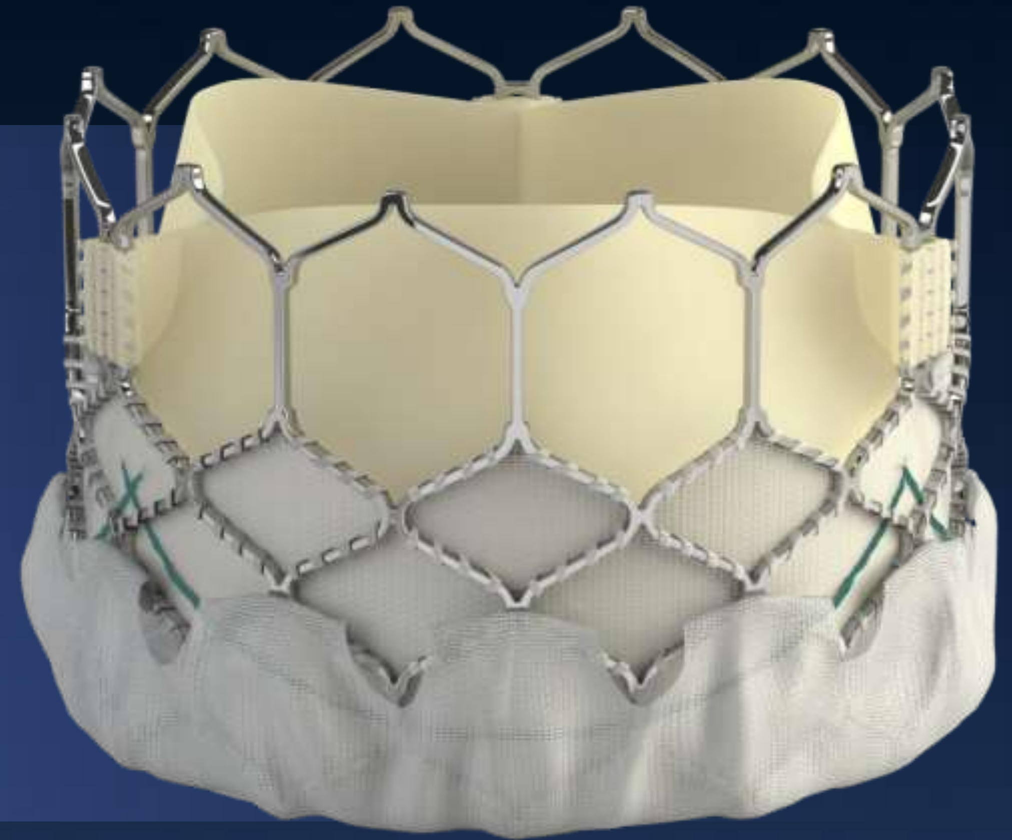
Korean Sapien3 experience



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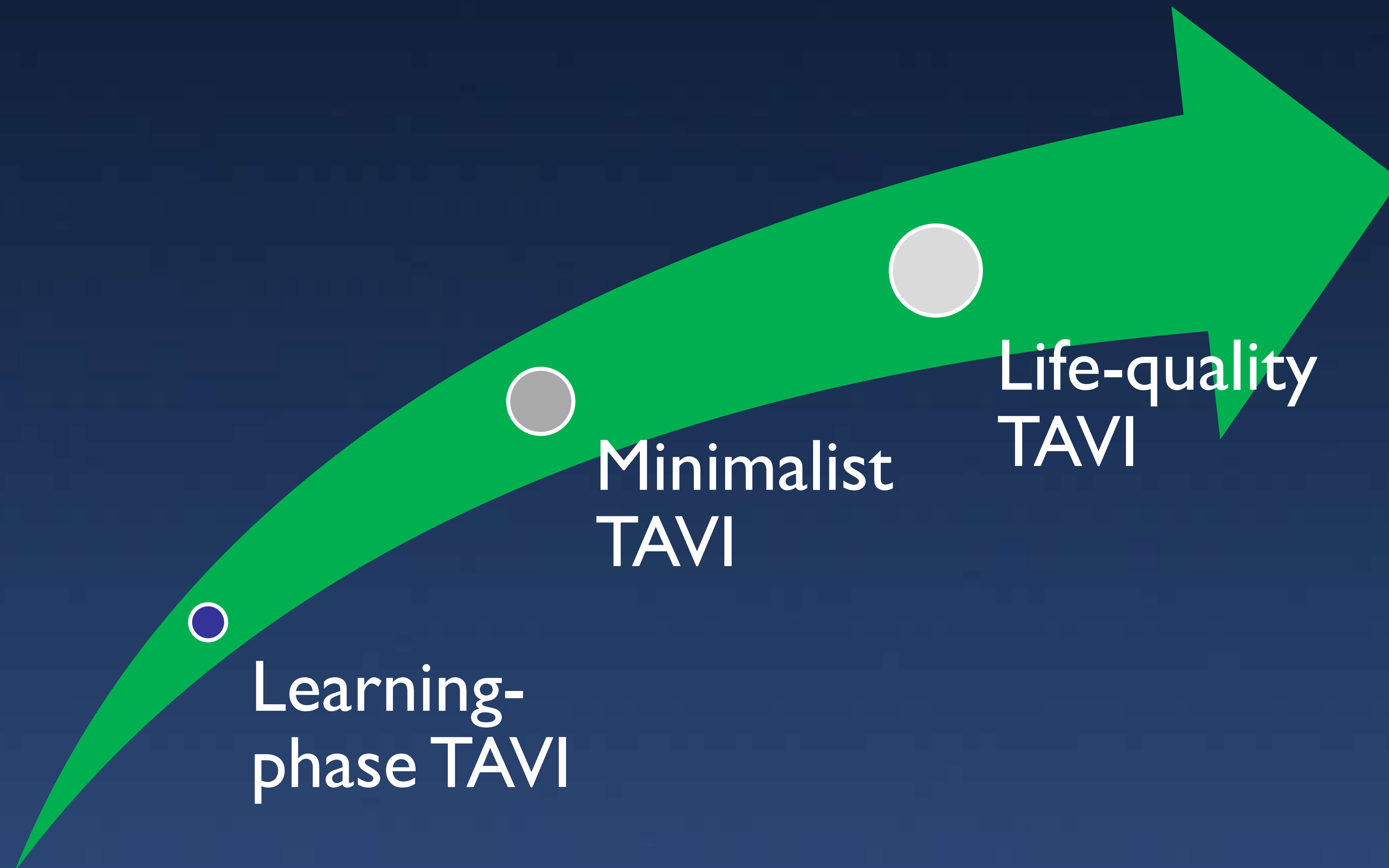
Cardiology

Seoul St. Mary's Hospital

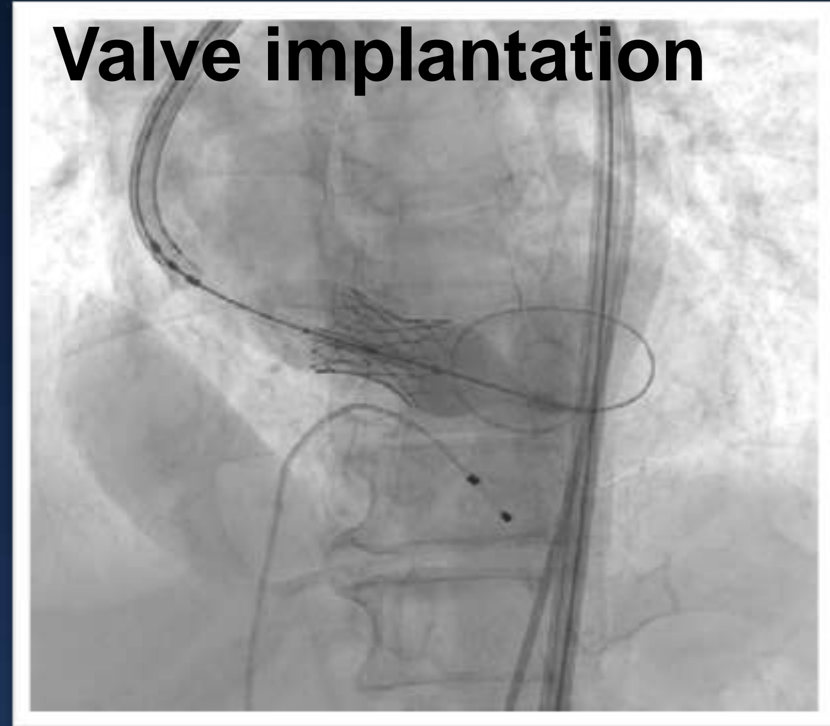
The Catholic University of Korea

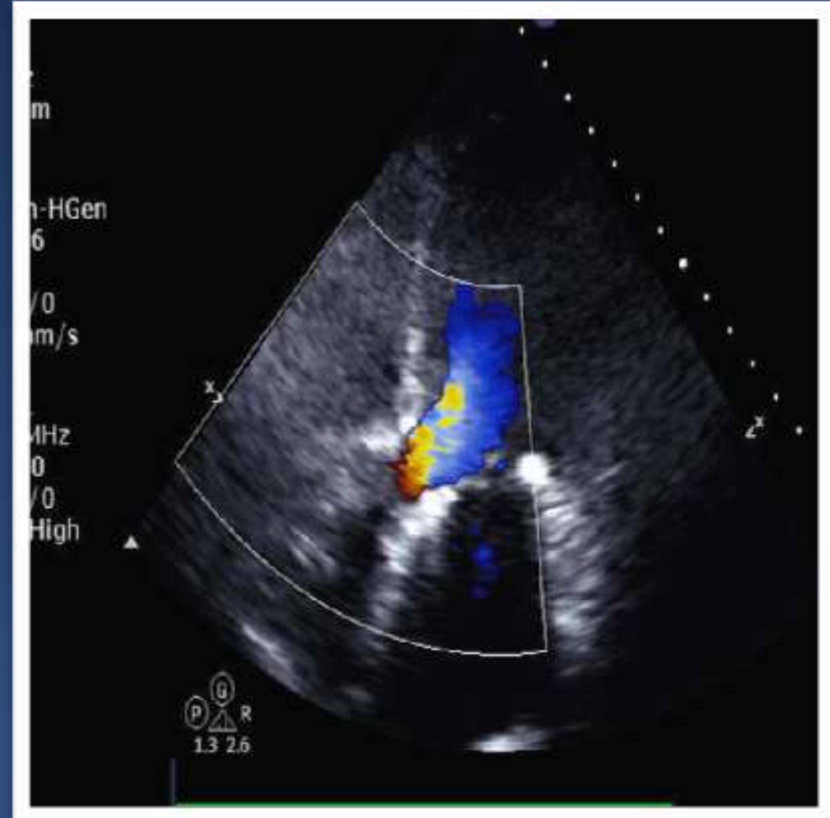
Where is TAVI going?



Learing-Phase TAVI

Minimalist TAVI: conscious sedation with LA





- 100 case: 85 yo female
- Procedure time: 25 min
- No TEE
- No complete AV block ,no PVL
- Dischared 2 days after TAVI

Quality-of-life TAVI

Better cognitive function

Better performance

Seoul St. Mary's Hospital Experience

Year	2012	2013	2014	2015	2016	2017
Cases	2	7	11	28	48	21

Seoul St. Mary's Hospital Data

2015.06.17~2017.03.16

	Total (n=80/121)
Sex	
Male	36 (45.0)
Female	44 (55.0)
Age	
Age (yrs)	80±7
<80	39 (48.8)
≥80	41 (51.3)
STS score	13.6 ± 10.6
low risk (≤3)	2 (2.5)
Intermediate (3-7)	5 (6.3)
High (≥8)	73 (91.3)
NYHA class	
class III	49 (60.8)
class IV	31 (39.2)

