TAVI in pure AR
Skiing out of bounds

Juan H. Alonso Briales
Hospital Virgen de la Victoria de Málaga

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!!!EMBOLIZATION
RESIDUAL >2 AR!!!

Recommendations on indications for surgery in (A) severe aortic regurgitation and (B) aortic root or tubular ascending aortic aneurysm (irrespective of the severity of aortic regurgitation)

Indications for surgery	Class[a]	Level[b]
A) Severe aortic regurgitation		
Surgery is recommended in symptomatic patients regardless of LV function.[105–109]		
Surgery is recommended in asym… patients with LVESD >… >25 mm/m^2 …		
… matic … mm/m^2 BSA (especially … small body size) or resting LVEF …%, if surgery is at low risk.	IIb	C
Surgery is recommended in symptomatic and asymptomatic patients with severe aortic regurgitation undergoing CABG or surgery of the ascending aorta or of another valve.	I	C
Aortic valve repair may be considered in selected patients at experienced centres when durable results are expected.	IIb	C

And yet, it can be done

Eur Heart J. 2022;43:561-632.

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TAVI may be considered in experienced centres for selected patients with aortic regurgitation and ineligible for SAVR.[119,120]

JACC: CARDIOVASCULAR INTERVENTIONS
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PUBLISHED BY ELSEVIER
VOL. 10, NO. 10, 2017
ISSN 1936-8798/$36.00
http://dx.doi.org/10.1016/j.jcin.2017.03.004

Safety and Efficacy of Transcatheter Aortic Valve Replacement in the Treatment of Pure Aortic Regurgitation in Native Valves and Failing Surgical Bioprostheses

Results From an International Registry Study

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JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
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PUBLISHED BY ELSEVIER
VOL. 70, NO. 22, 2017
ISSN 0735-1097/$36.00
https://doi.org/10.1016/j.jacc.2017.10.006

Transcatheter Aortic Valve Replacement in Pure Native Aortic Valve Regurgitation

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JACC. 2017;70:2752-63.

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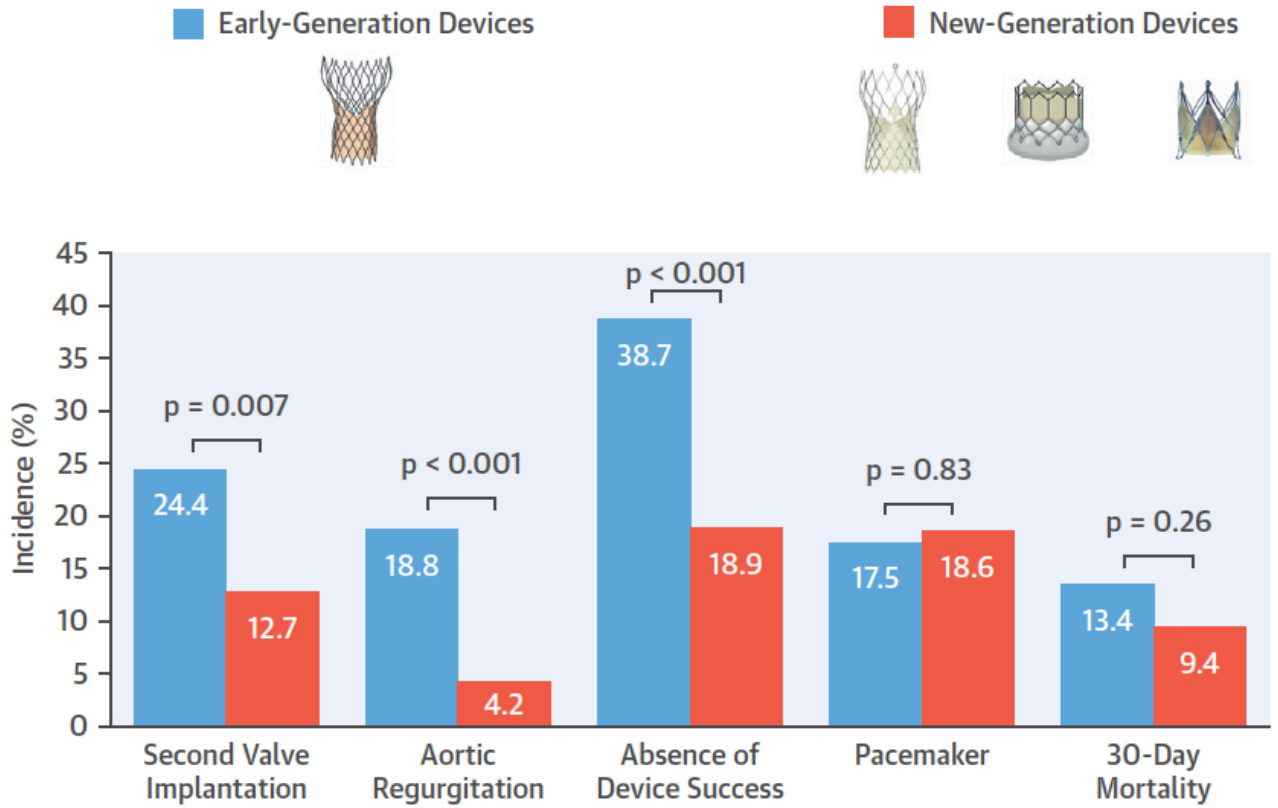
CENTRAL ILLUSTRATION TAVR for Pure Native Aortic Valve Regurgitation

Outcomes According to Devices



JACC. 2017;70:2752-63.

