Top 7 Reasons pre-procedural MDCT is essential for TAVR

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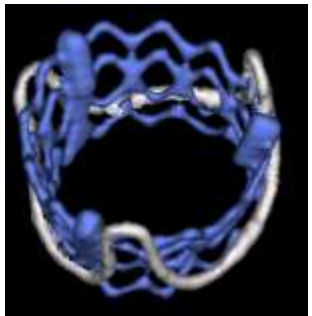


PROVIDENCE
HEART + LUNG INSTITUTE
AT ST. PAUL'S HOSPITAL
New solutions for health

Disclosures

Speaker's bureau: GE Healthcare and Edwards LifeSciences

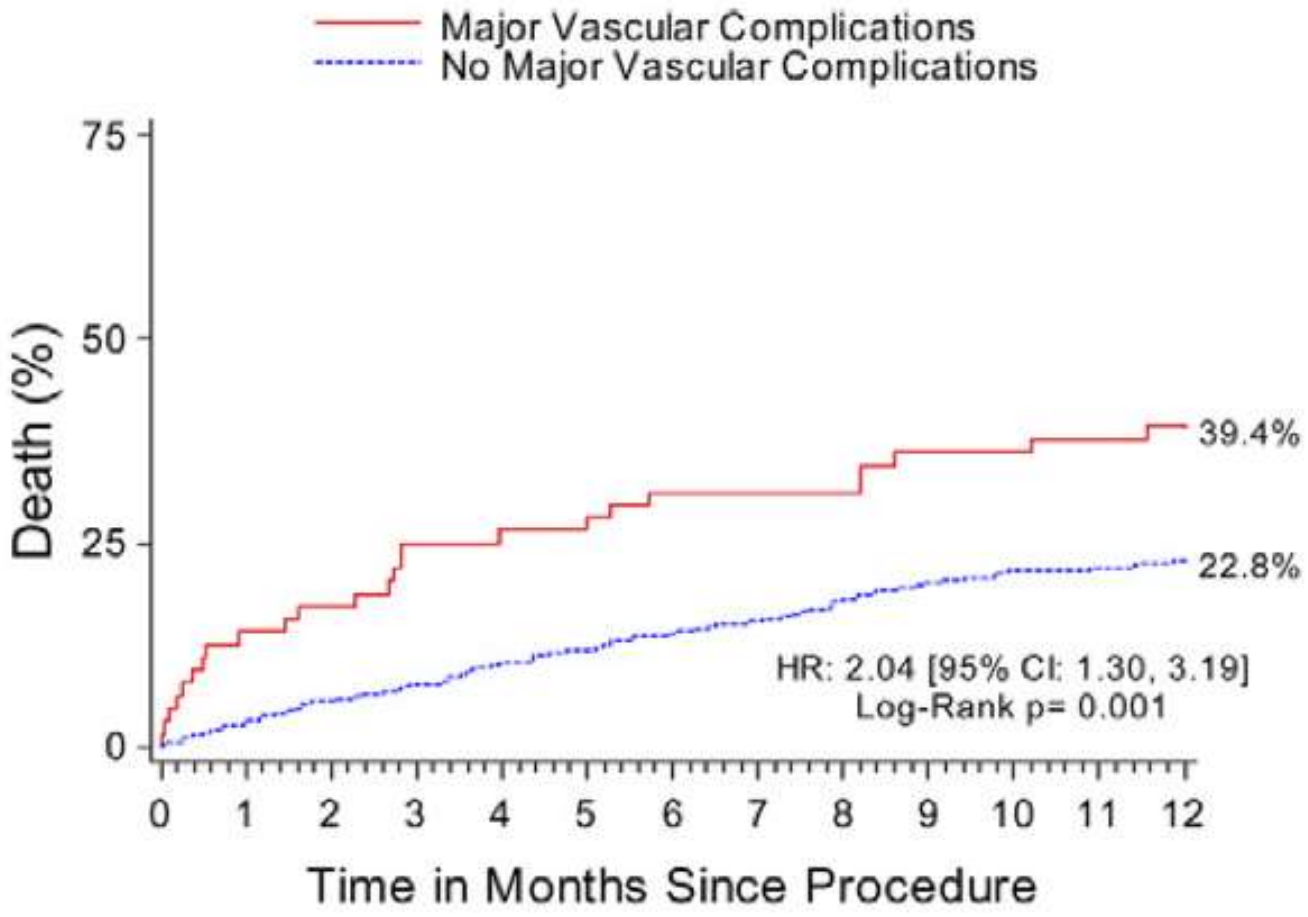
Grant Support- CIHR, NIH, GE Healthcare, Heartflow

Advisory Board- GE Healthcare,
Edwards LifeSciences, Vital Images, Neovasc, Circle CVI

Core Lab- NIH, Edwards Lifesciences, Neovasc, Tendyne

1- Vascular Injury

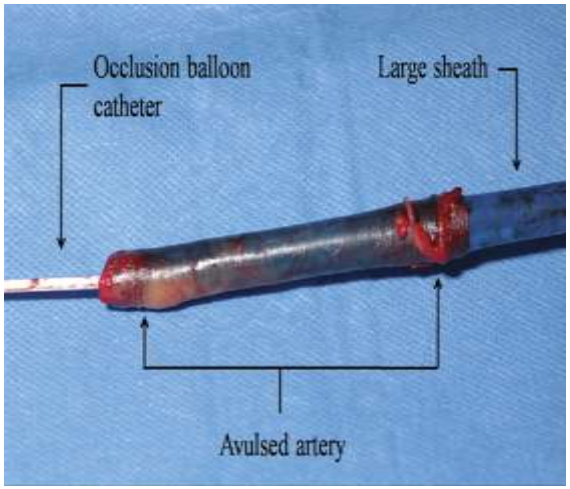
Major Vascular Complications and Mortality



Genereux, J Am Coll Card 2012; 60(12): 1043-52.

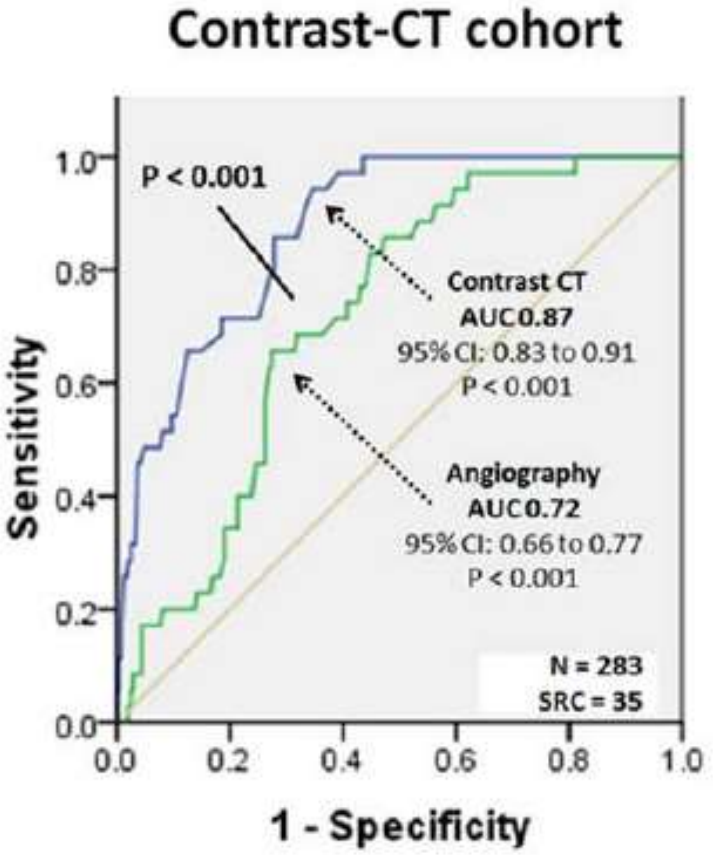
Aortoiliofemoral Complications

	SFAR		
Variables	**≥1.05 (n=55)**	**<1.05 (n=72)**	**P Value**
Any vascular complication	41.8%	16.7%	**<0.001**
VARC Major	30.9%	6.9%	**0.001**
VARC Minor	10.9%	9.7%	0.827
Femoral artery complication	27.3%	12.5%	**0.035**
Iliac artery complication	20.0%	2.8%	**0.002**
In-hospital mortality	20.0%	6.9%	**0.033**
30-daymortality	18.2%	4.2%	**0.016**



Hayashida et al. JACC Interventions 2011

Contemporary Re-appraisal of SFAR



	Contrast CT (P<0.001)		
	SRC	No SRC	Total
SIFAR≥1.12	33 (27.7%)	86 (72.3%)	119
SIFAR<1.12	2 (1.2%)	162 (98.8%)	164

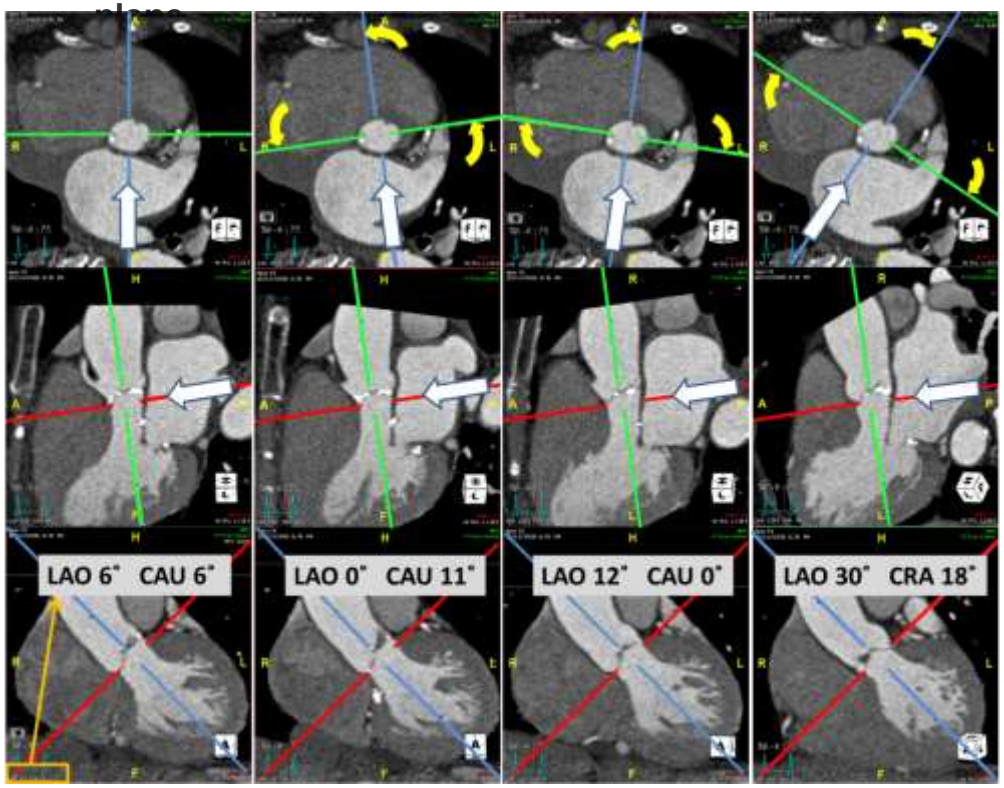
Source: Okuyama et al Circ Imaging 2014

2- Pre-procedural co-planar angle prediction

Fluoroscopic co-planar angle prediction

Line of perpendicularity

Identification of annulus plane | **Adjusting to LAO 0˚** | **Adjusting to CAU 0˚** | **Adjusting to LAO 30˚**



