ViV TAV in degenerated Trifecta valve Slovenia registry

Optimal treatment strategy

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Disclosure of Relevant Financial Relationships

Speaker's name: Matjaž Bunc

TAVR Proctor:

Edwards Lifesciences,

Medtronic, Meril, Abbott.

Medtronic, Abbott advisory board member

Background

Because of the **externally mounted leaflets** of the Trifecta valve there is potential for increased risk of **coronary obstruction** particularly in patients with a narrow aortic root and low coronary heights.

Performing a ViV-TAVI within a small valve size also has the potential to result in an **elevated post-procedure gradient**, which may be a concern in patients with a Trifecta valve because the titanium frame of the valve cannot be fractured using a balloon.

Arévalos V, Spione F, Vela P, Iacovelli F, Sanchis L, Freixa X, et al. Coronary obstruction following transcatheter aortic valve replacement. Risk evaluation and preventive strate- gies. Revista Española de Cardiologia: Interventional Cardiology. 2024;6:117–26.
Saxon JT, Allen KB, Cohen DJ, Hart A, Dvir D, Chhatriwalla AK. Bioprosthetic valve re- modeling of trifecta surgical valves to facilitate valve-in-valve TAVR. Structural Heart. 2020;4:99–104

Background

Mid-term durability of the Trifecta bioprosthesis for aortic valve replacement

Amedeo Anselmi, MD, PhD, Vito Giovanni Ruggieri, MD, PhD, Bernard Lelong, MD, Erwan Flecher, MD, PhD, Hervé Corbineau, MD, Thierry Langanay, MD, Jean-Philippe Verhoye, MD, PhD, and Alain Leguerrier, MD

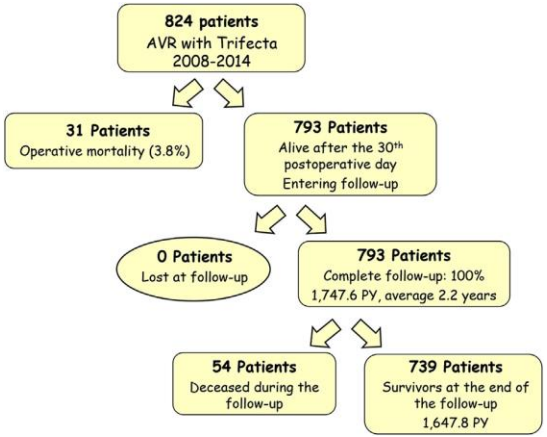


FIGURE 2. Study workflow. Among the 824 patients initially included, 739 (89.7%) were alive at the end of the follow-up. A total of 1747.6 patient/years (*P/Y*) were available. *AVR*, Aortic valve replacement.

Central Message

The Trifecta bioprosthesis is a reliable device for aortic valve replacement. Continued surveillance for SVD events is required.

Perspective

Durability is a pivotal characteristic for modern bioprostheses. In the present mid-term follow-up of 824 implants, the Trifecta valve showed excellent hemodynamic properties and consistent durability. Few SVD events were observed, characterized by peculiar timing, pathophysiology, and clinical presentation. Continued follow-up is required.

Conclusions: The Trifecta bioprosthesis is a reliable device for AVR. We confirm excellent immediate hemodynamic properties and a very low rate of patient–prosthesis mismatch. The absolute number of SVD cases observed remains limited; nevertheless, their timing, pathological characteristics, and clinical presentation mandate continued follow-up. (J Thorac Cardiovasc Surg 2017;153:21-8)

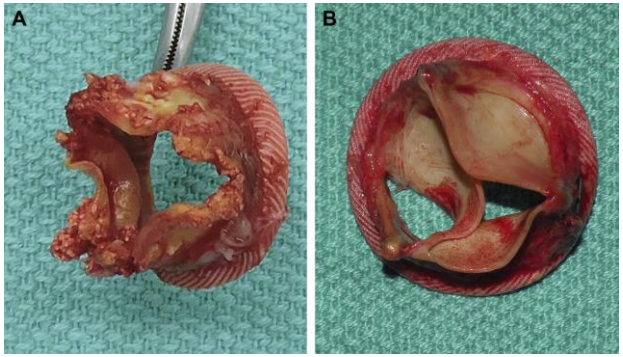
Background

ORIGINAL ARTICLES: ADULT CARDIAC

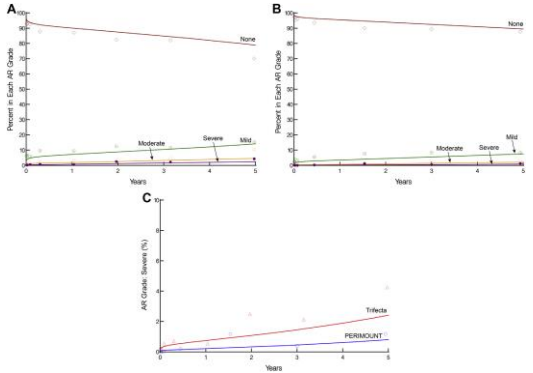
Durability and Performance of 2298 Trifecta Aortic Valve Prostheses: A Propensity-Matched Analysis

