TAVI: Cómo seleccionar la válvula para cada paciente

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November 2024

- Escasas o Nulas Evidencias, Guías o Consensos basados en estudios randomizados que indiquen que dispositivo utilizar en cada caso específico.
- Recomendaciones basadas en:
  - Registros.
  - Experiencias personales.
  - Sugerencias de expertos.

Factores a considerar al seleccionar la prótesis

Anatómicos:

- Tamaño del anillo
- Altura de las coronarias
- Bicúspides
- Calcificación del TSVI y del anillo
- Angulo de la raíz aórtica
- Accesos vasculares

Del Procedimiento:

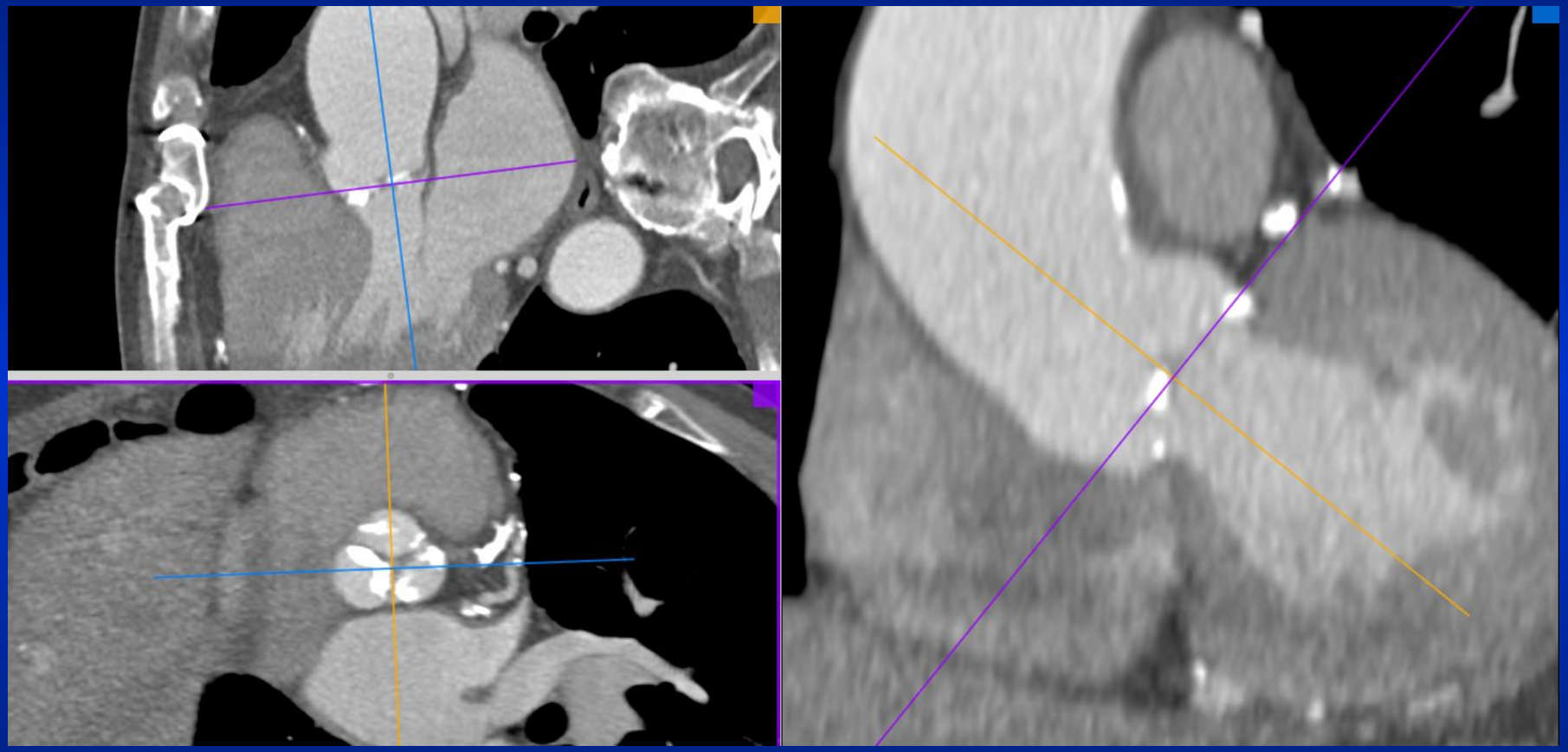
- ViV
- Marcapasos
- Leaks
- Stroke

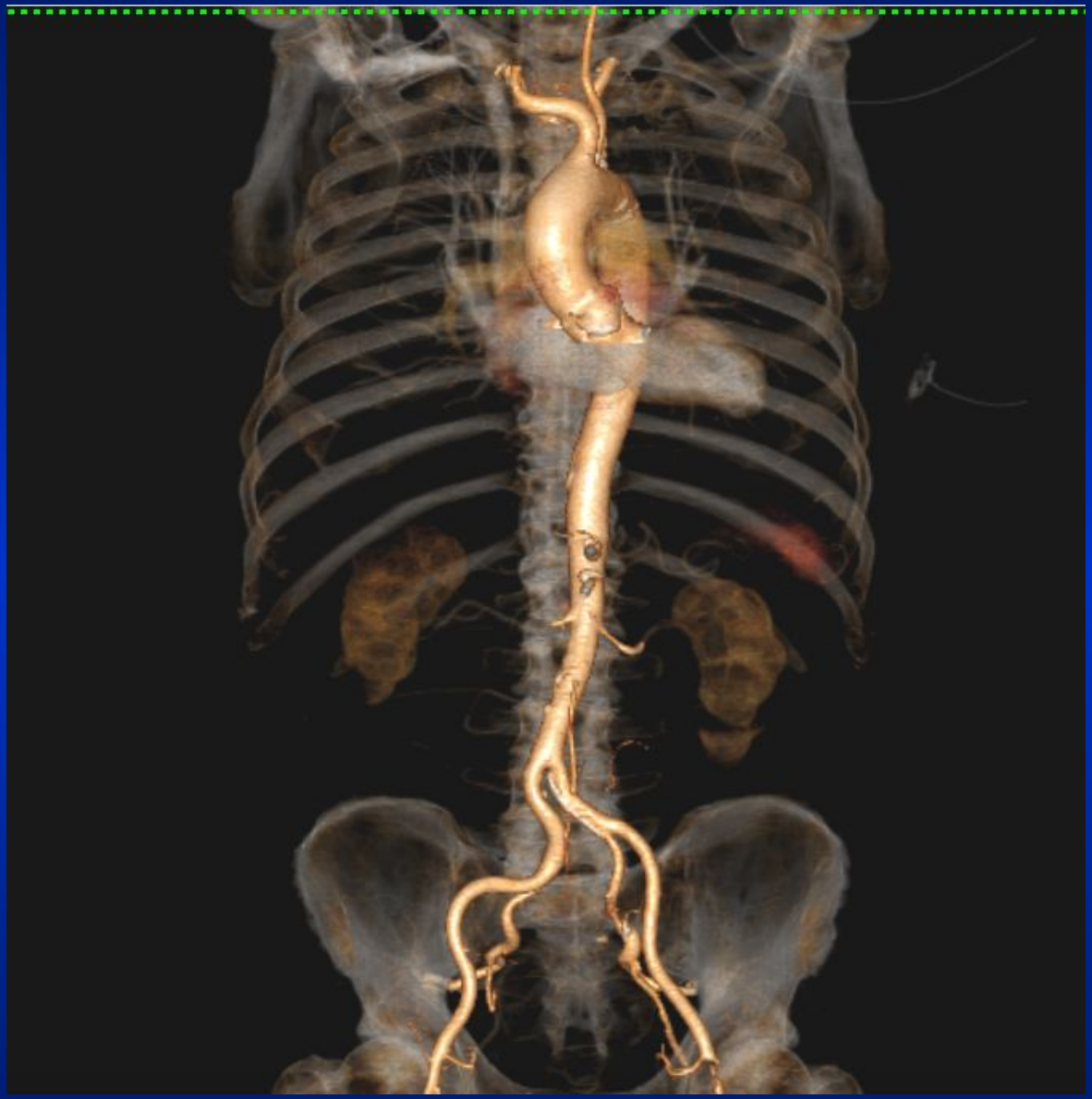
Seguimiento:

- Durabilidad
- Hemodinámicos

Anatomía favorable

TCMS



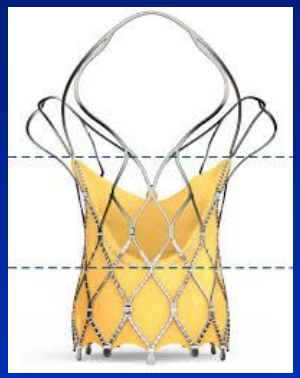


Cualquiera de los dispositivos actuales disponibles son aptos

Evolut Pro+

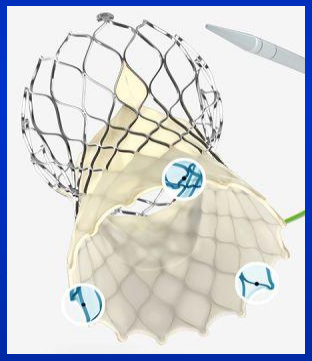
Acurate Neo TF

Navitor



Hydra

VitaFlow



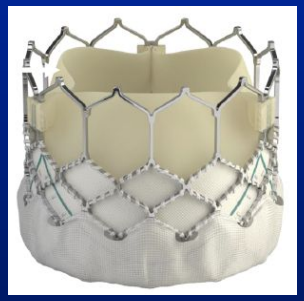
Evolut FX

Venus A

Power X

BALON EXPANDIBLES

Sapien 3

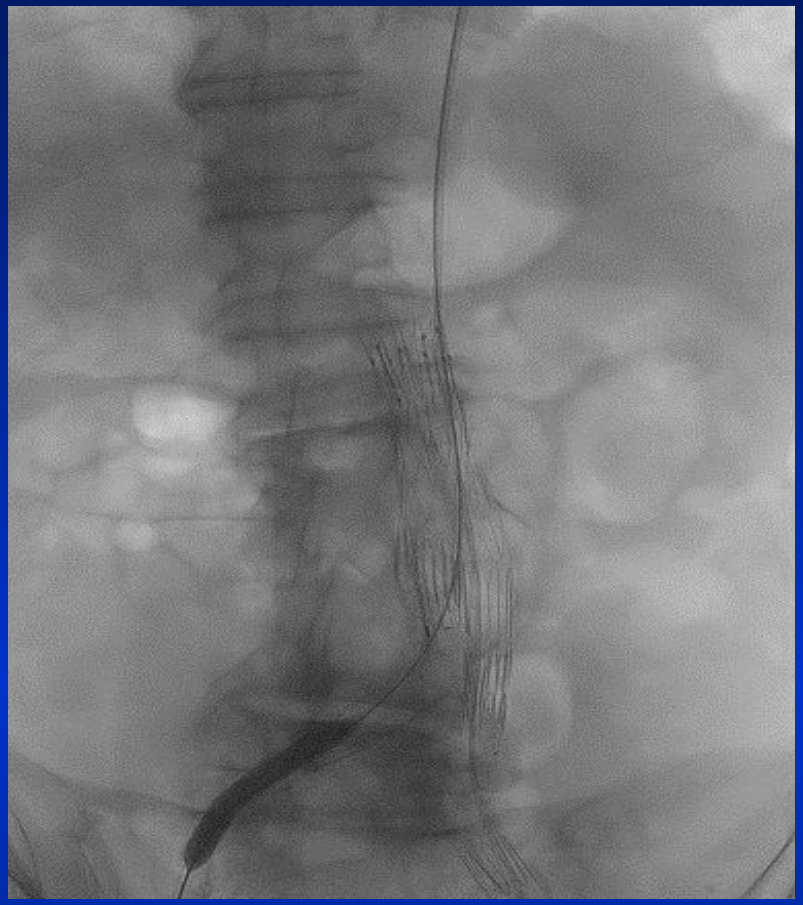


MyValve

Venus Vitae

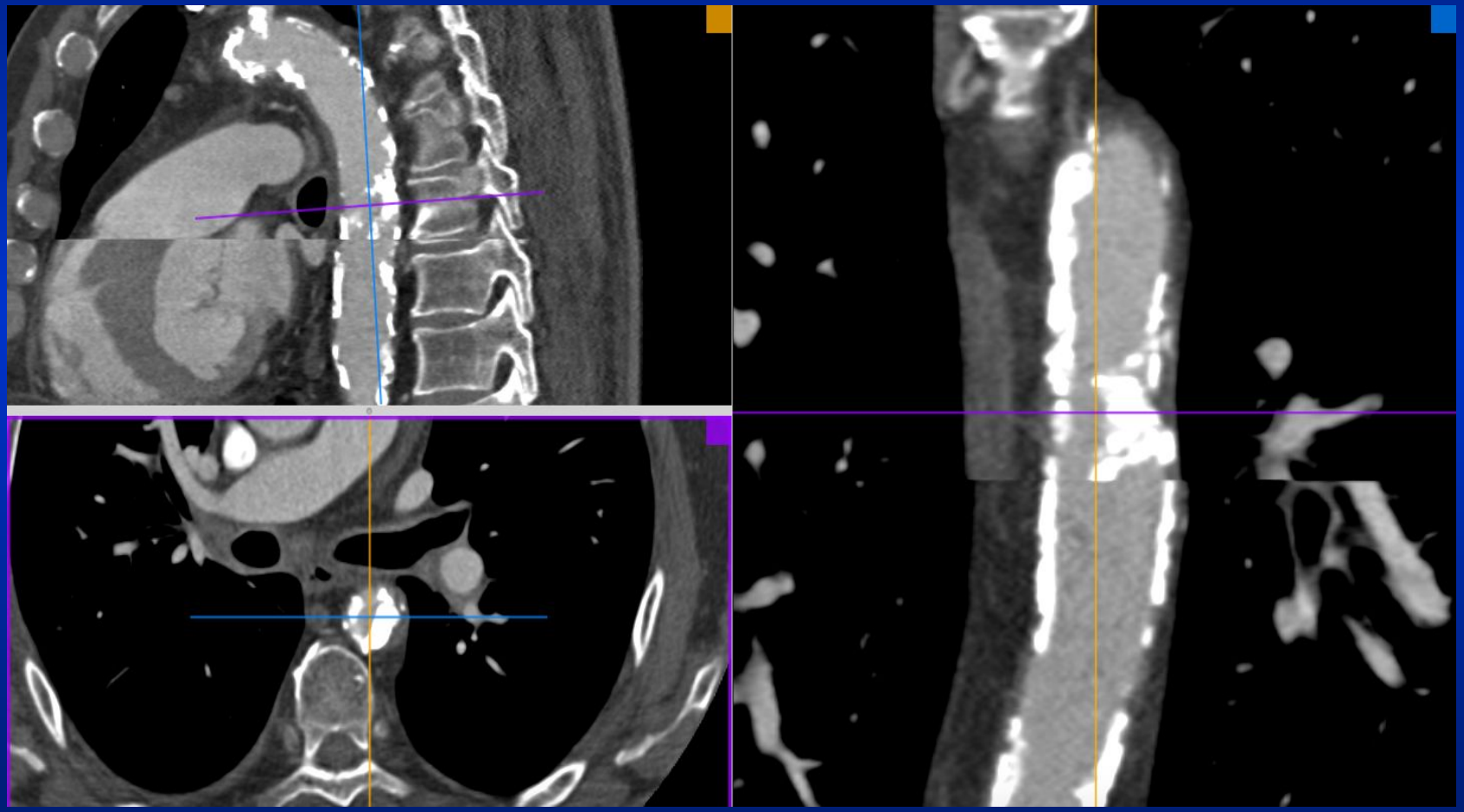
Accesos Complejos

TCMS



Dispositivos 14 Fch o con Introductor expandible

Subclavio/ Axilar o Carotideo: S3 o Evolut



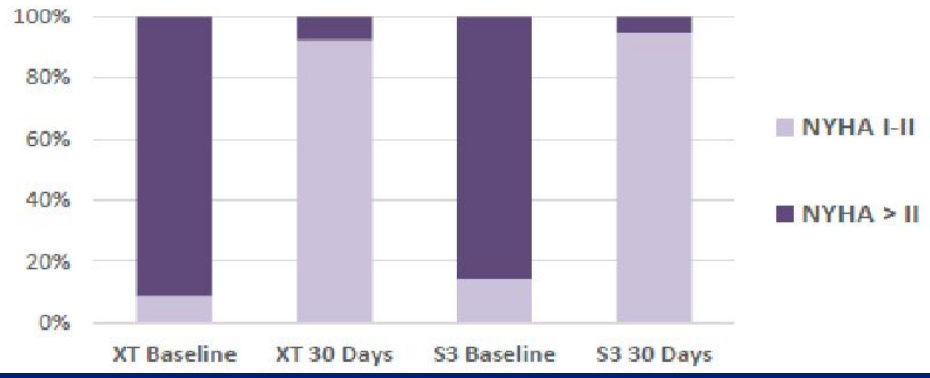
Valve in Valve

Registro VIVID

Resultados Peri Procedimiento

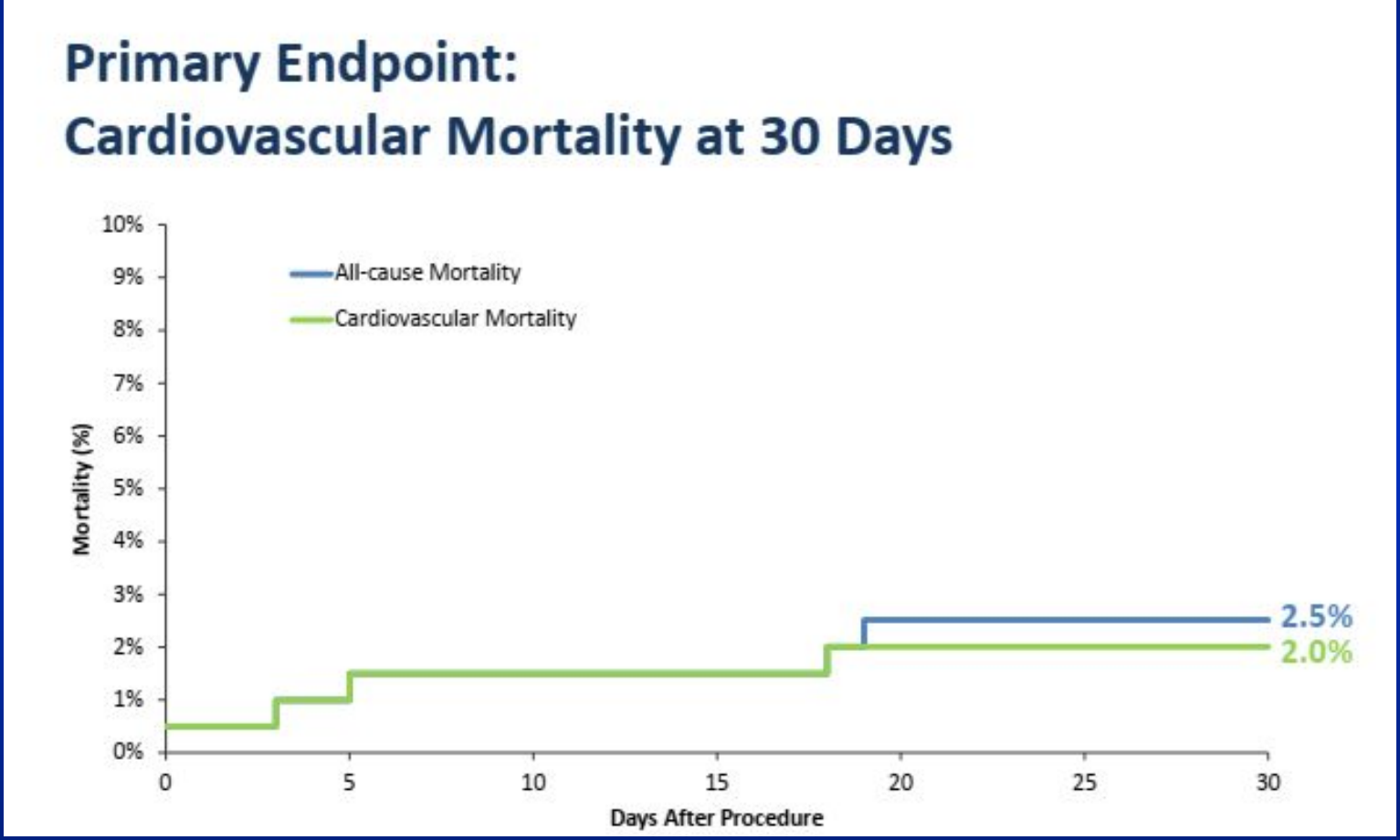
SAPIEN

	SAPIEN 3 n = 156	SAPIEN XT n = 156	P
Major stroke	0.6%	1.3%	0.56
Major/life-threatening bleeding	1.9%	3.2%	0.72
Major vascular complication	1.9%	1.9%	0.97
Acute kidney injury (stages II/III)	3.8%	3.8%	1.0
Permanent pacemaker implantation	6%	1.4%	**0.04**
All-cause mortality (at 30 days)	2%	2.6%	0.71



Resultados a 30 días del "prospective VIVA post-market study"

