Canadian Journal of Cardiology 41 (2025) 1480–1489

Clinical Research

Balloon-expandable Versus Self-expanding Valves in Patients With Prior Surgical Mitral Valve Replacement Undergoing Transcatheter Aortic Valve Replacement

Lluis Asmarats, MD, PhD,[a] Pilar Jiménez-Quevedo, MD, PhD,[b] Ignacio J. Amat-Santos, MD, PhD,[c,d] María-Cruz Ferrer-Gracia, MD, PhD,[e] Fernando Sarnago, MD,[f] Juan H. Alonso-Briales, MD,[g] Juan Francisco Oteo, MD,[h] Vicenç Serra, MD,[i] Guillem Muntané-Carol, MD, PhD,[j] Victoria Vilalta, MD, PhD,[k] David del Val, MD, PhD,[l] Manuel Pan, MD, PhD,[d,m] José M. De la Torre Hernández, MD, PhD,[n] Sergio García-Blas, MD, PhD,[d,o] José Luis Díez, MD,[p] Alberto Berenguer, MD,[q] Raquel Del Valle, MD,[r] Felipe Navarro del Amo, MD, PhD,[s] Miguel Artaiz, MD,[t] Ander Regueiro, MD, PhD,[u] Manuel López-Pérez, MD,[v] Albert Massó van-Roessel, MD,[a] José G. Paredes-Vázquez, MD,[b] Clara Fernández-Cordón, MD,[c] José Antonio Diarte de Miguel, MD,[e] Nicolás Maneiro, MD,[f] Alberto Piserra-López, MD, PhD,[g] Jorge De La Fuente, MD,[h] Juan Muñoz, MD,[i] Rafael Romaguera, MD, PhD,[j] Xavier Carrillo, MD, PhD,[k] Fernando Alfonso, MD, PhD,[l] Marco Alvarado, MD,[m] Gabriela Veiga, MD, PhD,[n] Xavier Millán, MD, PhD,[a] Luis Nombela-Franco, MD, PhD,[b] and Dabit Arzamendi, MD, PhD[a,d]

[a] Hospital Santa Creu i Sant Pau, Institut de Recerca Sant Pau (IR SANT PAU), Barcelona, Spain; [b] Cardiovascular Institute, Hospital Clínico San Carlos, Madrid, Spain; [c] Servicio de Cardiología, Hospital Clínico Universitario de Valladolid, Valladolid, Spain; [d] Centro de Investigación Biomédica en Red de Enfermedades Cardiovasculares, Madrid, Spain; [e] Servicio de Cardiología, Hospital Universitario Miguel Servet, Zaragoza, Spain; [f] Servicio de Cardiología, Hospital Universitario 12 de Octubre, Madrid, Spain; [g] Servicio de Cardiología, Hospital Universitario Virgen de la Victoria, Málaga, Spain; [h] Servicio de Cardiología, Hospital Universitario Puerta del Hierro, Madrid, Spain; [i] Vall d'Hebrón Research Institute, Hospital Universitari Vall d'Hebrón, Barcelona, Spain; [j] Servicio de Cardiologia, Hospital Universitari de Bellvitge, L'Hospitalet de Llobregat, Spain; [k] Servicio de Cardiología, Hospital Germans Trias i Pujol, Badalona, Spain; [l] Servicio de Cardiología, Hospital Universitario de La Princesa, Madrid, Spain; [m] Servicio de Cardiología, Hospital Universitario Reina Sofía, Córdoba, Spain; [n] Servicio de Cardiología, Hospital Universitario Marqués de Valdecilla, IDIVAL, Santander, Spain; [o] Servicio de Cardiología, Hospital Clínico Universitario de Valencia, Valencia, Spain; [p] Servicio de Cardiología, Hospital Universitari i Politecnic La Fe, Valencia, Spain; [q] Servicio de Cardiología, Hospital General Universitario de Valencia, Valencia, Spain; [r] Área del Corazón, Hospital Universitario Central de Asturias, Oviedo, Asturias, Spain; [s] Servicio de Cardiología, Fundación Jiménez Díaz, Madrid, Spain; [t] Servicio de Cardiología, Clínica Universitaria de Navarra, Pamplona, Navarra, Spain; [u] Hospital Clínic Barcelona, Institut d'Investigacions Biomèdiques August Pi i Sunyer, Barcelona, Spain; [v] Servicio de Cardiología, Hospital Universitario Clínico San Cecilio, Granada, Spain

Transcatheter aortic valve replacement (TAVR) has become the first-choice therapy for most elderly patients with symptomatic severe aortic stenosis.[1] With the increasingly aging population, the prevalence of patients with multiple or mixed valve heart disease is rising, a subset of patients who represent a challenge for both cardiac surgeons and interventional cardiologists. A significant proportion of patients with pre-existing surgical

Received for publication February 1, 2025. Accepted April 27, 2025.

Corresponding author: Dr Lluis Asmarats, Hospital de la Santa Creu i Sant Pau, Sant Antoni M. Claret, 167, 08025 Barcelona, Spain.
E-mail: lasmarats@santpau.cat

See page 1487 for disclosure information.

https://doi.org/10.1016/j.cjca.2025.04.026

ABSTRACT

Background: Pre-existing mitral prosthesis raises technical challenges for transcatheter aortic valve replacement (TAVR) but has been scarcely studied. In this work we sought to compare outcomes of patients with previous surgical mitral valve prostheses undergoing TAVR with balloon-expandable valve (BEV) or self-expanding valve (SEV) systems.

Methods: Patients from the Spanish TAVR registry with pre-existing surgical mitral prostheses were included in this investigation. The primary endpoints were Valve Academic Research Consortium-3 technical and device success, with analysis according to valve type. Transcatheter heart valve (THV) embolization, mitral valve impingement, THV performance, and pacemaker findings were also assessed.

Results: A total of 243 patients were included (37% BEVs, 63% SEVs). Overall technical success was 95.9%. Thirty-day device success was higher in BEV patients (94.4% vs 85.0%, $P = 0.036$), mainly driven by fewer incidences of moderate residual aortic regurgitation (0% vs 5.9%, $P = 0.028$) and THV embolization (0% vs 3.9%, $P = 0.087$). BEV recipients exhibited higher mean transvalvular gradients (10.5 vs 8.1 mm Hg, $P = 0.002$) and lower rates of permanent pacemaker implantation (5.6% vs 15.7%, $P = 0.023$). There were no differences in mortality, bleeding, or readmission at 30 days. In the multivariate analysis, a mitroaortic distance of $\leq$ 7 mm and lack of transesophageal echocardiography guidance were associated with increased device failure.

Conclusions: In patients with pre-existing MV prostheses, TAVR was safe and effective regardless of the THV type. Nevertheless, the use of BEVs resulted in an increased rate of device success, driven by lesser THV embolization and residual aortic regurgitation.

