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DE CARDIOLOGIE  
ET DE PNEUMOLOGIE  
DE QUÉBEC  
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# PUBLICATIONS SCIENTIFIQUES

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d'hémodynamie



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INSTITUT UNIVERSITAIRE DE CARDIOLOGIE ET DE PNEUMOLOGIE DE QUÉBEC – UNIVERSITÉ LAVAL  
2725 CHEMIN STE-FOY, QUÉBEC, QUÉBEC G1V 4G5



INSTITUT UNIVERSITAIRE  
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Chers collègues,

C'est avec une grande fierté que les cardiologues du secteur d'hémodynamie sont heureux de partager le document annuel réunissant les 91 publications issues des travaux initiés par le secteur (57) et par les collaborations de recherche (34) pour l'année 2025. Nous soulignons également que 24 publications ont été réalisées dans les principaux journaux de cardiologie tel que *The New England Journal of Medicine*, *Nature Reviews Cardiology*, *Circulation*, *Journal of the American College of Cardiology*, *JACC (Cardiovascular Imaging, Clinical Electrophysiology et Cardiovascular Interventions)*, *European Journal of Heart Failure* et *Circulation-Cardiovascular Interventions*.

Nous tenons à remercier chaleureusement le personnel du laboratoire d'hémodynamie, professionnels de recherche, étudiants et fellows qui ont grandement contribué à cette productivité scientifique qui assure un niveau d'excellence et un rayonnement international. Nous soulignons aussi le support remarquable de tous les membres du service de cardiologie, la direction du département de cardiologie et la direction de la recherche. Encore une fois, cette productivité démontre la vision d'excellence qui unit nos équipes et demeure une de nos priorités.

Merci et félicitations à tous,

Tomas Cieza, M.D.

Responsable médical du secteur d'hémodynamie

Institut universitaire de cardiologie et de pneumologie de Québec – Université Laval

## Table des matières

Clinical impact of complex percutaneous coronary intervention in the pre-TAVR workup .....	7
Five-year outcomes of transcarotid transcatheter aortic valve replacement .....	8
Early and late hospital readmissions after percutaneous left atrial appendage closure.....	9
Outcomes following antegrade-only versus retrograde chronic total occlusion percutaneous coronary intervention: insights from the CCTOP registry .....	10
Thrombocytopenia after transcatheter aortic valve implantation .....	11
Real-time analysis of conduction disturbances during TAVR with the CARA monitor.....	12
Surgical redo mitral replacement compared with transcatheter valve-in-valve in the mitral position.....	13
Visceral adiposity: A major mediator of the relationship between epicardial adiposity and cardiorespiratory fitness in adults.....	14
Validation of the Valve Academic Research Consortium High Bleeding Risk Definition in Patients Undergoing TAVR .....	15
Randomized Comparison of Novel Low-Dose Sirolimus-Eluting Biodegradable Polymer Stent vs Second-Generation DES: TARGET-IV NA Trial .....	16
Hemodynamic Performance of the SAPIEN 3 Ultra Resilia Valve: Insights From a Propensity-Matched Analysis .....	17
Routine Spironolactone in Acute Myocardial Infarction.....	18
Impact of intensive versus nonintensive antithrombotic treatment on device-related thrombus after left atrial appendage closure .....	19
Clinical Outcomes in Atrial Fibrillation Patients Undergoing Transcatheter Aortic Valve Replacement With Contemporary Devices .....	20
Prospective validation of a prespecified algorithm for the management of conduction disturbances after transcatheter aortic valve replacement: The PROMOTE study .....	21
Novel cardiac CT method for identifying the atrioventricular conduction axis by anatomic landmarks .....	22
Transcatheter Aortic Valve Replacement in Aortic Stenosis Patients With New York Heart Association Functional Class III or IV .....	23
Early safety after TAVR according to VARC-3 criteria: incidence, predictors, and clinical impact	24
Tailored hydration for the prevention of contrast-induced acute kidney injury after coronary angiogram or PCI: A systematic review and meta-analysis.....	25
Interatrial Shunt Therapy: A Rescue Option for Nonoperable Mitral Valve Disease Patients.....	26
Interventions for adult congenital heart disease .....	27
Evolution of Coagulation and Platelet Activation Markers After Transcatheter Edge-to-Edge Mitral Valve Repair .....	28
Feasibility of coronary access after transcatheter aortic valve implantation (TAVI): a systematic review and meta-analysis of observational studies .....	29

Acute Coronary Syndromes after Transcatheter Aortic Valve Implantation: Incidence, Unique Mechanisms, and Outcomes .....	30
Imaging assessment after percutaneous left atrial appendage closure: from immediate to long-term follow-up.....	31
'Incidence and impact of structural valve deterioration following TAVI: a multicenter real-world study' .....	32
Right heart failure and mortality in patients undergoing transcatheter tricuspid valve interventions .....	33
Late arrhythmic burden in patients with left bundle branch block after TAVR with the Evolut valve.....	34
Transcarotid Versus Surgical Aortic Valve Replacement for the Treatment of Severe Aortic Stenosis.....	35
Evolut Low-Risk Trial 5-Year Result: We're Halfway There .....	36
Vascular Complications in Patients Undergoing Transcatheter Aortic Valve Replacement With Contemporary Devices .....	37
Optimal Oversizing With the New-Generation Evolut (PRO/PRO+/FX) Self-Expanding Valves: A Multicenter Study.....	38
Risk of delayed atrioventricular block in patients without procedural conduction disturbances during transcatheter aortic valve replacement.....	39
Temporal Trends in Transcatheter Aortic Valve Replacement Outcomes in Patients With Low-Flow, Low-Gradient Aortic Stenosis: Insights From the TOPAS-TAVI Registry.....	40
Human Epididymis Protein 4 in Transcatheter Aortic Valve Implantation: Diagnostic and Prognostic Value.....	41
Evaluating the AltaValve as a novel method for transcatheter mitral valve replacement .....	42
Gender-Specific Outcomes in TAVI with Self-Expandable Valves: Insights from a Large Real-World Registry .....	43
Randomized Study Comparing Angiography Guidance With Physiology Guidance After PCI: The EASY-PREDICT Study .....	44
An evaluation of the SavvyWire as a support wire for TAVR procedures .....	45
PFO Device Closure in Patients >60 Years of Age With Ischemic Stroke: Results From U.S. Medicare Beneficiaries .....	46
Global Results From the Optimize PRO Study: Standardized TAVR Technique and Care Pathway .....	47
Role of visceral adiposity in the relationship between cardiorespiratory fitness and liver fat in asymptomatic adults .....	48
Transcatheter Aortic Valve Durability: Focus on Structural Valve Deterioration .....	49
Prognostic value of NT-proBNP in patients with primary mitral regurgitation undergoing transcatheter edge-to-edge repair.....	50
The Effect of 12-Week e-Cigarette Use on Smoking Abstinence at 1 Year: The E3 Trial .....	51
30-Day and 1-Year Outcomes From the Optimize PRO TAVR Evolut FX Addendum Study .....	52

Management of conduction disturbances after TAVI: the last step towards early discharge.....	53
Pacemaker Risk Stratification in Patients With Pre-existing Right Bundle Branch Block Undergoing Transcatheter Aortic Valve Replacement.....	54
New York Valves: The Structural Heart Summit (June 25-27, 2025).....	55
CT derived ECV in severe aortic stenosis: prognosticator and screening test for co-existent transthyretin cardiac amyloidosis .....	56
Transbrachial Catheter-Assisted Thrombolysis and Bailout Stenting for Massive Postoperative Pulmonary Embolism.....	57
Incidence, Predictors, and Management of Conduction Disturbances After Transcatheter Tricuspid Valve Replacement: The TRIPLACE Registry .....	58
Atrioventricular Conduction Disturbances in Patients Undergoing Transcatheter Tricuspid Valve Intervention: A Multidisciplinary Consensus.....	59
Same-Day Permanent Pacemaker Implantation Following Transcatheter Aortic Valve Replacement.....	60
Live Hemodynamics-Assisted Simultaneous Aortic and Mitral Valve-in-Valve Replacement .....	61
Response by Ulacia Flores and Bertrand to Letter Regarding Article, "Randomized Study Comparing Angiography Guidance With Physiology Guidance After PCI: The EASY-PREDICT Study" .....	62
Pectus Excavatum, Patent Foramen Ovale, and Migraine in the Same Patient.....	63
Honeycomb or Lotus Root-Like Intracoronary Pattern: Insights From Optical Coherence Tomography of a Recanalized Thrombus .....	64
The Evolving Risk of Infective Endocarditis After Transcatheter Aortic Valve Implantation .....	65
Early Hemodynamic Performance of the SAPIEN 3 Ultra Resilia and Evolut Valves: A Propensity- Matched Analysis .....	66
Efficacy and Safety of Transcatheter Mitral Valve Edge-to-Edge Repair with a MitraClip Device in Real-World Canadian Practice .....	67
Mechanistic Basis for Differential Effects of Interatrial Shunt Treatment in HFrEF vs HFpEF: The RELIEVE-HF Trial .....	68
Patent Foramen Ovale Closure in Older Patients With Cryptogenic Stroke: Current Evidence and Next Steps.....	69
Upper Extremity Vascular Access .....	70
Prophylactic Permanent Pacemaker Implantation After Transcatheter Aortic Valve Replacement .....	71
Role of Early Prothrombotic Evaluation in Device-Related Thrombus Risk Stratification After Left Atrial Appendage Closure.....	72
CLASP IID Trial and Registry: 2-Year Outcomes of Transcatheter Repair for Degenerative Mitral Regurgitation.....	73
Preprocedural CT and ECG Markers for Predicting Post-TAVR Pacemaker Requirement in High- Risk Patients .....	74

Clinical Impact of Concordant and Discordant Physiology Parameters Post-Percutaneous Coronary Intervention in the EASY-PREDICT Study .....	75
Visceral adipose tissue and hepatic fat as determinants of carotid atherosclerosis .....	76
Massive Anterior STEMI Due to Essential Thrombocythemia Leading to Urgent Thrombocytapheresis.....	77
Five-Year Clinical Outcomes and Durability of a Self-Expanding Transcatheter Heart Valve With Intra-Annular Leaflets.....	78
Novel Mother-in-Child Technique to Implant Coronary Sinus Reducer in a Challenging Anatomy .....	79
Short-Term Anticoagulation Versus Dual Antiplatelet Therapy for Preventing Device Thrombosis Following Left Atrial Appendage Closure: The ANDES Randomized Clinical Trial.....	80
Association Between Lipoprotein(a), Oxidized phospholipids, and Bioprosthetic Valve Dysfunction Following Transcatheter Aortic Valve Implantation .....	81
Impact of Balloon Postdilation on Long-Term Bioprostheses Durability After TAVR.....	82
Impact of Early Hemodynamic Valve Deterioration on Long-Term Outcomes Following Transcatheter Aortic Valve Replacement.....	83
Temporal trends and outcomes of left atrial appendage closure. A national population-based study .....	84
Structural Heart: The Journal of the Heart Team - Starting a New Era .....	85
Long-term outcomes after transcatheter tricuspid valve-in-valve replacement.....	86
Impact of Anticoagulation on Long-Term Bioprostheses Durability After Transcatheter Aortic Valve Replacement.....	87
Clinical Impact of In-Hospital Hemoglobin Decline Without Overt Bleeding After Transcatheter Aortic Valve Replacement .....	88
Risk of Delayed Atrioventricular Block in TAVR Recipients With Preexisting Right Bundle Branch Block .....	89
Contemporary and Emerging Therapies in the Management of Refractory Angina: A Clinical Review .....	90
Transcatheter interventions in adult patients with transposition of the great arteries.....	91
Low-dose direct oral anticoagulation vs dual antiplatelet therapy after left atrial appendage occlusion: 1-year results from the ADALA trial .....	92
The Additional Value of His Ventricular Interval in Left Bundle Branch Block After Transcatheter Aortic Valve Implantation: Precision Medicine or Not? .....	93
Balloon-Expandable Valve Performance Beyond 10 Years Following Transcatheter Aortic Valve Implantation .....	94
The Alternative Imaging Modalities in Ischemic Heart Failure (AIMI-HF) Trial-IMAGE HF Project 1A.....	95
Long-term Impact of Multivalvular Heart Disease in Patients Undergoing Transcatheter Aortic Valve Replacement.....	96
Transcatheter edge-to-edge repair in secondary mitral regurgitation .....	97

# Clinical impact of complex percutaneous coronary intervention in the pre-TAVR workup

[Article in English, Spanish]

Marisa Avvedimento <sup>1</sup>, Francisco Campelo-Parada <sup>2</sup>, Luis Nombela-Franco <sup>3</sup>, Quentin Fischer <sup>4</sup>, Pierre Donaint <sup>5</sup>, Vicenç Serra <sup>6</sup>, Gabriela Veiga <sup>7</sup>, Enrique Gutiérrez <sup>8</sup>, Anna Franzone <sup>9</sup>, Victoria Vilalta <sup>10</sup>, Alberto Alperi <sup>11</sup>, Ander Regueiro <sup>12</sup>, Lluis Asmarats <sup>13</sup>, Henrique B Ribeiro <sup>14</sup>, Anthony Matta <sup>2</sup>, Antonio Muñoz-García <sup>15</sup>, Gabriela Tirado <sup>3</sup>, Marina Urena <sup>4</sup>, Damien Metz <sup>5</sup>, Eduard Rodenas-Alesina <sup>6</sup>, Jose María de la Torre Hernández <sup>7</sup>, Domenico Angellotti <sup>9</sup>, Eduard Fernández-Nofreras <sup>10</sup>, Isaac Pascual <sup>11</sup>, Pablo Vidal-Calés <sup>12</sup>, Dabit Arzamendi <sup>13</sup>, Diego Carter Campanha-Borges <sup>14</sup>, Kim Hoang Trinh <sup>1</sup>, Jorge Nuche <sup>1</sup>, Mélanie Côté <sup>1</sup>, Laurent Faroux <sup>5</sup>, Josep Rodés-Cabau <sup>16</sup>

Affiliations + expand

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## Abstract

**Introduction and objectives:** In patients undergoing percutaneous coronary intervention (PCI) in the workup pre-transcatheter aortic valve replacement (TAVR), the clinical impact of coronary revascularization complexity remains unknown. This study sought to examine the impact of PCI complexity on clinical outcomes after TAVR in patients undergoing PCI in the preprocedural workup.

**Methods:** This was a multicenter study including consecutive patients scheduled for TAVR with concomitant significant coronary artery disease. Complex PCI was defined as having at least 1 of the following features: 3 vessels treated,  $\geq 3$  stents implanted,  $\geq 3$  lesions treated, bifurcation with 2 stents implanted, total stent length  $>60$  mm, or chronic total occlusion. The rates of major adverse cardiac events (MACE), including cardiovascular mortality, myocardial infarction, and coronary revascularization were evaluated.

**Results:** A total of 1550 patients were included, of which 454 (29.3%) underwent complex PCI in the pre-TAVR workup. After a median follow-up period of 2 [1-3] years after TAVR, the incidence of MACE was 9.6 events per 100 patients-years. Complex PCI significantly increased the risk of cardiac death (HR, 1.44; 95%CI, 1.01-2.07), nonperiprocedural myocardial infarction (HR, 1.52; 95%CI, 1.04-2.21), and coronary revascularization (HR, 2.46; 95%CI, 1.44-4.20). In addition, PCI complexity was identified as an independent predictor of MACE after TAVR (HR, 1.31; 95%CI, 1.01-1.71;  $P=.042$ ).

**Conclusions:** In TAVR candidates with significant coronary artery disease requiring percutaneous treatment, complex revascularization was associated with a higher risk of MACE. The degree of procedural complexity should be considered a strong determinant of prognosis in the PCI-TAVR population.

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## Five-year outcomes of transcarotid transcatheter aortic valve replacement

Juan Hernando Del Portillo <sup>1</sup>, Dimitri Kalavrouziotis <sup>1</sup>, Eric Dumont <sup>1</sup>, Jean-Michel Paradis <sup>1</sup>,  
Anthony Poulin <sup>1</sup>, Frederic Beaupré <sup>1</sup>, Marisa Avvedimento <sup>1</sup>, Silvia Mas-Peiro <sup>1</sup>,  
Pedro Cepas-Guillén <sup>1</sup>, Siddhartha Mengi <sup>1</sup>, Siamak Mohammadi <sup>1</sup>, Josep Rodés-Cabau <sup>2</sup>

Affiliations + expand

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### Abstract

**Background:** Transcarotid transcatheter aortic valve replacement (TC-TAVR) has emerged as an alternative access route for transcatheter aortic valve replacement (TAVR). However, scarce data exist on long-term outcomes following TC-TAVR. This study aimed to evaluate clinical outcomes at 5 years after TC-TAVR.

**Methods:** A total of 110 consecutive patients who underwent TC-TAVR were included. Baseline, procedural, and follow-up data were collected prospectively in a dedicated database. The primary endpoint was the incidence of a composite outcome of all-cause mortality, stroke, and repeat hospitalization at 5-year follow-up. Echocardiography results, New York Heart Association (NYHA) class, and quality of life (QoL) as assessed with the EuroQol visual analog scale (EQ-VAS) were examined over the 5-year follow-up.

**Results:** The median patient age was 77 years (interquartile range [IQR], 72-82.2 years), 42.3% were women, and the median Society of Thoracic Surgeons (STS) risk score was 5.02% (IQR, 3.4%-7.5%). The incidence of the composite primary endpoint was 54.5%. Death from any cause occurred in 45.6% of patients (11.9 per 100 patient-years); stroke in 8.2% (1.9 per 100 patient-years); disabling stroke in 2.7% (0.7 per 100 patient-years); and rehospitalization in 27.2%. The improvements in valve hemodynamics, NYHA class, and EQ-VAS following the procedure persisted at 5-year follow-up ( $P < .001$ ). The incidence of bioprosthetic valve failure was 0.9%.

**Conclusions:** About half of the moderate-to high-risk patients undergoing TC-TAVR survived with no major cardiovascular events at the 5-year follow-up. The yearly incidence of stroke events was low, and early improvements in valve hemodynamics, functional status, and QoL persisted at 5 years. These results suggest the long-term safety and efficacy of TC-TAVR and would support this approach as an alternative to surgery in non-transfemoral candidates.

# Early and late hospital readmissions after percutaneous left atrial appendage closure

[Article in English, Spanish]

Kim Hoang Trinh <sup>1</sup>, Jorge Nuche <sup>1</sup>, Ignacio Cruz-González <sup>2</sup>, Paul Guedeney <sup>3</sup>, Dabit Arzamendi <sup>4</sup>, Xavier Freixa <sup>5</sup>, Luis Nombela-Franco <sup>6</sup>, Vicente Peral <sup>7</sup>, Berenice Caneiro-Queija <sup>8</sup>, Antonio Mangieri <sup>9</sup>, Blanca Trejo-Velasco <sup>10</sup>, Lluís Asmarats <sup>4</sup>, Pedro Cepas-Guillén <sup>11</sup>, Pablo Salinas <sup>6</sup>, Joan Siquier-Padilla <sup>7</sup>, Rodrigo Estevez-Loureiro <sup>8</sup>, Alessandra Laricchia <sup>12</sup>, Gilles O'hara <sup>1</sup>, Gilles Montalescot <sup>3</sup>, Mélanie Côté <sup>1</sup>, Jules Mesnier <sup>1</sup>, Josep Rodés-Cabau <sup>13</sup>

Affiliations + expand

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## Abstract

**Introduction and objectives:** Percutaneous left atrial appendage closure (LAAC) has emerged as a nonpharmacological alternative for the prevention of thromboembolic events in patients with nonvalvular atrial fibrillation. However, there are few data on readmissions after LACC. The aim of this study was to determine the rate of early ( $\leq 30$  days) and late (31-365 days) readmission after LAAC, and to assess the predictors and clinical impact of rehospitalization.

**Methods:** This multicenter study included 1419 consecutive patients who underwent LAAC. The median follow-up was 33 [17-55] months, and follow-up was complete in all but 54 (3.8%) patients. The primary endpoint was readmissions for any cause. Logistic regression and Cox regression analysis were performed to determine the predictors of readmission and its clinical impact.

**Results:** A total of 257 (18.1%) patients were readmitted within the first year after LAAC (3.2% early, 14.9% late). The most common causes of readmission were bleeding (24.5%) and heart failure (20.6%). A previous gastrointestinal bleeding event was associated with a higher risk of early readmission (OR, 2.65; 95%CI, 1.23-5.71). The factors associated with a higher risk of late readmission were a lower body mass index (HR, 0.96-95%CI, 0.93-0.99), diabetes (HR, 1.38-95%CI, 1.02-1.86), chronic kidney disease (HR, 1.60; 95%CI, 1.21-2.13), and previous heart failure (HR, 1.69; 95%CI, 1.26-2.27). Both early (HR, 2.12-95%CI, 1.22-3.70) and late (HR, 1.75; 95%CI, 1.41-2.17) readmissions were associated with a higher risk of 2-year mortality.

**Conclusions:** Readmissions within the first year after LAAC were common, mainly related to bleeding and heart failure events, and associated with patients' comorbidity burden. Readmission after LAAC conferred a higher risk of mortality during the first 2 years after the procedure.

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## Outcomes following antegrade-only versus retrograde chronic total occlusion percutaneous coronary intervention: insights from the CCTOP registry

Louis Verreault-Julien <sup>1</sup>, Israth Jahan <sup>2</sup>, Nandini Dendukuri <sup>2</sup>, Luiz F Ybarra <sup>2</sup>, Samer Mansour <sup>3</sup>, Alexis Matteau <sup>3</sup>, Harindra C Wijeyesundara <sup>4</sup>, Anthony Fung <sup>5</sup>, Simon Robinson <sup>6</sup>, Jean-Michel Paradis <sup>7</sup>, Can Manh Nguyen <sup>8</sup>, Stéphane Rinfret <sup>9</sup>

Affiliations + expand

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Free article

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# Thrombocytopenia after transcatheter aortic valve implantation

[Article in English, Spanish]

Gabriela Tirado-Conte <sup>1</sup>, Vassili Panagides <sup>2</sup>, Carlos E Vergara-Uzcategui <sup>3</sup>,  
Gabriela Veiga Fernández <sup>4</sup>, Jean Paul Vilchez <sup>5</sup>, Pedro Cepas-Guillén <sup>6</sup>, Juan Francisco Oteo <sup>7</sup>,  
Alejandro Barrero <sup>8</sup>, Luis Marroquín <sup>9</sup>, Julio I Farjat-Pasos <sup>10</sup>, Ketina Arslan <sup>11</sup>,  
Pilar Jiménez-Quevedo <sup>3</sup>, Iván Núñez-Gil <sup>12</sup>, Hernán Mejía-Rentería <sup>3</sup>,  
José M de la Torre Hernández <sup>4</sup>, José Luis Díez Gil <sup>5</sup>, Ander Regueiro <sup>6</sup>, Ignacio Amat-Santos <sup>8</sup>,  
Antonio Fernández-Ortiz <sup>3</sup>, Guering Eid-Lidt <sup>10</sup>, Ole de Backer <sup>11</sup>, Josep Rodés-Cabau <sup>13</sup>,  
Luis Nombela-Franco <sup>14</sup>

## Abstract

**Introduction and objectives:** Thrombocytopenia frequently occurs after transcatheter aortic valve implantation (TAVI) but its impact is poorly understood. We aimed to analyze the incidence, clinical impact, and predictors of acquired thrombocytopenia after TAVI.

**Methods:** This retrospective multicenter registry included 3913 patients undergoing TAVI with a baseline platelet count of  $\geq 100 *10^9/L$ . Acquired thrombocytopenia was defined as a decrease in baseline platelet count of  $\geq 50\%$  (early nadir  $\leq 3$  days and late nadir  $\geq 4$  days) post-TAVI. The primary endpoint was 30-day all-cause mortality and secondary endpoints were procedural safety and 2-year all-cause mortality.

**Results:** The incidence of acquired thrombocytopenia was 14.8% (early nadir: 61.5%, late nadir: 38.5%). Thirty-day mortality occurred in 112 (3.0%) patients and was significantly higher in those with thrombocytopenia (8.5% vs 2.0%, adjusted OR, 2.3; 95%CI, 1.3-4.2). Procedural safety was lower and 2-year mortality was higher in patients with thrombocytopenia vs those without (52.1 vs 77.0%; P <.001, and 30.2% vs 16.8%; HR, 2.2, 95%IC, 1.3-2.7) and especially in those with late nadir thrombocytopenia (45.8% vs 54.5%; P=.056, and 38.6% vs 23.8%, HR, 2.1; 95%CI, 1.5-2.9). Independent predictors of thrombocytopenia comprised baseline and procedural factors such as body surface area, absence of diabetes, poorer renal function, peripheral vascular disease, nontransfemoral access, vascular complications, type of transcatheter heart valve, and earlier TAVI procedures.

**Conclusions:** Acquired thrombocytopenia was common (15%) after TAVI and was associated with increased short- and mid-term mortality and decreased procedural safety. Moreover, late thrombocytopenia compared with early thrombocytopenia was associated with significantly worse clinical outcomes. Further investigations are needed to elucidate the etiologic mechanisms behind these findings.

## Real-time analysis of conduction disturbances during TAVR with the CARA monitor

Attilio Galhardo <sup>1</sup>, Jorge Nuche <sup>1</sup>, Francesco Bedogni <sup>2</sup>, Luca Testa <sup>2</sup>, Ander Regueiro <sup>3</sup>,  
Pedro Cepas-Guillén <sup>3</sup>, Mackram F Eleid <sup>4</sup>, Shmuel Chen <sup>5</sup>, Mark Reisman <sup>5</sup>, Siddhartha Mengi <sup>1</sup>,  
François Philippon <sup>1</sup>, Josep Rodés-Cabau <sup>6</sup>

Affiliations + expand

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### Abstract

**Background:** The occurrence of conduction disturbances (CDs) remains the most frequent complication of transcatheter aortic valve replacement (TAVR). However, little is known about the timing of electrocardiogram (ECG) changes and CDs during the TAVR procedure.

**Objective:** The objective of this study was to describe ECG changes throughout the TAVR procedure using the CARA monitor.

**Methods:** This was a multicenter study including 196 prospectively enrolled patients without preexisting CDs undergoing TAVR. All patients were monitored with the CARA system, which uses a 12-lead ECG to measure PQ and QRS intervals, QRS axis, and variations with each heartbeat at every step: baseline, wire insertion, pre-dilatation, valve deployment, post-dilatation, and end of procedure.

**Results:** PQ and QRS intervals progressively increased throughout the procedure, with a cumulative increase from  $169.2 \pm 20.0$  ms to  $186.0 \pm 31.6$  ms ( $P < .001$ ) for the PQ interval and from  $101.3 \pm 10.5$  ms to  $126.0 \pm 25.4$  ms ( $P < .001$ ) for the QRS interval, from baseline to the end of the procedure. A significant increase in the number of patients with left axis deviation was observed (7.7% at baseline vs 31.8% at end of procedure;  $P < .001$ ). A total of 161 (82.1%) patients exhibited at least 1 CD episode ( $\text{PQ} > 200$  ms,  $\text{QRS} \geq 120$  ms, advanced heart block) during the procedure, with most episodes occurring during pre-dilatation and valve implantation maneuvers.

**Conclusion:** The CARA system facilitated real-time ECG monitoring, detecting subtle and progressive changes during TAVR. ECG changes occurred at each step, with most patients experiencing CDs, especially during pre-dilatation and valve implantation. The potential clinical impact of monitoring ECG dynamics and timing for early detection of severe CDs should be explored in future studies.

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## Surgical redo mitral replacement compared with transcatheter valve-in-valve in the mitral position

Pedro Cepas-Guillén <sup>1</sup>, Dimitri Kalavrouziotis <sup>2</sup>, Eric Dumont <sup>2</sup>, Jean Porterie <sup>2</sup>,  
Jean-Michel Paradis <sup>1</sup>, Josep Rodés-Cabau <sup>1</sup>, Siamak Mohammadi <sup>3</sup>

Affiliations + expand

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*No abstract available*

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# Visceral adiposity: A major mediator of the relationship between epicardial adiposity and cardiorespiratory fitness in adults

Dominic J Chartrand <sup>1</sup>, Eric Larose <sup>1</sup>, Paul Poirier <sup>2</sup>, Patrick Mathieu <sup>1</sup>, Natalie Alméras <sup>1</sup>,  
Philippe Pibarot <sup>1</sup>, Benoît Lamarche <sup>3</sup>, Caroline Rhéaume <sup>4</sup>, Isabelle Lemieux <sup>5</sup>,  
Jean-Pierre Després <sup>4</sup>, Marie-Eve Piché <sup>6</sup>

Affiliations + expand

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## Abstract

**Background and aims:** Epicardial adiposity has been positively associated with visceral adipose tissue (VAT). Few studies have examined the association between cardiorespiratory fitness (CRF) and epicardial adiposity. Furthermore, whether this relationship was independent of VAT remains unexplored. Our purpose was to investigate the contribution of VAT in the relationships between CRF, physical activity (PA) and epicardial adipose tissue (EAT) in asymptomatic women and men.