Camille Yongue, MD, Diana C. Lopez, BS, Edward G. Soltesz, MD, MPH, Eric E. Roselli, MD, Faisal G. Bakaeen, MD, A. Marc Gillinov, MD, Gösta B. Pettersson, MD, PhD, Marie E. Semple, MPH, Jeevanantham Rajeswaran, PhD, Michael Z. Tong, MD, MBA, Wael Jaber, MD, Eugene H. Blackstone, MD, Lars G. Svensson, MD, PhD, and Douglas R. Johnston, MD

Case Western Reserve University School of Medicine, Cleveland, Ohio; Cleveland Clinic Lerner College of Medicine, Cleveland, Ohio; Department of Thoracic and Cardiovascular Surgery, Heart, Vascular, and Thoracic Institute, Cleveland Clinic, Cleveland, Ohio; Aorta Center, Heart, Vascular, and Thoracic Institute, Cleveland Clinic, Cleveland, Ohio; Department of Quantitative Health Sciences, Lerner Research Institute, Cleveland Clinic, Cleveland, Ohio; and Department of Cardiovascular Medicine, Heart, Vascular, and Thoracic Institute, Cleveland Clinic, Cleveland, Ohio

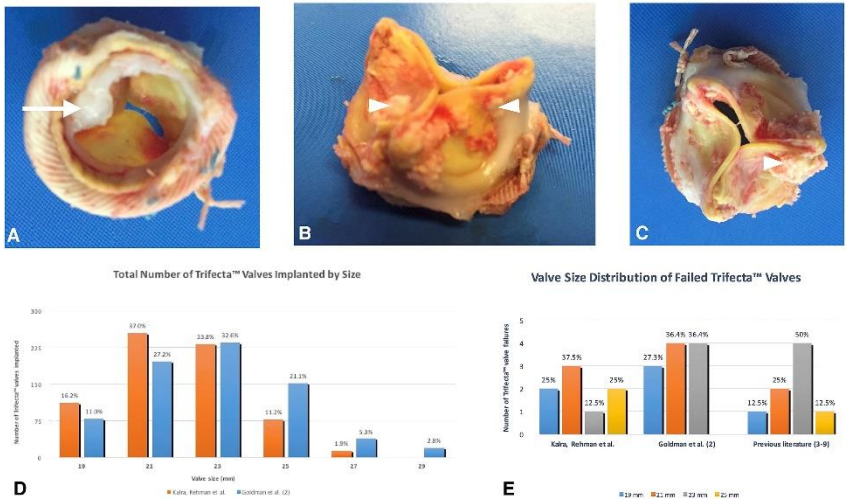


Background. Reports of early failure of the Trifecta externally wrapped, bovine pericardial aortic valve prosthesis (Abbott Laboratories, Abbott Park, IL) raise concerns about its durability. This study evaluated the hemodynamic performance and explant of Trifecta valves compared with the PERIMOUNT bovine pericardial prosthesis (Edwards Lifesciences, Irvine, CA).



Conclusions. Compared with an older-generation internally mounted bovine pericardial valve, the Trifecta externally wrapped bioprosthesis exhibits superior early hemodynamic performance, but has a rapid increase in transvalvular gradient and more aortic regurgitation, with lower freedom from explant at 5 years. These findings raise concern regarding long-term Trifecta durability despite favorable early hemodynamics.

(Ann Thorac Surg 2021;111:1198-206)



News ***Daily News***

Abbott to Stop Making Trifecta Surgical Aortic Valves

Red flags emerged last February when the FDA warned of early structural deterioration with the Trifecta family of valves.

By Michael O'Riordan

July 31, 2023.

The Journal of Thoracic and Cardiovascular Surgery
Volume 154, Number 4, Oct 2017.

Conclusions: Our findings provide further insights into the pathologic mechanisms leading to early Trifecta valve failure. In addition to tear of the noncoronary cusp of the Trifecta prosthesis described as the most common mechanism in the literature for its failure, circumferential pannus formation composed of fibrofatty tissue in the inflow portion and leaflet calcification concentrated around the posts in the outflow portion are important mechanisms contributing toward early Trifecta valve failure. (J Thorac Cardiovasc Surg 2017;154:1235-40)

Cardiovascular Revascularization Medicine 77 (2025) 75–82

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Real-world outcomes and management considerations following surgical aortic valve replacement with the Trifecta valve

Dan Gutfinger [a,*], Ibrahim Sultan [b], Gorav Ailawadi [c], Danny Ramzy [d], Tsuyoshi Kaneko [e], Yang Yu [a], Geetanjali Meka [a], Julie B. Prillinger [a], Joseph E. Bavaria [f]