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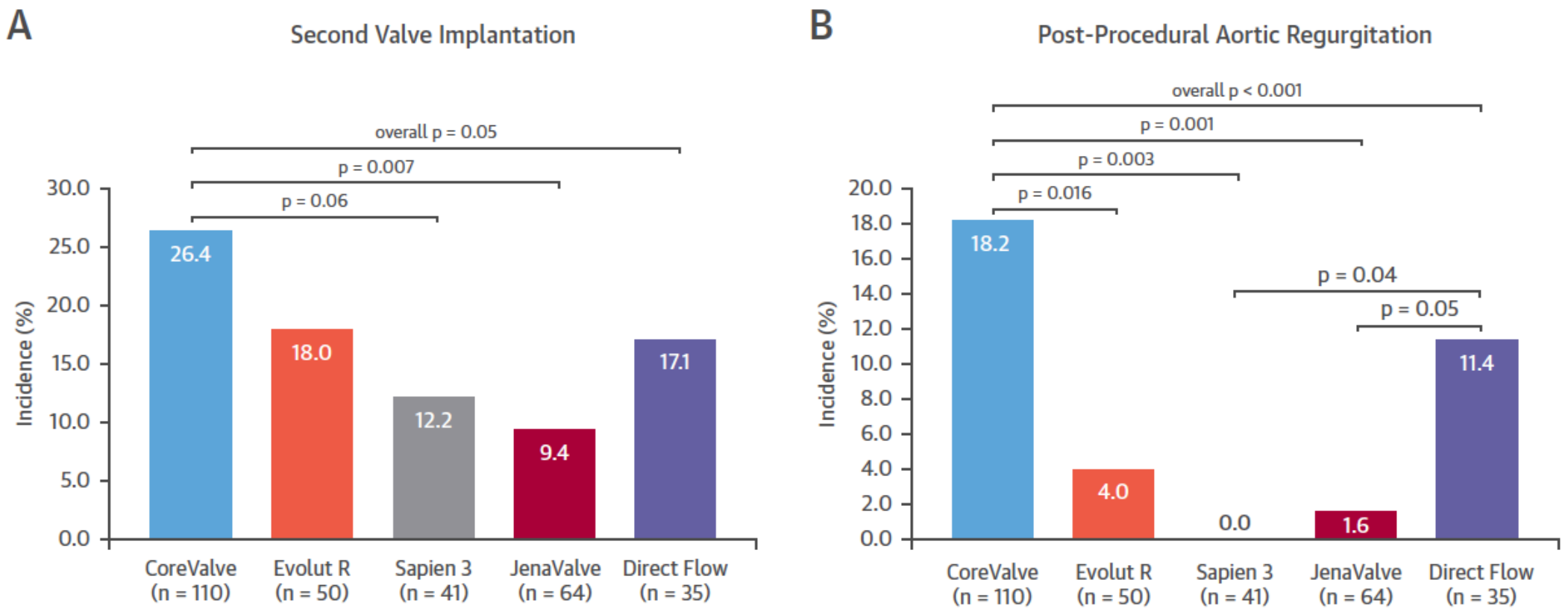
FIGURE 1 Procedural Outcomes According to Devices



JACC. 2017;70:2752-63.

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Prior assessment: Annulus, Ca^{++}, size and angulation ascending aorta (guía Lunderquist)

AR with mild Ca^{++} in leaflet/annular → **Size equal to AS (when it doubt choose big)**
Considerer pacemaker in self-expanding

Severe AR

Pure AR → **Clearly oversize (1 size up)**
Maximum perimeter 82 mm (29 mm border)
Mandatory pacemaker and high rates

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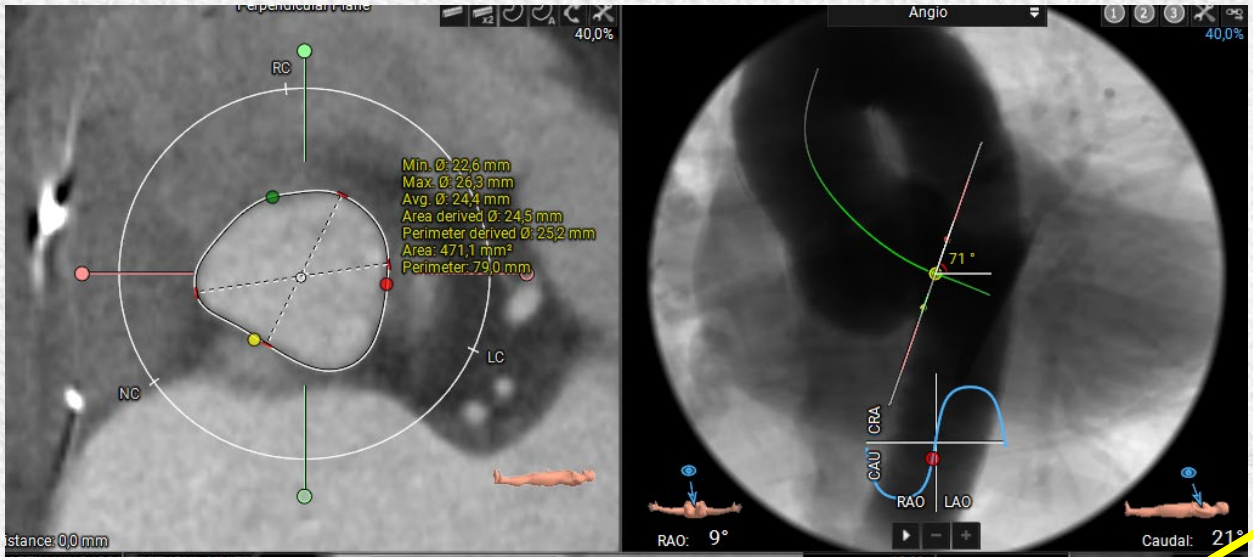
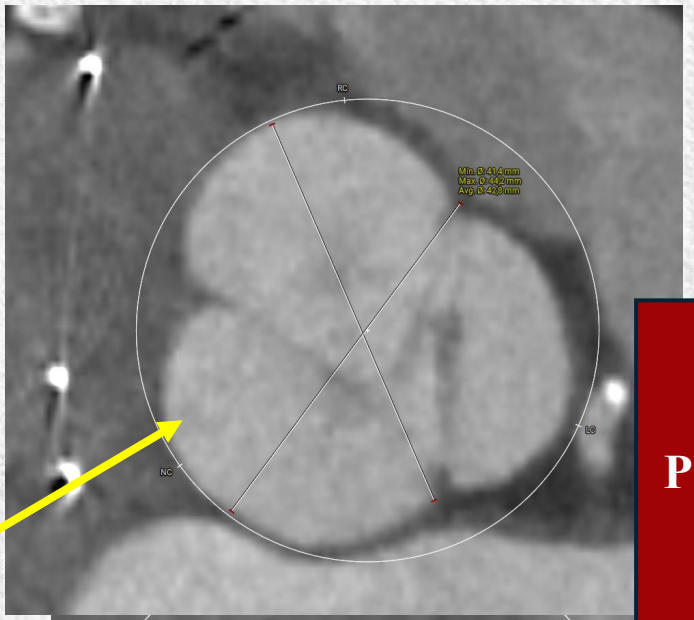
- Male 77 y
- HTA
- AR pure with IC NYHA II
- Bronquial asthma, SAOS
- Pacemaker tres years ago due to atrioventricular block
- ECOCARDIOGRAMA: Severe AR with dilated aortic root. Dilated VI with LVEF 30%
- EuroSCORE II y log: 6,32-11,71%

