What is still complex in TAVI?

How to avoid the Mismatch?

Dr. Aníbal Damonte; damontea@icronline.com
Director, Interventional Cardiology Department, Instituto Cardiovascular de Rosario, Rosario, Argentina
Past President of CACI; Past President of SOLACI

SOLACI SOCIME'25
MEXICO CITY

Speaker's name: Anibal Damonte

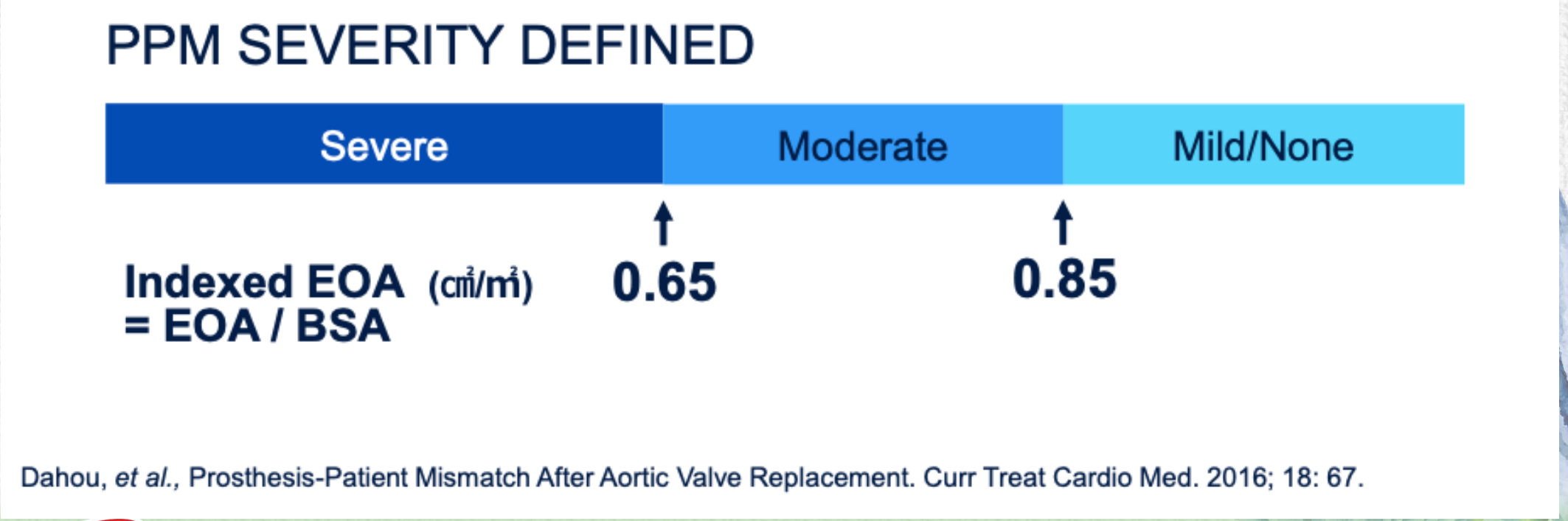
☑ I do not have any potential conflicts of interest to report

SOLACI

SOCIME
SOCIEDAD DE CARDIOLOGIA INTERVENCIONISTA DE MEXICO

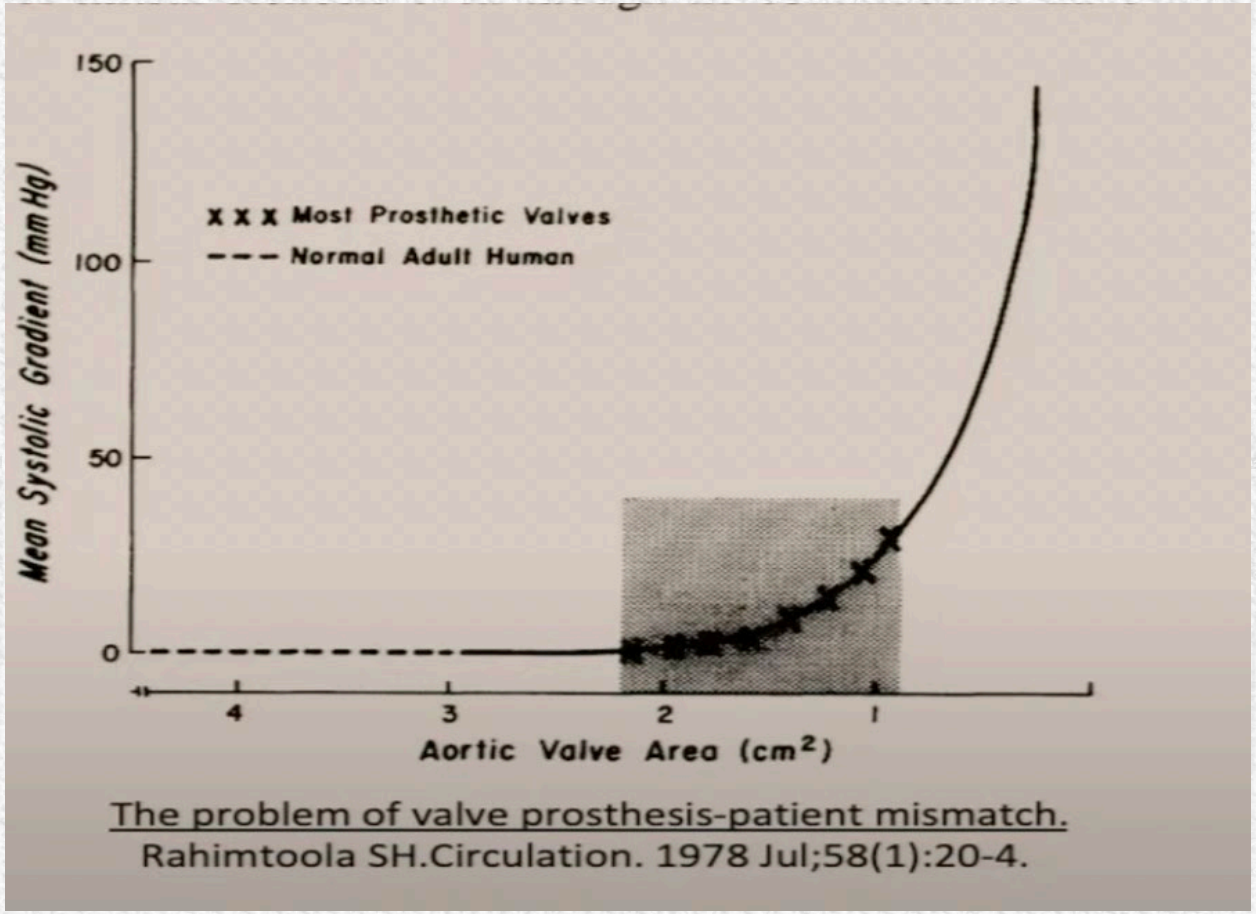
What does PPM mean?

PPM occurs when the effective orifice area (EOA) of the implanted prosthesis is too small in relation to the patient's body size, resulting in abnormally high postoperative gradients.

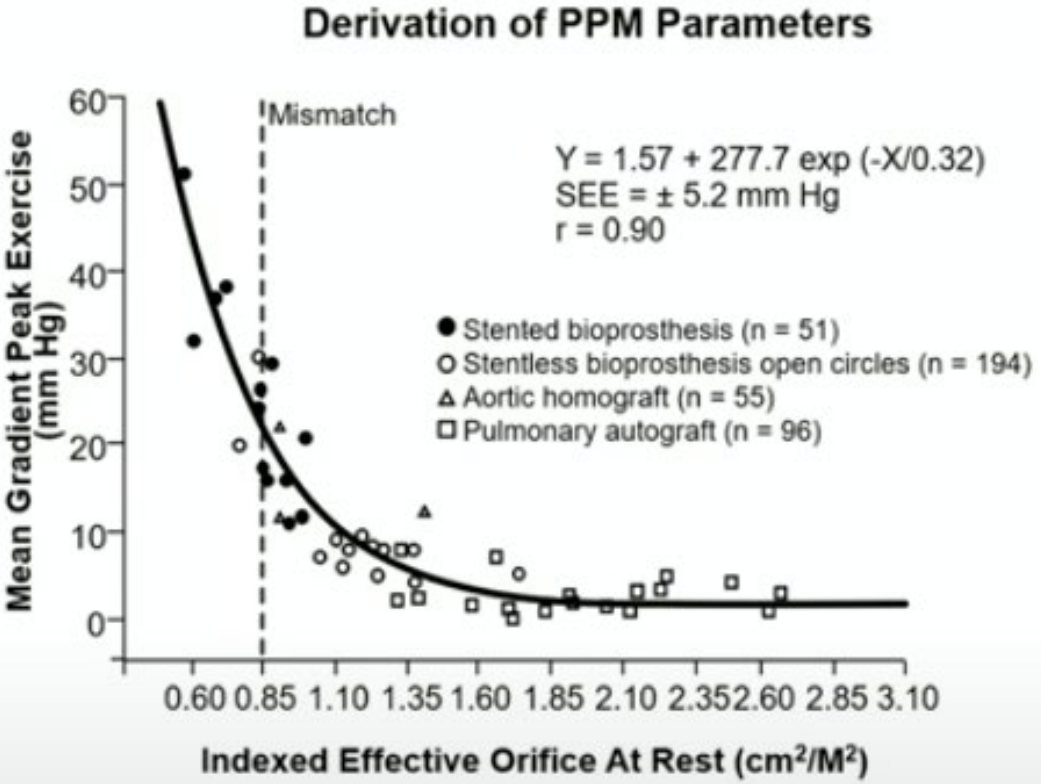


Dahou, *et al.*, Prosthesis-Patient Mismatch After Aortic Valve Replacement. Curr Treat Cardio Med. 2016; 18: 67.

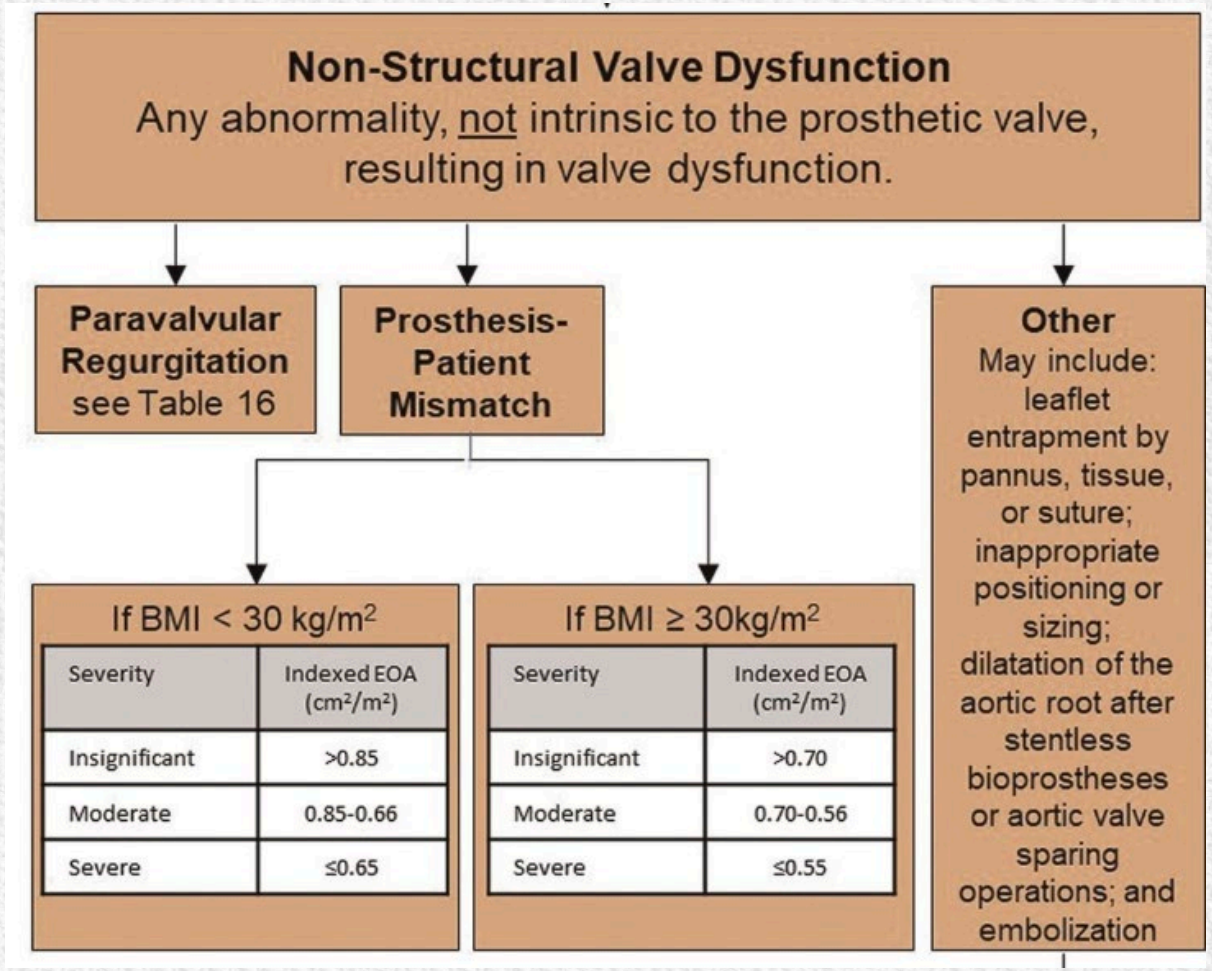
What is PPM?