RÉSUMÉ

Contexte: La présence d'une prothèse mitrale peut créer des difficultés techniques lors d'unremplacement valvulaire aortique par cathéter (RVAC), mais elle a été peu étudiée. Cette étude visait à comparer les résultats obtenus par des patients ayant déjà subi une chirurgie de la valve mitrale avec prothèse qui se prêtent à un RVAC avec ballonnet gonflable ou valve auto-expansible.

Méthodologie: Les patients inclus proviennent d'un registre espagnol de patients ayant déjà subi une chirurgie de la valve mitrale avec prothèse qui se sont prêtés à un RVAC. Les paramètres d'évaluation principaux étaient la réussite technique et la réussite de l'implantation du dispositif selon les critères du Valve Academic Research Consortium-3, et ont été analysés en fonction du type de valve. Les taux d'embolisation de la valve cardiaque transcathéter (VCT), d'interférence avec la valve mitrale, de performance de la VCT et de mise en place d'un stimulateur cardiaque ont également été évalués.

Résultats: Au total, 243 patients ont été inclus (ballonnet gonflable : 37 %; valve auto-expansible : 63 %). La réussite technique globale a été de 95,9 %. La réussite de l'implantation du dispositif à 30 jours était plus élevée chez les patients ayant eu recours au ballonnet gonflable (94,4 % *vs* 85,0 %; $p = 0{,}036$), surtout en raison de l'incidence plus faible de la régurgitation aortique résiduelle modérée (0 % *vs* 5,9 %; $p = 0{,}028$) et de l'embolisation de la VCT (0 % *vs* 3,9 %; $p = 0{,}087$). Les patients ayant eu recours au ballonnet gonflable ont présenté des gradients transvalvulaires moyens plus élevés (10,5 *vs* 8,1 mmHg; $p = 0{,}002$) et des taux plus faibles d'implantation permanente d'un stimulateur cardiaque (5,6 % *vs* 15,7 %; $p = 0{,}023$). Aucune différence n'a été observée au niveau de la mortalité, des saignements ou de la réadmission à 30 jours. Dans une analyse multivariée, une distance mitroaortique $\leq$ 7 mm et l'absence de guidage par échocardiographie transœsophagienne ont été associées à un taux accru de défaillance du dispositif.

Conclusions: Chez les patients porteurs d'une prothèse mitrale, le RVAC s'est avéré sûr et efficace, peu importe le type de VCT. Néanmoins, l'utilisation d'un ballonnet gonflable s'est traduite par un taux de réussite de l'implantation du dispositif plus élevé en réduisant l'embolisation de la VCT et la régurgitation aortique résiduelle.

mitral valve (MV) replacement will develop severe aortic stenosis, requiring either surgical or transcatheter reintervention. Current guidelines favor TAVR for patients with prior cardiac surgery.[1] However, some of these patients have been excluded from landmark randomized clinical trials.[2] Performing TAVR in this scenario may be particularly challenging due to the potential interference between the rigid MV prosthesis and the transcatheter heart valve (THV), which may reduce THV stability and enhance the risk of device embolization, migration, or underexpansion. Nevertheless, few studies have assessed the safety of TAVR in patients with prior MV prosthesis,[3-5] and no studies have evaluated to date the impact of THV design on outcomes in this setting. Indeed, this clinical scenario presents unique anatomic and procedural considerations, and the choice of THV type in this context remains a topic of debate. In this study we sought to analyze and compare periprocedural complications and clinical outcomes in patients with severe aortic stenosis and pre-existing surgical MV prosthesis undergoing TAVR with either balloon-expandable valves (BEVs) or self-expanding valves (SEVs).

Methods

Registry design

The Spanish TAVR registry is a prospective national registry supported by the Interventional Cardiology Association of the Spanish Society of Cardiology and participation is voluntary. All data are anonymized and each patient is assigned a code in accordance with current data protection regulations. Data from centers performing TAVR procedures are prospectively collected in a dedicated, centralized data set. Specific computed tomography parameters were retrospectively gathered for this analysis. The study was approved by a central ethics board and all participating patients provided written consent.

Study population

Consecutive patients with a pre-existing surgical mitral prosthesis undergoing TAVR between 2008 and 2023 in the Spanish TAVR registry were included. Patients were divided into 2 groups depending on whether they received a BEV or SEV. Patients receiving a mechanically expandable THV,

which was deployed via a unique mechanical expansion differing from both BEV and SEV and was commercially withdrawn in 2020, were excluded from the analysis.

Endpoint definitions

Outcomes were defined according to the **V**alve **A**cademic **R**esearch **C**onsortium-**3** (VARC-3) definitions.[6] Primary endpoints were technical success and 30-day device success. Technical success was defined as freedom from mortality, successful access, delivery of a single THV with correct positioning and retrieval of the delivery system, freedom from surgery or intervention related to the device or to a major vascular complication, and freedom from structural cardiac complications. Device success was defined as intraprocedural technical success, freedom from mortality, freedom from surgery or reintervention due to valve dysfunction, and intended THV performance (mean gradient < 20 mm Hg, less than moderate aortic regurgitation [AR]) at 30 days. In addition, we evaluated the occurrence of THV embolization, need for a second valve, interaction between the THV stent frame and the MV prosthesis, residual at least moderate AR and THV hemodynamics (mean aortic gradient) at discharge, and post-procedural pacemaker implantation at 30 days.

Computed tomography analysis

In addition to standard computed tomography measurements for TAVR, specific parameters were analyzed (Fig. 1). Mitroaortic distance was defined as the distance between the aortic annulus and the highest portion of the mitral prosthetic valve housing in the sagittal view (Fig. 1A). Also in the sagittal view, we assessed the angulation between the aortic annulus and MV (Fig. 1B) as well as whether the MV prosthesis housing protruded toward the left ventricular outflow tract (Fig. 1C) or not (Fig. 1D), by drawing a straight line perpendicular to the aortic annulus from the mitral portion of the aorta down to the left ventricular outflow tract, as described elsewhere.[7] Missing computed tomography data were not imputed and analyses for these variables were restricted to patients with available measurements.

Statistical analysis

Categorical variables are expressed as number (percent) and continuous variables as mean ± standard deviation (SD) or median (interquartile range [IQR]), according to their distribution. Assessment of normality of continuous data was performed using the Shapiro-Wilk test. Group comparisons were analyzed using the Student t test or Mann-Whitney U test according to distribution of variables for continuous variables and the χ^2 test or Fisher exact test for categorical variables. Survival analyses were performed using a Kaplan-Meier survival function, and comparisons were performed using the log-rank test. Two-step analysis was used to assess predictors of device failure. First, univariate logistic regression was performed for each clinical and procedural variable. To prevent omission bias, variables with a P value < 0.10 entered the multiple logistic regression analysis.[8] Results are reported as odds ratio (OR) with 95% confidence interval (CI). $P < 0.05$ was considered significant for all statistical tests. Statistical analyses were performed with STATA version 14.0 (StataCorp LP, College Station, TX).