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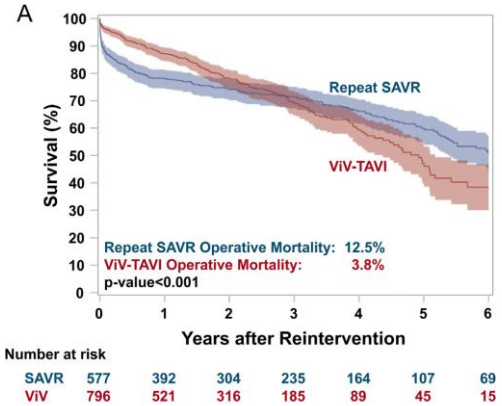
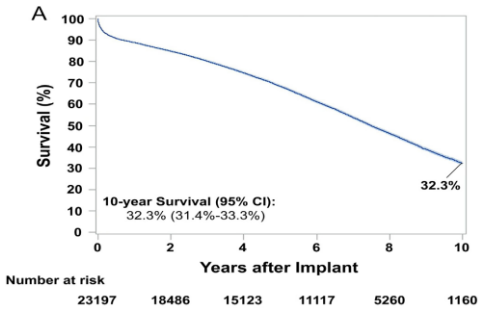
[e] Division of Cardiothoracic Surgery, Washington University School of Medicine, St Louis, MO, United States of America
[f] Division of Cardiovascular Surgery, Thomas Jefferson University Hospitals, Philadelphia, PA, United States of America





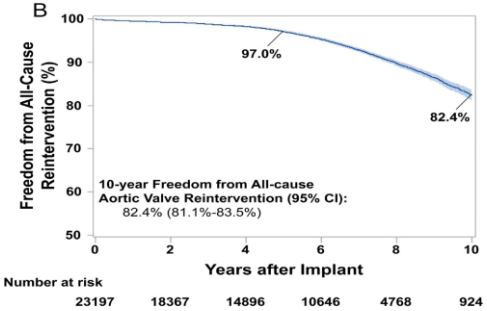


Fig. 1. (A) Kaplan-Meier 10-year survival following SAVR with Trifecta valve. (B) Kaplan-Meier 10-year freedom from all-cause reintervention for Trifecta valve (reintervention includes repeat surgical aortic valve replacement or a valve-in-valve transcatheter aortic valve implantation).
SAVR, surgical aortic valve replacement; *CI*, confidence interval.

Conclusion: This real-world nationwide study of Medicare beneficiaries receiving the Trifecta valve demonstrates >80 % freedom from all-cause valve reintervention at 10-years post-implant with reintervention using ViV-TAVI having improved operative survival compared to repeat SAVR.

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Higher operative mortality following reintervention with repeat SAVR compared to a ViV-TAVI (12.5 % versus 3.8 %, p < 0.001).

In both treatment options the freedom from repeat reintervention was >90 % at 6-years following reintervention.

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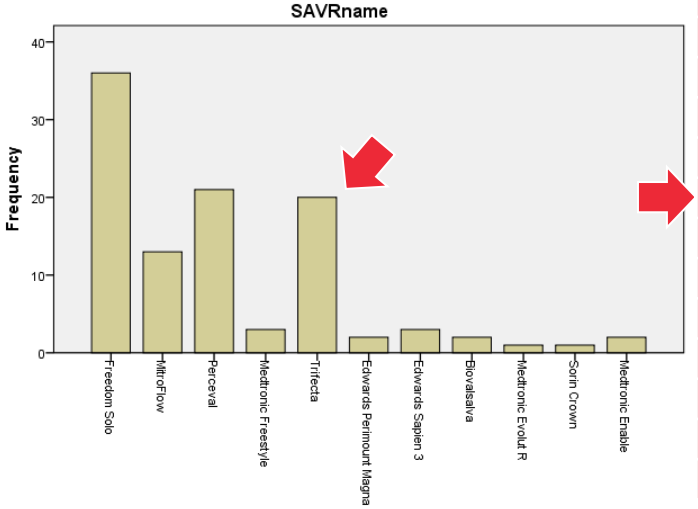
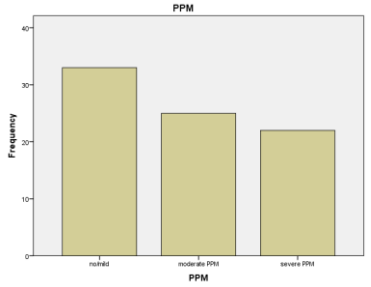
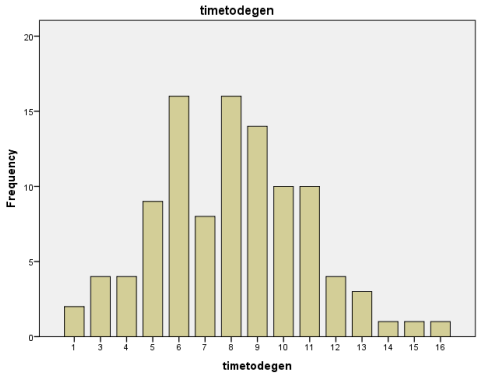


