Tratamiento intervencionista de la Insuficiencia Aórtica Pura: *¿En qué punto estamos?*

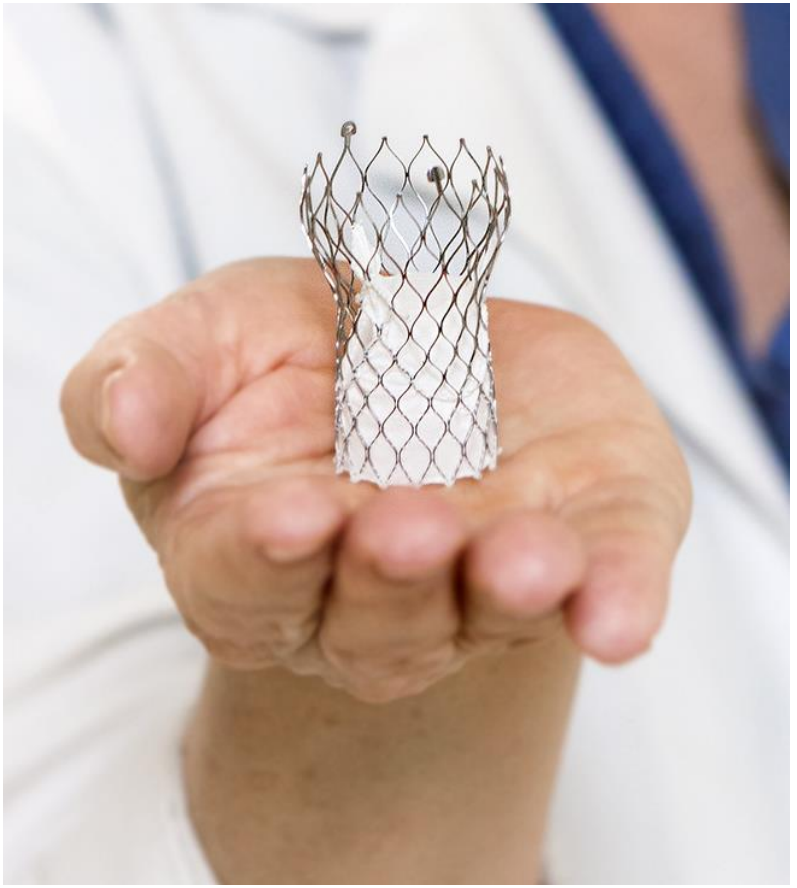
Juan Pablo Sánchez Luna
Cardiología Clínica e Intervencionista
Intervencionismo coronario y estructural

4ta Jornada SOPHIE de la Sociedad Peruana de Hemodinámica e Intervencionismo Endovascular
Lima, Peru a 25 de Octubre del 2024

INTRODUCCIÓN

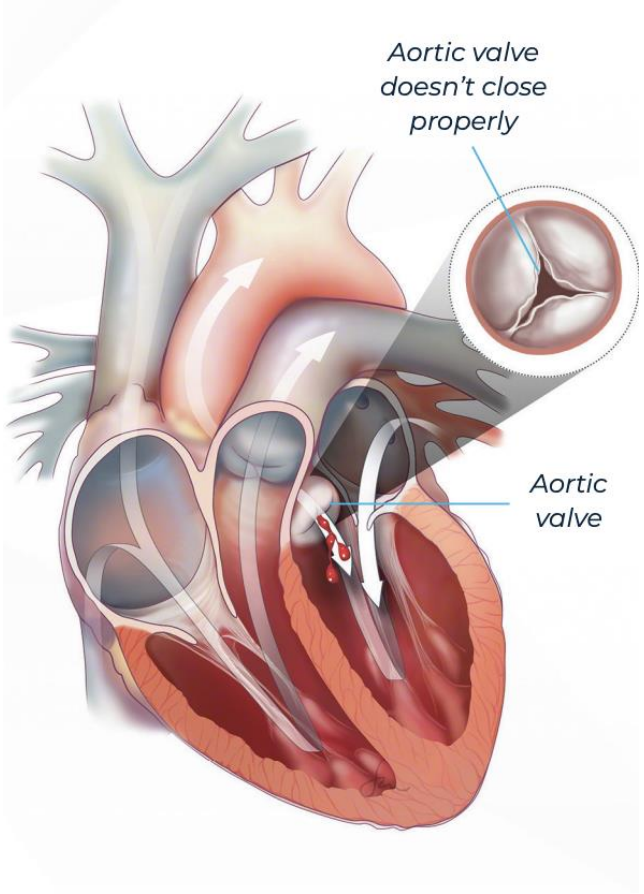
- El reemplazo de válvula aórtica transcatéter (TAVI) es un procedimiento bien establecido para el tratamiento de la estenosis aórtica severa sintomática, que ha pasado de ser exclusivamente para pacientes inoperables y de alto riesgo hasta considerarse como una práctica clínica habitual para poblaciones de intermedio y bajo riesgo.

- Este cambio está respaldado por una creciente experiencia global, lo que ha llevado a su utilización en varios escenarios *off label*, como válvulas bicúspides, Valve-in-Valve, Valve-in-Ring, Valve-in-MAC e insuficiencia aórtica no calcificada.



INSUFICIENCIA AÓRTICA

- Reflujo de sangre de la aorta hacía el ventrículo izquierdo en diástole
- Causado por el cierre incompleto de los velos
- Se puede acompañar de anormalidades en la raíz aortica o de los velos
- Puede ser de inicio agudo o crónico
- Incidencia aumenta con la edad (pico: 4ta-6ta década de vida)
- Más común en hombres que en mujeres
- La prevalencia 4.9% - Severa <1% (@ Framingham)



PRONÓSTICO

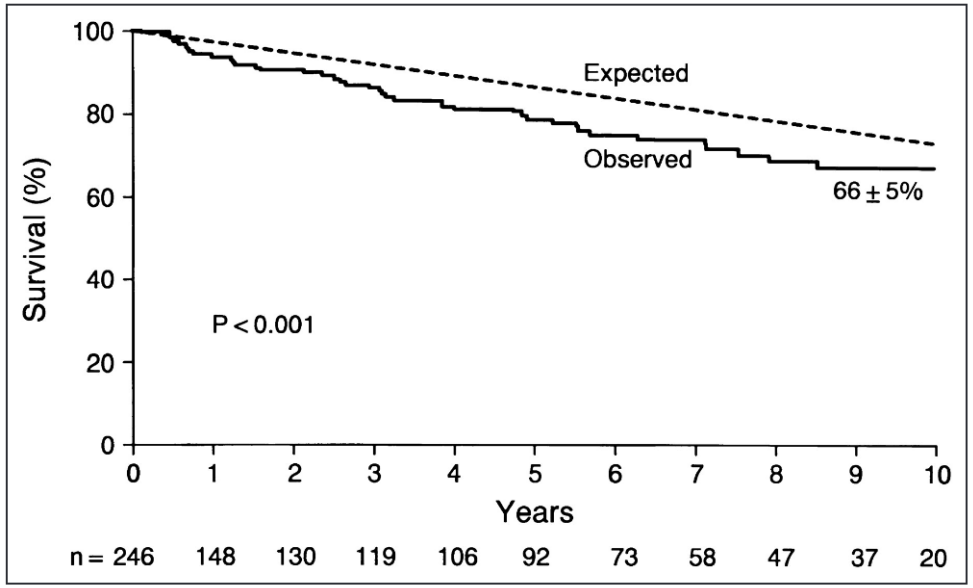
Circulation
Volume 99, Issue 14, 13 April 1999; Pages 1851-1857
https://doi.org/10.1161/01.CIR.99.14.1851

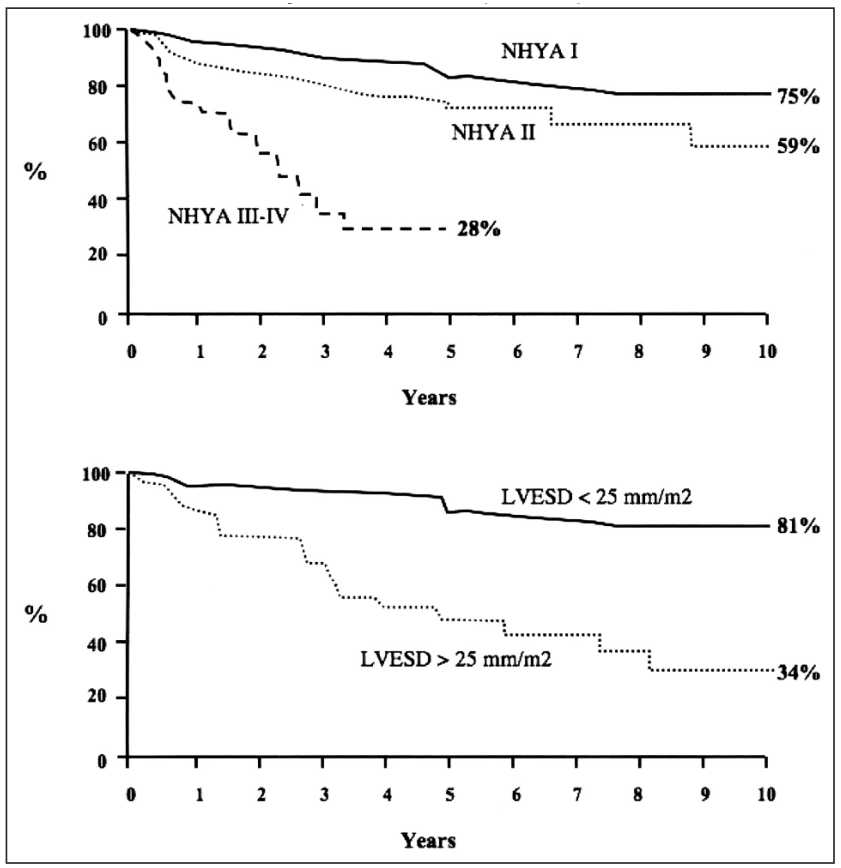
CLINICAL INVESTIGATION AND REPORTS

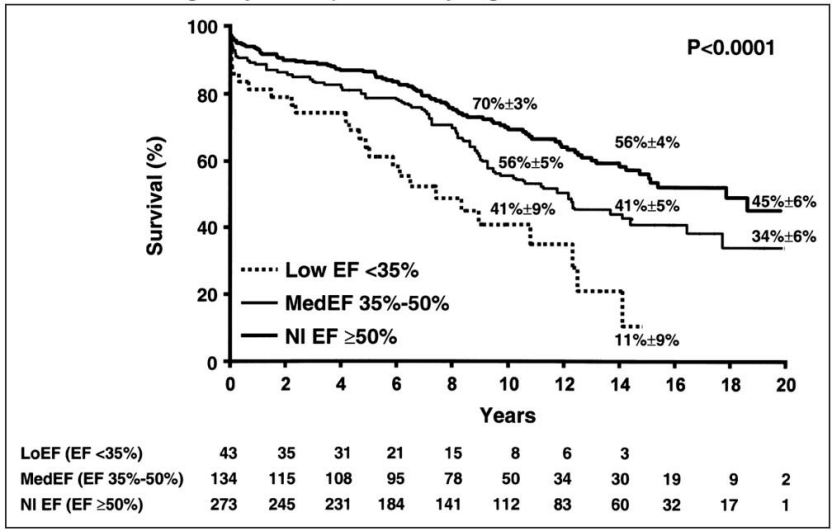
Mortality and Morbidity of Aortic Regurgitation in Clinical Practice

A Long-Term Follow-Up Study

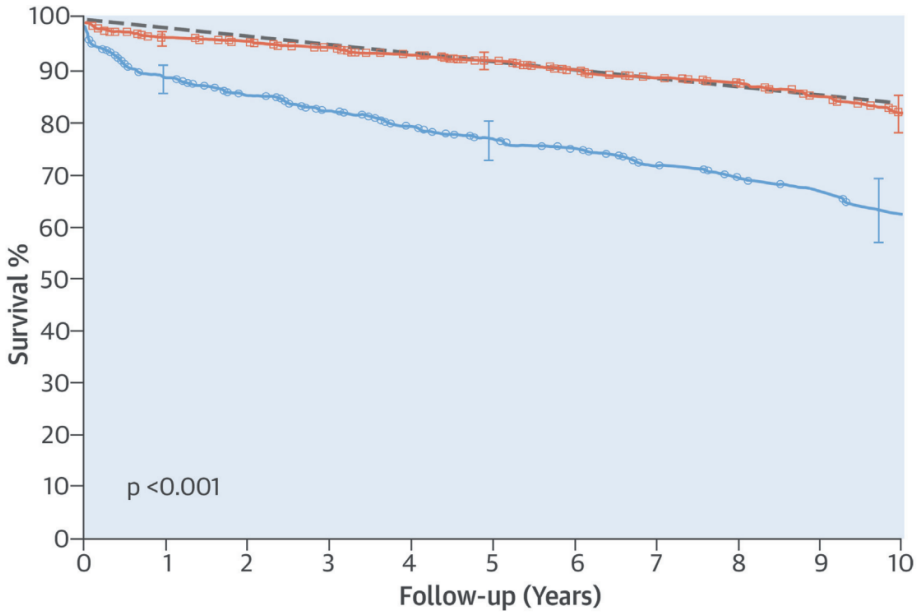
Karl S. Dujardin, Maurice Enriquez-Sarano, Hartzell V. Schaff, Kent R. Bailey, James B. Seward, and A. Jamil Tajik







CENTRAL ILLUSTRATION Long-Term Survival



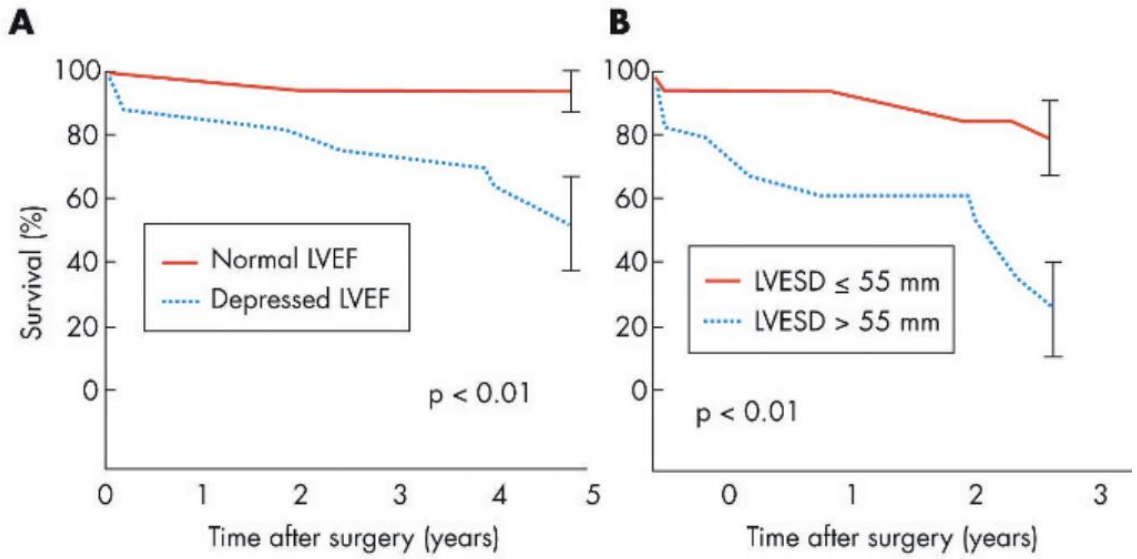
Number at Risk

AV Surgery During Follow-up						
No	484	414	359	234	122	44
Yes	933	821	821	598	259	171

AV Surgery During Follow-up
No AV Surgery During Follow-up
Normal Age-Gender Matched U.S. Population

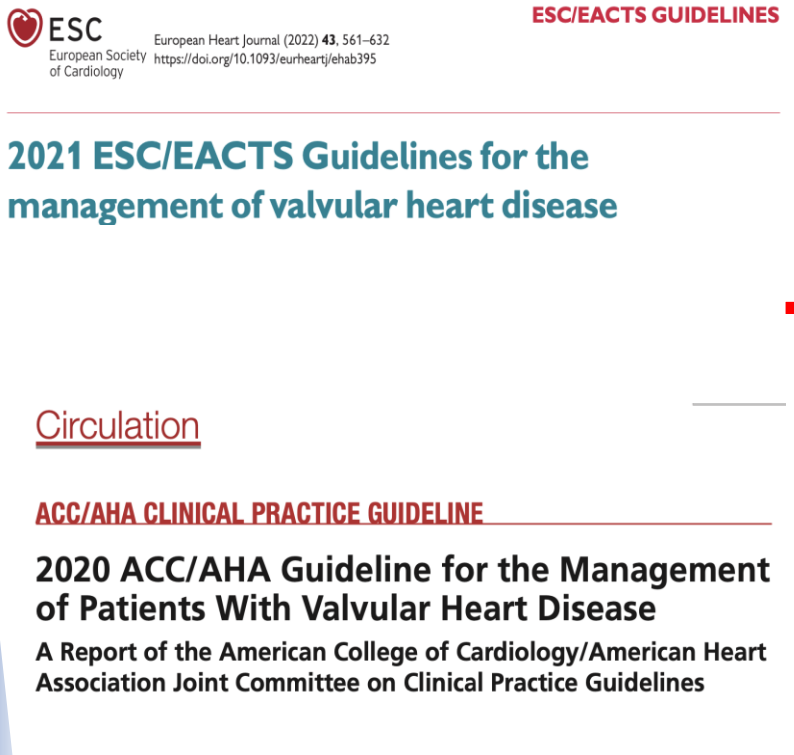
Mentias, A. et al. J Am Coll Cardiol. 2016;68(20):2144–53.

Mentias A, et al. Long-Term Outcomes in Patients With Aortic Regurgitation and Preserved Left Ventricular Ejection Fraction. J Am Coll Cardiol. 2016;68(20):2144–53.



Maurer G. Aortic regurgitation *Heart* 2006;**92:**994-1000.

RECOMENDACIONES



Indication for intervention in severe aortic regurgitation	ESC/EACTS	ACC/AHA
Symptomatic patients regardeless of left ventricle function	Indication: I B	Indication: I B
Assymptomatic patients with left ventricle dilatation or left ventricle dysfunction	Resting LVEF ≤ 50%	LVEF ≤ 55%
	Indication: I B	Indication: I B
	LVESD > 50 mm or LVESD > 25 mm/m²	LVESD > 50 mm or LVESD > 25 mm/m²
	Indication: I B	Indication: IIa C
Asymptomatic patients with left ventricle dilatation or dysfunction if surgery is at low risk	LVEF ≤ 55 %	Progressive decline on at least 3 serial studies with LVEF 55 – 60%
	Indication: IIb C	Indication: IIb C
	LVESD > 20 mm/m²	LVEDD > 65 mm
	Indication: IIb C	Indication: IIb B
Symptomatic and asymptomatic patients with severe aortic regurgitation undergoind CABG or surgery of the ascending aorta or of another valve	Indication: I C	Indication: I C

¿TAVI EN INSUFICIENCIA AÓRTICA?

- Muchos pacientes se consideran inoperables por su edad avanzada o comorbilidades, por lo que las opciones percutáneas están ganando interés.

- Debido a la experiencia y excelentes resultados de la TAVI en la EA, está emergiendo como una solución segura y eficaz para pacientes de alto riesgo o inoperables con IAO.


EDITORIAL COMMENT

Progressing Forward in Transcatheter Aortic Valve Replacement for Pure Aortic Regurgitation*

Amit N. Vora, MD, MPH, Jayakumar Sreenivasan, MD, MSc, John K. Forrest, MD

Alec

INSUFICIENCIA AÓRTICA vs ESTENOSIS AÓRTICA

Resultado de la incompetencia o de degeneración de los velos, de dilatación de la raíz aórtica con crecimiento del anillo aórtico o ambas.

Es el resultado de calcificación progresiva del anillo aórtico y de los velos.

DIFERENCIAS ANATÓMICAS Y FISIOPATOLÓGICAS

ESTENOSIS AÓRTICA

ANATÓMICAS

- Anillo aórtico: Tamaño “estándar”
- Raíz aórtica: No dilatada
- Ventrículo izquierdo: Hipertrófico

FISIOPATOLÓGICAS

- Volumen latido: Normal-Bajo

INSUFICIENCIA AÓRTICA

ANATÓMICAS

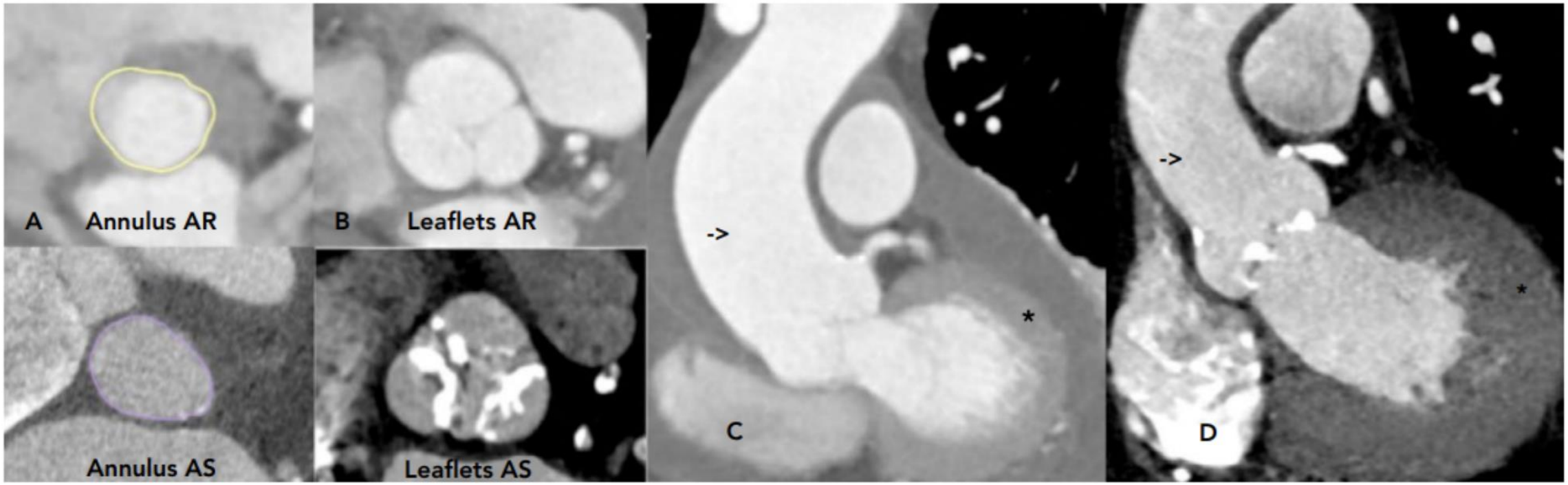
- Anillo aórtico: Grande
- Raíz aórtica: Dilatada
- Ventrículo izquierdo: Dilatado

FISIOPATOLÓGICAS

- Volumen latido: Aumentado

Tagliari AP et al. Transcatheter Aortic Valve Implantation for Pure Native Aortic Regurgitation: The Last Frontier. J Clin Med. 2022 Sep 1;11(17):5181

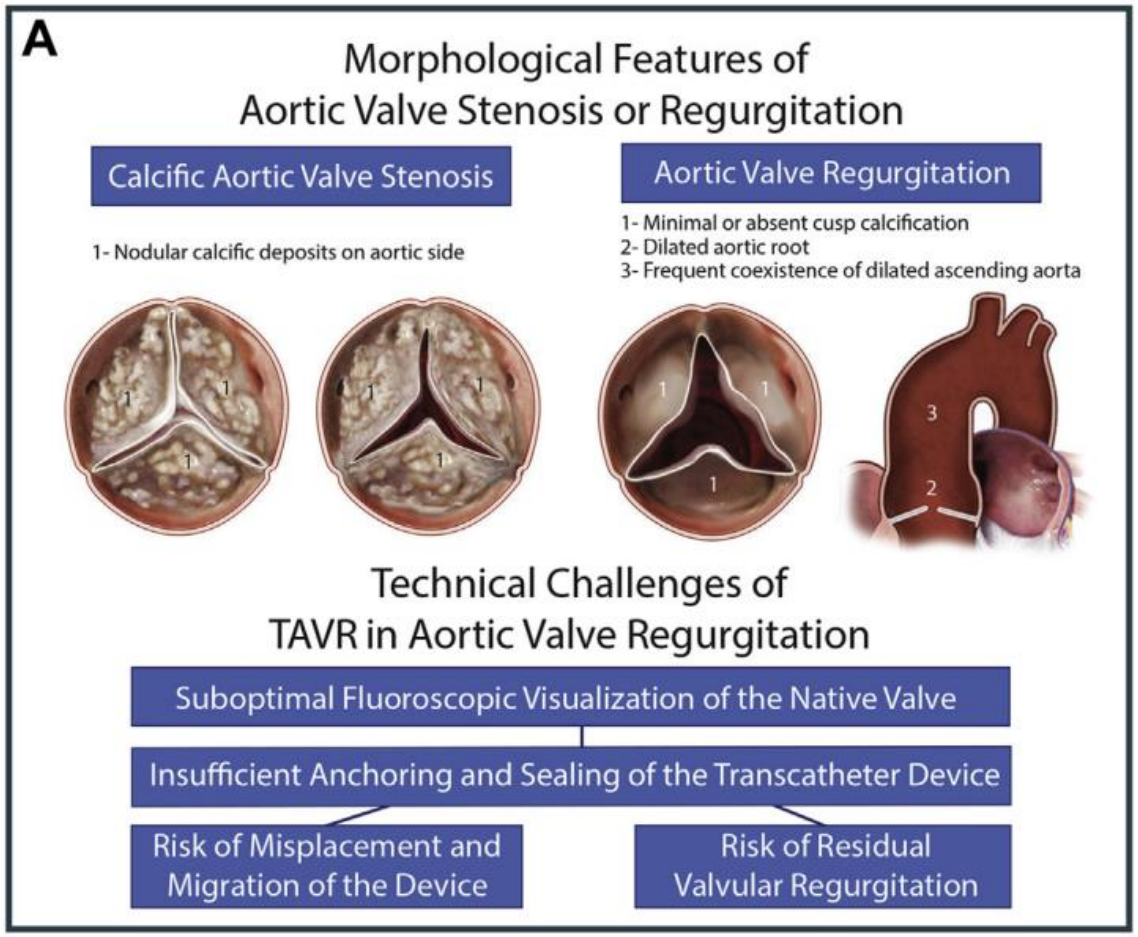
DIFERENCIAS ANATÓMICAS Y FISIOPATOLÓGICAS



Arias E et al. TAVI for Pure Native Aortic Regurgitation: Are We There Yet? Interv Cardiol. 2019 Feb;14(1):26-30.

