## TAVR Procedural Optimization for Asian Patients with Small Valve Size

## 11<sup>TH</sup> AP VALVES & STRUCTURAL HEART 2022 12/08/2022 1000 TO 1010

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# TAVI in SAA -Definition of SAA



# Definition of Small Aortic Annulus (SAA)

Many cutoffs

Some use cutoff based on THV used

Based on minimum size of BE-THV, <u>Area < 330mm<sup>2</sup></u>

3D Area-derived Diame	eter (mm)	18.0	18.2	18.5	18.6	18.9	19.0	19.2	19.6	19.9	20.0	20.2	20.5	20.7	21.0	21.1	21.4	21.7	22.0	22.3	22.6	22.8	23.0	23.1	23.4
3D Annular Area (mm²	)	254	260	270	273	280	283	290	300	310	314	320	330	338	345	350	360	370	380	390	400	410	415	420	430
	20 mm	29.1	26.2	21.5	20.1	17.1	15.9	13.1	9.3	5.8	4.5	2.5	-0.6	-3.0	-4.9	-6.3	-8.9								
% Annular Area Over (+) or	23 mm										29.3	26.9	23.0	20.1	17.7	16.0	12.8	9.7	6.8	4.1	1.5	-1.0	-2.2	-3.3	-5.6
Under (-) Nominal by 3D CT	26 mm																				29.8	26.6	25.1	23.6	20.7
	29 mm																								
													1												

Puri R, Byrne J, Muller R, et al. Transcatheter Aortic Valve Implantation in patients with small aortic annuli using a 20mm balloon-expandable valve. Heart 2017; 103: 148-153

Okuyama K, Izumo M, Ochiai T, et al. New-generation Transcatheter Aortic Valves in patients with small aortic annuli. Cir J 2020; 84: 2015-2022



3D Area-derived Diam	eter (mm)	18.0	18.2	18.5	18.6	18.9	19.0	19.2	19.6	19.9	: 0.0	20.2	20.5	20.7	21.0	21.1	21.4	21.7	22.0	22.3	22.6	22.8	23.0	23.1	23.4
3D Annular Area (mm	2)	254	260	270	273	280	283	290	300	310	314	320	330	338	345	350	360	370	380	390	400	410	415	420	430
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Under (-) Nominal by	26																				29.8	26.6	25.1	23.6	20.7
3D CT	26 mm																				25.0	20.0	2.5.11		

Meguro K, Kumamaru H, Kohsaka S, et al. Transcatheter Aortic Valve Replacement in patients with a small annulusc- from the Japanese Nationwide Registry (J-TVT). Circ J 2021; 85: 9670976

### < 314mm<sup>2</sup> = "extremely small"

Yashima F, Yamamoto M, Tanaka M, et al. Transcatheter aortic valve implantation in patients with an extremely small native aortic annulus: The OCEAN-TAVI Registry. Int J Cardiol. 2017 Aug 1;240:126-131

### Mean Diameter <= 23mm (small annulus), <= 21mm (extremely small annulus)</p>

		(XX ~ XX)
Size	23 mm	26 mm
Annulus Diameter (A)	17*/18-20 mm	20-23 mm
Annulus Perimeter†	53.4*/56.5-62.8 mm	62.8-72.3 mm
Sinus of Valsalva Diameter (Mean) (B)	≥25 mm	≥27 mm
Sinus of Valsalva Height (Mean) (C)	≥15 mm	≥15 mm

Meguro K, Kumamaru H, Kohsaka S, et al. Transcatheter Aortic Valve Replacement in patients with a small annulusc- from the Japanese Nationwide Registry (J-TVT). Circ J 2021; 85: 9670976

Abdelghani M, Mankerious N, Allali A, et al. Bioprosthetic valve performance after transcatheter aortic valve replacement with self-expanding versus balloon-expandable valves in large versus small aortic valve annuli – Insights from the CHOICE-Extend Registry. J Am Coll Cardiol Intv 2018; 11:2507-18

## SAA in Asian Population

Asian populations - significantly smaller AA diameter than European

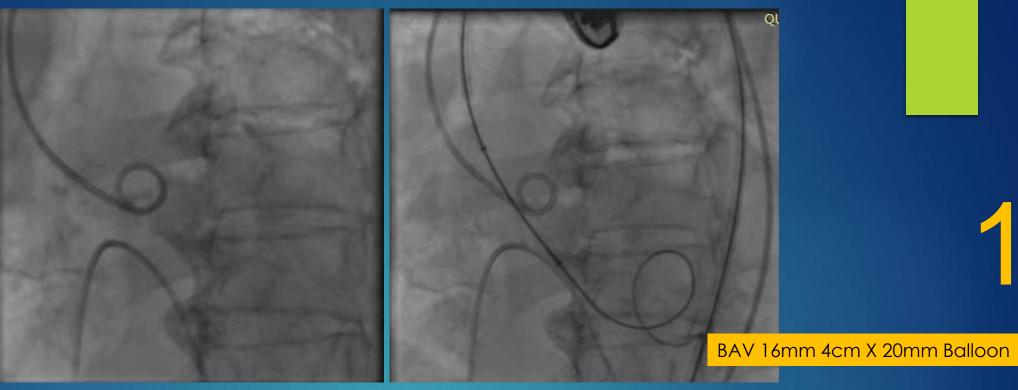
20.4±1.46mm vs 22.0±1.84mm, P< 0.01</p>

Watanabe Y, Hayashida K, Takayama M, Mitsudo K, et al. First direct comparison of clinical outcomes between European and Asian cohorts in transcatheter aortic valve implantation: the Massy study group vs. the PREVAIL JAPAN trial. J Cardiol. 2015 Feb;65(2):112-6. doi: 10.1016/j.jjcc.2014.05.001

