Top Ten Lessons for Complication Free TAVR

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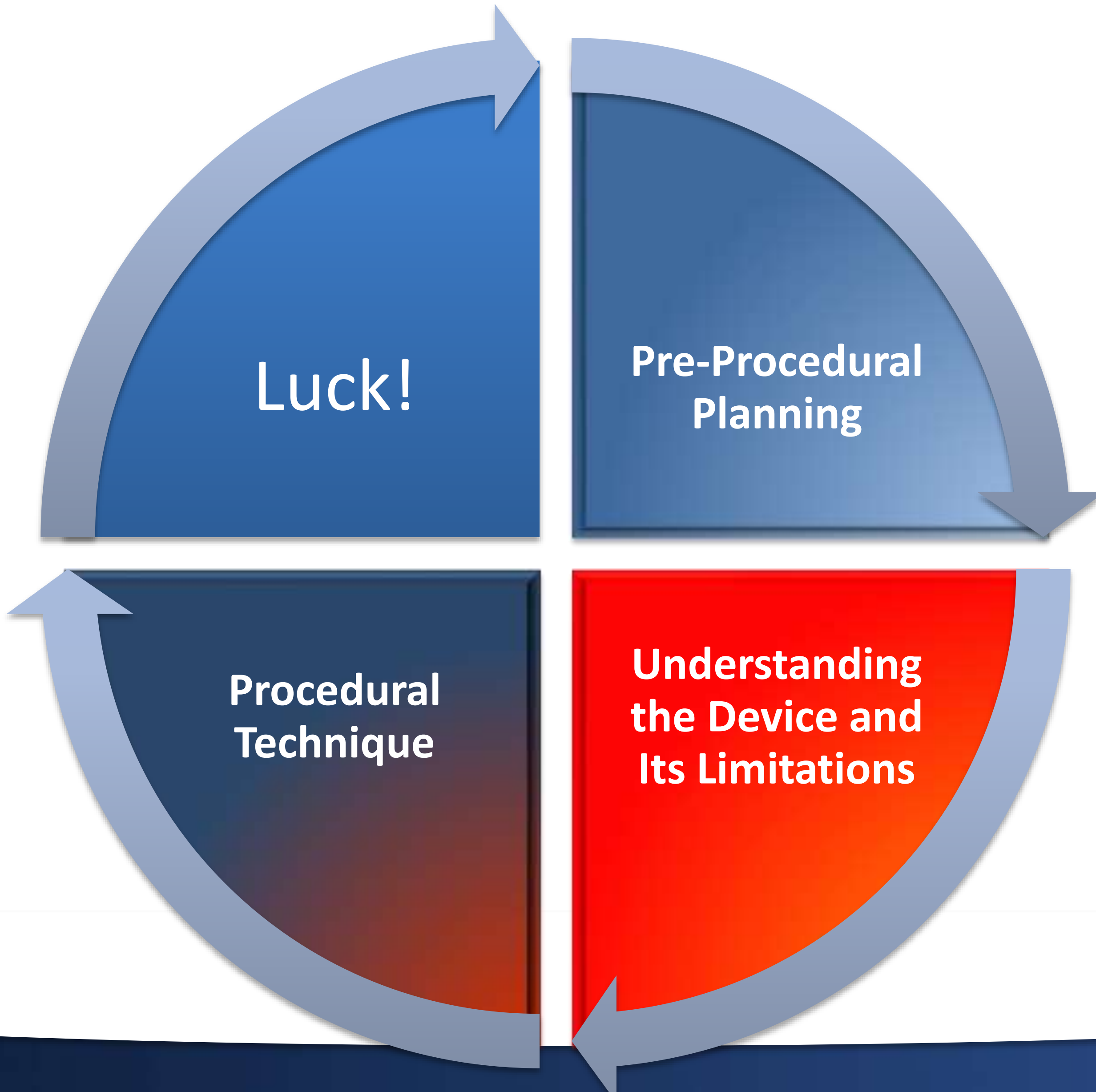
Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Honoraria	• St. Jude Medical, Claret Medical
• Steering Committee	• Edwards Lifesciences, Claret Medical
• SAB	• Thubrikar Aortic Valve, Inc, Dura Biotech, VS Medtech

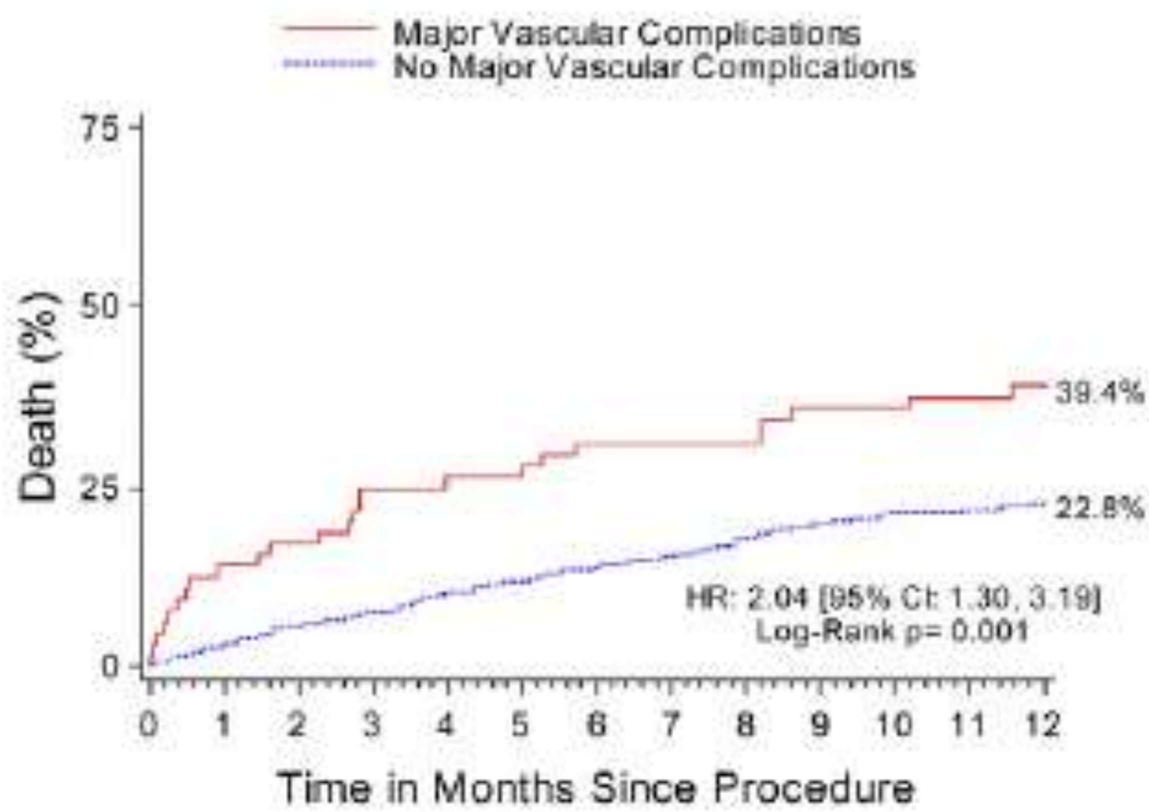
Keys to a Successful Procedure



Top Ten Tricks for Success

10. Understand limits of transfemoral approach

Major Vascular Complications Increase Mortality



Predictors of VARC major vascular complications

By multivariate analysis, the independent predictors of VARC major vascular complications were

1. The Sheath to Femoral Artery Ratio (SFAR)
   - HR = 1[illegible]
2. Early [illegible]ce
   - [illegible] (p=0.023)
3. [illegible]al artery calcium [illegible]core
   - HR = 3.44 (p=0.026)

Don't Push the Limits!

Table 5. Univariate and Multivariate Analysis of the Clinical and Procedural Characteristics According to the Incidence of VARC Major Vascular Complications

Variable	Univariat[illegible] p [illegible]	M[illegible]ltivariate		95% CI
Age, yrs				
Female				
BMI, [illegible]				
[illegible]	[illegible]222			
[illegible]	0.228			
[illegible]	0.212			
[illegible]coagulation	0.870			
[illegible]ctivated clotting time, s	0.710			
TAVI type	0.004	0.057		
Early center experience ★	0.007	0.023	3.66	1.17–11.49
Sheath outer diameter, mm	0.010	0.157		
Femoral artery MLD, mm	0.797			
SFAR ★	0.001	0.006	186.20	4.41–7,855.11
Femoral artery calcification (0–3) ★	0.023	0.026	3.44	1.16–10.17
Femoral artery tortuosity (0–3)	0.709			
Common iliac MLD, mm	0.419			
External iliac MLD, mm	0.264			
SEIAR	0.577			
Iliac artery calcification (0–3)	0.077			
Iliac artery tortuosity (0–3)	0.459			

Device Evolution ➔ Smaller Sheath Sizes

RetroFlex 3 delivery system

NovaFlex+ delivery system

Edwards Commander delivery system

RetroFlex 3 introducer sheath

Edwards eSheath introducer set

*Edwards eSheath introducer set**

SAPIEN valve 23 and 26 mm

MVD 7mm / 8mm

SAPIEN XT valve 23, 26, 29 mm

MVD 6 mm / 6.5 mm / 7mm

SAPIEN 3 valve 20, 23, 26, 29 mm

MVD 5.5mm / 6.0mm

CoreValve 23,26,29 and 31 mm

22 FR (OD)

18FR

w/ 18Fr Cook Sheath

MVD 6 mm

CoreValve Evolut 23,26,and 29

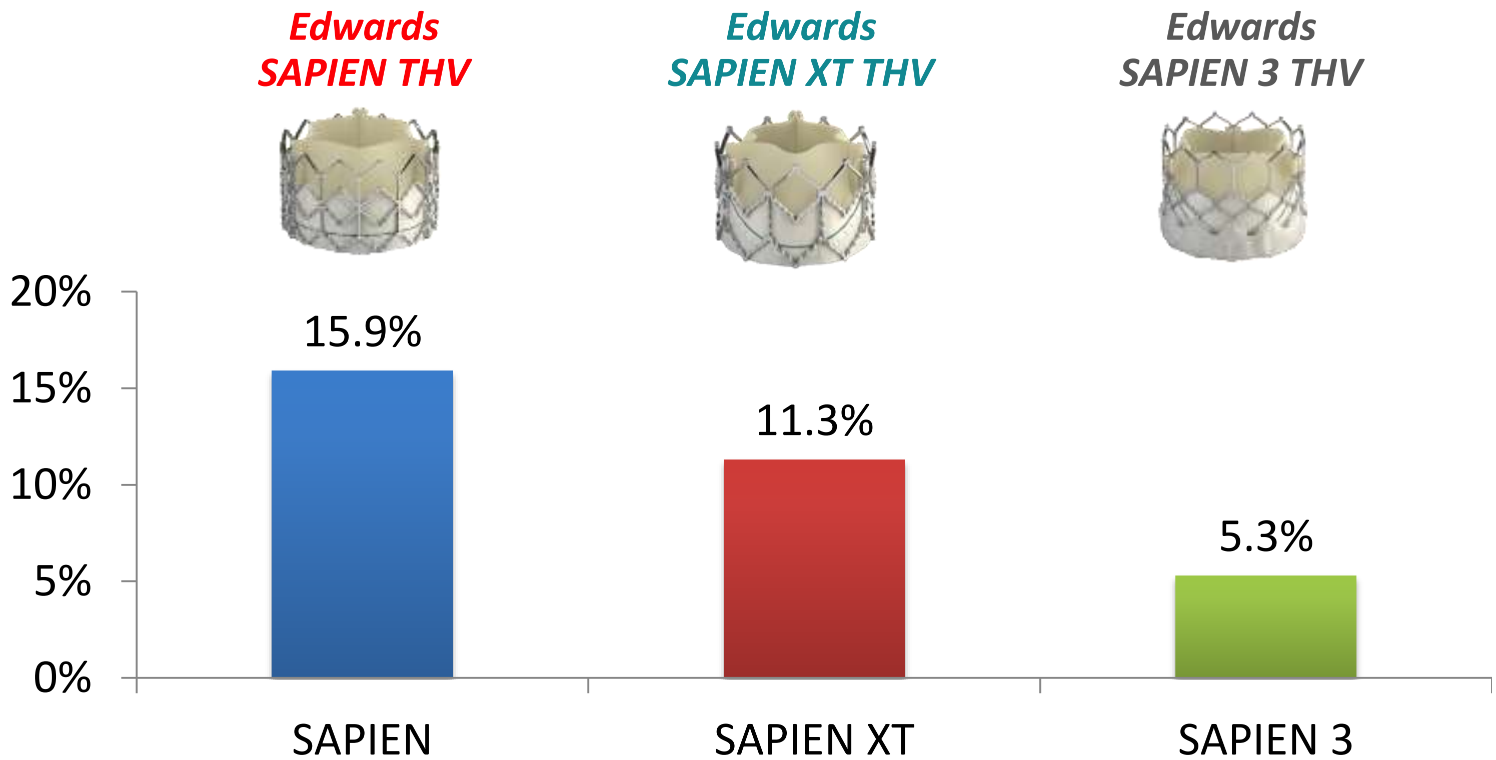
18 FR (OD)

18FR

w/ InLine Sheath

MVD 5 mm

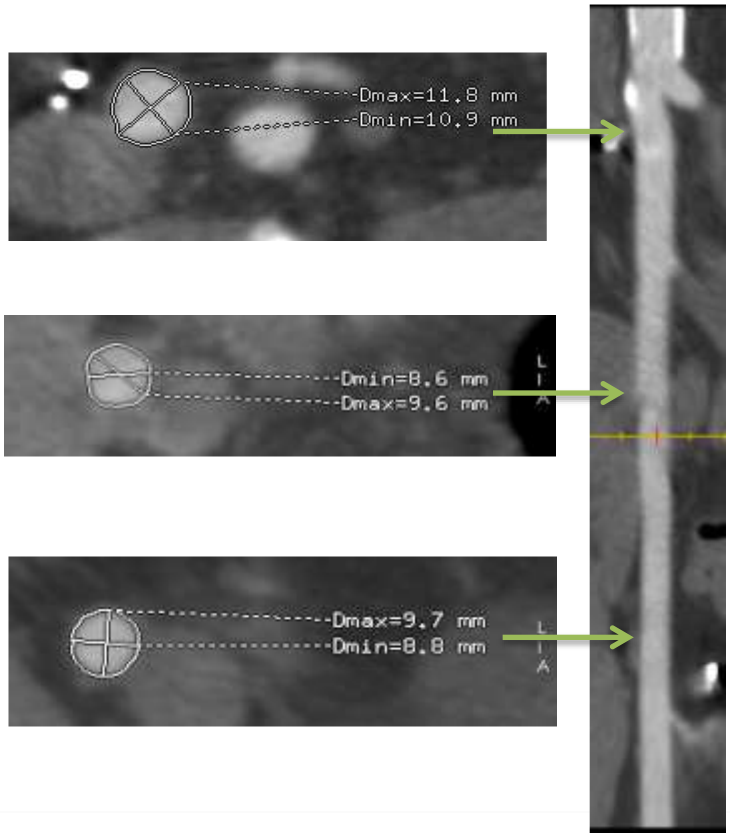
Smaller Sheath Size Results in Lower Complications

