Predictors & Prevention of Vascular Complications

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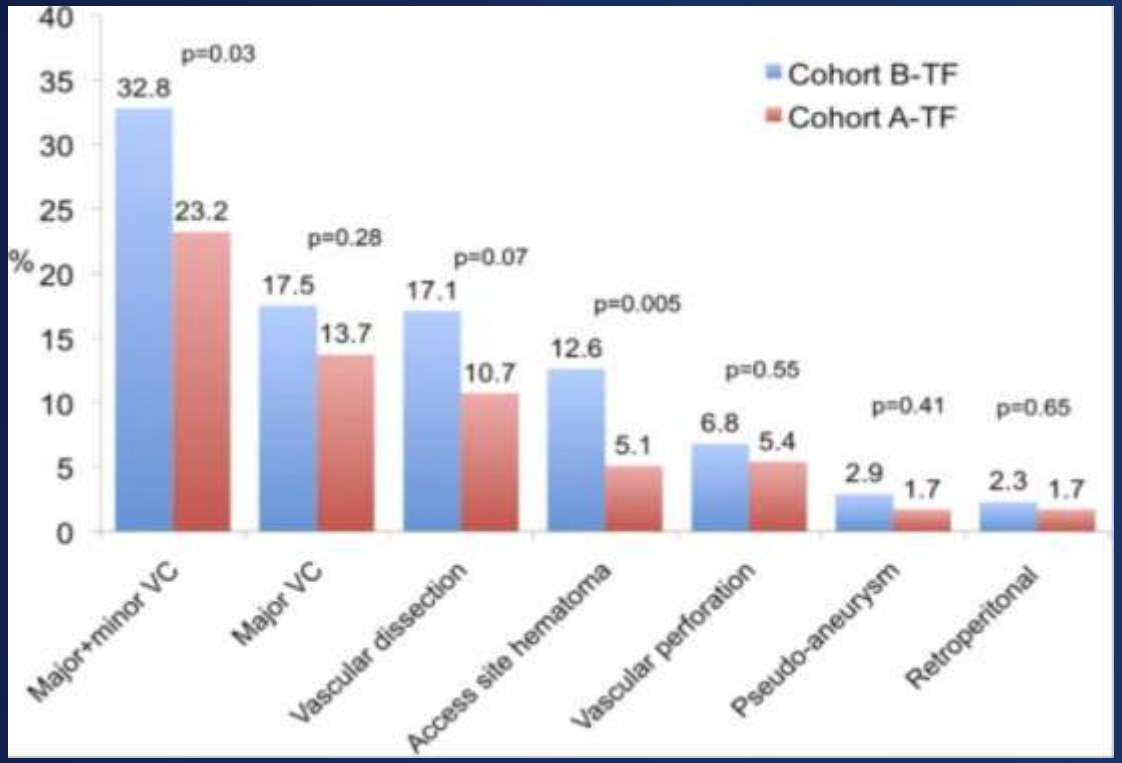
☑ I do not have any potential conflict of interest

Vascular Complications After Transcatheter Aortic Valve Replacement: Insights From the PARTNER (Placement of AoRTic TraNscathetER Valve) Trial



Difference in Rates of VC From Cohort 1B to Cohort 1A

The rates of all vascular complications (VC), vascular dissection, and access site hematoma d ecreased from cohort 1B to cohort 1A, suggesting improved outcomes in a lower-risk populati on and with more experienced operators. TF = transfemoral.

J Am Coll Cardiol. 2012;60(12):1043-1052. doi:10.1016/j.jacc.2012.07.003

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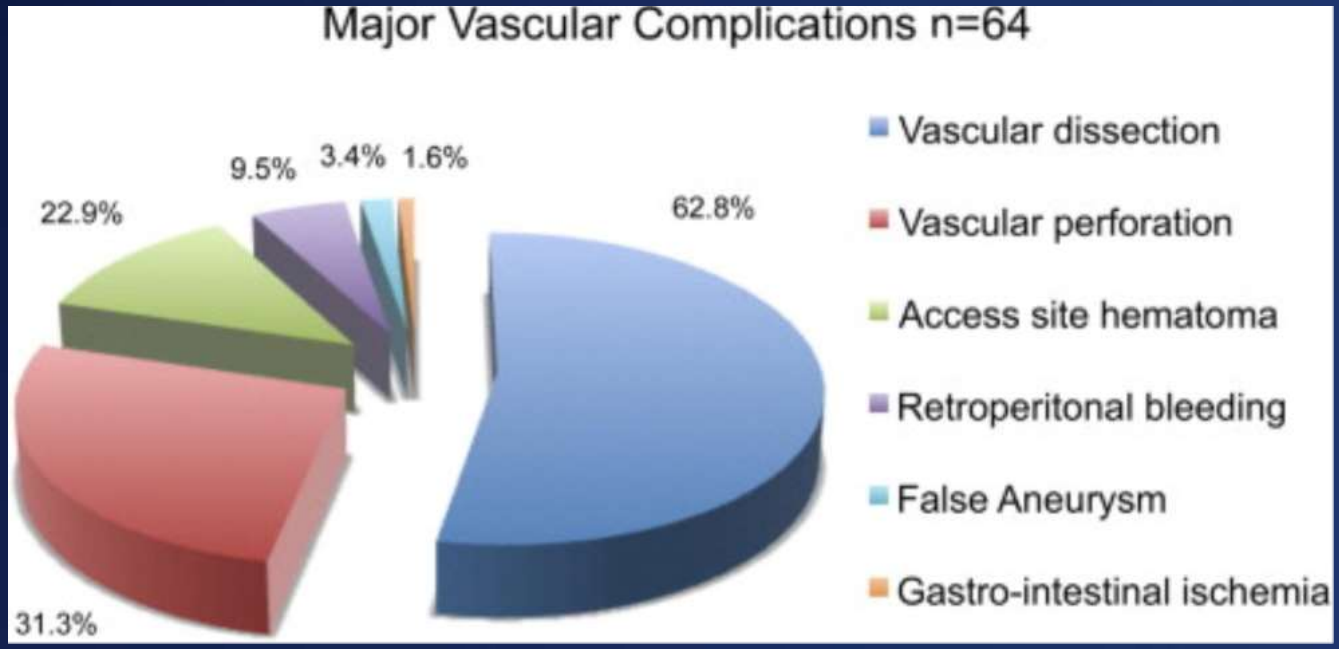

Distribution of Type of Major Vascular Complications After TAVR

Vascular dissection, vessel perforation, and access site hematoma were the most frequent causes of major vascular complications.