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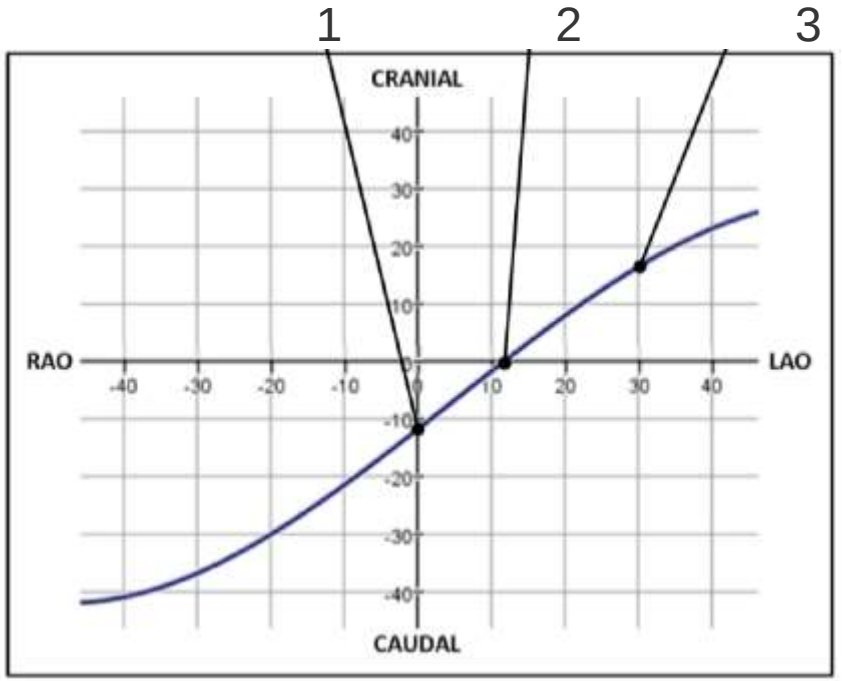
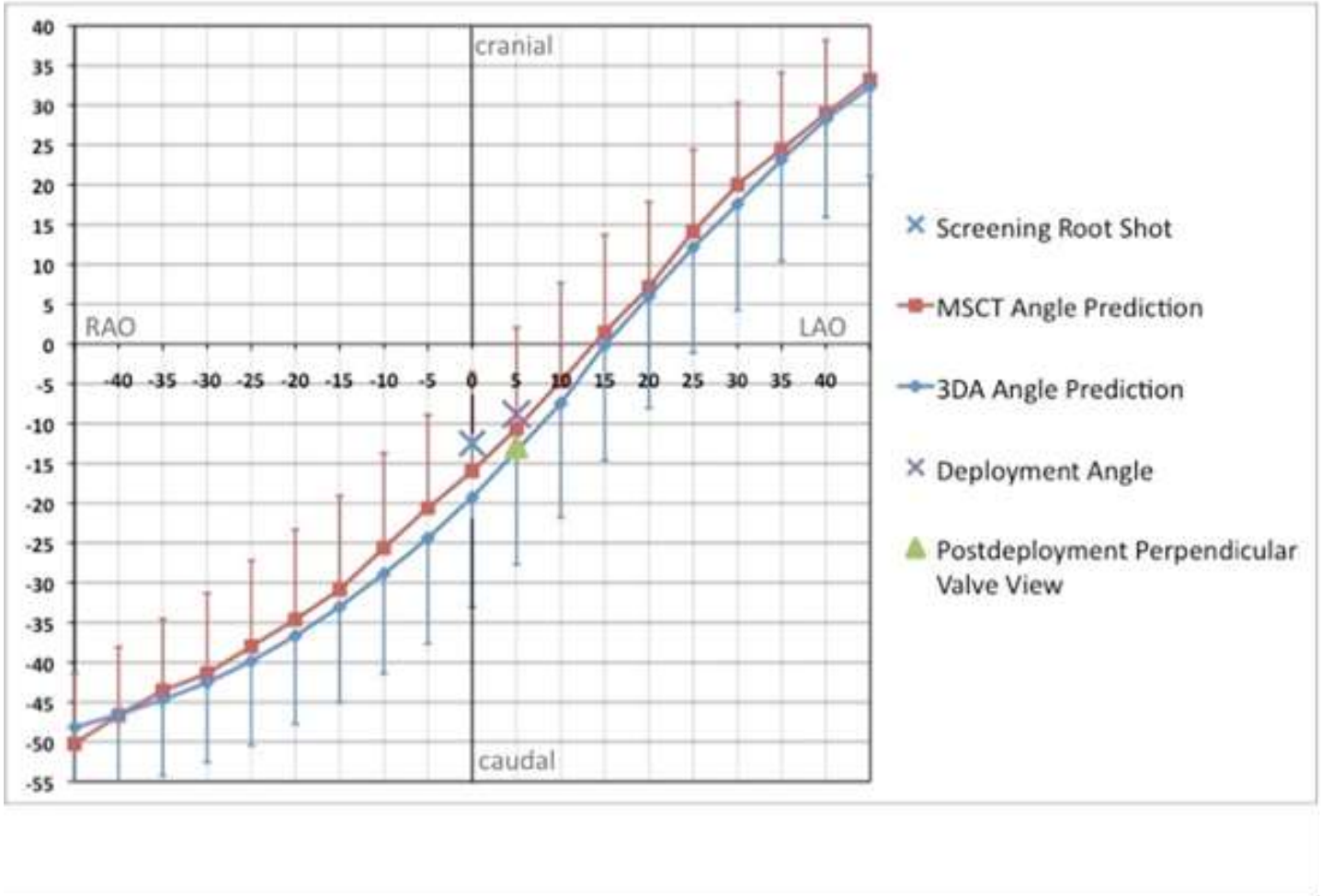


Blanke, Leipsic *Radiology 2013*

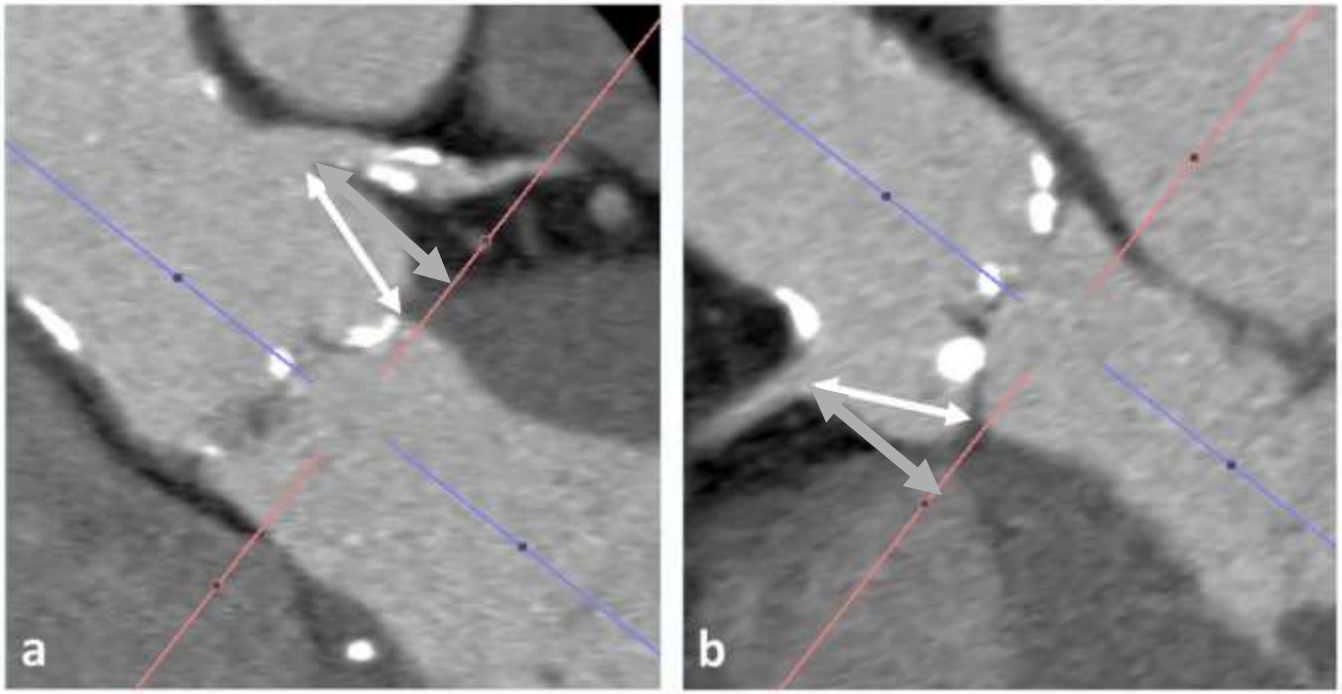
MDCT vs 3-D Angio CT for Angle Prediction



Source: Binder et al. TCT 2011 , Circ Interventions April 2012

3- Ancillary root measurements essential for planning

CT Provides Additional Important Data Regarding the Aortic Root - Coronary Ostial Height

