

Cardiac CT in TAVI/TAVR: Optimizing Outcome through Imaging

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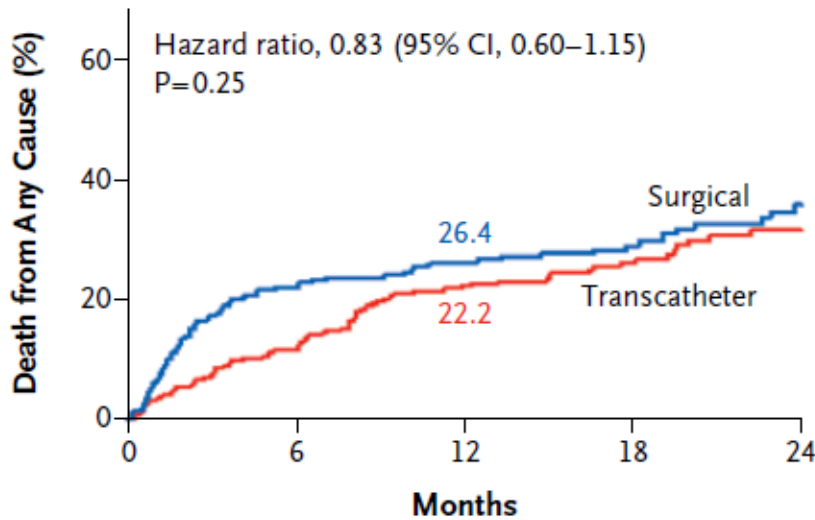
04.09.2017

Structure

- Device sizing
 - Annular rupture
 - Para-valvular leak
- New pacemakers
- Bicuspid aortic valve
- Peripheral access
- Post-TAVI CT

Partner 1: High risk

Death from Any Cause, Transfemoral-Placement Cohort

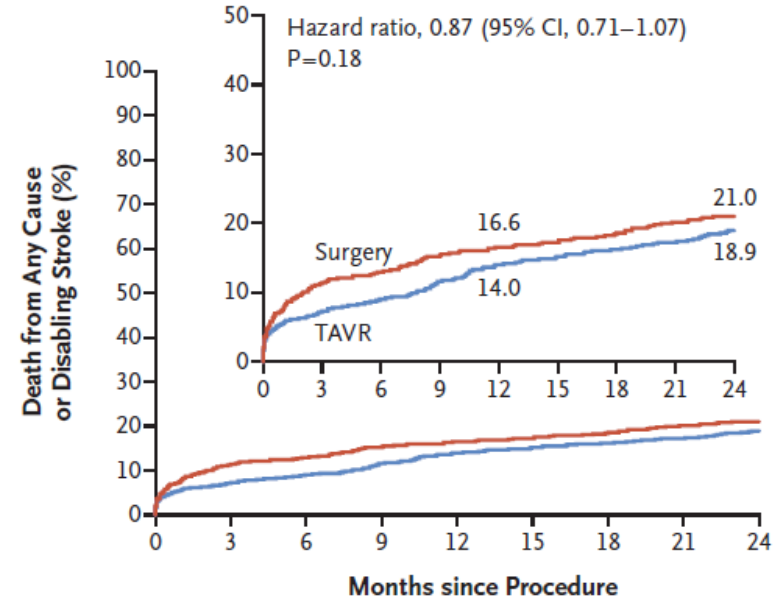


No. at Risk

Transcatheter	244	215	188	119	59
Surgical	248	180	168	109	56

Partner 2: Intermediate risk

As-Treated Population



No. at Risk

TAVR	994	917	900	870	842	825	811	801	774
Surgery	944	826	807	779	766	743	731	715	694

Low risk population?

N Engl J Med. 2011;364:2187-98

N Engl J Med. 2016;374:1609-20

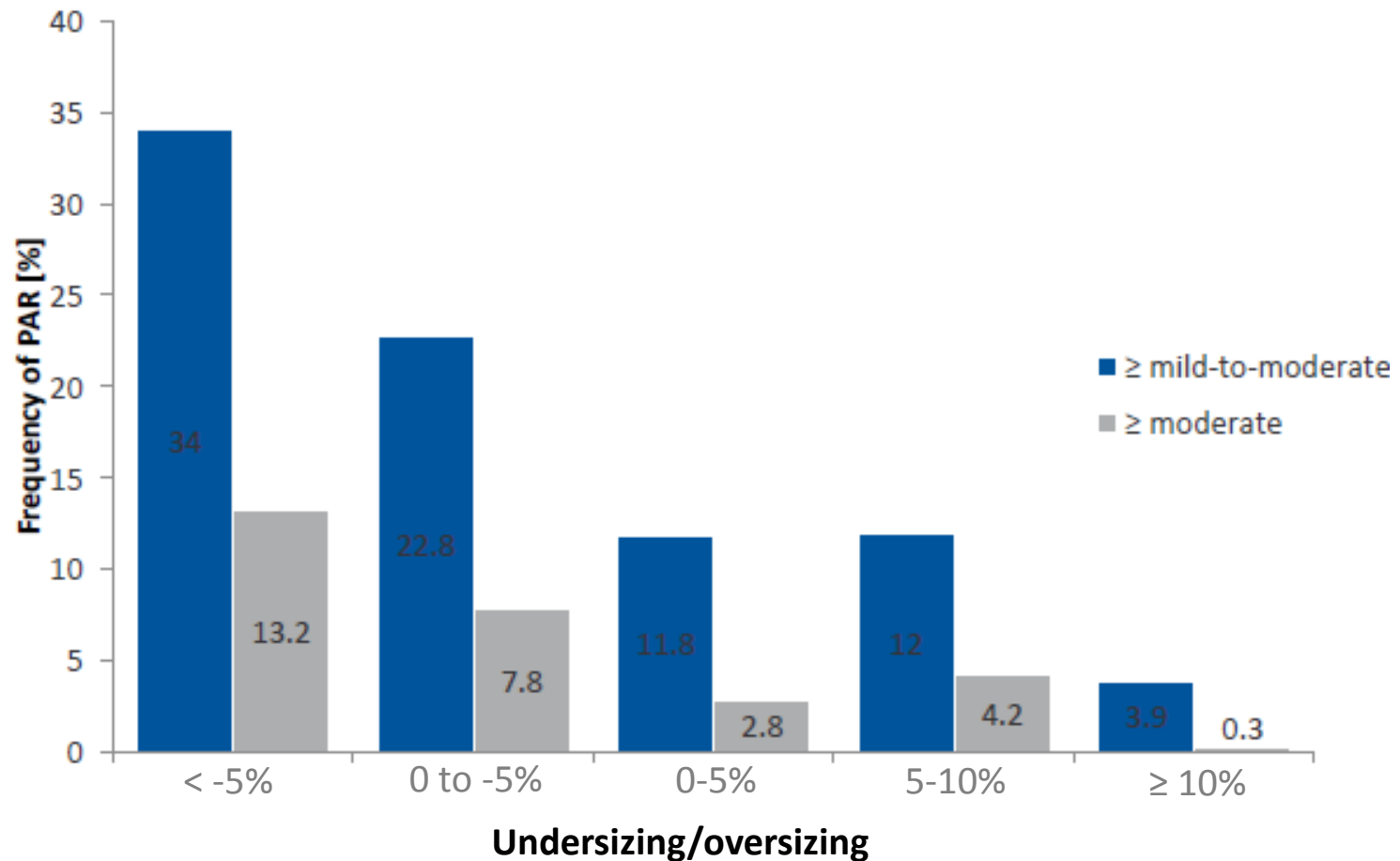
Excellent outcomes data compared with surgical AVR

PARTNER 2A/S3i Event	30 day Outcomes (%)		1 Year Outcomes (%)	
	SAPIEN 3 (n = 1077)	Surgery (n = 944)	SAPIEN 3 (n = 1077)	Surgery (n = 944)
Mortality	1.1	4.0	7.4	13.0
Disabling Stroke	1.0	4.4	2.3	5.9
All stroke	2.7	6.1	4.6	8.2
New Onset Atrial Fibrillation	5.0	28.3		
Acute Kidney Injury (stage 3)	0.5	3.3		
Life Threatening Bleeding	4.6	46.7		
New Permanent Pacemaker	10.2	7.3		

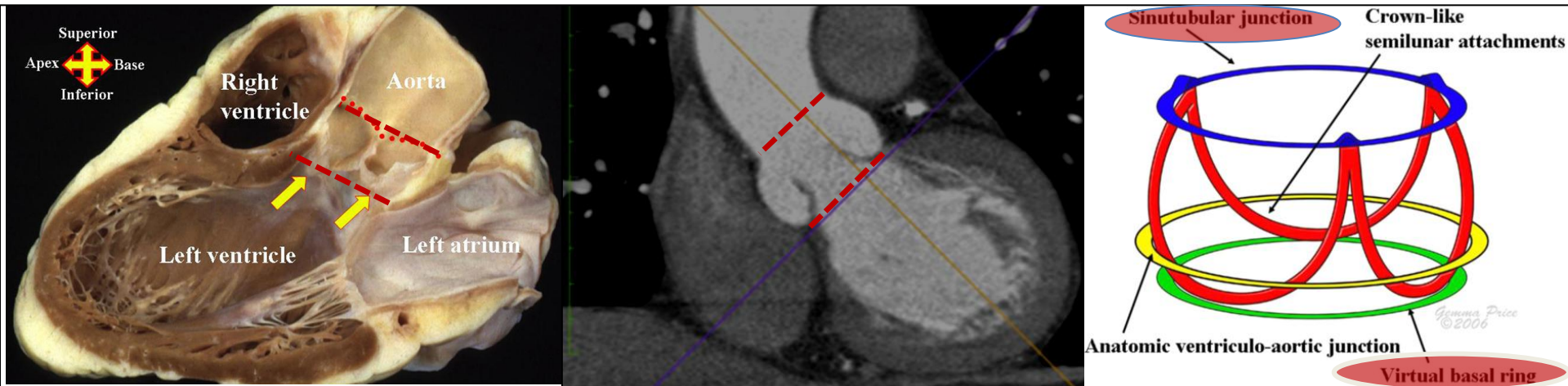
Based on the 2017 ESC Valvular Heart disease Guidelines:
Available data for TAVI mostly in population > 75 years:

- Bicuspid aortic valve
- Higher pacemaker rate

CT sizing algorithms need to evolve with the devices



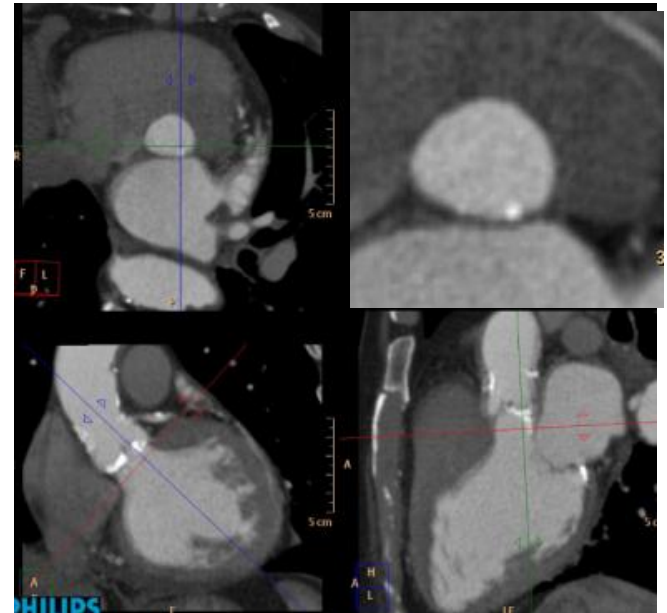
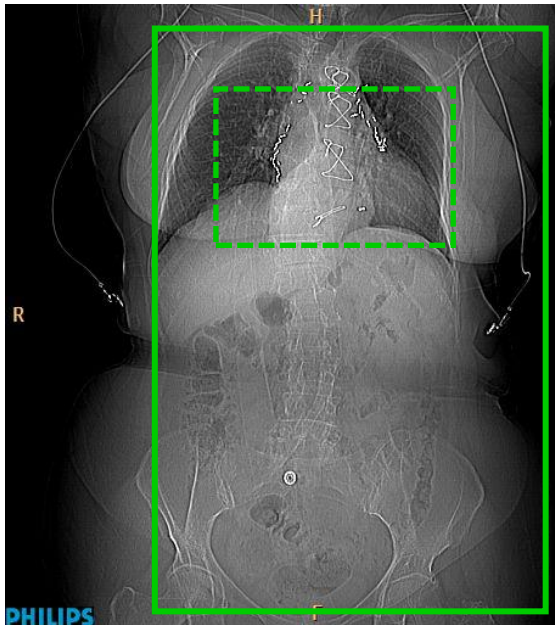
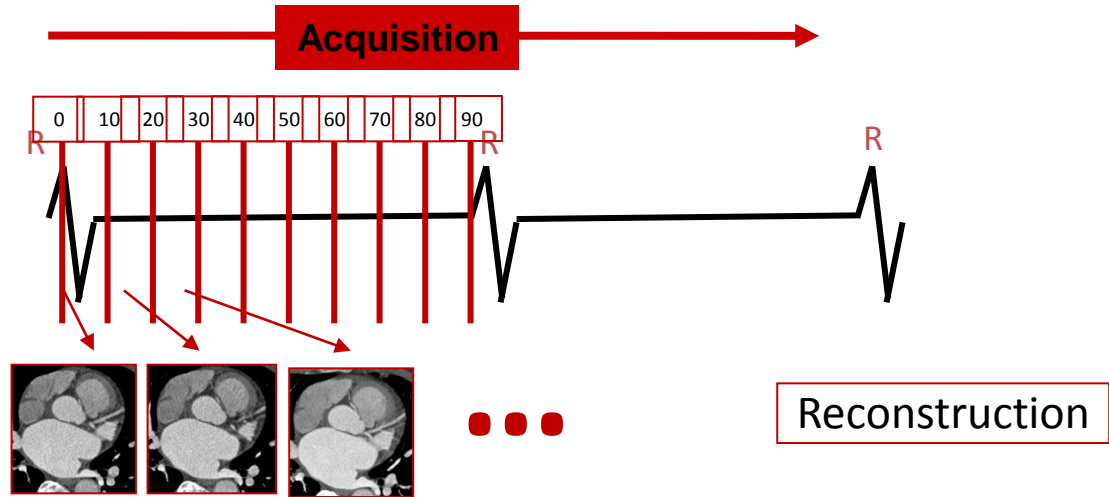
Aortic Root - Complex anatomy

