

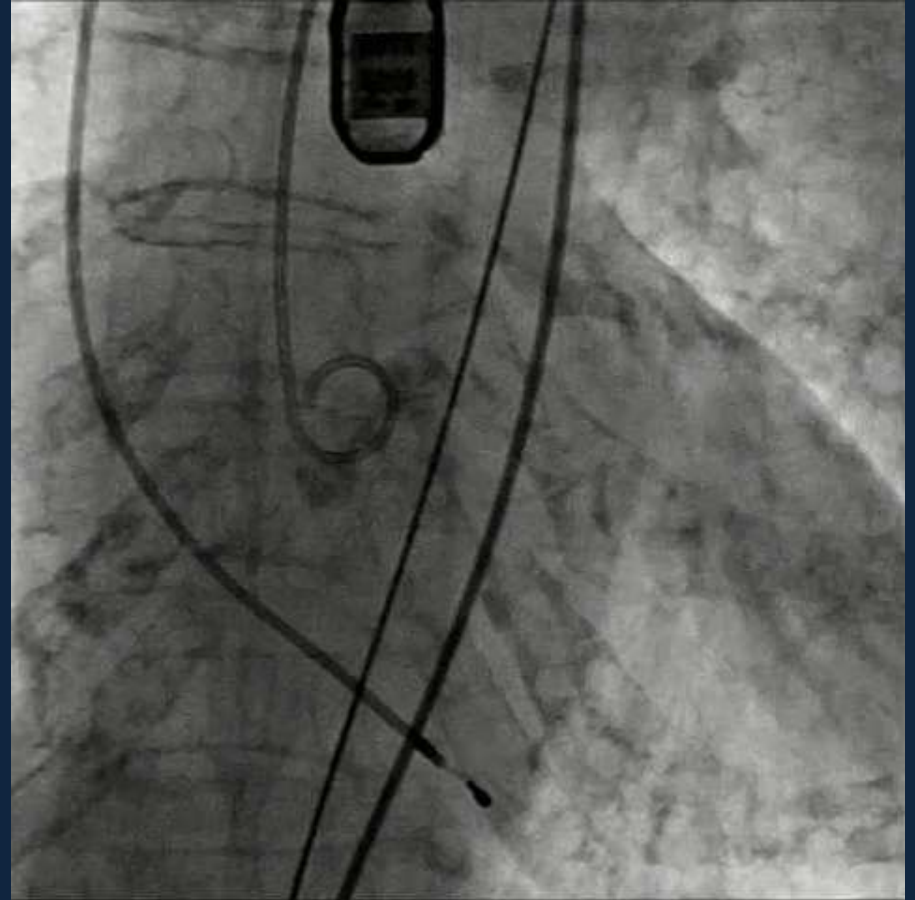
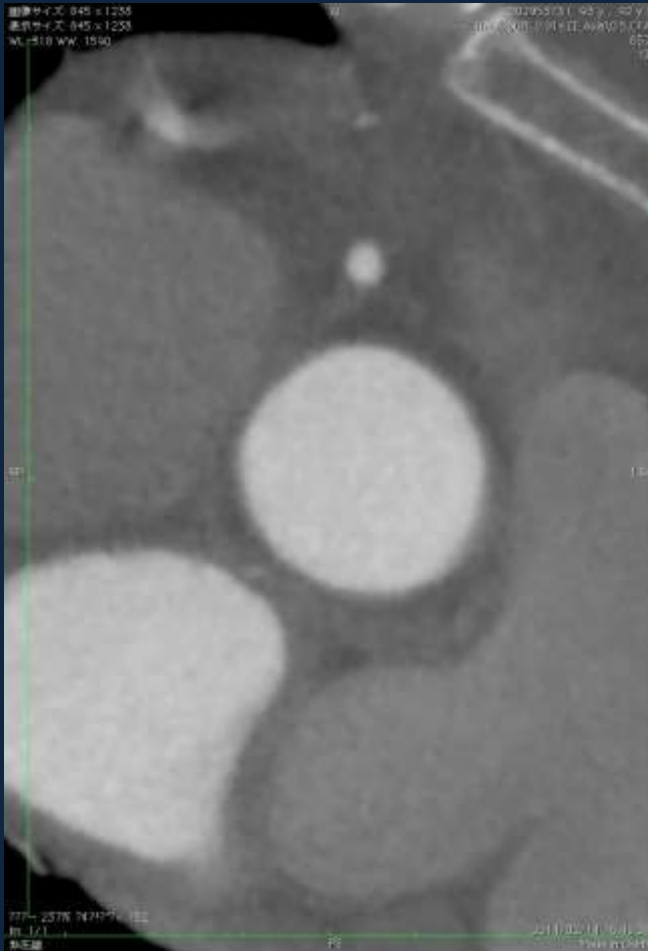
Aortic Root Injury

