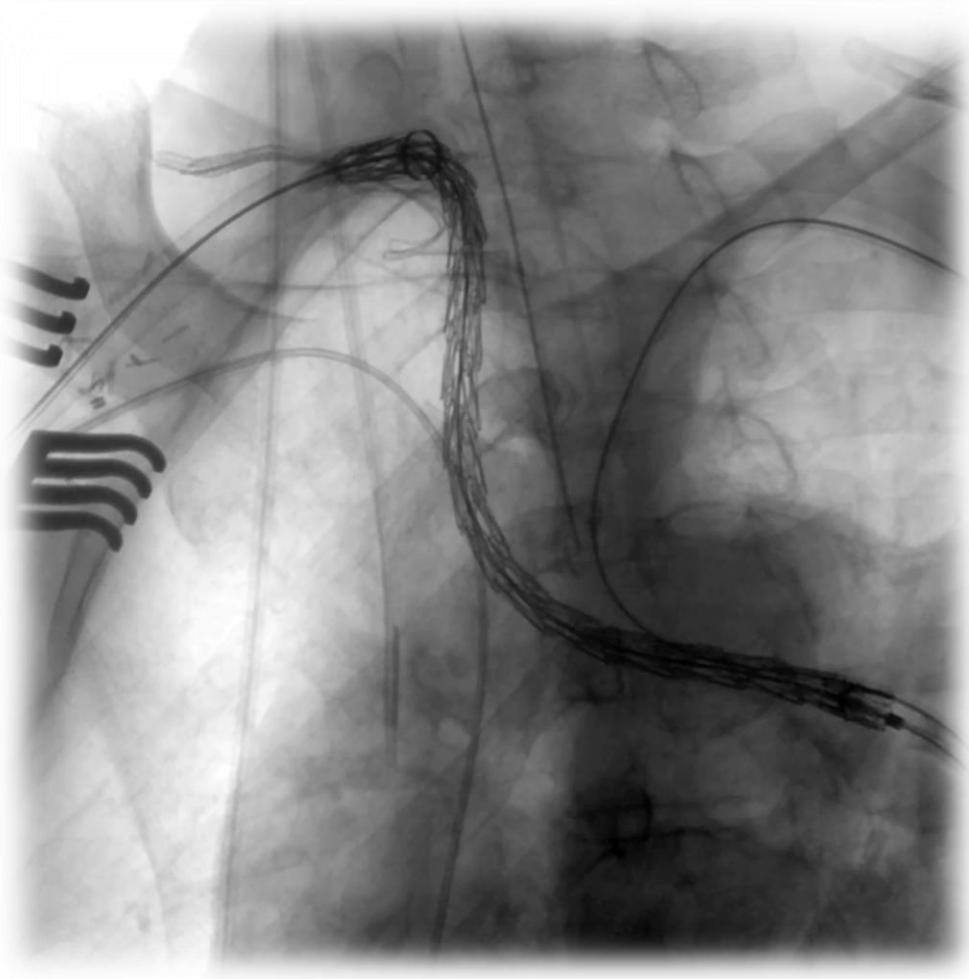

one vessel from above



14Fr. (2 vessels)

