8th Annual Emirates Cardiac Society Conference

ACC Middle East Conference 2017

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What is new/different for 2017 as compared to the previous guidelines?

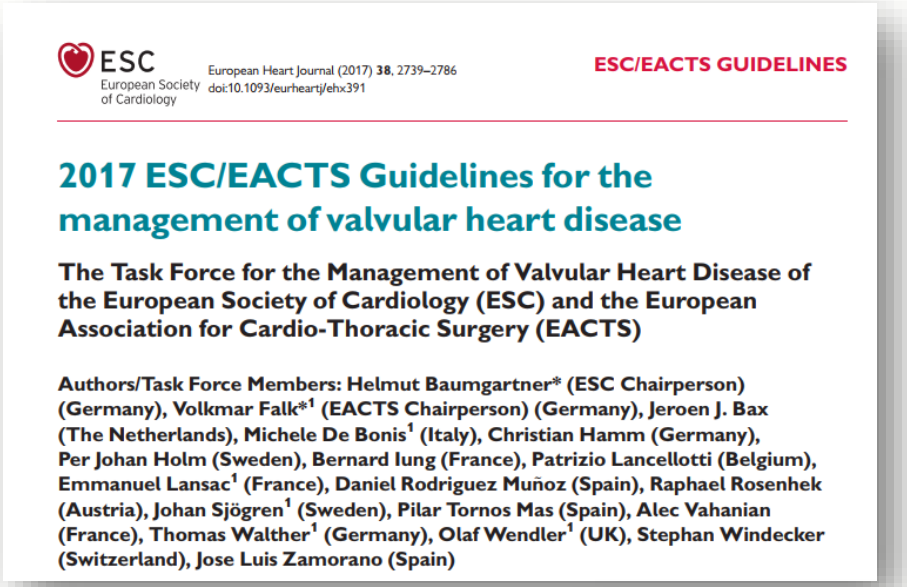
Necla Ozer

Hacettepe University Faculty of Medicine

Cardiology Department

ACC Middle East Conference 2017

A good year for valvular heart disease



ESC European Society of Cardiology

European Heart Journal (2017) 38, 2739–2786
doi:10.1093/eurheartj/ehx391

ESC/EACTS GUIDELINES

2017 ESC/EACTS Guidelines for the management of valvular heart disease

The Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Authors/Task Force Members: Helmut Baumgartner* (ESC Chairperson) (Germany), Volkmar Falk*[1] (EACTS Chairperson) (Germany), Jeroen J. Bax (The Netherlands), Michele De Bonis[1] (Italy), Christian Hamm (Germany), Per Johan Holm (Sweden), Bernard Iung (France), Patrizio Lancellotti (Belgium), Emmanuel Lansac[1] (France), Daniel Rodriguez Muñoz (Spain), Raphael Rosenhek (Austria), Johan Sjögren[1] (Sweden), Pilar Tornos Mas (Spain), Alec Vahanian (France), Thomas Walther[1] (Germany), Olaf Wendler[1] (UK), Stephan Windecker (Switzerland), Jose Luis Zamorano (Spain)

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APPROPRIATE USE CRITERIA

ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2017 Appropriate Use Criteria for Multimodality Imaging in Valvular Heart Disease

A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons

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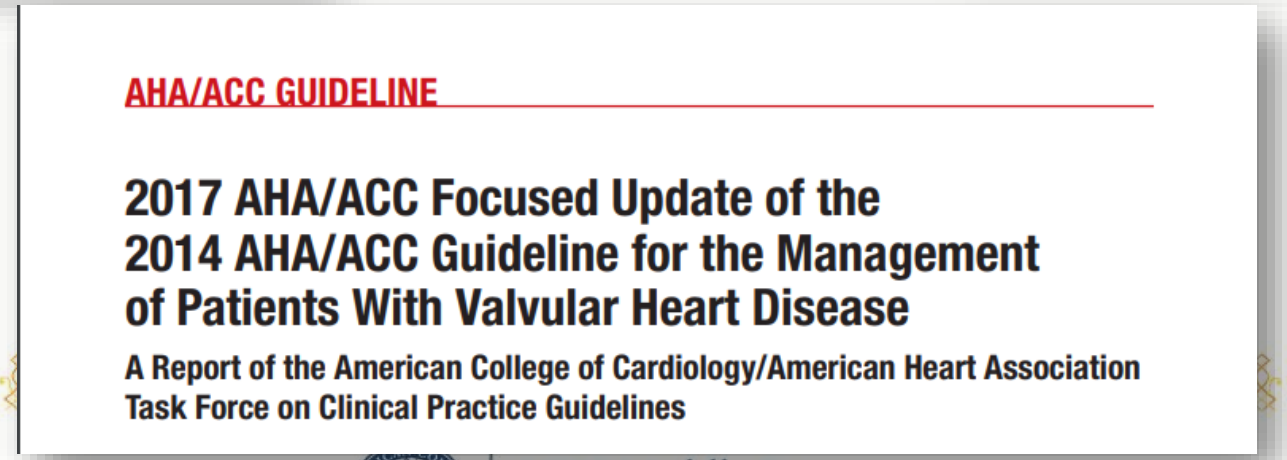