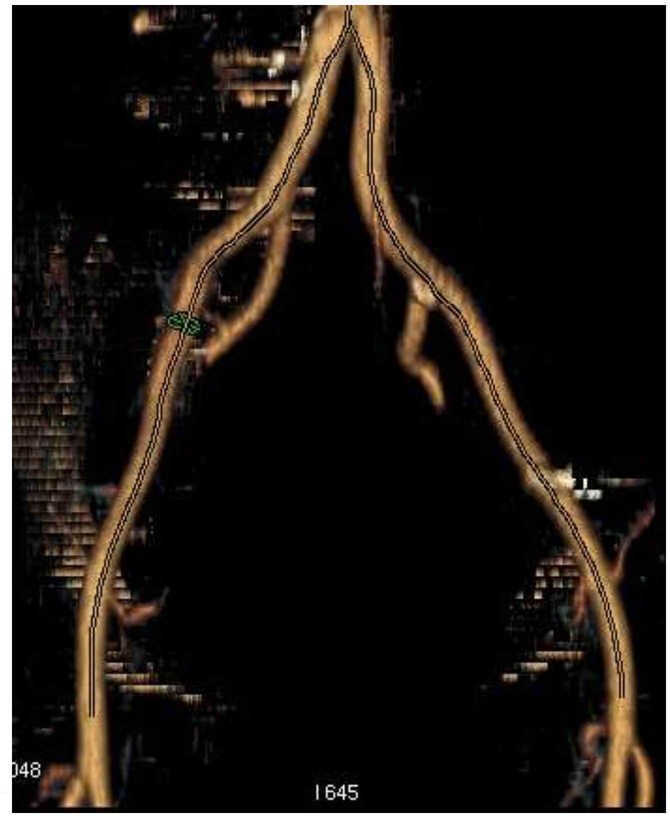


30-day major vascular complications by platform
From PARTNER 2B and S3 HR

Patient selection

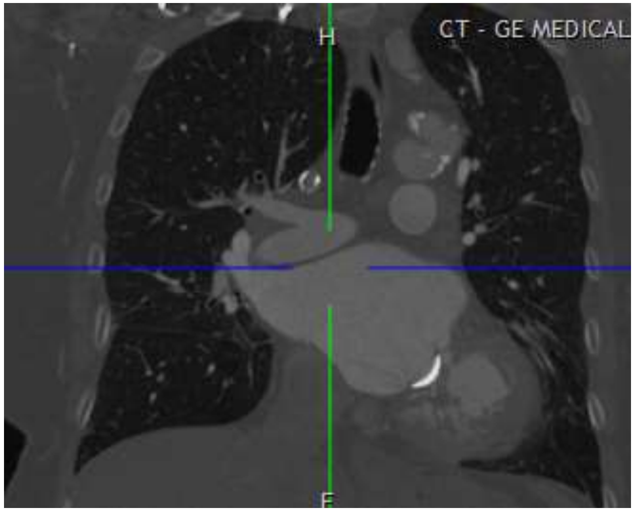
Vascular Access Screening
CTA: 3D reconstruction



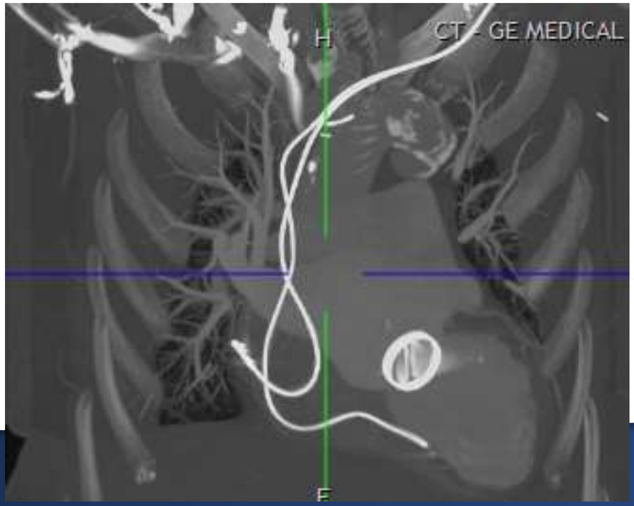


Evaluate Calcification - Vascular MIP

1.15mm Slab



60.0mm Slab



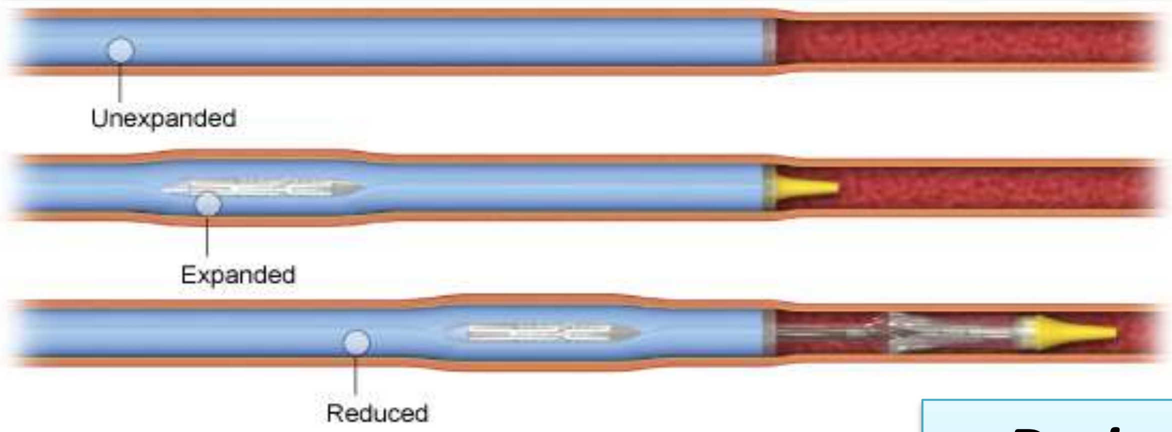
Top Ten Tricks for Success

10. Understand limits of transfemoral approach
9. Beware limitations of e-Sheath

Edwards eSheath
Expandable Introducer Sheath

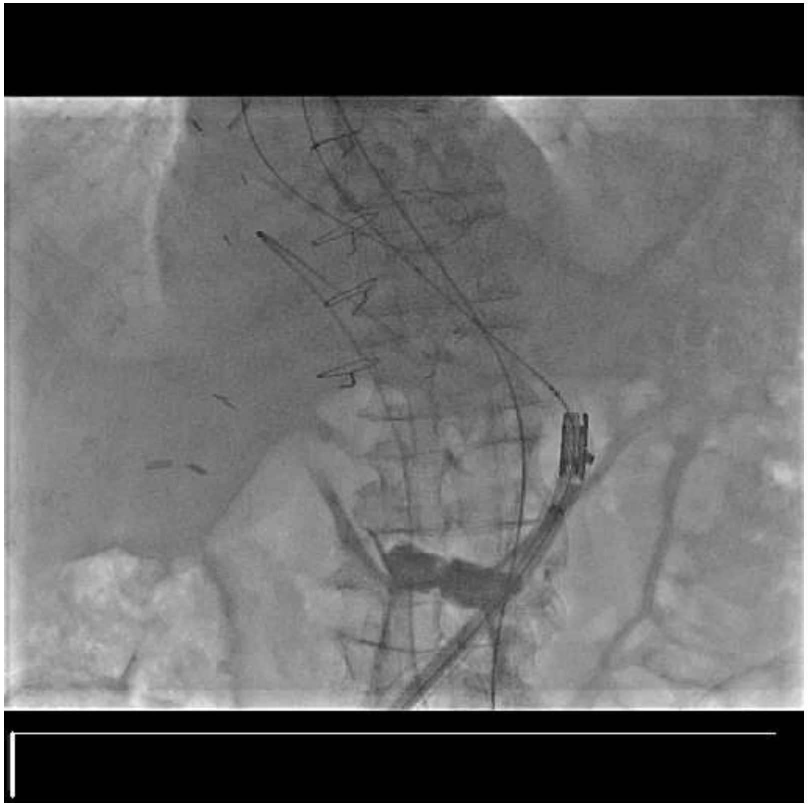
DEM: Dynamic Expansion mechanism

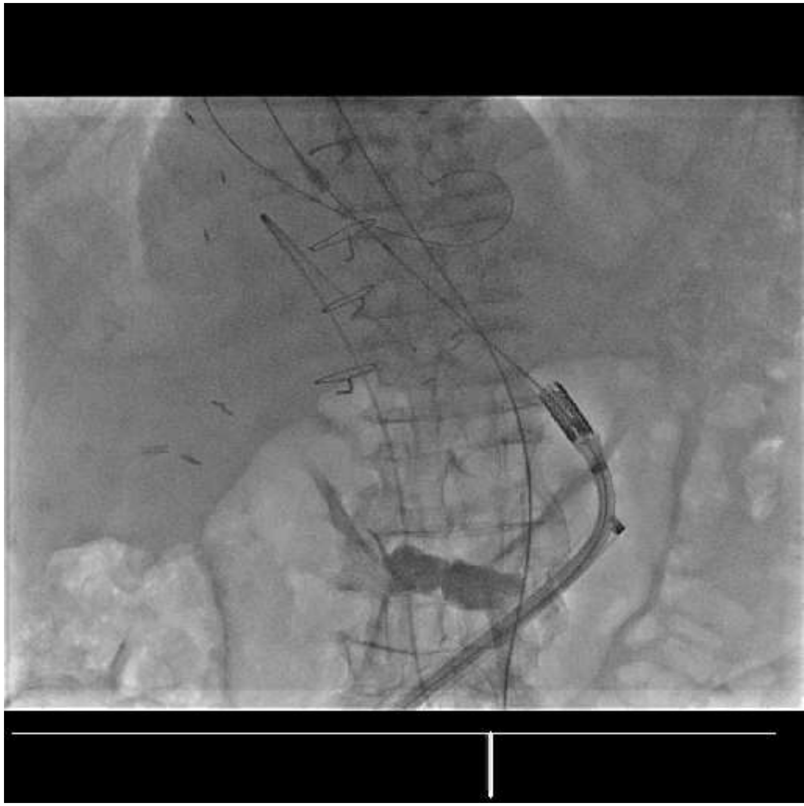
- ***Allows for transient sheath expansion during valve delivery***
- ***After the passage of the THV, allows the sheath to return to a low profile diameter***
- ***Reduces the time the access vessel is expanded***



During passage of the valve delivery catheter, sheath diameter can increase up above 8 mm for a 29mm valve

Evaluate the Entire Vascular Tree





E-sheath may cause damage if device doesn't exit at tip of sheath

Preventing Vascular Complications

Evaluate entire vascular tree and use caution with eSheath

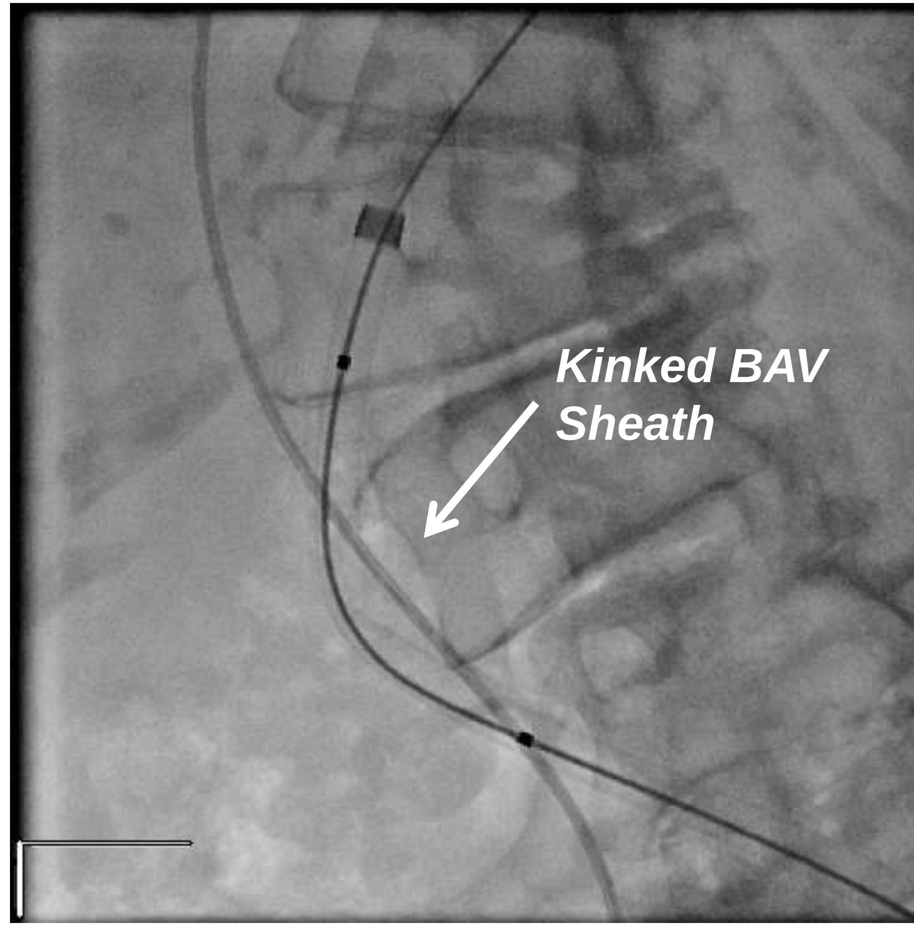
- Valve deployed with excellent result
- Sheath removed and perclose notes delivered
- Patient becomes hypotensive

Top Ten Tricks for Success

10. Understand limits of transfemoral approach
9. Beware limitations of e-Sheath
8. Be prepared to deal with complex vascular anatomy