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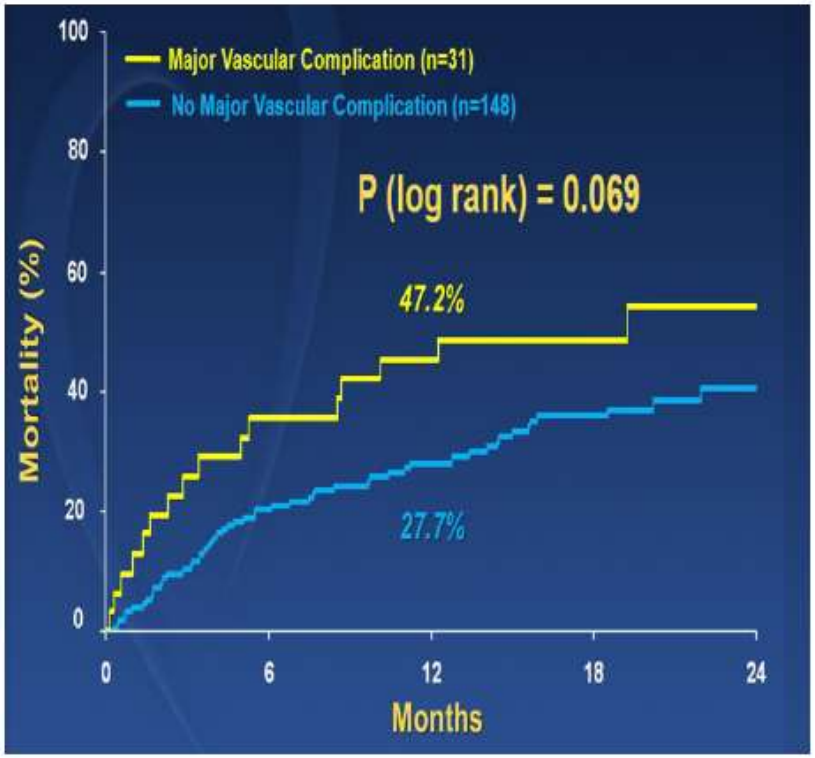
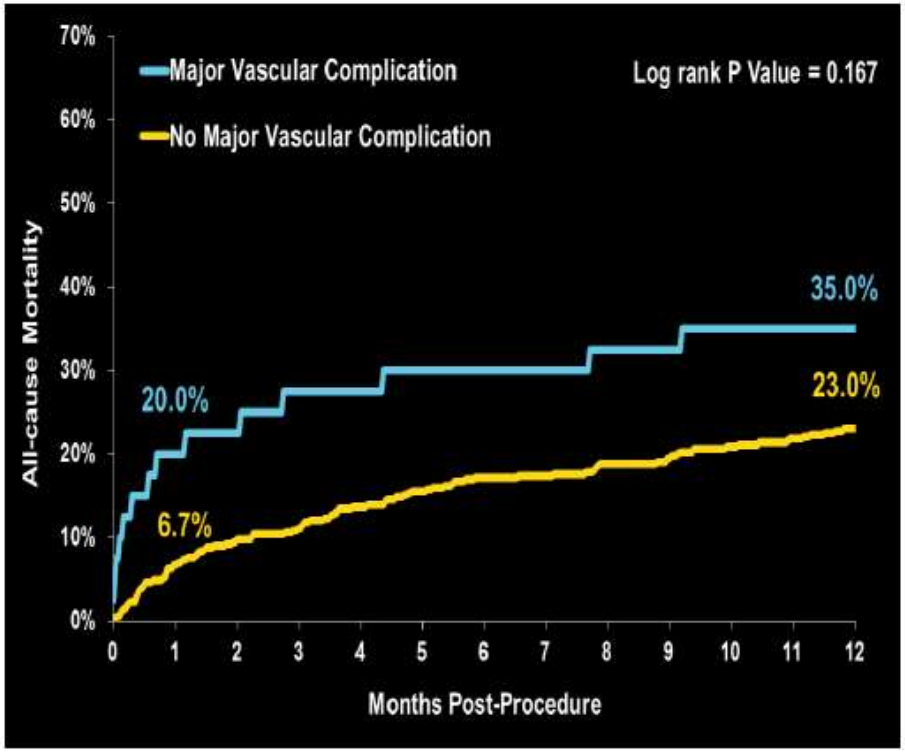
Major Vascular Complications Increase Mortality