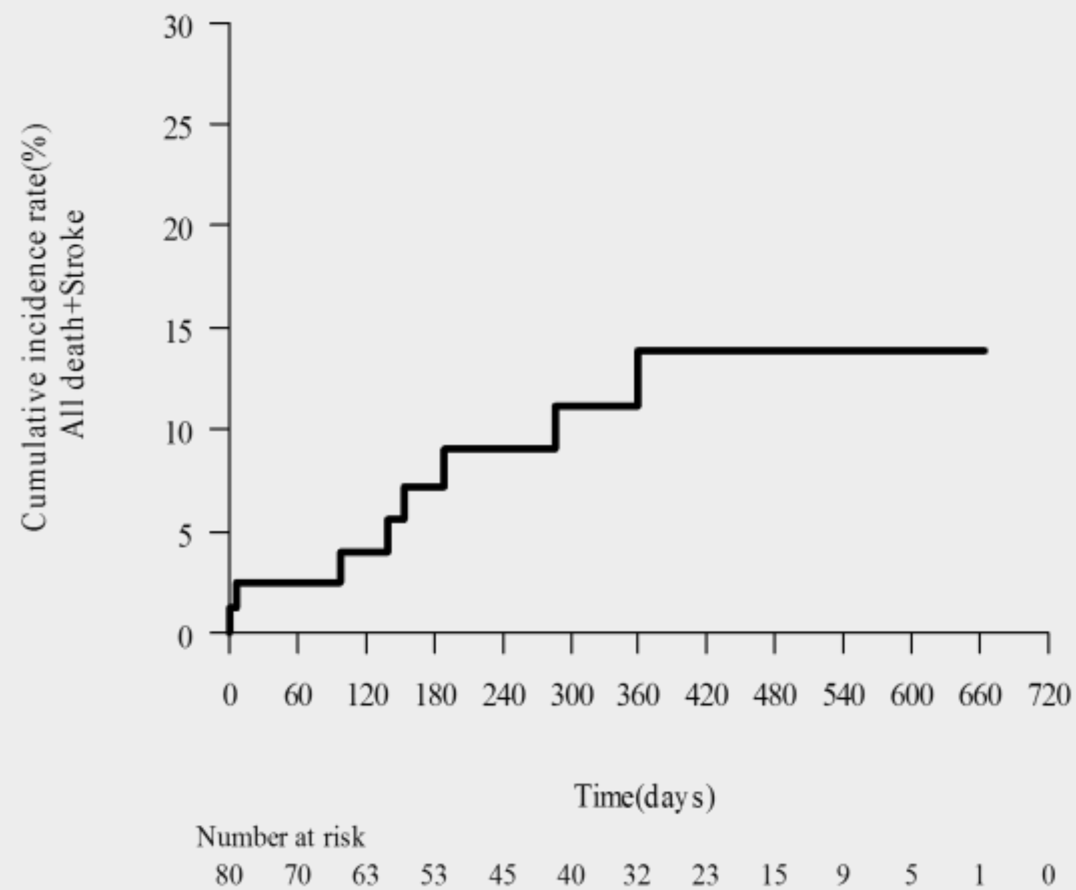
Seoul St. Mary's Hospital Data

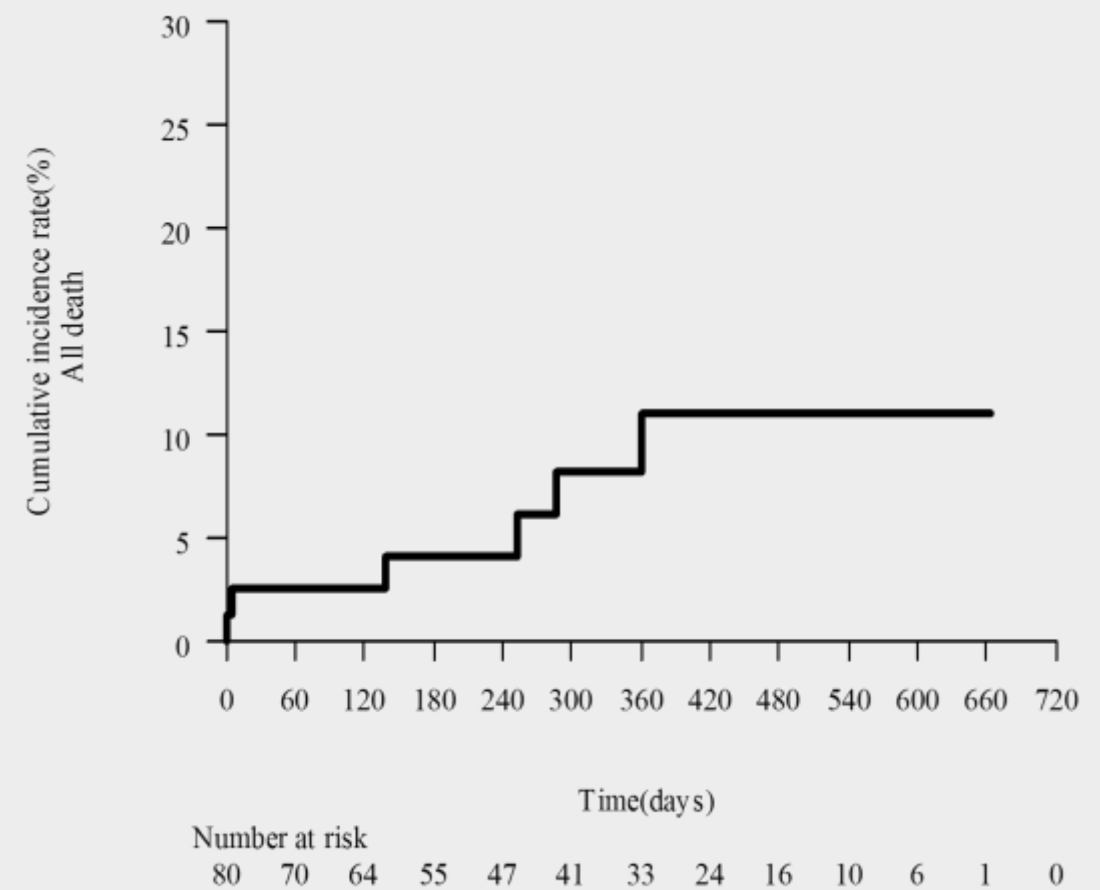
2015.06.17~2017.03.16

Total (n=32/121)

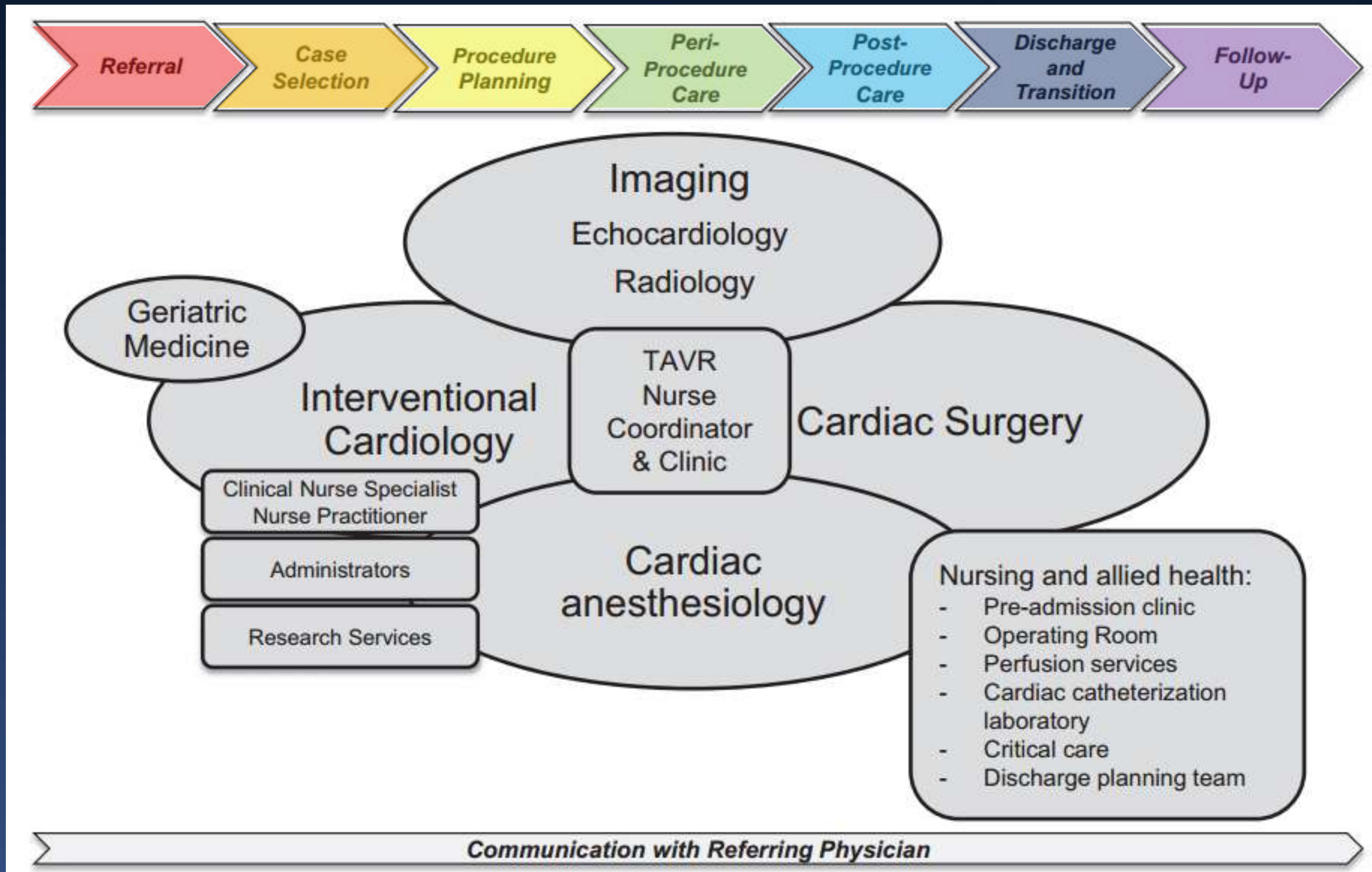
		Baseline (n=32)	1 year later (n=32)	p value
Mean PG 평균(표준편차)		54.8(13.9)	13.4(6.9)	<0.001
Vmax 평균(표준편차)		4.6(0.6)	2.5(0.6)	<0.001
EF 평균(표준편차)		59.7(9.4)	62.5(7.8)	0.211
NYHA Class	Class I	-	28(87.5)	<0.001
	Class II	-	3(9.4)	
	Class III	19(59.4)	1(3.1)	
	Class IV	13(40.6)	-	

Kaplan-Meier curve





Minimalist TAVI



Minimalist TAVI: Vancouver clinical pathway

	0–6 H	6–12 H	12–18 H	18–24 H	24–36 H
Monitoring					
Vital signs	Q15 min×4 Q1 h×3	Q4 h			
	Note: If hypertensive in immediate postprocedure period, consider watchful waiting approach to facilitate return to baseline hemodynamic stability as directed by physician				
Cardiac rhythm	Continuous			May discontinue for intermittent self-care	
	Note: Inform physician of any new intraventricular conduction delay				
Vascular access	Q15 min×4 Q1 h×3	Q4 h			Q8 h
Neuro vital signs and Cincinnati Stroke Scale assessment	Q15 min×4 Q30 min×2 Q1 h×3	Q4 h			
Pain and discomfort	Assess and treat access site and back/postural pain/ discomfort as required		No pain/discomfort anticipated		
	Note: Avoid opioids and sedative hypnotics to minimize risk of delirium; resume patient's usual analgesia or sedation if possible; and maximize effectiveness of repositioning and early mobilization				
Laboratory work and tests	12-lead ECG eGFR and CBC	If local anesthesia procedure and TTE not done at end of procedure: TTE (bedside in unit if possible)		12-lead ECG eGFR and CBC	
Invasive monitoring equipment	Avoid urinary catheter				
	Monitor central venous and peripheral arterial catheters as per standard protocols	Remove central venous catheter Remove peripheral arterial line	Maintain peripheral intravenous saline lock		Remove peripheral intravenous saline lock before discharge home

Minimalist TAVI: Vancouver clinical pathway

	0–6 H	6–12 H	12–18 H	18–24 H	24–36 H
Facilitated reconditioning					
Mobilization and activity	Bed rest Head of bed Flat×2 h Then ↑ at 30°	Implement progressive activity protocol:			
		Dangle to standing position at bedside Transfer to commode Mobilize short distance in room	Transfer to commode Up in chair for meals Mobilize short distance in room Encourage self-care behavior Mobilize short distance outside of room Facilitate uninterrupted rest/sleep and return to diurnal cycle		Up in chair for meals Mobilize for 5–10 min every 4–6 h Encourage self-care behavior Facilitate rest
Elimination	Assess need for elimination	Mobilize to commode or to standing position	Mobilize to commode or washroom	Mobilize to washroom with assistance	
	Note: Anticipate low-urine output in the early recovery period (usual low periprocedure fluid administration); avoid urinary catheterization to minimize risk of UTI, urinary retention, hematuria, and other complications; and consider intermittent catheterization if required (max. ×3)				
Hydration	NPO until hemostasis and confirmed clinical stability IV 50–75 cc/h	If LVEF ≥50%: encourage fluids If LVEF <50%: encourage fluids within limit of preprocedure fluid restrictions			
Nutrition		Light dinner up in chair	Up in chair for all meals Encourage nutritional intake and preferred foods Goal: 3 meals and 1–2 snacks/24 h		
Communication, patient teaching, and discharge planning					
Communication		Communicate early with the multidisciplinary team any clinical variables that may affect goals of care and to identify opportunities to maintain patient on clinical pathway			
Patient teaching	Provide patient teaching about maintaining vascular hemostasis	Provide coaching to support the facilitated reconditioning interventions (eg, motivation for mobilization) Begin discharge teaching			Complete discharge teaching Provide vascular access minor ooze dressing kit
Discharge planning		Confirm discharge plan with patient and family		Assess readiness for discharge	Confirm discharge criteria

Minimalist TAVI : 3M TAVR Study Design

Multi-modality, multi-disciplinary, minimalist

To evaluate the efficacy, feasibility and safety of next day discharge home in patients undergoing balloon expandable transfemoral TAVI utilizing the Vancouver 3M clinical pathway

Patients with severe symptomatic AS undergoing elective transfemoral TAVR

↓

Considered at increased surgical risk by the Heart Team

↓ ↓

Vancouver 3M Clinical Pathway
(n = 400)
Meets all general, anatomical, functional, and peri-procedural exclusion criteria

Standard TAVR
(n = 800)
All remaining patients at all sites
Standard Care

Staged PCI of all suitable

↓ ↓

Primary Outcomes: All-cause mortality and major stroke (modified Rankin Scale of 2 or more) at 30 days AND the proportion of patients who are discharged the next day

www.clinicaltrials.gov: NCT02287662

Why Sapien3 for minimalist TAVI?

- Safe & easy procedure
- Paravalvular leakage: no-to-mild
- Complete AV block: very rare

TAVI with Sapien3

Safe & Easy procedure?