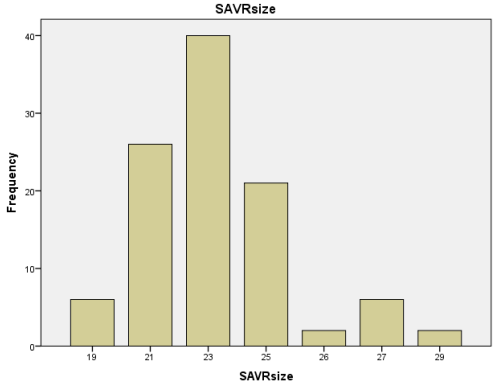
	number	%
Freedom Solo	36	34,6
MitroFlow	13	12,5
Perceval	21	20,2
Medtronic Freestyle	3	2,9
Trifecta	19	18.4
Edwards PMagna	2	1,9
Edwards Sapien 3	3	2,9
Biovalsalva	2	1,9
Medtronic Evolut R	1	1,0
Sorin Crown	1	1,0
Medtronic Enable	2	1,9
Total	103	100,0

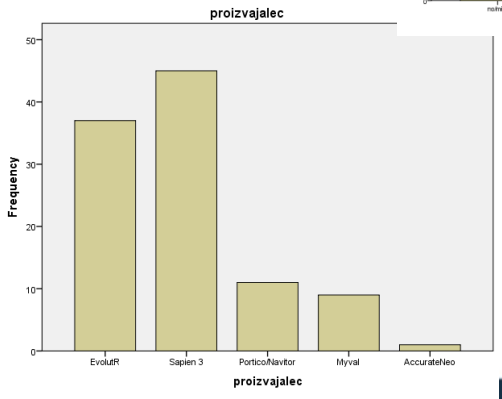
az_vmax	4,1791
avmax_after	2,539
az_grad_mean	45,59
avmean_after	15,27

no/mild	33
moderate PPM	25
severe PPM	22









	Overall	Supra-annular (N=14)	Intra-annular (N=5)	p-value	BVR (N=10)	No BVR (N=9)	p-value
Age (years)	76.3 ± 6.8	75.2 ± 7.1	79.4 ± 5.4	0.246	72.3 ± 3.8	80.8 ± 6.7	**0.003**
Sex (male)	47.4%	50.0%	40.0%	1.000	50.0%	44.4%	1.000
Height (cm)	166 ± 10	168 ± 10	160 ± 8	0.146	168 ± 9	164 ± 11	0.465
Weight (kg)	73.9 ± 14.2	75.1 ± 14.4	70.6 ± 14.8	0.555	79.0 (70.8-88.8)	65.0 (58.0-71.0)	0.348
BMI (kg/m^2)	26.8 ± 4.4	26.6 ± 4.3	27.4 ± 4.9	0.720	27.5 ± 4.4	26.0 ± 4.5	0.460
BSA (m^2)	1.8 ± 0.2	1.9 (1.7-2.0)	1.6 (1.6-1.8)	0.400	1.9 ± 0.2	1.8 ± 0.2	0.422
Euroscore II (%)	8.0 (5.8-12.8)	7.2 (5.8-12.1)	9.6 (8.0-13.2)	0.622	6.9 (5.3-10.4)	11.5 (7.2-13.2)	0.211
STS-score (%)	5.6 (3.4-10.2)	5.0 (3.2-6.5)	11.0 (4.8-11.7)	0.343	5.5 ± 3.8	8.3 ± 5.4	0.200
AH (%)	78.9	78.6	80.0	1.000	70.0	88.9	0.582
DM (%)	26.3	28.6	20.0	1.000	30.0	22.2	1.000
CPD (%)	5.3	7.1	0.0	1.000	10.0	0.0	1.000
CKD (%)	36.8	35.7	40.0	1.000	30.0	44.4	0.650
CAD (%)	36.8	35.7	40.0	1.000	40.0	33.3	1.000
HLP (%)	31.6	28.6	40.0	1.000	30.0	33.3	1.000
PAD (%)	5.3	0.0	20.0	0.263	0.0	11.1	0.474
RBBB (%)	5.3	0.0	20.0	0.263	10.0	0.0	1.000
LBBB (%)	10.5	14.3	0.0	1.000	10.0	11.1	1.000
Electrosystolic rhythm (%)	10.5	14.3	0.0	1.000	10.0	11.1	1.000
Annular perimeter (mm)	66.0 ± 7.3	63.5 ± 7.8	70.6 ± 3.2	0.079	68.2 ± 7.2	63.8 ± 7.3	0.278
Annular area (mm^2)	313 ± 58	281 ± 46	370 ± 20	**0.001**	321 ± 50	305 ± 69	0.626
Vmax (m/s)	3.8 ± 1.0	4.0 ± 0.8	3.2 ± 1.2	0.141	3.9 ± 0.9	3.7 ± 1.1	0.599
Mean gradient (mmHg)	38.1 ± 17.3	41.9 ± 16.6	27.6 ± 16.6	0.117	40.2 ± 17.0	35.8 ± 18.5	0.594
EOA (cm^2)	0.7 (0.6-1.2)	0.7 (0.6-1.0)	0.8 (0.6-1.5)	0.632	0.7 (0.6-0.9)	0.8 (0.6-1.5)	0.808
Severe AR (%)	42.1	42.9	40.0	1.000	50.0	33.3	0.650

