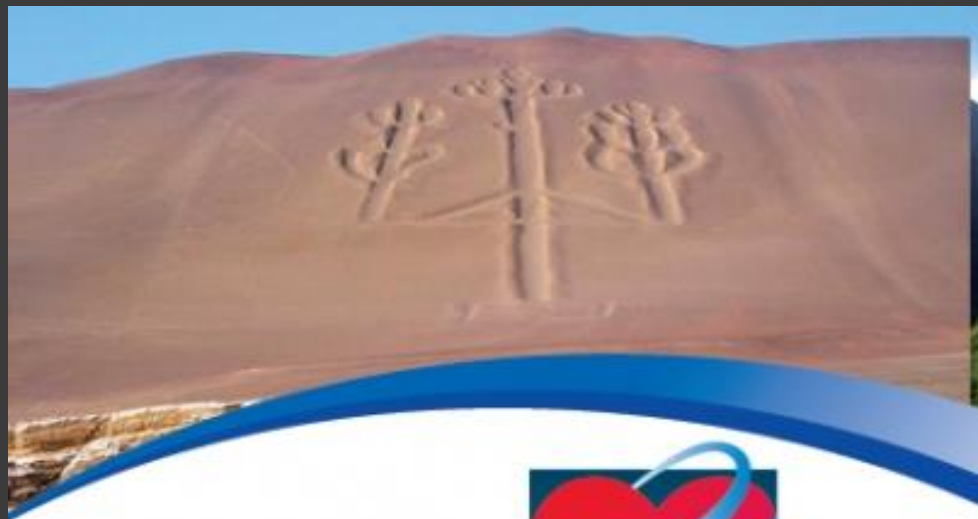

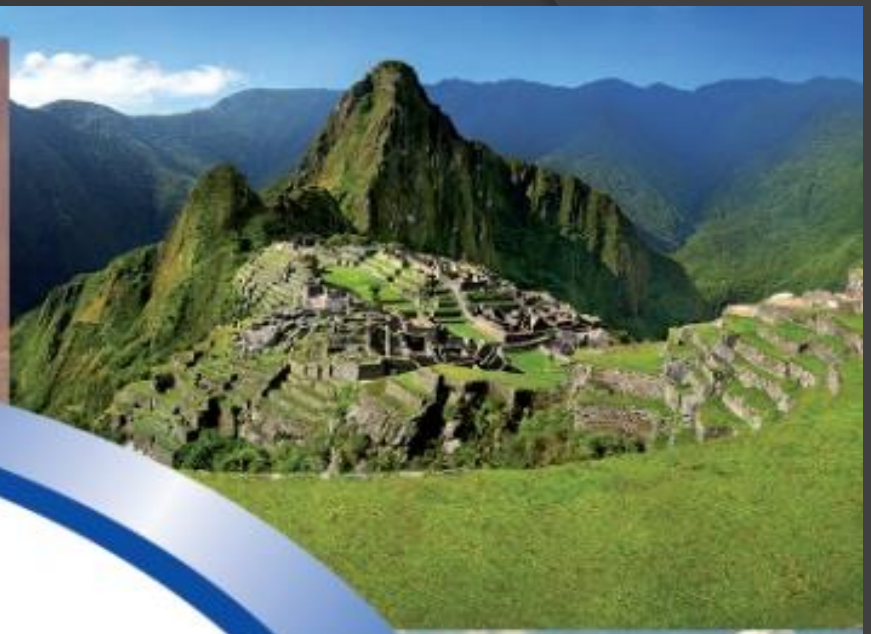

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Alternative Vascular Access

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
Consulting Fees/Honoraria	Medtronic

Percutaneous aortic valve replacement is 80% Peripheral and 20% Cardiac

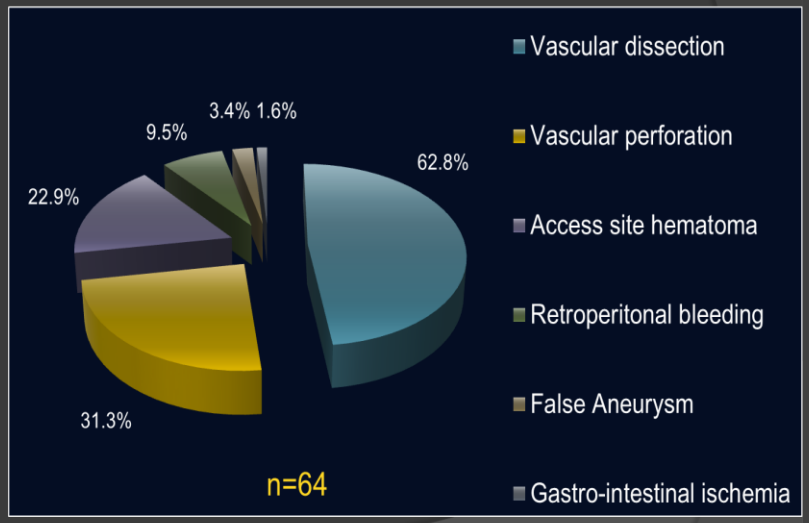
Challenging Vascular Access
Background

Events*	1 Month	1 Year
Any Stroke, %	3.9	6.7
Major, %	2.4	4.1
Minor, %	1.7	3.1
Myocardial Infarction, %	1.3	2.0
Reintervention, %	1.3	2.0
VARC Bleeding, %	35.1	41.4
Life Threatening or Disabling, %	11.7	16.6
Major, %	24.1	27.6
Major Vascular Complications, %	8.3	8.5
Permanent Pacemaker Implant, %	22.2	27.1
Per ACC Guidelines, %	17.4	19.9

* Percentages obtained from Kaplan Meier estimates

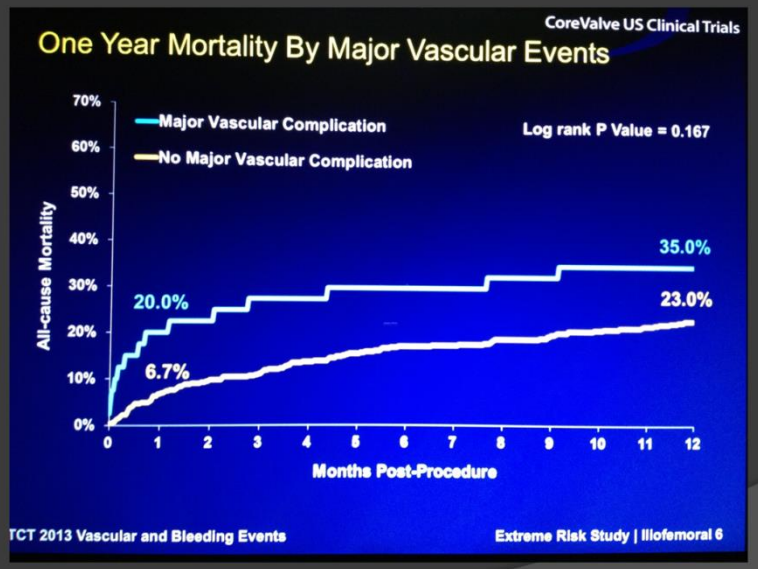
TCT 2013 LBCT Extreme Risk Study | Iliofemoral Pivotal

Major Vascular Complications
PARTNER 1 TF-Cohort A and B



Genereux P et al. J Am Coll Cardiol 2012;60:1043-52

One Year Mortality By Major Vascular Events



Devices and Mayor Vascular Events

Devices and Diameters

	 SAPIEN XT (26 mm)	 SAPIEN 3 (26 mm)	 Lotus (23 mm)	 CoreValve (26 mm)	 Direct Flow (27 mm)	 Evolut R (26 mm)
Recommended minimum artery diameter	6.5 mm	5.5 mm	6 mm	6 mm	6.5 mm	5 mm
Sheath OD (unexpanded)	21.6 Fr	18 Fr	21.8 Fr	20.4 Fr*	21.8 Fr**	18 Fr
Sheath OD (expanded)	26.7 Fr	24 Fr	21.8 Fr	20.4 Fr*	21.8 Fr**	18 Fr

CoreValve® and CoreValve Evolut	23mm (18-20mm)	26mm (20-23mm)	29mm (23-27mm)	31mm (26-29mm)
AccuTrak® with Cook Sheath	18FR 21.8FR			

Sapien XT ™	23mm (18-22mm)	26mm (21-25mm)	29mm (24-27mm)	(27-29mm)
w/ EDW e-Sheath (Unexpanded and While Expanded):	20.1FR 16FR 26.7FR* Max	21.6FR 18FR 26.7FR* Max	24.0FR 20FR 29.7FR* Max	NA

Vascular Access Complications

It is still a major contributor to our patients outcomes ?

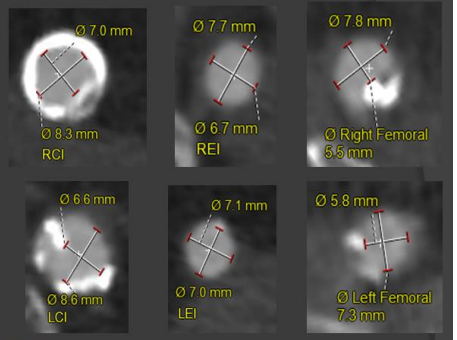
1. *Patient-related factors*
2. *Procedural- or operator-related factors*
3. *Device-related factors*

Access Selection

Safe vs Feasible

AP of Abdominal Aorta and iliacs

CT Images



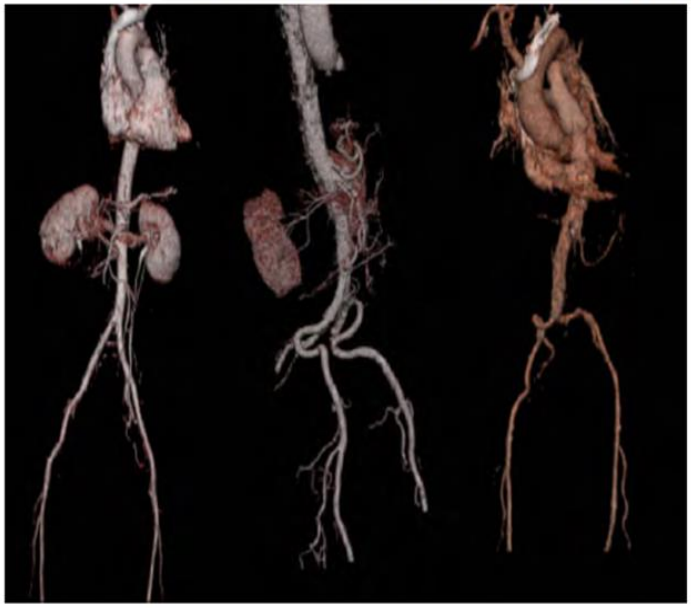
5.5x7.8	RFA min. diameter (mean 6.7)
6.7x7.7	REI min. diameter
7.0x8.3	RCI min. diameter
5.8x7.3	LFA min. diameter (mean 6.6)
7.0x7.1	LEI min. diameter
6.6x8.6	LCI min diameter

(all in mm)

Tortuosity: (per site) moderate- RCI, LCI/ mild- LFA, RFA, LEI

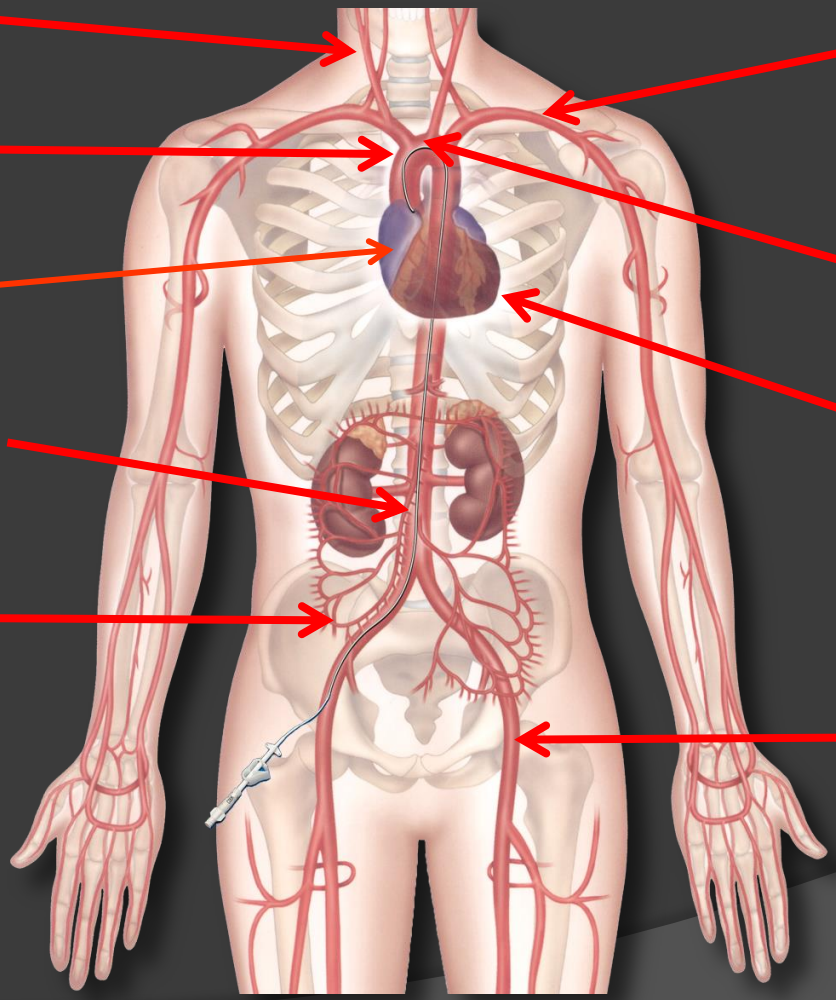
Calcification: (per site) mild- REI, LEI, RFA, LFA

Evaluation of Tortuosity



- 3D reconstructions particularly useful for assessment of tortuosity
- Vessels which are tortuous but *not* heavily calcified often can be straightened with stiffer wires
- Vessels which are tortuous *and* heavily calcified are not favorable for TF TAVR

Multiple Options for Vascular Access



Carotid

Direct aortic

Transeptal

IVC to Aorta Entry

Common Iliac
RPA

Subclavian/
Axillary

Supranavicular

Transapical

Transfemoral

Access Selection Strategy

Femoral Access

- ✓*Percutaneous*
- ✓*Local anesthesia*

Left Axillary Access

- *Caval-Aortic Access*
- *Trans Venous/Septal*
  - *Femoral Vein*
  - *Yugular Vein*

Illiac Access

- ✓*Surgical cut-down*
- ✓*General anesthesia*

- *Supranavicular Access*
- *Carotid Access*

Supra Aortic Arch Access

- ✓*Surgical cut-down*
- ✓*General anesthesia*
- ✓*Thoracotomy*

Direct Aortic Access

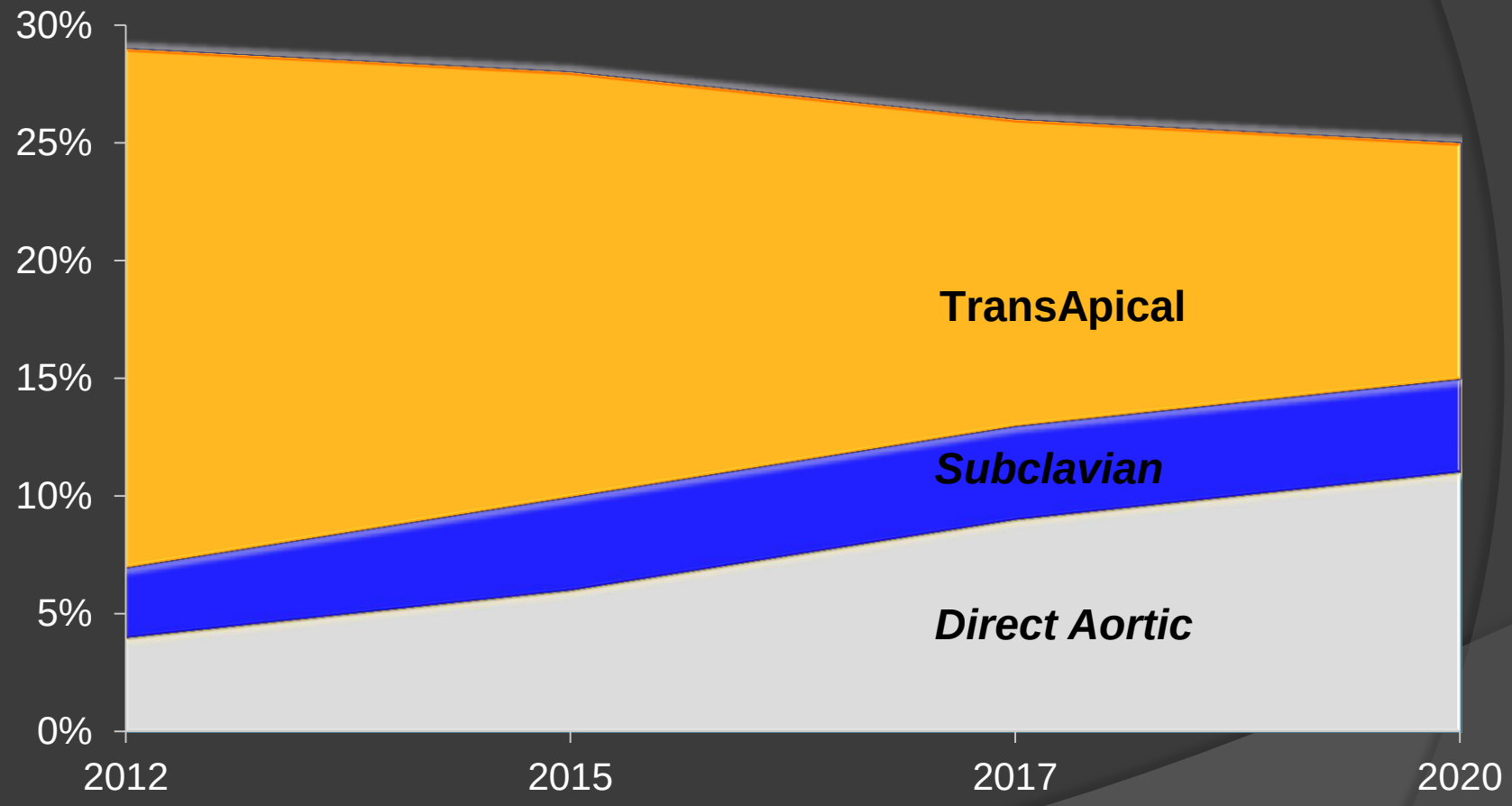
- *Subclavian access*

Trans-apical Access

- ✓*Surgical cut-down*
- ✓*General anesthesia*
- ✓*Thoracotomy*
- ✓*Ventriculotomy*