DIFERENCIAS ANATÓMICAS Y FISIOPATOLÓGICAS:

RETOS



Key Differences	TAVI for Aortic Stenosis	TAVI for Pure Severe AR	Technical Challenges for TAVI in Pure Severe AR
Leaflets	Calcified	Non-calcified	Inadequate anchoring
Aortic root	Non-dilated	Dilated	Limited ability to oversize current devices
Stroke volume	Low to normal	High	Less precise positioning

USO COMPASIVO

TAVI for Pure Aortic Valve Insufficiency in a Patient With a Left Ventricular Assist Device

Giuseppe D'Ancona, MD, PhD,
Miralem Pasic, MD, PhD, Semih Buz, MD,
Thorsten Drews, MD, Stephan Dreysse, MD,
Roland Hetzer, MD, PhD, and Axel Unbehaun, MD

Deutsches Herzzentrum Berlin, Berlin, Germany

We report transcatheter aortic valve implantation (TAVI) for pure aortic valve insufficiency in a patient with an otherwise normal aortic valve and a long-term left ventricular assist device (LVAD). An oversized 29-mm Edwards SAPIEN valve (Edwards Lifesciences, Irvine, CA) was implanted in the 21-mm native aortic valve annulus. Despite the complete absence of aortic calcifications, the prosthesis remained stably anchored inside the annulus. The reported experience demonstrates that TAVI is feasible even in patients with pure aortic valve regurgitation and can be a reasonable option in patients with aortic regurgitation after LVAD implantation.

(Ann Thorac Surg 2012;93:e89–91)

D'Ancona G, Pasic M, Buz, S, et al. TAVI for pure aortic valve insufficiency in a patient with a left ventricular assist device. Ann Thorac Surg. 2012;93:e89-e91.

Catheterization and Cardiovascular Interventions 82:E939–E943 (2013)

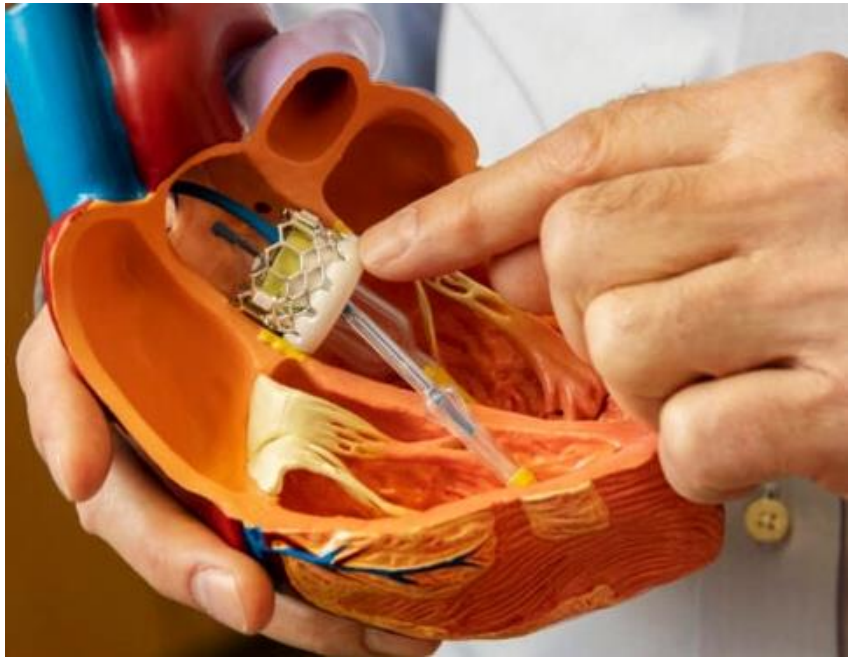
Compassionate Use of the Self-Expandable Medtronic CoreValve Prosthesis for the Treatment of Pure Aortic Regurgitation in a Patient at Prohibitive Risk for Surgical Valve Replacement

H.A. Hildebrandt, MD, R. Erbel, MD, and P. Kahlert,* MD

Transcatheter aortic valve implantation (TAVI) is a viable treatment option for high- and prohibitive-risk patients with severe, calcified pure or predominant aortic valve stenosis, but not for pure aortic valve regurgitation. In fact, the use of TAVI for this indication is even considered unlikely due to the lack of calcium which appears essential for anchoring the stent-valve and prevents dislocation. We report a case of a patient with severe, symptomatic pure aortic regurgitation, and a history of two previous open-heart surgeries who was successfully treated by compassionate use implantation of an oversized Medtronic CoreValve prosthesis as an ultima ratio treatment option.

Hildebrandt, HA et al. Compassionate use of the self-expandable medtronic corevalve prosthesis for the treatment of pure aortic regurgitation in a patient at prohibitive risk for surgical valve replacement. Catheterization and Cardiovascular Interventions (2013), 82(7), E939–E943.

TRATAMIENTO INTERVENCIONISTA



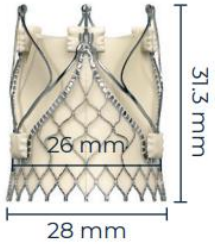
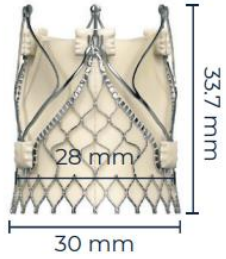
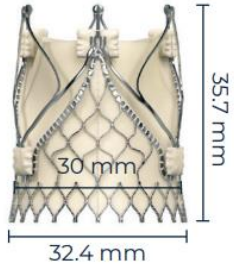
- Dispositivos dedicados
- Dispositivos no dedicados

DISPOSITIVOS DEDICADOS

JENA VALVE (TRILOGY SYSTEM)

JENAVALVE

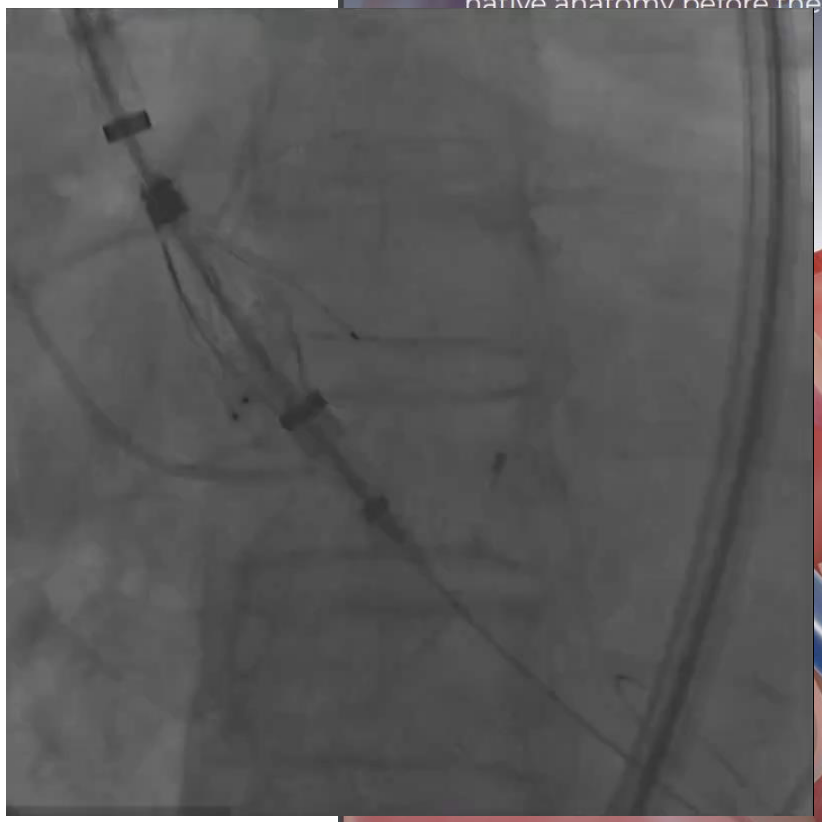
Trilogy Heart Valve Sizing

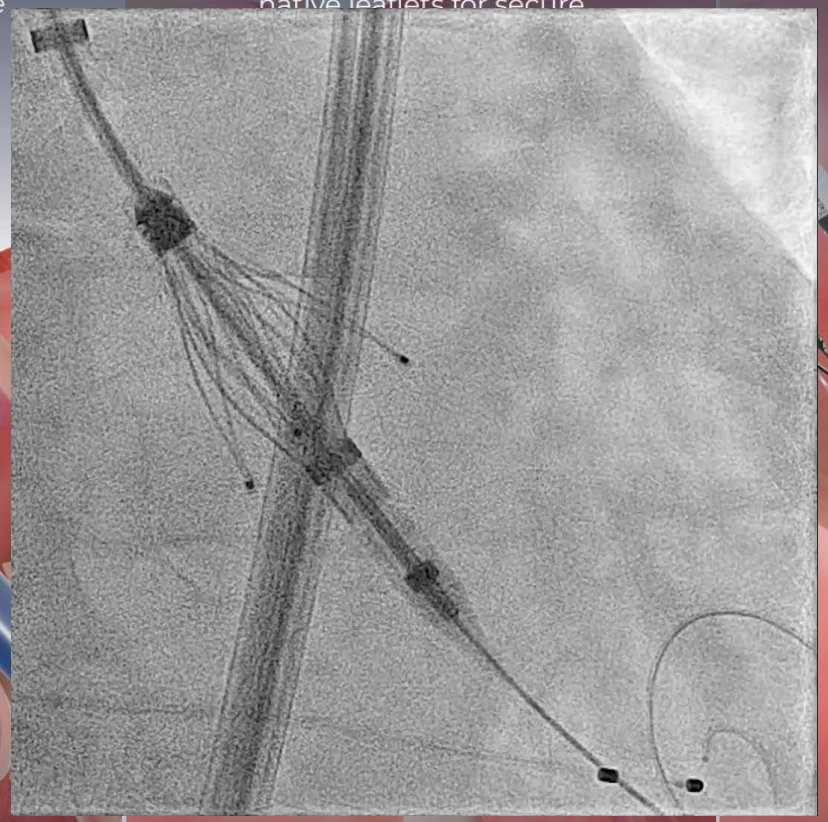
		
Trilogy-THV-S	**Trilogy-THV-M**	**Trilogy-THV-L**
	Annular Perimeter Range	
66 - 74 mm	71 - 79 mm	76 - 85 mm
	Annular Diameter Range	
21 - 23.6 mm	22.6 - 25.2 mm	24.2 - 27 mm

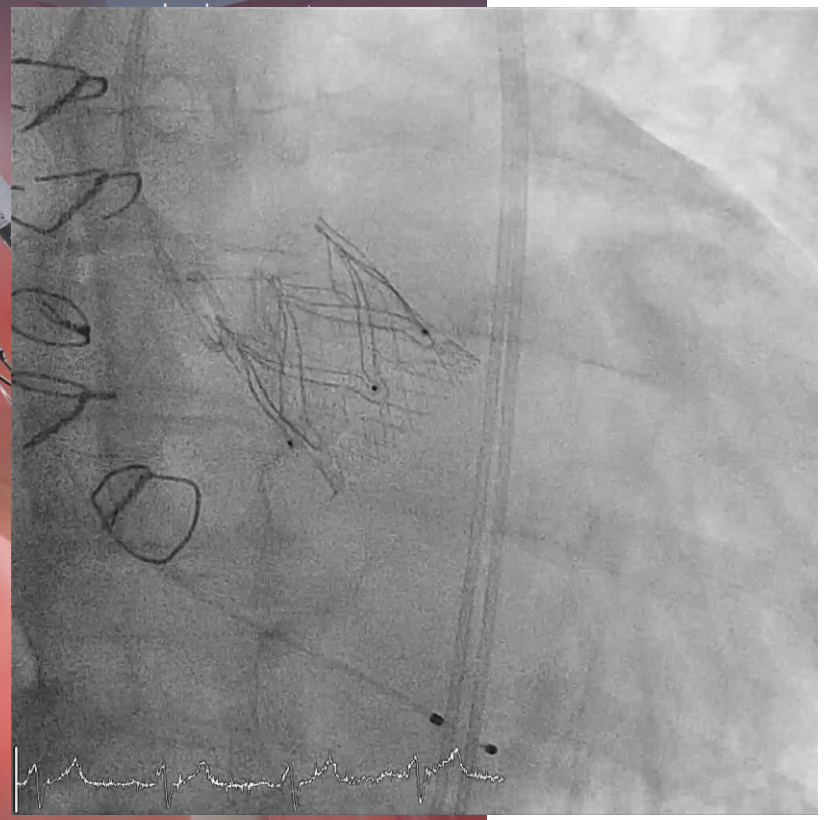
Alignment
Locator technology ensures proper alignment with native anatomy before the

Anchoring
Locators anchor the valve by attaching to native leaflets for secure

Deployment
Commissure-to-commissure alignment







EVIDENCIA

ELSEVIER

European Journal of Cardio-thoracic Surgery 40 (2011) 761–763

EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY

www.elsevier.com/locate/ejcts

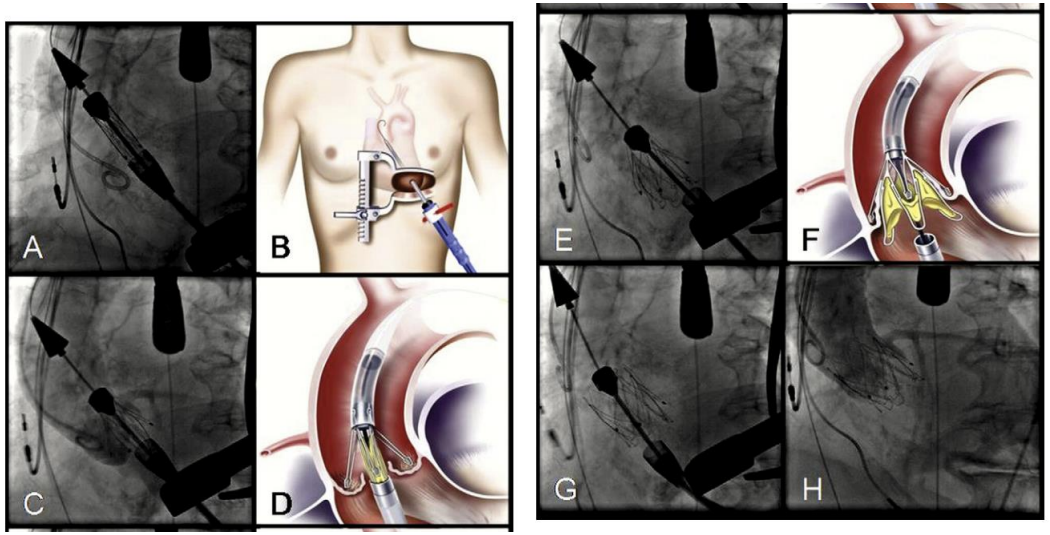
Case report

A new self-expanding transcatheter aortic valve for transapical implantation — first in man implantation of the JenaValve™

Jörg Kempfert [a,*], Ardawan J. Rastan [a], Friedrich-W. Mohr [a], Thomas Walther [b]

[a] Department of Cardiac Surgery, Heartcenter, University of Leipzig, Leipzig, Germany
[b] Department of Cardiac Surgery, Kerckhoff Clinic Bad Nauheim, Bad Nauheim, Germany

Received 23 August 2010; received in revised form 20 December 2010; accepted 21 December 2010; Available online 21 February 2011

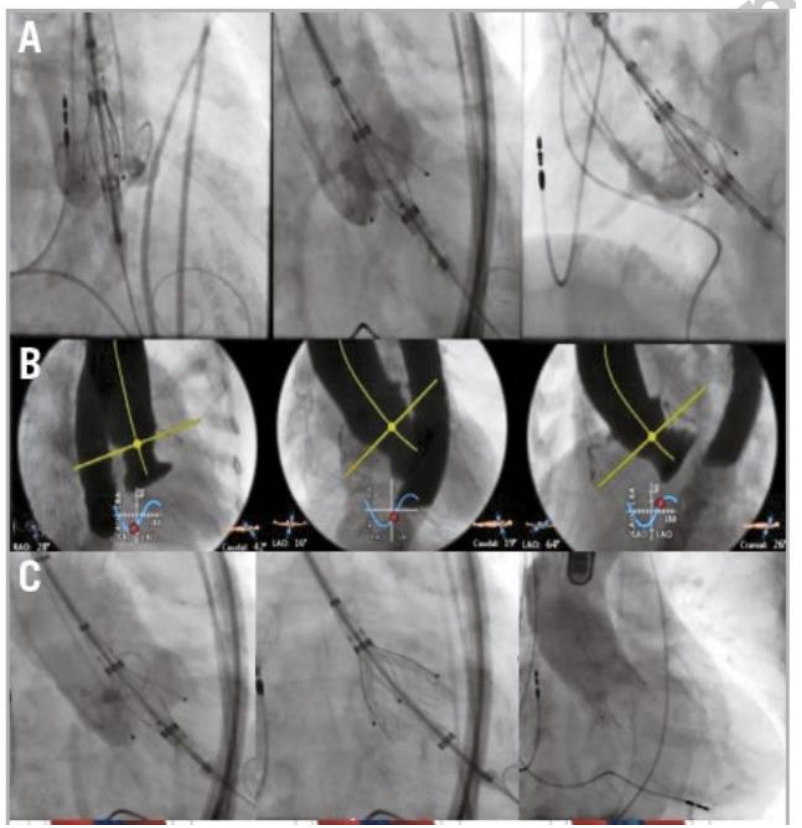


Kempfert J et al. A New Self-expanding transcatheter aortic valve for transapical Implantation – first In Man: Jena Valve. European Journal of Cardio-thoracic Surgery 40 (2011) 761–763

First-in-human implantation of a novel transfemoral self-expanding transcatheter heart valve to treat pure aortic regurgitation

Ulrich Schäfer, MD; Johannes Schirmer, MD; Niklas Schofer, MD; Eva Harmel, MD; Florian Deuschl, MD; Lenard Conradi, MD

University Heart Center, Hamburg, Hamburg, Germany



Schafer U et al. First-in-human implantation of a novel transfemoral self- expanding transcatheter heart valve to treat pure aortic regurgitation. EuroIntervention 2017;13:1297-1300

JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 16, NO. 16, 2023

PUBLISHED BY ELSEVIER

FOCUS ON AORTIC REGURGITATION AND TRANSCATHETER AORTIC VALVE REPLACEMENT

NEW RESEARCH PAPER: STRUCTURAL

Transcatheter Aortic Valve Replacement for Isolated Aortic Regurgitation Using a New Self-Expanding TAVR System

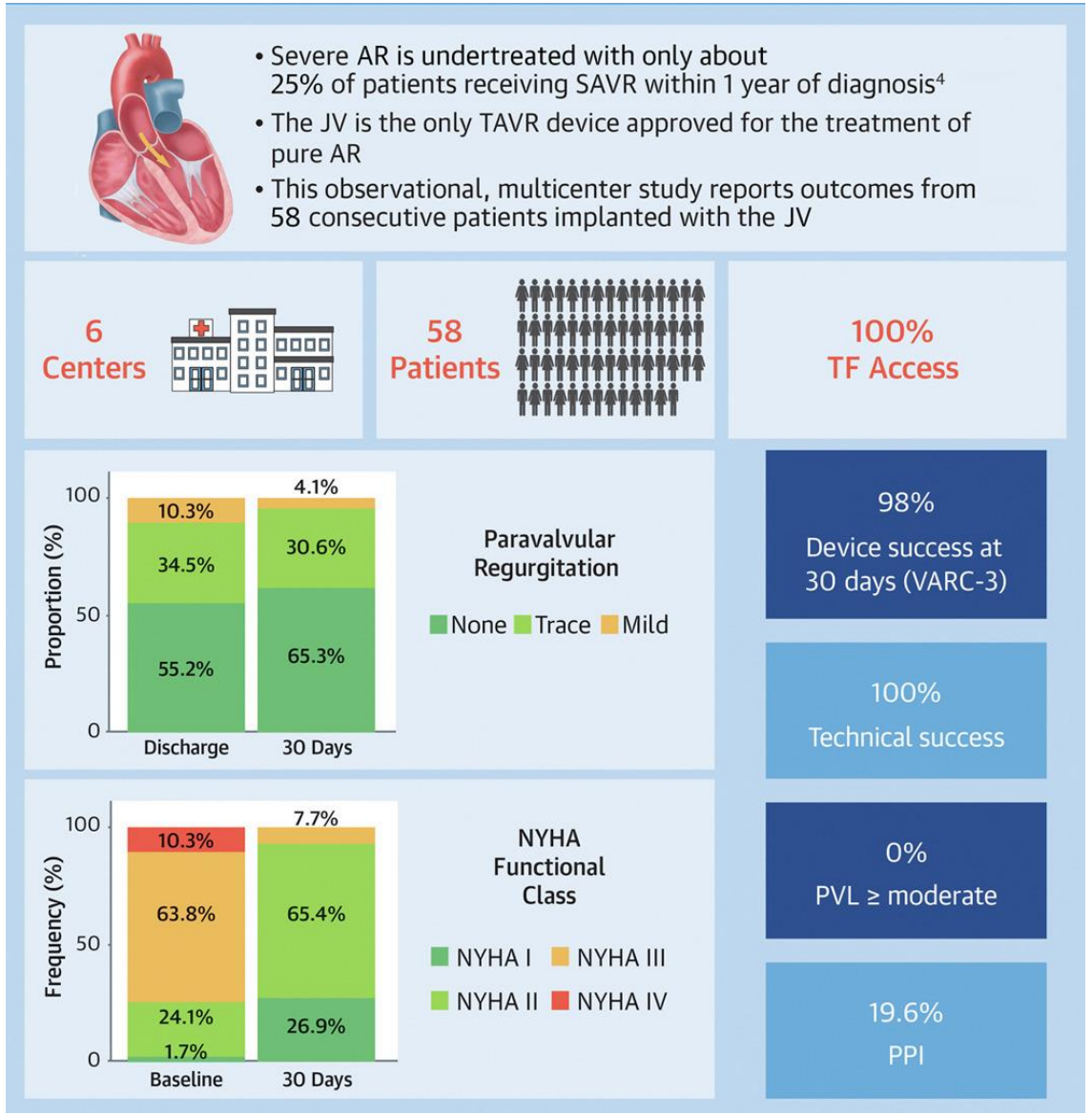
Matti Adam, MD,[a,*] Alexander R. Tamm, MD,[b,*] Hendrik Wienemann, MD,[a] Axel Unbehaun, MD,[c,d] Christoph Klein, MD,[e] Martin Arnold, MD,[f,g] Mohamed Marwan, MD,[f] Hans Theiss, MD,[h,i] Daniel Braun, MD,[h,i] Sabine Bleiziffer, MD,[j] Martin Geyer, MD,[b] Arseniy Goncharov, MD,[k] Elmar Kuhn, MD,[l] Volkmar Falk, MD,[c,d,m] Ralph Stephan von Bardeleben, MD,[b] Stephan Achenbach, MD,[f] Steffen Massberg, MD,[h,i] Stephan Baldus, MD,[a] Hendrik Treede, MD,[n,†] Tanja Katharina Rudolph, MD[k,†]

OBJECTIVES The authors describe the initial commercial experience of the first Conformité Européenne-marked transfemoral transcatheter aortic valve replacement system (JenaValve Trilogy [JV]) for the treatment of patients with AR.