Why Sapien3? Low delivery profile

Cribier-Edwards

2002

SAPIEN

2006

SAPIEN XT

2009

SAPIEN 3

2013

24F

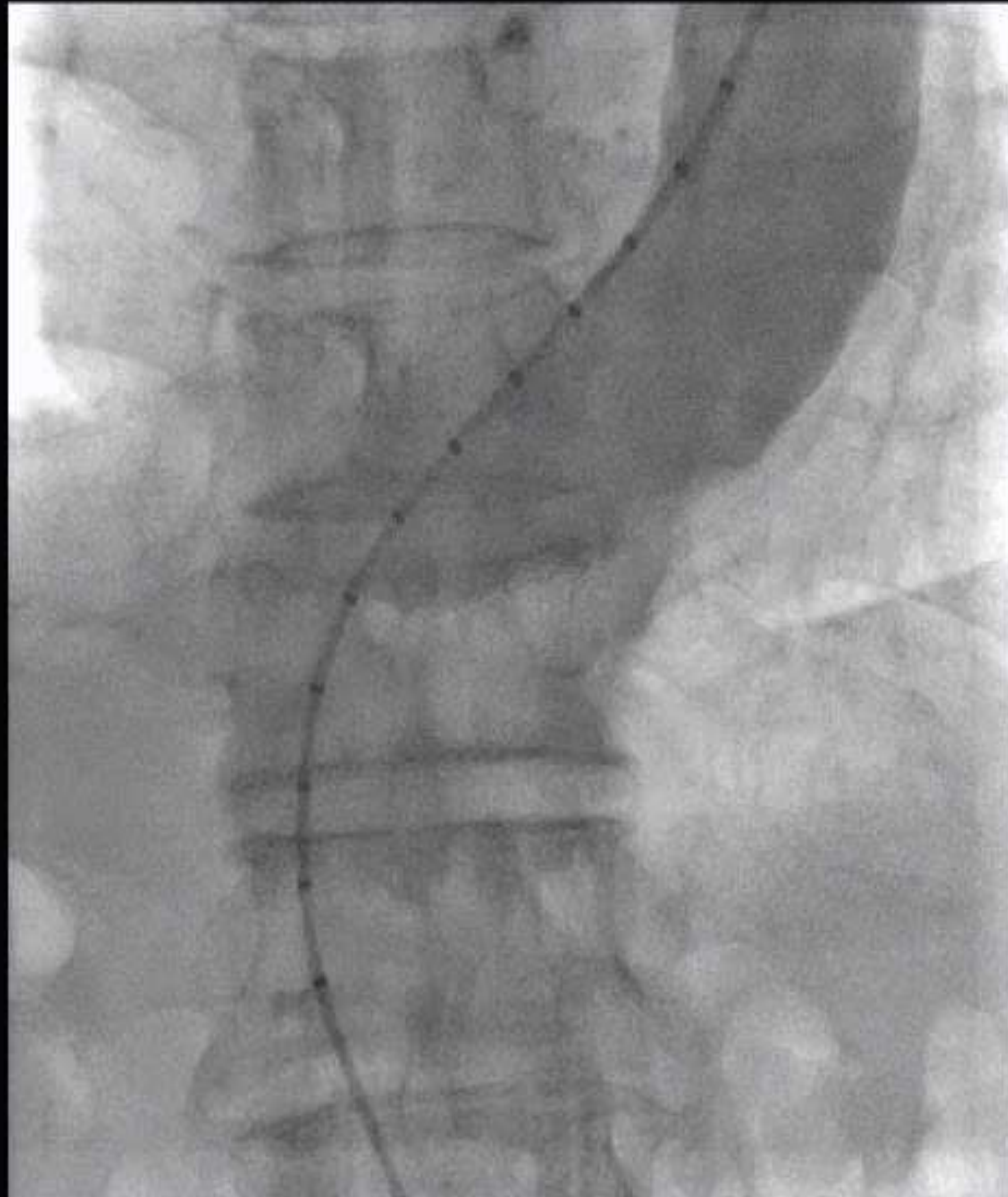
22F

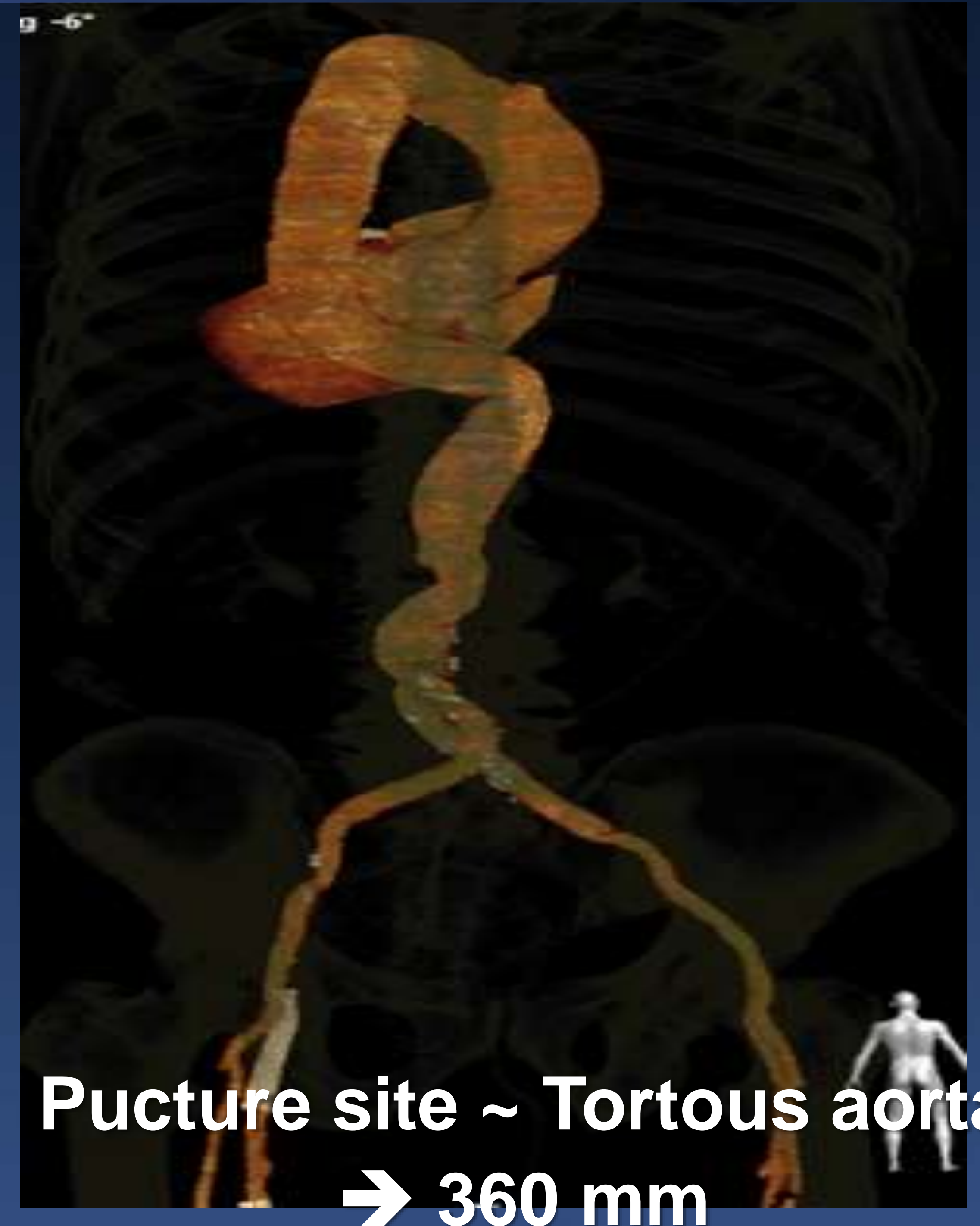
16F

14F

80 year-old male: Smooth delivery in tough aorta

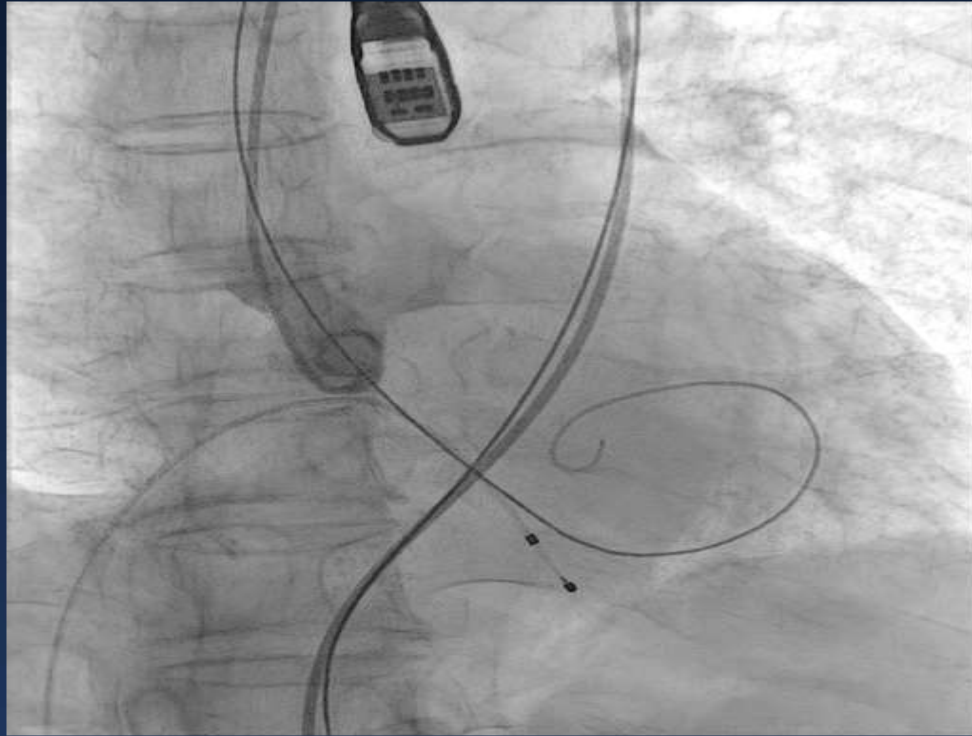
PCI for left main disease, 3 years ago
EVAR for AAA, 2 yaers ago
LVEF 30%

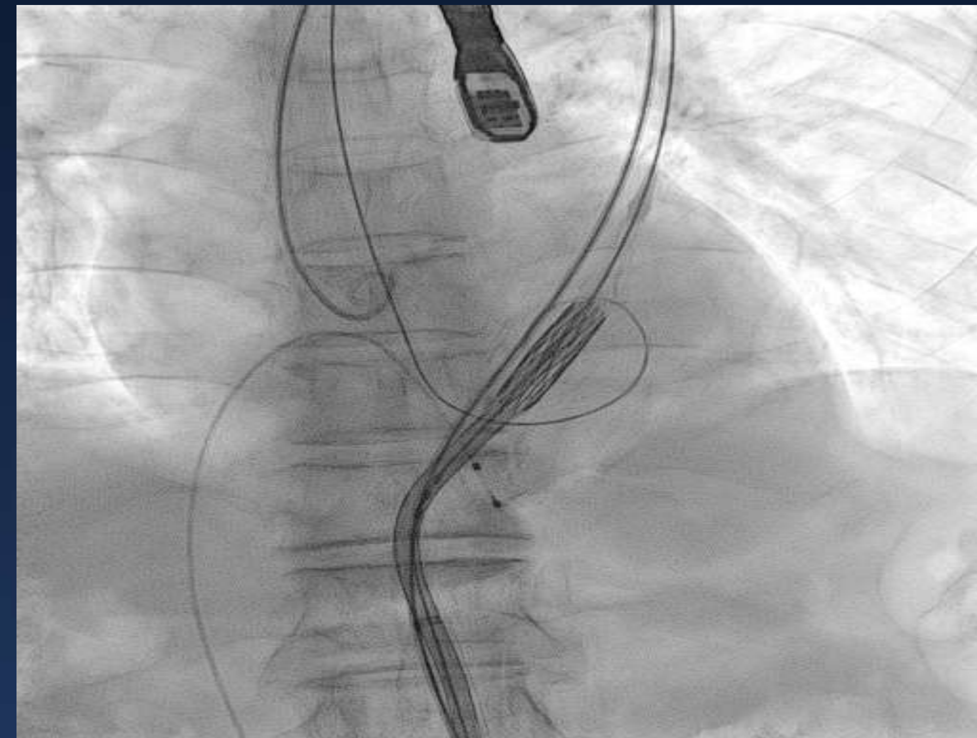


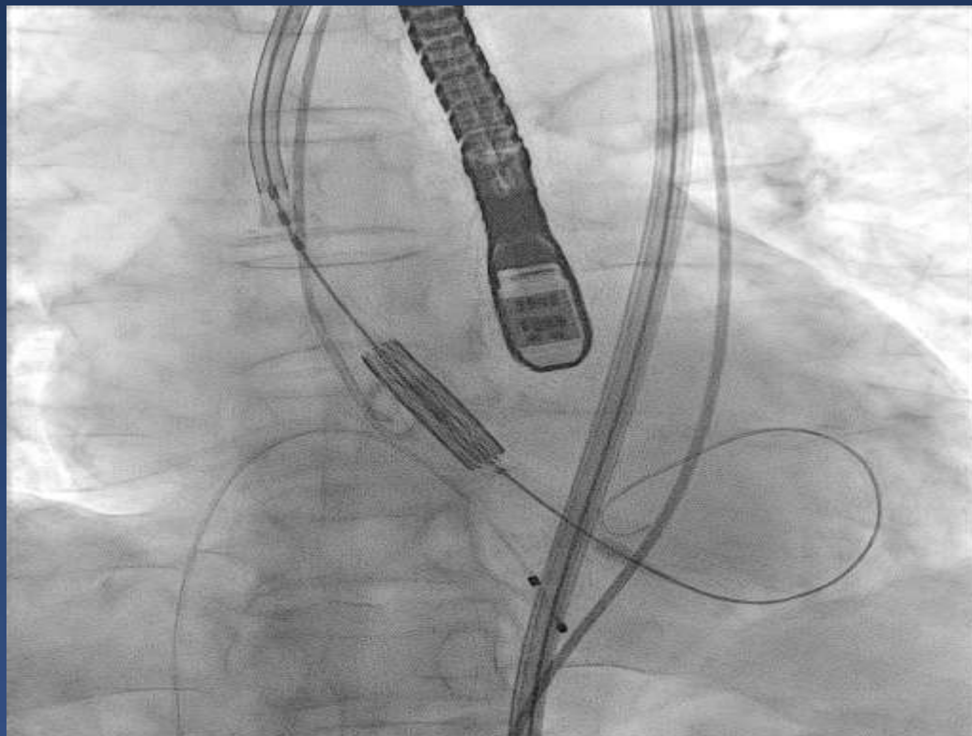


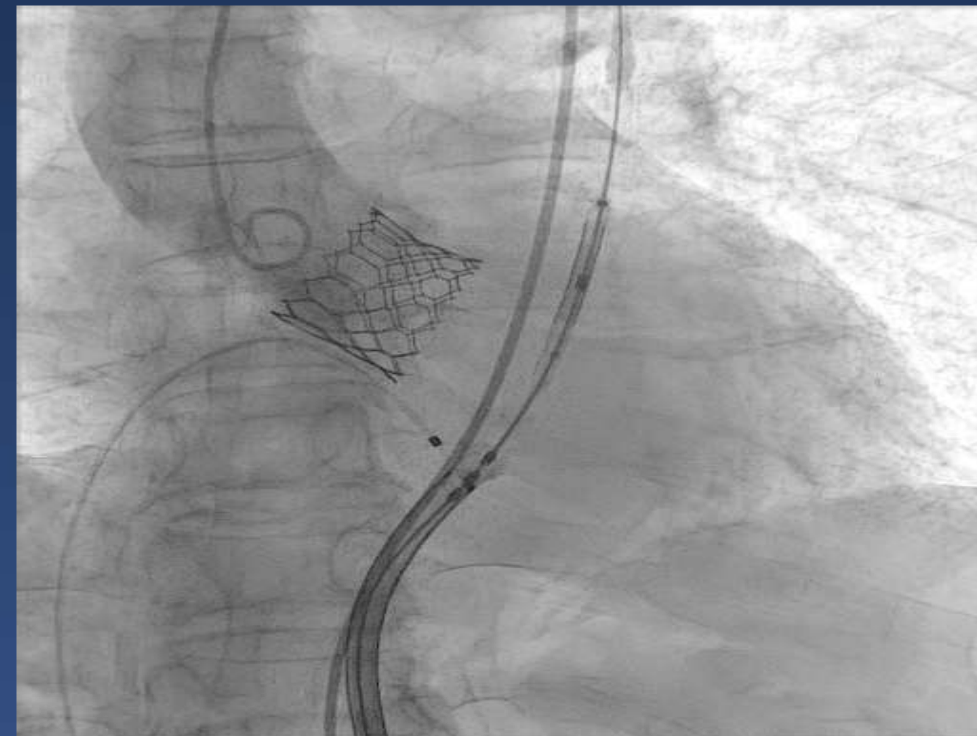
Pucture site ~ Tortous aorta
➔ 360 mm

Smooth delivery with two strong wire support from puncture to valve implantation: only 20 min