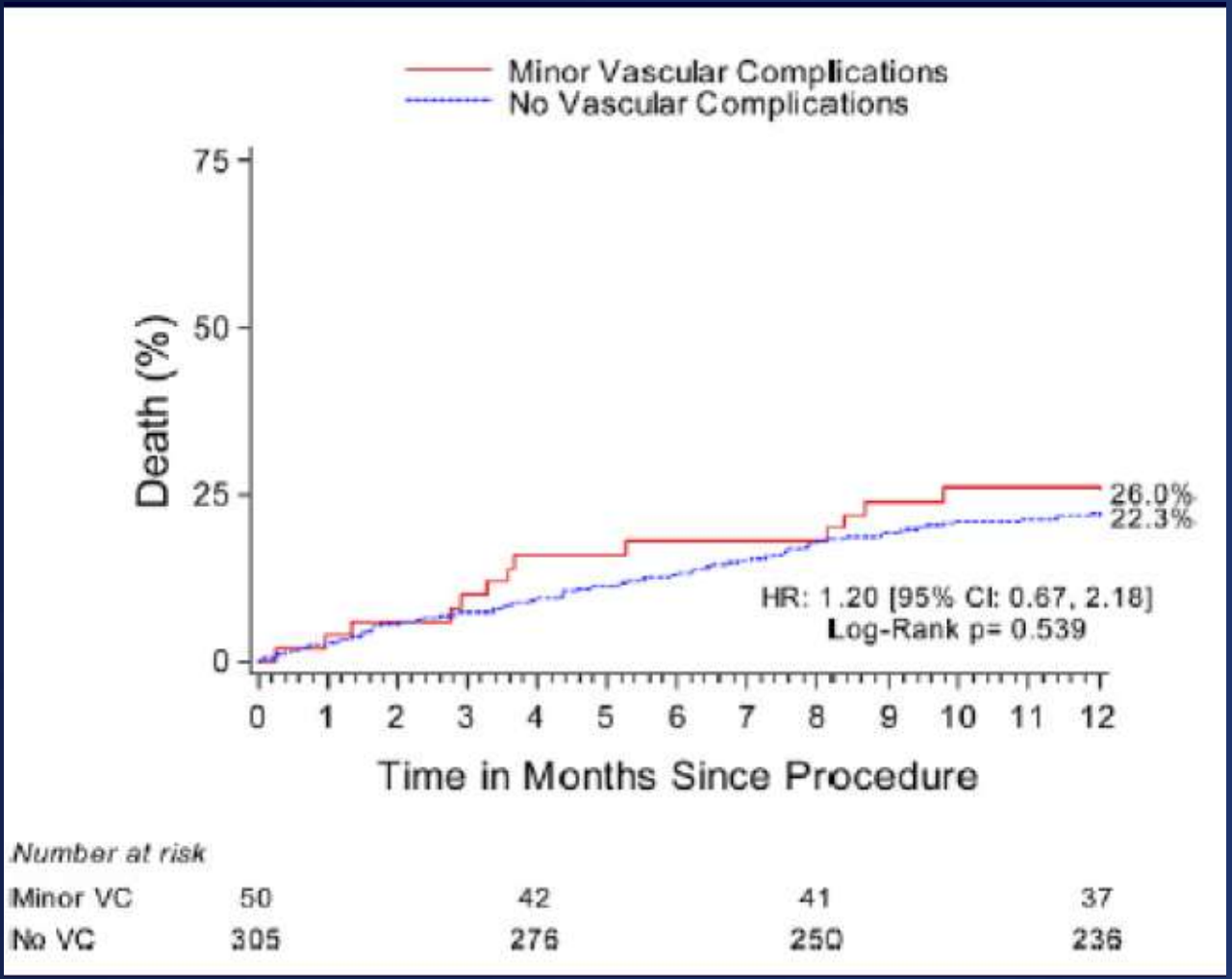
Partner 1 Trial



CoreValve Extreme Risk Trial

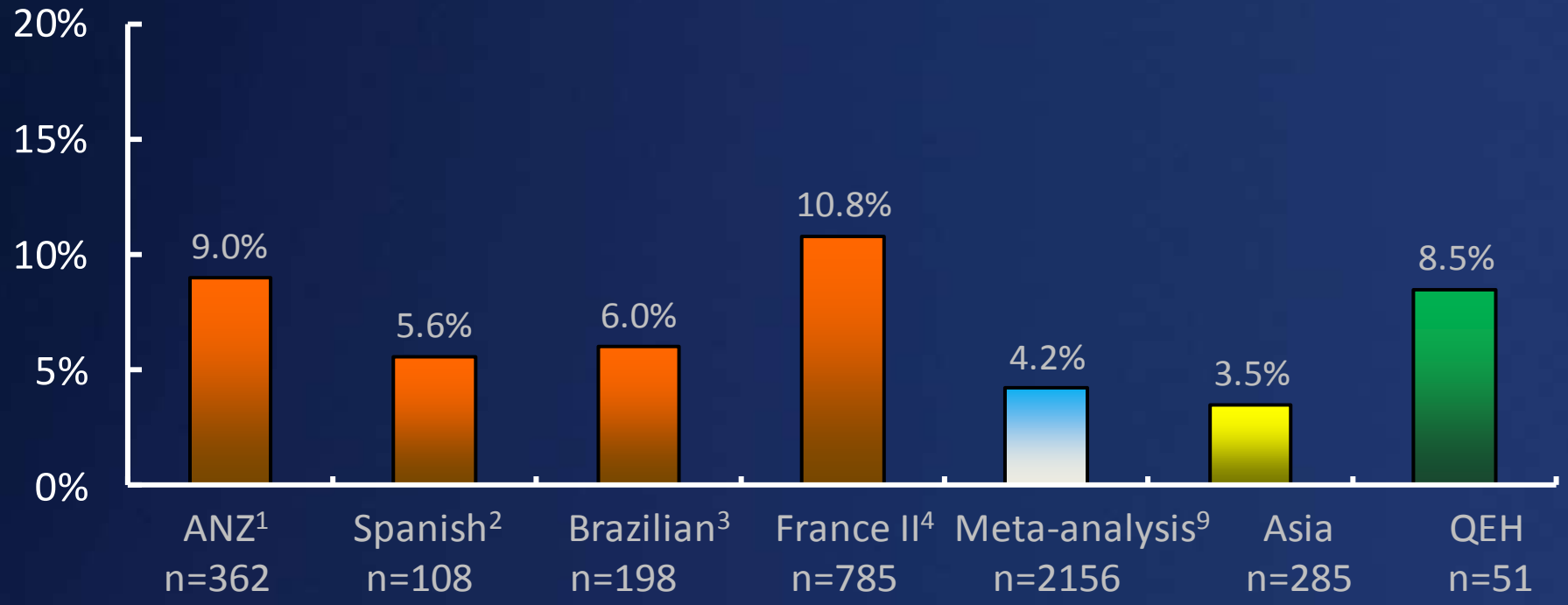


Minor vascular complications DO NOT increase mortality after TAVI



Genereux P et al. JACC 2012

Vascular Complications



1. Meredith I.T. 12 Month Results from ANZ CoreValve TAV Study. Presented at: TCT 2011. 2. Avanzas P, et al. *Rev Esp Cardiol*. 2010;63: 141-148. 3. Brito F.S. Brazilian Registry. Presented at TCT 2011. 4. Cribier A. FRANCE II Multicenter TAVR Registry. Presented at: TCT 2 011. 5. Ruiz C.E. Weighted meta-analysis of CoreValve® Outcomes. Presented at: EuroPCR 2011 (analysis sponsored by Medtronic, Inc.).