The problem of valve prosthesis-patient mismatch.
Rahimtoola SH.Circulation. 1978 Jul;58(1):20-4.

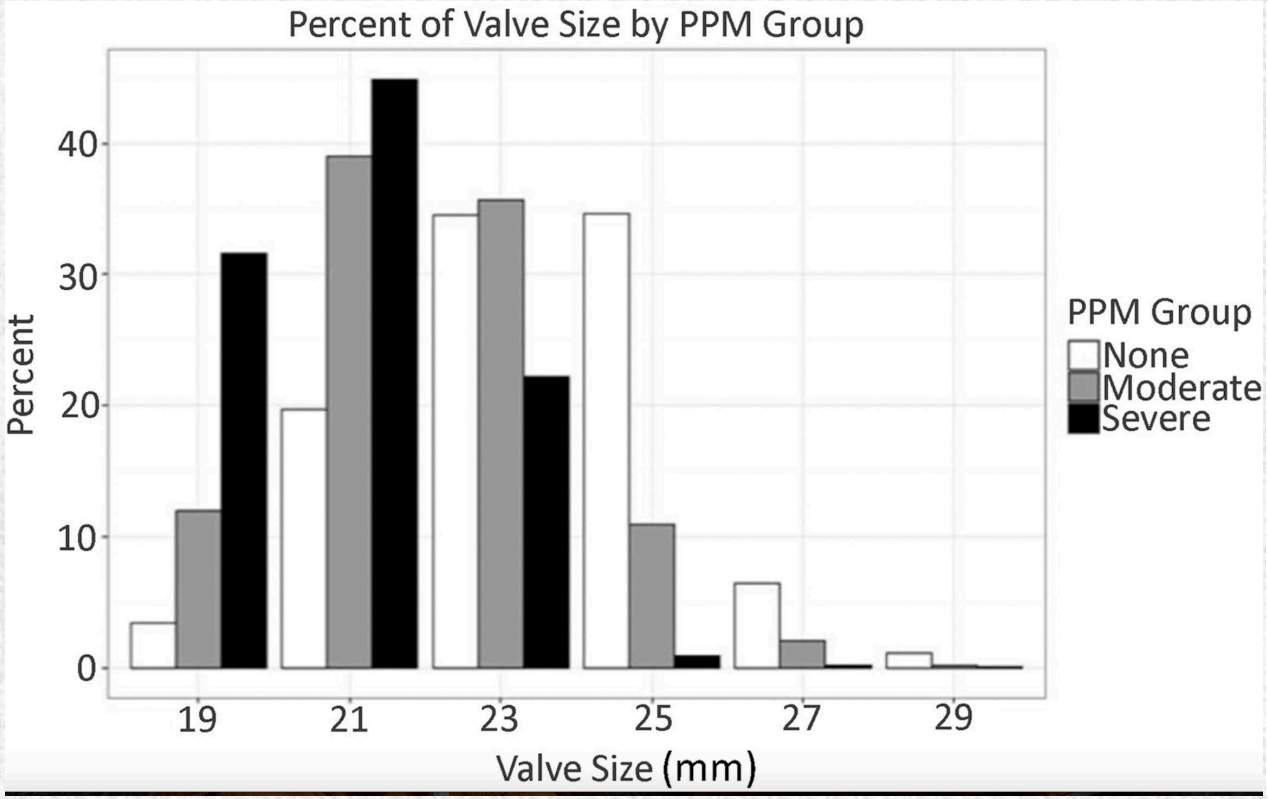


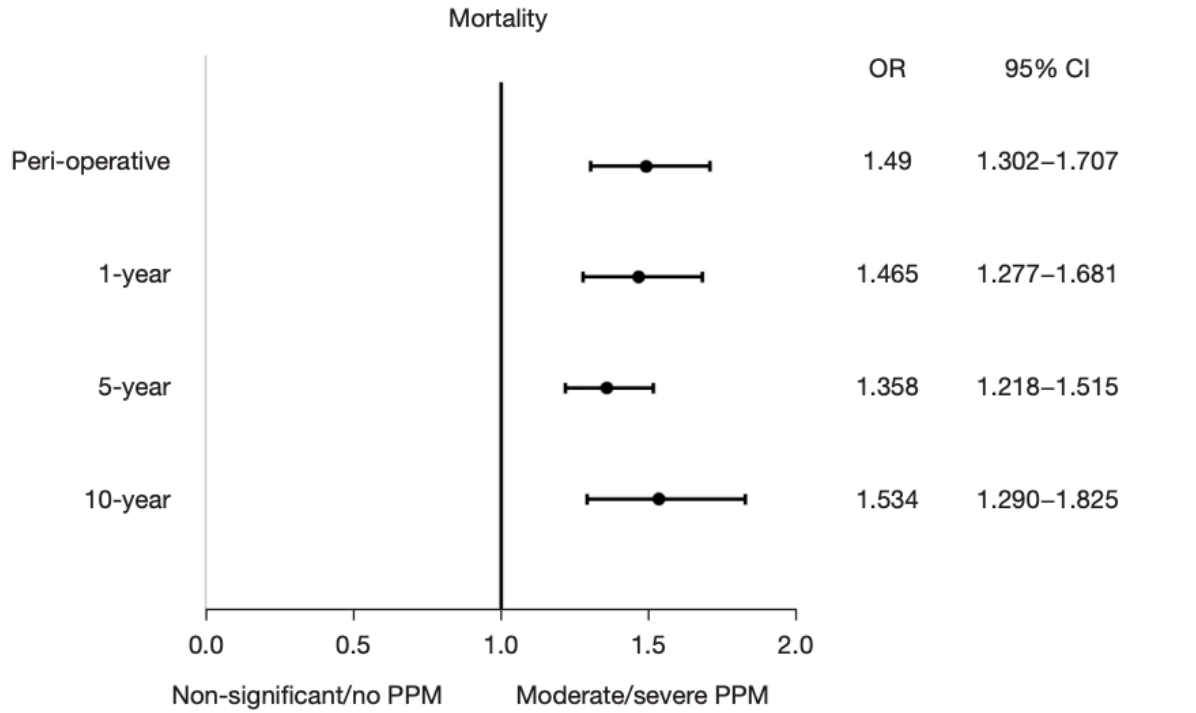
Pibarot,P; JACC 2000;36:1131-41



VARC III Definitions - JACC. 2021 Jun, 77 (21) 2717–2746

Prosthesis patient mismatch





Severe PPM - Higher mortality

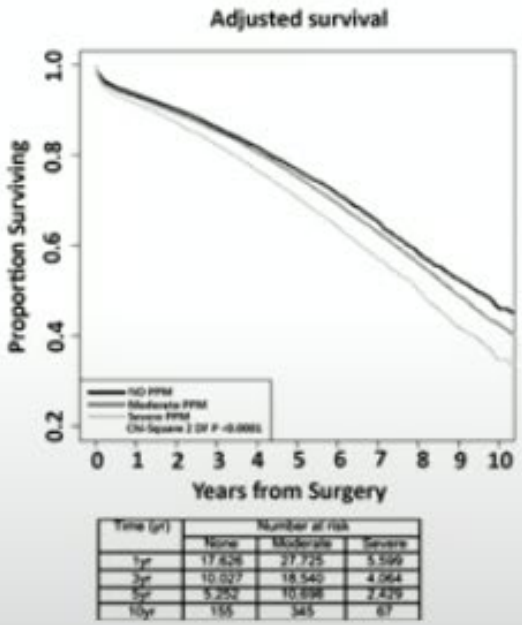
Pompeu Sá, et all - Eur J Cardiothorac Surg. 2019 Jul 1;56(1):44-54

Fallon JM, et al. Ann Thorac Surg 2018;106(1):14-22

10 – year outcomes in surgical AVR patients

59,779 patients ≥65 years undergoing isolated AVR between 2004 and 2014
54% moderate PPM and 11% severe PPM

1.32 HR for Mortality
severe PPM vs. no PPM

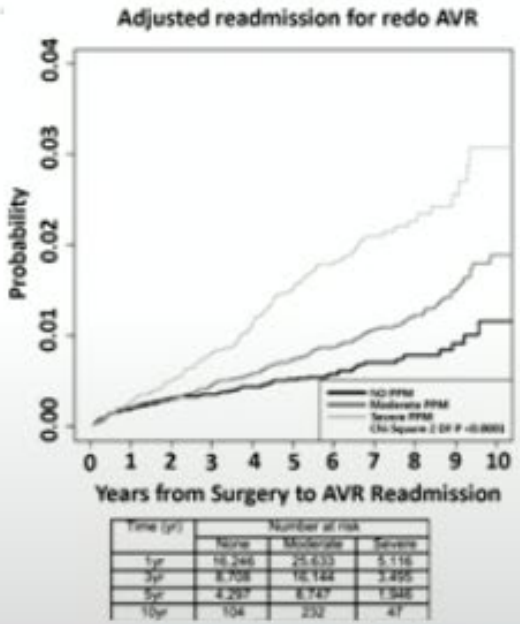


Time (yr)	Number at risk		
	None	Moderate	Severe
1yr	17 626	27 725	5 599
3yr	10 027	18 540	4 064
5yr	5 252	10 698	2 429
10yr	155	345	67

1.37 HR for HF Readmission
severe PPM vs. no PPM

Time (yr)	Number at risk		
	None	Moderate	Severe
1yr	15 401	23868	4684
3yr	8105	14210	3109
5yr	3940	7864	1685
10yr	96	216	41

2.68 HR for redo AVR
severe PPM vs. no PPM

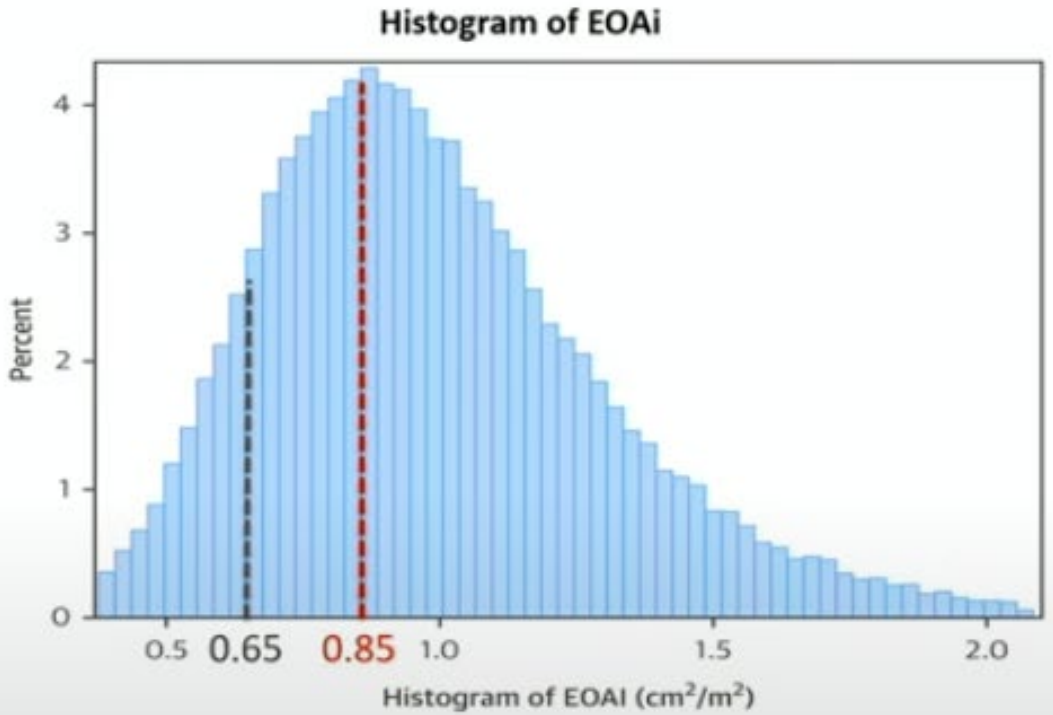


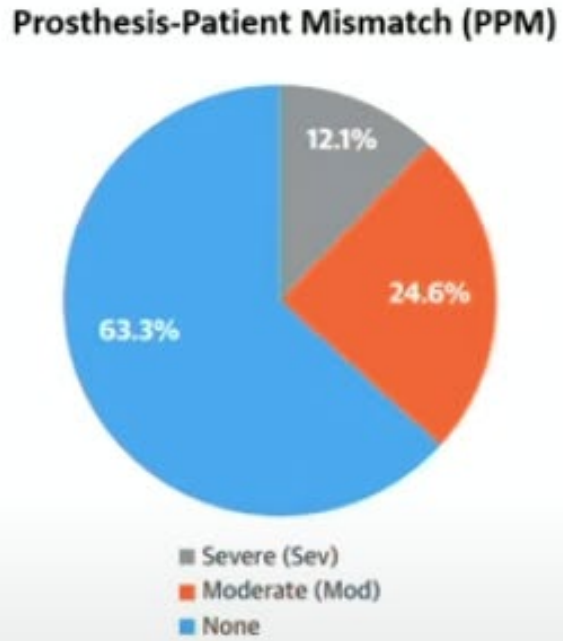
Time (yr)	Number at risk		
	None	Moderate	Severe
1yr	16 246	25 833	5 116
3yr	8 708	16 144	3 495
5yr	4 287	8 747	1 848
10yr	104	232	47