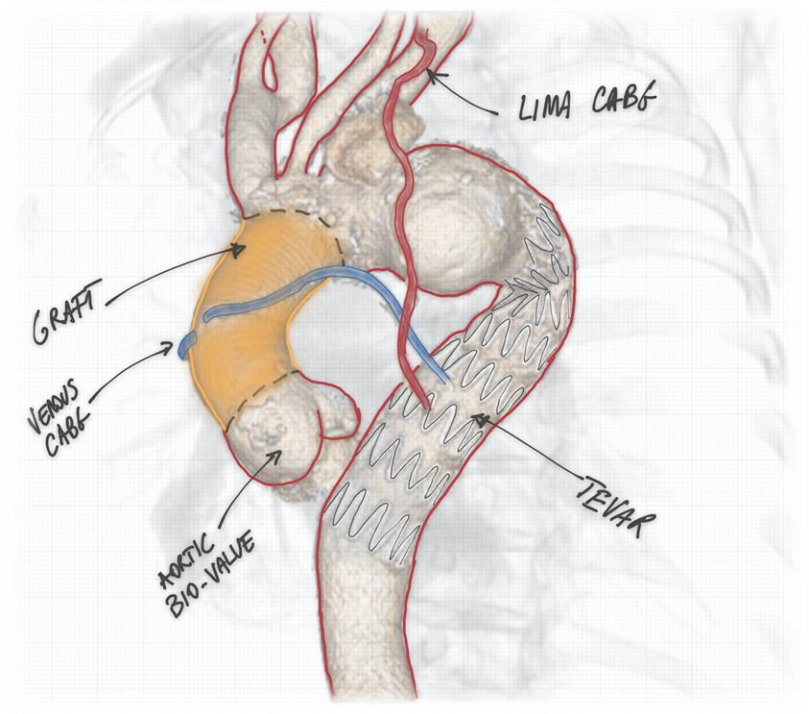
# UEA for TEVAR in Leriche syndrome

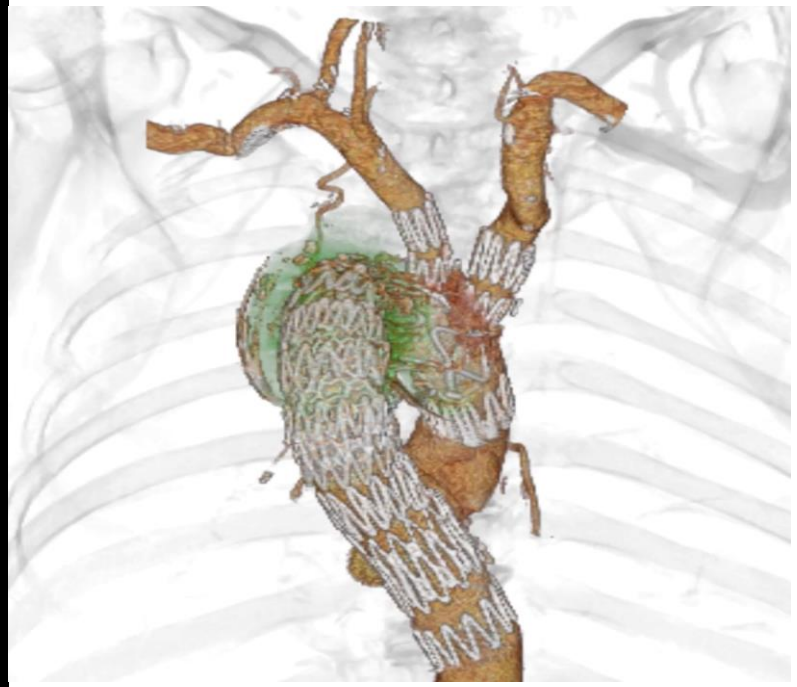
Axillary open access



# UEA for endo arch repair in bovine arch

Axillary open access

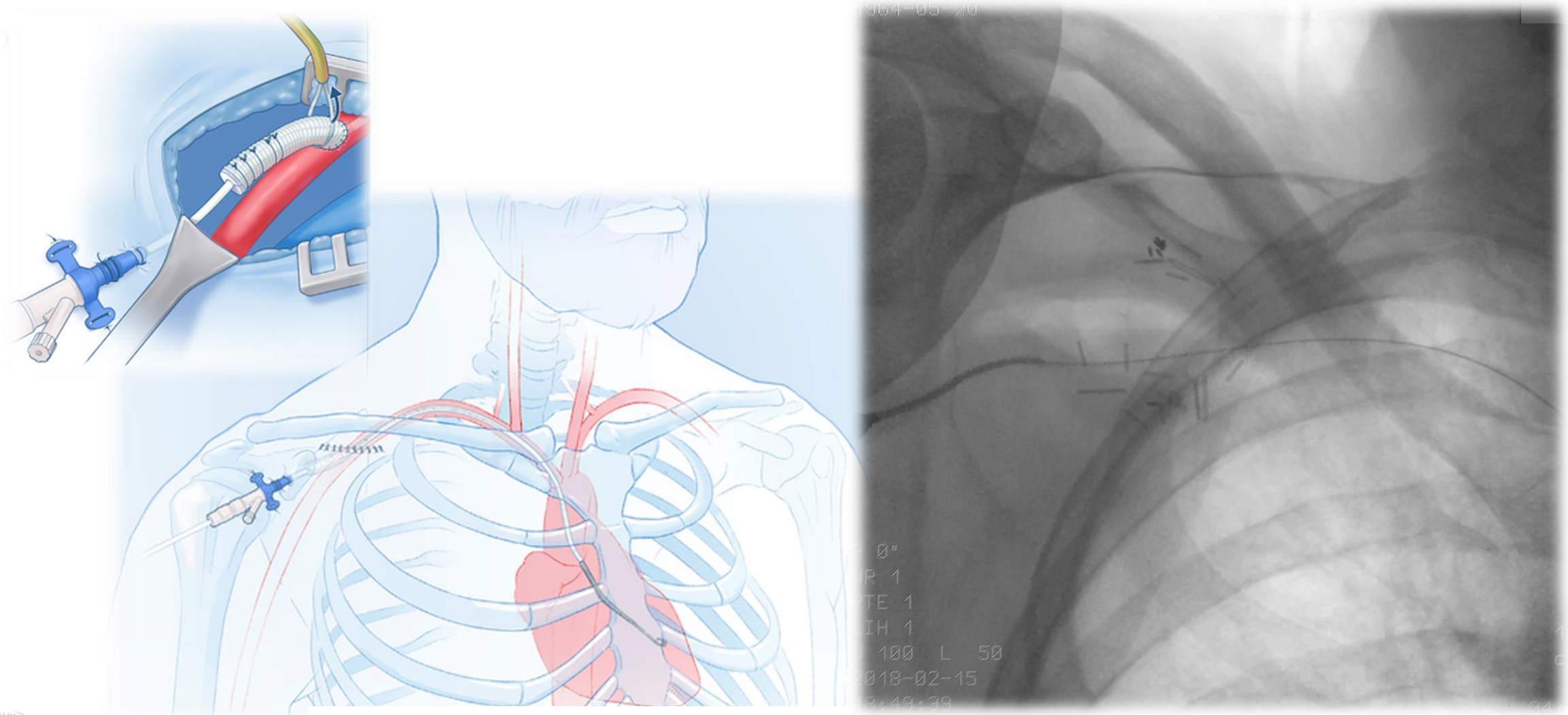


7 cases treated at OSR (2016-2019)