The Asian TAVR Registry
Clinical Outcomes

	Overall (N = 940)	SAPIEN (N = 615)	CoreValve (N = 325)	p value
Stroke				
All	3.0%	2.8%	3.4%	0.69
Disabling	1.2%	1.0%	1.5%	0.75
Non disabling	1.8%	1.8%	1.8%	
Vascular complications				
Major	5.2%	6.0%	3.7%	0.08
Minor	4.6%	5.4%	3.1%	
Acute kidney injury				
Stage 1	5.6%	6.0%	4.9%	0.36
Stage 2	2.4%	2.3%	2.8%	
Stage 3	1.8%	1.3%	2.8%	

Asian Anatomies

Small Iliofemoral Access

Small Aortic Root, Low Coronary Ostia

Small Surgical Bioprosthesis

Tortuous Iliofemoral

Bicuspid AV

Iliofemoral anatomy among Asians: Implications for transcatheter aortic valve implantation ☆

Paul T.L. Chiam [a,*,1], Angela S. Koh [a,1], See Hooi Ewe [a], Yoong Kong Sin [b], Victor T.T. Chao [b], Choo Khong Ng [b], Chung Yin Lee [a], Yeong Phang Lim [b], Jang Wen Su [b], See Lim Lim [b], Teing Ee Tan [b], Chong Hee Lim [b], Swee Yaw Tan [a], Soo Teik Lim [a], Terrance S.J. Chua [a], Tian Hai Koh [a], Yeow Leng Chua [b]

[a] *Department of Cardiology, National Heart Centre Singapore, Singapore*
[b] *Department of Cardiothoracic Surgery, National Heart Centre Singapore, Singapore*

- Reviewed characteristics and vessel dimensions of 549 patients undergoing ultrasound
- Mean iliac artery MLD 7.6 ± 1.7mm
  - Females 7.2mm vs. Males 7.8mm ($p < 0.001$)
- Mean common femoral artery MLD 7.0 ± 1.7mm
  - Females 6.3mm vs. Males 7.3mm ($p < 0.001$)
- Predictors of iliac diameters: female gender and body surface area
- Predictors of femoral diameters: female gender, diabetes, dyslipidemia and smoking history
- Predictors of iliac tortuosity: male gender and an elevated EuroSCORE

Smaller anatomies in Asian population
Greater risk of vascular complications

Sheath/Fem Artery Ratio Predicts Complications

Hayashida K et al. JACC Intv 2011;4:851-858

1. **Sheath to Femoral Artery Ratio (SFAR)**
   HR=1.86 (p=0.006)
2. **Early center experience**
   HR=3.66 (p=0.023)
3. **Femoral artery calcium score**
   HR=3.44 (p=0.026)

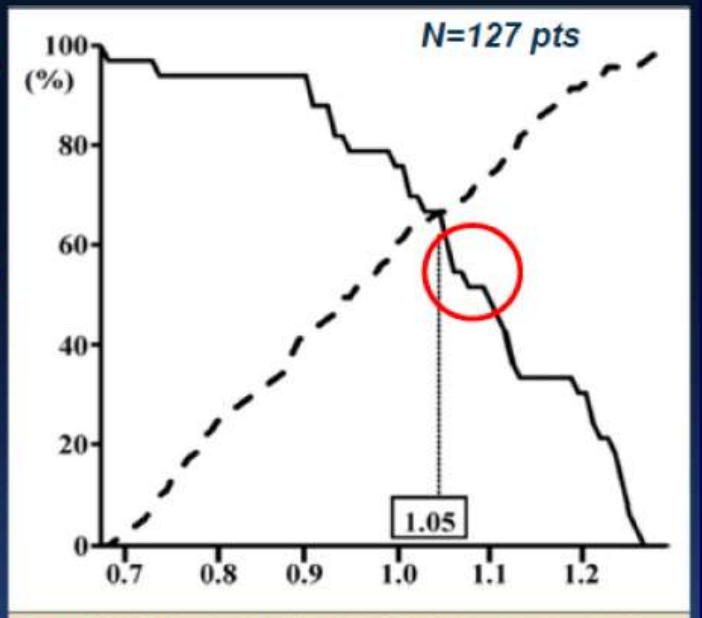


Figure 2. SFAR Threshold Predicts VARC Major Vascular Complications

The sensitivity and specificity curve identified the threshold SFAR of 1.05 as predictive of VARC major vascular complications

Sheath/FA ratio >1.05

VARC major complications: 30.9% vs. 6.9%, p=0.01

30-day mortality: 18.2% vs. 4.2%, p=0.016

Predictors of Vascular Complications

First Author (Year)	N	Predictors
Lange et al. (2011)	412	Center experience, planned surgical cutdown ↓ vascular complications
Hayashida et al. (2011)	130	Sheath-to-femoral artery ratio, femoral calcification, center experience
Toggweiler et al. (2012)	137	Sheath diameter > minimal artery diameter, mod/severe femoral calcification, learning curve
Genereux et al. (2012)	419	Female sex
Mwipatayi et al. (2013)	100	Logistic EuroSCORE, DM