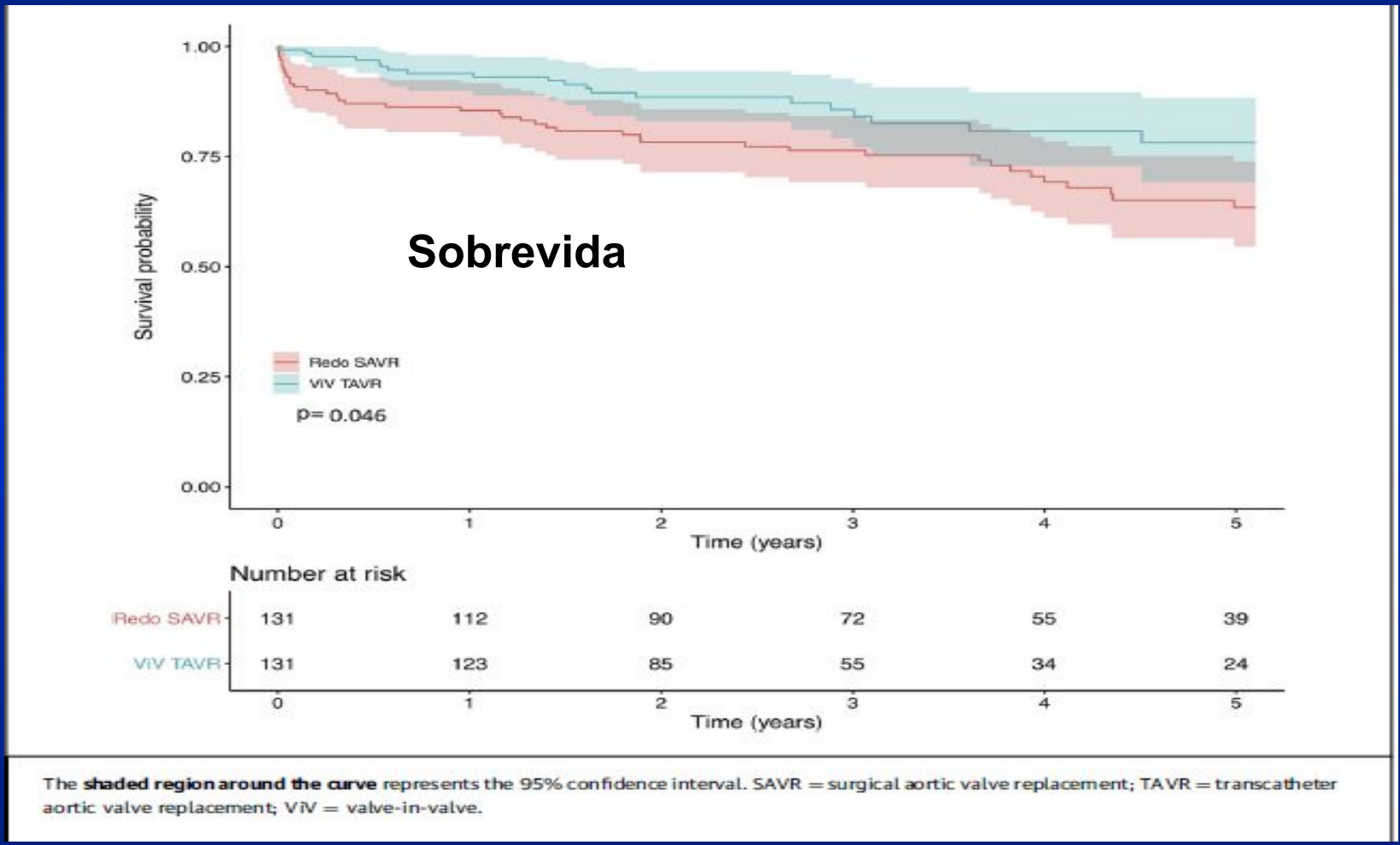
Evolut R



Ran Kornowsk. TVT 2018

Valve in Valve vs. Re cirugía

Resultados de cortes macheadas

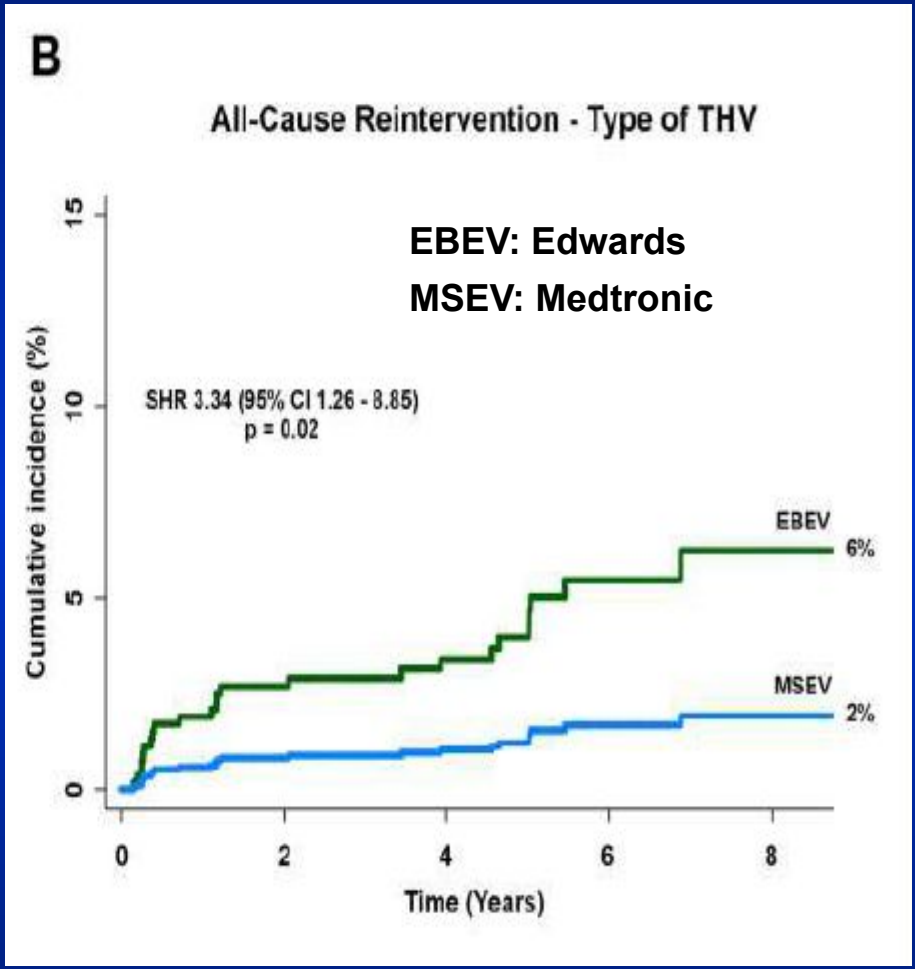


The **shaded region around the curve** represents the 95% confidence interval. SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement; ViV = valve-in-valve.

Tam DY. JACC Interv 2020;13:165-74

Resultados a Largo Plazo del Valve in Valve Aórtico

1006 pts



Bleiziffer S. European Heart Journal 2020, 0, 1-12

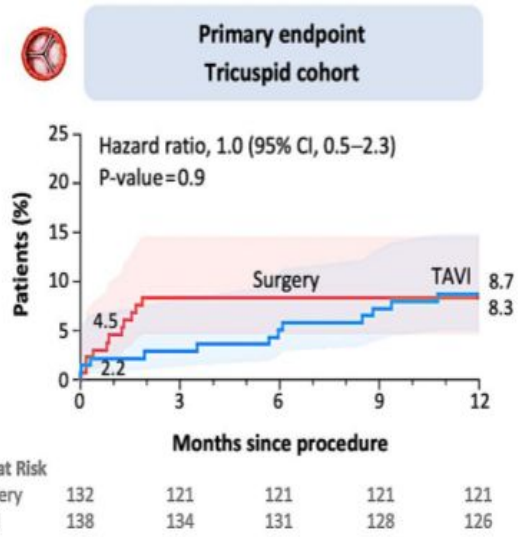
TAVI en BICUSPIDE

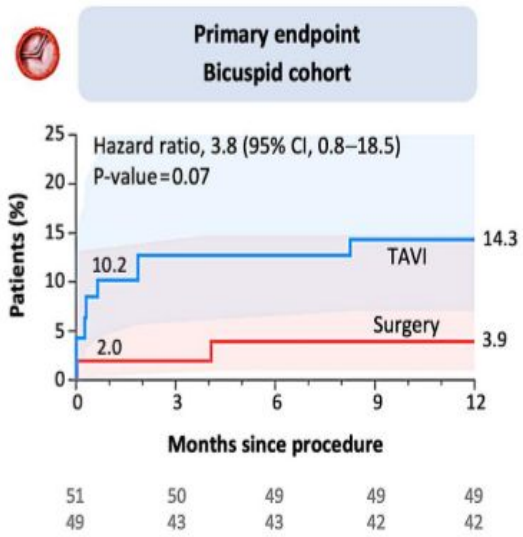
» Los dispositivos con mayor evidencia en el tratamiento de la EA en válvula Bicúspide son Sapien y Evolut.

Notion 2

First randomized evaluation of TAVI versus SAVR in patients that include bicuspid aortic valves