Preventing Vascular Complications

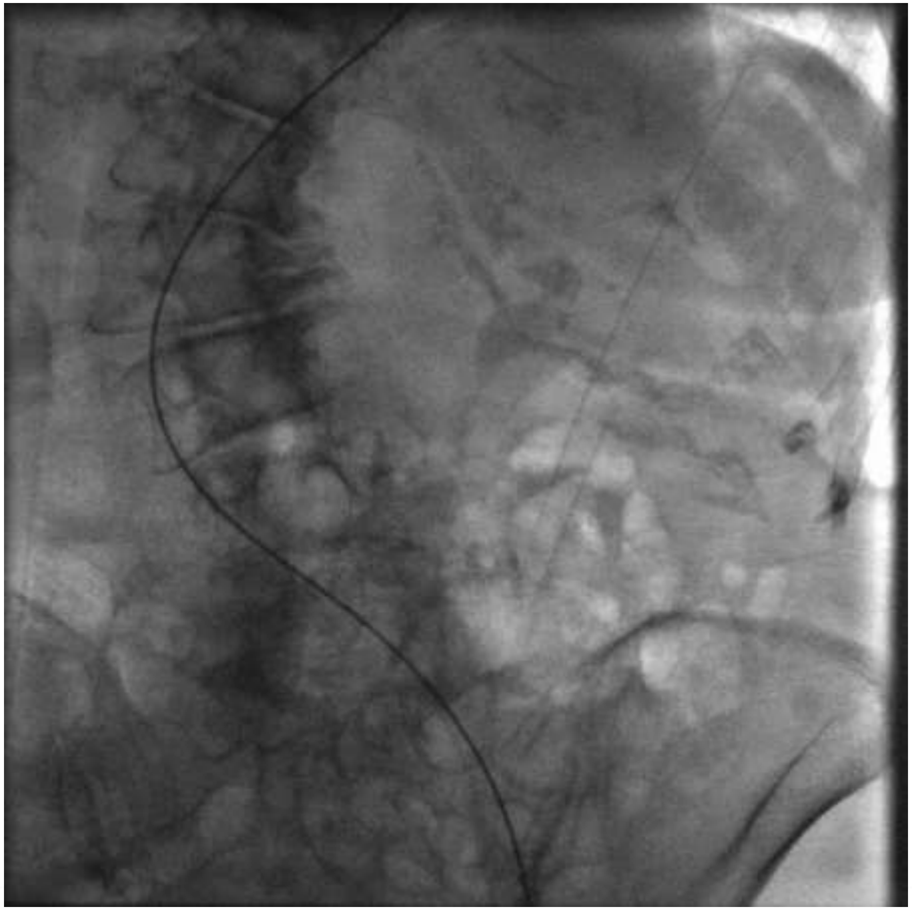
Tortuous Vasculature



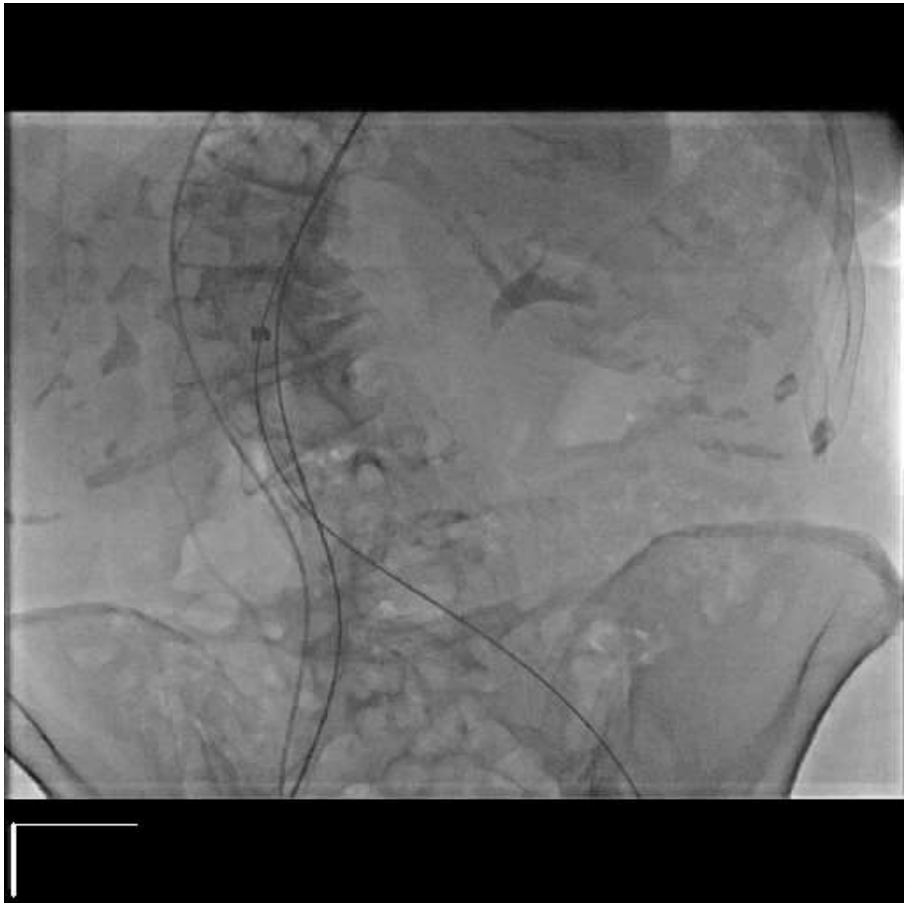
How to avoid vascular complication in this case?

Preventing Vascular Complications

Tortuous Vasculature – Use of two stiff wires



One Extra Stiff Wire



Two Meier Wires

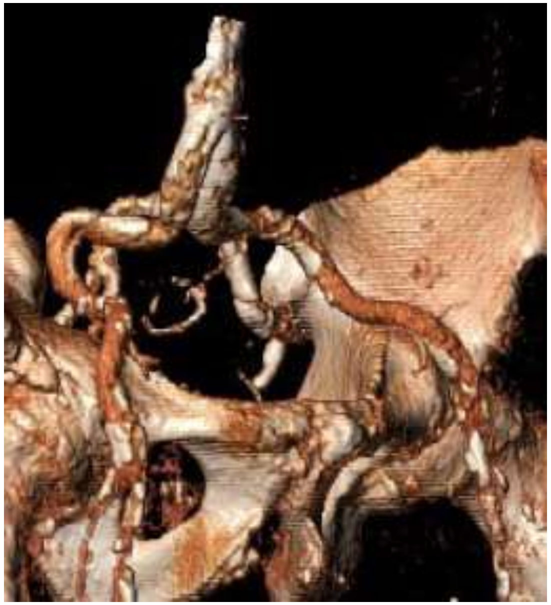
Preventing Vascular Complications

Tortuous Vasculature – Use of two stiff wires

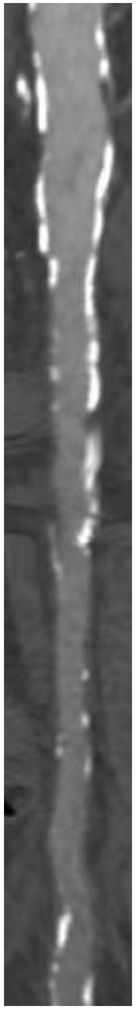
Meier wire kept in pigtail until Novoflex delivery catheter advanced through sheath to prevent kinking

Preventing Vascular Complications

Calcified and Tortuous Iliacs



- **Vessel size > 8mm**
- **Severe calcification**
- **Severe tortuosity**



Preventing Vascular Complications

Calcified and Tortuous Iliacs

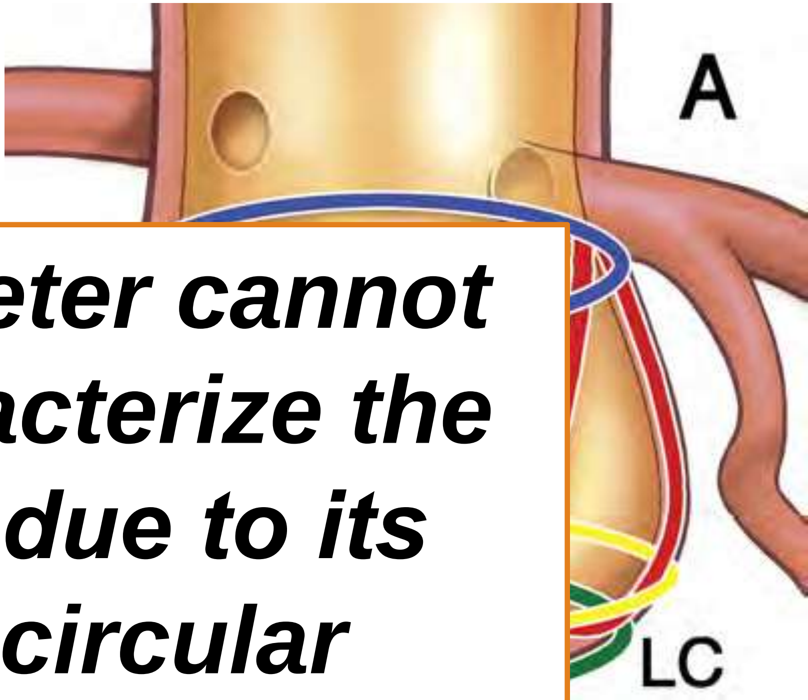
- **Separation between capsule and nosecone can lead to vascular damage**
- **Options**
  - **Stiff wire**
  - **Solopath sheath**

Top Ten Tricks for Success

10. Understand limits of transfemoral approach
9. Beware limitations of e-Sheath
8. Be prepared to deal with complex vascular anatomy
7. Appropriately size the annulus to prevent PVL

Aortic Annulus

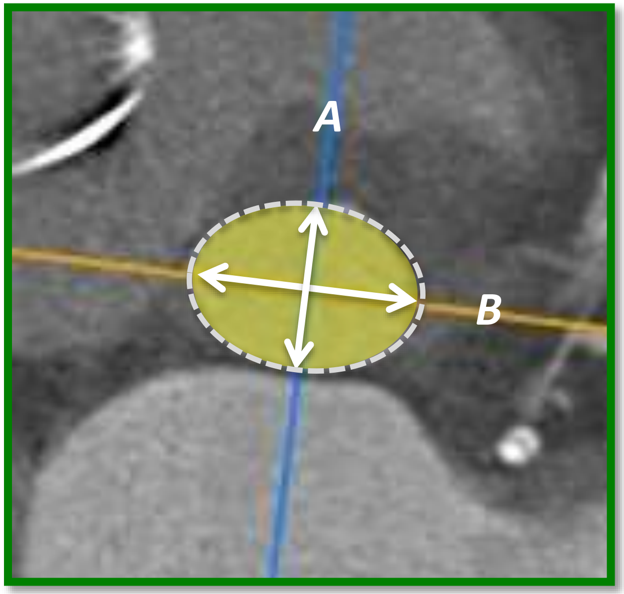
- Annulus Sizing
  – The aortic annulus is a complex 3 dimensional s
  – F s t p t
    -

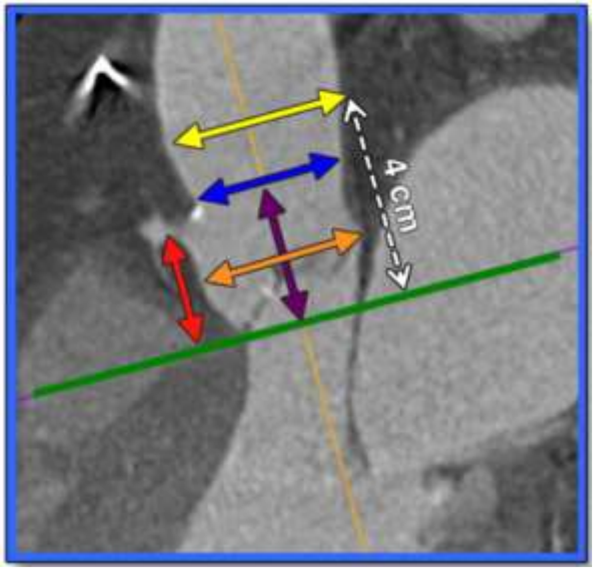


Any single diameter cannot adequately characterize the annulus "size" due to its elliptical non-circular configuration

each aortic cusp

Annular Measurements





$\frac{A + B}{2}$ = mean Diameter

= Area

= Perimeter

= Sinus Width

= Diamter of the Sinutubular Junction

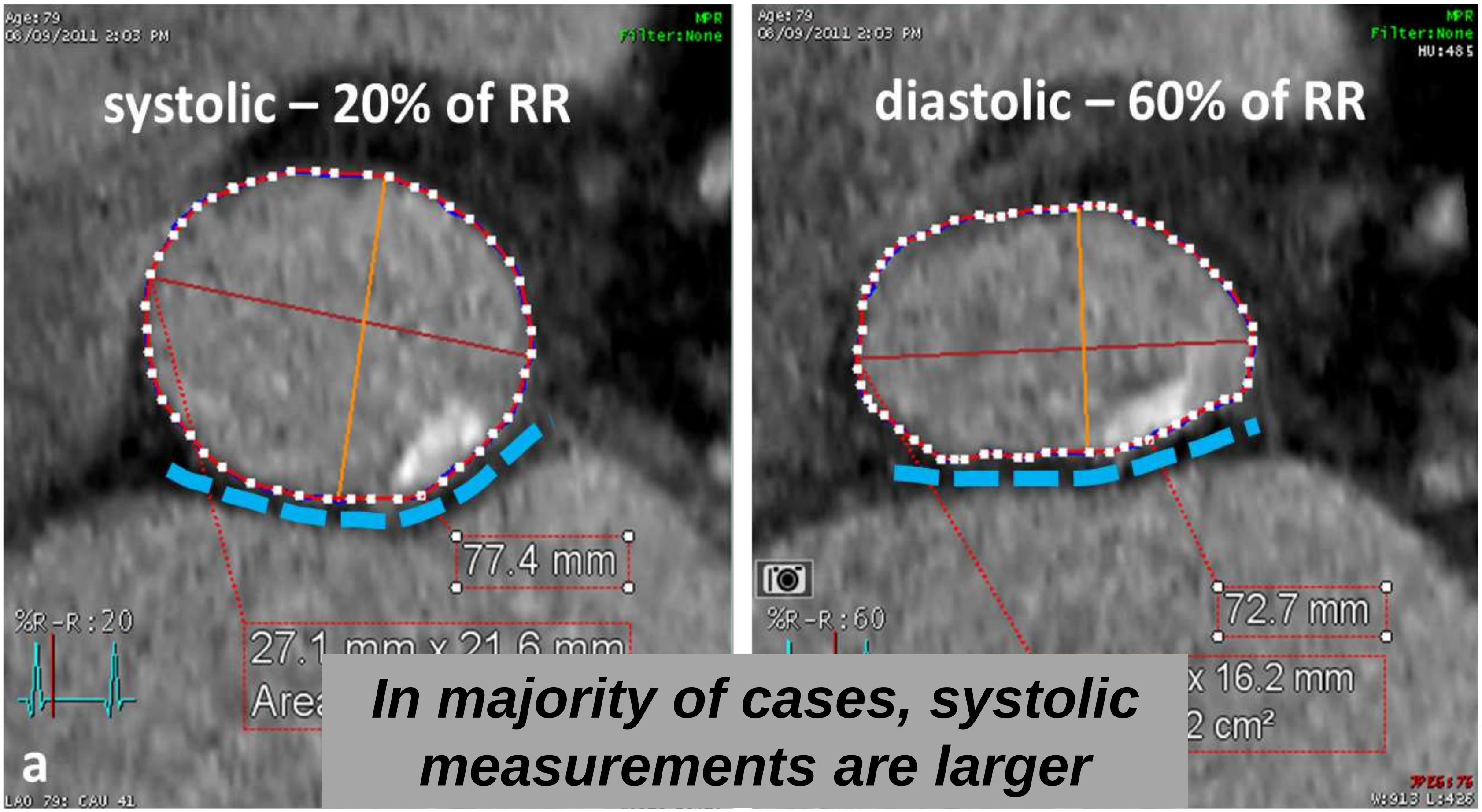
= AsAo Width in 4 cm Distance from Annulus