BSA – Asian (1.4m2) vs European (1.72±0.18m2)

# TAVI in SAA -Verifying "Truly" Small Annuli





### **F/82 DM IHD Severe AS** Area: 40% 245.9mm2 CT 20.6 mm X 14.5 mm TEE 17mm



# TAVI in SAA -Clinical Challenges of SAA



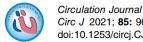
## Problems associated with SAA

Has been associated with poor outcomes after surgical AVR

- Mortality
- Ischaemic CV events and stroke
- Increased risk of Prosthesis-patient mismatch (PPM)
  - Increased risk of perioperative and overall mortality
    - Suboptimal valve haemodynamics
    - Less LV mass regression after AVR

### Surgical Ways to tackle

Root enlargement Stented prosthesis with supra-annular implantation Stentless bioprosthesis Sutureless valves



*Circ J* 2021; **85:** 967–976 doi:10.1253/circj.CJ-20-1084

### **ORIGINAL ARTICLE**

TAVR

### **Transcatheter Aortic Valve Replacement** in Patients With a Small Annulus

- From the Japanese Nationwide Registry (J-TVT) -

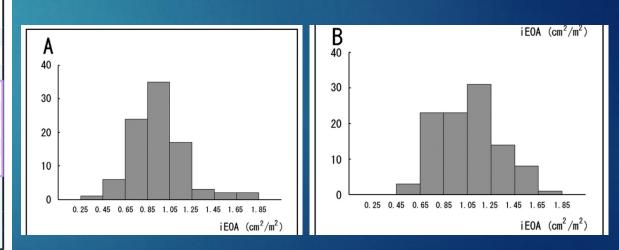
Kentaro Meguro, MD, PhD; Hiraku Kumamaru, PhD; Shun Kohsaka, MD, PhD; Takuya Hashimoto, MD, PhD; Ryota Kakizaki, MD, PhD; Tadashi Kitamura, MD, PhD; Hideyuki Shimizu, MD, PhD; Junya Ako, MD, PhD

Table 2. Clinical and Echocardiographic Out	tcomes Within 30 Days	S	
	Small annulus (n=647)	Normal-sized annulus (n=5,223)	P value
Clinical outcomes			
30-day mortality	9 (1.4)	35 (0.7)	0.05
New pacemaker implantation	42 (6.5)	287 (5.5)	0.30
Stroke	14 (2.2)	75 (1.4)	0.15
Echocardiographic outcomes			
Effective orifice area (cm <sup>2</sup> )	1.5 (1.2–1.8)	1.7 (1.4–2.0)	<0.001
Indexed effective orifice area (cm <sup>2</sup> /m <sup>2</sup> )	1.10 (0.92–1.35)	1.16 (0.96-1.39)	<0.001
Mean pressure gradient (mmHg)	10.0 (6.9–14.2)	8.5 (6.0–11.5)	<0.001
Paravalvular leakage ≥moderate	112 (17.3)	1,272 (24.4)	<0.001
Prosthesis-patient mismatch			0.002
Severe	17 (2.6)	107 (2.0)	
Moderate	101 (15.6)	580 (11.1)	
Insignificant	529 (81.8)	4,536 (86.8)	
Data are presented as n (%) and continuous va	ariables are presented a	s medians (interquartile range	).

Table 5. Clinical and Echocardiographic Outcomes Within 30 Days in Patients With SAPIEN3 20 mm and Evolut R 23 mm

Evolutiti Eomini			
	SAPIEN 3 20mm (n=90)	Evolut R 23mm (n=103)	P value
Clinical outcomes			
30-day mortality	0 (0.0)	0 (0.0)	1.00
New pacemaker implantation	4 (4.4)	10 (9.7)	0.16
Stroke	1 (1.1)	2 (1.9)	1.00
Echocardiographic outcomes			
Effective orifice area (cm <sup>2</sup> )	1.2 (1.0-1.4)	1.4 (1.1–1.5)	0.002
Indexed effective orifice area (cm <sup>2</sup> /m <sup>2</sup> )	0.94 (0.78–1.06)	1.07 (0.84–1.24)	0.001
Mean pressure gradient (mmHg)	14.0 (10.0–18.5)	11.0 (7.0–14.0)	< 0.001
Paravalvular leakage ≥moderate	13 (14.4)	17 (16.5)	0.69
Prosthesis-patient mismatch			0.21
Severe	7 (7.8)	3 (2.9)	
Moderate	24 (26.7)	23 (22.3)	
Insignificant	59 (65.6)	77 (74.8)	

Data are presented as n (%) and continuous variables are presented as medians (interquartile range).



Received: 6 August 2020 Revised: 20 August 2020 Accepted: 21 August 2020 DOI: 10.1002/ccd.29259

#### **ORIGINAL STUDIES**

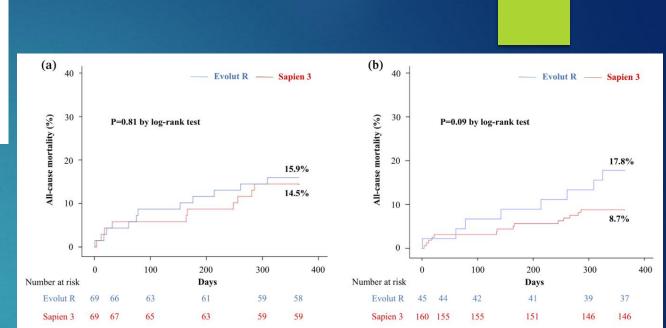
### WILEY

Transcatheter aortic valve replacement with Evolut R versus Sapien 3 in Japanese patients with a small aortic annulus: The **OCEAN-TAVI** registry