*Procedural Complications**

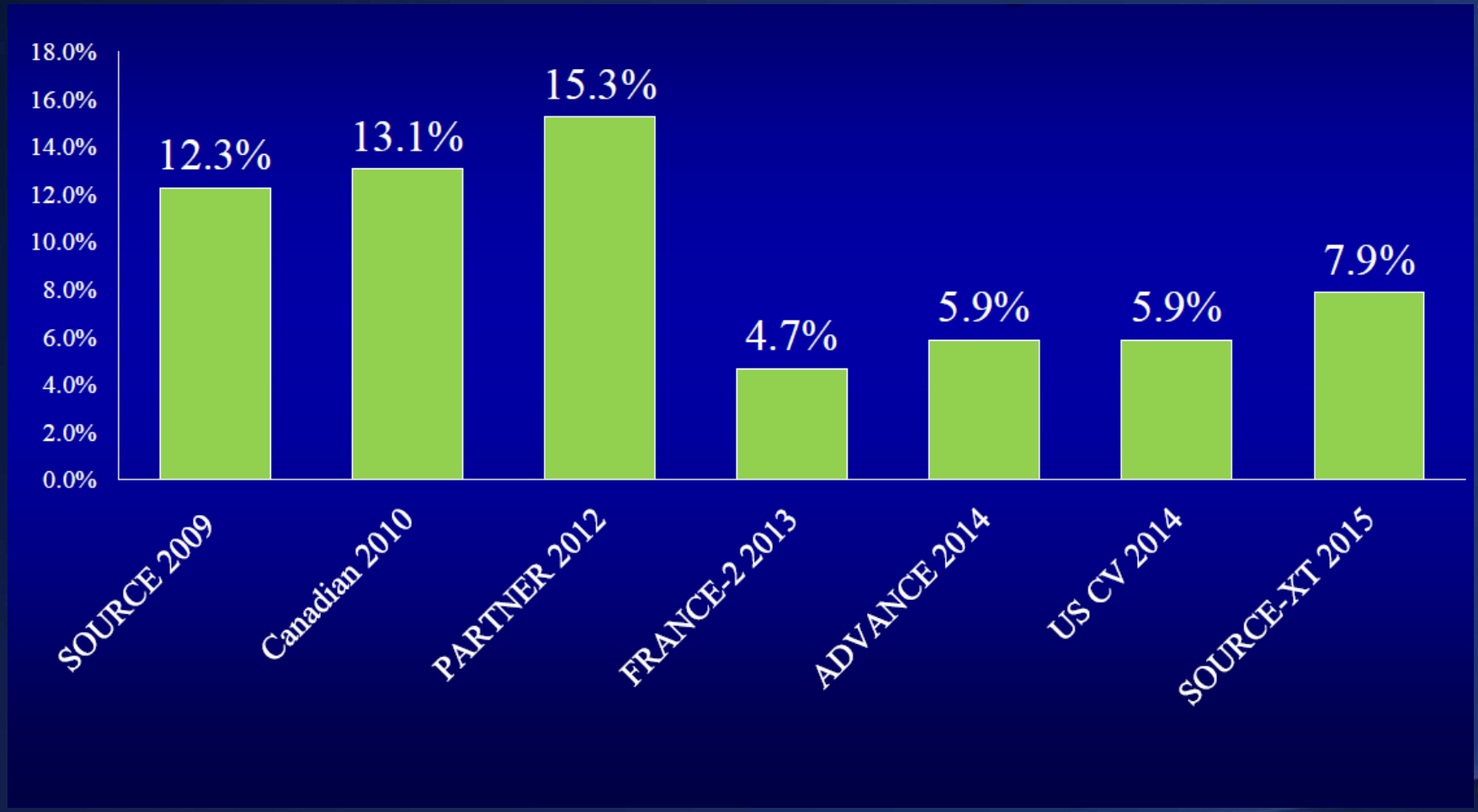
	21F S&E Study (N = 52)	18F S&E Study (N = 124)	18F EE Registry
≤ 24-Hour Mortality	0.0%	3.2%	1.5%
Aortic dissection	9.6%	0.8%	0.4%
Major bleeding	13.5%	8.0%	2.3%
Cardiac tamponade	5.8%)	6.5%	2.3%
Conversion to surgery	5.8%	2.4%	0.6%
Access site complication	9.6%	4.8%	1.7%

Site reported data only in the case of registry & not monitored

***Multiple events in same patients = data not cumulative**

Major vascular complications following TAVI

Randomized trials and registries



TAVI Access Evaluation

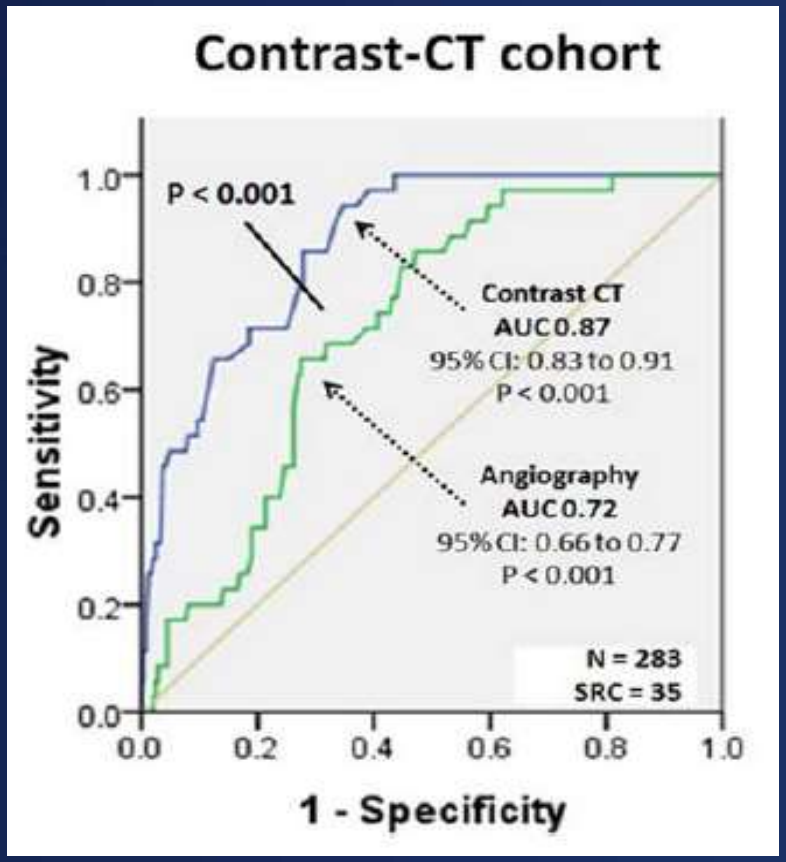
Diagnostic Modalities:

- Invasive Angiography → MDCT (The Gold Standard)
- Allows spatial resolution in 3 dimensions
- Overcomes limitations of conventional angiography and digital subtraction angiography

Detailed assessment:

- Iliofemoral diameters
- Calcifications: extent and location
- Vessel Tortuosity
- High-risk features (including dissection & atheroma)
- Alternative Access

Transfemoral Access Assessment - MDCT is better than Angiography



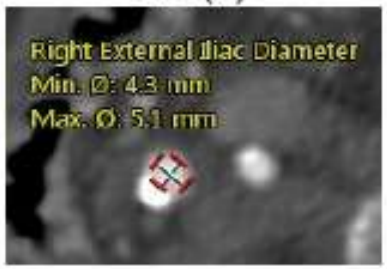
Comparison of predictive value for sheath-related complication

Okuyama K et al. Circ Cardiovasc Imaging 2015; ;8:e001995.

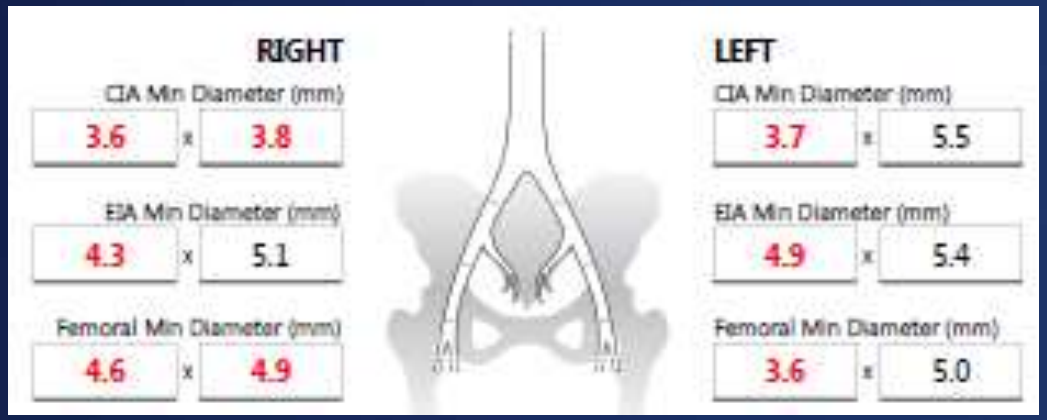
Iliofemoral diameters and calcifications

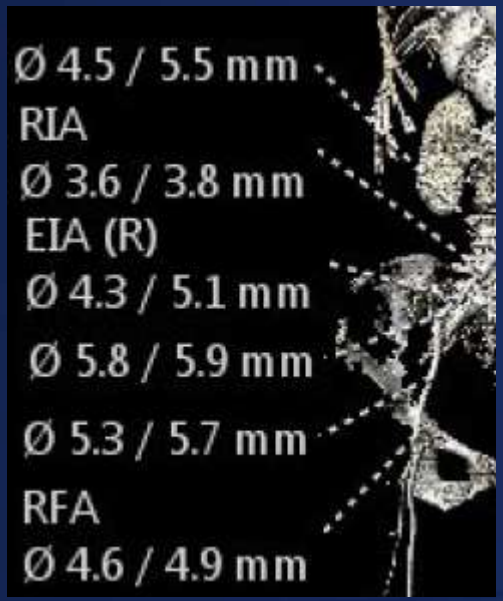
RIA

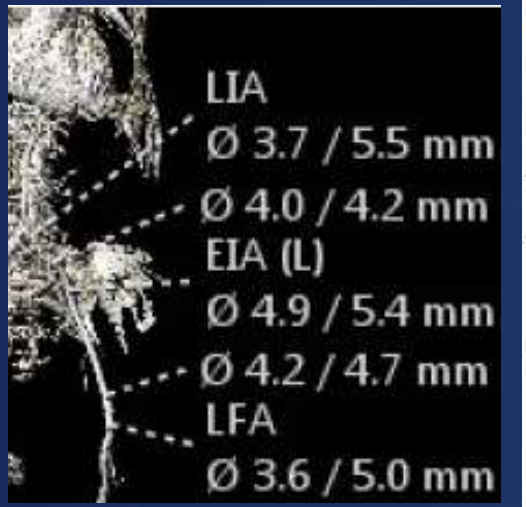
EIA (R)



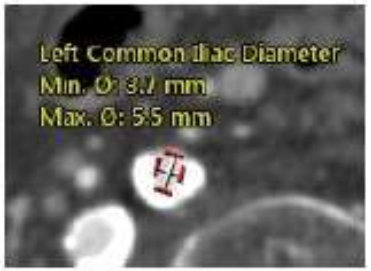
RFA



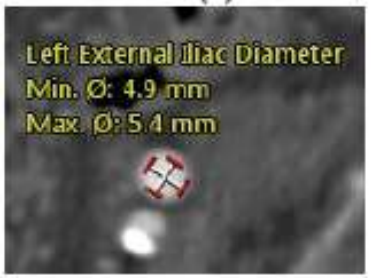




LIA



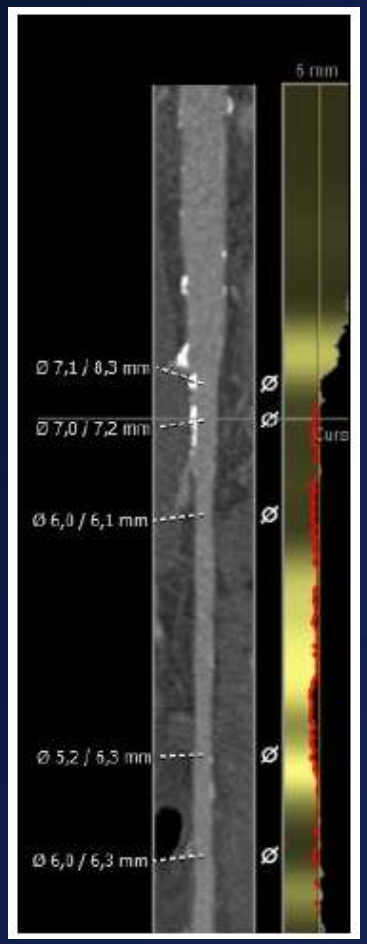
EIA (L)