**Methods and results:** We examined the associations between EAT and VAT measured by magnetic resonance imaging, CRF measured by cardiopulmonary exercise testing, and PA assessed using pedometers and a 3-day PA journal in 239 apparently healthy adults (43 % women). Participants were compared according to EAT tertiles and CRF level in both sexes. Participants with the highest EAT level presented more VAT ( $p < 0.001$ ), lower CRF ( $p < 0.01$ ), and a more deteriorated cardiometabolic health score ( $p < 0.01$ ) than those with the lowest EAT level. CRF was negatively associated with EAT in both sexes ( $p < 0.01$ ). No significant relationship was found with PA ( $p = \text{NS}$ ). Stepwise multivariable regression analyses showed that VAT explained most of the variance in EAT in women and men. Mediation analyses confirmed that VAT was a mediator of the association between CRF and EAT in both sexes.

**Conclusion:** In women and men, VAT appears as a major mediator of the association between CRF and EAT thereby suggesting that managing VAT by improving CRF could help in the prevention of cardiometabolic disorders related to excess EAT.

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# Validation of the Valve Academic Research Consortium High Bleeding Risk Definition in Patients Undergoing TAVR

Marisa Avvedimento <sup># 1</sup>, Pedro Cepas-Guillén <sup># 1</sup>, Julien Ternacle <sup>2</sup>, Marina Urena <sup>3</sup>, Alberto Alperi <sup>4</sup>, Asim Cheema <sup>5</sup>, Gabriela Veiga-Fernandez <sup>6</sup>, Luis Nombela-Franco <sup>7</sup>, Victoria Vilalta <sup>8</sup>, Giovanni Esposito <sup>9</sup>, Francisco Campelo-Parada <sup>10</sup>, Ciro Indolfi <sup>11</sup>, Maria Del Trigo <sup>12</sup>, Antonio Muñoz-García <sup>13</sup>, Nicolás Maneiro <sup>14</sup>, Lluís Asmarats <sup>15</sup>, Ander Regueiro <sup>16</sup>, David Del Val <sup>17</sup>, Vicenç Serra <sup>18</sup>, Vincent Auffret <sup>19</sup>, Thomas Modine <sup>2</sup>, Guillaume Bonnet <sup>2</sup>, Jules Mesnier <sup>3</sup>, Gaspard Suc <sup>3</sup>, Pablo Avanzas <sup>4</sup>, Effat Rezaei <sup>5</sup>, Victor Fradejas-Sastre <sup>6</sup>, Gabriela Tirado-Conte <sup>7</sup>, Eduard Fernández-Nofrarias <sup>8</sup>, Anna Franzone <sup>9</sup>, Thibaut Guitteny <sup>10</sup>, Sabato Sorrentino <sup>11</sup>, Juan Francisco Oteo <sup>12</sup>, Jorge Nuche <sup>1 14</sup>, Lola Gutiérrez-Alonso <sup>15</sup>, Eduardo Flores-Umanzor <sup>16</sup>, Fernando Alfonso <sup>17</sup>, Andrea Monastyrski <sup>18</sup>, Maxime Nolf <sup>19</sup>, Mélanie Côté <sup>1</sup>, Roxana Mehran <sup>20</sup>, Marie-Claude Morice <sup>21</sup>, Davide Capodanno <sup>22</sup>, Philippe Garot <sup>21</sup>, Josep Rodés-Cabau <sup>1</sup>

## Abstract

**Background:** The Valve Academic Research Consortium for High Bleeding Risk (VARC-HBR) has recently introduced a consensus document that outlines risk factors to identify high bleeding risk in patients undergoing transcatheter aortic valve replacement. The objective of the present study was to evaluate the prevalence and predictive value of the VARC-HBR definition in a contemporary, large-scale transcatheter aortic valve replacement population.

**Methods:** Multicenter study including 10 449 patients undergoing transcatheter aortic valve replacement. Based on consensus, 21 clinical and laboratory criteria were identified and classified as major or minor. Patients were stratified as at low, moderate, high, and very high bleeding risk according to the VARC-HBR definition. The primary end point was the rate of Bleeding Academic Research Consortium type 3 or 5 bleeding at 1 year, defined as the composite of periprocedural (within 30 days) or late (after 30 days) bleeding.

**Results:** Patients with at least 1 VARC-HBR criterion (n=9267, 88.7%) had a higher risk of Bleeding Academic Research Consortium 3 or 5 bleeding, proportional to the severity of risk assessment (10.8%, 16.1%, and 24.6% for moderate, high, and very-high-risk groups, respectively). However, a comparable rate of bleeding events was observed in the low-risk and moderate-risk groups. The area under receiver operating characteristic curve was 0.58. Patients with VARC-HBR criteria also exhibited a gradual increase in 1-year all-cause mortality, with an up to 2-fold increased mortality risk for high and very-high-risk groups (hazard ratio, 1.33 [95% CI, 1.04-1.70] and 1.97 [95% CI, 1.53-2.53], respectively).

**Conclusions:** The VARC-HBR consensus offered a pragmatic approach to guide bleeding risk stratification in transcatheter aortic valve replacement. The results of the present study would support the predictive validity of the new definition and promote its application in clinical practice to minimize bleeding risk and improve patient outcomes.

## Randomized Comparison of Novel Low-Dose Sirolimus-Eluting Biodegradable Polymer Stent vs Second-Generation DES: TARGET-IV NA Trial

Robert W Yeh <sup>1</sup>, Olivier F Bertrand <sup>2</sup>, Ehtisham Mahmud <sup>3</sup>, Emanuele Barbato <sup>4</sup>, Batla Falah <sup>5</sup>, Melek Ozgu Issever <sup>5</sup>, Björn Redfors <sup>6</sup>, Alexandra Popma <sup>5</sup>, Michael Curtis <sup>7</sup>, Niels van Royen <sup>8</sup>, Jean-Francois Tanguay <sup>9</sup>, Luc Janssens <sup>10</sup>, William N Newman <sup>11</sup>, Koen Teeuwen <sup>12</sup>, James W Choi <sup>13</sup>, Maurits T Dirksen <sup>14</sup>, Akiko Maehara <sup>15</sup>, Martin B Leon <sup>15</sup>

### Abstract

**Background:** Drug-eluting stents (DESs) with controlled antiproliferative drug release reduce restenosis risk, but durable polymers can delay healing and inhibit reendothelialization. The Firehawk biodegradable polymer sirolimus-eluting stent (BP-SES) has a fully biodegradable sirolimus-containing polymer coating localized to recessed abluminal grooves on the stent surface and delivers roughly one-third the drug dose of other DESs.

**Objectives:** We report the primary results of the TARGET-IV NA (Firehawk Rapamycin Target Eluting Coronary Stent North American Trial) randomized controlled trial comparing clinical outcomes with BP-SES vs currently used second-generation DESs.

**Methods:** The TARGET-IV NA study was a prospective, multicenter, single-blind, 1:1 randomized noninferiority trial comparing the BP-SES with control in North America and Europe among patients undergoing percutaneous coronary intervention for chronic or acute coronary syndromes. The primary endpoint was target lesion failure (TLF) at 12 months (composite of cardiac death, target vessel-related myocardial infarction, or ischemia-driven target lesion revascularization). The primary analysis (intention-to-treat) tested noninferiority of BP-SES vs control using an absolute margin of 3.85% and 1-sided  $\alpha$  of 0.025. Noninferiority-powered secondary endpoints were tested in an optical coherence tomography substudy (endpoint: mean neointimal hyperplasia thickness) and an angiography substudy (endpoint: in-stent late lumen loss).

**Results:** A total of 1,720 patients (mean age 66 years; 74% male) with 2,159 lesions were randomly allocated to receive either BP-SES (860 patients, 1,057 lesions) or control second-generation DES (860 patients, 1,084 lesions). A total of 61% of patients presented with stable coronary disease, 32% had unstable angina, and 7% had non-ST-segment elevation myocardial infarction (NSTEMI) or recent ST-segment elevation myocardial infarction. The rate of TLF with BP-SES was noninferior to control at 12 months (3.4% vs 3.3%, absolute risk difference 0.13%, upper bound 97.5% CI: 2.03,  $P_{\text{noninferiority}} < 0.0001$ ). Cardiac death, myocardial infarction, and stent thrombosis rates were similar between groups. Angiographic follow-up was available in 104 patients (97.2% of those enrolled in the angiographic substudy) and 128 (94.1%) lesions. At 13 months, the powered secondary endpoint of mean in-stent late lumen loss was  $0.149 \pm 0.263$  mm for BP-SES and  $0.327 \pm 0.463$  mm for control (least squares mean difference: -0.178; 90% CI: -0.2943 to -0.0632;  $P_{\text{noninferiority}} < 0.0001$ ). The optical coherence tomography substudy included 37 patients (42 lesions) with no difference in mean neointimal hyperplasia thickness between groups at 13 months ( $P_{\text{noninferiority}} = 0.01$ ).

**Conclusions:** The biodegradable polymer sirolimus-eluting stent was noninferior to currently used second-generation DES with regard to TLF at 1 year. (Firehawk® Rapamycin Target Eluting Coronary Stent North American Trial; [NCT04562532](#)).

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## Hemodynamic Performance of the SAPIEN 3 Ultra Resilia Valve: Insights From a Propensity-Matched Analysis

Marisa Avvedimento <sup>1</sup>, Carlos Giuliani <sup>1</sup>, Antonela Zanuttini <sup>1</sup>, Siddhartha Mengi <sup>1</sup>,  
Silvia Mas-Peiro <sup>1</sup>, Anthony Poulin <sup>1</sup>, Frederic Beaupré <sup>1</sup>, Jean-Michel Paradis <sup>1</sup>, Jean Porterie <sup>1</sup>,  
Dimitri Kalavrouziotis <sup>1</sup>, Eric Dumont <sup>1</sup>, Siamak Mohammadi <sup>1</sup>, Mélanie Côté <sup>1</sup>, Philippe Pibarot <sup>1</sup>,  
Josep Rodés-Cabau <sup>2</sup>

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## Routine Spironolactone in Acute Myocardial Infarction

Sanjit S Jolly <sup>1 2</sup>, Marc-André d'Entremont <sup>1 2 3</sup>, Bertram Pitt <sup>4</sup>, Shun Fu Lee <sup>1 2</sup>, Rajibul Mian <sup>1 2</sup>, Jessica Tyrwhitt <sup>1</sup>, Sasko Kedev <sup>5</sup>, Gilles Montalescot <sup>6</sup>, Jan H Cornel <sup>7 8 9</sup>, Goran Stanković <sup>10</sup>, Raul Moreno <sup>11</sup>, Robert F Storey <sup>12 13</sup>, Timothy D Henry <sup>14</sup>, Shamir R Mehta <sup>1 2</sup>, Matthias Bossard <sup>15</sup>, Petr Kala <sup>16</sup>, Ravinay Bhindi <sup>17 18</sup>, Biljana Zafirovska <sup>5</sup>, P J Devereaux <sup>1 2</sup>, John Eikelboom <sup>1 2</sup>, John A Cairns <sup>19</sup>, Madhu K Natarajan <sup>1 2</sup>, J D Schwalm <sup>1 2</sup>, Sanjib K Sharma <sup>20</sup>, Wadea Tarhuni <sup>21</sup>, David Conen <sup>1 2</sup>, Sarah Tawadros <sup>1</sup>, Shahar Lavi <sup>22</sup>, Valon Asani <sup>23</sup>, Dragan Topic <sup>24</sup>, Warren J Cantor <sup>25</sup>, Olivier F Bertrand <sup>26</sup>, Ali Pourdjabbar <sup>27</sup>, Salim Yusuf <sup>1</sup>; CLEAR Investigators; CLEAR Investigators

### Abstract

**Background:** Mineralocorticoid receptor antagonists have been shown to reduce mortality in patients after myocardial infarction with congestive heart failure. Whether routine use of spironolactone is beneficial after myocardial infarction is uncertain.

**Methods:** In this multicenter trial with a 2-by-2 factorial design, we randomly assigned patients with myocardial infarction who had undergone percutaneous coronary intervention to receive either spironolactone or placebo and either colchicine or placebo. The results of the spironolactone trial are reported here. The two primary outcomes were a composite of death from cardiovascular causes or new or worsening heart failure, evaluated as the total number of events; and a composite of the first occurrence of myocardial infarction, stroke, new or worsening heart failure, or death from cardiovascular causes. Safety was also assessed.

**Results:** We enrolled 7062 patients at 104 centers in 14 countries; 3537 patients were assigned to receive spironolactone and 3525 to receive placebo. At the time of our analyses, the vital status was unknown for 45 patients (0.6%). For the first primary outcome, there were 183 events (1.7 per 100 patient-years) in the spironolactone group as compared with 220 events (2.1 per 100 patient-years) in the placebo group over a median follow-up period of 3 years (hazard ratio adjusted for competing risk of death from noncardiovascular causes, 0.91; 95% confidence interval [CI], 0.69 to 1.21;  $P = 0.51$ ). With respect to the second primary outcome, an event occurred in 280 of 3537 patients (7.9%) in the spironolactone group and 294 of 3525 patients (8.3%) in the placebo group (hazard ratio adjusted for competing risk, 0.96; 95% CI, 0.81 to 1.13;  $P = 0.60$ ). Serious adverse events were reported in 255 patients (7.2%) in the spironolactone group and 241 (6.8%) in the placebo group.

**Conclusions:** Among patients with myocardial infarction, spironolactone did not reduce the incidence of death from cardiovascular causes or new or worsening heart failure or the incidence of a composite of death from cardiovascular causes, myocardial infarction, stroke, or new or worsening heart failure. (Funded by the Canadian Institutes of Health Research and others; CLEAR ClinicalTrials.gov number, NCT03048825.).

# Impact of intensive versus nonintensive antithrombotic treatment on device-related thrombus after left atrial appendage closure

[Article in English, Spanish]

Philippe Garot <sup>1</sup>, Pedro Cepas-Guillén <sup>2</sup>, Eduardo Flores-Umanzor <sup>3</sup>, Nina Leduc <sup>4</sup>, Vilhemas Bajoras <sup>5</sup>, Nils Perrin <sup>6</sup>, Angela McInerney <sup>7</sup>, Ana Lafond <sup>8</sup>, Julio Farjat-Pasos <sup>9</sup>, Xavi Millán <sup>10</sup>, Sandra Zendjebil <sup>11</sup>, Reda Ibrahim <sup>6</sup>, Pablo Salinas <sup>7</sup>, Ole de Backer <sup>12</sup>, Ignacio Cruz-González <sup>8</sup>, Dabit Arzamendi <sup>10</sup>, Laura Sanchis <sup>3</sup>, Luis Nombela-Franco <sup>7</sup>, Gilles ÓHara <sup>9</sup>, Adel Aminian <sup>4</sup>, Jens Erik Nielsen-Kudsk <sup>13</sup>, Josep Rodés-Cabau <sup>14</sup>, Xavier Freixa <sup>3</sup>

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## Abstract

**Introduction and objectives:** The optimal antithrombotic therapy (AT) after left atrial appendage closure (LAAC) is debated. We assessed the impact of intensive vs nonintensive AT on the incidence of device-related thrombus (DRT) based on whether the device implantation was classified as optimal or suboptimal.

**Methods:** This study included patients who underwent successful LAAC in 9 centers. Patients were classified according to the quality of device implantation: optimal (proximal implant without  $\geq 3$ mm peridevice leak) or suboptimal (distal implant and/or  $\geq 3$ mm peridevice leak). Postimplant AT was classified as either intensive (dual antiplatelet therapy, anticoagulants, or a combination of both) or nonintensive (no AT or a single antiplatelet therapy). The primary endpoint was the incidence of DRT between the 6th and 12th weeks postprocedure.

**Results:** A total of 1225 patients underwent LAAC, with 757 (61.8%) achieving optimal device implantation and 468 (38.2%) classified as suboptimal. After a median follow-up of 20 months, the incidence of DRT in the optimal implant group was 2.6% with intensive AT and 3.7% with nonintensive AT ( $P=.38$ ). In the suboptimal implant group, the incidence of DRT increased to 11.2% with intensive AT and 15.5% with nonintensive AT ( $P=.19$ ). On multivariate analysis, suboptimal implantation (HR, 4.51; 95%CI, 2.70-7.54,  $P<.001$ ) but not intensive AT (HR, 0.66; 95%CI, 0.40-1.07,  $P=.09$ ) emerged as an independent predictor of DRT.

**Conclusions:** The incidence of DRT after LAAC was higher in patients with suboptimal device implantation. In patients with optimal implantation, the incidence of DRT was low and similar between nonintensive and intensive AT strategies. Large, randomized trials are warranted to confirm these results.

# Clinical Outcomes in Atrial Fibrillation Patients Undergoing Transcatheter Aortic Valve Replacement With Contemporary Devices

Siddhartha Mengi <sup>1</sup>, Pedro Cepas-Guillén <sup>1</sup>, Julien Ternacle <sup>2</sup>, Marina Urena <sup>3</sup>, Alberto Alperi <sup>4</sup>, Asim N Cheema <sup>5</sup>, Gabriela Veiga-Fernandez <sup>6</sup>, Luis Nombela-Franco <sup>7</sup>, Victoria Vilalta <sup>8</sup>, Giovanni Esposito <sup>9</sup>, Francisco Campelo-Parada <sup>10</sup>, Ciro Indolfi <sup>11</sup>, Maria Del Trigo <sup>12</sup>, Antonio Muñoz-García <sup>13</sup>, Nicolas Maneiro <sup>14</sup>, Lluís Asmarats <sup>15</sup>, Ander Regueiro <sup>16</sup>, David Del Val <sup>17</sup>, Vicenç Serra <sup>18</sup>, Vincent Auffret <sup>19</sup>, Lionel Leroux <sup>2</sup>, Thomas Modine <sup>2</sup>, Jules Mesnier <sup>3</sup>, Gaspard Suc <sup>3</sup>, Pablo Avanzas <sup>4</sup>, Effat Rezaei <sup>5</sup>, Victor Fradejas-Sastre <sup>6</sup>, Gabriela Tirado-Conte <sup>7</sup>, Eduard Fernández-Nofrarias <sup>8</sup>, Domenico Angellotti <sup>9</sup>, Thibaut Guittency <sup>10</sup>, Sabato Sorrentino <sup>11</sup>, Juan Francisco Oteo <sup>12</sup>, Felipe Díez-Delhoyo <sup>14</sup>, Lola Gutiérrez-Alonso <sup>15</sup>, Pablo Vidal-Calés <sup>16</sup>, Fernando Alfonso <sup>17</sup>, Andrea Monastyrski <sup>18</sup>, Maxime Nolf <sup>19</sup>, Marisa Avvedimento <sup>1</sup>, Josep Rodés-Cabau <sup>20</sup>

## Abstract

**Background:** Atrial fibrillation (AF) has been identified as a marker of advanced cardiac damage in patients with aortic stenosis. However, the factors associated with poorer outcomes among AF patients in contemporary transcatheter aortic valve replacement (TAVR) practice, particularly regarding mortality and heart failure (HF)-related hospitalizations, remain largely unknown.

**Methods:** In this multicenter study, we assessed consecutive patients with a history of AF and evaluated the clinical outcomes of those who underwent TAVR with newer generation devices using either balloon- or self-expandable valves.

**Results:** A total of 3476 patients were included in the study. After a median follow-up of 2 (interquartile range, 1-4) years, 36.1% patients had died, with 51.5% of deaths being cardiovascular-related, including 15.6% from HF. HF-related hospitalizations post-TAVR accounted for 34.8% of all hospitalizations and were associated with a higher mortality risk (hazard ratio [HR], 1.54; 95% confidence interval [CI], 1.32-1.81;  $P < 0.001$ ). Permanent AF was identified as an independent predictor of all-cause mortality or HF-related hospitalizations (HR, 1.25; 95% CI, 1.10-1.40;  $P < 0.001$ ), as did other baseline characteristics, including chronic kidney disease (HR, 1.23; 95% CI, 1.09-1.38;  $P = 0.001$ ), anemia (HR, 1.21; 95% CI, 1.07-1.36;  $P = 0.002$ ), and New York Heart Association functional class III or IV (HR, 1.13; 95% CI, 1.01-1.27;  $P = 0.045$ ). In addition, early postprocedural complications, including stroke and bleeding, also significantly increased the risk of mortality (HR, 5.52; 95% CI, 3.12-9.79;  $P < 0.001$ ) and HF-related hospitalizations (HR, 1.17; 95% CI, 1.03-1.33;  $P = 0.014$ ).

**Conclusions:** AF patients exhibited a high risk of mortality and HF-related hospitalizations in a contemporary TAVR cohort. Several baseline comorbidities and periprocedural complications, along with permanent (vs paroxysmal) AF, were associated with poorer outcomes. These findings confirm the negative impact of AF despite the continued improvements in TAVR technology and underscore the importance of early intervention and optimization of HF management to improve outcomes in this high-risk population.

# Prospective validation of a prespecified algorithm for the management of conduction disturbances after transcatheter aortic valve replacement: The PROMOTE study

Josep Rodés-Cabau <sup>1</sup>, Luis Nombela-Franco <sup>2</sup>, Guillem Muntané-Carol <sup>3</sup>, Gabriela Veiga <sup>4</sup>,  
Ander Regueiro <sup>5</sup>, Tamim Nazif <sup>6</sup>, Vicenç Serra <sup>7</sup>, Lluís Asmarats <sup>8</sup>, Henrique B Ribeiro <sup>9</sup>,  
Azeem Latib <sup>10</sup>, Anthony Poulin <sup>11</sup>, Asim N Cheema <sup>12</sup>, Pilar Jiménez-Quevedo <sup>2</sup>,  
Joan Antoni Gomez-Hospital <sup>3</sup>, Aritz Gil Ongay <sup>4</sup>, Rami Gabani <sup>5</sup>, Dabit Arzamendi <sup>8</sup>,  
Michael Brener <sup>6</sup>, Alvaro Calabuig <sup>7</sup>, Andrea Scotti <sup>10</sup>, Marco Antonio S Gelain <sup>9</sup>, Marino Labinaz <sup>13</sup>,  
Pedro Cepas-Guillén <sup>14</sup>, Jorge Nuche <sup>14</sup>, Melanie Côté <sup>14</sup>, Juan H Del Portillo <sup>14</sup>,  
François Philippon <sup>14</sup>

## Abstract

**Background:** There is a large variability in the management of conduction disturbances (CDs) after transcatheter aortic valve replacement (TAVR).

**Objective:** This study aimed to validate a prespecified algorithm for managing CDs in patients undergoing TAVR.

**Methods:** This was a prospective multicenter study including consecutive patients without prior pacemaker undergoing TAVR. Patients were stratified in different groups according to the presence of prior right bundle branch block (RBBB) and the occurrence of CDs during the procedure: no prior RBBB and no CDs (group NCD), prior RBBB and no CDs (group RBBB-NCD), and occurrence of CDs (group CD). A management algorithm was prespecified for each group. Permanent pacemaker (PPM) and mortality (overall, sudden cardiac death) at 30 days were the primary end points.

**Results:** A total of 2110 TAVR recipients were included. Patients were distributed in NCD (32.0%), RBBB-NCD (5.1%), and CD (62.9%) groups. A total of 329 patients (15.6%) received a PPM at 30 days, with a PPM rate of 5.5%, 15.9%, and 20.7% in the NCD, RBBB-NCD, and CD groups, respectively ( $P < .001$ ). The PPM rate was 17.4% and 57.2% in patients with procedural new-onset left bundle branch block and high-degree atrioventricular block/complete heart block, respectively. There were no differences in 30-day all-cause mortality and sudden cardiac death between groups (NCD group, 1.2% and 0.2%; RBBB-NCD group, 0% and 0%; CD group, 0.7% and 0.1%;  $P = .45$  and  $P = .99$  for all-cause mortality and sudden cardiac death, respectively).

**Conclusion:** A prespecified strategy for the management of CDs in contemporary TAVR recipients was feasible and safe, with no increased mortality and an extremely low rate of sudden cardiac death in patients with CDs. However, PPM rates remained high, and continued efforts for preventing the occurrence of CDs are warranted.

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# Novel cardiac CT method for identifying the atrioventricular conduction axis by anatomic landmarks

Justin T Tretter <sup>1</sup>, Francisco Bedogni <sup>2</sup>, Josep Rodés-Cabau <sup>3</sup>, Ander Regueiro <sup>4</sup>, Luca Testa <sup>2</sup>, Mackram F Eleid <sup>5</sup>, Shmuel Chen <sup>6</sup>, Atilio Galhardo <sup>3</sup>, Kenneth A Ellenbogen <sup>7</sup>, Martin B Leon <sup>8</sup>, Shlomo Ben-Haim <sup>9</sup>

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## Abstract

**Background:** Understanding the conduction axis location aids in avoiding iatrogenic damage and guiding targeted heart rhythm therapy.

**Objective:** Cardiac structures visible with clinical imaging have been demonstrated to correlate with variability in the conduction system course. We aimed to standardize and assess the reproducibility of predicting the location of the atrioventricular conduction axis by cardiac computed tomography.

**Methods:** We evaluated 477 patients with acquired aortic valve disease by cardiac computed tomography to assess variability in cardiac structures established to relate to the conduction system. We standardized 3 points (points A-C) to estimate the course from the atrioventricular node to the nonbranching bundle and left bundle branch origin and further compared this with measures of variability in the aortic root and membranous septum.

**Results:** The mean distances between the aortic valve virtual basal ring and points A, B, and C were  $9.5 \pm 3.5$  (0.3-20.1) mm,  $5.0 \pm 2.6$  (-1.7 to 15.9) mm, and  $2.9 \pm 2.5$  (-5.2 to 12.0) mm, respectively. The midpoint of the membranous septum deviated posteriorly a median of -4.4 (interquartile range, -12.4 to +3.0) degrees relative to the commissure between the right coronary and noncoronary leaflets. Intraclass coefficients for both intraobserver and interobserver variability for all measured points were excellent ( $\geq 0.78$ ).

**Conclusion:** These findings further infer the intimate yet highly variable relationship between the conduction axis and aortic root. This reproducible and standardized approach needs validation in populations of patients requiring accurate identification of the atrioventricular components of the conduction axis, which may serve as a noninvasive means for estimating its location.

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# Transcatheter Aortic Valve Replacement in Aortic Stenosis Patients With New York Heart Association Functional Class III or IV

Jorge Nuche <sup>1</sup>, Jules Mesnier <sup>2</sup>, Julien Ternacle <sup>3</sup>, Effat Rezaei <sup>4</sup>, Francisco Campelo-Parada <sup>5</sup>, Marina Urena <sup>2</sup>, Gabriela Veiga-Fernandez <sup>6</sup>, Luis Nombela-Franco <sup>7</sup>, Anna Franzone <sup>8</sup>, Antonio J Munoz-Garcia <sup>9</sup>, Victoria Vilalta <sup>10</sup>, Ander Regueiro <sup>11</sup>, David Del Val <sup>12</sup>, Lluis Asmarats <sup>13</sup>, Maria Del Trigo <sup>14</sup>, Vicenç Serra <sup>15</sup>, Guillaume Bonnet <sup>3</sup>, Melchior Jonveaux <sup>3</sup>, Ronan Canitrot <sup>5</sup>, Dominique Himbert <sup>2</sup>, Jose Maria de la Torre Hernandez <sup>6</sup>, Gabriela Tirado-Conte <sup>7</sup>, Eduard Fernandez-Nofrarias <sup>10</sup>, Pedro Cepas <sup>11</sup>, Fernando Alfonso <sup>12</sup>, Lola Gutierrez-Alonso <sup>13</sup>, Juan Francisco Oteo <sup>14</sup>, Yassin Belahnech <sup>15</sup>, Siamak Mohammadi <sup>1</sup>, Thomas Modine <sup>3</sup>, Marisa Avvedimento <sup>1</sup>, Josep Rodés-Cabau <sup>16</sup>, Asim N Cheema <sup>17</sup>

## Abstract

**Background:** Patients with symptomatic aortic stenosis are a vulnerable population with associated cardiac damage and a significant comorbidity burden. In this study we aimed to determine the rate, factors associated with, and prognostic value of poor functional status (New York Heart Association [NYHA] class III-IV) in patients with severe aortic stenosis undergoing transcatheter aortic valve replacement (TAVR).

**Methods:** This multicenter study included 6363 transarterial TAVR patients, classified according to baseline functional status (NYHA class I or II vs III or IV).