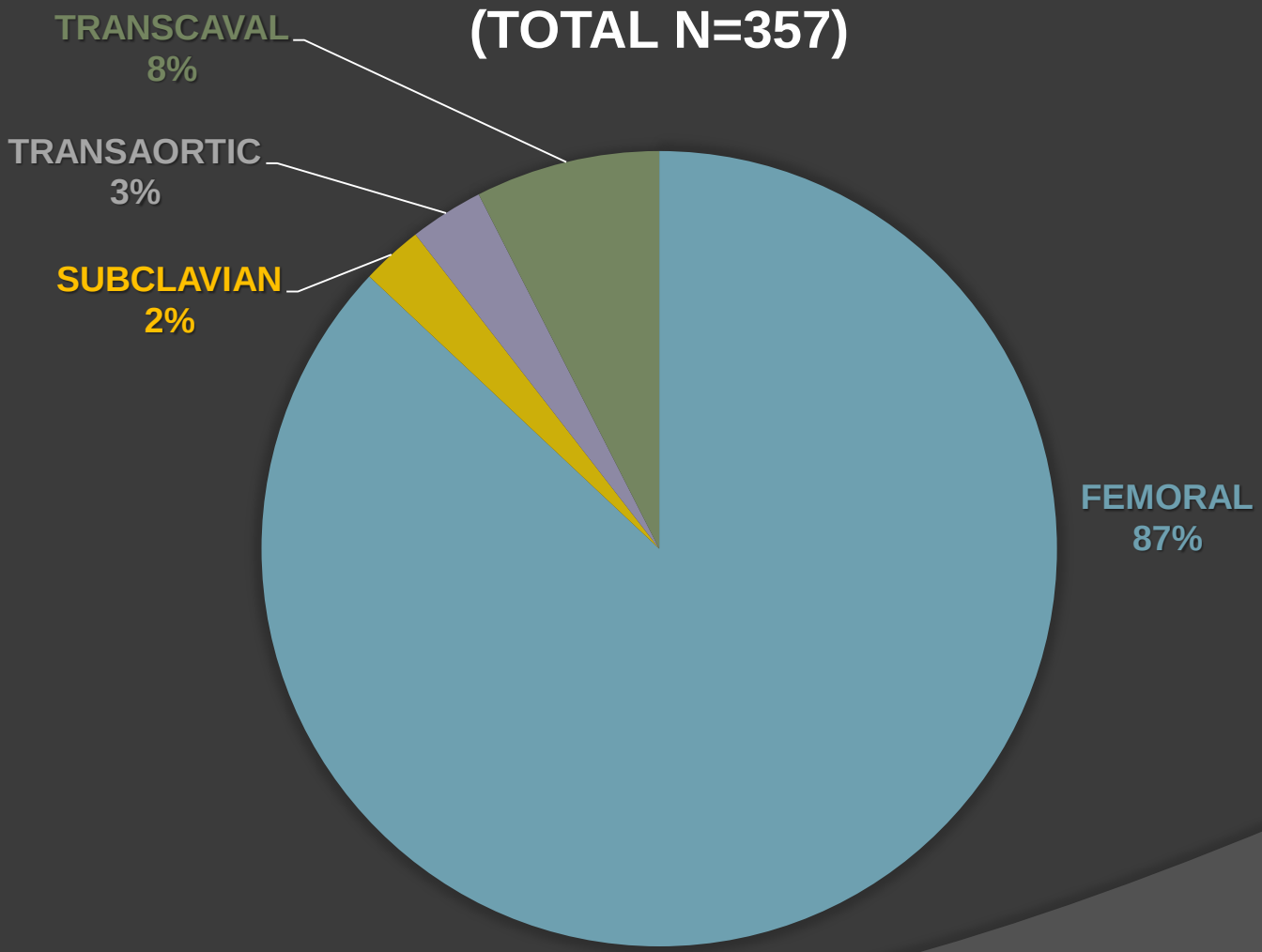
Non-Femoral Access Trends

1 in 4 Patients Will Continue to Benefit From Non-TF access



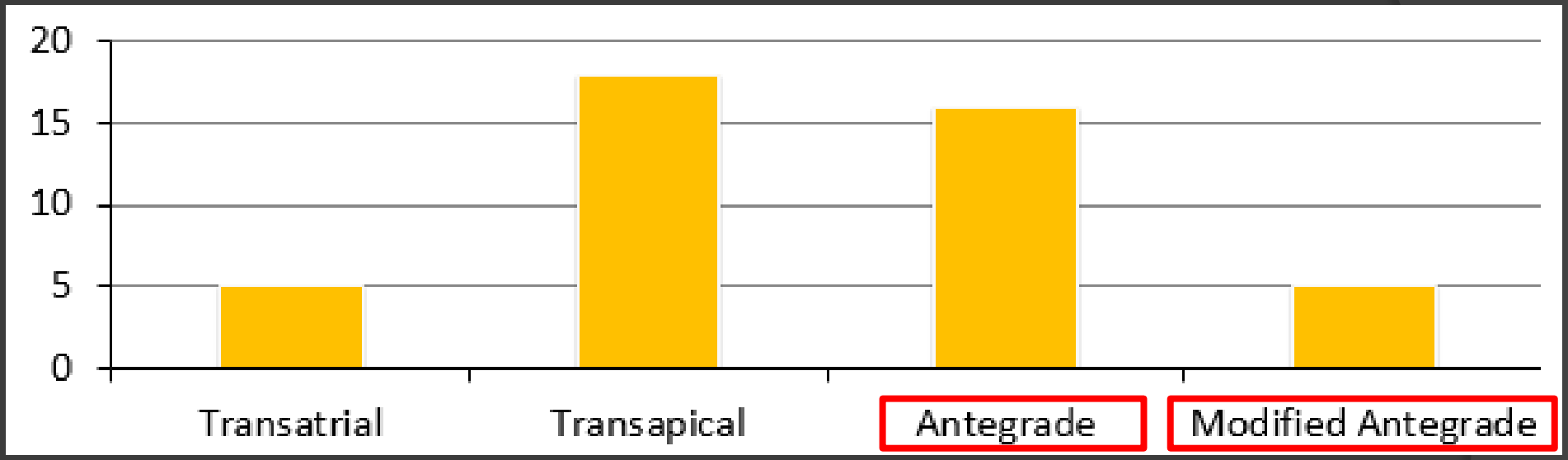
Medtronic, Edwards, St Jude, Boston Scientific, Symmetis investor meetings.
BIBA Medical Quarterly TAVI Report, 2012.

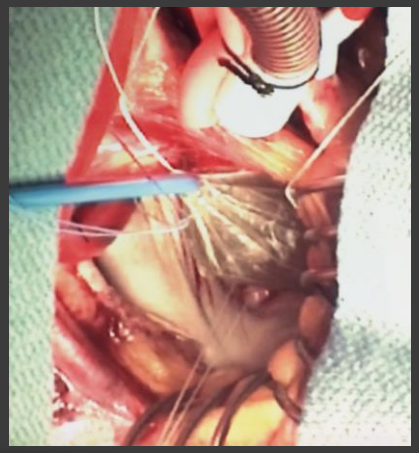
LAST 200 CASES IN ANGIOGRAFIA DE OCCIDENTE CALI (TOTAL N=357)

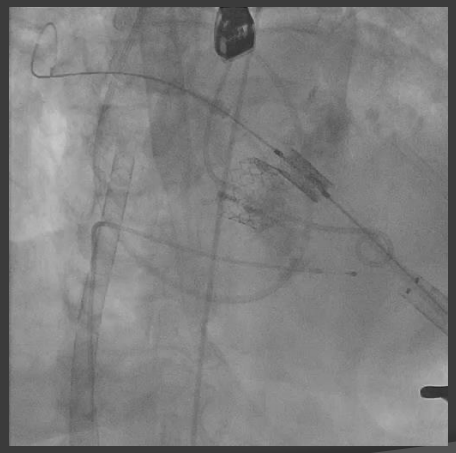


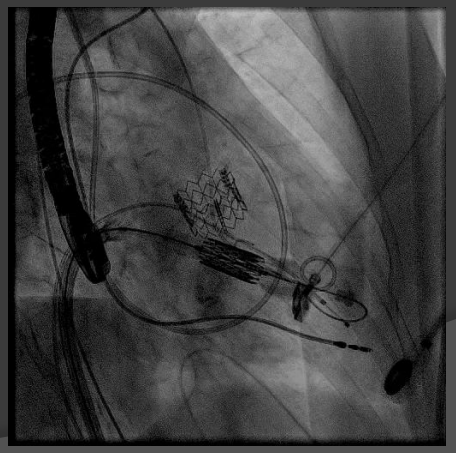
90% of all femoral were Percutaneous

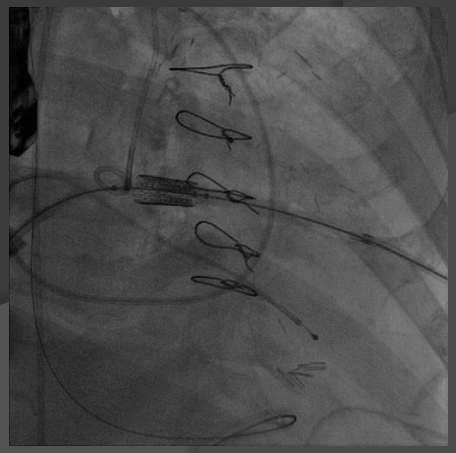
Trans-Venous / Trans-Septal Delivery Approach











Guerrero Mayra; SAPIEN for Native Calcific Mitral Valve Disease Indications, Techniques and Outcomes, TVT Chicago 2015

Trans-Venous / Trans-Septal SAPIEN in MAC Global Registry

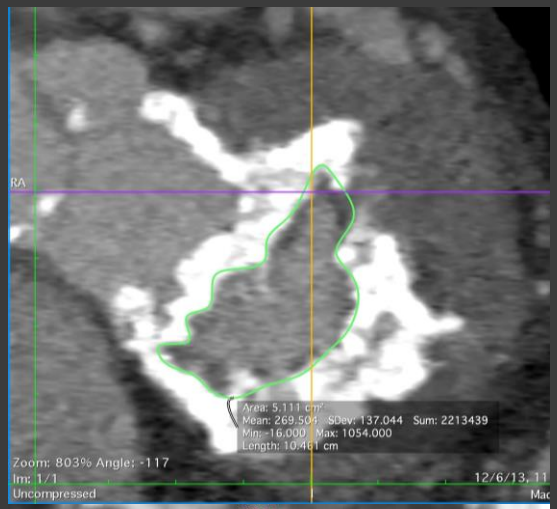
44 patients in 8 countries (Sept 2012-April 2015)
Underwent TMVR with compassionate use of SAPIEN valves
Mean follow-up 5 months (1 to 32 months)

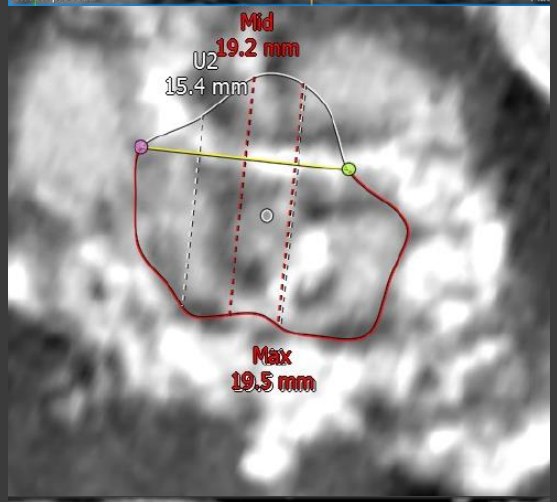
Institutions

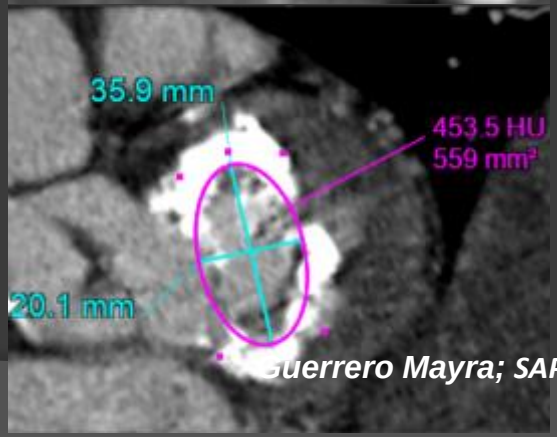
- *Aurora St. Lukes Medical Center (Milwaukee, USA)*
- *Bichat Hospital. Univ of Paris (Paris, France)*
- *Angiografía de Occidente (Cali, Colombia)*
- *Central Manchester Univ Hospitals (Manchester, UK)*
- *Henry Ford Hospital (Detroit, MI. USA)*
- *Heart Center Leipzig (Leipzig, Germany)*
- *Institute of Cardiology (Warsaw, Poland)*
- *King's College Hospital (London, UK)*
- *Laval University (Quebec, Canada)*
- *Mayo Clinic (Rochester, MN. USA)*
- *Rangueil University Hospital (Toulouse, France)*
- *St. Francis Medical Center (Peoria, IL. USA)*
- *St. Paul's Hospital (Vancouver, Canada)*
- *UCLA Medical Center (Los Angeles, CA. USA)*
- *Univ Hospital of Lausanne (Laussane, Switzerland)*
- *Uniersitats Klinikum Bonn*
- *University of Rouen's Charles Nicolle Hospital*

Collaborators

- *Daniel O'Nair*
- *D. Himbert, M. Urena, A. Vahanian*
- *Antonio Dager, Pedro Martinez-Clark*
- *Vaikom Mahadevan*
- *M. Guerrero, A. Greenbaum, W. O'Neill*
- *David Holzhey*
- *A. Witkowski, M. Dabrowski, K. Kusmierski*
- *Olaf Wendler, Phillip MacCarthy*
- *Josep Rodes-Cabau*
- *Eleid Mackram, Charanjit Rihal*
- *Nicolas Dumonteil*
- *Daniel Ciaburri*
- *Danny Dvir, John Webb*
- *William Suh, G. Vorobiof, Richard Shemin*
- *Enrico Ferrari*
- *Georg Nickenig*
- *Alain Cribier*







Trans-Venous / Trans-Septal Techniques

Mitral Annulus Sizing

- ***Cardiac CT best method***
- ***Better assessment of Calcium***
- ***Diameters and Area are helpful***
- ***Perimeter less helpful at this time***

Guerrero Mayra; SAPIEN for Native Calcific Mitral Valve Disease Indications, Techniques and Outcomes, TVT Chicago 2015

Trans-Venous / Trans-Septal Techniques

Predicting LVOT Obstruction

- ***Pre-existing LVOT gradient***
- ***Aorto-Mitral angle***
- ***Septal bulge***
- ***Small LV cavity***
- ***Length of anterior MV leaflet***
- ***Size of SAPIEN valve***
- ***Depth of implantation***

When annulus size is borderline between SAPIEN sizes and risk of LVOTO is a concern, select the shorter valve to decrease risk of LVOTO

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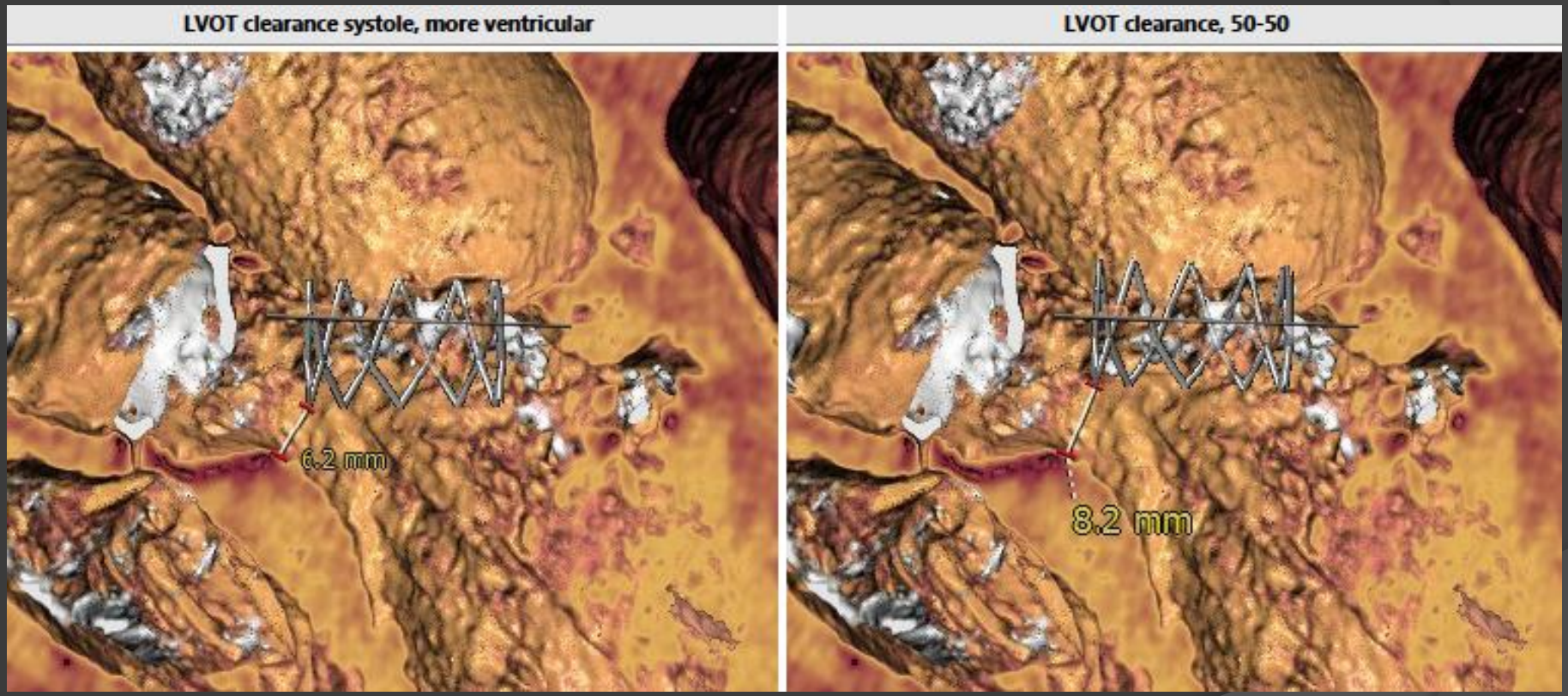
Trans-Venous / Trans-Septal Techniques

Predicting LVOT Obstruction



Look at both, systole and diastole

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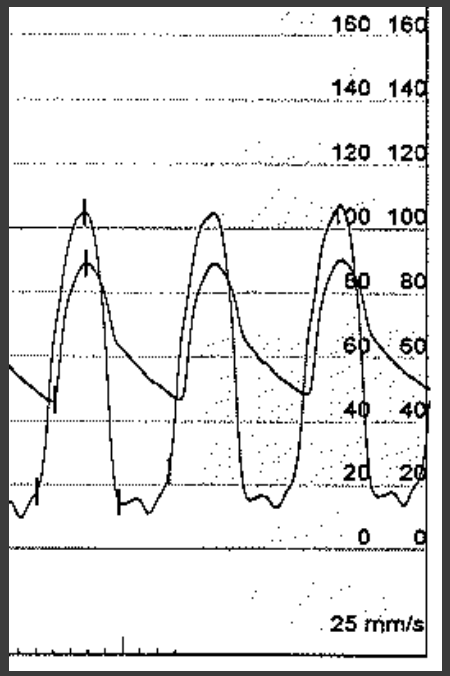
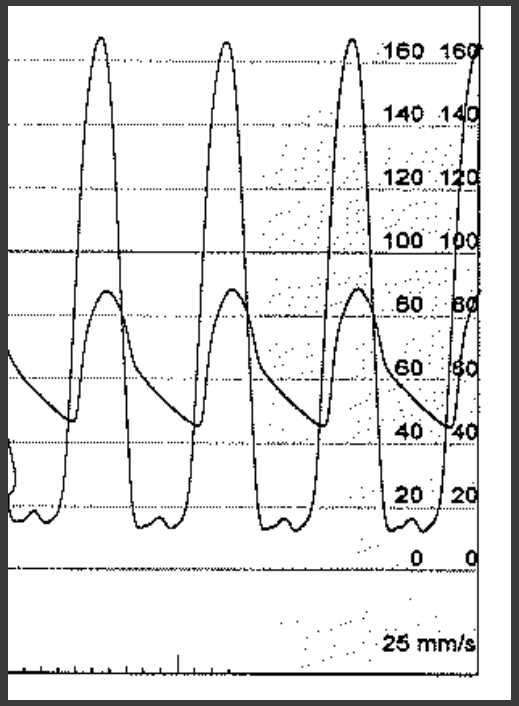
Trans-Venous / Trans-Septal Techniques

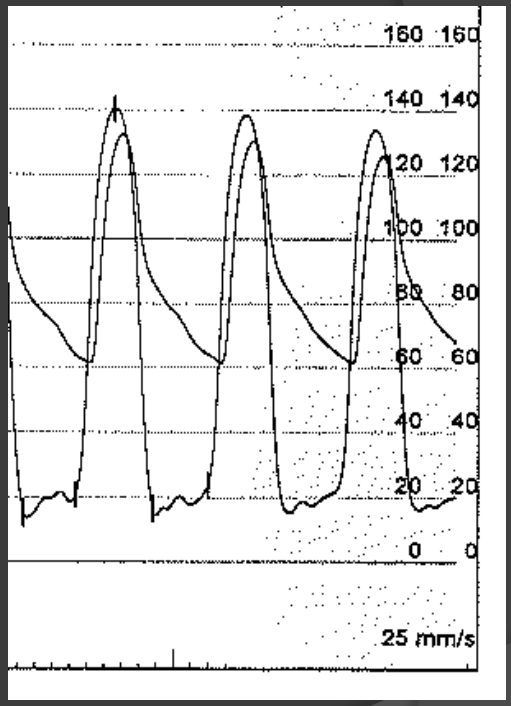
Dealing with LVOT Obstruction



Baseline



After TMVR



Alcohol Septal Ablation

Two successful rescues (US and France)

Guerrero Mayra; SAPIEN for Native Calcific Mitral Valve Disease Indications, Techniques and Outcomes, TVT Chicago 2015

