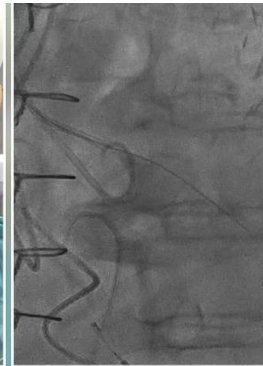




DEUTSCHES HERZZENTRUM BERLIN

STIFTUNG DES BÜRGERLICHEN RECHTS



Transfemoral for the Surgeon

Aortic Live 2016

October 17-18 2016 Essen

The Future of Surgery !

Ablation over excision

Image-guided over direct vision

Reconstruction without suturing

Access via natural orifice or blood vessel over incision

and contact with the organ or tissue has remained the same. However, during the last quarter of the 20th century, and especially during the last decade, there has been a paradigm shift in the meth-

der remote control and navigation, so that truly "noninvasive" surgery will be a reality.

Henning Anderson



Clinical Problem:
How can you
replace an aortic
valve without
opening the chest?

Henning Anderson and Michael Mack



Clinical Problem:
How can you
replace an aortic
valve without
opening the chest?

In the right framework as
defined by Michael Mack:

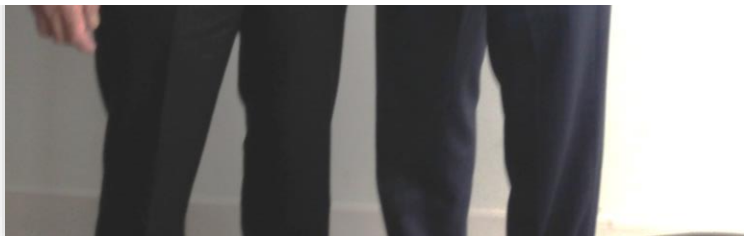
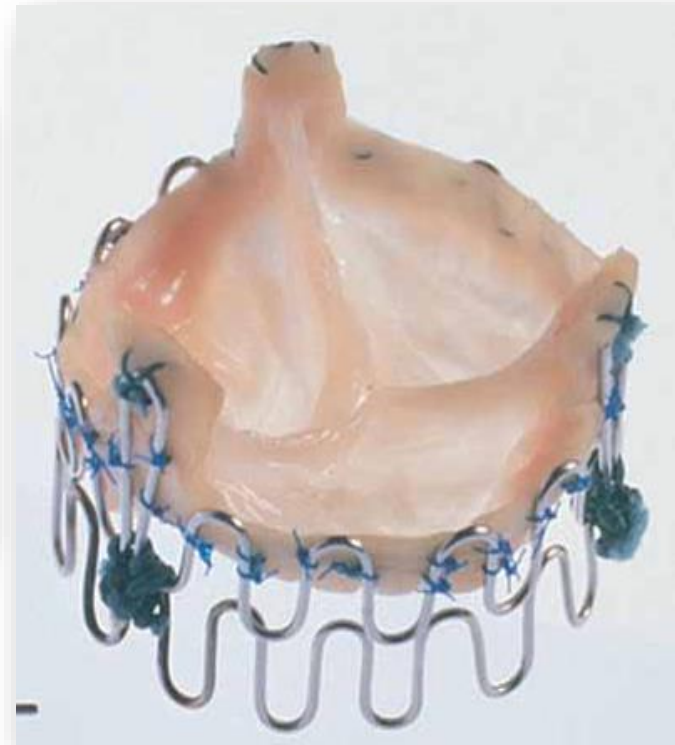
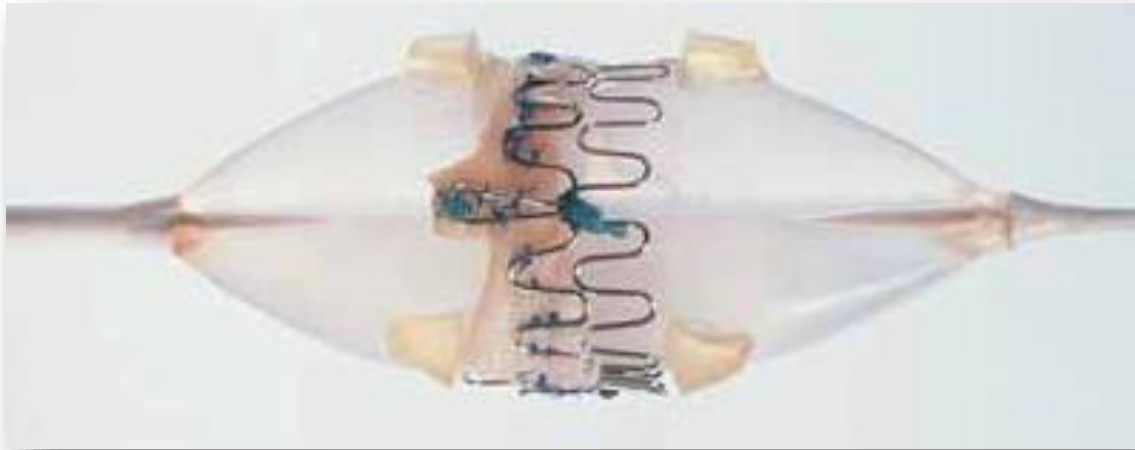


Image-guided over visual
Reconstruction without suturing
Access via blood vessel over incision

Anderson Valve 1992



Anderson Patent 1995

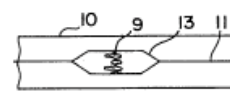
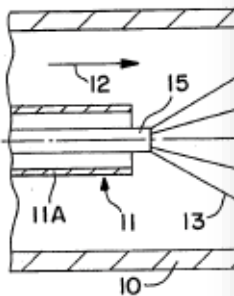
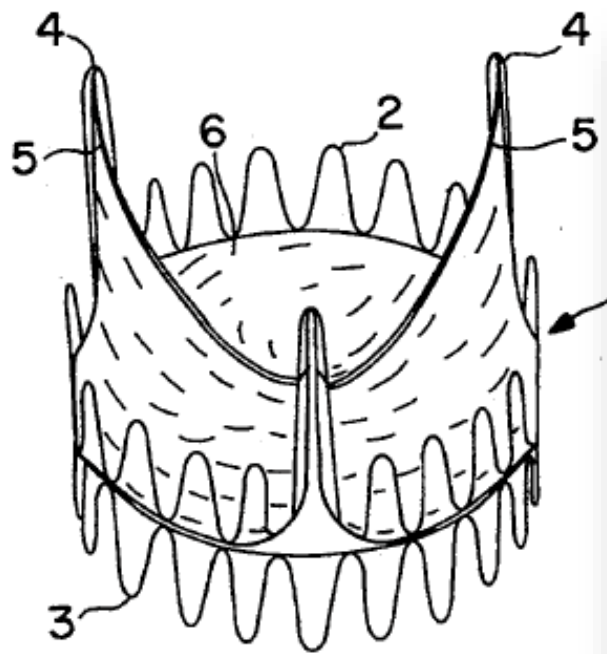


FIG. 5

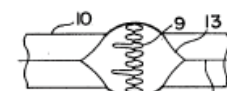


FIG. 6

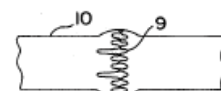


FIG. 7

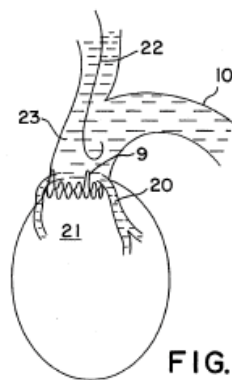


FIG. 8

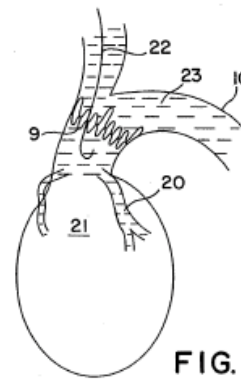


FIG. 9

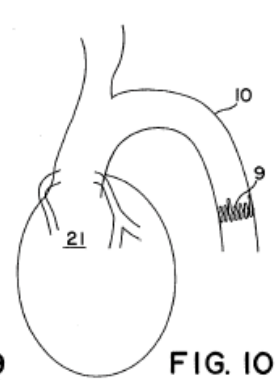


FIG. 10

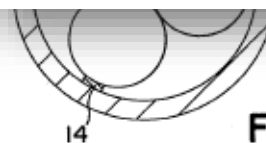


FIG. 4

First in Man by Allan Cribier

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart
Association
Learn and Live...

10 Years from Invention to First in Man

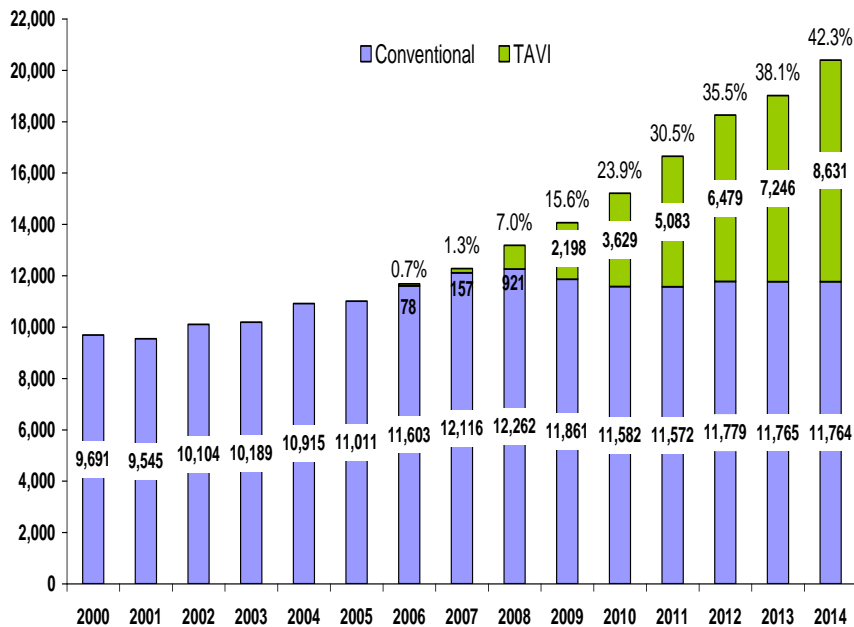
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MD;

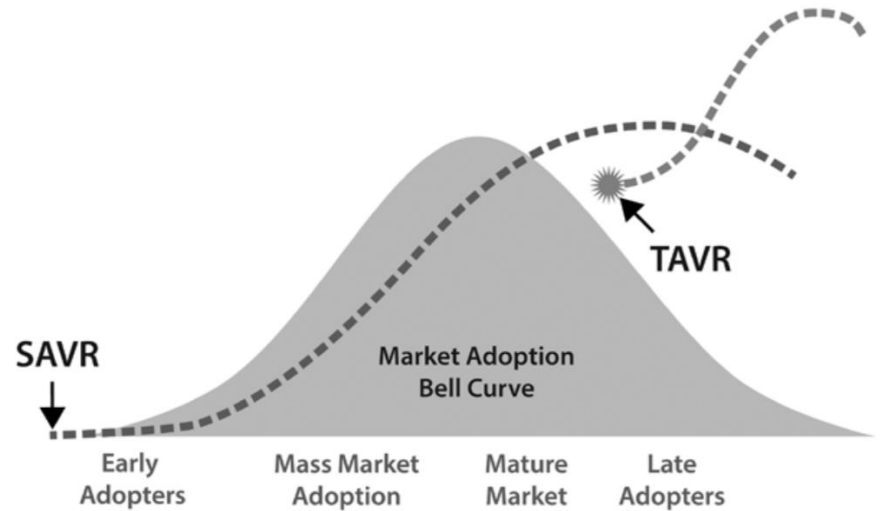
April 16, 2002

TAVI market penetration in Germany

Isolated aortic valve implantation
2000 - 2014



B



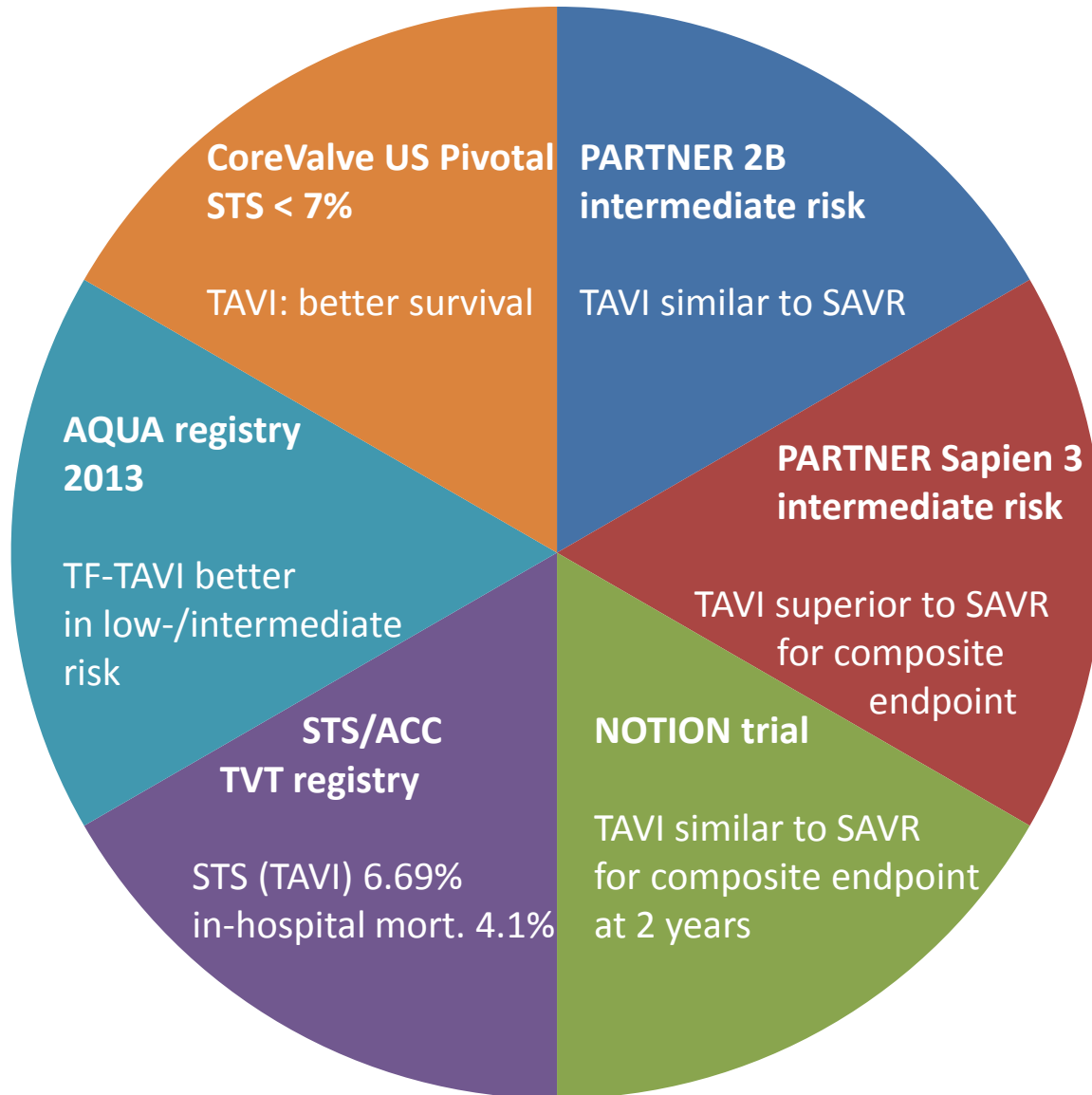
AQUA Data 2013

	Klinik		Bund	
	n	%	n	%
Allgemeine Daten zu O				
Anzahl herzchirurgisch		100,0	67.761	100,0
davon				
Aortenklappenchirurgie		13,0	9.899	14,6
konventionell chirurgi				
Aortenklappenchirurgie		16,1	10.441	15,4
kathetergestützt				
davon				
endovaskulär	137	95,8	7.620	73,0
transapikal	6	4,2	2.821	27,0
Koronarchirurgie, isoliert	497	56,1	39.768	58,7
Kombinierte Koronar- und	106	12,0	6.719	9,9
Aortenklappenchirurgie				
sonstige Operation	25	2,8	934	1,4

In 2013 for the first time the number of TAVI exceeded SAVR!