Subanalysis - tricuspid & bicuspid AS cohorts





TAVI Group:

- 73% SEV
- 27% BEV

Three-Year Outcomes from the Evolut Low Risk TAVR Bicuspid Study

Firas Zahr, MD

Oregon Health & Science University, Portland, OR

On behalf of the Low Risk Bicuspid Investigators

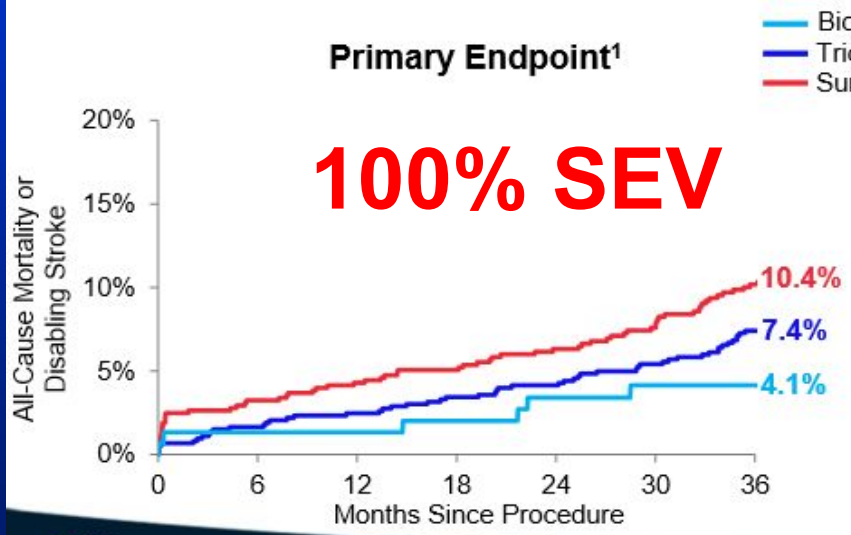
idytac HEMODINAMIA HOSPITAL ESPAÑOL

Clinical Perspective

Evolut™ Low Risk Bicuspid Study

- At 3 years, low risk TAVR patients with bicuspid valves had comparable outcomes to TAVR patients with tricuspid valves.

Primary Endpoint[1]



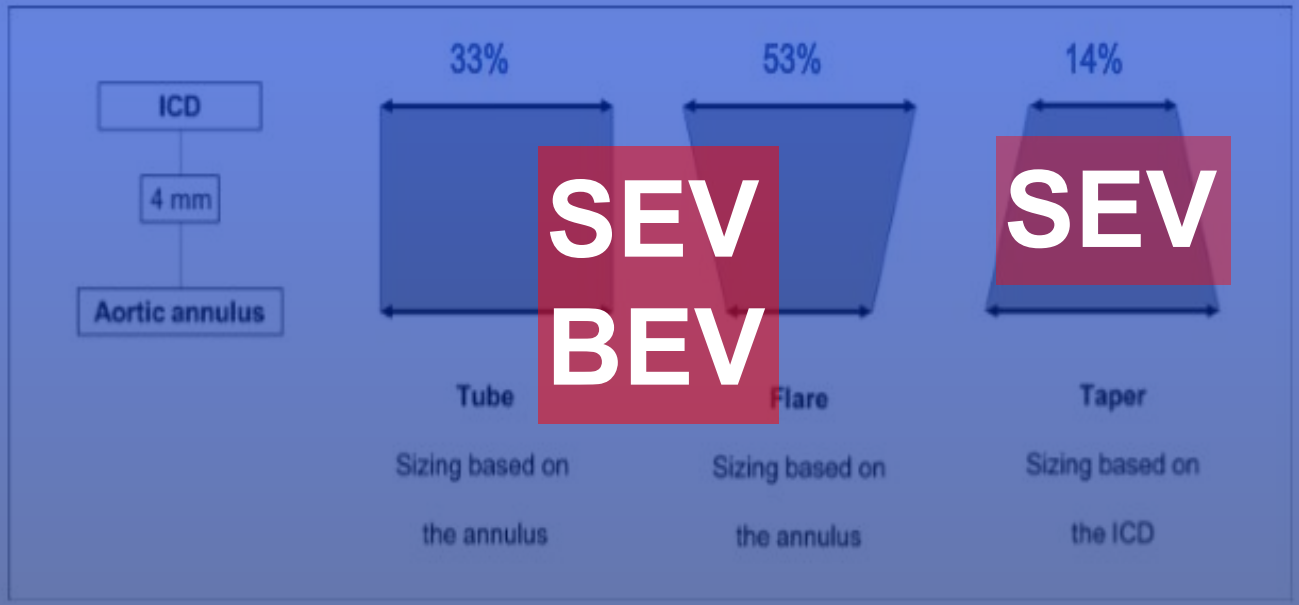
Hemodynamics[1]

JACC 2023,81:1663

Sizing algorithms & Bicuspid Aortic Valves

Question 1: Is the intercommissural area the most constraining region?