TAVI in pure AR
Skiing out of bounds





ANNULUS
Perimeter 79 mm (25.2 mm)
Area 471 mm² (24.5 mm)
TSVI 80.9 mm
Senos 41-44 mm
Angulación 71°

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TAVI in pure AR
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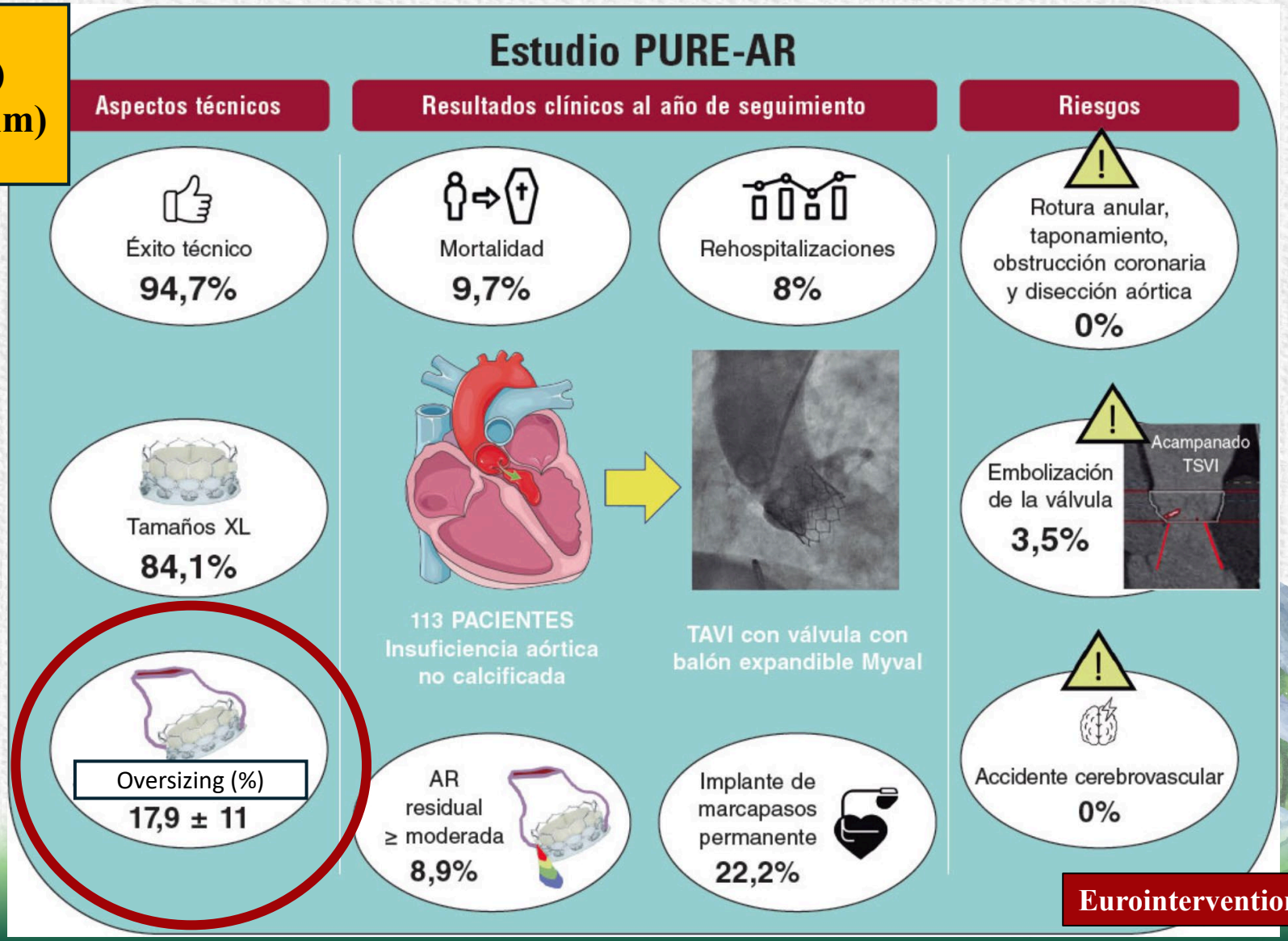
Area 638 mm² (28.5 mm)
Perimeter 88.5 mm (28.2 mm)



Eurointervention. 2023;19:580-8.

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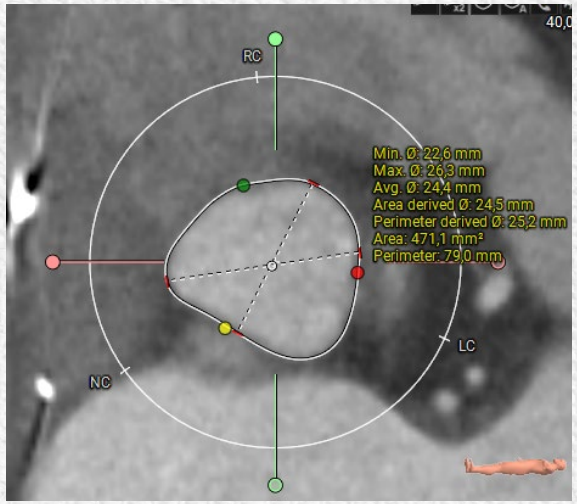
Skiing out of bounds



ANNULUS
Perimeter 79 mm (25.2 mm)
Area 471 mm² (24.5 mm)
TSVI 80.9 mm
Senos 41-44 mm
Angulación 71º

PRÓTESIS
Annulus + 25%
Perimeter > 98,75 mm
Area > 589 mm²

EVOLUT FX 34 mm

32 mm – 100,5 mm
31,5 mm – 98,9 mm
31 mm – 97,4 mm
30,5 mm – 95,8 mm
30 mm – 94,2 mm

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FIGURE 1 Delivery Concept of the JenaValve Trilogy System