METHODS This multicenter registry included 58 consecutive patients from 6 centers across Germany. Transcatheter aortic valve replacement was performed with the JV system for isolated severe and symptomatic AR. Patient characteristics, primary implantation outcomes, and valve performance up to 30 days were analyzed using Valve Academic Research Consortium 3 definitions.

RESULTS The mean patient age was 76.5 ± 9 years, with a mean Society of Thoracic Surgeons score of 4.2% ± 4.3%. Device success was achieved in 98% of patients. The mean gradient was 4.3 ± 1.6 mm Hg, and no moderate or severe paravalvular regurgitation occurred. No conversion to open heart surgery or valve embolization was reported. There were no major vascular complications or bleeding events. The rate of new permanent pacemaker implantation was 19.6%. At 30 days, 92% of the patients were in NYHA functional class I or II, and the 30-day mortality rate was 1.7%.

CONCLUSIONS Treatment of patients with severe symptomatic AR using the transfemoral JV system is safe and effective. Given its favorable hemodynamic performance and low complication rates, this system may offer a new treatment option for patients with AR not suitable for surgery. (J Am Coll Cardiol Intv 2023;16:1965-1973)



Transcatheter aortic valve implantation in patients with high-risk symptomatic native aortic regurgitation (ALIGN-AR): a prospective, multicentre, single-arm study

Torsten P Vahl, Vinod H Thourani, Raj R Makkar, Nadira Hamid, Omar K Khalique, David Daniels, James M McCabe, Lowell Satler, Mark Russo, Wen Cheng, Isaac George, Gabriel Aldea, Brett Sheridan, Dean Kereiakes, Harsh Golwala, Firas Zahr, Stanley Chetcuti, Pradeep Yadav, Susheel K Kodali, Hendrik Treede, Stephan Baldus, Nicholas Amoroso, Lauren S Ranard, Duane S Pinto, Martin B Leon

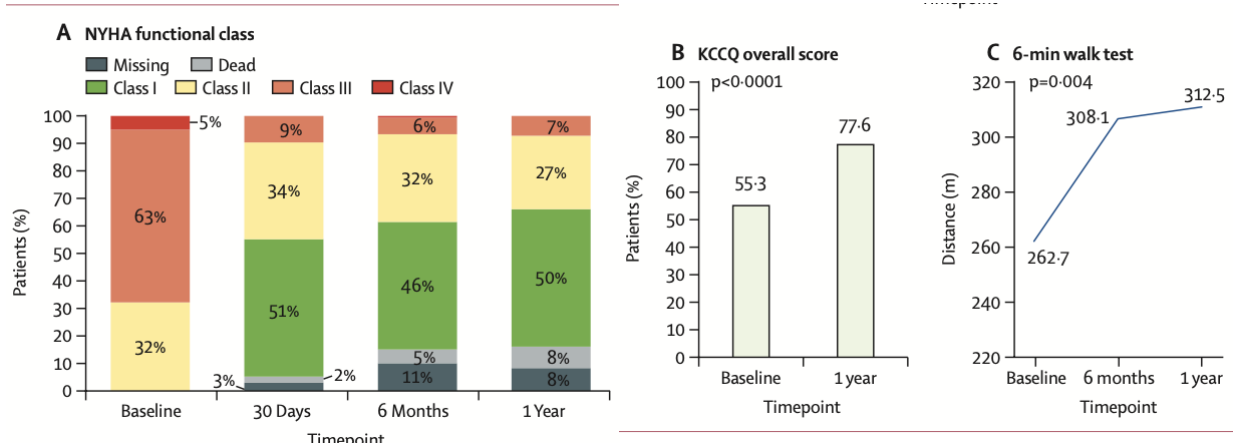
Methods The ALIGN-AR trial is a prospective, multicentre, single-arm study. We recruited symptomatic patients (aged ≥18 years) with moderate-to-severe or severe aortic regurgitation at high risk for mortality and complications after surgical aortic valve replacement at 20 US sites for treatment with the Trilogy transcatheter heart valve. The 30-day composite primary safety endpoint was compared for non-inferiority with a prespecified performance goal of 40·5%. The primary efficacy endpoint was 1-year all-cause mortality compared for non-inferiority with a performance goal of 25%. This trial is registered with ClinicalTrials.gov, NCT 04415047, and is ongoing.

Findings Between June 8, 2018, and Aug 29, 2022, we screened 346 patients. We excluded 166 (48%) patients and enrolled 180 (52%) patients with symptomatic aortic regurgitation deemed high risk by the heart team and independent screening committee assessments. The mean age of the study population was 75·5 years (SD 10·8), and 85 (47%) were female, 95 (53%) were male, and 131 (73%) were White. Technical success was achieved in 171 (95%) patients. At 30 days, four (2%) deaths, two (1%) disabling strokes, and two (1%) non-disabling strokes occurred. Using standard Valve Academic Research Consortium-2 definitions, the primary safety endpoint was achieved, with events occurring in 48 (27% [97·5% CI 19·2–34·0]) patients ($p_{non\text{-}inferiority}$<0·0001), with new pacemaker implantation in 36 (24%) patients. The primary efficacy endpoint was achieved, with mortality in 14 (7·8% [3·3–12·3]) patients at 1 year ($p_{non\text{-}inferiority}$<0·0001).

	Patients (n=180)
Death	4 (2%)
Any stroke	4 (2%)
Disabling stroke	2 (1%)
Non-disabling stroke	2 (1%)
Major or life-threatening bleeding	8 (4%)
Major vascular complication	7 (4%)
Acute kidney injury stage 2 or 3 or dialysis (7 days)	2 (1%)
Surgery or intervention related to the device	5 (3%)
Aortic Endograft and Commercial THV for aortic dissection	1 (<1%)
Surgical aortic valve replacement for Trilogy transcatheter heart valve embolisation	1 (<1%)
Commercial transcatheter heart valve for Trilogy transcatheter heart valve embolisation	1 (<1%)
Trilogy transcatheter heart valve for Trilogy transcatheter heart valve embolisation	2 (1%)
New pacemaker implantation	36/150 (24%)*
Moderate or greater aortic regurgitation	1 (<1%)
Total	48 (27%)

Data are n (%) or n/N (%). *30 patients had a previous pacemaker.

***Table 2*: Primary safety endpoint at 30 days**

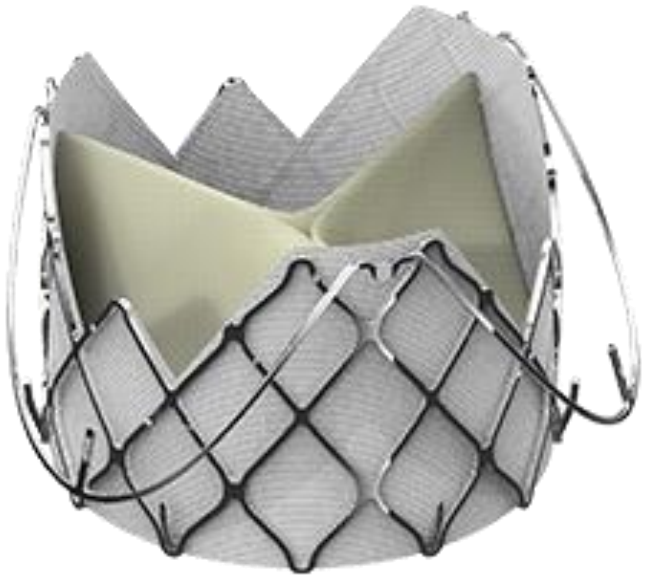


	Baseline (n=180)	30 days (n=172)	6 months (n=154)	1 year (n=141)
Left-ventricular end systolic dimension, mm	39·6 (10·2)	37·4 (10·2)	34·7 (9·4)	34·2 (9·0)
Left-ventricular end systolic dimension index, mm/m²	22·8 (6·5)	21·3 (6·0)	19·0 (5·6)	19·3 (5·2)
Left-ventricular end systolic volume, mL	70·6 (38·9)	67·3 (41·0)	59·0 (39·2)	52·1 (39·8)
Left-ventricular end diastolic volume, mL	144·8 (56·6)	132·6 (83·1)	115·9 (50·3)	109·9 (50·1)
Left-ventricular mass, g	323·7 (123·4)	254·3 (109·0)	235·1 (95·4)	219·5 (101·4)
Left-ventricular mass index, g/m²	172·7 (61·8)	133·8 (48·1)	126·8 (46·9)	117·5 (47·1)
Mean gradient, mm Hg	8·7 (6·6)	3·9 (1·6)	4·3 (2·0)	4·3 (1·8)
Effective orifice area, cm²	..	2·9 (0·6)	2·7 (0·6)	2·8 (0·6)
Effective orifice area index, cm²/m²	..	1·7 (0·4)	1·5 (0·4)	1·6 (0·3)
Left ventricular ejection fraction, %	53·8 (11·4)	49·7(12·6)	51·9 (12·0)	55·0 (11·6)

Data are mean (SD).

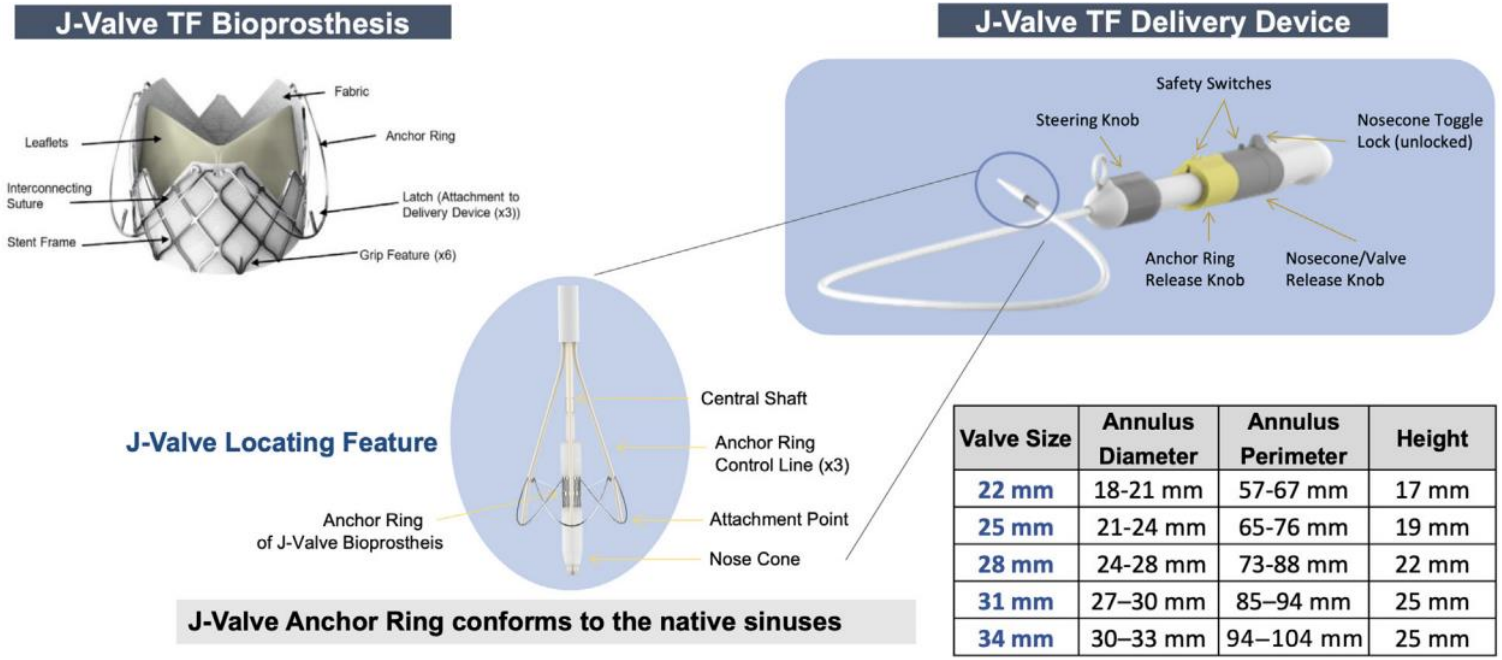
***Table 3*: Left-ventricular dimensions and valve haemodynamic outcomes**

J-VALVE

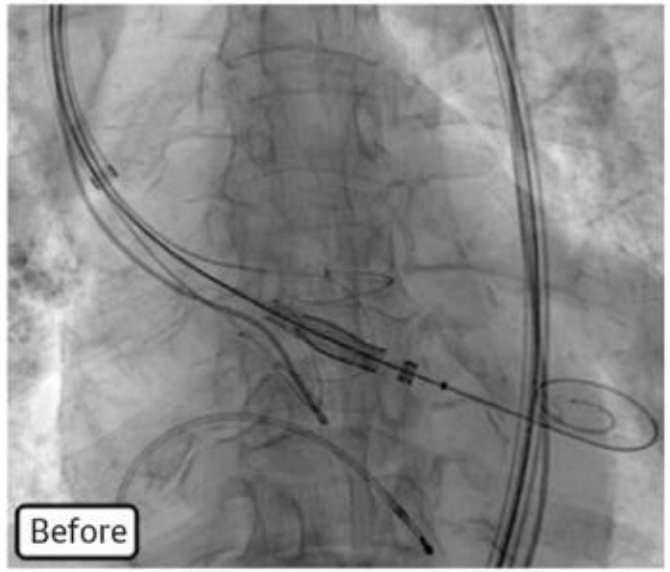


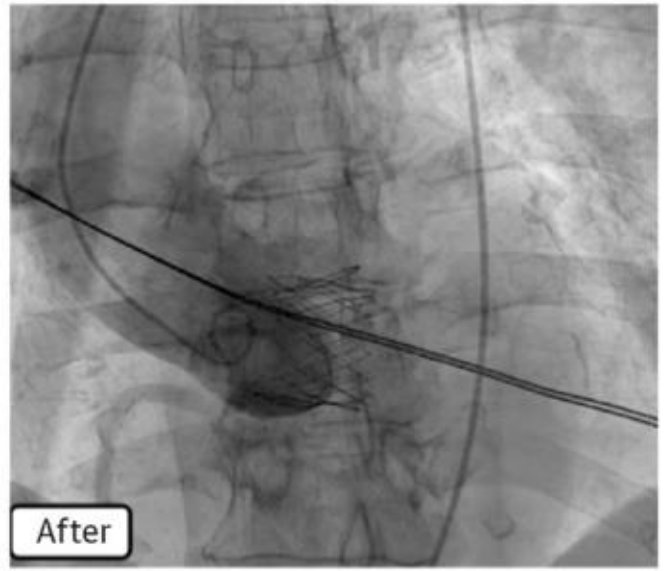
JC Medical
A Genesis MedTech Company

FIGURE 1 Overview of J-Valve TF System and Size Matrix



Valve Size	Annulus Diameter	Annulus Perimeter	Height
22 mm	18-21 mm	57-67 mm	17 mm
25 mm	21-24 mm	65-76 mm	19 mm
28 mm	24-28 mm	73-88 mm	22 mm
31 mm	27–30 mm	85–94 mm	25 mm
34 mm	30–33 mm	94–104 mm	25 mm





EVIDENCIA

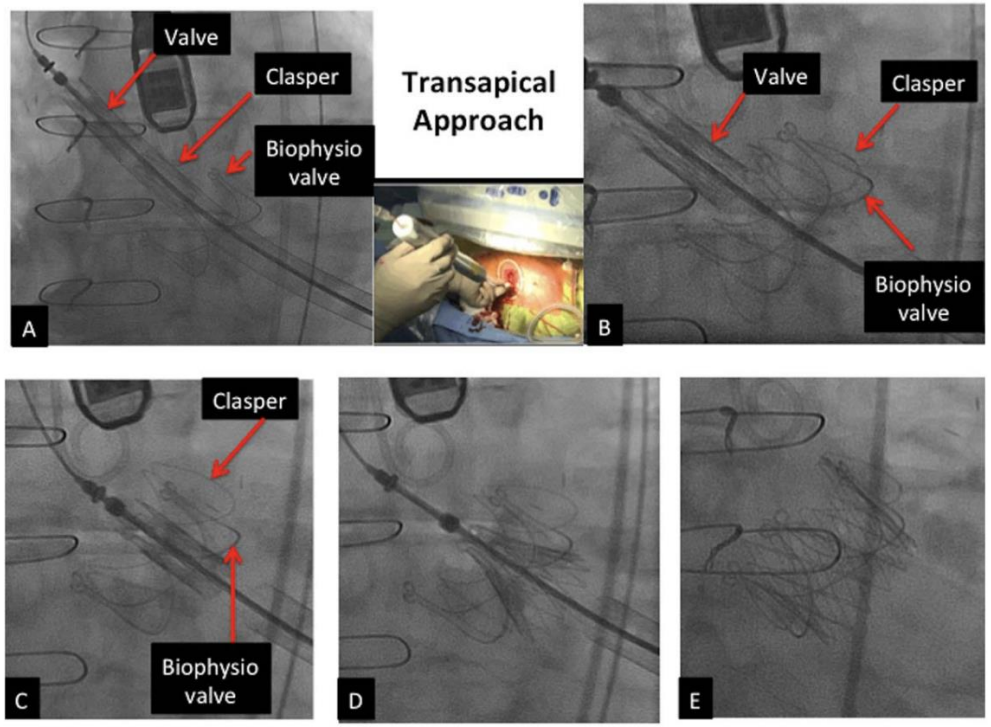
Received: 30 October 2017 | Revised: 4 February 2018 | Accepted: 23 February 2018
DOI: 10.1002/ccd.27604

CASE REPORT

WILEY

The first transapical transcatheter aortic valve-in-valve implantation using the J-valve system into a failed biophysio aortic prosthesis in a patient with high risk of coronary obstruction

Jian Ye, MD[1] | Arthur J. Lee, MD[1] | Philipp Blanke, MD[2] | John Webb, MD[3]



Transapical transcatheter aortic valve replacement with a novel transcatheter aortic valve replacement system in high-risk patients with severe aortic valve diseases

Liming Zhu, MD,[a] Yingqiang Guo, MD,[b] Wei Wang, MD,[c] Huan Liu, MD,[a] Ye Yang, MD,[a] Lai Wei, MD,[a] and Chunsheng Wang, MD[a]

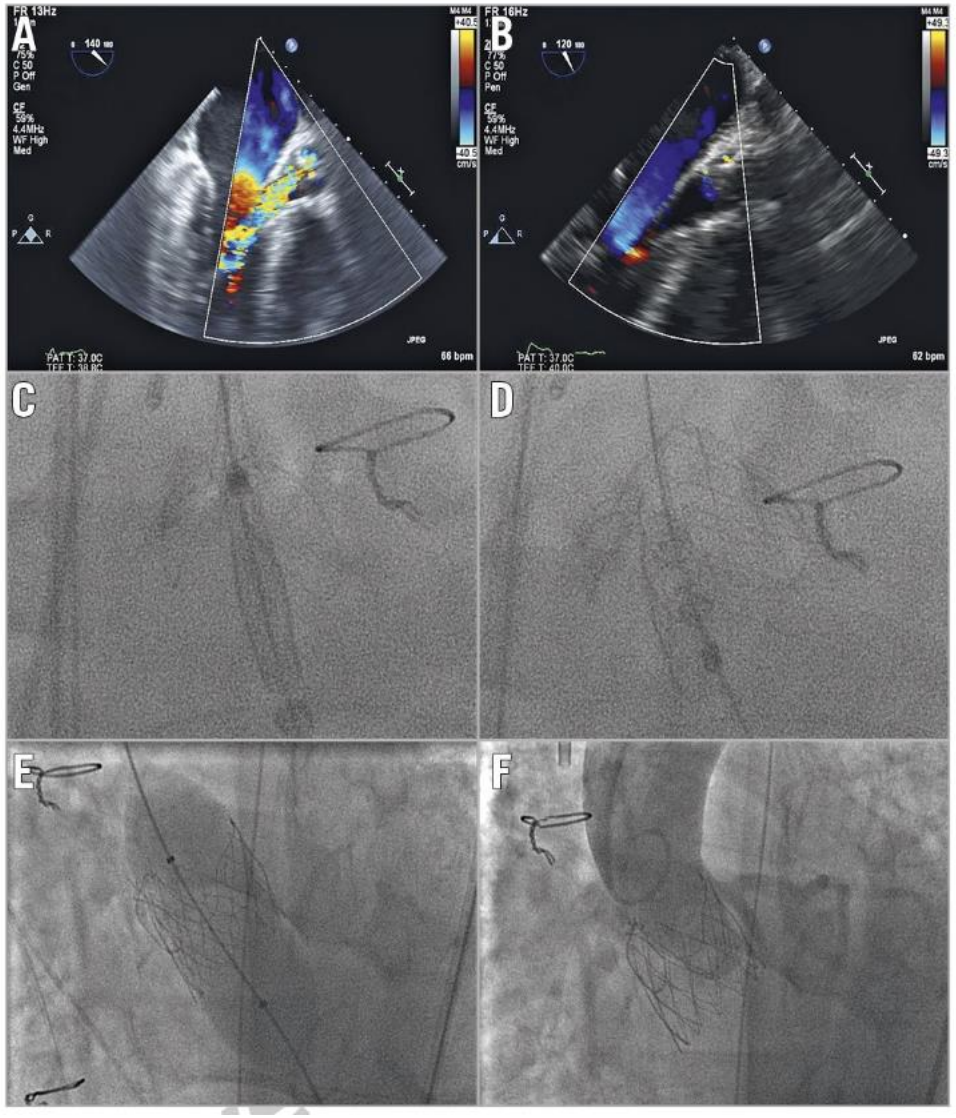
TABLE 2. Procedural results

Variable	Aortic stenosis (n = 63)	Aortic regurgitation (n = 44)
Implantation of prosthesis	63 (100)	44 (100)
Annulus size by TEE (mm)	21.9 ± 1.9	23.7 ± 2.0
Annulus size by CT (mm)	24.2 ± 2.2	25.4 ± 1.4
Prosthesis size		
Mean size (mm)	24.1 ± 1.7	26.4 ± 0.9
21 mm	7 (11.1)	0 (0)
23 mm	22 (34.9)	0 (0)
25 mm	25 (39.7)	13 (29.5)
27 mm	9 (14.3)	31 (70.5)
Conversion to open surgery	4 (6.3)	1 (2.3)
Cardiopulmonary bypass	5 (7.9)	1 (2.3)
Prosthesis dislocation	2 (3.2%)	0 (0)
Coronary obstruction	0 (0)	0 (0)
Annulus rupture	0 (0)	0 (0)
Mean aortic gradient (mm Hg)	14.4 ± 7.8	7.1 ± 2.9
Peak aortic valve velocity (m/s)	2.45 ± 0.57	1.81 ± 0.31
LVEF (%)	58.6 ± 11.0	52.1 ± 10.0
Paravalvular AR		
None or trace	32 (54.2)	32 (74.4)
Mild	25 (42.4)	10 (23.3)
Moderate	2 (3.4)	1 (2.3)
Severe	0 (0)	0 (0)

First-in-human experience of a new-generation transfemoral transcatheter aortic valve for the treatment of severe aortic regurgitation: the J-Valve transfemoral system

Mark Hensey, MB, BCh, BAO; Dale J. Murdoch, MBBS; Janarthanan Sathananthan, MBChB; Abdullah Alenezi, MD; Gnalini Sathananthan, MD; Robert Moss, MBBS; Philipp Blanke, MD; Jonathon Leipsic, MD; David A. Wood, MD; Anson Cheung, MD; Jian Ye, MD; John G. Webb*, MD

Centre for Heart Valve Innovation, St. Paul's Hospital, University of British Columbia, Vancouver, Canada



Hensey M et al. First-in-human experience of a new-generation transfemoral transcatheter aortic valve for the treatment of severe aortic regurgitation: the J-Valve transfemoral system. EuroIntervention 2019;14:e1553-e1555

NEW RESEARCH PAPERS: STRUCTURAL

Transcatheter Treatment of Native Aortic Valve Regurgitation

The North American Experience With a Novel Device

Santiago Garcia, MD,[a] Jian Ye, MD,[b] John Webb, MD,[b] Michael Reardon, MD,[c] Neal Kleiman, MD,[c] Sachin Goel, MD,[c] Taha Hatab, MD,[c] Neil Fam, MD,[d] Mark Peterson, MD,[d] Samantha Liauw, MD,[d] Tiberio M. Frisoli, MD,[e] Hanad Bashir, MD,[a] Debra Paige, RN,[a] Darlene Rock, RN,[a] Christian Schmidt, MS,[a] James G. Jollis, MD,[a] Dean J. Kereiakes, MD[a]

OBJECTIVES The aim of this study was to describe the compassionate-use experience in North America with a dedicated transcatheter device (J-Valve).