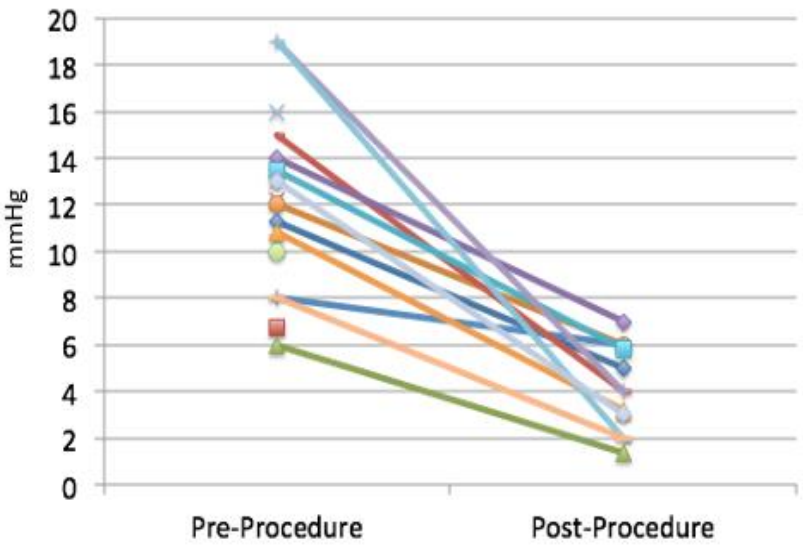
Procedural Outcomes

	n (%)
Successful Implantation/positioning	41 (93%)
LVOT obstruction with hemodynamic compromise	5 (11%)
Conversion to open surgery (emb=2, perf=1, LVOTO=1)	4 (9 %)
Valve embolization	3 (6.8%)
LV perforation (surgery=1, conservative=1)	2 (4.5%)
Pulmonary Vein Perforation	1 (2.3%)
Need for second valve (migration=2, MR=1)	3 (6.8%)

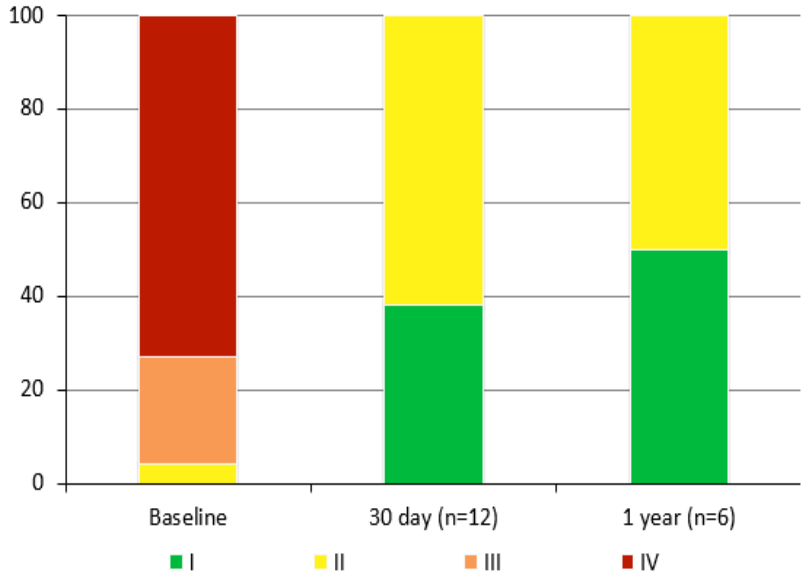
30 Day Mortality

	n (%)
Cardiac	6 (13.6 %)
LVOT Obstruction	2 (4.5%)
LV Perforation	2 (4.5%)
Complete AV block	1 (2.3%)
MI due to air emboli / Pulmonary vein perforation	1 (2.3%)
Non-Cardiac	9 (20.4 %)
Multi-organ failure	5 (11.3 %)
Pneumonia	2 (4.5%)
Stroke	1 (2.3%)
Thoracentesis related bleeding complication	1 (2.3%)

Mean Mitral Valve Gradients



NYHA Class



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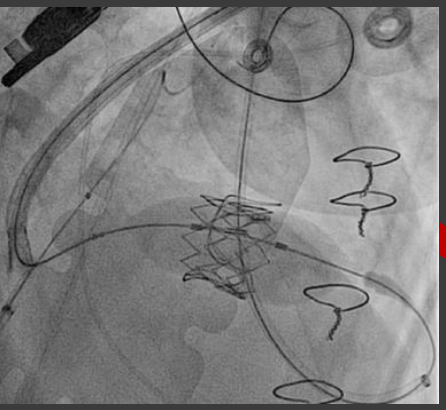
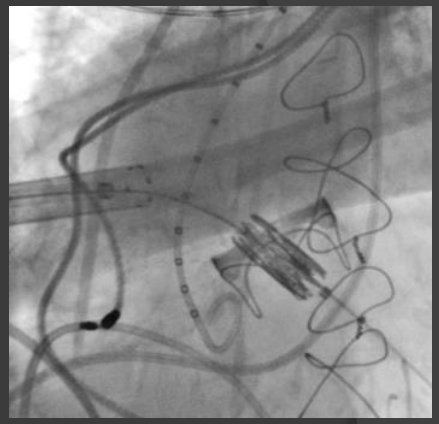
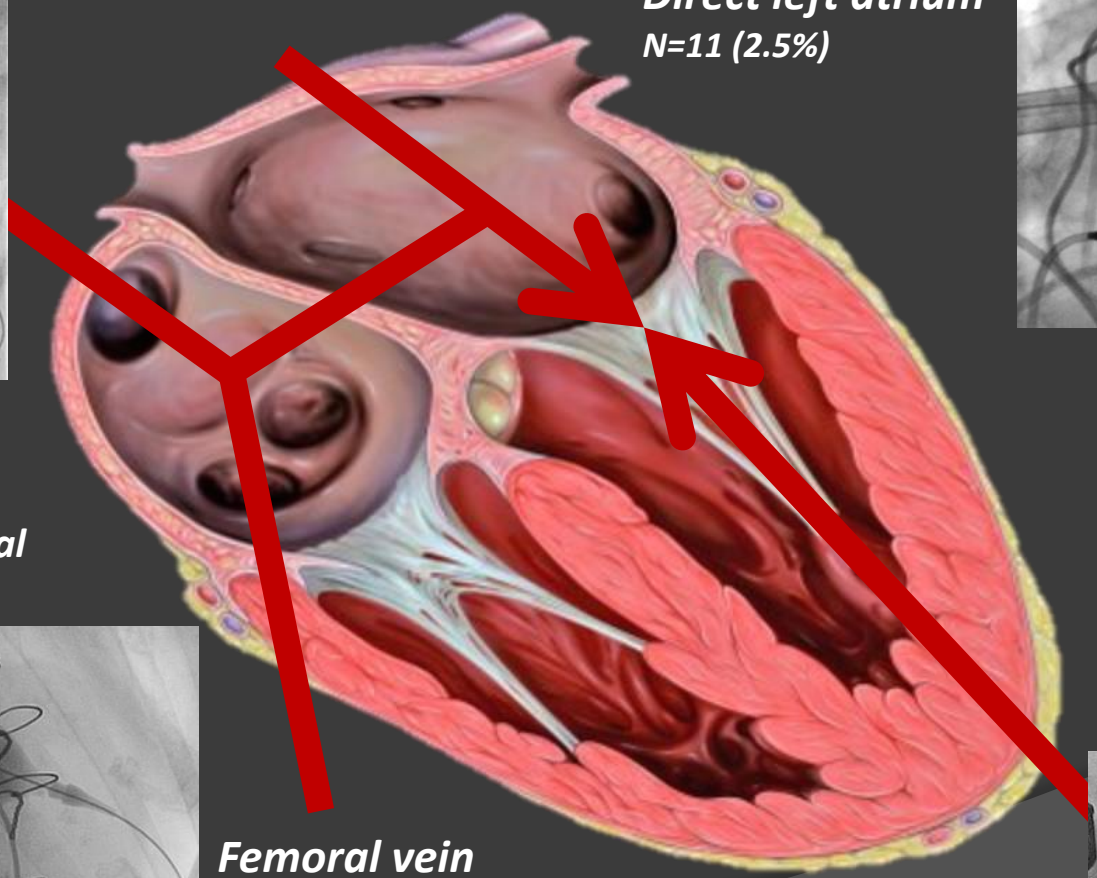
Access during Mitral VinV / VinR and other Mitral procedures (n=437)

Jugular Vein



Direct left atrium
N=11 (2.5%)

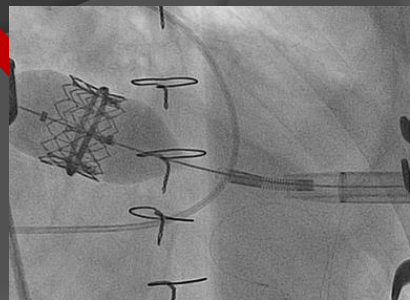




Total trans-septal
n=81 (18.5%)

Femoral vein

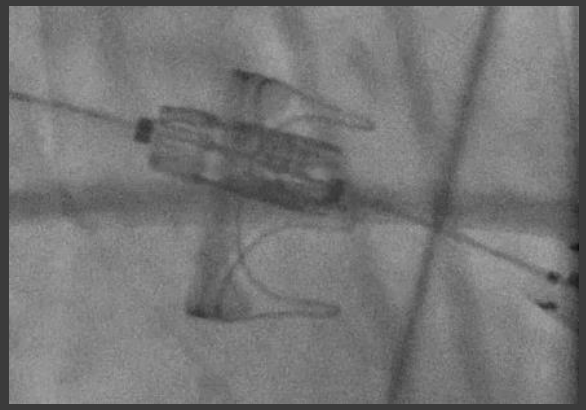
Transapical
n=345 (78.9%)



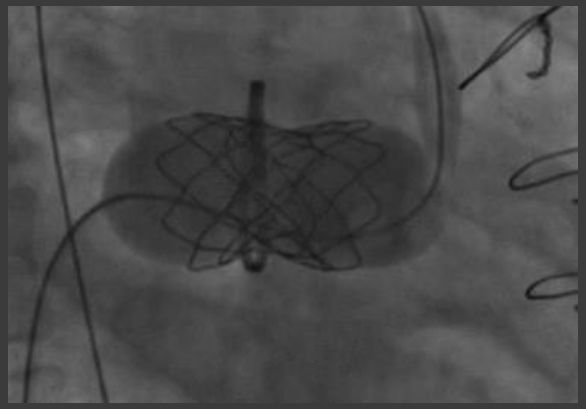
Dvir, Danny; Transcatheter Mitral Valve-in-Valve and Valve-in-Ring Implantations, TVT Chicago 2015

Transcatheter devices (n=437)

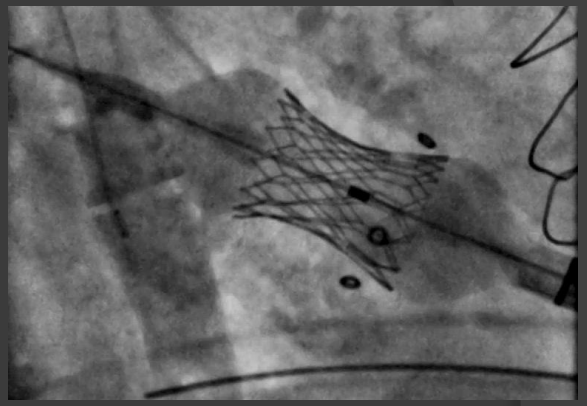
Edwards Cribier / SAPIEN / XT (Edwards Lifesciences) n= 374, 85.6%



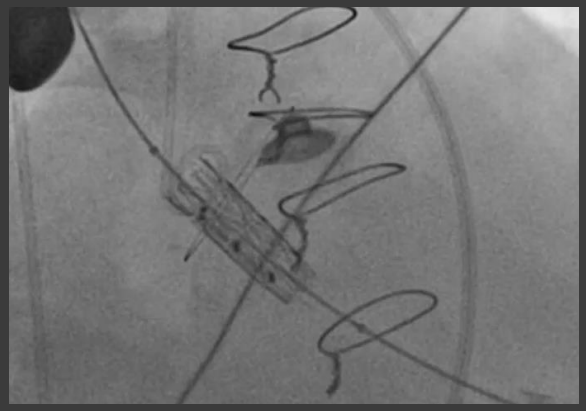
Melody (Medtronic) n=28, 6.4%



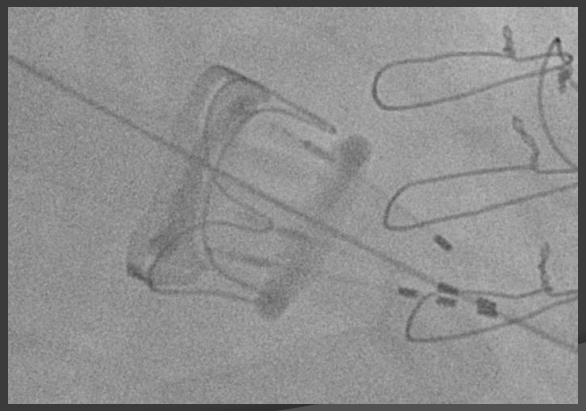
SAPIEN 3 (Edwards Lifesciences) n= 17, 3.9%



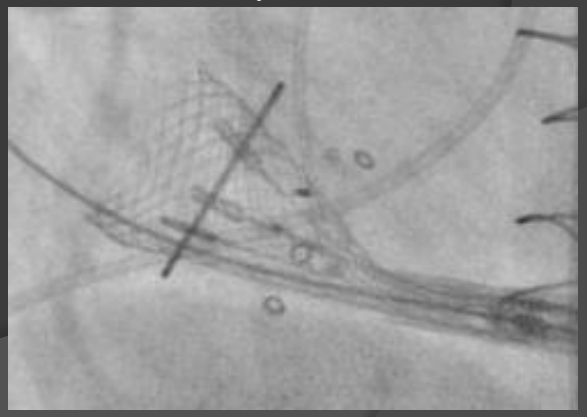
Inovare (Braile) n= 12, 2.7%



Direct Flow (Direct Flow Medical) n= 3, 0.7%



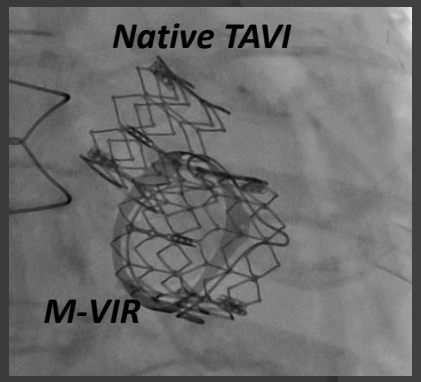
Lotus (Boston Scientific) n= 3, 0.7%

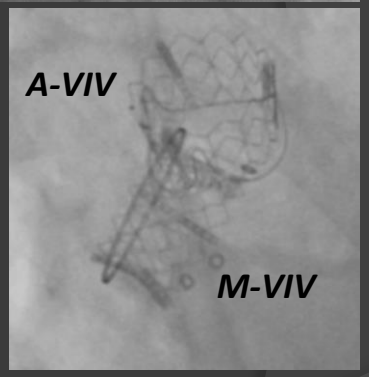


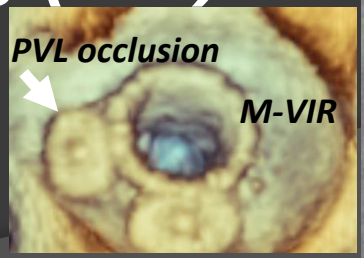
Dvir, Danny; Transcatheter Mitral Valve-in-Valve and Valve-in-Ring Implantations, TVT Chicago 2015

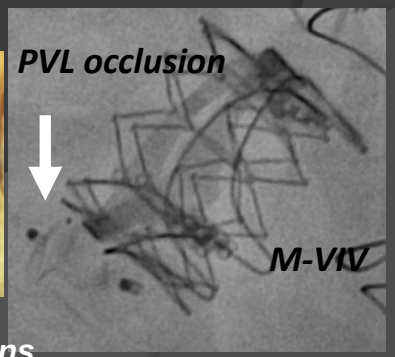
Combined procedures (n= 57, 13%)
Mitral VIV / VIR and…

- Native aortic valve TAVI (n=22)
- Aortic valve-in-valve (n=20)
- Mitral paravalvular leak closure (n=12)
- Tricuspid valve-in-valve/ring (n=3)



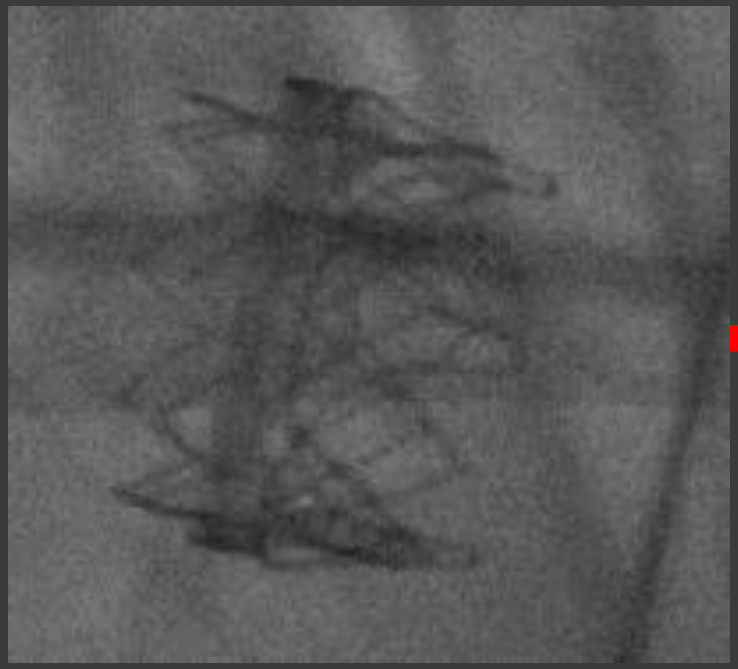


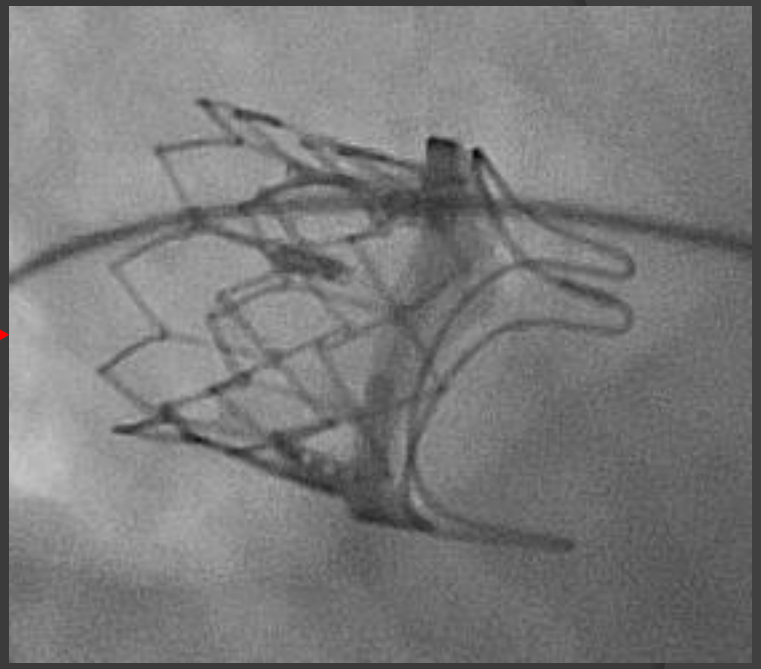




Dvir, Danny; Transcatheter Mitral Valve-in-Valve and Valve-in-Ring Implantations, TVT Chicago 2015

Delayed malpositioning





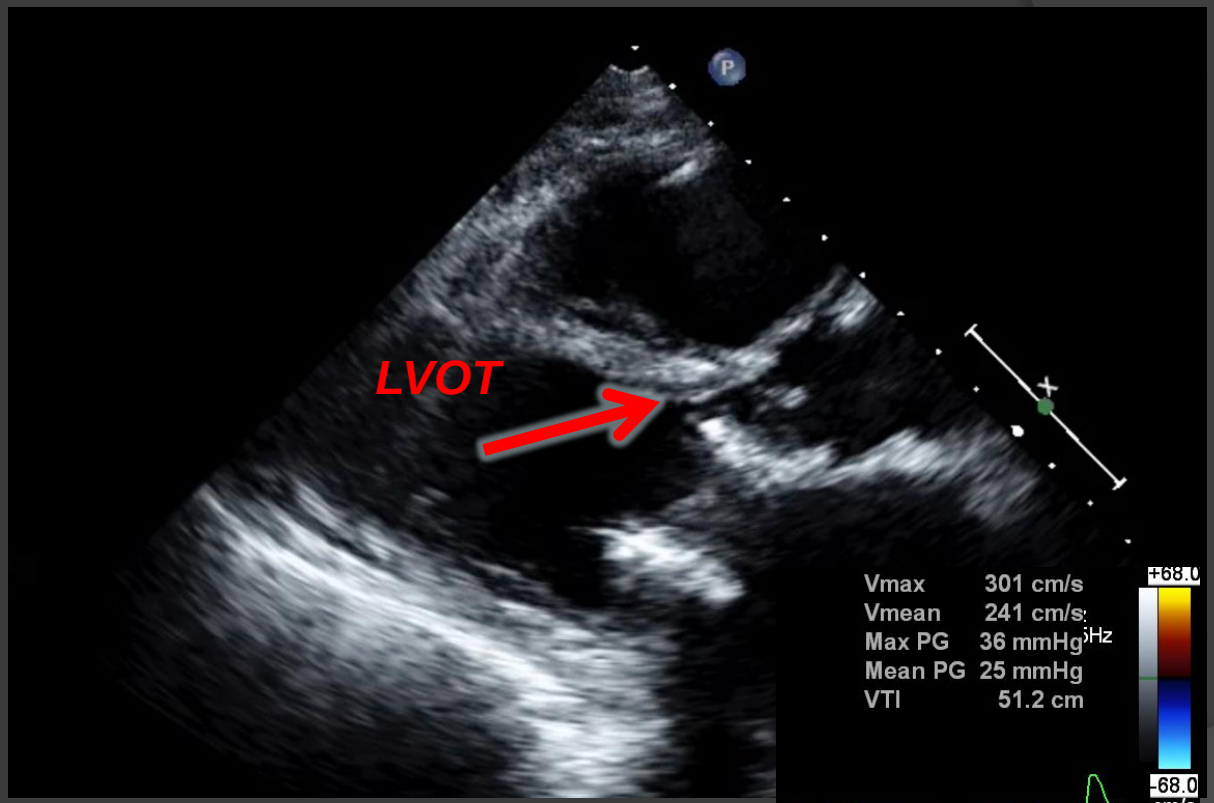
Mitral Valve-in-Valve

After 2 months

Delayed malpositioning (>1 week) in 1.1%.