Why Sapien3? Low delivery profile
No need for pre-ballooning

Cribier-Edwards

2002

SAPIEN

2006

SAPIEN XT

2009

SAPIEN 3

2013

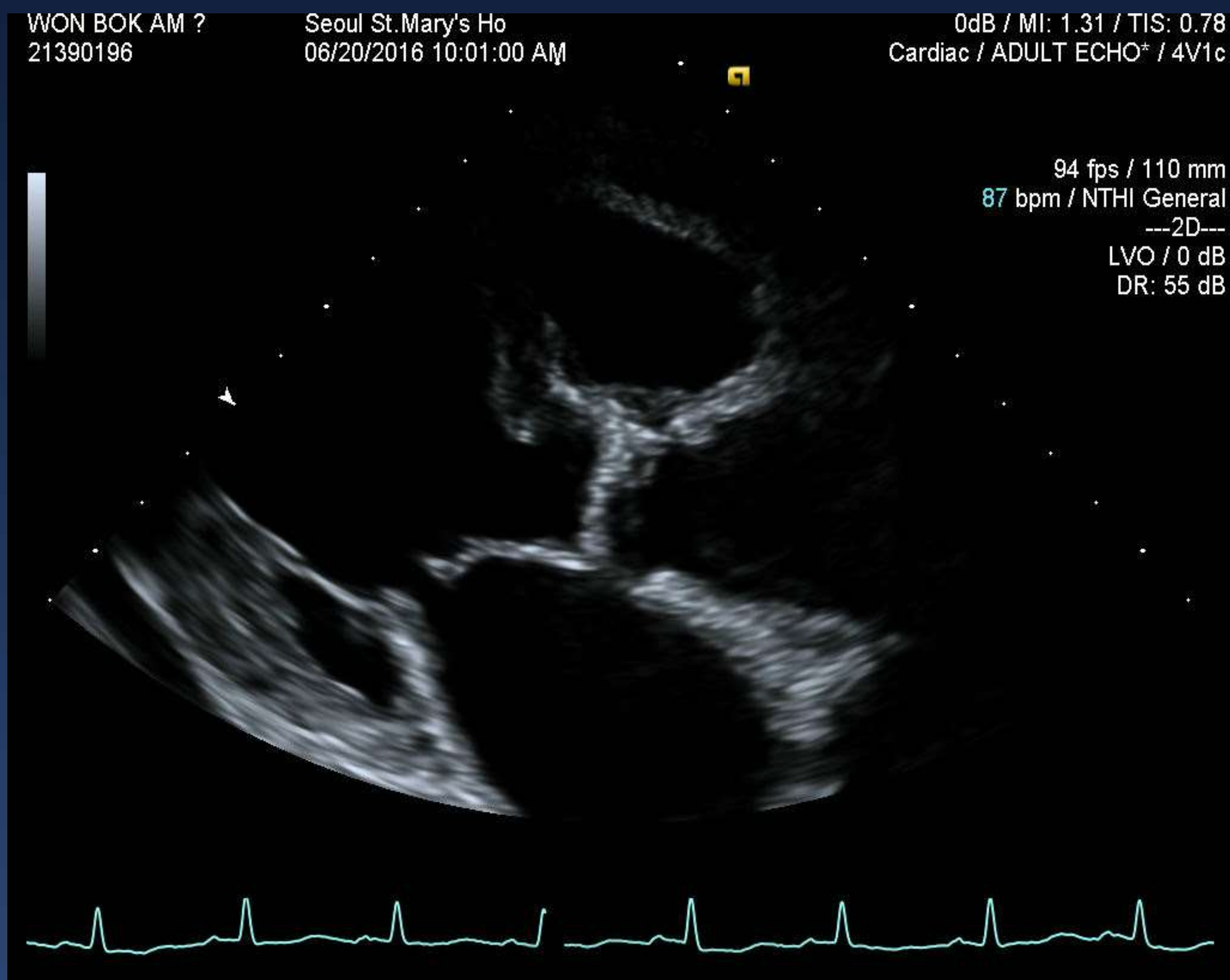
24F

22F

16F

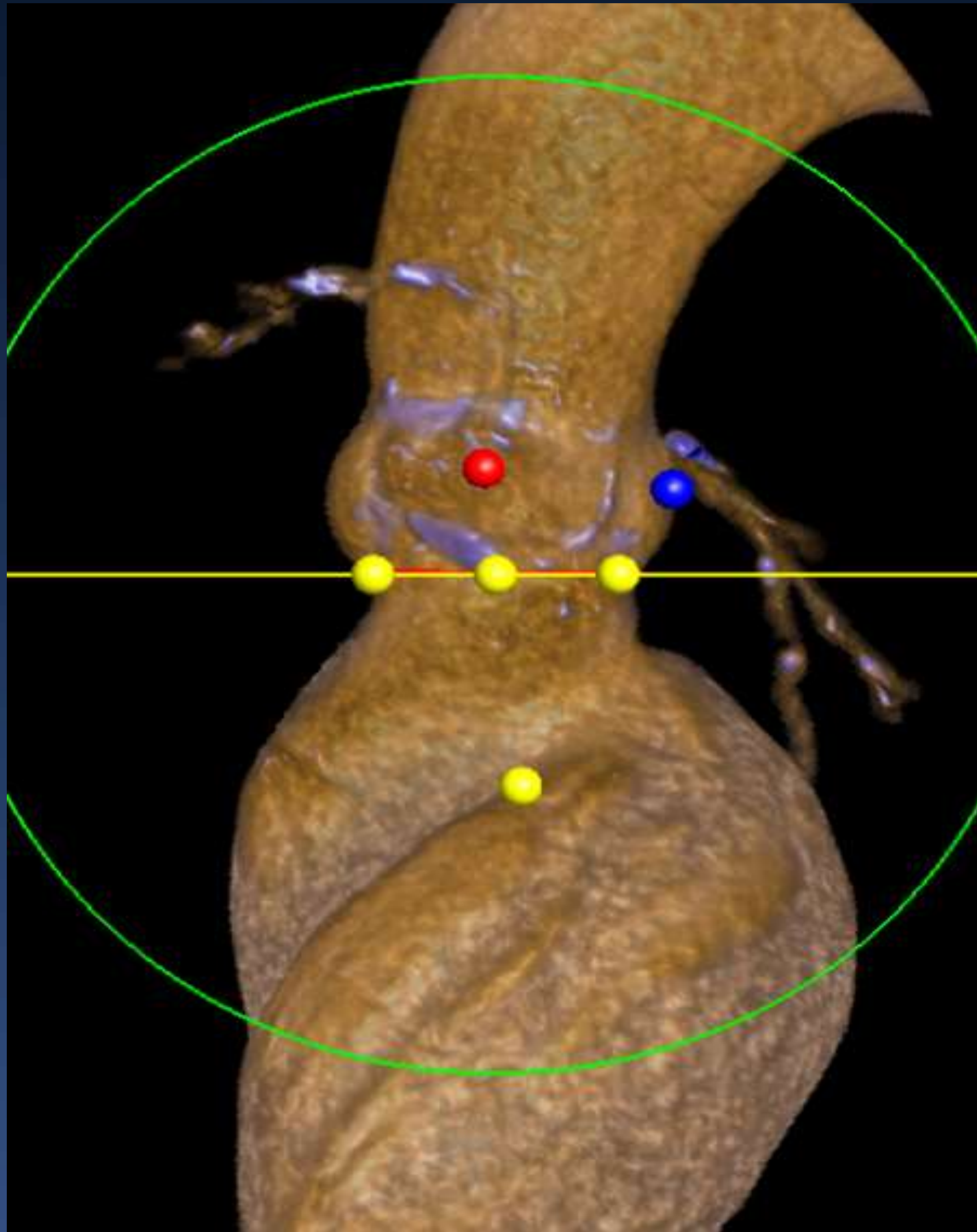
14F

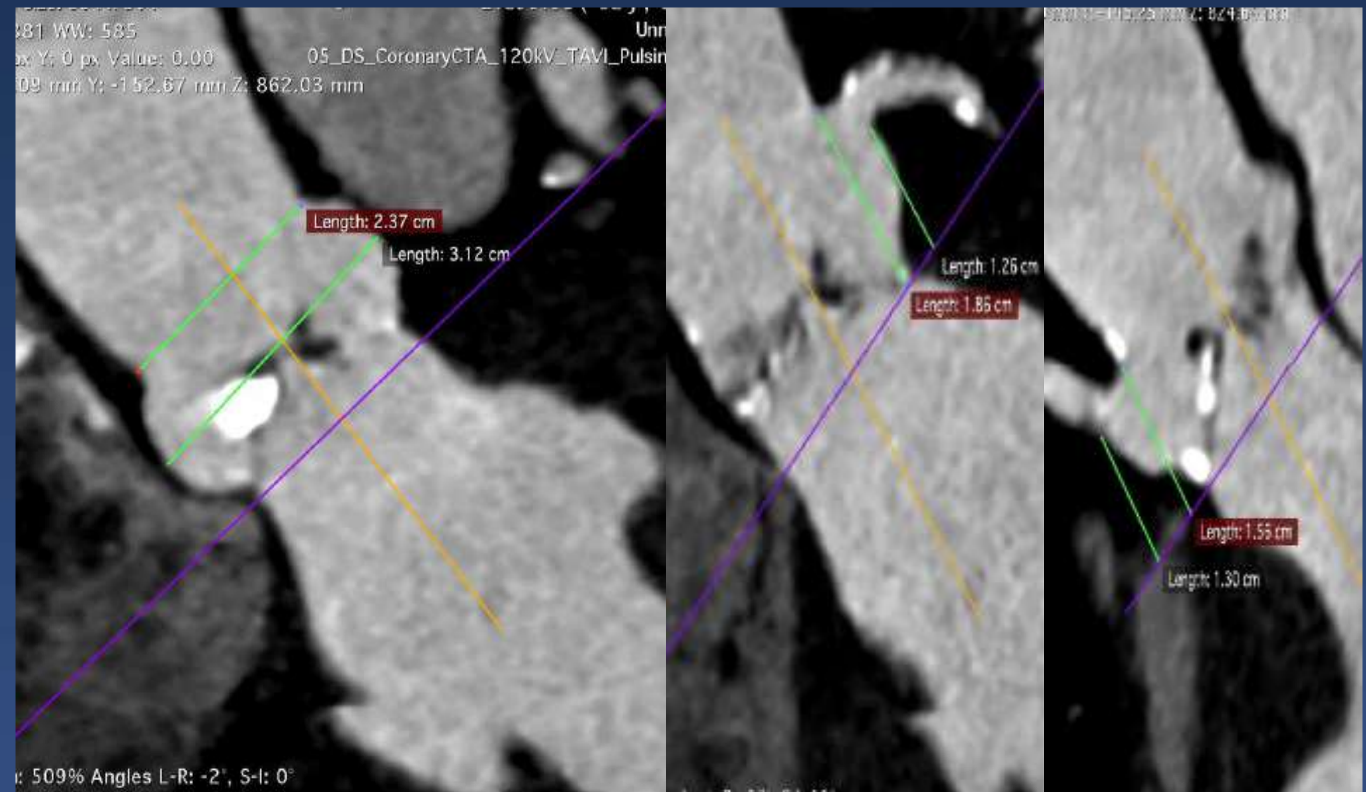
98-years old female



1. AV meanPG= 55 mmHg
2. AV Vmax= 4.7 m/s
3. AVA=0.67/0.73 cm2 by 2D/CE
4. AVA Index = 0.48 cm2/m2 by2D
5, LVEF 42%

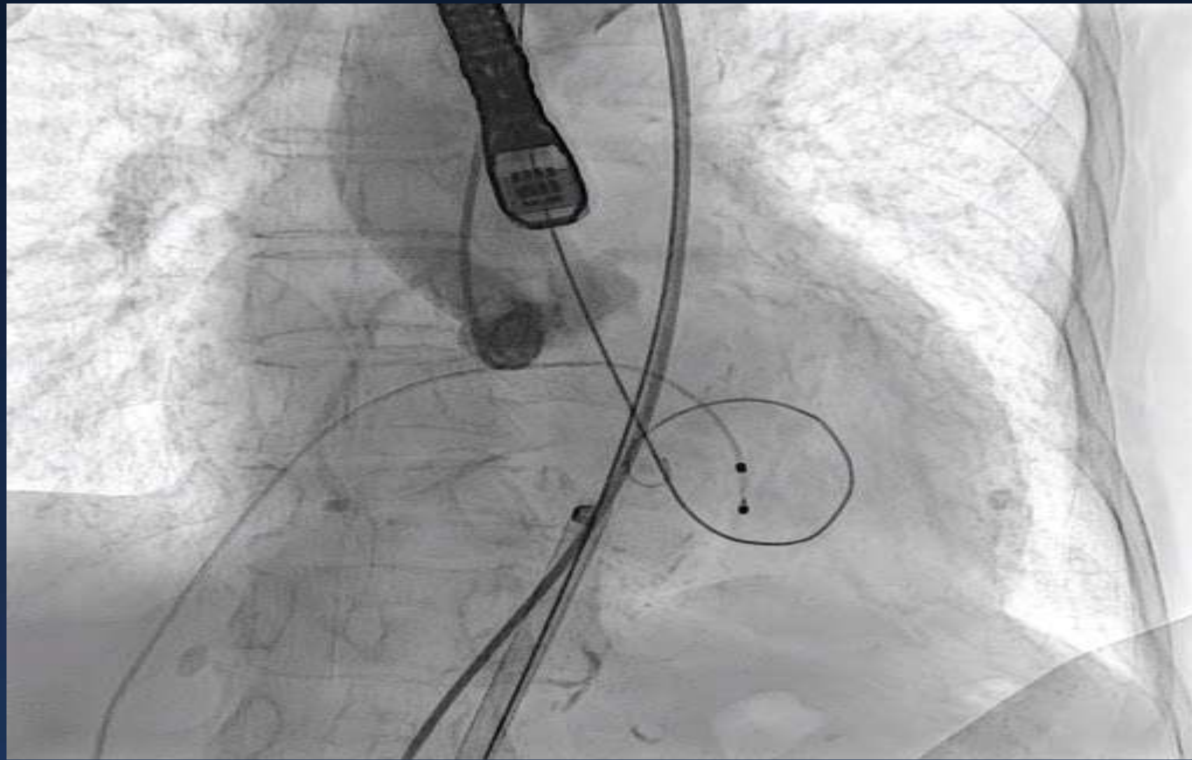
98-years old female: CCTA

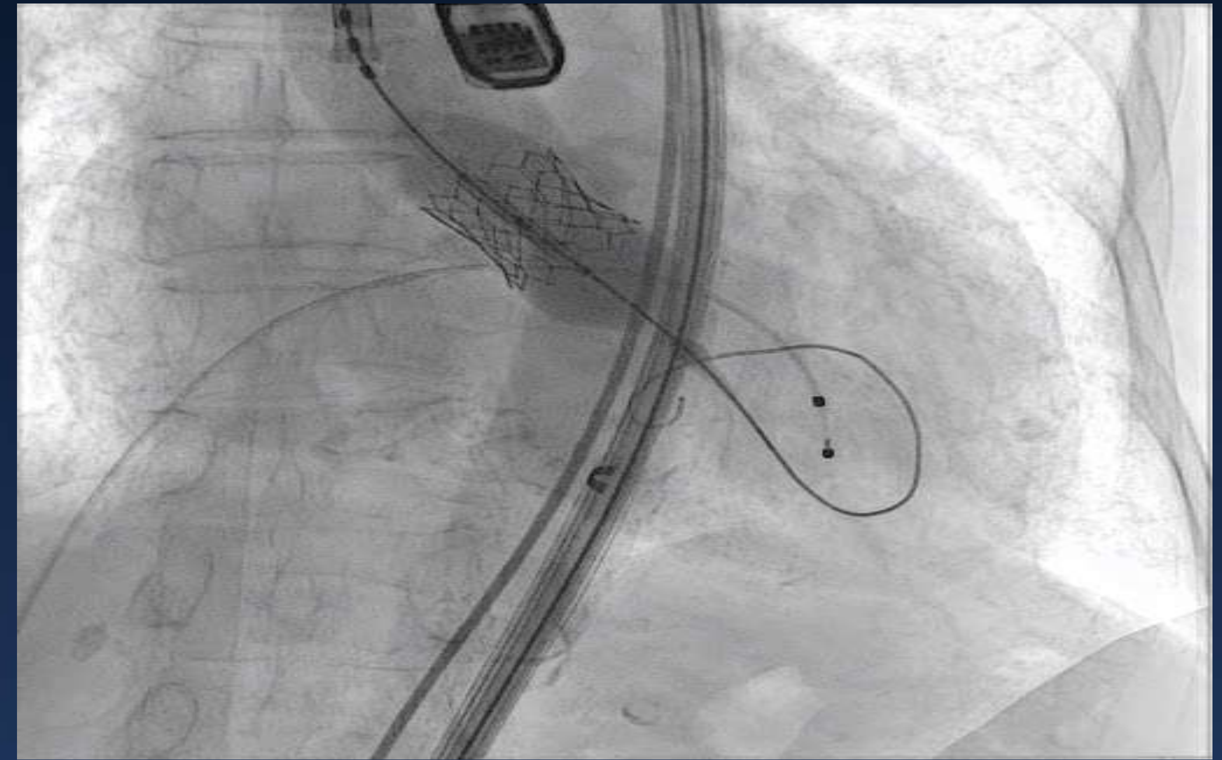


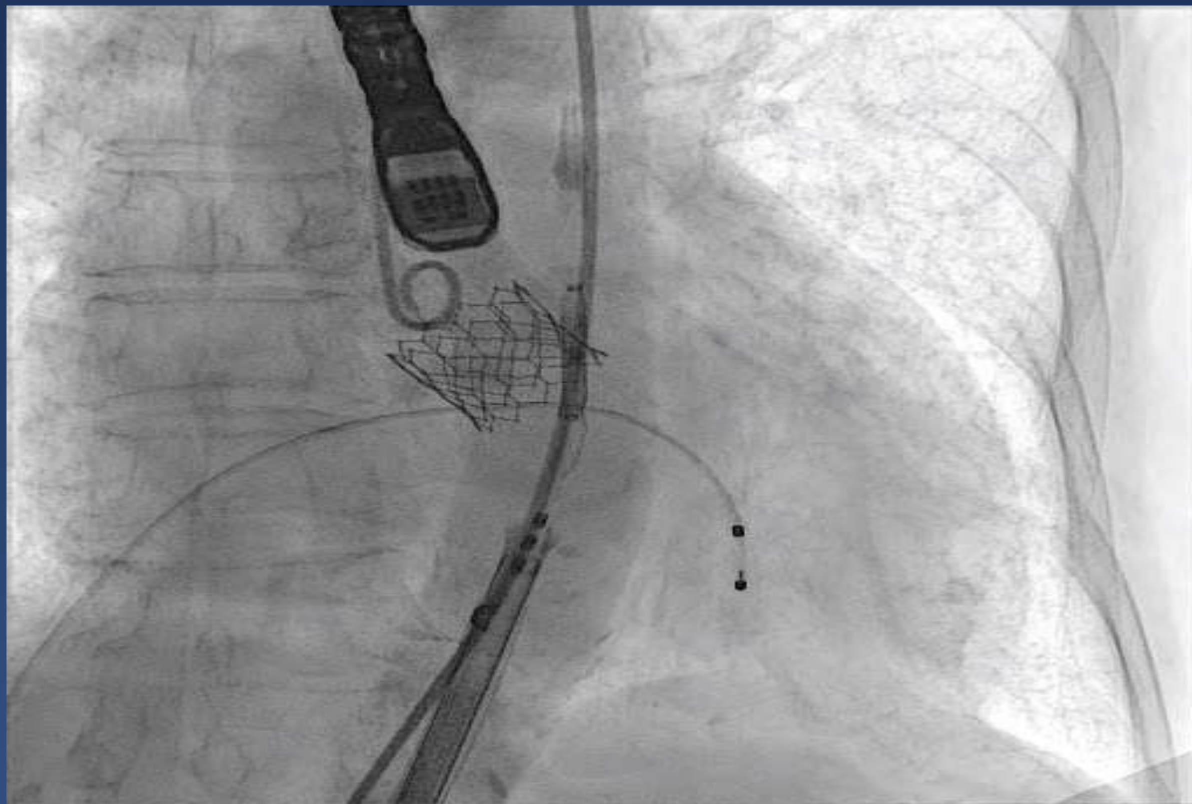


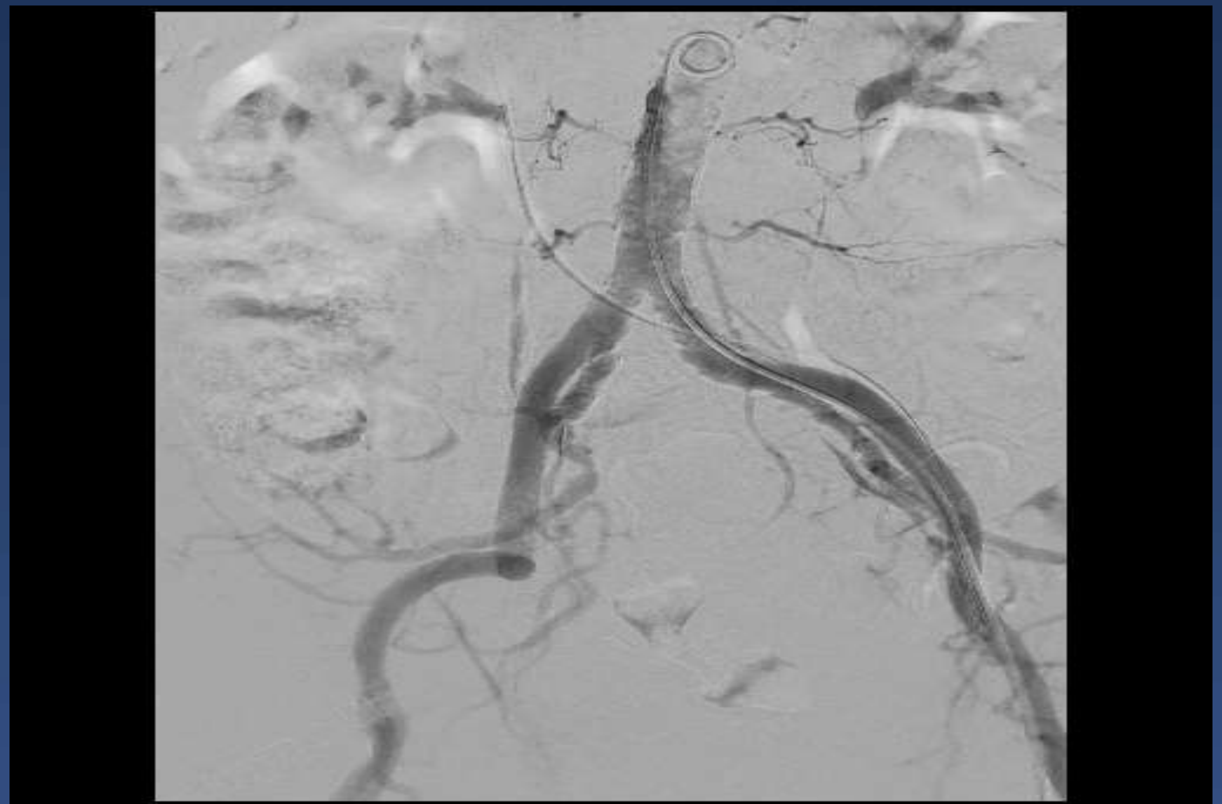
TAVI without predilation

From puncture to closure: 22 min, contrast volume 180 mL





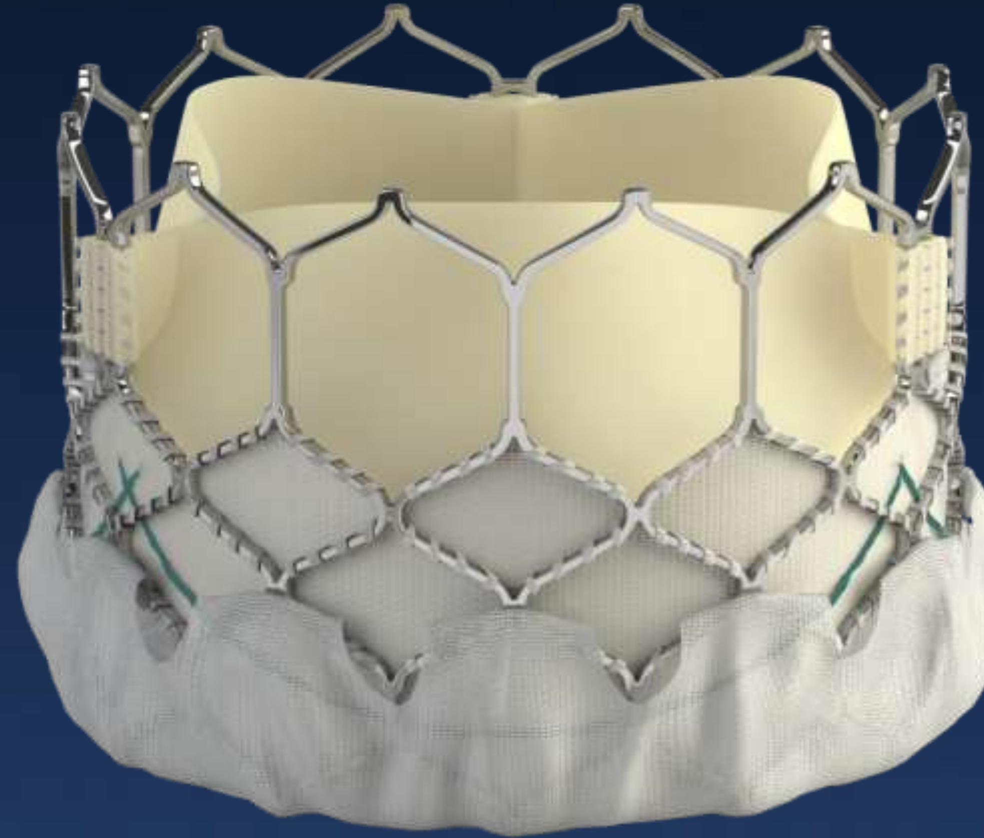




Comparison: Sapien XT vs Sapien3

	Sapien XT (n=44)	Sapien 3 (n=50)
Procedure time (from anethesia to extubation)	2h 23m	1h 25m
Total Fluoro time	42m 10s	21m 57s
Contrast volume	226	200