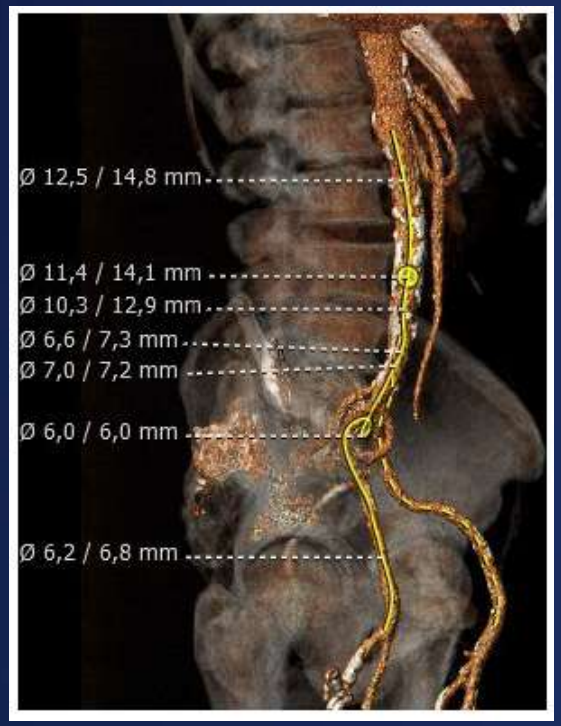


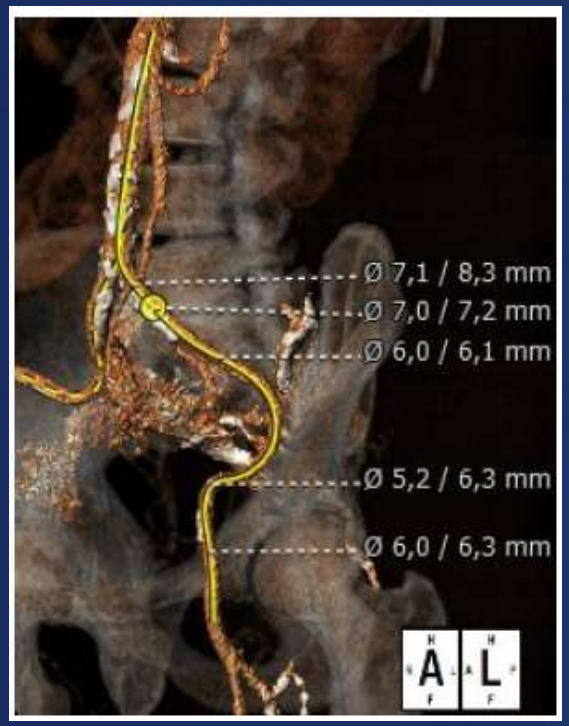
LFA

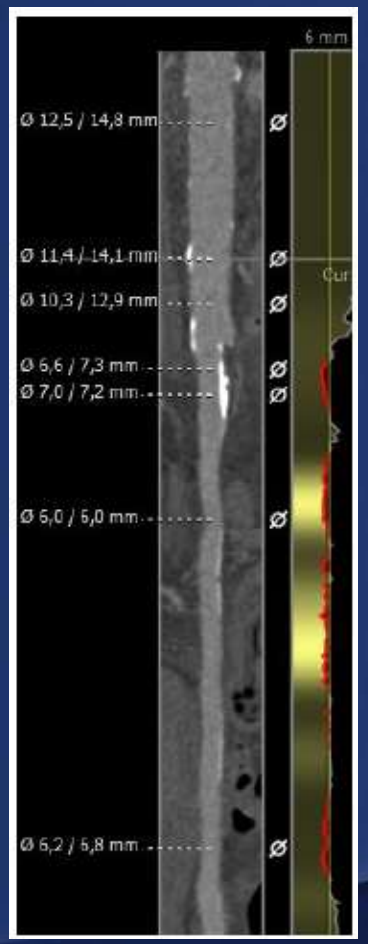
Tortuosity

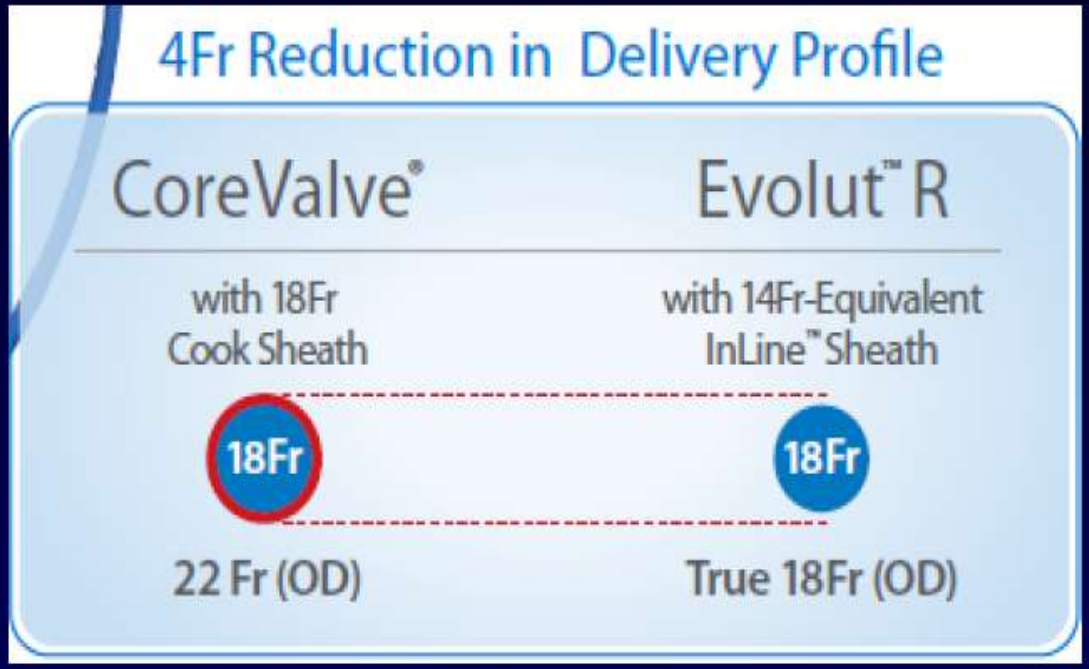
increase risk when tortuosity and calcification co-exist