# UEA for Impella ventricular assist device (VAD)

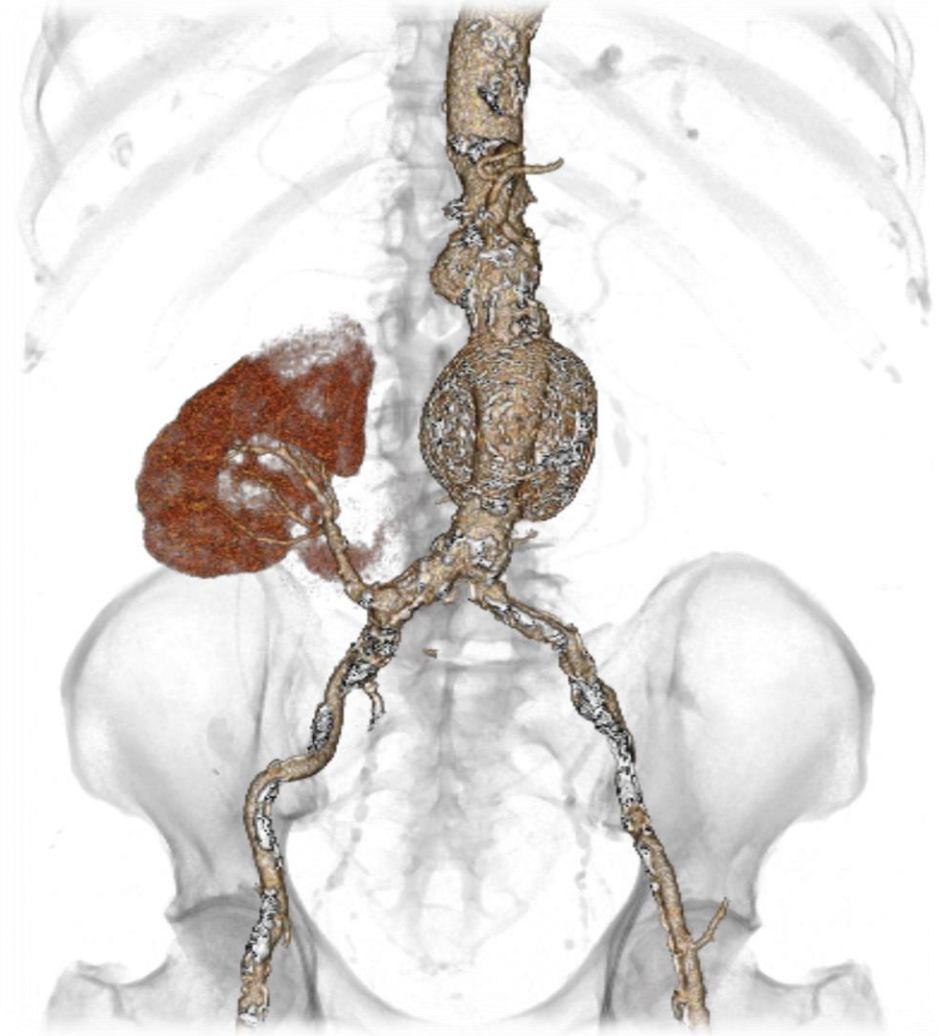
Axillary open access with conduit



Bertoglio et al. J Card Surg. 2019

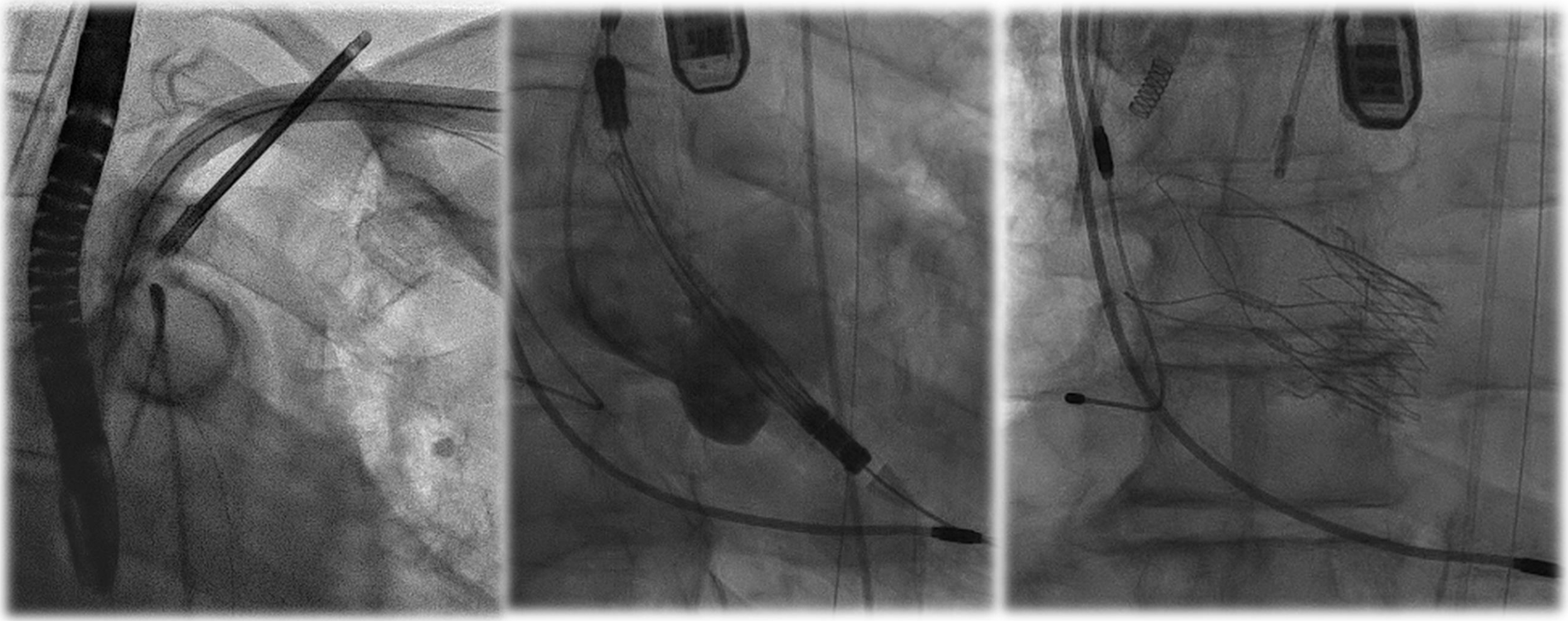
# UEA for contralateral limb deployment in EVAR