Dvir, Danny; Transcatheter Mitral Valve-in-Valve and Valve-in-Ring Implantations, TVT Chicago 2015

LVOT obstruction



3.7% in the studied population.
More common after Valve-in-Ring
(8% vs. 2.6% in Valve-in-Valve , p=0.03).

Alternative Access Approaches

- Alternative access routes are essential

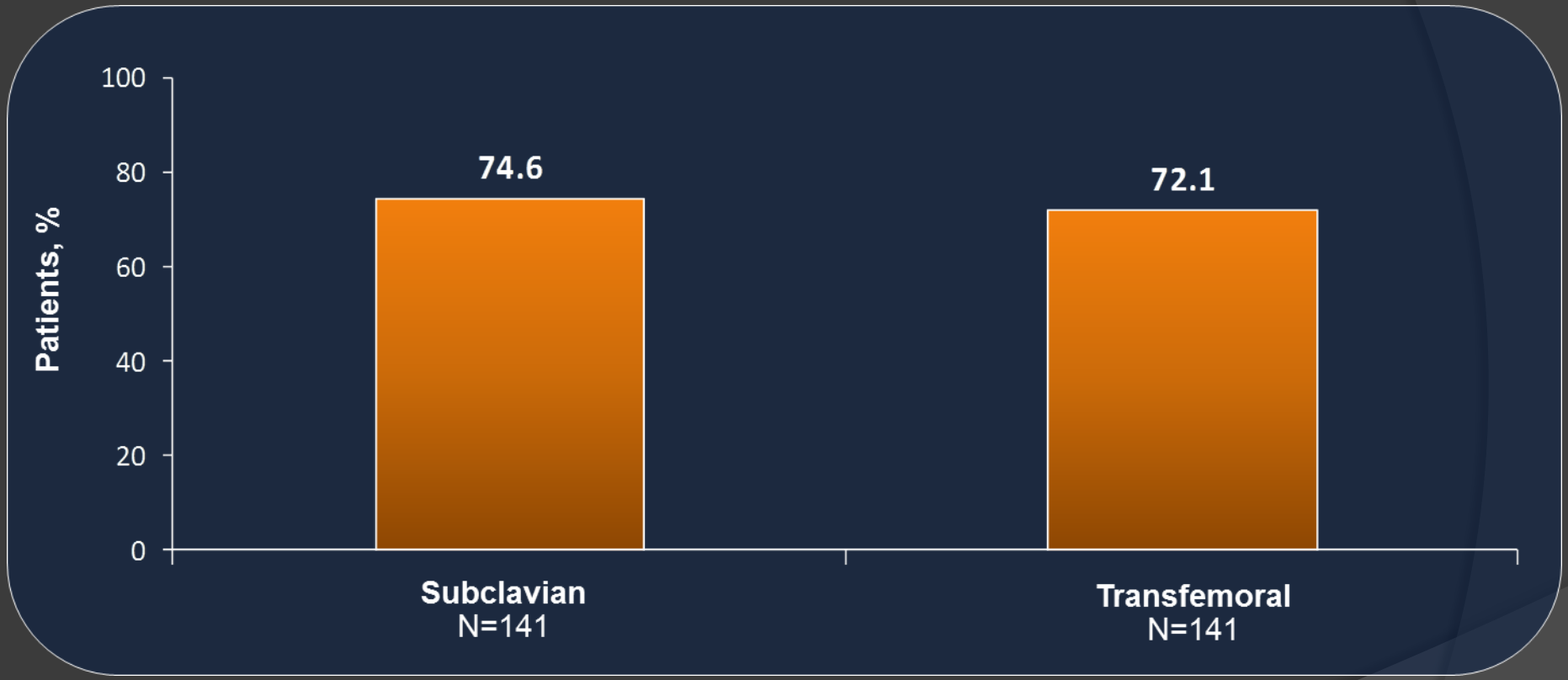
- Subclavian
- Axillary

- Caval-Aortic Access
- Direct Aortic
- Supranavicular

Axillary artery approach

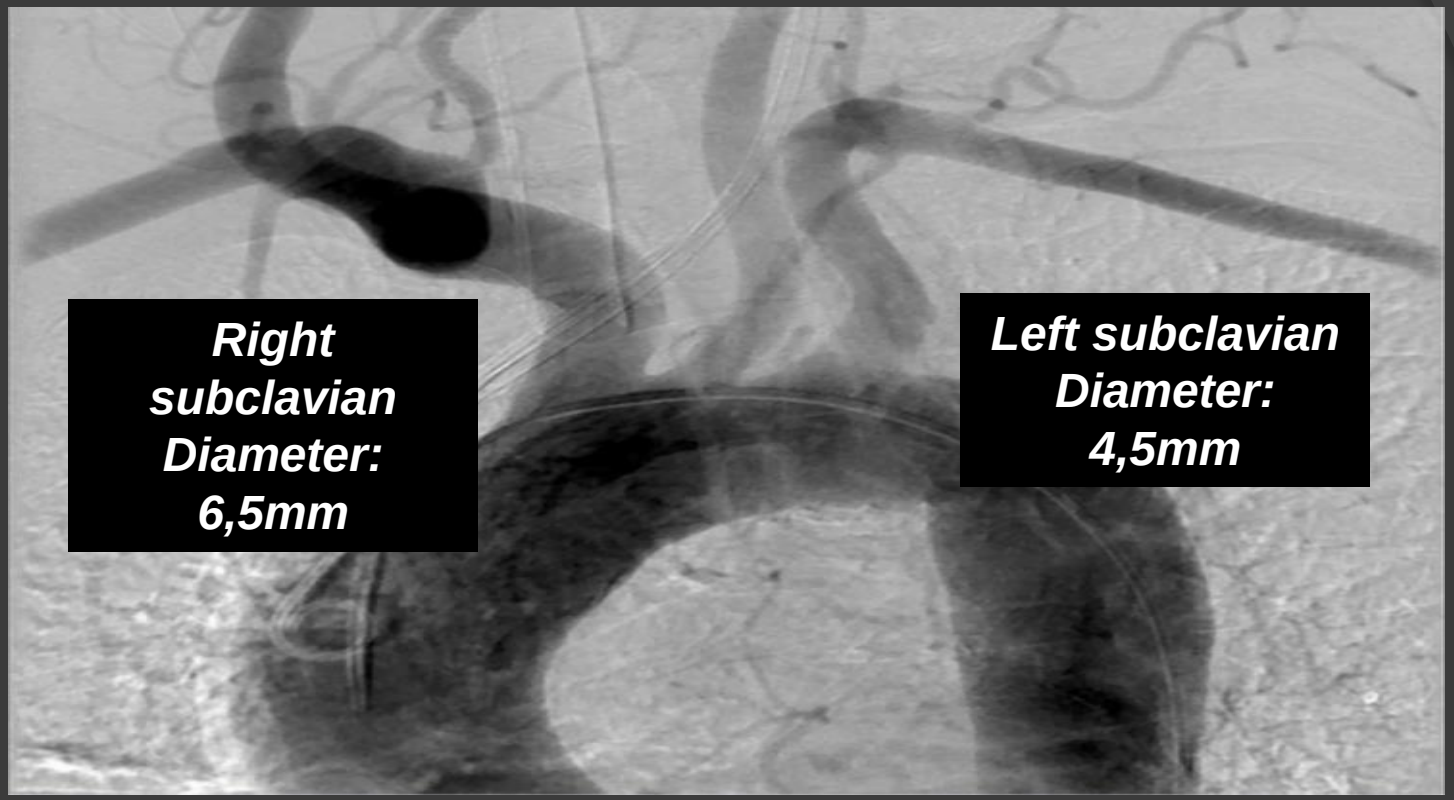
- ***Advantages***
  - No groin access, early mobilization
  - Shorter route to the valve - more control
  - Less manipulation in the arch
  - Feasible under local anesthesia in most patients
  - Option for concomitant PM implant
- ***Disadvantages***
  - Requires surgical exposure
  - Subclavian artery lesions
  - Open LIMA
  - Neurologic embolic events (retrograde approach vs TA approach)
  - Nerve lesions

Overall Survival 2-Years



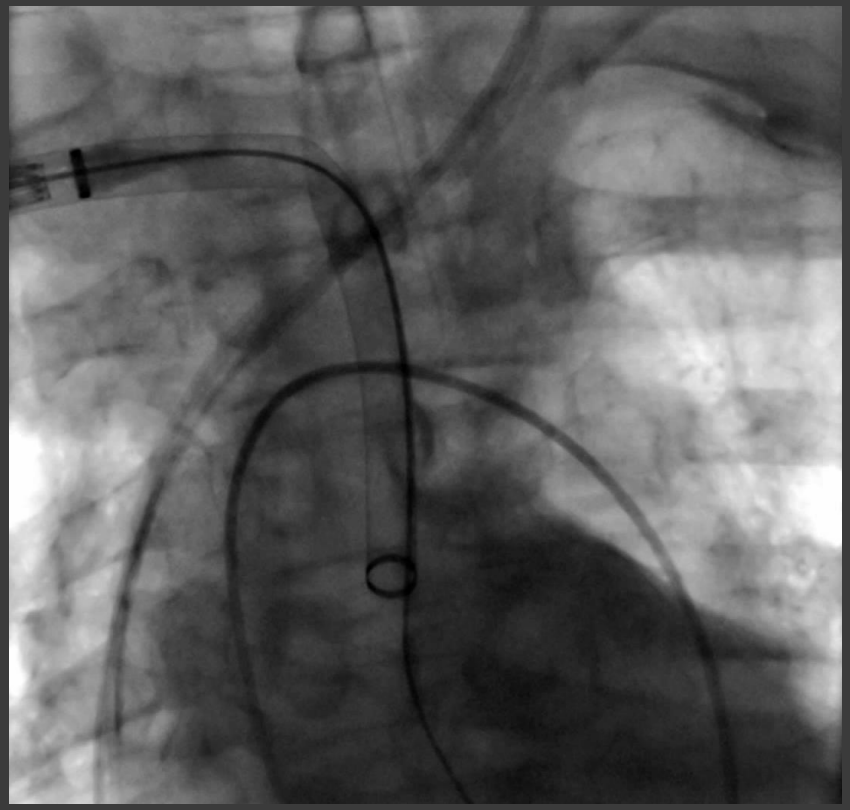
Petronio AS. Italian Experience Subclavian vs. Transfemoral. Presented at TCT 2011

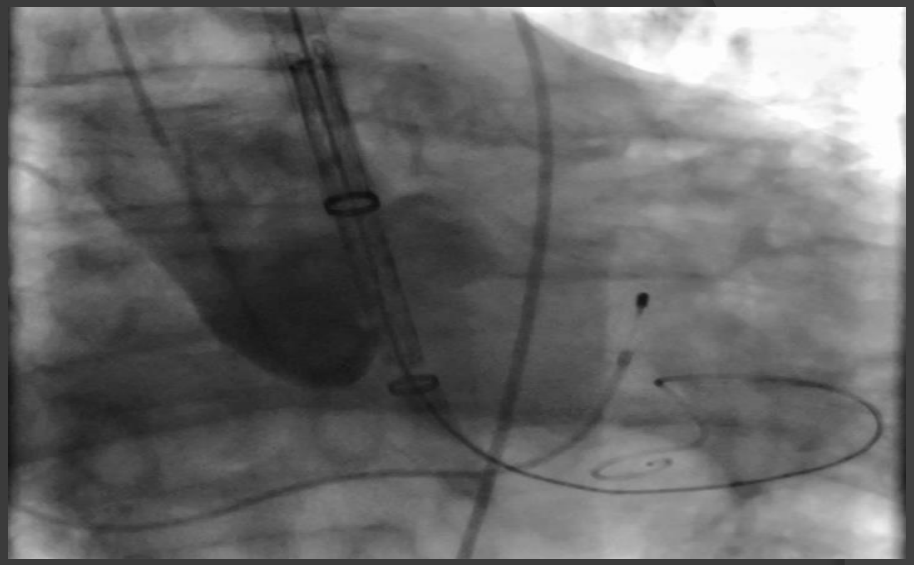
Right Subclavian Access

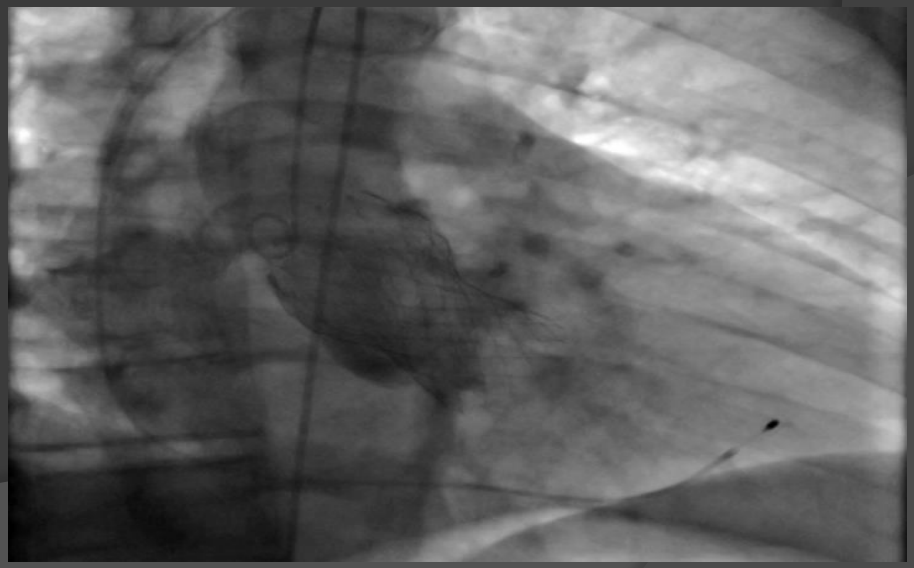


82 Years Old
Severe AS: 90 mmHg
COPD
DM
Severe peripheral artery disease
Supracondylar Amputation

Right Subclavian Access







Left Subclavian Access

Patient History: HR

- ***Age (y.o.): 71***
- ***Gender: M***
- ***Height (cm): 173***
- ***Weight (kg): 72***
- ***BMI: 1.85***

RISK FACTORS AND COMORBILITIES:
DM 2
HTA
Coronary Artery Disease

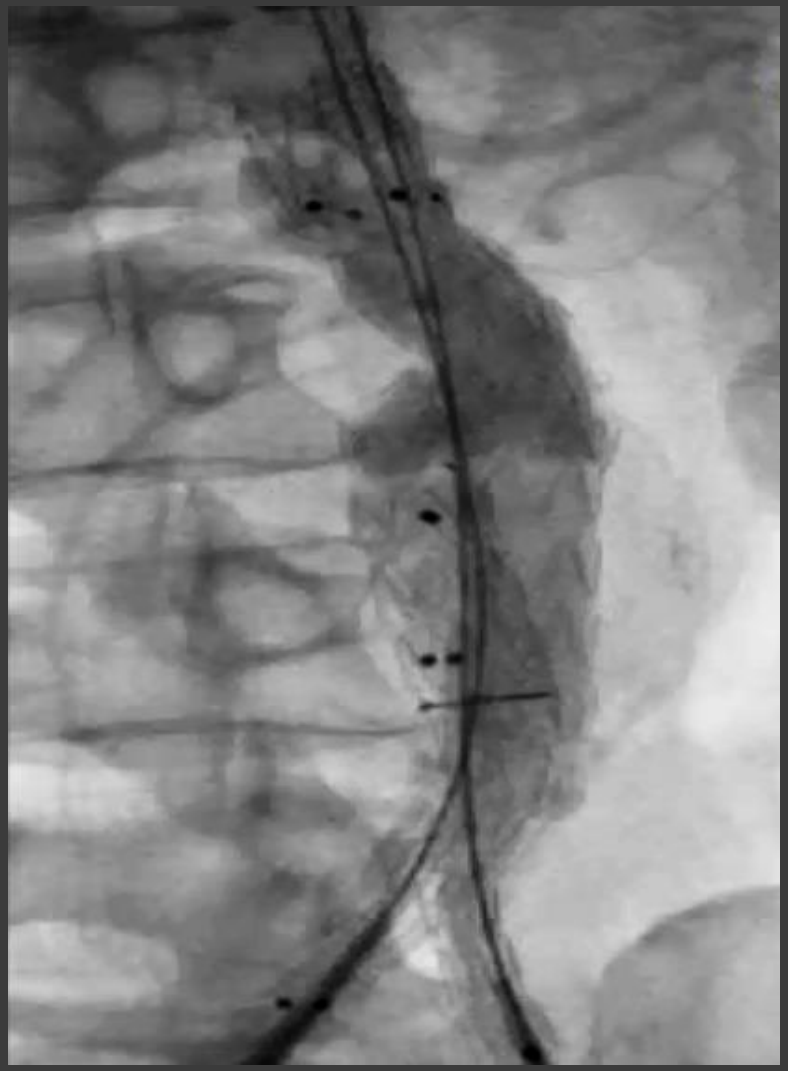
Previous Cardiac Interventions:
CABG (1994)
LIMA to ADA
Saphenous to OMA and saphenous to PDA
PTCA + stents RCA + CX (2005)
PTCA + medical stent RCA for restenosis intrastent (2014)
Vascular stent graft repair of abdominal aortic aneurysm (2014)

Cardiac and Hemodynamic State:

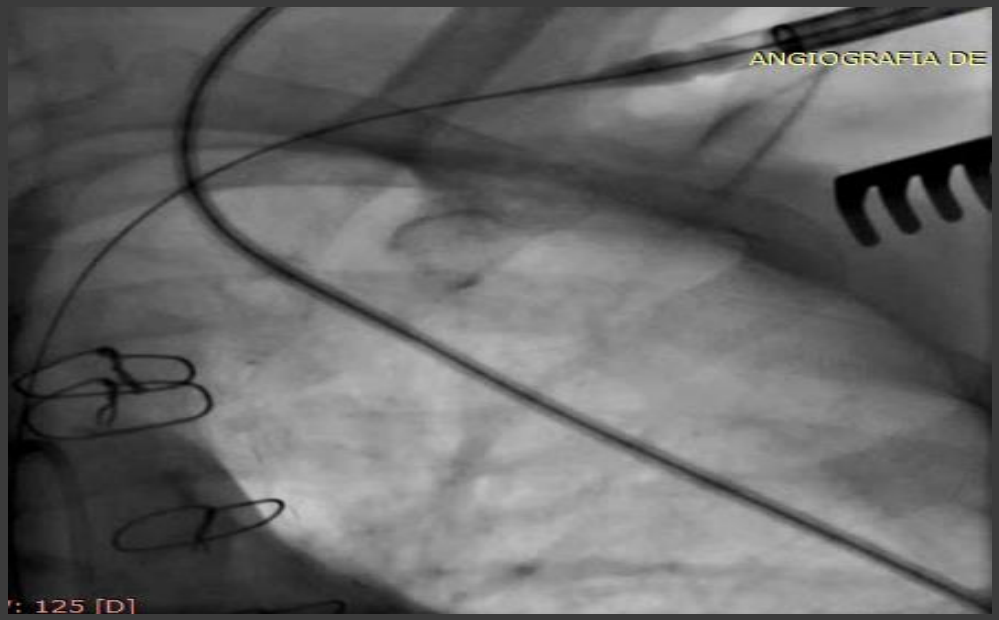
Eco Stress (Sept 2015):
- ***TAPSE: 1.5cm***
- ***FEVI: 70%***