METHODS A multicenter, observational registry was assembled of compassionate-use cases of J-Valve implantation for the treatment of patients with severe symptomatic AR and elevated surgical risk in North America. The J-Valve consists of a self-expanding Nitinol frame, bovine pericardial leaflets, and a valve-locating feature. The available size matrix (5 sizes) can treat a wide range of anatomies (minimum and maximum annular perimeters 57-104 mm).

RESULTS A total of 27 patients (median age 81 years [IQR: 72-85 years], 81% at high surgical risk, 96% in NYHA functional class III or IV) with native valve AR were treated with the J-Valve during the study period (2018-2022). Procedural success (J-Valve delivered to the intended location without the need for surgical conversion or a second transcatheter heart valve) was 81% (22 of 27 cases) in the overall experience and 100% in the last 15 cases. Two cases required conversion to surgery in the early experience, leading to changes in valve design. At 30 days, there was 1 death, 1 stroke, and 3 new pacemakers (13%), and 88% of patients were in NYHA functional class I or II. No patient had residual AR of moderate or greater degree at 30 days.

CONCLUSIONS The J-Valve appears to provide a safe and effective alternative to surgery in patients with pure AR and elevated or prohibitive surgical risk. (J Am Coll Cardiol Intv 2023;16:1953-1960) © 2023 by the American College of Cardiology Foundation.

Compassionate Use Experience (2018-2023)

81%	Procedural success (n = 22/27)
100%	Procedural success with re-designed valve (n = 15/15)
0%	≥ Moderate aortic regurgitation at 30-day
!	Hemodynamic profile: • Average mean gradient ≤ 10 mm Hg • Effective orifice area (EOA) >2 cm^2

TABLE 4 Short- and Mid-Term Outcomes After J-Valve Implantation

	30 Days (n = 24)	30 Days to 1 Year (n = 17)
Death	1 (4)	2 (12)
Stroke	1 (4)	0
New pacemaker	3 (13)	1 (6)
NYHA functional class I or II	88	100
AR moderate or greater	0	1 (7)
Mean gradient, mm Hg	7 ± 4	8 ± 4
EOA, cm^2	2.1 ± 0.6	2.3 ± 0.8

Values are n (%), %, or mean ± SD.
AR = aortic regurgitation; EOA = effective orifice area.

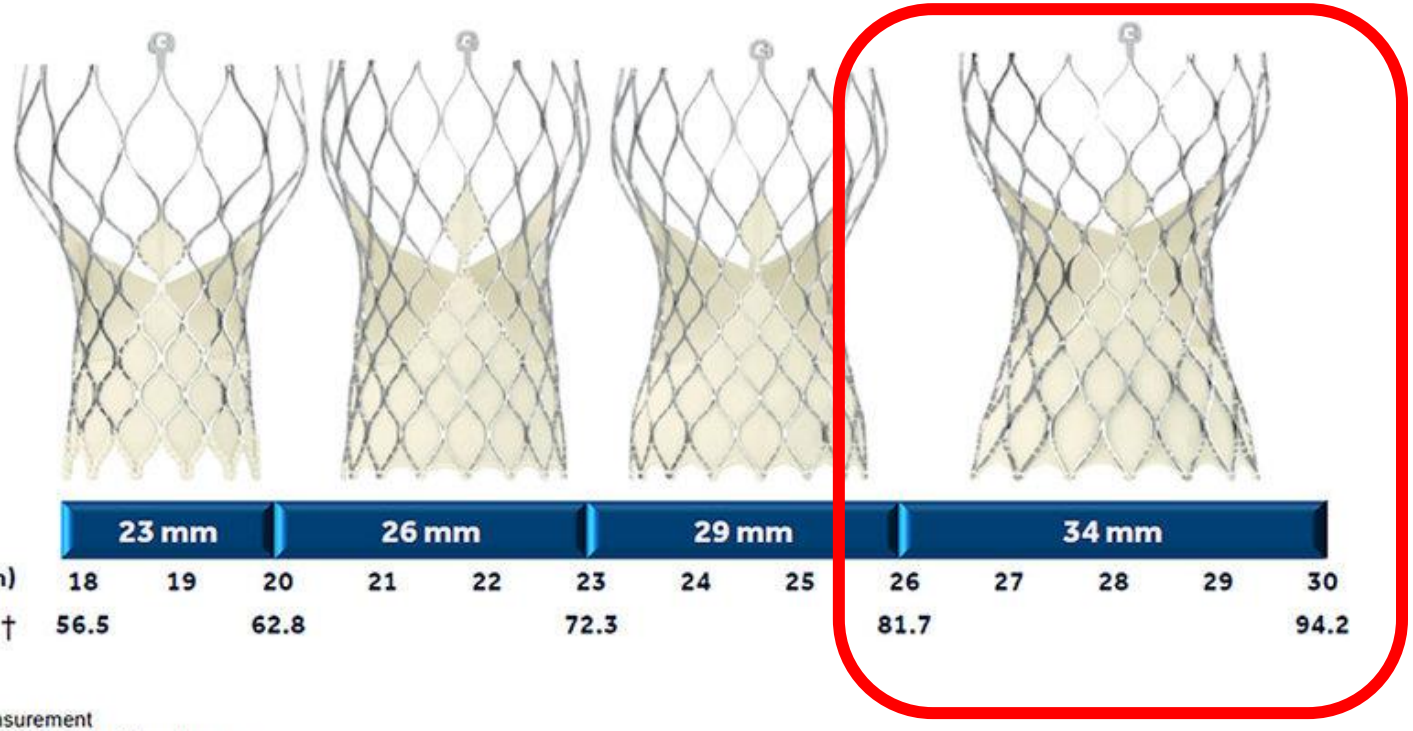
DISPOSITIVOS NO DEDICADOS

ACURATE *neo2*

Boston Scientific

Valve Size	S – 23 mm	M – 25 mm	L – 27 mm
Aortic annulus diameter*	21 mm ≤ annulus ≤ 23 mm	23 mm < annulus ≤ 25 mm	25 mm < annulus ≤ 27 mm
Aortic annulus perimeter	66 mm ≤ annulus ≤ 72 mm	72 mm < annulus ≤ 79 mm	79 mm < annulus ≤ 85 mm

EVOLUT R / PRO+ / FX



* Based on CT measurement
† Annulus Perimeter = Annulus Diameter x π

Medtronic

Portico/Navitor

Abbott

Abbott NG TAVR Valve Labeled Use	Labeled Use Range – Mean Diameter (mm)	Use Range – Area (mm^2)	Use Range – Perimeter (mm)	Ascending Aorta Diameter (mm)	Sinus of Valsalva Width (mm)	Sinus of Valsalva Height (mm)	Vascular Access Diameter (mm)
23 mm	19-21	277-346	60-66	26-36	≥ 25	≥ 15	≥ 5.0
25 mm	21-23	338-415	66-73	28-38	≥ 27	≥ 15	≥ 5.0
27 mm	23-25	405-491	72-79	30-40	≥ 29	≥ 15	≥ 5.5
29 mm	25-27	479-573	79-85	32-42	≥ 31	≥ 15	≥ 5.5

SAPIEN 3 / 3 ULTRA

Edwards SAPIEN 3 valve size (mm)	3-D Area-derived Diameter (mm)	3-D Annular Area (mm2)	Delivery System COMMANDER
20	18.6-21.0	273-345	14F e-Sheath
23	20.7-23.4	338-430	14F e-Sheath
26	23.4-26.4	430-546	14F e-Sheath
29	26.2-29.5	540-683	16F e-Sheath

Edwards

Transcatheter Aortic Valve Implantation for Pure Severe Native Aortic Valve Regurgitation

David A. Roy, MD,* Ulrich Schaefer, MD, PhD,† Victor Guetta, MD,‡ David Hildick-Smith, MD,§ Helge Möllmann, MD,‖ Nicholas Dumonteil, MD,¶ Thomas Modine, MD,# Johan Bosmans, MD,** Anna Sonia Petronio, MD,†† Neil Moat, MBBS, MS,‡‡ Axel Linke, MD,§§ Cesar Moris, MD,‖‖ Didier Champagnac, MD,¶¶ Radoslaw Parma, MD, PhD,## Andrzej Ochala, MD,## Diego Medvedofsky, MD,‡ Tiffany Patterson, MD,‡‡ Felix Woitek, MD,§§ Marjan Jahangiri, MD,* Jean-Claude Laborde, MD,* Stephen J. Brecker, MD*

Objectives This study sought to collect data and evaluate the anecdotal use of transcatheter aortic valve implantation (TAVI) in pure native aortic valve regurgitation (NAVR) for patients who were deemed surgically inoperable

Background Data and experience with TAVI in the treatment of patients with pure severe NAVR are limited.

Methods Data on baseline patient characteristics, device and procedure parameters, echocardiographic parameters, and outcomes up to July 2012 were collected retrospectively from 14 centers that have performed TAVI for NAVR.

Results A total of 43 patients underwent TAVI with the CoreValve prosthesis (Medtronic, Minneapolis, Minnesota) at 14 centers (mean age, 75.3 ± 8.8 years; 53% female; mean logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation), 26.9 ± 17.9%; and mean Society of Thoracic Surgeons score, 10.2 ± 5.3%). All patients had severe NAVR on echocardiography without aortic stenosis and 17 patients (39.5%) had the degree of aortic valvular calcification documented on CT or echocardiography. Vascular access was transfemoral (n = 35), subclavian (n = 4), direct aortic (n = 3), and carotid (n = 1). Implantation of a TAVI was performed in 42 patients (97.7%), and 8 patients (18.6%) required a second valve during the index procedure for residual aortic regurgitation. In all patients requiring second valves, valvular calcification was absent (p = 0.014). Post-procedure aortic regurgitation grade I or lower was present in 34 patients (79.1%). At 30 days, the major stroke incidence was 4.7%, and the all-cause mortality rate was 9.3%. At 12 months, the all-cause mortality rate was 21.4% (6 of 28 patients).

Conclusions This registry analysis demonstrates the feasibility and potential procedure difficulties when using TAVI for severe NAVR. Acceptable results may be achieved in carefully selected patients who are deemed too high risk for conventional surgery, but the possibility of requiring 2 valves and leaving residual aortic regurgitation remain important considerations. (J Am Coll Cardiol 2013;61:1577–84) © 2013 by the American College of Cardiology Foundation

Table 4 Procedural Results

Access	
Transfemoral	35 (81.4)
Subclavian	4 (9.3)
Direct aortic	3 (7.0)
Carotid	1 (2.3)
Implantation of prosthesis	42 (97.7)
Annulus size, mm	24.0 ± 2.3
Prosthesis size, mm	
29	22 (51.2)
26	14 (32.6)
31	7 (16.3)
Valve post-dilation	4 (9.3)
Second valve required	8 (18.6)
Post-procedure AR grade	
I or lower	34 (79.1)
II	7 (16.3)
III	2 (4.7)
New permanent pacemaker	7 (16.3)

Table 5 Clinical and Safety Outcomes According to VARC*

Mortality	
30-day all-cause	4 (9.3%)
30-day cardiovascular	1 (2.3%)
12 month all-cause	6/28 (21.4)
12-month cardiovascular	3/28 (10.7)
Major stroke (30 days)	2 (4.7)
Major bleeding	8 (18.6)
Acute kidney injury (stage 3)	2 (4.7)
Myocardial infarction	0
Access site complications	6 (14.0)
Major	3 (7.0)
Minor	3 (7.0)
VARC procedure success	32 (74.4)

The American Journal of Cardiology

Usefulness of Transcatheter Aortic Valve Implantation for Treatment of Pure Native Aortic Valve Regurgitation

Ole De Backer, MD • Thomas Pilgrim, MD • Matheus Simonato • G. Burkhard Mackensen, MD • Claudia Fiorina, MD • Verena Veulemanns, MD • Alfredo Cerillo, MD • Joachim Schofer, MD • Nicolas Amabile, MD • Guy Achkouty, MD • Ulrich Schäfer, MD • Marcus-André Deutsch, MD • Jan-Malte Sinning, MD • Mohammed S. Rahman, MBBS • Fadi J. Sawaya, MD • David Hildick-Smith, MD • Jose Maria Hernandez, MD • Won-Keun Kim, MD • Thierry Lefevre, MD • Moritz Seiffert, MD • Sabine Bleiziffer, MD • Anna Sonia Petronio, MD • Nicolas Van Mieghem, MD • Maurizio Taramasso, MD • Lars Søndergaard, MD • Stephan Windecker, MD • Azeem Latib, MD • Danny Dvir, MD • Show less

Published: June 22, 2018 • DOI: https://doi.org/10.1016/j.amjcard.2018.05.044 • Check for updates

Patients with pure native aortic valve regurgitation (NAVR) and increased surgical risk are often denied surgery.

This retrospective study aimed to evaluate the “off-label” use of transcatheter heart valves (THV) for the treatment of NAVR.

A total of 254 high surgical risk patients with NAVR (age 74 ± 12 years, Society of Thoracic Surgeons risk score 6.6 ± 6.2%) underwent TAVI with early generation (43%) or newer generation (57%) devices at 46 different sites.

Device success was significantly higher in patients treated with newer as compared with early generation THV (82% vs 47%, p <0.001). The difference was driven **by lower rates of device malpositioning (9% vs 33%) and aortic regurgitation (AR) ≥ moderate (4% vs 31%) and translated into higher clinical efficacy at 30 days in patients treated with newer as compared with early generation THV (72% vs 56%, p = 0.041).** Both THV under- and oversizing were associated with an increased risk of THV malpositioning.

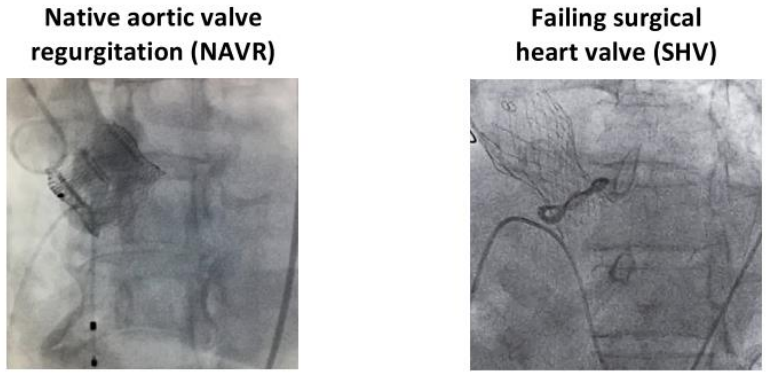
In conclusion, TAVI is a feasible treatment strategy in selected high-risk patients with NAVR but is associated with a considerable risk of THV malpositioning and residual AR. Although newer-generation THV are associated with better outcomes, novel devices for the treatment of NAVR are warranted.

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

Fadi J. Sawaya, MD,[a] Marcus-André Deutsch, MD,[b] Moritz Seiffert, MD,[c] Sung-Han Yoon, MD,[d] Pablo Codner, MD,[e] Upul Wickramarachchi, MD,[f] Azeem Latib, MD,[g] A. Sonia Petronio, MD,[h] Josep Rodés-Cabau, MD,[i] Maurizio Taramasso, MD,[j] Marco Spaziano, MD,[k] Johan Bosmans, MD,[l] Luigi Biasco, MD,[m] Darren Mylotte, MD,[n] Mikko Savontaus, MD,[o] Peter Gheeraert, MD,[p] Jason Chan, MD,[q] Troels H. Jørgensen, MD,[a] Horst Sievert, MD,[r] Marco Mocetti, MD,[m] Thierry Lefèvre, MD,[k] Francesco Maisano, MD,[j] Antonio Mangieri, MD,[g] David Hildick-Smith, MD,[f] Ran Kornowski, MD,[e] Raj Makkar, MD,[d] Sabine Bleiziffer, MD,[e] Lars Søndergaard, MD, DMSc,[a] Ole De Backer, MD, PhD[a]

A Safety & efficacy of TAVR in the treatment of pure severe aortic regurgitation



Old-Gen THV	New-Gen THV		Old-Gen THV	New-Gen THV
54%	85%	Device success	69%	77%
62%	69%	Early safety	90%	92%
46%	75%	Clinical efficacy	77%	77%

TABLE 3 Early Safety and Clinical Efficacy at 30 Days

	Pure Severe NAVR (n = 78)	Failing SHV With Severe AR (n = 68)	p Value
Early safety at 30 days	50/76 (66%)	55/61 (90%)	0.002
All-cause mortality	11/77 (14%)	1/66 (2%)	0.015
All stroke	3/76 (4%)	1/65 (2%)	0.726
Major vascular complications	6/77 (8%)	2/68 (3%)	0.362
Life-threatening bleeding	2/76 (3%)	2/65 (3%)	1.000
Acute kidney injury stage ≥2	8/76 (11%)	1/61 (2%)	0.082
Coronary artery obstruction requiring intervention	0/77 (0%)	0/65 (0%)	1.000
Repeat procedure for valve-related dysfunction	2/77 (3%)	1/68 (1%)	1.000
Clinical efficacy at 30 days	47/77 (61%)	47/61 (77%)	0.069
All-cause mortality	11/77 (14%)	1/66 (2%)	0.015
Cardiac mortality	6/77 (8%)	1/66 (1%)	0.172
Noncardiac mortality	5/77 (6%)	0/66 (0%)	0.096
All stroke	3/76 (4%)	1/65 (2%)	0.726
Valve-related dysfunction	11/67 (16%)	14/64 (22%)	0.340
Mean gradient ≥20 mm Hg or EOA ≤0.9–1.1 cm^2	2/66 (3%)	12/64 (19%)	0.009
Moderate or severe AR	9/67 (13%)	4/65 (6%)	0.267
NYHA functional class III or IV	10/66 (15%)	3/60 (5%)	0.115

TABLE 2 Procedural Characteristics and Outcomes

	Pure Severe NAVR (n = 78)	Failing SHV With Severe AR (n = 68)	p Value
New pacemaker implantation	12/65 (18%)	3/64 (5%)	0.030
Device success (VARC-2)	55/78 (72%)	48/68 (71%)	1.000
Absence of procedural mortality	78/78 (100%)	68/68 (100%)	1.000
No moderate or severe AR	65/76 (86%)	62/68 (91%)	0.429

Sawaya FJ, Deutsch MA, Seiffert M, et al. 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. JACC Cardiovasc Interv. 2017;10: 1048-1056.