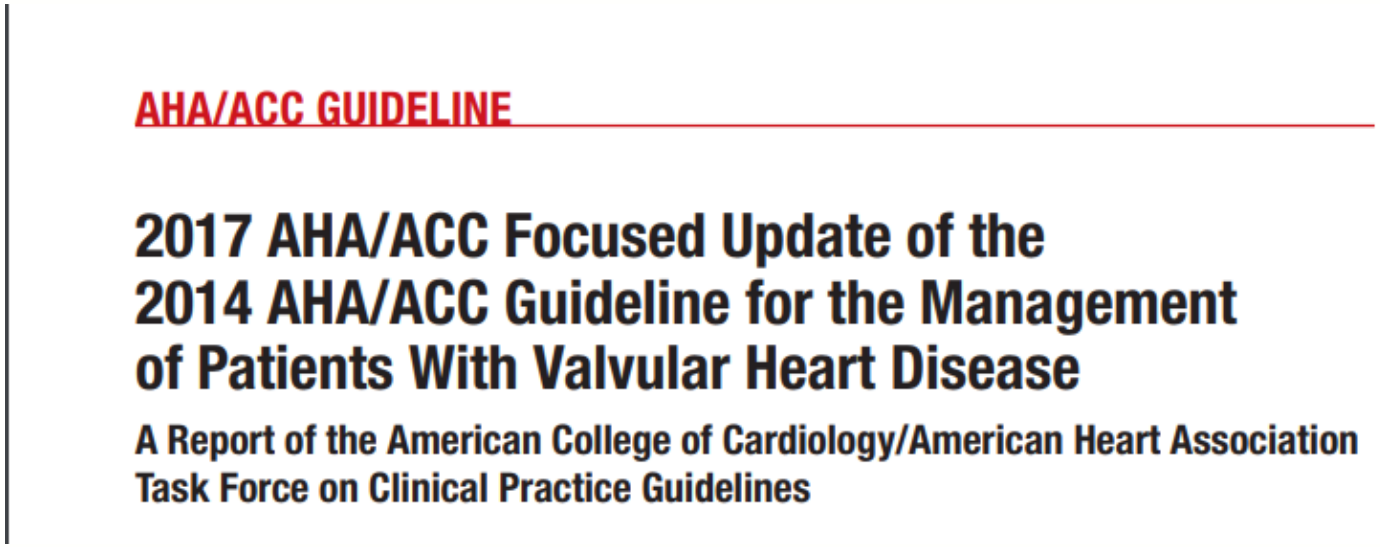
AHA/ACC GUIDELINE

2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

ACC Middle East Conference 2017

- ACC/AHA has very recently released a focused update only 3 years after the latest 2014 guidelines on VHD



Infective endocarditis prophylaxis

- Although limited prophylaxis is still underscored in the focused update, all implanted prosthetic materials used in transcatheter or surgical procedures for VHD are now considered to be a reasonable indication for antibiotic prophylaxis.

Recommendation for IE Prophylaxis			
COR	**LOE**	**Recommendation**	**Comment/Rationale**
IIa	**C-LD**	Prophylaxis against IE is reasonable before dental procedures that involve manipulation of gingival tissue, manipulation of the periapical region of teeth, or perforation of the oral mucosa in patients with the following[13,15,23–29]: 1. Prosthetic cardiac valves, including transcatheter-implanted prostheses and homografts. 2. Prosthetic material used for cardiac valve repair, such as annuloplasty rings and chords. 3. Previous IE. 4. Unrepaired cyanotic congenital heart disease or repaired congenital heart disease, with residual shunts or valvular regurgitation at the site of or adjacent to the site of a prosthetic patch or prosthetic device. 5. Cardiac transplant with valve regurgitation due to a structurally abnormal valve.	**MODIFIED: LOE updated from B to C-LD.** Patients with transcatheter prosthetic valves and patients with prosthetic material used for valve repair, such as annuloplasty rings and chords, were specifically identified as those to whom it is reasonable to give IE prophylaxis. This addition is based on observational studies demonstrating the increased risk of developing IE and high risk of adverse outcomes from IE in these subgroups. Categories were rearranged for clarity to the caregiver.
See Online Data Supplements 1 and 2.			

Infective endocarditis/surgery/stroke

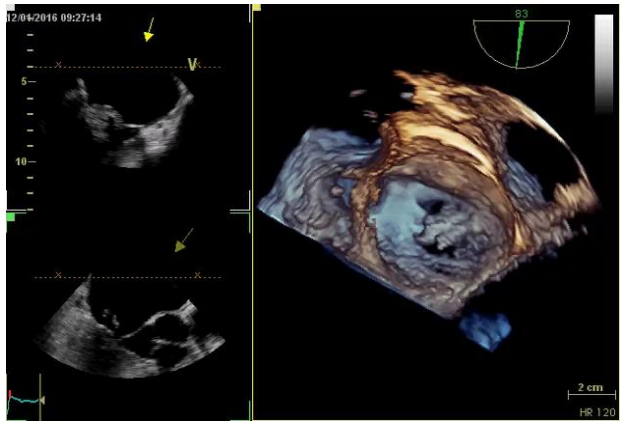
IIb	B-NR

See Online Data Supplement 24 (Updated From 2014 VHD Guideline)

Operation without delay may be considered in patients with IE and an indication for surgery who have suffered a stroke but have no evidence of intracranial hemorrhage or extensive neurological damage (284,285).