**Results:** A total of 3800 (60%) patients presented with NYHA class III or IV before the TAVR procedure. Atrial fibrillation (odds ratio [OR], 1.32; 95% confidence interval [CI], 1.11-1.58;  $P = 0.002$ ), chronic kidney disease (CKD; OR, 1.73; 95% CI, 1.45-2.05;  $P < 0.001$ ), chronic obstructive pulmonary disease (COPD; OR, 1.65; 95% CI, 1.32-2.05;  $P < 0.001$ ), reduced left ventricular ejection fraction (OR, 2.28; 95% CI, 1.70-3.05;  $P < 0.001$ ), and moderate and severe pulmonary hypertension were associated with a poor functional status. At 1-year follow-up, patients with NYHA class III or IV had higher rates of mortality (8.81 per 100 person-years [95% CI, 7.57-10.15] vs 13.12 per 100 person-years [95% CI, 11.80-14.58]; log rank,  $P < 0.001$ ) and heart failure hospitalization (8.25 per 100 person-years [95% CI, 7.05-9.65] vs 12.5 per 100 person-years [95% CI, 11.24-14.00]; log rank,  $P = 0.005$ ). Comorbidity factors (COPD, CKD) and signs of cardiac damage (atrial fibrillation, pulmonary hypertension) determined an increased risk of poorer clinical outcomes ( $P < 0.01$  for all).

**Conclusions:** More than half of the patients undergoing TAVR in the contemporary era have presented with advanced functional class before the procedure, and this was associated with a greater comorbidity and cardiac damage burden. Patients with poorer baseline functional status exhibited worse clinical outcomes at 1-year follow-up. These findings highlight the need for further study on earlier interventions for patients with aortic stenosis.

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# Early safety after TAVR according to VARC-3 criteria: incidence, predictors, and clinical impact

[Article in English, Spanish]

Ariana González-García <sup>1</sup>, Pedro Cepas-Guillén <sup>2</sup>, Julien Ternacle <sup>3</sup>, Marina Urena <sup>4</sup>, Alberto Alperi <sup>5</sup>, Asim N Cheema <sup>6</sup>, Gabriela Veiga-Fernández <sup>7</sup>, Luis Nombela-Franco <sup>8</sup>, Victoria Vilalta <sup>9</sup>, Giovanni Esposito <sup>10</sup>, Francisco Campelo-Parada <sup>11</sup>, Ciro Idolfi <sup>12</sup>, María Del Trigo <sup>13</sup>, Antonio Muñoz-García <sup>14</sup>, Nicolás Maneiro <sup>15</sup>, Luis Asmarats <sup>16</sup>, Ander Regueiro <sup>17</sup>, David Del Val <sup>18</sup>, Vicenç Serra <sup>19</sup>, Vincent Auffret <sup>20</sup>, Melchior Jonveaux <sup>3</sup>, Guillaume Bonnet <sup>3</sup>, Jules Mesnier <sup>4</sup>, Suc Gaspard <sup>4</sup>, Pablo Avanzas <sup>5</sup>, Effat Rezaei <sup>6</sup>, Víctor Frajedas-Sastre <sup>7</sup>, Gabriela Tirado-Conte <sup>8</sup>, Eduard Fernández-Nofrías <sup>9</sup>, Anna Franzone <sup>10</sup>, Thibaut Guitteny <sup>11</sup>, Sabato Sorrentino <sup>12</sup>, Juan Francisco Oteo <sup>13</sup>, Felipe Díez-Delhoyo <sup>15</sup>, Lola Gutiérrez-Alonso <sup>16</sup>, Pablo Vidal <sup>17</sup>, Fernando Alfonso <sup>18</sup>, Andrea Monastyrski <sup>19</sup>, Maxime Nolf <sup>20</sup>, Emilie Pelletier-Beaumont <sup>21</sup>, Marisa Avvedimento <sup>22</sup>, Josep Rodés-Cabau <sup>23</sup>

## Abstract

**Introduction and objectives:** The Valve Academic Research Consortium (VARC)-3 definition of the early safety (ES) composite endpoint after transcatheter aortic valve replacement (TAVR) lacks clinical validation. The aim of this study was to determine the incidence, predictors, and clinical impact of ES after TAVR as defined by VARC-3 criteria.

**Methods:** We performed a multicenter study including 10 078 patients with severe aortic stenosis undergoing transarterial TAVR. According to VARC-3 criteria, ES at 30 days was defined as freedom from all-cause mortality, stroke, VARC type 2-4 bleeding, major vascular, access-related, or cardiac structural complications, acute kidney injury stages 3-4, moderate or severe aortic regurgitation, new permanent pacemaker implantation, and surgery or intervention related to the device. Baseline, procedural, and follow-up data were prospectively collected in a dedicated database.

**Results:** ES was achieved in 6598 patients (65.5%). The main factors associated with a lack of ES were the occurrence of type 2-4 bleeding (18.9%), and new pacemaker implantation (13.6%). Advanced age, peripheral artery disease, chronic kidney disease, and balloon postdilation were associated with an increased risk of no-ES ( $P < .01$  for all). Failure to achieve ES was associated with higher all-cause mortality up to 1-year after TAVR (HR, 3.17; 95%CI, 2.76-3.65;  $P < .001$ ).

**Conclusions:** VARC-3 ES was not achieved in up to one-third of contemporary TAVR patients, which was associated with worse mid-term outcomes. The factors associated with increased risk were advanced age, baseline comorbidities, and some procedural features (postdilation). These findings highlight the importance of continued efforts to minimize the risk of TAVR-related procedural complications.

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# Tailored hydration for the prevention of contrast-induced acute kidney injury after coronary angiogram or PCI: A systematic review and meta-analysis

François Cossette <sup>1</sup>, Alexandru Trifan <sup>1</sup>, Gabriel Prévost-Marcotte <sup>1</sup>, Gemina Doolub <sup>2</sup>, Derek F So <sup>3</sup>, William Beaubien-Souigny <sup>4</sup>, Dana Abou-Saleh <sup>2</sup>, Jean-François Tanguay <sup>2</sup>, Brian J Potter <sup>4</sup>, Hung Q Ly <sup>2</sup>, Istok Menkovic <sup>1</sup>, Tomas Cieza <sup>5</sup>, Robert Avram <sup>2</sup>, Alexandra Bastiany <sup>6</sup>, Guillaume Marquis-Gravel <sup>7</sup>

Affiliations + expand

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## Abstract

**Background:** Contrast-induced acute kidney injury (CI-AKI) is a frequent complication of coronary interventions associated with an increased risk of mortality and morbidity. The optimal intravenous hydration strategy to prevent CI-AKI is not well-established. The primary objective is to determine if a tailored hydration strategy reduces the risk of CI-AKI and of major adverse cardiovascular events (MACE) in patients undergoing coronary angiography compared with a nontailored hydration strategy.

**Methods:** A study-level meta-analysis of randomized controlled trials comparing tailored versus nontailored hydration strategies for the prevention of CI-AKI (primary outcome) and of MACE (main secondary outcome) in patients undergoing coronary angiography for any indication was performed. Tailored hydration was defined as the administration of intravenous fluids based on patient-specific parameters other than weight only.

**Results:** A total of 13 studies were included (n = 4,458 participants). The overall risk of bias was moderate. A tailored strategy was associated with a significant reduction in the risk of CI-AKI (RR = 0.56, 95% CI, [0.46-0.69], P < .00001;  $I^2$  = 26%), and of MACE (RR = 0.57, 95% CI, [0.42-0.78], P = .0005;  $I^2$  = 12%). A tailored hydration strategy was not associated with a significant reduction in the other prespecified secondary outcomes, except for all-cause mortality (RR = 0.57, 95% CI, [0.35, 0.94], P = .03;  $I^2$  = 0%). The impact of a tailored strategy on the primary outcome was consistent in sensitivity analyses.

**Conclusion:** These results suggest that tailored hydration is superior to nontailored hydration in reducing the risk of CI-AKI and MACE in patients undergoing coronary angiography. Future trials are required to identify the optimal tailored hydration strategy.

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## Interatrial Shunt Therapy: A Rescue Option for Nonoperable Mitral Valve Disease Patients

Eduard Solé-González <sup>1</sup>, Marta Farrero <sup>1</sup>, Xavier Freixa <sup>1</sup>, Estefanía Torrecilla <sup>1</sup>, Laura Sanchís <sup>1</sup>, Pedro Caravaca-Pérez <sup>1</sup>, Ana García-Álvarez <sup>2</sup>, Marta Sitges <sup>3</sup>, William T Abraham <sup>4</sup>, Josep Rodés-Cabau <sup>5</sup>, Omar Abdul-Jawad Altisent <sup>6</sup>

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Review > *Nat Rev Cardiol.* 2025 Jul;22(7):510-526. doi: 10.1038/s41569-025-01118-1.

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## Interventions for adult congenital heart disease

Pedro Cepas-Guillén <sup>1</sup>, Eduardo Flores-Umanzor <sup>2</sup>, Eric Horlick <sup>3</sup>, Jamil Aboulhosn <sup>4</sup>,  
Lee Benson <sup>3</sup> <sup>5</sup>, Xavier Freixa <sup>2</sup>, Christine Houde <sup>6</sup>, Josep Rodés-Cabau <sup>7</sup> <sup>8</sup> <sup>9</sup>

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### Abstract

Advances in imaging diagnostics, surgical techniques and transcatheter interventions for paediatric patients with severe congenital heart disease (CHD) have substantially reduced mortality, thereby extending the lifespan of these individuals and increasing the number of adults with complex CHD. Transcatheter interventions have emerged as an alternative to traditional open-heart surgery to mitigate congenital defects. The evolution of techniques, the introduction of new devices and the growing experience of operators have enabled the treatment of patients with progressively more complex conditions. The general cardiology community might be less aware of contemporary interventions for adult CHD, their clinical indications and associated outcomes than interventional cardiologists and congenital heart specialists. In this Review, we provide a comprehensive evaluation of the available transcatheter interventions for adult patients with CHD.

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# Evolution of Coagulation and Platelet Activation Markers After Transcatheter Edge-to-Edge Mitral Valve Repair

Sandra Hadjadj <sup>1</sup>, Jonathan Beaudoin <sup>1</sup>, Frédéric Beaupré <sup>1</sup>, Caroline Gravel <sup>1</sup>, Ons Marsit <sup>1</sup>, Sylvain Pouliot <sup>1</sup>, Benoit J Arsenault <sup>1</sup>, Philippe Pibarot <sup>1</sup>, Julio Farjat-Pasos <sup>1</sup>, Jorge Nuche-Berenguer <sup>1</sup>, Benoît M-Labbé <sup>1</sup>, Kim O'Connor <sup>1</sup>, Mathieu Bernier <sup>1</sup>, Erwan Salaun <sup>1</sup>, Josep Rodés-Cabau <sup>1</sup>, Jean-Michel Paradis <sup>1</sup>

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## Abstract

**Background/Objectives:** The recommendations for antithrombotic therapy after transcatheter edge-to-edge mitral valve repair (TEER) are empirical, and the benefit of antiplatelet (APT) or anticoagulation therapy (ACT) remains undetermined. The study sought to investigate the degree and the timing of coagulation and platelet marker activation after TEER. **Methods:** This was a prospective study including 46 patients undergoing TEER. The markers of coagulation activation, namely prothrombin fragment 1 + 2 (F1 + 2) and thrombin-antithrombin III (TAT), and the markers of platelet activation, namely soluble P-Selectin and soluble CD-40 ligand (sCD40L), were measured at baseline, 24 h, 1 month, and 1 year after TEER. **Results:** At discharge, 20 (43%) patients received APT (single: 16, dual: 4), 24 (52%) received ACT, and 2 (4%) had both single APT and ACT. Levels of F1 + 2 and TAT significantly increased at 24 h post TEER (both  $p < 0.001$ ), rapidly returning to baseline levels at 1 month. However, levels of F1 + 2 and TAT remained higher at 1 month in patients without ACT compared to patients with ACT (respectively, 303.1 vs. 148.1 pmol/L;  $p < 0.001$  and 4.6 vs. 3.0  $\mu$ g/L;  $p = 0.020$ ), with a similar trend at 1 year. Levels of soluble P-selectin and sCD40L remained stable at all times after TEER (respectively,  $p = 0.071$  and  $p = 0.056$ ), regardless of the APT. **Conclusions:** TEER is associated with an acute activation of the coagulation system, with no increase in platelet activation markers. Hence, the use of dual APT is questionable in this population. Our results raise the hypothesis that the optimal antithrombotic therapy after TEER could be short-term ACT over APT. Further larger studies are warranted.

# Feasibility of coronary access after transcatheter aortic valve implantation (TAVI): a systematic review and meta-analysis of observational studies

Federico Giacobbe <sup>1 2</sup>, Arianna Morena <sup>1 2</sup>, Francesco Bruno <sup>1</sup>, Marco Nebiolo <sup>1 2</sup>, Ovidio De Filippo <sup>1</sup>, Yasser Odeh <sup>1 2</sup>, Gianluca Di Pietro <sup>3</sup>, Josep Rodes Cabau <sup>4</sup>, Federico Conrotto <sup>1</sup>, Annapoorna Kini <sup>5</sup>, Giuseppe Giannino <sup>1 2</sup>, Azeem Latib <sup>6</sup>, Pierluigi Omedé <sup>1</sup>, Stephane Noble <sup>7</sup>, Michele William La Torre <sup>8</sup>, Marco Barbanti <sup>9</sup>, Giuseppe Tarantini <sup>10</sup>, Won-Keun Kim <sup>11</sup>, Johannes Blumenstein <sup>11</sup>, Madjid Boukantar <sup>12</sup>, Wan Wan Htun <sup>13 14</sup>, Gaetano Maria de Ferrari <sup>1 2</sup>, Stefano Salizzoni <sup>8</sup>, Fabrizio D'Ascenzo <sup>1 2</sup>

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## Abstract

**Introduction:** The expanding indications for transcatheter aortic valve implantation (TAVI) to younger, lower-risk patients, entails assessing not only the short-term clinical outcomes but also the long-term considerations for future interventions. The prevalence of coronary artery disease in TAVI patients is relevant, and the optimal timing of percutaneous coronary intervention remains a question.

**Methods and results:** We conducted a systematic literature review and meta-analysis including 20 eligible studies involving 1660 patients who underwent coronary angiography after TAVI. The primary endpoint was the incidence of successful selective coronary re-access. Secondary endpoints included semi-selective and non-selective access rates. The analysis was stratified by balloon-expandable (BEVs) and self-expandable valve (SEVs) types. Successful coronary access after TAVI was feasible in the majority of patients, with a higher success rate observed for the left main (LM) compared to the right coronary artery (RCA). BEVs demonstrated the highest success rates in coronary ostia cannulation, achieving nearly 100% success for both LM and RCA. Among SEVs, the Acurate Neo and Evolut R/PRO showed superior success rates in selective coronary access (68 and 77% for LM; 57 and 72% for RCA, respectively) compared to the CoreValve (46% for LM and 49% for RCA). Notably, the majority of coronary angiograms were performed due to acute coronary syndrome, primarily non-ST-segment elevation myocardial infarction, and unstable angina.

**Conclusion:** Selective coronary engagement after TAVI is generally achievable, with BEVs demonstrating superior success rates compared to SEVs. Among SEVs, the Acurate NEO showed better outcomes than the other types.

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## Acute Coronary Syndromes after Transcatheter Aortic Valve Implantation: Incidence, Unique Mechanisms, and Outcomes

Mohammad Abdelghani <sup>1</sup>, Rayyan Hemetsberger <sup>2</sup>, Ahmed Hassan <sup>3</sup>, Mahmoud Abdelshafy <sup>4</sup>, Martin Landt <sup>5</sup>, Ahmed Helmi <sup>6</sup>, Shrouk Ramadan <sup>7</sup>, Josep Rodés-Cabau <sup>8</sup>, Marwan Saad <sup>9</sup>, Robbert J de Winter <sup>10</sup>

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### Abstract

Transcatheter aortic valve implantation (TAVI) has become a first-line management option across all risk categories of elderly patients with symptomatic severe aortic stenosis. As the indications of TAVI expand, the age and the surgical risk of patients who undergo TAVI is decreasing making lifetime management after TAVI more compelling. After TAVI, patients endure an incremental risk of acute coronary syndromes, which have unique mechanisms and management challenges that are yet to be fully understood. In this report, we review the mechanisms, the natural history, and the management of post-TAVI acute coronary syndromes.

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# Imaging assessment after percutaneous left atrial appendage closure: from immediate to long-term follow-up

Pedro Cepas-Guillén <sup>1</sup>, David R Holmes Jr <sup>2</sup>, Joao Cavalcante <sup>3</sup>, Xavier Freixa <sup>4</sup>, Gilles O'Hara <sup>1</sup>, Jonathan Beaudoin <sup>1</sup>, Julio Farjat-Pasos <sup>1</sup>, Benoit Labbé <sup>1</sup>, Josep Rodés-Cabau <sup>1, 5</sup>, Erwan Salaun <sup>1</sup>

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## Abstract

Growing evidence has demonstrated the clinical benefit of percutaneous left atrial appendage closure (LAAC) in patients with atrial fibrillation. Although procedural complication rates have declined with increasing experience, post-procedural device-related complications persist, impacting prognosis and reducing the long-term benefits of the procedure. Given the potential impact of these complications, surveillance imaging after LAAC is mandatory. Currently, different imaging modalities offer unique advantages to manage these complications which warrant a combined approach to optimize both short- and long-term follow-up. The aims of this review are to explore the distinct characteristics of each imaging modality, highlighting the primary findings to be assessed during follow-up imaging. Additionally, we propose an optimized clinical imaging surveillance roadmap from discharge to long-term follow-up.

# 'Incidence and impact of structural valve deterioration following TAVI: a multicenter real-world study'

Iria Silva <sup>1 2</sup>, Alberto Alperi <sup>1 2</sup>, Antonio Muñoz <sup>3</sup>, Asim Cheema <sup>4</sup>, Luis Nombela <sup>5</sup>, Gabriela Veiga-Fernandez <sup>6</sup>, Edgar Tay <sup>7</sup>, Marina Urena <sup>8</sup>, Lluis Asmarats <sup>9</sup>, María Del Trigo <sup>10</sup>, Yinghao Lim <sup>7</sup>, Lola Gutierrez Alonso <sup>9</sup>, Ander Regueiro <sup>11</sup>, Francisco Campelo-Parada <sup>12</sup>, Vicenç Serra <sup>13</sup>, David Del Val <sup>14</sup>, Henrique Barbosa Ribeiro <sup>15</sup>, Julien Ternacle <sup>16</sup>, Victoria Vilalta <sup>17</sup>, Pablo Vidal <sup>11</sup>, Yassin Belahnech <sup>13</sup>, Fernando Alfonso <sup>14</sup>, Jorge Nuche <sup>1</sup>, Josep Rodes-Cabau <sup>1 11</sup>, Philippe Pibarot <sup>1</sup>

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## Abstract

**Aims:** Valve durability becomes a major issue as transcatheter aortic valve implantation (TAVI) is expanding to populations with longer life expectancy. We sought to (i) determine the incidence of structural valve deterioration (SVD), (ii) compare the incidence of SVD between balloon-expandable (BE) and self-expandable (SE) valves, and (iii) analyse the impact of SVD.

**Methods and results:** 2040 patients who underwent TAVI (2007-2020) from 9 centres were included. After inverse probability treatment weighting (IPTW), 1848 patients were selected (973 BE and 875 SE). SVD was defined using recent echocardiographic definitions according to VARC-3 criteria: Median follow-up was 4.2 (IQR: 2.5-5.7) years. The estimated incidence of SVD and bioprosthetic valve failure (BVF) at 8 years follow-up for the overall cohort were 13.3% [95% confidence interval (CI) 9.8-18%] and 11.5% (95% CI 8.9-14.8%), respectively. After IPTW and a median follow-up of 4 years, the risk of SVD (5.25% vs. 1.19%; HR 10.25, 95% CI 3.79-27.71,  $P < 0.001$ ), and all-cause BVF (6.41% vs. 3.2%; HR 2.1, 95% CI 1.27-3.47  $P = 0.004$ ), was significantly higher for BE compared with SE recipients. Patients developing SVD had a trend towards a higher incidence of cardiovascular death ( $P = 0.06$ ), as well as a significantly higher risk of heart failure rehospitalization ( $P = 0.048$ ). After IPTW, there were no differences between BE and SE recipients in the combined endpoint of cardiovascular death, heart failure rehospitalization and valve reintervention ( $P = 0.46$ ).

**Conclusion:** In this real-world registry, the incidence of SVD at 8 years after TAVI was relatively low. The risk of SVD was higher among BE compared with SE valve recipients. SVD was associated with an increased risk of heart failure rehospitalization and a trend towards a higher risk of cardiovascular death.

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# Right heart failure and mortality in patients undergoing transcatheter tricuspid valve interventions

Edoardo Pancaldi <sup>1</sup>, Marianna Adamo <sup>2</sup>, Matteo Pagnesi <sup>1</sup>, Giulio Russo <sup>3</sup>, Hannes Alessandrini <sup>4</sup>, Martin Andreas <sup>5</sup>, Daniel Braun <sup>6</sup>, Dario Cani <sup>1</sup>, Kim A Connelly <sup>7</sup>, Paolo Denti <sup>8</sup>, Rodrigo Estevez-Loureiro <sup>9</sup>, Neil Fam <sup>7</sup>, Rebecca T Hahn <sup>10</sup>, Claudia Harr <sup>4</sup>, Joerg Hausleiter <sup>6</sup>, Dominique Himbert <sup>11</sup>, Daniel Kalbacher <sup>12</sup>, Edwin Ho <sup>13</sup>, Azeem Latib <sup>13</sup>, Edith Lubos <sup>14</sup>, Sebastian Ludwig <sup>12</sup>, Philipp Lurz <sup>15</sup>, Vanessa Monivas <sup>16</sup>, Georg Nickenig <sup>17</sup>, Daniela Pedicino <sup>18</sup>, Giovanni Pedrazzini <sup>19</sup>, Fabien Praz <sup>20</sup>, Joseph Rodes-Cabau <sup>21</sup>, Christian Besler <sup>22</sup>, Anne Rebecca Schöber <sup>15</sup>, Joachim Schofer <sup>23</sup>, Andrea Scotti <sup>13</sup>, Kerstin Piayda <sup>24</sup>, Horst Sievert <sup>25</sup>, Gilbert H L Tang <sup>26</sup>, David Messika-Zeitoun <sup>27</sup>, Holger Thiele <sup>22</sup>, Florian Schlotter <sup>15</sup>, Ralph Stephan von Bardeleben <sup>28</sup>, John Webb <sup>29</sup>, Julien Dreyfus <sup>30</sup>, Stephan Windecker <sup>20</sup>, Martin Leon <sup>10</sup>, Francesco Maisano <sup>31</sup>, Marco Metra <sup>1</sup>, Maurizio Taramasso <sup>32</sup>

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## Abstract

**Aims:** To assess the association between right heart failure (RHF) and mortality in patients with severe tricuspid regurgitation (TR) undergoing transcatheter tricuspid valve intervention (TTVI), and to determine whether clinical RHF status reduces the survival benefit of successful versus failed TTVI.

**Methods and results:** The TriValve International Registry (Transcatheter Tricuspid Valve Therapies) is a multicenter registry collecting data of patients with symptomatic, severe or greater TR undergoing TTVI. The population was stratified according to RHF status defined by the following clinical criteria: history of previous hospitalization for RHF (<1 year) OR presence of signs of RHF (jugular venous distension, ascites, peripheral oedema) OR high dose diuretic ( $\geq 125$  mg/day of furosemide or equivalent). The outcome of interest was 1-year all-cause death. Among 639 patients included in the TriValve registry, 498 had complete data regarding RHF status. Overall, 54 (10.8 %) patients had no criteria for RHF, 133 (26.7 %) patients fulfilled 1 criterion, 240 (48.2 %) 2 criteria and 71 (14.3 %) 3 criteria. At a median follow-up of 216 days (IQR 49-372 days), cumulative incidence of all-cause death was higher in patients with 2 or 3 RHF criteria versus those with no or 1 RHF criterion (adjusted HR 2.91-95 % CI 1.46-5.83,  $P = 0.002$ ). However, RHF status did not influence the association between procedural success and all-cause death at 1-year follow-up ( $p$  for interaction 0.857).

**Conclusions:** In a large real-world population undergoing TTVI for severe TR, the presence of at least 2 RHF clinical criteria was independently associated with an increased risk of 1-year mortality. Procedural success was associated with a lower risk of mortality regardless of RHF status.

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## Late arrhythmic burden in patients with left bundle branch block after TAVR with the Evolut valve

Silvia Mas-Peiro <sup>1</sup>, Thibault Lhermusier <sup>2</sup>, Marina Urena <sup>3</sup>, Luis Nombela-Franco <sup>4</sup>, Victoria Vilalta <sup>5</sup>, Antonio Muñoz-García <sup>6</sup>, Ignacio Amat-Santos <sup>7</sup>, Felipe Atienza <sup>8</sup>, Neal Kleiman <sup>9</sup>, Chekrallah Chamandi <sup>10</sup>, Vicenç Serra <sup>11</sup>, Marc W Deyell <sup>12</sup>, Francisco Campelo-Parada <sup>2</sup>, Pierre Mondoly <sup>2</sup>, Gaspard Suc <sup>3</sup>, Victoria Canadas-Godoy <sup>4</sup>, Eduard Fernandez-Nofrieras <sup>5</sup>, Javier Castrodeza <sup>7</sup>, Jaime Elizaga <sup>8</sup>, Pierre Baudinaud <sup>10</sup>, Jaume Francisco Pascual <sup>11</sup>, John G Webb <sup>12</sup>, Emilie Pelletier-Beaumont <sup>1</sup>, François Philippon <sup>1</sup>, Josep Rodés-Cabau <sup>1</sup>

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### Abstract

**Aims:** Arrhythmic burden after discharge in patients with new-onset persistent left bundle branch block (NOP-LBBB) following transcatheter aortic valve replacement (TAVR) with Evolut devices remains largely unknown. The aim of this study is to assess the incidence and type of arrhythmias at 2-year follow-up in patients with NOP-LBBB post-TAVR.

**Methods and results:** This is a prospective multicentre study including 88 patients with LBBB persisting for  $\geq 3$  days post-implantation. Before discharge, an implantable loop recorder (REVEAL XT/LINQ) was implanted; patients had continuous monitoring for 2 years. Arrhythmic events were adjudicated in a central core lab. Of the arrhythmic events, 411 were detected in 58 patients [65.9%; 2 (1-4) events per patient]. Symptoms were reported in 12/58 (20.7%), and therapy was changed in 25/58 (43.1%). There were 101 bradyarrhythmic events in 33 patients [35 high-grade atrioventricular block (HAVB) and 66 severe bradycardia]. The HAVB incidence was higher in the early (4-week) phase and remained stable over time, whereas severe bradycardia increased after 1 year. Permanent pacemaker was required in 11 (12.5%) patients (6.8% and 5.7% in the first and second year, respectively). There were 310 tachyarrhythmic events in 29 patients (120 AF/AFL, 111 AT, 72 SVT, 6 NSVT, and 1 VT); its incidence decreased throughout the 2 years. New AF/AFL episodes occurred in 20/69 patients [29%; symptomatic in 2/20 (10%)].

**Conclusion:** Patients with NOP-LBBB post-TAVR with Evolut devices exhibited a high burden of late arrhythmias, with events occurring in two-thirds of patients and leading to treatment changes in about half of them. These data should inform future studies on cardiac monitoring devices for follow-up and treatment optimization in this challenging population.

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# Transcarotid Versus Surgical Aortic Valve Replacement for the Treatment of Severe Aortic Stenosis

Juan Hernando Del Portillo <sup>1</sup>, Pedro Cepas-Guillén <sup>1</sup>, Dimitri Kalavrouziotis <sup>1</sup>, Eric Dumont <sup>1</sup>, Jean Porterie <sup>1</sup>, Jean-Michel Paradis <sup>1</sup>, Anthony Poulin <sup>1</sup>, Frederic Beaupré <sup>1</sup>, Marisa Avvedimento <sup>1</sup>, Silvia Mas-Peiro <sup>1</sup>, Siddhartha Mengi <sup>1</sup>, Siamak Mohammadi <sup>1</sup>, Josep Rodés-Cabau <sup>1</sup>

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## Abstract

**Background:** Current guidelines recommend surgical aortic valve replacement (SAVR) for patients with severe aortic stenosis and unfavorable iliofemoral access. Transcarotid transcatheter aortic valve replacement (TC-TAVR) has emerged as an alternative access in suboptimal transfemoral candidates, but no data exist comparing TC-TAVR and SAVR. The main objective of this study was to compare the clinical outcomes in a propensity-matched population of TC-TAVR and SAVR patients with severe aortic stenosis.

**Methods:** A total of 786 patients (SAVR, 352; TC-TAVR, 434) were included, and a total of 182 patients were propensity-matched and included in each group. The primary outcome was a composite of death from any cause, stroke/transient ischemic attack, and procedure-related or valve-related hospitalization at 30 days and at 1 year. Data were prospectively collected in dedicated databases, and clinical events were defined according to Valve Academic Research Consortium-3 criteria.

**Results:** Baseline characteristics were well balanced between the matched groups, and the mean age and Society for Thoracic Surgeons score of the study population were 75 years and 3.6%, respectively. At 30 days, the SAVR group showed a higher rate of the primary composite outcome compared with the TC-TAVR group (12.6% versus 4.3%; hazard ratio, 2.93 [95% CI, 1.45-5.94]). Acute kidney injury stages 2 to 4, bleeding events, and new-onset atrial fibrillation occurred more often in the SAVR group during the hospital period ( $P<0.001$ ). In contrast, vascular complications and the need for permanent pacemaker implantation occurred more often in the TC-TAVR group ( $P=0.01$  and  $P=0.001$ , respectively). At 1-year follow-up, there were no significant differences between groups in the primary outcome rates (SAVR, 19.7% versus TC-TAVR, 12.7%; hazard ratio, 1.63 [95% CI, 0.98-2.73]).