How to expect and when to say No?

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Sendai Kousei Hospital, JAPAN

APVALVE 2017

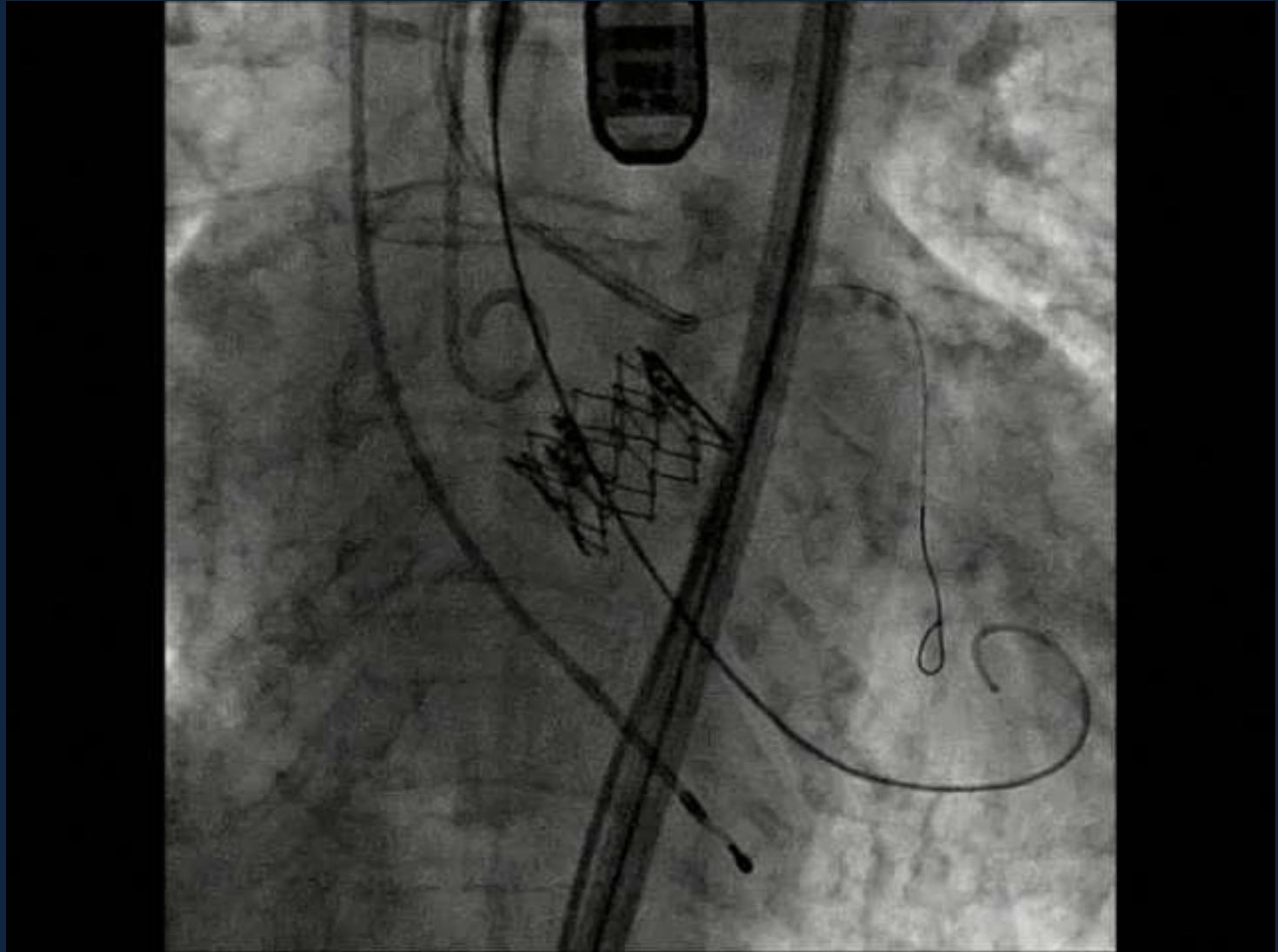
Annulus Area 320 mm²



SAPIEN XT 23mm (27% oversize) -2.5ml underfilling



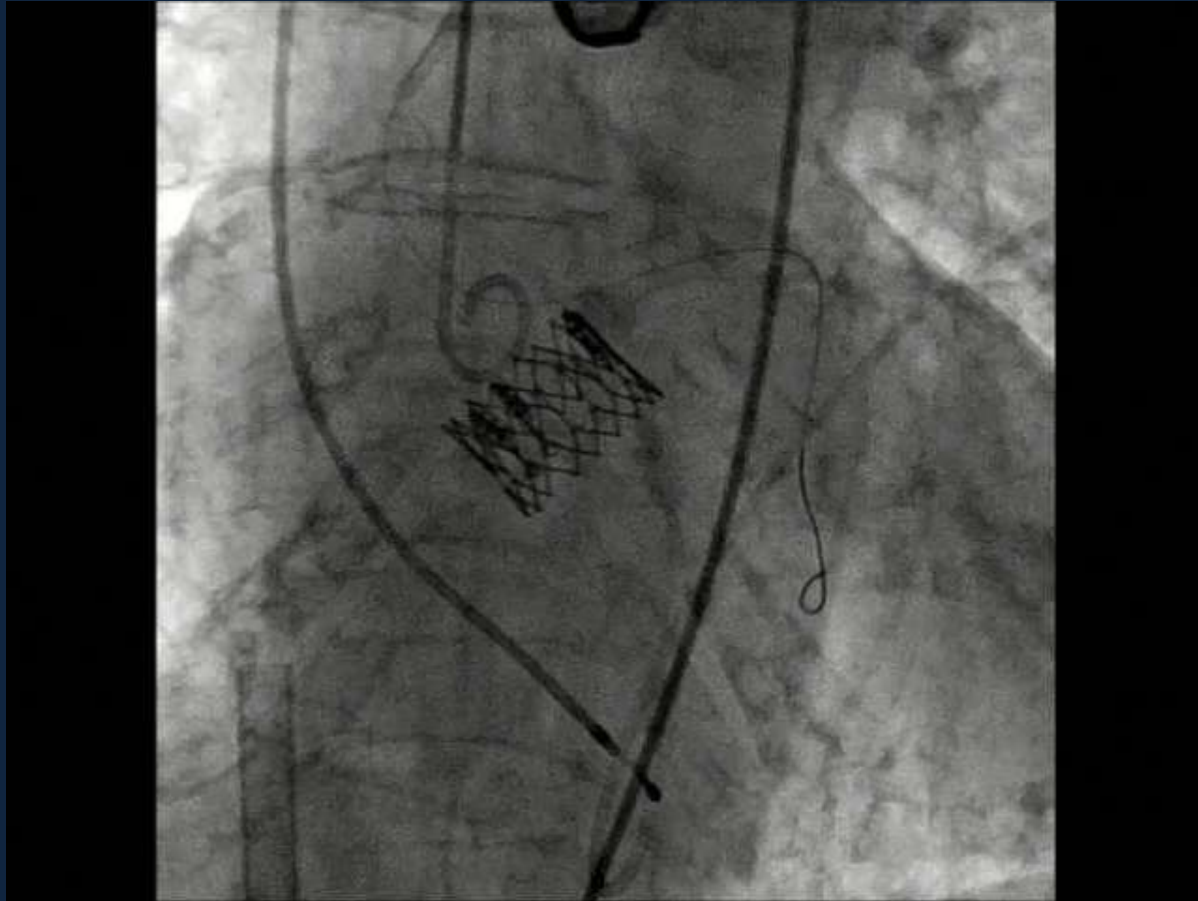
Annulus rupture



Pericardial effusion



Healed after heparin neutralization



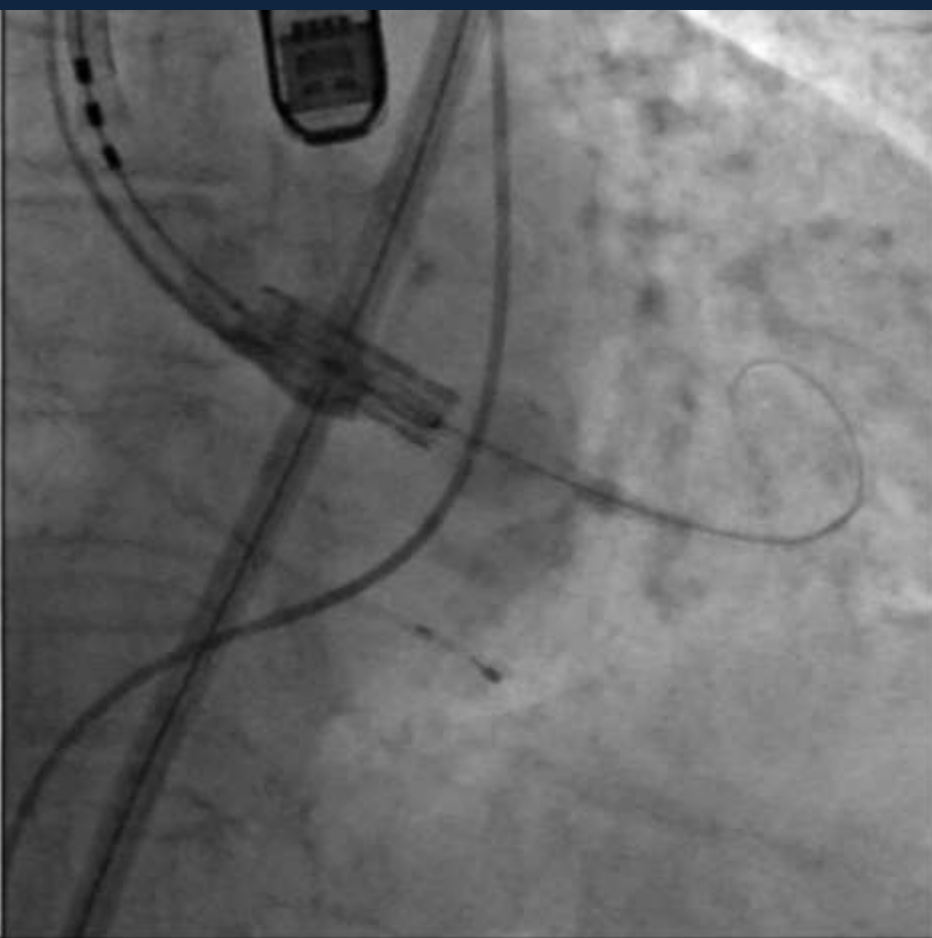
Platform



- Longitudinal bars
- 0.5mm thickness
- Few cells



- No bars
- 0.3mm thickness
- Many cells



S3 experience in US and Canada

Table 2 Procedural characteristics and outcomes^a

Characteristic	HR/inoperable (N = 583)	Intermediate risk (N = 1078)	Overall (N = 1661)
THV size			
20 mm	11/583 (1.9)	42/1073 (3.9)	53/1656 (3.2)
23 mm	200/583 (34.3)	345/1073 (32.2)	545/1656 (32.9)
26 mm	227/583 (38.9)	471/1073 (43.9)	698/1656 (42.1)
29 mm	145/583 (24.9)	215/1073 (20.0)	360/1656 (21.7)
Access			