Axillary open / percutaneous access



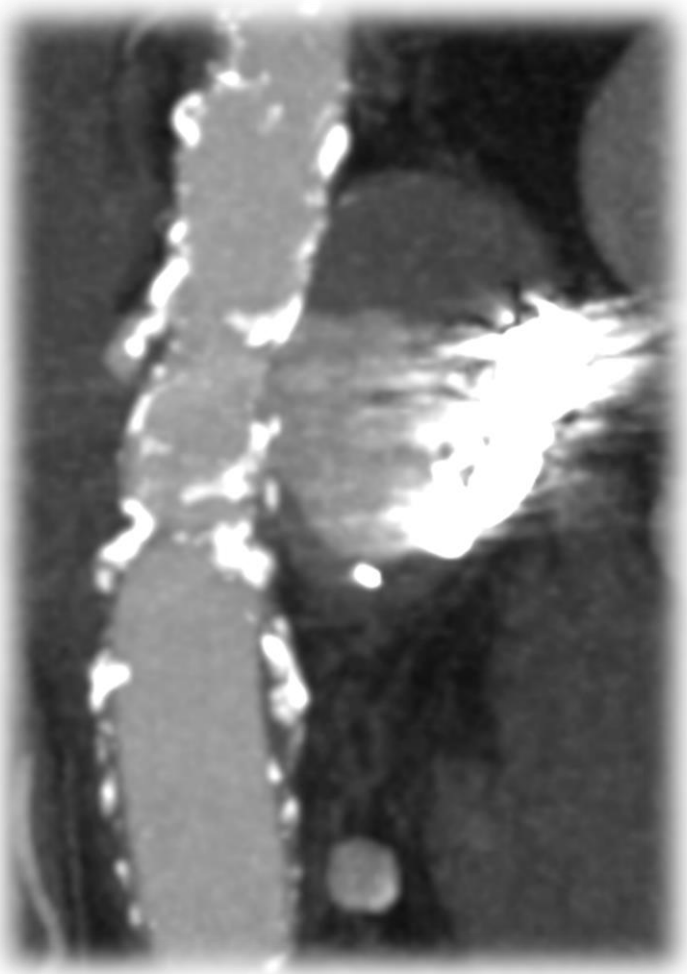
# UEA for TAVI / TAVR

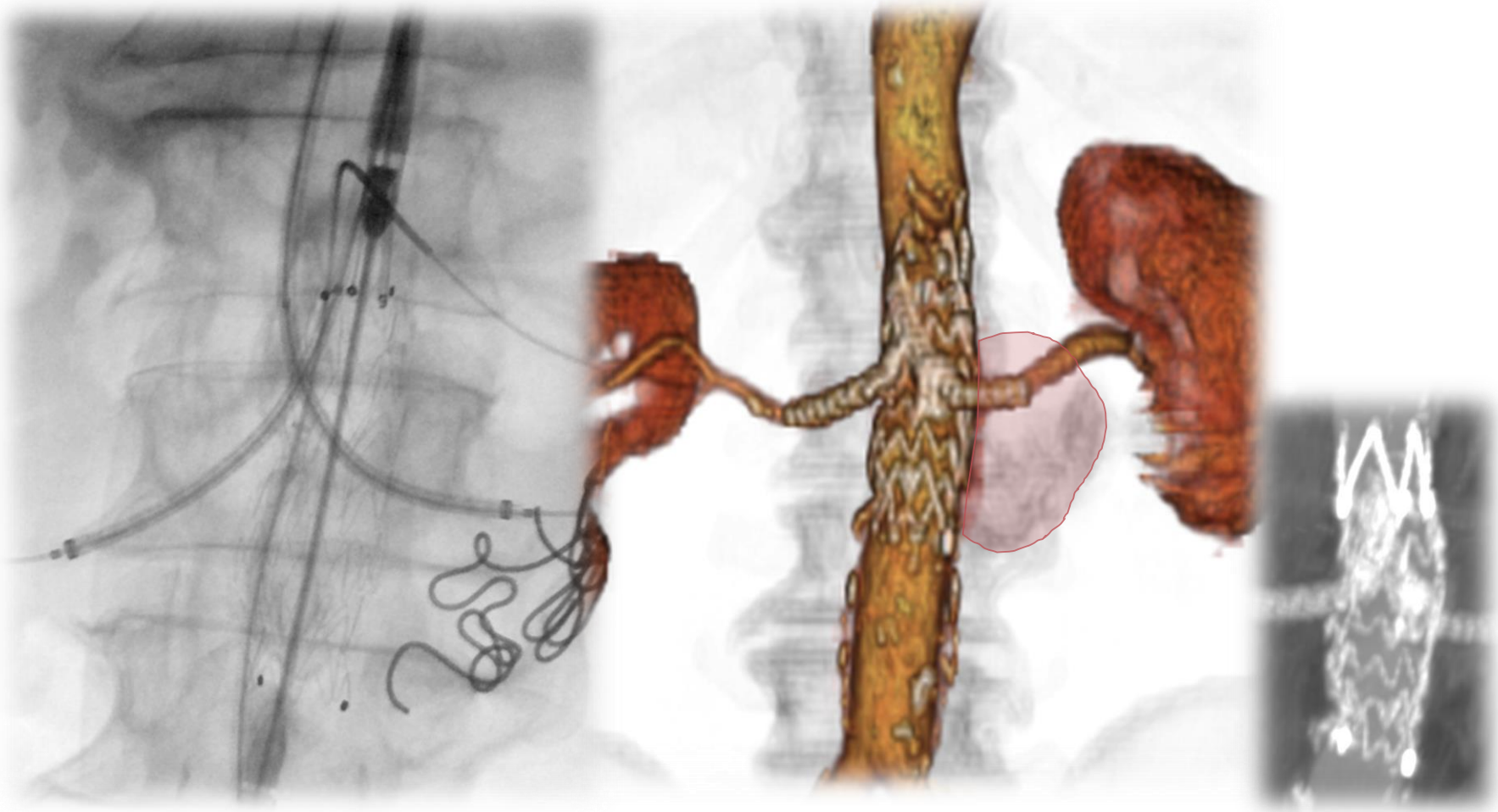
Axillary open / percutaneous access



# UEA for ChEVAR

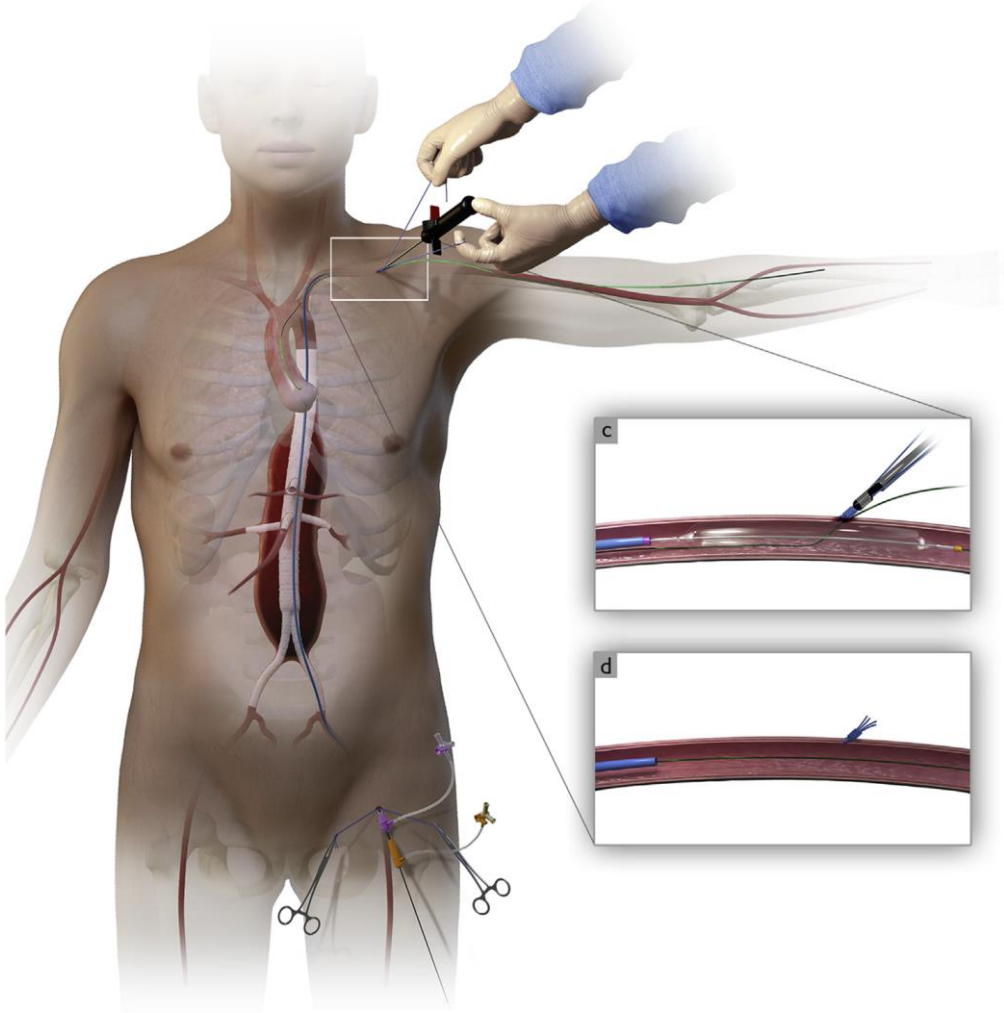
Axillary or brachial open / percutaneous access





# Percutaneous 1st segment AXA endo TAAAs

San Raffaele first 14 cases (2014-2017)




Percutaneous axillary artery access for fenestrated and branched thoracoabdominal endovascular repair

Check for updates

Luca Bertoglio, MD, Daniele Mascia, MD, Tommaso Cambiaghi, MD, Andrea Kahlberg, MD, Germano Melissano, MD, and Roberto Chiesa, MD, Milan, Italy

ABSTRACT

**Objective:** The aim of this study was to assess the safety and effectiveness of upper extremity access (UEA) with percutaneous closure of the axillary artery (AxA) during endovascular treatment of thoracoabdominal aortic aneurysms with fenestrated and branched endografts.

**Methods:** Between January 2014 and 2017, 34 out of 37 patients (92%) required UEA during a staged branched and fenestrated endovascular approach. A percutaneous AxA (pAxA) approach was used in 14 consecutive patients (41%) with the off-label use of two Perclose ProGlide (Abbott Vascular, Santa Clara, Calif) devices. The results of patients who had received a pAxA access were analyzed; technical success was defined as successful arterial closure with no evidence of persistent bleeding or arterial occlusion requiring secondary interventions. Early (30 days) and short-term (6 months) success rates were recorded. The anatomic characteristics of the AxA of the entire cohort (34 cases) were studied.