Results

Study population

Among 10,861 patients who underwent TAVR between 2008 and 2023 in the 21 participating centers, 250 (2.3%) had previous surgical MV replacement. Seven patients treated with mechanically expandable THVs were excluded, leading to a final study population of 243 patients (Supplemental Fig. S1). SEVs were implanted in most patients. Baseline clinical and imaging characteristics are shown in Table 1. Overall mean age was 77 ± 6 years; 72% were women and had high surgical risk (**S**ociety of **T**horacic **S**urgeons **P**redicted **R**isk **o**f **M**ortality [STS-PROM] score of 8.1 ± 7.7%), with no differences between BEV and SEV groups. Pre-existing atrial fibrillation was present in 92% of patients, chronic kidney disease in 73%, and prior permanent pacemaker in 10%, with a consistent distribution across groups. Patients undergoing TAVR with SEV had a smaller aortic annulus area and perimeter ($P = 0.004$ and $P = 0.021$, respectively), lower left main height ($P = 0.048$), and shorter mitroaortic distance ($P < 0.001$; overall mean mitroaortic distance: 6.6 ± 3.0 mm).

Procedural characteristics

Procedural data are shown in Table 2. Transfemoral access was used in 97.1% of patients and transaxilar access in 2.9%. Most patients received a SEV (n = 153, 63.0%), with the Evolut (Medtronic) being the SEV used most often (76.5%), followed by Portico/Navitor (Abbott; 9.1%) and Acurate (Boston; 4.5%) SEVs. The Edwards Sapien THV was used in all BEV patients, with 1 exception (98.9%). BEV procedures were more commonly performed under general anesthesia (62.2% vs 37.3%, $P < 0.001$) and transesophageal echocardiography (TEE) guidance (51.1% vs 28.8%, $P < 0.001$), and required less commonly pre- and postdilatation ($P = 0.007$ and $P < 0.001$, respectively). There were no differences in procedural time and THV implantation depth between groups. Bridging therapy pre-TAVR was used in 76.1% of the patients, with an average time to anticoagulation post-TAVR of 1.4 ± 2.8 days, and there were no differences regardless of THV type.

Procedural and clinical outcomes

Procedural and clinical outcomes are outlined in Table 3 and Figure 2. The overall technical success rate according to VARC-3 criteria was 95.9% (similar in both groups). Overall 30-day device success was 88.5% and was higher in the BEV group (94.4% vs 85.0%, $P = 0.036$), primarily driven by a lower incidence of at least moderate residual AR (0% vs 5.9%, $P = 0.028$) and THV embolization (0% vs 3.9%, $P = 0.087$). All THV embolizations (n = 6) occurred with SEV. One patient in the BEV group required a second THV due to low implantation of the first device.

Interference with the MV prosthesis was uncommon (n = 2 [<1%]) and comparable between groups. The first patient had a previous bileaflet mechanical valve and very short mitroaortic distance (2 mm), and the interaction between the 2 prostheses led to aortic embolization of a SEV. In the second case, with a pre-existing MV bioprosthesis, a transient transmitral flow acceleration was observed on TEE during BEV deployment, which resolved after balloon deflation.

Patients with BEV, as compared with SEV, showed higher mean transaortic gradients (10.5 ± 5.0 vs 8.1 ± 5.3, $P =$

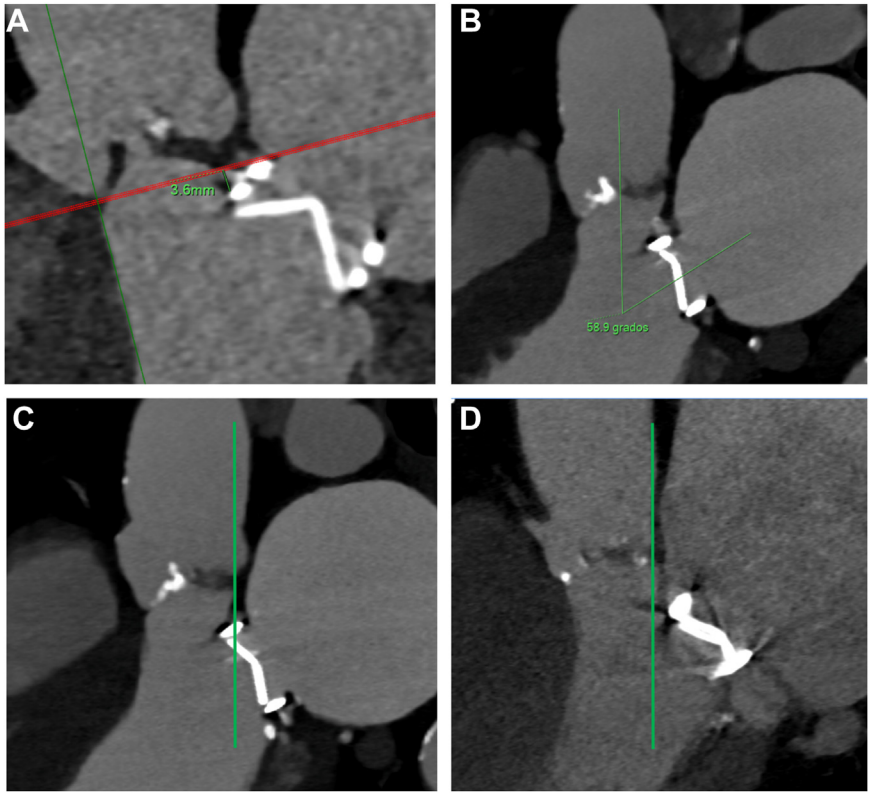

Figure 1. Preprocedural computed tomography images in patients with previous mitral prostheses. (**A**) Mitroaortic distance (distance between the aortic annulus and the mitral prosthesis). (**B**) Angle between the mitral prosthesis and aortic valve planes. Line perpendicular to the mitral side of the aortic annulus to delimit protrusion (**C**) or not (**D**) of the mitral prosthesis housing toward the left ventricular outflow tract.

0.002), but had lower rates of permanent pacemaker implantation (5.6% vs 15.7%, $P = 0.023$). There were no cases of coronary occlusion or surgical conversion.

The rates of technical success and THV embolization remained stable throughout the study period, with a trend toward a declining incidence of THV embolization in SEV procedures over the years ($P = 0.077$) (Supplemental Fig. S2). The numbers of patients included per center are outlined in Supplemental Table S1, showing no difference in patient outcomes according to the institutional volume.