Question 2: Do we need to adjust sizing algorithms in this setting?



Tchetche et al. Circulation VI 2019

CT Classification

Sievers Type 1 or 2

Sievers Type 0

Tricommissural
21/91 (23.3%)

Bicommissural Raphe-type
50/91 (55.6%)

Bicommissural Non Raphe-type
19/91 (21.1%)

Leaflet Morphology

Leaflet Orientation

SEV

Coronary Cusp Fusion
13/21 (61.9%)

Mixed Cusp Fusion
8/21 (38.1%)

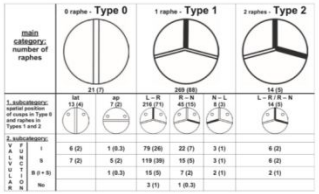
Coronary Cusp Fusion
44/50 (88.0%)

Mixed Cusp Fusion
6/50 (12.0%)

Coronary Cusp Fusion
4/19 (21.1%)

Mixed Cusp Fusion
15/19 (78.9%)

Pre-CT / Pre-TAVR BAV classification
Sievers classification

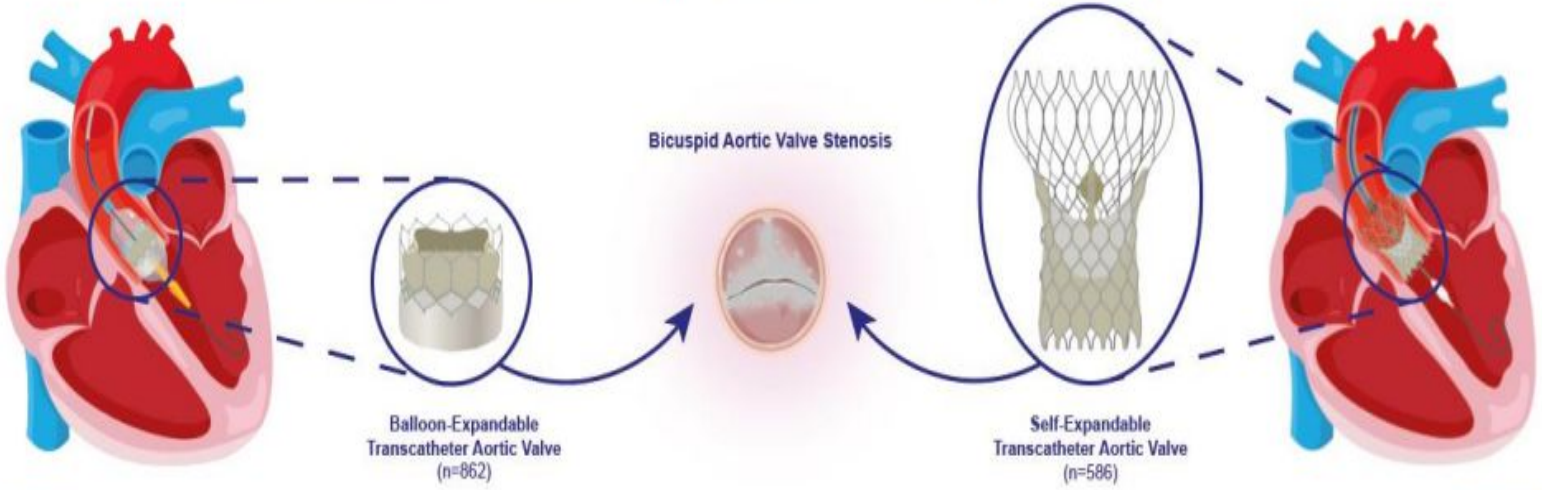


Jiahawl et al. JACC Imaging 2016,9:1145

Head to Head SEV and BEV in BAV

Study Design

- Long-time established institutional program
- Consecutive patients from May 2007 to Jan 2022 (n=1556)
- Computed tomography-defined bicuspid aortic valve stenosis
- TAVR with balloon- or self-expandable THV (n=1448)



Giacoppo D. TCT 2023

3-Year Outcomes

	Total (n=1448)	BE-THV (n=862)	SE-THV (n=586)	P	OR [95% CI]	OR_{MVA} [95% CI]	OR_{IPTW} [95% CI]	OR_{PSM} [95% CI]
Death or Stroke	206 (24.5)	119 (23.6)	87 (25.9)	0.305	0.87 [0.66-1.14]	0.98 [0.70-1.37]	0.98 [0.71-1.35]	1.02 [0.69-1.51]
Death	158 (21.2)	94 (20.8)	64 (21.9)	0.589	0.92 [0.67-1.26]	1.07 [0.72-1.60]	1.10 [0.73-1.66]	1.10 [0.68-1.78]
Cardiac Death	73 (9.0)	37 (7.1)	36 (12.1)	0.065	0.65 [0.41-1.03]	0.76 [0.42-1.40]	0.99 [0.49-2.00]	0.82 [0.37-1.83]
Stroke	66 (5.7)	32 (4.2)	34 (8.0)	0.057	0.63 [0.39-1.02]	0.69 [0.36-1.30]	0.63 [0.33-1.20]	0.78 [0.38-1.61]
Repeat Valve Replacement	19 (1.9)	6 (1.1)	13 (3.1)	0.007	0.29 [0.11-0.76]	0.36 [0.11-1.25]	0.54 [0.13-2.06]	0.36 [0.05-2.45]
Valve Thrombosis	11 (1.6)	10 (2.4)	1 (0.2)	0.051	6.03 [0.77-47.17]	4.83 [0.52-44.91]	3.30 [0.66-16.46]	4.54 [0.41-50.18]
Endocarditis	11 (1.5)	7 (1.3)	4 (1.7)	0.864	1.11 [0.33-3.81]	0.93 [0.19-4.67]	1.10 [0.23-5.13]	0.94 [0.16-5.64]
Myocardial Infarction	20 (2.8)	10 (2.1)	10 (4.0)	0.325	0.65 [0.27-1.55]	0.80 [0.22-2.91]	1.06 [0.30-3.78]	0.41 [0.08-2.25]
Pacemaker Implantation	215 (19.4)	105 (15.5)	110 (25.5)	<0.001	0.62 [0.47-0.80]	0.54 [0.39-0.74]	0.57 [0.40-0.80]	0.55 [0.35-0.88]
Valve-Related Rehospitalization	91 (11.1)	38 (7.9)	53 (16.1)	<0.001	0.46 [0.30-0.69]	0.84 [0.47-1.50]	0.94 [0.50-1.76]	0.71 [0.27-1.83]
All-Cause Death, Stroke, Repeat Valve Replacement, or Valve-Related Rehospitalization	281 (31.9)	151 (28.8)	130 (37.0)	0.004	0.71 [0.56-0.90]	0.93 [0.69-1.25]	0.96 [0.72-1.28]	0.90 [0.61-1.32]

Giacoppo D. TCT 2023

Importancia de la anatomía

Anillo Pequeño

Annulus Sizing		20 mm	23 mm	26 mm	29 mm
Native Valve Annulus Size (CT)	Area	273 - 345 mm²	338 - 430 mm²	430 - 546 mm²	540 - 683 mm²
	Area Derived Diameter	18.6 - 21 mm	20.7 - 23.4 mm	23.4 - 26.4 mm	26.2 - 29.5 mm
Native Valve Annulus Size TEE		18 - 19 mm	18 - 22 mm	21 - 25 mm	24 - 28 mm

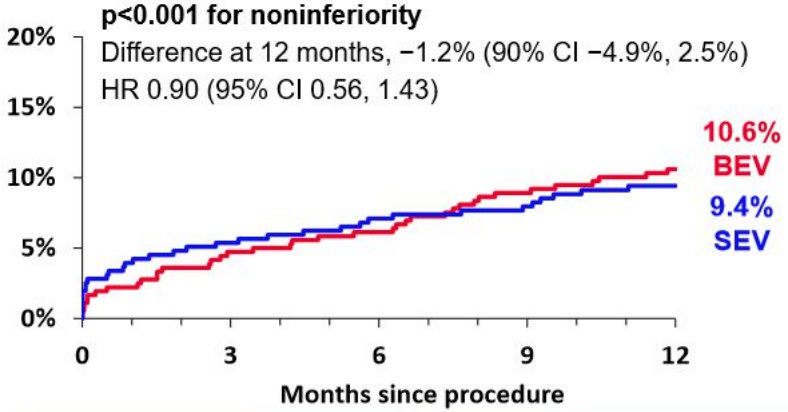
Size	23 mm	26 mm	29 mm	34 mm
Annulus Diameter (A)	17*/18-20 mm	20-23 mm	23-26 mm	26-30 mm
Annulus Perimeter	53.4*/56.5-62.8 mm	62.8-72.3 mm	72.3-81.7 mm	81.7-94.2 mm
Sinus of Valsalva Diameter (Mean) (B)	≥25 mm	≥27 mm	≥29 mm	≥31 mm
Sinus of Valsalva Height (Mean) (C)	≥15 mm	≥15 mm	≥15 mm	≥16 mm