= Sinus Height

= Distance to Coronaries

Understand what you are measuring is not a static structure

Variability throughout the Cardiac Cycle

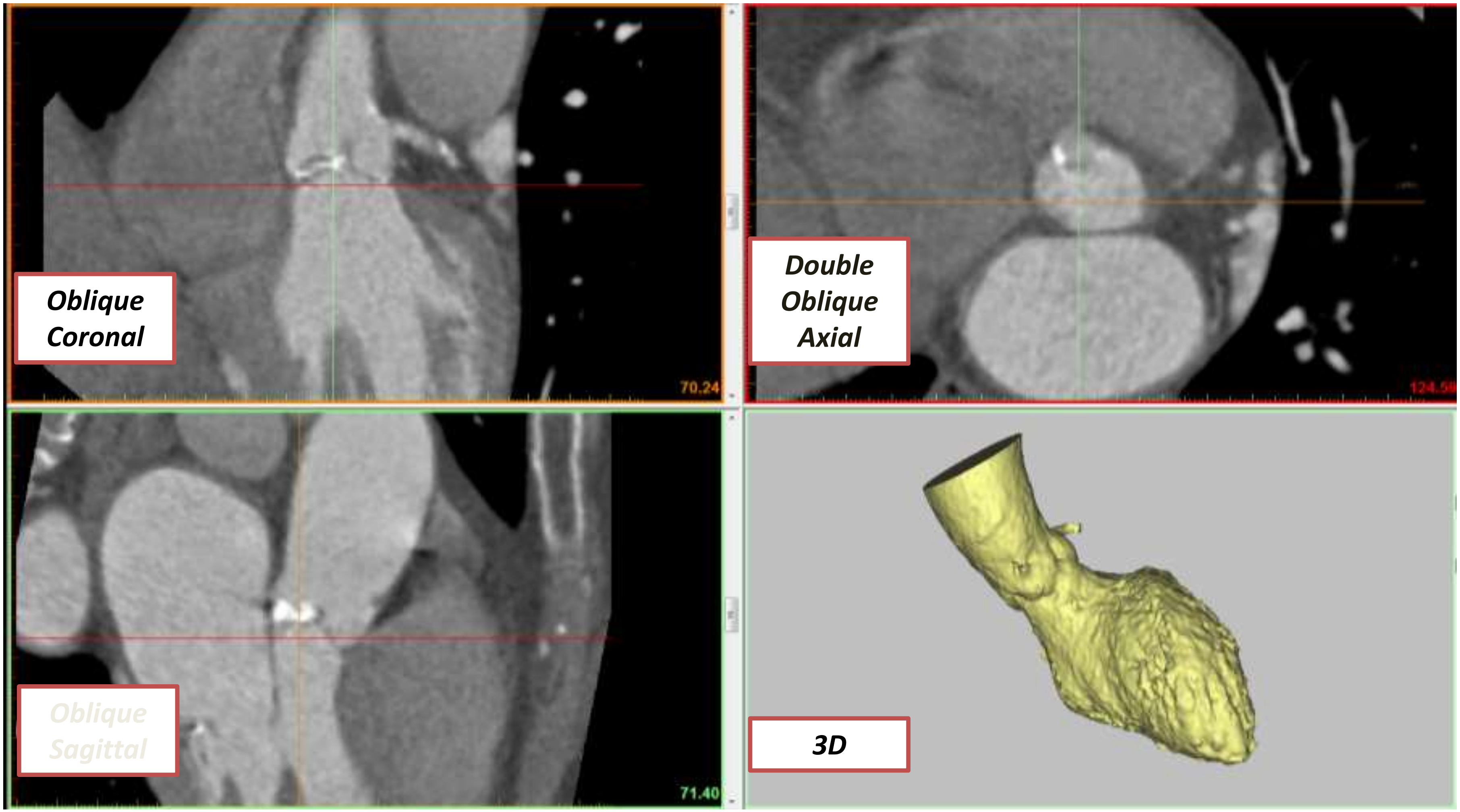


In majority of cases, systolic measurements are larger

Leipsic et al Circ Imaging Jun 2013

A poorly performed analysis can be dangerous

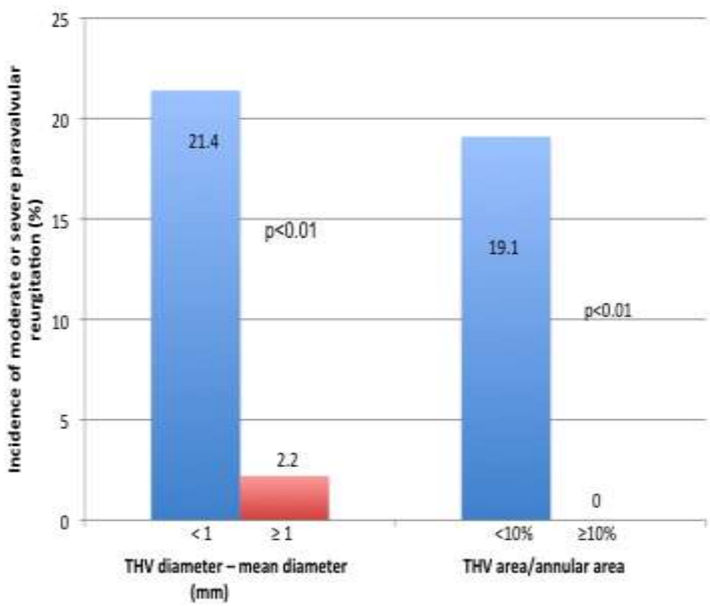
Example of Incorrect Plane – Wrong Orientation

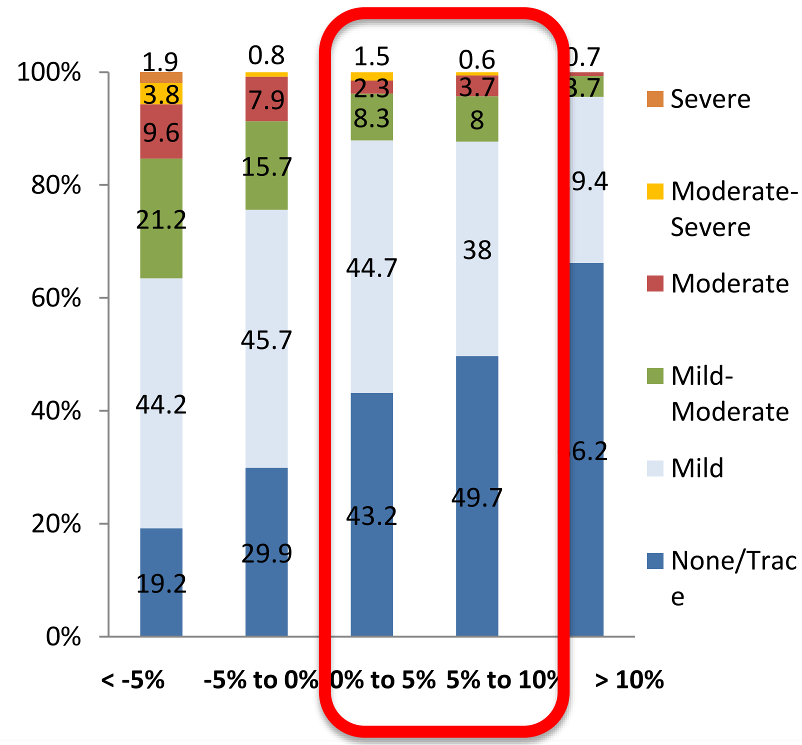


Beware of Artifacts

stair step/misalignment artifact

Know your device characteristics





Willson et al. JACC April 3 2012

Blanke et al. EuroPCR 2015

3D Echo Annular Measurements: CoreValve

26 mm CoreValve
Perimeter = 8.16 cm

29 mm CoreValve
Perimeter = 9.11 cm

Goal: Relative Perimeter Oversizing of 10-25%

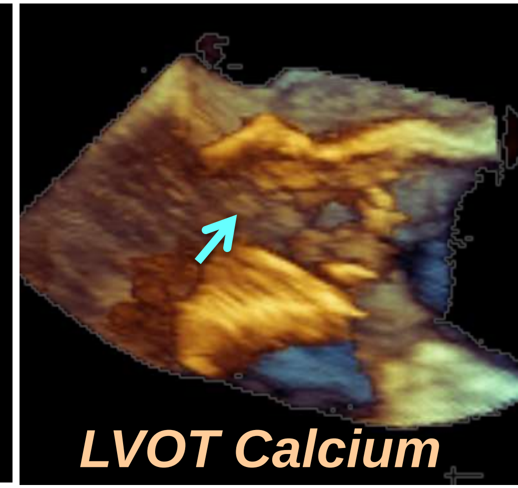
Range: 6.1-7.3 cm

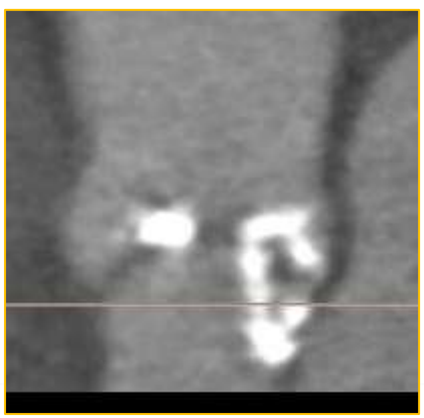
Range: 6. 8- 8.2 cm

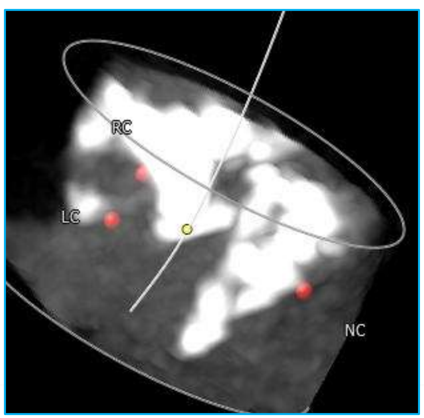
Top Ten Tricks for Success

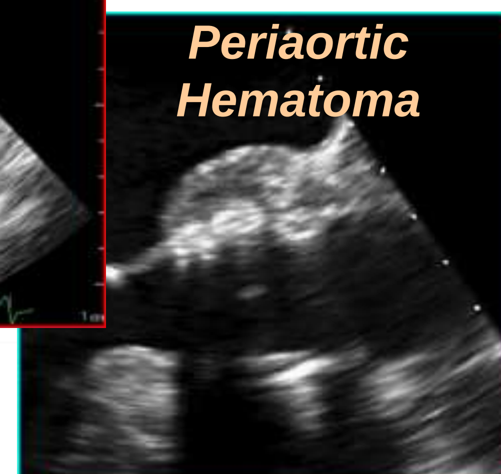
10. Understand limits of transfemoral approach
9. Beware limitations of e-Sheath
8. Be prepared to deal with complex vascular anatomy
7. Appropriately size the annulus to prevent PVL
6. Understand limitations of anatomy (Don't push your luck!)

Impact of Landing Zone Anatomy



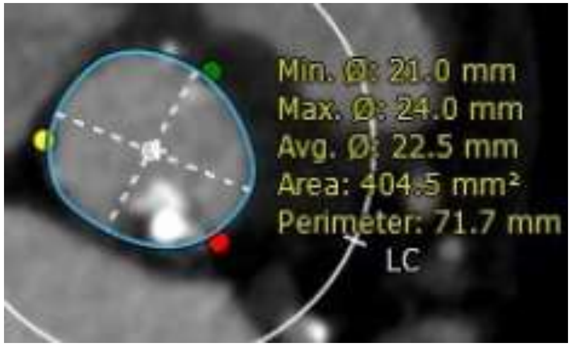


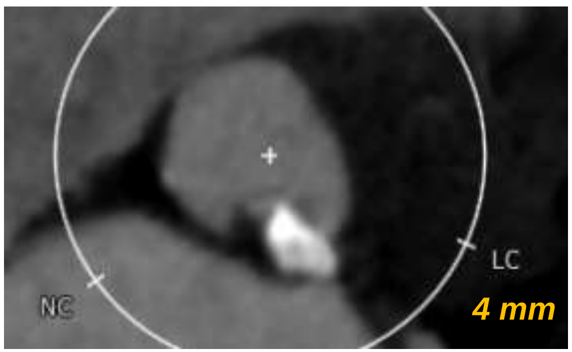


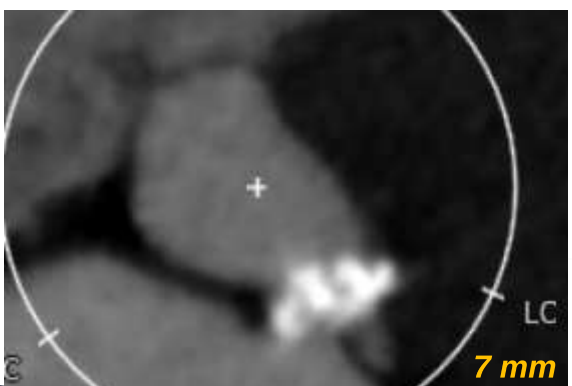


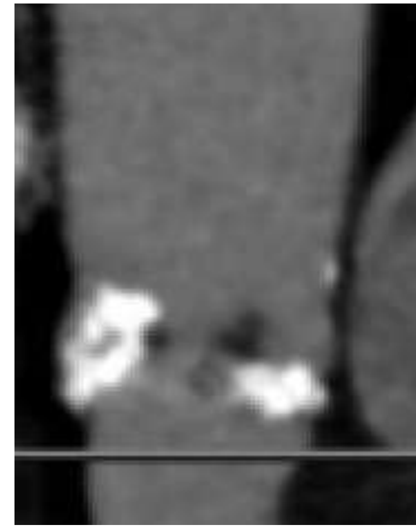
In certain cases, patient anatomy will dictate PVR result