Why Sapien3 valve: no oversizing, no PVL

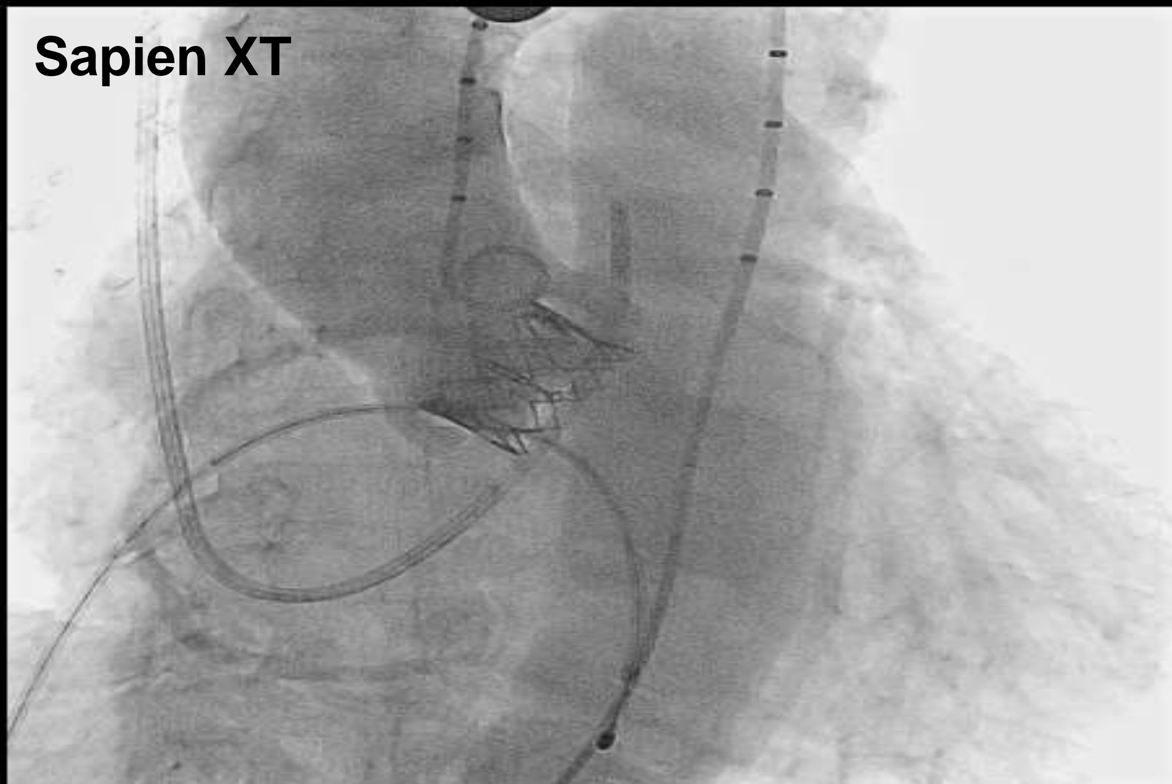


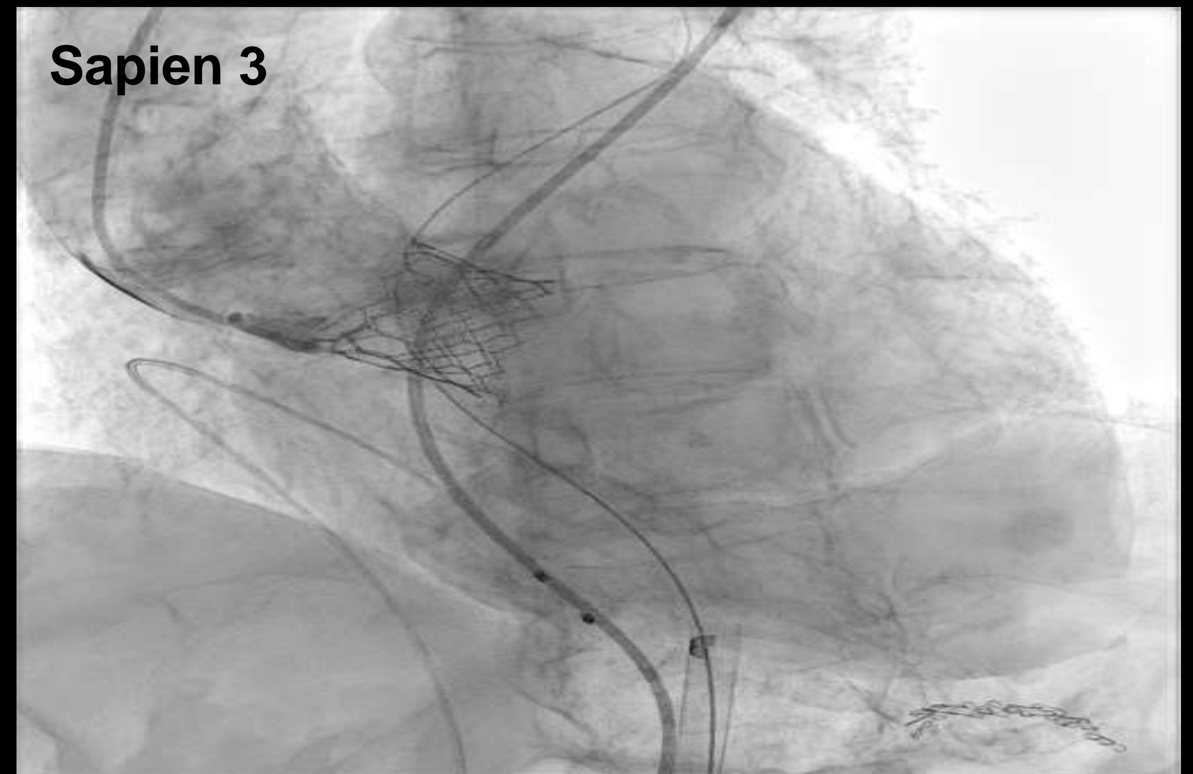
Outer Sealing Skirt

- **Virtually eliminates moderate-to-severe PV leak → no need for oversizing**

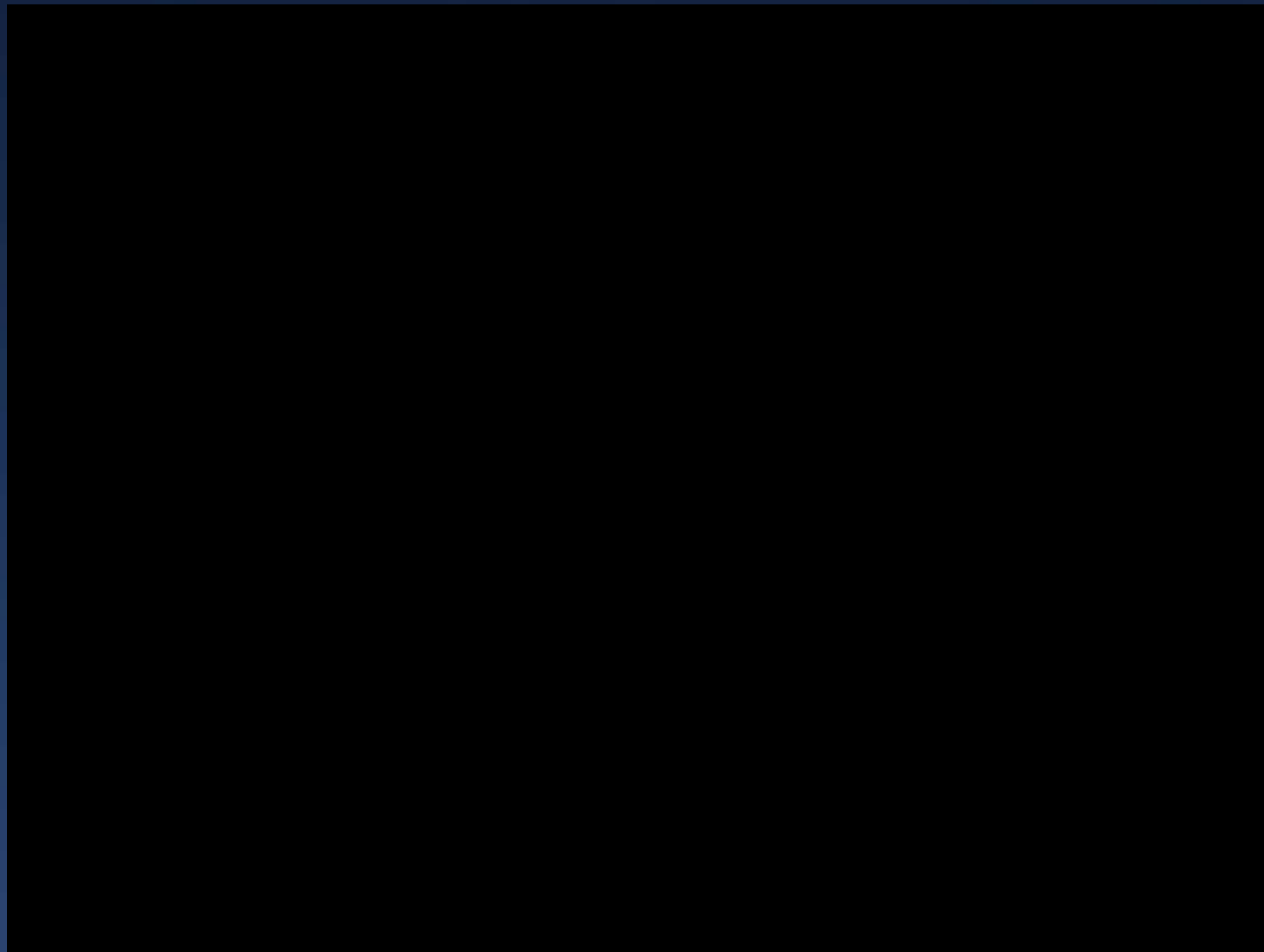
Paravalvular Leakage

	no/trivial	mild	moderate	severe
SAPIEN XT (n=44)	3	32	9	0
%	6.8	72.7	20.5	0
SAPIEN 3 (n=50)	27	23	0	0
%	54.0	46.0	0	0