... THE NEW KID IN TOWN

MYVAL/OCTACOR

Meril

Myval THV Size Matrix & Technical Specifications	Area 314 mm²  17.35 mm 20 mm	Area 363 mm²  18.35 mm 21.5 mm	Area 415 mm²  17.85 mm 23 mm	Area 471 mm²  18.75 mm 24.5 mm
Perimeter	62.83 mm	67.54 mm	72.26 mm	76.97 mm
Native annulus area	270 - 330 mm²	314 - 380 mm²	360 - 440 mm²	410 - 500 mm²
Area-derived diameter	18.5 - 20.5 mm	20 - 22 mm	21.4 - 23.7 mm	22.8 - 25.2 mm
Native annulus size by TEE	16 - 19 mm	17.5 - 20.5 mm	18 - 22 mm	19.5 - 23.5 mm

Myval THV XL Sizes

Area 531 mm²  18.85 mm 26 mm	Area 594 mm²  19.25 mm 27.5 mm	Area 661 mm²  20.35 mm 29 mm	Area 731 mm²  20.9 mm 30.5 mm	Area 804 mm²  21.14 mm 32 mm
81.68 mm	86.39 mm	91.11 mm	95.82 mm	100.53 mm
460 - 560 mm²	510 - 630 mm²	570 - 700 mm²	630 - 770 mm²	700 - 840 mm²
24.2 - 26.7 mm	25.5 - 28.3 mm	26.9 - 29.9 mm	28.3 - 31.3 mm	29.9 - 32.7 mm
21 - 25 mm	22.5 - 26.5 mm	24 - 28 mm	25.5 - 29.5 mm	27 - 31 mm

JACC: CARDIOVASCULAR INTERVENTIONS
VOL. ■, NO. ■, 2024

PUBLISHED BY ELSEVIER

IMAGES IN INTERVENTION

Novel 35-mm Balloon-Expandable Transcatheter Aortic Valve Replacement

John Jose, DM, MD, Paul V. George, DM, MD, Shohiab Ur Riyaz Mirza, DM, MD, Pratheesh George Mathen, DM, MD, Sakthivel Selvaraj, DM, MD, Haynes Raja, DM, MD

FIGURE 1 Computed Tomography

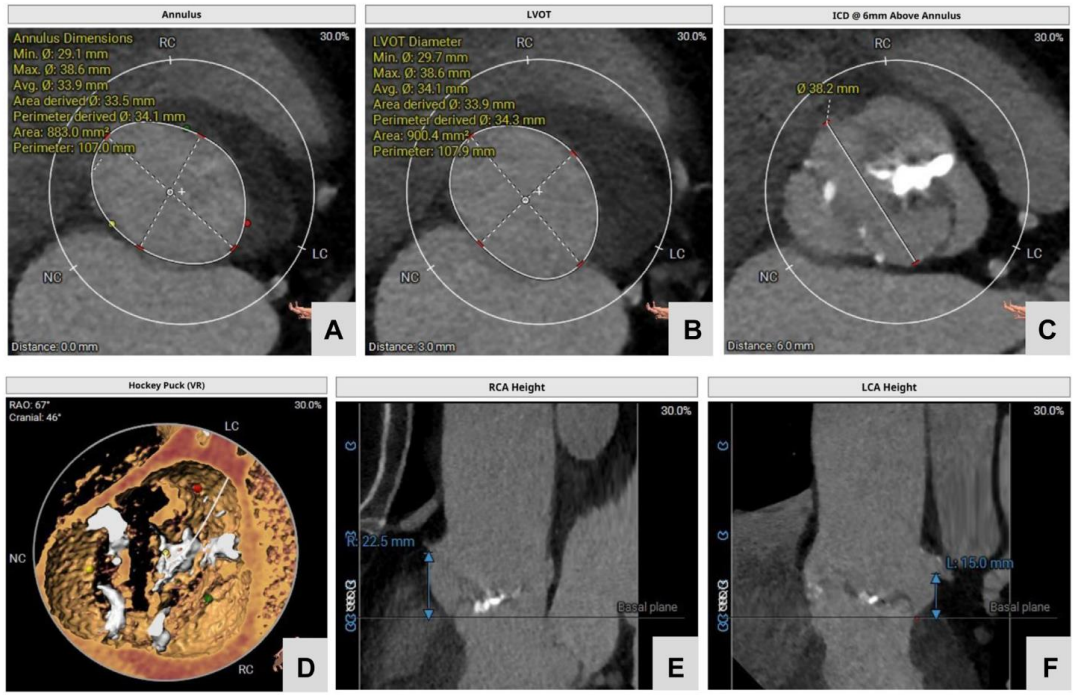
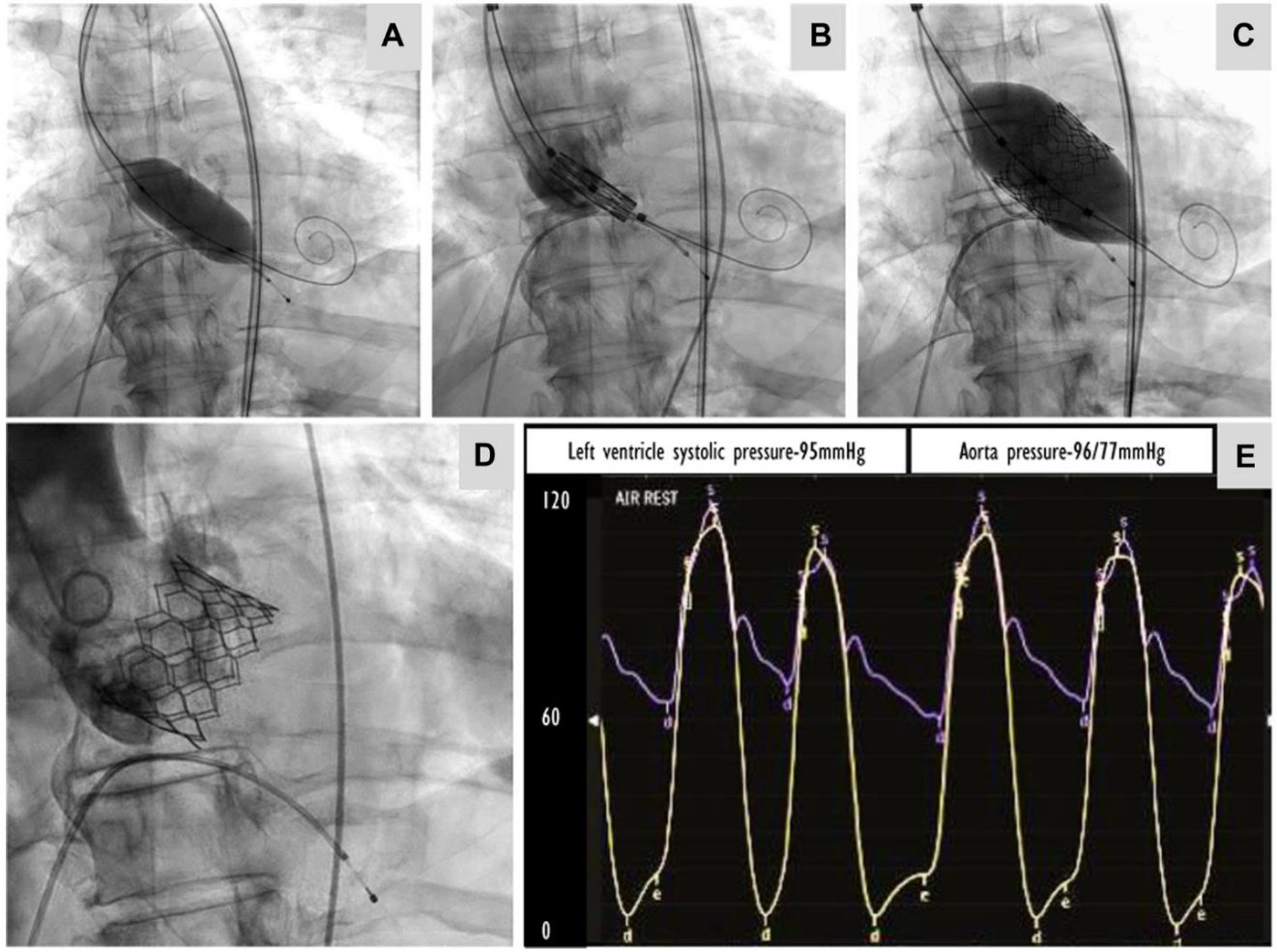


FIGURE 2 TAVR Procedure



EuroIntervention
INTERVENTIONS FOR VALVULAR DISEASE AND HEART FAILURE
CLINICAL RESEARCH

Clinical outcomes of TAVI with the Myval balloon-expandable valve for non-calcified aortic regurgitation

Juan Pablo Sánchez-Luna[1], MD; Pedro Martín[2], MD; Antonio E. Dager[3], MD; Pablo D. Charry[4], MD; Javier R. Beltrán[5], MD; Ángel Sánchez-Recalde[6], MD; Francesco Giannini[7], MD; Antonio Gómez-Menchero[8], MD; Manuel Pan[9], MD; Alfonso Ielasi[10], MD; Andrea Monastyrski[11], MD; Marco Barbanti[12], MD; Francisco Fernandez Avilés[13], MD, PhD; Marco Ancona[14], MD; Abdurashid Mussayev[15], MD; Juan Pablo De Brahi[16], MD; Pablo Lamelas[17], MD; Andrés Sánchez-Pérez[2], MD; Melissa Garcia Puerta[3], MD; Miguel Ortiz[3], MD; Jose Carlos Gonzalez-Gutiérrez[1], MD; Giorgio Marengo[1], MD; Javier Gómez[1], MD; Esther Gonzalez-Bartol[1], MD; Alexander Stepanenko[1], MD; Itziar Gómez-Salvador[18], MSc; J. Alberto San Román[1,18], MD, PhD; Ignacio J. Amat-Santos[1,18]*, MD, PhD

Table 1. Baseline clinical and anatomical characteristics.

Clinical characteristics	N=113
Age, years	78.4±7.46
Male	73 (64.6)
NYHA Class III-IV	71 (62.8)
Urgent preoperative state	14 (12.4)
STS score	2.71±1.7
EuroSCORE II	3.48±2.7

Computed tomography findings		
Annulus area, mm^2		638.5±106.1
Annulus perimeter, mm		88.5±8.0
Agatston units, HU		56.4±159.5
STJ mean diameter, mm		37.0±5.6
SoV mean diameter, mm		39.15±6.0
Leaflet calcification		17 (15.0)
LVOT calcification		1 (0.9)
LVOT shape	Tubular	14 (12.4)
	Flared	66 (58.4)
	Tapered	32 (28.3)
Horizontal aorta		4 (3.5)
Bicuspid aortic valve		8 (7.1)

Table 2. Procedural and in-hospital characteristics.

Procedural characteristics		N=113
Intraprocedural TOE		22 (19.5)
Transfemoral access		113 (100)
Annular rupture		0 (0)
Coronary obstruction		0 (0)
Procedural death		1 (0.9)
VARC-3 technical success		107 (94.7)
First valve size	23 mm	1 (0.9)
	24.5 mm	1 (0.9)
	26 mm	2 (1.8)
	27.5 mm	3 (2.7)
	29 mm	11 (9.7)
	30.5 mm	14 (12.4)
	32 mm	81 (71.7)
Balloon with more than nominal volume		80 (70.8)
Volume in the prosthesis balloon	Nominal	26 (24.5)
	+1 cc	14 (13.2)
	+2 cc	15 (14.2)
	+3 cc	21 (19.8)
	+4 cc	8 (7.5)
	+5 cc	4 (3.8)
	+6 cc	7 (6.6)
	+7 cc	1 (0.9)
	+8 cc	9 (8.5)
	+9 cc	1 (0.9)
% of oversizing		17.9±11.0
Mean extra cc in the prosthesis balloon		2.7±2.5
Need for a 2nd valve implantation		4 (3.5)
Valve embolisation		4 (3.5)
Ventricular embolisation		3 (2.7)
Antegrade embolisation		1 (0.9)
Embolisation management	Conversion to surgery	1 (25.0)
	Balloon pullout of 1st valve + 2nd valve implantation	3 (75.0)

Sánchez-Luna JP et al. Clinical outcomes of TAVI with the Myval balloon-expandable valve for non-calcified aortic regurgitation. EuroIntervention. 2023;19:580-588.

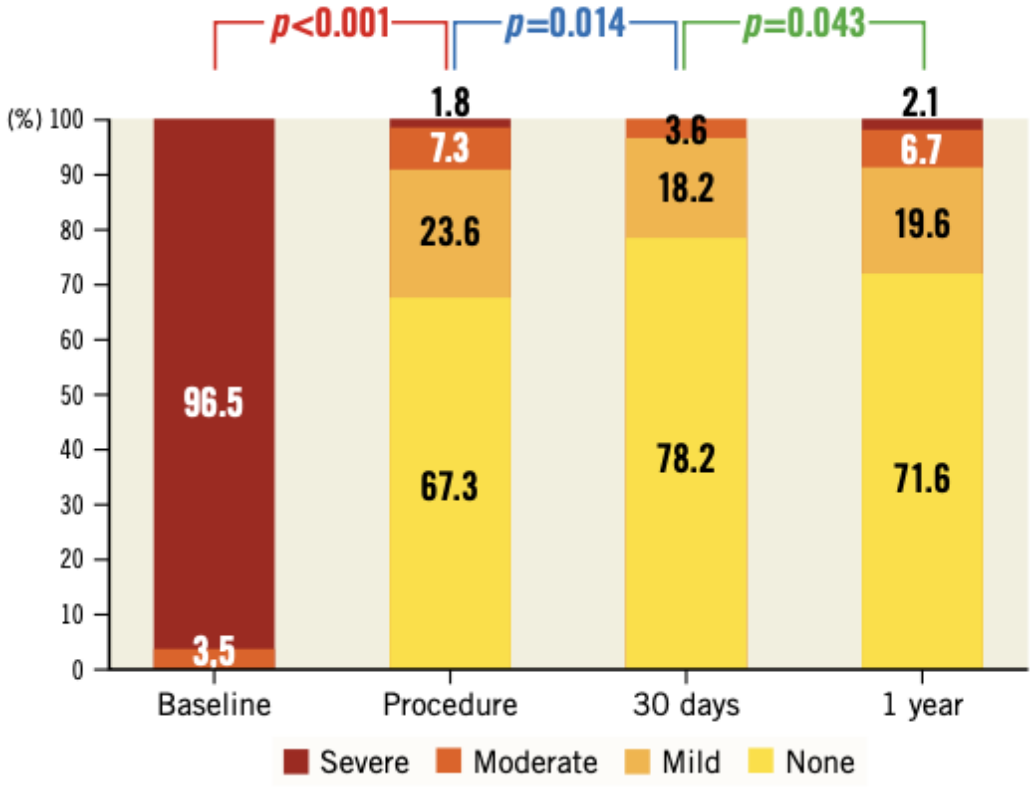


Figure 2. *Degree of aortic regurgitation from baseline to 1-year follow-up.*

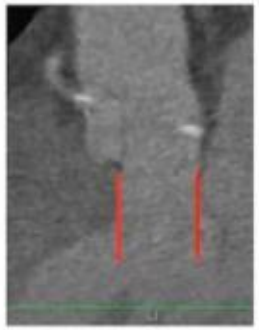
Table 3. Thirty-day and 1-year outcomes.

30-day outcomes	N=113
All-cause mortality	6 (5.3)
Stroke	1 (0.9)
TIA	1 (0.9)
Myocardial infarction	4 (3.5)
Permanent pacemaker implantation	17 (15.0)
Rehospitalisation for heart failure	4 (3.5)
LVEF, %	41.6±14.9
LVEDD, mm	64.0±8.8
Aortic valve mean pressure gradient, mmHg	4.7±2.0
Residual aortic regurgitation (moderate-severe)	10 (9.1)
Device success	107 (94.7)
1-year follow-up	
All-cause mortality	11 (9.7)
Stroke	2 (1.8)
TIA	2 (1.8)
Permanent pacemaker implantation	25 (22.1)
Rehospitalisation for heart failure	9 (8.0)
Residual aortic regurgitation (moderate-severe)	9 (8.0)

Sánchez-Luna JP et al. Clinical outcomes of TAVI with the Myval balloon-expandable valve for non-calcified aortic regurgitation. EuroIntervention. 2023;19:580-588.

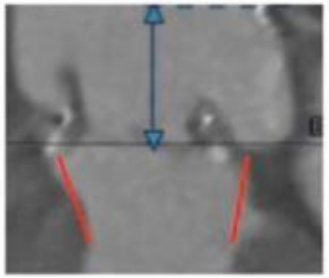
CENTRAL **ILLUSTRATION** Rate of device embolisation according to the morphology of the left ventricular outflow tract.

TUBULAR (12.4%)
Codominant (annulus - LVOT)
(Sizing based on the annulus)



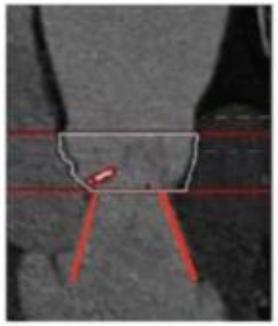
Embolisation rate: 0%

FLARED (58.4%)
Annular dominant
(Sizing based on the annulus)

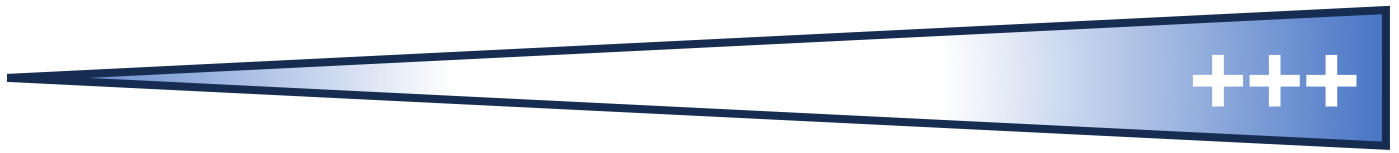


Embolisation rate: 0%

TAPERED (28.3%)
LVOT dominant
(Sizing based on the LVOT)

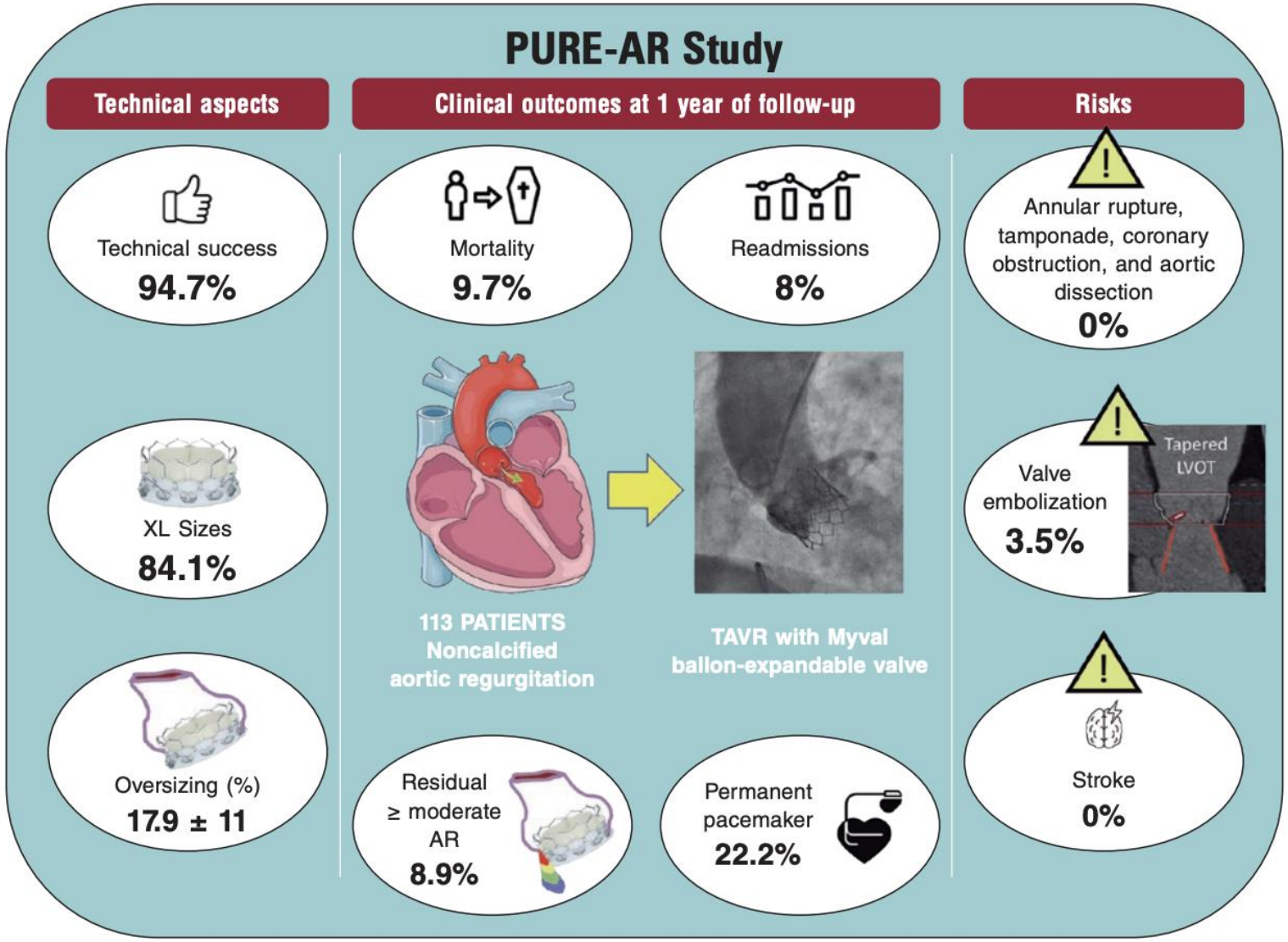


Embolisation rate: 12.5%



Sánchez-Luna JP et al. Clinical outcomes of TAVI with the Myval balloon-expandable valve for non-calcified aortic regurgitation. EuroIntervention. 2023;19:580-588.

Percutaneous Updated management of PuRE Aortic Regurgitation with Myval Device



I.J. Amat-Santos, J.P. Sánchez-Luna. Implante de prótesis aórtica transcatéter en insuficiencia aórtica no calcificada. ¿En qué punto estamos? REC Interv Cardiol. 2024;6(1):3-6

JACC: CARDIOVASCULAR INTERVENTIONS
© 2023 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
PUBLISHED BY ELSEVIER
VOL. 16, NO. 16, 2023

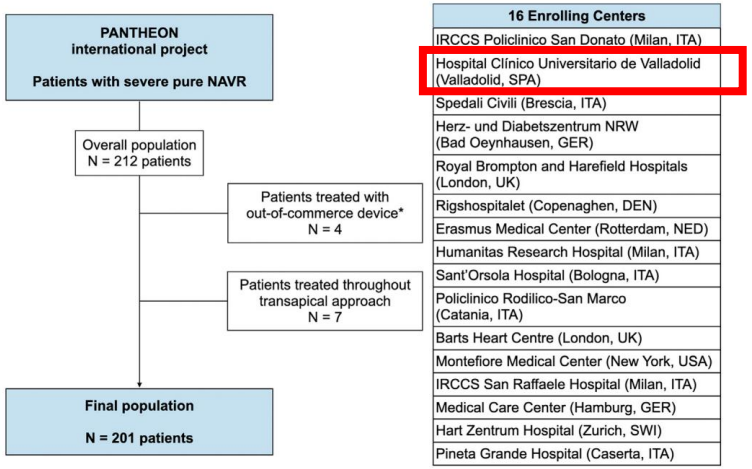
FOCUS ON AORTIC REGURGITATION AND TRANSCATHETER AORTIC VALVE REPLACEMENT

NEW RESEARCH PAPER: STRUCTURAL

Transcatheter Aortic Valve Replacement for Pure Native Aortic Valve Regurgitation

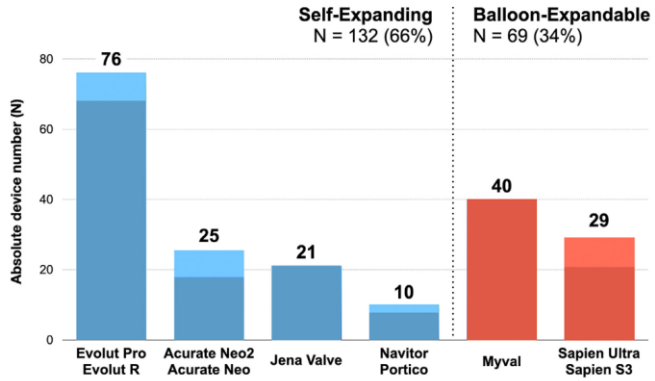
The PANTHEON International Project

FIGURE 1 Study Population



16 Enrolling Centers
IRCCS Policlinico San Donato (Milan, ITA)
Hospital Clínico Universitario de Valladolid (Valladolid, SPA)
Spedali Civili (Brescia, ITA)
Herz- und Diabetszentrum NRW (Bad Oeynhausen, GER)
Royal Brompton and Harefield Hospitals (London, UK)
Rigshospitalet (Copenaghen, DEN)
Erasmus Medical Center (Rotterdam, NED)
Humanitas Research Hospital (Milan, ITA)
Sant'Orsola Hospital (Bologna, ITA)
Policlinico Rodilico-San Marco (Catania, ITA)
Barts Heart Centre (London, UK)
Montefiore Medical Center (New York, USA)
IRCCS San Raffaele Hospital (Milan, ITA)
Medical Care Center (Hamburg, GER)
Hart Zentrum Hospital (Zurich, SWI)
Pineta Grande Hospital (Caserta, ITA)

FIGURE 2 Transcatheter Heart Valve Type Between the 2 Groups

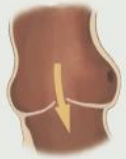


¿PRÓTESIS AUTO-EXPANDIBLES?
¿PRÓTESIS BALÓN-EXPANDIBLES?