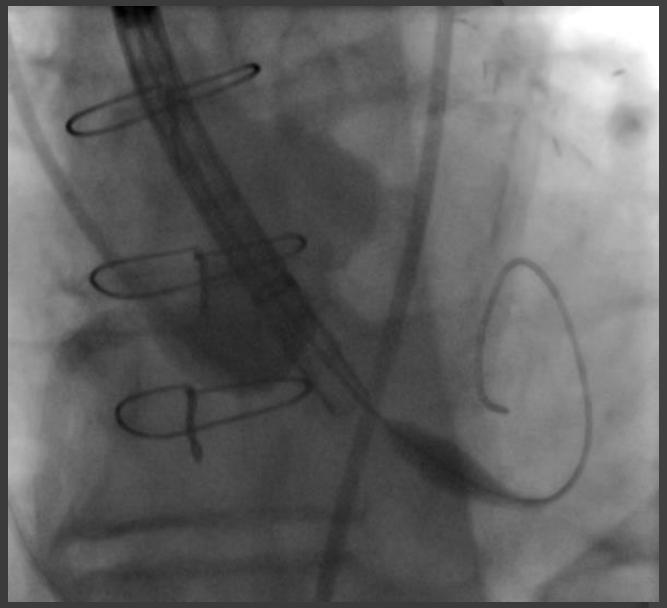
	Repose	Stress
Peak Speed	3.2 m/seg	4.2 m/seg
Peak Gradient	46 mmHg	70 mmHg
Area systole Max	0.9 Cm^2	0.8 Cm^2

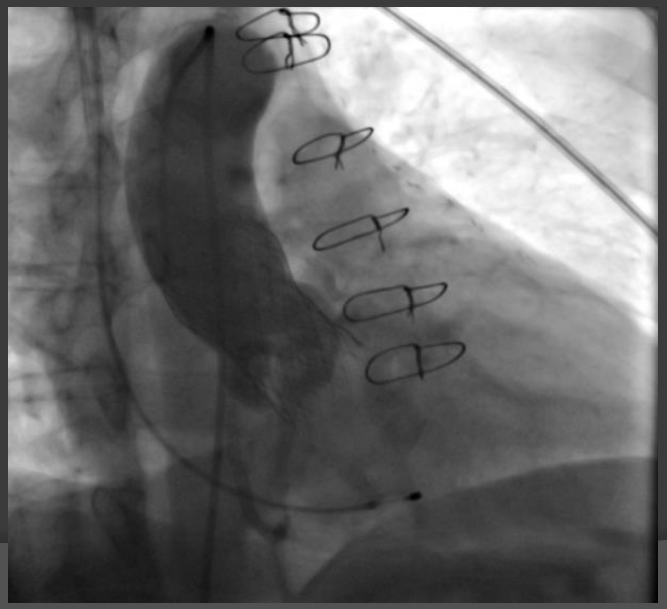
Left Subclavian Access



Left Subclavian Access



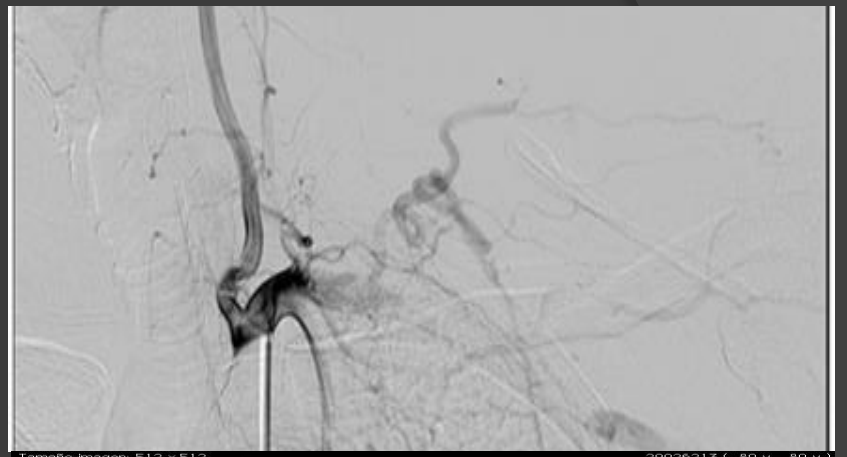


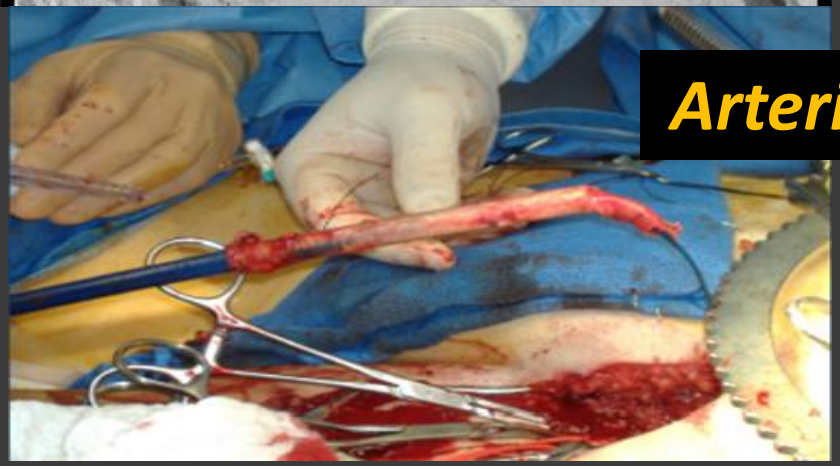


Complications

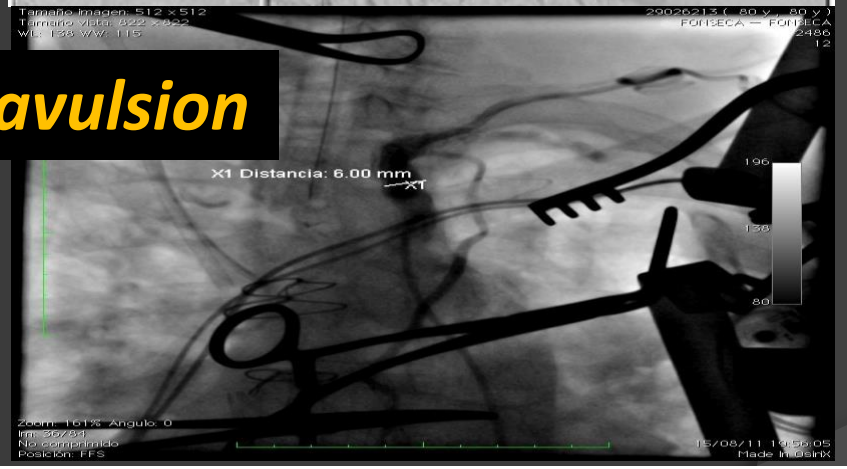
Aneurysm subclavian artery

Occlusion subclavian artery





Arterial avulsion



This is the WORST VASCULAR COMPLICATION

van Schaik P, de Borst G, Moll F, TooropR. Vascular. 2014 Dec 18.

Alternative Access Approaches

- Alternative access routes are essential

- Subclavian
- Axillary

- Caval-Aortic Access

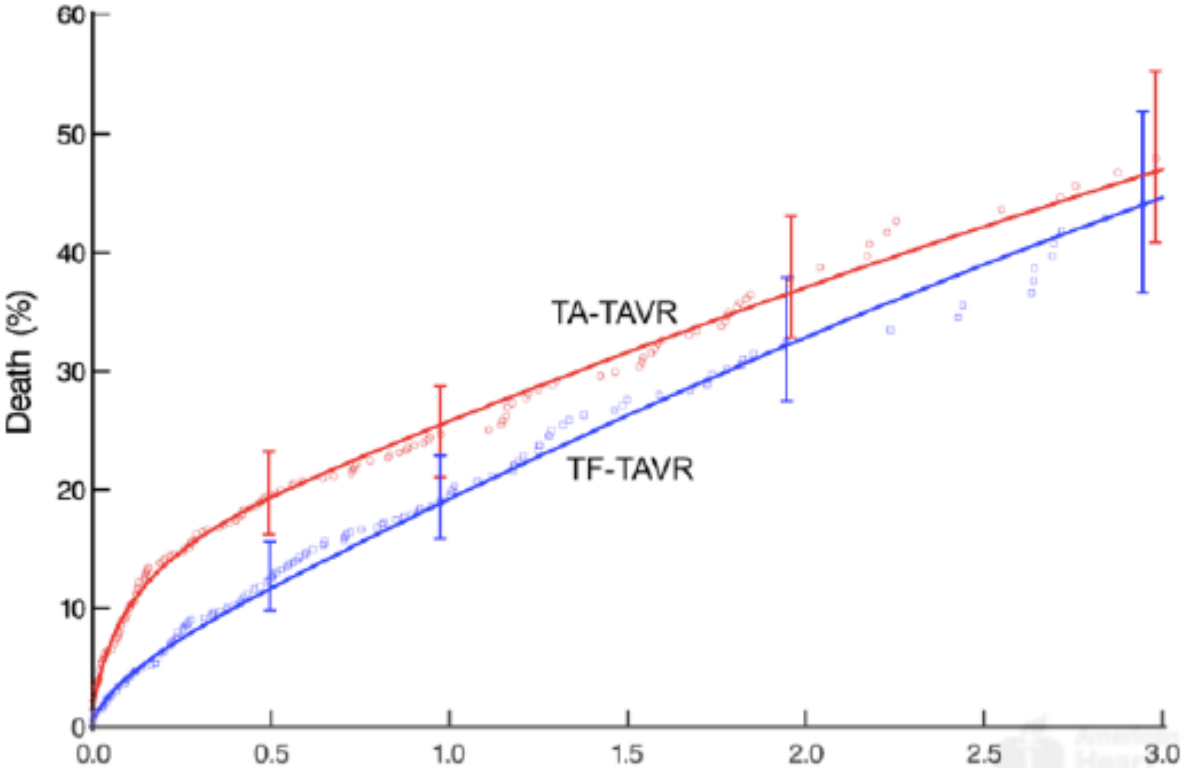
- Direct Aortic
- Supranavicular

Background

- Current US devices require large sheaths (18-24F; 9.3mm OD)
  - Eliminates a significant segment of the population from the benefits of the technology – women, PAD
- Vascular complications remain significant even with adequate vessel size and newer lower-profile technology
- Transapical & transaortic access also associated with significant morbidity and mortality and contraindicated in some

Transfemoral vs. Transapical TAVR

501 propensity-matched Partner trial patients

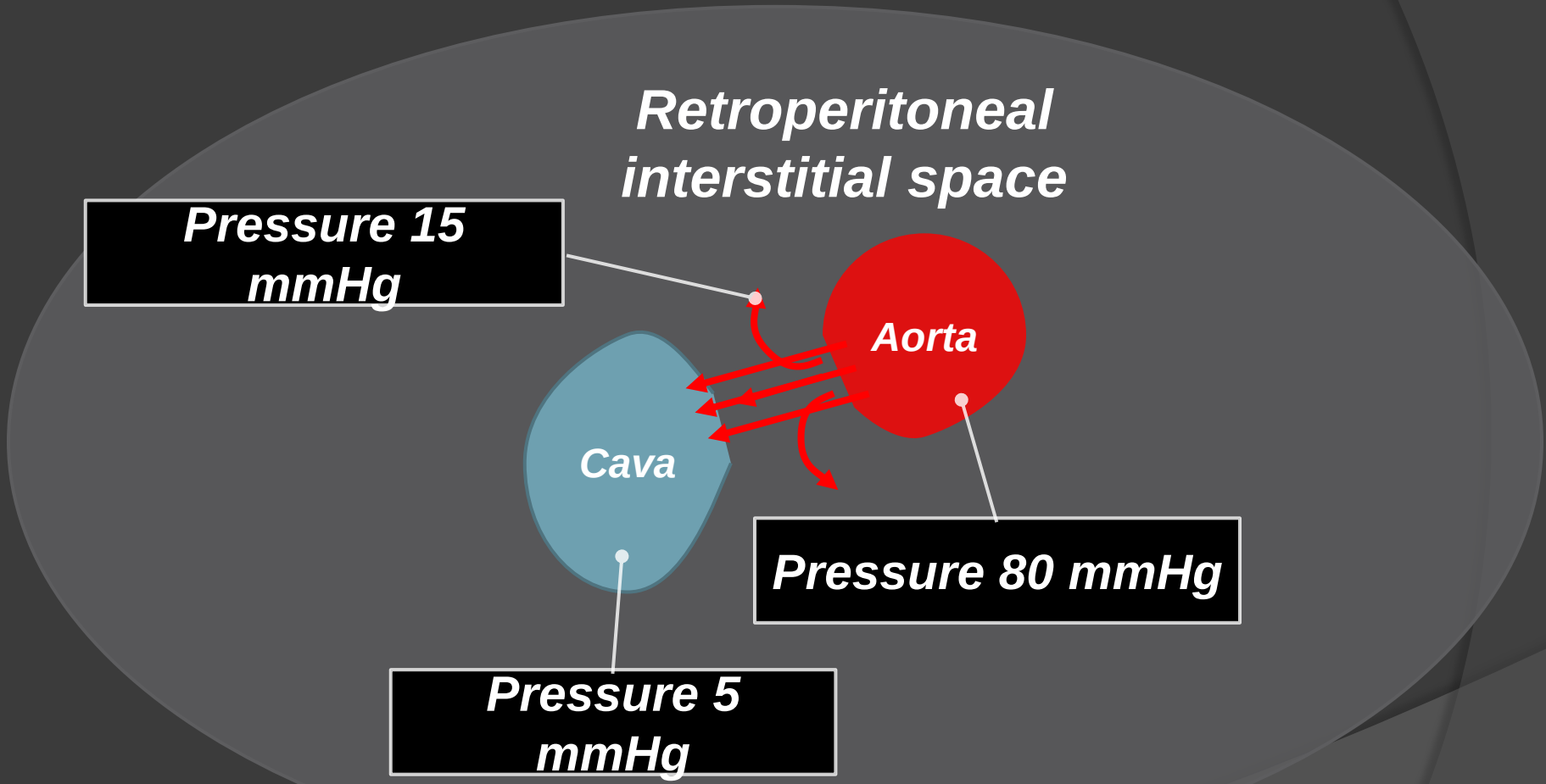


Patients at Risk							
TA-TAVR	501	389	304	184	139	59	43
TF-TAVR	501	429	326	170	132	63	49

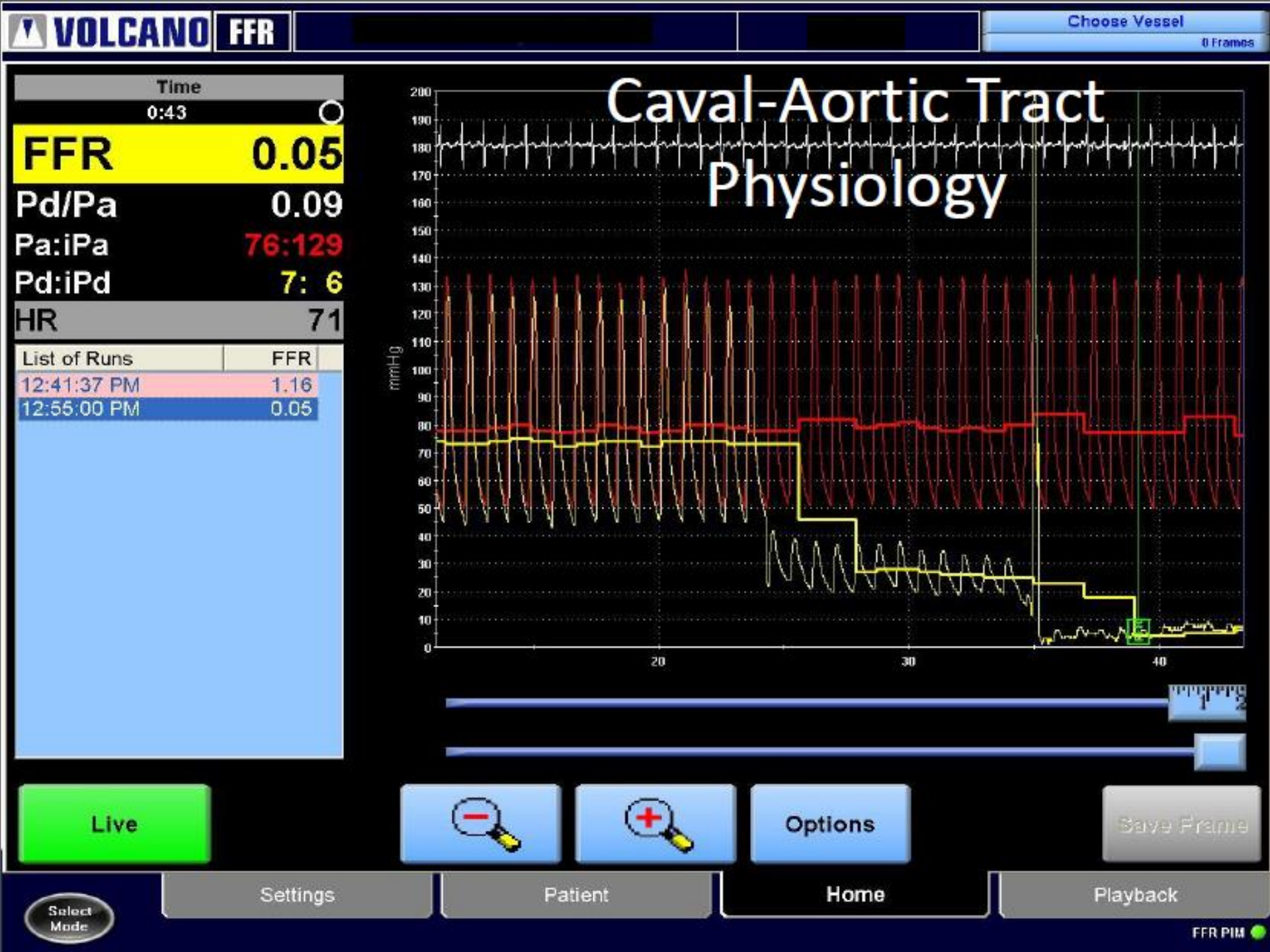
If One Can Convert a Nontransfemoral TAVR to a "Transfemoral Like" TAVR One Might Anticipate…

- *Decreased length of stay*
- *Faster recovery (improvement in NYHA class)*
- *Improved survival*
- *Cost savings*

Caval-Aortic Shunt Physiology

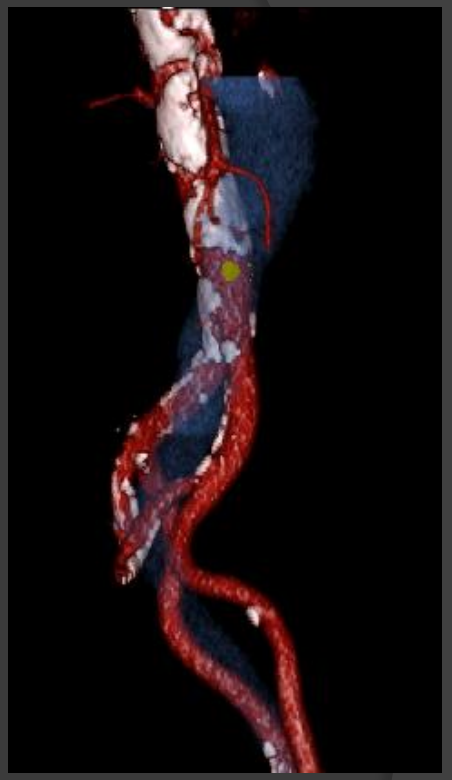


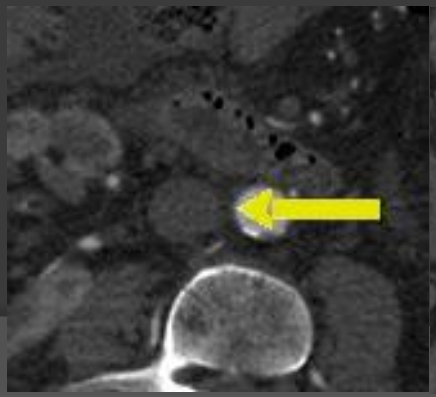
Observation: Intravenous decompression


VOLCANO
FFR
Choose Vessel
0 Frames
Time
0:43
FFR 0.05
Pd/Pa 0.09
Pa:iPa 76:129
Pd:iPd 7: 6
HR 71
List of Runs
FFR
12:41:37 PM 1.16
12:55:00 PM 0.05
Caval-Aortic Tract Physiology
mmHg
200
190
180
170
160
150
140
130
120
110
100
90
80
70
60
50
40
30
20
10
0
20
30
40
Live
Options
Save Frame
Settings
Patient
Home
Playback
Select Mode
FFR PIM