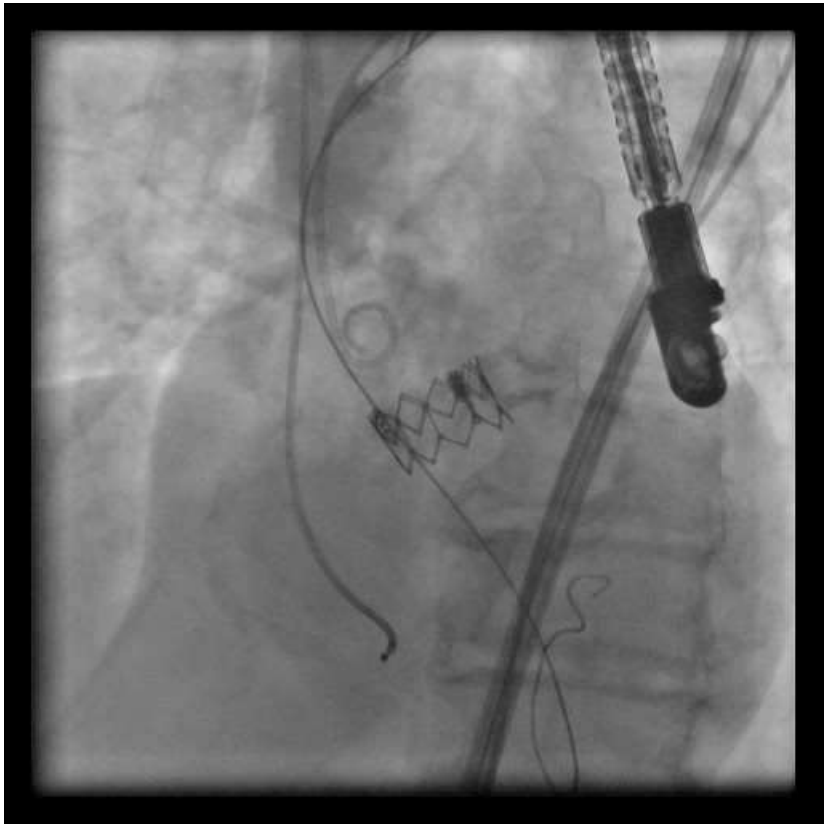


IFU - Minimum 10/11 mm

Limitations : Measurements not standardized, „bulky calcifications“

Ancillary root measurements & Coronary height

Coronary artery occlusion



- displacement of the calcified native cusp over the coronary ostia

- < 1% of cases
- 0.66% (Ribiero et al, JACC 2013)

- More common in
  - Women
  - Balloon-expandable TAVI
  - Valve-in-Valve

Anatomical Predictors of Coronary occlusion

CLINICAL RESEARCH — Interventional Cardiology

Predictive Factors, Management, and Clinical Outcomes of Coronary Obstruction Following Transcatheter Aortic Valve Implantation

Insights From a Large Multicenter Registry

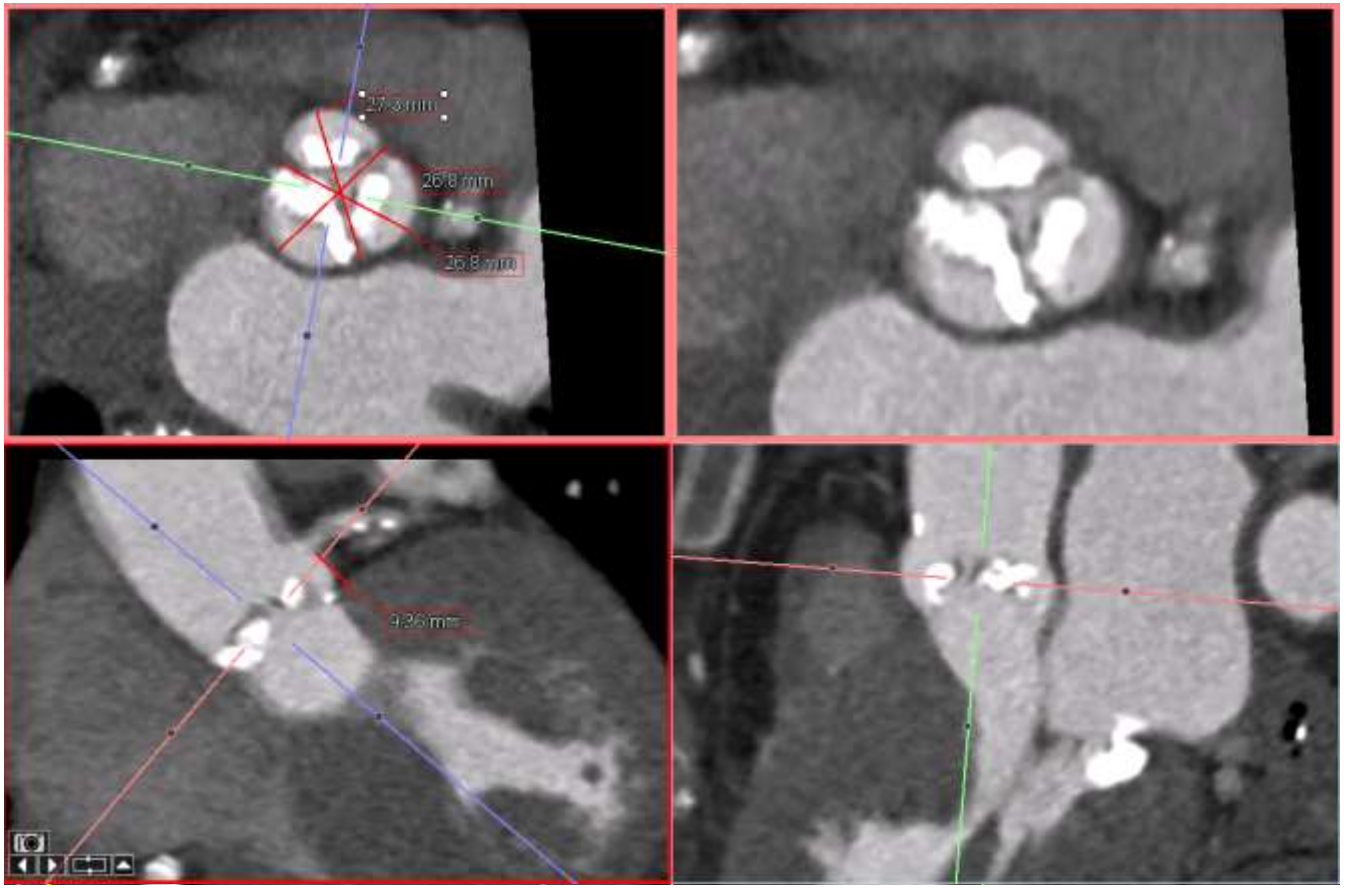
Henrique B. Ribeiro, MD,* John G. Webb, MD,† Raj R. Makkar, MD,‡ Mauricio G. Cohen, MD,§ Samir R. Kapadia, MD,‖ Susheel Kodali, MD,¶ Corrado Tamburino, MD,# Marco Barbanti, MD,†# Tarun Chakravarty, MD,‡ Hasan Jilaihawi, MD,‡ Jean-Michel Paradis, MD,¶ Fabio S. de Brito, Jr, MD,** Sergio J. Cánovas, MD,†† Asim N. Cheema, MD,‡‡ Peter P. de Jaegere, MD,§§ Raquel del Valle, MD,‖‖ Paul T. L. Chiam, MD,¶¶ Raúl Moreno, MD,## Gonzalo Pradas, MD,*** Marc Ruel, MD,††† Jorge Salgado-Fernández, MD,‡‡‡ Rogerio Sarmento-Leite, MD,§§§ Hadi D. Toeg, MD,††† James L. Velianou, MD,‖‖‖ Alan Zajarias, MD,¶¶¶ Vasilis Babaliaros, MD,### Fernando Cura, MD,**** Antonio E. Dager, MD,†††† Ganesh Manoharan, MD,‡‡‡‡ Stamatios Lerakis, MD,### Augusto D. Pichard, MD,§§§§ Sam Radhakrishnan, MD,‖‖‖‖ Marco Antonio Perin, MD,** Eric Dumont, MD,* Eric Larose, MD,* Sergio G. Pasian, MD,* Luis Nombela-Franco, MD,* Marina Urena, MD,* E. Murat Tuzcu, MD,‖ Martin B. Leon, MD,¶ Ignacio J. Amat-Santos, MD,¶¶¶¶ Jonathon Leipsic, MD,† Josep Rodés-Cabau, MD*

Quebec City, Quebec, Toronto, Ottawa, Hamilton, Ontario, and Vancouver, British Columbia, Canada; Los Angeles, California; Miami, Florida; Cleveland, Ohio; New York, New York; Catania, Italy; Sao Paulo, and Porto Alegre, Brazil; Valencia, Oviedo, Madrid, Vigo, La Coruna, and Valladolid, Spain; Rotterdam, the Netherlands; Singapore; St. Louis, Missouri; Atlanta, Georgia; Buenos Aires, Argentina; Cali, Colombia; Belfast, Northern Ireland; and Washington, DC

- 44/6688 (0.66%)
- Predominantly LM
- More common in
  - Women
  - Balloon-expandable TAVI
  - Valve-in-Valve

- **LMH**:
  - 10.6±2.1mm vs. 13.4±2.1mm
  - <12mm – in obstruction 86%
  - <12mm – controls 26%
- **SOV**:
  - 28.1±3.8mm vs. 31.9±4.1 mm
  - <30mm – in obstruction 71%
  - <30mm – controls 33%
- **LMH** <12mm and **SOV** <30mm
  - obstruction 68%
  - controls 13%