CENTRAL ILLUSTRATION: Performance of Currently Available THVs in Pure NAVR

Performance of currently Available traNscaTHEter aortic valve platforms in inoperable patients with pure aortic regurgitatiON of a native valve [PANTHEON] registry

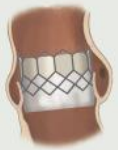
Study Design



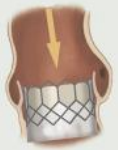
201 patients with pure NAVR undergoing off-label TAVR

Self-expanding n = 132

versus

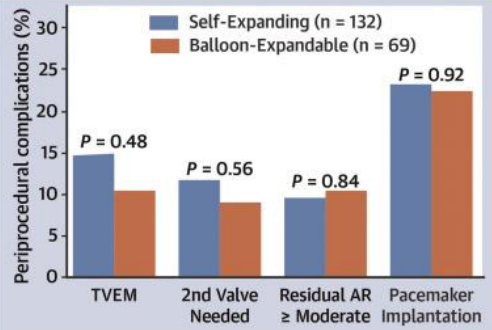


Balloon-expandable n = 69



Focus on transcatheter valve embolization and migration (TVEM)

Short-Term Performance



TVEM in NAVR Setting

- **Incidence of TVEM:** 12.4% in the overall population
- **TVEM causes:** malpositioning, oversizing, THV failure to anchor, manipulation
- **Bail-out strategies:** 2nd THV implantation, snaring, balloon repositioning, conversion to surgery and procedure abortion
- **Predictor:** post-dilation (OR: 4.00, *P* = 0.049)
- **Composite endpoint:** 25.7% incidence of composite endpoint at 1-year follow-up

Poletti E, et al. J Am Coll Cardiol Intv. 2023;16(16):1974-1985.

JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 16, NO. 16, 2023

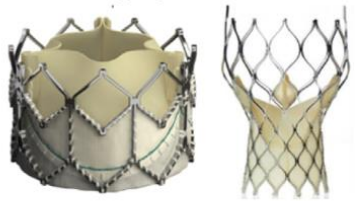
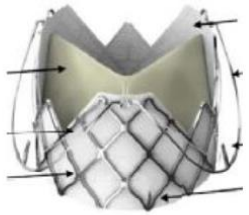
PUBLISHED BY ELSEVIER

EDITORIAL COMMENT

Progressing Forward in Transcatheter Aortic Valve Replacement for Pure Aortic Regurgitation*

Amit N. Vora, MD, MPH, Jayakumar Sreenivasan, MD, MSc, John K. Forrest, MD

TABLE 1 Comparison of Key Outcomes of Various THVs for Severe Pure Native AR

	New-Generation THVs: PANTHEON Registry[8] (n = 201)	J-Valve: North American Compassionate-Use Experience[13] (n = 27)	JenaValve Trilogy: First Commercial Experience[10] (n = 58)
			
Mean age, y	79.0	81.0	76.5
Mean STS Predicted Risk of Mortality	5.1	4.3	4.2
Participating centers	16 international sites	5 major centers in the United States and Canada	6 tertiary care centers in Germany
Type of valve implanted	132 SE THVs and 69 BE THVs	SE J-Valve THV system	SE JenaValve Trilogy HV system
Technical success	83.6%	81%	100%
Device success	76.1%	81%	98%
Residual AR of more than moderate severity	9.5%	0%	0%
Transcatheter migration or embolization (%)	12.4%	14.8%	0%
Need for second valve	10.5%	11.1%	0%
Conversion to surgery	2.0%	7.4%	0%
Postprocedural mean gradient, mm Hg	6.7	7.0	4.3
New pacemaker implantation	22.3%	13.0%	19.6%
Stroke/transient ischemic attack	1.5%	4.0%	0%
Major vascular complication	7.5%	–	0%
Major bleeding	10.6%	–	0%
In-hospital all-cause death	5.0%	4.0%	0%

REVISTA ESPAÑOLA DE CARDIOLOGÍA
REC: INTERVENTIONAL CARDIOLOGY

REC Interv Cardiol. 2024;6(1):3-6
https://doi.org/10.24875/RECIC.M23000421

Implante de prótesis aórtica transcatéter en insuficiencia aórtica no calcificada. ¿En qué punto estamos?

Transcatheter aortic valve replacement for noncalcified aortic regurgitation. Where are we now?

Ignacio J. Amat-Santos[a,b,*] y Juan Pablo Sánchez-Luna[a]

[a] *Servicio de Cardiología, Hospital Clínico Universitario, Valladolid, España*
[b] *Centro de Investigación Biomédica en Red de Enfermedades Cardiovasculares (CIBERCV), España*

Tabla 1. Comparativa de resultados entre los distintos registros internacionales

Registro	Nº. de pacientes	Tipo de dispositivo	Éxito del dispositivo	Mortalidad por cualquier causa	Insuficiencia aórtica residual ≥ moderada	Tasa de implante de marcapasos permanente
Yoon et al.[13] (2017)	331 pacientes con IANC y VCQF	Dispositivos no dedicados	Total: 74,3%	Total: 10,9%	Total: 9,6%	Total: 18,2%
		Dispositivos de primera generación (CoreValve, SAPIEN XT)	Dispositivos de primera generación: 61,3%	Dispositivos de primera generación: 13,4%	Dispositivos de primera generación: 18,8%	Dispositivos de primera generación: 17,5%
		Dispositivos de nueva generación (Evolut R, JenaValve, Engager, Portico, ACURATE, Lotus, Direct Flow, SAPIEN 3)	Dispositivos de nueva generación: 81,1%	Dispositivos de nueva generación: 9,4%	Dispositivos de nueva generación: 4,2%	Dispositivos de nueva generación: 18,6%
De Backer et al.[14] (2018)	254 pacientes con IANC	Dispositivos no dedicados Dispositivos de primera generación (CoreValve, SAPIEN XT)	Dispositivos de primera generación: 47%	Dispositivos de primera generación: 17%	THV de primera generación: 36%	No informado
		Dispositivos de nueva generación (Evolut R, JenaValve, Engager, Portico, ACURATE, Lotus, Direct Flow, SAPIEN 3)	Dispositivos de nueva generación: 82%	Dispositivos de nueva generación: 8%	THV de nueva generación: 5%	
Sawaya et al.[15] (2018)	146 pacientes con IANC y VCQF	Dispositivos de primera generación (CoreValve SAPIEN XT)	IANC: 72%	IANC: 13%	IANC: 13%	IANC: 18%
		Dispositivos de nueva generación (Evolut R, JenaValve, Lotus, Direct Flow, SAPIEN 3)	VCQF: 71%	VCQF: 6%	VCQF: 6%	VCQF: 5%
			Dispositivos de primera generación: 54%	Dispositivos de primera generación: 22%	Dispositivos de primera generación: 27%	
			Dispositivos de nueva generación: 85%	Dispositivos de nueva generación: 8%	Dispositivos de nueva generación: 3%	
Sánchez-Luna et al.[11] 2023	113 pacientes con IANC	Dispositivo no dedicado de nueva generación: Myval	94,7%	9,7%	8,9%	22,2%
Poletti et al.[12] 2023	201 pacientes con IANC	Dispositivos de nueva generación: VAE (Evolut R/Pro, ACURATE Neo/Neo2, Jena Valve, Navitor/Portico)	Total: 76,1%	Total: 5%	Total: 9,5%	Total: 22,3%
		VAE (SAPIEN, Myval)	VAE: 75,8%	VAE: 5,3%	VAE: 9,2%	VAE: 22,6%
		VBE (SAPIEN, Myval)	VBE: 76,8%	VBE: 4,4%	VBE: 10,1%	VBE: 21,8%
Adam et al.[6] (2023)	58 pacientes con IANC	Dispositivo dedicado: sistema Trilogy (JenaValve)	98%	1,7%	0%	19,6%
Garcia S et al.[7] (2023)	27 pacientes con IANC	Dispositivo dedicado: J-Valve	81%	3,7%	0%	13%

I.J. Amat-Santos, J.P. Sánchez-Luna. Implante de prótesis aórtica trasncatéter en insuficiencia aórtica no calcificada. ¿En qué punto estamos? REC Interv Cardiol. 2024;6(1):3-6

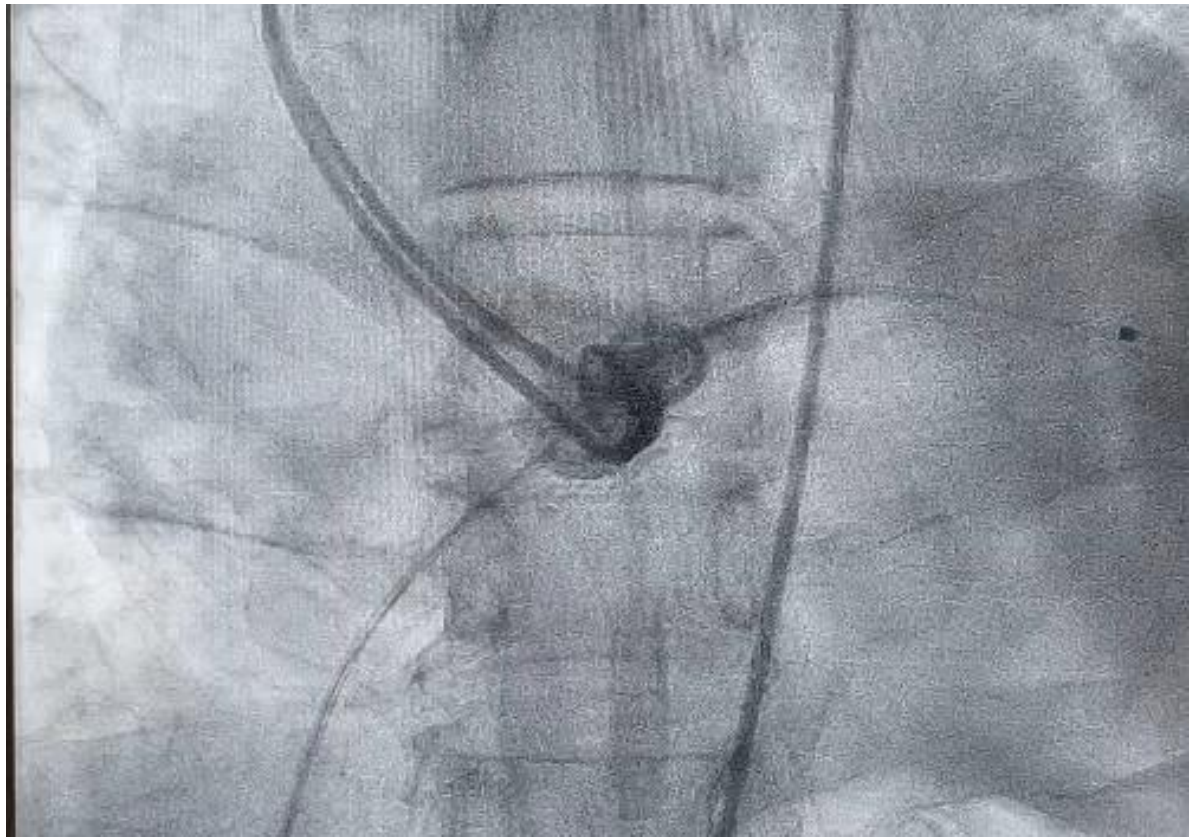
OVERSIZING SI… ¿CUÁNTO?

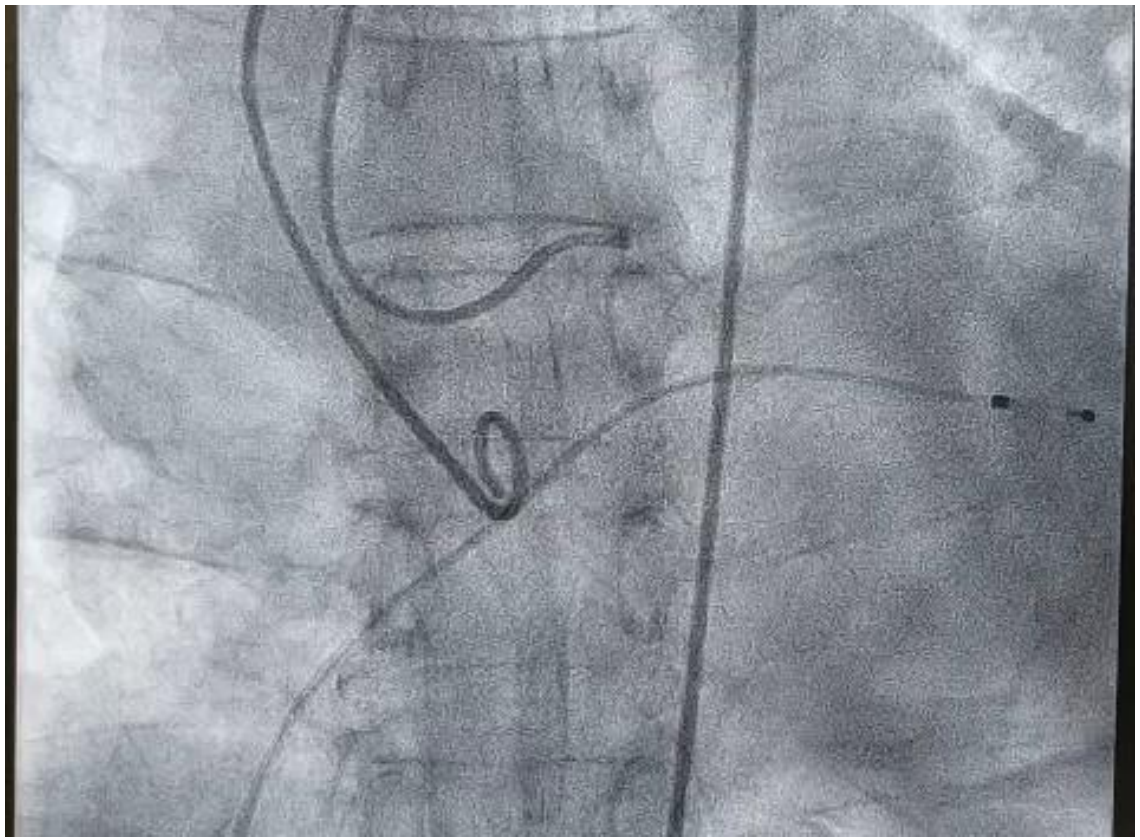
- No existe ninguna recomendación oficial
- Estenosis aórtica: 5-15%

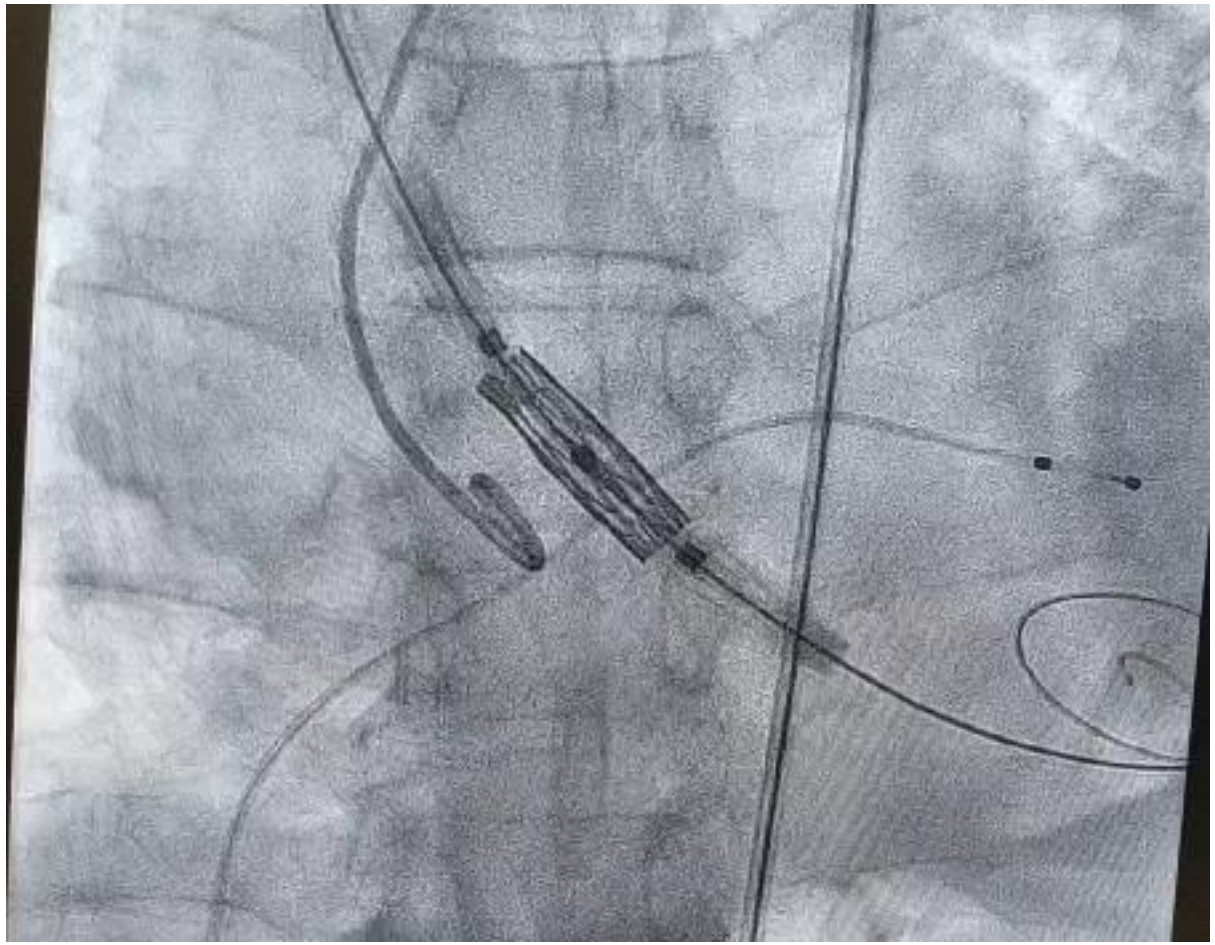
Oversizing*:

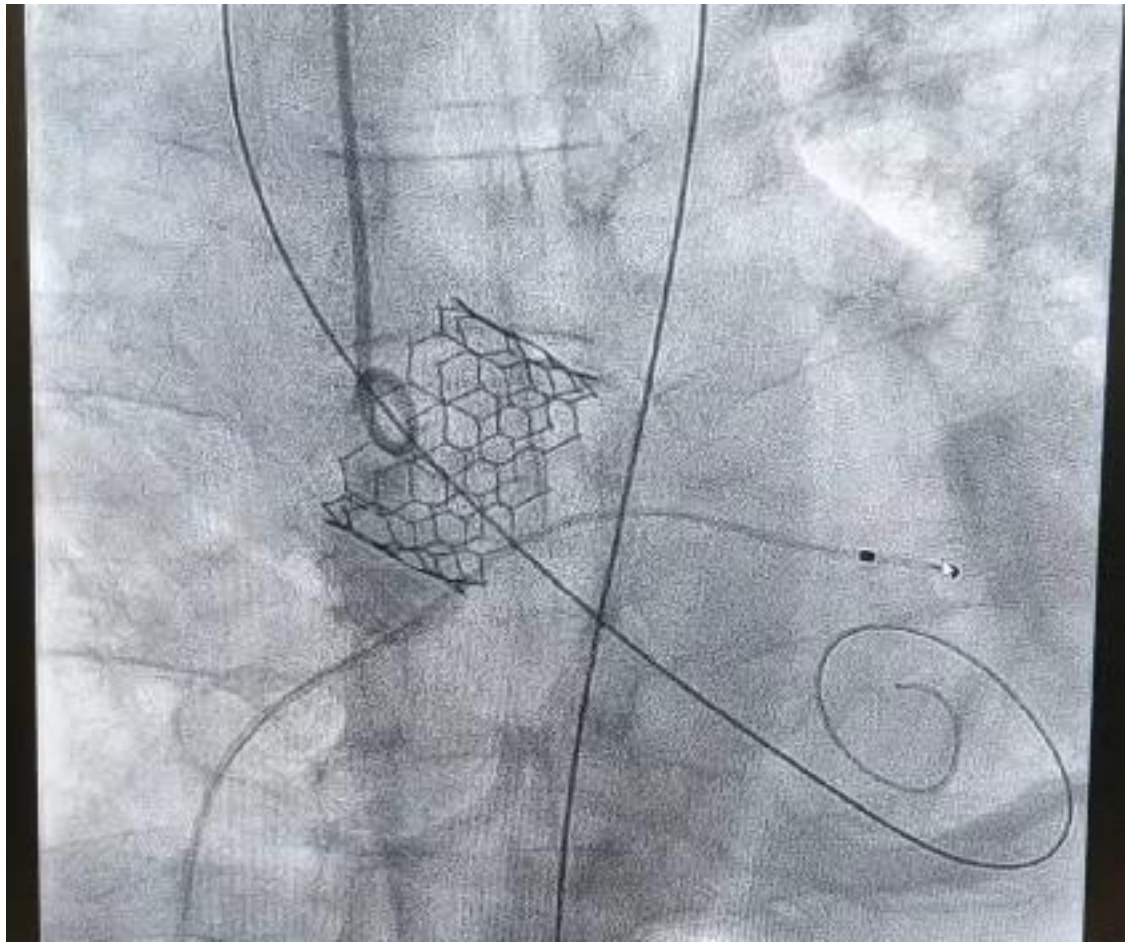
- Medtronic SE: 15%
- Edwards Sapien: ≥ 15%
- Accurate Neo: 10%
- JenaValve: 10%-20%
- Myval o BEV: 20-30%

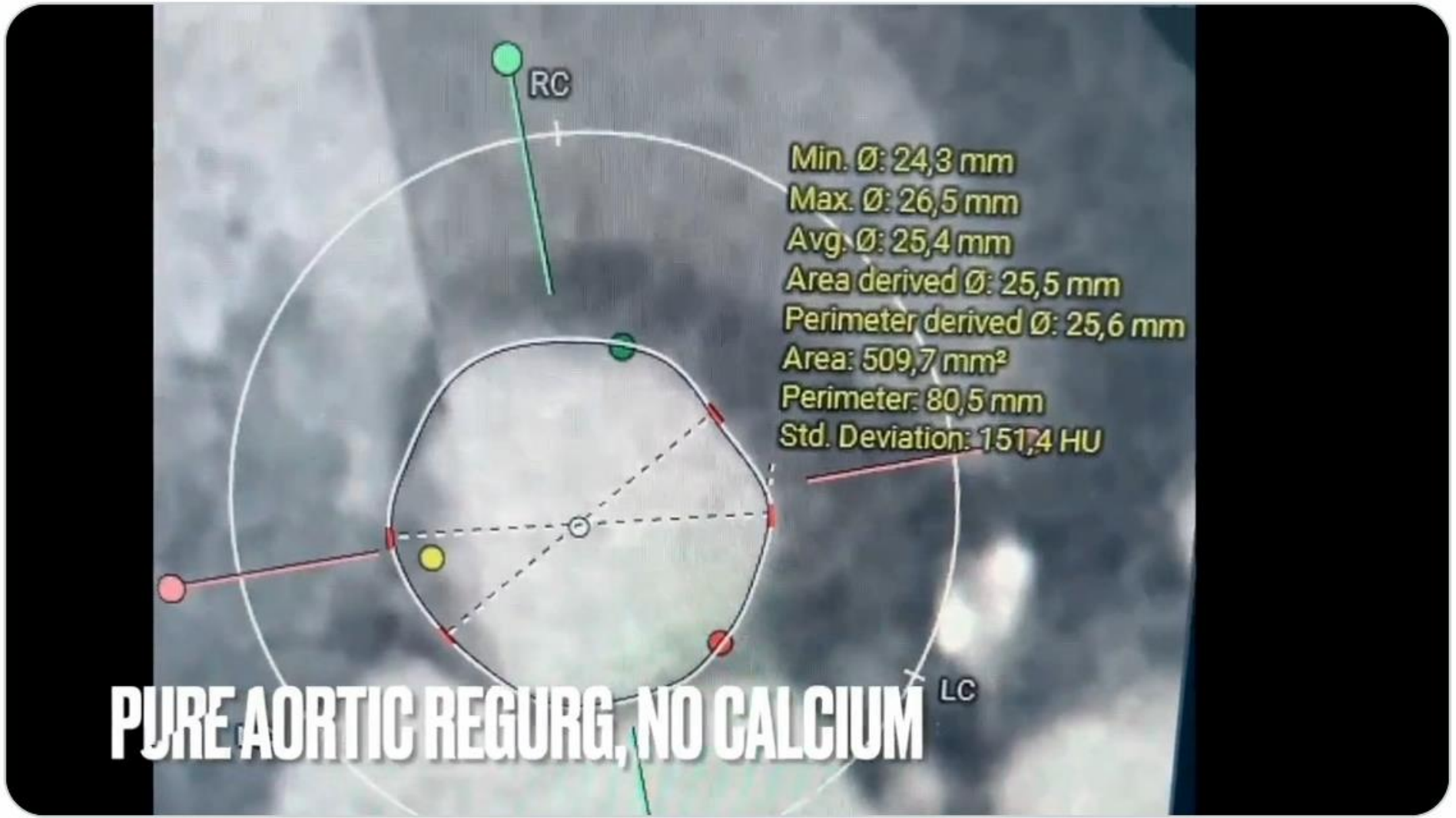
I.J. Amat-Santos, J.P. Sánchez-Luna. Implante de prótesis aórtica trasncatéter en insuficiencia aórtica no calcificada. ¿En qué punto estamos? REC Interv Cardiol. 2024;6(1):3-6