Transfemoral	491/583 (84.2)	952/1078 (88.3)	1443/1661 (86.9)
Transapical	57/583 (9.8)	81/1078 (7.5)	138/1661 (8.3)
Transaortic	35/583 (6.0)	45/1078 (4.2)	80/1661 (4.8)
Monitored anaesthesia care	78/583 (13.4)	179/1076 (16.6)	257/1659 (15.5)
General anaesthesia	505/583 (86.6)	897/1076 (83.4)	1402/1659 (84.5)
Fluoroscopy time (min)	18.8 ± 10.1	19.3 ± 30.4	19.1 ± 25.2
Post-dilatation	86/583 (14.8)	122/1076 (11.3)	208/1659 (12.5)
Percutaneous closure	471/580 (81.2)	858/1075 (79.8)	1329/1655 (80.3)
Procedural death	4/583 (0.7)	2/1078 (0.2)	6/1661 (0.4)
Multiple valves implanted	5/583 (0.9)	4/1075 (0.4)	9/1658 (0.5)
Valve embolization	1/583 (0.2)	1/1078 (0.1)	2/1661 (0.1)
Coronary obstruction	1/583 (0.2)	4/1078 (0.4)	5/1661 (0.3)
Aortic rupture	0/583	2/1078 (0.2)	2/1661 (0.1)
Urgent cardiac surgery	1/583 (0.2)	5/1078 (0.5)	4/1661 (0.2)
IABP inserted	3/583 (0.5)	4/1076 (0.4)	7/1659 (0.4)
Cardiopulmonary bypass	13/583 (2.2)	10/1076 (0.9)	23/1659 (1.4)