**Conclusions:** TC-TAVR was associated with improved 30-day clinical outcomes compared with SAVR, with no significant differences in death, stroke, and hospitalization at 1-year follow-up. These findings suggest that TC-TAVR may be a valid alternative to SAVR in nontransfemoral-TAVR candidates.

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## Evolut Low-Risk Trial 5-Year Result: We're Halfway There

Tsuyoshi Kaneko <sup>1</sup>, Josep Rodés-Cabau <sup>2</sup>, Alan Zajarias <sup>3</sup>, Stephan Windecker <sup>4</sup>

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# Vascular Complications in Patients Undergoing Transcatheter Aortic Valve Replacement With Contemporary Devices

Pedro Cepas-Guillén <sup>1</sup>, Marisa Avvedimento <sup>1</sup>, Julien Ternacle <sup>2</sup>, Marina Urena <sup>3</sup>, Alberto Alperi <sup>4</sup>, Asim N Cheema <sup>5</sup>, Gabriela Veiga-Fernandez <sup>6</sup>, Luis Nombela-Franco <sup>7</sup>, Victoria Vilalta <sup>8</sup>, Giovanni Esposito <sup>9</sup>, Ciro Indolfi <sup>10</sup>, Maria Del Trigo <sup>11</sup>, Antonio Muñoz-García <sup>12</sup>, Nicolas Maneiro <sup>13</sup>, Lluís Asmarats <sup>14</sup>, Ander Regueiro <sup>15</sup>, David Del Val <sup>16</sup>, Vicenç Serra <sup>17</sup>, Ariana González-García <sup>18</sup>, Guillaume Bonnet <sup>2</sup>, Antonio Di Renzo <sup>2</sup>, Jules Mesnier <sup>3</sup>, Gaspard Suc <sup>3</sup>, Pablo Avanzas <sup>5</sup>, Effat Rezaei <sup>5</sup>, Victor Fradejas-Sastre <sup>6</sup>, Jorge F Chavez Solsol <sup>8</sup>, Eduard Fernández-Nofrarias <sup>8</sup>, Domenico Angelotti <sup>9</sup>, Sabato Sorrentino <sup>10</sup>, Juan Francisco Oteo <sup>13</sup>, Felipe Diez-Delhoyo <sup>13</sup>, Lola Gutiérrez-Alonso <sup>14</sup>, Andrea Ruberti <sup>15</sup>, Fernando Alfonso <sup>16</sup>, Andrea Monastyrski <sup>17</sup>, Emilie Pelletier-Beaumont <sup>1</sup>, Josep Rodés-Cabau <sup>19</sup>

## Abstract

**Background:** Vascular complications (VCs) remain a major concern after transcatheter aortic valve replacement (TAVR). However, their occurrence in patients treated with newer generation devices has been scarcely studied. Therefore, the aim of this study was to determine the incidence, management, predictors, and clinical impact of VCs in patients undergoing TAVR with contemporary devices.

**Methods:** Multicenter study including 8815 patients that underwent transfemoral TAVR. VCs were classified based on the Valve Academic Research Consortium-3 criteria. Baseline, procedural, and follow-up data were prospectively collected in a dedicated database.

**Results:** VCs occurred in 1464 patients (16.5%), being major and minor in 44.7% and 55.3% of cases, respectively, and most of them related to primary access (87%). Vascular injury (75.2%) and device closure failure (21.2%) were the most predominant subtypes. Major VCs were independently associated with a substantial increase in 1-year mortality (hazard ratio [HR] 2.33, 95% confidence interval [CI] 1.92-2.82,  $P = 0.001$ ). However, this association was absent in minor VCs, even if an unplanned intervention occurred. Female sex, dual-antiplatelet therapy, access-related anatomic factors, and use of large plug-based vascular closure were associated with an increased risk of major VCs ( $P < 0.05$  for all), with echocardiography-guided access and secondary radial access emerging as protective factors ( $P < 0.01$  for all).

**Conclusions:** VCs persist as a major issue in patients undergoing TAVR with contemporary devices, with multiple modifiable factors determining a higher risk. Major, but not minor VCs were associated with poorer short- and long-term survival. Given their negative impact on clinical outcomes, every effort should be made to minimize the occurrence of VCs after TAVR.

# Optimal Oversizing With the New-Generation Evolut (PRO/PRO+/FX) Self-Expanding Valves: A Multicenter Study

Silvia Mas-Peiro <sup>1</sup>, Alberto Alperi <sup>2</sup>, Ander Regueiro <sup>3 4</sup>, Ignacio Cruz-Gonzalez <sup>5</sup>, Domenico Angellotti <sup>6</sup>, Francisco Campelo-Parada <sup>7</sup>, Marina Urena <sup>8</sup>, Pablo Avanzas <sup>2</sup>, Pablo Vidal-Cailes <sup>3 4</sup>, Gilles Jose Barreira de Sousa <sup>5</sup>, Giovanni Esposito <sup>7</sup>, Mehdi Tamir <sup>7</sup>, Gaspard Suc <sup>8</sup>, Anthony Poulin <sup>1</sup>, Siamak Mohammadi <sup>1</sup>, Marisa Avvedimento <sup>1</sup>, Josep Rodés-Cabau <sup>1 3 4</sup>

Affiliations + expand

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## Abstract

**Background:** Paravalvular leaks (PVLs) after transcatheter aortic valve replacement have a significant prognostic impact, and valve oversizing, particularly with self-expanding valves, may prevent postprocedural PVL occurrence. Recent iterations of the Evolut valve system are intended to reduce PVL, but the effects of oversizing with such valves on PVL are largely unknown. We aimed to assess, in a real-world contemporary setting, the impact of Evolut valve oversizing on PVL after transcatheter aortic valve replacement.

**Methods:** This was a multicenter observational ambispective study of patients undergoing transcatheter aortic valve replacement with the Evolut PRO/PRO+/FX valves. Aortic annulus perimeter, as determined by multidetector computed tomography, was used to estimate the oversizing degree. The primary end point was the presence of PVL (mild/moderate-severe), as determined by echocardiography at hospital discharge. Secondary end points included in-hospital outcomes as defined by the Valve Academic Research Consortium-3 recommendations.

**Results:** A total of 762 patients were included (Evolut PRO/PRO+/FX, 55.5%/34.8%/9.7%), and the median valve oversizing was 20 (17-25)%, with no differences in baseline characteristics between low ( $\leq 20\%$ , n=381) and high ( $> 20\%$ , n=381) valve oversizing recipients. In-hospital mortality and stroke rates were 2.4% and 4.3%, respectively, with no oversizing-related differences in clinical outcomes. Permanent pacemaker rates were similar in patients with low (19.4%) and high (15.8%) valve oversizing,  $P=0.21$ . PVL was found in 35.6% of patients (mild: 32.6%, moderate-severe: 3.0%), with a higher incidence of PVL in patients with low (40.9%) versus high (30.2%) oversizing,  $P=0.002$ . In a multivariable analysis, a higher oversizing degree was associated with a lower risk of PVL (odds ratio, 0.95 [0.92-0.99] for each 1% increase in oversizing,  $P=0.006$ ).

**Conclusions:** In transcatheter aortic valve replacement with recent Evolut valve iterations (PRO/PRO+/FX), a higher oversizing degree was associated with a lower frequency of PVL without increasing the risk of other complications (including permanent pacemaker). These data suggest that a low degree of valve oversizing should probably be avoided when using Evolut valves, particularly in borderline cases.

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# Risk of delayed atrioventricular block in patients without procedural conduction disturbances during transcatheter aortic valve replacement

Quentin Fischer <sup>1</sup>, Luis Nombela-Franco <sup>2</sup>, Guillem Muntané-Carol <sup>3</sup>, Gabriela Veiga <sup>4</sup>, Ander Regueiro <sup>5</sup>, Tamim Nazif <sup>6</sup>, Vicenç Serra <sup>7</sup>, Lluís Asmarats <sup>8</sup>, Henrique B Ribeiro <sup>9</sup>, Azeem Latib <sup>10</sup>, Anthony Poulin <sup>11</sup>, Asim N Cheema <sup>12</sup>, Pilar Jiménez-Quevedo <sup>2</sup>, Joan Antoni Gomez-Hospital <sup>3</sup>, Aritz Gil Ongay <sup>4</sup>, Andrea Ruberti <sup>5</sup>, Dabit Arzamendi <sup>8</sup>, Michael Brener <sup>6</sup>, Alvaro Calabuig <sup>7</sup>, Andrea Scotti <sup>10</sup>, Marco Antonio S Gelain <sup>9</sup>, Marino Labinaz <sup>13</sup>, Pedro Cepas-Guillén <sup>1</sup>, Melanie Côté <sup>1</sup>, Juan H Del Portillo <sup>1</sup>, François Philippon <sup>1</sup>, Josep Rodés-Cabau <sup>14</sup>

## Abstract

**Background:** Among patients undergoing transcatheter aortic valve replacement (TAVR), the risk of delayed atrioventricular block (AVB) in those without procedural conduction disturbances (CDs) remains largely unknown. This may affect hospital stay, particularly same- or next-day discharge after the procedure.

**Objective:** The purpose of this study was to evaluate the timing, type, and factors associated with delayed (up to 30 days) AVB in patients without procedural CDs.

**Methods:** This was a subanalysis of the PRospective Application of a Pre-Specified Scientific Expert Panel AlgOrithm for the Management of COnduction Disturbances Following Transcatheter Aortic Valve REplacement (PROMOTE) trial, a prospective multicenter study including consecutive patients without a prior pacemaker undergoing TAVR and with a prespecified strategy for managing CDs. Patients with no prior right bundle branch block and no procedural CDs were included in this subanalysis. Data on 30-day occurrence and timing of AVB and permanent pacemaker implantation (PPI) were collected in a dedicated database, and analyzed overall and according to the preprocedural electrocardiographic (ECG) abnormalities (either first-degree AVB or abnormal QRS morphology).

**Results:** A total of 675 patients were included, 334 of which (49.5%) exhibited baseline ECG abnormalities. At 30 days, 23 patients (3.4%) had delayed AVB (0.6% vs 6.3% in patients with normal and abnormal ECGs preprocedurally, respectively;  $P < .001$ ). Most (74%) delayed AVB occurred on day 1 or 2 after the procedure. In the multivariable analysis, the factors associated with an increased risk of delayed AVB were preexisting abnormal ECG (odds ratio 5.28; 95% confidence interval 1.53-18.27;  $P = .009$ ) and left ventricular ejection fraction  $< 50\%$  (odds ratio 4.17; 95% confidence interval 1.75-9.93;  $P = .001$ ). Among patients in sinus rhythm with a preprocedural abnormal ECG, those with QRS duration  $> 120$  ms and first-degree AVB exhibited the highest risk (PPI rate: 17.8%) followed by those with isolated QRS duration  $> 120$  ms (PPI rate: 8.7%).

**Conclusion:** Among TAVR recipients with no procedural CDs, those with a preexisting abnormal ECG represent a high-risk group for delayed AVB requiring PPI. This would support a tailored strategy, with a minimalist approach (same- or next-day discharge) in low-risk patients and a more prolonged hospitalization or continuous ECG ambulatory monitoring in those at higher risk.

**Trial registration:** Clinicaltrials.gov identifier: [NCT04139616](https://clinicaltrials.gov/ct2/show/NCT04139616).

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# Temporal Trends in Transcatheter Aortic Valve Replacement Outcomes in Patients With Low-Flow, Low-Gradient Aortic Stenosis: Insights From the TOPAS-TAVI Registry

Siddhartha Mengi <sup>1</sup>, Luis Nombela-Franco <sup>2</sup>, Pedro Cepas-Guillén <sup>1</sup>, Stamatios Lerakis <sup>3</sup>,  
Raj Makkar <sup>4</sup>, Tarun Chakravarty <sup>4</sup>, Vasilis Babalarios <sup>5</sup>, Henrique Barbosa Ribeiro <sup>6</sup>,  
Emilie Pelletier-Beaumont <sup>1</sup>, Philippe Pibarot <sup>1</sup>, Josep Rodés-Cabau <sup>7</sup>

Affiliations + expand

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## Abstract

**Background:** Transcatheter aortic valve replacement (TAVR) technology and techniques have continuously improved, but data on their impact in low-flow, low-gradient aortic stenosis (LFLG-AS) remain limited. In particular, scarce data exist comparing the results of TAVR with new-generation devices vs early-generation devices in these patients. This study evaluated the temporal trends in TAVR practices among LFLG-AS patients.

**Methods:** This multicentre registry included 424 LFLG-AS patients undergoing TAVR from 2007 to 2023, stratified by device generation: new-generation devices (n = 193) and early-generation devices (n = 231). All-cause mortality or heart failure hospitalization (HFH) at 1-year follow-up was the primary end point.

**Results:** The median Society of Thoracic Surgeons score was lower in the new-generation group (5.3% [interquartile range [IQR] 3.4%-8.2%] vs 7.4% [IQR 5.0%-12.1%]; P < 0.001), whereas left ventricular ejection fractions (LVEFs) were similar (new: 31.2 ± 8.3%; early: 30.0 ± 8.8%; P = 0.16). New-generation devices were associated with a significant reduction in moderate-to-severe paravalvular leak after TAVR (2.6% vs 9.1%; P = 0.005), although 30-day mortality was similar (new: 1.6%; early: 3.9%; P = 0.15). At 1 year, new-generation devices were associated with a greater LVEF improvement (43.8 ± 12.5% vs 39.8 ± 11.5%; P = 0.003), but without a significant reduction in all-cause mortality or HFH (new: 23.8%; early: 28.1%; P = 0.32). Chronic kidney disease and low hemoglobin independently predicted worse outcomes (P < 0.05).

**Conclusions:** Despite procedural improvements with new-generation TAVR devices, clinical outcomes in LFLG-AS patients remain suboptimal. LVEF significantly improved after TAVR with new-generation devices but failed to translate into improved clinical outcomes. These findings suggest that TAVR alone may not suffice in this population and underscore the need for a comprehensive therapeutic approach that integrates TAVR with optimized medical management and cardiac rehabilitation.

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# Human Epididymis Protein 4 in Transcatheter Aortic Valve Implantation: Diagnostic and Prognostic Value

Carlos Giuliani <sup>1</sup>, Antonela Zanuttini <sup>1</sup>, Jorge Nuche <sup>1</sup>, Julio I Farjat Pasos <sup>1</sup>, Jérémie Bernard <sup>1</sup>, Tastet Lionel <sup>1</sup>, Simon Jacob <sup>1</sup>, Rami Abu-Alhayja'a <sup>1</sup>, Jonathan Beaudoin <sup>1</sup>, Nancy Côté <sup>1</sup>, Robert DeLarochellière <sup>1</sup>, Jean-Michel Paradis <sup>1</sup>, Marie-Annick Clavel <sup>1</sup>, Benoit J Arsenault <sup>1</sup>, Josep Rodés-Cabau <sup>1</sup>, Philippe Pibarot <sup>1</sup>, Sébastien Hecht <sup>2</sup>

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## Abstract

**Background:** The utility of the human epididymis protein 4 (HE4) in patients undergoing transcatheter aortic valve implantation (TAVI) has not been established yet.

**Objectives:** The present study aimed at examining the prognostic value of HE4 in patients undergoing TAVI.

**Methods:** In this prospective study, the prognostic value of HE4 to predict adverse clinical events was evaluated in 362 patients who underwent TAVI. The association between HE4 and diffuse myocardial fibrosis was also assessed using T1 mapping on cardiac magnetic resonance in a subgroup of 43 patients.

**Results:** During a median follow-up of 2.5 (IQR: 1.9-3.2) years, 34/362 (9.4%) patients were rehospitalized for heart failure, 99/362 (27.3%) died, and 113/362 (31.2%) met the composite endpoint of rehospitalization for heart failure or all-cause mortality. In multivariable Cox regression analyses, patients with higher HE4 serum levels (ie, HE4  $\geq$ 130 pmol/L) vs lower serum levels (ie, HE4  $<$ 130 pmol/L) had increased risk of all-cause mortality (adjusted HR: 3.26 [95% CI: 2.04-5.20],  $P < 0.001$ ), and of the composite endpoint (adjusted HR: 2.48 [95% CI: 1.64-3.74],  $P < 0.001$ ) following TAVI, respectively. Patients with higher HE4 serum levels had higher median native T1 mapping values (1,278 [95% CI: 1,239-1,280] ms vs 1,352 [95% CI: 1,303-1,376] ms,  $P < 0.001$ ) at 1 to 3 months following the procedure.

**Conclusions:** Elevated HE4 serum levels are associated with diffuse myocardial fibrosis and increased risk of adverse clinical events following TAVI. This promising blood biomarker may be helpful to enhance risk stratification in patients undergoing TAVI.

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## Evaluating the AltaValve as a novel method for transcatheter mitral valve replacement

Pablo Vidal-Calés <sup>1</sup>, Pedro L Cepas-Guillén <sup>1</sup>, Juan H Del Portillo <sup>1</sup>, Josep Rodés-Cabau <sup>1</sup>

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### Abstract

Mitral regurgitation (MR) is the most common heart valve disease, and severe MR is associated with a poor prognosis if left untreated. Although surgical repair or replacement constitutes the standard therapy when indicated, many high-risk patients are considered ineligible for surgery. Transcatheter mitral valve replacement (TMVR) offers a less invasive alternative to conventional surgery and may also overcome some of the limitations of percutaneous repair techniques. Currently, multiple TMVR devices are undergoing clinical evaluation, showing promising results. However, challenges mainly related to the complex mitral valve anatomy along with the interaction with the left ventricular outflow tract (LVOT) have resulted in high stent failure rates among TMVR candidates. The AltaValve System features a supra-annular design, ensuring secure fixation in the left atrium above the native mitral valve annulus without anchoring mechanisms that could interfere with the left ventricle (LV). These distinctive attributes aim to address the existing TMVR limitations across a broad patient population and help to avoid complications such as LVOT obstruction, LV damage, and/or prosthesis embolization. Initial safety and feasibility data are encouraging, but a larger cohort of patients with longer follow-up will be essential to confirm the safety and efficacy of the AltaValve system.

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# Gender-Specific Outcomes in TAVI with Self-Expandable Valves: Insights from a Large Real-World Registry

Alessandro Sticchi <sup>1 2 3</sup>, Dario Grassini <sup>1</sup>, Francesco Gallo <sup>4</sup>, Stefano Benenati <sup>5</sup>, Won-Keun Kim <sup>6</sup>, Arif A Khokhar <sup>7</sup>, Tobias Zeus <sup>8</sup>, Stefan Toggweiler <sup>9</sup>, Roberto Galea <sup>10</sup>, Federico De Marco <sup>11</sup>, Antonio Mangieri <sup>2 3</sup>, Damiano Regazzoli <sup>2 3</sup>, Bernhard Reimers <sup>2 3</sup>, Luis Nombela-Franco <sup>12</sup>, Marco Barbanti <sup>13</sup>, Ander Regueiro <sup>14</sup>, Tommaso Piva <sup>15</sup>, Josep Rodés-Cabau <sup>16</sup>, Italo Porto <sup>5</sup>, Antonio Colombo <sup>2 3</sup>, Francesco Giannini <sup>17</sup>

Affiliations + expand

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## Abstract

**Background/Objectives:** Aortic stenosis (AS) is the most prevalent valvular heart disease in developed countries and imposes an increasing burden on aging populations. Although transcatheter aortic valve implantation (TAVI) has transformed the treatment of severe AS, current guidelines do not differentiate management based on gender. This study aimed to investigate gender-based differences in procedural complications and one-year clinical outcomes in patients treated with next-generation self-expandable TAVI devices. **Methods:** This retrospective, multicenter international registry included 3862 consecutive patients who received either the ACURATE neo or Evolut R/Pro valve. Patients were stratified by gender; propensity score matching (PSM) adjusted for baseline differences. The primary endpoint was a composite of all-cause mortality or stroke at one year. Secondary endpoints included major vascular complications, major or life-threatening bleeding and acute kidney injury (AKI).

**Results:** Of 3353 patients included (64.5% female), women were older ( $82.3 \pm 5.6$  vs.  $81.1 \pm 6.2$  years,  $p < 0.001$ ) and had higher STS scores ( $5.2 \pm 3.9$  vs.  $4.5 \pm 3.4$ ,  $p < 0.001$ ). In the unmatched population, major vascular complications occurred in 7.7% of females versus 4.1% of males ( $p < 0.001$ ), life-threatening bleeding in 2.8% vs. 1.4% ( $p = 0.016$ ) and AKI in 8.5% vs. 5.7% ( $p = 0.009$ ). After PSM, the primary endpoint was more frequent in females (9.4% vs. 6.0%,  $p = 0.014$ ), largely driven by stroke (2.8% vs. 1.2%,  $p = 0.024$ ), while overall mortality was similar (11.3% vs. 9.5%,  $p = 0.264$ ). **Conclusions:** Despite comparable long-term survival, female patients undergoing TAVI with self-expandable valves experience higher rates of procedural complications, notably stroke and major vascular events. These findings underscore the need for tailored procedural strategies to improve outcomes in female patients.

# Randomized Study Comparing Angiography Guidance With Physiology Guidance After PCI: The EASY-PREDICT Study

Paola Ulacia Flores <sup>1</sup>, Tomas Cieza <sup>1</sup>, Safia Ouarrak <sup>1</sup>, Andrés Ruhl <sup>1</sup>, Siddharta Mengi <sup>1</sup>, Robert De Laroche <sup>1</sup>, David Garcia-Labbé <sup>1</sup>, Jean-Pierre Déry <sup>1</sup>, Anthony Poulin <sup>1</sup>, Éric Larose <sup>1</sup>, Bernard Noël <sup>1</sup>, Can Manh Nguyen <sup>1</sup>, Jean-Michel Paradis <sup>1</sup>, Olivier F Bertrand <sup>1</sup>

## Abstract

**Background:** Physiology assessment of coronary lesion prepercutaneous coronary intervention (PCI) using hyperemic and nonhyperemic pressure ratios is useful to determine if a lesion requires treatment. Whether the physiology after PCI is superior to angiography guidance only is unknown. The study sought to investigate whether post-PCI physiology improves clinical outcomes compared with standard angiographic guidance.

**Methods:** All-comers patients referred for diagnostic angiography and possible PCI were recruited in a high-volume tertiary care hospital. After uncomplicated PCI, patients were randomized to angiography guidance or target vessel physiology, including nonhyperemic pressure ratio (resting distal coronary pressure to aortic pressure ratio and diastolic pressure ratio) and fractional flow reserve. The primary outcome was the rate of target vessel failure, including cardiac death, myocardial infarction, and target vessel revascularization at 18 months post-PCI. Angina score, medications, and quality of life were also assessed.

**Results:** Two hundred twenty-one patients were randomized in the angiography group (110 patients, 166 lesions) and the physiology group (111 patients, 159 lesions). Immediate post-PCI physiology results were deemed suboptimal in 22 (17%) cases, and operators performed further optimization steps. Final post-PCI results were resting distal coronary pressure to aortic pressure ratio of  $0.95 \pm 0.04$ , the diastolic pressure ratio of  $0.94 \pm 0.06$ , and the fractional flow reserve of  $0.90 \pm 0.07$ . Ultimately, 9 lesions (7%) remained with fractional flow reserve values  $\leq 0.80$ . At 18-month follow-up, target vessel failure was 17.4% in the angiography group and 18% in the physiology group ( $P=0.88$ ). Rates of cardiac death (1% versus 0%;  $P=0.32$ ), myocardial infarction (13% versus 11%;  $P=0.66$ ), and target vessel revascularization (4% versus 7%;  $P=0.24$ ) remained similar in both groups. No difference in angina score, medication, or quality of life was found.

**Conclusions:** In all-comers patients undergoing uncomplicated PCI, routine post-PCI physiology assessment was not associated with clinical benefit compared with standard angiographic guidance. Further study is required to determine how post-PCI physiology guidance can be helpful in selected lesions.

**Registration:** URL: <https://clinicaltrials.gov/>; Unique identifier: NCT04929496.

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## An evaluation of the SavvyWire as a support wire for TAVR procedures

Julio I Farjat-Pasos <sup>1</sup>, Marisa Avvedimento <sup>1</sup>, Josep Rodes-Cabau <sup>1</sup>

Affiliations + expand

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### Abstract

Transcatheter aortic valve replacement (TAVR) represents a minimally invasive alternative for the treatment of severe symptomatic aortic stenosis and is increasingly adopted in younger and lower-risk patients. A support guidewire placed in the left ventricle is required in all TAVR procedures, and rapid ventricular pacing is frequently used to ensure valve implant stability. Also, recent studies showed a correlation between post-TAVR hemodynamic gradients and clinical outcomes, underscoring the importance of accurate invasive measurements. The SavvyWire™ (Opsens Medical) is a novel support guidewire designed for TAVR procedures that integrates left ventricular pacing and invasive pressure measurement capabilities, enabling continuous hemodynamic monitoring and simplifying the procedure. This review outlines the SavvyWire's™ design features and summarizes clinical evidence supporting its use in TAVR procedures.

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# PFO Device Closure in Patients >60 Years of Age With Ischemic Stroke: Results From U.S. Medicare Beneficiaries

Ruby Satpathy <sup>1</sup>, Josep Rodés-Cabau <sup>2</sup>, David E Thaler <sup>3</sup>, David M Kent <sup>4</sup>, Samuel Turner <sup>5</sup>, Srinivasa Potluri <sup>6</sup>, Kranthi K Kolli <sup>7</sup>, Nils Peter Borgstrom <sup>7</sup>, Julie B Prillinger <sup>7</sup>, Jeffrey L Saver <sup>8</sup>

Affiliations + expand

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Free article

## Abstract

**Background:** Transcatheter closure of patent foramen ovale (PFO) is a recommended stroke reduction option in patients  $\leq$ 60 years of age with cryptogenic ischemic stroke, but data on clinical outcomes following PFO closure in patients  $>$ 60 years of age are scarce.

**Objectives:** The aim of this real-world evidence study was to evaluate the clinical outcomes of PFO closure in patients  $>$ 60 years of age in the United States.

**Methods:** Medicare fee-for-service data from 2016 to 2022 were used to identify patients  $>$ 60 years of age who were hospitalized with ischemic stroke and diagnosed with PFO or atrial septal defect and also had  $\geq$ 6 months of prior fee-for-service coverage. Patients who were implanted with the Amplatzer or Talisman PFO occluder (device group) were identified by linkage to a manufacturer device-tracking database and were propensity score matched (1:4) to those who did not undergo device implantation (control group). Acute safety events through 30 days and recurrent ischemic stroke through 3 years were evaluated.

**Results:** A total of 20,999 Medicare beneficiaries (device group,  $n = 1,132$ ; control group,  $n = 19,867$ ) met the inclusion criteria. The matched cohort included 5,508 Medicare beneficiaries (device group,  $n = 1,132$ ; control group,  $n = 4,376$ ), with 45% women, a median age of 71 years (Q1-Q3: 67-75 years), and median follow-up of 2.58 years (Q1-Q3: 1.17-3.97 years). The risk for recurrent ischemic stroke was significantly lower in the device group (1.65 [95% CI: 1.18-2.13] events per 100 patient-years) than the control group (2.66 [95% CI: 2.33-3.00] events per 100 patient-years) (HR: 0.62; 95% CI: 0.44-0.88;  $P = 0.007$ ). Rates of 30-day safety events were not different for death, but venous thromboembolism (1.86% vs 0.37%;  $P < 0.001$ ) and atrial fibrillation or flutter (1.41% vs 0.64%;  $P = 0.01$ ) were more common in the device group.

**Conclusions:** In a real-world U.S. cohort of patients  $>$ 60 years of age, PFO closure was associated with a reduced risk for recurrent ischemic stroke compared with medical therapy alone, while maintaining a clinically acceptable safety profile.