Fallon JM, et al. Ann Thorac Surg 2018;106(1):14-22

Is PPM after TAVI an issue? Insights from the STS/ACC TVT Registry

62,125 TAVI patients from 2014 to 2017, including BE and SE valves

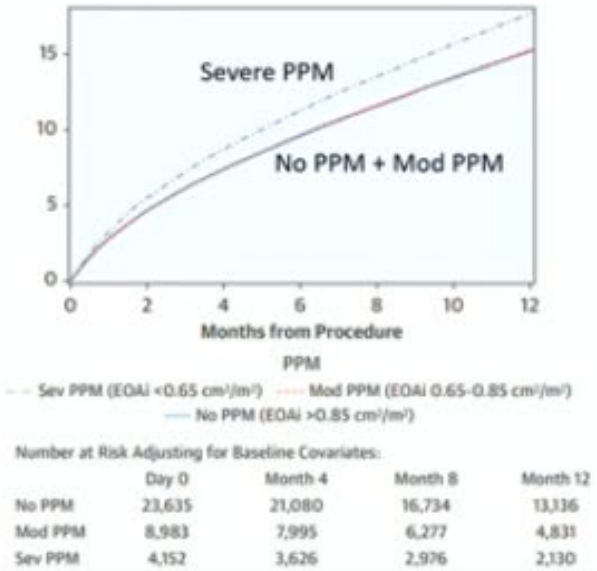




Herman H, et al.JACC2018;72(22):2701-11

Effects and predictor of PPM
Insights from the STS/ACC TVT Registry

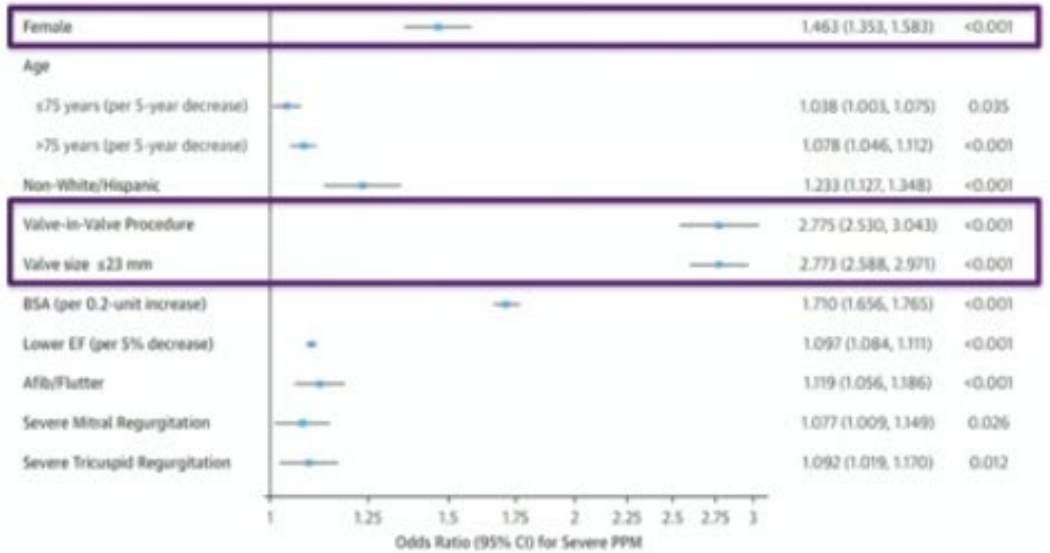
Severe PPM increases mortality after TAVI



Number at Risk Adjusting for Baseline Covariates:

	Day 0	Month 4	Month 8	Month 12
No PPM	23,635	21,080	16,734	13,336
Mod PPM	8,983	7,995	6,277	4,831
Sev PPM	4,152	3,626	2,976	2,130

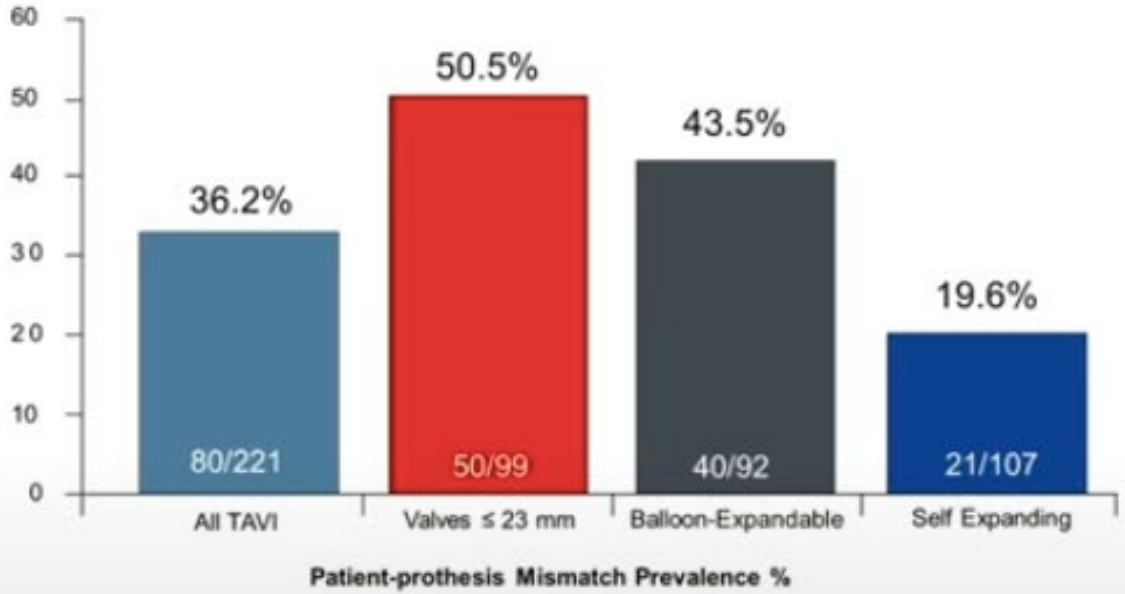
Female sex, Valve-in-Valve, and small TAVI valves predict severe PPM

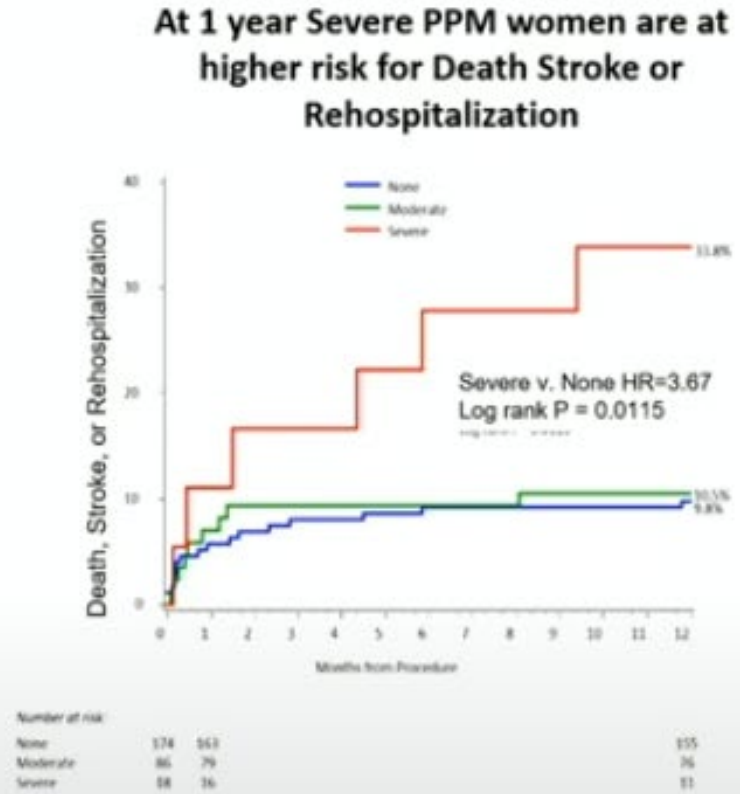


HF hospitalization: severe PPM vs. no PPM: 14.7% vs 11.9%, p<0.001
QOL: KCCQ score improved less in patients with severe PPM