NEW: The risk of postoperative neurological deterioration is low after a cerebral event that has not resulted in extensive neurological damage or intracranial hemorrhage. If surgery is required after a neurological event, recent data favor early surgery for better overall outcomes.

- Stroke is an independent risk factor for postoperative death in IE patients
- A delay in the procedure is deemed unnecessary unless a hemorrhagic or major embolic stroke is present



MAJOR ARTICLE

Influence of the Timing of Cardiac Surgery on the Outcome of Patients With Infective Endocarditis and Stroke

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Background. The timing of cardiac surgery after stroke in infective endocarditis (IE) remains controversial. We examined the relationship between the timing of surgery after stroke and the incidence of in-hospital and 1-year mortalities.

Methods. Data were obtained from the International Collaboration on Endocarditis–Prospective Cohort Study of 4794 patients with definite IE who were admitted to 64 centers from June 2000 through December 2006. Multivariate logistic regression and Cox regression analyses were performed to estimate the impact of early surgery on hospital and 1-year mortality after adjustments for other significant covariates.

Results. Of the 857 patients with IE complicated by ischemic stroke syndromes, 198 who underwent valve replacement surgery poststroke were available for analysis. Overall, 58 (29.3%) patients underwent early surgical treatment vs 140 (70.7%) patients who underwent late surgical treatment. After adjustment for other risk factors, early surgery was not significantly associated with increased in-hospital mortality rates (odds ratio, 2.308; 95% confidence interval [CI], .942–5.652). Overall, probability of death after 1-year follow-up did not differ between 2 treatment groups (27.1% in early surgery and 19.2% in late surgery group, $P = .328$; adjusted hazard ratio, 1.138; 95% CI, .802–1.650).

Conclusions. There is no apparent survival benefit in delaying surgery when indicated in IE patients after ischemic stroke. Further observational analyses that include detailed pre- and postoperative clinical neurologic findings and advanced imaging data (eg, ischemic stroke size), may allow for more refined recommendations on the optimal timing of valvular surgery in patients with IE and recent stroke syndromes.

Infective endocarditis/surgery/stroke

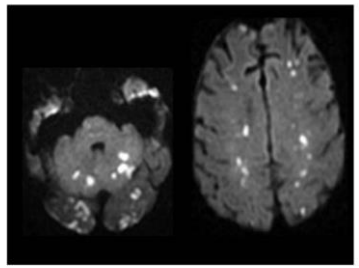
IIb	B-NR

See Online Data Supplement 24 (Updated From 2014 VHD Guideline)

Delaying valve surgery for at least 4 weeks may be considered for patients with IE and major ischemic stroke or intracranial hemorrhage if the patient is hemodynamically stable (286).

NEW: In patients with extensive neurological damage or intracranial hemorrhage, cardiac surgery carries a high risk of death if performed within 4 weeks of a hemorrhagic stroke.

- Patients with hemorrhagic stroke and IE have a high surgical risk for at least 4 weeks after the hemorrhagic event.
- If hemorrhagic or major embolic stroke is present, delaying surgery for 4 weeks may be reasonable based on nonrandomized data



Epidemiology and Prevention

Neurological Complications of Infective Endocarditis
Risk Factors, Outcome, and Impact of Cardiac Surgery: A Multicenter Observational Study

Emilio García-Cabrera, MSc; Nuria Fernández-Hidalgo, MD; Benito Almirante, MD, PhD; Radka Ivanova-Georgieva, MD, PhD; Mariam Noureddine, MD; Antonio Plata, MD; Jose M. Lomas, MD; Juan Gálvez-Acebal, MD, PhD; Carmen Hidalgo-Tenorio, MD, PhD; Josefa Ruíz-Morales, MD; Francisco J. Martínez-Marcos, MD, PhD; Jose M. Reguera, MD; Javier de la Torre-Lima, MD, PhD; Arístides de Alarcón González, MD, PhD; on behalf of the Group for the Study of Cardiovascular Infections of the Andalusian Society of Infectious Diseases (SAEI) and the Spanish Network for Research in Infectious Diseases (REIPI)

***Background*—**The purpose of this study was to assess the incidence of neurological complications in patients with infective endocarditis, the risk factors for their development, their influence on the clinical outcome, and the impact of cardiac surgery.
***Methods and Results*—**This was a retrospective analysis of prospectively collected data on a multicenter cohort of 1345 consecutive episodes of left-sided infective endocarditis from 8 centers in Spain. Cox regression models were developed to analyze variables predictive of neurological complications and associated mortality. Three hundred forty patients (25%) experienced such complications: 192 patients (14%) had ischemic events, 86 (6%) had encephalopathy/meningitis, 60 (4%) had hemorrhages, and 2 (1%) had brain abscesses. Independent risk factors associated with all neurological complications were vegetation size ≥3 cm (hazard ratio [HR] 1.91), *Staphylococcus aureus* as a cause (HR 2.47), mitral valve involvement (HR 1.29), and anticoagulant therapy (HR 1.31). This last variable was particularly related to a greater incidence of hemorrhagic events (HR 2.71). Overall mortality was 30%, and neurological complications had a negative impact on outcome (45% of deaths versus 24% in patients without these complications; $P<0.01$), although only moderate to severe ischemic stroke (HR 1.63) and brain hemorrhage (HR 1.73) were significantly associated with a poorer prognosis. Antimicrobial treatment reduced (by 33% to 75%) the risk of neurological complications. In patients with hemorrhage, mortality was higher when surgery was performed within 4 weeks of the hemorrhagic event (75% versus 40% in later surgery).
***Conclusions*—**Moderate to severe ischemic stroke and brain hemorrhage were found to have a significant negative impact on the outcome of infective endocarditis. Early appropriate antimicrobial treatment is critical, and transitory discontinuation of anticoagulant therapy should be considered. **(*Circulation*. 2013;127:2272-2284.)**