Courtesy N. Röder, Münster

TAVI similar/better than SAVR in IR patients...



Reardon MJ et al.
JAMA Cardiol 2016; e-pub ahead of print

Leon MB et al.
N Engl J Med 2016;374:1609-1620

Thourani VH et al.
Lancet 2016;387:2218-2225

Søndergaard L et al.
Circulation Intv 2016; e-pub ahead of print

Rosenhek L et al.
Eur Heart J 2012

Möller H et al.
Clin Res Cardiol 2016

TAVI – TF access

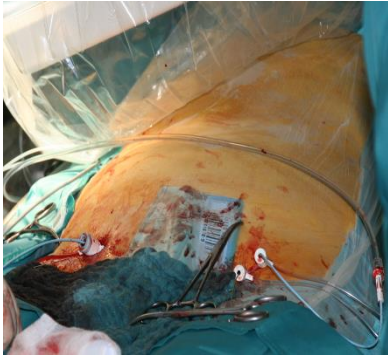
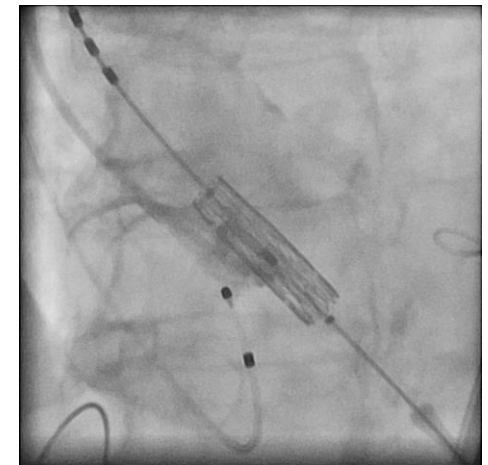


Image-guided over visual
Reconstruction without suturing
Access via blood vessel over incision



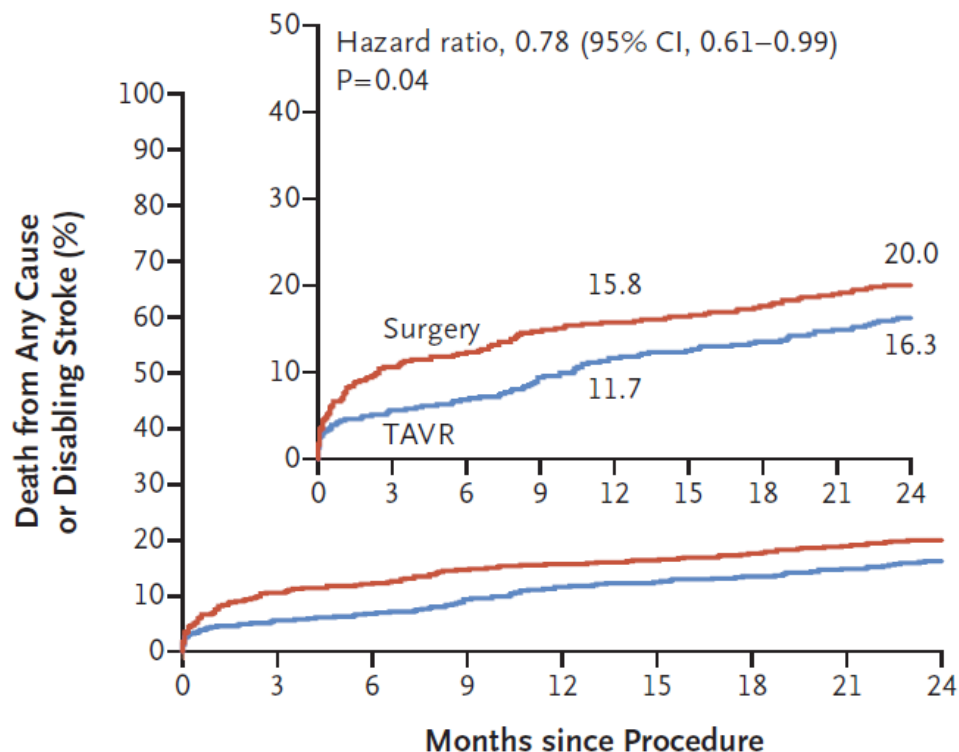
The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

APRIL 28, 2016

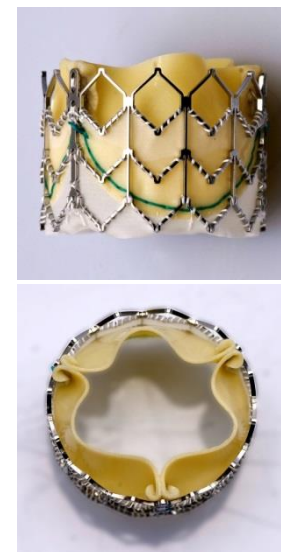
VOL. 374 NO. 17

D Transfemoral-Access Cohort, As-Treated Analysis

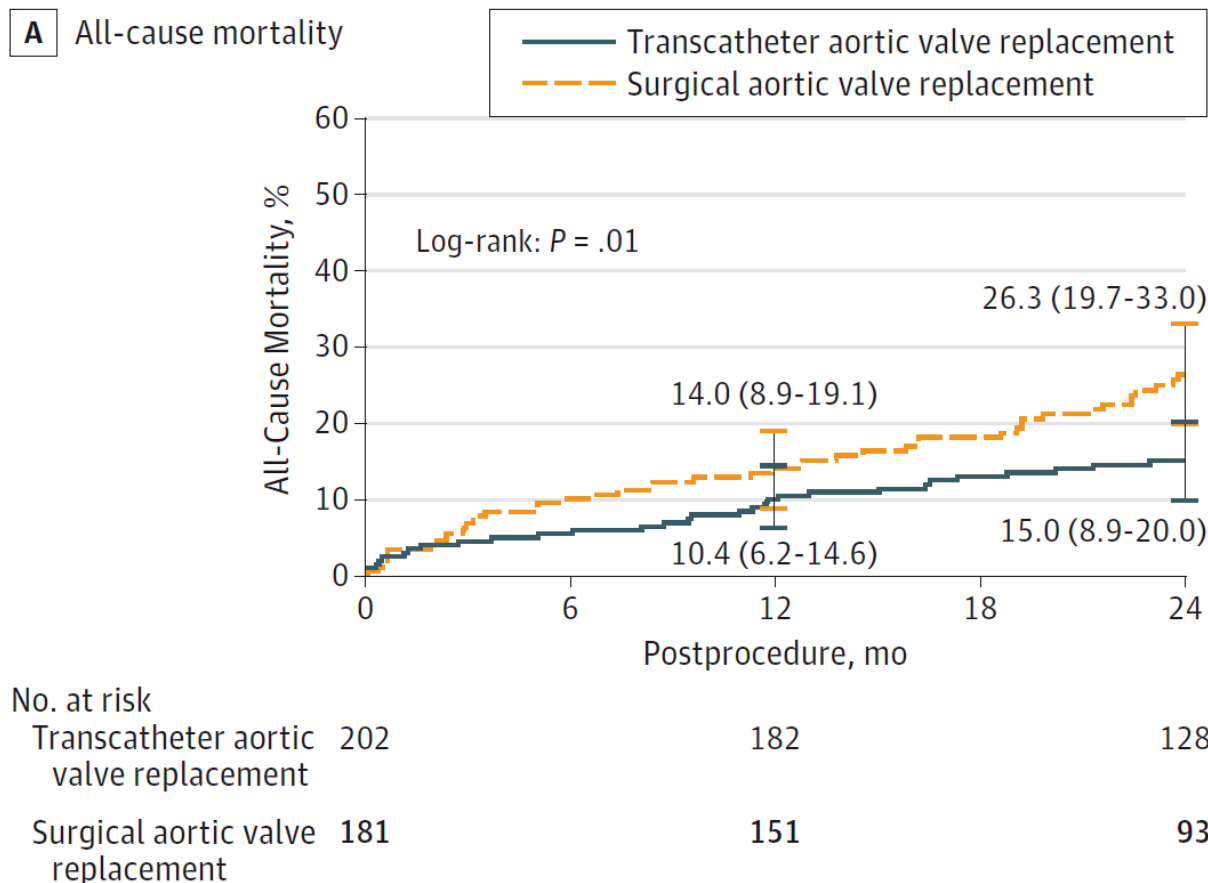


No. at Risk

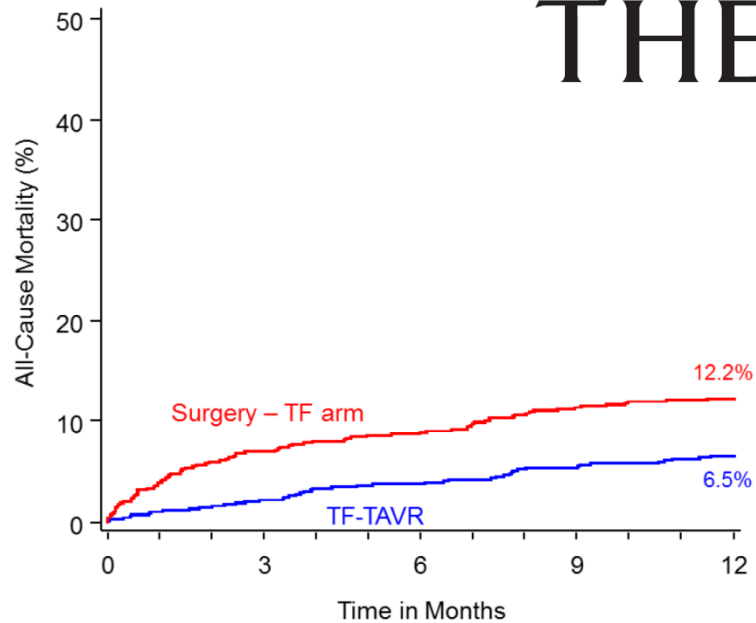
TAVR	762	717	708	685	663	652	644	634	612
Surgery	722	636	624	600	591	573	565	555	537



Outcomes in the Randomized CoreValve US Pivotal High-risk Trial in Patients With a Society of Thoracic Surgeons Risk Score of 7% or Less



THE LANCET

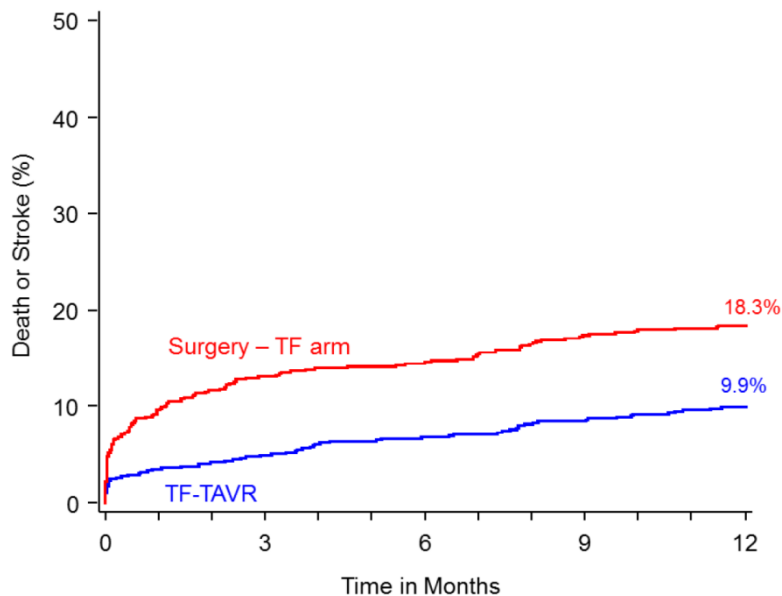


TAVI superior to SAVR for:

death, $p = 0.0003$

stroke, $p = 0.0038$

composite endpoint, $p < 0.001$

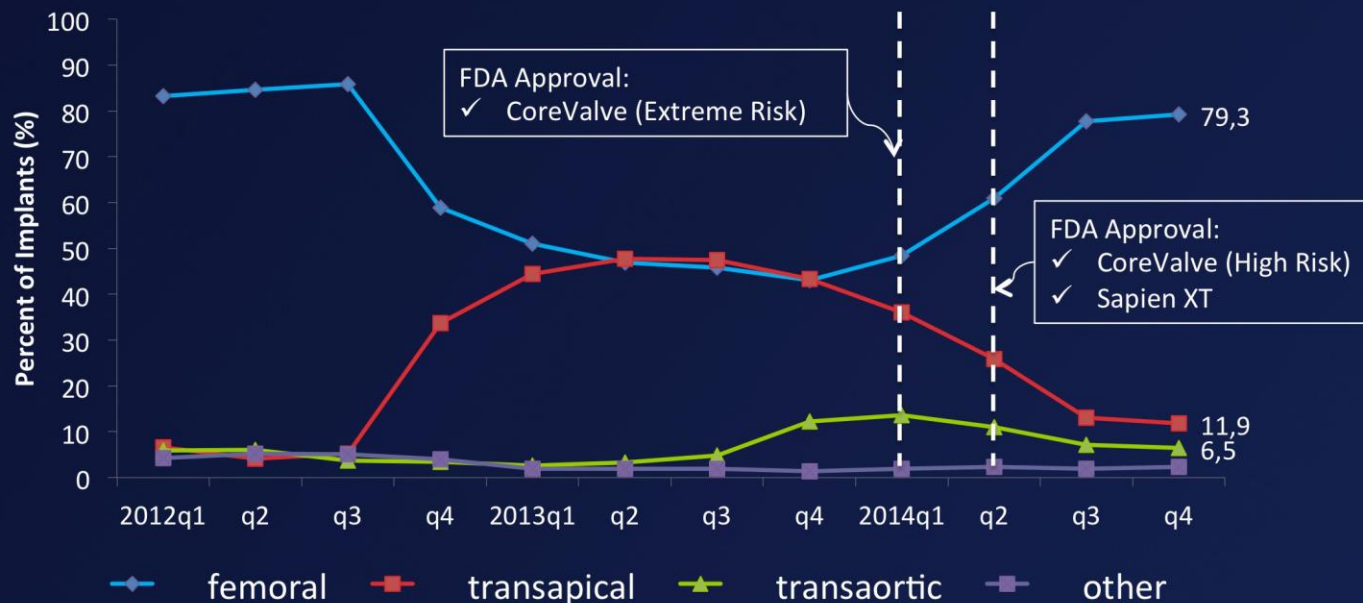


TAVI: access routes in real life: 2014 80% TF

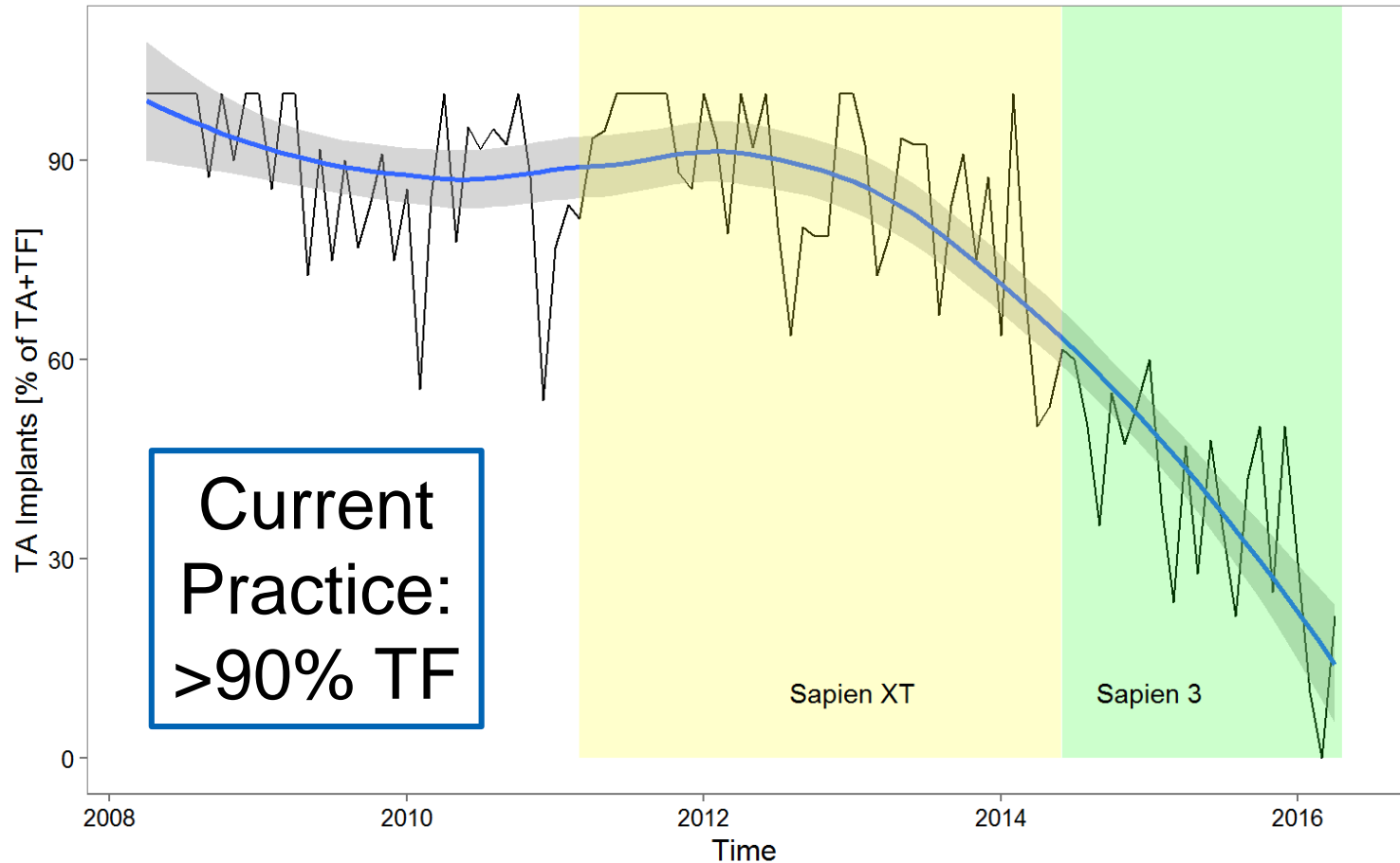
U.S. Trends in Transfemoral Access

Source: STS/ACC TVT Registry Database
28,658 records from 2012 as of 6-3-15

- Introduction of smaller sheaths increased the number of patients eligible for the TF approach
- 80% of procedures in current clinical practice are transfemoral



Femoral access @ DHZB



Femoral access devices

Sheath to Femoral Artery Ratio (SFAR)

Maximum oversizing may be 40% with S3, and 20% with Evolut R



most TAVI procedures will be TF

if surgical involvement is defined by
alternative access

->

we give up 90% of the cake...

max SFAR

1.5

1.4

1.4

1.4

1.5

1.2

1.2

1.2

1.2

1.2

1.2

From a surgeons perspective:

- Will there be any conventional AVR cases left?
- Maybe a few mechanical valves?
- Or not even that because of VinVinVinV...?
- But there is root abscess and endocarditis...
- Do I finally need to become a cardiologist?





From a surgeons perspective:

There is no other solution:

We must master transfemoral access!

Femoral access complication rate

Vascular Complications After Transcatheter Aortic Valve Implantation and Their Association With Mortality Reevaluated by the Valve Academic Research Consortium Definitions



Arie Steinvil, MD, MHA^{a,*}, Eran Leshem-Rubinow, MD, MHA^a, Amir Halkin, MD^a,
Yigal Abramowitz, MD^a, Eyal Ben-Assa, MD^a, Yacov Shacham, MD^a, Avner Bar-Dayana, MD^b,
Gad Keren, MD^a, Shmuel Banai, MD^a, and Ariel Finkelstein, MD^a

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definition, patients with minor VC had similar mortality and complications rates as those
patients without VC. In multivariate analyses, referenced to patients with minor or no VC, only
VARC-1–defined major VC were significantly associated with increased mortality (hazard
ratio 3.52; confidence interval 1.5 to 8.4; $p = 0.005$), whereas VARC-2–defined major VC
were found to be only marginally significant (hazard ratio 1.9; confidence interval 0.9 to 3.9;
 $p = 0.08$). In conclusion, the implementation of the VARC-2 criteria resulted in a higher rate
of reported major VC after TAVI compared with VARC-1 criteria, mainly by the inclusion
of major bleeding events and a reduced association with patient mortality. © 2015 Elsevier
Inc. All rights reserved. (Am J Cardiol 2015;115:100–106)

Major Vascular Complication
→ Mortality HR 3.5, CI95
1.5-8.4, $p = 0.005$

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ARC

definition, patients with minor VC had similar mortality and complications rates as those
patients without VC. In multivariate analyses, referenced to patients with minor or no VC, only
VARC-1–defined major VC were significantly associated with increased mortality (hazard
ratio 3.52; confidence interval 1.5 to 8.4; $p = 0.005$), whereas VARC-2–defined major VC
were found to be only marginally significant (hazard ratio 1.9; confidence interval 0.9 to 3.9;
 $p = 0.08$). In conclusion, the implementation of the VARC-2 criteria resulted in a higher rate
of reported major VC after TAVI compared with VARC-1 criteria, mainly by the inclusion
of major bleeding events and a reduced association with patient mortality. © 2015 Elsevier
Inc. All rights reserved. (Am J Cardiol 2015;115:100–106)



Femoral access site complications are still an issue!




Determinants of Vascular Complications

- Access device
- Access site
- Access approach
- Access closure
- Handling of complications

Femoral access devices

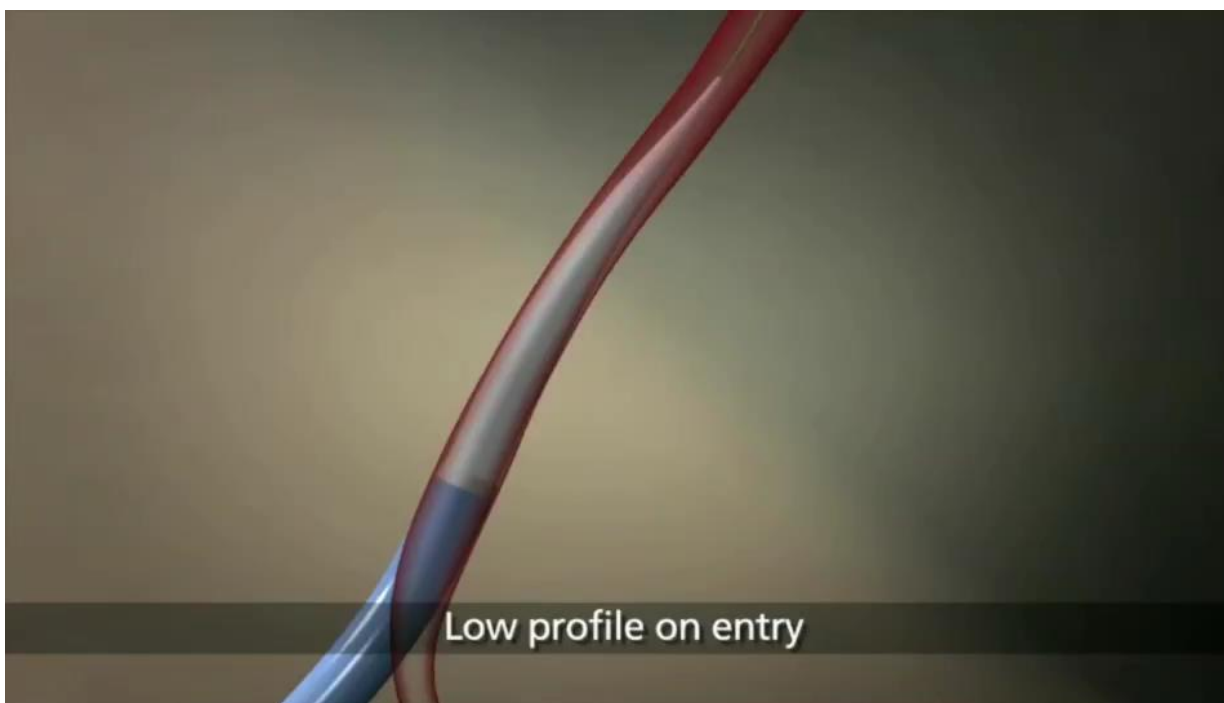
Sheath to Femoral Artery Ratio (SFAR)

Maximum oversizing may be 40% with S3, and 20% with Evolut R

								
	SAPIEN XT			SAPIEN 3		Lotus	CoreValve	Evolut R
Valve Size (mm)	20, 23	26	29	20, 23, 26	29	23, 25, 27	23, 26, 29, 31	23, 26, 29
Indicated minimum artery diameter (mm)	6.0	6.5	7.0	5.5	6.0	6.0	6.0	5.0
Sheath OD Unexpanded (mm)	6.7	7.2	8	5.7	6.5	7.2	6.7	5.9
Sheath OD Expanded (mm)	8.9	8.9	9.9	7.7	8.2	Not Applicable	Not Applicable	Not Applicable
Max SFAR	1.5	1.4	1.4	1.4	1.3	1.2	1.1	1.2

Femoral access devices

Marketing example: Edwards eSheath for Sapien 3 – 16F?



Sheath ID (unexpanded)	Sheath OD (unexpanded)	Sheath OD (expanded)	Loader ID	Compatible NovaFlex+ device	Minimum vessel diameter ^a
16F (5.3 mm)	6.7 mm	Up to 8.9 mm	21F	9355NF23 (23 mm THV)	6.0 mm
18F (5.9 mm)	7.2 mm	Up to 8.9 mm	21F	9355NF26 (26 mm THV)	6.5 mm
20F (6.7 mm)	8.0 mm	Up to 9.9 mm	23F	9355NF29 (29 mm THV)	7.0 mm

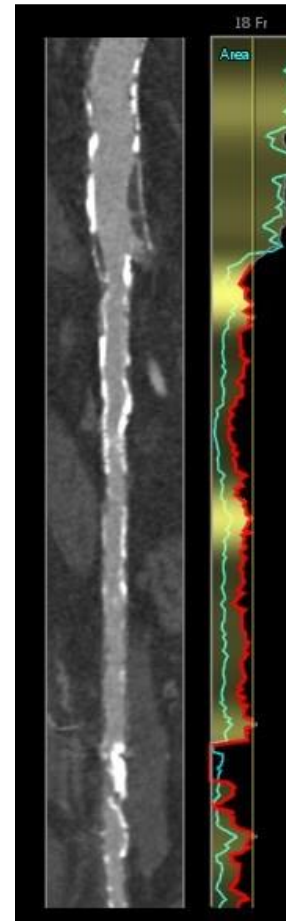
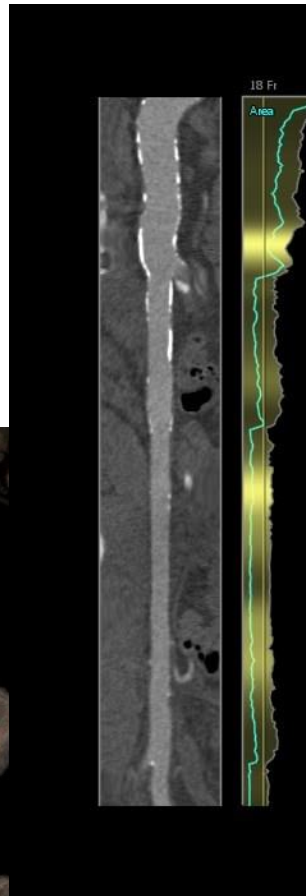
Femoral access devices

Example: CoreValve InLine Sheath – **14F?**



Femoral access site

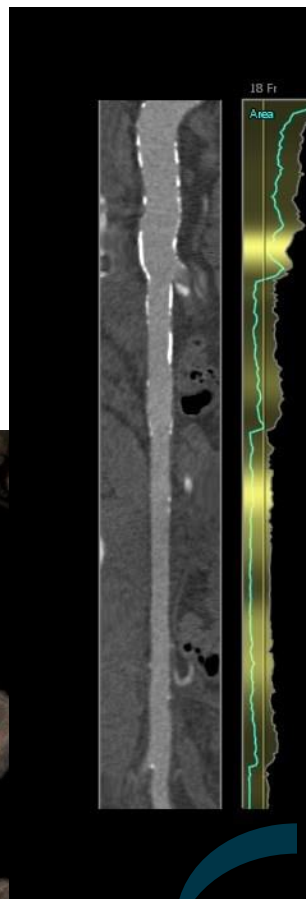
The good ...



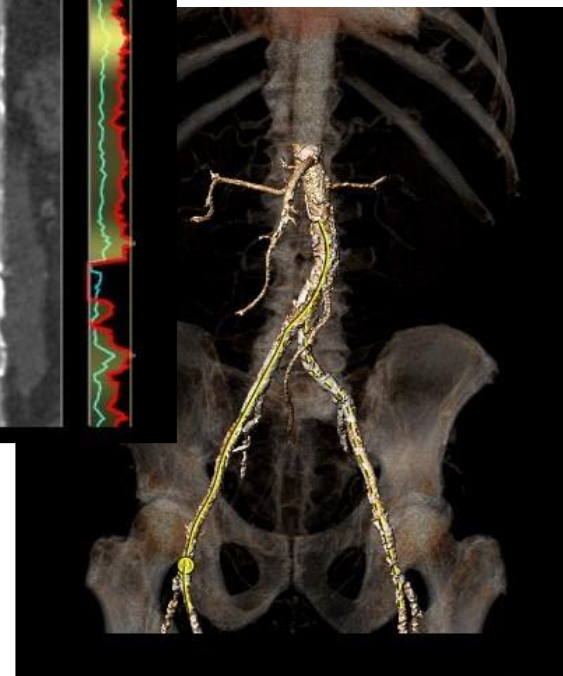
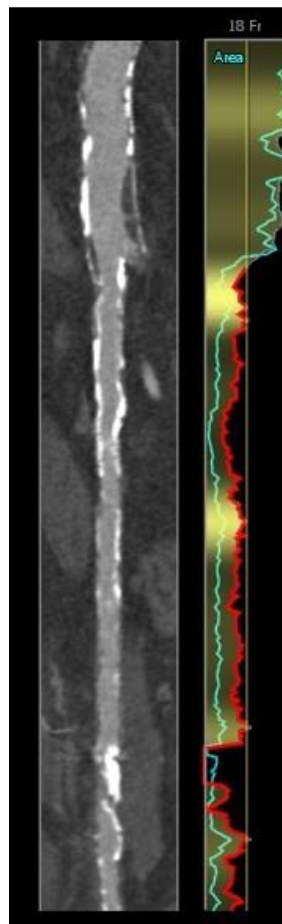
The bad...

Femoral access site

The good ...



The bad...



Imaging is key...