Impact of Severe LVOT Calcium









- Perimeter: 72 mm Area 404 mm2
- Diameter: Max 24 mm Min 17 mm
- Severe protruding 6 mm calcification in the posterior region of the aortic annulus.
- The calcification extends deeply into the LVOT

Valvular Heart Disease

Anatomical and Procedural Features Associated With Aortic Root Rupture During Balloon-Expandable Transcatheter Aortic Valve Replacement

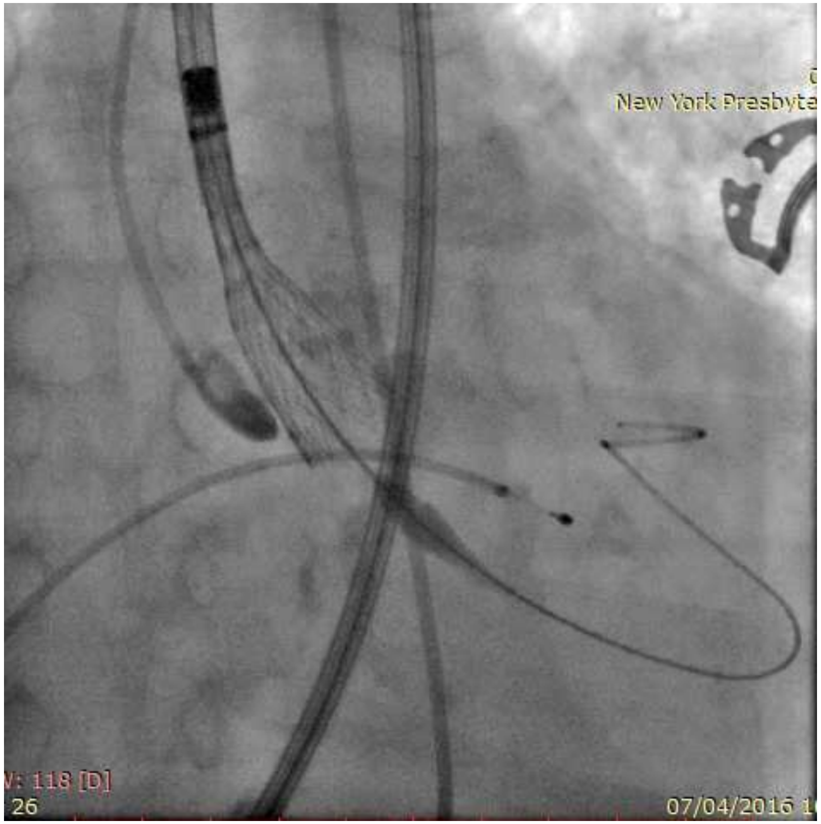
Marco Barbanti, MD; Tae-Hyun Yang, MD, Josep Rodès Cabau, MD; Corrado Tamburino, MD; David A. Wood, MD; Hasan Jilaihawi, MD; Phillip Blanke, MD; Raj R. Makkar, MD; Azeem Latib, MD; Antonio Colombo, MD; Giuseppe Tarantini, MD; Rekha Raju, MD; Ronald K. Binder, MD; Giang Nguyen, MD; Melanie Freeman, MD; Henrique B. Ribeiro, MD; Samir Kapadia, MD; James Min, MD; Gudrun Feuchtner, MD; Ronen Gurtvich, MD; Faisal Alqoofi, MD; Marc Pelletier, MD; Gian Paolo Ussia, MD; Massimo Napodano, MD; Fabio Sandoli de Brito, Jr, MD; Susheel Kodali, MD; Bjarne L. Norgaard, MD; Nicolaj C. Hansson, MD; Gregor Pache, MD; Sergio J. Canovas, MD; Hongbin Zhang, PhD; Martin B. Leon, MD; John G. Webb, MD; Jonathon Leipsic, MD

- Higher calcium in the R coronary LVOT
- No difference if small or large valve
- No difference if sinus large vs effaced
- No difference if annulus eccentric
- Annular oversizing (>20%) (OR – 8.38)
- Post-dilation (same size, 1-2 mm larger)

(*Circulation*. 2013;128:244-253.)

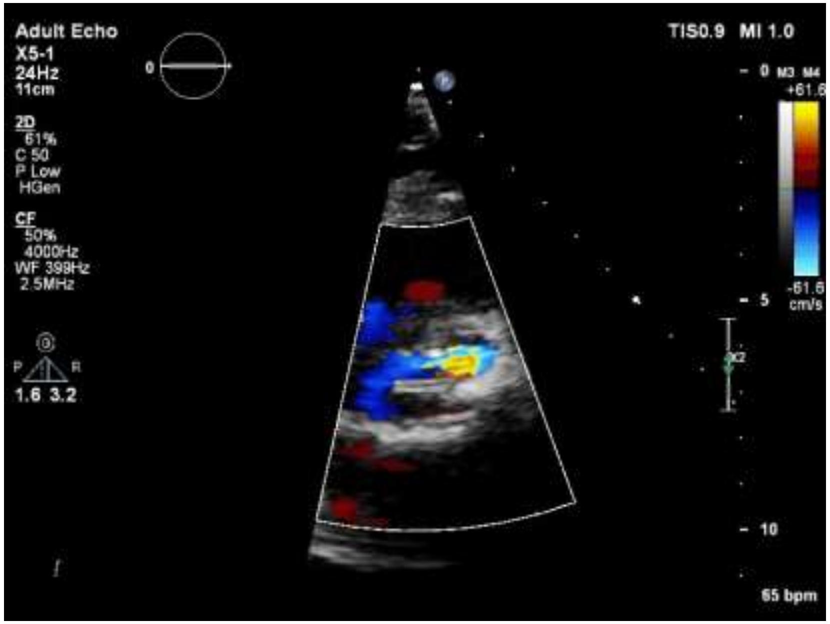
26mm Evolut Deployed

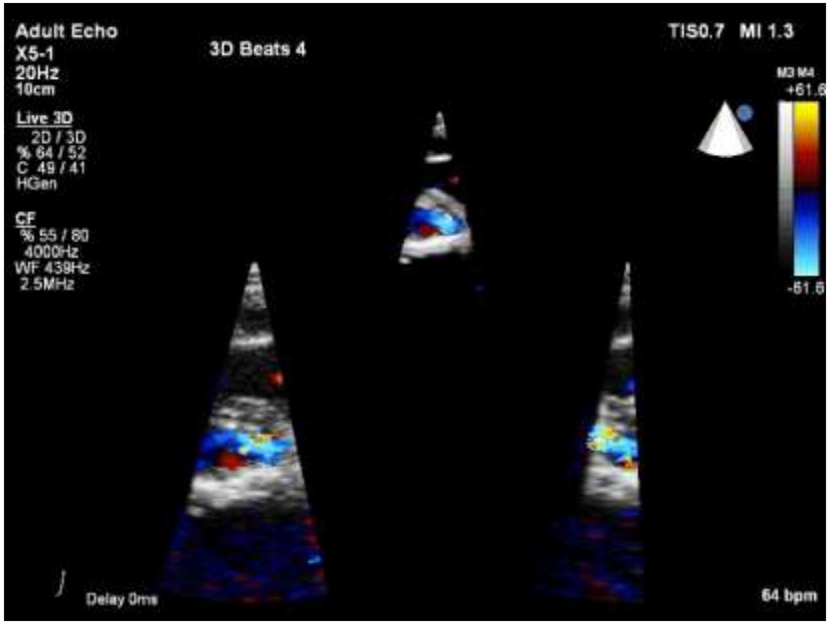
Aortogram

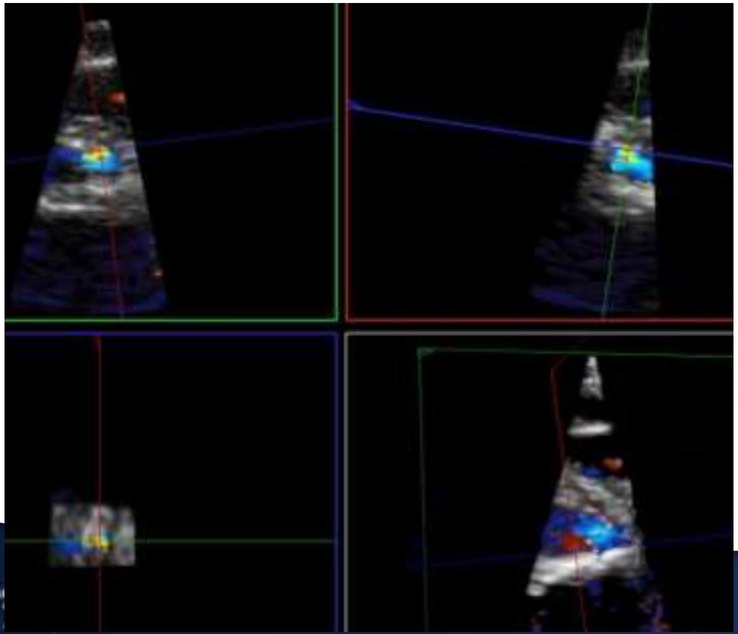


Evolut Deployed

Severe PVL despite Post-Dilatation







What to do next?

Paravalvular Leak Closure

- ***Crossing the PVL:***
- ***5 Fr AL1 diagnostic catheter***
- ***Soft angled Glidewire – Terumo***
- ***TTE guided***

Paravalvular Leak Closure

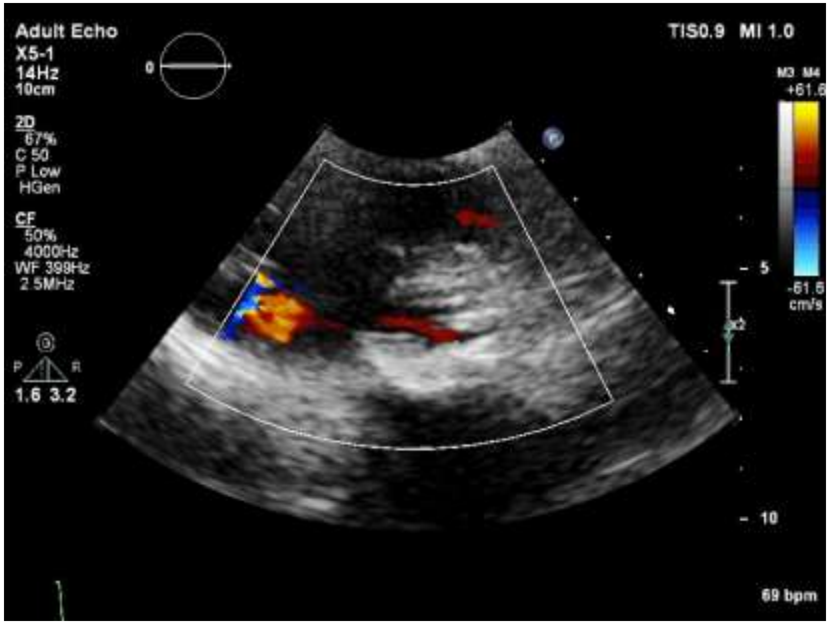
- ***Deliver distal portion of 8 mm AVP II***
- ***Pull Catheter and AVP as a system***
- ***Reposition if necessary***
- ***Deploy, push Catheter and review before releasement***

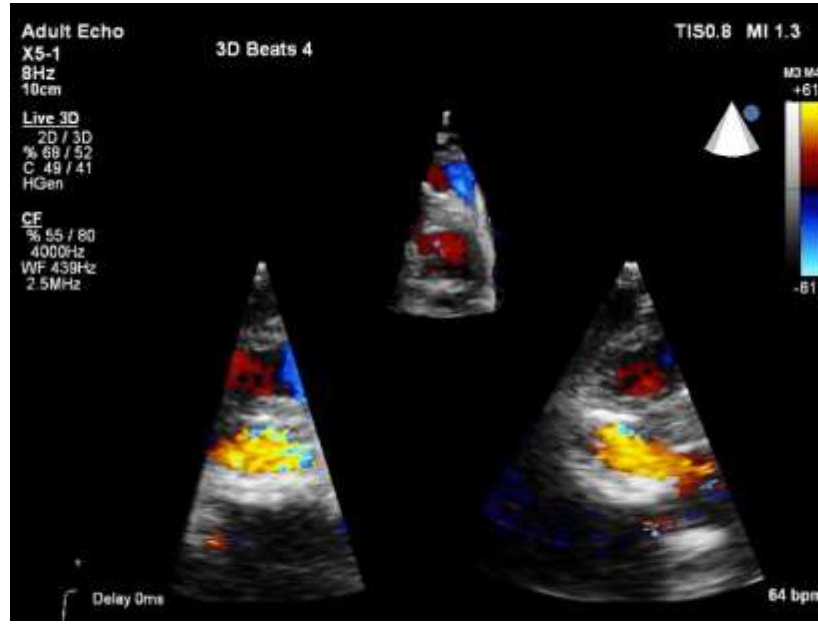
Paravalvular Leak Closure

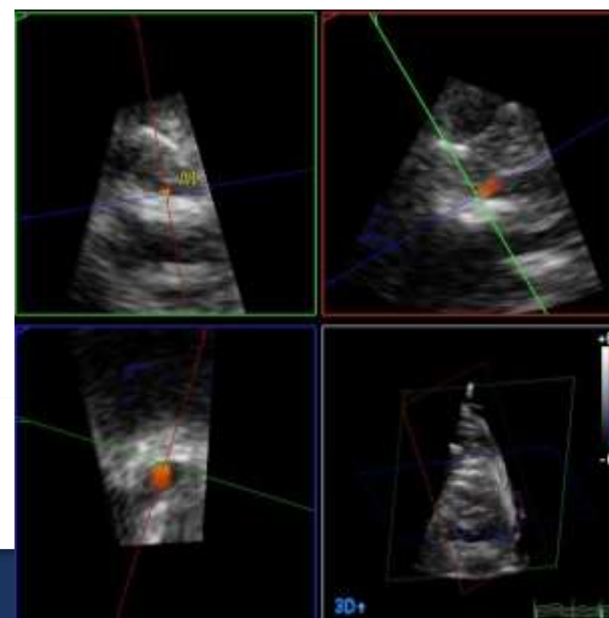
Tug Test

Final Aortogram

TTE post PVLC







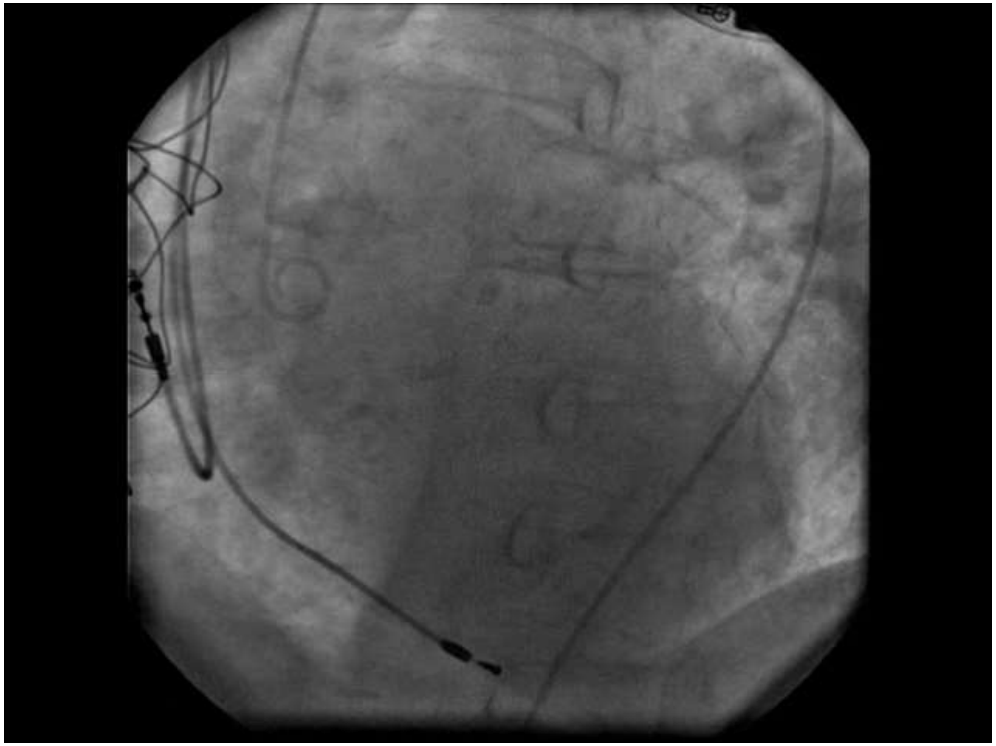
- Plug remained well seated.
- Final PVL: Trace
- EROA of the jet: 3 mm2
- AVA: 1.96 cm2
- PV 2 m/s, P/MG: 17/7 mmHg DI:0.69