Key Words: endocardium ■ infection ■ nervous system ■ complications

Anticoagulation for Atrial Fibrillation in Patients With VHD: Recommendations (New Section)

I B-NR See Online Data Supplements 3 and 4.	Anticoagulation with a vitamin K antagonist (VKA) is indicated for patients with rheumatic mitral stenosis (MS) and AF (34,35).	MODIFIED: VKA as opposed to the direct oral anticoagulants (DOACs) are indicated in patients with AF and rheumatic MS to prevent thromboembolic events. The RCTs of DOACs versus VKA have not included patients with MS. The specific recommendation for anticoagulation of patients with MS is contained in a subsection of the topic on anticoagulation (previously in Section 6.2.2).
I C-LD See Online Data Supplements 3 and 4.	Anticoagulation is indicated in patients with AF and a CHA_2DS_2-VASc score of 2 or greater with native aortic valve disease, tricuspid valve disease, or MR (36-38).	NEW: Post hoc subgroup analyses of large RCTs comparing DOAC versus warfarin in patients with AF have analyzed patients with native valve disease other than MS and patients who have undergone cardiac surgery. These analyses consistently demonstrated that the risk of stroke is similar to or higher than that of patients without VHD. Thus, the indication for anticoagulation in these patients should follow GDMT according to the CHA_2DS_2-VASc score (35-38).
IIa C-LD See Online Data Supplements 3 and 4.	It is reasonable to use a DOAC as an alternative to a VKA in patients with AF and native aortic valve disease, tricuspid valve disease, or MR and a CHA_2DS_2-VASc score of 2 or greater (35-38).	NEW: Several thousand patients with native VHD (exclusive of more than mild rheumatic MS) have been evaluated in RCTs comparing DOACs versus warfarin. Subgroup analyses have demonstrated that DOACs, when compared with warfarin, appear as effective and safe in patients with VHD as in those without VHD.

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Correspondence

Comparative effectiveness and safety of non-vitamin K antagonist oral anticoagulants versus warfarin in patients with atrial fibrillation and valvular heart disease

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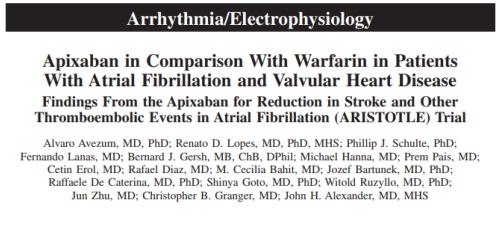


Arrhythmia/Electrophysiology

Apixaban in Comparison With Warfarin in Patients With Atrial Fibrillation and Valvular Heart Disease

Findings From the Apixaban for Reduction in Stroke and Other Thromboembolic Events in Atrial Fibrillation (ARISTOTLE) Trial

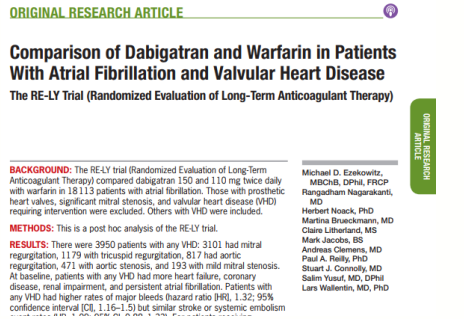
Alvaro Avezum, MD, PhD; Renato D. Lopes, MD, PhD, MHS; Phillip J. Schulte, PhD; Fernando Lanas, MD; Bernard J. Gersh, MB, ChB, DPhil; Michael Hanna, MD; Prem Pais, MD; Cetin Erol, MD; Rafael Diaz, MD; M. Cecilia Bahit, MD; Jozef Bartunek, MD, PhD; Raffaele De Caterina, MD, PhD; Shinya Goto, MD, PhD; Witold Ruzyllo, MD, PhD; Jun Zhu, MD; Christopher B. Granger, MD; John H. Alexander, MD, MHS

European Heart Journal (2014) 35, 3377–3385
doi:10.1093/eurheartj/ehu305

CLINICAL RESEARCH
Atrial fibrillation

Clinical characteristics and outcomes with rivaroxaban vs. warfarin in patients with non-valvular atrial fibrillation but underlying native mitral and aortic valve disease participating in the ROCKET AF trial

Günter Breithardt[1*], Helmut Baumgartner[2], Scott D. Berkowitz[3], Anne S. Hellkamp[4], Jonathan P. Piccini[4], Susanna R. Stevens[4], Yuliya Lokhnygina[4], Manesh R. Patel[4], Jonathan L. Halperin[5], Daniel E. Singer[6], Graeme J. Hankey[7], Werner Hacke[8], Richard C. Becker[4], Christopher C. Nessel[9], Kenneth W. Mahaffey[10], Keith A. A. Fox[11], and Robert M. Califf[12], for the ROCKET AF Steering Committee & Investigators