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TRIFECTA

Abbreviations: AH – arterial hypertension, AR – aortic regurgitation, BMI – body mass index, BSA – body surface area, BVR – balloon valve remodeling, CAD – coronary artery disease, CKD – chronic kidney disease, CPD – chronic pulmonary disease, DM – diabetes mellitus, EOA – effective orifice area, HLP – hyperlipidemia, LBBB – left bundle branch block, N – number, PAD – peripheral artery disease, RBBB – right bundle branch block, STS – Society of Thoracic Surgeons, Vmax – maximal aortic bioprosthetic valve velocity

Table 1: Baseline patient characteristics

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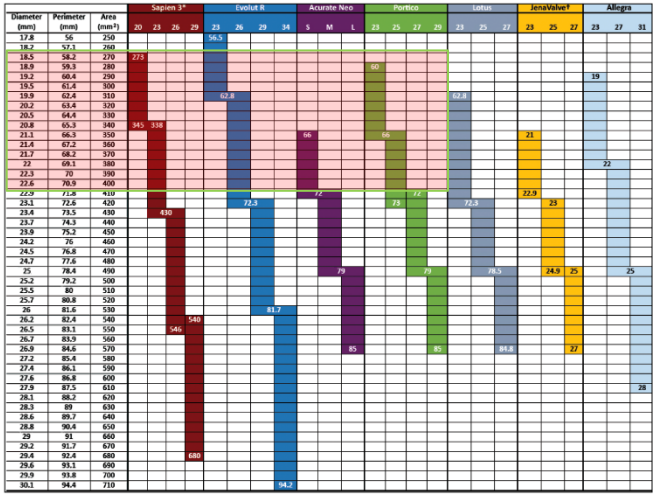
TRIFECTA

	Overall	Supra-annular (N=14)	Intra-annular (N=5)	p-value	BVR (N=10)	No BVR (N=9)	p-value
Annular perimeter (mm)	66.0 ± 7.3	63.5 ± 7.8	70.6 ± 3.2	0.079	68.2 ± 7.2	63.8 ± 7.3	0.278
Annular area (mm^2)	313 ± 58	281 ± 46	370 ± 20	0.001	321 ± 50	305 ± 69	0.626
Vmax (m/s)	3.8 ± 1.0	4.0 ± 0.8	3.2 ± 1.2	0.141	3.9 ± 0.9	3.7 ± 1.1	0.599
Mean gradient (mmHg)	38.1 ± 17.3	41.9 ± 16.6	27.6 ± 16.6	0.117	40.2 ± 17.0	35.8 ± 18.5	0.594
EOA (cm^2)	0.7 (0.6-1.2)	0.7 (0.6-1.0)	0.8 (0.6-1.5)	0.632	0.7 (0.6-0.9)	0.8 (0.6-1.5)	0.808
Severe AR (%)	42.1	42.9	40.0	1.000	50.0	33.3	0.650



EvolutR	15
Sapien 3	3
Portico/Navitor	1
Total	19

Trifecta	
19 mm	6
21 mm	10
23-27 mm	3
Total	19

	PPM			Total
	no/mild	moderate PPM	severe PPM	
EvolutR	5	7	3	15
Sapien 3	0	2	1	3
Total	5	9	4	18

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	Overall	Supra-annular (N=14)	Intra-annular (N=5)	p-value	BVR (N=10)	No BVR (N=9)	p-value
Peri-procedural mortality (%)	0.0	0.0	0.0	NA	0.0	0.0	NA
In-hospital mortality (%)	0.0	0.0	0.0	NA	0.0	0.0	NA
30-day survival (%)	100.0	100.0	100.0	NA	100.0	100.0	NA
Vmax (m/s)	2.2 ± 0.4	2.1 ± 0.3	2.6 ± 0.4	**0.016**	2.3 ± 0.4	2.0 ± 0.4	0.142
Mean gradient (mmHg)	11.4 ± 4.0	10.2 ± 3.4	15.5 ± 3.7	**0.015**	12.0 ± 4.2	10.6 ± 4.0	0.489
DVI	0.44 ± 0.11	0.46 ± 0.12	0.37 ± 0.08	0.190	0.45 ± 0.06	0.43 ± 0.16	0.713
More than mild PVR (%)	0.0	0.0	0.0	NA	0.0	0.0	NA

Abbreviations: BVR – balloon valve remodeling, DVI – Doppler velocity index, N – number, NA – not applicable, PVR – paravalvular regurgitation, Vmax – maximal trans-prosthetic valve velocity.