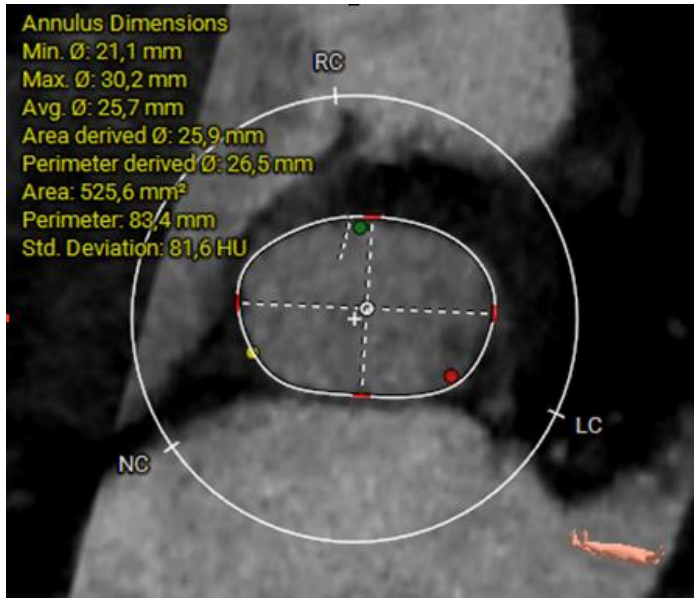


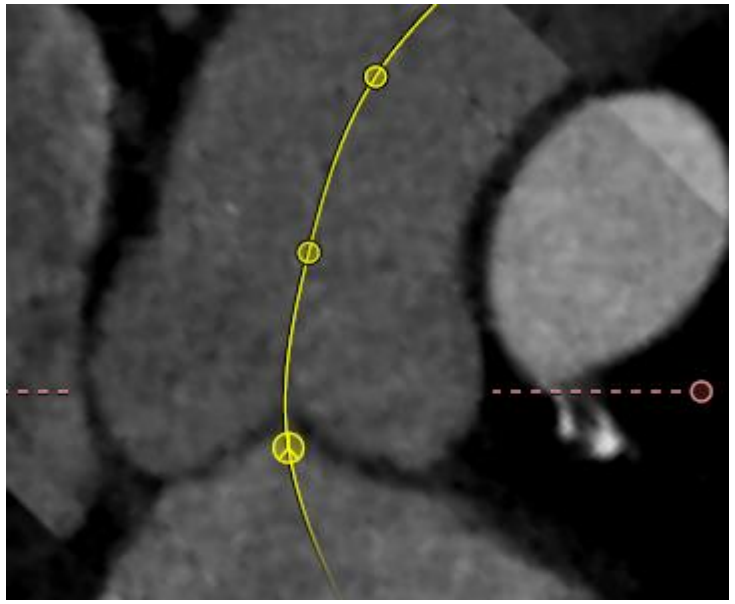


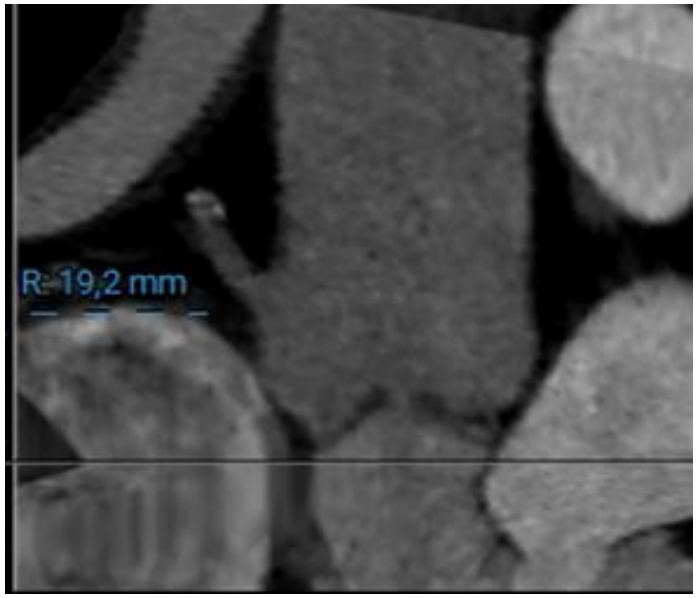


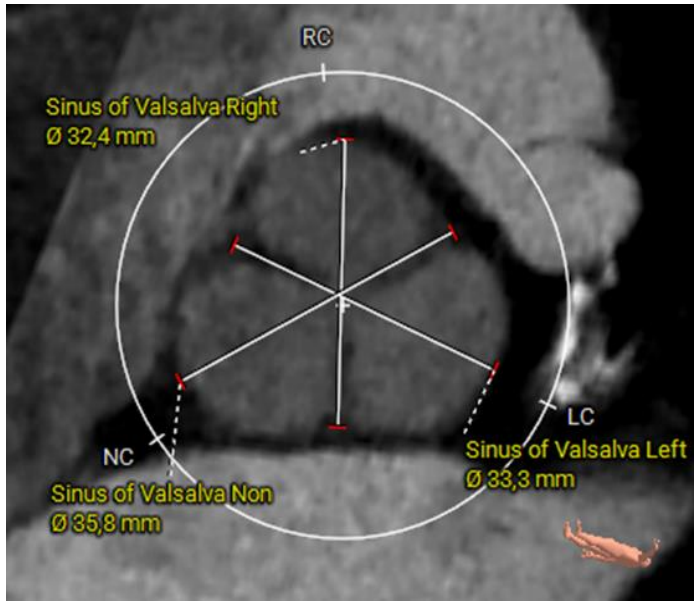


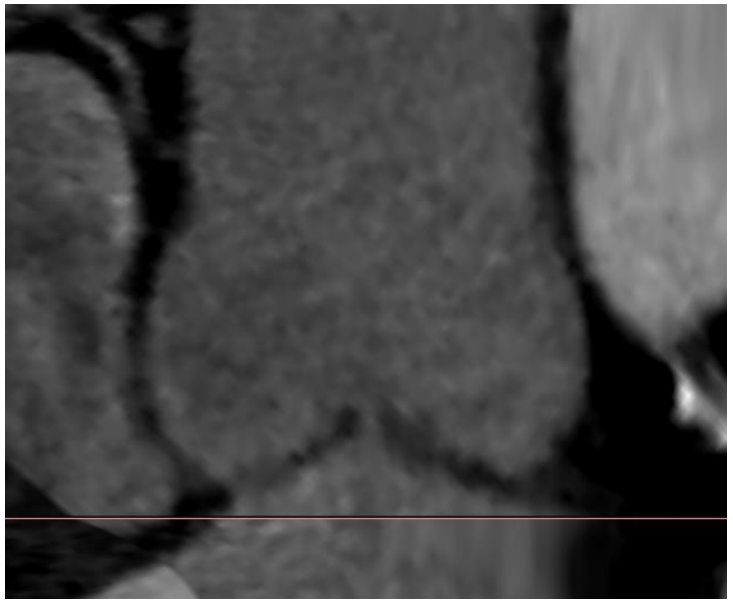

RC
Min. Ø: 24,3 mm
Max. Ø: 26,5 mm
Avg. Ø: 25,4 mm
Area derived Ø: 25,5 mm
Perimeter derived Ø: 25,6 mm
Area: 509,7 mm²
Perimeter: 80,5 mm
Std. Deviation: 151,4 HU
LC
PURE AORTIC REGURG, NO CALCIUM

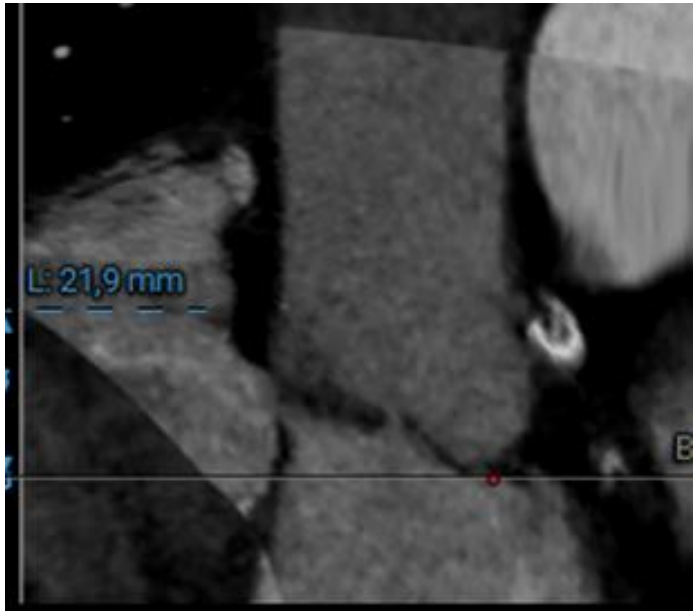

Annulus Dimensions
Min. Ø: 21,1 mm
Max. Ø: 30,2 mm
Avg. Ø: 25,7 mm
Area derived Ø: 25,9 mm
Perimeter derived Ø: 26,5 mm
Area: 525,6 mm²
Perimeter: 83,4 mm
Std. Deviation: 81,6 HU
RC
LC
NC

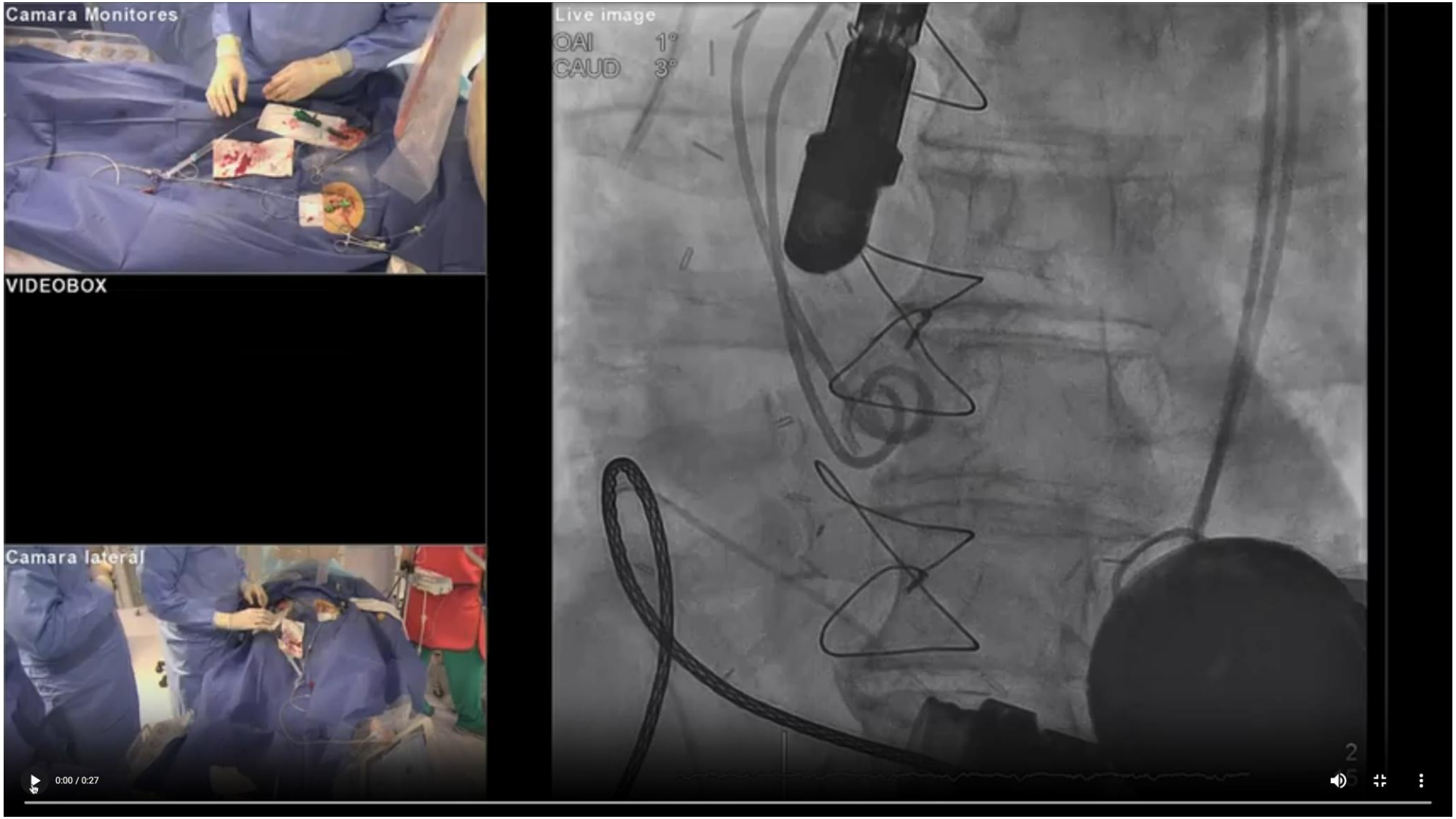


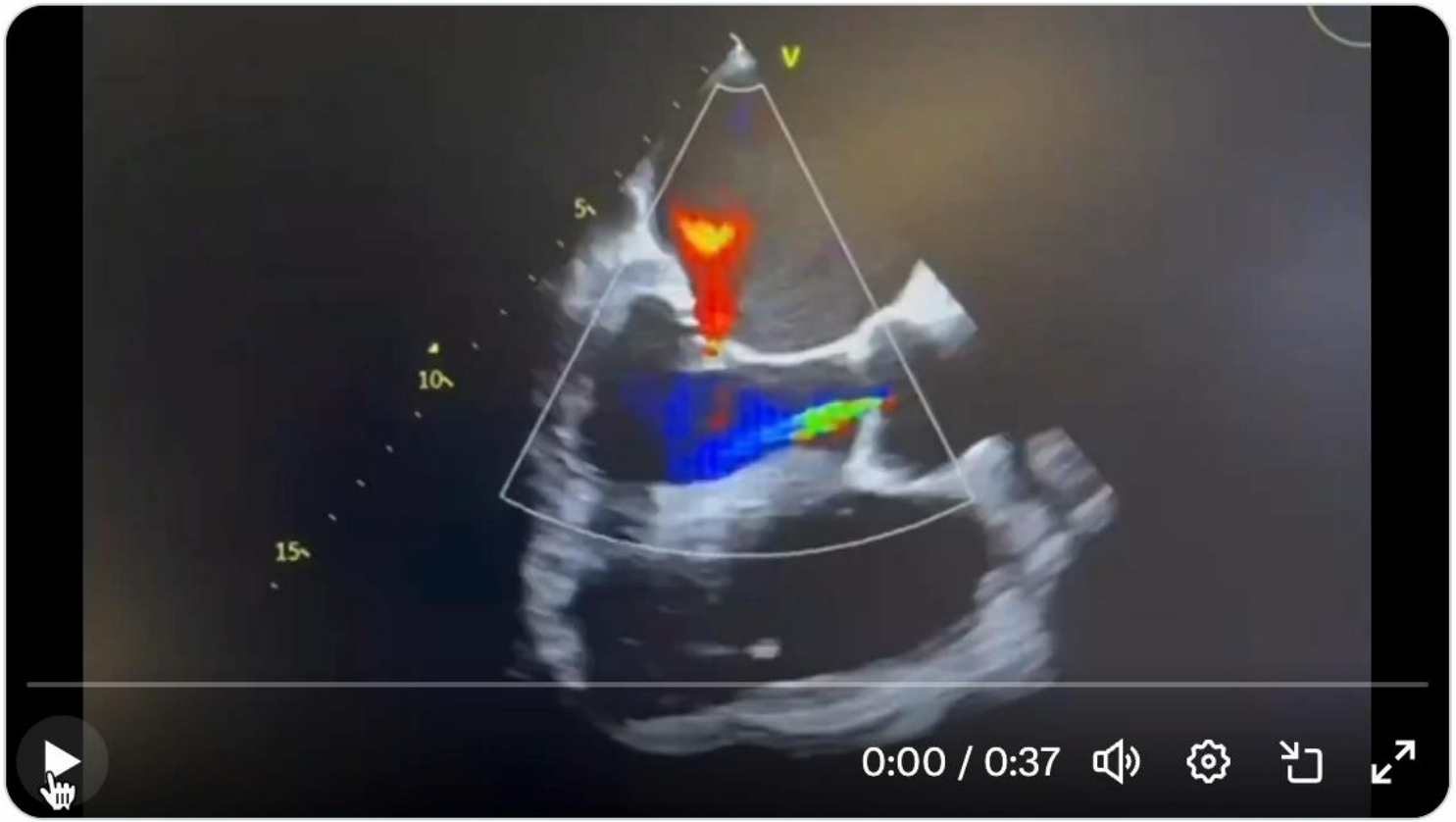

R: 19,2 mm

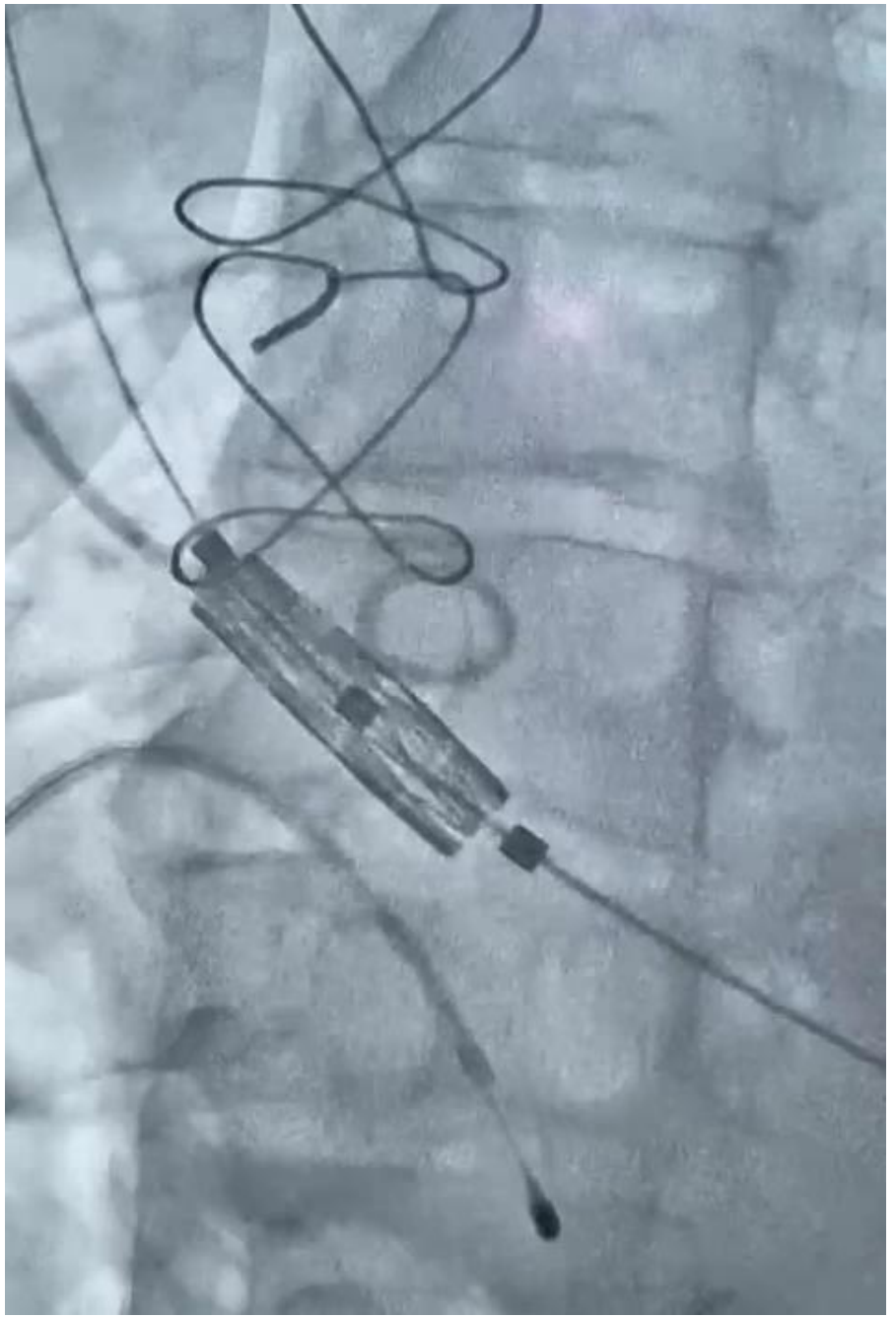

RC
Sinus of Valsalva Right
Ø 32,4 mm
LC
NC
Sinus of Valsalva Left
Ø 33,3 mm
Sinus of Valsalva Non
Ø 35,8 mm