ORIGINAL RESEARCH ARTICLE

Comparison of Dabigatran and Warfarin in Patients With Atrial Fibrillation and Valvular Heart Disease

The RE-LY Trial (Randomized Evaluation of Long-Term Anticoagulant Therapy)

BACKGROUND: The RE-LY trial (Randomized Evaluation of Long-Term Anticoagulant Therapy) compared dabigatran 150 and 110 mg twice daily with warfarin in 18 113 patients with atrial fibrillation. Those with prosthetic heart valves, significant mitral stenosis, and valvular heart disease (VHD) requiring intervention were excluded. Others with VHD were included.

METHODS: This is a post hoc analysis of the RE-LY trial.

RESULTS: There were 3950 patients with any VHD: 3101 had mitral regurgitation, 1179 with tricuspid regurgitation, 817 had aortic regurgitation, 471 with aortic stenosis, and 193 with mild mitral stenosis. At baseline, patients with any VHD had more heart failure, coronary disease, renal impairment, and persistent atrial fibrillation. Patients with any VHD had higher rates of major bleeds (hazard ratio [HR], 1.32; 95% confidence interval [CI], 1.16–1.5) but similar stroke or systemic embolism

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Rangadham Nagarakanti, MD
Herbert Noack, PhD
Martina Brueckmann, MD
Claire Litherland, MS
Mark Jacobs, BS
Andreas Clemens, MD
Paul A. Reilly, PhD
Stuart J. Connolly, MD
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ORIGINAL RESEARCH ARTICLE

Aortic stenosis

IIa	B-R

See Online Data Supplements 5 and 9 (Updated From 2014 VHD Guideline)

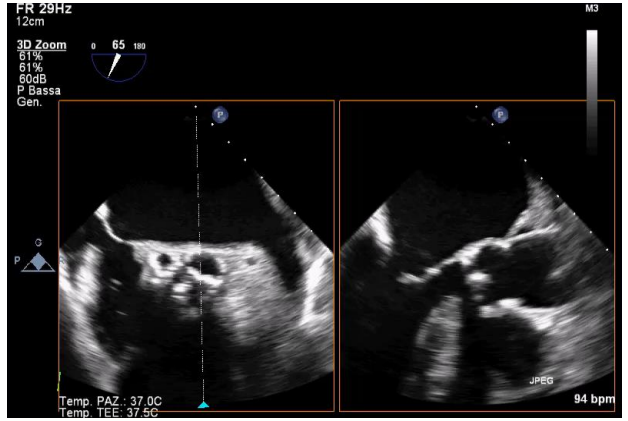
TAVR is a reasonable alternative to surgical AVR for symptomatic patients with severe AS (Stage D) and an intermediate surgical risk, depending on patient-specific procedural risks, values, and preferences (62-65).

NEW: New RCT showed noninferiority of TAVR to surgical AVR in symptomatic patients with severe AS at intermediate surgical risk.

Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis

Vinod H Thourani, Susheel Kodali, Raj R Makkar, Howard C Herrmann, Mathew Williams, Vasilis Babaliaros, Richard Smalling, Scott Lim, S Chris Malaisrie, Samir Kapadia, Wilson Y Szeto, Kevin L Greason, Dean Kereiakes, Gorav Ailawadi, Brian K Whisenant, Chandan Devireddy, Jonathon Leipsic, Rebecca T Hahn, Philippe Pibarot, Neil J Weissman, Wael A Jaber, David J Cohen, Rakesh Suri, E Murat Tuzcu, Lars G Svensson, John G Webb, Jeffrey W Moses, Michael J Mack, D Craig Miller, Craig R Smith, Maria C Alu, Rupa Parvataneni, Ralph B D'Agostino Jr, Martin B Leon

After new studies showing noninferiority end-points, transcatheter aortic valve implantation (TAVI) has now taken its place for patients with an intermediate risk for surgical aortic valve replacement



The NEW ENGLAND JOURNAL of MEDICINE

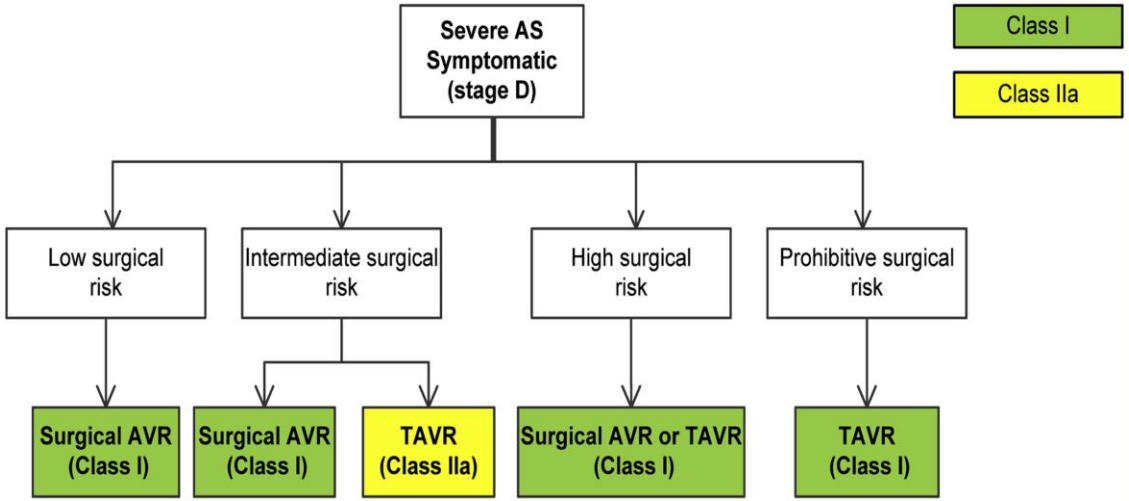
ESTABLISHED IN 1812 APRIL 28, 2016 VOL. 374 NO. 17