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- **There were no cardiac complications, no cases of coronary obstruction, major or life-threatening bleeding, or acute kidney injury.**
- **Implantation of a new permanent pacemaker was not required in any patient.**
- **One patient (5.3%) had access site complications, and two patients (10.5%) had ischemic stroke.**

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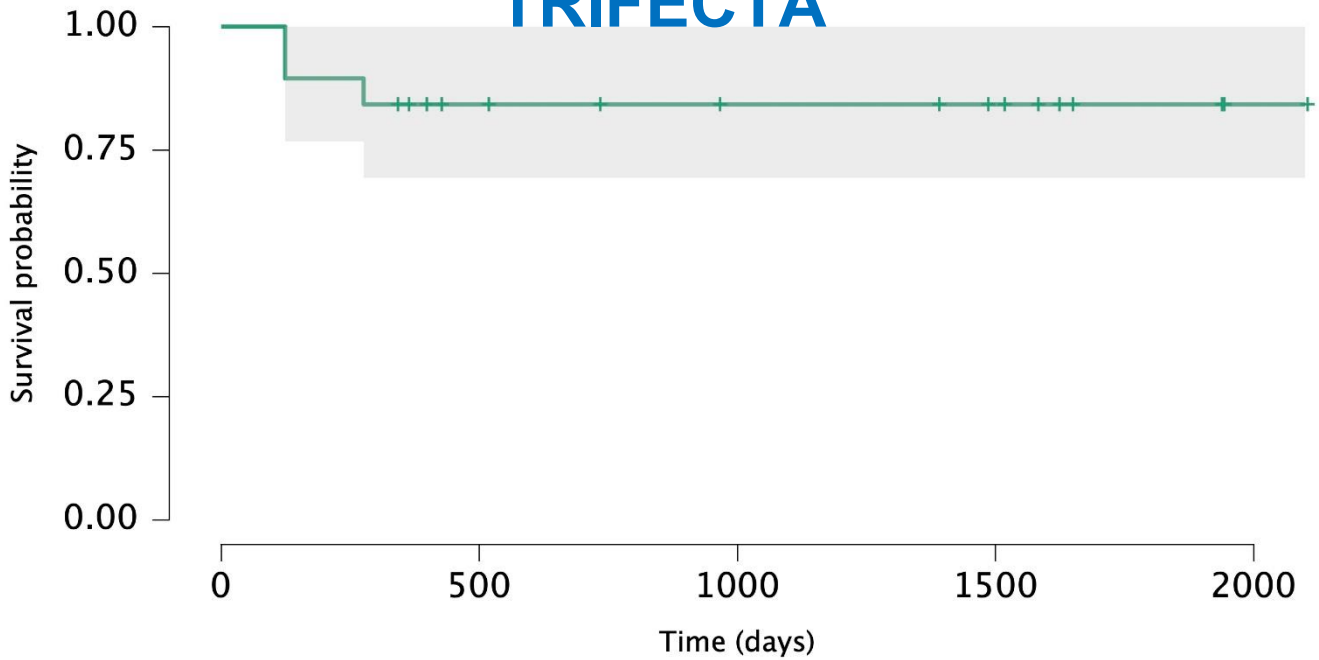

Figure 1: Kaplan-Meier curve for overall survival following valve-in-valve transcatheter aortic valve replacement for failed Trifecta valves. The estimated 12-month survival probability was 84.2%, with a 95% confidence interval of 69.3-100% (represented by the gray shaded area).