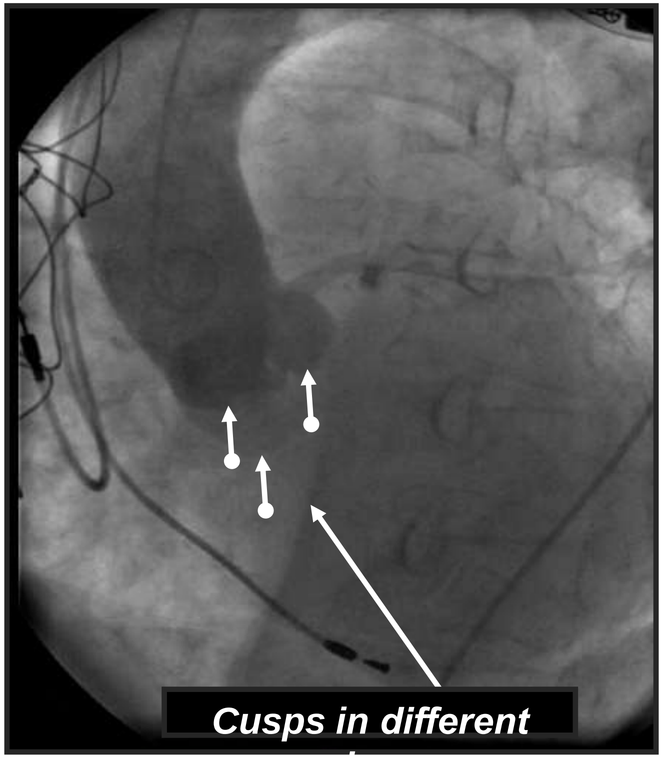
Top Ten Tricks for Success

5. Find a coaxial view for proper deployment

Limitations of Fluoroscopy

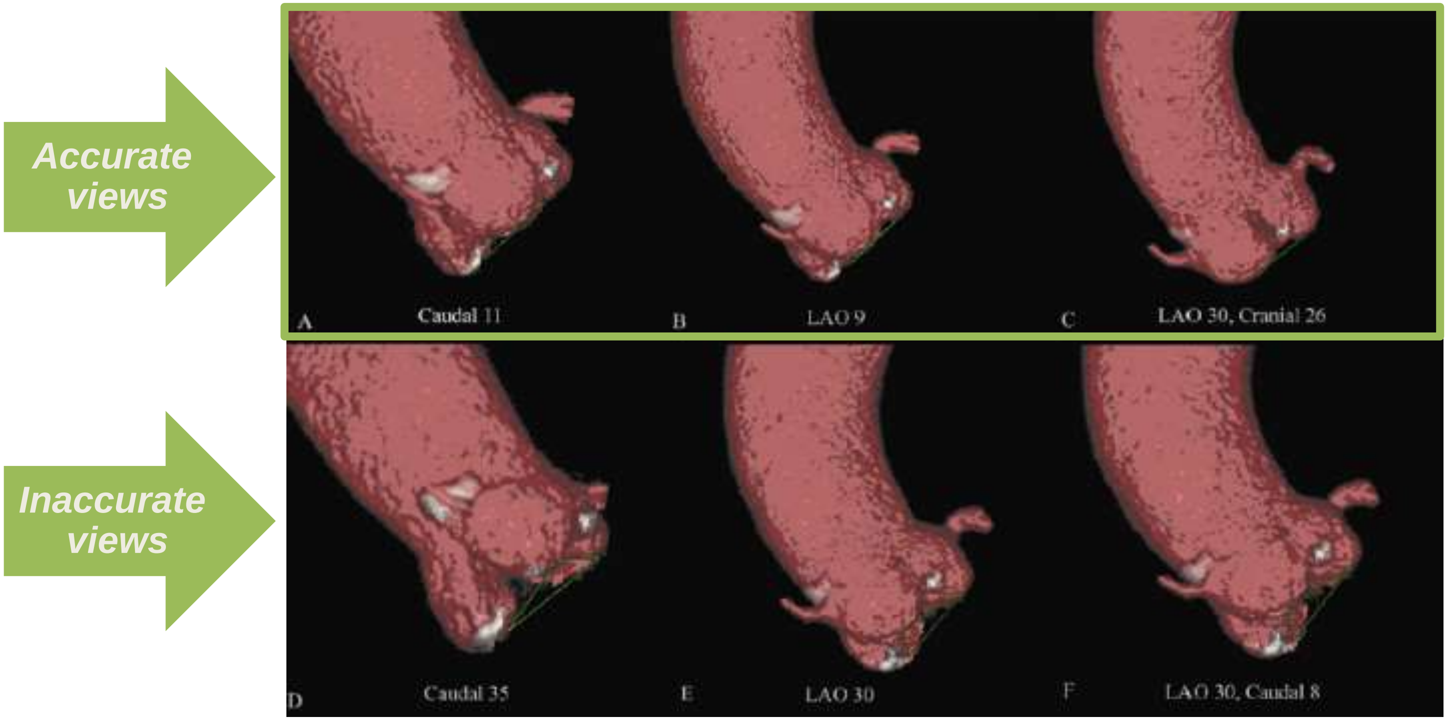
Finding a Coplanar View



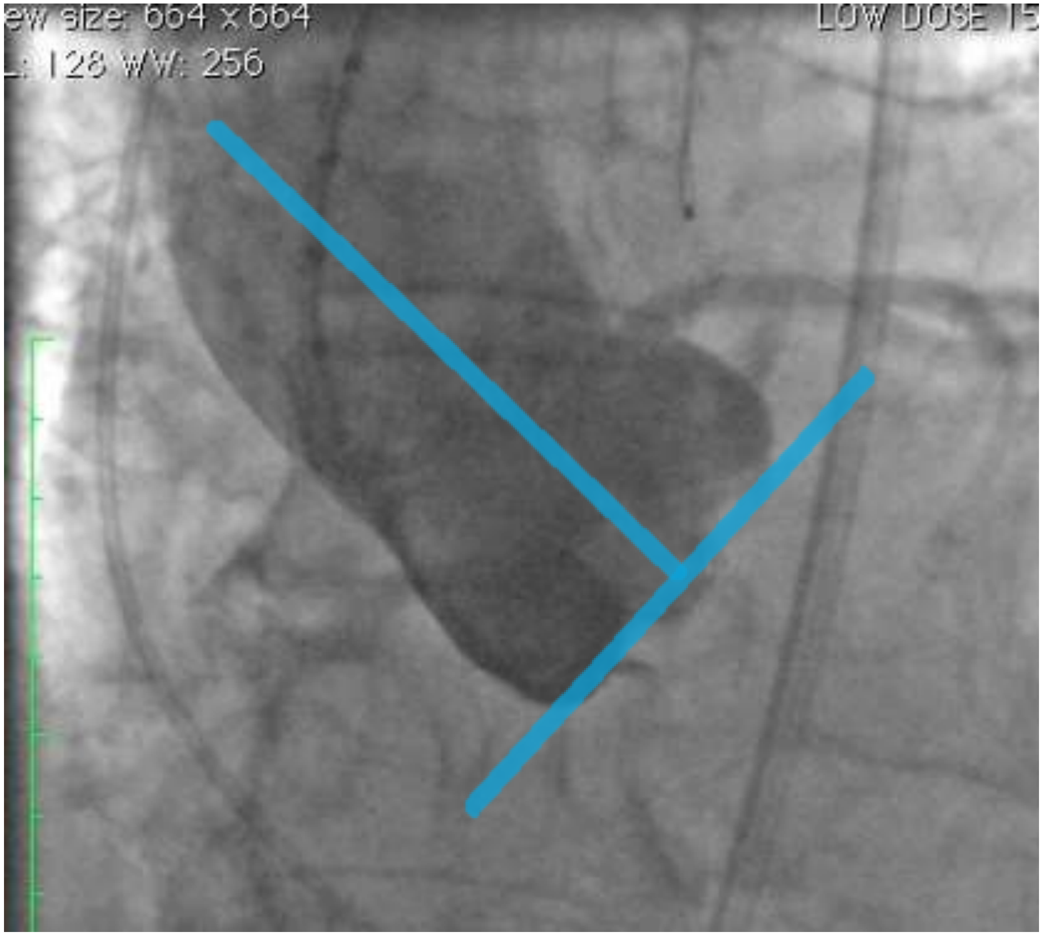


Finding a Coplanar View

- CT can be used to identify the appropriate view, by aligning the inferior aspects of each valve cusp in the same plane

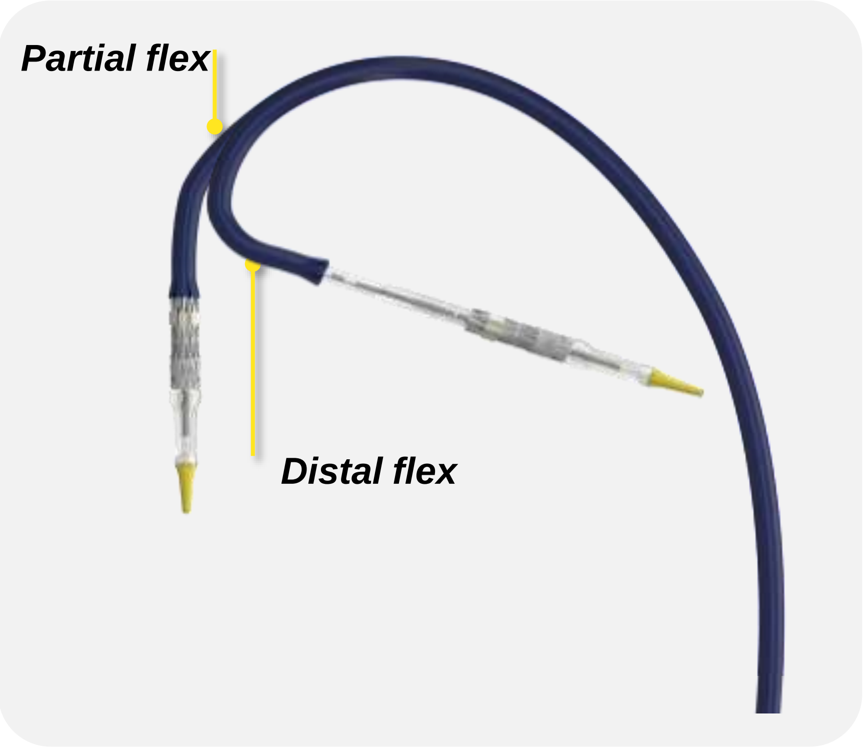


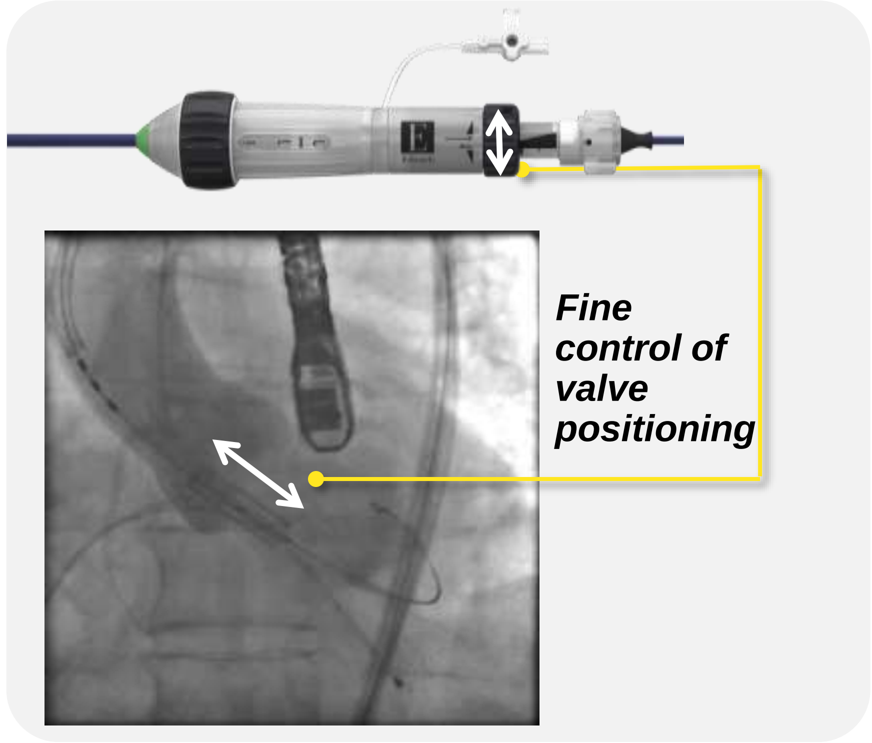
Optimal Aortography



- **Challenge is using 2D imaging to deploy the valve**
- **Target coaxial alignment of catheter and annulus**
- **Adjust catheter and guidewire tension to ensure valve is aligned within the annulus and perpendicular to the basal plane**