The 30-day clinical outcomes were comparable between the 2 groups (Table 3). At 30 days, VARC-3 type $\geq$ 2 bleeding was relatively high (11.5%), with no differences according to the type of THV or type of prosthetic mitral valve (mechanical or biological).

Predictors of device failure

There were 28 cases (11.5%) of 30-day device failure. A mitroaortic distance of $\leq$ 7 mm was associated with an increased risk of device failure (17.1% vs 4.6%, $P = 0.017$). In the multivariate analysis, a mitroaortic distance of $\leq$ 7 mm (OR = 3.94, 95% CI 1.09-14.25, $P = 0.037$) and not using TEE guidance (OR = 0.18, 95% CI 0.04-0.83, $P = 0.028$), but not THV type, were associated with increased device failure (Table 4).

Follow-up outcomes

Follow-up data were available for all cases, with a median time of 35.0 (interquartile range 17.5-54.7) months. At 30 months, all-cause mortality was 24.0% (BEV 19.5% vs SEV 25.9%, $P = 0.627$), cardiovascular mortality was 15.9% (BEV 13.7% vs SEV 17.4%, $P = 0.700$), bleeding complications occurred in 16.2% (BEV 13.8% vs SEV 17.9%, $P = 0.453$), and hospital readmission was required in 16.5% (BEV 20.2% vs SEV 14.1%, $P = 0.622$) (Fig. 3).

Discussion

The results of our study comparing BEV vs SEV TAVR in patients with prior surgical MV replacement can be summarized as follows: (1) technical success (96%) and 30-day device success (89%) were high with both platforms, although BEV showed greater device success rates; (2) the incidence of THV embolization was relatively low (2.5%) and occurred only with SEVs; (3) SEVs were used more commonly in this setting and were associated with better hemodynamics but higher rates of pacemaker use; (4) BEV and SEV approaches showed comparable outcomes at 30 days; and (5) short mitroaortic distance ($\leq$ 7 mm) and lack of TEE guidance during TAVR were associated with an increased odds of device failure.

Concerns about the safety and efficacy of TAVR in patients with pre-existing mitral prosthesis have been raised due to the potential interaction between the THV system with the rigid prosthetic MV struts or cage of the mechanical MV, which may favor shift of the THV device with subsequent risk of THV embolization, mitral disc impingement, or THV underexpansion with significant paravalvular AR.[9,10]

Table 1. Baseline clinical characteristics

	Overall (N = 243)	Overall cohort		*P* value
		SEV (n = 153)	BEV (n = 90)	
Demographics				
Age, years	77.4 ± 6.3	77.5 ± 6.4	77.3 ± 6.0	0.832
Female	176 (72.4%)	117 (76.5%)	59 (65.6%)	0.075
Hypertension	167 (68.7%)	107 (69.9%)	60 (66.7%)	0.596
Diabetes	80 (32.9%)	50 (32.7%)	30 (33.3%)	0.917
Body mass index, kg/m^2	25.5 ± 5.0	25.4 ± 4.3	25.7 ± 6.1	0.650
Atrial fibrillation	223 (91.8%)	140 (91.5%)	83 (92.2%)	0.844
Prior myocardial infarction	16 (6.6%)	13 (8.5%)	3 (3.3%)	0.179
Prior CABG	27 (11.1%)	17 (11.1%)	10 (11.1%)	0.999
Stroke	47 (19.3%)	30 (19.6%)	17 (18.9%)	0.891
Peripheral artery disease	22 (9.1%)	15 (9.8%)	7 (7.8%)	0.595
CKD, eGFR < 60 mL/min/m^2	178 (73.3%)	114 (74.5%)	64 (71.1%)	0.563
NYHA class III or IV	121 (49.8%)	75 (49.0%)	46 (51.1%)	0.791
STS risk score	8.1 ± 7.7	8.5 ± 7.9	7.6 ± 7.3	0.426
Prior pacemaker	25 (10.3%)	19 (12.4%)	6 (6.7%)	0.154
MVP type				0.449
Biological	30 (12.4%)	20 (13.1%)	10 (11.1%)	
Mechanical, monodisc	32 (13.2%)	17 (11.1%)	15 (16.7%)	
Mechanical, bidisc	181 (74.5%)	116 (75.8%)	65 (72.2%)	
MVP size, mm	27.4 ± 1.9	27.3 ± 1.9	27.6 ± 1.8	0.316
Echocardiography				
LVEF, %	53.2 ± 13.2	53.7 ± 12.9	52.3 ± 13.7	0.425
Mean gradient, mm Hg	41.0 ± 13.9	41.5 ± 13.4	40.0 ± 14.8	0.413
Aortic valve area, cm^2	0.67 ± 0.18	0.69 ± 0.18	0.65 ± 0.19	0.223
Anticoagulation treatment				0.473
None	9 (3.7)	4 (2.6)	5 (5.6)	
Vitamin K antagonists	229 (94.2%)	145 (94.8%)	84 (93.3%)	
DOAC	5 (2.1)	4 (2.6)	1 (1.1)	
Computed tomography*				
Annulus area, mm^2	434.3 ± 81.2	422.4 ± 74.9	458.5 ± 88.5	0.004
Annulus perimeter, mm	74.5 ± 9.0	73.5 ± 8.0	76.7 ± 10.5	0.021
LVOT diameter, mm	24.8 ± 7.0	24.5 ± 5.9	25.6 ± 9.1	0.326
LM height, mm	12.9 ± 3.3	12.6 ± 3.3	13.6 ± 3.2	0.048
RCA height, mm	14.6 ± 3.4	14.6 ± 3.5	14.7 ± 3.1	0.869
Mitro-aortic distance, mm	6.6 ± 3.0	6.1 ± 2.9	7.8 ± 3.1	< 0.001
Mitro-aortic angle, degrees	60.7 ± 14.2	61.1 ± 14.1	59.8 ± 14.5	0.586
MVP protrusion	63 (33.9)	45 (36.0)	18 (29.5)	0.380

Data expressed as mean ± standard deviation or as number (%).

BEV, balloon-expandable valve; CABG, coronary artery bypass graft; CKD, chronic kidney disease; DOAC, direct oral anticoagulant agent; eGFR, estimated glomerular filtration rate; LM, left main; LVEF, left ventricular ejection fraction; LVOT, left ventricular outflow tract; MVP, mitral valve prosthesis; NYHA, New York Heart Association; RCA, right coronary artery; SEV, self-expanding valve; STS, Society of Thoracic Surgeons.

*Data available for 189 patients.