**Results:** Primary technical success of pAxA was 100% in one case, an adjunctive Perclose ProClide device was used to achieve complete closure. No secondary open or endovascular procedures were required. At predischarge computed tomography, no intimal defects, pseudoaneurysms, or signs of bleeding were observed, and all patients were discharged without neurologic deficits related to the AxA puncture site. All 14 patients are alive at follow-up, and 9 of 14 patients completed a 6-month clinical follow-up with computed tomography examination; no late complications were observed at the site of UEA percutaneous repair. With regard to the anatomic characteristics of the AxA, the vessel diameters in the first and third segments were statistically different ($P < .001$) with a median difference of 1.5 mm (1.0-2.0 mm), with no differences between the right and left sides. The distance between the end of the first segment of the AxA and the origin from the aortic arch was statistically different between the right and left sides, with a median difference of 36 mm (7-50 mm). A positive linear correlation was found between the diameter of the AxA and the height of the patients.

**Conclusions:** AxA is adequate in terms of both caliber and lack of calcifications as an access vessel for large-sheath catheterizations, and it might be considered an alternative UEA for complex aortic endovascular procedures thanks to its proximity to visceral target vessels. In this preliminary experience, percutaneous closure of AxA access with the Perclose ProClide device is clinically safe and technically feasible with high rates of success. (J Vasc Surg 2018;68:12-23.)

An upper extremity access (UEA) for endovascular repair of thoracoabdominal aortic aneurysms (TAAAs) is necessary for endografts with branched designs as well as for chimney, periscope, and snorkel procedures.[1,2] Moreover, it is largely used with fenestrated endografts to successfully catheterize target vessels with a caudal orientation to decrease the number of vessels addressed from the femoral access to obtain early pelvis and lower limb revascularization.[3]

The most used UEA vessel is the high brachial artery, which is usually large enough to accommodate the 10F to 12F sheath required for such procedures. However, it is usually surgically exposed and repaired after sheath removal, and access site-related complications are not negligible.[4] The subclavian artery and axillary artery (AxA) have largely been described as alternative UEA sites for different endovascular aortic and cardiac interventions with large sheaths (such as transcatheter aortic valve replacement) because of their similarities to the femoral artery, despite requiring surgical cutdown as well.[5] At present, percutaneous vessel closure devices (VCDs) are employed during complex aortic repair to close the femoral access site, but no specific device has been designed to perform percutaneous closure of UEAs, thus allowing a totally percutaneous procedure.[6,7] The aim of this study was to assess the safety and effectiveness of percutaneous closure of the AxA access by employing currently available VCDs during branched or fenestrated endovascular repair of TAAAs.

## METHODS

**Patients.** Between January 2014 and 2017, 37 high-risk surgical candidates (28 men; median age, 75 years [range, 69-78 years]) were treated for TAAA by means of a staged branched or fenestrated endovascular repair

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Clinical Trial registration: NCT02223311.
Author conflict of interest: none.
Additional material for this article may be found online at www.jvascsurg.org.

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https://doi.org/10.1016/j.jvs.2017.08.065

Bertoglio et al. J Vasc 2018

# San Raffaele pAXA study

*ClinicalTrials.gov Identifier: NCT03223311*

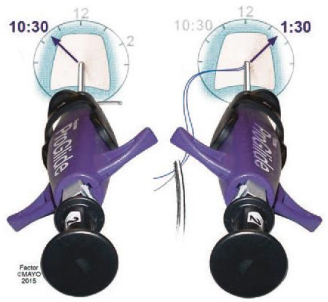
**Population:** 60 patients treated with F/BEVAR requiring UEA

- 20 patients retrospective [14 cases already published in J Vasc Surg 2018]
- 40 patients prospective [30 patients enrolled]