**OCEAN-TAVI** Investigators

Small Annulus with 3<sup>rd</sup> generation devices – Evolut R sees to be superior to Sapien 3 Haemodynamic performance, up to 1 year after TAVR

All-cause mortality - no differences



70

60

50

40

30

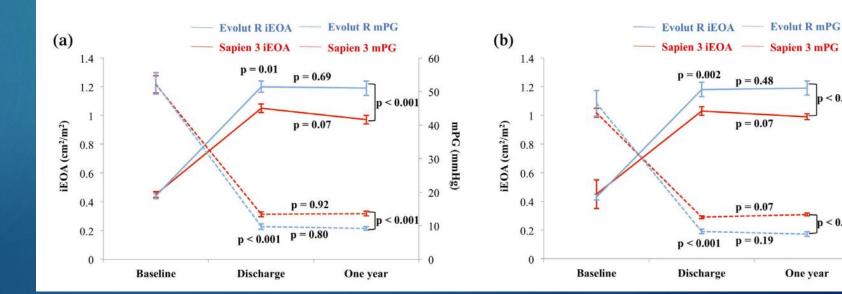
20

10

mPG (mmHg)

p < 0.001

< 0.001



PPM

#### TABLE 5 Postprocedural echocardiographic data at discharge and at 1 year after TAVR in the matched cohort

	Discharge				One year			
	Overall (N = 138)	Evolut R (N = 69)	Sapien 3 (N = 69)	p-Value	Overall (N = 97)	Evolut R (N = 47)	Sapien 3 (N = 50)	p-Value
Indexed EOA, cm <sup>2</sup> /m <sup>2</sup>	1.12 (0.95 - 1.35)	1.20 (1.01-1.46)	1.08 (0.90-1.28)	.01	1.04 (0.87-1.26)	1.21 (0.92-1.35)	0.96 (0.83-1.12)	<.001
Moderate PPM (iEOA ≦0.85), n (%)	17 (12.9)	5 (7.7)	12 (17.9)	.08	21 (21.6)	7 (14.9)	14 (28.0)	.12
Severe PPM (iEOA ≦0.65), n (%)	3 (2.3)	1 (1.5)	2 (3.0)	1.00	2 (2.1)	0 (0.0)	2 (4.0)	.50
Mean PG, mmHg	11.0 (8.0-13.8)	9.0 (6.0-12.0)	12.0 (10.0-14.8)	<.001	10.0 (8.0-14.8)	9.0 (6.0-11.9)	12.0 (9.9-16.3)	<.001
AR				.05				.24
None, n (%)	25 (18.5)	15 (22.4)	10 (14.7)		20 (20.6)	11 (23.4)	9 (18.0)	
Trivial, n (%)	52 (38.5)	19 (28.4)	33 (48.5)		38 (39.2)	16 (34.0)	22 (44.0)	
Mild, n (%)	58 (43.0)	33 (49.3)	25 (36.8)		36 (37.1)	17 (36.2)	19 (38.0)	
≧Moderate, n (%)	0 (0.0)	0 (0.0)	0(0.0)		3 (3.1)	3 (6.4)	0 (0.0)	

Note: Values are medians (25th-75th percentiles) or n (%).

Abbreviations: AR, aortic regurgitation; EOA, effective orifice area; PG, pressure gradient; PPM, prosthesis-patient mismatch.

#### TABLE 6 Postprocedural echocardiographic data at discharge and at 1 year after TAVR in the extreme small annulus cohort

	Discharge				One year			
	Overall (N = 205)	Evolut R (N = 45)	Sapien 3 (N = 160)	p-Value	Overall (N = 145)	Evolut R (N = 29)	Sapien 3 (N = 116)	p-Value
Indexed EOA, cm <sup>2</sup> /m <sup>2</sup>	1.07 (0.90-1.27)	1.17 (0.99-1.46)	1.04 (0.88-1.18)	.002	1.00 (0.86-1.19)	1.20 (1.01-1.37)	0.97 (0.82-1.14)	<.001
Moderate PPM (iEOA ≦0.85), n (%)	34 (17.0)	4 (9.1)	30 (19.2)	.11	35 (24.1)	2 (6.9)	33 (28.4)	.015
Severe PPM (iEOA ≦0.65), n (%)	4 (2.0)	1 (2.3)	3 (1.9)	1.00	5 (3.4)	0 (0.0)	5 (4.3)	.26
Mean PG, mmHg	12.5 (9.0-16.3)	9.0 (6.0-11.0)	13.6 (10.0-16.9)	<0.001	13.1 (10.0-17.8)	8.0 (5.0-11.2)	15.0 (11.3-18.0)	<.001
AR				<0.001				.31
None, n (%)	46 (22.5)	8 (17.8)	38 (23.9)		51 (35.2)	7 (24.1)	44 (37.9)	
Trivial, n (%)	93 (45.6)	13 (28.9)	80 (50.3)		42 (29.0)	9 (31.0)	33 (28.4)	
Mild, n (%)	61 (29.9)	20 (44.4)	41 (25.8)		38 (26.2)	11 (37.9)	27 (23.3)	
≧Moderate, n (%)	4 (2.0)	4 (8.9)	O (0.0)		8 (5.5)	2 (6.9)	6 (5.2)	

Note: Values are medians (25th-75th percentiles) or n (%).

Abbreviations: AR, aortic regurgitation; EOA, effective orifice area; PG, pressure gradient; PPM, prosthesis-patient mismatch.