Anatomic	BE	SE
Annulus size	–	–
Coronary location		
LVOT calcification		
Aortic root angulation		
Procedural risks		
Vascular access		
Permanent pacemaker		
Paravalvular leak (AR)		
Stroke		
Follow-up		
Durability		
Hemodynamics		
Cost effectiveness		

- Most (87%) of these patients were women, often underrepresented in clinical trials
- Therefore, we evaluated clinical and hemodynamic outcomes in women from the SMART trial (pre-specified analysis)

SMART Trial Results (Co-Primary Outcomes)

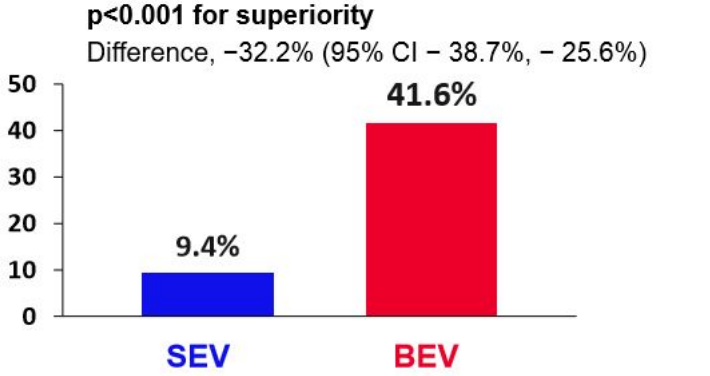
Mortality, Disabling Stroke, or HF Rehospitalization



12 Months	SEV (N=355)	BEV (N=361)	HR (95% CI)
All-cause mortality	5.1%	5.9%	0.88 (0.47, 1.65)
Disabling stroke	3.1%	2.6%	1.26 (0.52, 3.03)
HF rehosp	3.8%	3.5%	1.11 (0.51, 2.44)

Herrmann HC, et al. *N Engl J Med*. Published online April 7, 2024

Bioprosthetic Valve Dysfunction through 12 months



	SEV (N=350)	BEV (N=365)	P Value
BVD composite	**9.4%**	**41.6%**	**<0.001**
HSVD	3.2%	32.2%	
NSVD	5.9%	18.2%	
Thrombosis (clinical)	0.3%	0.3%	
Endocarditis	0.6%	2.3%	
AV Reintervention	0.9%	0.6%	

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

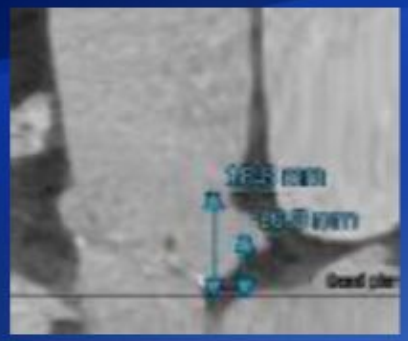
SMART Trial

HSVC: disfunción estructural hemodinámica
NSVD: disfunción valvular no estructural

Herrmann H et al. **N Engl J Med 2024;390:1959-1971**

Importancia de la anatomía

Altura coronarias: S3, MyValve, Evolut Fx o Fx+, Acurate



Risk factors for coronary obstruction:

- Small SOV diameter
- Low coronary height
- Leaflet height and bulk
- Valve-in-valve

- Coronary protection and later access easier with BE
- Repositioning only with SE

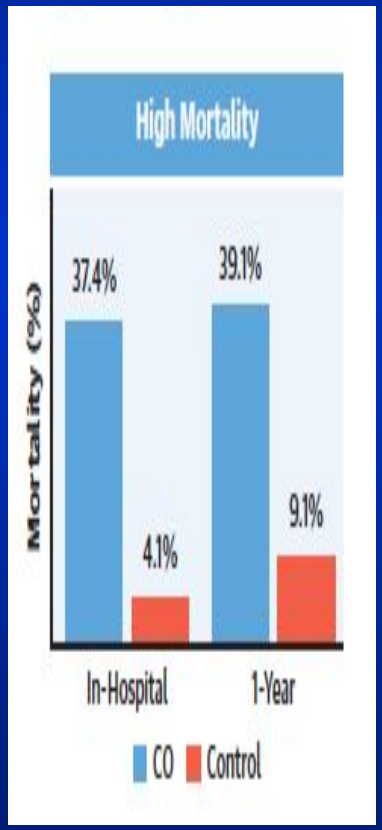
Ribiero et al, JACC 2013;62:1552

Anatomic	BE	SE
Annulus size	–	–
Coronary location	–	–
LVOT calcification		
Aortic root angulation		
Procedural risks		
Vascular access		
Permanent pacemaker		
Paravalvular leak (AR)		
Stroke		
Follow-up		
Durability		
Hemodynamics		
Cost effectiveness		

Coronary obstruction can be Catastrophic

- Overall incidence <1% (mortality 30% - 50%).

- Higher in ViV cases (2.3% from VIVID Registry)
  - 6.4% in valve with externally mounted leaflets



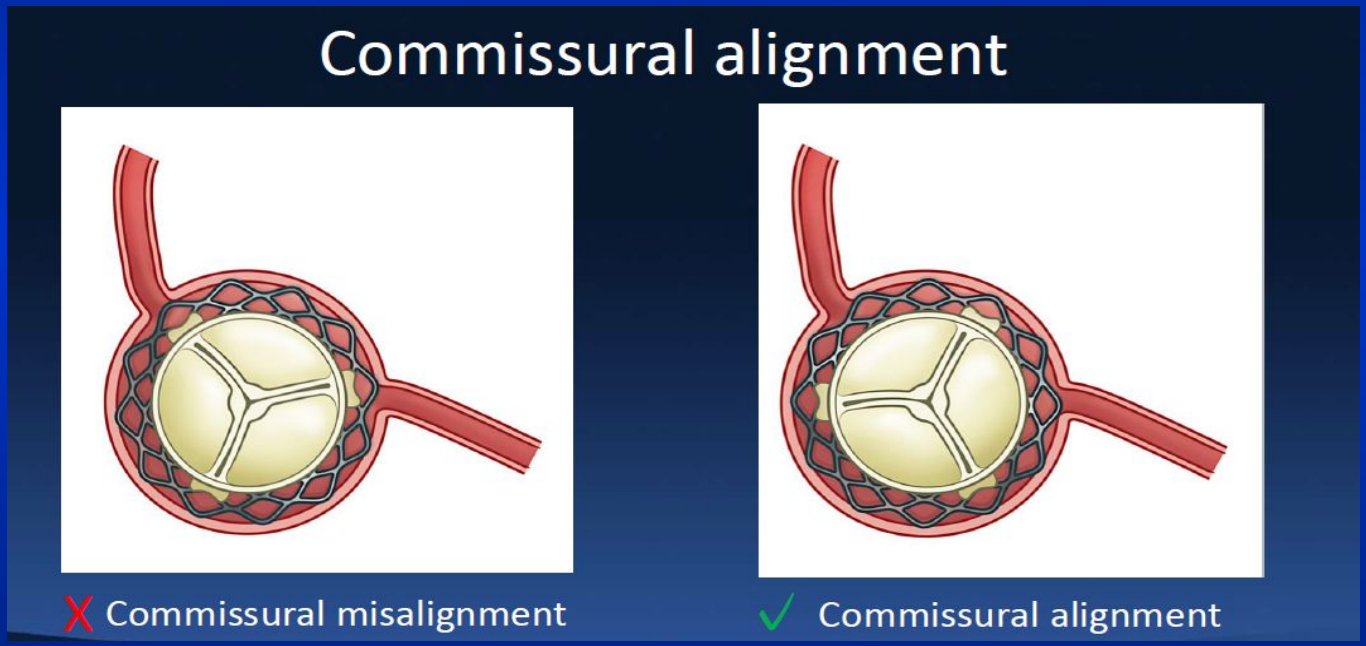
Ribeiro et. al. JACC Cardiovasc Intv2013
Ribeiro et. al. EHJ 2018
Ojeda et al. JACC Cardiovasc Intv2023

RE-ACCESS study

300 patients with attempted coronary cannulation before and after TAVI:

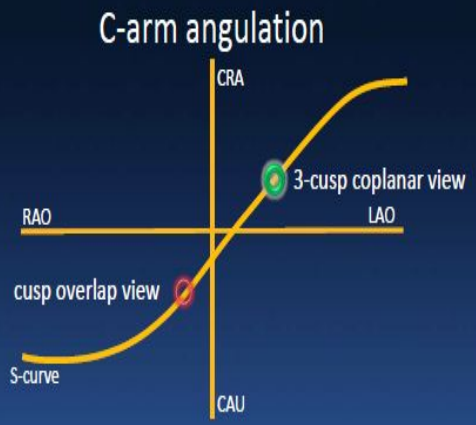
- **Unsuccessful in 23 patients (7.7%) after TAVI**
- **Unsuccessful in 17.9% of Evolut THV vs. 0.4% of other THV**