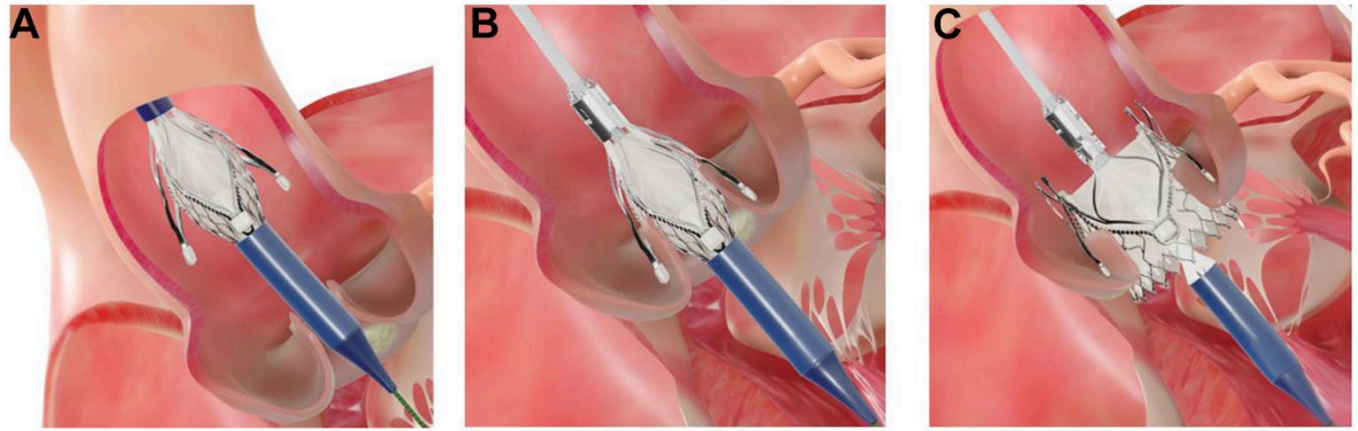

TABLE 1 Continued

Mean annular perimeter, mm	80.3 ± 9.7
Mean aortic annular area, mm^2	512.3 ± 81.7
Aortic annulus-LCA distance, mm	14.0 ± 4.1
Aortic annulus-RCA distance, mm	17.7 ± 4.3
Sinus of Valsalva diameter, mm	36.5 ± 5.5
Sinotubular junction diameter, mm	33.7 ± 4.9
Sinotubular junction height, mm	25.5 ± 5.0
Agatston score	4.0 (0.0-87.5)

25,5 mm

TABLE 3 Outcome Characteristics

Conversion to open surgery	0 (0)
Technical success	58 (100)
In-hospital mortality	0 (0)
Bleeding complication	
None	55 (95)
Type 1	3 (5.2)
Type 2	0 (0)
Type 3/4	0 (0)
Vascular complication	
None	54 (93)
Minor vascular complication	4 (6.9)
Major vascular complication	0 (0)
Acute kidney injury	
None	51 (88)
Stage 1	6 (10)
Stage 2	0 (0)
Stage 3	1 (1.7)
New stroke	0 (0)
Permanent pacemaker implantation (n = 51)	10 (19.6)
Left ventricular ejection fraction at discharge	
>50%	22 (38)
41%-50%	18 (31)
31%-40%	11 (19)
<31%	7 (12)
Mean aortic valve gradient at discharge, mm Hg	4.3 ± 1.6
Aortic valve area at discharge, cm^2	2.7 ± 0.6
Paravalvular regurgitation	
None	32 (55)
Trace	20 (34)
Mild	6 (10)
Mild to moderate	0 (0)
Moderate	0 (0)
Moderate to severe	0 (0)
Severe	0 (0)

Adam M. JACC Cardiovac Interv. 2023;16:1965-73.

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PURPOSE STUDY

TABLE 2 Computed Tomography Scan Assessment

	Overall (N = 256)	OL-THV (n = 168, 66%)	JVT (n = 88, 34%)	*P* Value
Annular area, mm^2	510 (431-582)	503 (424-592)	526 (441-569)	0.80
Annular perimeter, mm	81 (74-88)	81 (74-88)	77 (74-81)	0.60
Sinotubular junction diameter, mm	33 (29-38)	33 (29-38)	33 (30-37)	0.70
Sinus of Valsalva diameter, mm	36 (32-40)	35 (32-40)	37 (33-40)	0.11
Left coronary artery height, mm	14.6 (12.0-17.0)	14.8 (11.8-17.8)	14.6 (12.4-16.9)	0.90
Right coronary artery height, mm	17.6 (15.0-20.1)	17.4 (15.0-20.0)	18.0 (15.8-20.9)	0.20
Leaflet calcification				0.60
No calcification	133 (58)	88 (58)	45 (58)	
Mild	66 (29)	42 (28)	24 (31)	
Moderate	30 (23)	22 (14)	8 (10)	

Values are median (Q1-Q3) or n (%).
Abbreviations as in Table 1.

TABLE 3 Procedural Characteristics

	Overall (N = 256)	OL-THV (n = 168, 66%)	JVT (n = 88, 34%)	*P* Value
Device type				–
Self-expanding	186 (73)	98 (58)	88 (100)	
Balloon-expandable	70 (27)	70 (42)	0 (0)	
Perimeter oversizing, %	12 ± 10	14 ± 9	11 ± 5	0.016
Predilation	6 (2.3)	5 (3.0)	1 (1.1)	0.70
Postdilation	16 (6.3)	15 (8.9)	1 (1.1)	0.015
General anesthesia	50 (20)	25 (15)	25 (28)	0.010
Annular rupture	0 (0)	0 (0)	0 (0)	–
Coronary obstruction	0 (0)	0 (0)	0 (0)	–
Contrast, mL	123 (94-170)	110 (88-148)	160 (118-209)	<0.001
Procedural time, min	71 (55-100)	69 (52-104)	78 (60-92)	0.20
Fluoroscopy time, min	14 (11-22)	13 (9-22)	17 (13-22)	0.003
In-hospital stay, d	6 (4, 9)	6 (4, 10)	7 (5, 9)	0.20

Values are n (%), mean ± SD, or median (Q1-Q3).
Abbreviations as in Table 1.

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Poletti E. JACC Cardiovasc Interv. 2024;17:1597-1606.

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Supplemental Table 3. Largest Size of Latest Iteration THVs for the Treatment of Large Annuli.

Valve Type	Largest size available	Area range [mm²] Perimeter range [mm]
ACURATE Neo 2 **[Boston Scientific]**	Prime XL	83 – 91 mm
Evolut R/PRO **[Medtronic]**	34 mm	510 – 730 mm² 81.7 – 94.2 mm
MyVal/Octacor THV **[Meril]**	32 mm	700 – 840 mm²
Navitor Titan **[Abbott]**	35 mm	559 – 707 mm² 79 – 85 mm
Sapien 3/ULTRA **[Edwards Lifesciences]**	29 mm	540 – 680 mm²
JenaValve Trilogy System **[JenaValve Technology]**	27 mm	490 – 570 mm² 78.4 – 90.0 mm

Abbreviations: THV = transcatheter heart valve.