Edwards Commander delivery system





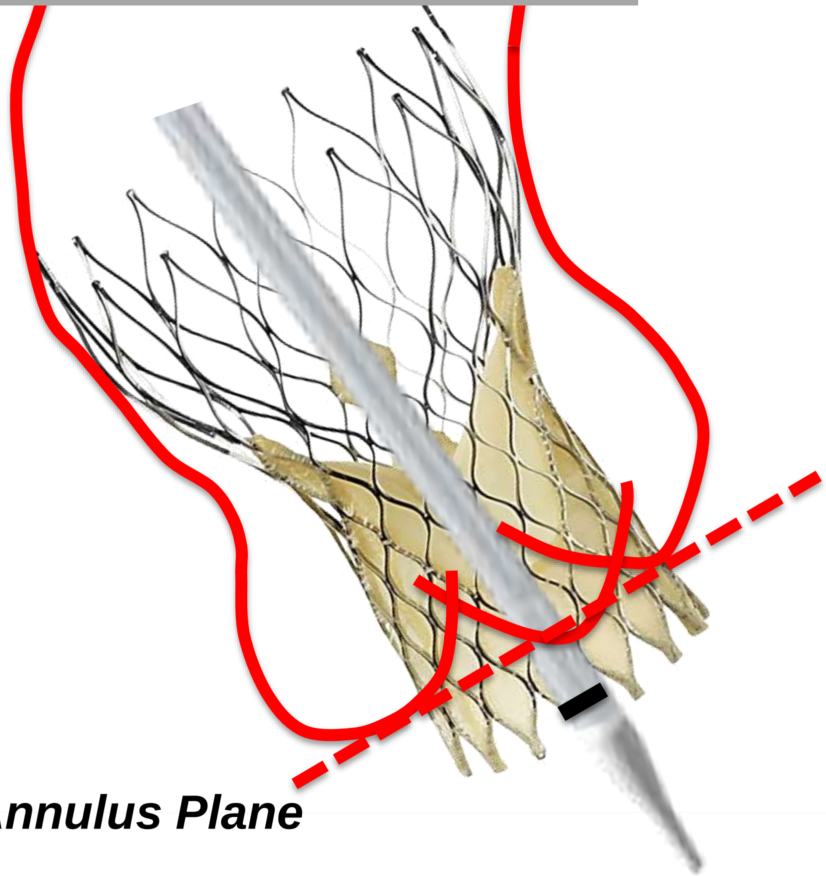
Distal hyperflexion and fine control knob allows for improved coaxial positioning of the valve

Sapien 3 Deployment

- **Valve positioned so that central marker just above annulus**
- **During deployment, valve foreshortens from ventricular side (up to 8.5mm)**
- **Ideal position is for Sapien 3 valve to sit 0-3mm below annulus**

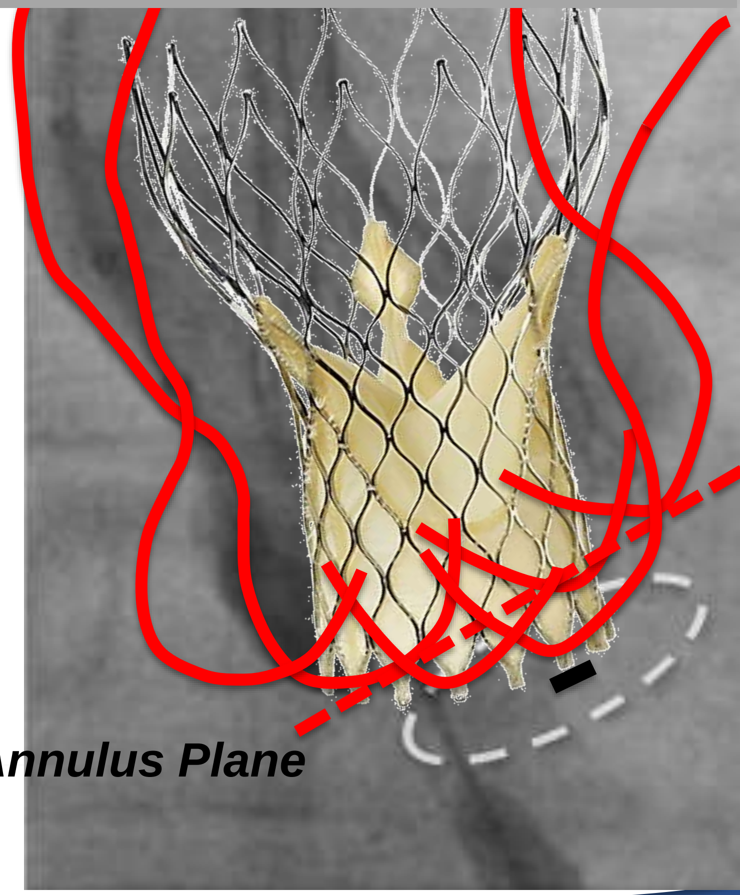
Beware of Parallax

Implantation depth even across annulus



Annulus Plane

What happens if you deploy with parallax?
non-coaxial valve position

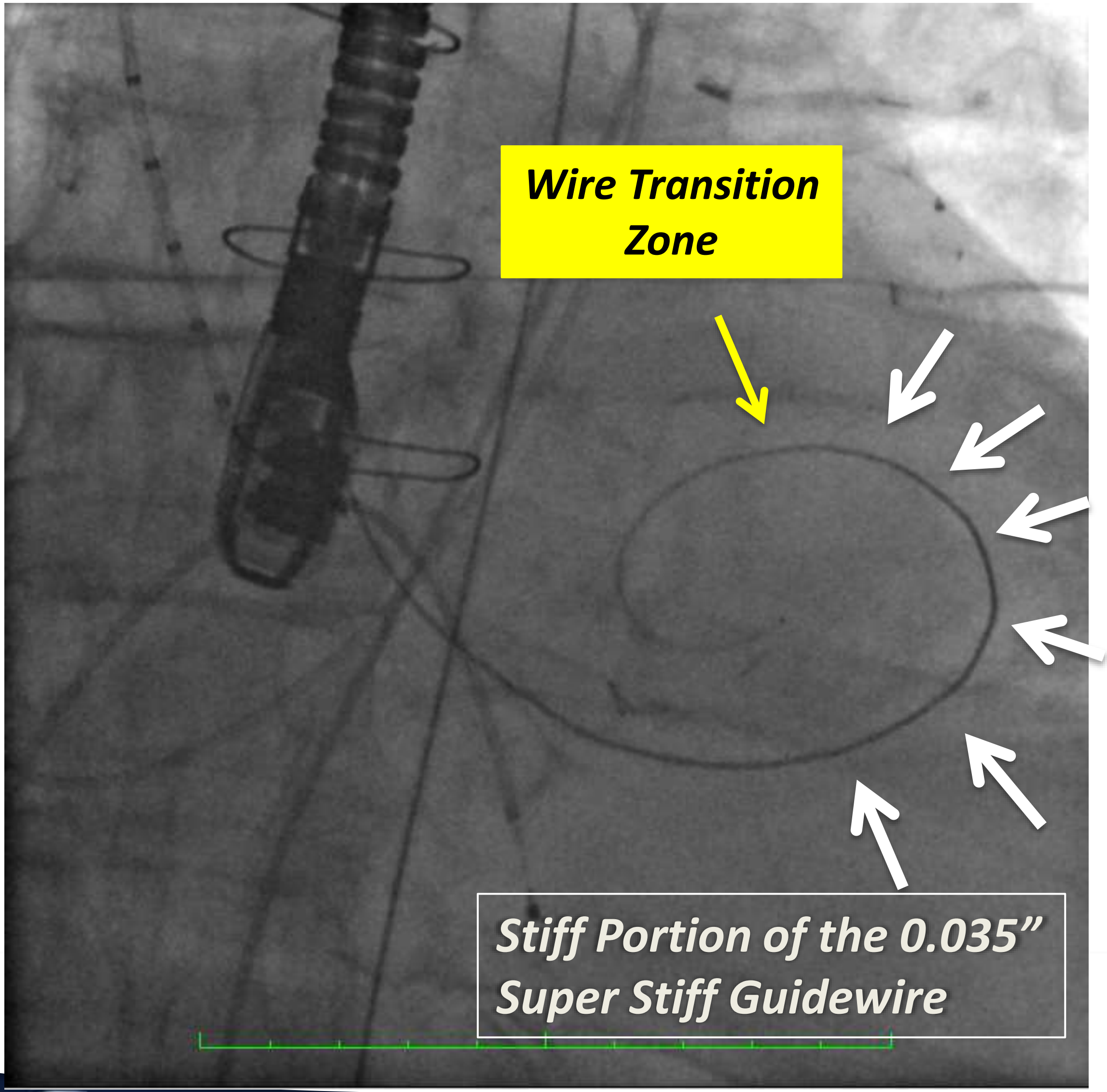


Annulus Plane

Top Ten Tricks for Success

5. Find a coaxial view for proper deployment
4. Proper wire position in LV crucial

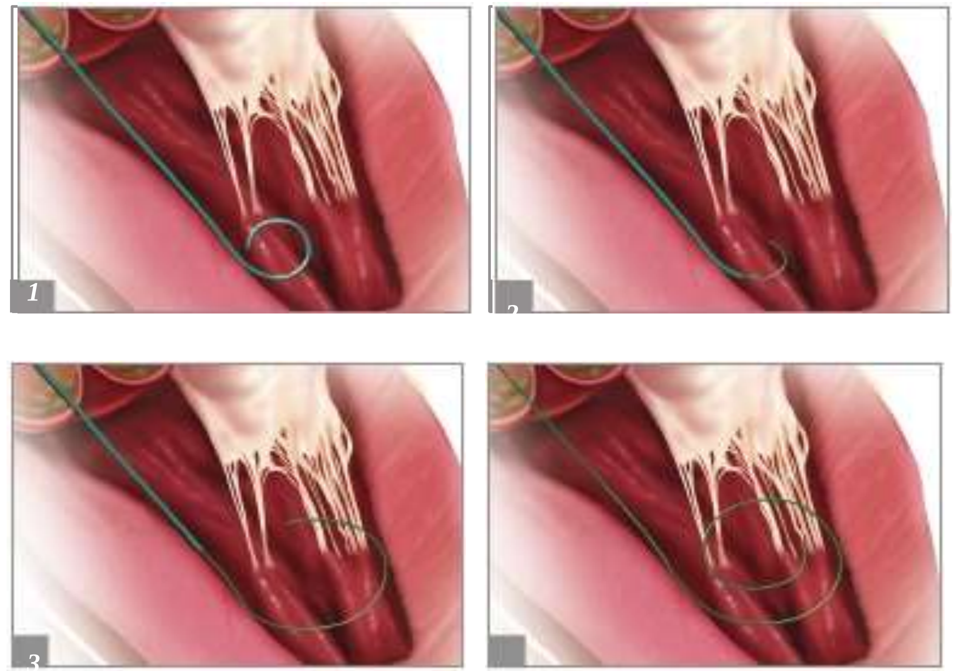
Guidewire Management



- Wire position in the LV apex crucial for successful deployment
- Proper wire position results in device stability and fine adjustments in device position can be made by pushing or pulling on the wire
- A stiff guidewire should be used

The Medtronic Confida™ Guidewire

- **Preshaped wire retains its shape**
- **Increased stiffness may result in difficulty maintaining position in apex in hyperdynamic LV**



Top Ten Tricks for Success

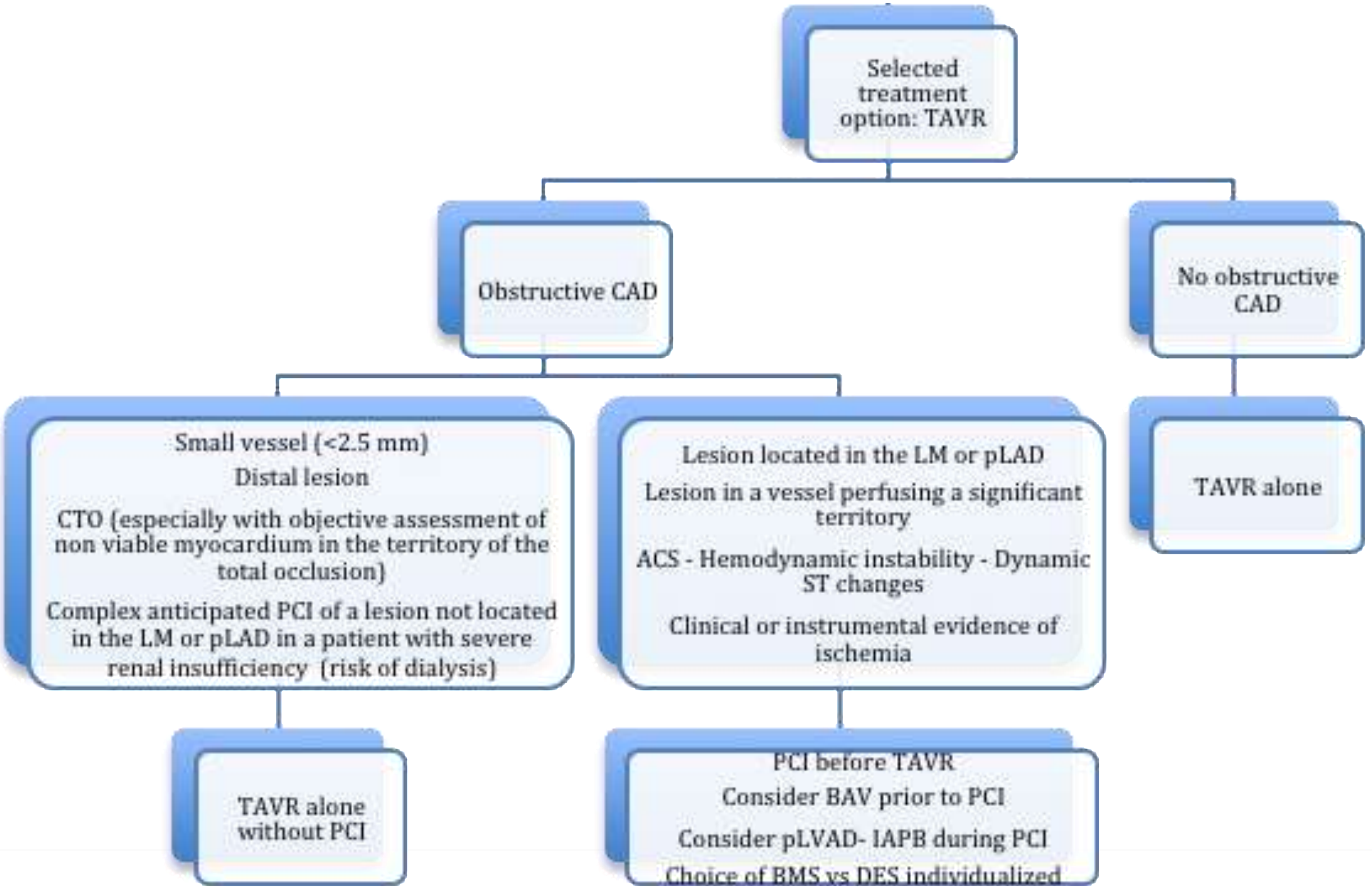
5. Find a coaxial view for proper deployment
4. Proper wire position in LV crucial
3. Treat critical CAD (especially in patients with depressed LV function)

CAD – When to treat?