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## Global Results From the Optimize PRO Study: Standardized TAVR Technique and Care Pathway

Kendra J Grubb <sup>1</sup>, Hemal Gada <sup>2</sup>, Douglas Fraser <sup>3</sup>, Josep Rodes-Cabau <sup>4</sup>, Tamim M Nazif <sup>5</sup>,  
Suneet Mittal <sup>6</sup>, Danny Dvir <sup>7</sup>, Emmanuel Teiger <sup>8</sup>, Lang Lin <sup>9</sup>, Joshua D Rovin <sup>10</sup>, Ramzi F Khalil <sup>11</sup>,  
Ibrahim Sultan <sup>12</sup>, Matias B Yudi <sup>13</sup>, Blake Gardner <sup>14</sup>, David Lorenz <sup>15</sup>, Stanley Chetcuti <sup>16</sup>,  
Nainesh C Patel <sup>17</sup>, James Harvey <sup>18</sup>, Paul Mahoney <sup>19</sup> <sup>20</sup>, Deepak Talreja <sup>19</sup>, Carlo Trani <sup>21</sup> <sup>22</sup>,  
Darren Mylotte <sup>23</sup>, Brian Schwartz <sup>24</sup>, Zubair Jafar <sup>25</sup>, Jan Van der Heyden <sup>26</sup>, Diego Maffeo <sup>27</sup>,  
Gerald Yong <sup>28</sup>, Cesar Moris <sup>29</sup>, John Wang <sup>30</sup>, Robert Gooley <sup>31</sup>, Katie Flor <sup>32</sup>, Yu Jung Yeh <sup>32</sup>,  
Steven J Yakubov <sup>33</sup>

Affiliations + expand

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### Abstract

**Background:** The safety and efficacy of utilizing standardized implant protocols and care pathways are limited in large global prospective studies of transcatheter aortic valve replacement (TAVR), and institutional variability remains. This analysis aims to report 30-day outcomes from the global Optimize PRO study evaluating valve performance and procedural outcomes using an "optimized" TAVR care pathway and the cusp overlap technique (COT) in patients receiving Evolut PRO/PRO+ valves.

**Methods:** The Optimize PRO study is a multicenter, postmarket, prospective study conducted in 50 centers in the United States, Canada, Europe, the Middle East, and Australia. Patients with symptomatic severe aortic stenosis and no preexisting pacemakers underwent TAVR with standardized optimized preprocedure, periprocedure, and postprocedure pathways.

**Results:** There were 653 patients with attempted TAVR implants, a mean age of  $79.1 \pm 6.5$  years, and a mean Society of Thoracic Surgeons predictive risk of mortality of  $3.2\% \pm 2.5\%$ . The primary 30-day end point of all-cause mortality or all stroke was 5.1%, all-cause mortality 0.8%, and disabling stroke 1.7%. The new 30-day permanent pacemaker implantation rate was 6.4% with 4-step COT compliance and 11.1% overall. At discharge, there were no instances of moderate or severe aortic regurgitation, and 76.2% of patients had none/trace aortic regurgitation. The median length of stay was 2 days.

**Conclusions:** The Optimize PRO study demonstrated low rates of new permanent pacemaker implantation and no moderate to severe aortic regurgitation after TAVR with Evolut PRO/PRO+ using COT and perioperative protocols in a global cohort of severe aortic stenosis patients. Best practices resulted in consistent implantation depth and low complication rates.

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# Role of visceral adiposity in the relationship between cardiorespiratory fitness and liver fat in asymptomatic adults

Dominic J Chartrand <sup>1 2</sup>, Eric Larose <sup>1 2</sup>, Paul Poirier <sup>1 3</sup>, Patrick Mathieu <sup>1 2</sup>, Natalie Alméras <sup>1 2</sup>, Philippe Pibarot <sup>1 2</sup>, Benoît Lamarche <sup>4 5</sup>, Caroline Rhéaume <sup>1 2 6</sup>, Isabelle Lemieux <sup>1</sup>, Jean-Pierre Després <sup>1 2 6</sup>, Marie-Eve Piché <sup>1</sup>

Affiliations + expand

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## Abstract

Excess liver fat (LF) is associated with low cardiorespiratory fitness (CRF), low physical activity, and a deteriorated cardiometabolic health profile including increased visceral adipose tissue (VAT). Whether the association between LF and CRF is mediated by visceral adiposity is unknown. We studied the contribution of VAT to the relationship between CRF and LF in asymptomatic women and men. The sample included 320 participants (43% women) who underwent LF quantification by magnetic resonance spectroscopy. VAT was measured by magnetic resonance imaging, CRF using maximal cardiorespiratory exercise testing, and moderate-to-vigorous intensity physical activity (MVPA) using a 3-day journal. Mean age was  $50.3 \pm 8.6$  years, waist circumference was  $89.3 \pm 11.4$  cm, and LF content was  $4.3 \pm 5.7\%$ . LF was inversely correlated with CRF ( $p < 0.0001$ ), MVPA ( $p < 0.05$ ) and cardiometabolic health score ( $p < 0.0001$ ), and positively related with VAT ( $p < 0.0001$ ) in both sexes. Significantly higher levels of VAT ( $p < 0.0001$ ) and subcutaneous adipose tissue ( $p < 0.0001$ ) and a worsening cardiometabolic health score ( $p < 0.05$ ) and CRF ( $p = 0.0001$ ) were found across increasing sex-specific tertiles of LF levels. Lower levels of LF ( $p < 0.01$ ) and VAT ( $p < 0.0001$ ) and a higher cardiometabolic health score ( $p < 0.0001$ ) and MVPA ( $p < 0.05$ ) were noted across increasing sex-specific CRF tertiles. Multivariable regression analyses showed that visceral adiposity explained the majority of the variance in LF in both sexes ( $p < 0.0001$ ). Finally, serial mediation analyses revealed that VAT but not body fat percentage was a mediator in the relationship between CRF and LF in both sexes. Thus, visceral adiposity appears to be an important mediator in the relationship between CRF and LF, even after controlling for total adiposity.

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## Transcatheter Aortic Valve Durability: Focus on Structural Valve Deterioration

Antonin Trimaille <sup>1 2 3</sup>, Adrien Carmona <sup>1</sup>, Sandy Hmadeh <sup>2</sup>, Dinh Phi Truong <sup>4</sup>,  
Benjamin Marchandot <sup>1</sup>, Shinnosuke Kikuchi <sup>1 2</sup>, Kensuke Matsushita <sup>1 2</sup>, Patrick Ohlmann <sup>1</sup>,  
Valérie Schini-Kerth <sup>2</sup>, Josep Rodés-Cabau <sup>3</sup>, Philippe Pibarot <sup>3</sup>, Olivier Morel <sup>1 2 4</sup>

Affiliations + expand

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### Abstract

Transcatheter aortic valve replacement has emerged as a valuable alternative to surgical aortic valve replacement in patients with severe aortic stenosis. Given the expansion of transcatheter aortic valve replacement to lower-risk and younger populations with longer life expectancy, the durability of transcatheter heart valves (THVs) has become an important issue that may impact cardiovascular outcomes. THVs share similarities with surgical valves but have unique features, including a trend to larger effective orifice area and less prosthesis-patient mismatch, interactions with the native valve, and crimping process, that may all potentially influence a THV's life span. Multiple mechanisms may lead to bioprosthetic valve dysfunction, including structural valve deterioration, thrombosis, endocarditis, and nonstructural valve deterioration. With an incidence of up to 12.3% 5 years after transcatheter aortic valve replacement, structural valve deterioration represents the ultimate consequence of fibrotic remodeling and calcification within the bioprosthetic, driven by thrombotic and inflammatory processes involving the native aortic valve and influenced by patient and procedural factors. Understanding these mechanisms is crucial for improving THV durability.

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# Prognostic value of NT-proBNP in patients with primary mitral regurgitation undergoing transcatheter edge-to-edge repair

Philipp von Stein <sup>1 2</sup>, Jessica Weimann <sup>3</sup>, Roman Pfister <sup>1</sup>, Sebastian Ludwig <sup>2 3 4</sup>,  
Benedikt Koell <sup>3 4</sup>, Erwan Donal <sup>5</sup>, Dhairy Patel <sup>6</sup>, Lukas Stolz <sup>7 8</sup>, Tetsu Tanaka <sup>9</sup>,  
Andrea Scotti <sup>10</sup>, Teresa Trenkwalder <sup>11</sup>, Felix Rudolph <sup>12</sup>, Daryoush Samim <sup>13</sup>, Cristina Giannini <sup>14</sup>,  
Julien Dreyfus <sup>15</sup>, Jean-Michel Paradis <sup>16</sup>, Marianna Adamo <sup>17</sup>, Nicole Karam <sup>18</sup>, Yohann Bohbot <sup>19</sup>,  
Anne Bernard <sup>20</sup>, Bruno Melica <sup>21</sup>, Angelo Quagliana <sup>22</sup>, Yoan Lavie Badie <sup>23</sup>, Mirjam Kessler <sup>24</sup>,  
Omar Chehab <sup>25</sup>, Simon Redwood <sup>25</sup>, Edith Lubos <sup>26</sup>, Lars Sondergaard <sup>22</sup>, Marco Metra <sup>17</sup>,  
Chiara Primerano <sup>14</sup>, Fabien Praz <sup>13</sup>, Muhammed Gerçek <sup>12</sup>, Erion Xhepa <sup>11</sup>, Georg Nickenig <sup>9</sup>,  
Azeem Latib <sup>10</sup>, Niklas Schofer <sup>3 4</sup>, Raj Makkar <sup>6</sup>, Juan F Granada <sup>2</sup>, Thomas Modine <sup>27</sup>,  
Jörg Hausleiter <sup>7 8</sup>, Augustin Coisne <sup>2 28</sup>, Daniel Kalbacher <sup>3 4</sup>, Christos Iliadis <sup>1</sup>;  
on behalf of the PRIME-MR Investigators

Collaborators, Affiliations + expand

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## Abstract

**Aims:** The prognostic value of N-terminal pro-B-type natriuretic peptide (NT-proBNP) in patients undergoing mitral valve transcatheter edge-to-edge repair (M-TEER) for primary mitral regurgitation (PMR) is unclear. This study assessed the association between NT-proBNP and outcomes and explored its additive value to the Mitral Regurgitation International Database (MIDA) score.

**Methods and results:** PRIME-MR, a retrospective, international, multicentre registry, includes 3083 consecutive PMR patients treated with M-TEER. This analysis focused on 1382 patients (median age 81 years, 47% female, 82% New York Heart Association [NYHA] functional class III/IV, median EuroSCORE II 4.1%) with available NT-proBNP levels and follow-up. The primary endpoint was death or heart failure hospitalization within 3 years. Median NT-proBNP level was 1991 pg/ml (T1: 578, T3: 6285), and 384 patients reached the primary endpoint (Kaplan-Meier estimate: 48.5%). Log-transformed NT-proBNP levels independently predicted the primary endpoint (adjusted hazard ratio [HR] 1.17, 95% confidence interval [CI] 1.07-1.28;  $p < 0.001$ ) after adjusting for NYHA class, haemoglobin, creatinine, and atrial fibrillation. In 1041 patients with a modified MIDA score (median 9), the score was initially associated with the primary endpoint (HR 1.10, 95% CI 1.04-1.17;  $p = 0.002$ ), but lost significance when adjusting for NT-proBNP levels, which remained independently predictive (adjusted HR 1.20, 95% CI 1.07-1.34;  $p = 0.002$ ).

**Conclusions:** NT-proBNP, but not the MIDA score, was independently associated with death or heart failure hospitalizations within 3 years in M-TEER-treated PMR patients. Incorporating NT-proBNP levels into clinical assessment may improve risk stratification and potentially supports earlier intervention at lower NT-proBNP levels to optimize outcomes.

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## The Effect of 12-Week e-Cigarette Use on Smoking Abstinence at 1 Year: The E3 Trial

Kristian B Filion <sup>1</sup>, Tetiana Zolotarova <sup>2</sup>, Andréa Hébert-Losier <sup>2</sup>, Sarah B Windle <sup>2</sup>,  
Pauline Reynier <sup>2</sup>, Todd Greenspoon <sup>3</sup>, Tim Brandy <sup>4</sup>, Tamás Fülöp <sup>5</sup>, Thang Nguyen <sup>6</sup>,  
Stéphane Elkouri <sup>7</sup>, Igor Wilderman <sup>8</sup>, Olivier F Bertrand <sup>9</sup>, Joanna Alexis Bostwick <sup>10</sup>,  
Yves Lacasse <sup>11</sup>, Smita Pakhale <sup>12</sup>, Mark J Eisenberg <sup>13</sup>

Affiliations + expand

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### Abstract

**Background:** The current evidence regarding the long-term efficacy of electronic cigarettes (e-cigarettes) for smoking cessation is unclear.

**Objectives:** The purpose of this study was to assess the efficacy, safety, and tolerability of nicotine and non-nicotine e-cigarettes for smoking cessation in the general population.

**Methods:** We randomized 376 adults who smoked  $\geq 10$  cigarettes/day and were motivated to quit at 17 Canadian sites to 12 weeks of nicotine (15 mg/mL) e-cigarettes ( $n = 128$ ), non-nicotine e-cigarettes ( $n = 127$ ), or no e-cigarettes ( $n = 121$ ). All groups received individual counseling. The primary endpoint was point prevalence abstinence (7-day recall, biochemically validated using expired carbon monoxide) at 12 weeks. The 52-week follow-up results are reported here.

**Results:** Participants (mean age  $52 \pm 13$  years; 47% female) smoked a mean of  $21 \pm 11$  cigarettes/day at baseline. Compared to individual counseling alone, participants randomized to nicotine e-cigarettes plus counseling had higher rates of point prevalence (23.6% vs 9.9%; difference: 13.7%; 95% CI: 4.6%-22.8%) and continuous abstinence (3.1% vs 0.0%; difference: 3.1%; 95% CI: 0.1%-6.2%) and greater reductions in the number of cigarettes smoked ( $-9.5 \pm 10.5$  vs  $-5.6 \pm 9.5$ ; difference: -3.9; 95% CI: -6.5 to -1.4) at 52 weeks. Benefits were also observed among participants randomized to non-nicotine e-cigarettes plus counseling vs counseling alone. No differences in abstinence or reduction were found between nicotine and non-nicotine e-cigarettes.

**Conclusions:** Compared to individual counseling alone, short-term use of standardized nicotine and non-nicotine e-cigarettes plus counseling is efficacious at increasing smoking abstinence at 52 weeks.

## 30-Day and 1-Year Outcomes From the Optimize PRO TAVR Evolut FX Addendum Study

Hemal Gada <sup>1</sup>, Ramzi F Khalil <sup>2</sup>, Stanley J Chetcuti <sup>3</sup>, G Michael Deeb <sup>3</sup>, Kendra J Grubb <sup>4</sup>, Adam B Greenbaum <sup>4</sup>, David Lorenz <sup>5</sup>, Robert D Jumper <sup>5</sup>, Ibrahim Sultan <sup>6</sup>, Dustin Kliner <sup>6</sup>, Paul Mahoney <sup>7</sup>, Deepak R Talreja <sup>8</sup>, Mustafa I Ahmed <sup>9</sup>, Joshua D Rovin <sup>10</sup>, Lang Lin <sup>10</sup>,

### Abstract

**Background:** Primary results from the Optimize PRO study demonstrated that transcatheter aortic valve replacement (TAVR) with the cusp overlap technique (COT) resulted in low 30-day permanent pacemaker implantation (PPI) rates and no moderate or greater aortic regurgitation (AR).

**Objectives:** The aim of this study was to evaluate outcomes after Evolut FX implantation using the COT and postprocedural computed tomography (CT).

**Methods:** The Optimize PRO FX Addendum study is a postmarket, prospective, multicenter, nonrandomized study. Patients with severe aortic stenosis underwent TAVR with the Evolut FX using the COT protocol. Postprocedurally, COT adherence was evaluated to identify key steps, and CT-assessed transcatheter aortic valve orientation was compared with fluoroscopically guided commissural alignment.

**Results:** A total of 151 patients received the Evolut FX device from September 2022 to October 2023. The median duration of follow-up was 371 days (Q1-Q3: 352-388 days). Compliance with the refined COT was 86.0%. The median length of stay was 1 day. The rate of the primary endpoint of all-cause mortality or all stroke was 2.7% (95% CI: 1.0%-6.9%) at 30 days and 7.5% (95% CI: 4.2%-13.1%) at 1 year. The new PPI rate was 6.7% (95% CI: 3.7%-12.1%) at 30 days and 8.8% (95% CI: 5.2%-14.6%) at 1 year. One patient had moderate AR and none had severe AR at 1 year. The rate of commissural alignment was 91.5% (107 of 117) when assessed by marker positioning on fluoroscopy and 86.9% (113 of 130) when assessed using CT, indicating good agreement. CT indicated no severe coronary misalignment in >92% of patients.

**Conclusions:** Implantation of the Evolut FX device with a refined COT was associated with low PPI rates and no severe AR at 1 year. Postprocedural CT demonstrated consistent commissural and coronary alignment.

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## Management of conduction disturbances after TAVI: the last step towards early discharge

Guillem Muntané-Carol <sup>1 2</sup>, Rafael Romaguera <sup>1 2</sup>, Joan Antoni Gómez-Hospital <sup>1 2</sup>, Jorge Nuche <sup>3 4</sup>, François Philippon <sup>3</sup>, Josep Rodés-Cabau <sup>3 5</sup>

Affiliations + expand

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### Abstract

The incidence of new-onset cardiac conduction disturbances following transcatheter aortic valve implantation (TAVI) has not decreased compared to other complications, and nowadays is by far the most frequent drawback following the procedure. Meanwhile, the global management of TAVI recipients has led to a minimalist approach with short postprocedural length of stay, which may be limited by the occurrence of late arrhythmic events in patients at high-risk. This review focuses on those strategies to overcome the conundrum between early discharge and new-onset conduction disturbances in elderly TAVI candidates and provides a perspective on future improvements in this field.

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# Pacemaker Risk Stratification in Patients With Pre-existing Right Bundle Branch Block Undergoing Transcatheter Aortic Valve Replacement

Alejandro Travieso <sup>1</sup>, Jorge Nuche <sup>2</sup>, Gabriela Tirado-Conte <sup>3</sup>, Asim N Cheema <sup>4</sup>, Maria Tamargo <sup>5</sup>, Guillem Muntané-Carol <sup>6</sup>, Lluís Asmarats <sup>7</sup>, Victor M Becerra-Muñoz <sup>8</sup>, Raquel Del Valle <sup>9</sup>, Fernando Rivero <sup>10</sup>, Juan Carlos Sanmartín Pena <sup>11</sup>, Clara Fernandez Cordón <sup>5</sup>, Manuel Martínez-Selles <sup>5</sup>, Antonio J Muñoz-García <sup>8</sup>, Diego Lopez <sup>12</sup>, Juan H Alonso-Briales <sup>8</sup>, Nieves Gonzalo <sup>3</sup>, Fernando Alfonso <sup>10</sup>, Dabit Arzamendi <sup>7</sup>, Joan Antoni Gomez-Hospital <sup>6</sup>, Josep Rodés-Cabau <sup>2</sup>, Luis Nombela-Franco <sup>13</sup>

Affiliations + expand

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## Abstract

**Background:** Patients with pre-existing right bundle branch block (RBBB) undergoing transcatheter aortic valve replacement (TAVR) face a high risk of permanent pacemaker implantation (PPI). However, additional predictors of PPI in this subpopulation are unknown.

**Methods:** This retrospective, multicenter study enrolled 530 patients with baseline RBBB without pacemakers undergoing TAVR in native aortic valve stenosis. The primary endpoint was incidence of PPI at 30 days and predictors of the primary endpoint were used to determine PPI risk.

**Results:** PPI occurred in 229 (42.2%) patients at 30 days. Female sex (49.5% in women vs 39.9% in men,  $P = 0.034$ ), prolonged PR segment (61.1% if  $PR > 240$  ms vs 42.2% if  $PR < 240$  ms), and use of self-expanding valves (51.9% vs 36.2% in balloon-expandable valves,  $P = 0.001$ ) were associated with higher rates of PPI at 30 days. Other electrocardiographic parameters (QRS duration or left fascicular hemiblock) were unrelated to PPI. Computed tomography subanalysis showed that valve-to-annulus oversizing  $> 10\%$  and left ventricular outflow tract smaller than the annulus were significantly associated with PPI ( $P = 0.026$  and  $P = 0.017$ , respectively). Multivariate analysis demonstrated that the best predictive model for PPI included female sex (odds ratio [OR] 1.38,  $P = 0.088$ ),  $PR > 240$  ms (OR 2.62,  $P = 0.008$ ), and self-expanding valves (OR 1.95,  $P < 0.001$ ). The probability estimation for PPI was 76.8% with all these factors present compared with 32.0% in the absence of these factors.

**Conclusions:** Among patients with baseline RBBB undergoing TAVR, PPI was more frequent in women with  $PR > 240$  ms and treated with self-expanding valves. Appropriate risk stratification may help to detect low- or high-risk individuals of PPI.

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eCollection 2025 Jun.

## New York Valves: The Structural Heart Summit (June 25–27, 2025)

Josep Rodés-Cabau <sup>1</sup> <sup>2</sup>

Affiliations + expand

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*No abstract available*

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## CT derived ECV in severe aortic stenosis: prognosticator and screening test for co-existent transthyretin cardiac amyloidosis

Joshua N McShane <sup>1</sup>, Anahita Tavoosi <sup>1</sup>, Huda El Mais <sup>1</sup>, Keren Mbondo Kasuku <sup>1</sup>, Anthony Poulin <sup>2</sup>, Mehmet Onur Omaygenc <sup>1</sup>, Ian G Burwash <sup>1</sup>, David Messika-Zeitoun <sup>1</sup>, Benjamin J W Chow <sup>1</sup>, Gary R Small <sup>1</sup>

Affiliations + expand

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### Abstract

**Introduction:** Prior to transcatheter aortic valve replacement (TAVR), a CT is performed (TAVR-CT). With modification, the CT exam can measure myocardial extracellular volume (ECV). A small increase in ECV occurs in severe aortic stenosis. A large increase in ECV occurs when transthyretin cardiac amyloidosis (ATTR-CA) co-exists. We sought to determine the prognostic potential of ECV in severe aortic stenosis and test the utility of threshold ECV to instigate screening for ATTR-CA.

**Methods:** This was a prospective observation study of consecutive severe AS patients undergoing CT -TAVR. A delayed cardiac acquisition was acquired 5 min post TAVR-CT. Pre-contrast and delayed - images were used to determine ECV. When ECV  $\geq$  31 %  $^{99m}$ Tc-pyrophosphate (PYP) imaging was performed. The primary end point was all cause mortality.

**Results:** During the study, 161 patients underwent aortic valve replacement and were included in the analysis. Mean age was 81.6 ( $\pm 6.2$ ) years. During median follow up of 29 (21-36) months, 24 deaths occurred. In 30 patients ECV  $\geq$  31 %, 2 had positive  $^{99m}$ Tc-PYP imaging for ATTR-CA. On Cox regression analysis increased ECV associated with increased risk of all cause mortality (HR 2.54 (95 % CI 1.09-5.93) and was incremental to age, LV function and renal impairment ( $p = 0.03$ ).

**Conclusion:** In severe AS, elevated ECV was a risk for all cause mortality, but this was not related to co-existent ATTR-CA. Threshold-ECV testing for ATTR-CA demonstrated a low yield. Threshold testing may therefore not be warranted in all severe AS patients with an ECV  $\geq$  31 %.

# Transbrachial Catheter-Assisted Thrombolysis and Bailout Stenting for Massive Postoperative Pulmonary Embolism

Safia Ouarrak <sup>1</sup>, Tomas Cieza <sup>1</sup>, Guylaine Gleeton <sup>1</sup>, Andres Rhul <sup>1</sup>, Paola Ulacia <sup>1</sup>, Jocelyn Gregoire <sup>1</sup>, Zoltan Ruzsa <sup>2</sup>, Olivier F Bertrand <sup>3</sup>

Affiliations + expand

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## Abstract

**Background:** A 61-year-old patient developed acute dyspnea and hypoxemia 72 hours after open lung lobectomy. An urgent computed tomography angiography revealed an acute pulmonary embolism with complete left pulmonary artery occlusion.

**Case summary:** The patient was referred for urgent catheterization by a multidisciplinary team due to bleeding risks. Using right transbrachial access, the left pulmonary artery was recanalized. After balloon angioplasty, intravascular imaging guided the optimal placement of a stent to resolve vessel recoil. Local low-dose thrombolysis was initiated after partial reopening. After 24 hours, control angiography showed significant improvement in pulmonary artery perfusion.

**Discussion:** To our knowledge, this is the first reported case of using a coronary stent with local thrombolysis via brachial access to treat acute pulmonary embolism. The procedure successfully restored vessel patency with no complications. This case emphasizes the potential of catheter-based interventions, especially when intravenous thrombolysis is contraindicated.

**Take-home message:** Innovative catheter-based interventions with stenting and local thrombolysis via transbrachial approach may offer a valuable option for managing acute pulmonary embolism in select patients.

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# Incidence, Predictors, and Management of Conduction Disturbances After Transcatheter Tricuspid Valve Replacement: The TRIPLACE Registry

Andrea Scotti <sup>1</sup>, Rishi Puri <sup>2</sup>, Matteo Sturla <sup>1</sup>, Firas Zahr <sup>3</sup>, Robert Boone <sup>4</sup>, Susheel Kodali <sup>5</sup>, Didier Tchétché <sup>6</sup>, Ole De Backer <sup>7</sup>, Augustin Coisne <sup>8</sup>, Sebastian Ludwig <sup>9</sup>, Lukas Stolz <sup>10</sup>, Rodrigo Estevez Loureiro <sup>11</sup>, Matti Adam <sup>12</sup>, Federico De Marco <sup>13</sup>, Edwin C Ho <sup>1</sup>, Anson Cheung <sup>4</sup>, Melissa Moey <sup>14</sup>, Geraldine Ong <sup>14</sup>, Scott Chadderdon <sup>3</sup>, Davorka Lulic <sup>7</sup>, Joanna Bartkowiak <sup>5</sup>, Julio Echarte <sup>11</sup>, Horst Sievert <sup>15</sup>, Timothy Byrne <sup>16</sup>, Francesco Maisano <sup>17</sup>, Christian Frerker <sup>18</sup>, Nicolas Dumonteil <sup>6</sup>, Omar A Oliva <sup>6</sup>, Tanja K Rudolph <sup>19</sup>, Johannes Kirchner <sup>19</sup>, Beka Bakhtadze <sup>20</sup>, Samir R Kapadia <sup>20</sup>, Josep Rodés-Cabau <sup>21</sup>, Niklas Schofer <sup>9</sup>, Juan Granada <sup>22</sup>, Jörg Hausleiter <sup>10</sup>, Rebecca T Hahn <sup>5</sup>, Thomas Modine <sup>23</sup>, Neil Fam <sup>14</sup>, Azeem Latib <sup>24</sup>

## Abstract

**Background:** Transcatheter tricuspid valve replacement (TTVR) can induce high-grade atrioventricular block (HAVB), necessitating permanent pacemaker implantation (PPI). Limited data are available regarding this complication and management post-TTVR.

**Objectives:** The aim of this study was to investigate the incidence, predictors, and management of conduction disturbances after TTVR.

**Methods:** All consecutive patients undergoing TTVR in the multicenter TRIPLACE (Global Multicenter Registry on Transcatheter Tricuspid Valve Replacement) registry were analyzed. The primary endpoint was the occurrence of HAVB at 1 month post-TTVR.

**Results:** Of 263 TTVR patients, 75 (28.5%) were excluded because of pre-existing PPI and 3 (1.1%) because of surgical conversion. At 1 month, HAVB had occurred in 25 of the remaining 185 patients (13.5%), 88% within the first week post-TTVR (median 3.0 days; Q1-Q3: 2.0-5.0). New-onset right bundle branch block was observed in 20.6% of patients. Baseline left bundle branch block or left anterior or posterior fascicular block (adjusted OR: 3.63; 95% CI: 1.28-10.37; P = 0.016) was independently associated with HAVB, after adjusting for age and degree of device oversizing. PPI was performed using leadless technologies (45.5%), coronary sinus leads (27.3%), or transvalvular dual-chamber pacemakers (27.3%).

**Conclusions:** HAVB occurred in 13.5% of PPI-naive patients who underwent TTVR. The majority of cases of HAVB (88%) were observed in the first week after TTVR. Baseline left bundle branch block or left anterior or posterior fascicular block confers a high risk for HAVB after TTVR. (Global Multicenter Registry on Transcatheter Tricuspid Valve Replacement [TRIPLACE]; NCT06033274).

# Atrioventricular Conduction Disturbances in Patients Undergoing Transcatheter Tricuspid Valve Intervention: A Multidisciplinary Consensus

Quentin Fischer <sup>1</sup>, Kenneth A Ellenbogen <sup>2</sup>, Suneet Mittal <sup>3</sup>, Jörg Hausleiter <sup>4</sup>, Jorge Nuche <sup>5</sup>, Paul Sorajja <sup>6</sup>, Maurizio Taramasso <sup>7</sup>, Vinod H Thourani <sup>8</sup>, Stephan Windecker <sup>9</sup>, Benoit Labb   <sup>1</sup>, Fran  ois Philippon <sup>1</sup>, Josep Rod  s-Cabau <sup>10</sup>

Affiliations + expand

PMID: 40738569 DOI: 10.1016/j.jcin.2025.06.026

## Abstract

Tricuspid regurgitation (TR) is a highly prevalent valve disease, and cardiac surgery has been used in patients with severe symptomatic TR undergoing surgery for other cardiac lesions or less frequently for isolated TR. More recently, transcatheter therapies, particularly transcatheter edge-to-edge repair and valve replacement, have emerged as therapeutic alternatives in those considered at high to extreme risk for surgery. Because of the anatomical proximity of the tricuspid valve (TV) and the atrioventricular conduction system, the risk for high-degree atrioventricular block and permanent pacemaker implantation remains important, as they are common adverse events after transcatheter valve replacement. Furthermore, a significant number of these patients have cardiac implantable electronic devices with leads that may either worsen TR or complicate the treatment procedure. The aim of this review is to provide an overview of different TV interventions, focusing on the risk for atrioventricular conduction disturbances in patients without previous cardiac implantable electronic devices as well as the risk for pacemaker lead-related adverse events following transcatheter TV interventions. Finally, the authors propose a management algorithm for patients with conduction disturbances following TV intervention and for those with permanent leads undergoing transcatheter interventions.