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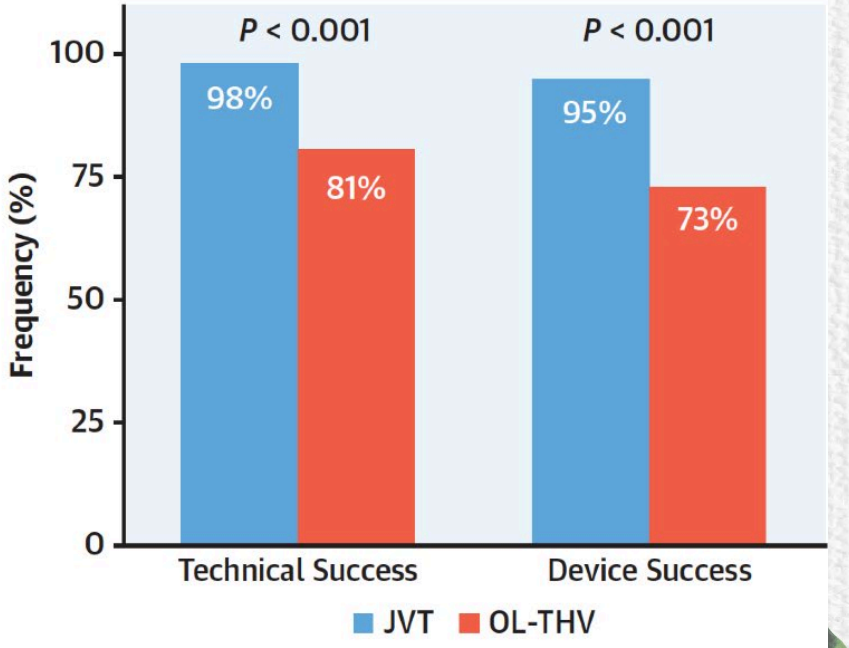
Procedural and Clinical Outcomes With Dedicated THV Versus Off-Label Devices for Aortic Regurgitation, N = 256

JenaValve Trilogy

Off-Label THVs



Periprocedural Complications

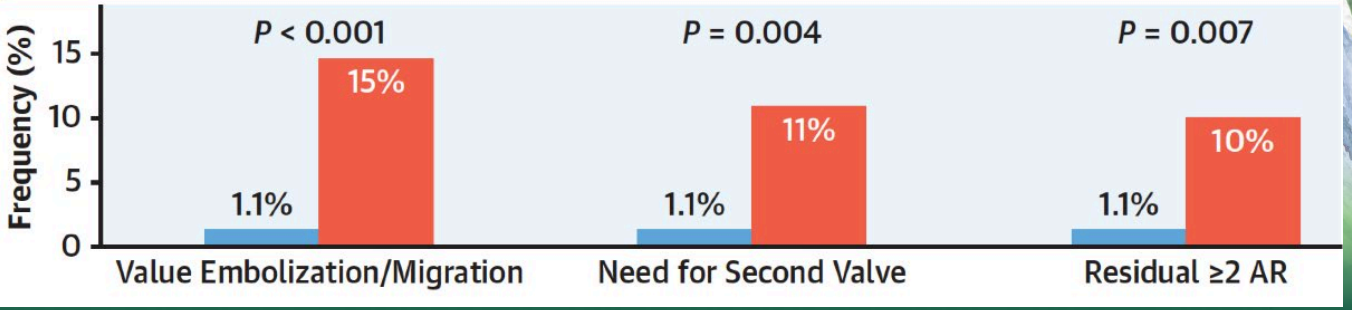


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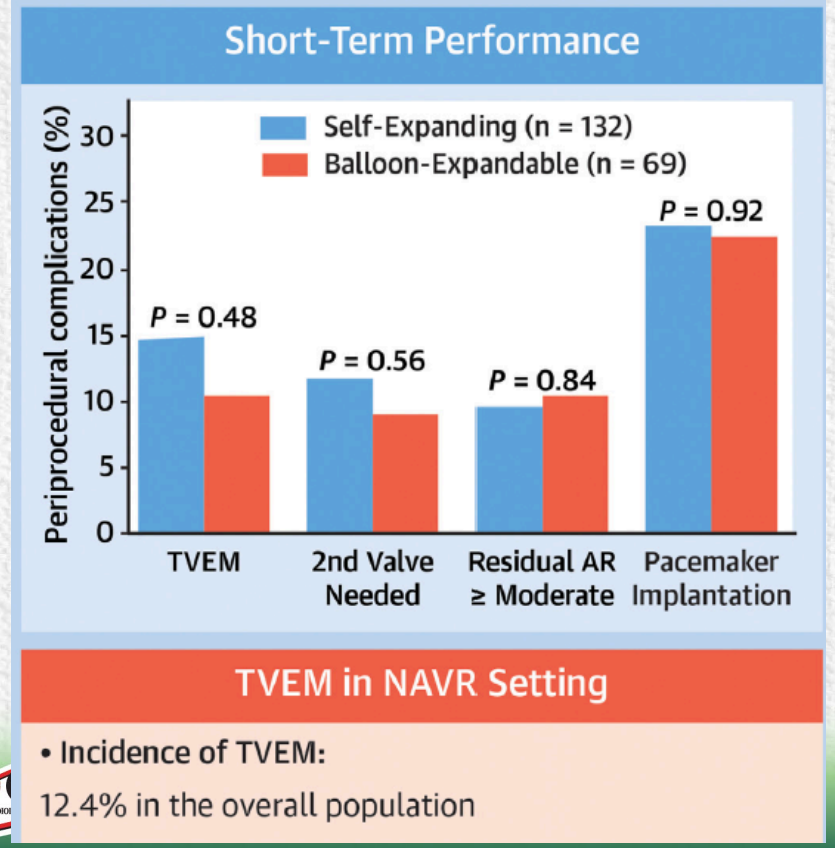
TABLE 2 Baseline Computed Tomographic and Procedural Characteristics

	Overall (N = 201)	Self-Expanding (n = 132, 66%)	Balloon Expandable (n = 69, 34%)	*P* Value
Aortic annular area, mm^2	502 (427-591)	472 (414-531)	602 (486-700)	<0.001
Annular perimeter, mm	81 (74-88)	78 (74-83)	88 (80-94)	<0.001



upplemental Table 2. Distribution of valve types and sizes utilized in the study opulation.