Femoral Access

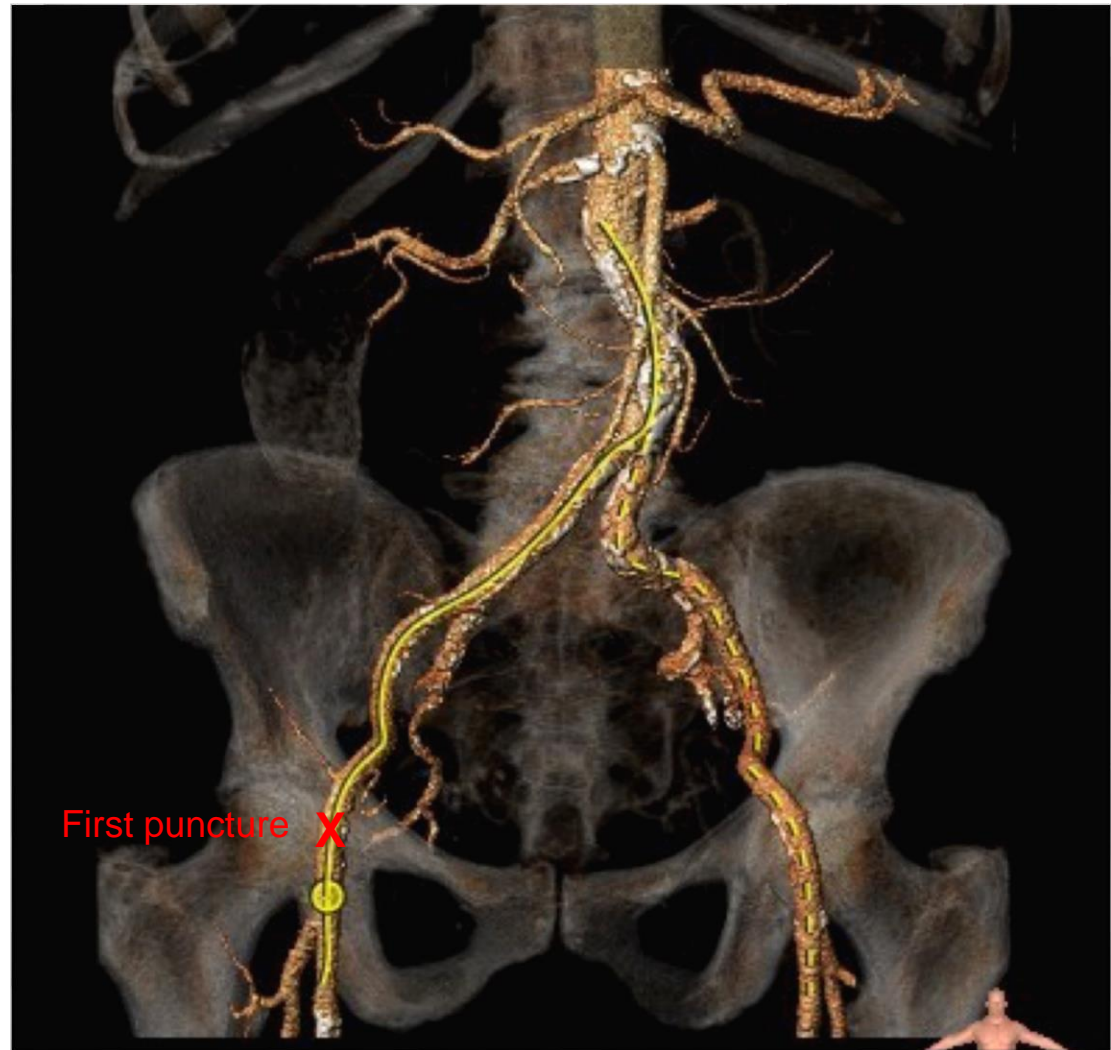
„Blind“ puncture

Femoral Access



Femoral Access

„Blind“ puncture

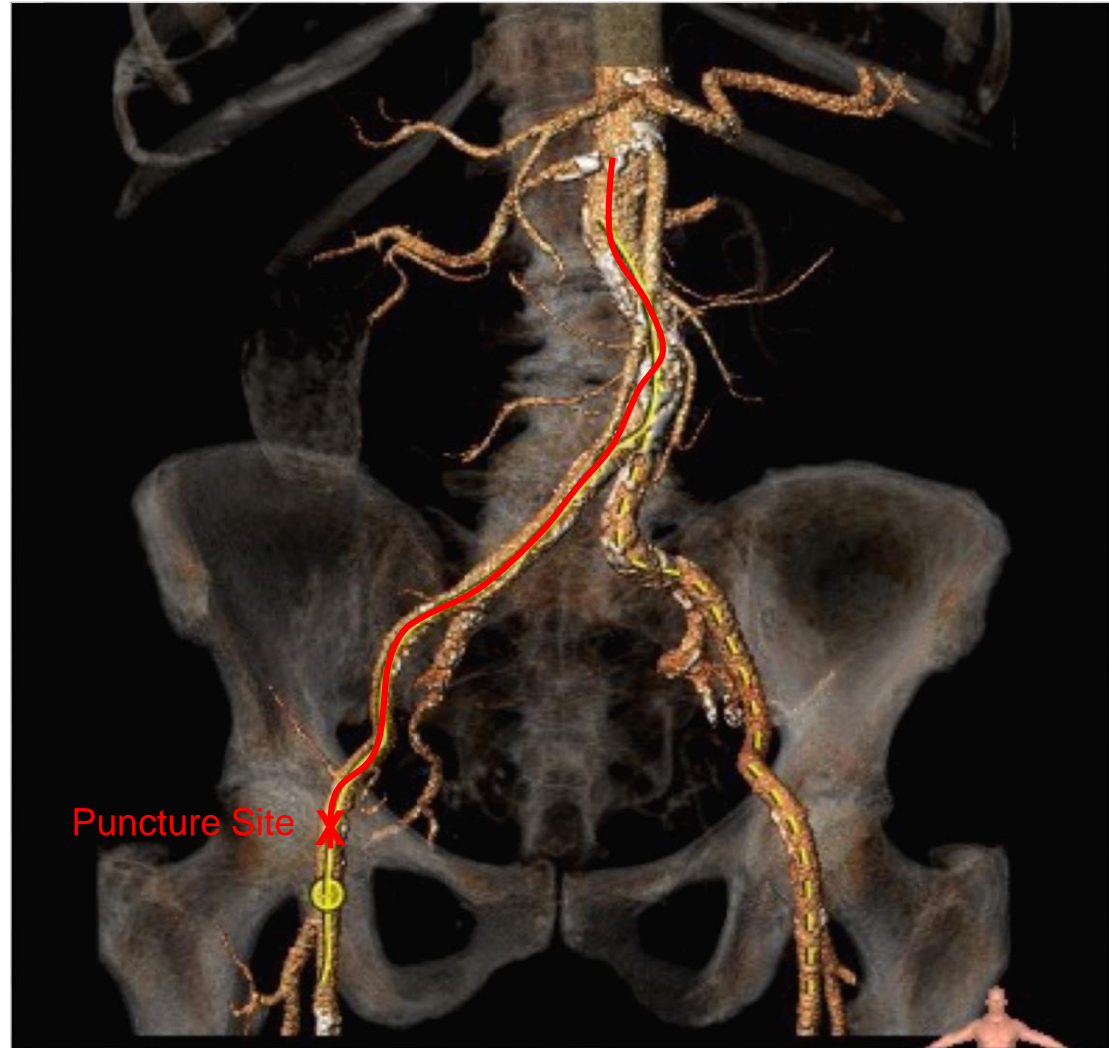


Femoral Access

„Blind“ puncture

Pro:

- Quick and dirty;
direct acces

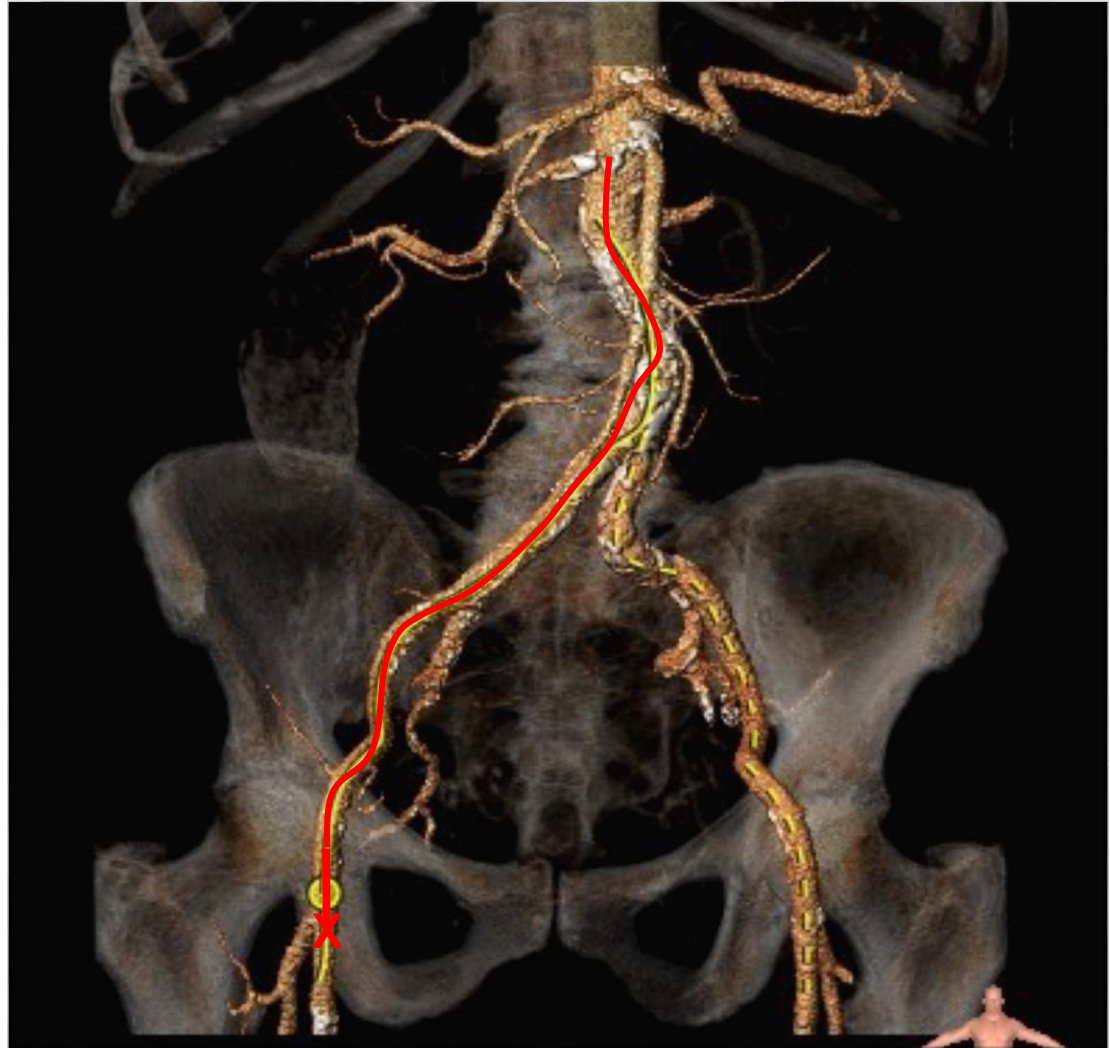


Femoral Access

„Blind“ puncture

Con:

- „Blind“ → Bifurcation Occlusion
- No back-up wire

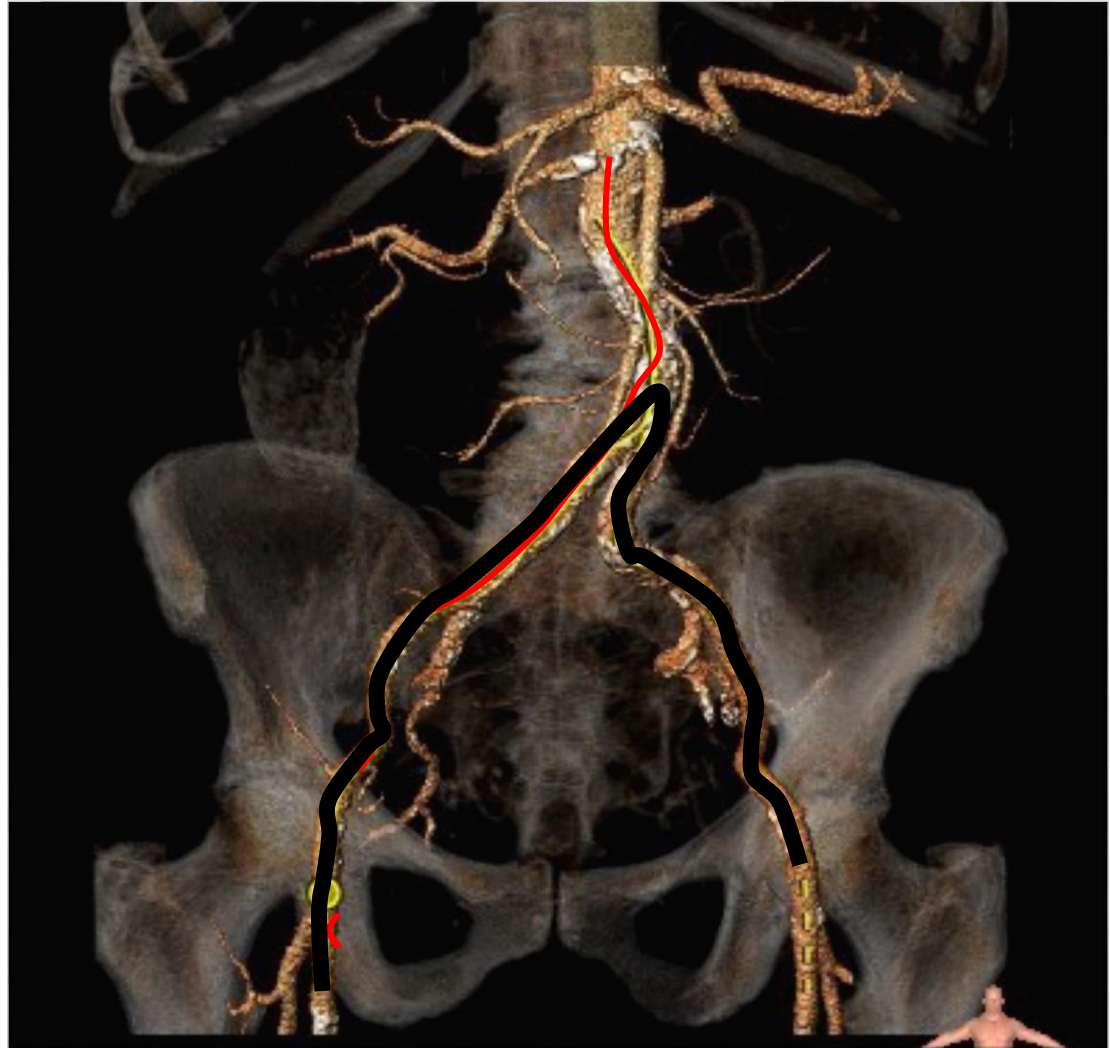


Femoral Access

„Blind“ puncture

Con:

- „Blind“ → Bifurcation Occlusion
- No back-up wire
- Amount of contrast for control