Median hospital stay, days (IQR)	3 (2–6)	3 (2–4)	3 (2–5)

^aPlus–minus values are means ± standard deviation. Duration of hospital stay is reported as median (interquartile range). All other values are reported as n/N (%). IABP, intra-aortic balloon pump; THV, transcatheter heart valve.

SOURCE 3 Registry

Design and 30-Day Results of the European Postapproval Registry of the Latest Generation of the SAPIEN 3 Transcatheter Heart Valve

Table 3. Procedural and 30-Day Events and Clinical Outcomes: TF (n=1695) Versus Non-TF (n=252)

	Total, KM-Estimated Event Rates or n/N (%)	TF, KM-Estimated Event Rates or n/N (%)	Non-TF, KM-Estimated Event Rates or n/N (%)	P Value, TF vs Non-TF
Procedural events				
Valve-in-valve bailout	14/1947 (0.7)	11/1695 (0.7)	3/252 (1.2)	0.41
Conversion to surgery	11/1947 (0.6)	10/1695 (0.6)	1/252 (0.4)	>0.999
Cardiopulmonary bypass	4/1940 (0.7)	4/1692 (0.2)	0/248 (0)	>0.99
Coronary obstruction	7/1947 (0.4)	6/1695 (0.4)	1/252 (0.4)	>0.99