# TAVI in SAA -Other concerns of TAVI in SAA



## Additional Technical Concerns – TAVI in SAA

- Risk of Annulus Rupture
  - Relative valve oversizing
  - In particular dense calcifications
  - Low BSA
- Acute Coronary Obstruction
- Vascular Complications Small femoral arteries
- Coronary reassess
- Future management of TAV bioprosthetic failure

## Techniques to optimize TAVI in SAA

- Verify with multiple methods to ascertain small annulus size in the first place
- Enhancement in haemodynamic performance
  - Relatively higher implants for \$3/Intra-annular valve platform
  - Use of supra-annular TAV
  - Optimization of TAV frame expansion (balloon pre dil/post dil, volume adj)
- Selection of BEV/SEV take the whole aortic valve/annulus complex anatomy into considerations
  - STJ/Sinus/LVOT
- Device Size selection in borderline cases
- Coronary protection

# TAVI in SAA -SAPIEN 3

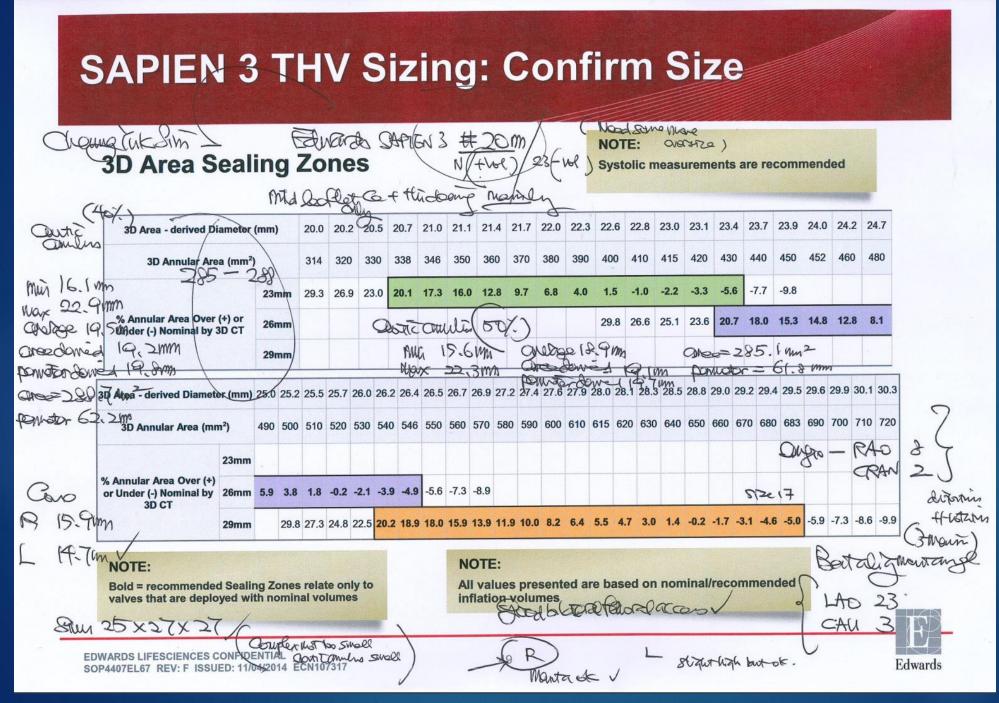




Area 311.1mm2 Perimeter 64.1mm

Average 20.3mm

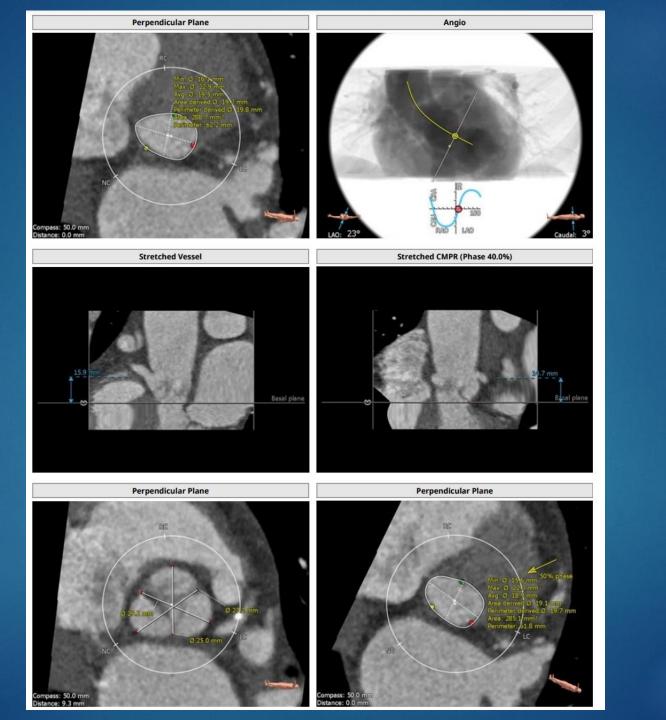




3

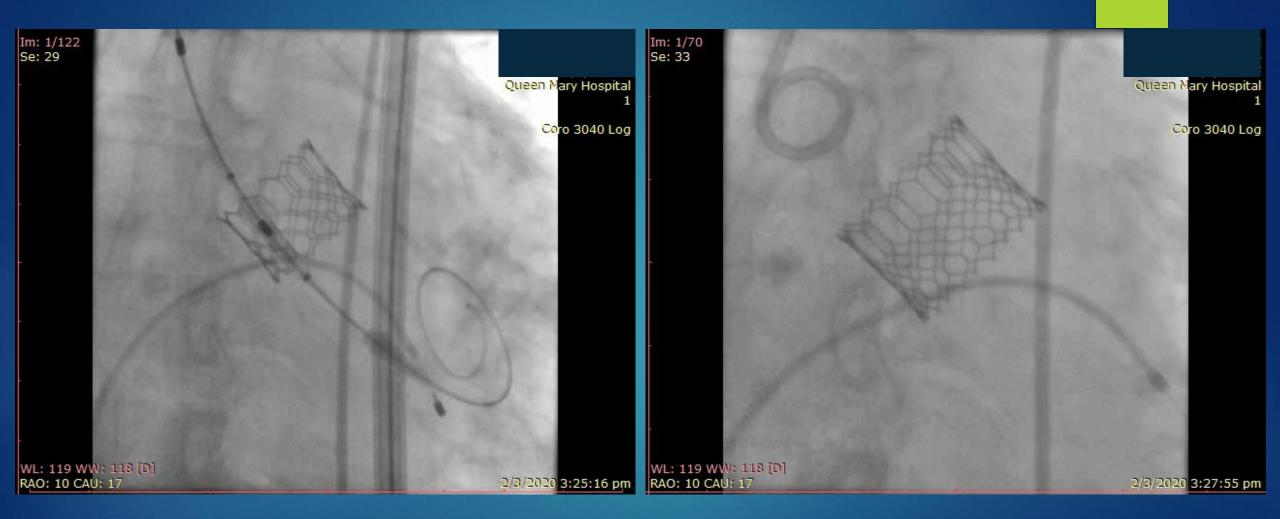
Area 288.7mm2 Perimeter 62.2mm

Average 19.5mm





Delivery Nominal +1 ml



Post dilatation Delivery System Balloon additional +1 ml (Nominal +2)