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael J. Mack, M.D., Raj R. Makkar, M.D., Lars G. Svensson, M.D., Ph.D., Susheel K. Kodali, M.D., Vinod H. Thourani, M.D., E. Murat Tuzcu, M.D., D. Craig Miller, M.D., Howard C. Herrmann, M.D., Darshan Doshi, M.D., David J. Cohen, M.D., Augusto D. Pichard, M.D., Samir Kapadia, M.D., Todd Dewey, M.D., Vasilis Babaliaros, M.D., Wilson Y. Szeto, M.D., Mathew R. Williams, M.D., Dean Kereiakes, M.D., Alan Zajarias, M.D., Kevin L. Greason, M.D., Brian K. Whisenant, M.D., Robert W. Hodson, M.D., Jeffrey W. Moses, M.D., Alfredo Trento, M.D., David L. Brown, M.D., William F. Fearon, M.D., Philippe Pibarot, D.V.M., Ph.D., Rebecca T. Hahn, M.D., Wael A. Jaber, M.D., William N. Anderson, Ph.D., Maria C. Alu, M.M., and John G. Webb, M.D., for the PARTNER 2 Investigators*

Aortic stenosis

- New evidence from longer term follow-up of patients with prohibitive and/or high surgical risk who have undergone TAVI has strengthened the previous recommendation favoring TAVI over surgery in this subgroup



I B-NR See Online Data Supplements 5 and 9 (Updated From 2014 VHD Guideline)	Surgical AR is recommended for symptomatic patients with severe AS (Stage D) and asymptomatic patients with severe AS (Stage C) who meet an indication for AVR when surgical risk is low or intermediate (42,43).	MODIFIED: LOE updated from A to B-NR. Prior recommendations for intervention choice did not specify patient symptoms. The patient population recommended for surgical AVR encompasses both symptomatic and asymptomatic patients who meet an indication for AVR with low-to-intermediate surgical risk. This is opposed to the patient population recommended for TAVR, in whom symptoms are required to be present. Thus, all recommendations for type of intervention now specify the symptomatic status of the patient.
I A See Online Data Supplement 9 (Updated From 2014 VHD Guideline)	Surgical AVR or TAVR is recommended for symptomatic patients with severe AS (Stage D) and high risk for surgical AVR, depending on patient-specific procedural risks, values, and preferences (49-51).	MODIFIED: COR updated from IIa to I, LOE updated from B to A. Longer-term follow-up and additional RCTs have demonstrated that TAVR is equivalent to surgical AVR for severe symptomatic AS when surgical risk is high.
I A See Online Data Supplements 5 and 9 (Updated From 2014 VHD Guideline)	TAVR is recommended for symptomatic patients with severe AS (Stage D) and a prohibitive risk for surgical AVR who have a predicted post-TAVR survival greater than 12 months (58-61).	MODIFIED: LOE updated from B to A. Longer-term follow-up from RCTs and additional observational studies has demonstrated the benefit of TAVR in patients with a prohibitive surgical risk.

Primary mitral regurgitation

IIa	C-LD		
See Online Data Supplement 17 (Updated From 2014 VHD Guideline)		Mitral valve surgery is reasonable for asymptomatic patients with chronic severe primary MR (stage C1) and preserved LV function (LVEF >60% and LVESD <40 mm) with a progressive increase in LV size or decrease in ejection fraction (EF) on serial imaging studies.[112–115] (Figure 2)	**NEW:** Patients with severe MR who reach an EF ≤60% or LVESD ≥40 have already developed LV systolic dysfunction, so operating before reaching these parameters, particularly with a progressive increase in LV size or decrease in EF on serial studies, is reasonable.

European Journal of Echocardiography (2011) 12, 702–710
doi:10.1093/ejechocard/jer128

Predicting left ventricular dysfunction after valve repair for mitral regurgitation due to leaflet prolapse: additive value of left ventricular end-systolic dimension to ejection fraction

Christophe Tribouilloy[1,2*], Dan Rusinaru[3], Catherine Szymanski[1], Sonia Mezghani[1], Alexandre Fournier[1], Franck Lévy[1,3], Marcel Peltier[1], Ammar Ben Ammar[4], Doron Carmi[3], Jean-Paul Remadi[3], Thierry Caus[2,3], and Gilles Touati[3]