Our study represents the largest compilation of patients with pre-existing surgical mitral prostheses undergoing TAVR. Previous reports have shown comparable rates of technical success but variable rates of THV embolization in this setting.[3-5,7] Most patients included in these studies were relatively young, at high surgical risk, with a predominance of women and mechanical MV prostheses. The high proportion of female patients (~ 70%) aligns with previous studies in patients with pre-existing mitral prostheses, possibly reflecting the female predominance for rheumatic disease and other MV diseases.[4,5] The predominance of mechanical MVs (with a lower profile and usually thinner struts than biological prostheses) is consistent with prior literature and may explain the high rates of technical success observed in this population. In the **O**utcome of **P**atients Undergoing **T**ranscatheter **I**mplantation of Aortic Valve with Previous **M**itral V**al**ve Prosthesis (OPTIMAL) study, Baldetti et al.[5] analyzed 154 patients with previous MV prosthesis who underwent TAVR. In line with our results, the study showed high procedural and device success (97% and 86%, respectively), a low rate of procedural complications (device embolization 0.6%, second valve implanted 1.3%, 1.4% MV prosthesis impingement), and acceptable 30-day outcomes, although a high rate of major bleeding (13.1%; 11.5% in our study). Of note, SEVs were more commonly used, with interference or THV embolization being observed only in patients with self-expanding platforms—albeit with no significant differences in procedural success seen according to type of THV. The study was, however, limited by considerable missing data regarding pre-procedural computed tomography data (available for only 105 [68%] patients and mitroaortic distance in 45 [29%]; noticeably lower than ours in 189 [78%], mitroaortic distance in 177 [73%]). In another study of 91 patients with previous mitral prosthesis undergoing TAVR, Amat-Santos et al.[4] reported lower device success rate (72%), likely explained by a higher incidence of device embolization (6.7% vs 2.5% in our study) in the earlier TAVR period (before 2017), in contrast to our study (~ 70% of the procedures performed between 2017 and 2023). Although no significant differences were found for rate of device embolization for THV type, this

Table 2. Procedural data

		Overall cohort		
	Overall (N = 243)	SEV (n = 153)	BEV (n = 90)	*P* value
General anesthesia	113 (46.5%)	57 (37.3%)	56 (62.2%)	< 0.001
TEE guidance	90 (37.0%)	44 (28.8%)	46 (51.1%)	< 0.001
Transfemoral access	236 (97.1%)	149 (97.4%)	87 (96.7%)	0.182
THV type				—
CoreValve/Evolut	117 (48.1%)	117 (76.5%)		
Portico/Navitor	22 (9.1%)	22 (14.4%)		
Symetis/Acurate	11 (4.5%)	11 (7.2%)		
Allegra	2 (0.8%)	2 (1.3%)		
Centera	1 (0.4%)	1 (0.7%)		
Sapien	89 (36.6%)		89 (98.9%)	
Myval	1 (0.4%)		1 (1.1%)	
THV size, mm	26.3 ± 2.5	27.0 ± 2.4	25.1 ± 2.3	< 0.001
Predilation	97 (39.9%)	71 (46.4%)	26 (28.9%)	0.007
Postdilation	49 (20.2%)	43 (28.1%)	6 (6.7%)	< 0.001
NCC depth, mm	5.1 ± 2.5	5.0 ± 2.5	5.2 ± 2.6	0.672
Procedural time, minutes	109.3 ± 42.3	110.1 ± 40.2	107.9 ± 45.8	0.738
Management of antithrombotic therapy				
Bridging therapy pre-TAVR				0.756
None	58 (23.9%)	38 (24.8%)	20 (22.2%)	
LMWH	141 (58.0%)	86 (56.2%)	55 (61.1%)	
UFH	44 (18.1%)	29 (19.0%)	15 (16.7%)	
Anticoagulation resumption, days	1.4 ± 2.8	1.5 ± 3.4	1.1 ± 1.3	0.309
Anticoagulation at discharge				0.846
None	9 (3.7%)	5 (3.3%)	4 (4.4%)	
Vitamin K antagonists	227 (93.4%)	143 (93.5%)	84 (93.3%)	
DOAC	7 (2.9%)	5 (3.3%)	2 (2.2%)	

Data expressed as mean ± standard deviation or as number (%).

BEV, balloon-expandable valve; DOAC, direct oral anticoagulant; LMWH, low-molecular weight heparin; NCC, noncoronary cusp; SEV, self-expanding valve; TAVR, transcatheter aortic valve replacement; TEE, transesophageal echocardiography; THV, transcatheter heart valve; UFH, unfractionated heparin; VKA, vitamin K antagonist.

complication was numerically observed more commonly with SEVs (11.1% vs 3.7%, $P = 0.213$), in line with our study. Of note, this complication occurred only in patients with a distance between the MV prosthesis and the aortic annulus of $<$ 7 mm. Interestingly, a short mitroaortic distance of $\leq$ 7 mm, along with lack of intraprocedural TEE guidance during TAVR, emerged as independent predictors of device failure in our population. This highlights the importance of precise preprocedural computed tomography planning in this subset of patients as well as consideration of imaging support for patients with a close proximity between the aortic annulus and the mitral prosthesis.

Table 3. Procedural and clinical outcomes

		Overall cohort		
	Overall (N = 243)	SEV (n = 153)	BEV (n = 90)	*P* value
Primary endpoint				
VARC-3 technical success	233 (95.9%)	145 (94.8%)	88 (97.8%)	0.331
VARC-3 device success	215 (88.5%)	130 (85.0%)	85 (94.4%)	0.036
Secondary outcome				
THV embolization	6 (2.5%)	6 (3.9%)	0 (0%)	0.087
Need for second valve	6 (2.5%)	5 (3.3%)	1 (1.1%)	0.417
MV prosthesis interference	2 (0.8%)	1 (0.7%)	1 (1.1%)	0.999
THV underexpansion	8 (3.3%)	8 (5.2%)	0 (0%)	0.028
Residual AR ≥ moderate	9 (3.7%)	9 (5.9%)	0 (0%)	0.028
Mean aortic gradient, mm Hg	9.0 ± 5.3	8.1 ± 5.3	10.5 ± 5.0	0.002
30-day outcome				
All-cause death	5 (2.1%)	4 (2.6%)	1 (1.1%)	0.654
Stroke/TIA	2 (0.8%)	2 (1.3%)	0 (0%)	0.532
Permanent pacemaker	29 (11.9%)	24 (15.7%)	5 (5.6%)	0.023
VARC-3 type 2-4 bleeding	28 (11.5%)	22 (14.4%)	6 (6.7%)	0.069
Major vascular complications	13 (5.4%)	10 (6.5%)	3 (3.3%)	0.382
Myocardial infarction	1 (0.4%)	0 (0%)	1 (1.1%)	0.370
In-hospital stay, days	7 (5-11)	7 (5-11)	7 (4-11)	0.529

Data expressed as number (%), mean ± standard deviation, or median (interquartile range).