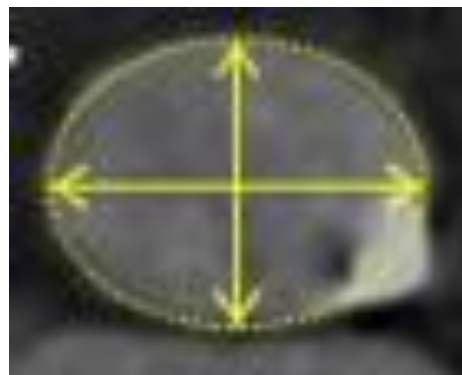
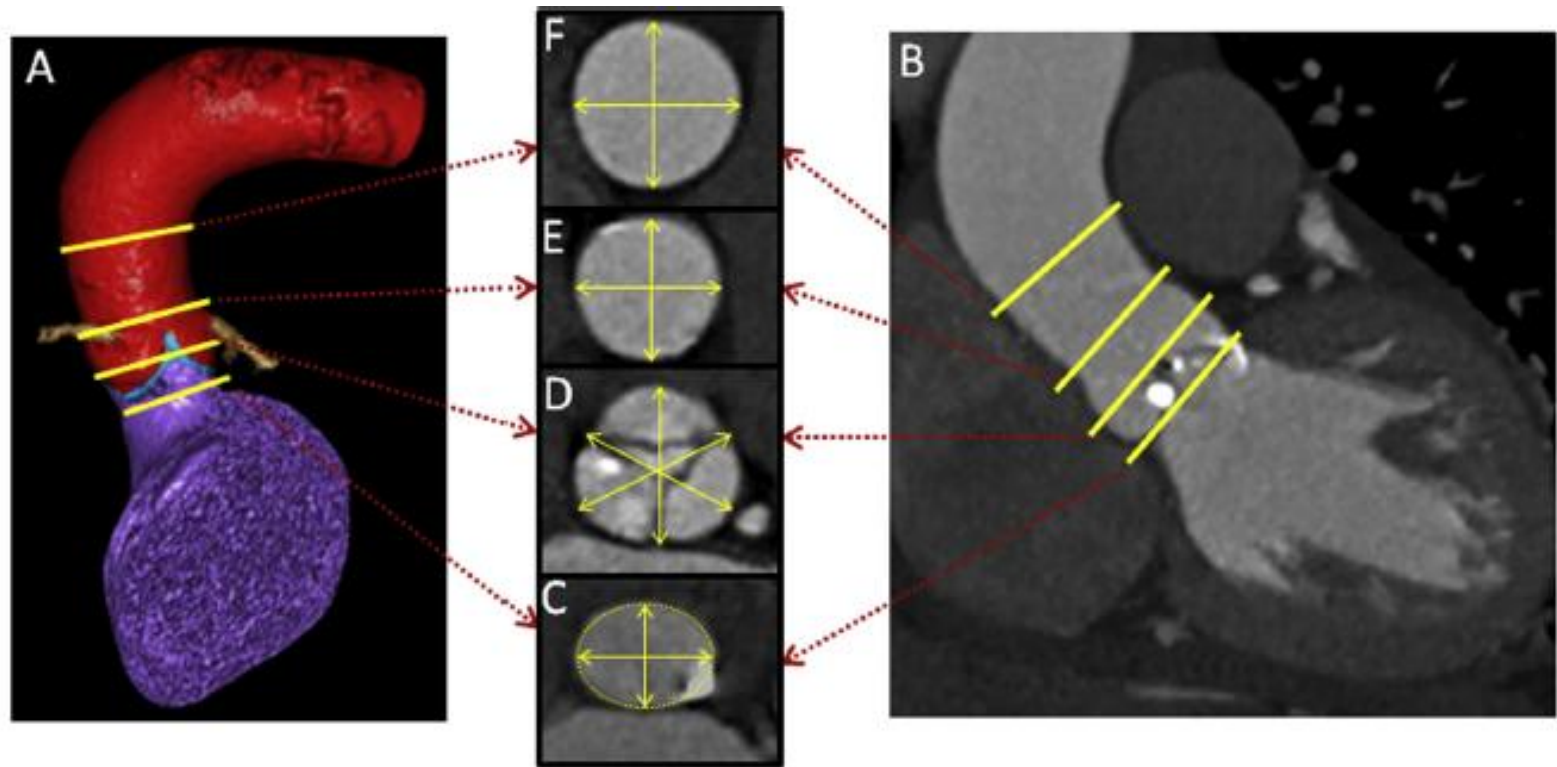


- Complex anatomy
- No direct vision of the aortic annulus as in surgery
- Accurate assessment of the aortic annulus is important for TAVI

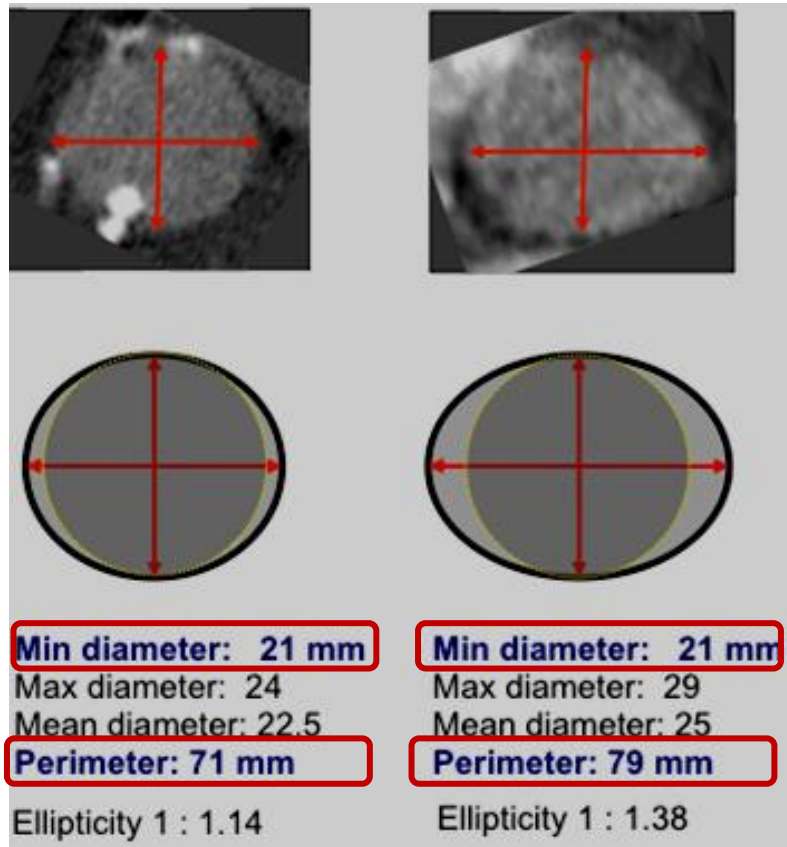
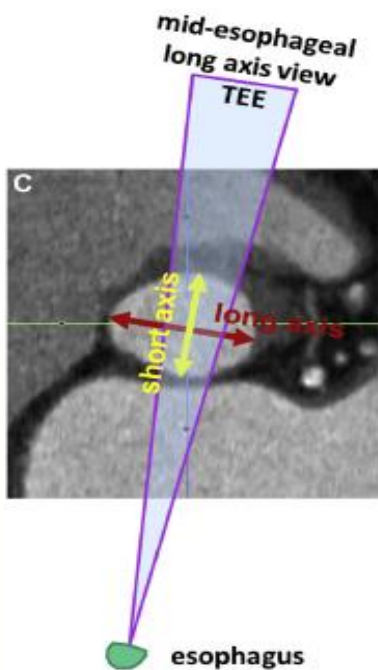
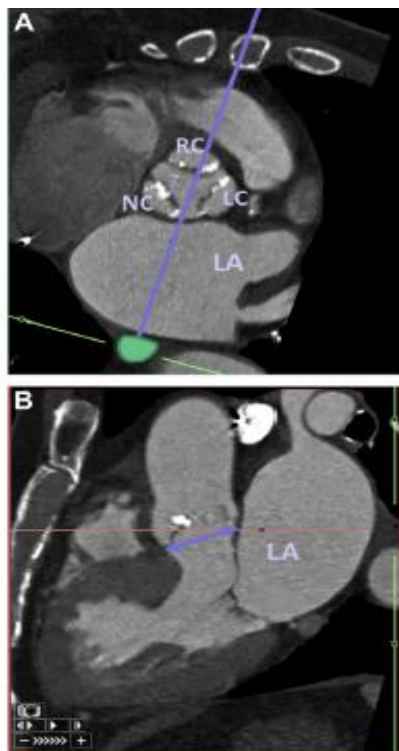
CT Scan: Data Acquisition