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## Same-Day Permanent Pacemaker Implantation Following Transcatheter Aortic Valve Replacement

Quentin Fischer <sup>1</sup>, Marina Urena <sup>2</sup>, Guillem Muntané-Carol <sup>3</sup>, Alberto Alperi <sup>4</sup>,  
Luis Nombela-Franco <sup>5</sup>, Gabriela Veiga <sup>6</sup>, Ander Regueiro <sup>7</sup>, Gaspard Suc <sup>2</sup>, Rafael Romaguera <sup>3</sup>,  
Pablo Avanzas <sup>4</sup>, Gabriela Tirado-Conte <sup>8</sup>, Jose M de la Torre Hernandez <sup>6</sup>, Pedro Cepas-Guillén <sup>1</sup>,  
Mélanie Côté <sup>1</sup>, François Philippon <sup>9</sup>, Josep Rodés-Cabau <sup>10</sup>

Affiliations + expand

PMID: 40738576 DOI: 10.1016/j.jcin.2025.05.041

### Abstract

**Background:** The development of conduction disturbances leading to permanent pacemaker implantation (PPI) remains the main complication of transcatheter aortic valve replacement (TAVR).

**Objectives:** The aim of this study was to determine the impact of same-day PPI in patients developing persistent complete or high-degree atrio-ventricular block (CHB/HAVB) during TAVR.

**Methods:** This was a multicenter study including consecutive patients without prior pacemaker and developing procedural persistent CHB/HAVB. Baseline, procedural, and follow-up clinical and pacing interrogation data were prospectively collected in a dedicated database.

**Results:** A total of 584 consecutive patients (mean age:  $81 \pm 8$  years, 50% of women) were included; 157 (26.9%) had same-day PPI (SDP), and 427 (73.1%) were observed to assess for potential conduction recovery (n-SDP). In the n-SDP group, 376 patients (88%) finally received a PPI at a median of 3 [1-4] days following TAVR. There were no differences in periprocedural complications between groups, including pacemaker pocket hematomas, and the hospitalization length was shorter in the SDP group (5 [2-7] days vs 8[4-9] days;  $P < 0.001$ ). At 1-month follow-up, the median percentage of ventricular pacing (SDP: 96% (22%-99%), n-SDP: 90% (10%-99%);  $P = 0.203$ ) and pacemaker dependency rate (SDP: 56%, n-SDP: 50%;  $P = 0.277$ ) were similar in both groups.

**Conclusions:** In patients developing procedural persistent CHB/HAVB during TAVR, SDP was safe and associated with a shorter hospitalization length and a very high pacing burden at 30 days. These results, along with the very low rate of conduction recovery in the n-SDP group, would support SDP as a reasonable strategy in these patients.

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## Live Hemodynamics-Assisted Simultaneous Aortic and Mitral Valve-in-Value Replacement

Siddhartha Mengi <sup>1</sup>, Dimitri Kalavrouziotis <sup>1</sup>, Pierre-Yves Turgeon <sup>1</sup>, Jean-Michel Paradis <sup>2</sup>

Affiliations + expand

PMID: 40750182 PMCID: [PMC12441542](#) DOI: [10.1016/j.jaccas.2025.104345](#)

### Abstract

**Background:** Bioprosthetic valve failure is a growing challenge, particularly in high-risk patients who are poor surgical candidates. Simultaneous valve-in-valve (ViV) transcatheter aortic valve replacement (TAVR) and transcatheter mitral valve replacement (TMVR) via a fully percutaneous approach remains a novel and evolving strategy with limited data.

**Case summary:** A 70-year-old man with failed aortic and mitral bioprostheses leading to severe intraprosthetic regurgitation presented with progressive heart failure symptoms. Owing to high surgical risk, he underwent transfemoral ViV-TAVR and transeptal ViV-TMVR using the SavvyWire for real-time hemodynamic monitoring and dedicated left ventricular pacing. The procedure was successful, with immediate hemodynamic improvement and no complications.

**Discussion:** This case demonstrates the feasibility, safety, and efficiency of simultaneous transfemoral ViV-TAVR and ViV-TMVR in high-risk patients with bioprosthetic valve failure. Although further data are needed, this case highlights a novel application of the SavvyWire, demonstrating its potential to enhance procedural precision, enable real-time hemodynamic assessment, and improve safety in simultaneous ViV-TAVR and ViV-TMVR.

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› [Circ Cardiovasc Interv.](#) 2025 Sep;18(9):e015633. doi: 10.1161/CIRCINTERVENTIONS.125.015633.  
Epub 2025 Aug 7.

## Response by Ulacia Flores and Bertrand to Letter Regarding Article, "Randomized Study Comparing Angiography Guidance With Physiology Guidance After PCI: The EASY-PREDICT Study"

Paola Ulacia Flores <sup>1</sup>, Olivier F Bertrand <sup>1</sup>

Affiliations + expand

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*No abstract available*

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# Pectus Excavatum, Patent Foramen Ovale, and Migraine in the Same Patient

Jeremy Tricard <sup>1</sup>, François Maltais <sup>2</sup>, Josep Rodès-Cabau <sup>3</sup>, Massimo Conti <sup>4</sup>

Affiliations + expand

PMID: 40780778 PMCID: PMC12426515 DOI: 10.1016/j.jaccas.2025.104629

## Abstract

**Background:** A patent foramen ovale (PFO) can be found in patients with pectus excavatum (PE); PFO can be associated with migraines.

**Case summary:** A 22-year-old woman presents a PE and a history of recurrent migraines. Pulsed oxygen saturation at effort decreased from 97% to 92%. A transthoracic echocardiography showed a PFO. Five years after the Ravitch procedure, pulsed oxygen saturation remained stable at effort, no PFO was shown on transthoracic echocardiography, and migraine disappeared.

**Discussion:** Our observation is the first description of the PE, PFO, and migraine association. The correction of PE has allowed the closure of the PFO and improved migraines.

**Take-home messages:** This case report suggests that a patient presenting a PE should undergo a comprehensive cardiorespiratory evaluation. Similarly, patients with a symptomatic PFO and PE should benefit from a multidisciplinary discussion involving thoracic surgeons to determine the best approach to treat the PFO.

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## Honeycomb or Lotus Root-Like Intracoronary Pattern: Insights From Optical Coherence Tomography of a Recanalized Thrombus

Fernando Quevedo <sup>1</sup>, Julio Farjat-Pasos <sup>1</sup>, Olivier Bertrand <sup>1</sup>, Anthony Poulin <sup>1</sup>, Jean Pierre Déry <sup>1</sup>, David Garcia-Labbé <sup>1</sup>, Can Nguyen <sup>1</sup>, Jean Michel Paradis <sup>1</sup>, Natalia Pinilla <sup>2</sup>, Tomas Cieza <sup>1</sup>

Affiliations + expand

PMID: 40798907 PMCID: PMC12502023 DOI: 10.1002/ccd.70089

### Abstract

Spontaneous recanalized coronary thrombus (SRCT) has been identified in autopsy studies as multiple interconnected channels separated by thin septa. Despite its potential clinical significance, SRCT remains underdiagnosed. Recent advances in intracoronary imaging, including optical coherence tomography (OCT), have elucidated its pathophysiology, angiographic patterns, and therapeutic strategies. This review summarizes the epidemiological data, angiographic and OCT features, histopathological correlations, physiopathology, and interventional strategies for SRCT. A comprehensive literature review was performed, including data from dedicated registries and studies employing advanced intracoronary imaging modalities. Patients with SRCT are predominantly men in their fifth decade of life with cardiovascular risk factors and a history of acute or chronic coronary syndromes. Angiographic findings frequently include a braid-like or hazy appearance with TIMI 3 distal flow. OCT imaging reveals honeycomb-like patterns of multiple microchannels divided by fibrous septa. Histopathology corroborates these findings, highlighting organized thrombus with endothelialized septa and atherosclerotic features. Functional assessments indicate that most lesions are hemodynamically significant ( $FFR < 0.8$ ). Treatment strategies include drug-eluting stents (DES) and drug-coated balloons, with post-procedural OCT confirming lesion resolution. Challenges include side branch occlusion during an intervention, necessitating specific technical considerations to mitigate risks. SRCT is a distinct pathological and imaging entity characterized by multiple communicating channels. Advanced imaging and physiological assessment are pivotal for accurate diagnosis and management. DES remains the cornerstone of treatment, but procedural planning must address the risk of side branch occlusion. Further studies are warranted to explore long-term outcomes and optimize therapeutic approaches.

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## The Evolving Risk of Infective Endocarditis After Transcatheter Aortic Valve Implantation

Sundos H Alabbadi <sup>1</sup>, Alexander Iribarne <sup>2</sup>, Josep Rodés-Cabau <sup>3 4</sup>, Torsten Doenst <sup>5</sup>, Joanna Chikwe <sup>6</sup>, Shinobu Itagaki <sup>1</sup>, Nana Toyoda <sup>1</sup>, Raj Makkar <sup>6</sup>, Enoch F Akowuah <sup>7</sup>, Marissa Perez <sup>1</sup>, W Patricia Bandettini <sup>8</sup>, Shahab A Akhter <sup>9</sup>, Sabine Bleiziffer <sup>10</sup>, Markus Krane <sup>11</sup>, Hirsh Makhija <sup>12</sup>, Ranjit Deshpande <sup>13</sup>, Annetine C Gelijns <sup>1</sup>, Natalia N Egorova <sup>1</sup>

Affiliations + expand

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### Abstract

**Objectives:** Despite increased use of transcatheter aortic valve implantation (TAVI) in older adults with severe aortic stenosis, contemporary data on infective endocarditis (IE)-an infrequent but serious complication-are lacking. This study addresses this gap in knowledge.

**Methods:** We analysed 280 073 Medicare beneficiaries who underwent TAVI between 2013 and 2022. The primary outcome was the change in the 1-year incidence rate of IE post-TAVI. Joinpoint regression was used to evaluate the trend in the IE incidence as annual percent change (APC). Adjusted Cox models were used to evaluate associations between IE incidence and patient characteristics, as well as 12-month outcomes.

**Results:** The incidence rate of IE 1 year post-TAVI decreased from 20.0/1000 person-years in 2013 to 13.1/1000 in 2021. There was no change in incidence between 2013 and 2018 but a significant decline thereafter (-12.1% [CI, -20.7% to -7.5%],  $P < .001$ ). This decline was associated with the decrease in non-elective TAVI (sub-distribution hazard ratio: 0.98 [CI, 0.94-0.99],  $P < .001$ ); 4.8% of patients with IE underwent aortic valve reintervention. The 30-day aortic valve reintervention rate after IE increased significantly from 2013 to 2022 (APC: 24.9% [CI, 17.2%-33.0%],  $P < .001$ ). The 30-day mortality rate after TAVI explant was 9.3%; the adjusted risk of death declined over time (HR: 0.73 [CI, 0.58-0.92],  $P = .01$ ). However, the overall 30-day risk-adjusted mortality rate of TAVI-IE remained unchanged.

**Conclusions:** The post-TAVI incidence of IE in Medicare patients decreased after 2019. This decrease was associated with declining rates of non-elective TAVI and coincided with FDA approval of TAVI for low-risk patients. TAVI explant rates were low but increased recently. The lack of improvement in 30-day mortality underscores the challenges of elderly care after TAVI.

## Early Hemodynamic Performance of the SAPIEN 3 Ultra Resilia and Evolut Valves: A Propensity-Matched Analysis

Marisa Avvedimento <sup>1</sup>, Silvia Mas-Peiro <sup>1</sup>, Suleman Aktaa <sup>2</sup>, Luis Nombela-Franco <sup>3</sup>, Alberto Alperi <sup>4</sup>, Ignacio Cruz Gonzalez <sup>5</sup>, Anna Franzone <sup>6</sup>, Francisco Campelo-Parada <sup>7</sup>, Marina Urena <sup>8</sup>, Pedro Cepas-Guillén <sup>1</sup>, Gabriela Tirado <sup>3</sup>, Pablo Avanzas <sup>4</sup>, Ana E Laffond <sup>5</sup>, Giovanni Esposito <sup>6</sup>, Mehdi Tamir <sup>7</sup>, Gaspard Suc <sup>8</sup>, Siamak Mohammadi <sup>1</sup>, Philippe Pibarot <sup>1</sup>, Mélanie Côté <sup>1</sup>, John G Webb <sup>2</sup>, Josep Rodés-Cabau <sup>9</sup>

Affiliations + expand

PMID: 40812524 DOI: [10.1016/j.cjca.2025.07.040](https://doi.org/10.1016/j.cjca.2025.07.040)

### Abstract

**Background:** Limited data are available on early hemodynamic outcomes of the balloon-expandable SAPIEN 3 Ultra Resilia (S3UR) (Edwards Lifesciences, Irvine, CA) compared with the self-expandable Evolut (Medtronic, Minneapolis, MN) transcatheter heart valves. In this study we aimed to compare the hemodynamic performance of the S3UR with contemporary Evolut platforms (Evolut PRO, PRO+, FX) in a propensity-matched study.

**Methods:** A total of 307 patients who received an S3UR valve were matched with 488 patients who received Evolut valves (mean age,  $80.1 \pm 7$  years; 46.2% women). The primary end point was valve hemodynamics (aortic mean gradient, effective orifice area [EOA], severe prosthesis-patient mismatch [PPM], and moderate to severe aortic regurgitation [AR]) at 1-3 months after transcatheter aortic valve replacement. Secondary end points included clinical outcomes.

**Results:** Evolut valves were associated with lower mean gradients ( $8.0 \pm 3.1$  mm Hg vs  $9.8 \pm 3.8$  mm Hg;  $P < 0.001$ ) but higher rates of residual AR (mild AR, 10.7% vs 4.1%; moderate to severe AR, 4.2% vs 1.4%;  $P < 0.001$ ). EOA values and PPM rates were comparable. In patients with small aortic annulus ( $< 430 \text{ mm}^2$ ), Evolut valves showed larger EOA ( $1.94 \pm 0.3 \text{ cm}^2$  vs  $1.83 \pm 0.4 \text{ cm}^2$ ;  $P = 0.038$ ) and lower gradients ( $7.8 \pm 2.4$  mmHg vs  $10.9 \pm 4.5$  mmHg;  $P < 0.010$ ). Moderate to severe AR and PPM were similar between groups. Despite comparable device success, early safety outcomes favoured the S3UR (81.8% vs 60.5%;  $P < 0.010$  for S3UR and Evolut, respectively), because of higher rates of pacemaker implantation, atrial fibrillation, major vascular complication, and type 2-3 bleeding in the Evolut cohort.

**Conclusions:** Evolut valves showed lower transprosthetic gradients but a higher rate of residual AR compared with the S3UR. Further studies are needed to validate these findings and investigate their effect on long-term outcomes.

# Efficacy and Safety of Transcatheter Mitral Valve Edge-to-Edge Repair with a MitraClip Device in Real-World Canadian Practice

Shamir R Mehta <sup>1 2</sup>, Anita Asgar <sup>3</sup>, Robert Boone <sup>4</sup>, Josep Rodes-Cabau <sup>5</sup>, Eric A Cohen <sup>6</sup>, Andrew Czarnecki <sup>6</sup>, Marino Labinaz <sup>7</sup>, Shahar Lavi <sup>8</sup>, Nicolo Piazza <sup>9</sup>, Kevin R Bainey <sup>10</sup>, Akshay Bagai <sup>11</sup>, Jean-Michel Paradis <sup>5</sup>, J D Schwalm <sup>1 2</sup>, Douglas Wright <sup>2</sup>, Helen Nguyen <sup>1</sup>, Tara McCready <sup>1</sup>, Rajibul Mian <sup>1 2</sup>, John Webb <sup>4</sup>, Neil Fam <sup>11</sup>

Affiliations + expand

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## Abstract

in English, [French](#)

**Background:** Mitral transcatheter edge-to-edge repair (M-TEER) is a treatment option for patients with symptomatic mitral regurgitation (MR). The real-world experience with M-TEER in Canada has not been reported previously.

**Methods:** We conducted an observational study of 1191 patients from 11 Canadian centres undergoing M-TEER with a MitraClip device (Abbott, location). M-TEER databases from each centre were collected centrally and merged into a single Canada-wide database. The primary outcome was MR severity before M-TEER vs at up to 1 year after M-TEER. Secondary outcomes included hospitalizations for heart failure (HF) and New York Heart Association (NYHA) functional class.

**Results:** MR etiology was degenerative in 41%, and functional in 59%. The mean age was 76 years, and 36% were women. The proportion with MR  $\geq 3+$  was 97.3% before vs 11.0% at up to 1 year after M-TEER (absolute risk difference [ARD] 86.4%,  $P < 0.001$ ). Hospitalization for HF occurred in 50.7% before vs 10.3% at up to 1 year after M-TEER (ARD 40.4%,  $P < 0.001$ ), with similar benefit in patients with functional (ARD 44.8%, 95% confidence interval 39.5-50.1) and degenerative (ARD 34.8%, 95% confidence interval 29.0-40.6) MR. NYHA class III-IV HF was present in 82.8% before vs in 16.6% at up to 1 year after M-TEER (ARD 66.2%,  $P < 0.001$ ). Single-leaflet detachment (1.0%) and mitral valve surgery (2.2%) were infrequent. Mortality was 1.3% in-hospital, and 12.7% at 1 year.

**Conclusions:** In this first national registry of patients undergoing M-TEER in Canada, M-TEER resulted in a sustained reduction in MR and was associated with reduced HF hospitalizations and improvement in NYHA functional class, with a high degree of safety. This benefit was consistent in patients with functional and degenerative MR.

## Mechanistic Basis for Differential Effects of Interatrial Shunt Treatment in HFrEF vs HFpEF: The RELIEVE-HF Trial

Michael R Zile <sup>1</sup>, William T Abraham <sup>2</sup>, JoAnn Lindenfeld <sup>3</sup>, Stefan D Anker <sup>4</sup>, Josep Rodés-Cabau <sup>5</sup>, Michael P Pfeiffer <sup>6</sup>, John P Boehmer <sup>6</sup>, Sheldon Litwin <sup>7</sup>, Catalin F Baicu <sup>7</sup>, Julio Núñez Villota <sup>8</sup>, Elizabeth C Lee <sup>9</sup>, Richard Holcomb <sup>10</sup>, Patrick O'Keefe <sup>11</sup>, Neal L Eigler <sup>12</sup>, Gregg W Stone <sup>13</sup>; RELIEVE-HF Investigators

### Abstract

**Background:** The RELIEVE-HF (REducing Lung congestion symptoms using the v-wavE shunt in adVancEd Heart Failure) trial randomized 508 patients with heart failure (HF) to interatrial shunt treatment vs placebo procedure. Randomization was stratified into 2 patient groups: heart failure with reduced ejection fraction (HFrEF) (left ventricular ejection fraction [LVEF]  $\leq$ 40%); and heart failure with preserved ejection fraction (HFpEF) (LVEF  $>$ 40%). HF event rates (all-cause death, transplantation or left ventricular (LV) assist device, HF hospitalization or outpatient worsening) after shunt treatment during 2-year follow-up were directionally opposite: decreased by 51% in HFrEF, increased by 69% in HFpEF.

**Objectives:** This study aims to examine differences in cardiac structure and function before and after interatrial shunt placement in patients with HFrEF vs HFpEF that could underlie these discordant clinical outcomes.

**Methods:** Serial changes from baseline to 12 months in 17 transthoracic echocardiographic parameters in shunt-treated vs control patients in HFrEF vs HFpEF were assessed and compared by ANCOVA (analysis of covariance).

**Results:** In shunt-treated vs control patients with HFrEF, there were reductions in median LV end-diastolic volumes (-11.9 mL/m<sup>2</sup> [Q1-Q3: -21.3 to -2.5 mL/m<sup>2</sup>];  $P = 0.01$ ) and LV end-systolic volumes (-8.9 mL/m<sup>2</sup> [Q1-Q3: -17.2 to -20.7 mL/m<sup>2</sup>];  $P = 0.01$ ) indicative of reverse LV remodeling. There were no significant changes in right ventricular (RV), right atrial, or inferior vena cava sizes or pulmonary artery systolic pressure (PASP). In contrast, shunt-treated vs control patients with HFpEF did not have LV remodeling, but they had increased RV, right atrial, and inferior vena cava dimensions, and PASP also increased (4.7 mm Hg [Q1-Q3: 0.9-8.5 mm Hg];  $P = 0.02$ ). LV and RV diastolic compliance were decreased in HFpEF vs HFrEF at baseline and decreased further after shunt treatment in HFpEF.

**Conclusions:** Differential changes in left-sided and right-sided heart remodeling and PASP following interatrial shunt placement in patients with HFrEF vs HFpEF provide a mechanistic basis for the variable effects on clinical outcomes observed in RELIEVE-HF. (REducing Lung congestion symptoms using the v-wavE shunt in adVancEd Heart Failure [RELIEVE-HF]; [NCT03499236](#)).

Review

> *Struct Heart*. 2025 Jul 9;9(8):100699. doi: 10.1016/j.shj.2025.100699.

eCollection 2025 Aug.

## Patent Foramen Ovale Closure in Older Patients With Cryptogenic Stroke: Current Evidence and Next Steps

Pablo Vidal-Calés <sup>1</sup>, Laura Llull <sup>2</sup>, Sylvain Lanthier <sup>3</sup>, Juan H Del Portillo <sup>1</sup>, Laurent Desjardins <sup>4</sup>, Christine Houde <sup>4</sup>, Pierre-Olivier Sirois <sup>1</sup>, Xavier Freixa <sup>5</sup> <sup>6</sup>, Ángel Chamorro <sup>2</sup>, Josep Rodés-Cabau <sup>1</sup> <sup>4</sup> <sup>7</sup>

Affiliations + expand

PMID: 40894374 PMCID: [PMC12399247](#) DOI: [10.1016/j.shj.2025.100699](#)

### Abstract

Stroke is a major cause of morbidity and mortality worldwide, with recurrence risk increasing with age. In patients over 60 years of age with cryptogenic stroke, paradoxical embolism through a patent foramen ovale may be an important pathophysiology contributor, particularly when high-risk anatomical features (e.g., large shunt, atrial septal aneurysm) are present. Although patent foramen ovale closure has become a standard therapy in younger cryptogenic stroke patients, its benefit in older adults remains uncertain due to limited evidence and the need to exclude highly prevalent alternative causes like atrial fibrillation or carotid disease. A multidisciplinary heart-brain team is critical for accurate diagnosis, patient selection, and shared decision-making. Current guidelines vary and highlight the need for more robust data in this population. Recent observational studies suggest that patent foramen ovale closure in older patients may be safe and potentially reduce stroke recurrence compared to antithrombotic therapy alone. Ongoing randomized controlled trials are expected to provide definitive evidence on the efficacy and safety of patent foramen ovale closure in this age group, guiding future clinical decisions.

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Epub 2025 Aug 12.

## Upper Extremity Vascular Access

Avtandil M Babunashvili <sup>1</sup>, Olivier Francois Bertrand <sup>2</sup>, Safia Ouarrak <sup>2</sup>

Affiliations + expand

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### Abstract

Vascular arterial access is one of the key steps of percutaneous interventions. Both upper and lower extremity arteries can be used for percutaneous entry point, but choice of the arterial access depends on the interventional procedure type, knowing arterial anatomy, patient's clinical conditions. Proper choice of the vascular access plays crucial role in planning, safety, and effectiveness of interventional procedures. Upper extremity vascular access becomes dominant in interventional cardiology practice, and therefore, interventionalists should be familiar with technical details how to successfully obtain arterial access, avoid complications, and manage of appropriate post-procedure hemostasis.

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## Prophylactic Permanent Pacemaker Implantation After Transcatheter Aortic Valve Replacement

Quentin Fischer <sup>1</sup>, Luis Nombela-Franco <sup>2</sup>, Guillem Muntané-Carol <sup>3</sup>, Gabriela Veiga <sup>4</sup>, Ander Regueiro <sup>5</sup>, Tamim Nazif <sup>6</sup>, Vicenç Serra <sup>7</sup>, Lluis Asmarats <sup>8</sup>, Henrique B Ribeiro <sup>9</sup>, Azeem Latib <sup>10</sup>, Anthony Poulin <sup>11</sup>, Asim N Cheema <sup>12</sup>, Gabriela Tirado-Conte <sup>2</sup>, Joan Antoni Gomez-Hospital <sup>3</sup>, Aritz Gil Ongay <sup>4</sup>, Rami Gabani <sup>5</sup>, Dabit Arzamendi <sup>8</sup>, Michael Brener <sup>6</sup>, Alvaro Calabuig <sup>7</sup>, Andrea Scotti <sup>10</sup>, Marco Antonio S Gelain <sup>9</sup>, Marino Labinaz <sup>13</sup>, Pedro Cepas-Guillén <sup>1</sup>, Mélanie Côté <sup>1</sup>, Juan H Del Portillo <sup>1</sup>, François Philippon <sup>1</sup>, Josep Rodés-Cabau <sup>14</sup>

### Abstract

**Background:** The management of patients developing new conduction disturbances after transcatheter aortic valve replacement (TAVR) remains largely debated.

**Objectives:** The purpose of this study was to evaluate the incidence and clinical impact of prophylactic permanent pacemaker implantation (PPI) after TAVR.

**Methods:** This was a prespecified subanalysis of the PROMOTE (PRospective Application of a Pre-Specified Scientific Expert Panel AlgOrithm for the Management of COnduction Disturbances Following Transcatheter Aortic Valve Replacement) trial, a prospective multicenter study including 2,110 consecutive patients without prior pacemaker undergoing TAVR. Prophylactic PPI was considered in case of enlarged QRS with active electrocardiogram changes (daily PR or QRS interval increase  $\geq 20$  ms during 2 consecutive days), or new-onset persistent with either QRS  $> 150$  ms or PR  $> 240$  ms.

**Results:** A total of 329 patients with PPI post-TAVR were included, 80 (24.3%) of which had a prophylactic indication. The main indication (90%) of prophylactic PPI was new-onset persistent left bundle branch block with QRS  $> 150$  ms and/or PR  $> 240$  ms. The 30-day clinical outcomes were similar in prophylactic and nonprophylactic PPI patients, but the median rate of ventricular pacing percentage was significantly lower in the prophylactic PPI group (2% vs 73%;  $P < 0.001$ ), with a higher rate of patients with ventricular pacing percentage  $< 1\%$  (42.6% vs 14.5%;  $P < 0.001$ ). Prophylactic PPI after a positive electrophysiological study (His-Ventricle interval  $\geq 70$  ms) did not seem to impact the pacing burden at follow-up (median: 2.0% vs 1.9% in no electrophysiological study patients;  $P = 0.585$ ).

**Conclusions:** About one fourth of patients receiving PPI after TAVR had a prophylactic indication. Despite similar clinical outcomes, prophylactic PPI patients exhibited a very low pacing burden at 30 days. These findings would question the systematic use of prophylactic PPI after TAVR. (PRospective Application of a Pre-Specified Scientific Expert Panel AlgOrithm for the Management of COnduction Disturbances Following Transcatheter Aortic Valve Replacement [PROMOTE]; [NCT04139616](#)).

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# Role of Early Prothrombotic Evaluation in Device-Related Thrombus Risk Stratification After Left Atrial Appendage Closure

Pedro Cepas-Guillén <sup>1</sup>, Mathieu Robichaud <sup>1</sup>, Gilles O Hara <sup>1</sup>, Jean-Michel Paradis <sup>1</sup>, Jean Champagne <sup>1</sup>, Hugo Delarochelliere <sup>1</sup>, Erwan Salaun <sup>1</sup>, Pierre-Olivier Sirois <sup>1</sup>, Mélanie Coté <sup>1</sup>, Josep Rodés-Cabau <sup>1</sup>

Affiliations + expand

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## Abstract

**Background:** Left atrial appendage closure (LAAC) is increasingly used for stroke prevention in patients with non-valvular atrial fibrillation and contraindications to oral anticoagulation. The potential role of early prothrombotic status assessment in evaluating device-related thrombus (DRT) risk following LAAC remains unclear.

**Methods:** The study included 147 patients undergoing LAAC with oral anticoagulation contraindication. Coagulation activation markers-prothrombin fragment 1 + 2 and thrombin antithrombin III-were measured at baseline and 7 days postprocedure. Based on the 50th percentile of delta (%) changes, patients were classified into low or high prothrombotic status. Specific delta % thresholds were assessed, which could serve as noninvasive cutoffs to rule out DRT.