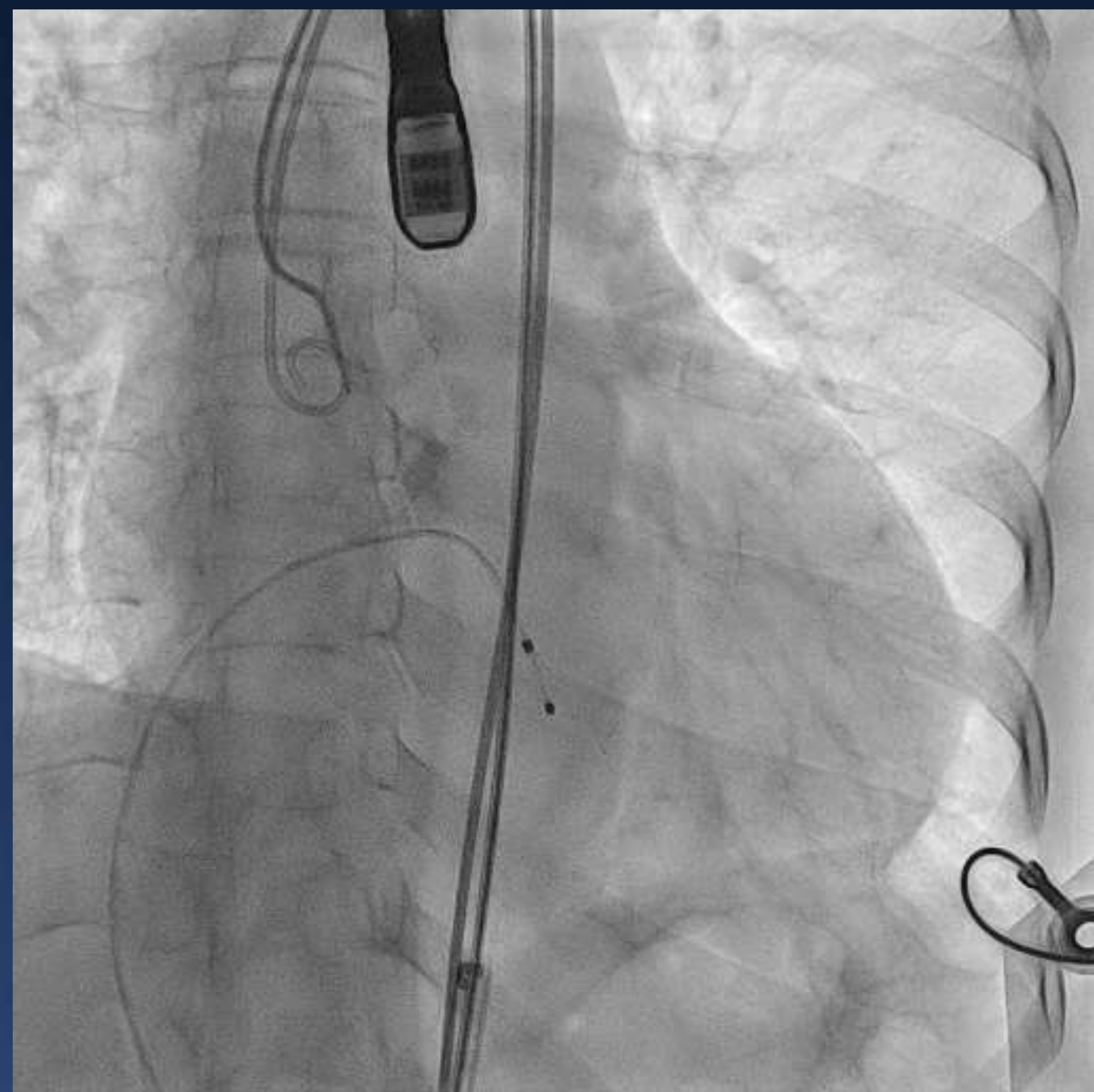


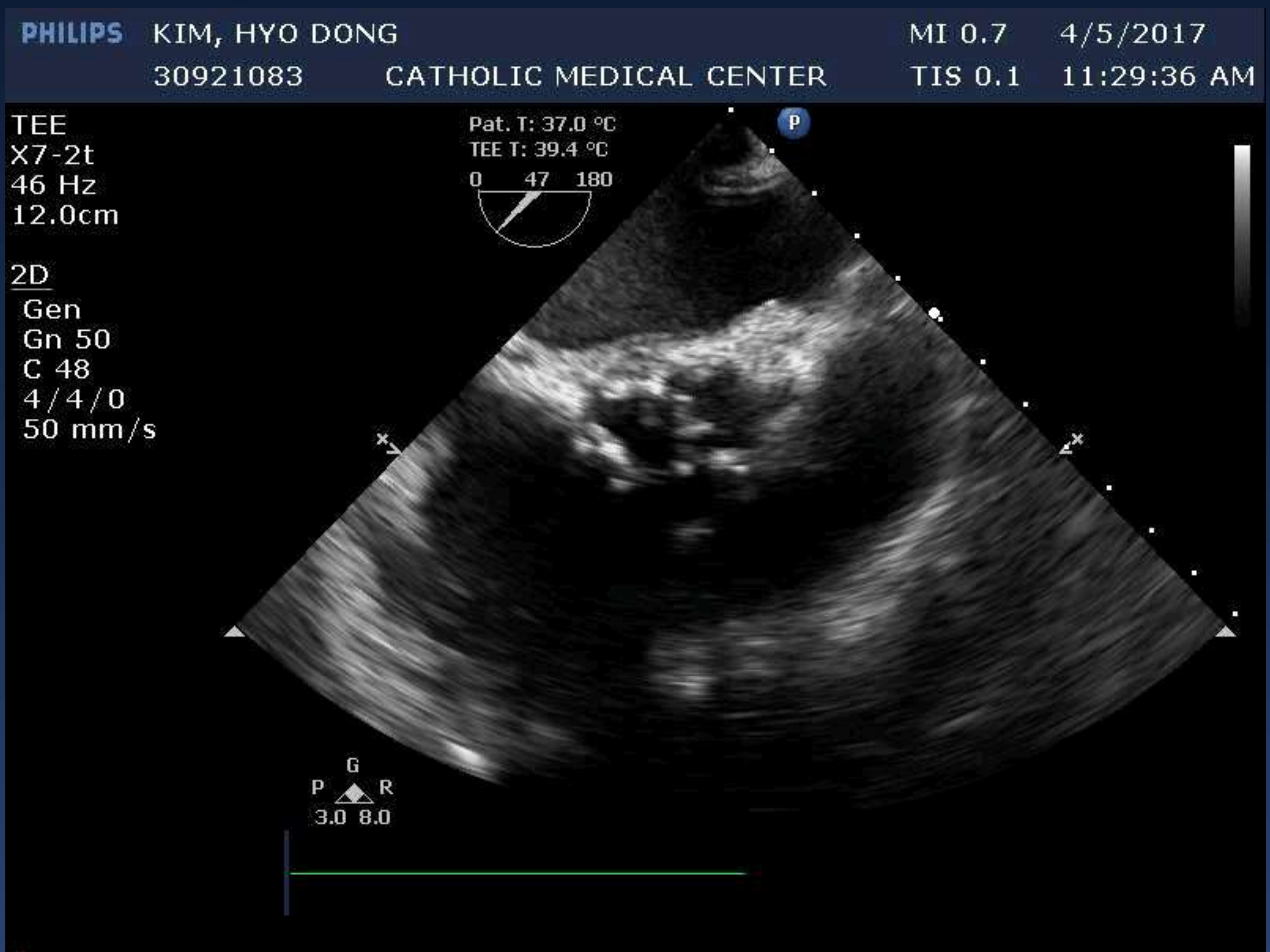


Case: patient with heavily calcified aortic valve 82 yo male

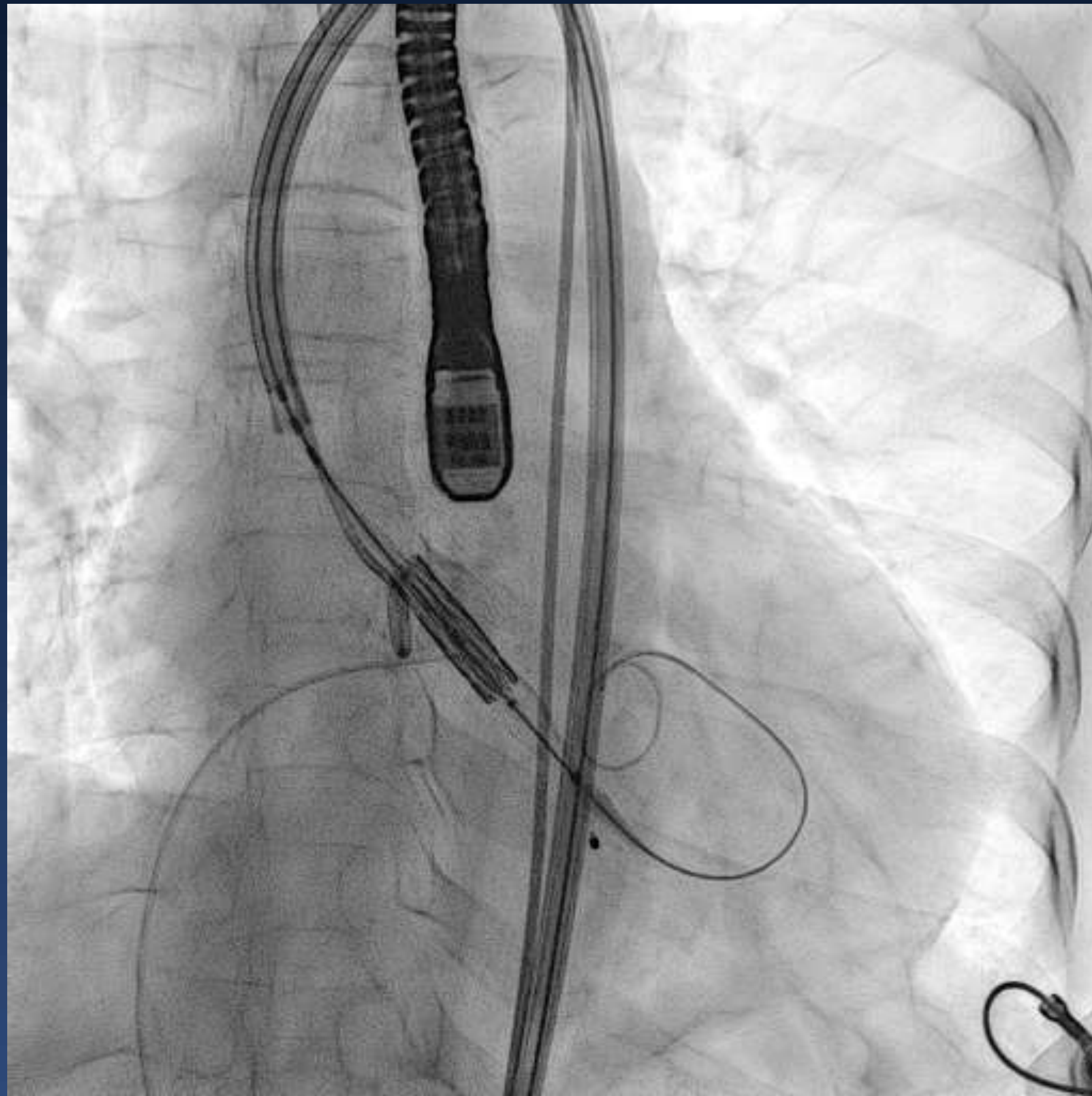


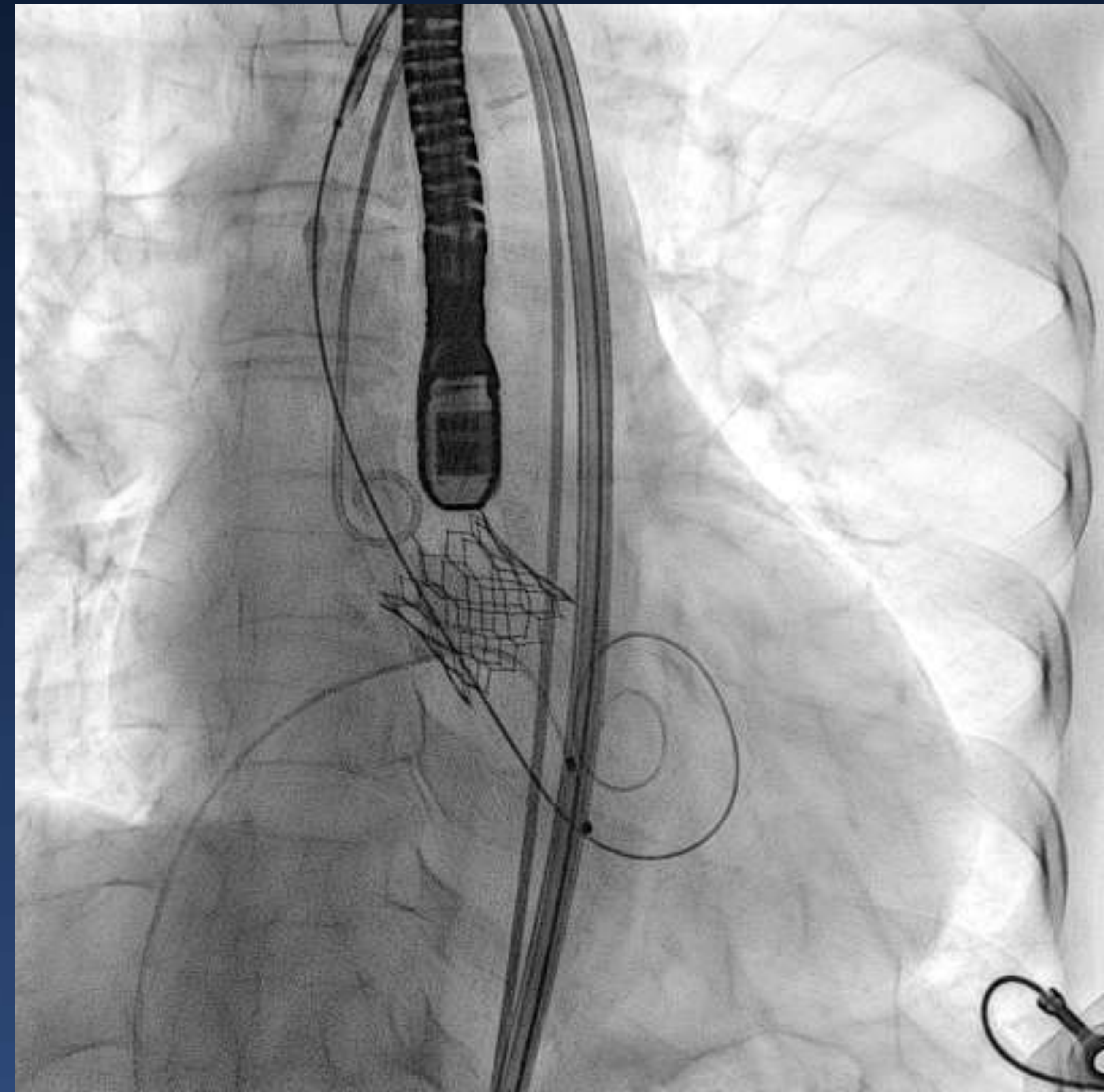
Aortic leaflet calcification