Ancillary root measurements & Coronary height



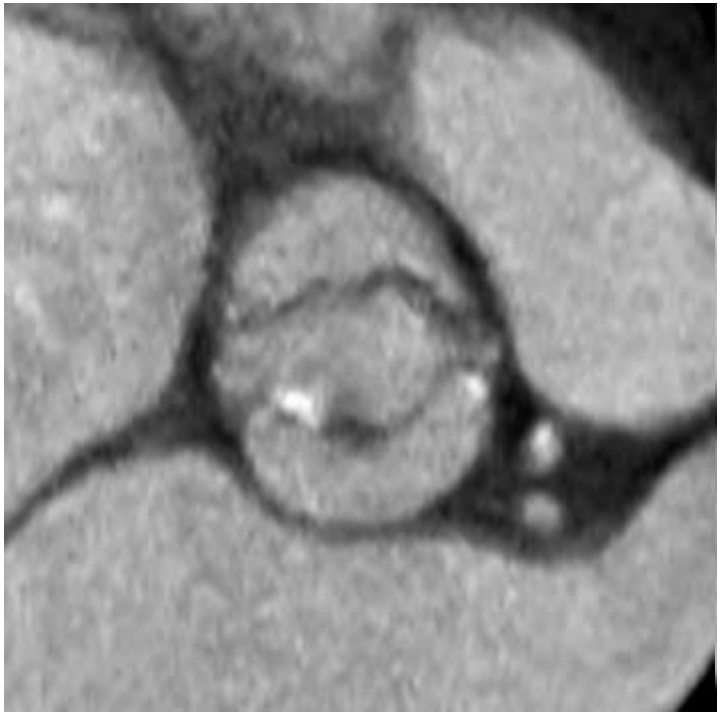
Bulky calcifications & Low LMH & Shallow sinus

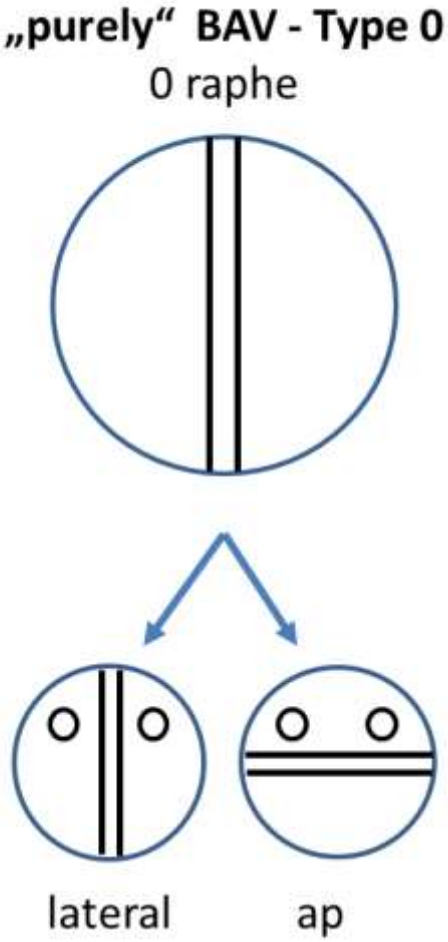
4- Help adjudicate Valve morphology in difficult cases

Tricuspid or not tricuspid?

Valve anatomy

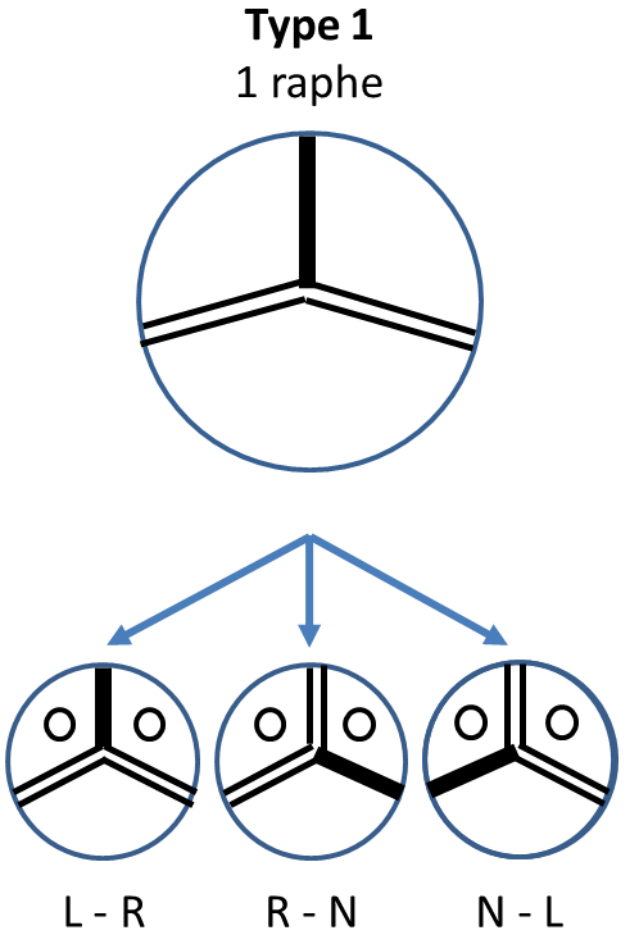
Bicuspid





Valve anatomy

Bicuspid



5- MDCT for Annular Sizing and THV Selection

The Annulus is Elliptical

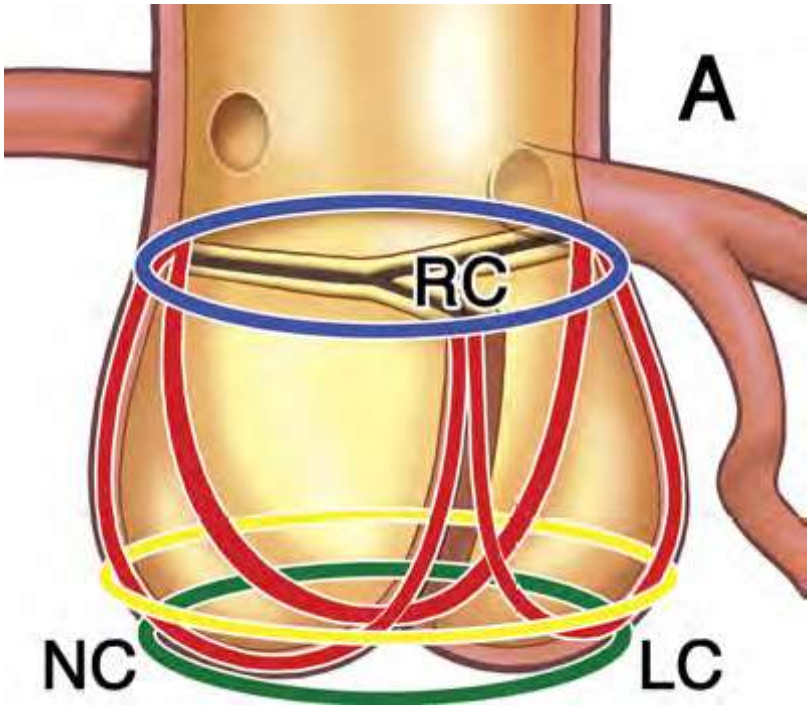
The annulus is commonly oval-shaped

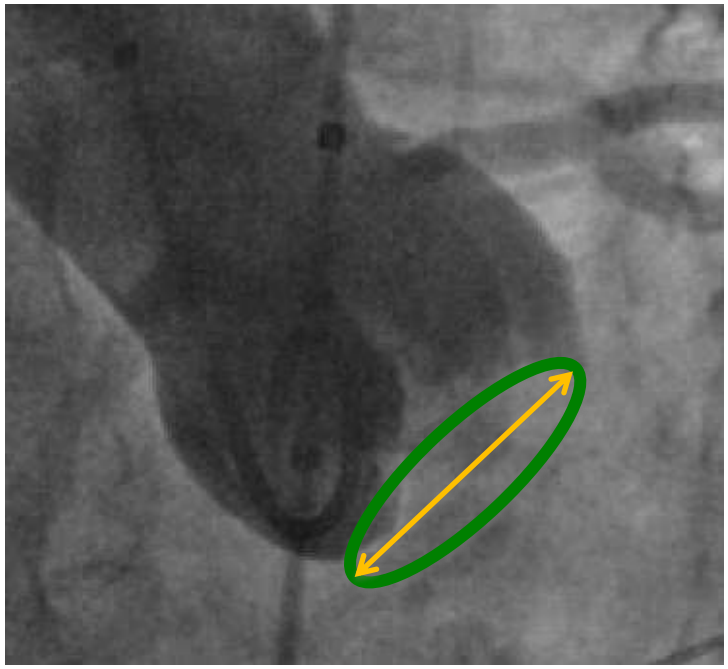
Reported in approximately 50% of patients

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

Tops LF, Wood DA, Delgado V, et al. Noninvasive evaluation of the aortic root with multislice computed tomography: implications for transcatheter aortic valve replacement. *JACC Cardiovasc Imaging* 2008; 3:25 -32

The Virtual Basal Ring





Sinotubular junction

Aortic leaflets

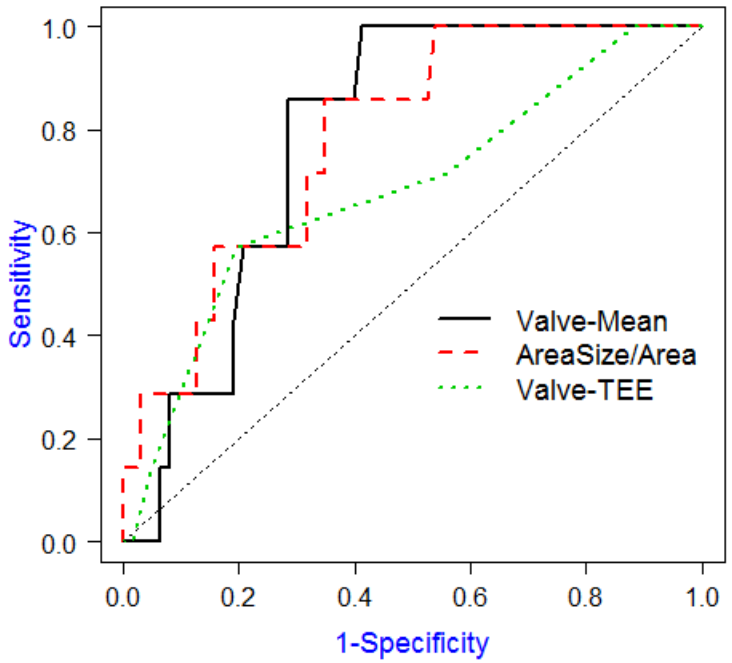
Aortic Annulus

Aortic Annular Diameter

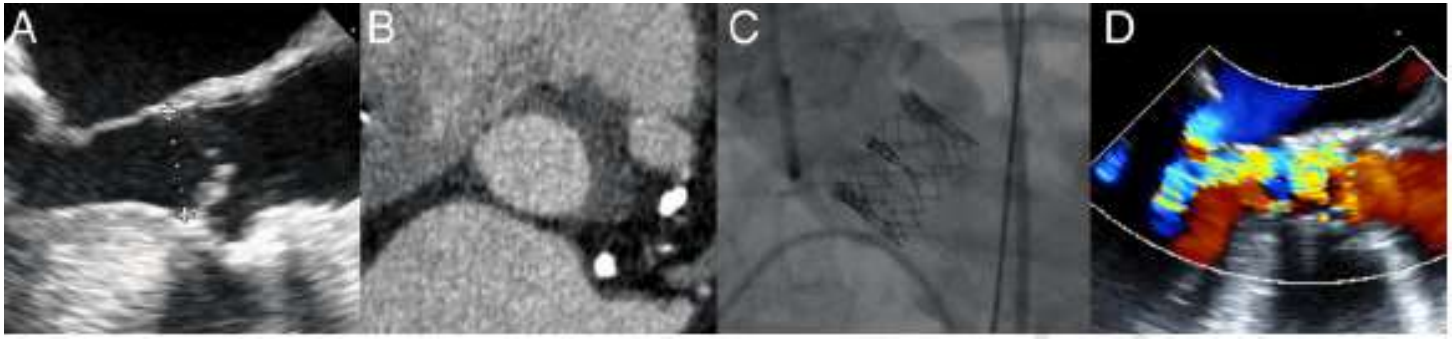
RC = Right coronary cusp; NC = Non-coronary cusp;
LC = Left coronary cusp