**Results:** A total of 53 patients (36.1%) were classified as having high prothrombotic status. DRT occurred in 9 patients (6.1%), with a significantly higher incidence in the high prothrombotic group (15.1 vs. 1.1%,  $p < 0.001$ ). Multivariable analysis identified elevated post-LAAC coagulation activation markers as independent predictors of DRT (adjusted odds ratio: 13.84 [1.65-115.89],  $p = 0.015$ ). Proposed thresholds for prothrombin fragment 1 + 2 (74.11%) and thrombin antithrombin III (120.74%) demonstrated negative predictive values of 98.9%. Using these thresholds, 75.5% of patients were classified as low risk for DRT. No clinical differences were observed at follow-up between the low- and high-risk DRT groups.

**Conclusions:** Early evaluation of coagulation markers provides valuable insight into DRT risk after LAAC. The proposed thresholds demonstrate a high negative predictive value, effectively identifying patients at low risk for DRT and supporting their use as noninvasive tools to safely rule out DRT. These markers could enable early antithrombotic de-escalation and reduce the need for repeat imaging. Further studies are warranted.

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# CLASP IID Trial and Registry: 2-Year Outcomes of Transcatheter Repair for Degenerative Mitral Regurgitation

Raj Makkar <sup>1</sup>, Firas Zahr <sup>2</sup>, Tarun Chakravarty <sup>3</sup>, Scott Chadderton <sup>4</sup>, Moody Makar <sup>3</sup>, Tobias Friedrich Ruf <sup>5</sup>, Robert M Kipperman <sup>6</sup>, Andrew N Rassi <sup>7</sup>, Jörg Hausleiter <sup>8</sup>, Robert L Smith <sup>9</sup>, Molly Szerlip <sup>9</sup>, Scott Goldman <sup>10</sup>, D Scott Lim <sup>11</sup>, Ignacio Inglessis-Azuaje <sup>12</sup>, Pradeep Yadav <sup>13</sup>, Philipp Lurz <sup>14</sup>, Tobias Kister <sup>14</sup>, Charles J Davidson <sup>15</sup>, Mubashir Mumtaz <sup>16</sup>, Hemal Gada <sup>16</sup>, Saibal Kar <sup>17</sup>, Susheel K Kodali <sup>18</sup>, Roger Laham <sup>19</sup>, William Hiesinger <sup>20</sup>, Neil P Fam <sup>21</sup>, Mirjam Keßler <sup>22</sup>, William W O'Neill <sup>23</sup>, Brian Whisenant <sup>24</sup>, Chad Klier <sup>25</sup>, Volker Rudolph <sup>26</sup>, James Hermiller <sup>27</sup>, Abhijeet Dhoble <sup>28</sup>, Richard Smalling <sup>29</sup>, Azeem Latib <sup>30</sup>, Mohamad Lazkani <sup>31</sup>, Joseph Choo <sup>32</sup>, Santiago Garcia <sup>32</sup>, Josep Rodés-Cabau <sup>33</sup>, Niklas Schofer <sup>34</sup>, Stephan Baldus <sup>35</sup>, Samir Kapadia <sup>36</sup>, Konstantinos Koulogiannis <sup>6</sup>, Leo Maroff <sup>6</sup>, Linda D Gillam <sup>6</sup>, Ralph Stephan von Bardeleben <sup>37</sup>; CLASP IID Trial and Registry Investigators

## Abstract

**Background:** One-year outcomes from the CLASP IID Trial (Edwards PASCAL TrAnScatheter Valve RePair System Pivotal Clinical Trial; NCT03706833) and Registry established the PASCAL transcatheter valve repair system as a safe and effective treatment for prohibitive-risk degenerative mitral regurgitation (DMR). Longer-term follow-up is ongoing.

**Objectives:** This paper reports the CLASP IID Trial and Registry 2-year outcomes.

**Methods:** In the CLASP IID Trial, prohibitive-risk patients with 3+/4+ DMR, deemed suitable for both the PASCAL and MitraClip systems, were randomized 2:1 (PASCAL: n = 204; MitraClip: n = 96). Patients with complex anatomy deemed ineligible for randomization were enrolled in the CLASP IID Registry (N = 98) and treated with the PASCAL system.

**Results:** In the randomized cohort, significant and sustained MR reduction was achieved at 2 years. MR  $\leq 2+$  rate was 95.0% (96/101) in the PASCAL group vs 91.5% (54/59) in the MitraClip group ( $P = 0.500$ ), and MR  $\leq 1+$  rate was 77.2% (78/101) vs 67.8% (40/59) ( $P = 0.198$ ), respectively. Kaplan-Meier estimates for freedom from all-cause mortality, cardiovascular mortality, heart failure hospitalization, and nonelective mitral valve reinterventions were 80.8% vs 86.2% ( $P = 0.216$ ), 88.6% vs 90.4% ( $P = 0.666$ ), 86.4% vs 94.3% ( $P = 0.058$ ), and 97.9% vs 97.9% ( $P = 0.962$ ), respectively. In the registry cohort, 91.9% (34/37) achieved MR  $\leq 2+$  and 64.9% (24/37) achieved MR  $\leq 1+$ . Kaplan-Meier estimates for freedom from all-cause mortality, cardiovascular mortality, heart failure hospitalization, and nonelective mitral valve reinterventions were 77.2%, 84.0%, 85.1%, and 99.0%, respectively. Significant improvements in functional status and quality of life were observed in both cohorts.

**Conclusions:** Two-year outcomes from the CLASP IID Trial and Registry show favorable survival, and significant and sustained MR reduction with functional and quality-of-life improvements, confirming sustained safety and effectiveness of the PASCAL system in treating a broad population of DMR patients.

# Preprocedural CT and ECG Markers for Predicting Post-TAVR Pacemaker Requirement in High-Risk Patients

Justin T Tretter <sup>1</sup>, Mackram F Eleid <sup>2</sup>, Francesco Bedogni <sup>3</sup>, Josep Rodés-Cabau <sup>4</sup>, Ander Regueiro <sup>5</sup>, Luca Testa <sup>3</sup>, Shmuel Chen <sup>6</sup>, Attilio Galhardo <sup>4</sup>, Kenneth A Ellenbogen <sup>7</sup>, Martin B Leon <sup>8 9</sup>, Shlomo Ben-Haim <sup>1</sup>

Affiliations + expand

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## Abstract

**Background:** Need for permanent pacemaker implantation (PPI) following transcatheter aortic valve replacement (TAVR) remains a common complication. We aimed to assess computed tomography (CT)-based anatomical and electrocardiogram (ECG)-based parameters in a predictive model for PPI following TAVR.

**Methods:** We assessed CT-based parameters, including the predicted course of the conduction axis from atrioventricular node to left bundle branch origin relative to the aortic virtual basal ring. Electrophysiological variables were combined in assessing a model to predict post-TAVR PPI.

**Results:** Among 433 patients (mean age 82.0 [9.0] years, 54.0% female), 90 (21.0%) required PPI. Multiple binary logistic modeling demonstrated a shallower position of the membranous septum inferior margin midpoint increased the odds of PPI by 20% for every 1 mm (adjusted odds ratio [aOR]: 1.20) adjusted for the CT assessment phase. Increasing aortic root rotational angle associated with lower PPI odds (odds ratio [OR]: 0.98; 95% CI [0.95-1.00]), while an angle between the membranous septum midpoint and noncoronary leaflet nadir associated with increased PPI odds (OR: 1.04; 95% CI [1.01-1.08]). Preprocedural right bundle branch block and first-degree atrioventricular block associated with increased odds for PPI (OR: 3.76; 95% CI [1.71-8.21]; and OR: 1.84; 95% CI [1.06-3.18], respectively). The model had an area under the curve of 0.73 (95% CI [0.67-0.79]), sensitivity of 0.74 (95% CI [0.47-0.93]), and specificity of 0.65 (95% CI [0.40-0.87]) for predicting PPI requirement.

**Conclusions:** A predictive model for determining the risk of PPI following TAVR is reported, combining comprehensive conduction-specific anatomical measurements relative to the aortic root and electrical measurements with clinical parameters. This model requires prospective application to understand its performance in the real-world.

# Clinical Impact of Concordant and Discordant Physiology Parameters Post-Percutaneous Coronary Intervention in the EASY-PREDICT Study

Paola Ulacia Flores <sup>1</sup>, Tomas Cieza <sup>1</sup>, Safia Ouarrak <sup>1</sup>, Andrés Ruhl <sup>1</sup>, Siddhartha Mengi <sup>1</sup>, Robert De Laroche <sup>1</sup>, David Garcia-Labbé <sup>1</sup>, Jean-Pierre Déry <sup>1</sup>, Anthony Poulin <sup>1</sup>, Éric Larose <sup>1</sup>, Bernard Noël <sup>1</sup>, Can Manh Nguyen <sup>1</sup>, Jean-Michel Paradis <sup>1</sup>, Olivier F Bertrand <sup>1</sup>

Affiliations + expand

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## Abstract

**Background:** In the EASY-PREDICT Study, patients were randomized to angiography-guidance or post-percutaneous coronary intervention (PCI) physiology-guidance. Discordance between resting and hyperemic physiology post-PCI might have a different relationship with clinical outcomes.

**Aims:** The EASY-PREDICT study showed that routine post-PCI physiology assessment was not associated with improved outcomes compared to angiography-guidance only. We aimed to assess whether resting and hyperemic post-PCI physiology had a different clinical impact.

**Methods:** All-comer patients referred for diagnostic angiography and possible PCI were recruited in a high-volume university hospital and randomized after uncomplicated PCI to angiography-only or target vessel physiology. We studied the concordance and discordance between resting (dPR) and hyperemic (FFR) physiologic parameters post-PCI using ischemic thresholds (dPR  $\leq$  0.89 and FFR  $\leq$  0.80) and clinical outcomes up to 18 months post-PCI.

**Results:** A total of 221 patients (325 lesions) with successful PCI were randomized to either group, 219 of which were included in the per protocol analysis. In the physiology group, 132 lesions with available post-PCI physiology were included and 109 (82.6%) had final concordant physiology results post-PCI. Discordance was observed in 15.15% of lesions, 2.3% FFR ischemic (dPR-|FFR+) and 12.9% dPR ischemic (dPR+|FFR-) respectively. At 18 months clinical follow-up, Target Vessel Failure (TVF) was 12.3% in the concordant sub-group whereas TVF was 40.0% in the discordant subgroup.

**Conclusions:** After PCI, physiology discordance between dPR and FFR occurred in ~15% of the cases. Patients with discordant physiology results post-PCI appeared to have higher TVF rates compared to concordant physiology sub-groups.

## Visceral adipose tissue and hepatic fat as determinants of carotid atherosclerosis

Russell J de Souza <sup>1 2 3</sup>, Marie E Pigeyre <sup>2 4 5</sup>, Karleen M Schulze <sup>2 4</sup>, Amel Lamri <sup>2 4</sup>, Baraa K Al-Khazraji <sup>6</sup>, Philip Awadalla <sup>7 8 9</sup>, Joseph Beyene <sup>1</sup>, Dipika Desai <sup>1 2</sup>, Jean-Pierre Despres <sup>10 11 12</sup>, Trevor J B Dummer <sup>13</sup>, Matthias G Friedrich <sup>14 15</sup>, Jason Hicks <sup>16</sup>, Vikki Ho <sup>17 18</sup>, Éric LaRose <sup>10</sup>, Scott A Lear <sup>19</sup>, Douglas S Lee <sup>20 21</sup>, Jonathon A Leipsic <sup>22</sup>, Guillaume Lettre <sup>23 24</sup>, Alan R Moody <sup>25</sup>, Michael D Noseworthy <sup>26 27 28 29</sup>, Guillaume Pare <sup>1 2 3 4 5 30</sup>, Grace Parraga <sup>31 32</sup>, Paul Poirier <sup>10 33</sup>, Jean-Claude Tardif <sup>23 24</sup>, Salim Yusuf <sup>2 4</sup>, Jennifer Vena <sup>34</sup>, Sonia S Anand <sup>35 36 37 38</sup>

Affiliations + expand

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### Abstract

**Background:** Visceral adipose tissue (VAT) and hepatic fat (HF) contribute to multiple health risks, including diabetes, hypertension, cardiovascular disease, cognitive decline, and cancer. The objective of this study is to determine whether VAT and HF are associated with carotid atherosclerosis beyond traditional cardiovascular risk factors.

**Methods:** Participants in the Canadian Alliance of Healthy Hearts and Minds (CAHHM) cohort study ( $n = 6760$ ; average age = 57.1; 54.9% female) underwent MRI for VAT volume, hepatic fat fraction (HFF), and carotid atherosclerosis assessed by carotid wall volume (CWV). Regression models were used to assess the associations of VAT and HF with carotid atherosclerosis, separately in males and females, controlling for other cardiovascular risk factors. Associations of VAT and proton-density hepatic fat fraction (PDFF) with ultrasound-measured carotid-intima media thickness (CIMT) were also assessed in the UK Biobank (UKB;  $n = 26,547$ ; average age = 54.7; 51.9% female).

**Results:** In CAHHM, we show that a 1-SD higher VAT volume is associated with a  $6.16 \text{ mm}^3$  higher CWV (95% CI: 1.68 to 10.63), but there is no association between HFF and CWV. In the UK Biobank cohort, a 1-SD higher VAT volume is associated with a  $0.016 \pm 0.009 \text{ mm}$  higher CIMT, and a 1-SD higher PDFF is associated with a  $0.012 \pm 0.010 \text{ mm}$  higher CIMT. After adjustment for CV risk factors, these associations are attenuated. A pooled analyses of CAHHM and UKB support a direct, positive association of VAT and HFF with subclinical atherosclerosis in both sexes, albeit slightly weaker for hepatic fat.

**Conclusion:** Visceral fat, and to a lesser extent, hepatic fat, are associated with increased carotid atherosclerosis.

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## Massive Anterior STEMI Due to Essential Thrombocythemia Leading to Urgent Thrombocytapheresis

Alexis V Rioux <sup>1</sup>, Laurence Morin <sup>2</sup>, Mathieu Bernier <sup>3</sup>, Adelina-Teona Avram <sup>2</sup>, Anthony Poulin <sup>3</sup>

Affiliations + expand

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Free article

### Abstract

**Background:** Myocardial infarction in essential thrombocythemia (ET) is a rare but severe complication of this myeloproliferative disorder, occurring in approximately 2% to 3% of the population.

**Case summary:** A 78-year-old man with calreticulin-mutated ET presented with massive anterior ST-segment elevation myocardial infarction (STEMI). Urgent coronary angiogram revealed subtotal left anterior descending artery stenosis due to heavy thrombus burden, leading to partial revascularization. His platelet count exceeded  $1,200 \times 10^9/L$  on admission, justifying prompt thrombocytapheresis in the coronary care unit.

**Discussion:** In acute symptomatic thrombohemorrhagic complications, the American Society for Apheresis designates thrombocytapheresis as a Class II recommendation. This case describes the novel use of thrombocytapheresis in the setting of anterior STEMI with ET.

**Take-home messages:** STEMI complicating acutely decompensated ET is life threatening, and early thrombocytapheresis should be considered in select patients. This case demonstrates the potential benefit of more aggressive cytoreductive therapy in patients with ET and underlying cardiovascular risk factors.

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# Five-Year Clinical Outcomes and Durability of a Self-Expanding Transcatheter Heart Valve With Intra-Annular Leaflets

Rishi Puri <sup>1</sup>, Holger Thiele <sup>2</sup>, Stephan Fichtlscherer <sup>3</sup>, Dirk Westermann <sup>4</sup>, Raj Makkar <sup>5</sup>,  
Ron Waksman <sup>6</sup>, Samer Hakmi <sup>7</sup>, Lars Sondergaard <sup>8</sup>, Mark Groh <sup>9</sup>, Joseph K Montarello <sup>10</sup>,  
Joerg Kempfert <sup>11</sup>, Gerald Yong <sup>12</sup>, Francesco Bedogni <sup>13</sup>, Francesco Maisano <sup>14</sup>,  
Stephen G Worthley <sup>15</sup>, Josep Rodes-Cabau <sup>16</sup>, Gregory P Fontana <sup>17</sup>, Helge Möllmann <sup>18</sup>

## Abstract

**Background:** There is a paucity of data regarding the longer-term durability of transcatheter heart valves. This analysis aimed to describe the 5-year clinical outcomes and valve durability for patients treated with the Portico transcatheter heart valves across 3 studies harmonized in their prospective enrollment, inclusion/exclusion criteria, centralized independent core laboratory echocardiographic analysis, and independent clinical events committee adjudication.

**Methods:** Patient-level data from the PORTICO IDE randomized controlled trial, the PORTICO I postmarket study, and the PORTICO continued access protocol were pooled using a random-effects meta-analysis model. All 3 studies collected follow-up data at discharge, 30 days, and annually through 5 years. Adverse events and pooled echocardiographic data were assessed using Valve Academic Research Consortium-2 definitions. Durability definitions were adapted from Valve Academic Research Consortium-3 and European Association of Percutaneous Cardiovascular Interventions/European Society of Cardiology/European Association for Cardio-Thoracic Surgery consensus guidelines.

**Results:** A total of 1464 patients with severe symptomatic aortic stenosis and high or extreme surgical risk were included. Median age was 83 years, 61.7% were women, and the median Society of Thoracic Surgeons score was 4.9%. At 5 years, all-cause mortality and stroke rates were 49.4% and 12.3%, respectively. Transvalvular gradient and effective orifice area at 5 years were 6.2 mm Hg and 1.83 cm<sup>2</sup>, respectively, with paravalvular leak  $\geq$ moderate severity occurring in 1.9%. The 5-year bioprosthetic valve failure rate was 2.7%, including a 0.7% valve-related death rate and a 2.0% valve reintervention rate, but no patients with severe hemodynamic structural valve deterioration. Moderate hemodynamic structural valve deterioration occurred in 0.9% of the patients at 5 years. Hemodynamic performance and transcatheter heart valve durability remained stable irrespective of annular size.

**Conclusions:** The use of the Portico transcatheter heart valve system in patients at high or extreme surgical risk demonstrated favorable clinical outcomes and hemodynamic performance with low transvalvular gradients and greater than mild paravalvular leak. Furthermore, bioprosthetic valve failure rates were low with no incidence of severe hemodynamic structural valve deterioration at 5 years, irrespective of annular size.

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## Novel Mother-in-Child Technique to Implant Coronary Sinus Reducer in a Challenging Anatomy

Jean-Benoît Veillette <sup>1</sup>, Juan Hernando Del Portillo-Navarrete <sup>2</sup>, Francesco Giannini <sup>3</sup>,  
Can Manh Nguyen <sup>1</sup>, Jean-Michel Paradis <sup>4</sup>

Affiliations + expand

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Free article

### Abstract

**Background:** A 73-year-old woman with a history of complete revascularization for coronary artery disease presented with refractory angina despite multiple antianginal treatments.

**Case summary:** Repeated coronary angiography revealed no significant obstructive lesions. Functional invasive coronary assessment confirmed coronary microvascular dysfunction. An A-Flux coronary sinus reducer (VahatiCor) was proposed. Given a very vertically oriented coronary sinus, device deployment was challenging. We then employed a novel mother-in-child technique using a 10 F Oscor Adelante Breezaway 120 degrees catheter (Oscor) to optimize support during A-Flux implantation.

**Discussion:** Coronary sinus reducers may provide a favorable hemodynamic response in patients with microvascular angina. The A-Flux device's design may facilitate navigation in complex anatomies, although inadequate support remains a potential limitation. The mother-in-child technique may help overcome this challenge.

**Take-home messages:** Insufficient support during coronary sinus reduction procedures is a major challenge for interventionists. Using the mother-in-child technique with a 10 F Oscor Adelante Breezaway 120 degrees catheter may help address this issue in certain patients.

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# Short-Term Anticoagulation Versus Dual Antiplatelet Therapy for Preventing Device Thrombosis Following Left Atrial Appendage Closure: The ANDES Randomized Clinical Trial

Josep Rodés-Cabau <sup>1 2 3</sup>, Luis Nombela-Franco <sup>4</sup>, Ignacio Cruz-Gonzalez <sup>5</sup>, Benjamin Hibbert <sup>6 7</sup>, Xavier Freixa <sup>2</sup>, Jean-Bernard Masson <sup>8</sup>, Réda Ibrahim <sup>9</sup>, Rodrigo Estevez-Loureiro <sup>10</sup>, Xavier Millan <sup>11</sup>, Malek Kass <sup>12</sup>, Jean-Michel Paradis <sup>1</sup>, Jean Champagne <sup>1</sup>, Pablo Salinas <sup>4</sup>, Ana Laffond <sup>5</sup>, Omar Abdel-Razek <sup>6</sup>, Marino Labinaz <sup>6</sup>, Pedro Cepas-Guillen <sup>2</sup>, Dabit Arzamendi <sup>11</sup>, Pablo Vidal-Cales <sup>1</sup>, Marco Pavesi <sup>3</sup>, Mélanie Côté <sup>1</sup>, Gilles O'Hara <sup>1</sup>, Erwan Salaun <sup>1</sup>

## Abstract

**Background:** The optimal antithrombotic treatment after transcatheter left atrial appendage closure (LAAC) remains to be determined. The objective of this trial was to compare anticoagulation and antiplatelet therapy for preventing device-related thrombosis (DRT) after LAAC.

**Methods:** This was a prospective multicenter international randomized trial comparing 2 different antithrombotic strategies for preventing DRT after LAAC in patients with nonvalvular atrial fibrillation. Patients were randomized (1:1) to receive direct oral anticoagulants (DOACs) or dual antiplatelet therapy (DAPT; aspirin+clopidogrel) for 60 days. Patients underwent transesophageal echocardiography at 60 days, and the images were analyzed in a central echocardiography laboratory by experienced echocardiographers blinded to the allocated treatment. The primary outcome was DRT as determined by transesophageal echocardiography 60 days after LAAC in patients receiving the allocated treatment at the time of transesophageal echocardiography (per-protocol analysis). The safety outcome included all-cause mortality, stroke, bleeding, or site-reported DRT within 60 days after LAAC in all randomized patients (intention-to-treat analysis).

**Results:** A total of 510 patients (mean age  $77 \pm 9$  years, 35% women) were included between October 2018 and May 2025, and 253 and 257 patients were randomized to the DOAC and DAPT groups, respectively. Of these, 399 patients underwent transesophageal echocardiography and were receiving the allocated treatment at 60 days after LAAC. The primary outcome occurred in 3 patients (1.5%) in the DOAC group compared with 8 patients (4.1%) in the DAPT group (difference, -2.7% [95% CI, -6.0% to 0.6%];  $P=0.110$ ). The safety outcome occurred in 52 patients (22.5%) in the DOAC group compared with 82 patients (34.9%) in the DAPT group (difference, -12.4% [95% CI, -20.6% to -4.2%];  $P=0.003$ ), and differences were mainly driven by a lower rate of bleeding events in the DOAC group (44 patients [17.4%] versus 64 patients [24.9%]; difference, -7.5% [95% CI, -14.6% to -0.4%];  $P=0.038$ ).

**Conclusions:** The use of DOACs after LAAC failed to reduce DRT compared with DAPT, but it was associated with an improved safety profile. The results of this study should be interpreted with caution because of statistical power issues related to the narrower-than-expected between-group differences and will need confirmation in future larger studies.

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## Association Between Lipoprotein(a), Oxidized phospholipids, and Bioprosthetic Valve Dysfunction Following Transcatheter Aortic Valve Implantation

Carlos Giuliani <sup>1 2</sup>, Sébastien Hecht <sup>1 2</sup>, Antonela Zanuttini <sup>1 2</sup>, Marisa Avvedimento <sup>1 2</sup>, Jorge Nuche <sup>1 2</sup>, Julio I Farjat Pasos <sup>1 2</sup>, Jérémie Bernard <sup>1 2</sup>, Tastet Lionel <sup>1 2</sup>, Rami Abu-Alhayja'a <sup>1 2</sup>, Jonathan Beaudoin <sup>1 2</sup>, Nancy Côté <sup>1 2</sup>, Frédéric Beaupré <sup>1 2</sup>, Anthony Poulin <sup>1 2</sup>, Robert DeLarochellière <sup>1 2</sup>, Jean-Michel Paradis <sup>1 2</sup>, Marie-Annick Clavel <sup>1 2</sup>, Benoit J Arsenault <sup>1 2</sup>, Romain Capoulade <sup>3</sup>, Josep Rodés-Cabau <sup>1 2</sup>, Sotirios Tsimikas <sup>4</sup>, Philippe Pibarot <sup>1 2</sup>

Affiliations + expand

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## Impact of Balloon Postdilation on Long-Term Bioprostheses Durability After TAVR

Antonin Trimaille <sup>1</sup>, Pedro Cepas-Guillén <sup>1</sup>, Juan Hernando Del Portillo <sup>1</sup>, Carlos Giuliani <sup>1</sup>,  
Jean-Michel Paradis <sup>1</sup>, Eric Dumont <sup>1</sup>, Anthony Poulin <sup>1</sup>, Dimitri Kalavrouziotis <sup>1</sup>,  
Frederic Beaupré <sup>1</sup>, Jean Porterie <sup>1</sup>, Siamak Mohammadi <sup>1</sup>, Josep Rodés-Cabau <sup>1</sup>

Affiliations + expand

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Free article

### Abstract

**Background:** While balloon postdilation (BPD) during transcatheter aortic valve replacement may enhance hemodynamic performance by optimizing valve expansion, it was also linked with leaflet mechanical stress, potentially reducing valve durability. The aim of this study was to investigate the impact of BPD on long-term bioprosthetic valve durability.

**Methods:** We analyzed the data of a prospective single-center registry including consecutive patients undergoing transcatheter aortic valve replacement between May 2007 and March 2024 alive at 1-year and without a valve-in-valve procedure. To reduce imbalance in baseline and procedural characteristics, the effect of BPD on events was assessed using a propensity score-matched population (215 patients with BPD versus 761 patients without BPD, out of a total of 1911 patients). The primary end point was the occurrence of stage 2 or 3 hemodynamic valve deterioration according to Valve Academic Research Consortium-3.

**Results:** In the propensity-score matched population, BPD was associated with a lower risk of stage 2 or 3 hemodynamic valve deterioration occurrence compared with no-BPD (2.8% versus 5.8%; subdistribution hazard ratio, 0.37 [95% CI, 0.15-0.95];  $P=0.039$ ), and a lower rate of bioprosthetic valve failure (2.8% versus 5.1%; subdistribution hazard ratio, 0.39 [95% CI, 0.15-0.98];  $P=0.046$ ). Long-term echocardiographic follow-up up to 10 years showed better hemodynamic parameters over time in patients with BPD. A trend toward a higher prevalence of heart failure hospitalization was observed in patients with BPD.

**Conclusions:** BPD was associated with a lower incidence of stage 2 and 3 hemodynamic valve deterioration and bioprosthetic valve failure, along with improved bioprosthetic valve hemodynamic parameters over time. Further studies are warranted.

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# Impact of Early Hemodynamic Valve Deterioration on Long-Term Outcomes Following Transcatheter Aortic Valve Replacement

Antonin Trimaille <sup>1</sup>, Pedro Cepas-Guillen <sup>1</sup>, Juan Hernando Del Portillo <sup>1</sup>, Jean-Michel Paradis <sup>1</sup>, Eric Dumont <sup>1</sup>, Anthony Poulin <sup>1</sup>, Dimitri Kalavrouziotis <sup>1</sup>, Frederic Beaupré <sup>1</sup>, Jean Porterie <sup>1</sup>, Siamak Mohammadi <sup>1</sup>, Josep Rodés-Cabau <sup>2</sup>

Affiliations + expand

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## Abstract

**Background:** The incidence, predictors, and impact of early hemodynamic valve deterioration (HVD) after transcatheter aortic valve replacement (TAVR) are unclear.

**Objectives:** The aim of this study was to explore the impact of early HVD on long-term clinical outcomes and bioprosthetic durability after TAVR.

**Methods:** Data from a prospective single-center registry including all consecutive patients undergoing TAVR between 2007 and 2023 were analyzed. Early HVD was defined as an increase of at least 10 mm Hg in the mean transaortic gradient on echocardiography performed within the first 3 months after TAVR, compared with discharge echocardiography. The primary endpoint was valve-related long-term clinical efficacy according to the Valve Academic Research Consortium 3.

**Results:** Among 1,912 patients, early HVD was observed in 68 (3.6%). Smaller annular area (OR per 10-mm<sup>2</sup> decrease: 1.03; 95% CI: 1.00-1.08), valve-in-valve procedure (OR: 3.86; 95% CI: 1.95-7.45), and the absence of anticoagulation at discharge (OR: 2.44; 95% CI: 1.28-5.26) were independent predictors of early HVD ( $P < 0.05$  for all). After a median follow-up period of 1,107 days (Q1-Q3: 369-1,697 days), early HVD was independently associated with lower valve-related long-term clinical efficacy (subdistribution HR [sHR]: 0.43; 95% CI: 0.27-0.68;  $P < 0.001$ ) and a higher risk for stroke (sHR: 3.03; 95% CI: 1.59-5.76;  $P < 0.001$ ), stage 2 or 3 (sHR: 7.40; 95% CI: 4.51-12.6;  $P < 0.001$ ) or stage 3 (sHR: 5.43; 95% CI: 2.44-12.1;  $P < 0.001$ ) bioprosthetic valve deterioration, and bioprosthetic valve failure (sHR: 2.70; 95% CI: 1.30-5.61;  $P = 0.007$ ). Similar results were observed in a propensity score-matched cohort including 272 patients without and 68 with early HVD.