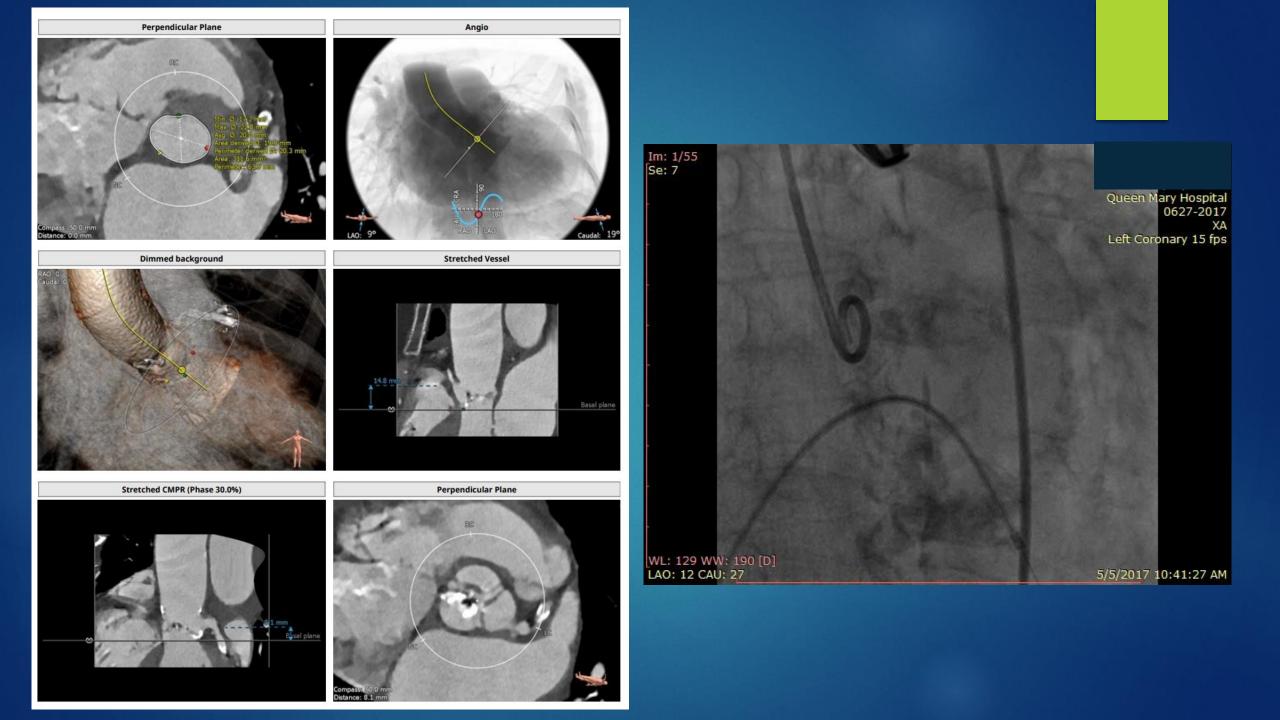
## **SAPIEN 3 Valve Sizing: Confirm THV Size**

3D Area - deriv	ed Diameter	(mm)	1	20.0	20.2	20.	5 20	0.7	21.0	21.1	3N 21.4	21.7	22.0	22.3	22.6	22.8	23.0	23.1	23.4	23.7	23.9	24.0	24.2	24
3D Annula	r Area (mm <sup>3</sup>	*)		314	320	33	0 33	38	346	350	360	370	380	390	400	410	415	420	430	440	450	452	460	4
omm)		23n	nm	29.3	26.9	23	0 20	0.1	17.3	16.0	12.8	9.7	6.8	4.0	1.5	-1.0	-2.2	-3.3	-5.6	-7.7	-9.8			
≥ % Annular Area Under (-) Nomina	Over (+) or I by 3D CT	26n	nm												29.8	26.6	25.1	23.6	20.7	18.0	15.3	14.8	12.8	
	/	29n	nm	/																				
3D Area - derived Di	meter (mm)	25.0	25.2	25.5	25.7	26.0	26.2	26.4	26.5	26.7	26.9 2	7.2 27.	4 27.6	27.9	28.0 2	3.1 28.3	3 28.5	28.8	29.0 2	29.2 29	.4 29.	5 29.6	29.9	30.1
3D Annular Are	(mm²)	490	500	510	520	530	540	546	550	560	570 5	80 590	600	610	615 6	20 630	640	650	660	670 6	30 683	690	700	710
	23mm																							
% Annular Area Ove or Under (-) Nomina 3D CT		5.9	3.8	1.8	-0.2	-2.1	-3.9	-4.9	-5.6	-7.3	-8.9						-							
in)	29mm		29.8	27.3	24.8	22.5	20.2	18.9	18.0	15.9	13.9 1	1.9 10.	0 8.2	6.4	5.5 4	.7 3.0	1.4	-0.2	-1.7	-3.1 -4	.6 -5.0	-5.9	-7.3	-8.6