Retrospective gating

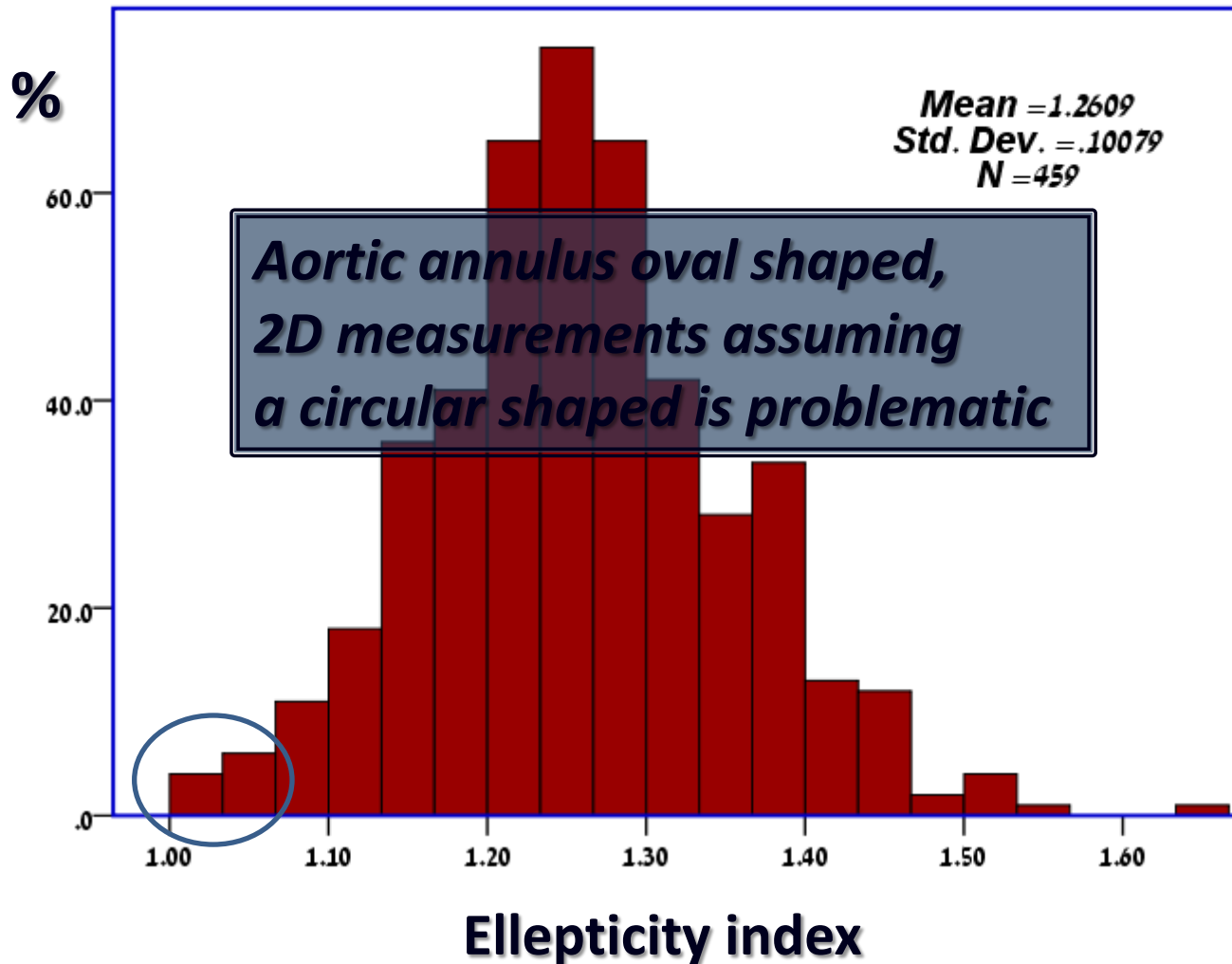




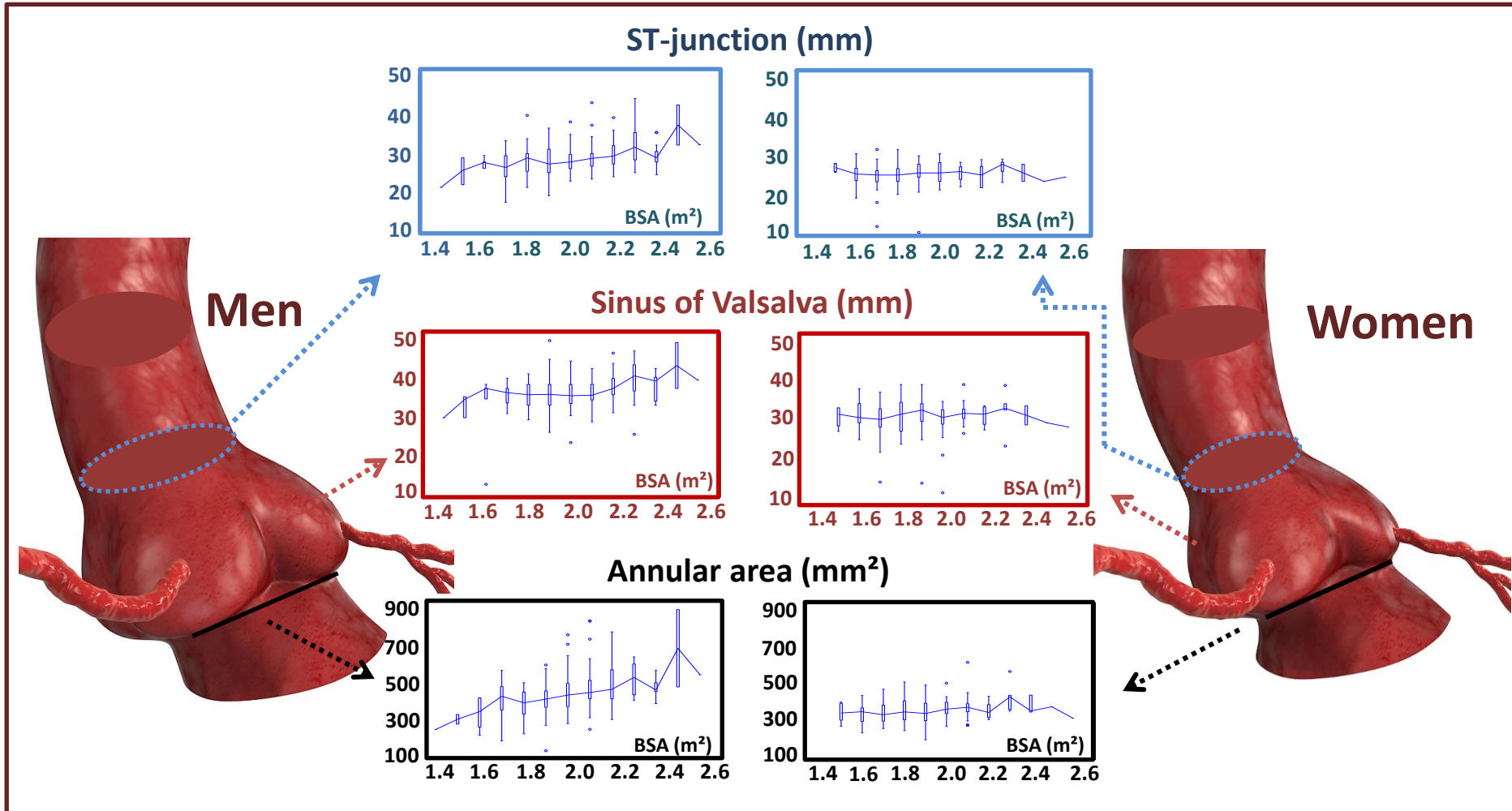
Why 1-D measurement (min diameter) of the aortic annulus is not enough?



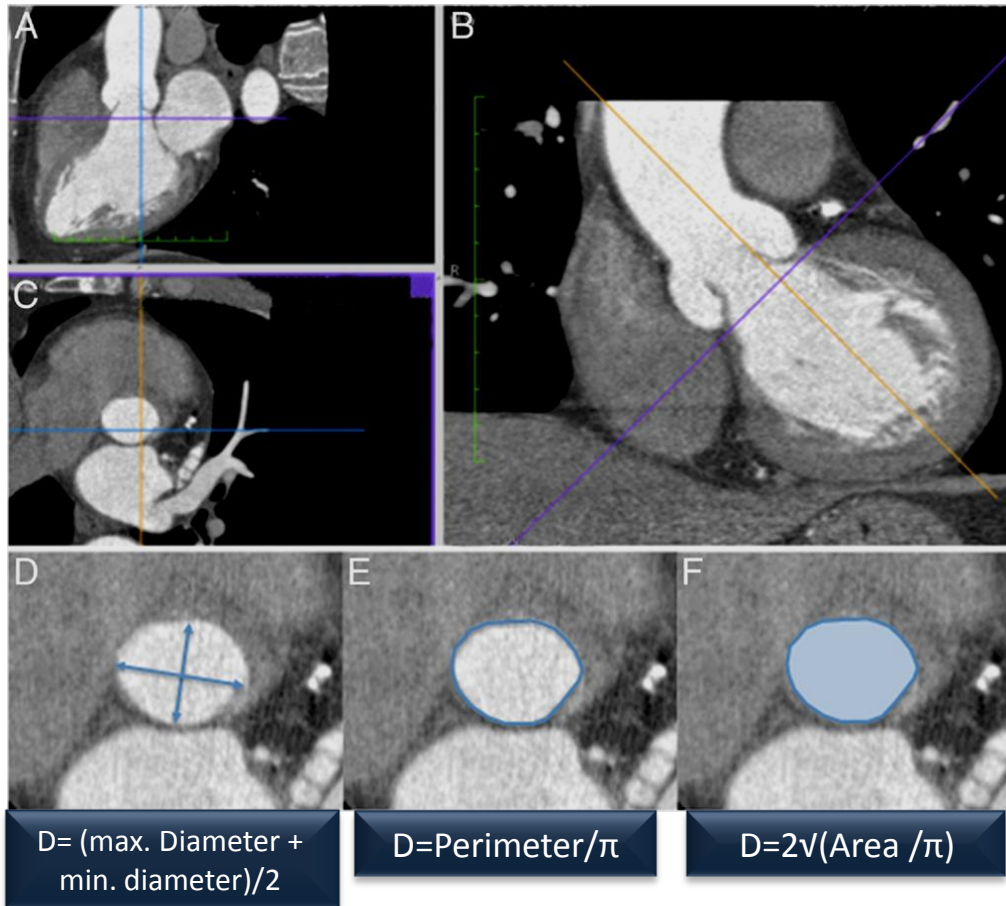
Distribution of Ellepticity index



Sex differences in aortic root and vascular anatomy



Which parameter should be used for aortic annulus assessment?



Multimodal Assessment of Aortic Annulus Diameter

	TAVI Strategy			Agreement With TTE		Agreement With TEE	
	23-mm Prosthesis	26-mm Prosthesis	No Implantation	n (%)	Kappa	n (%)	Kappa
Echocardiographic measurements							
TTE	5	29	11	—	—	37 (83)	0.68
TEE	6	25	14	37 (83)	0.68	—	—
MSCT measurements							
Virtual basal ring							
Long-axis	0	10	35	16 (36)	0.03	19 (42)	0.07
Short-axis	16	21	8	21 (47)	0.13	19 (42)	0.09
Mean	4	24	17	28 (62)	0.32	28 (62)	0.34
3-chamber view	7	25	13	27 (60)	0.28	26 (58)	0.27

CT would have modified the TAVI strategy in 42% of patients

Aortic annulus size

Prosthesis

Oversizing



Annular rupture

Prosthesis

Undersizing



Para-valvular
regurgitation



Embolization

Cross-Sectional Computed Tomographic Assessment Improves Accuracy of Aortic Annular Sizing for Transcatheter Aortic Valve Replacement and Reduces the Incidence of Paravalvular Aortic Regurgitation

Hasan Jilaihawi, BSc (HONS), MBCHB,* Mohammad Kashif, MD,* Gregory Fontana, MD,† Azusa Furugen, MD, PhD,* Takahiro Shiota, MD,* Gerald Friede, BS, MS,* Rakhee Makhija, Niraj Doctor, MBBS,* Martin B. Leon, MD,‡ Raj R. Makkar, MD*

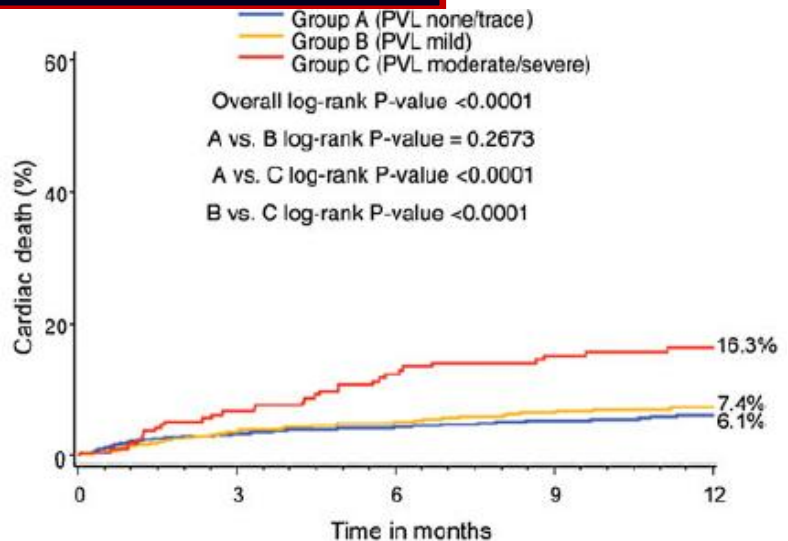
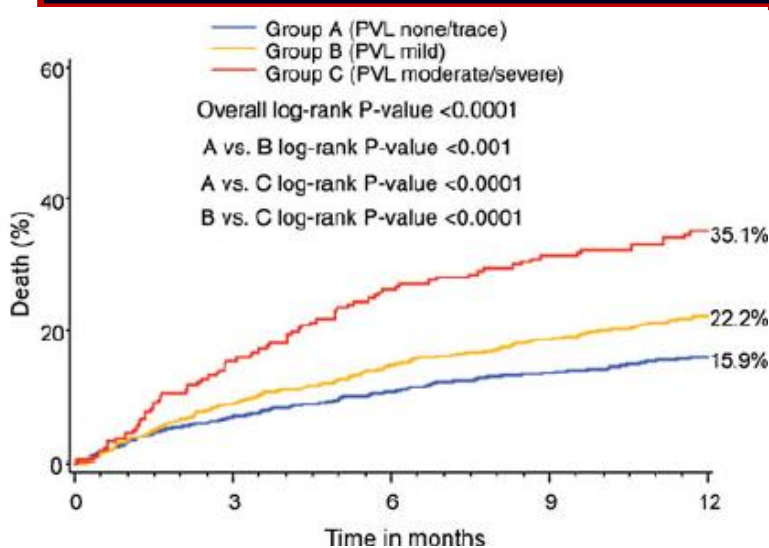
Los Angeles, California; and New York, New York

Outcomes	All Studied Patients (n = 136)	2D TEE-Guided Annular Sizing (n = 96)	Cross-Sectional CT-Guided Annular Sizing (n = 40)	p Value
PV AR				0.001
None	41 (30.1)	23 (24)	18 (45)	
Trivial or mild	71 (52.2)	52 (54.1)	19 (47.5)	
Mild-moderate	9 (6.6)	8 (8.3)	1 (2.5)	
Moderate	12 (8.8)	10 (10.4)	2 (5)	
Moderate-severe	3 (2.2)	3 (3.1)	0	
Severe		0	0	
PV AR > mild	24 (17.6)	21 (21.9)	3 (7.5)	0.045
Need for bail-out valve-in-valve	1 (0.7)	1 (1)	0	0.52
Annular rupture	1 (0.7)	1 (1)	0	0.52
Prosthesis instability (rocking)	1 (0.7)	1 (1)	0	0.52
Peri-procedural mortality	4 (3)	3 (3.2)	1 (2.5)	0.82

Paravalvular regurgitation after transcatheter aortic valve replacement with the Edwards sapien valve in the PARTNER trial: characterizing patients and impact on outcomes

Susheel Kodali^{1*}, Philippe Pibarot², Pamela S. Douglas³, Mathew Williams¹, Ke Xu⁴, Vinod Thourani⁵, Charanjit S. Rihal⁶, Alan Zajarias⁷, Darshan Doshi¹, Michael Davidson⁸, E. Murat Tuzcu⁹, William Stewart⁹, Neil J. Weissman¹⁰, Lars Svensson⁹, Kevin Greason⁶, Hersh Maniar⁷, Michael Mack¹¹, Saif Anwaruddin¹², Martin B. Leon¹, and Rebecca T. Hahn¹

- PVL following TAVI with Sapien valve in 2434 patients
- None/trace in 52.9%
- Mild in 38.0%
- **Moderate/severe in 9.1%.**