**Inclusion:** pAXA access closed with double Proglide technique

**Primary endpoint:** Primary technical success rates

**Status:** 100% completed




Bertoglio et al. J Vasc Surg 2018

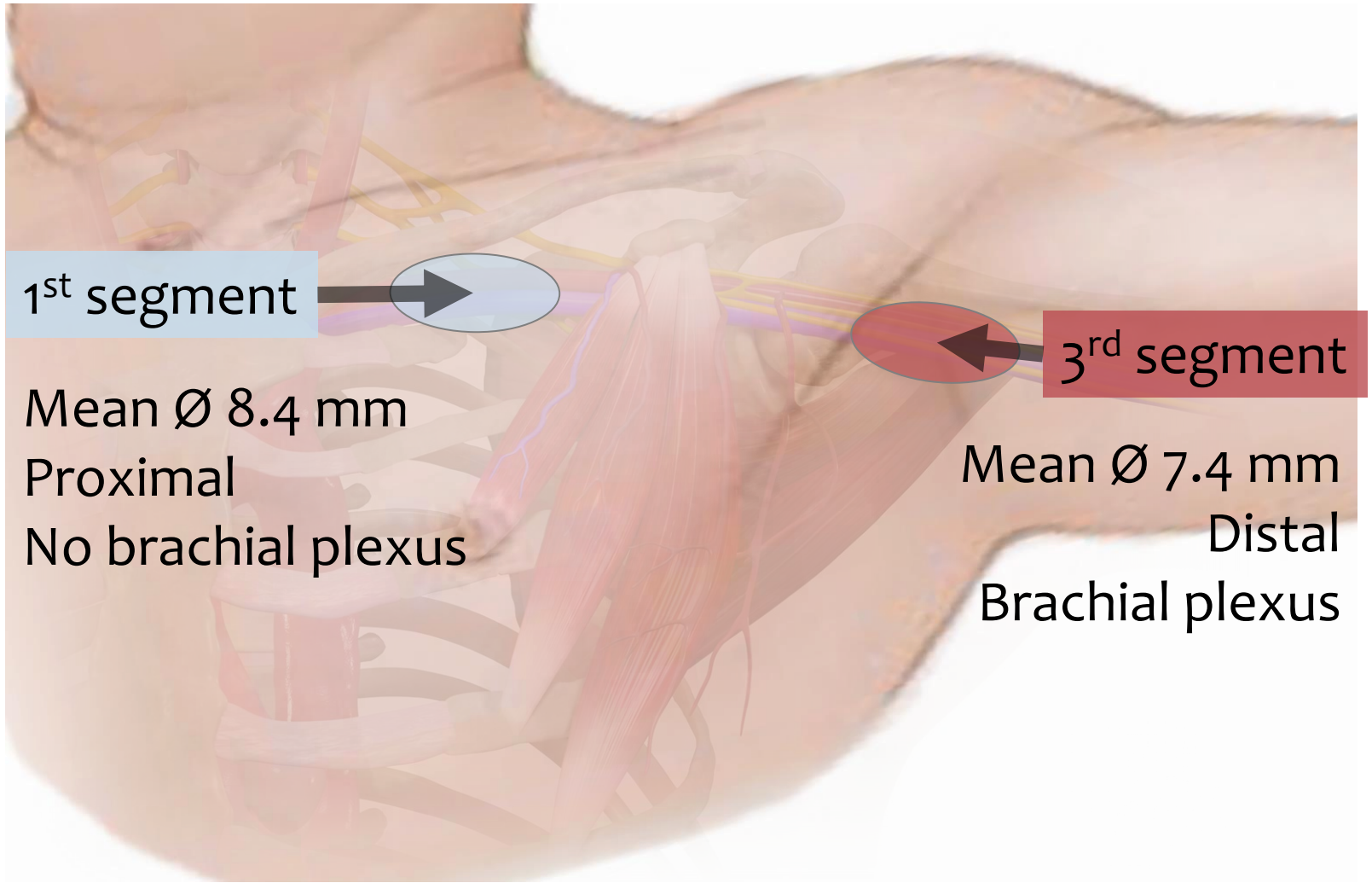
# pAXA study: Access details

60 cases (Apr. 2015 – Mar. 2019)

| | |
|---|---|
| Left access side | 54 (90%) |
| Median AXA diameter (mm) | 8.4 mm (7.6 -9.8) |
| Median AXA tortuosity index | 1.5 (1.4-1.6) |

# Discussion

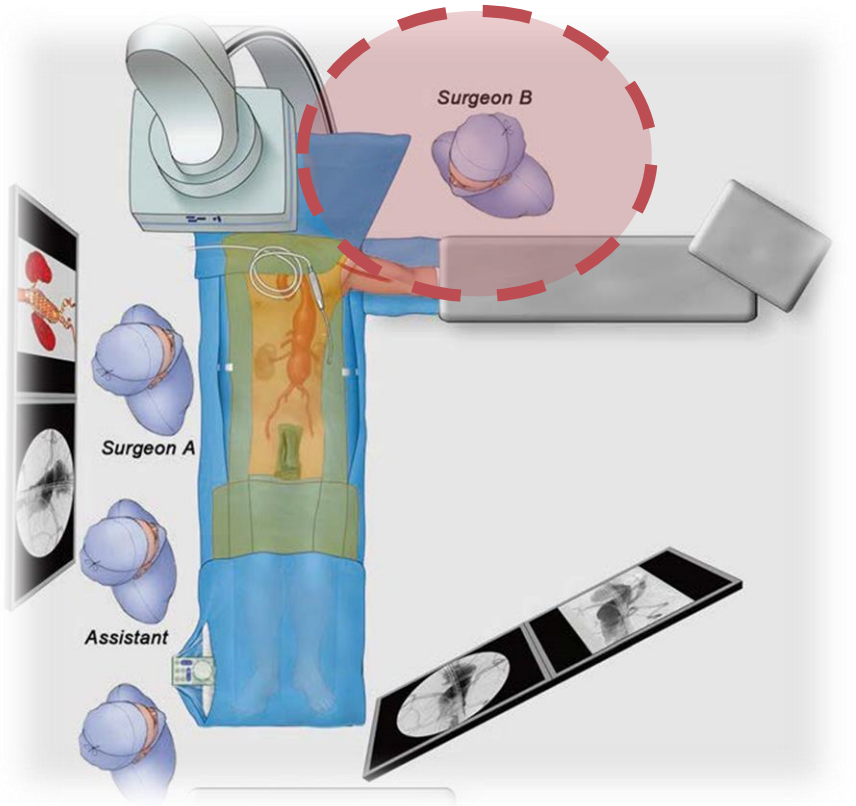
# a) Axillary puncture site: 1 st segment vs 3rd segment




Bertoglio et al. J Vasc Surg 2018
Harris et al. J Vasc Surg 2018
Schäfer et al. Int J Cardiol 2017
Puippe et al. Vasa 2018