Annular rupture	3/1947 (0.2)	3/1695 (0.2)	0/252 (0.0)	0.50
30-d Events				
All-cause mortality	42 (2.2)	32 (1.9)	10 (4.0)	0.0023
Cardiovascular mortality	20 (1.1)	17 (1.0)	3 (1.2)	0.47
Major vascular complication	80 (4.1)	72 (4.3)	8 (3.2)	0.37
Life-threatening bleeding	97 (5.0)	73 (4.3)	24 (9.6)	0.0004
Myocardial infarction	5 (0.3)	3 (0.2)	2 (0.8)	0.36
New permanent pacemaker	233 (12.0)	208 (12.3)	25 (10.0)	0.15
Stroke	28 (1.4)	21 (1.3)	7 (2.8)	0.47
Disabling stroke	10 (0.5)	8 (0.5)	2 (0.8)	0.58
Acute kidney injury (II–III)	22 (1.1)	14(0.8)	8 (3.2)	<0.0001
New-onset atrial fibrillation	120 (6.2)	91 (4.8)	29 (12.5)	<0.0001
Ventilated when leaving the procedural theater	109/1945 (5.6)	60/1693 (3.5)	49/252 (19.4)	<0.0001
ICU length of stay (Q1–Q3), d	1 (0–2)	2(1–3)	2 (1–4)	0.0024
Median length of stay (Q1–Q3), d	7 (5–10)	7 (5–9)	9 (7–13)	<0.0001

ICU indicates intensive care unit; KM, Kaplan-Meier; Q, quartile; and TF, transfemoral.