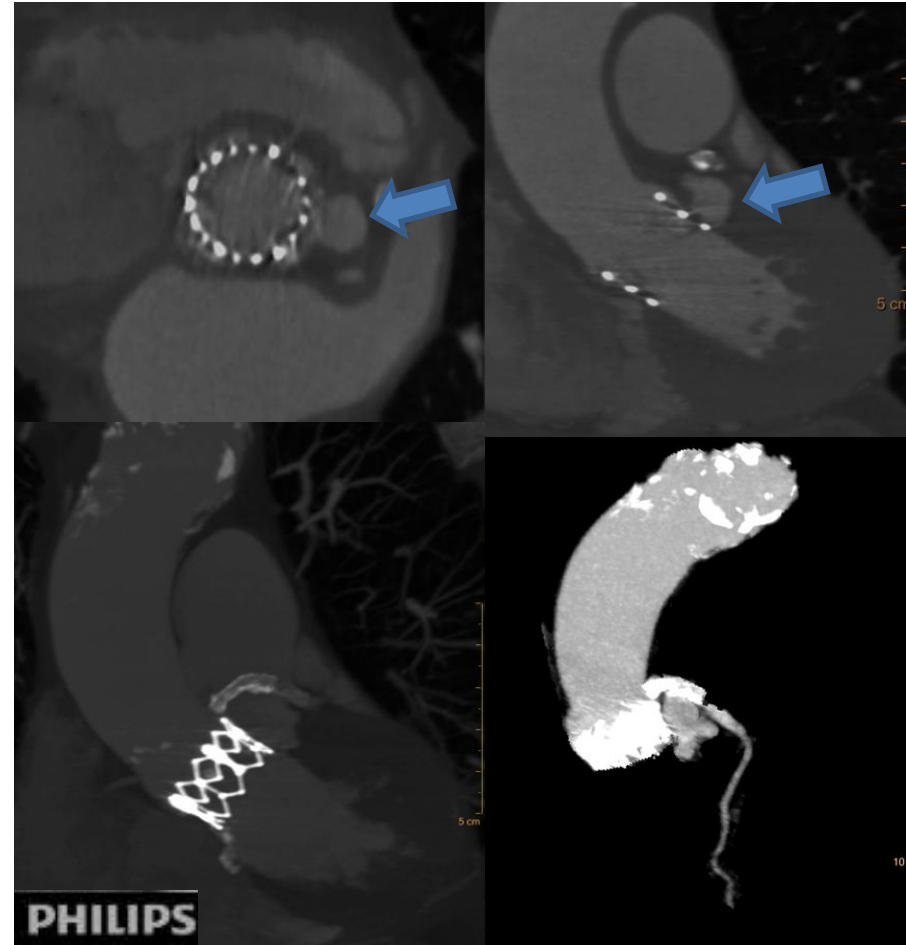


CT before TAVI



Perimeter interference (oversizing) = 15%
Area interference (oversizing) = 23%

CT after TAVI



Annular Rupture

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

- Occurred in **1.1%** Metaanalysis: JACC 2012
- Associated with high **mortality rate (48%)**: Circulation CV intervention 2012
- 16-Center Study center with 31 annular contained/noncontained rupture

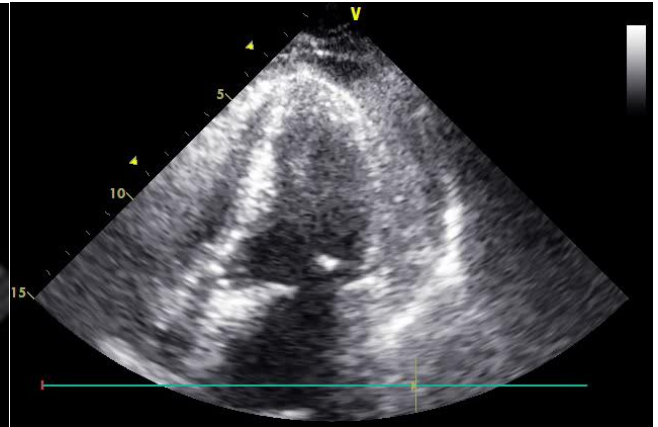
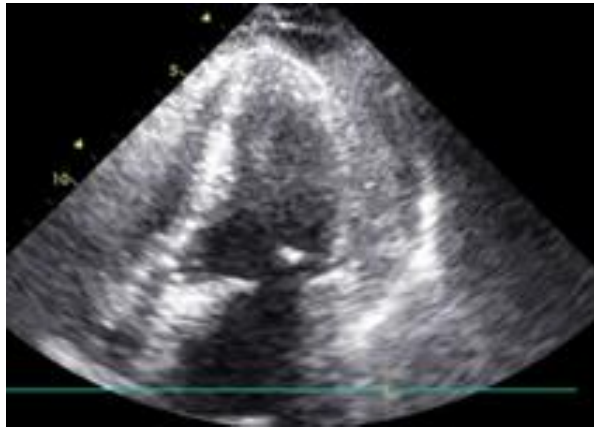
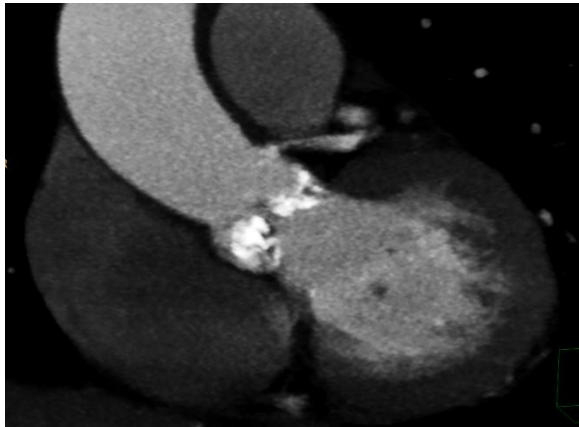
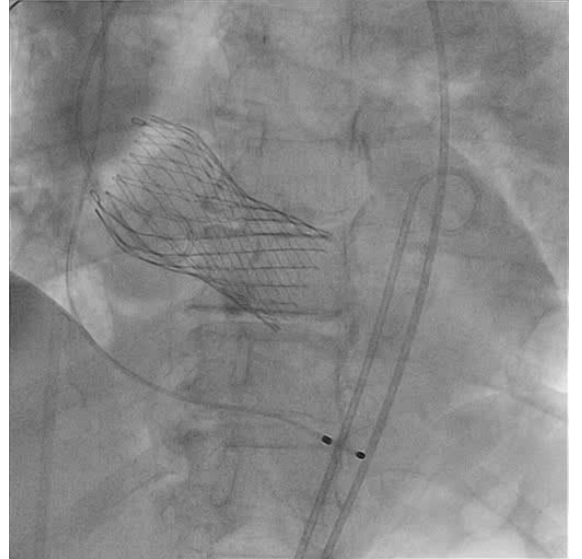
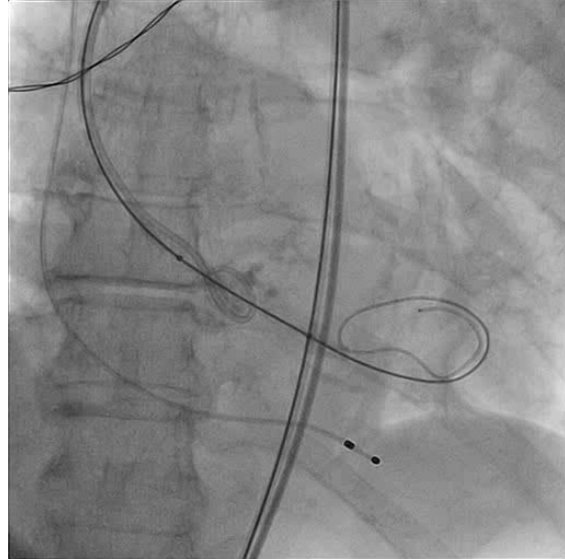
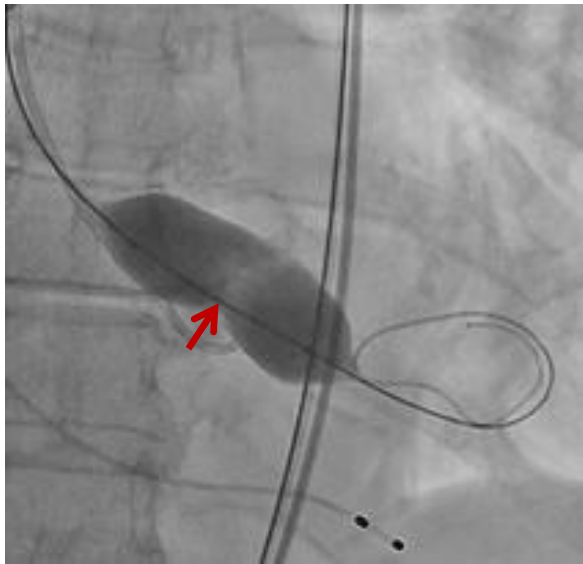
Predictors of aortic root rupture	Odds ratio	P value
LVOT subannular (Rt/Lt Cusp) calcification mod./severe	30.9 (3.23 – 36.91)	< 0.001
Prosthesis oversizing calculated by area(> 20%)	8.38 (2.67 – 26.33)	< 0.001
Balloon Postdilatation	<i>Sig. in univariate analysis only</i>	< 0.001

The Impact of Integration of a Multidetector Computed Tomography Annulus Area Sizing Algorithm on Outcomes of Transcatheter Aortic Valve Replacement

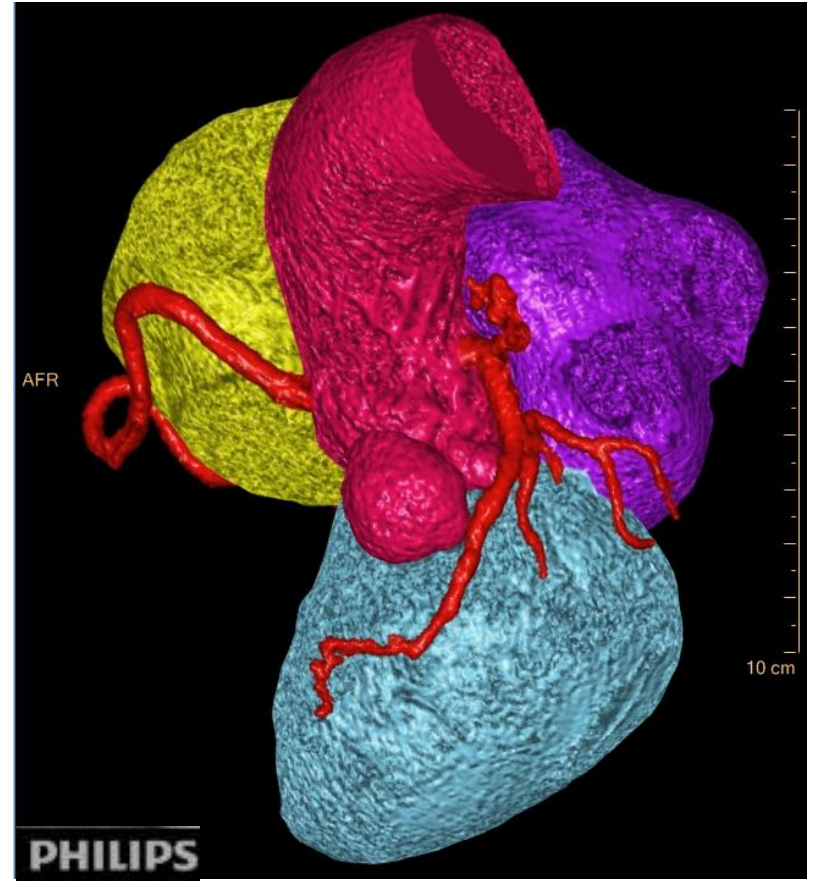
A Prospective, Multicenter, Controlled Trial

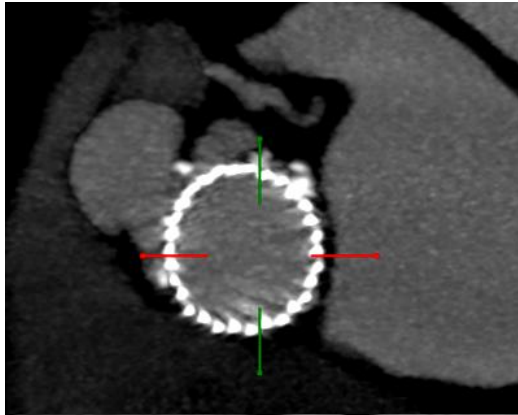
Balloon expandable valve
optimal goal: annulus area
oversizing (5% to 10%)

	MDCT Group (n = 133)	Control Group (n = 133)	p Value
Procedural mortality	0 (0)	0.8 (1)	0.316
In-hospital mortality	3.8 (5)	6.8 (9)	0.272
30-day mortality	5.3 (7)	6.8 (9)	0.606
Annular rupture	0.8 (1)	0.8 (1)	1.000
THV embolization	0 (0)	1.5 (2)	0.156
THV-in-THV implantation	0.8 (1)	2.3 (3)	0.314
Procedural myocardial infarction	0.8 (1)	0 (0)	0.316
Post-dilation	12.8 (17)	12.8 (17)	1.000
Permanent pacemaker implantation	8.3 (11)	9 (12)	0.827
Paravalvular regurgitation			
None	27.8 (37)	28.6 (38)	0.892
Mild	66.9 (89)	58.6 (78)	0.163
More than mild	5.3 (7)	12.8 (17)	0.032
Severe	0 (0)	4.5 (6)	0.013