Herman H, et al.JACC2018;72(22):2701-11

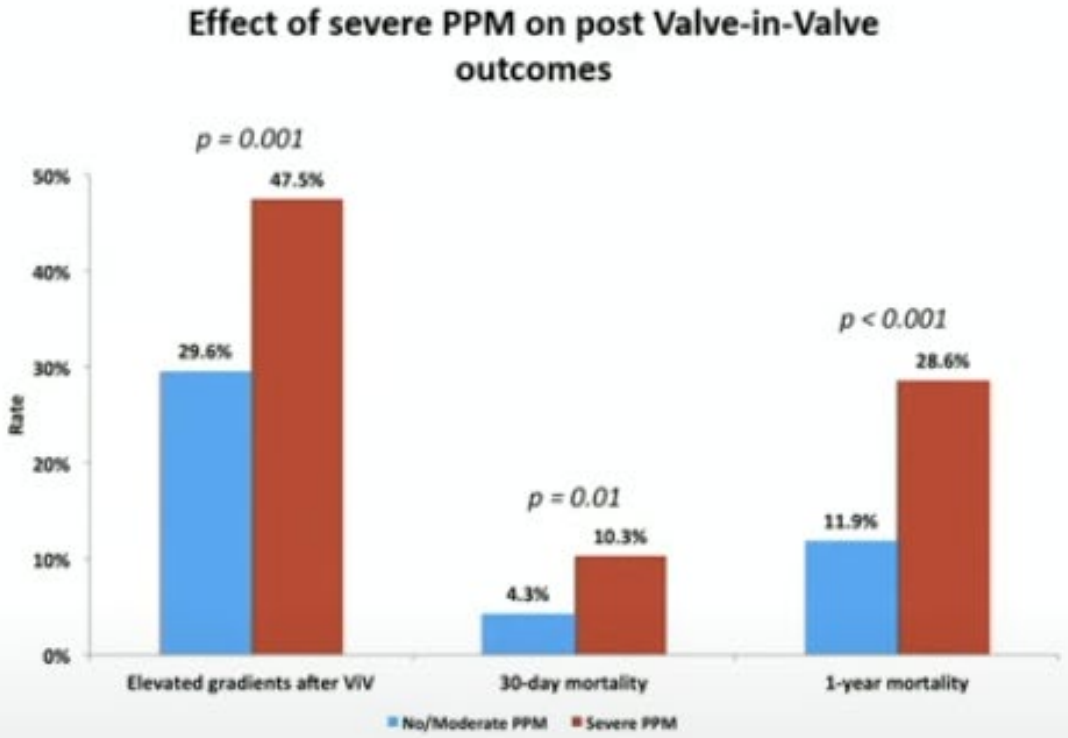
PPM in females: The WIN TAVI Registry



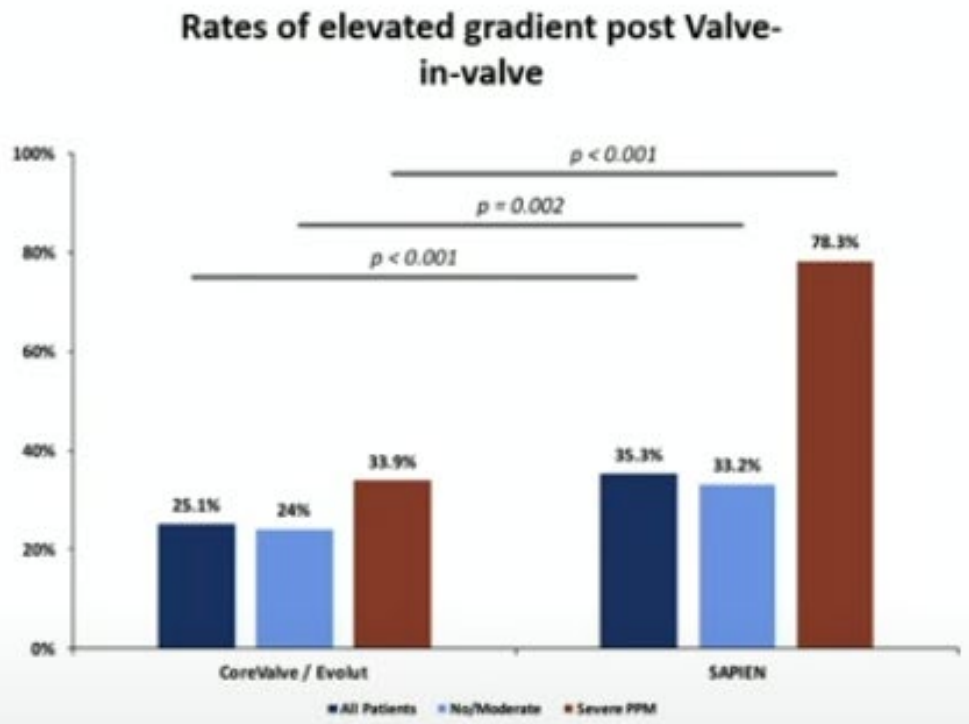


Pibarot P, et al.Circulation2020;14:1527-37
Panoulas V, et al. CCI2021;97:516-526

Impact of pre existing PPM on survival following VIV-TAVI



In 1168 patients with AVR, 89 (7.6%) had pre-existing severe PPM
Severe PPM pre-TAVI was associated elevated post TAVI gradients, higher mortality at 30days and 1year.

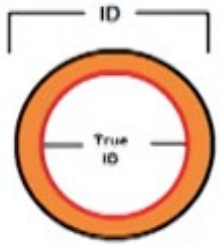
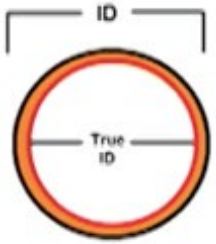
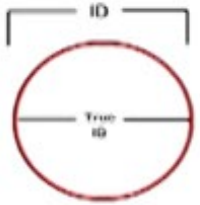


Proportion of high gradients between self-expanding and balloon-expandable pre-existing severe PPM
(34% SE vs. 78% BE; p < 0.001)

Pibarot P, et al.JACC Cardiovasc Interv 2018;11:135-141

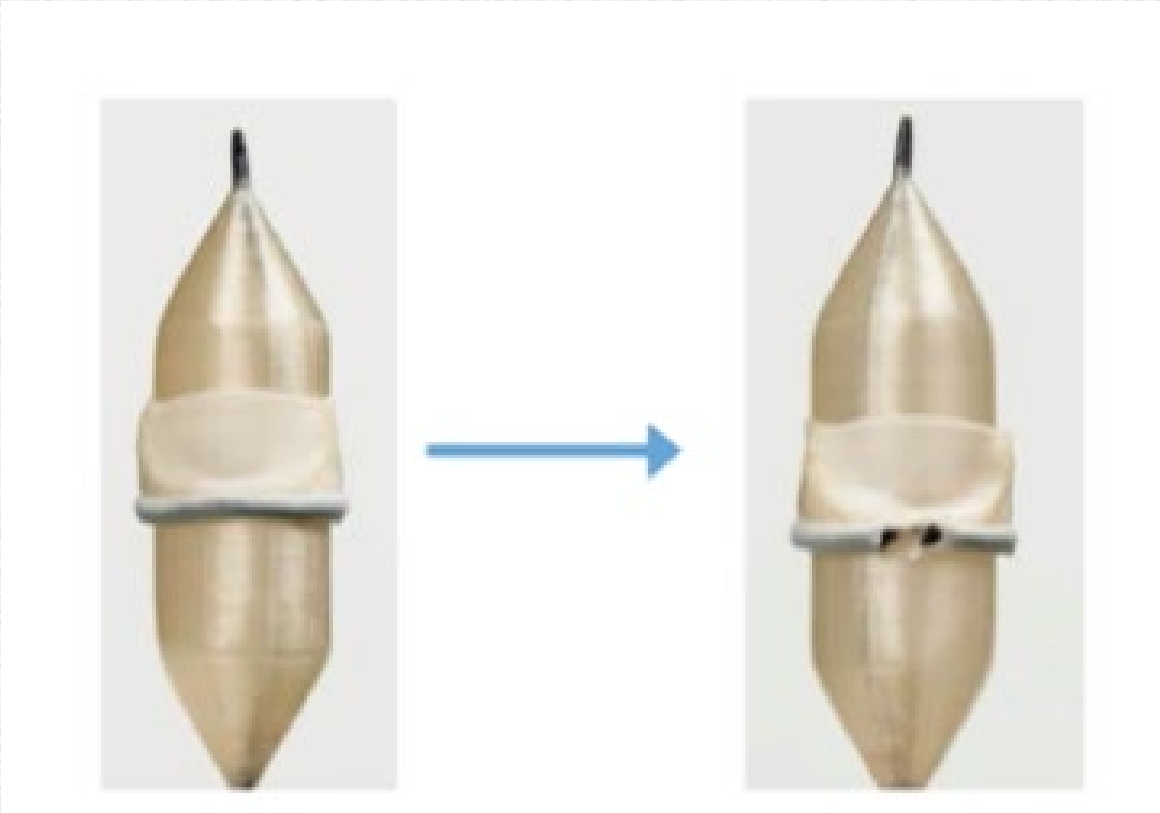
PPM in VIV TAVI

3 Types of Valves – different True ID

Porcine Leaflets Mounted inside	Pericardial Leaflets Mounted inside	Pericardial Leaflets Mounted outside
		
		
True ID = Stent ID – 2mm	True ID = Stent ID – 1mm	Stent ID = True ID

True ID <21
Increases
Risk of PPM

Bioprosthesis valve fracture in VIV TAVI



	BVF before TAVI	BVF after TAVI
Advantages	– Easier to implant self-expanding valve with less sizing mismatch – Can confirm successful fracture before finalising TAV size	– Better TAV expansion, especially in balloon-expandable valves – Less risk of acute severe aortic regurgitation
Disadvantages	– Acute severe aortic regurgitation causing haemodynamic collapse – May need to post-dilate to optimise haemodynamics	– TAV migration or embolisation – Acute TAV failure from leaflet injury – Unknown effect on TAV durability

Tarantini G; EuroInt 2021

Minimizing prosthesis patient mismatch is not a luxury …

It is key to improving the durability of the THV

It has an impact on patient´s survival

EOAs of normal transcatheter valves

Mean gradients and EOA were measured by the echo core lab in PARTNER I and II CoreValve US Pivotal Trials, and Evolut R US IDE Clinical Study

TABLE 2 Mean Gradient and EOA for Balloon-Expandable SAPIEN Valves

	Prosthetic Valve Size, mm					
Valve Iteration	20	23	26	29	All Sizes	p Value
SAPIEN						
EOA, cm^2	NA	1.56 ± 0.43 (1,212)	1.84 ± 0.52 (1,130)	NA	1.70 ± 0.49 (2,342)	<0.001
Mean gradient, mm Hg	NA	9.92 ± 4.27 (1,212)	8.76 ± 3.89 (1,130)	NA	9.36 ± 4.13 (2,342)	<0.001
DVI	NA	0.53 ± 0.13 (1,212)	0.53 ± 0.13 (1,130)	NA	0.53 ± 0.13 (2,342)	0.64
SAPIEN XT						
EOA, cm^2	NA	1.41 ± 0.30 (545)	1.74 ± 0.42 (675)	2.06 ± 0.52 (251)	1.67 ± 0.46 (1471)	<0.001
Mean gradient, mm Hg	NA	10.41 ± 3.74 (545)	9.24 ± 3.57 (675)	8.36 ± 3.14 (251)	9.52 ± 3.64 (1,471)	<0.001
DVI	NA	0.52 ± 0.10 (545)	0.54 ± 0.11 (675)	0.53 ± 0.11 (251)	0.53 ± 0.11 (1,471)	0.004
SAPIEN 3						
EOA, cm^2	1.22 ± 0.22 (47)	1.45 ± 0.26 (471)	1.74 ± 0.35 (626)	1.89 ± 0.37 (326)	1.66 ± 0.38 (1,470)	<0.001
Mean gradient, mm Hg	16.23 ± 5.01 (47)	12.79 ± 4.65 (471)	10.59 ± 3.88 (626)	9.28 ± 3.16 (326)	11.18 ± 4.35 (1,470)	<0.001
DVI	0.42 ± 0.07 (47)	0.43 ± 0.08 (471)	0.43 ± 0.09 (626)	0.40 ± 0.09 (326)	0.43 ± 0.09 (1,470)	<0.001

TABLE 4 Mean Gradient and EOA for CoreValve and Evolut R by Valve Size in Native Aortic Stenosis at 30 Days

	Prosthetic Valve Size, mm					
Valve Iteration	23	26	29	31	All Sizes	p Value
CoreValve						
EOA, cm^2	1.12 ± 0.36 (19)	1.74 ± 0.49 (289)	1.97 ± 0.53 (446)	2.15 ± 0.72 (81)	1.88 ± 0.56 (835)	<0.001
Mean gradient, mm Hg	14.43 ± 5.72 (22)	8.27 ± 3.82 (307)	8.85 ± 4.17 (478)	9.55 ± 3.44 (83)	8.85 ± 4.14 (890)	<0.001
DVI	0.44 ± 0.09 (20)	0.59 ± 0.15 (300)	0.54 ± 0.12 (463)	0.49 ± 0.12 (83)	0.55 ± 0.13 (866)	<0.001
Evolut R						
EOA, cm^2	1.09 ± 0.26 (3)	1.69 ± 0.40 (71)	1.97 ± 0.54 (129)	2.60 ± 0.75 (52)	2.01 ± 0.65 (255)	<0.001
Mean gradient, mm Hg	14.97 ± 7.15 (3)	7.53 ± 2.65 (77)	7.85 ± 3.08 (141)	6.30 ± 3.23 (57)	7.52 ± 3.19 (278)	<0.001
DVI	0.42 ± 0.04 (3)	0.61 ± 0.13 (75)	0.59 ± 0.14 (135)	0.58 ± 0.15 (55)	0.59 ± 0.14 (268)	0.09

Hahn, *et al.*, Comprehensive Echocardiographic Assessment of Normal Transcatheter Valve Function. J Am Coll Cardiol Img. Published online June 8, 2018.