AR, aortic regurgitation; BEV, balloon-expandable valve; MV, mitral valve; SEV, self-expanding valve; TIA, transient ischemic attack; THV, transcatheter heart valve; VARC-3, Valve Academic Research Consortium-3.

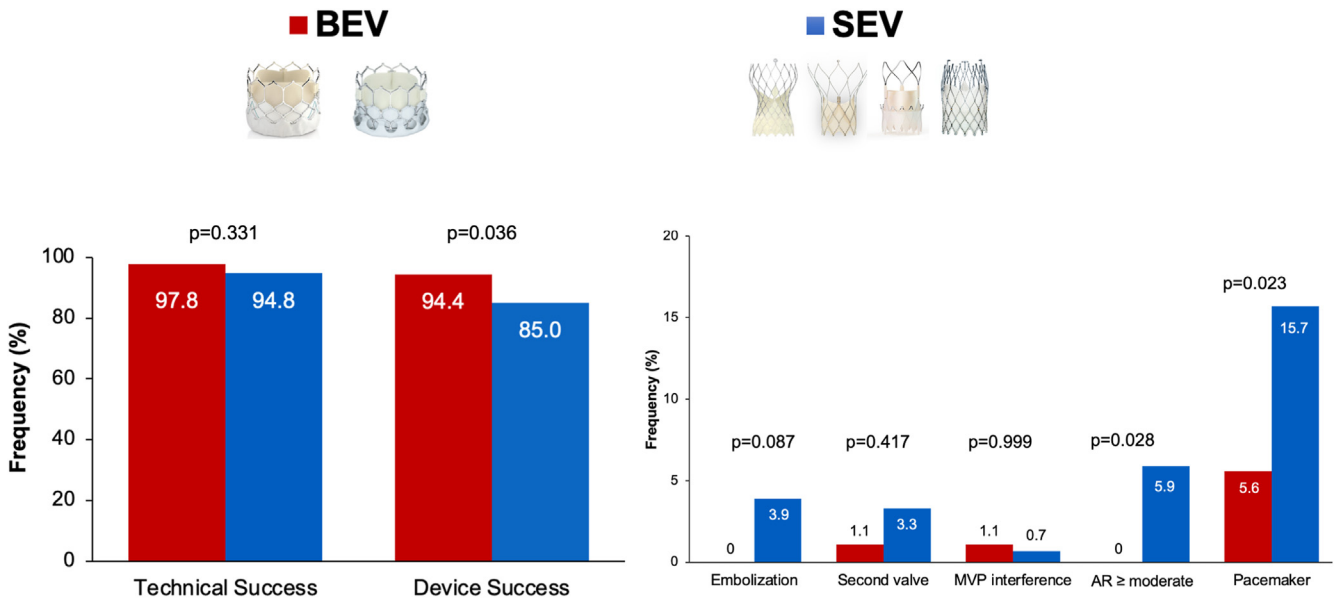

Figure 2. Technical, device success, and procedural complications in patients with pre-existing mitral prosthesis undergoing transcatheter aortic valve replacement. Procedural outcomes in the overall population. AR, aortic regurgitation; BEV, balloon-expandable valves; MVP, mitral valve prosthesis; SEV, self-expanding valves.

Other reports with smaller patient cohorts (n < 40) provided support for the feasibility and safety of TAVR in this setting.[3,7] In a computed tomography study of the **O**ptimized Trans**c**ath**e**ter V**a**lvular I**n**tervention **TAVI** (OCEAN-TAVI) registry with 31 patients, although no cases of device embolization occurred, a THV shift during deployment was observed in 29% of patients, especially in those with a larger aortic annulus.[7] Although interesting, this parameter was not evaluated in our study given the lack of standardized definitions.

Device success occurred more commonly with BEV (vs SEV), driven mainly by a lower frequency of residual more-than-moderate AR and device embolization in the BEV group. This is consistent with the findings of the **C**omparison of Transcatheter **H**eart Valves in High-Risk Patients With Severe A**o**rt**i**c Stenosis: **C**oreValve vs **E**dwards Sapien XT (CHOICE) study, which had a device success rate of 95.9% in BEVs (vs 77.5% in SEVs, $P < 0.001$) due to less residual AR (4.1% vs 18.3%, $P < 0.001$) and less need for > 1 THV (0.8% vs 5.8%) in the BEV patients.[11] Our findings are consistent with studies that compared different THV generations of BEV vs SEV independently of the presence of MV replacement.[11,12] Nevertheless, the findings should be interpreted with caution, given the different results encountered in some specific scenarios (eg, small aortic annuli).[13] Overall, SEV was associated with better hemodynamic performance but a higher incidence of significant paravalvular leak and permanent pacemaker implantation, consistent with other randomized and propensity-matched studies.[14] The lower gradients observed with SEV were likely related to the supra-annular design used in 85% of SEV patients. However, the absolute difference in mean gradient between groups was discrete (2-3 mm Hg), and the long-term clinical impact remains unknown. These findings may be considered especially in patients with small annuli or a higher risk of patient-prosthesis mismatch, but the downside of higher pacemaker risk due to greater interaction with the conduction system with tall-frame THVs should also be taken into account. Importantly, no differences between groups were observed regarding mortality, bleeding, stroke, or readmission, providing reassuring data on the safety and efficacy of TAVR in patients with pre-existing mitral prosthesis, irrespective of the type of THV.

We observed a substantially greater use of general anesthesia and TEE guidance in BEV recipients. Although TEE use may reflect early clinical practice, this may well be due to the less forgiving "one-shot" deployment of these non-recapturable or repositionable THVs. Interestingly, use of TEE appeared to reduce significantly the risk of device failure in our study. Despite the clear trend toward minimalist TAVR in which transthoracic echocardiography is the predominant imaging modality,[15] TEE guidance may still play a role in selected cases at risk for procedural complications (mitral prosthesis, valve-in-valve, extreme calcification, leaflet modification, etc).[16]

Limitations

Our study has limitations inherent in any observational retrospective study. Patients' participation in the registry was voluntary and not externally audited; nevertheless, the centralized database was systematically and periodically checked for discrepancies or missing data. Second, computed tomography analyses were interpreted at each participating center by experienced imaging specialists with no central core laboratory, and computed tomography data were not available in ∼ 20% of patients. Third, although no significant mitral prosthetic valve malfunction occurred during follow-up, systematic transmitral gradients and left ventricular outflow tract measurements were not available for all patients, and the impact of TAVR in prosthetic MV function requires further exploration. Fourth, although a potential confounding and learning-curve effect cannot be fully excluded given the long