Source: Leipsic et al JACC Img April 2011

CT Annular Measures Can Predict PV Leak



- Valve stent diameter – Mean annular diameter$_{MDCT}$ AUC 0.84
- Valve stent diameter – Area-derived annular diameter$_{MDCT}$ AUC 0.86
- Valve stent area/ Annular area$_{MDCT}$ AUC 0.87

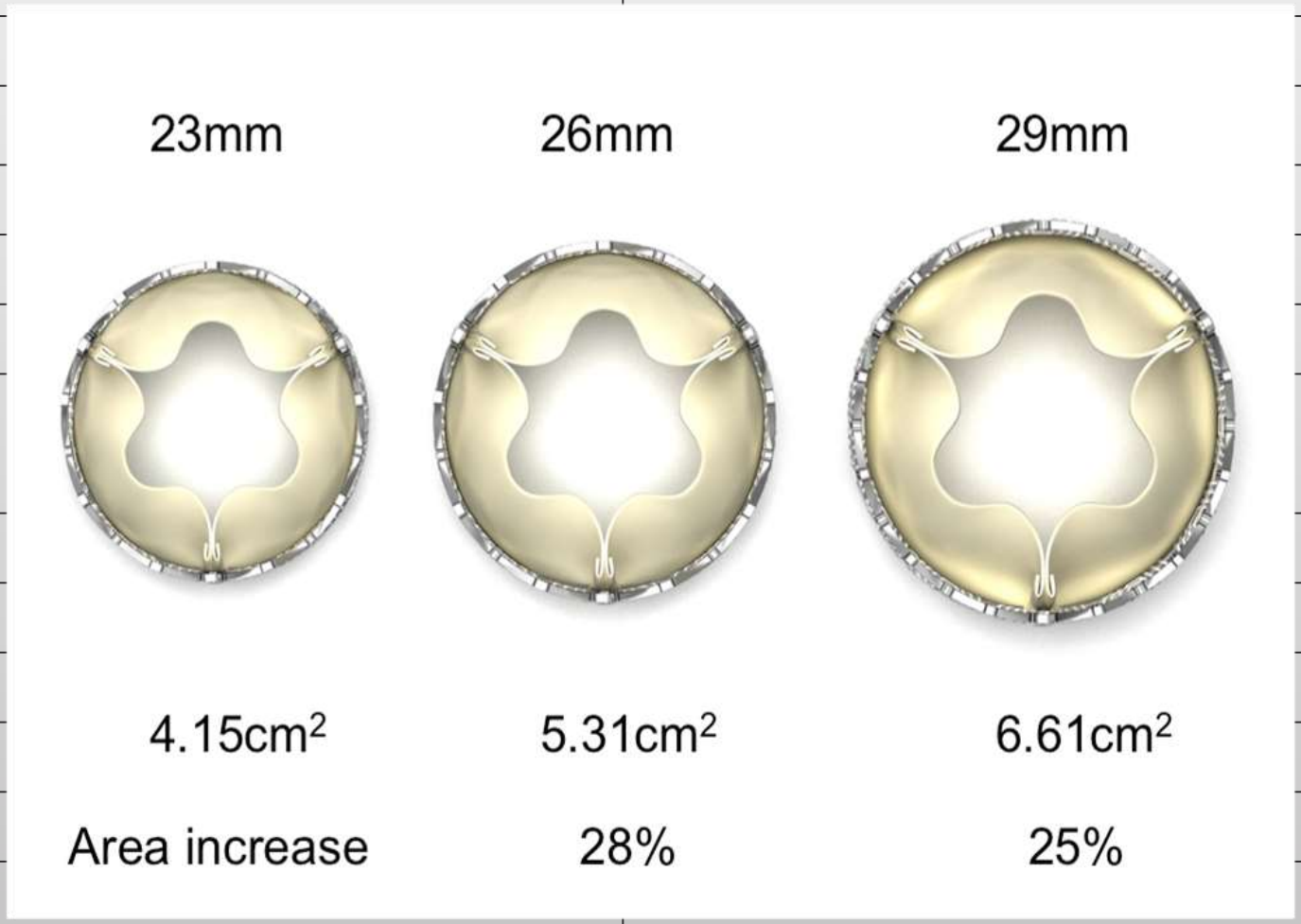


Willson et al. JACC 2012

MDCT Can Provide Reproducible and Robust Sizing Recommendations

Vancouver MDCT Sizing Guidelines

Annular Area (mm^2)	26mm SAPIEN XT THV
520	2.1
530	0.2



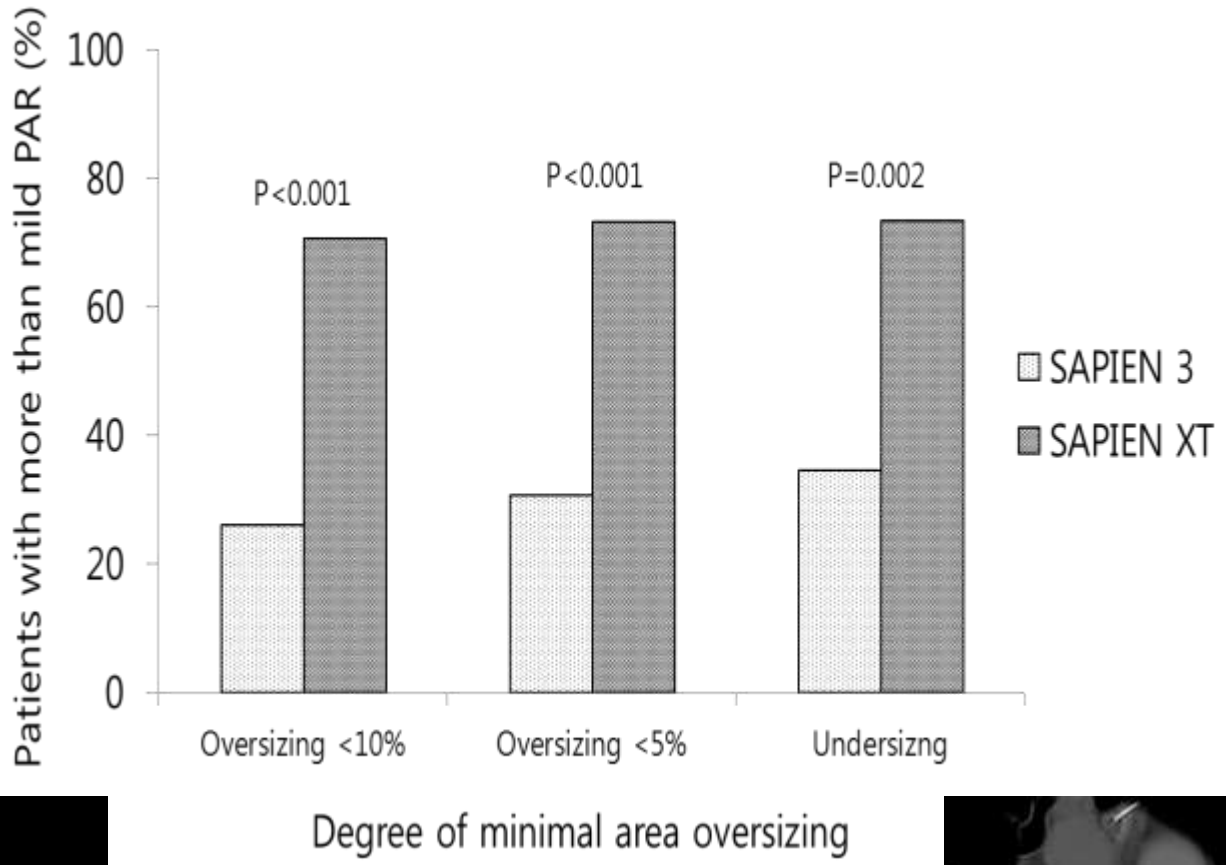
Source: RSNA 2012
Willson et al JCCT

Self Expanding Valve Sizing Recommendations Based on MDCT

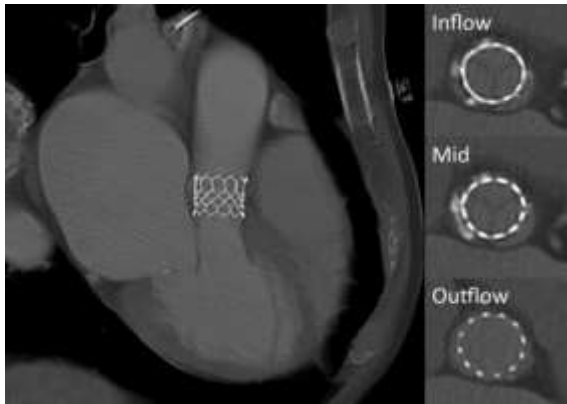
	Diameter Range (mm)	Perimeter Range (mm)	Area Range (mm^2)
23	18 - 20	56.5 - 62.8	254.5 - 314.2
26	20 - 23	62.8 - 72.3	314.2 - 415.5
29	23 - 27	72.3 - 84.8	415.5 - 572.6
31	26 - 29	81.7 - 91.1	530.9 – 660.5