In-hospital complications (TF, XT vs. S3)

	XT (n=1010)	S3 (n=140)	P valve
Procedural time (min.)	87.3±48.2	60.9±27.2	<0.001
Contrast (ml)	130.9±61.1	109.6±54.8	<0.001
Complications			
Tamponade	22 (2.2%)	0	0.078
Pacemaker implantation	75 (7.4%)	13 (9.3%)	0.438
PVL grade≥2	359 (35.5%)	37 (26.4%)	0.033
PVL grade ≥3	9 (0.9%)	0	0.262
Surgical conversion	15 (1.5%)	0	0.147
Life-threatening or major bleeding	157 (15.5%)	8 (5.7%)	0.002
Major vascular complication	69 (6.8%)	4 (2.9%)	0.071
Ischemic stroke	20 (2.0%)	2 (1.4%)	0.655
AKI stage 3	15 (1.5%)	1 (0.7%)	0.466

Optimal sizing for SAPIEN 3 transcatheter aortic valve replacement in patients with or without left ventricular outflow tract calcification



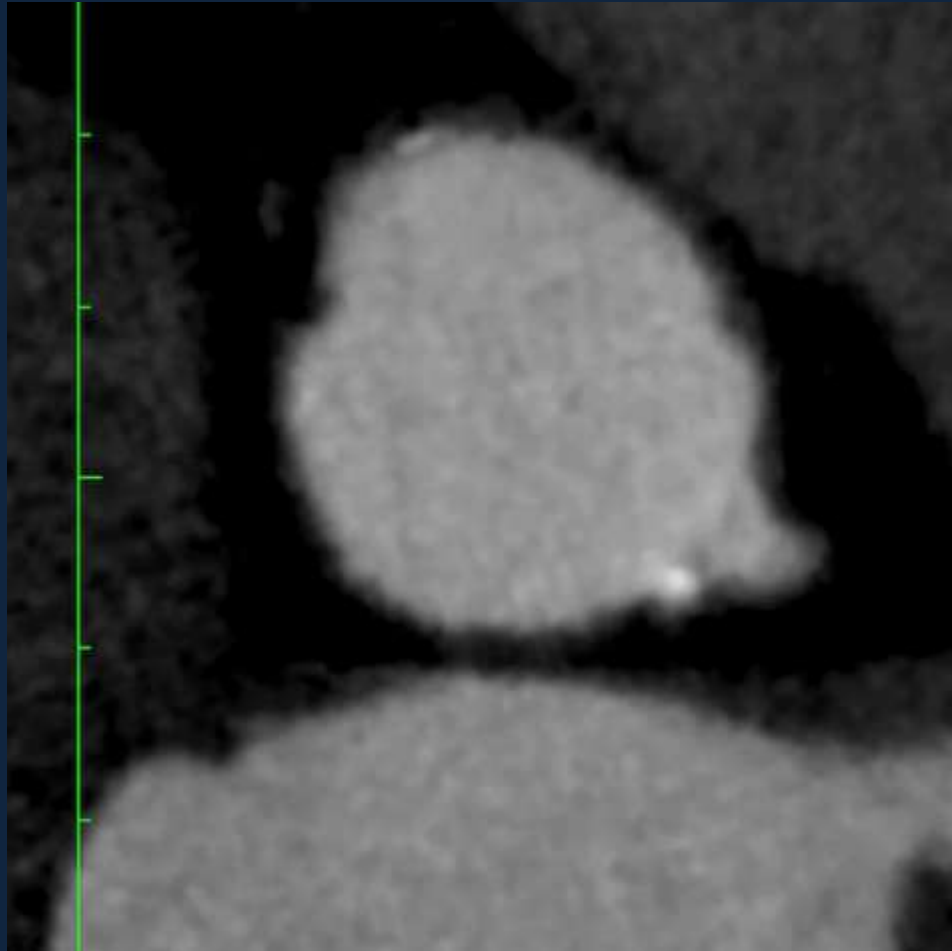
Yoshio Maeno, MD, PhD; Yigal Abramowitz, MD; Hasan Jilaihawi, MD; Sharjeel Israr, MD; Sunghan Yoon, MD; Rahul P. Sharma, MD; Yoshio Kazuno, MD; Hiroyuki Kawamori, MD, PhD; Masaki Miyasaka, MD; Tanya Rami, MBA; Geeteshwar Mangat, MD; Nobuyuki Takahashi, MD; Kazuaki Okuyama, MD; Mohammad Kashif, MD; Tarun Chakravarty, MD; Mamoo Nakamura, MD; Wen Cheng, MD; Raj R. Makkar*, MD