Table 4. Predictors of device failure

	Univariate			Multivariate		
	OR	95% CI	*P* value	OR	95% CI	*P* value
Age, years	0.99	0.93-1.05	0.641			
Female	0.95	0.39-2.26	0.900			
Hypertension	0.80	0.35-1.82	0.591			
Diabetes	0.79	0.33-1.89	0.603			
Body mass index, kg/m^2	0.97	0.88-1.07	0.578			
Atrial fibrillation	1.19	0.26-5.41	0.824			
Previous CABG	0.96	0.27-3.40	0.943			
Peripheral artery disease	1.82	0.57-5.84	0.311			
Stroke	1.46	0.58-3.67	0.422			
CKD	0.90	0.38-2.16	0.817			
NYHA class III or IV	0.62	0.28-1.38	0.240			
STS risk score	1.01	0.96-1.07	0.659			
Prior pacemaker	1.05	0.29-3.77	0.937			
Biological MV prosthesis	1.21	0.39-3.77	0.740			
MV prosthesis size	1.00	0.78-1.27	0.967			
LVEF, %	1.00	0.97-1.03	0.820			
Mean gradient, mm Hg	0.99	0.97-1.02	0.676			
Aortic valve area, cm^2	1.44	0.11-18.28	0.778			
Antithrombotic therapy pre-TAVR	1.14	0.44-2.92	0.793			
Annulus area	1.00	0.99-1.00	0.243			
Annulus perimeter	0.98	0.94-1.02	0.362			
LVOT diameter	0.89	0.73-1.07	0.220			
Mitroaortic distance $\leq$ 7 mm	4.34	1.23-15.28	0.022	3.94	1.09-14.25	0.037*
Mitroaortic angle	1.00	0.97-1.03	0.906			
MV prosthesis protrusion	1.23	0.48-3.15	0.664			
SEV	3.01	1.10-8.22	0.032	1.93	0.52-7.17	0.327
THV size	1.00	0.86-1.18	0.964			
TEE guidance	0.43	0.17-1.09	0.076	0.18	0.04-0.83	0.028*
Bridging therapy pre-TAVR	1.50	0.55-4.16	0.430			
Bridging therapy post-TAVR	0.74	0.30-1.84	0.512			
Predilation	1.15	0.52-2.54	0.736			
Postdilation	0.84	0.30-2.35	0.747			

CABG, coronary artery bypass graft; CI, confidence interval; CKD, chronic kidney disease; LVEF, left ventricular ejection; fraction; LVOT, left ventricular outflow tract; MV, mitral valve; NYHA, New York Heart Association; OAC, oral anticoagulation; OR, odds ratio; SEV, self-expanding valve; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement; THV, transcatheter heart valve.

*Statistically significant ($P < 0.05$).

study period, the rates of technical success and THV embolization remained relatively stable over time. Finally, absence of a matched control group of patients with no MV prosthesis should be acknowledged. However, our study represents the largest analysis to focus on TAVR candidates with prior MV surgery.

Conclusions

TAVR in patients with pre-existing MV prosthesis was safe and effective regardless of the THV type. However, the use of BEVs resulted in a higher rate of device success driven by lower rates of THV embolization and residual aortic regurgitation. Overall, the results of our study support that TAVR can be performed safely and effectively in patients with previous MV prosthesis with both types of THV. Careful preprocedural work-up and selective use of TEE guidance can avert complications, especially in patients with a short mitroaortic distance ($\leq$ 7 mm). The final choice between BEV and SEV should be made according to anatomic features and valve preference of the center. However, the fact that THV embolization occurred solely with SEVs may suggest considering short-frame design THVs when dealing with patients who have a very short mitraortic distance or those being treated at BEV-dominant centers.[17]

Acknowledgements

The authors thank Maria Jose Perez-Vizcayno, MD, for her contribution during the process of database review. We also thank the participant centers of the national Spanish TAVR registry.

Ethics Statement

The study was approved by a central ethics board and was conducted in accordance with the Helsinki Declaration.

Patient Consent

The authors confirm that patient consent forms have been obtained for this work

Funding Sources

The Spanish TAVR registry is managed with funding from the Interventional Cardiology Association of the Spanish Society of Cardiology.

Disclosures

L.A. is a proctor for Abbott and a consultant for Edwards Lifesciences. P.J.-Q. is a consultant and has received lecture fees from Edwards Lifesciences and Abbott. I,J.A.-S. is proctor