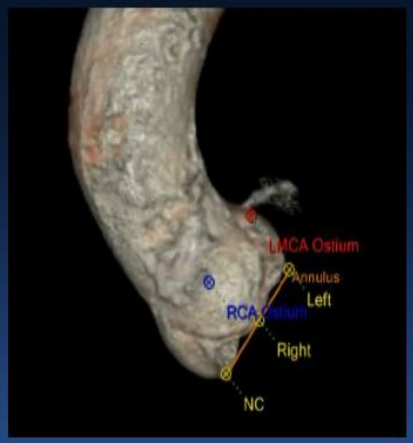
Barbantiet al. JACC CardiovascInterv. 2020;13:2542-55



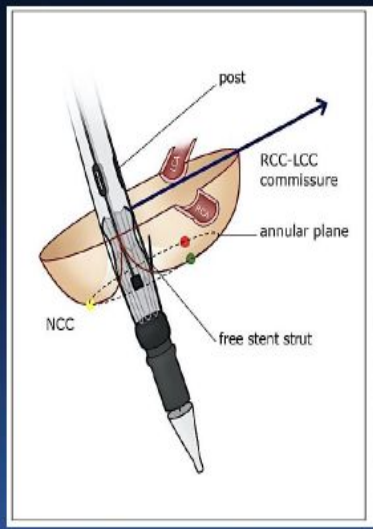
Sondergaard et al, Eurointerv, 2018;14:147

Left/right cusp overlap view





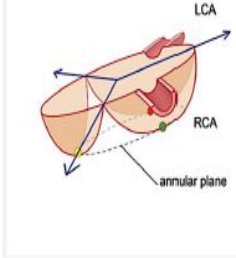
Acurate neo2 - positioning commissures

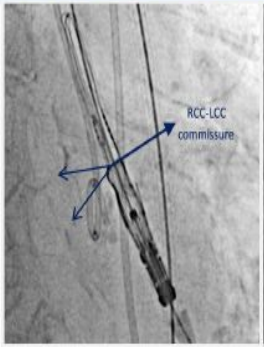


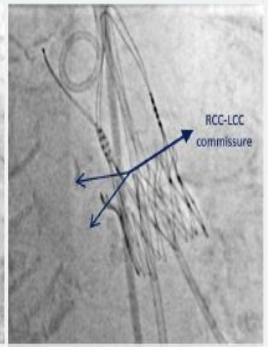
ACURATE neo2

Commissural alignment implant technique

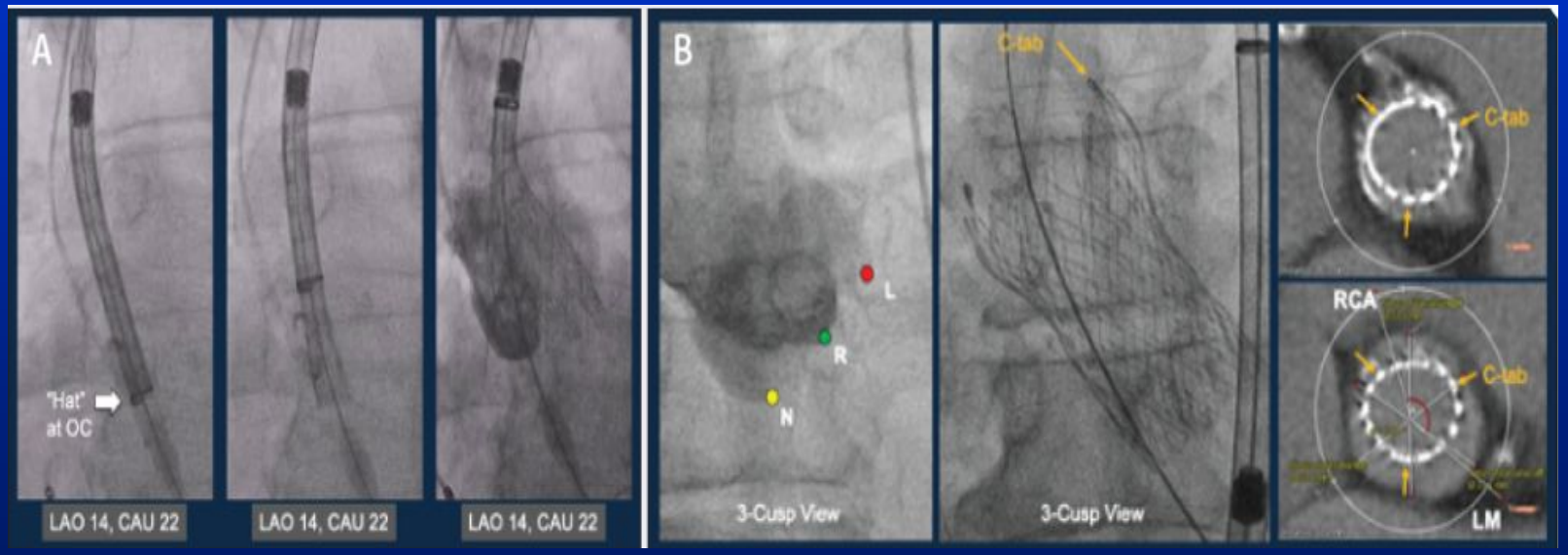
IMPLANTATION TECHNIQUE IN RCC/LCC CUSP OVERLAP VIEW – COMMISSURAL ORIENTATION







Evolut Commissural Alignment



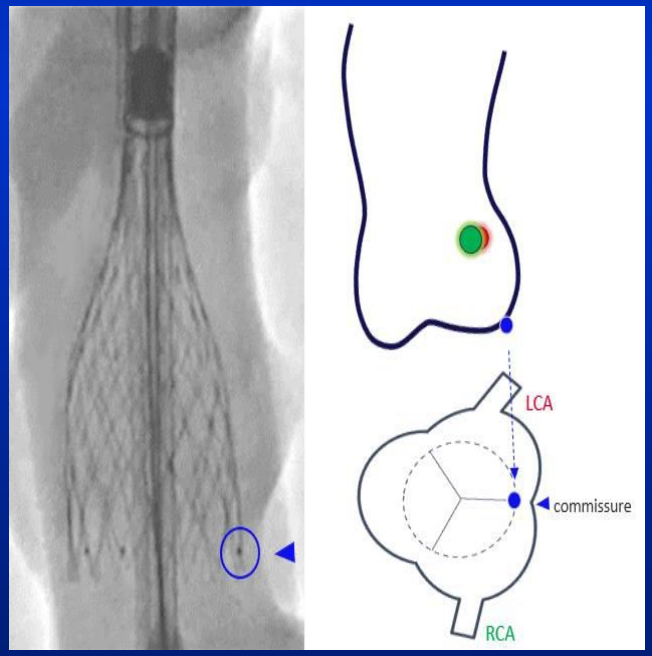
Commissural Alignment with Evolut FX y FX+

- Flush port at 3 o'clock

¡Hat marker on R side of screen

¡Hat marker is "center-front" in cusp overlap view

- Gold markers are 3mm from inflow and offset 1.5mm from the commissural posts
- Can help to facilitate commissural alignment



SAPIEN X4 Transcatheter Heart Valve

RESILIA tissue

- Offers enhanced anti-calcification technology and enables dry storage
- Maintains bovine pericardial leaflets matched for thickness and elasticity

Enhanced PET outer skirt

- Designed to further minimize PVL
- Maintains low profile access

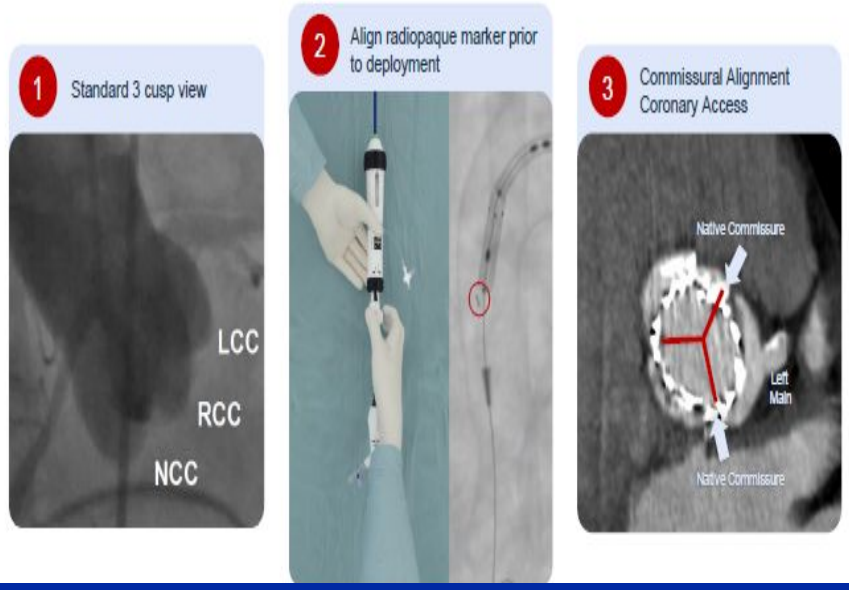
Novel frame and leaflet design

- Enables adjustable sizing while maintaining valve performance over the deployment diameter range
- Maintains high radial strength cobalt chromium balloon-expandable design