QUESTIONS – Treat or Not Treat

- Is there an unstable lesion ? ACS ?
- Are the symptoms related to AS or CAD ?
- Is the lesion located in a critical location ? LM – pLAD ?
- What is LV function?
- Will the pt tolerate hypotension (pacing runs) during TAVR ?
- What is the LVEDP- coronary perfusion pressure ?

Treatment Algorithm



Timing of PCI

- Staged PCI in patients with CRI or complex coronary anatomy
- Consider BAV prior to PCI in patients with elevated filling pressures, depressed LV function, etc.
- Same setting PCI is safe and feasible with simple lesions
- PCI post TAVR is feasible but poses challenges
- Randomized trials in the future may provide answers

Top Ten Tricks for Success

5. Find a coaxial view for proper deployment
4. Proper wire position in LV crucial
3. Treat critical CAD (especially in patients with depressed LV function)
2. Intraprocedural TEE crucial in high risk cases (? early experience)

Role of Intraprocedural TEE

Risk Assessment

- **Aortic Annulus**
- **Aortic Valve Morphology/Ca**
- **Aortic Root and LVOT**
  - **Aortic root morphology**
  - **Ectopic calcification**
  - **Sigmoid septum**
- **Wire position**
  - **Mitral Valve apparatus**
  - **Left Ventricular size and function**
- **Balloon Aortic Valvuloplasty**
- **Positioning and deployment of THV**
  - **Aortic valve, root and LVOT morphology**

Hemodynamic Emergencies

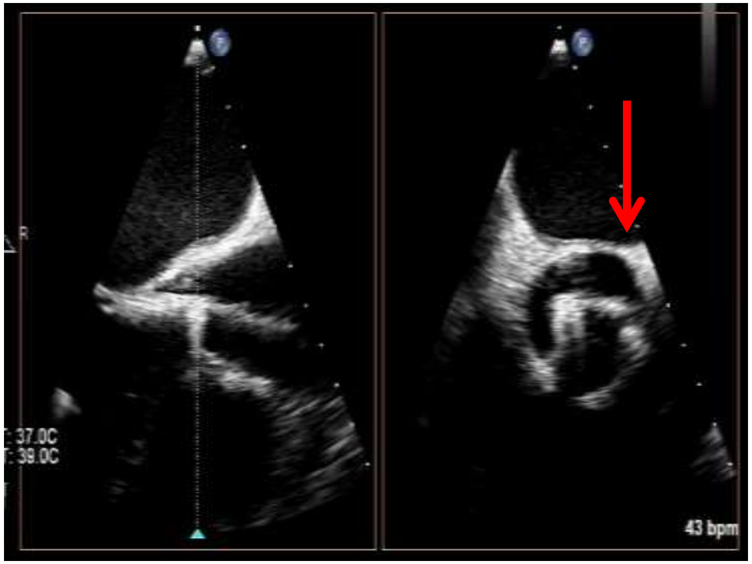
- Aortic/AV trauma
  - Periaortic hematoma
  - Aortic dissection
  - Annular rupture
- Pericardial tamponade
- Mitral valve compromise
- Left main coronary occlusion
- Severe aortic regurgitation
  - Central regurgitation
  - Paravalvular regurgitation

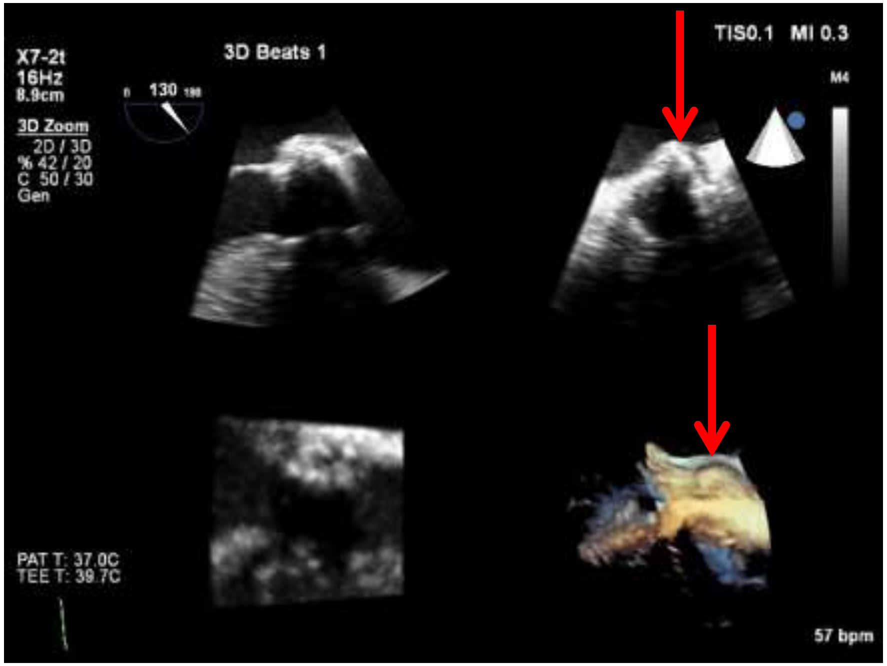
TEE can help identify cause of hypotension quickly

Use of TEE to Prevent Root Injury

Bicuspid Aortic Valve

Threatened Aorta





CAVEAT: Controlled Deployment: Slow stretch of native tissue and deployment stopped prior to injury

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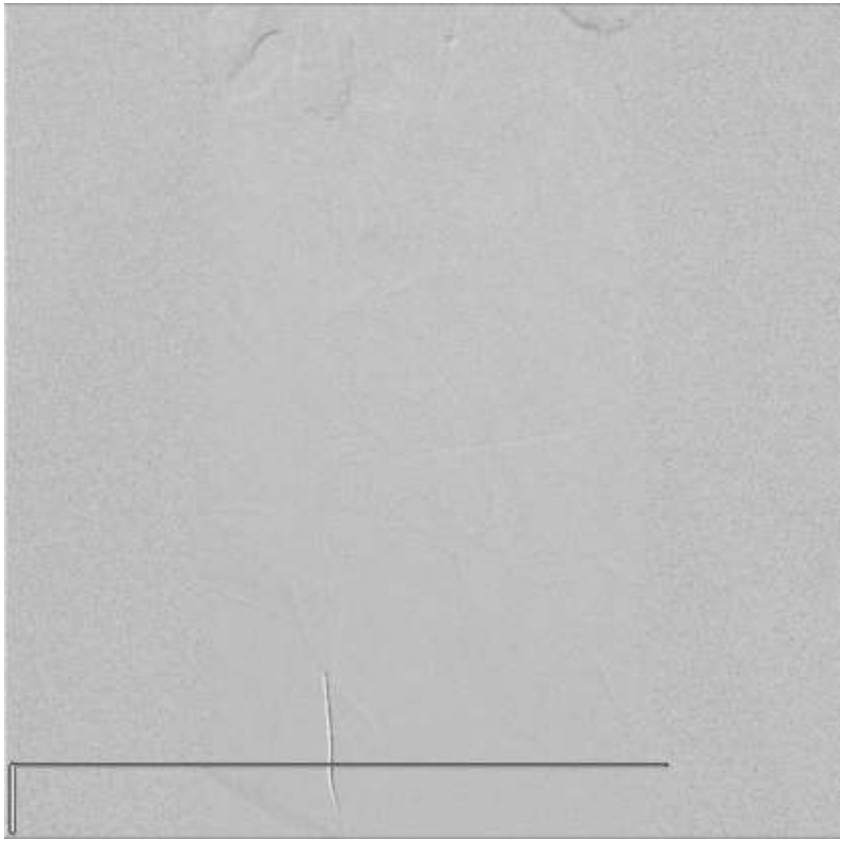
1. Careful vascular access management after closure

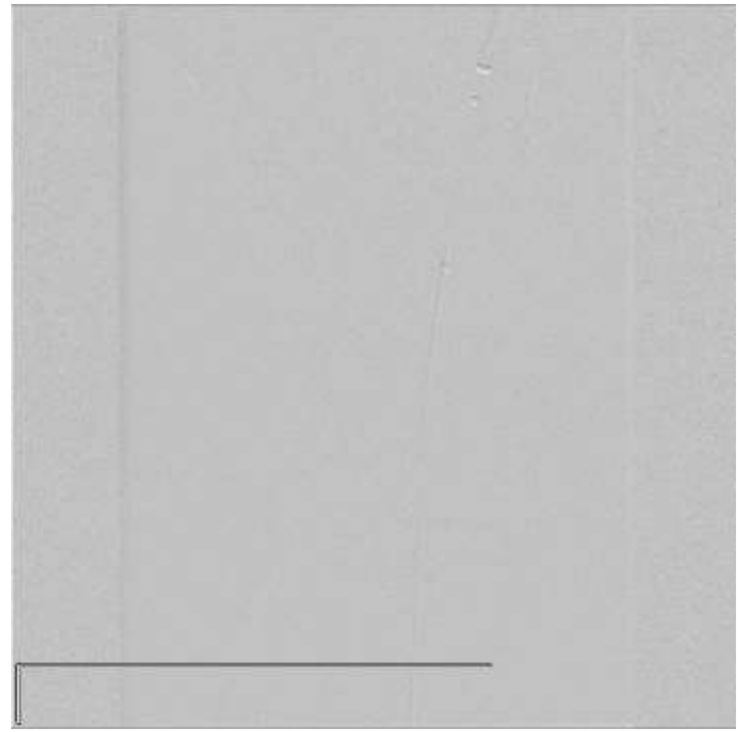
Completion Angiogram

- **Completion angiogram should be performed everytime**
  - **Early identification of complications**
  - **Minor bleeding and stenosis can be controlled with balloon inflation and reversal of anticoagulation**
- **After procedure complete, hold gentle pressure for 10-15 minutes**
- **Monitor for 24 hours for vascular complications**
  - **Low threshold for ultrasound imaging**



Completion Angiogram Can Prevent Major Complication

Occlusive dissection



- Balloon advanced across arteriotomy and inflated at <1 atm for 2 minutes
- If flow still compromised, consider self-expanding stent

Top Ten Tricks for Success

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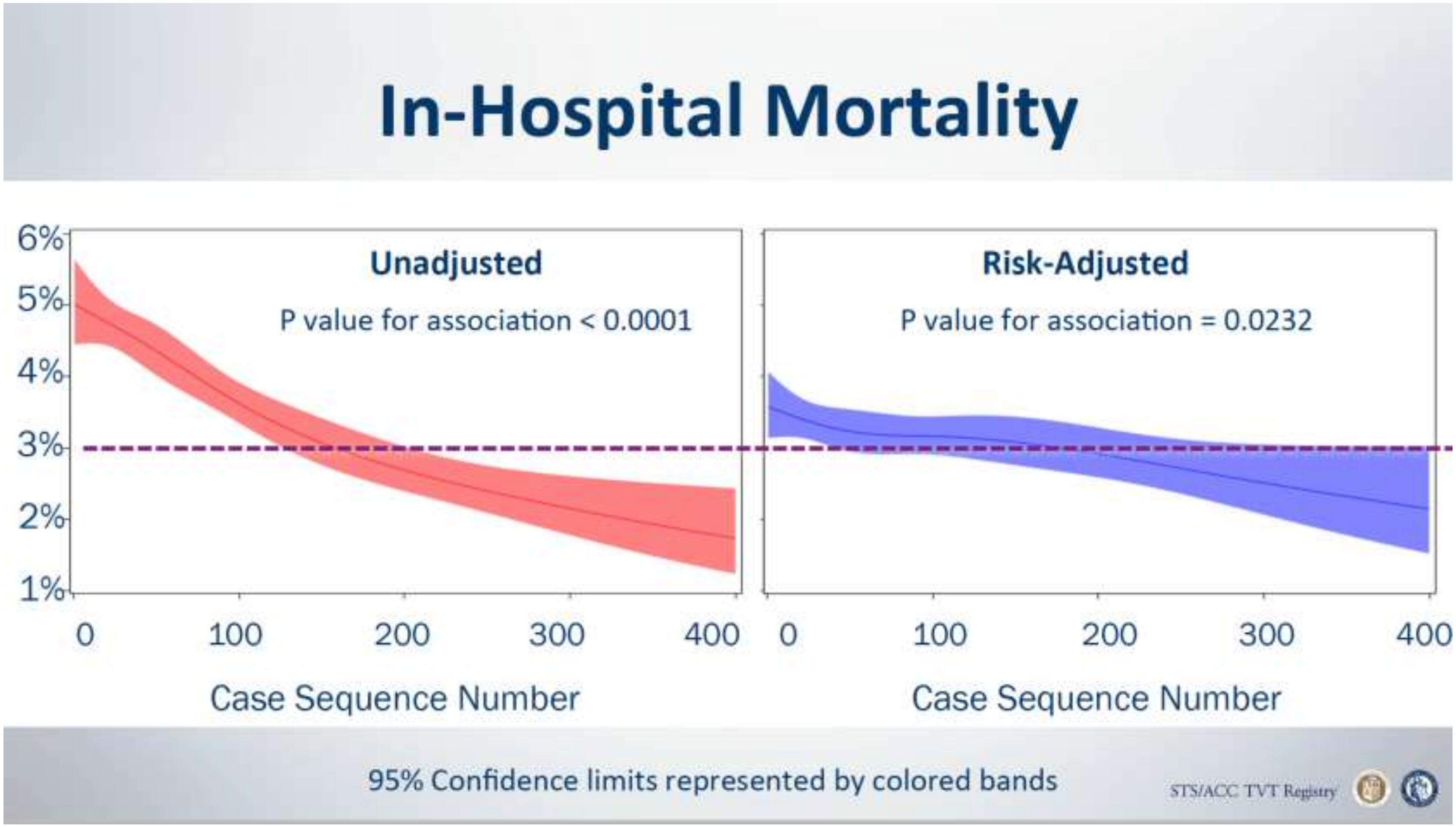
Final Thought – Experience Improves Outcomes

Experience improves outcomes



Thank you!