PPM in small aortic annulus

SMART Trial Design

Prospective, randomized controlled, post-market trial conducted at 83 international sites

All-comer trial with all surgical risk categories including bicuspid patients

716 Patients Treated

Randomization

1:1 stratified by site & sex

(N=355)
Medtronic Evolut PRO/PRO+/FX

(N=361)
Edwards SAPIEN 3/SAPIEN 3 Ultra

Key eligibility

- Symptomatic severe AS*
- Small aortic annulus (≤430 mm^2 by MDCT)

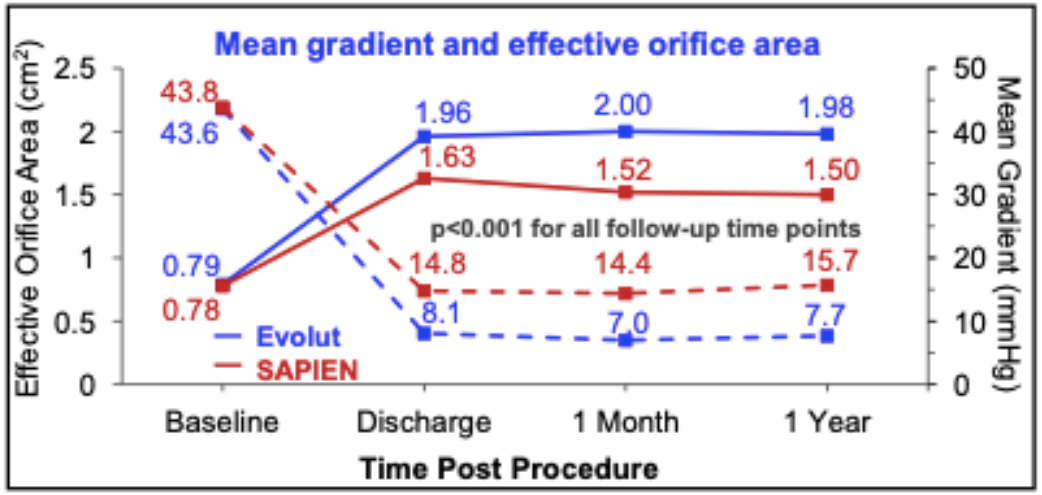
Co-primary endpoints powered at 1 year

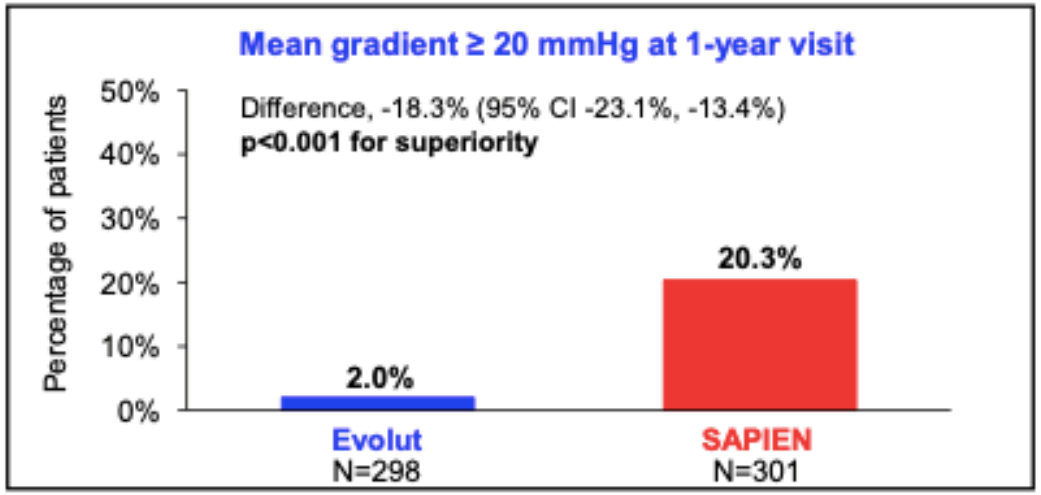
- **Co-Primary Endpoint 1:** Composite of mortality, disabling stroke, or heart failure rehospitalization through 12 months
- **Co-Primary Endpoint 2:** Bioprosthetic valve dysfunction through 12 months

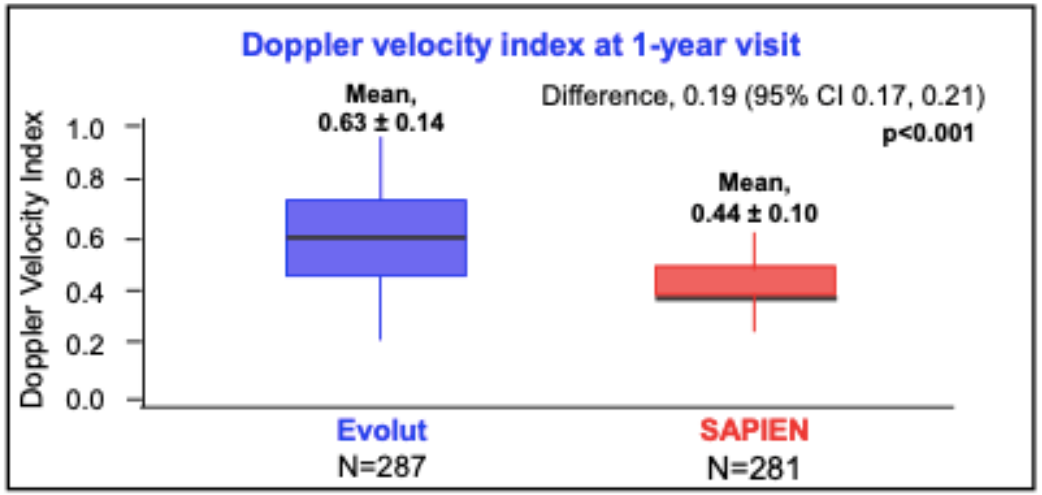
*AVA ≤1.0 cm^2 (AVAi ≤0.6 cm^2/m^2) or mean gradient ≥40 mmHg or max velocity ≥4.0 m/s; 30-day predicted risk of surgical mortality <15% by heart team assessment.

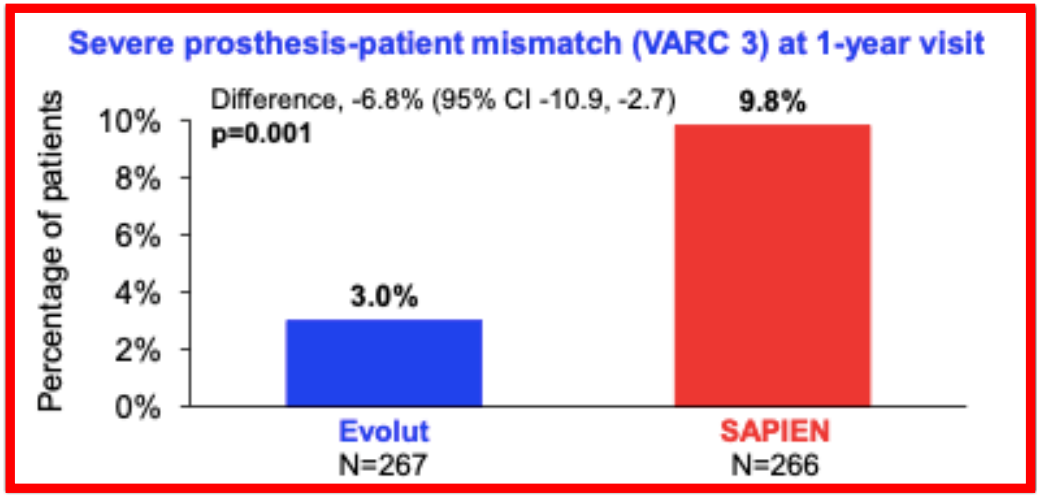
SMART Trial

SMART Trial results at 1 year: Hemodynamics







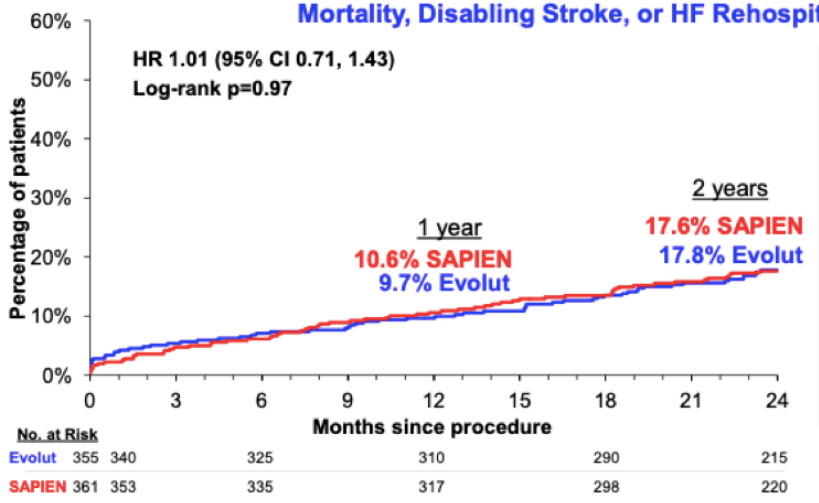


SMART Trial

Values based on independent Echocardiography Core Laboratory (Mayo) assessment.

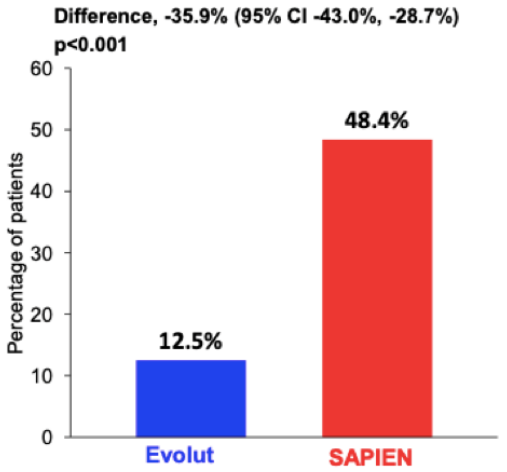
SMART Trial

Clinical outcome composite & components through 2 years



2 Years	Evolut (N=355)	SAPIEN (N=361)	P Value
All-cause mortality	12.7%	11.4%	0.66
Disabling stroke	4.7%	3.2%	0.30
HF rehosp	6.1%	6.0%	0.95

Bioprosthetic valve dysfunction through 2 years



	Evolut (N=350)	SAPIEN (N=365)	P Value
BVD composite	**12.5%**	**48.4%**	**<0.001**
HSVD	4.7%	42.4%	<0.001
NSVD	6.7%	18.0%	<0.001
Thrombosis (clinical)	0.3%	1.2%	0.17
Endocarditis	2.2%	2.6%	0.76
AV Reintervention	0.9%	0.9%	>0.99

HSVD = Mean gradient ≥ 20 mmHg
NSVD = Severe PPM through 1 year per VARC-3 or ≥moderate total AR

Clinical Case

73 year-old female patient;

Weight 58 kg; height 159 cm; BMI 23; BSA 1,59

CRF: Dyslipidemia

Clinical presentation: Severe, symptomatic aortic stenosis, dyspnea NYHA III. Recent hospitalization for heart failure.

TTE: LV 61/48; EF 40%; global hypokinesis; peak aortic velocity 4,6m/seg; aortic gradient 72/43mmHg; area 0,6; moderate/severe mitral insufficiency; PASP 40mmHg

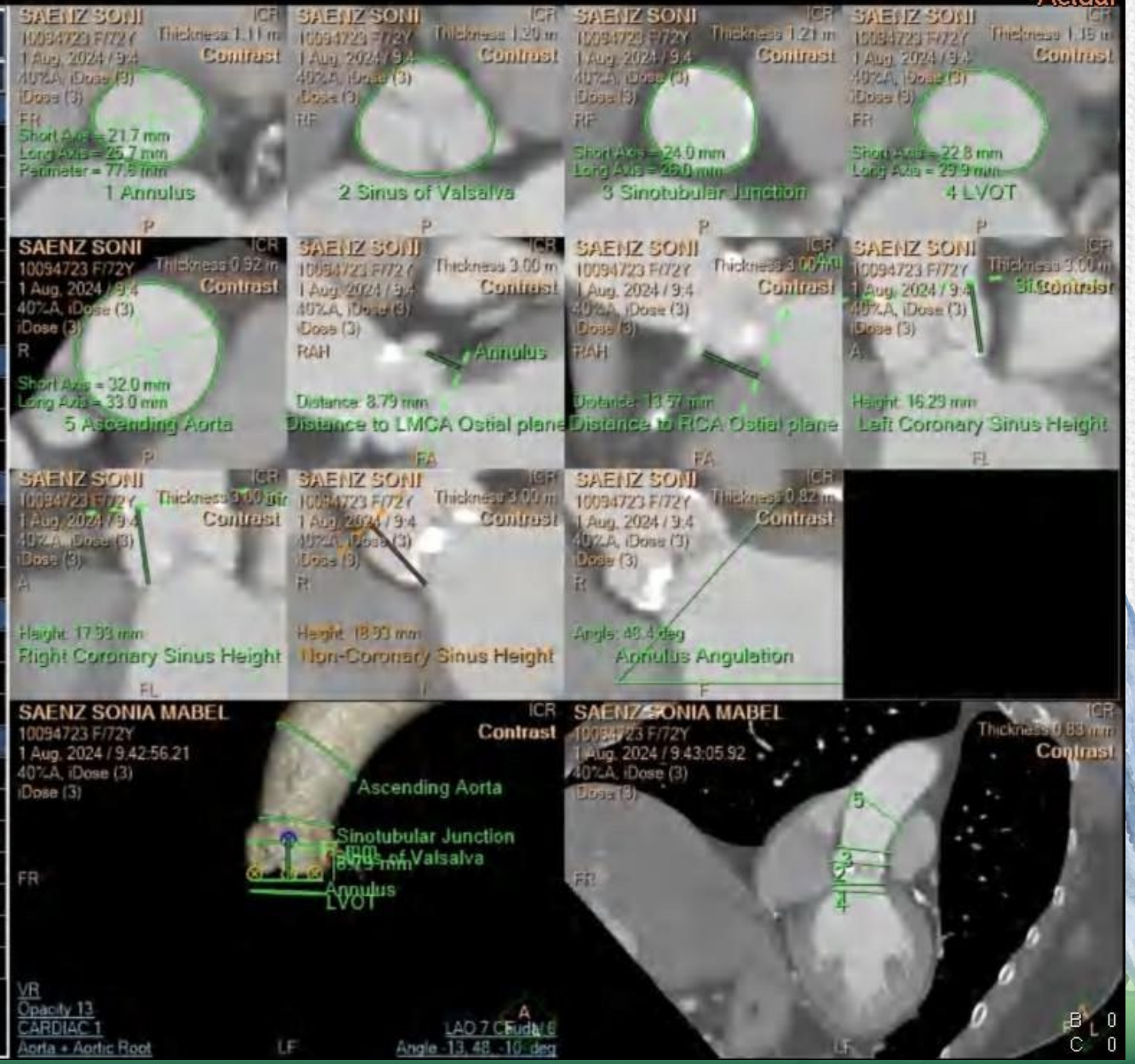
Coronary angiography: moderate LAD and CX disease.