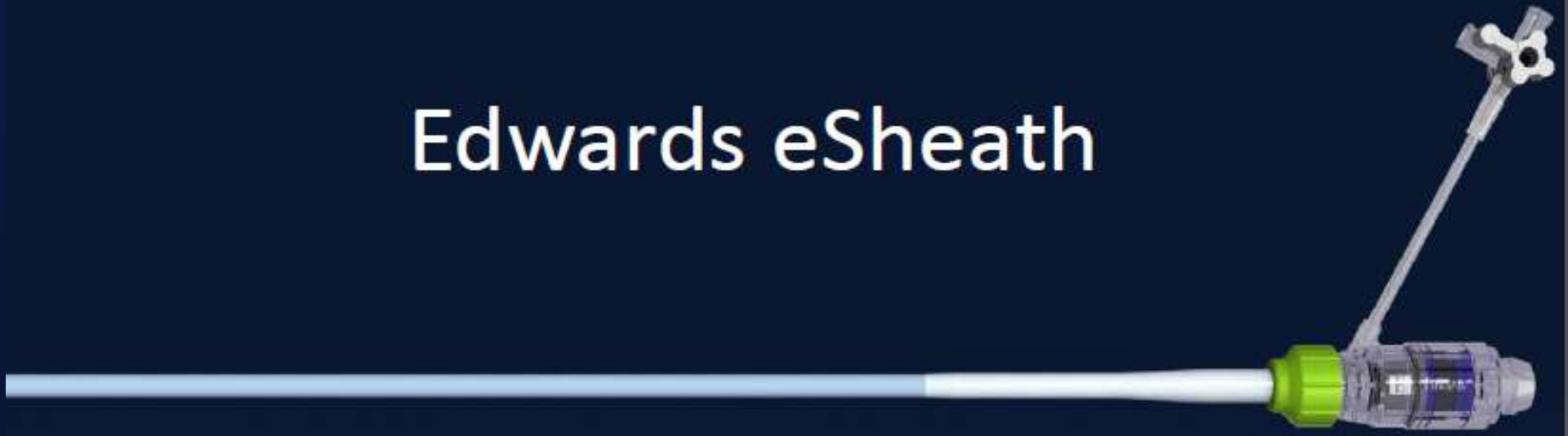






CoreValve® and CoreValve Evolut R	23mm (18-20mm)	26mm (20-23mm)	29mm (23-27mm)	31mm (26-29mm)
With InLine™ Sheath	18 Fr OD 14Fr Equivalent	18 Fr OD 14Fr Equivalent	18 Fr OD 14Fr Equivalent	18 Fr OD 14Fr Equivalent

Edwards eSheath



		14F	16F	18F	20F
Valve		SAPIEN 3 26 mm	SAPIEN XT 23 mm	SAPIEN XT 26 mm	SAPIEN XT 29 mm
Sheath ID	Unexpanded	4.7 mm	5.3 mm	6.0 mm	6.7 mm
Sheath OD	Unexpanded	6.0 mm	6.7 mm	7.2 mm	8.0 mm
	Expanded w/valve	8.0 mm	8.9 mm	8.9 mm	9.9 mm
Rec Minimum Diameter		5.5 mm	6.0 mm	6.5 mm	7.0 mm
SFAR	Unexpanded	1.0	1.12	1.11	1.14
	Expanded w/ valve	1.45	1.48	1.37	1.41

Binder, R et al. JACC CV Int 2013

Increasing TF Options for the Future

Vessel Diameter in mm	5.0	6.00	6.25	6.50	6.75	7.00	7.25	7.50	7.75	8.00
18 Fr Sheath	1.5	1.2	1.2	1.1	1.1	1.0	1	1.0	0.9	0.9
14 Fr Sheath	1.2	1	1.0	0.9	0.9	0.9	0.8	0.8	0.8	0.8
13 Fr Sheath	1.1	0.9	0.9	0.9	0.8	0.8	0.8	0.7	0.7	0.7

SFAR <= 1.05 1.05<SFAR<=1.2 SFAR>1.2

Babaliaros, V. TVT 2013

Tips and tricks to enhance successful TF-TAVI

- MDCT - Extra caution when dealing with Asian anatomies
- Balloon pre-dilatation if there is PVD:
  - Adequate size balloon
  - Oversize endovascular conduit for very severely calcified iliac arteries (Taiwan Experience)
- Amplatz extrastiff/Lunderquest GW for tortuous iliacs
- Solopath sheath (13F → 19F)
- Low profile TAVI device
- For high risk of perforation:
  - Cross-over balloon
  - Safety wire
- Always take final peripheral angiogram to ensure no perforation/dissection

To Conclude:

- Specific Asian anatomies
  - Smaller aortic root
  - Smaller iliofemoral arteries
  - More tortuous iliofemoral arteries
  - Bicuspid AV
- Transfemoral TAVI procedures
  - MDCT assessment – diameters, calcification, tortuosity
  - Center experience
  - Low profile devices
  - Alternative access
  - Readily available equipment
  - Try not to push the limits….ready for more complications (dissections, perforations)

Thank You For Your Attention!