4

Area 311.6mm2

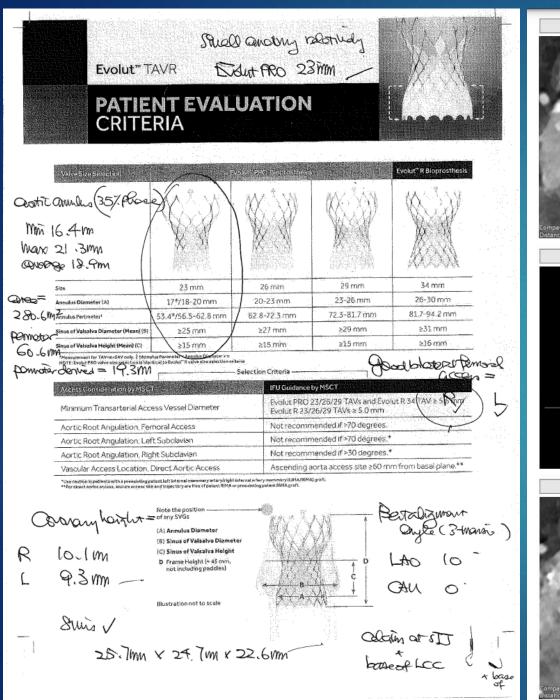
Average 20.0mm





# TAVI in SAA -EVOLUT PRO/+



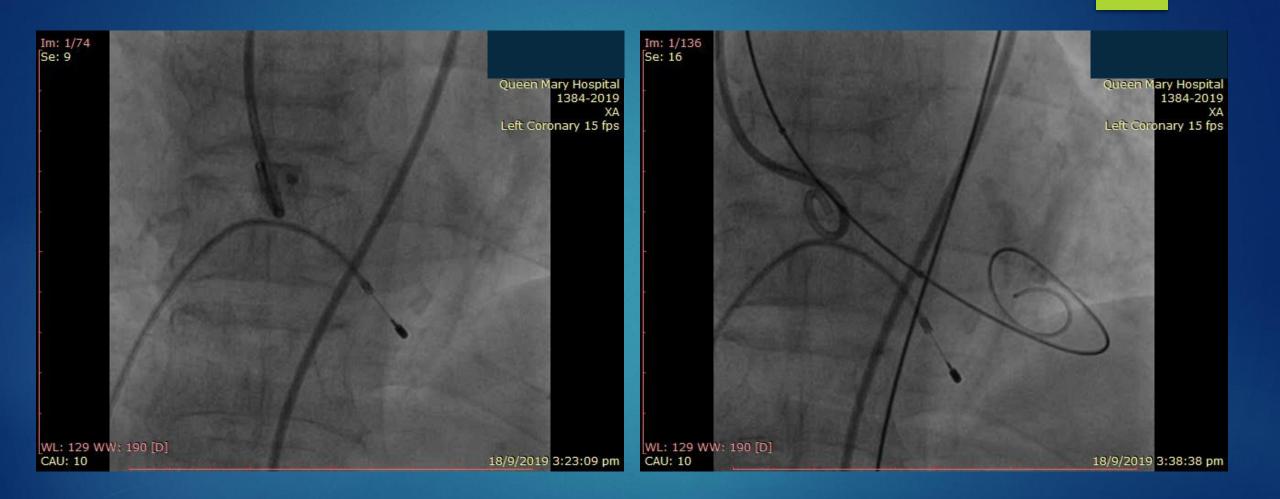


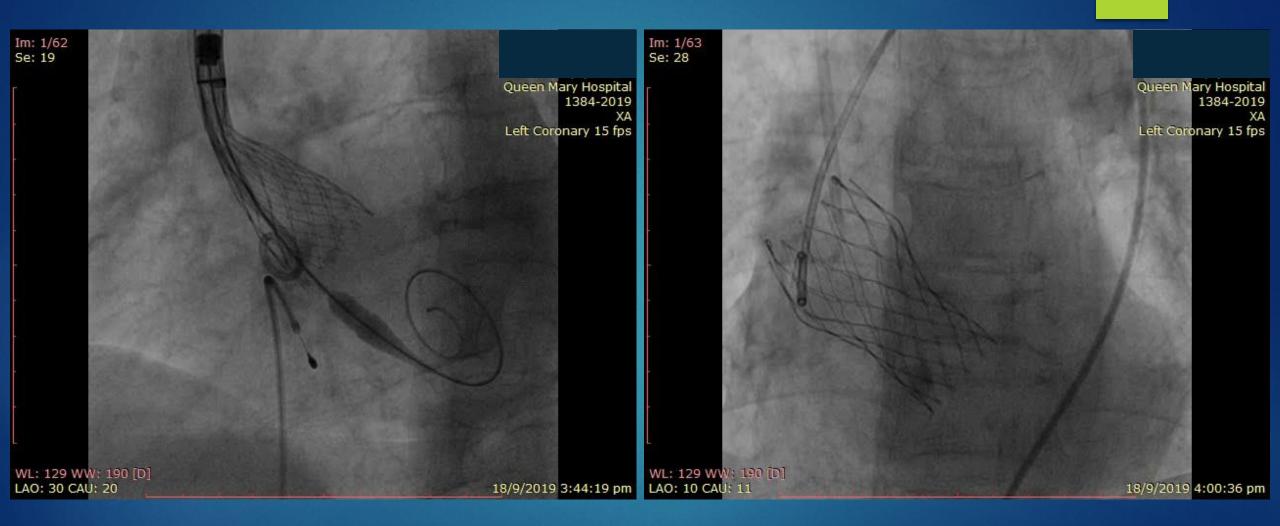


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### Area 280.6mm2 Perimeter 60.6mm