Comorbidities: Asthma on treatment (Budesonide)

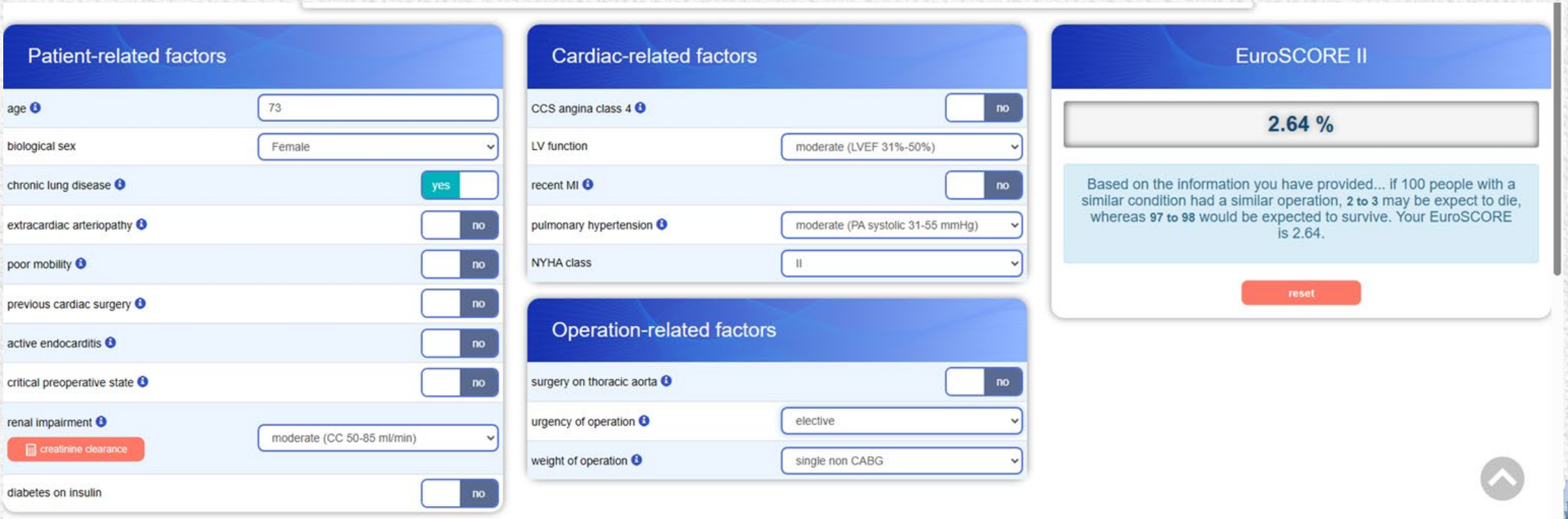
Phase 40%

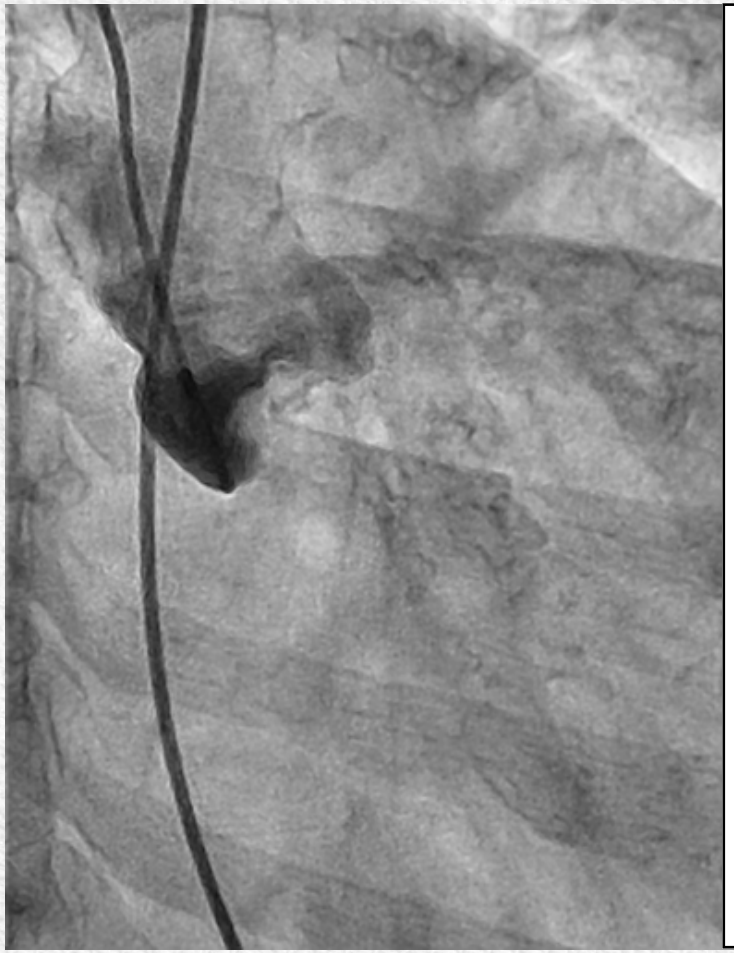
Actual

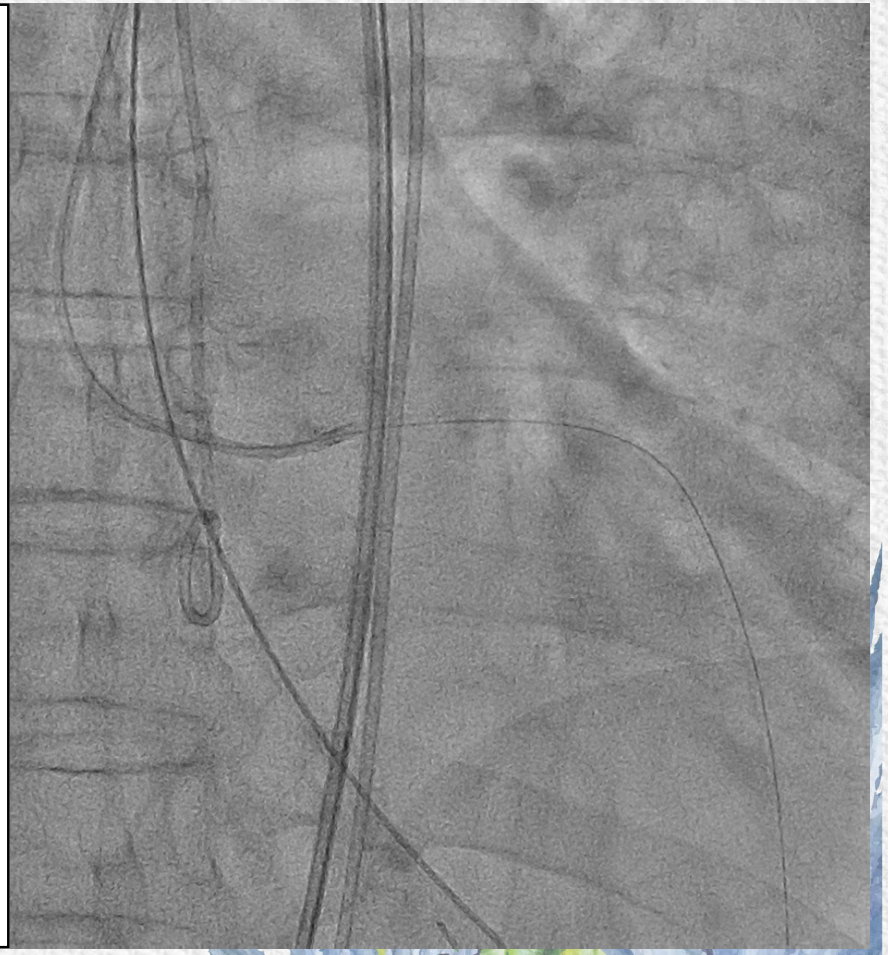
Measurements table	
Measurement	Value
Annulus	
Short Axis	21.7 mm
Long Axis	25.7 mm
Area	429.0 mm²
Perimeter	77.6 mm
Effective diameter based on area	23.4 mm
Effective diameter based on perime...	24.7 mm
(Long Axis + Short Axis) / 2	23.7 mm
Sinotubular Junction	
Short Axis	24.0 mm
Long Axis	26.0 mm
(Long Axis + Short Axis) / 2	25.0 mm
LVOT	
Short Axis	22.8 mm
Long Axis	29.9 mm
(Long Axis + Short Axis) / 2	26.4 mm
Ascending Aorta	
Short Axis	32.0 mm
Long Axis	33.0 mm
(Long Axis + Short Axis) / 2	32.5 mm
Distances	
Distance to RCA Ostial plane	13.6 mm
Distance to LMCA Ostial plane	8.8 mm
Left Coronary Sinus Height	16.3 mm
Right Coronary Sinus Height	17.9 mm
Non-Coronary Sinus Height	18.9 mm
Average Sinus Height	17.7 mm
Annulus Angulation	48.4 deg