Low frame height and large cells

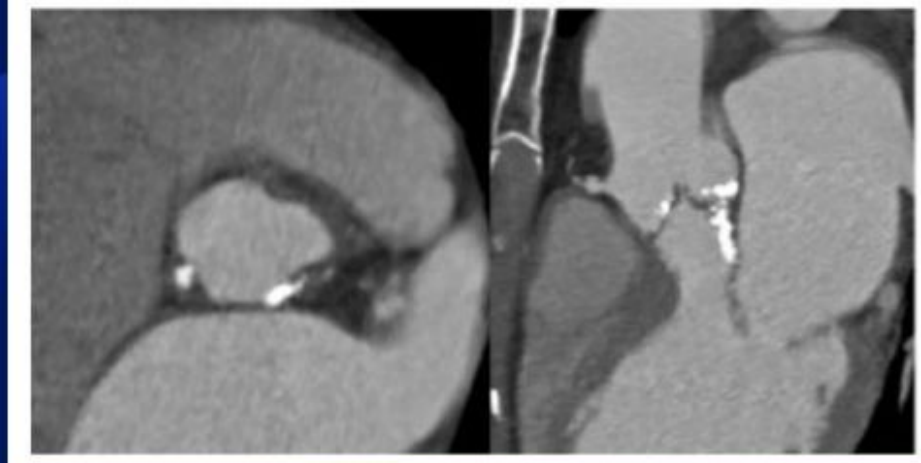
- Facilitates future coronary access

SAPIEN X4: Commissural Alignment



Importancia de la anatomía

Calcificación del TSVI: Autoexpandible



LVOT calcification and prosthesis oversizing have been associated with:

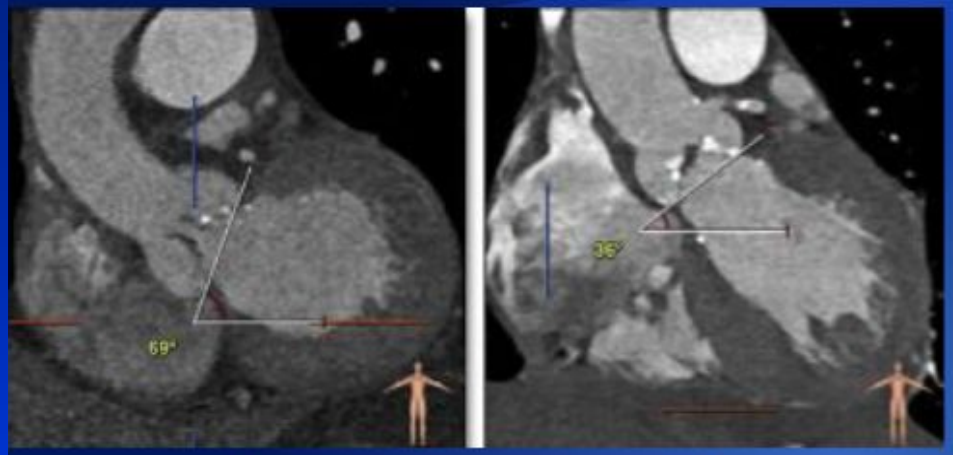
- Annular disruption
- VSD
- PVL

Barbanti et al, Circ 2013;128:244
Bullesfeld et al, EuroIntv 2014;10:732
Rene et al, J Inv Card 2016;28:E59

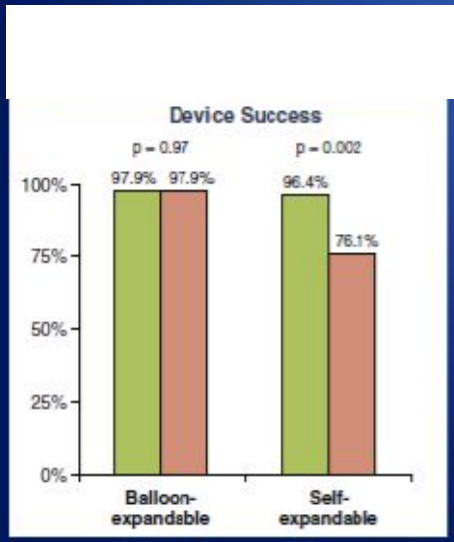
Anatomic	BE	SE
Annulus size	–	–
Coronary location	–	–
LVOT calcification	–	+
Aortic root angulation		
Procedural risks		
Vascular access		
Permanent pacemaker		
Paravalvular leak (AR)		
Stroke		
Follow-up		
Durability		
Hemodynamics		
Cost effectiveness		

Importancia de la anatomía

Angulo de la raíz aórtica: BE en >70°

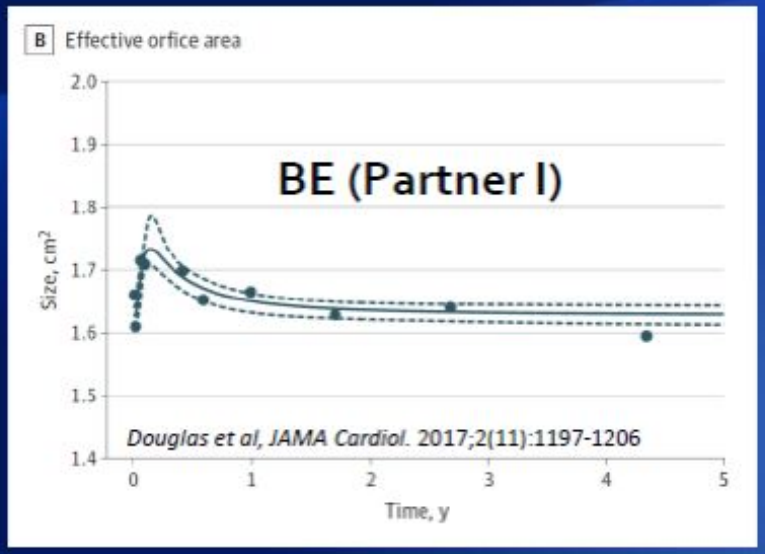


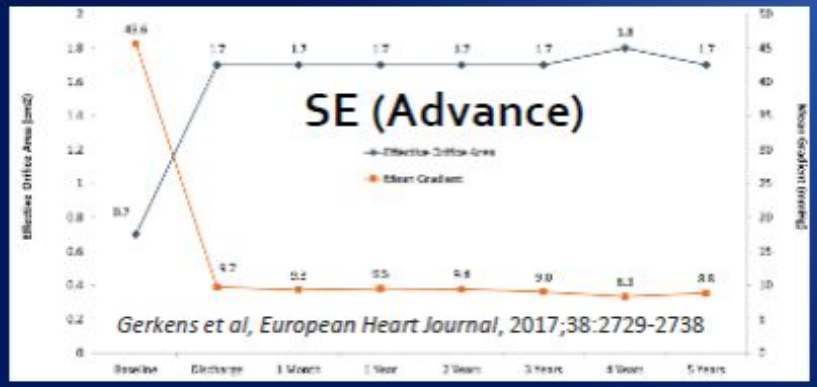
Anatomic	BE	SE
Annulus size	–	–
Coronary location	–	–
LVOT calcification	–	+
Aortic root angulation	+	–
Procedural risks		
Vascular access		
Permanent pacemaker		
Paravalvular leak (AR)		
Stroke		
Follow-up		
Durability		
Hemodynamics		
Cost effectiveness		



Abramowitz et al, JACC CV Imaging 2016;9:964

Durabilidad: Sin diferencias, Salvo en Anillo Pequeño (mejor SEV)





Anatomic	BE	SE
Annulus size	–	–
Coronary location	–	–
LVOT calcification	–	+
Aortic root angulation	+	–
Procedural risks		
Vascular access	+	–
Permanent pacemaker	±	–
Paravalvular leak (AR)	–	–
Stroke	±	–
Follow-up		
Durability	–	–
Hemodynamics		
Cost effectiveness		

Conclusiones:

- La gran mayoría de los casos pueden ser realizados con cualquier dispositivo del mercado.
- En los casos de mayor calcificación es recomendable utilizar **SEV** (menor riesgo de ruptura pero más leaks)
- En raíz aórtica horizontal: **BEV**
- Bicúspides: **TIPO «0» o Taper SEV**
- Accesos chicos o tortuosos: **dispositivos 14 Fch o con Intro expandible**
- Coronarias bajas: **S3, MyValve, Acurate, Evolut Fx o Fx+**
- Valve in Valve: **BEV o SEV supra anular (mejor en válvulas chicas).**
- Anillo Pequeño: **SEV supra anular**

CACI

Muchas Gracias por su atención ¡¡¡

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