Peri-aortic Hematoma/Pseudoaneurysm

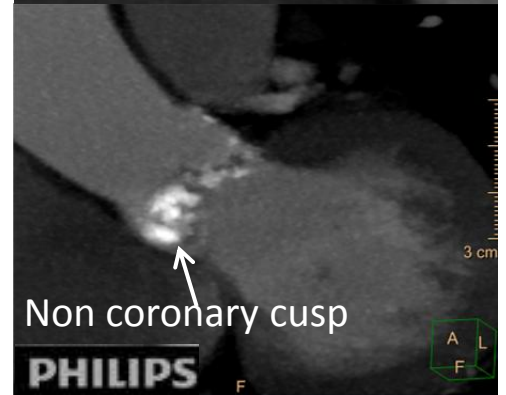
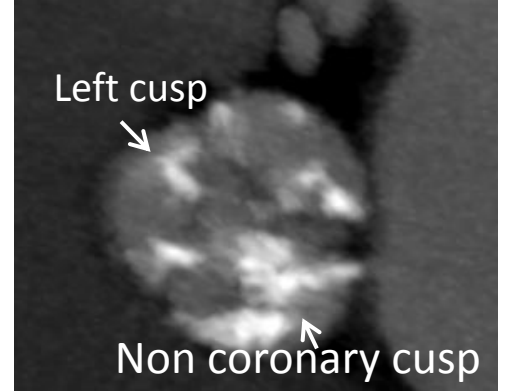
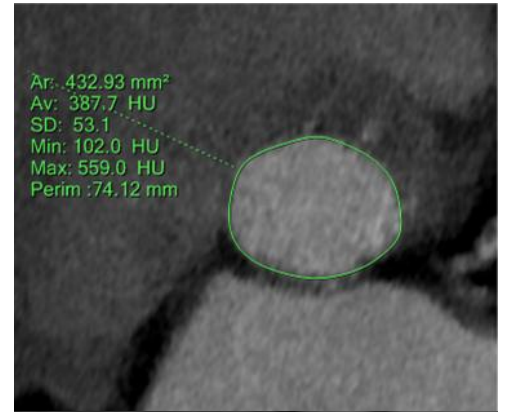
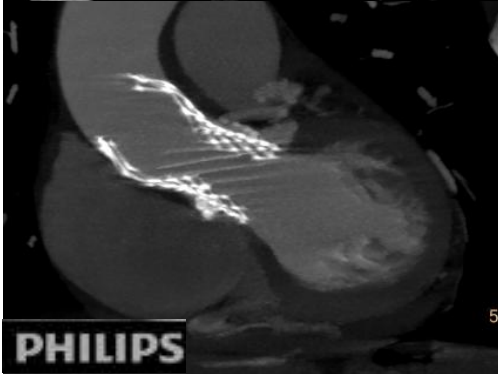
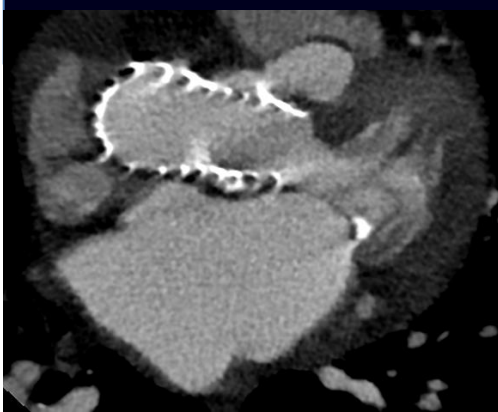
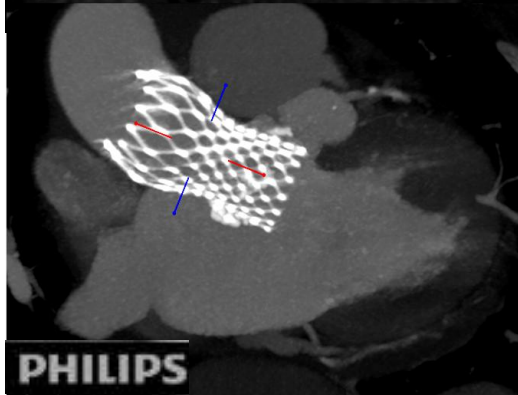
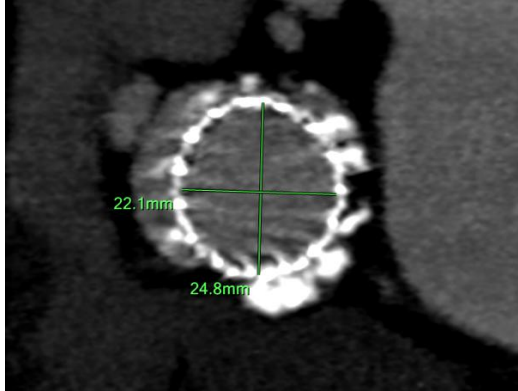




Core Valve 29

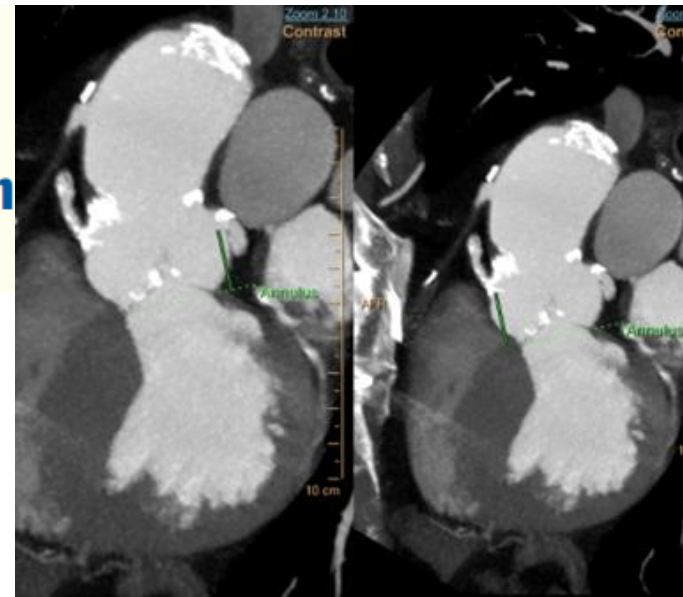
Perimeter interference = 23%

Area interference = 34%



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

Insights From a Large Multicenter Registry



- 44/66888 (0.66%)
- Predominantly LM
- More common in:
 - Women
 - Balloon-expandable TAVI
 - Valve in Valve

	Coronary Obstruction (n = 27)	Control Subjects (n = 27)	OR (95% CI)	p Value
Annulus diameter, mm	23.0 ± 0.6	23.6 ± 0.4	1.15 (0.92-1.45)	0.510
Annulus area, mm ²	410 ± 18	458 ± 17	1.01 (0.99-1.02)	0.126
Aortic SOV diameter, mm < 30mm	28.3 ± 0.8	31.3 ± 0.6	1.37 (1.13-1.66)	0.011
Relation prosthesis size/annulus	1.08 ± 0.02	1.05 ± 0.02	0.02 (0.01-3.99)	0.315
Relation SOV/annulus	1.26 ± 0.04	1.34 ± 0.03	20.0 (1.28-333)	0.003
Left coronary height, mm	10.7 ± 0.4	13.3 ± 0.3	2.17 (1.62-2.90)	<0.001
Right coronary height, mm	12.7 ± 0.8	14.2 ± 0.4	1.36 (1.10-1.68)	0.047
Calcium score, Agatston units	2,284 ± 318	2,733 ± 313	1.00 (0.99-1.10)	0.333

LM < 12 mm and SOV < 30 mm

- Obstruction 68%
- Control 13%

30-days mortality 41%

Ribeiro et al. JACC 2013; 62:1552

Approach to coronary obstruction risk assessment in VIV

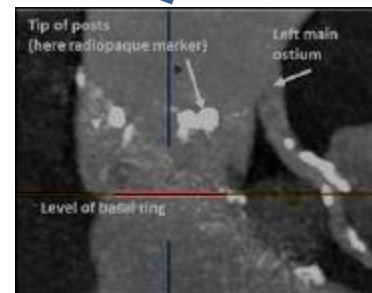
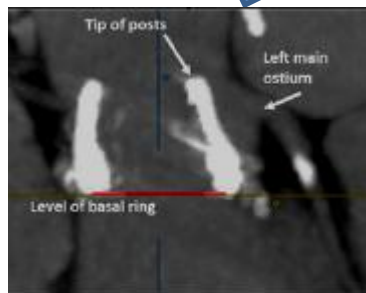
Assessment of valve type:
Stented vs. stentless

Stented

Level of coronary ostia

No

Yes



Potential risk of
coronary occlusion

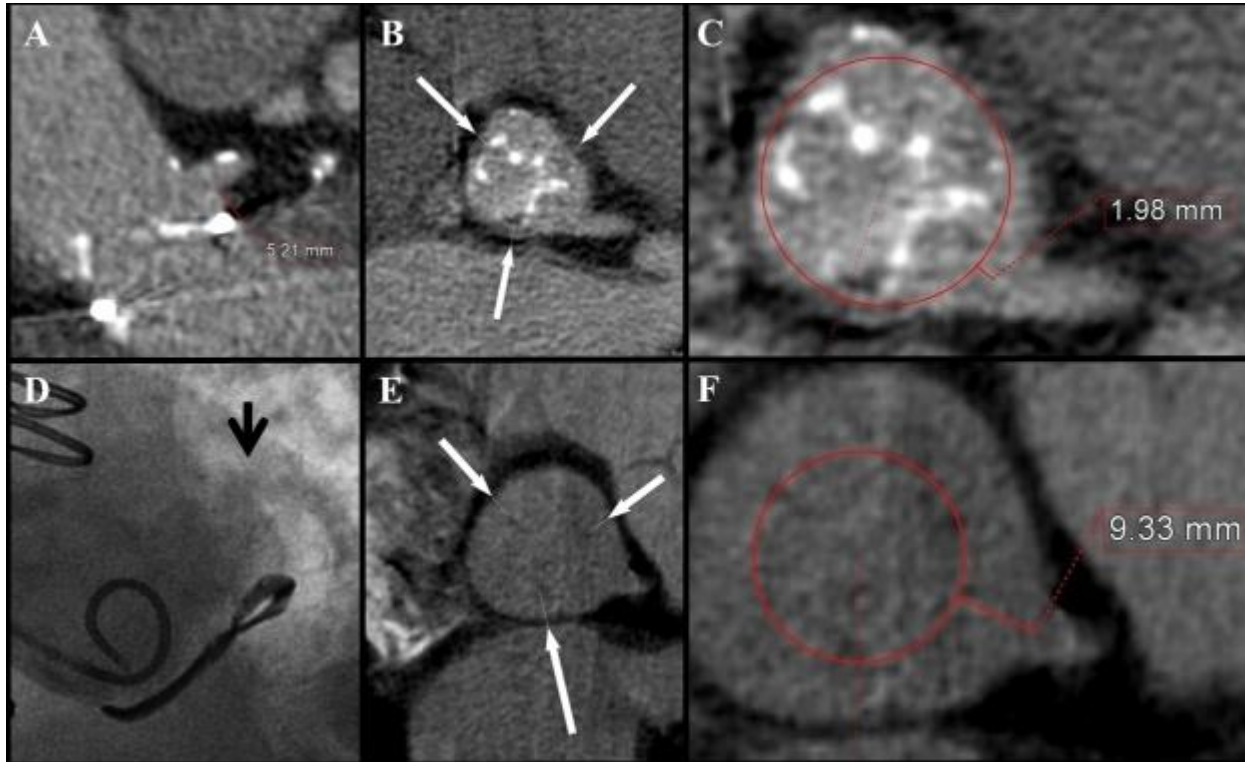
No risk of
coronary occlusion

Stentless

Coronary height and SoV
assessment

Assessment of VTC: virtual
distance between transcatheter
valve and coronary orifice

Assessment of VTC

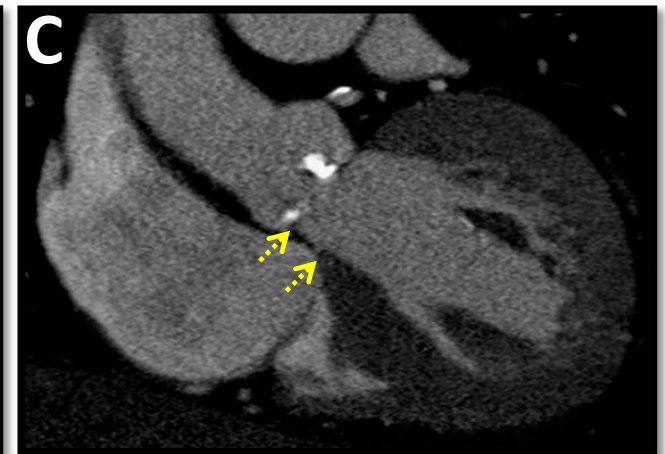
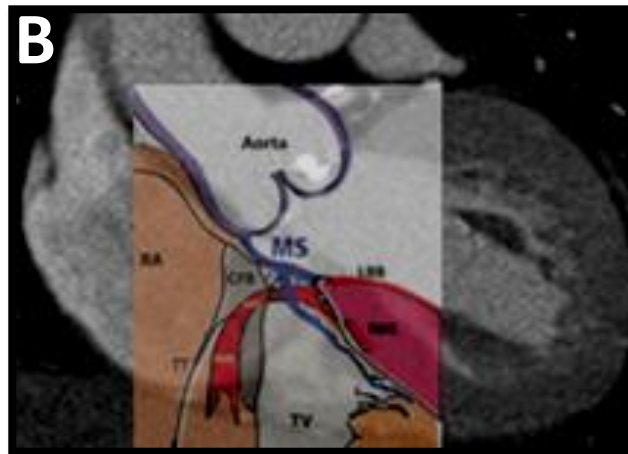
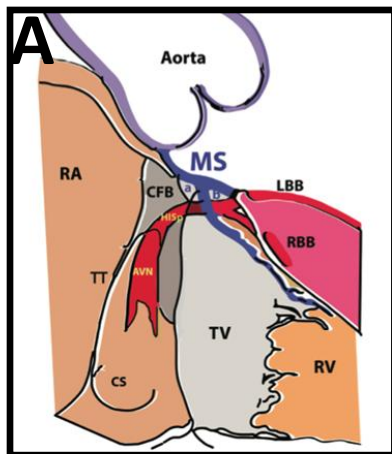