Obtain CT-based Treatment Plan

Recommendation (CA-TAVR eligibility)	Favorable; ~~Uncertain; Unfavorable~~
Aortic Ca^{2+} / thickening / ectasia	Aortic calcium grade 2
Target entry site lumbar vertebra	Mid Body L3 (L3.0)
Orthogonal projection	AP
Caval-aortic distance X-Y	6 mm (including 1 mm non-calcified atheroma)
Interposed structures	none
Nearby structures	Bowel anterior to target
Caval lumen diameter	23 mm
Aortic lumen diameter (+3/0/-1.2cm)	15 mm / **16 mm** / 14 mm
Target distance above aorto-iliac bifurcation	12 mm
Target distance below R renal artery	75 mm
Endograft bailout limb access	**RCIA 5.2 mm**, LCIA 3.0 mm
CFV to target centerline distance	24 cm
Caveat & Comments	15x20 mm target window
Lies flat on the CT scanner?	Yes
Reviewers NHLBI	M Chen read. 2014-xx-xx

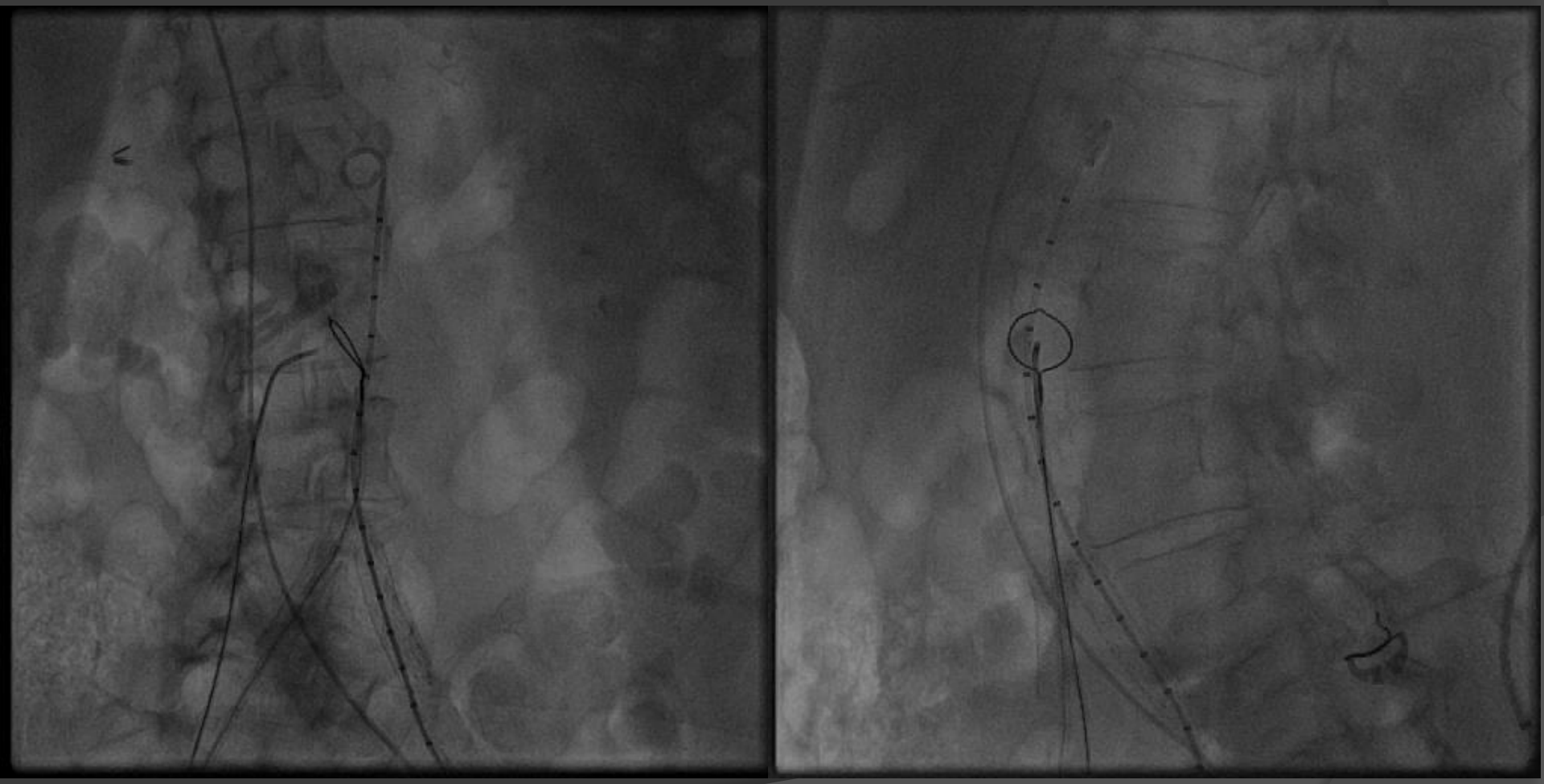




Caval-Aortic Relationship

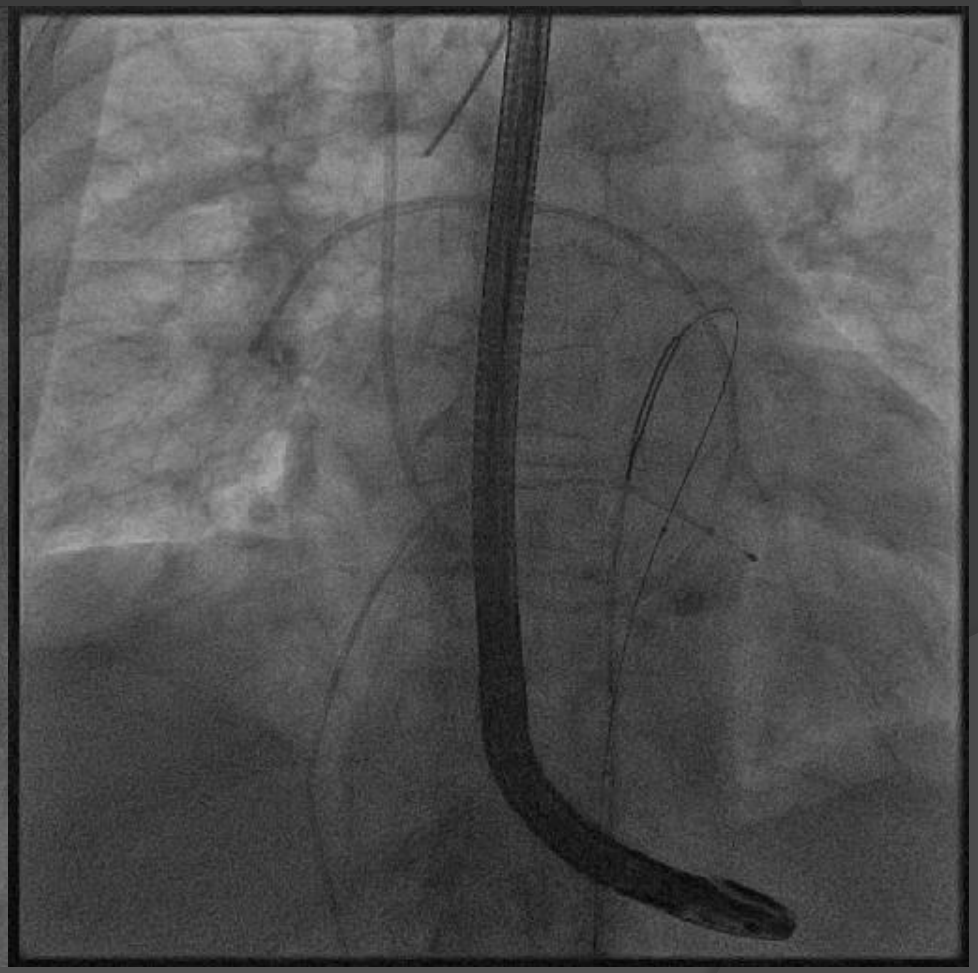
Simultaneous: ***Power inject artery below SMA***
Hand-inject vein simultaneously

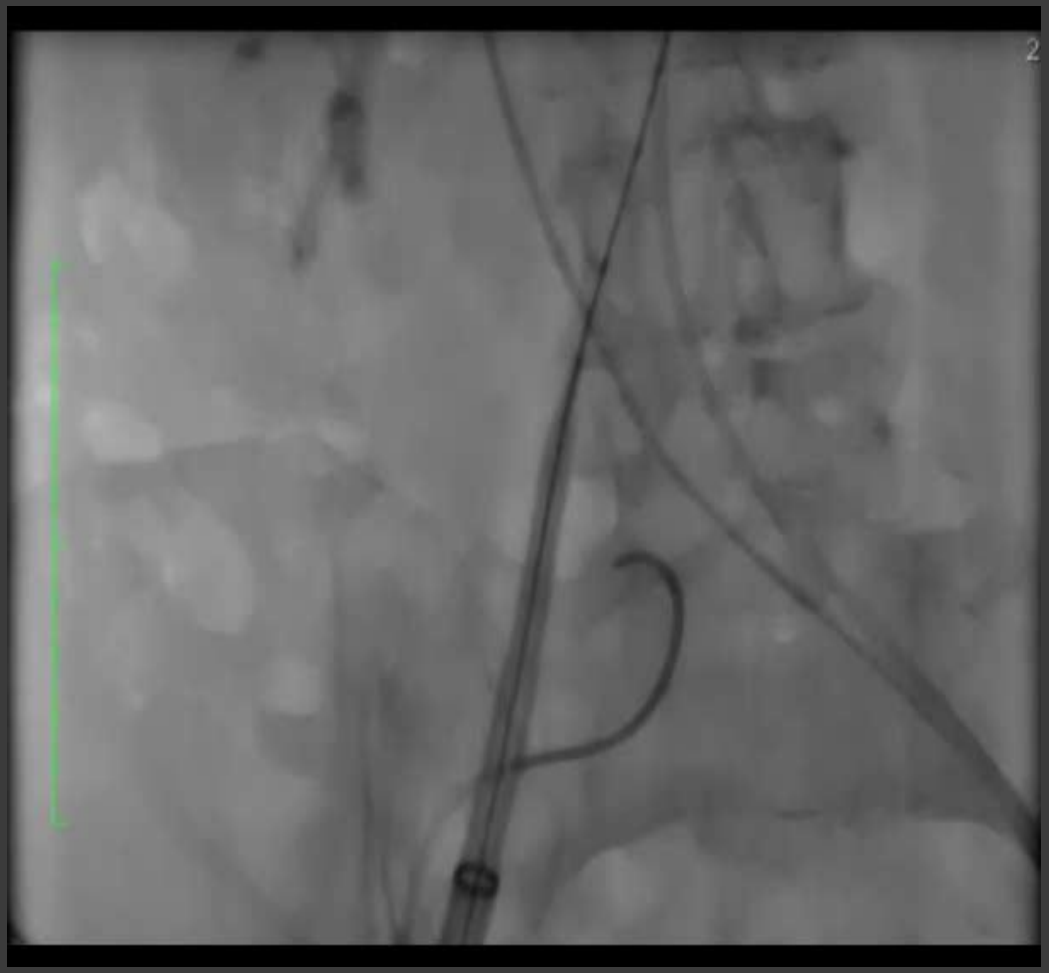
Caval-Aortic Access - Alignment



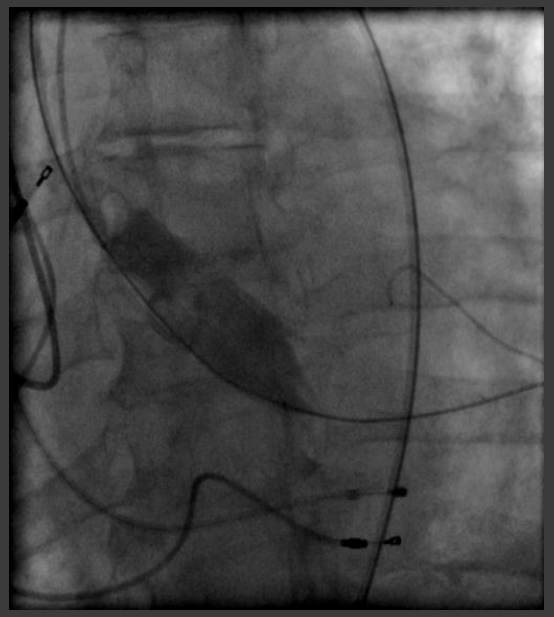
Caval-Aortic Access - Crossing

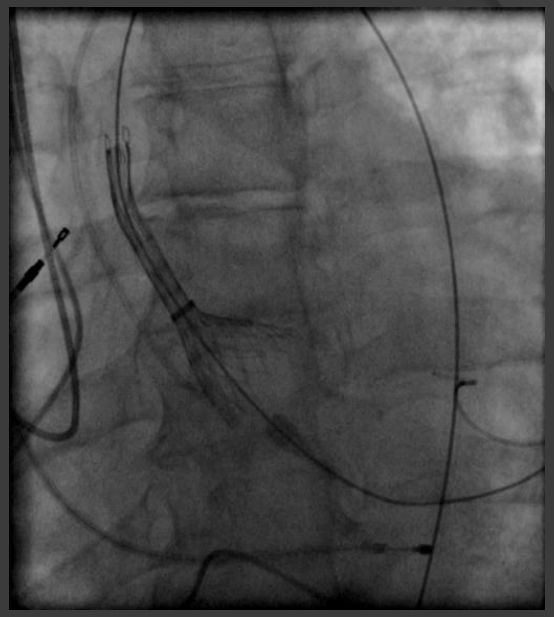
Caval-Aortic Access – Wire Transition

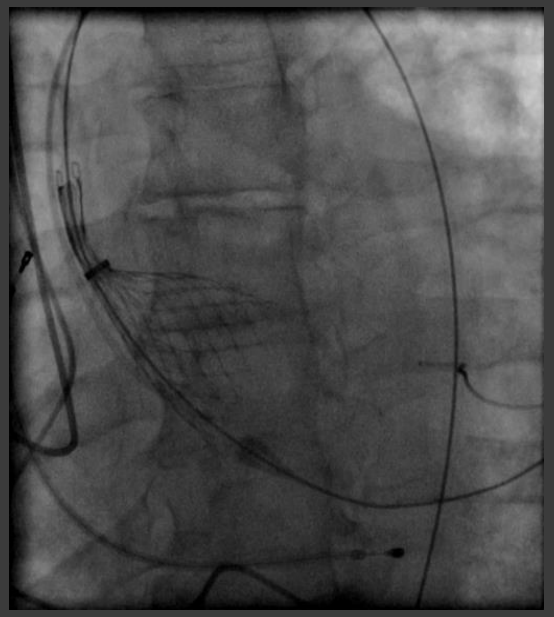


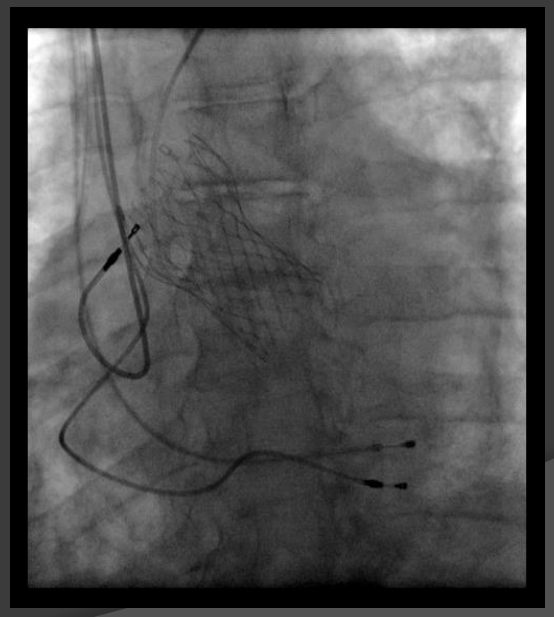



Tamaño imagen: 512
Tamaño vista: 644 x 644
WL: 120 WW: 165
Vertebral — Vertebral
Zoom: 126% Angulo: 0
Im: 1/2
No comprimido
Posición: HFS
Made in Osirix









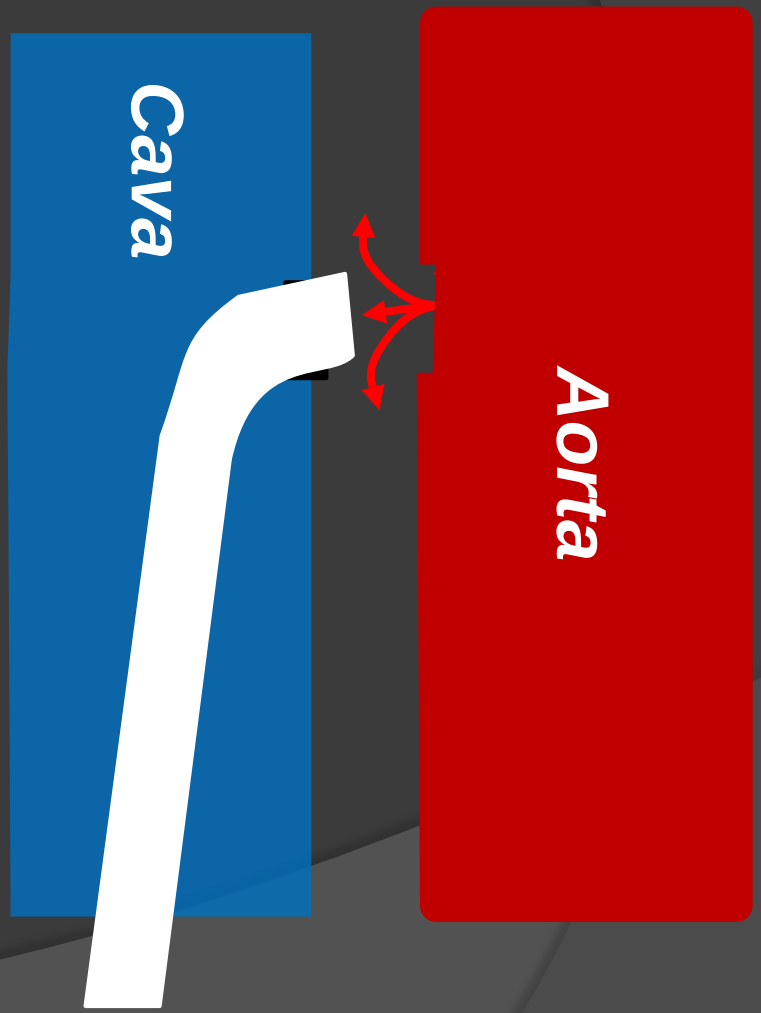
Current Closure Device Algorithm

Sheath	> 18Fr ID	<= 18Fr ID
Aorto-caval tract length ≤ 7mm	8mm Amplatzer Muscular VSD Occluder	6mm Amplatzer Muscular VSD Occluder
Aorto-caval tract length > 7mm	10/8 Amplatzer Duct Occluder generation 1	8/6 Amplatzer Duct Occluder generation 1