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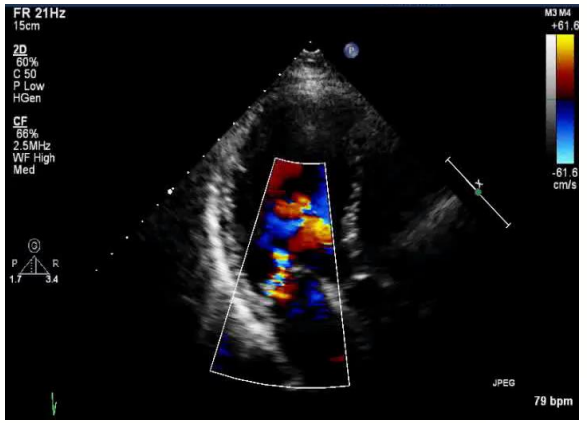
Received 8 May 2011; accepted after revision 6 July 2011; online publish-ahead-of-print 4 August 2011

- The ongoing concern over the timing of surgery for asymptomatic severe mitral regurgitation is still emphasized
- Early intervention for pts with progressive LV impairment or enlargement detected on serial imaging much before the conventional cut-offs of LVESD of 40 mm and EF of 0.60



ACQUIRED CARDIOVASCULAR DISEASE: MITRAL VALVE

Is there an outcome penalty linked to guideline-based indications for valvular surgery? Early and long-term analysis of patients with organic mitral regurgitation

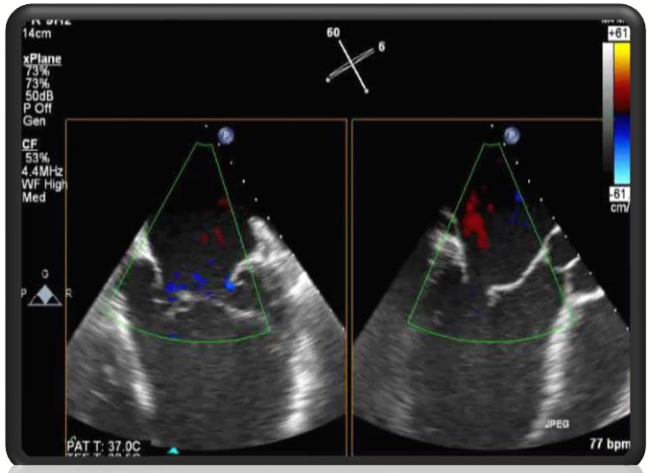
Maurice Enriquez-Sarano, MD,[a] Rakesh M. Suri, MD, DPhil,[b] Marie-Annick Clavel, DVM, PhD,[a] Francesca Mantovani, MD,[a] Hector I. Michelena, MD,[a] Sorin Pislaru, MD,[a] Douglas W. Mahoney, MS,[c] and Hartzell V. Schaff, MD[b]

Determinants of early decline in ejection fraction after surgical correction of mitral regurgitation

Rakesh M. Suri, MD, DPhil,[a] Hartzell V. Schaff, MD,[a] Joseph A. Dearani, MD,[a] Thoralf M. Sundt III, MD,[a] Richard C. Daly, MD,[a] Charles J. Mullany, MB, MS,[a] Maurice E. Sarano, MD,[b] and Thomas A. Orszulak, MD[a]

Secondary mitral regurgitation

IIa	B-R		
See Online Data Supplement 18 (Updated From 2014 VHD Guideline)		It is reasonable to choose chordal-sparing MVR over downsized annuloplasty repair if operation is considered for severely symptomatic patients (NYHA class III to IV) with chronic severe ischemic MR (stage D) and persistent symptoms despite GDMT for HF.[69,70,125,127,130–139]	**NEW:** An RCT has shown that mitral valve repair is associated with a higher rate of recurrence of moderate or severe MR than that associated with mitral valve replacement (MVR) in patients with severe, symptomatic, ischemic MR, without a difference in mortality rate at 2 years' follow-up.



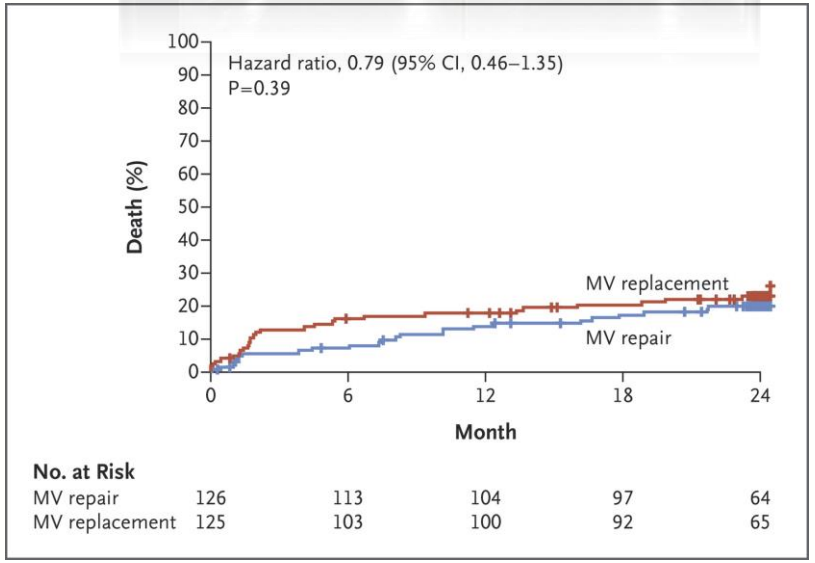
- Chordal sparing valve replacement is now favored over repair in terms of durability