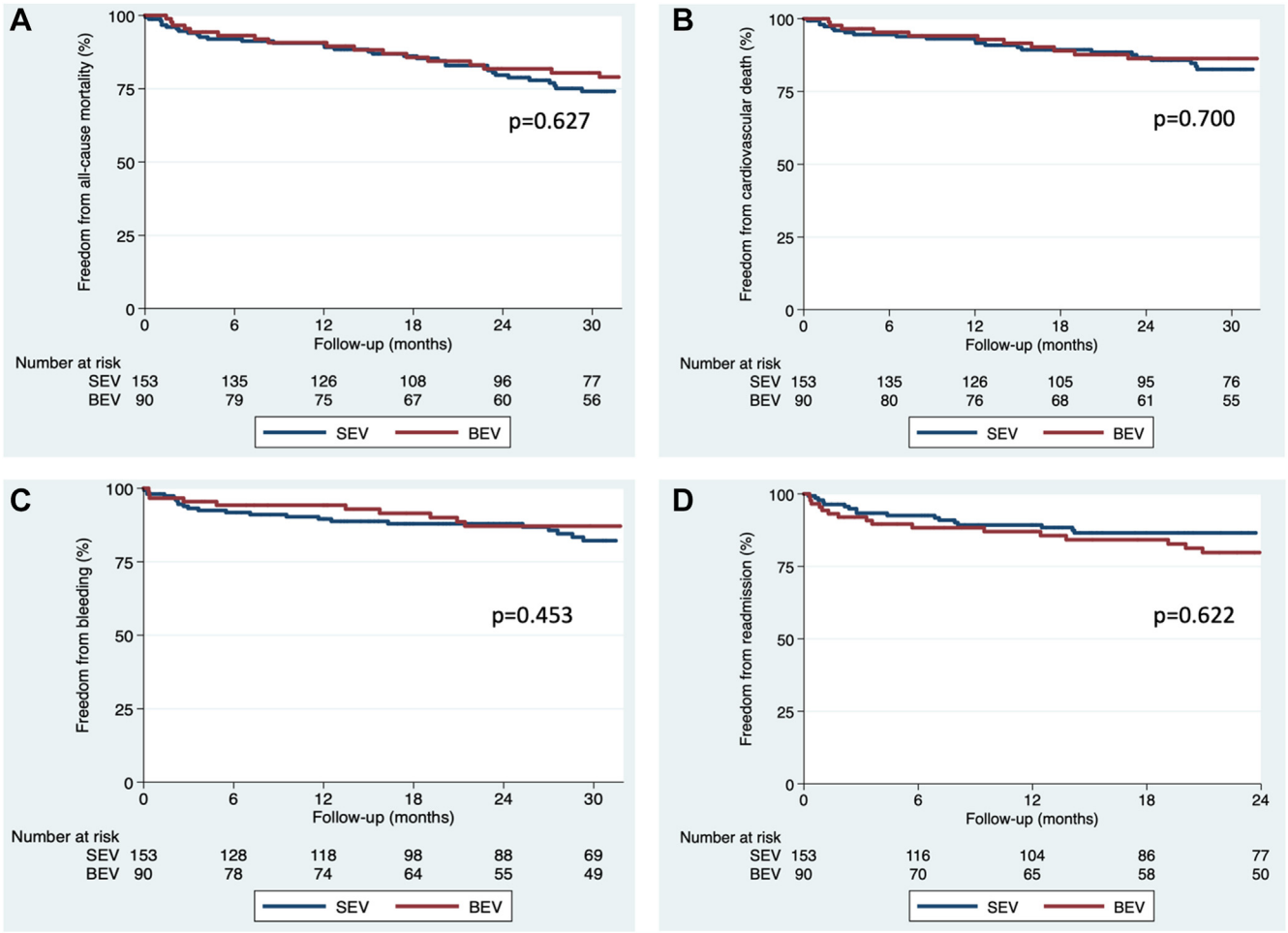

Figure 3. Kaplan-Meier survival curves after TAVR in patients with previous mitral prostheses. (**A**) All-cause mortality. (**B**) Cardiovascular mortality. (**C**) Bleeding. (**D**) Readmission. BEV, balloon-expandable valve; SEV, self-expanding valve.

for Medtronic, Meril Life, and Boston Scientific. M.P. has received minor lecture fees from Medtronic. J.M.D.l.T.H. is a consultant for Medtronic, Philips, Abbott, and Daichii; has received lecture fees from Boston Scientific, Abbott, and Medtronic, and research grants from Abbott and Biotronik. S.G.-B. has participated on advisory boards for Medtronic and has received lecture fees from Boston Scientific and research grants from Edwards. A.B. is a proctor for Boston Scientific and a consultant for Abbott and has received educational grants from Edwards, Terumo, Abbott, Boston Scientific, and Medtronic. R.d.V. has received consulting fees from Medtronic and speaker fees from Medtronic and Merce. V.F.N.d.A. has received lecture fees from B-Braun. M.A. has received travel fees from Medtronic. A.R. is a consultant for Abbott, Edwards, Meril, and Haemonetics. R.R. is a consultant for Meril and Biosensors, and has received lecture fees from Boston Scientific, Abbott, and Medtronic. X.C. has received lecture fees from Abbott and Edwards. X.M. is a proctor for Abbott and Boston Scientific. L.N.-F. is a consultant and has received lecture fees from Boston Scientific, Abbott, and Edwards Lifesciences, and lecture fees from Products&Features. The other authors have no conflicts of interest to disclose.

References

1. Vahanian A, Beyersdorf F, Praz F, et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. EuroIntervention 2022;17:e1126-96.

2. Sedaghat A, Al-Rashid F, Sinning JM, et al. Outcome in TAVI patients with symptomatic aortic stenosis not fulfilling PARTNER study inclusion criteria. Catheter Cardiovasc Interv 2015;86:1097-104.

3. Barbanti M, Ussia GP, Latib A, et al. Transcatheter aortic valve implantation in patients with mitral prosthesis. J Am Coll Cardiol 2012;60:1841-2.

4. Amat-Santos IJ, Cortes C, Nombela Franco L, et al. Prosthetic mitral surgical valve in transcatheter aortic valve replacement recipients: a multicenter analysis. JACC Cardiovasc Interv 2017;10:1973-81.

5. Baldetti L, Giannini F, Van Mieghem N, et al. Outcome of Patients Undergoing Transcatheter Implantation of Aortic Valve With Previous Mitral Valve Prosthesis (OPTIMAL) study. Can J Cardiol 2019;35:866-74.

6. VARC-3 Writing Committee, Genereux P, Piazza N, et al. Valve Academic Research Consortium 3: updated endpoint definitions for aortic valve clinical research. J Am Coll Cardiol 2021;77:2717-46.

7. Tanaka M, Yanagisawa R, Yashima F, et al. Previously implanted mitral surgical prosthesis in patients undergoing transcatheter aortic valve implantation: procedural outcome and morphologic assessment using multidetector computed tomography. PLoS One 2019;14:e0226512.

8. Chowdhury MZI, Turin TC. Variable selection strategies and its importance in clinical prediction modelling. Fam Med Commun Health 2020;8:e000262.

9. Sarkar K, Speciale G, Ussia GP. Core valve implant failure in the presence of mechanical mitral prosthesis: importance of assessing left ventricular outflow tract. Catheter Cardiovasc Interv 2015;85:920-4.

10. Squiers JJ, Hebeler KR, DiMaio JM, et al. Impingement of single-tilting disc mitral prosthesis during transcatheter aortic valve replacement. Ann Thorac Surg 2016;102:e529-31.

11. Abdel-Wahab M, Mehilli J, Frerker C, et al. Comparison of balloon-expandable vs self-expandable valves in patients undergoing transcatheter aortic valve replacement: the CHOICE randomized clinical trial. JAMA 2014;311:1503-14.

12. Siddiqui SA, Kazemian S, Gupta T, et al. Outcomes of transcatheter aortic valve replacement using third-generation balloon-expandable versus self-expanding valves: a meta-analysis. J Soc Cardiovasc Angiogr Interv 2024;3:102146.

13. Herrmann HC, Mehran R, Blackman DJ, et al. Self-expanding or balloon-expandable TAVR in patients with a small aortic annulus. N Engl J Med 2024;390:1959-71.

14. Wang B, Mei Z, Ge X, et al. Comparison of outcomes of self-expanding versus balloon-expandable valves for transcatheter aortic valve replacement: a meta-analysis of randomized and propensity-matched studies. BMC Cardiovasc Disord 2023;23:382.

15. Butala NM, Chung M, Secemsky EA, et al. Conscious sedation versus general anesthesia for transcatheter aortic valve replacement: variation in practice and outcomes. JACC Cardiovasc Interv 2020;13:1277-87.

16. de Agustin JA, Pozo Osinalde E, Olmos C, et al. Current usefulness of transesophageal echocardiography in patients undergoing transcatheter aortic valve replacement. J Clin Med 2023;12:7748.

17. Witberg G, Landes U, Talmor-Barkan Y, et al. Center valve preference and outcomes of transcatheter aortic valve replacement: insights from the AMTRAC registry. JACC Cardiovasc Interv 2022;15:1266-74.

Supplementary Material

To access the supplementary material accompanying this article, visit *CJC Pediatric and Congenital Heart Disease* at https://www.cjcpc.ca/ and at https://doi.org/10.1016/j.cjca.2025.04.026