**High risk: <3 mm,
intermediate: 3 to 6 mm,
low: >6 mm**

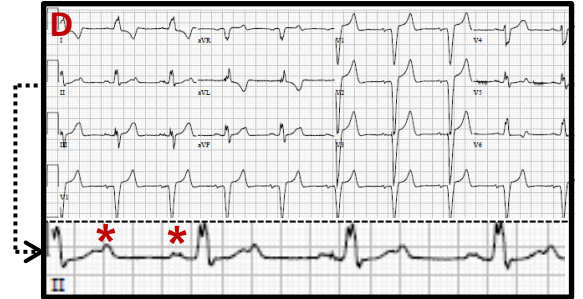
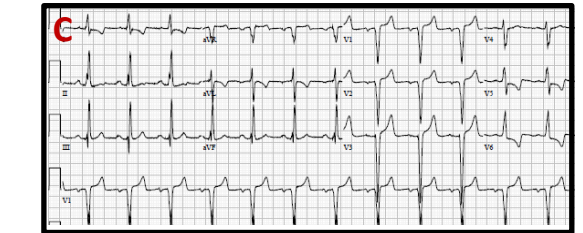
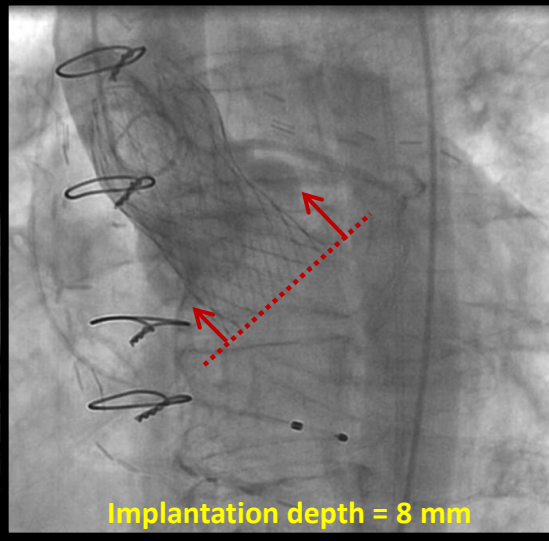
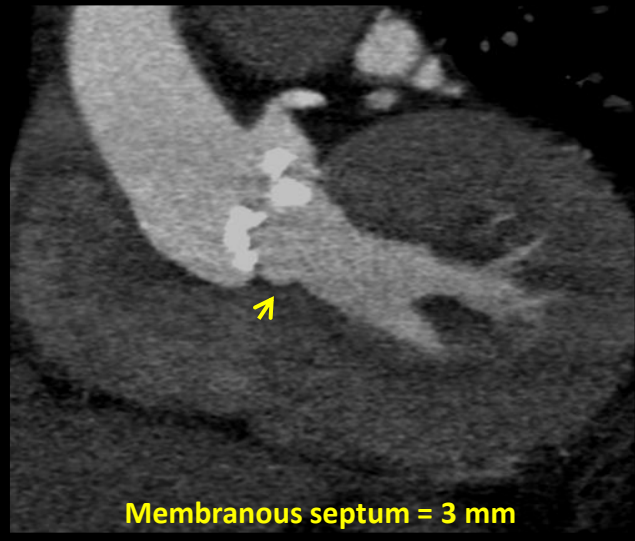


Inverse Relationship Between Membranous Septal Length and the Risk of Atrioventricular Block in Patients Undergoing Transcatheter Aortic Valve Implantation

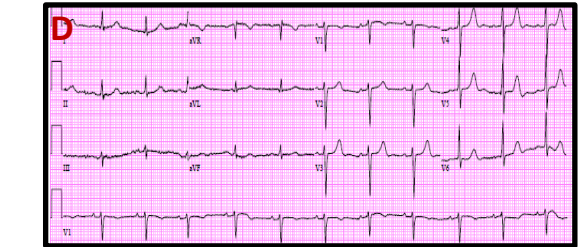
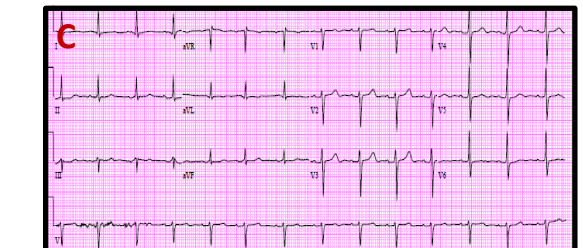
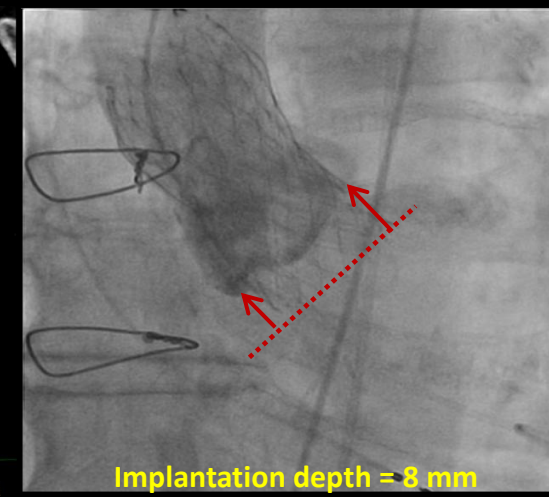
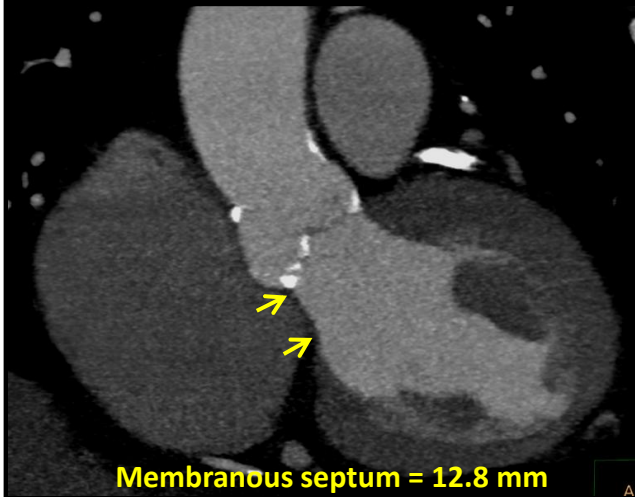
Ashraf Hamdan, MD,*† Victor Guetta, MD,* Robert Klempfner, MD,* Eli Konen, MD,† Ehud Raanani, MD,‡
Michael Glikson, MD,* Orly Goitein, MD,† Amit Segev, MD,* Israel Barbash, MD,* Paul Fefer, MD,*
Dan Spiegelstein, MD,‡ Ilan Goldenberg, MD,* Ehud Schwammenthal, MD, PhD*



Patients with PPM implantation after TAVI

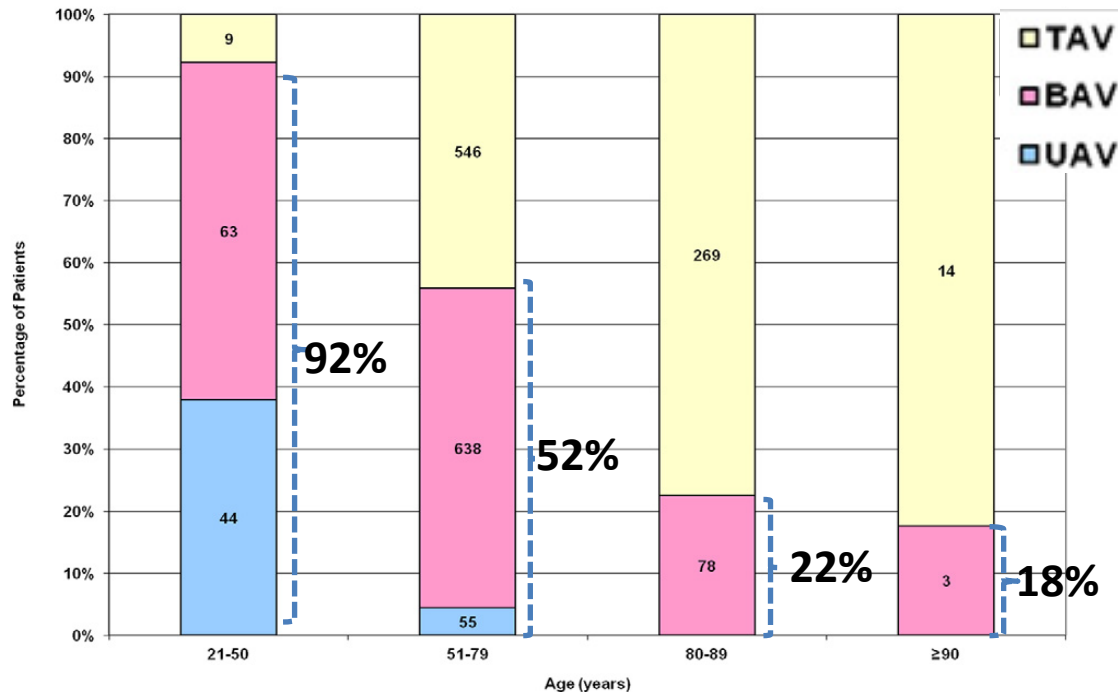


Patients without PPM implantation after TAVI

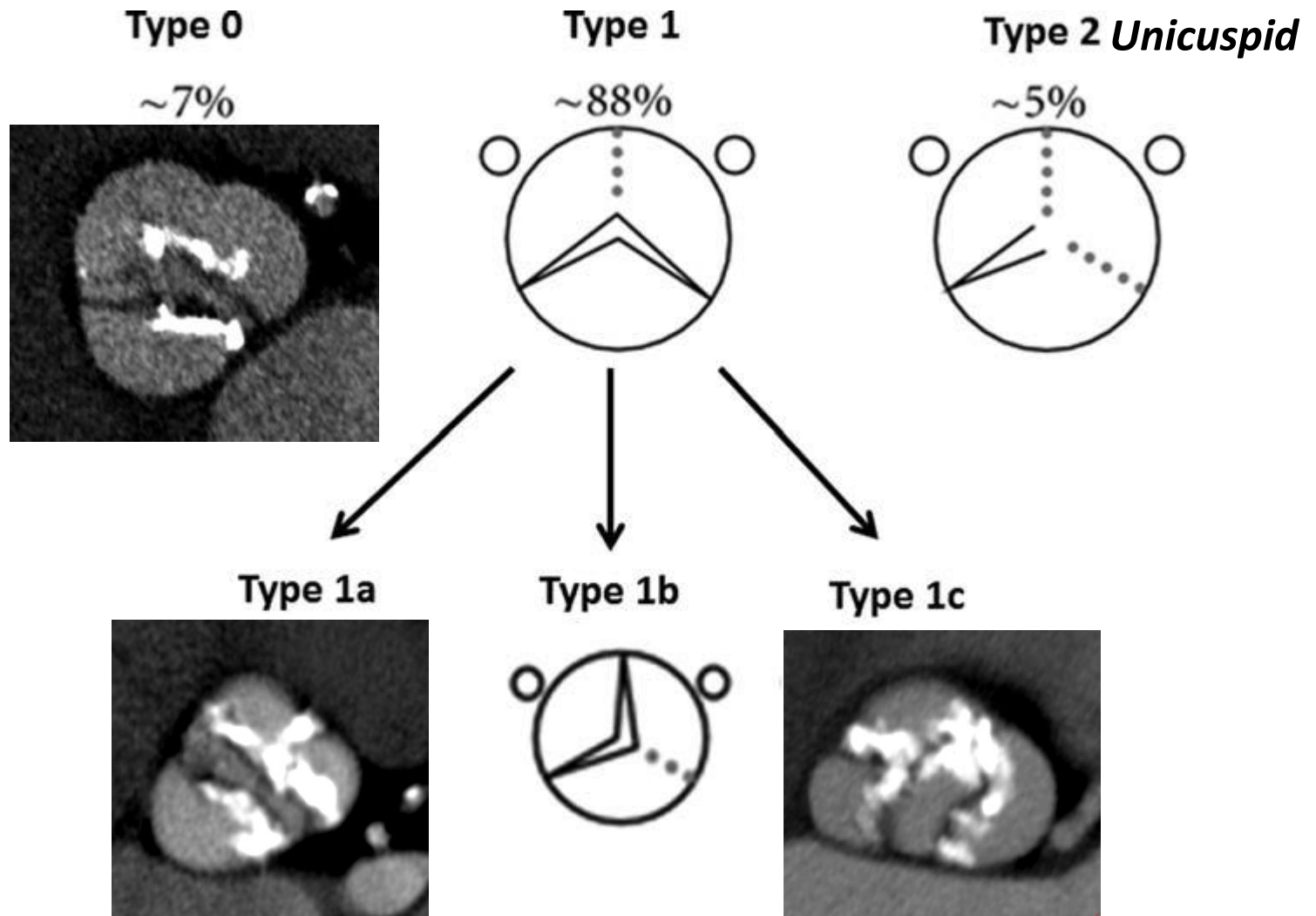


Frequency of Congenitally Bicuspid Aortic Valves in Patients >80 Years of Age Undergoing Surgical AVR

- The most common congenital heart disease: 1.3% of the population worldwide
- Bicuspid AV is the most common cause of AS requiring surgery in young adults