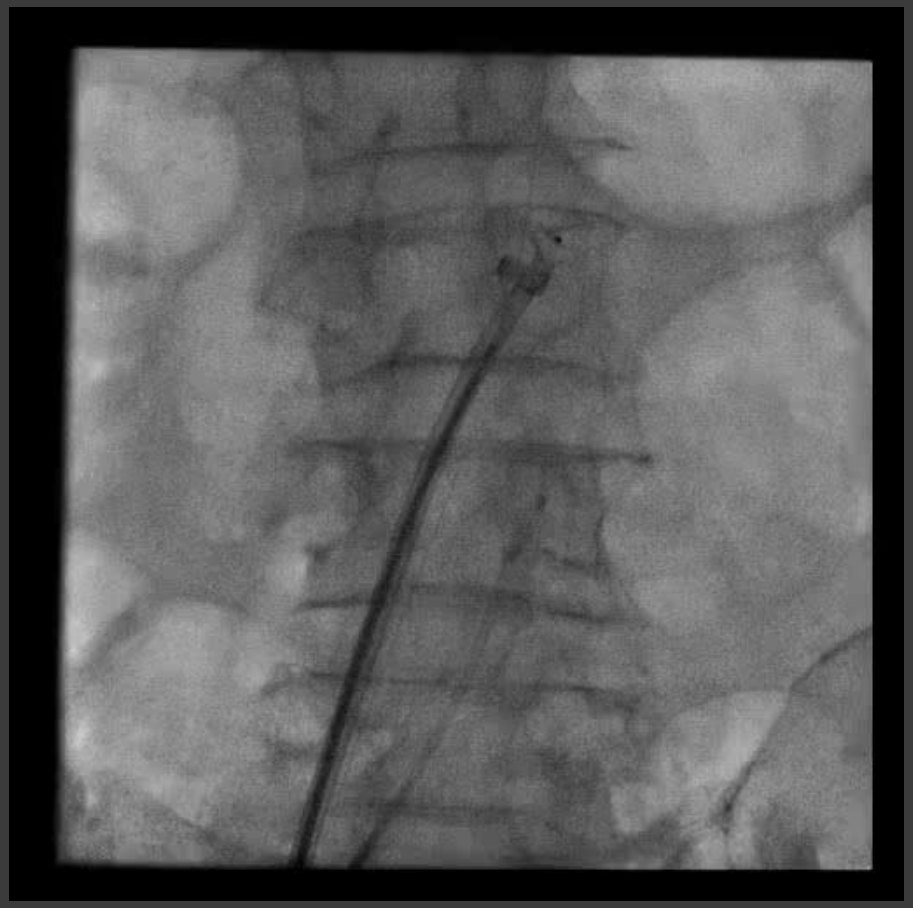
Fundamental Pathophysiology Principle

Venous sink

- *A venous sink/sump is required to decompress arterial hemorrhage*
- *The hole in the IVC must not be occluded unless the hole in the aorta is occluded*
- *Only withdraw aortic sheath COMPLETELY into cava*



Closure

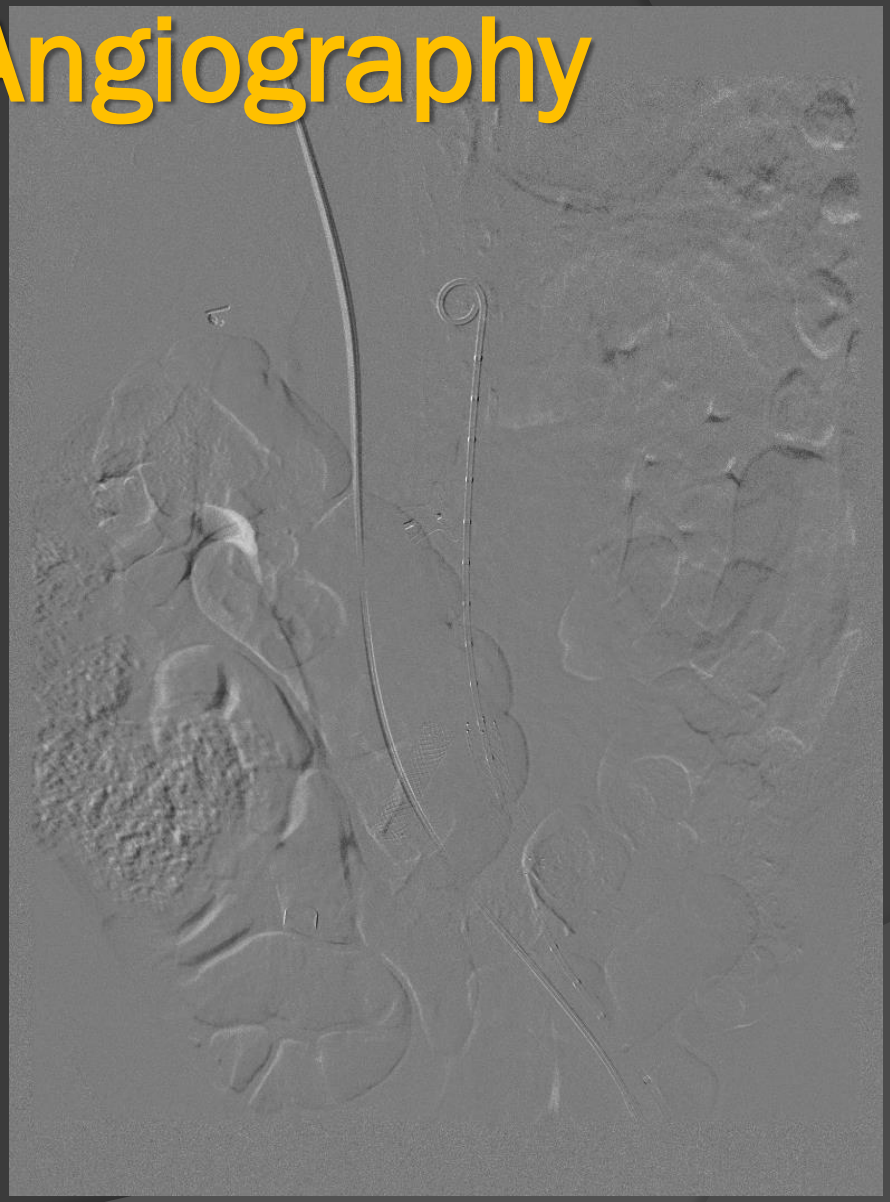


Place buddy wire

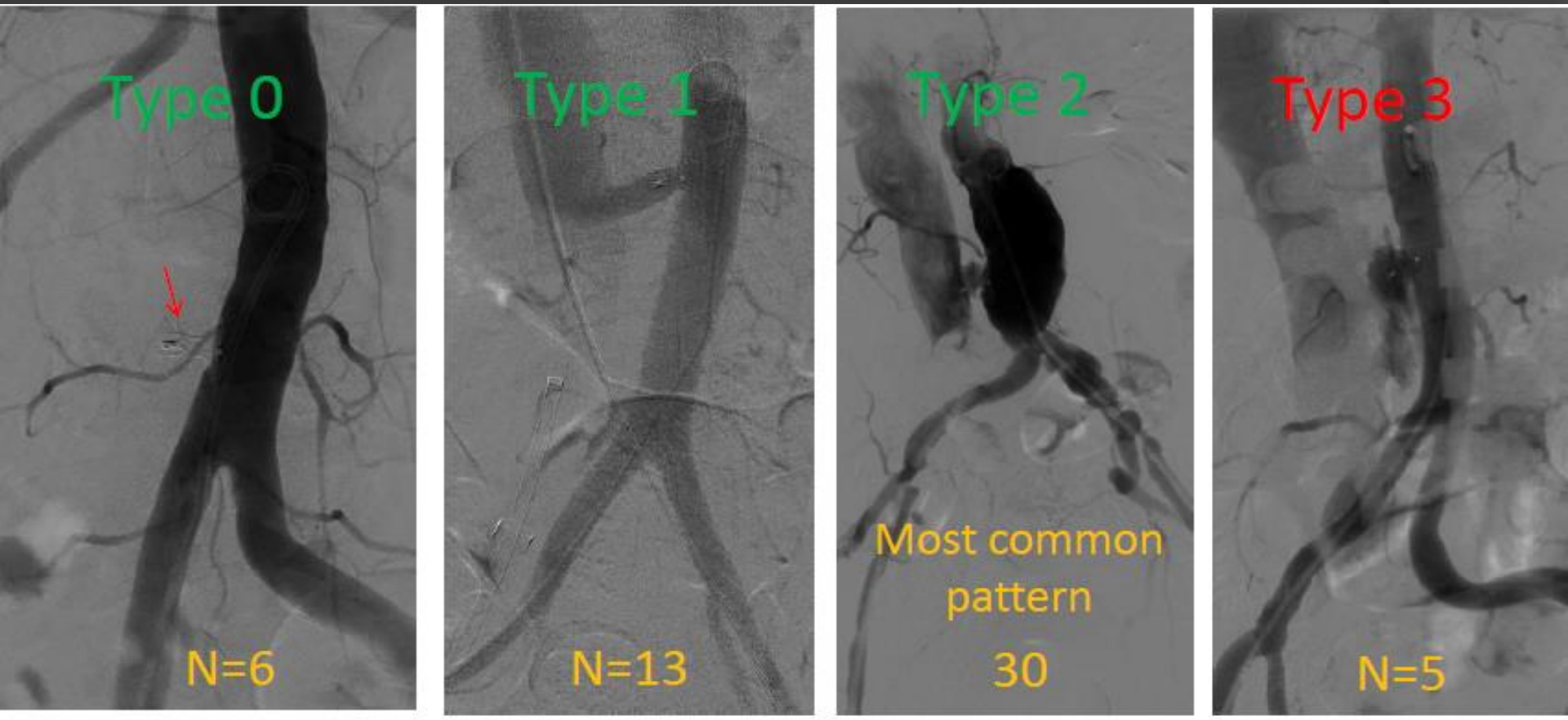
- *Insert deflectable sheath*
- *Passively expose aortic disc*
- *Position pigtail*
- *Withdraw and deflect sheath to crossing point*
- *Withdraw TAVI sheath into IVC*
- *Advance pigtail cephalad & test*
- *Retract disc onto R aortic wall*
- *Straighten Agilis during withdrawal through tract into cava*
- *Pull Amplatzer cable to reach cava, then push cable to re-form venous side*

Completion Angiography

- *Review angio before release cable and buddy wire*
- *If bleeding:*
  - *Consider balloon aortic tamponade*
  - *Consider endograft*
- *Close venous access site and wait 10 minutes*
- *Completion angiogram*

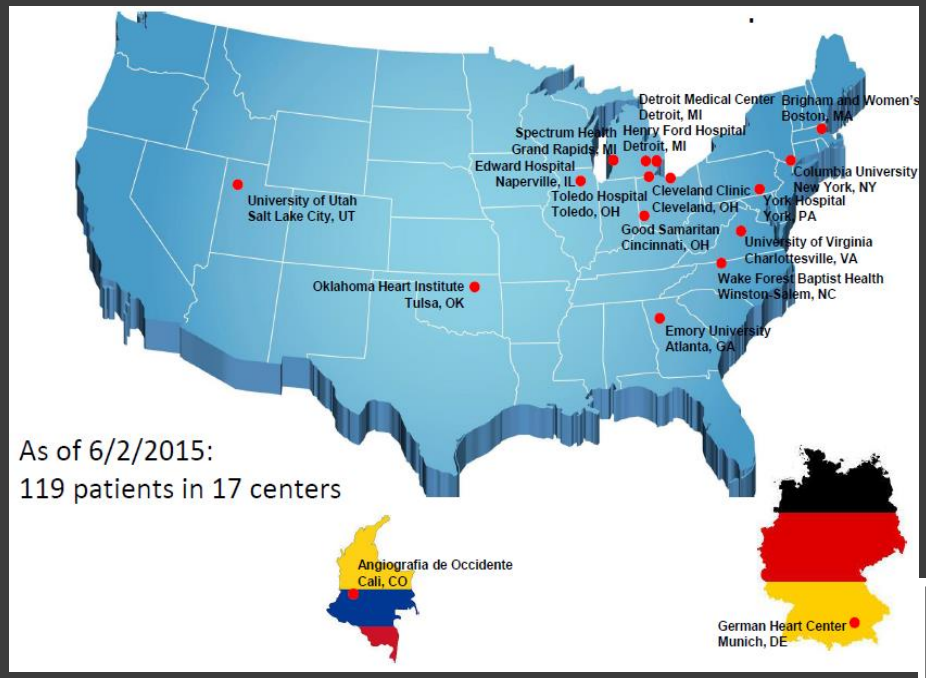


Patterns of Completion Angiography



Complete occlusion	Caval-aortic fistula with long tunnel, no extravasation	Caval-aortic fistula + "cruciform" extra-aortic contrast	Extravasation (Endograft 7 hrs. later)

Transcaval TAVR Worldwide Experience



Center	Total
Henry Ford Hospital[1] Detroit, MI	**54**
Angiografia de Occidente[2] Cali, Colombia	**15**
Detroit Medical Center Detroit, MI	3
Spectrum Health Grand Rapids, MI	1
Emory University Atlanta, GA	**11**
University of Utah Salt Lake City, UT	2
Oklahoma Heart Tulsa, OK	**6**
Brigham and Women's Boston, MA	1
Columbia University New York, NY	2

Center	Total
German Heart Center Munich, GE	**2**
Wake Forest Baptist Health Winston Salem, NC	**5**
Good Samaritan Cincinnati, OH	**3**
Edward Hospital Naperville, IL	2
Cleveland Clinic Foundation Cleveland, OH	3
University of Virginia Charlottesville, VA	**5**
York Hospital York, PA	2
Toledo Hospital Toledo, OH	2
Total	119

Alternative Access Approaches

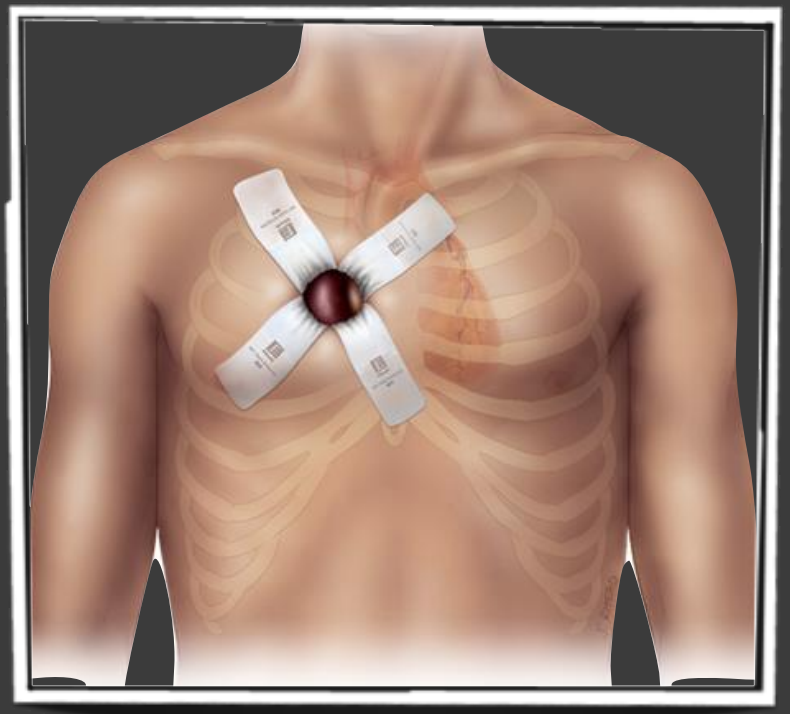
- Alternative access routes are essential

- Subclavian
- Axillary
- Caval-Aortic Access

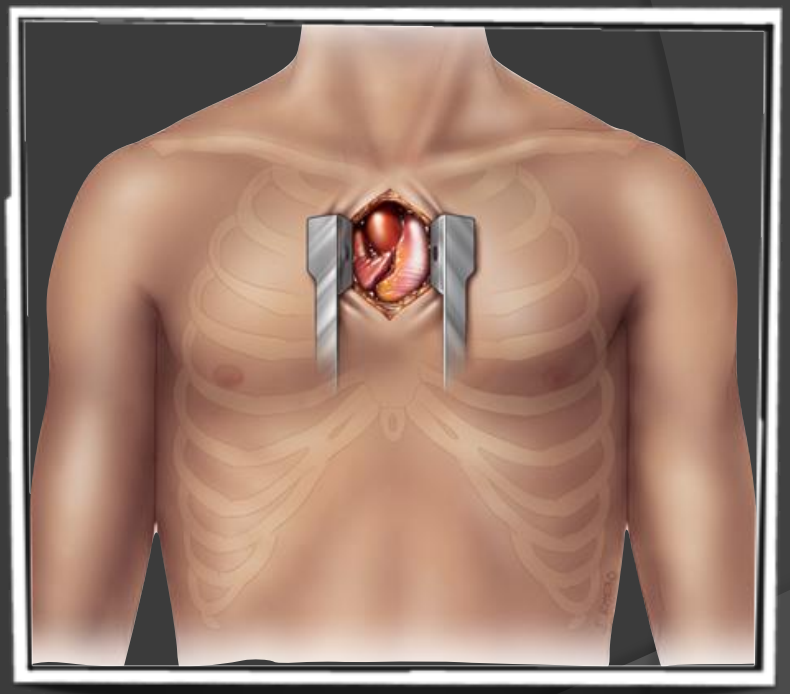
- Direct Aortic
- Supranavicular

Direct Aortic Procedure

Global Registry Clinical Experience



R anterior mini-thoracotomy
N = 72 (47.7%)



Upper mini-sternotomy
N = 79 (52.3%)

Direct Aortic Global Registry

Baseline Characteristics

Study Size	151 Patients

Characteristics	N	SD or %
Age (years)	82.0	± 6.5
Gender (female)	77	50.9%
NYHA class ≥ III	132	87.4%
Coronary disease	89	58.9%
Prior CABG	36	23.8%
Peripheral Vascular disease	118	78.1%
Mean Aortic Δ (mmHg) @ Echo	48	± 14
Mean Logistic Euroscore	26.1	± 16.8

Bruschi, et al. European experience of direct aortic transcatheter aortic valve implantation with a self-expanding prosthesis:. Presented at STS 2013.

Direct Aortic Global Registry

Results: 151 patients

Characteristics	Nr	SD or %
Procedural Mortality	0	--
30-day Mortality	13	8.6%
In Hospital Stroke	6	3.9%
Aortic Dissection	0	--
Life treating Bleeding (VARC)	7	4.6%
Conversion to Sternotomy	5	3.3%
New Pace-maker Implant	30	19.8%

Bruschi, et al. European experience of direct aortic transcatheter aortic valve implantation with a self-expanding prosthesis:. Presented at STS 2013.