**Conclusions:** Early HVD was associated with worse long-term clinical and hemodynamic outcomes after TAVR. These results highlight the importance of identifying early HVD along with the need for future studies to evaluate the most appropriate treatment for this challenging group of patients.

# Temporal trends and outcomes of left atrial appendage closure. A national population-based study

[Article in English, Spanish]

María Anguita-Gámez <sup>1</sup>, Náyade Del Prado <sup>2</sup>, Pablo Salinas <sup>1</sup>, José Luis Bernal <sup>2</sup>,  
Cristina Fernández-Pérez <sup>3</sup>, Pilar Jiménez-Quevedo <sup>1</sup>, Gabriela Tirado-Conte <sup>1</sup>, Alejandro Travieso <sup>1</sup>,  
Hernán Mejía-Rentería <sup>1</sup>, Fernando Macaya <sup>1</sup>, Ricardo Ortiz-Lozada <sup>1</sup>, Xavier Freixa <sup>4</sup>,  
Rodrigo Estévez-Loureiro <sup>5</sup>, Dabit Arzamendi <sup>6</sup>, Ignacio Cruz-González <sup>7</sup>, Nieves Gonzalo <sup>1</sup>,  
Josep Rodés-Cabau <sup>8</sup>, Antonio Fernández-Ortiz <sup>1</sup>, Javier Escaned <sup>1</sup>, Julián Villacastín <sup>1</sup>,  
Javier Elola <sup>2</sup>, Luis Nombela-Franco <sup>9</sup>

Affiliations + expand

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## Abstract

**Introduction and objectives:** Left atrial appendage closure (LAAC) has emerged as a viable stroke prevention strategy in selected patients with nonvalvular atrial fibrillation. The objective of the study was to analyze temporal trends and outcomes of LAAC in a nationwide study.

**Methods:** This population-based study analyzed the incidence, epidemiological and clinical characteristics, and outcomes of all patients discharged with a diagnosis of percutaneous LAAC from hospitals included in the Spanish National Health System over a 7-year period (from January 2016 to December 2022).

**Results:** A total of 3786 patients undergoing percutaneous LAAC were identified. The rate of procedures significantly increased over the study period (annual growth of 23%; IRR, 1.23; 95%CI, 1.17-1.28;  $P < .001$ ), both in men and in women. The in-hospital mortality rate was 1%, and the incidences of in-hospital concomitant adverse events (AE) and 30-day readmission were 14.0% and 3.5%, respectively. The most frequent AE was the need for blood transfusion (11.5%), followed by vascular complications (2.2%) and acute renal failure (1.9%). The HAS-BLED score was a predictor of in-hospital mortality (OR, 2.55; 95%CI, 1.73-3.74,  $P < .001$ ) and AE (OR, 1.82, 95%CI, 1.58-2.10;  $P < .001$ ). Periprocedural AE was less frequent in elective procedures (24.5% vs 11.2%;  $P < .001$ ) and in high-volume ( $> 120$  procedures) centers (OR, 0.76; 95%CI, 0.63-0.93;  $P = .008$ ).

**Conclusions:** The rate of percutaneous LAAC procedures significantly increased over recent years, with a low in-hospital mortality rate. High volume centers and elective LAAC procedures were significantly associated with a lower risk of AE.

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eCollection 2025 Sep.

## Structural Heart: The Journal of the Heart Team - Starting a New Era

Josep Rodés-Cabau [1](#) [2](#)

Affiliations + expand

PMID: 41170394 PMCID: [PMC12570036](#) DOI: [10.1016/j.shj.2025.100722](#)

*No abstract available*

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# Long-term outcomes after transcatheter tricuspid valve-in-valve replacement

Émile Voisine <sup>1</sup>, Juan Hernando Del Portillo <sup>1</sup>, Laurent Desjardins <sup>1</sup>, Christine Houde <sup>1</sup>,  
Jean Perron <sup>1</sup>, Frédéric Jacques <sup>1</sup>, Philippe Chetaille <sup>1</sup>, François Philippon <sup>1</sup>, Émilie Laflamme <sup>1</sup>,  
Élisabeth Bédard <sup>1</sup>, Josep Rodés-Cabau <sup>2</sup>

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PMID: 41197041 DOI: [10.25270/jic/25.00266](https://doi.org/10.25270/jic/25.00266)

Free article

## Abstract

**Objectives:** Transcatheter tricuspid valve-in-valve (ViV) replacement has emerged as a less invasive alternative to redo surgery in patients with failing bioprosthetic tricuspid valves. While short- and mid-term outcomes have been reported, data on long-term follow-up remain limited.

**Methods:** The authors conducted a single-center observational study including 12 consecutive patients who underwent transcatheter tricuspid ViV replacement. Clinical, echocardiographic, and procedural data were prospectively collected. Patients were followed at 1 and 12 months, and yearly thereafter; follow-up included annual clinical visits and echocardiography.

**Results:** The mean age of the patients was 45 years (range, 23-69 years); 92% were women, and the indication for ViV was prosthetic valve regurgitation in most (58%) cases. A balloon-expandable SAPIEN valve (Edwards Lifesciences) was implanted in all cases, with 100% procedural success. After a mean follow-up of 6 years (range, 1-11 years), 3 (25%) patients died, and 1 was readmitted because of heart failure. Functional status improved significantly, with all surviving patients in New York Heart Association class I or II at last follow-up. Transvalvular gradients remained stable over time in 83% of the patients. Two (17%) patients developed bioprosthetic valve dysfunction during follow-up: one due to significant tricuspid stenosis and the other due to severe tricuspid regurgitation.

**Conclusions:** Tricuspid ViV replacement offers durable symptomatic improvement and stable prosthesis function during long-term follow-up in most cases. This study is the first to report outcomes greater than or equal to 5 years in this population and supports the continued use of ViV as a viable option for these patients. Larger studies are warranted to validate these findings.

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# Impact of Anticoagulation on Long-Term Bioprostheses Durability After Transcatheter Aortic Valve Replacement

Antonin Trimaille <sup>1</sup>, Juan Hernando Del Portillo <sup>1</sup>, Carlos Giuliani <sup>1</sup>, Pablo Vidal-Cales <sup>1</sup>,  
Erwan Salaun <sup>1</sup>, Marisa Avvedimento <sup>1</sup>, Josep Rodés-Cabau <sup>2</sup>

Affiliations + expand

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## Abstract

**Background:** Leaflet thrombosis has emerged as a potential contributor to structural valve deterioration, raising interest in the role of oral anticoagulation (OAC) after transcatheter aortic valve replacement (TAVR). However, current data on the impact of OAC on valve durability are scarce and debated. The aim of this study was to investigate the impact of OAC on long-term bioprosthetic valve durability.

**Methods:** We analysed the data of a prospective registry including consecutive patients undergoing TAVR from May 2007 to January 2019 alive at 1 year. To reduce imbalance in baseline and procedural characteristics, the effect of OAC was assessed with the use of a propensity score-matched population (321 patients with OAC vs 559 patients without OAC). The primary end point was the occurrence of stage 2 or 3 hemodynamic valve deterioration (HVD) according to VARC-3 criteria.

**Results:** In the propensity score-matched population, OAC was associated with a lower risk of stage 2 or 3 HVD occurrence compared with no OAC (6.9% vs 13.1%, subdistribution hazard ratio (sHR) 0.50, 95% CI 0.31-0.81;  $P = 0.005$ ) after a median follow-up of 5 years (IQR 3-7 years). Long-term echocardiographic follow-up of up to 10-years showed better hemodynamic parameters over time in patients with OAC. OAC was associated with an increased risk of major bleeding events (13.7% vs 8.8%, sHR 1.66, 95% CI 1.10-2.50;  $P = 0.016$ ).

**Conclusions:** OAC was associated with a lower incidence of stage 2 and 3 HVD, and improved valve hemodynamic parameters over time. This apparent benefit must be weighed against the increased risk of bleeding. Further studies exploring individualised antithrombotic strategies are warranted.

# Clinical Impact of In-Hospital Hemoglobin Decline Without Overt Bleeding After Transcatheter Aortic Valve Replacement

Marisa Avvedimento <sup>1</sup>, Pedro Cepas-Guillén <sup>1</sup>, Jorge Nuche <sup>2</sup>, Julien Ternacle <sup>3</sup>, Marina Urena <sup>4</sup>, Alberto Alperi <sup>5</sup>, Asim Cheema <sup>6</sup>, Gabriela Veiga-Fernandez <sup>7</sup>, Luis Nombela-Franco <sup>8</sup>, Victoria Vilalta <sup>9</sup>, Giovanni Esposito <sup>10</sup>, Francisco Campelo-Parada <sup>11</sup>, Ciro Idolfi <sup>12</sup>, Maria Del Trigo <sup>13</sup>, Antonio Munoz-Garcia <sup>14</sup>, Lluis Asmarats <sup>15</sup>, Ander Regueiro <sup>16</sup>, David Del Val <sup>17</sup>, Vincent Auffret <sup>18</sup>, Nicolas Maneiro Melon <sup>19</sup>, Guillaume Bonnet <sup>3</sup>, Melchior Jonveaux <sup>3</sup>, Jules Mesnier <sup>4</sup>, Pablo Avanzas <sup>5</sup>, Effat Rezaei <sup>6</sup>, Victor Fradejas-Sastre <sup>7</sup>, Gabriela Tirado-Conte <sup>8</sup>, Eduard Fernández-Nofreiras <sup>9</sup>, Anna Franzone <sup>10</sup>, Thibaut Guitteny <sup>11</sup>, Sabato Sorrentino <sup>12</sup>, Juan Francisco Oteo <sup>13</sup>, Lola Gutiérrez-Alonso <sup>15</sup>, Eduardo Flores-Umanzor <sup>16</sup>, Fernando Alfonso <sup>17</sup>, Maxime Nolf <sup>18</sup>, Mélanie Côté <sup>1</sup>, Emilie Pelletier-Beaumont <sup>1</sup>, Josep Rodés-Cabau <sup>20</sup>

## Abstract

**Background:** The Valve Academic Research Consortium recently expanded its bleeding endpoint definition, recommending that any procedure-related blood loss should be classified as bleeding, even in the absence of a clinically evident source. However, the lack of specific reference thresholds for hemoglobin decline limits the ability to discriminate clinically relevant events and the prognostic utility of these criteria.

**Objectives:** To evaluate the incidence, predictors, and prognostic implications of hemoglobin declines without overt bleeding in patients undergoing transcatheter aortic valve replacement (TAVR).

**Methods:** In this multicenter study, 9,759 TAVR patients were stratified according to the presence or absence of overt bleeding during hospitalization. Among patients without overt bleeding, hemoglobin decrease was classified according to baseline and nadir in-hospital values as minimal ( $>1$  and  $<3$  g/dL), minor ( $\geq 3$  and  $<5$  g/dL), or major ( $\geq 5$  g/dL). The median follow-up duration was 28 months (Q1-Q3: 12-48 months).

**Results:** Hemoglobin decreases occurred in 5,645 patients (57.8%), classified as minimal in 79.1%, minor in 18.3%, and major in 2.6%. Female sex, dual antiplatelet therapy, chronic kidney disease, and higher baseline hemoglobin determined an increased risk for significant decline ( $P < 0.01$  for all), whereas radial secondary access acted as a protective factor ( $P = 0.001$ ). A major hemoglobin decline significantly increased 30-day mortality (adjusted HR [aHR]: 3.05; 95% CI: 1.15-8.96). At 1 year, both minor (aHR: 1.42; 95% CI: 1.09-1.86) and major (aHR: 1.85; 95% CI: 1.13-3.03) declines were independently associated with up to a 2-fold increase in mortality risk.

**Conclusions:** An in-hospital hemoglobin decrease  $\geq 3$  g/dL after TAVR, even in the absence of overt bleeding, was very common and independently associated with worse outcomes. Stratifying periprocedural hemoglobin loss may support early risk identification, guide postprocedural management, and refine future endpoint definitions.

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Online ahead of print.

## **Risk of Delayed Atrioventricular Block in TAVR Recipients With Preexisting Right Bundle Branch Block**

Quentin Fischer <sup>1</sup>, Marina Urena <sup>2</sup>, Gabriela Veiga <sup>3</sup>, Luis Nombela-Franco <sup>4</sup>,  
Guillem Muntané-Carol <sup>5</sup>, Ander Regueiro <sup>6</sup>, Gaspard Suc <sup>2</sup>, Jose M de la Torre Hernandez <sup>3</sup>,  
Gabriela Tirado-Conte <sup>4</sup>, Rafael Romaguera <sup>5</sup>, Pedro Cepas-Guillén <sup>1</sup>, Melanie Côté <sup>1</sup>,  
François Philippon <sup>1</sup>, Josep Rodés-Cabau <sup>1</sup>

Affiliations + expand

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*No abstract available*

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# Contemporary and Emerging Therapies in the Management of Refractory Angina: A Clinical Review

Alex Angers-Goulet <sup>1</sup> <sup>2</sup>, Siddhartha Mengi <sup>1</sup>, David Garcia Labb   <sup>1</sup>, Can Manh Nguyen <sup>1</sup>, Jean-Michel Paradis <sup>1</sup>

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## Abstract

Refractory angina (RA) represents a growing challenge in clinical cardiology, particularly in patients with obstructive coronary artery disease (CAD) who remain symptomatic despite optimal medical therapy and who are not candidates for revascularization. Advances in both device-based and biologic therapies have introduced promising adjunctive strategies. This review critically appraises current and investigational treatment modalities for RA in order to give clinicians an informed up to date picture and to guide them with this difficult to treat population (Figure 1). Emphasis is placed on evaluating the safety profiles, therapeutic efficacy, and the strength of clinical evidence supporting each modality. This review aims to assist clinicians in individualized decision-making for RA management.

Review

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## Transcatheter interventions in adult patients with transposition of the great arteries

Raquel Luna-López <sup>1</sup>, Eduardo Flores-Umanzor <sup>1</sup>, Pedro Cepas-Guillén <sup>2</sup>, Andrea Ruberti <sup>1</sup>,  
Sílvia Montserrat <sup>1</sup>, Lusine Abrahamyan <sup>3</sup>, Juan M Carretero Bellón <sup>4</sup>, Leyre Álvarez Rodríguez <sup>5</sup>,  
Lore Schrutka <sup>6</sup>, Igor Morr-Verenzuela <sup>1</sup>, Susanna Prat-González <sup>1</sup>, Daniel Pereda <sup>1</sup>, Xavier Freixa <sup>1</sup>,  
Ricardo Sanz-Ruiz <sup>7</sup>, Josep Rodés-Cabau <sup>8</sup>, Matthew J Gillespie <sup>9</sup>, Jamil A Aboulhosn <sup>10</sup>,  
Lee Benson <sup>11</sup>, Mark Osten <sup>12</sup>, Rafael Alonso-Gonzalez <sup>13</sup>, Eric Horlick <sup>14</sup>

Affiliations + expand

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### Abstract

Transposition of the great arteries (TGA) is a complex congenital heart defect with two primary anatomical subtypes: dextro-TGA and levo-TGA. Advances in neonatal surgical techniques, particularly the arterial switch operation, have significantly improved survival rates. However, as this population ages, late complications such as heart failure and valve dysfunction present new clinical challenges. Transcatheter interventions have emerged as valid alternatives to surgical reintervention for these patients, providing effective symptom relief and improved quality of life, reducing the need for repeated sternotomies. As more adults with repaired TGA reach advanced ages, long-term studies are needed to assess the durability and safety of transcatheter therapies. Expanding the indications, refining procedural techniques, and developing specialized devices will be essential in optimizing outcomes for this growing patient population.

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# Low-dose direct oral anticoagulation vs dual antiplatelet therapy after left atrial appendage occlusion: 1-year results from the ADALA trial

[Article in English, Spanish]

Eduardo Flores-Umanzor <sup>1</sup>, Ignacio Cruz-González <sup>2</sup>, Pedro Cepas-Guillén <sup>1</sup>, Xavi Millán <sup>3</sup>,  
Pablo Antúnez-Muiños <sup>1</sup>, Lluís Asmarats <sup>3</sup>, Ana Laffond <sup>2</sup>, Ander Regueiro <sup>1</sup>, Sergio López-Tejero <sup>2</sup>,  
Chi-Hion Pedro Li <sup>3</sup>, Laura Sanchis <sup>1</sup>, Josep Rodés-Cabau <sup>4</sup>, Dabit Arzamendi <sup>3</sup>, Xavier Freixa <sup>5</sup>

Affiliations + expand

PMID: 41412468 DOI: [10.1016/j.rec.2025.12.008](https://doi.org/10.1016/j.rec.2025.12.008)

## Abstract

**Introduction and objectives:** The ADALA trial showed a more favorable efficacy-safety profile with low-dose direct oral anticoagulation (LD-DOAC) vs dual antiplatelet therapy (DAPT) at 3 months after left atrial appendage occlusion (LAAO). However, outcomes after switching both regimens to single antiplatelet therapy (SAPT) remain uncertain. This study reports the 1-year results, focusing on outcomes after the switch to SAPT.

**Methods:** The ADALA trial was a multicenter, randomized clinical trial that enrolled 91 patients with atrial fibrillation and contraindications to oral anticoagulation. After successful LAAO, participants were randomized to receive LD-DOAC or DAPT for 3 months, after which all patients transitioned to SAPT. The primary endpoint was a composite of thromboembolic events, device-related thrombus (DRT), or major bleeding at 1-year.

**Results:** At 12 months, the primary endpoint was significantly lower in the LD-DOAC group compared with the DAPT group (9.1% vs 32.6%; HR, 0.25; 95%CI, 0.08-0.74;  $P = .013$ ), mainly driven by a reduction in DRT (0% vs 11.6%;  $P = .023$ ). Major bleeding was numerically lower with LD-DOAC (9.1% vs 19.6%;  $P = .167$ ), and total bleeding events were significantly reduced (13.6% vs 37.0%;  $P = .013$ ). Landmark analysis showed significant differences during the initial 3 months ( $P < .001$ ) but not from 3 to 12 months ( $P = .195$ ). All DRT cases treated with LD-DOAC ( $n = 4$ ) resolved completely without bleeding.

**Conclusions:** LD-DOAC reduced thromboembolic and bleeding events compared with DAPT during the first year after LAAO, driven by a marked reduction in early DRT. No DRT events occurred after LD-DOAC withdrawal, supporting a strategy of LD-DOAC for 3 months followed by SAPT in this high-risk population.

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Online ahead of print.

## The Additional Value of His Ventricular Interval in Left Bundle Branch Block After Transcatheter Aortic Valve Implantation: Precision Medicine or Not?

François Philippon <sup>1</sup>, Josep Rodés-Cabau <sup>2</sup>

Affiliations + expand

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*No abstract available*

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# Balloon-Expandable Valve Performance Beyond 10 Years Following Transcatheter Aortic Valve Implantation

Antonin Trimaille <sup>1</sup>, Marisa Avvedimento <sup>1</sup>, Pedro Cepas-Guillén <sup>1</sup>, Robert Delarochellière <sup>1</sup>, Eric Dumont <sup>1</sup>, Siamak Mohammadi <sup>1</sup>, Mélanie Côté <sup>1</sup>, Erwan Salaun <sup>1</sup>, Josep Rodés-Cabau <sup>2</sup>

Affiliations + expand

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## Abstract

**Background:** Data on very long-term bioprosthetic durability after transcatheter aortic valve implantation (TAVI) are lacking. We sought to assess bioprosthetic valve durability beyond 10 years following TAVI with balloon-expandable valves.

**Methods:** We analyzed the data of a prospective single-center registry including consecutive patients undergoing TAVI with first-, second-, and third-generation balloon-expandable valves between 2007 and 2015 alive at one-year. The primary outcome was the valve-related long-term clinical efficacy according to VARC-3 consensus. Death was treated as a competing risk.

**Results:** Among the 431 patients included, the median follow-up was 5 years (interquartile range 3-8 years) for the overall population, and 10 years (interquartile range 8-12 years) for the survived patients, with the longest follow-up reaching 15 years. The overall 10-year mortality rate was 87%. At 10 years, the cumulative incidence of the composite endpoint of valve-related long-term clinical efficacy (bioprosthetic valve failure, stroke and bleeding secondary to antithrombotic used for valve-related concerns) was 29%. Conversely, 71% remained free from the composite outcome after accounting for death as a competing risk. The cumulative incidence of moderate or severe HVD was 17%. The independent factors associated with moderate or severe HVD were age (subdistribution hazard ratio (sHR) 0.96, confidence interval (CI) 95% 0.94-0.99,  $p=0.009$ ), severe patient-prosthesis mismatch (sHR 5.26, 95% CI 1.44-19.2,  $p = 0.012$ ), and the absence of anticoagulant therapy at discharge (sHR 1.96, CI 95% 1.12-3.45,  $p=0.018$ ). Bioprosthetic valve failure occurred in 9.1% of the population, and aortic valve reintervention in 4.4%. Echocardiographic parameters of bioprosthetic hemodynamic performance showed a slight progressive deterioration over time, with an increase in mean transaortic gradient (+0.54 mmHg/year, 95% CI 0.44-0.65) and a corresponding decrease in effective orifice area (-0.016 cm<sup>2</sup>/year, 95% CI -0.023 - -0.009).

**Conclusions:** These findings provide reassuring evidence supporting the very long-term durability of balloon-expandable valves after TAVI, although some signs of HVD were observed in about one fifth of patients. The protective effects of anticoagulation therapy on valve durability need further evaluation.

# The Alternative Imaging Modalities in Ischemic Heart Failure (AIMI-HF) Trial-IMAGE HF Project 1A

Lisa M Mielniczuk <sup>1</sup>, Eileen O'Meara <sup>2</sup>, Christiane Wiefels <sup>3</sup>, Li Chen <sup>4</sup>, Linda Garrard <sup>1</sup>, James White <sup>5</sup>, Robert A deKemp <sup>1</sup>, Marcelo F Di Carli <sup>6</sup>, Eric Larose <sup>7</sup>, David I Paterson <sup>1 8</sup>, Justin Ezekowitz <sup>8</sup>, Riina M Kandolin <sup>9</sup>, Graham Wright <sup>10</sup>, Roxana Campisi <sup>11</sup>, Mika K Laine <sup>12</sup>, Kim Connelly <sup>13</sup>, Miroslaw Rajda <sup>14</sup>, Joao V Vitola <sup>15</sup>, Serge Lepage <sup>16</sup>, Juha Hartikainen <sup>17</sup>, Benjamin Chow <sup>1</sup>, Anahita Tavoosi <sup>1</sup>, Juhani Knuuti <sup>18</sup>, George A Wells <sup>4</sup>, Rob S B Beanlands <sup>1 3</sup>; IMAGE HF Investigators

Affiliations + expand

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## Abstract

in English, [French](#)

**Background:** The role of advanced (cardiac magnetic resonance [CMR] or positron emission tomography [PET]) vs single-photon emission computerized tomography (SPECT) ischemia imaging to guide management remains unclear in patients with ischemic heart failure (IHF). The primary aim was to determine the effect of imaging modality on a composite cardiovascular endpoint and cardiac death in patients with IHF who require ischemia assessment.

**Methods:** Patients with IHF were randomized to advanced or SPECT imaging. A parallel registry also was performed. The primary endpoint was the composite of cardiac death, infarction, arrest, and cardiac rehospitalization. The key secondary endpoint was cardiac death.

**Results:** Patients in the randomized population (advanced imaging [PET or CMR; n = 64] or SPECT [n = 56]) had a cumulative incidence rate (CIR) for the primary endpoint of 33.1% and 33.0%, respectively (hazard ratio [HR] 0.94, 95% confidence interval [CI] 0.49, 1.80,  $P = 0.853$ ). CIRs for cardiac death were 13.8% and 25.1%, respectively (HR 0.62, 95% CI 0.25, 1.80,  $P = 0.296$ ). In the parallel registry (n = 336 advanced; n = 216 SPECT), the primary endpoint CIRs were 31.2% and 35.3%, respectively (HR 0.81, 95% CI 0.56, 1.19,  $P = 0.284$ ). CIRs for cardiac death were 11.0% and 16.6%, respectively (HR 0.53, 95% CI 0.27, 1.04,  $P = 0.066$ ). Patients were followed for a median (interquartile range) of 24.1 (11.6, 27.5) months. Pooled analysis from the randomized and registry populations revealed a significant benefit of advanced imaging for reduction of cardiac death (HR 0.56, 95% CI 0.33, 0.96,  $P = 0.04$ ) with minimal heterogeneity ( $I^2 = 0\%$ ).

**Conclusion:** Among IHF patients assessed for ischemia, advanced imaging (PET or CMR) was not associated with reduced composite cardiac events, compared to SPECT.

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# Long-term Impact of Multivalvular Heart Disease in Patients Undergoing Transcatheter Aortic Valve Replacement

Quentin Battistolo <sup>1</sup>, Marisa Avvedimento <sup>1</sup>, Pedro Cepas-Guillen <sup>1</sup>, Alberto Jiménez-Lozano <sup>1</sup>, Jean-Michel Paradis <sup>1</sup>, Jonathan Beaudoin <sup>1</sup>, David Belzile <sup>1</sup>, Mathieu Bernier <sup>1</sup>, Kim O Connor <sup>1</sup>, Benoit Labbé <sup>1</sup>, Erwan Salaun <sup>1</sup>, Pierre-Yves Turgeon <sup>1</sup>, Josep Rodés-Cabau <sup>2</sup>

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## Abstract

**Background:** Multivalvular heart disease (MVHD) is frequently encountered in patients undergoing transcatheter aortic valve replacement (TAVR). However, the long-term prognostic impact of MVHD in this population remains poorly characterized. The aim of this study was to evaluate the long-term clinical outcomes and echocardiographic evolution of MVHD in TAVR recipients.

**Methods:** A total of 1,918 consecutive patients with severe symptomatic aortic stenosis (AS) undergoing TAVR were included. MVHD was defined as the presence of moderate or greater mitral (MR) and/or tricuspid regurgitation (TR) prior to the procedure. Baseline, procedural, and follow-up data (median of 4.0 [2.8-5.2] years) were prospectively collected. Changes in MR and/or TR severity were assessed from baseline to the last available echocardiography RESULTS: A total of 450 (23.5%) patients had MVHD at baseline. The presence of MVHD was associated with an increased all-cause mortality (adjusted HR: 1.21, 95% CI: 1.04-1.40;  $p=0.011$ ) and cardiovascular mortality (adjusted HR: 1.29, 95% CI: 1.04-1.61;  $p=0.018$ ) at follow-up. After adjustment, only baseline moderate or greater TR remained independently associated with all-cause mortality (HR: 1.38; CI: 1.04-1.84;  $p=0.027$ ). At discharge, MR improved in 181 patients (51.7%) with similar rates across MR mechanism ( $p = 0.582$ ), while those with TR improved in 71 (40.5%). MVHD improvement was sustained over time, whereas the absence of recovery was associated with a higher risk of all-cause mortality and cardiovascular mortality up to 6 years.

**Conclusions:** Patients with MVHD exhibit worse long-term outcomes after TAVR. While TAVR provides sustained improvement of concomitant valvular lesions in about half of patients, lack of recovery at discharge, predicted poorer long-term survival, highlighting the need for comprehensive baseline assessment and close echocardiographic follow-up in this high-risk population.

# Transcatheter edge-to-edge repair in secondary mitral regurgitation

Josep Rodés-Cabau <sup>1</sup> <sup>2</sup>, Siddhartha Mengi <sup>1</sup>, Erwan Salaun <sup>1</sup>, Jean-Michel Paradis <sup>1</sup>, William T Abraham <sup>3</sup>

Affiliations + expand

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## Abstract

Secondary mitral regurgitation (SMR) is frequent among patients with heart failure (HF) with reduced ejection fraction (HFrEF), and it is strongly associated with increased mortality, frequent hospitalisations, and poor quality of life. The mechanisms underlying SMR are multifactorial. While guideline-directed medical therapy and cardiac resynchronisation therapy remain the cornerstone of HFrEF management, many patients with significant SMR continue to experience significant symptoms and adverse outcomes. Managing SMR within the context of HF necessitates a multifaceted approach. Transcatheter edge-to-edge repair (TEER) has emerged as a transformative intervention, demonstrating improvements in survival, functional capacity, and HF-related hospitalisations in clinical trials and real-world registries in selected patients. This review provides a comprehensive overview of the evidence supporting TEER, focusing on procedural and follow-up outcomes, and its role in reshaping the therapeutic approach for HF patients with SMR. Additionally, we highlight the critical role of patient selection and identify predictors of poor outcomes as key determinants of TEER success.

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