Femoral Access

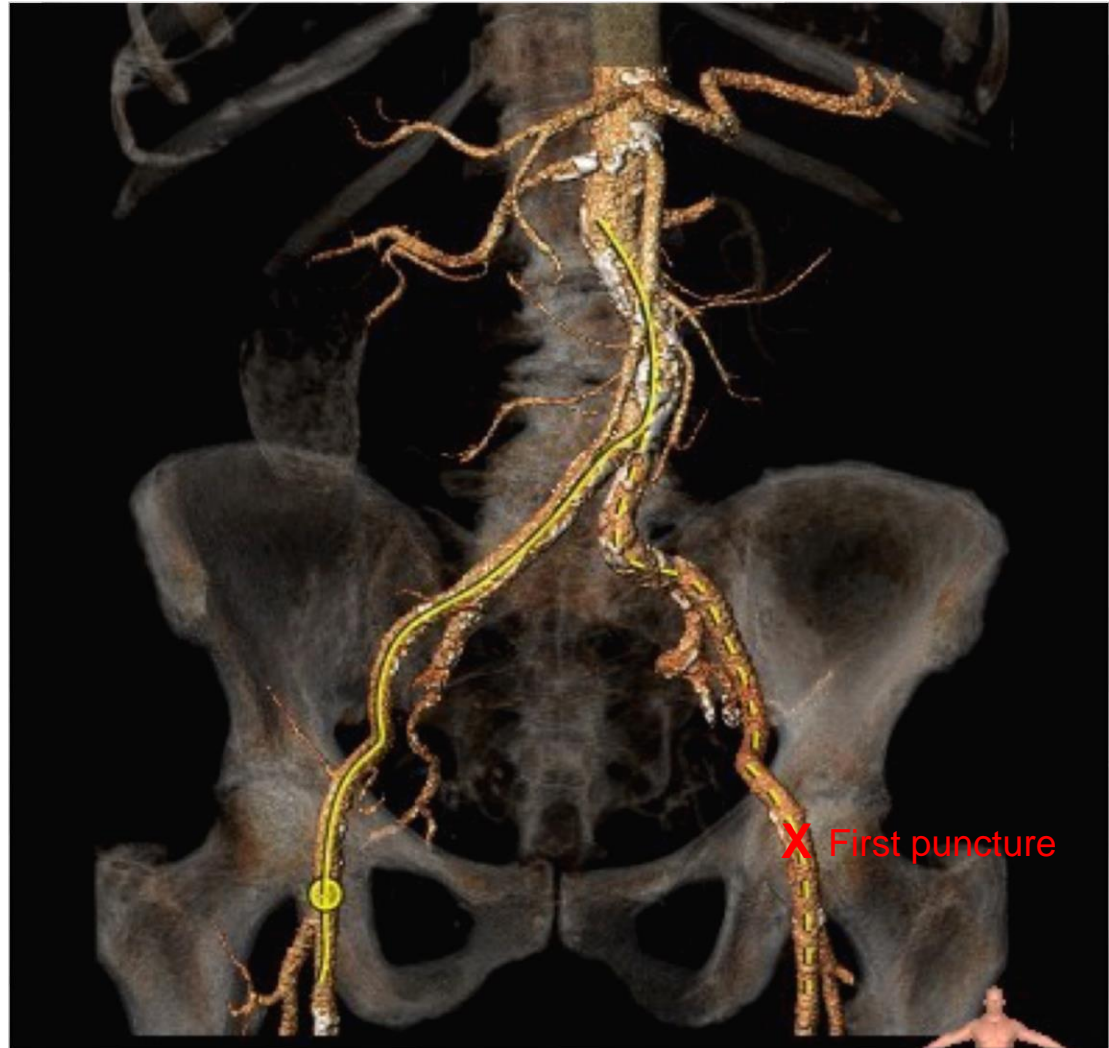
Cross over puncture

Femoral Access



Femoral Access

Cross-over puncture

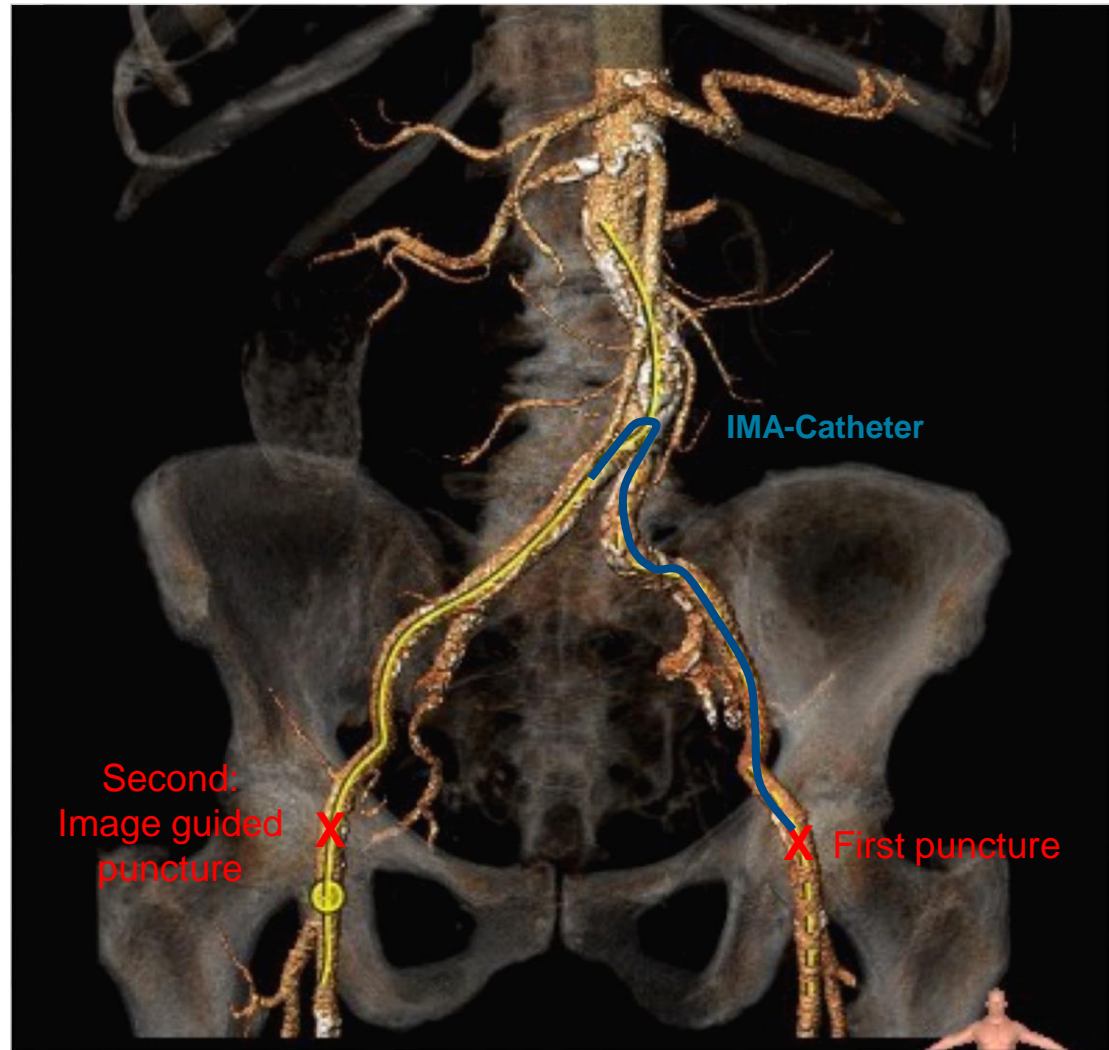


Femoral Access

Cross-over puncture

Pro:

- Image guided puncture

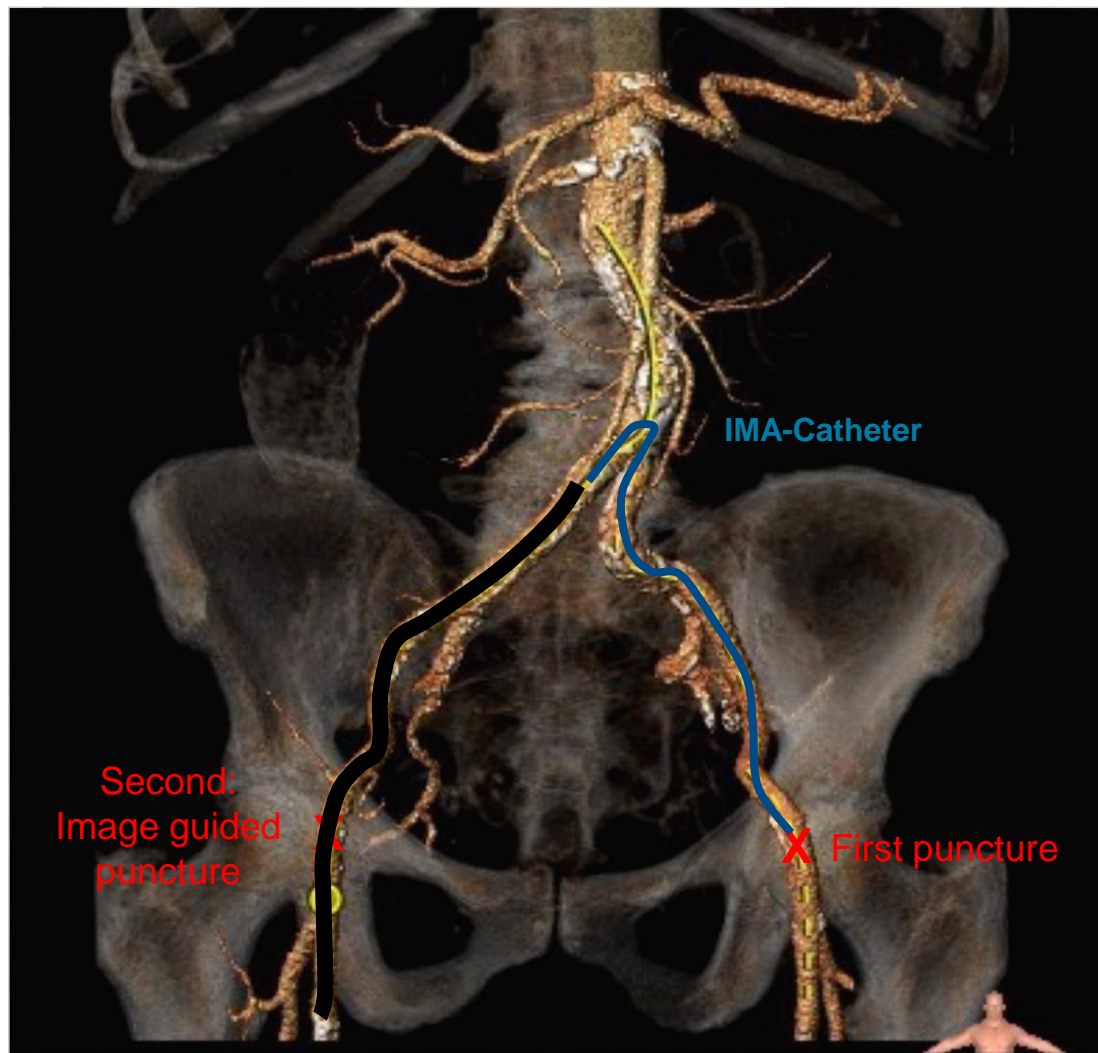


Femoral Access

Cross-over puncture

Pro:

- Image guided puncture
- Less contrast

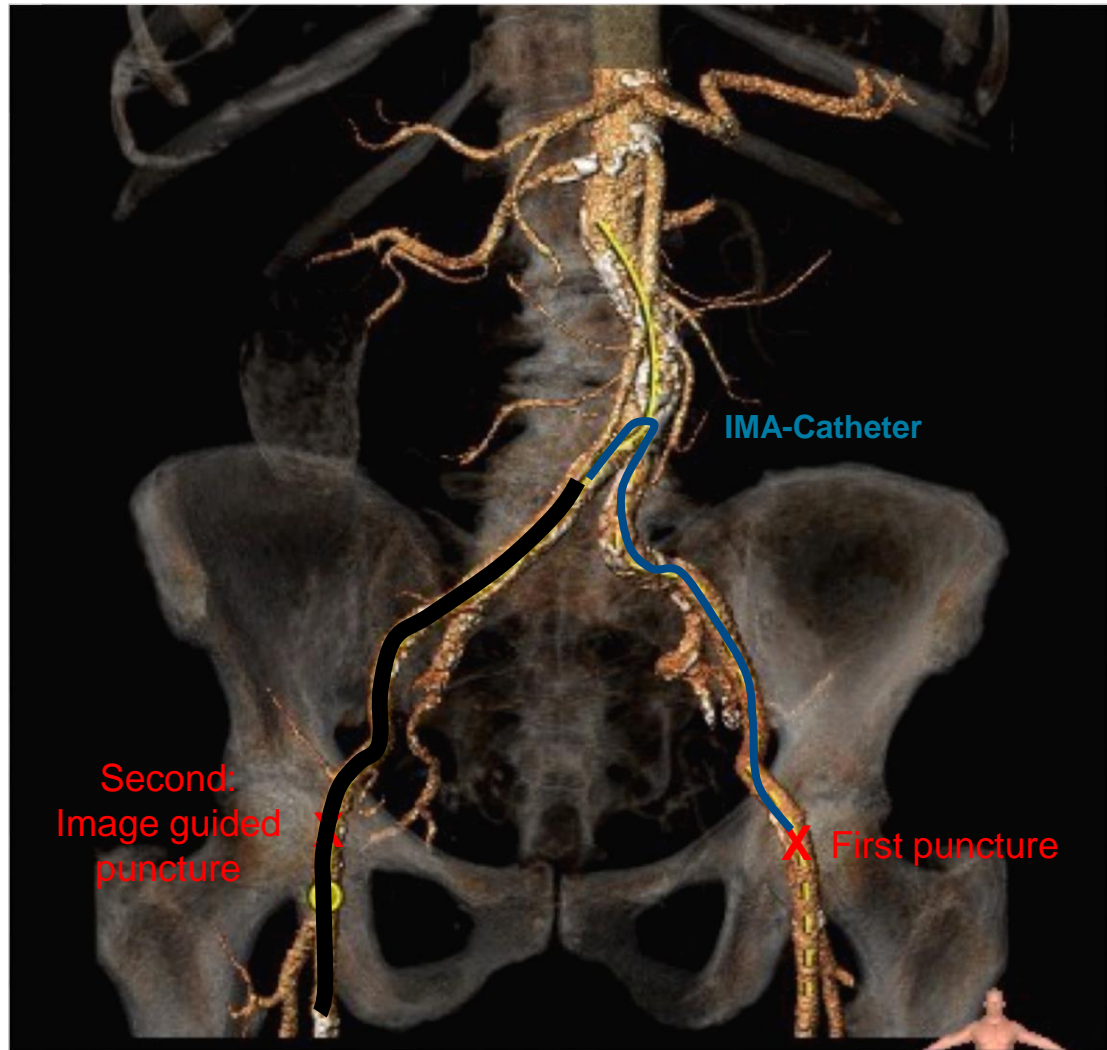


Femoral Access

Cross-over puncture

Con:

- Extra step
- No back-up wire



Femoral Access

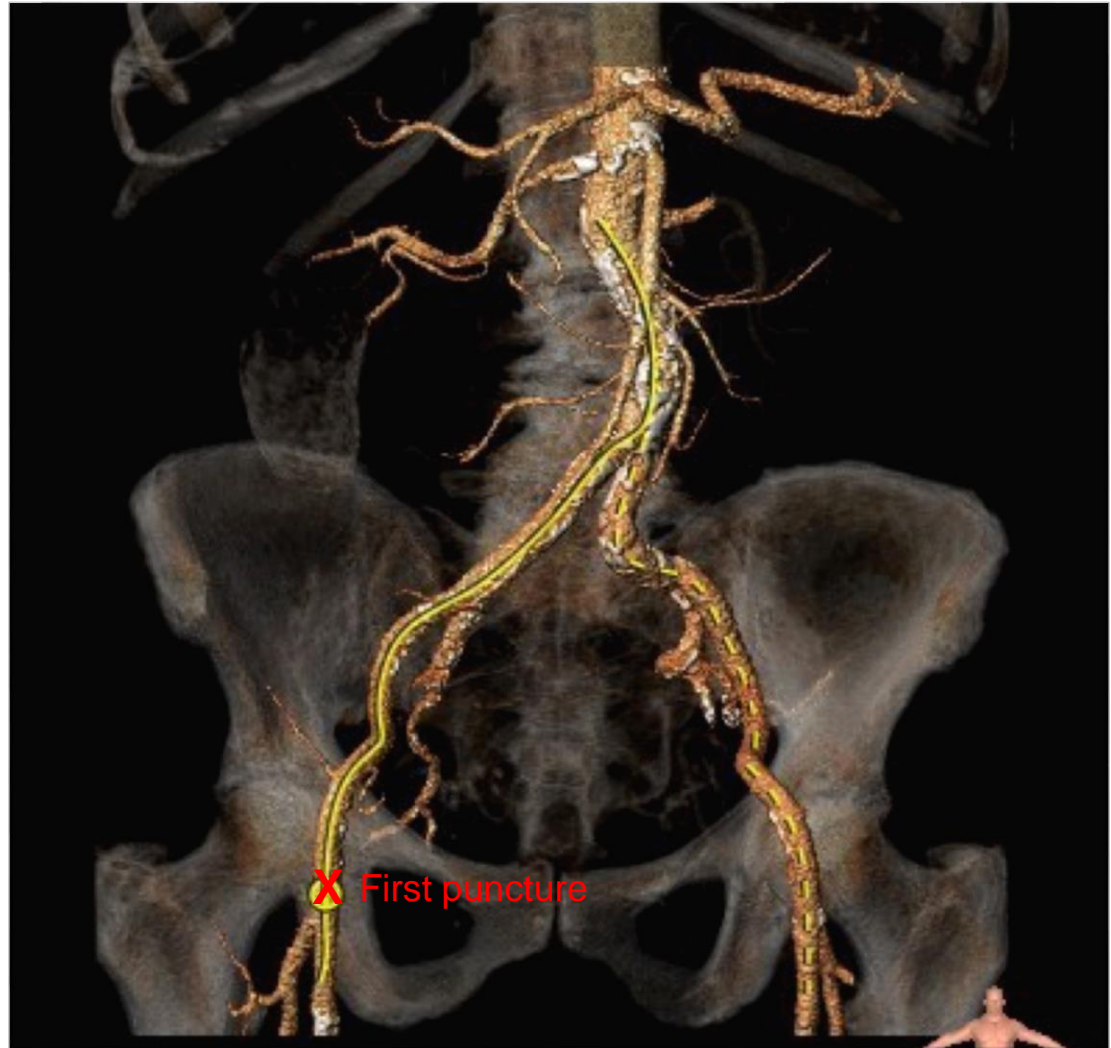
Ipsilateral
back-up puncture

Femoral Access



Femoral Access

Ipsilateral
back-up puncture

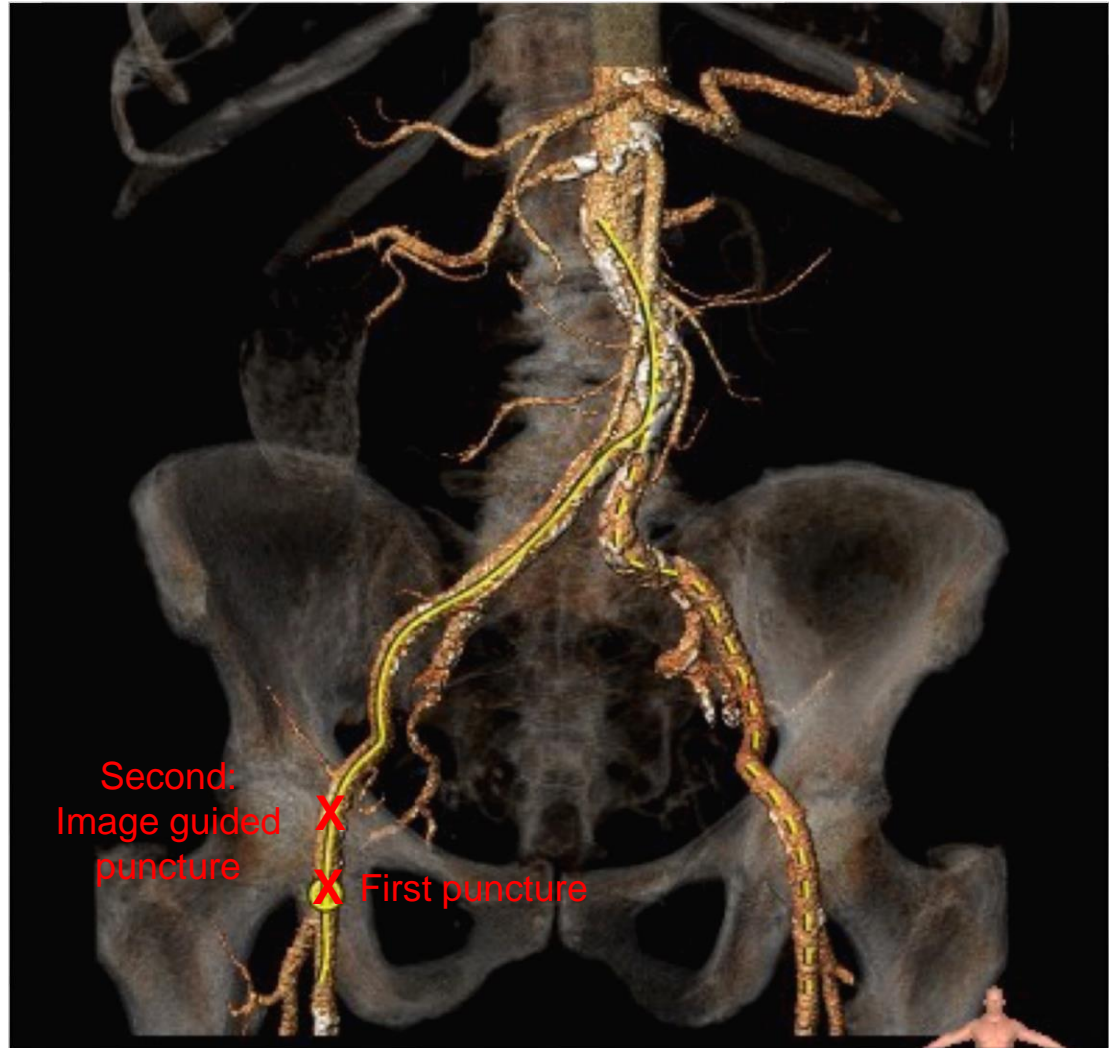


Femoral Access

Ipsilateral
back-up puncture

Pro:

- Image guided puncture

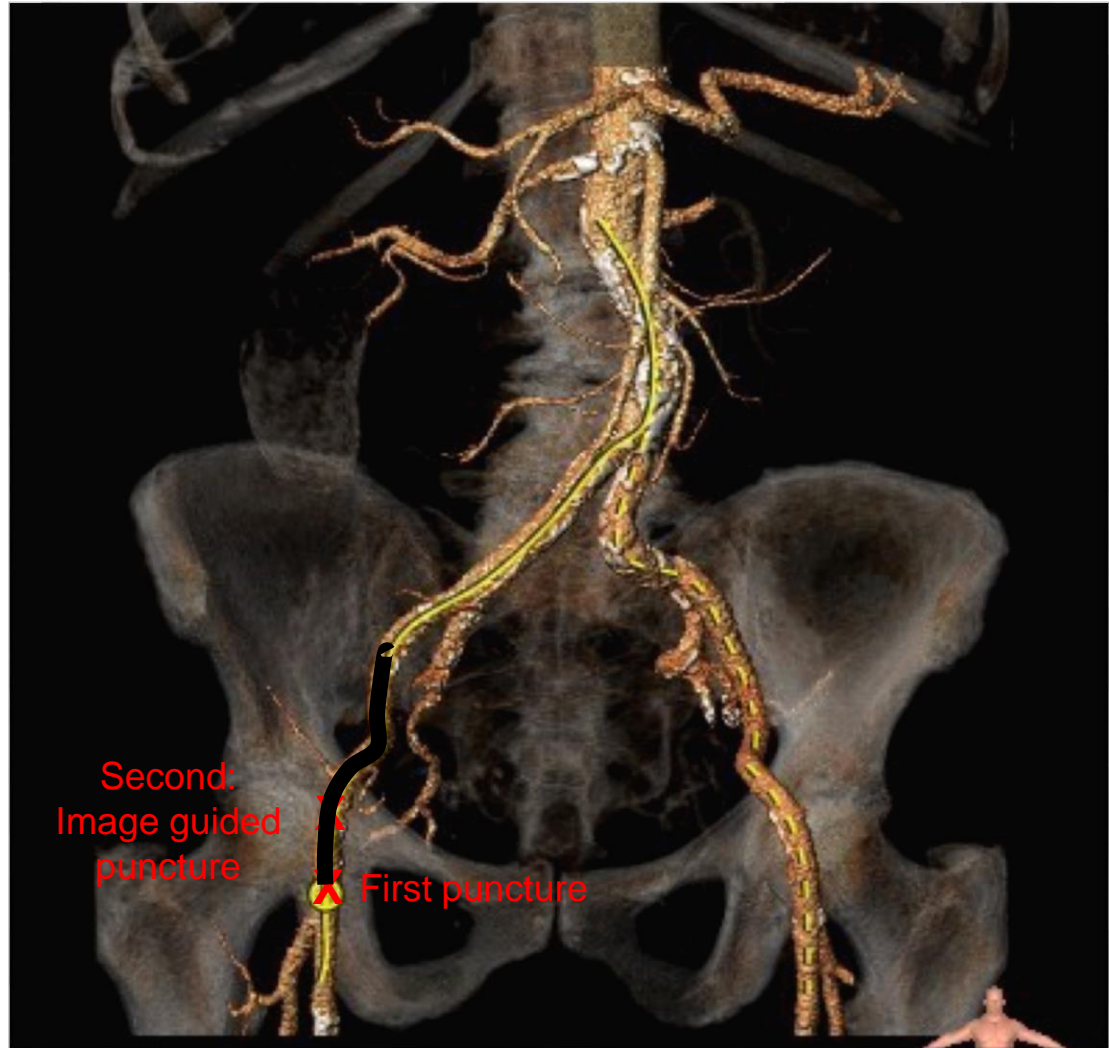


Femoral Access

Ipsilateral
back-up puncture

Pro:

- Image guided puncture
- Mini contrast

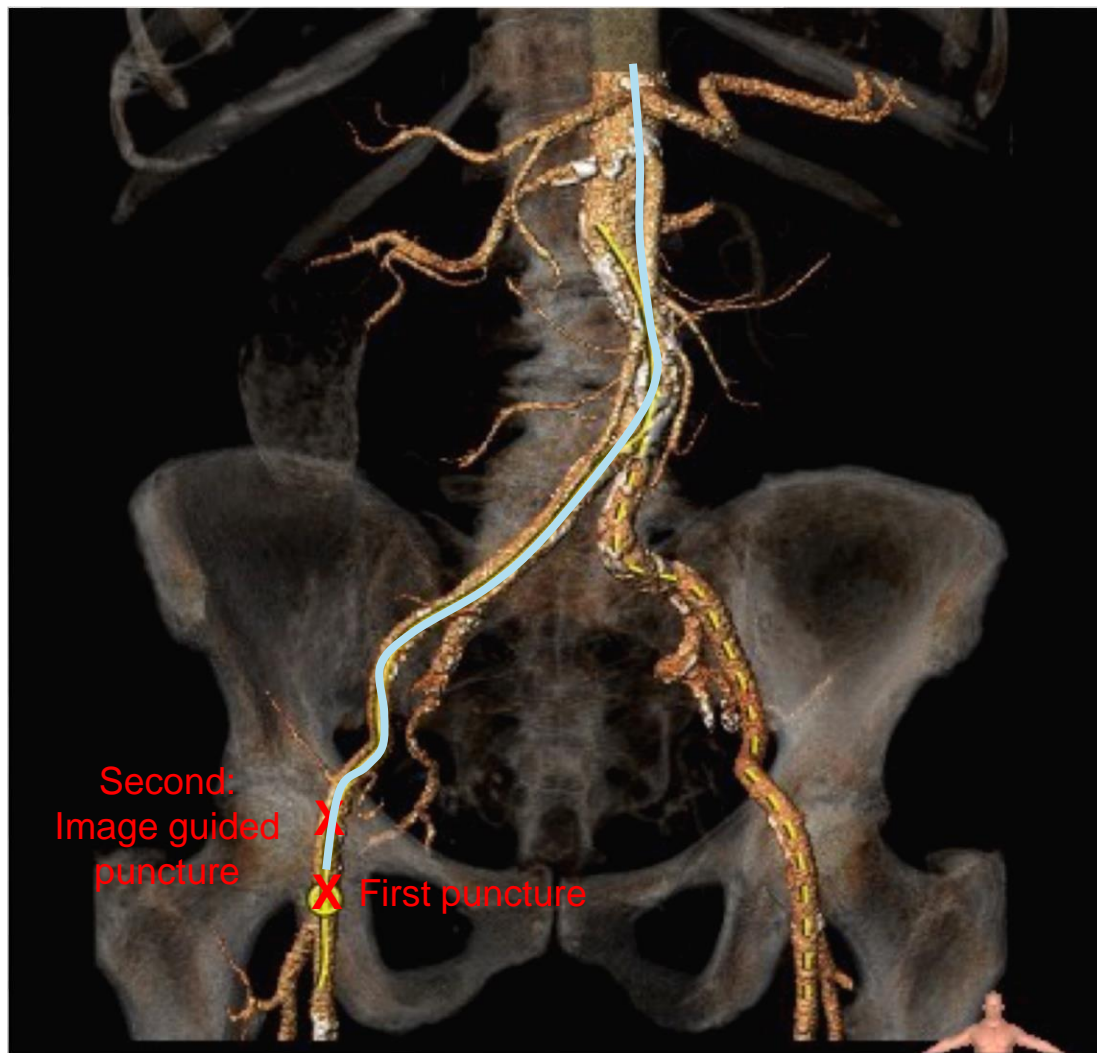


Femoral Access

Ipsilateral
back-up puncture

Pro:

- Image guided puncture
- Mini contrast
- Back-up wire

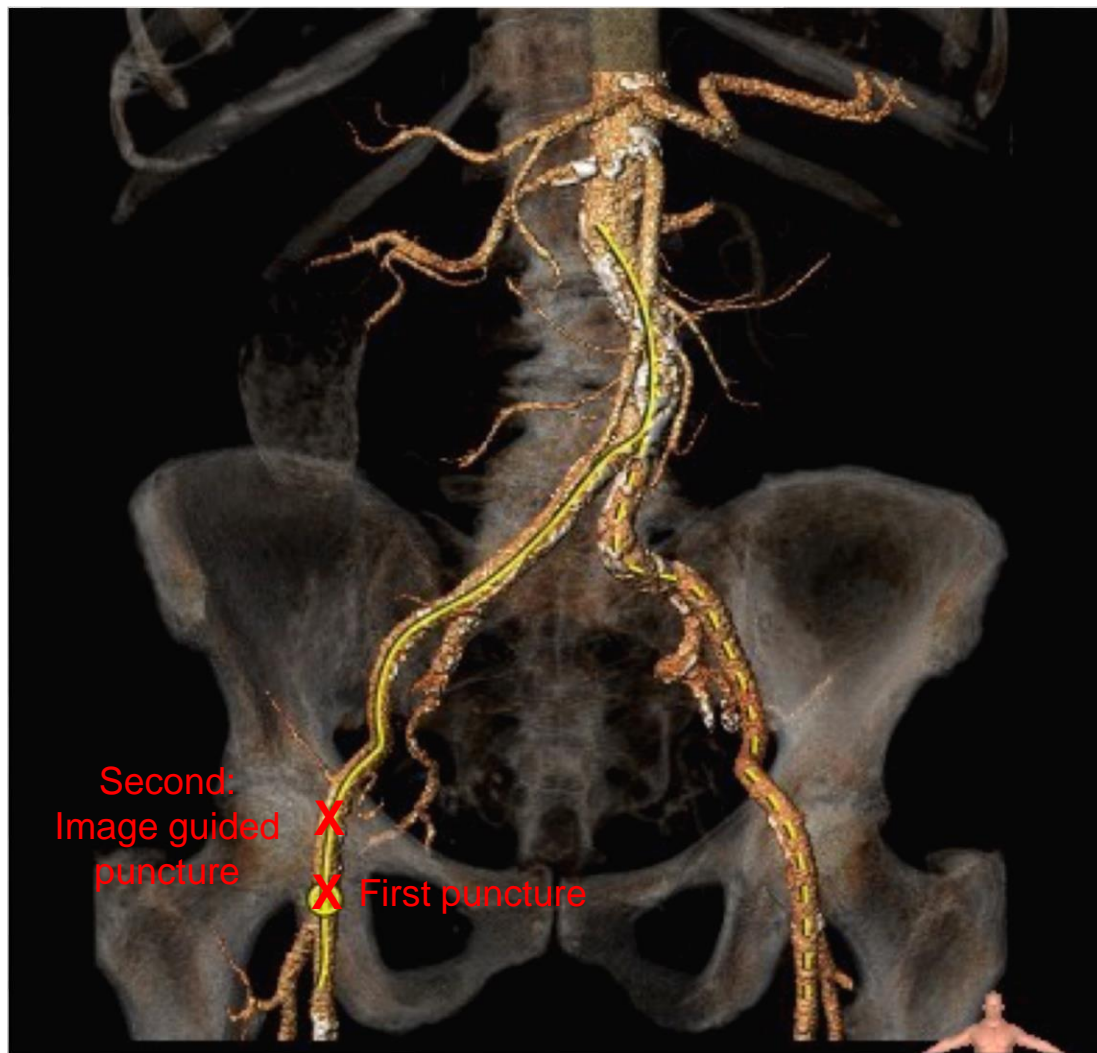


Femoral Access

Ipsilateral
back-up puncture

Con:

- Extra puncture
- Potential trapping of closure devices





Safe access site closure (small holes)

Safe access site closure (small holes)

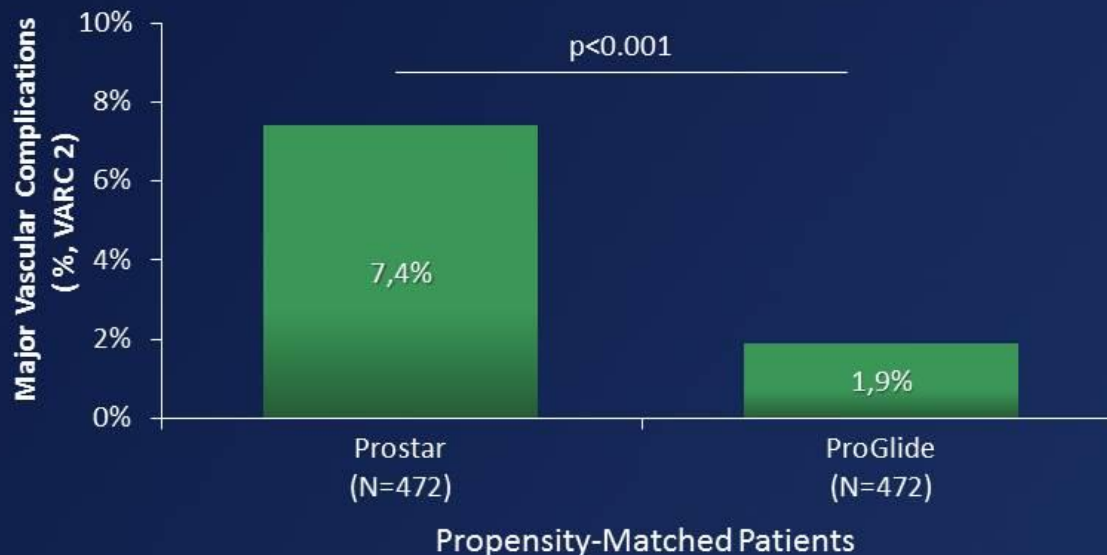


Safe access site closure (large holes)

Predictors of Major Vascular Complications

✓ Closure Device Failure

- Closure device failure contributed ~5% of the vascular complications in the PARTNER IIB study¹
- The CONTROL Study demonstrated that major vascular complications due to closure device failure are significantly less common with ProGlide compared to Prostar²



¹Pichard, et al., presented at ACC 2014; ²Barbash, et al., *Eur Heart J* 2015; epub ahead of print

Safe access site closure



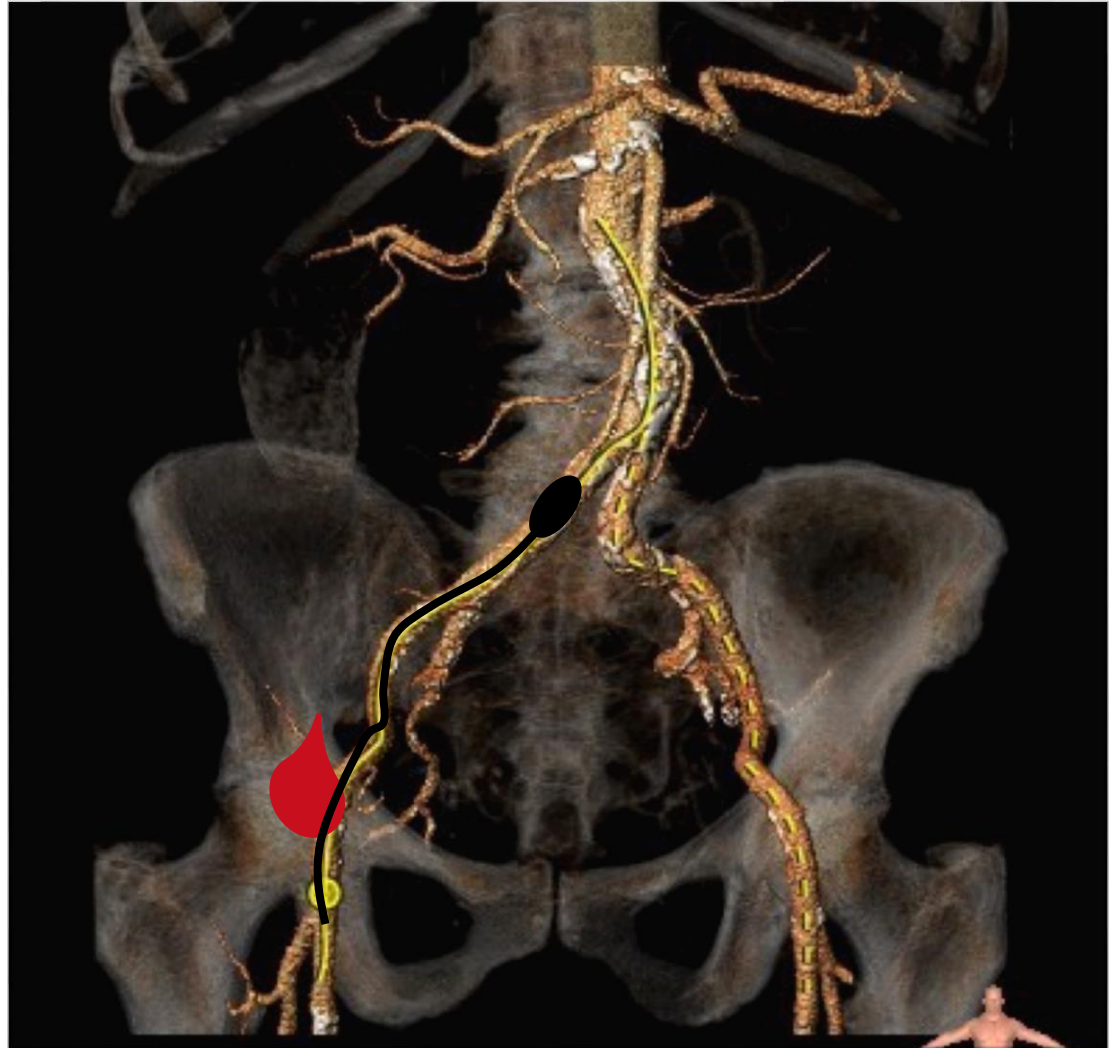


Safe access site closure



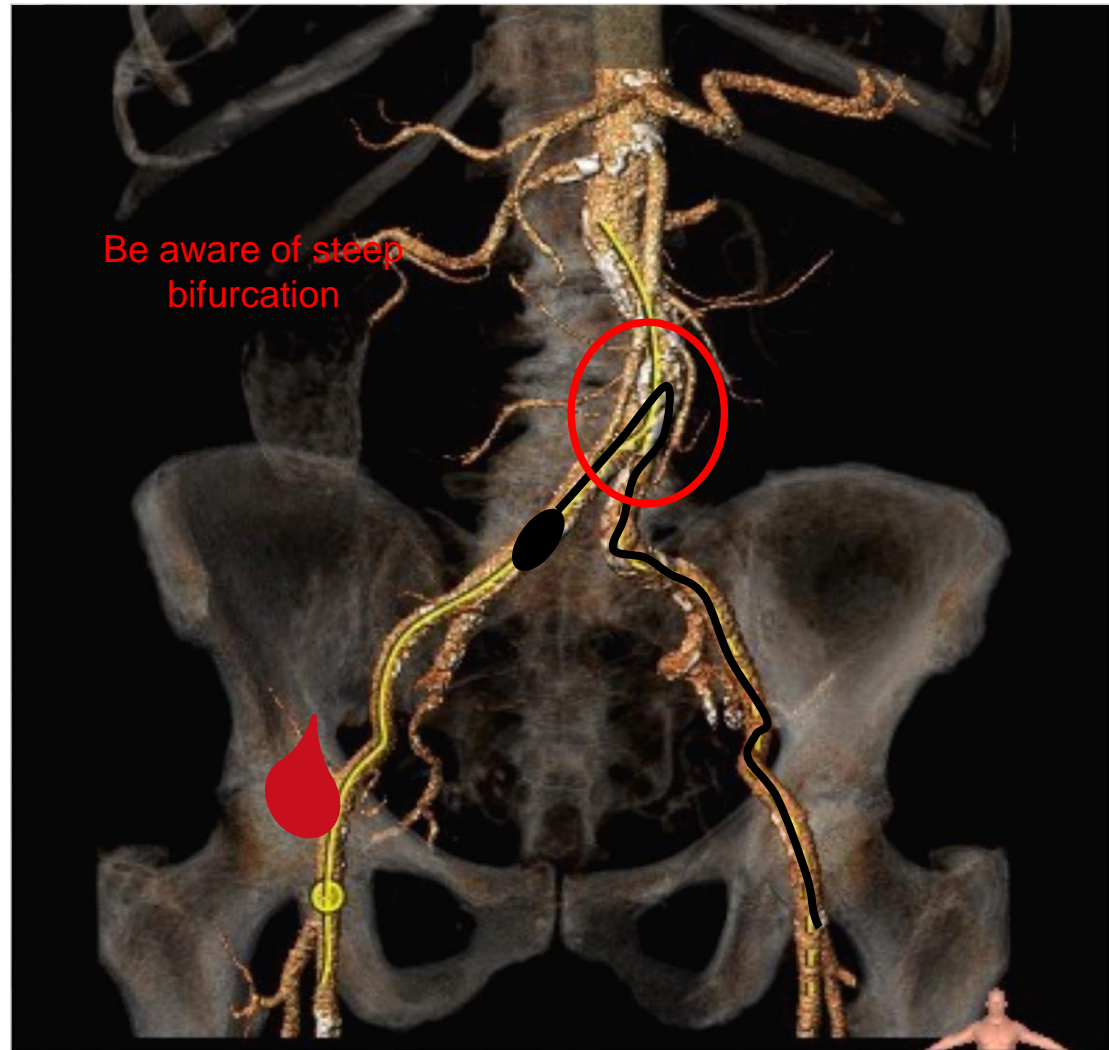
Bail-out options

Iliac occlusion
->
stenting or surgical repair
(Ipsilateral)



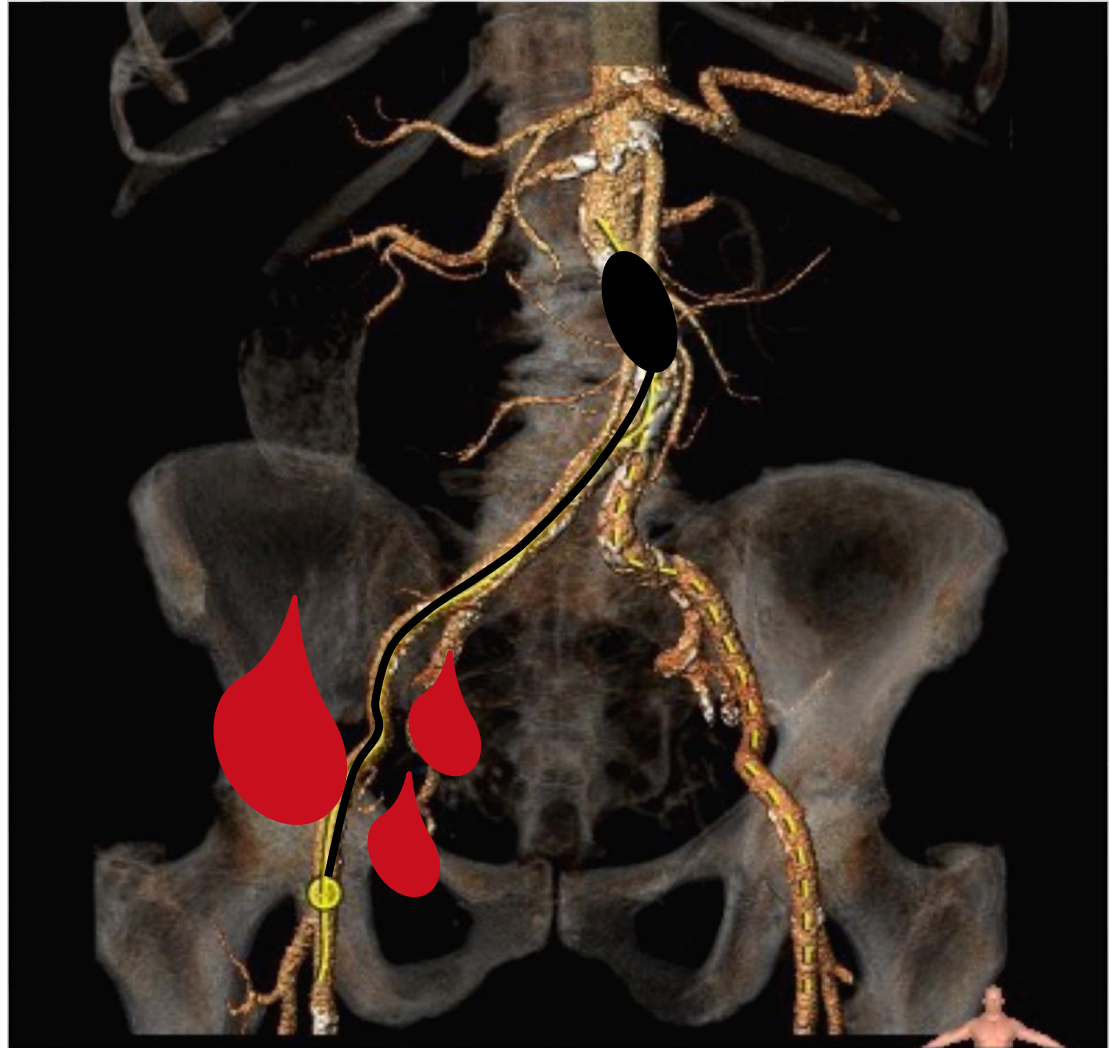
Bail-out options

Iliac occlusion
->
stenting or surgical repair
(Contralateral)