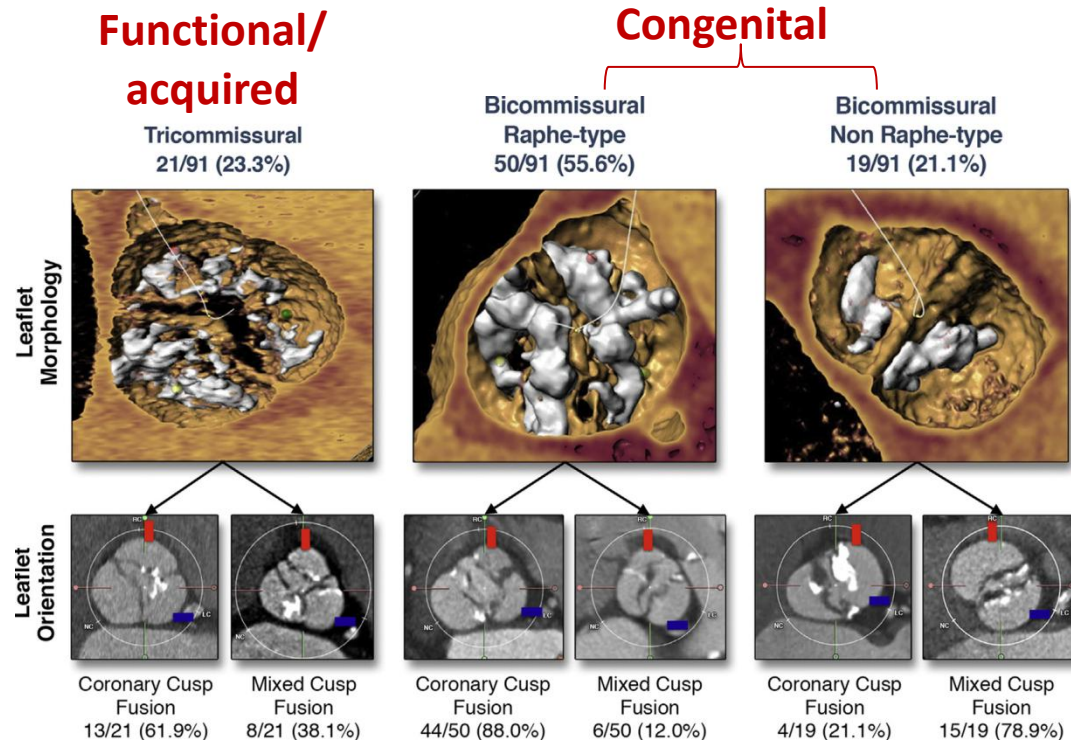


Traditional Classification of BAV by Sievers



A Bicuspid Aortic Valve Imaging Classification for the TAVI Era to better Predict Outcomes

- Possible predictors of post-procedural aortic regurgitation:
 - Inter-commissural distance
 - Absence of baseline CT
 - Raphe length > 4mm
 - Extent and distribution of calcium
 - Extent of leaflet asymmetry



Larger diameter of:
 STJ, Ascending aorta,
 intercommissural distance
 Annular rupture risk

Great Challenges for TAVI

- Diagnosis & complex anatomy
- Sizing:
 - Annular sizing
 - Supra-annular sizing
 - Balloon sizing
- Aortopathy
- Optimization of the positioning and full device expansion for:
 - Better final haemodynamics
 - Lower rate of AR and pacemaker implantation

Guidelines on the management of valvular heart disease (version 2012)

Table 10 Contraindications for transcatheter aortic valve implantation

Absolute contraindications
Absence of a 'heart team' and no cardiac surgery on the site
Appropriateness of TAVI, as an alternative to AVR, not confirmed by a 'heart team'
<i>Clinical</i>
Estimated life expectancy <1 year Improvement of quality of life by TAVI unlikely because of comorbidities Severe primary associated disease of other valves with major contribution to the patient's symptoms, that can be treated only by surgery
<i>Anatomical</i>
Inadequate annulus size (<18 mm, >29 mm ²)
Thrombus in the left ventricle
Active endocarditis
Elevated risk of coronary ostium obstruction (asymmetric valve calcification, short distance between annulus and coronary ostium, small aortic sinuses)
Plaques with mobile thrombi in the ascending aorta, or arch
For transfemoral/subclavian approach: inadequate vascular access (vessel size, calcification, tortuosity)
Relative contraindications
Bicuspid or non-calcified valves
Untreated coronary artery disease requiring revascularization
Haemodynamic instability
LVEF <20%
For transapical approach: severe pulmonary disease, LV apex not accessible

Transcatheter Aortic Valve Replacement in Bicuspid Aortic Valve Disease

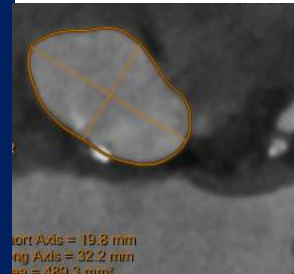
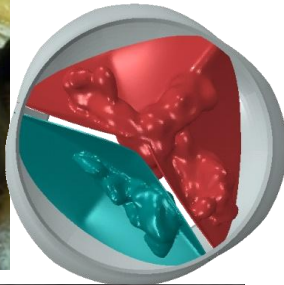


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- Multicenter study, 139 Bicuspid AS (9%)
- Old Generation valves: Saphien XT, Core Valve
- TAVR with is feasible in selected patients with BAV (device success of 90%, 1-year mortality of 17.5%, 30-day incidence of stroke of 2%)
- **Excess of aortic regurgitation: 28.4%**

Challenges: Complex Anatomy

- Extreme and asymmetric calcification
- Heterogeneity of leaflet morphology
- Densely calcified raphe
- Annular eccentricity,
- Calcification of the left ventricular outflow tract

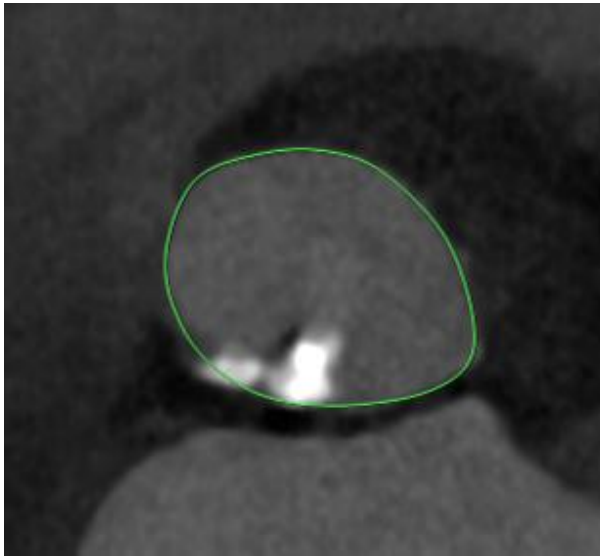


Advantages of 3D imaging (Cardiac CT)

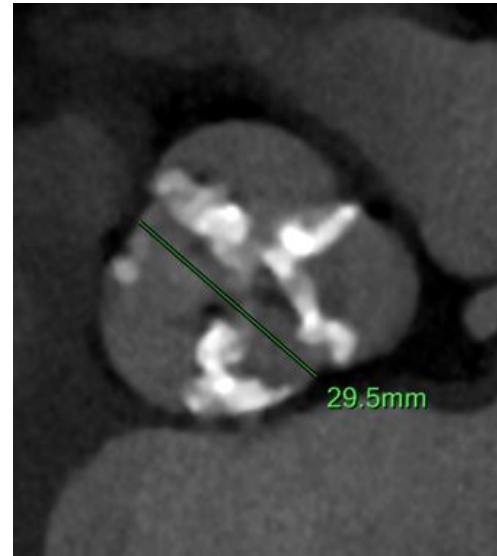
- Bicuspid AS is often **underestimated** by 2D-imaging and may sometimes be **overestimated*** (diagnostic performance 53-93%)
- Incidence of significant aortic regurgitation is high in old generation TAVI valve (24%) but **3D assessment (CT)** reduced aortic regurgitation to **17%**

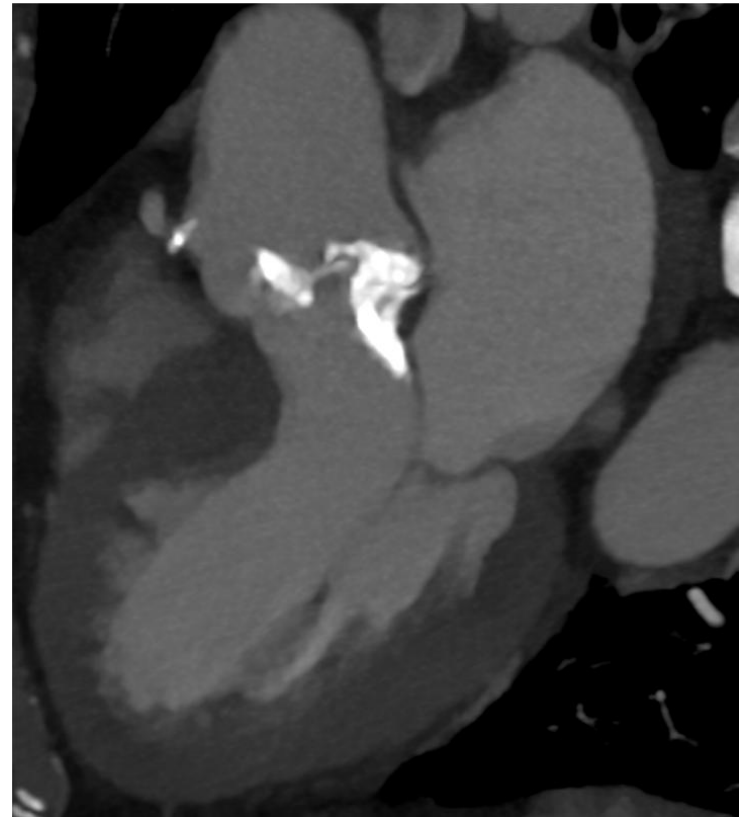
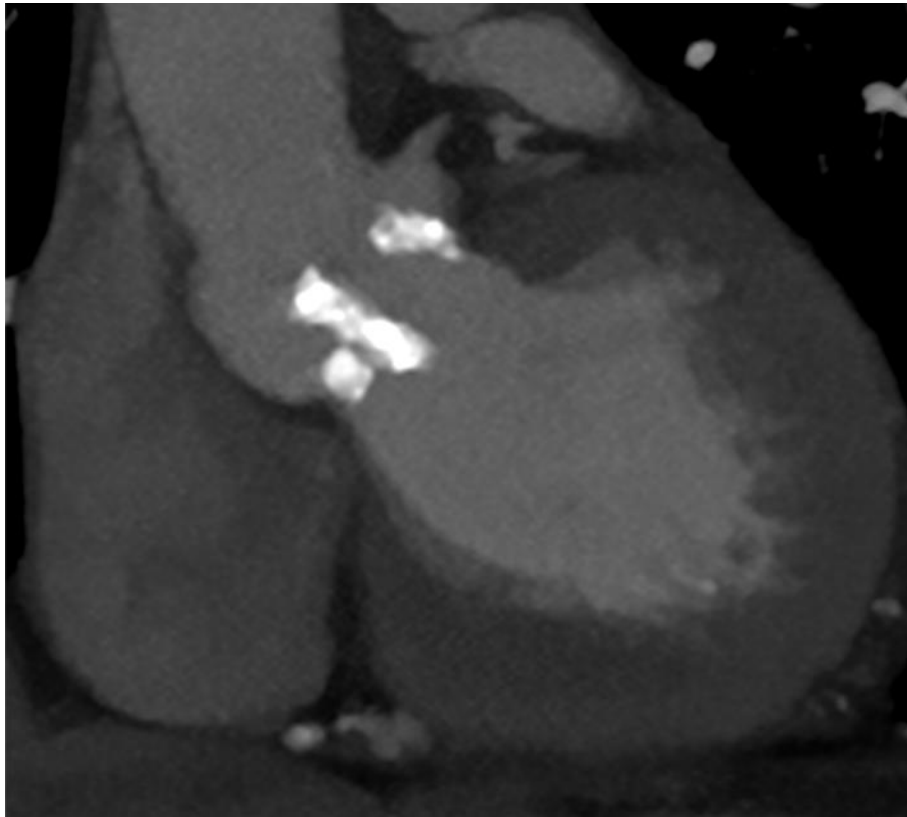
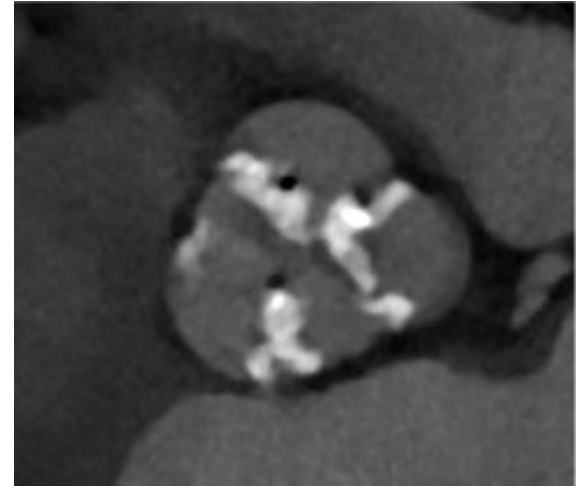
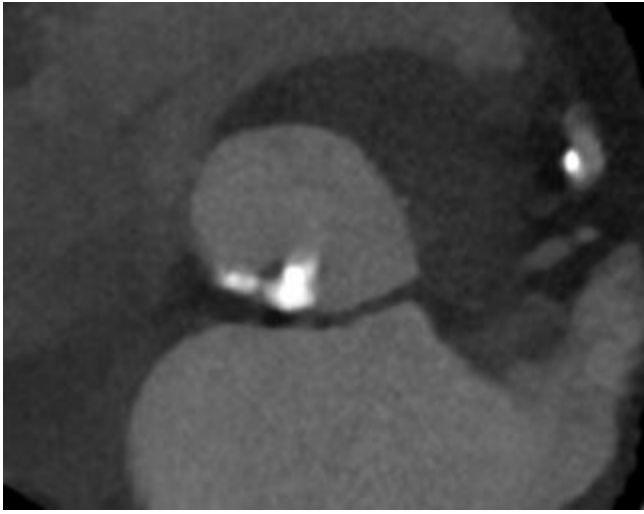
Challenges: TAVI Sizing