Branzan et al. ESVS annual meeting 2017
Pratesi et al. Veith symposium 2017

# b) Decreased X-ray exposure



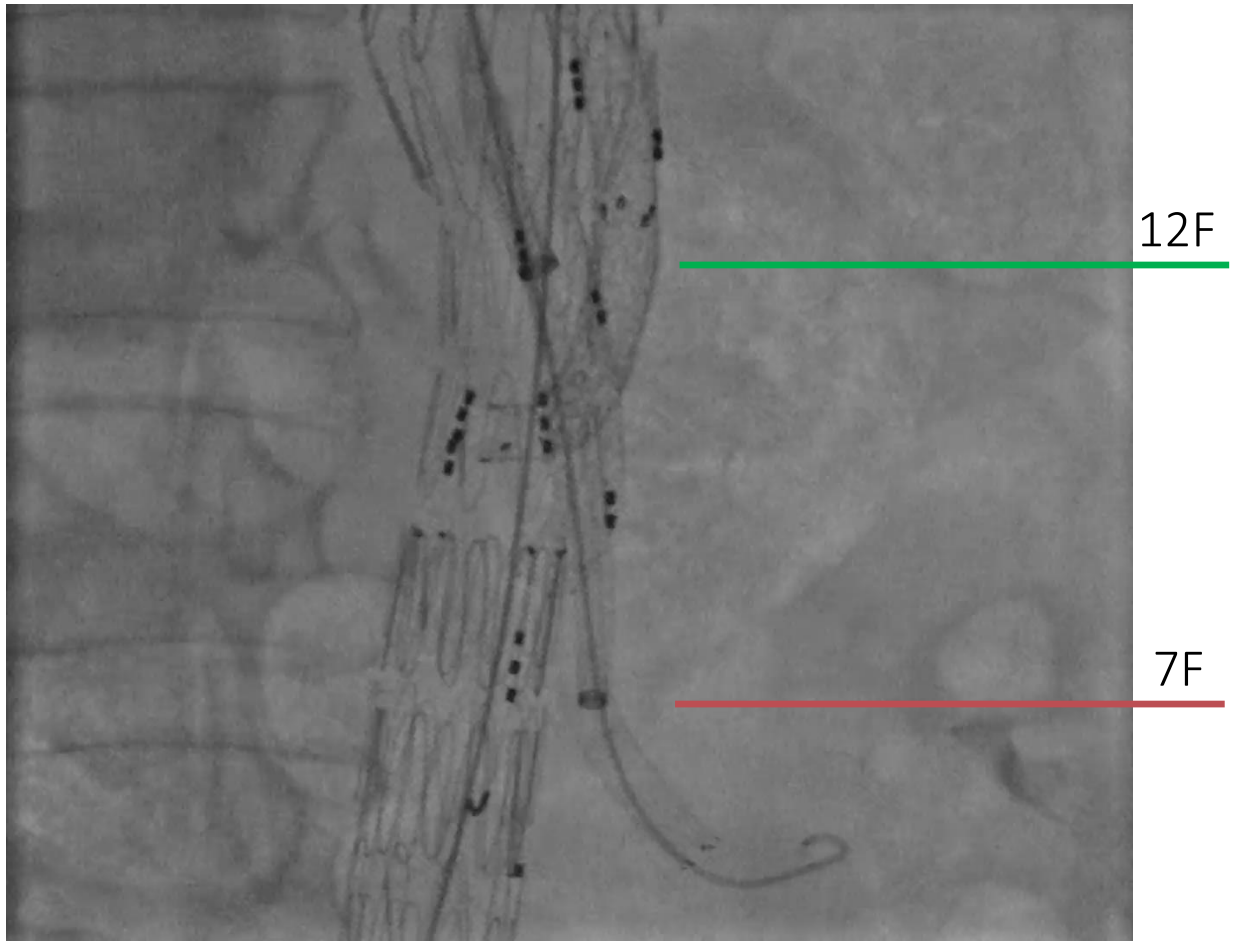

Standard: Working from the left

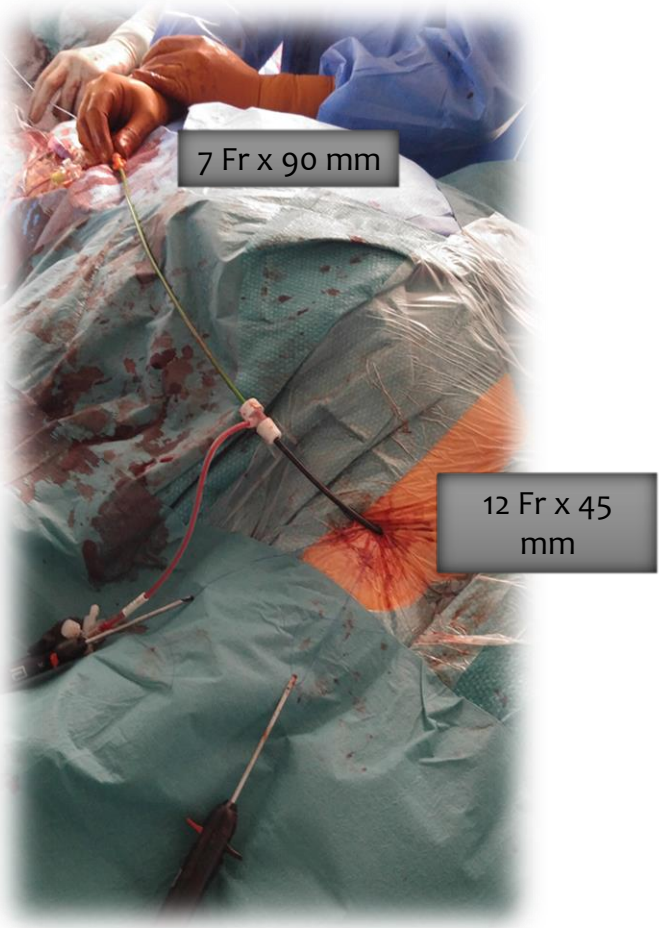
New: Working from the right

Illustration from David Factor (Mayo Clinic) in Oderich GS edition. Springer 2017

Mohapatra A. et al.. J Vasc Surg 2013

# c) Enhanced pushability from upper extermities access



# Conclusions

pAXA study: NCT03223311

TECHNIQUE

- 1st segment of axillary artery
- Ecoguided puncture
- Balloon-assisted removal

STUDY RESULTS

- Feasible and safe
- No open conversion