Valve Type	Size	Number (n)
Abbott Navitor	27 mm	1
	29 mm	1
Abbott Portico	25 mm	3
	27 mm	3
	29 mm	2
Boston Scientific Acurate Neo	Size M	5
	Size L	13
Boston Scientific Acurate Neo 2	Size S	1
	Size M	3
	Size L	3
Edwards Sapien S3	23 mm	4
	26 mm	4
	29 mm	13
Edwards Sapien Ultra	23 mm	3
	26 mm	5
Jena Valve	23 mm	1
	25 mm	3
	27 mm	17
Medtronic Corevalve Evolut R	23 mm	2
	26 mm	2
	29 mm	14
	34 mm	50
Medtronic Corevalve Evolut Pro/Pro+	23 mm	1
	26 mm	2
	29 mm	5
Meril Life Myval	23 mm	1
	26 mm	1
	27.5 mm	1
	29 mm	6
	30.5 mm	6
	32 mm	25

Poletti E. JACC Cardiovasc Interv. 2023;16:1978-85.

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My recommendations

- **The measurement used for aortic stenosis are not valid**
- Oversize 25-30% (no risk of rupture)
- High-rate pacemaker during implantation
- Although I prefer self-expanding, most AR must be treated with balloon-expandable
- With EVOLUT FX 34 mm (maximum perimeter 78 mm)
- With NAVITOR 35 mm (I have no experience, maybe maximum perimeter 86 mm?)
- SAPIEN better than MYVAL in horizontal aorta and equal measurement

TAVI in pure AR
Skiing out of bounds

DO NOT VALID THE RECOMMENDATION MEASUREMENTS FOR AORTIC STENOSIS

Navitor™ TAVI System

PRODUCT SPECIFICATION

SIZING[1]	23			35 mm
Annulus Use Range Diameter (mm)	19–21		25–27	27-30
Annulus Area (mm^2)	277–346		479–573	559-707
Annulus Perimeter (mm)				85-95

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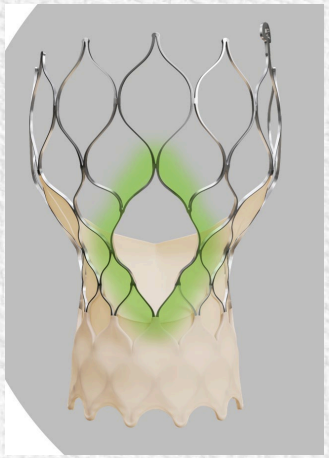
MY NEW MEASUREMENTS FOR PURE AORTIC REGURGITATION

25	78,5
27	84,8
29	91,1
35	110



26 (25,5)	80
29 (28)	87
34 (31)	97

26	530
29	660

27,5	594
30,5	730
32	804-855
35	960

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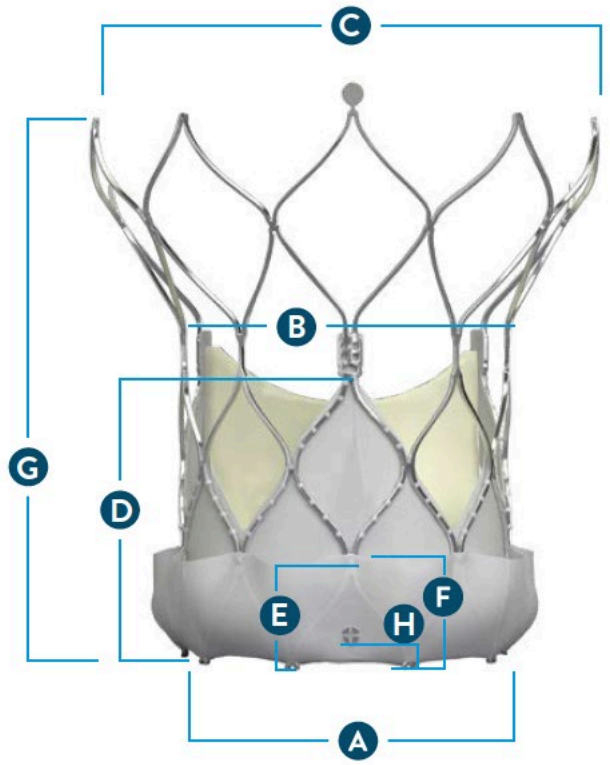

SIZING[1]	35 mm
Annulus Use Range Diameter (mm)	27-30
Annulus Area (mm^2)	559-707
Annulus Perimeter (mm)	85-95
Ascending Aorta Diameter (mm)	27-44
Minimum Vessel Diameter (mm)	≥ 5.5
Implant Target Depth Below Annulus (mm)	3
NAVITOR™ VISION* VALVE[1]	
A Valve Inflow Diameter** (mm)	35
B Valve Outflow Diameter** (mm)	35
C Aortic Stent Diameter** (mm)	48
D Commissure Height** (mm)	27
E Half Cell Height** (mm)	9
F Active Sealing Cuff Height**† (mm)	11
G Stent Height** (mm)	47
H Marker Height (mm)	3

110 mm
960 mm^2

- **Could the implant be easier than Evolut FX+ 34 mm?**
- **Can it compete with ballon-expandable valves in large annulus?**
- **Possibility of coronary artery sequestration in normal sinus?**

TAVI in pure AR
Skiing out of bounds

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- **With NAVITOR 35 mm (I have no experience, maybe maximum perimeter 86 mm?)**
- SAPIEN better than MYVAL in horizontal aorta and equal measurement

TAVI in pure AR
Skiing out of bounds

FOR THOSE WHO PREFER SELF-EXPANDING

Prior assessment: Annulus, Ca^{++}, size and angulation ascending aorta (guía Lunderquist)

Severa AR

- **AR with mild Ca^{++} in leaflet/annular** → **Size equal to AS (when it doubt choose big)**
  Considerer pacemaker
- **Pure AR** →
  - **Clearly oversize (25-30%)**
  - **Maximum perimeter with Evolut 78 mm, ¿with Navitor 85-86 mm?**
  - **Be careful with horizontal aorta**
  - **Mandatory pacemaker and high rates**
  - **Push the guide before releasing**
  - **Just before release, pull the guide and push gently the valve (test)**

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- Female 59 y
- Chronic subdural hematoma in 2017
- MSI monoparesia with ischemic lesions
- Possible myeloid artery disease
- IC NYHA III
- ECHO: Pure AR severe. Dilated LV with LVEF 48%.
- EuroSCORE log: 6,98%