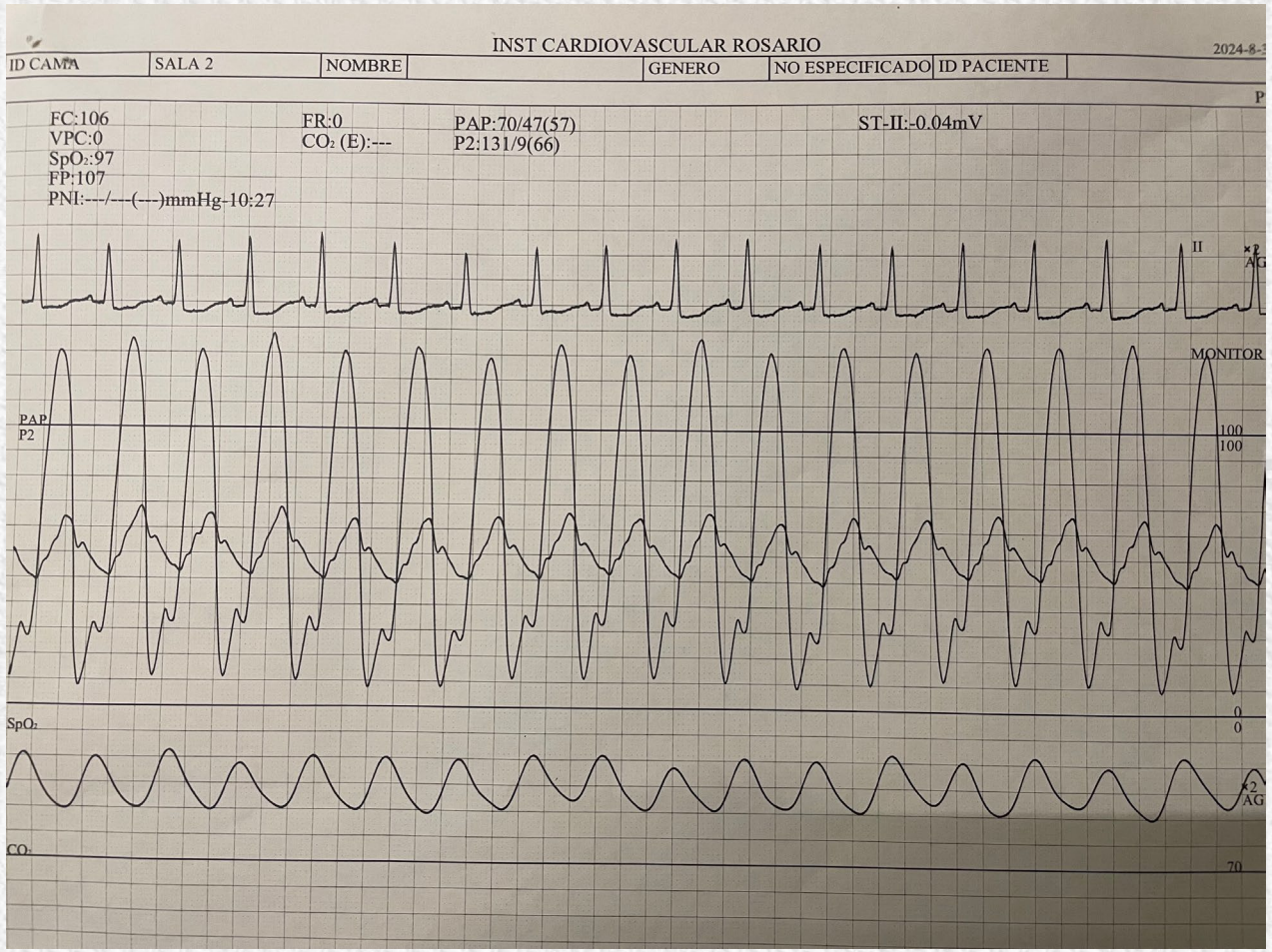


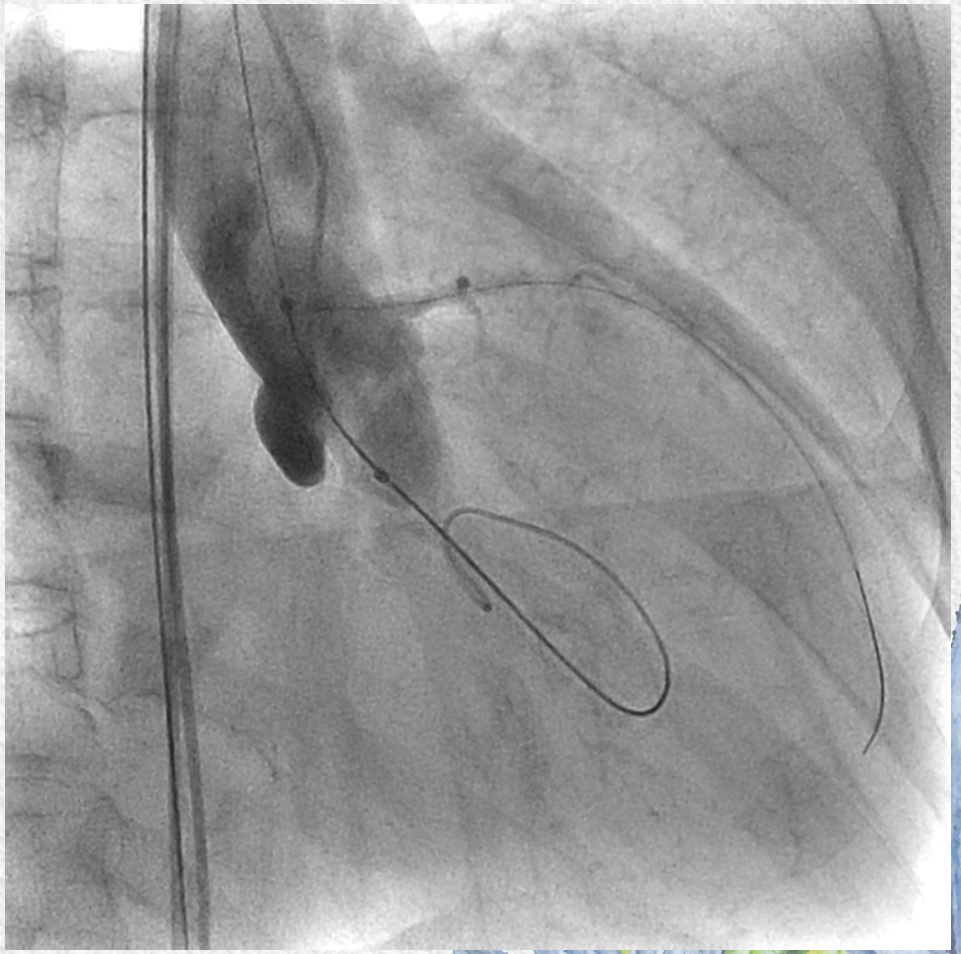
EuroSCORE II

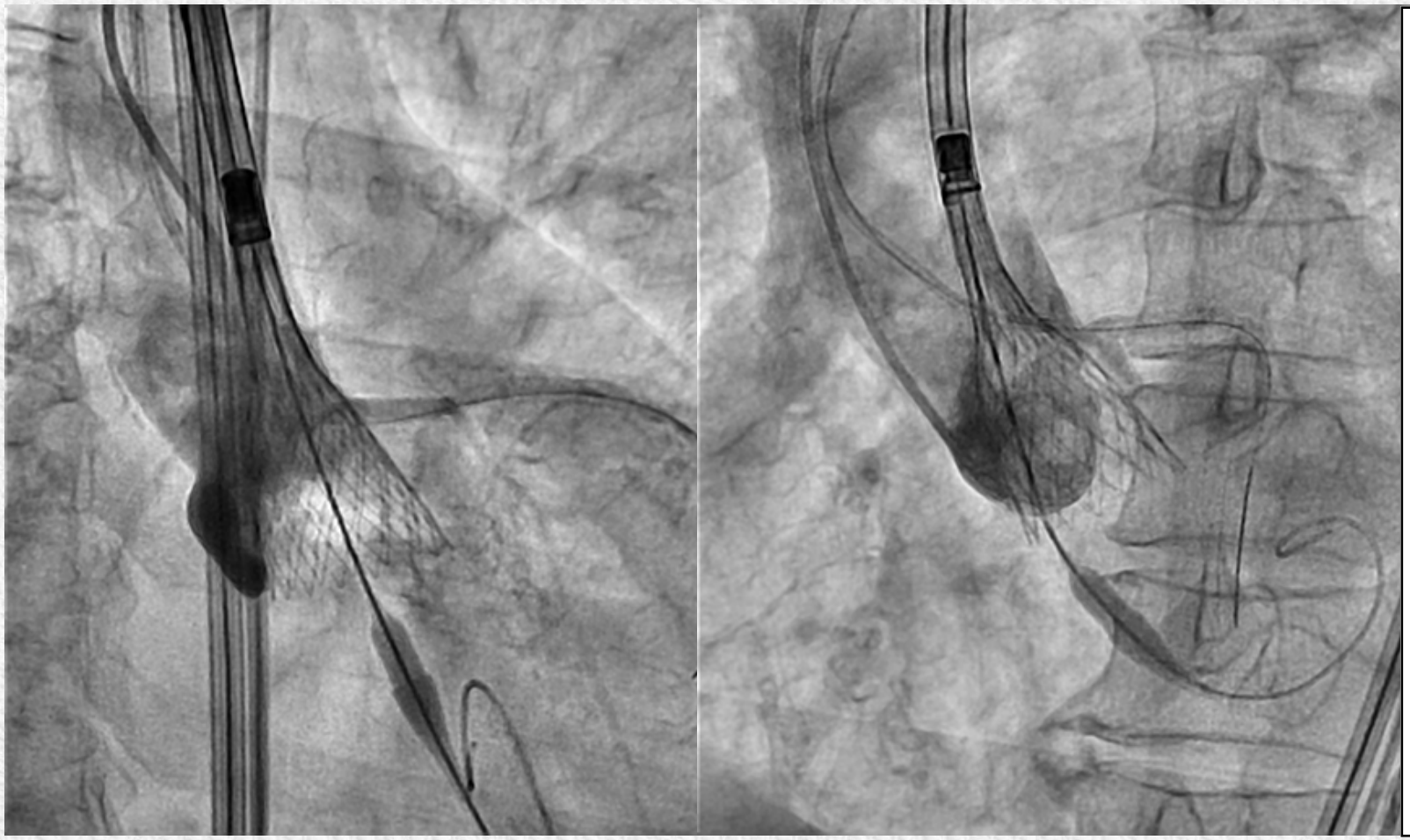


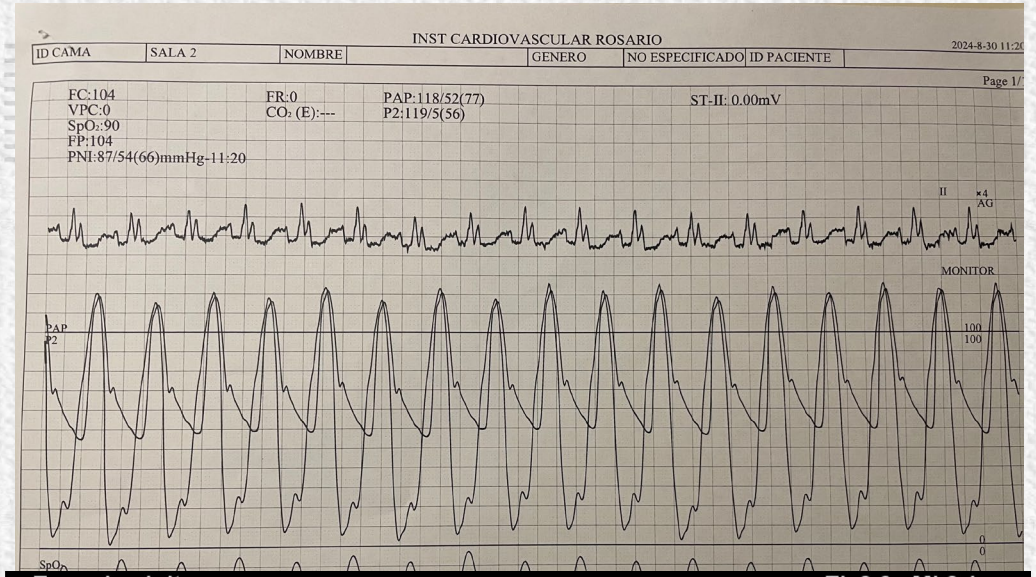


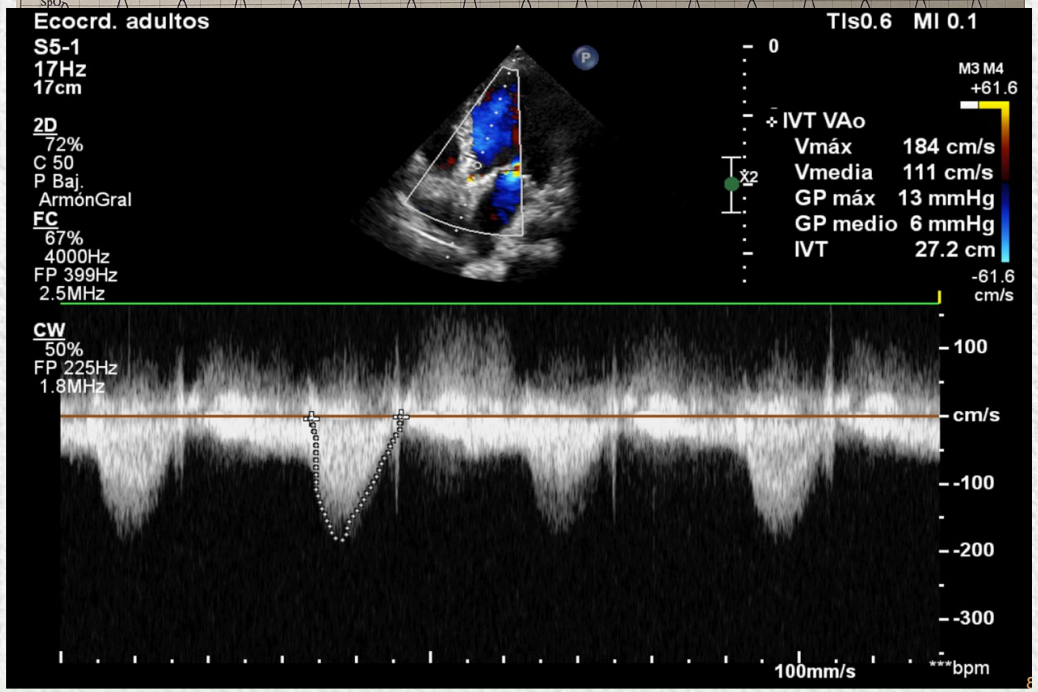


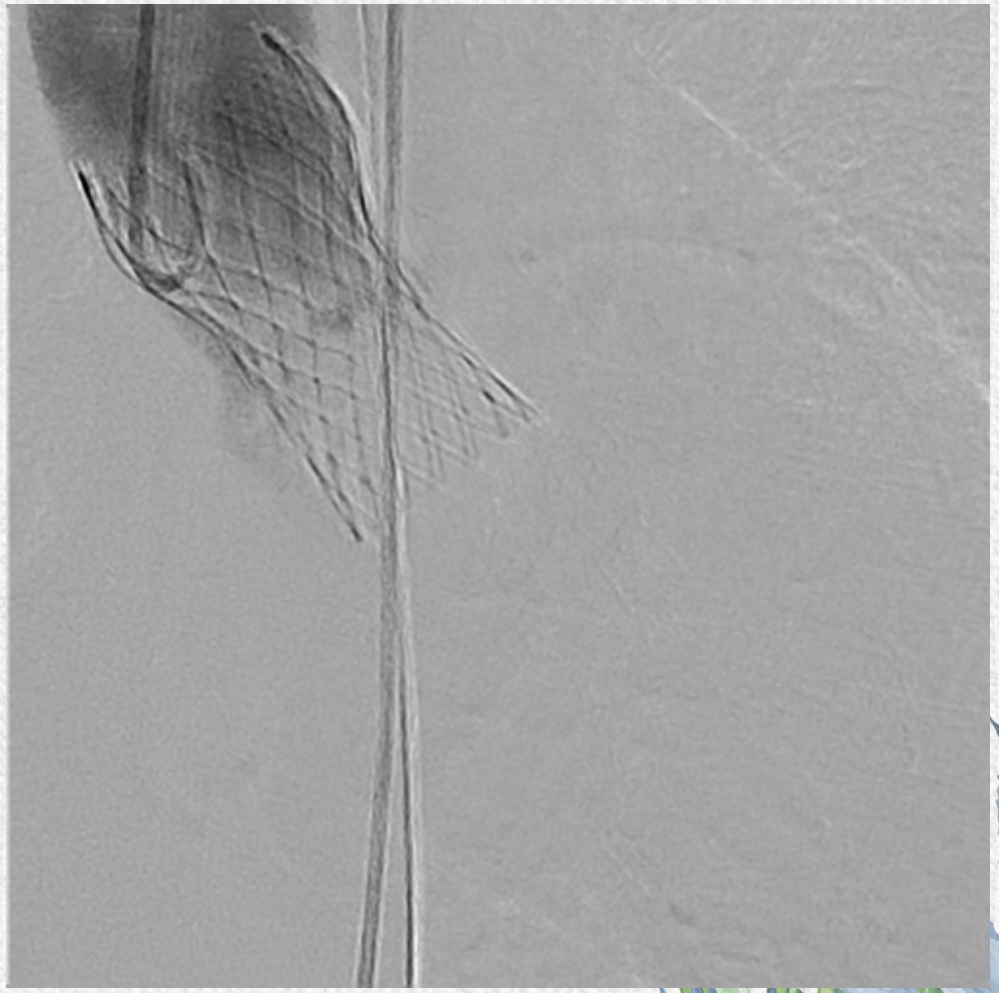

INST CARDIOVASCULAR ROSARIO
ID CAMA
SALA 2
NOMBRE
GENERO
NO ESPECIFICADO
ID PACIENTE
FC:106
VPC:0
SpO2:97
FP:107
PNI:---/---(---)mmHg-10:27
FR:0
CO2 (E):---
PAP:70/47(57)
P2:131/9(66)
ST-II:-0.04mV
II
MONITOR
PAP
P2
100
100
0
0
SpO2
CO2
70






INST CARDIOVASCULAR ROSARIO
ID CAMA
SALA 2
NOMBRE
GENERO
NO ESPECIFICADO
ID PACIENTE
FC:104
VPC:0
SpO₂:90
FP:104
PNI:87/54(66)mmHg-11:20
FR:0
CO₂ (E):---
PAP:118/52(77)
P2:119/5(56)
ST-II: 0.00mV
MONITOR
PAP
P2

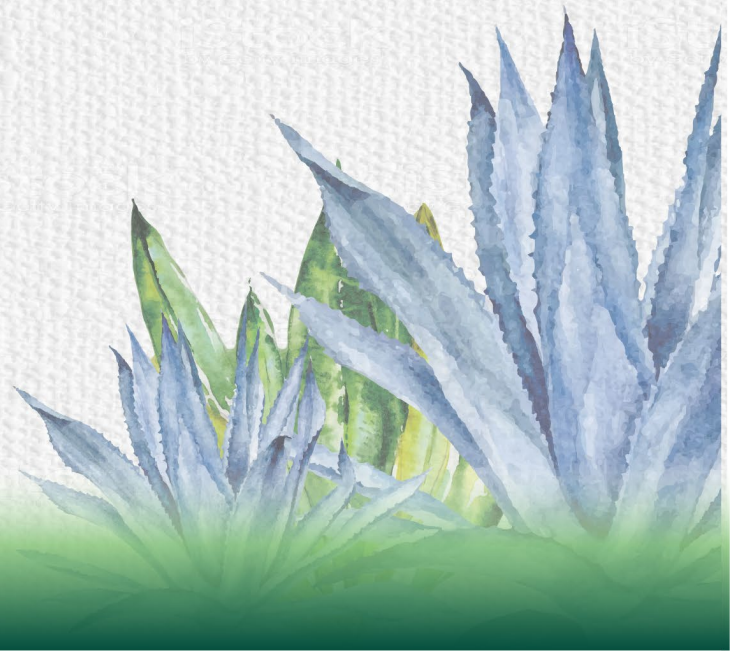

Ecocrd. adultos
TIs0.6 MI 0.1
S5-1
17Hz
17cm
2D
72%
C 50
P Baj.
ArmónGral
FC
67%
4000Hz
FP 399Hz
2.5MHz
M3 M4
+61.6
IVT VAo
Vmáx 184 cm/s
Vmedia 111 cm/s
GP máx 13 mmHg
GP medio 6 mmHg
IVT 27.2 cm
-61.6
cm/s
CW
50%
FP 225Hz
1.8MHz
100
cm/s
-100
-200