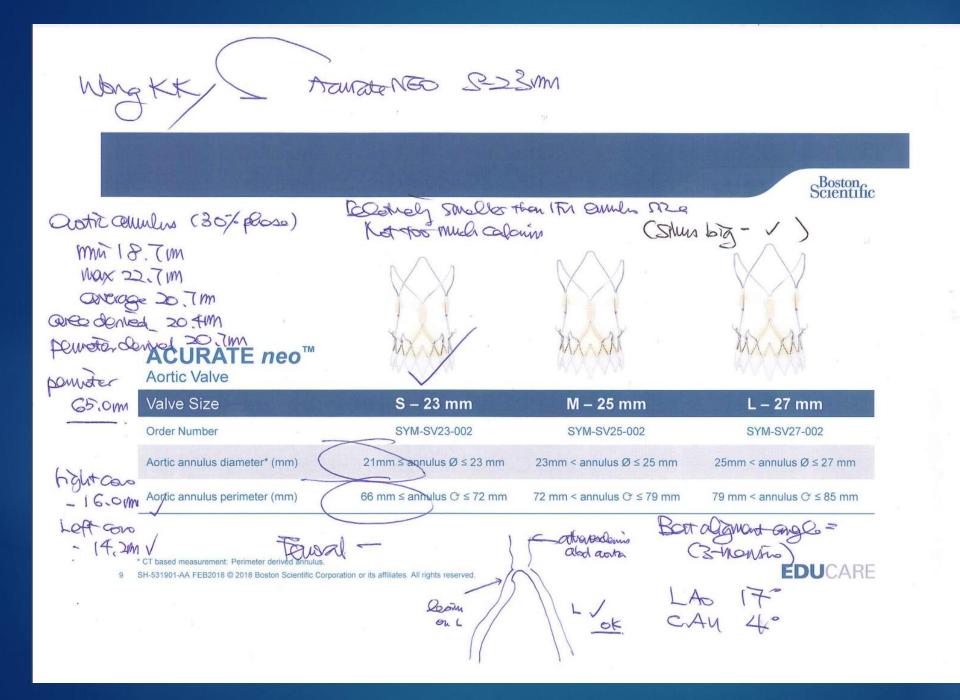
Average 18.9mm





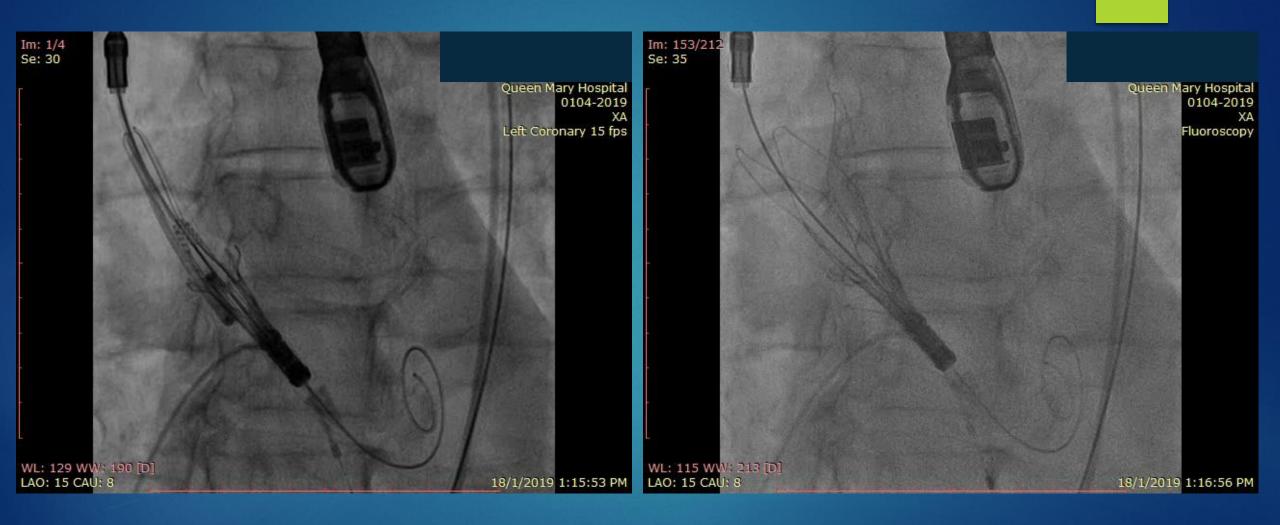
# TAVI in SAA -ACURATE NEO

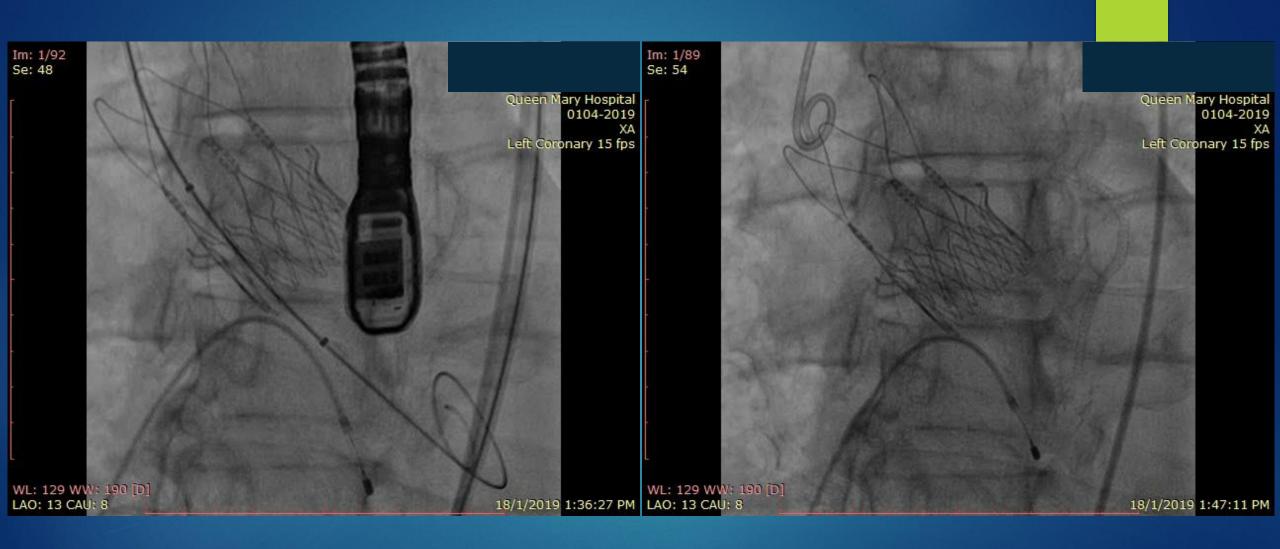




Perimeter 65.0mm Average 20.7mm

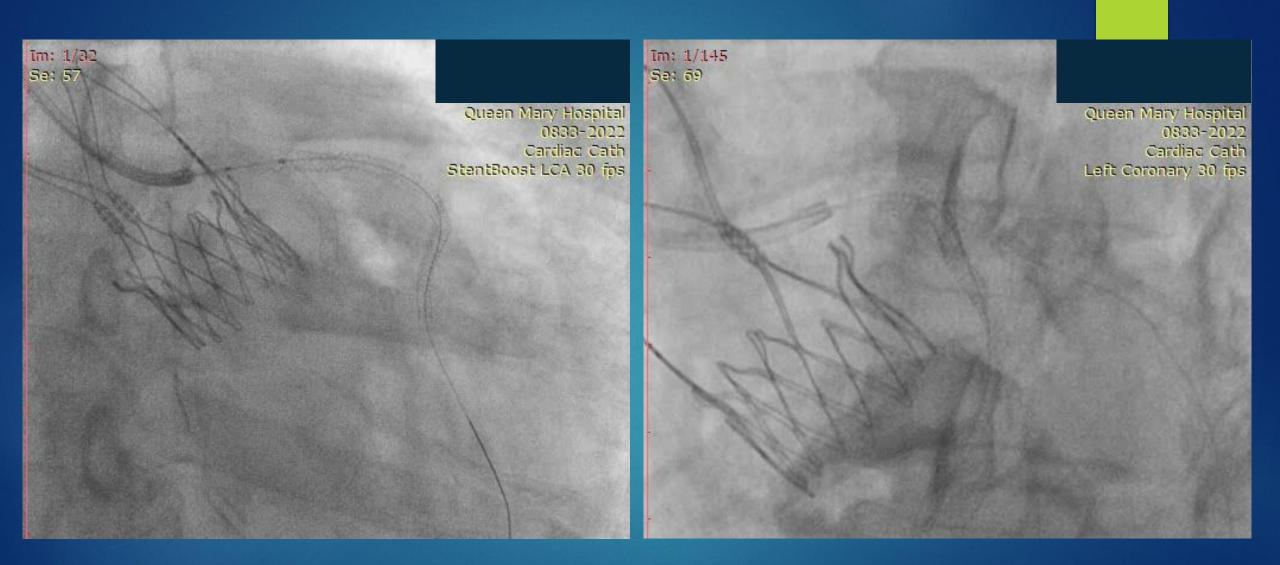






Gradient remained PG/MG 11/6mmHg at 3 years
CT coro – progression of underying IHD plan coro+/-PCI





# TAVI in SAA -Conclusion



## Conclusion

- Small/(extremely small) Aortic Annulus commonly seen in Asian Population
- Verify the measurements
- Taking whole AV Complex into considerations
- Procedural Optimization
  - Techniques
  - Avoid complications
  - Device selection
- Heart Team Evaluation
- Patient Factors and Expectations
- Systematic and careful long term FU





## **HONG KONG VALVES 2022**

15-16th October 2022 (Sat & Sun) Board Room, Faculty Administration Wing, Faculty of Medicine Building, 21 Sassoon Road, Hong Kong

Case demonstrations from local and overseas centers

Plenary lectures by overseas & local experts

- Life-time management of patients with valvular heart disease

- Innovative mitral and tricuspid transcatheter valve therapies
- Structural heart and coronary interventions crossover CHIP & hemodynamics support

- Electrophysiology and device therapies for structural heart disease NEW

#### Hands-on workshops

- INCEMENT - Cardiac anatomical surgical basics with Hands-on Web-lab
- Point-of-care echocardiography with live demo: from A to Z
- Cardiac catheterization skills for surgeons and interventionists





### https://onemediachannel.com/event/register/HKValve2022