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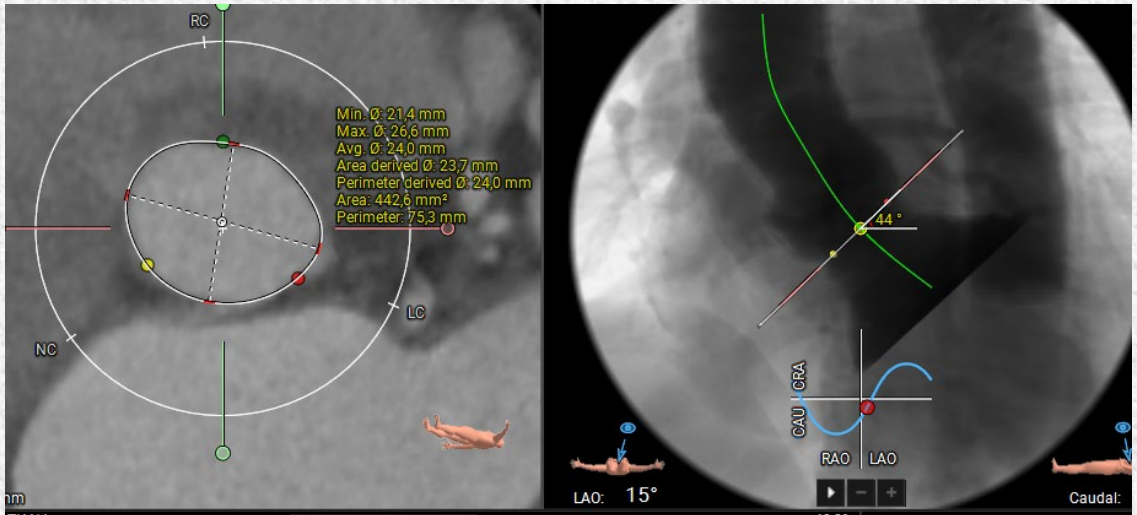

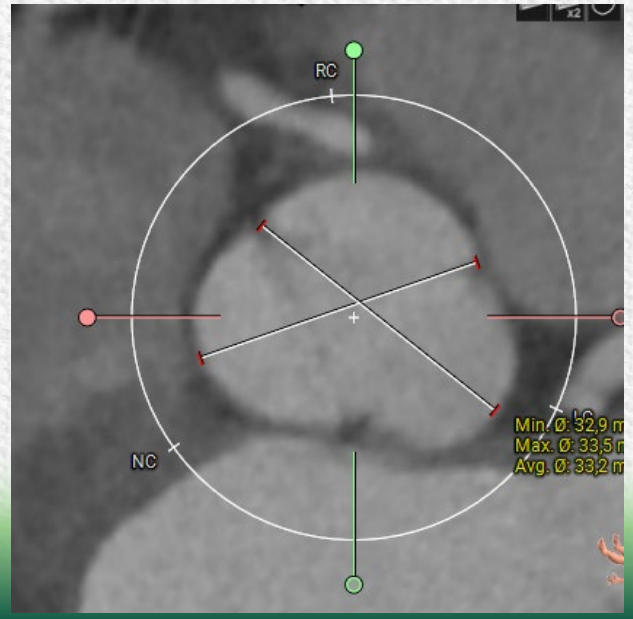

ANNULUS
Perimeter 75,3 mm (24 mm)
Area 443 mm² (23,7 mm)
TSVI 73,8 mm
Senos 33-34 mm
Angulación 44º

PROTHESIS
Annulus + 25%
Perimeter 94 mm

Evolut FX 34 mm

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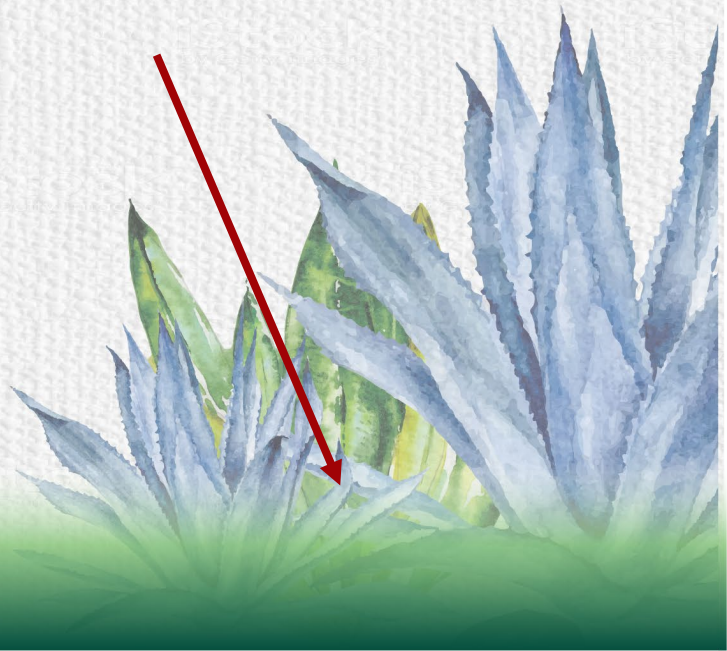