-300
100mm/s
***bpm



How to avoid PPM in TAVI?

- Calculate the minimal prosthesis EOA required for each patient
  Minimally required EOA = BSA x 0.85
- Select the appropriate prosthesis. (Expected EOAs for each size of each product)
- Supra-annular design THV should be selected to avoid PPM especially in patients with a small annulus
- Consider post – dilatation for patients at high risk of PPM. (Post dilatation may have ”root enlargement effect”). (Balloon valve fracture for VIV after SAVR)

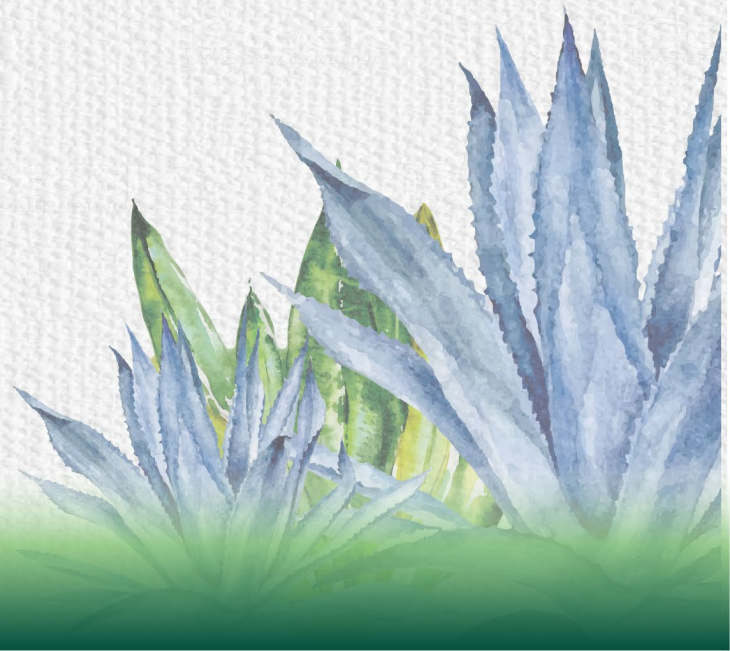
SOLACI SOCIME'25
MEXICO CITY



SOLACI

SOCIME
SOCIEDAD DE CARDIOLOGIA INTERVENCIONISTA DE MEXICO

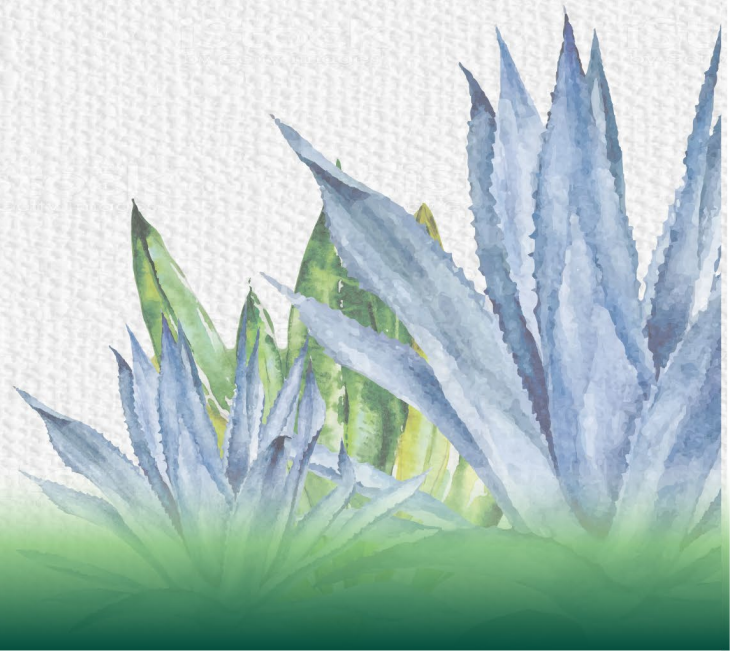
SOLACI SOCIME'25
MEXICO CITY



SOLACI

SOCIME
SOCIEDAD DE CARDIOLOGIA INTERVENCIONISTA DE MEXICO

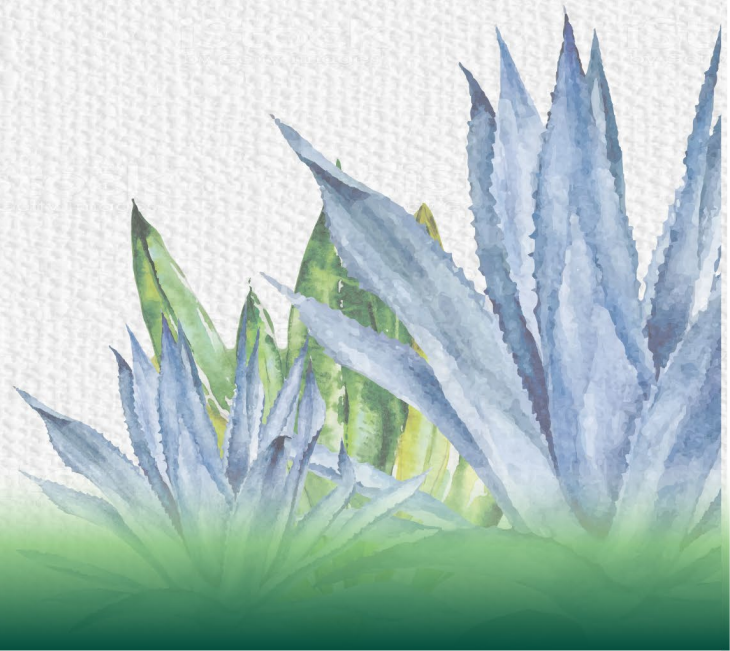
SOLACI SOCIME'25
MEXICO CITY



SOLACI

SOCIME
SOCIEDAD DE CARDIOLOGIA INTERVENCIONISTA DE MEXICO

SOLACI SOCIME'25
MEXICO CITY



SOLACI

SOCIME
SOCIEDAD DE CARDIOLOGIA INTERVENCIONISTA DE MEXICO