**Annular
method**

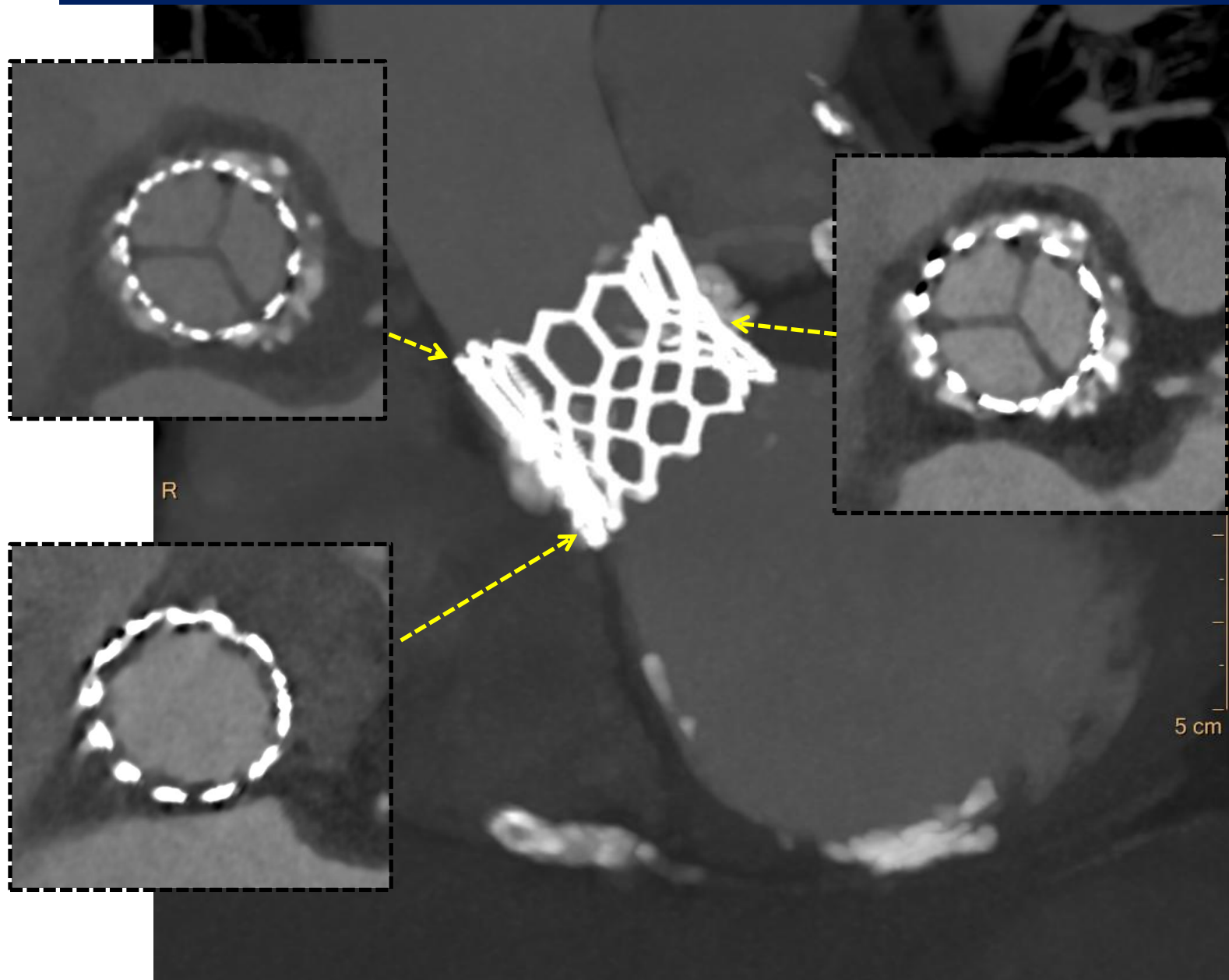


**Commissure to Commissure
method**



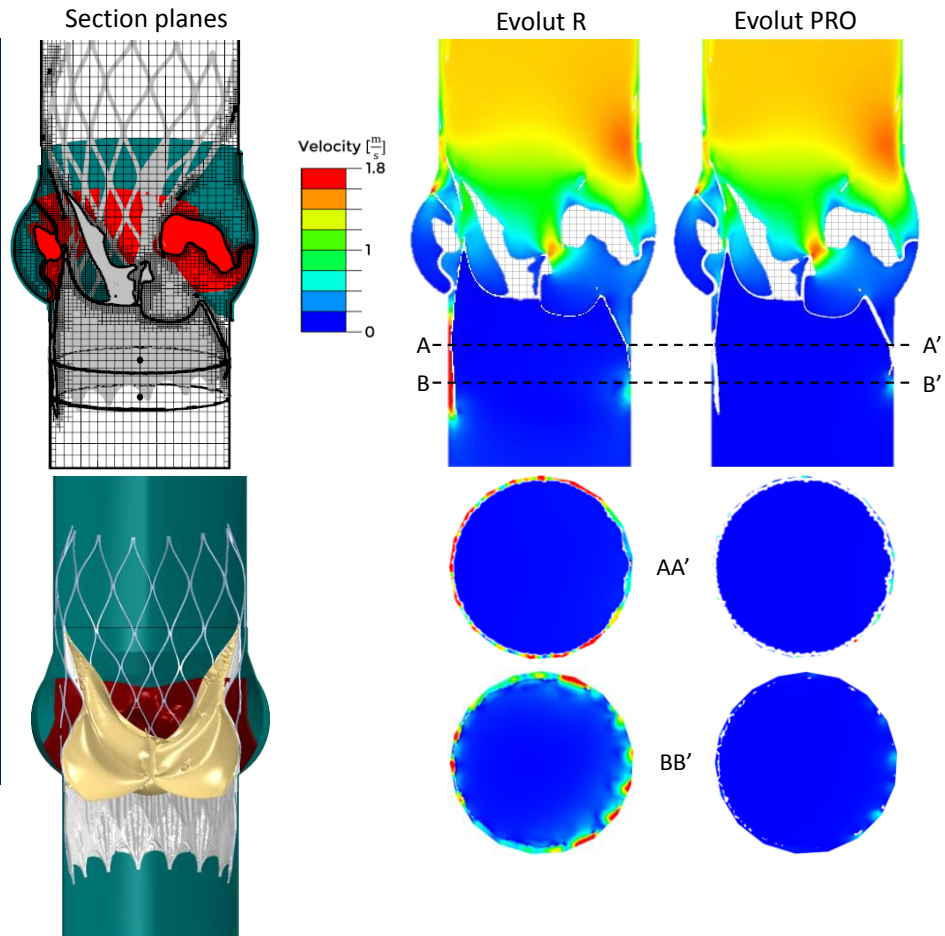


Challenges: TAVI Deployment



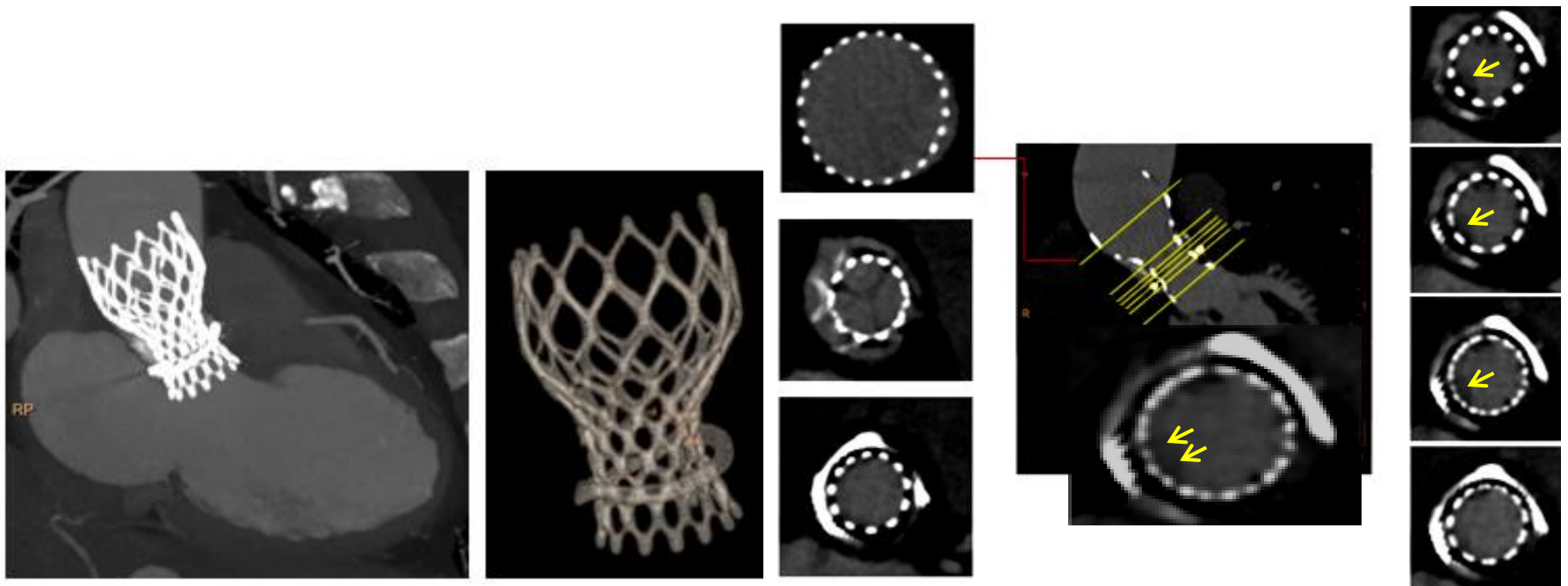
TAVI deployment

- The regurgitant flow through the Evolut PRO is 20 times smaller than in the Evolut R
- The presence of the outer cuff in the Evolut PRO leads to a reduction in the degree of paravalvular leaks with respect to the Evolut R when deployed in BAV



Post-TAVI CT

- A 78-year-old woman
- 10 y: Surgical AVR Mitroflow 21mm
- 7 months: TAVI Evolute-R-23 mm for degenerative Mitroflow valve
- Clinical presentation: effort dyspnea
- Echo: increased gradient (peak gradient 46 mmHg)

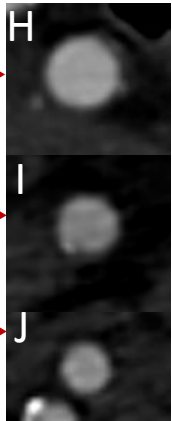
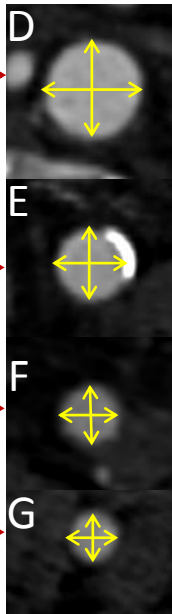
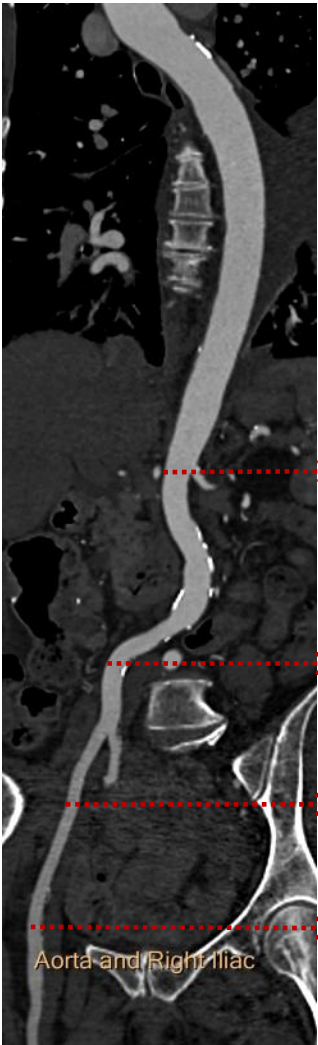


Peripheral access

Minimal lumen diameter

Vascular calcification

Tortuosity



Reduction of Vascular Complication

Predictors of VARC major vascular complications

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)

Hayashida K. JACC Cardiovasc Interv 2011

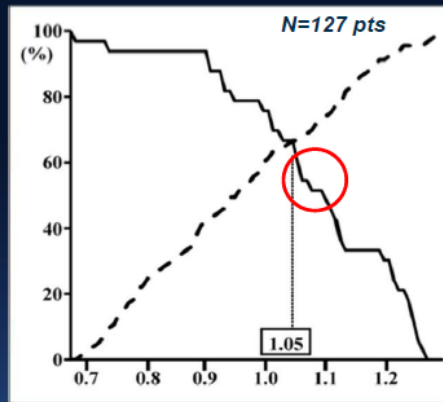


Figure 2. SFAR Threshold Predicts VARC Major Vascular Complications

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

137 consecutive pts undergoing TAVR during 2009 and 2010 were prospectively evaluated

From 2009 to 2010:

- **Major** vascular complications decreased from **8% to 1%**
- **Minor** vascular complications decreased from **24% to 8%**
- **Major bleeding** fell from **14% to 1%**

- **Moderate-to-severe arterial calcification** 3-fold increase in vascular complications (29% vs. 9%)
- **minimal arterial lumen diameter** less than that of the external sheath showed a 4-fold increase (23% vs. 5%)

Key messages

- **Major role of CT** for the assessment of morphology /sizing of the valve, aortic root and the ascending aorta – major role for device selection
- Field is moving from historical device selection based on sex or 2 D measurements to a truly patient's specific approach to TAVI selection
- **Patient's specific anatomy** (not the STS score) predict the risk in TAVI
- There will be **zero tolerance for adverse outcomes** with TAVI in intermediate and low-risk patients, as these patients continue to be excellent candidates for surgery
- Bicuspid valves are not a contraindication to TAVI with equivalent outcomes to tricuspid valves