Recent evidence supports Area/Perimeter as the recommended method for TAVI sizing

Different Sizing Algorithms for Different Valves



Source: Yang et al ACC 2014, JACC Int in press



From Theoretical to Practical

Impact of CT sizing on TAVR outcomes

The Impact of Integration of a Multidetector Computed Tomography Annulus Area Sizing Algorithm on Outcomes of Transcatheter Aortic Valve Replacement: A Prospective, Multicenter, Controlled Trial

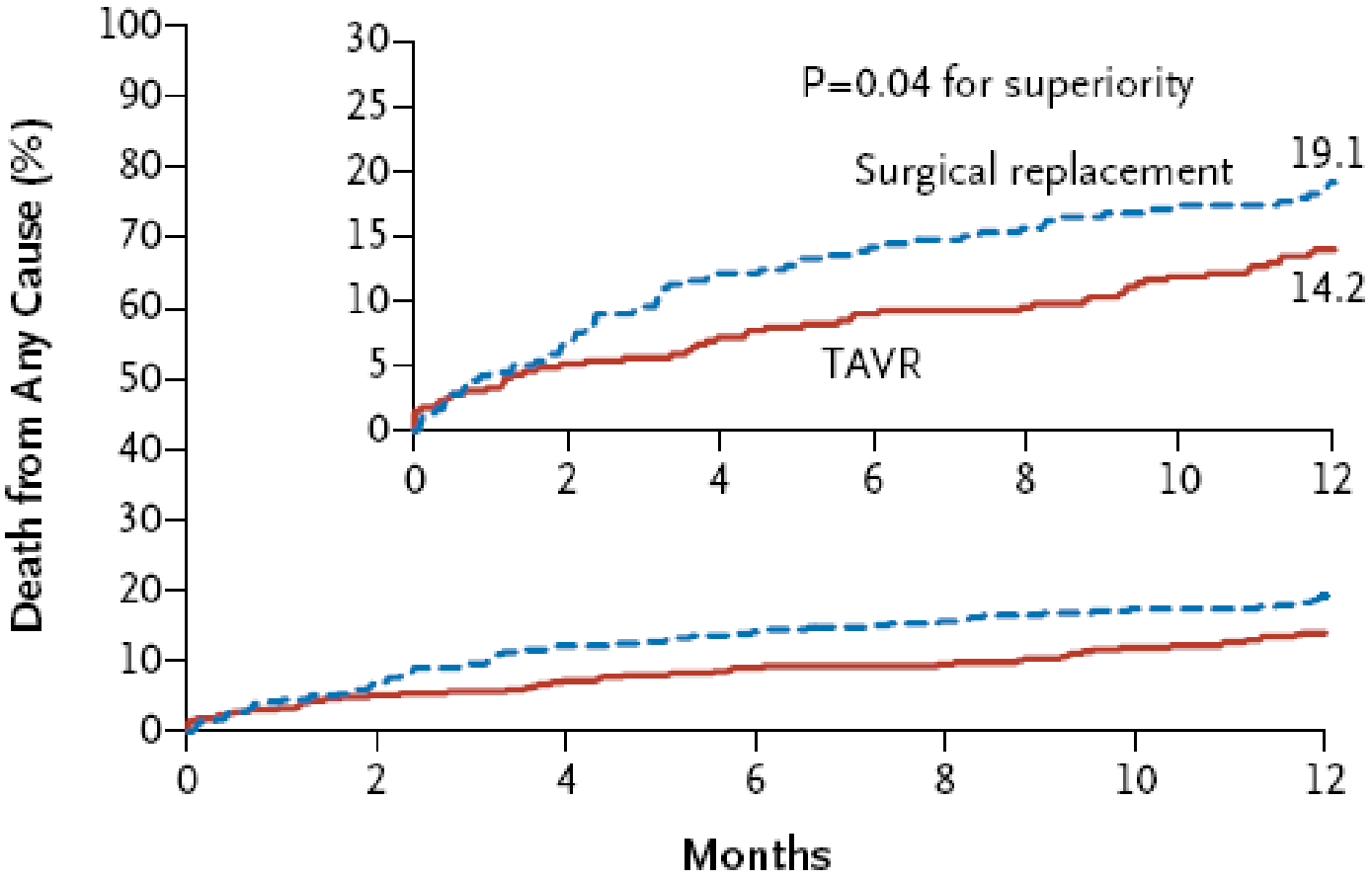
Short Title: Computed Tomography Area Sizing for TAVR

Ronald K. Binder[1], MD; John G. Webb[1], MD; Alexander B. Willson[1], MBBS; Marina Urena[2], MD; Nicolaj C. Hansson[3], MD; Bjarne L. Norgaard[3], MD; Philippe Pibarot[2], MD; Marco Barbanti[1], MD; Eric Larose[2], MD; Melanie Freeman[1], MBBS; Eric Dumont[2], MD; Chris Thompson[1], MD; Miriam Wheeler[1], MBChB; Robert R. Moss[1], MD; Tae-hyun Yang[1], MD; Sergio Pasian[2], MD; Cameron Hague[1], MD; Giang Nguyen[1], MD; Rekha Raju[1], MD; Stefan Toggweiler[1], MD; James K. Min, MD[5]; David A. Wood[4], MD; Josep Rodés-Cabau[2], MD; Jonathon Leipsic[1], MD.

- 266 patients in the trial
- 133 patients underwent TAVR with the MDCT sizing algorithm recommendation and 133 patients without the algorithm
- PVL> mild was present in 5.3% in the MDCT group and in 12.8% in the control group (p=0.032)
- Composite of in-hospital death, aortic annulus rupture and PVL> moderate 3.8% in the MDCT group and in 11.3% in the control group (p=0.020)

Source: JACC Jun 2013

CT Sizing helps optimize outcomes with Self Expanding Prosthesis



Source : Adams et al NEJM 2014

6- Preventing Annular Injury with MDCT

Annular rupture

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

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

	Study group (n = 31)	Uncontained rupture (n = 20)	Contained rupture (n = 11)	P value
Mortality	48.4%	75.0%	0.0%	<0.001
Cardiovascular mortality	45.2%	70.0%	0.0%	<0.001
Disabling stroke	12.9%	10.0%	18.2%	0.447
Life-threatening bleeding	45.2%	60.0%	18.2%	0.049

Source: Barbanti et al. Circulation July 2013

Annular Rupture May not Be Random- Insights from MDCT

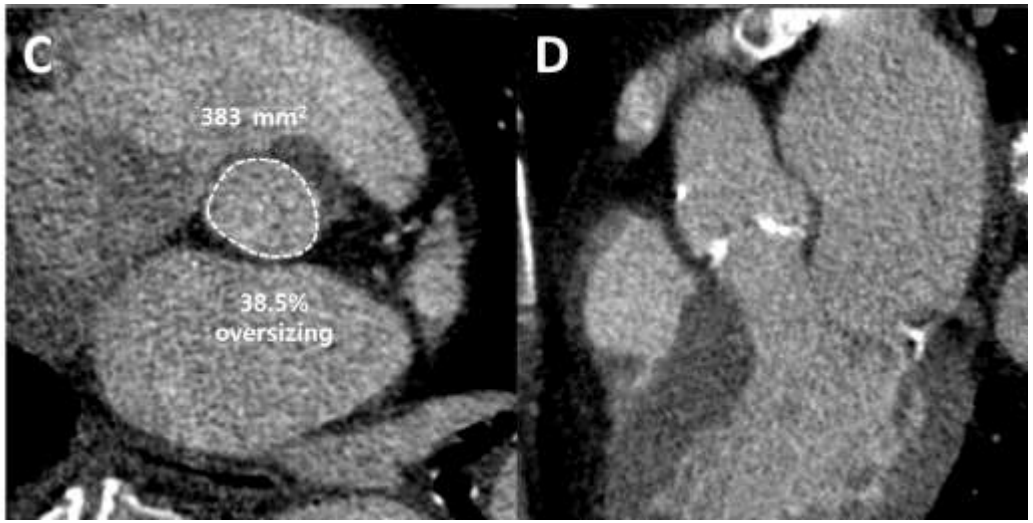
	Univariate	
Predictors of aortic root rupture	Odds Ratio (95%CI)	P value
LVOT calcifications moderate/severe	10.92 (3.23-36.91)	<0.001
Prosthesis oversizing ≥ 20%	8.38 (2.67-26.33)	<0.001

Source: ACC 2013 and Circulation July 2013

Preventing extreme annular oversizing particularly in the setting of LVOT calcification

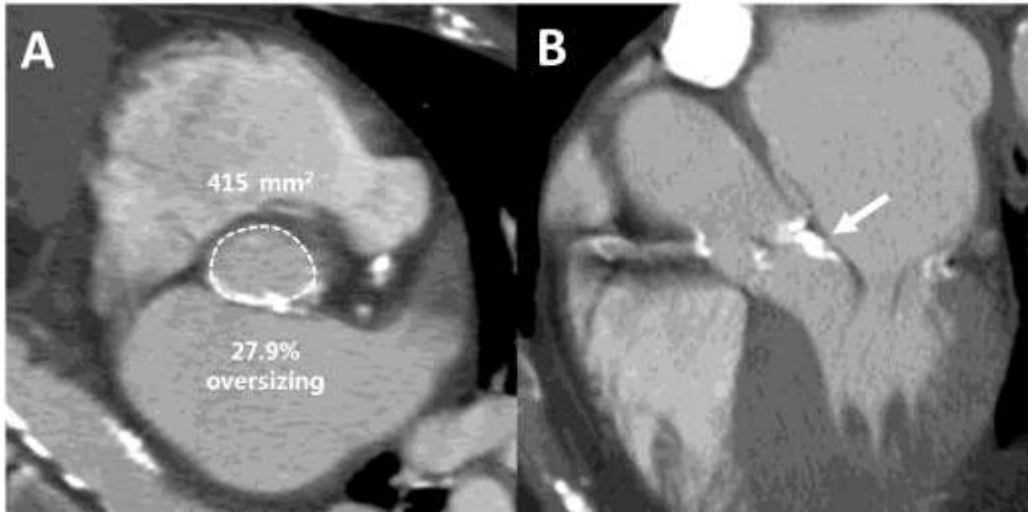
Case examples

Significant oversizing (>20%) is possible…Just do it in the right patient!