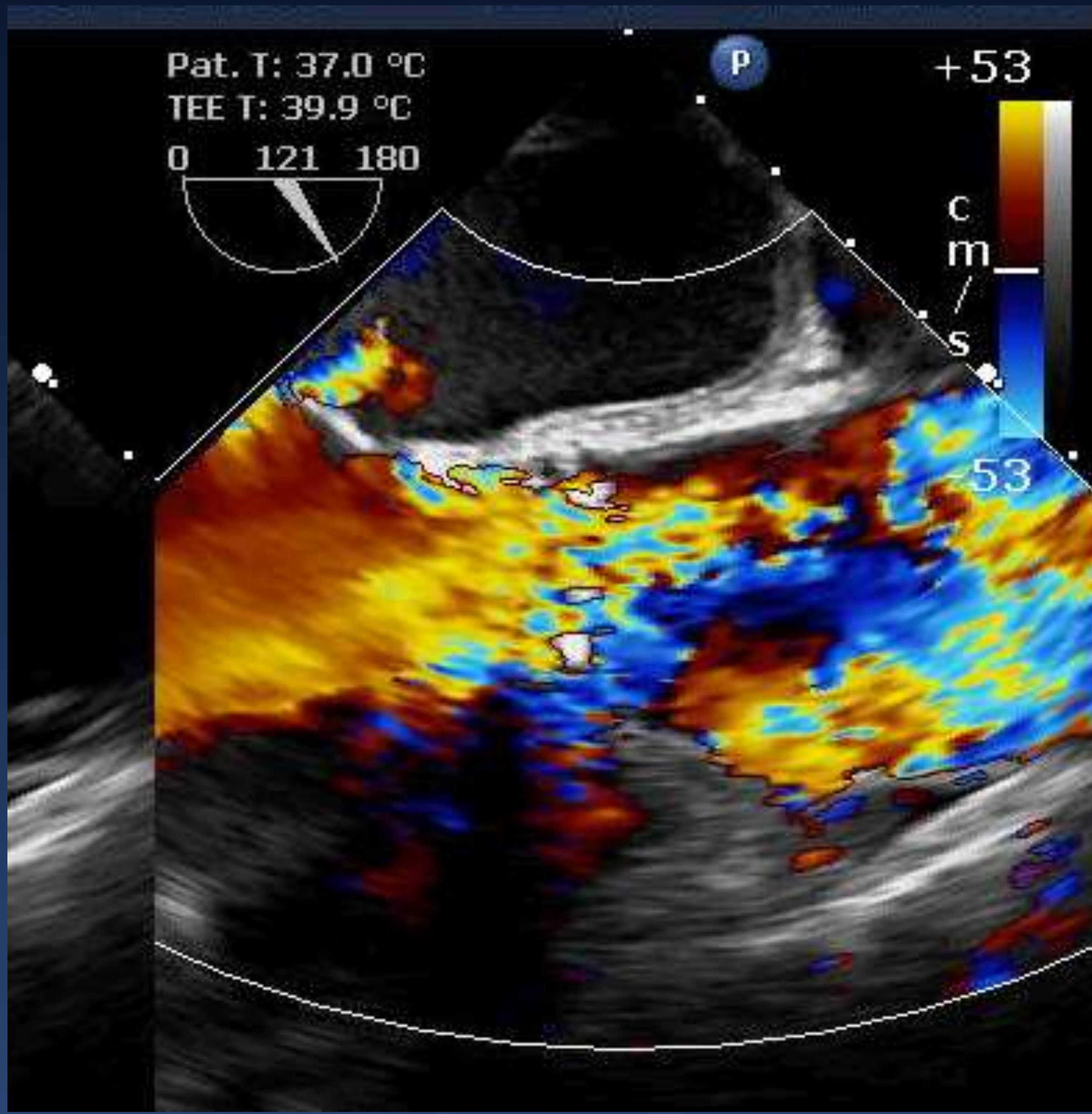
Very slow valve implantation & no/minimal oversizing virtually eliminate annular rupture

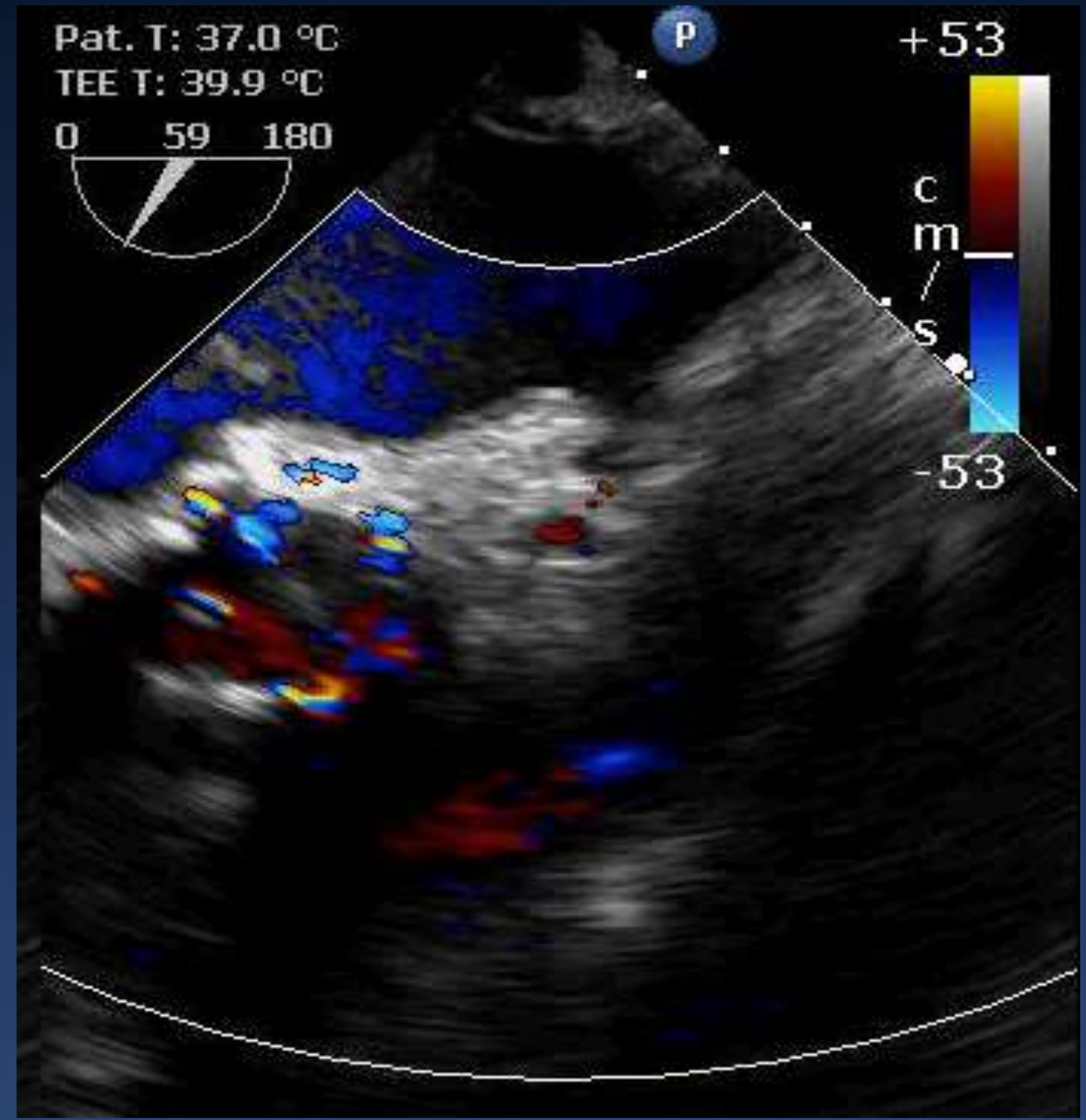




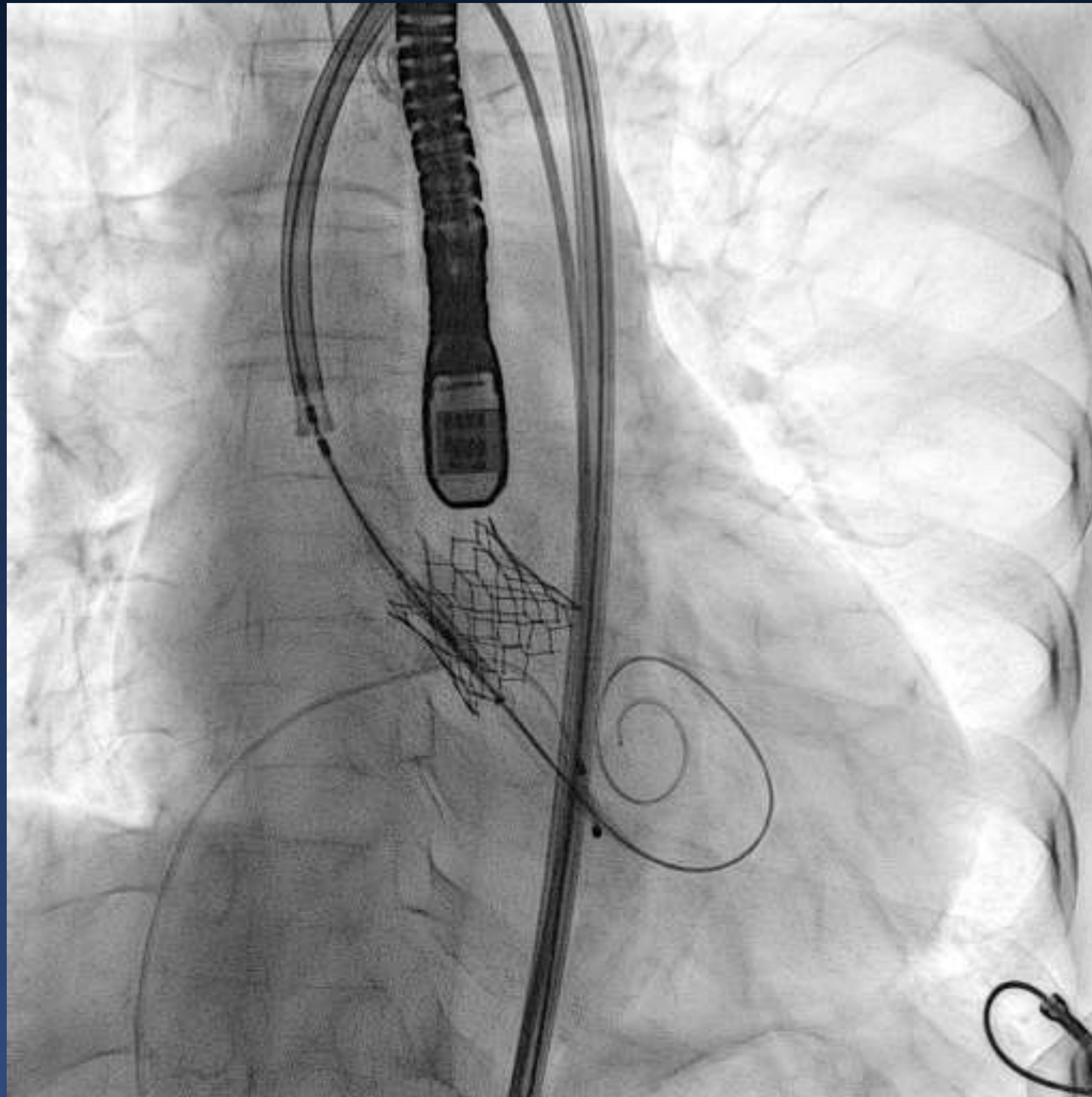
- 1cc off: from 15% oversizing to 6% oversizing