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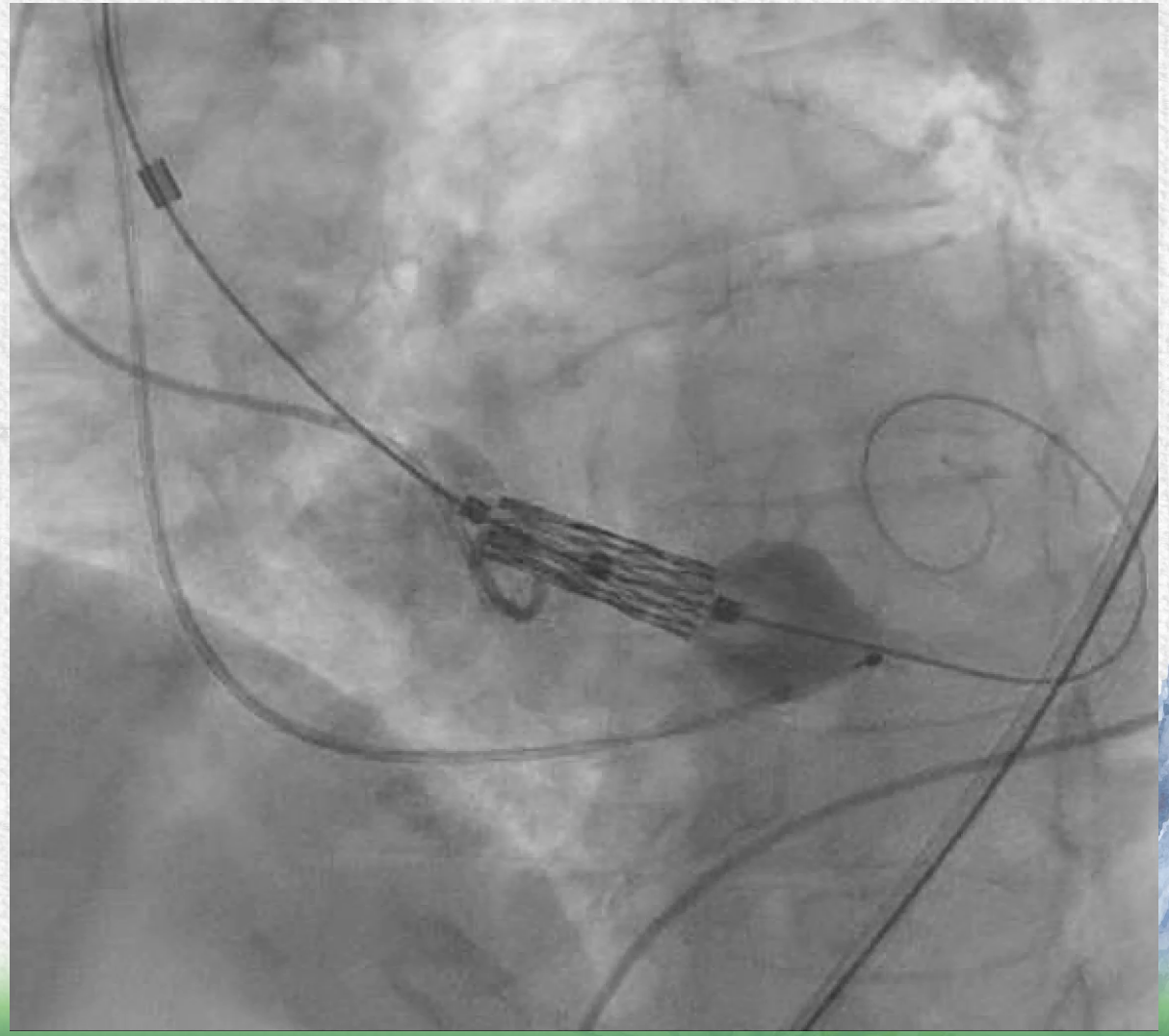

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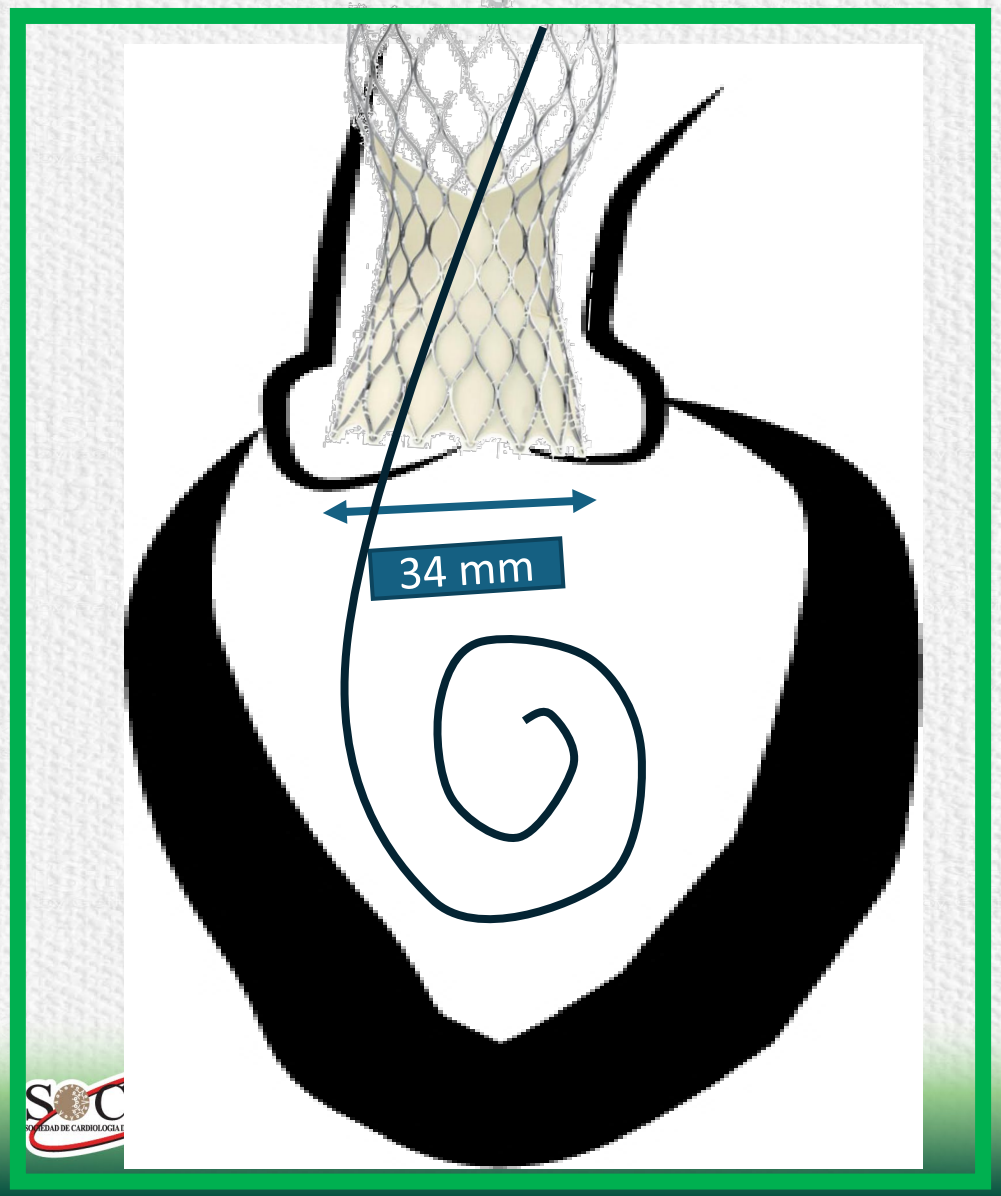

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Skiing out of bounds