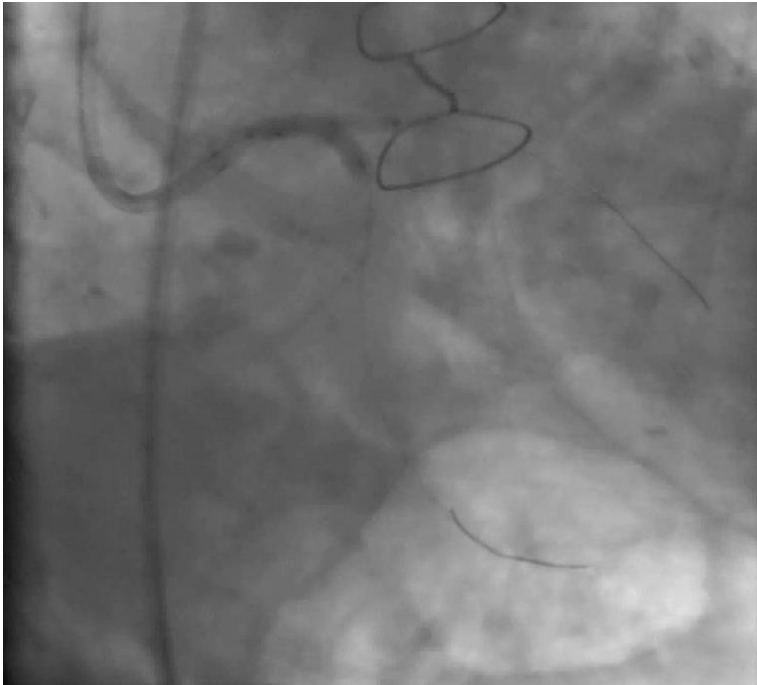
Bail-out options

Rescue balloon
in abdominal aorta
->
stenting or surgical repair

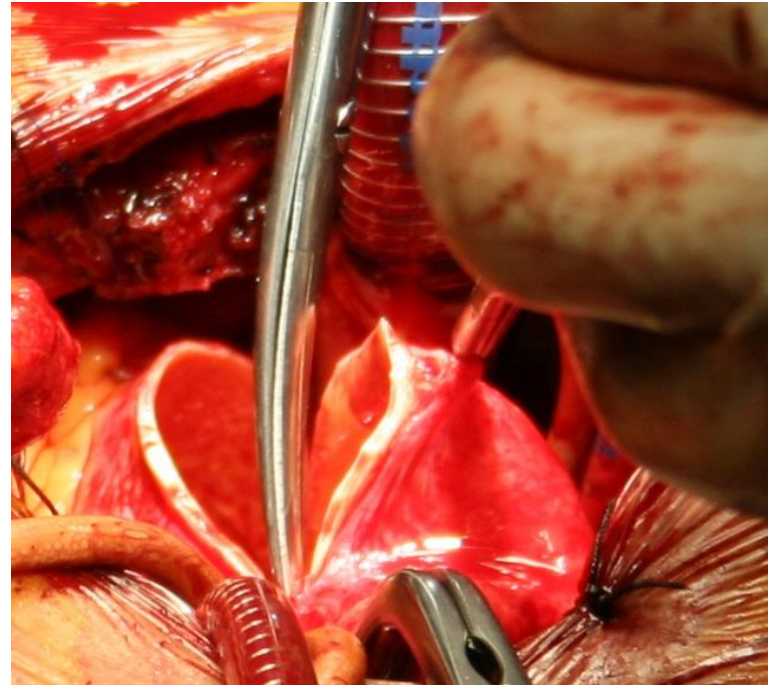


“Transcatheter Fellow” – a new profession?

“classic”
interventional cardiology



“classic”
cardiac surgery



the cardiovascular world used to be simple...

“Transcatheter Fellow” – a new profession?

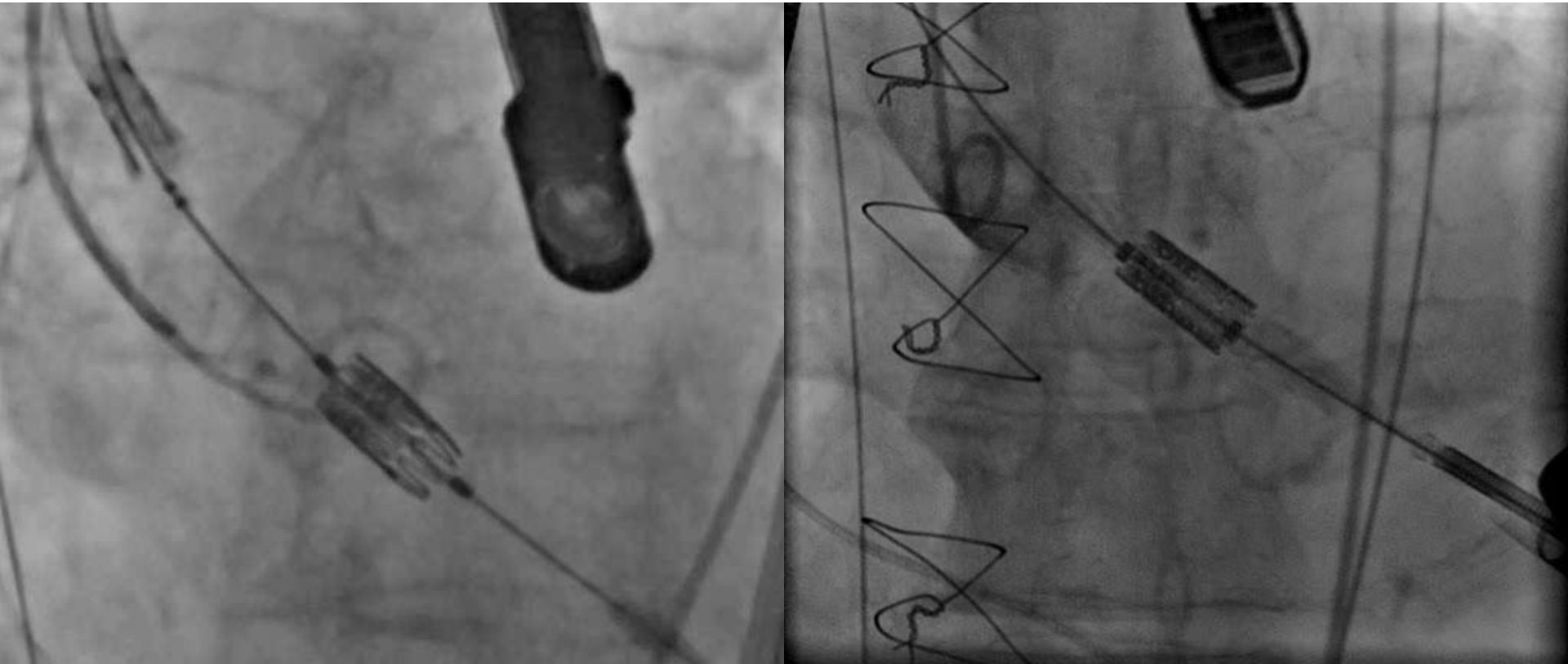
cardiac surgery



interventional cardiology

TF-AVI

TA-AVI



“Transcatheter Fellow” – a new profession?

transfemoral AVI
interventional cardiology

TAVI
Fellow

transapical AVI
cardiac surgery



A new profession = “classic” specialization?

New subdiscipline
within the two classic CV professions (cardiology/surgery)



- specialized
interventional cardiologists + cardiac surgeons

Future independent valve interventionalist ?

A truly NEW future profession
independent from classic CV departments

- TAVI;
TF, TA, TS, TAo..
- transcatheter MV:
MitraClip, NeoChord, Mitralign,
Cardioband, T-MV replacement?...
- Competence in Imaging
- New procedures ???...

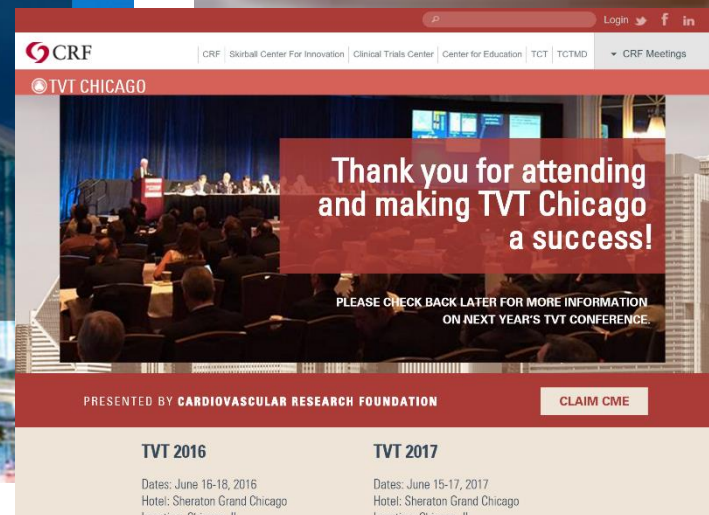
a new animal called ?
 - Transcatheter Fellow
 - Valve Interventionalist
 - Percutaneous surgeon
 - ...



TAVI is mostly not happening “at home”

go where the hype is...

do not stay restricted to YOUR own society meetings



TAVI: “Political environment”

“Heart Team” –
catchword for talks or real life?

- initial TAVI collaboration was mainly driven by:
 - large sheath diameters -> surgical cutdown
 - relatively high complication rates -> surgical bail-out
- based on the SYNTAX experience a true Heart Team developed in some centers
- the idea of a Heart Team became increasingly popular over the last years to offer best patient care
- Heart team Class 1 recommendation in ESC/EACTS GL's



TAVI G-BA regulations -> Team mandatory

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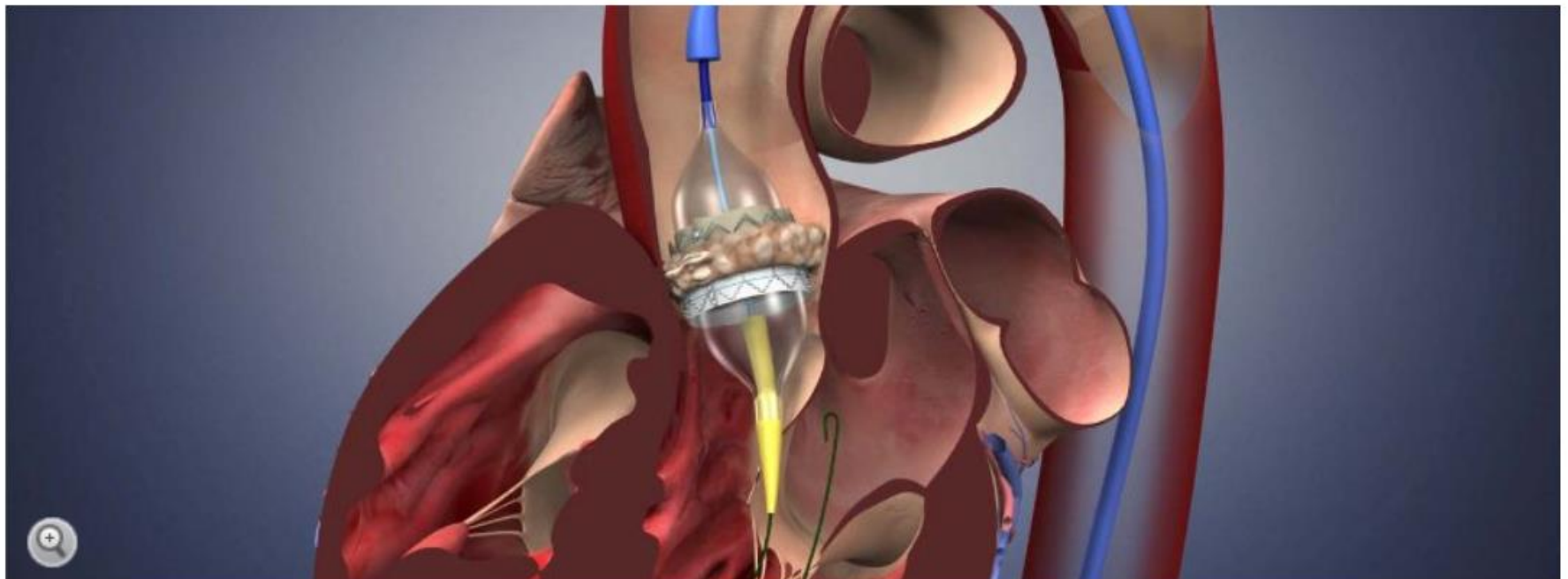
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Fachärzte-Streit: Gremium setzt enge Grenzen für neue Herz-OP



TAVI: “Political environment”

The future of the “Heart Team”:



the idea will only survive if both team partners are equally involved (same profit):

- “fair” 50/50 distribution of cases (first operator)
- joint budget
- ideal scenario: „multidisciplinary transcatheter unit“

TAVI: “Political environment”

The future of the “Heart Team”:



surgeons need to be
actively involved



- A “sleeping” cardiac surgeon on “stand-by” present during TAVI procedures can NOT be considered a “Heart Team”

Living the Team idea: cross-training !

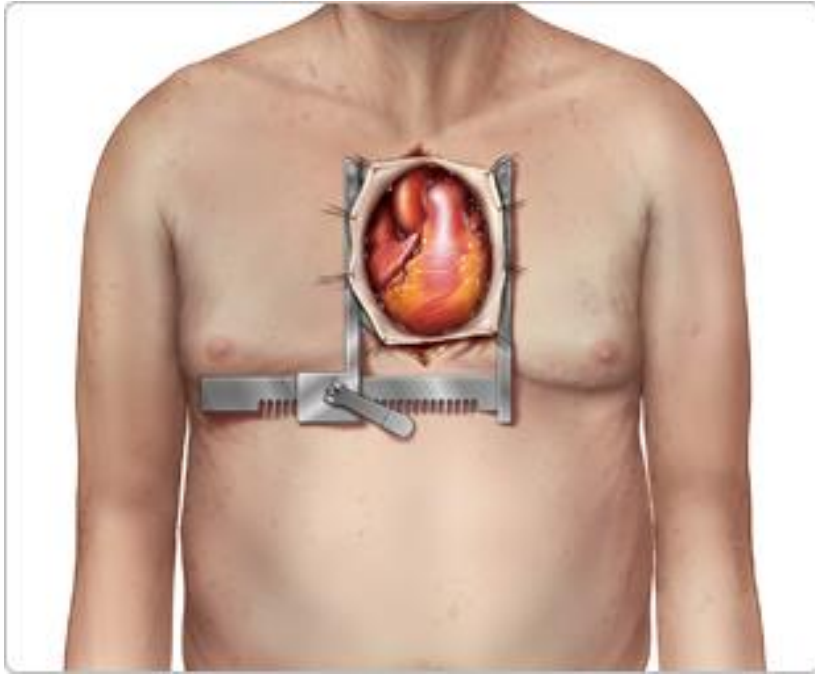
“cross-trained” TF case



surgeon:
“AngioSeal”

interventionalist:
“skin-sutures”

**same principle for
“cross-trained” TA cases**



SAVR via full sternotomy is becoming a “*no seller*”

Cannot compete with (TF) TAVI

Low Risk Trials start enrolling

TF TAVI

- Reality now → intermediate risk TAVI
Reality soon → low risk TAVI
- Dramatic decline of AVR cases to be expected

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Trial record **2 of 6** for: tavr low risk

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The Safety and Effectiveness of the SAPIEN 3 Transcatheter Heart Valve in Low Risk Patients With Aortic Stenosis (PARTNER 3)

This study is not yet open for participant recruitment. (see [Contacts and Locations](#))

Verified February 2016 by Edwards Lifesciences

Sponsor:
Edwards Lifesciences

Information provided by (Responsible Party):
Edwards Lifesciences

ClinicalTrials.gov Identifier:
NCT02675114

First received: January 22, 2015
Last updated: February 2, 2016
Last verified: February 2016
[History of Changes](#)

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Trial record **1 of 6** for: tavr low risk

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Feasibility of Transcatheter Aortic Valve Replacement in Low-Risk Patients With Symptomatic, Severe Aortic Stenosis

This study is not yet open for participant recruitment. (see [Contacts and Locations](#))

Verified December 2015 by Medstar Research Institute

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Information provided by (Responsible Party):
Medstar Research Institute

ClinicalTrials.gov Identifier:
NCT02628899

First received: December 4, 2015
Last updated: December 9, 2015
Last verified: December 2015
[History of Changes](#)

**TF TAVI train is leaving the station:
Last chance to get on board now...**



Thank You!