Case example #1

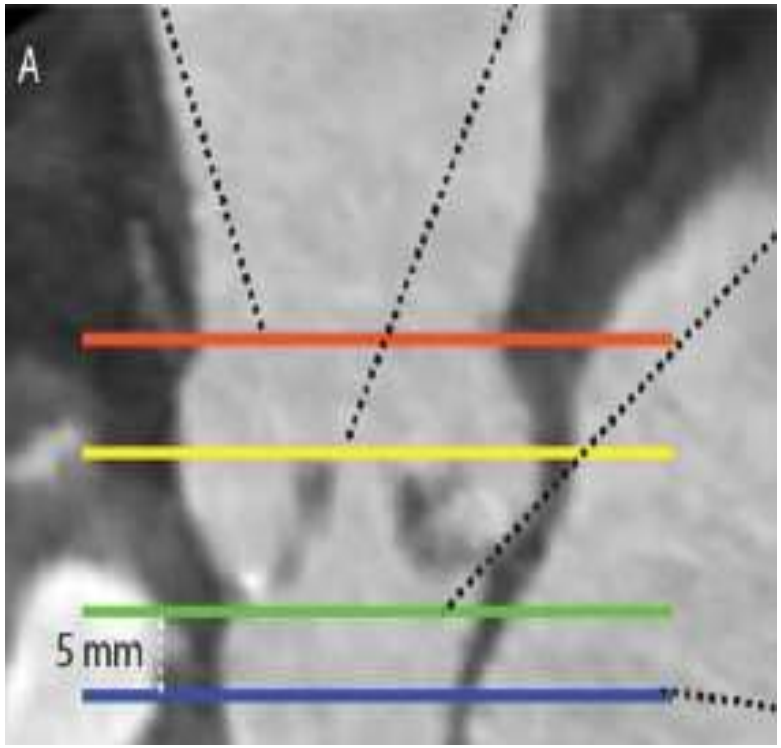
- ❑ 26-mm SAPIEN XT
- ❑ 38.5% oversizing
- ❑ No LVOT calcification
- ❑ Uneventful TAVR!

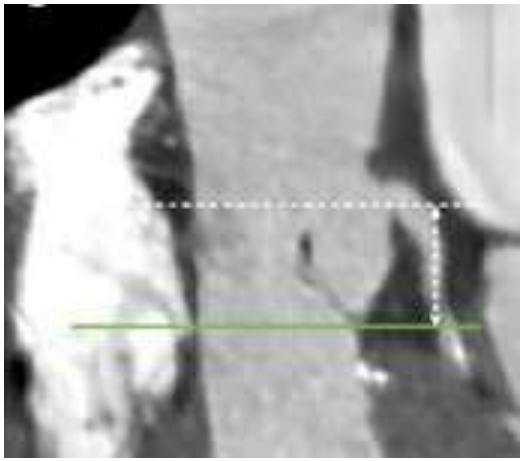


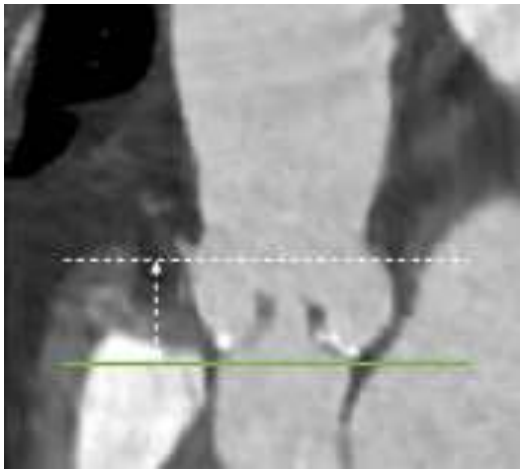
Case example #2

- ❑ 26-mm SAPIEN XT
- ❑ 27.9% oversizing
- ❑ Severe LVOT calcification
- ❑ Annular rupture!

Does calcium distribution matter?

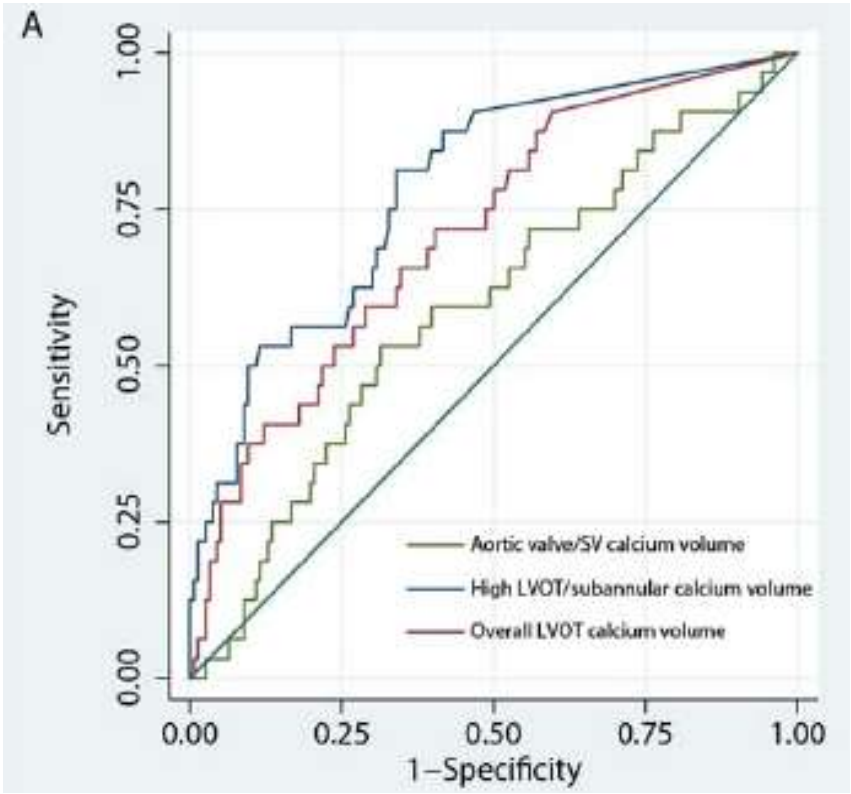


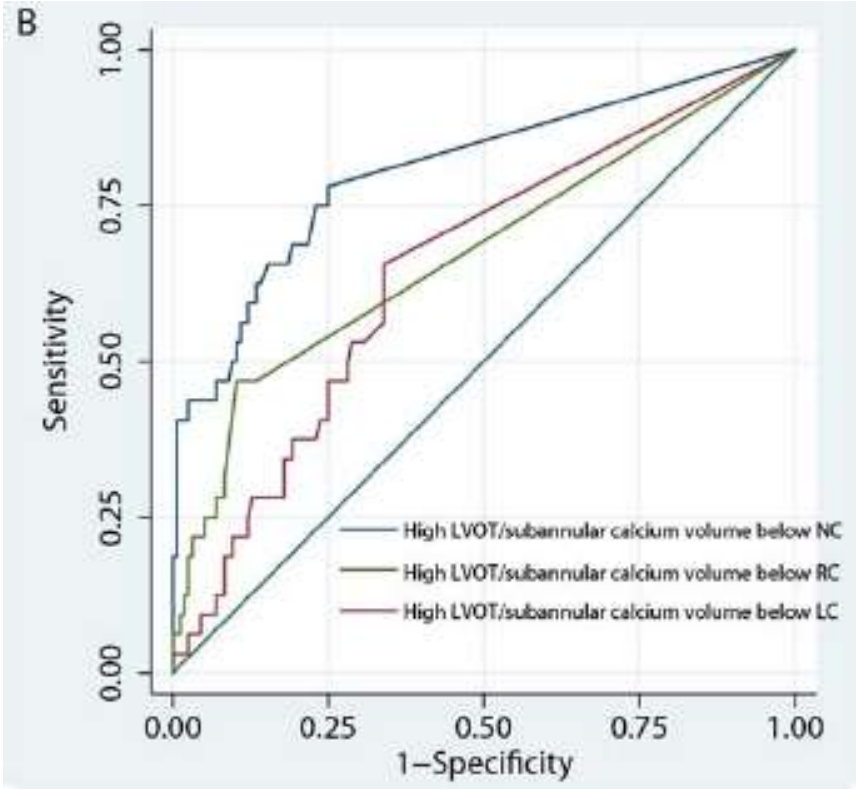




Source: Leipsic RSNA 2014, Hansson et al in press JCCT

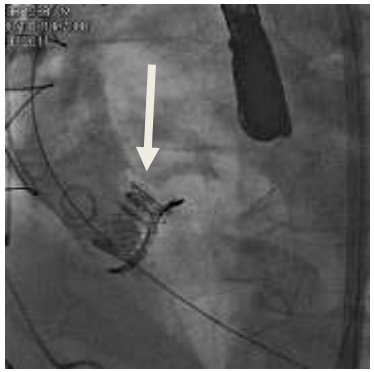
Sub-annular calcium below the non-coronary cusp is most predictive of rupture



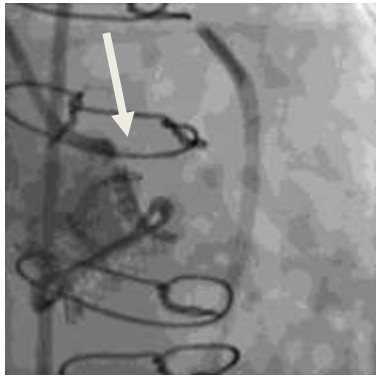


7- Coronary occlusion in Valve-in-Valve Procedures

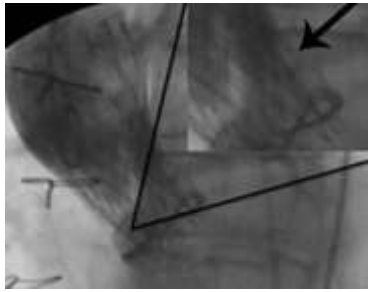
Complications Remain- Ostial Coronary Obstruction



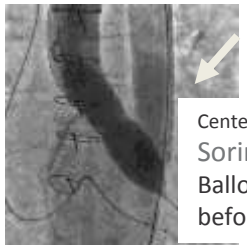
Center #30, case#3
Mitroflow 25mm (ID 21mm)
Tranapical Edwards-SAPIEN 23mm