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	LVOT-CA (n=144)	No LVOT-CA (n=136)	p-value
Valve size, mm			0.74
20	2 (1.4%)	7 (5.2%)	
23	39 (27.1%)	33 (24.4%)	
26	65 (45.1%)	57 (42.2%)	
29	38 (26.4%)	38 (28.1%)	
Degree of annular area sizing, %	7.0 (2.3-13.9)	9.9 (2.7-15.6)	0.08
Undersizing (<0%)	27 (18.8%)	24 (17.6%)	0.81
LVOT cover index by area, %	11.5 (-1.1-20.3)	10.0 (0.10-22.8)	0.79
Alternative approach	2 (1.4%)	6 (4.4%)	0.12
Implantation depth, mm	5.4 (4.6-6.3)	5.3 (4.3-6.4)	0.69
Predilatation	74 (51.4%)	40 (29.4%)	<0.001
Post-dilatation	12 (8.3%)	6 (4.4%)	0.19
Need for a second prosthesis	0	1 (0.7%)	0.48
Aortic annular injury	3 (2.1%)	1 (0.7%)	0.33

	LVOT calcium	Valve size	Annular area oversizing	Inflation volume, cc	Post-dilatation	Lesion type	Treatment	In-hospital mortality
Case 1	Yes	29 mm	20.4%	−1.5	No	Rupture	Drainage	No
Case 2	Yes	26 mm	17.8%	Nominal	No	Rupture	Surgical	No
Case 3	Yes	29 mm	9.6%	−2	Yes*	Rupture	Drainage	Yes
Case 4	No	26 mm	14.1%	Nominal	No	Rupture	Conservative	No