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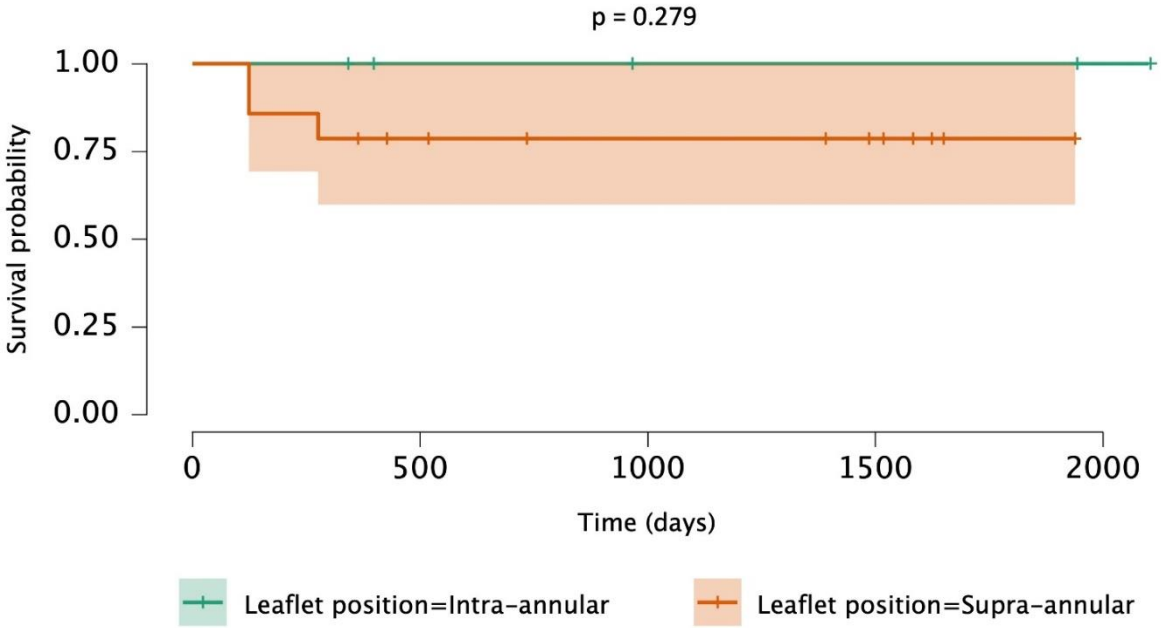
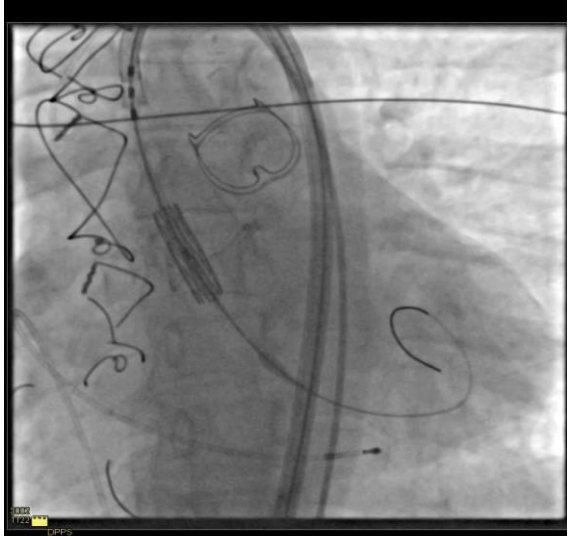
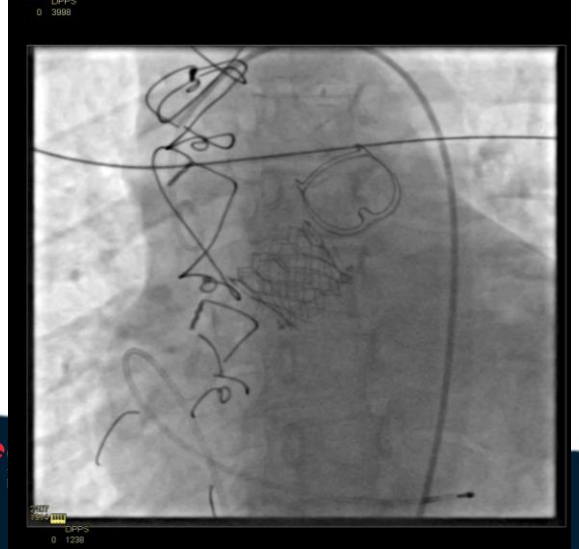
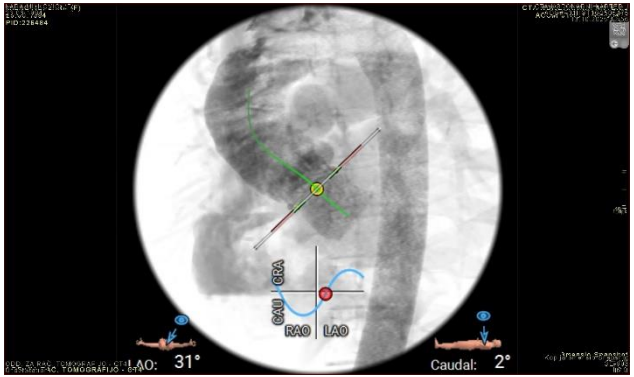


Figure 2: Kaplan-Meier survival curves following valve-in-valve transcatheter aortic valve replacement for failed Trifecta valves with respect to valve type. Differences in survival were assessed with the log-rank test and were not statistically significant (p=0.279). The shaded area represents the 95% confidence interval.

Case viv in very young patients (31 yw)







Trifecta 27 mm
Edw Resilia 26 mm

	Before viv	After viv 6/10/25
Vmax m/s	4.5	2.2
LVEF %	58	62
Mean grad mmHg	58	11
CV pressure mmHg	29 +CVP	21+CVP

Session: TAVR-in-SAVR - II

TCT-710

Valve-in-Valve Transcatheter Aortic Valve Replacement in Failed Trifecta Bioprosthetic Aortic Valve

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[1]Cleveland Clinic Foundation, Cleveland Heights, Ohio, USA; [2]Cleveland Clinic Foundation, Cleveland, Ohio, USA; [3]Cleveland Clinic, Cleveland, Ohio, USA; [4]Cleveland Clinic Akron General, Akron, Ohio, USA; [5]Cleveland Clinic Foundation, Shaker Heights, Ohio, USA

METHODS A retrospective cohort study was conducted at the Cleveland Clinic, including patients who underwent a ViV TAVR intervention caused by failing Trifecta surgical aortic valve replacements (SAVRs) between January 1, 2013, and July 7th, 2023. Data on patient demographics, procedures, and clinical outcomes were collected.