Center #37, case#9
Mitroflow 21mm (ID 17.3mm)
Transapical Edwards-SAPIEN 23mm

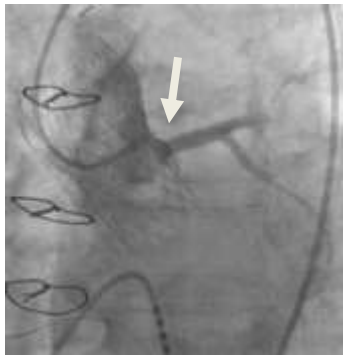


Center #34, case#6
Mitroflow 21mm (ID 17.3mm)
Tranfemoral CoreValve 26mm

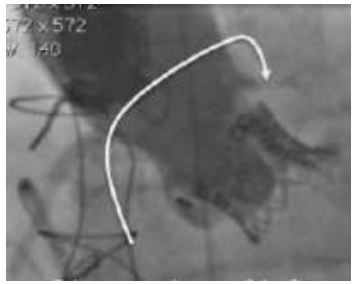


Center #29, case#7
Sorin Freedom Stentless 21mm (ID 19mm)
Balloon Valvuloplasty
before attempted CoreValve implantation

Center #13, case#4
Sorin Freedom Stentless 23mm (ID 21mm)
Transfemoral CoreValve 26mm



Center #27, case#3
CryoLife O'Brien (stentless) 25mm (ID 23mm)
Transfemoral CoreValve 29mm



Center #11, case#11
Mosaic 21mm (ID 18.5mm)
Transapical Edwards-SAPIEN 23mm

Courtesy of Danny Dvir/VIVID Registry

Coronary obstruction in Valve-in-Valve Procedures

Valve design

Mitroflow #27 in an aortic root model

Valve-in-Valve with SAPIEN 29mm

Dvir et al. 2014

Assessment for Valve-in-Valve Procedures

Anatomical issues and potential measurements

1. Root anatomy
   - Coronary artery height
   - Sinus of Valsalva with
   - Sinus height

2. Distortion of Anatomy
   - Tilting of the surgical prosthesis
   - Lower coronary height

Prediction of the the proximity of the coronary ostia to the anticipated final position of the displaced bioprosthetic leaflets after THV implantation

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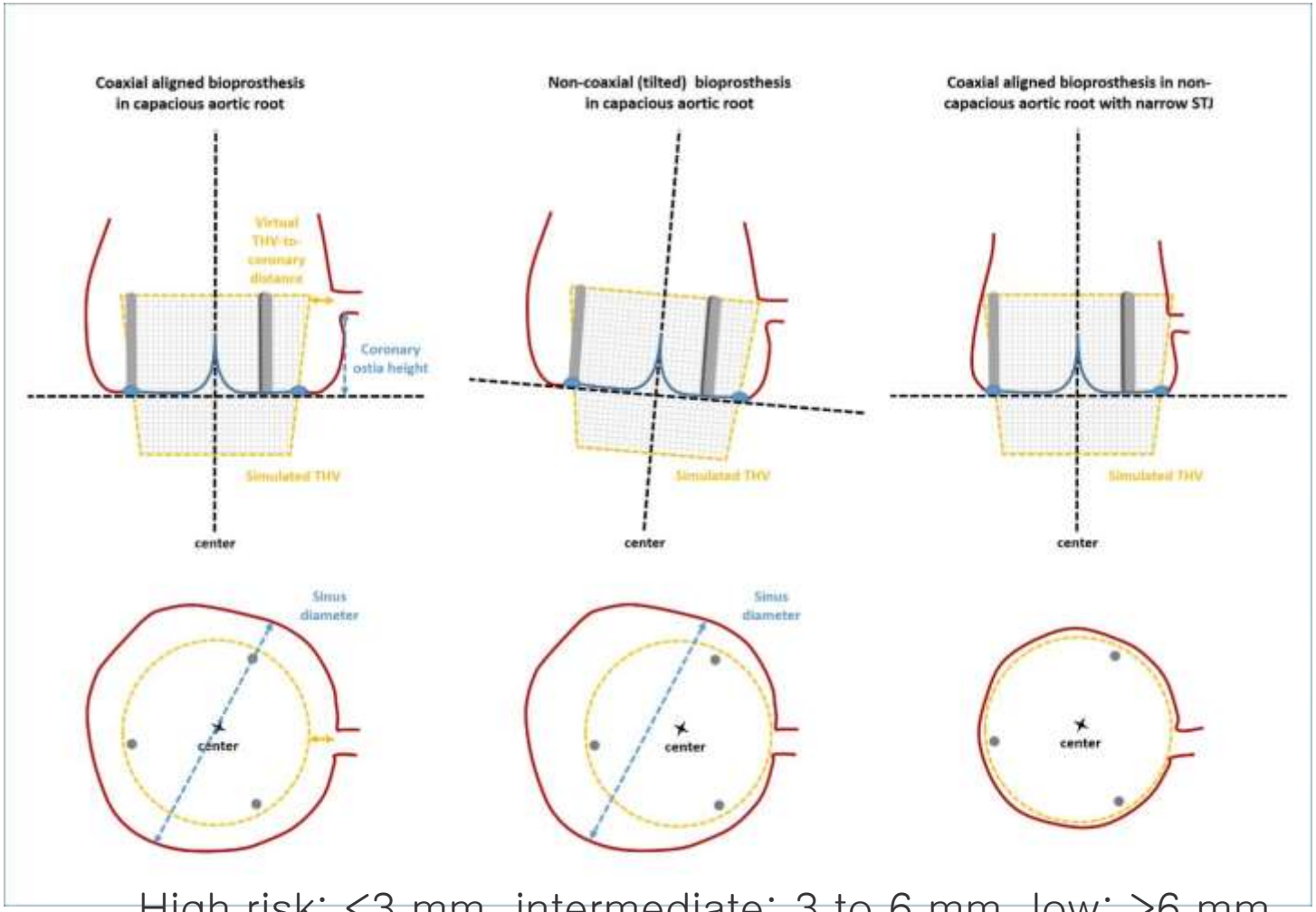
Assessment for Valve-in-Valve Procedures

Virtual THV to Coronary (VTC) distance



High risk: <3 mm, intermediate: 3 to 6 mm, low: >6 mm.

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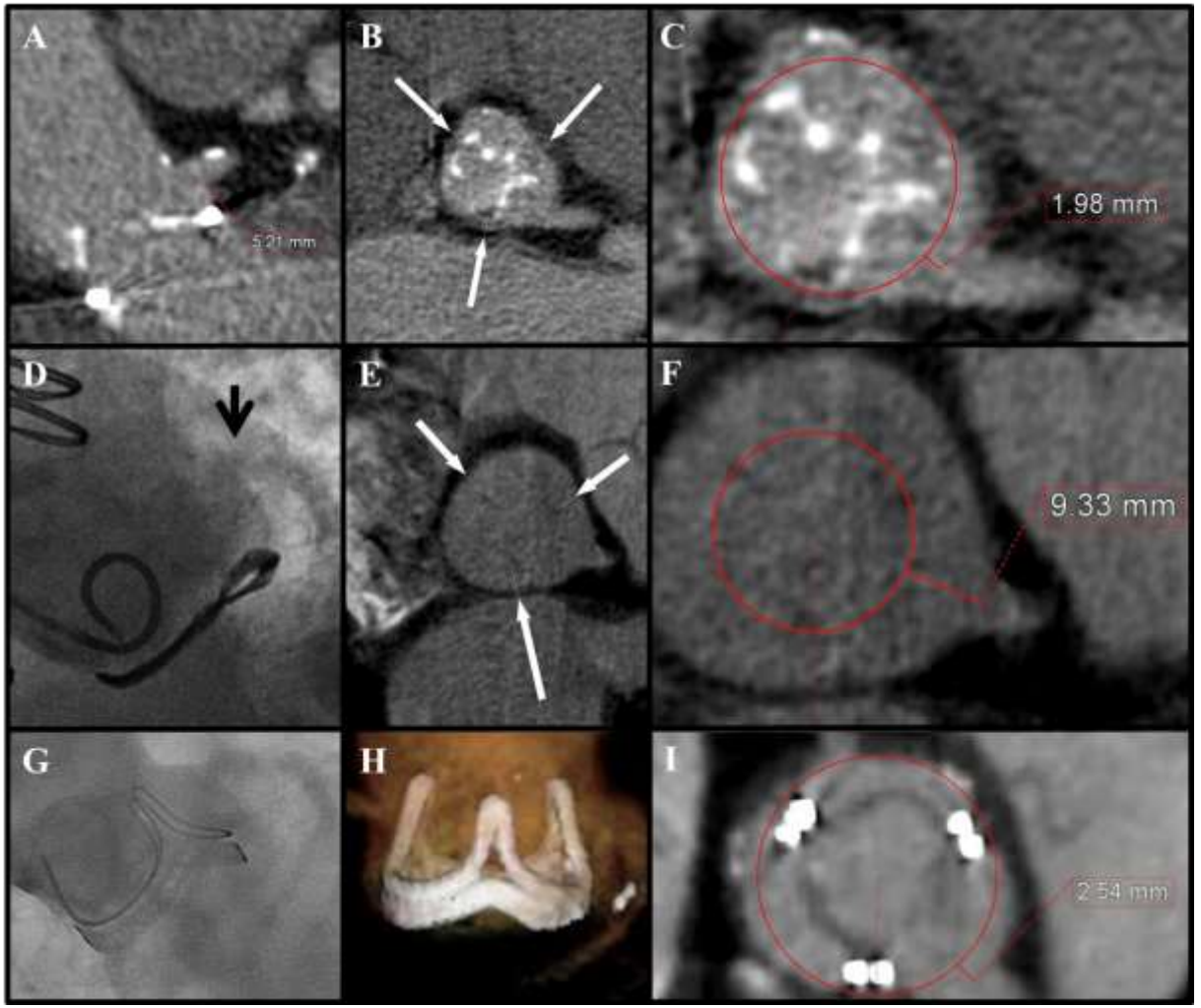
Assessment for Valve-in-Valve Procedures

Example



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Conclusions

- MDCT is now well established as an important tool for annular sizing
- Allows for the discrimination of those patients historically at risk for annular rupture, coronary occlusion and PAR
- Field is moving from historical device selection based on sex or 2 D measurements to a truly individualized approach to THV selection
- Growing role in the assessment of risk of coronary occlusion in valve in valve procedures