Annulus bulky calc area 414mm²



SAPIEN 3 23mm -1ml underfilling

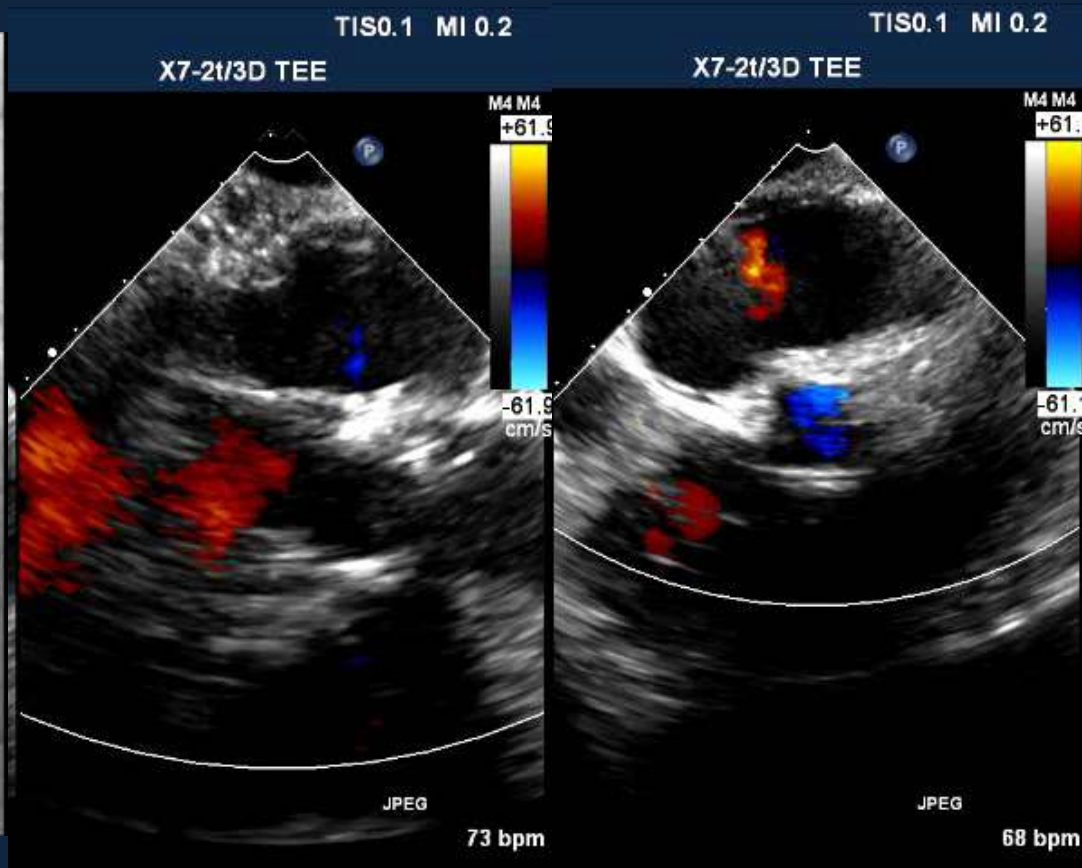
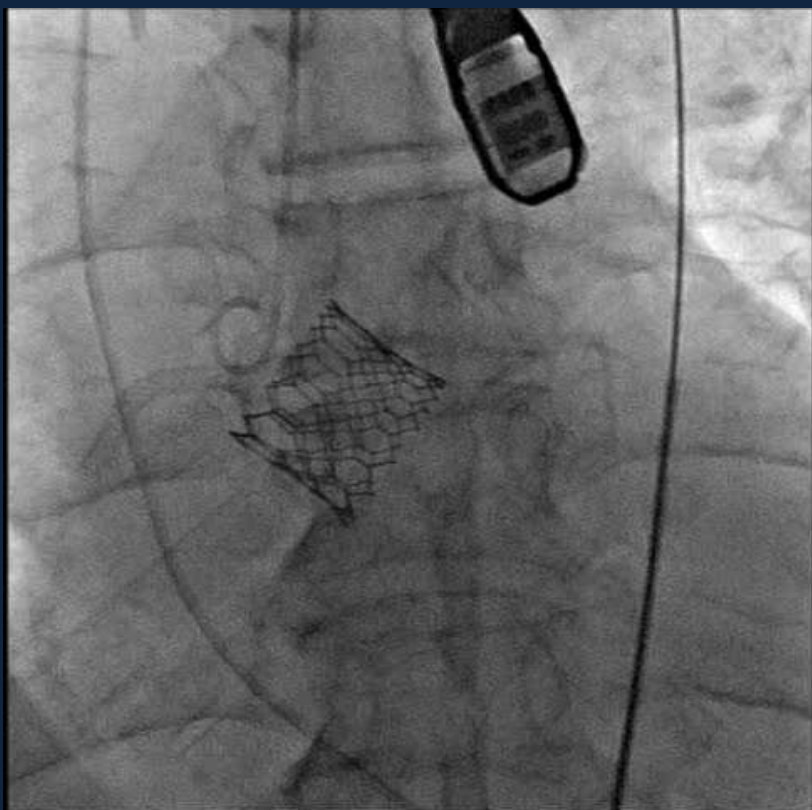


LIH

RAO 1°
CIP 0°
SID 96 cm
CIP 6°
CIP -30 cm
CIP -4 cm
CIP 90°
11%
N 13.1 mm
304.15 mmHg
7464.99 mmHg
04:27



SAPIEN 3 23mm -1ml underfilling



Summary

- Annulus rupture in SAPIEN 3 is rare thank to improved platform.
- However LVOT-Ca and >15% oversizing are still risks of rupture.
- Optimal sizing and slow inflation are keys for prevention of annulus rupture.