Post-TAVI TEE

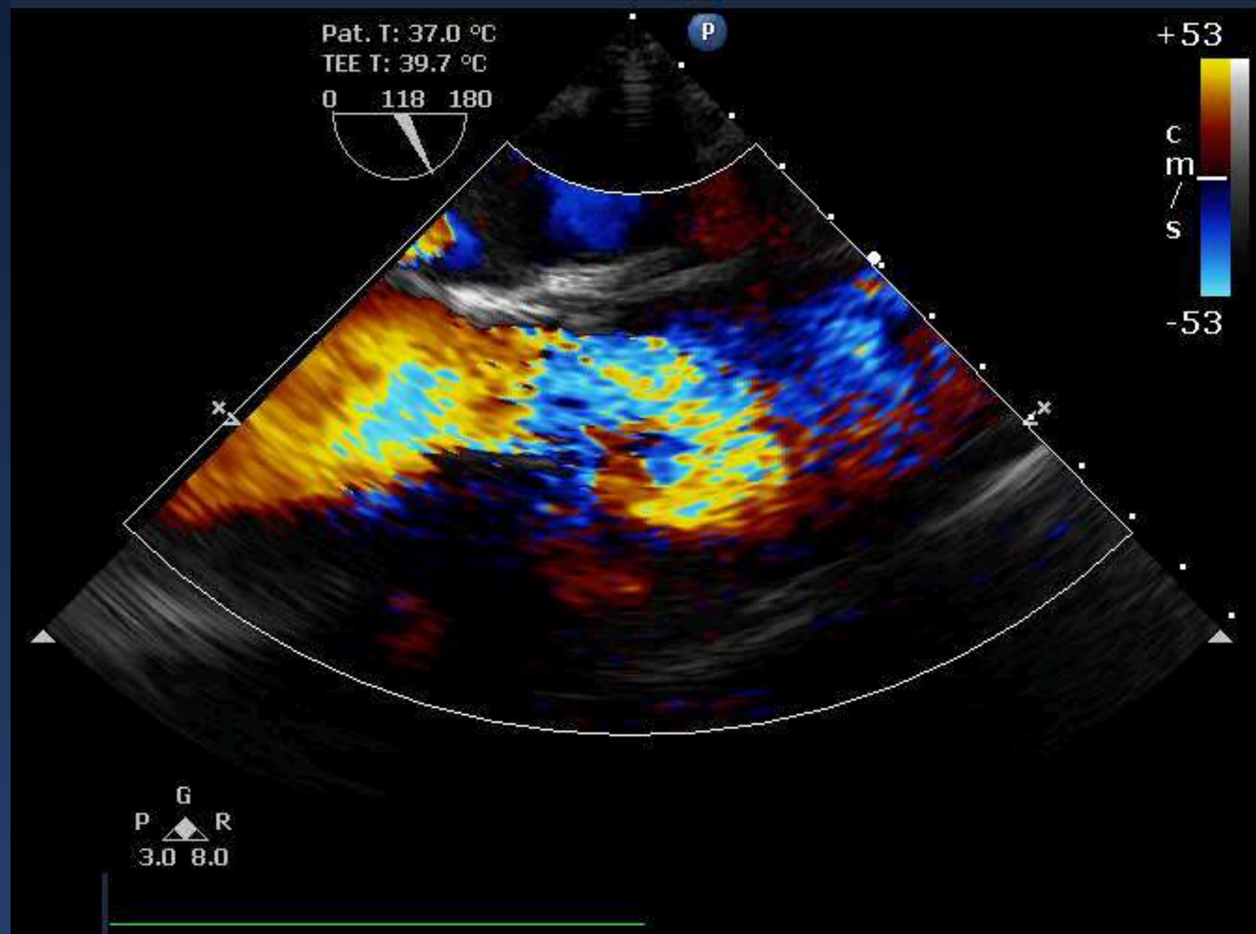


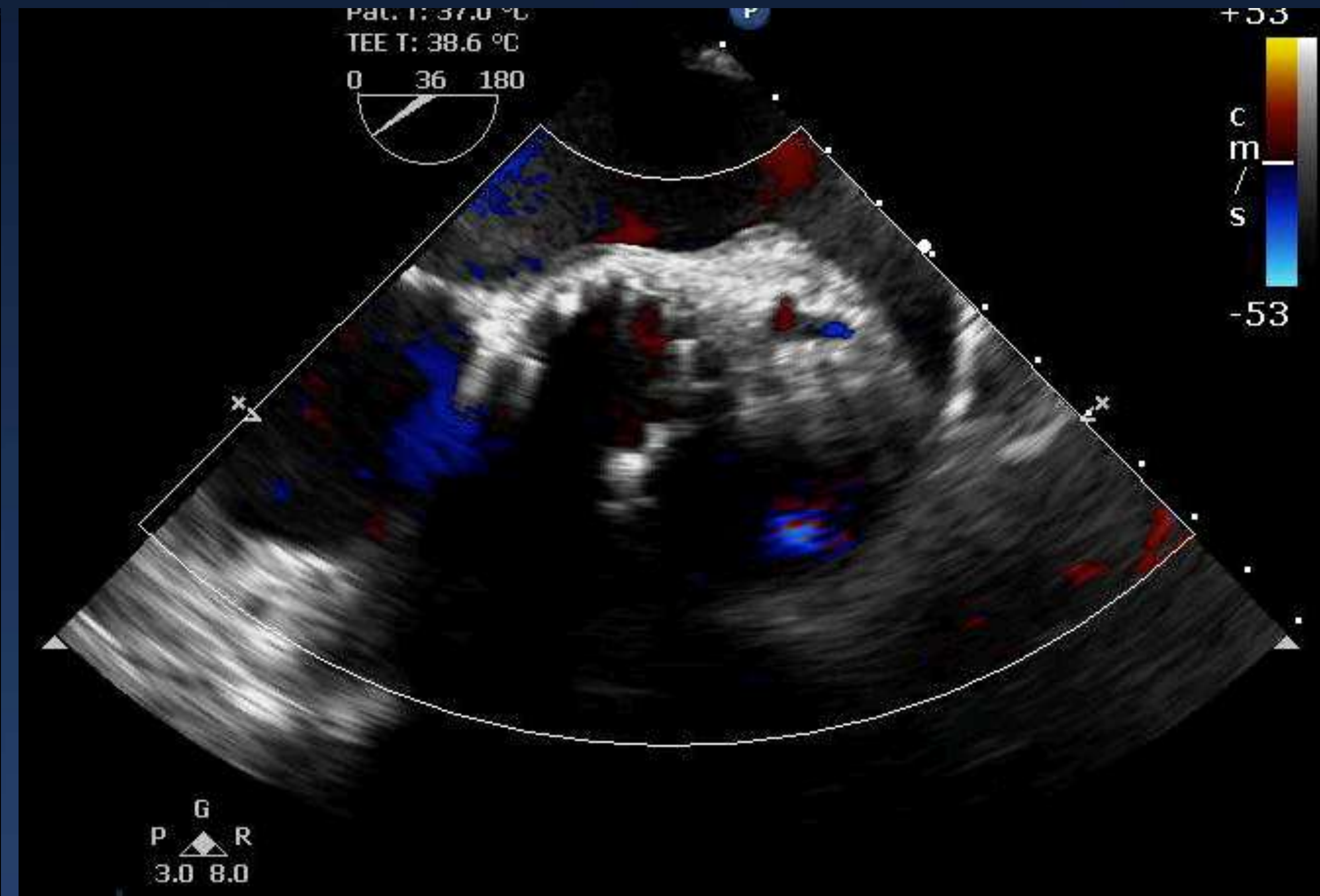


Post-TAVI ballooning

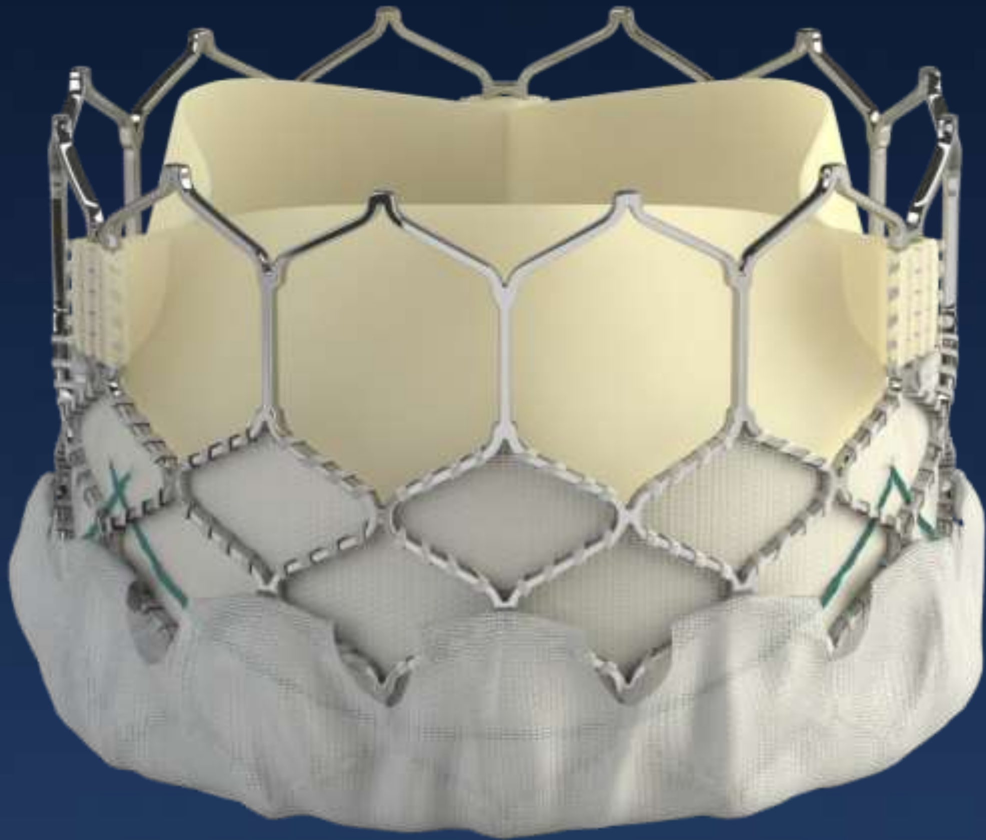


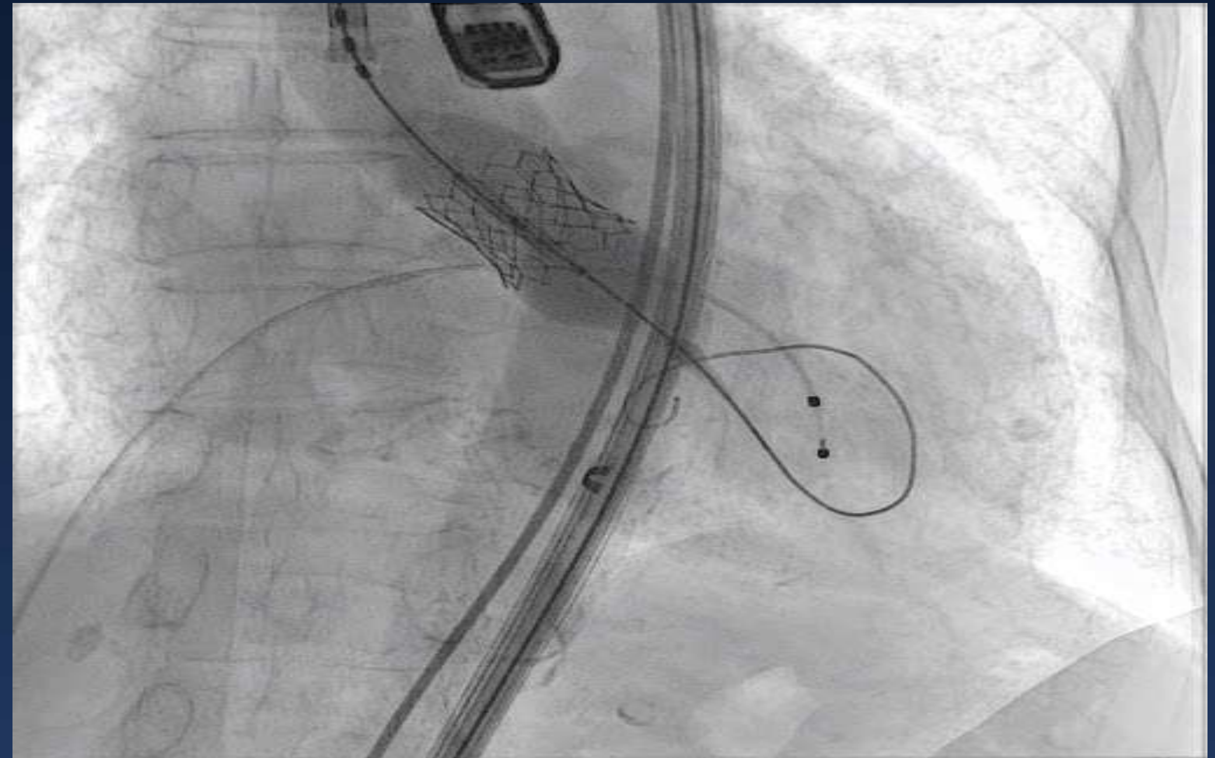
Post-dil TEE





Why Sapien3 valve: few complete AV block



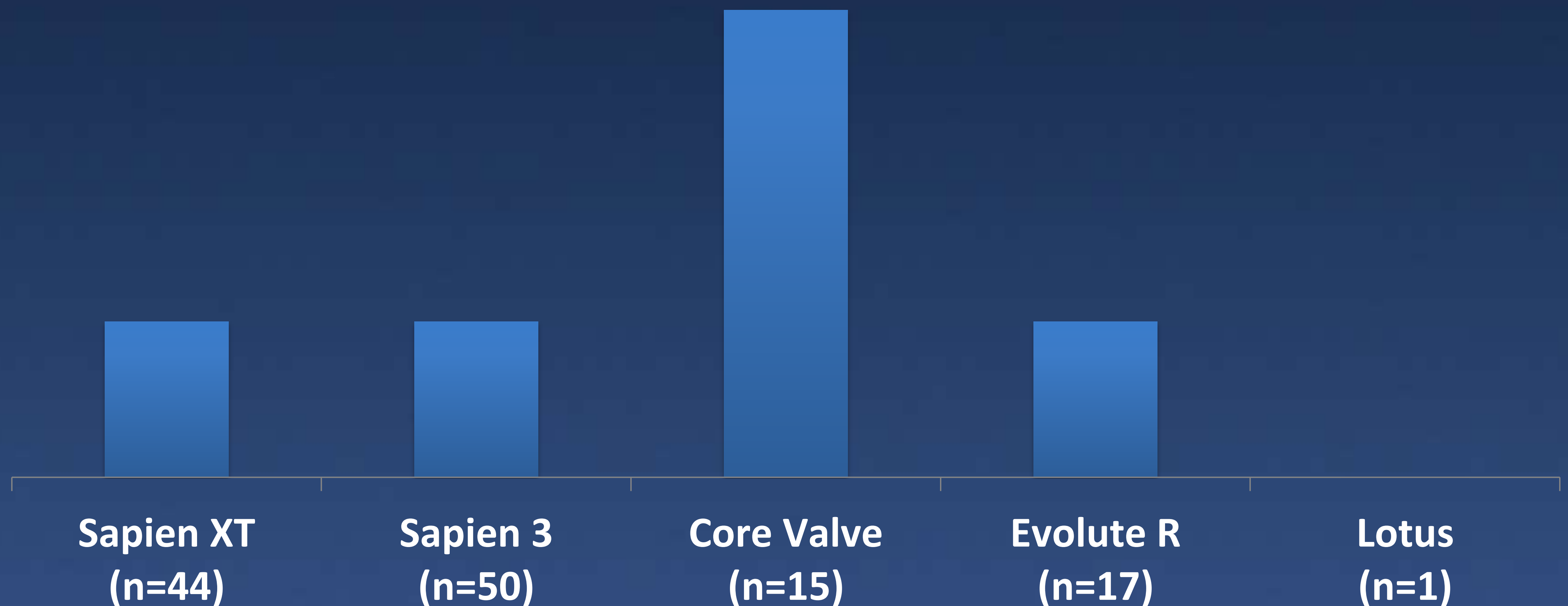


Very slow inflation of Sapine3 with twice contrast injection

- permit accurate high positioning of Sapien3
- Complete AV block: never experienced
- Combind with no oversizing, annular rupture never

Pacemaker Insertion

	Sapien XT (n=44)	Sapien 3 (n=50)	Core Valve (n=16)	Evolute R (n=17)	Lotus (n=1)
Pacemaker	1	1	3	1	0



Summary of Sapien3

- Low delivery profile of Sapien3 can permit easy and smooth TAVI procedure even in tough aortoiliac arteries.
- Low delivery profile and wide sizing range of Sapien 3 actually eliminates the need for predilation.
- Outer sealing skirt significantly reduced the incidence of PVL.
- Small valve length and high positioning virtually eliminate the chance of pacemaker implantation