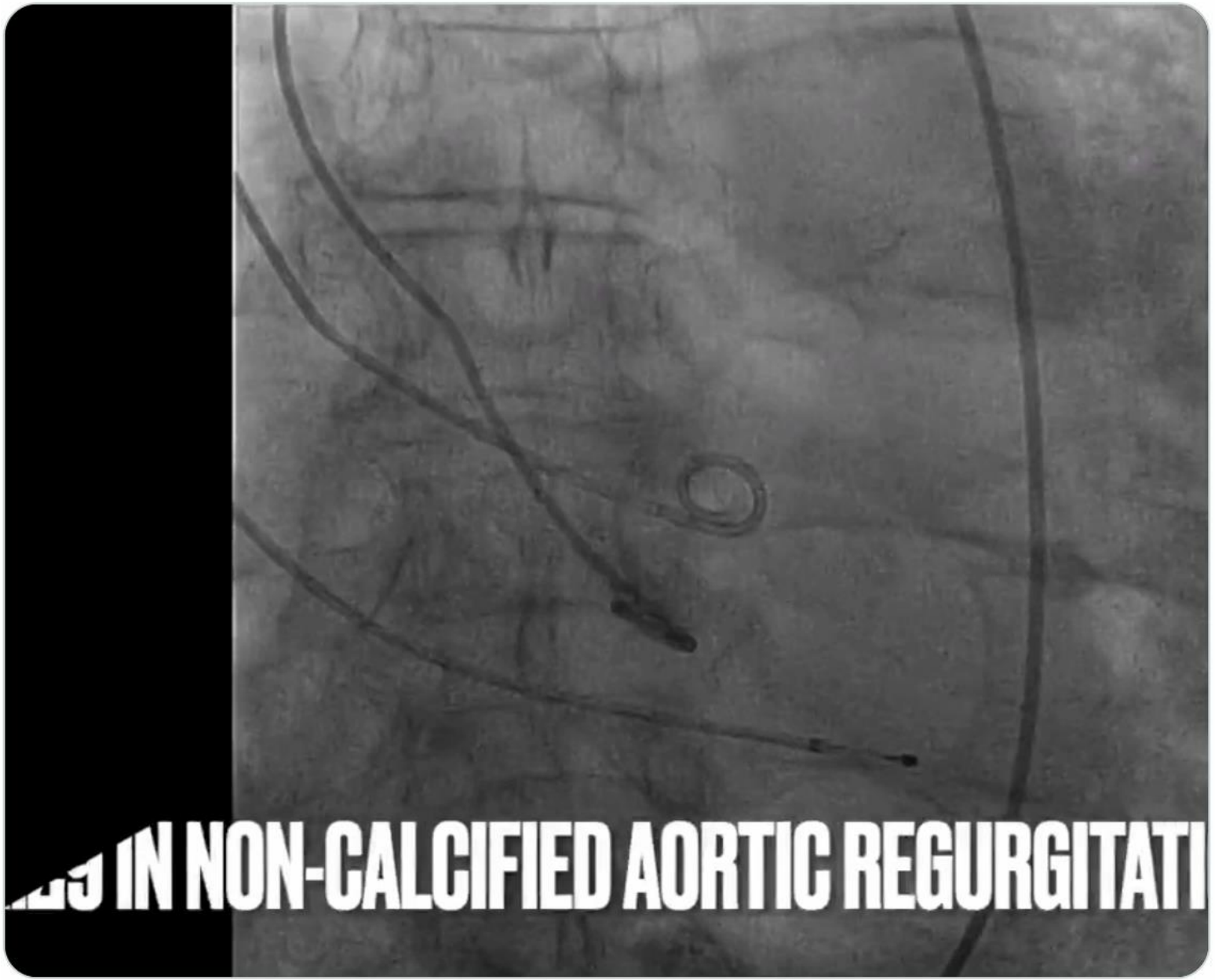



L: 21,9 mm

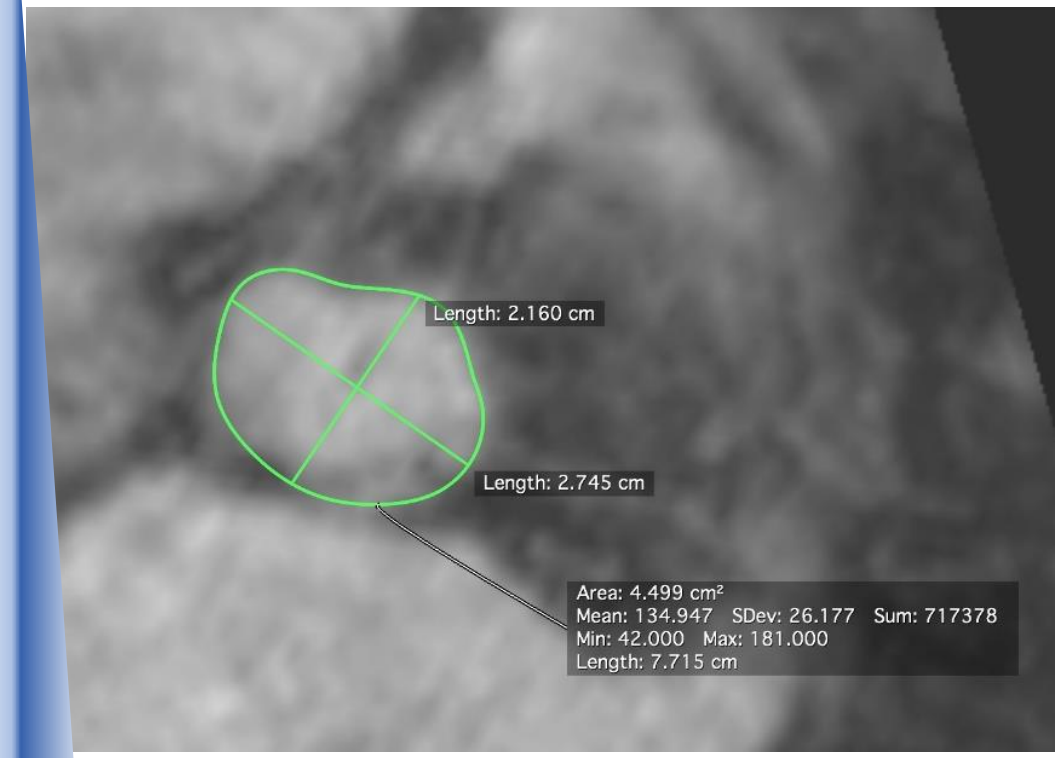

Camara Monitores
VIDEOBOX
Camara lateral
0:00 / 0:27
Live image
OAI 1°
CAUD 3°

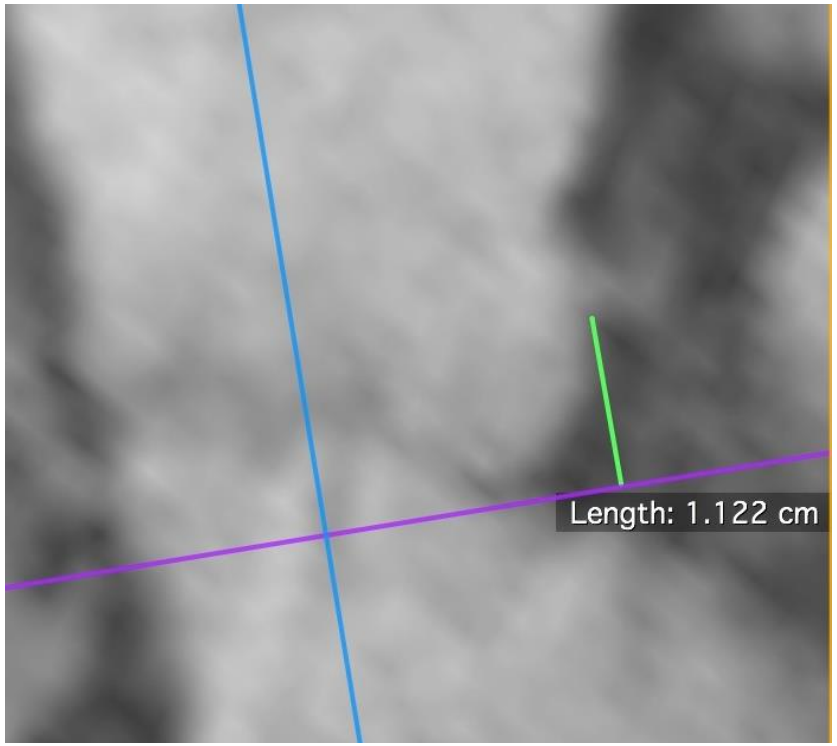

V
5
10
15
0:00 / 0:37



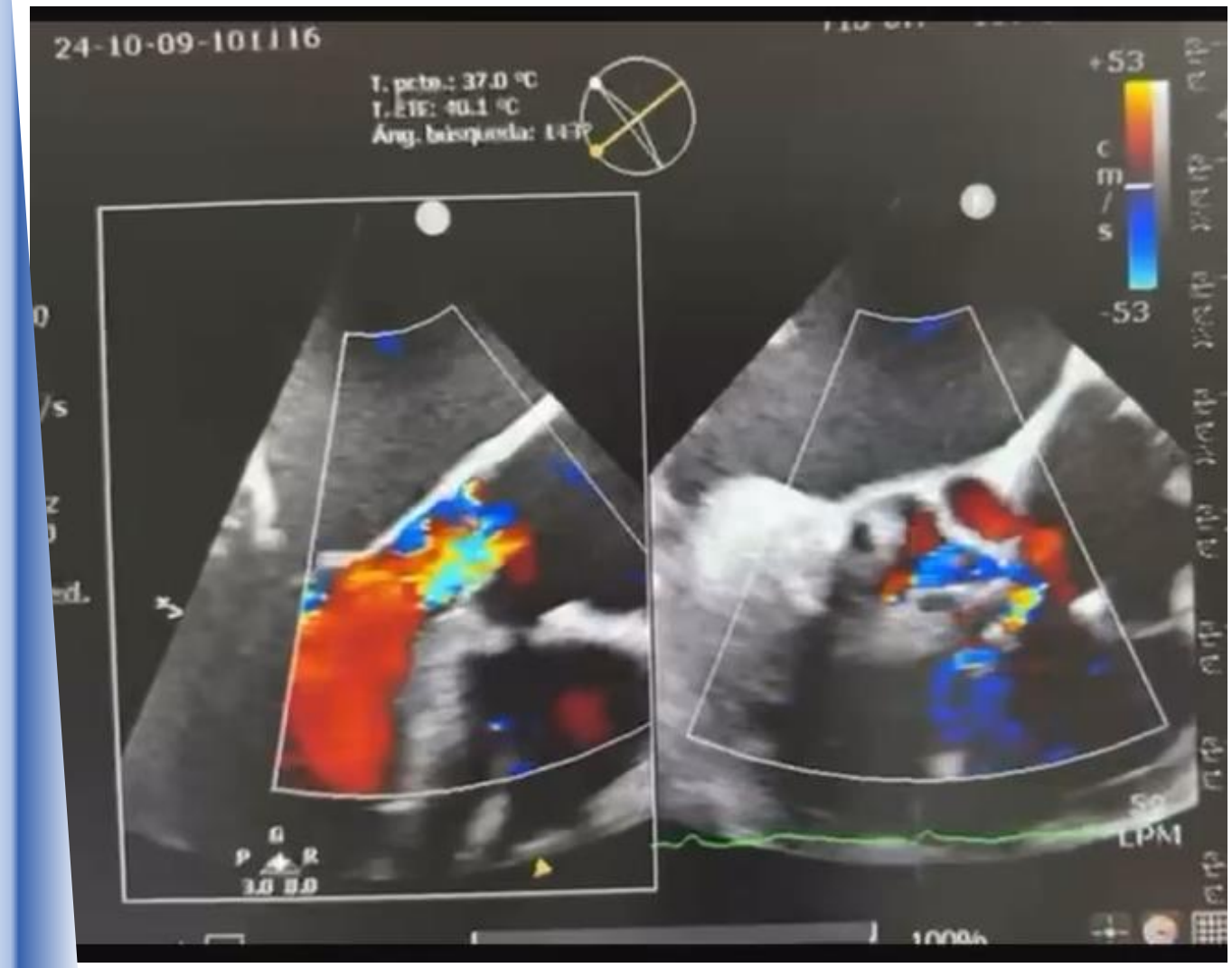

IN NON-CALCIFIED AORTIC REGURGITATI

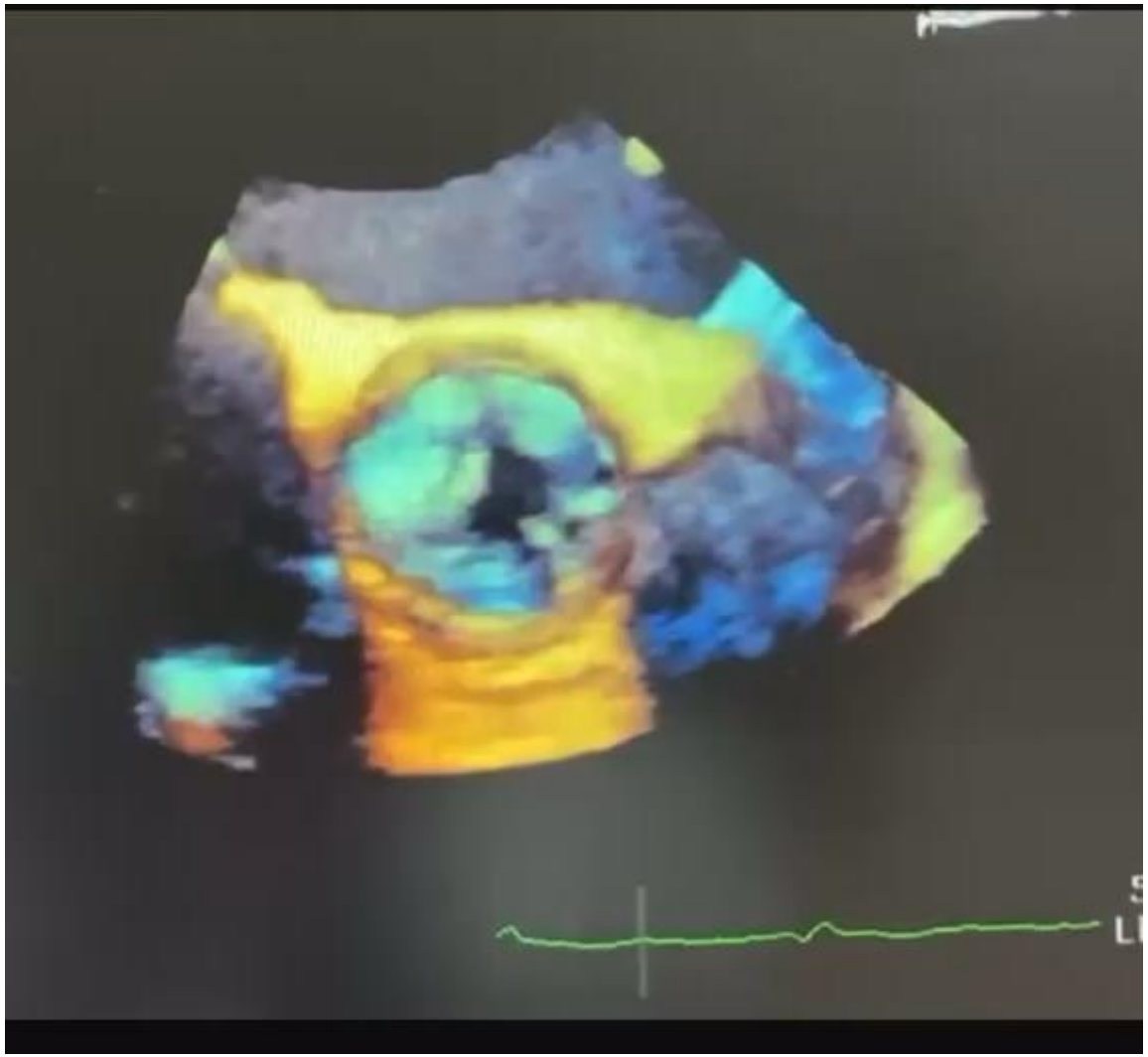
1ER CASO DE INSUFICIENCIA AÓRTICA PURA TRATADO CON OCTACOR EN MÉXICO Y LATINOAMÉRICA


Length: 2.160 cm
Length: 2.745 cm
Area: 4.499 cm²
Mean: 134.947 SDev: 26.177 Sum: 717378
Min: 42.000 Max: 181.000
Length: 7.715 cm

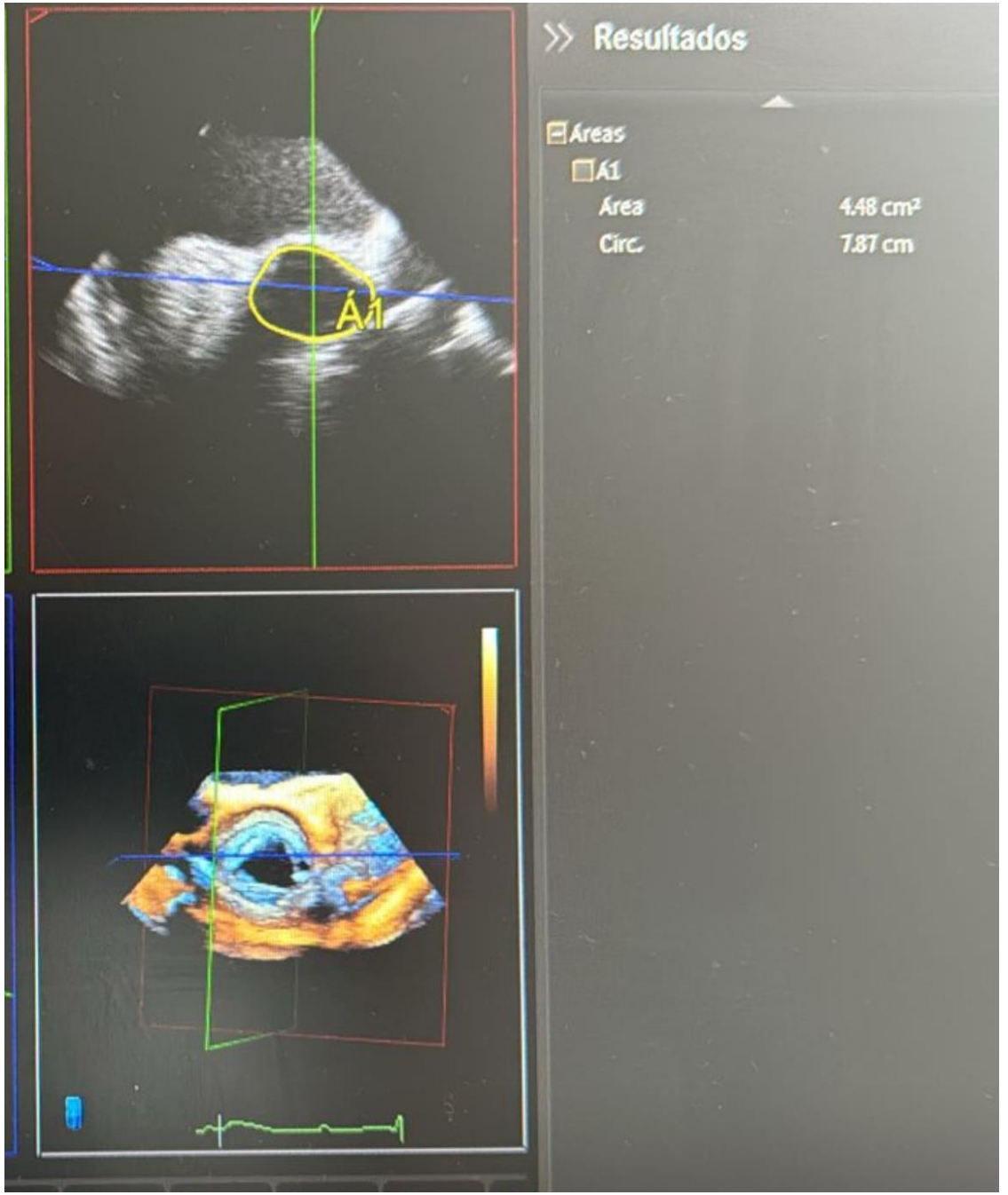

Length: 1.122 cm

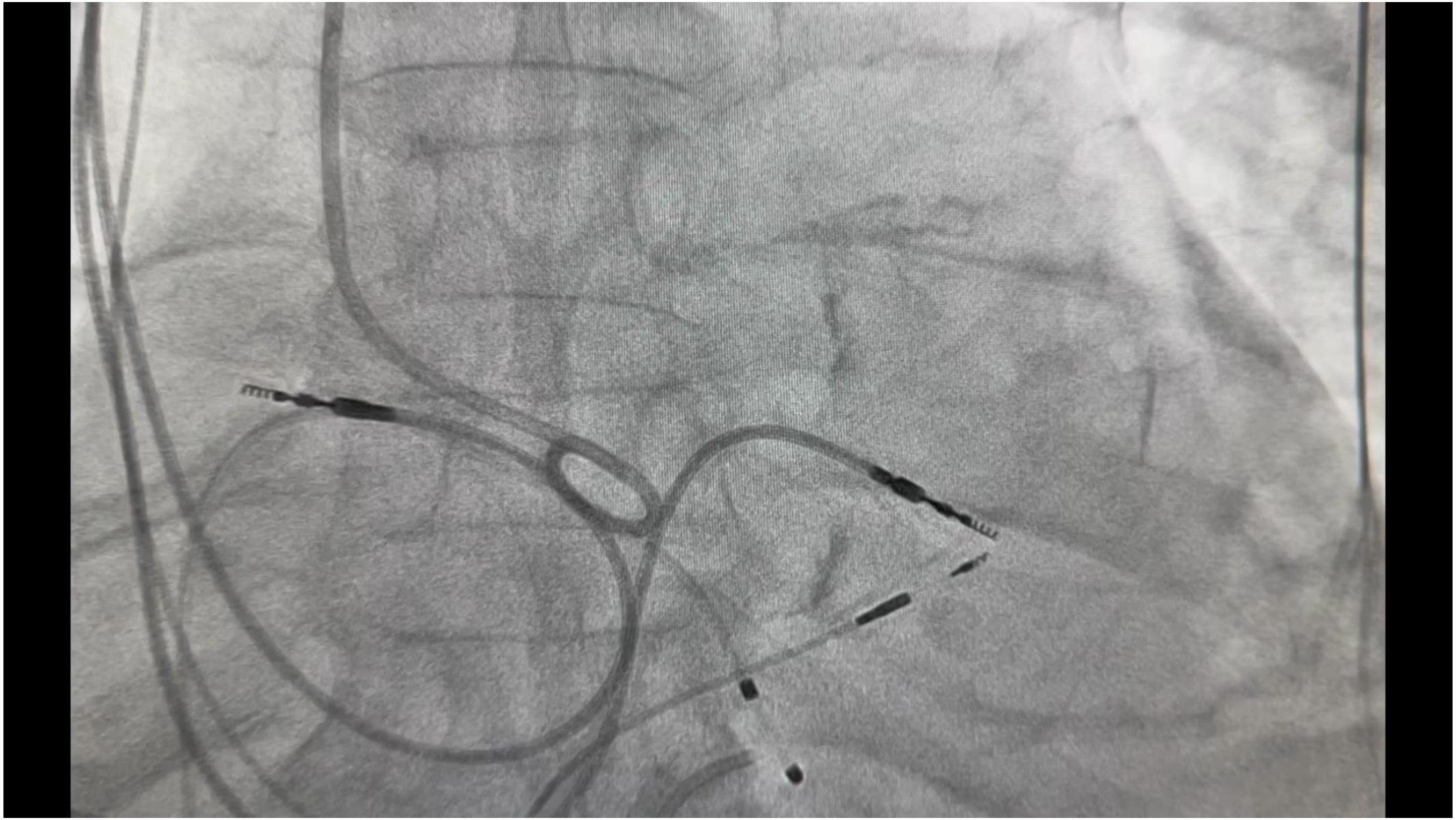

Length: 1.340 cm


24-10-09-101116
+53
cm/s
-53
LPM




nte 24-10-09-101116
Tiempo estudio 9-oct.-2024 10:11:16 a. m.
D3
A3D2
Resultados
Distancias
D1 2.20 cm
D2 2.65 cm
D3 2.17 cm
Áreas
A3
Área 4.67 cm²
Circ. 8.16 cm


Á1
Resultados
Áreas
A1
Área 4.48 cm²
Circ. 7.87 cm




Navigator™
INCEPTION
Transcatheter Heart Valve Delivery System
Meril

MENSAJES FINALES

- En conclusión, aunque el abordaje quirúrgico sigue siendo el tratamiento estándar de pacientes con IANC, los resultados de los dispositivos TAVI de nueva generación (tanto dedicados como no dedicados), han mejorado notablemente.

- Es clave hacer un análisis minucioso del TC y una planeación adecuada.

- Las principales limitaciones son la falta de dispositivos dedicados de gran tamaño y el riesgo de embolización de la válvula con dispositivos no dedicados.

- La tasa de trastornos de la conducción es más alta que en el TAVI en la estenosis aórtica.

¡Gracias!

DR. JUAN PABLO
SÁNCHEZ LUNA
CARDIOLOGÍA CLÍNICA
E INTERVENCIONISTA
INTERVENCIONISMO CORONARIO Y ESTRUCTURAL

dr.jpsanchezluna@gmail.com
cardiologia.guadalajara
jpsanchezluna