RESULTS A total of 78 patients who underwent ViV TAVR for failing Trifecta bioprosthesis were included (73 Trifecta and 5 Trifecta GT valves). The median age was 73 years (IQR: 69-80 years), 38.4% were women, and the mean STS risk score was 4.77 ± 0.64. The majority of the patients had a 21-mm (27 patients, 34.6%) or a 23-mm (25 patients, 32.1%) degenerated Trifecta valve. The median time to ViV TAVR was 75.71 months (IQR: 67.11-92.44 months). The most common indication for ViV TAVR was prosthetic aortic stenosis (46 cases, 59%). Transfemoral access was utilized in most cases (96.2%), with a balloon-expandable valve (Sapien 3 or Sapien 3 Ultra) being the preferred choice (80.8%). TAVR valve size most frequently used was 23 mm (56.4%), with balloon postdilation performed in 74.7% of cases. The mean transvalvular aortic valve gradient at discharge was 14.81 ± 0.9 mm Hg. Notably, patients with an SAVR internal diameter ≤21 mm had a higher postprocedural mean aortic valve gradient compared with the other group (16.07 ± 1.10 vs 12.01 ± 6.89; P = 0.035). There were no instances of 30-day mortality, and 30-day heart failure admissions occurred in 3.8% of patients.

CONCLUSION This study, the largest to date on ViV TAVR interventions in patients with failing Trifecta SAVRs, demonstrated satisfactory short-term outcomes with no 30-day mortality and a low rate of heart failure admissions. Further research is warranted to assess the long-term durability and clinical implications of ViV TAVR for degenerated Trifecta valves.

Conclusion

- **ViV treatment TAV in bio-AVR is part of lifetime management of aortic stenosis.**

- **ViV TAVR for failed Trifecta bioprosthetic aortic valves was associated with excellent short-term and acceptable 12-month survival, favorable hemodynamics, and low complication rates except for ischemic stroke.**

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ORIGINAL RESEARCH

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Bioprosthetic Valve Remodeling of Trifecta Surgical Valves to Facilitate Valve-in-Valve TAVR

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Conclusion: BVR distorts the frame of Trifecta valves, improving THV expansion and procedural hemodynamics of VIV TAVR.

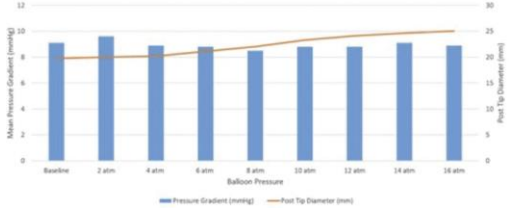
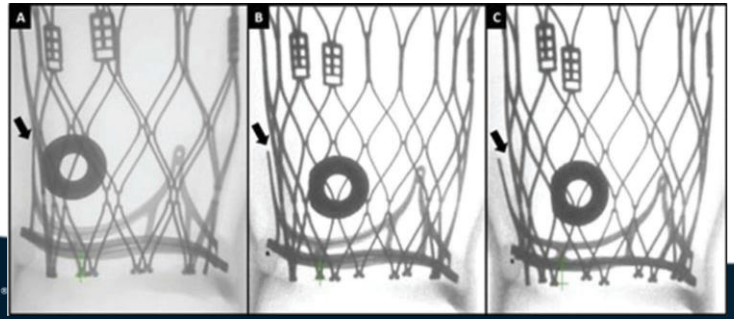


Figure 2. Effect of BVR on a 23 mm Portico THV implanted in a 21 mm Trifecta GT valve. BVR = bioprosthetic valve remodeling; THV = transcatheter heart valve; atm = atmospheres



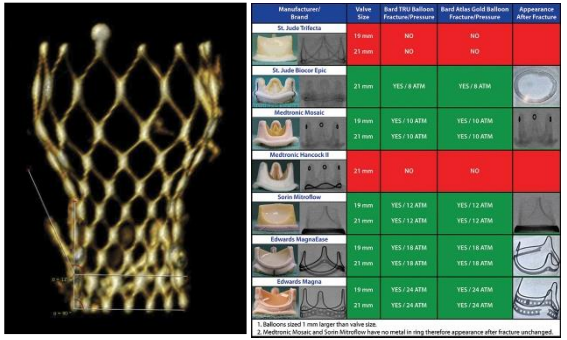


Figure 5. CT reconstruction with angular measurement of trifecta post following BVR and VIV TAVR. The angle between the sewing ring plane and the valve post is 115° (previously 90° at baseline).