Current Direct Aortic Experience

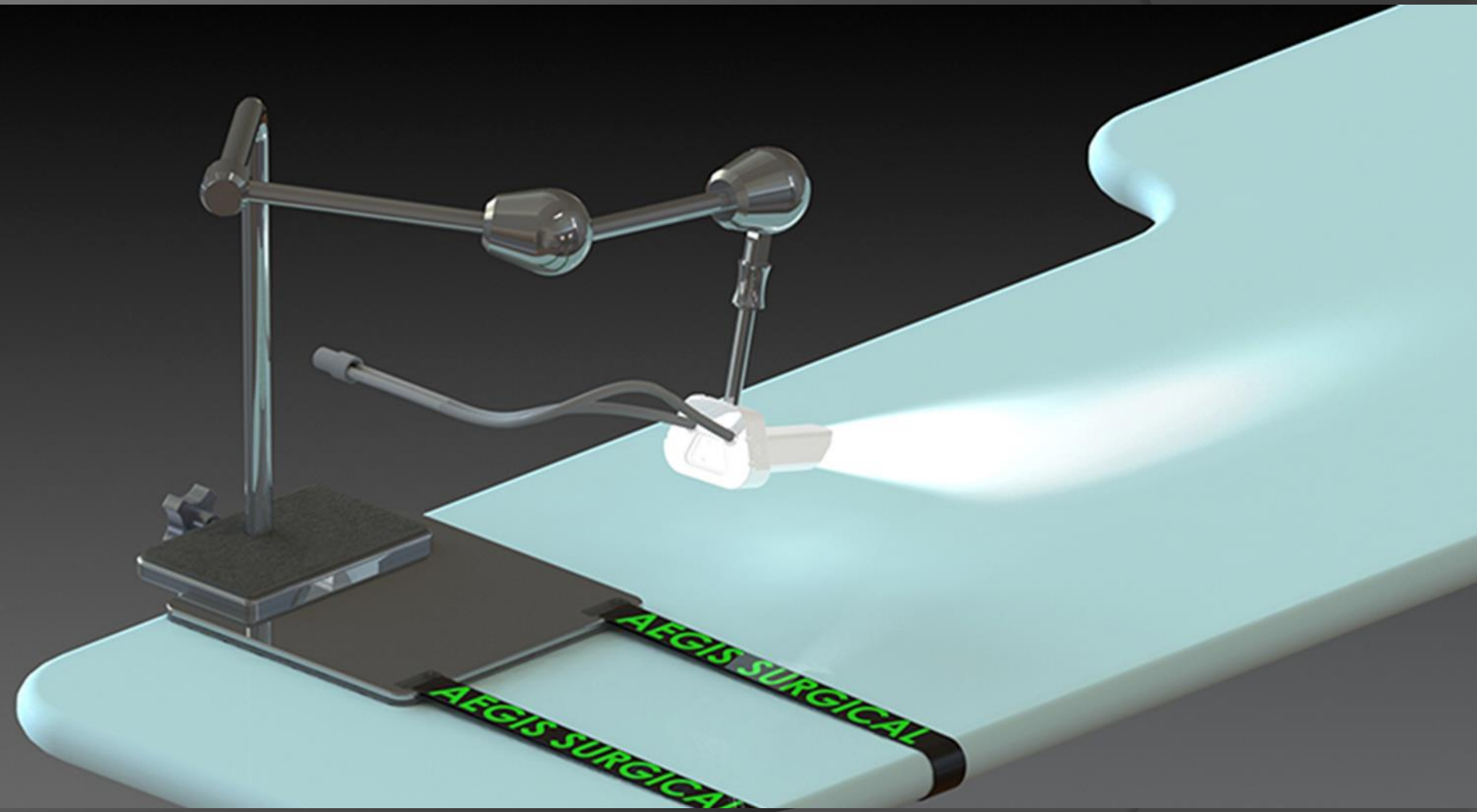
CoreValve ADVANCE Study | 30-Day Outcomes

Primary Endpoint (%)	All (N=996)	TF 88.3% (N=879)	DA 2.1% (N=21)	P-value
MACCE	8.3	7.9	4.8	0.62
All-cause Mortality	4.5	4.3	0.0	0.34
Myocardial Infarctions	0.2	0.2	0.0	0.83
Stroke	2.9	2.9	0.0	0.43
Emergent cardiac surgery or percutaneous re-intervention	1.7	1.5	4.8	0.22

Additional VARC Endpoints (%)	All (N=996)	TF 88.3% (N=879)	DA 2.1% (N=21)	P-value
Cardiovascular Mortality	3.4	3.2	0.0	0.41
Major Bleeding	9.7	9.5	19.1	0.13
Life Threatening Bleeding	4.0	4.0	4.8	0.86
Major Vascular Complications	10.7	11.2	0	0.11
Acute Kidney Injury - Stage III	0.4	0.3	4.8	< 0.01

AEGIS:

AEGIS



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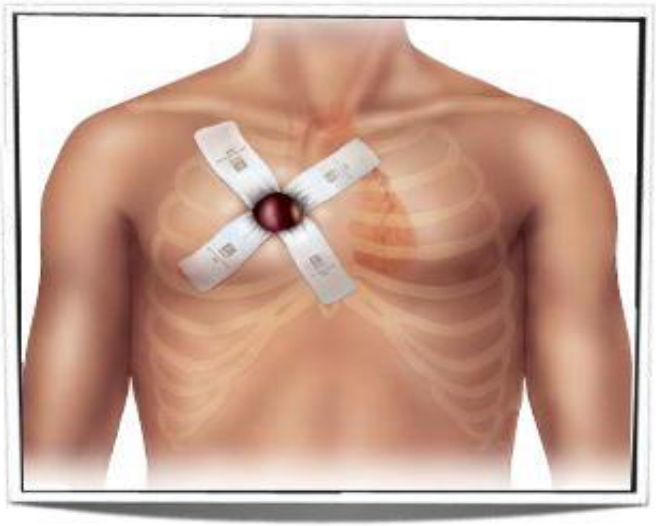

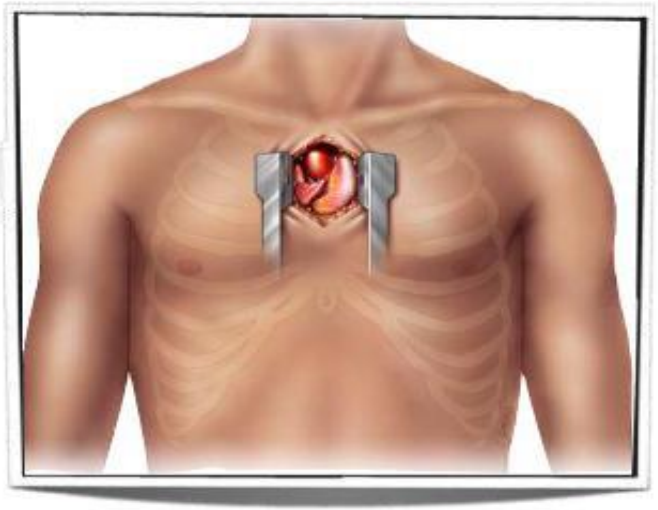

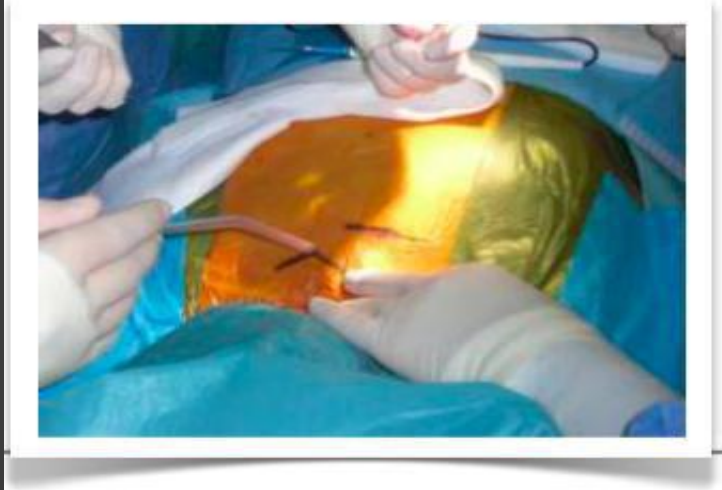

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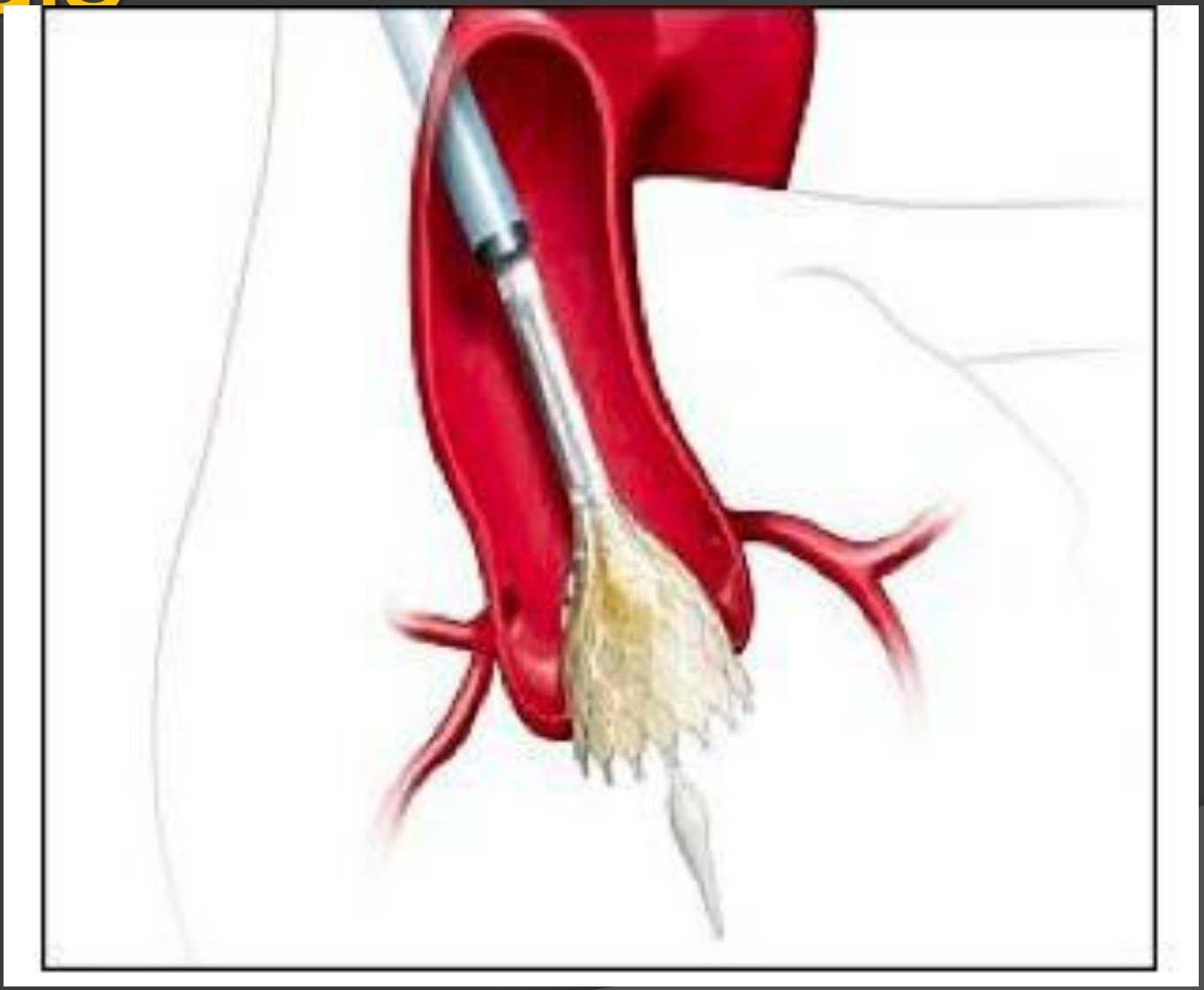
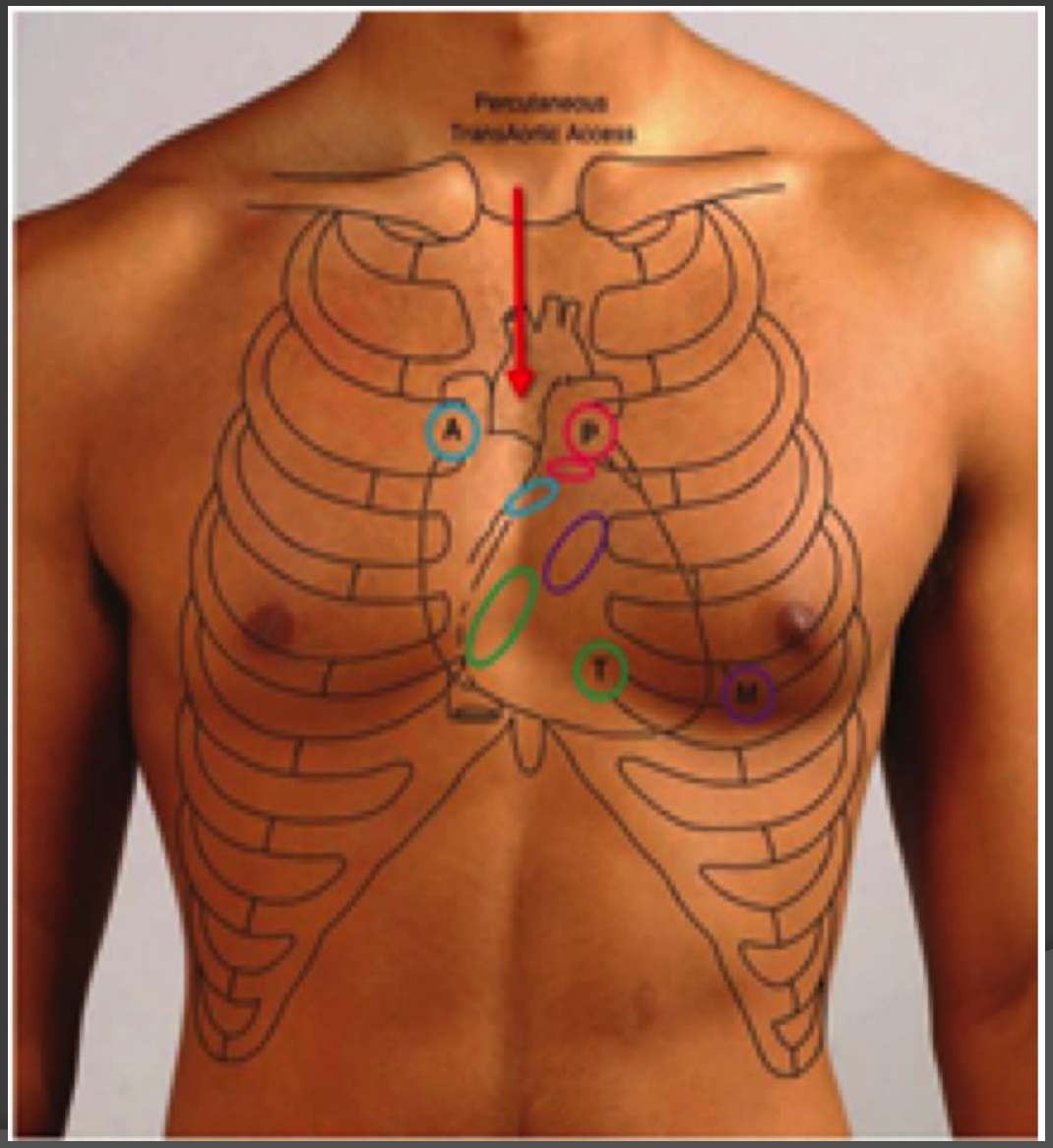


AEGIS



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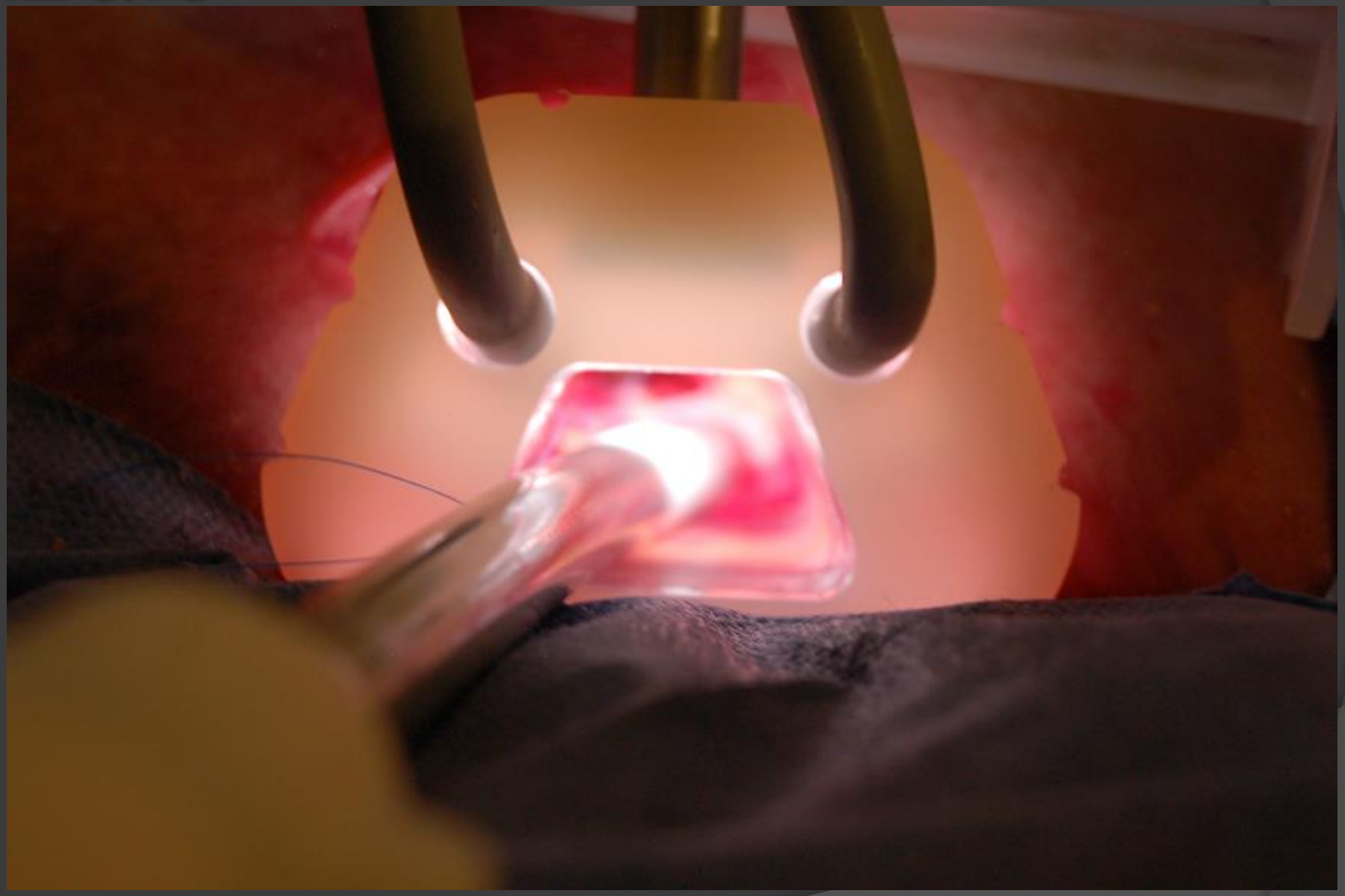


AEGIS Procedure

Conclusions

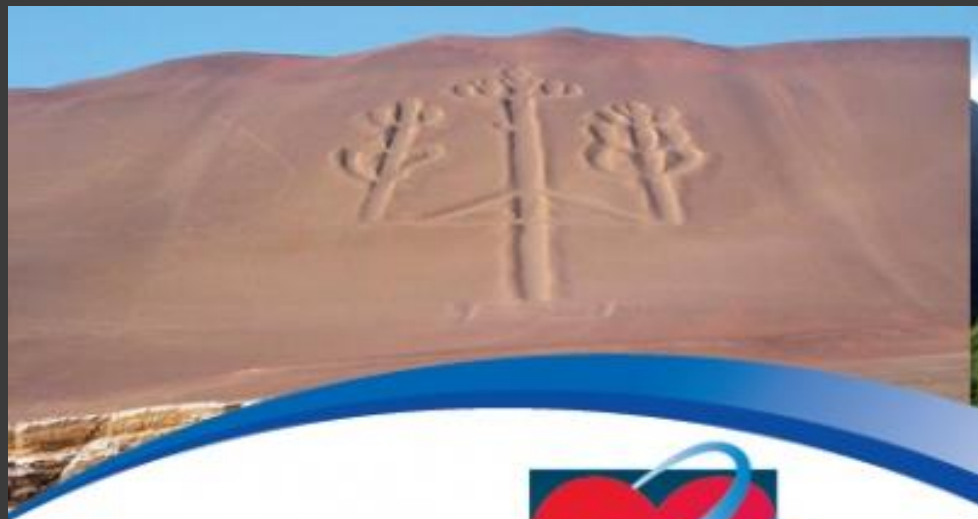
- Options are Critical for TAVI Patient Success
  - Vascular limitations and anatomical challenges are common in the TAVI population
- Alternative Access Options are Safe and Feasible
- Subclavian and Direct Aortic Implantation Show Positive Results
  - High procedural success
  - Positive long-term outcomes
- Heart teams need the right options to achieve the best outcomes with every patient

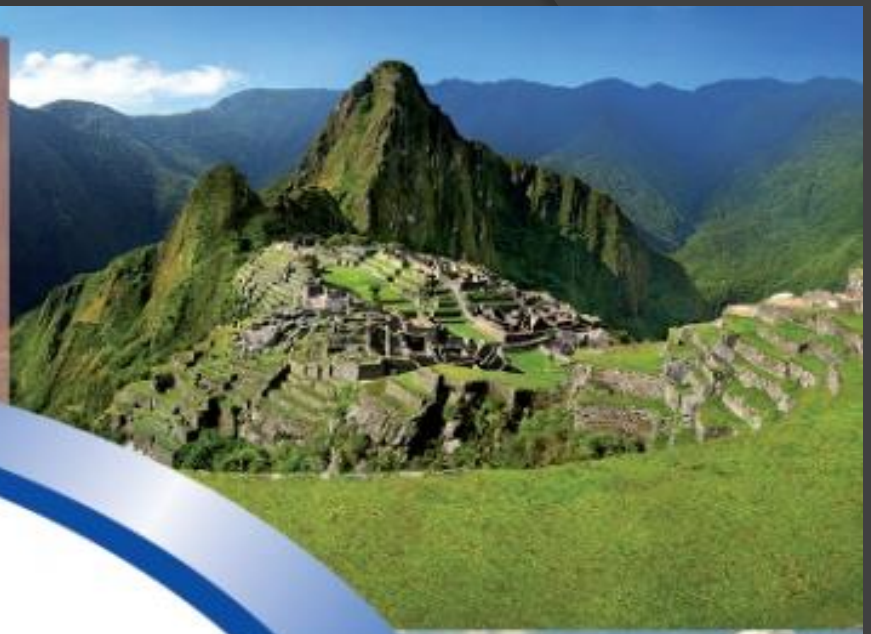
Thank you

Suprasternal direct aortic approach transcatheter aortic valve replacement avoids sternotomy and thoracotomy: first-in-man experience†

Kiser AC, O'Neill WW, de Marchena E, Stack R, Zarate M, Dager A, Reardon M

Eur J Cardiothorac Surg. 2015 Jan 18





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