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Two-Year Outcomes of Surgical Treatment of Severe Ischemic Mitral Regurgitation

D. Goldstein, A.J. Moskowitz, A.C. Gelijns, G. Ailawadi, M.K. Parides, L.P. Perrault, J.W. Hung, P. Voisine, F. Dagenais, A.M. Gillinov, V. Thourani, M. Argenziano, J.S. Gammie, M. Mack, P. Demers, P. Atluri, E.A. Rose, K. O'Sullivan, D.L. Williams, E. Bagiella, R.E. Michler, R.D. Weisel, M.A. Miller, N.L. Geller, W.C. Taddei-Peters, P.K. Smith, E. Moquete, J.R. Overbey, I.L. Kron, P.T. O'Gara, and M.A. Acker, for the CTSN*



Secondary mitral regurgitation

IIb	B-R		
See Online Data Supplement 18 (Updated From 2014 VHD Guideline)		In patients with chronic, moderate, ischemic MR (stage B) undergoing CABG, the usefulness of mitral valve repair is uncertain.[71,72]	**MODIFIED: LOE updated from C to B-R.** The 2014 recommendation supported mitral valve repair in this group of patients. An RCT showed no clinical benefit of mitral repair in this population of patients, with increased risk of postoperative complications.

- In contrast to previous guidelines, the benefit of repair for moderate ischemic mitral regurgitation in patients undergoing coronary artery bypass grafting is also questioned.

ORIGINAL ARTICLE

Two-Year Outcomes of Surgical Treatment of Moderate Ischemic Mitral Regurgitation

R.E. Michler, P.K. Smith, M.K. Parides, G. Ailawadi, V. Thourani, A.J. Moskowitz, M.A. Acker, J.W. Hung, H.L. Chang, L.P. Perrault, A.M. Gillinov, M. Argenziano, E. Bagiella, J.R. Overbey, E.G. Moquete, L.N. Gupta, M.A. Miller, W.C. Taddei-Peters, N. Jeffries, R.D. Weisel, E.A. Rose, J.S. Gammie, J.J. DeRose, Jr., J.D. Puskas, F. Dagenais, S.G. Burks, I. El-Hamamsy, C.A. Milano, P. Atluri, P. Voisine, P.T. O'Gara, and A.C. Gelijns, for the CTSN*

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*A list of members of the Cardiothoracic Surgical Trials Network (CTSN) is provided in the Supplementary Appendix, available at NEJM.org

Drs. Michler and Smith contributed equally to this article.

This article was published on April 3, 2016, at NEJM.org.

N Engl J Med 2016;374:1932-41.
DOI: 10.1056/NEJMoa1602003

ABSTRACT

BACKGROUND

In a trial comparing coronary-artery bypass grafting (CABG) alone with CABG plus mitral-valve repair in patients with moderate ischemic mitral regurgitation, we found no significant difference in the left ventricular end-systolic volume index (LVESVI) or survival after 1 year. Concomitant mitral-valve repair was associated with a reduced prevalence of moderate or severe mitral regurgitation, but patients had more adverse events. We now report 2-year outcomes.

METHODS

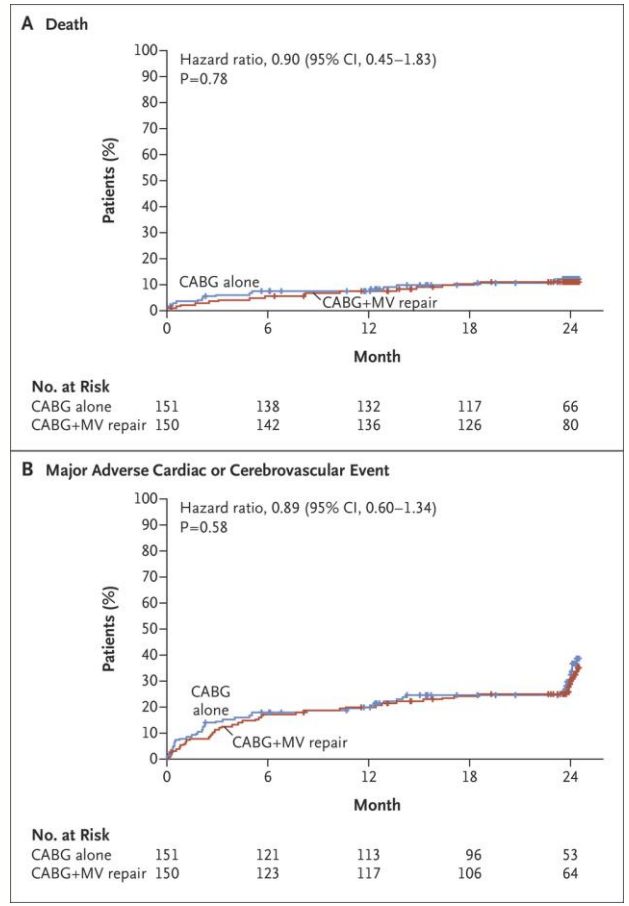
We randomly assigned 301 patients to undergo either CABG alone or the combined procedure. Patients were followed for 2 years for clinical and echocardiographic outcomes.

RESULTS

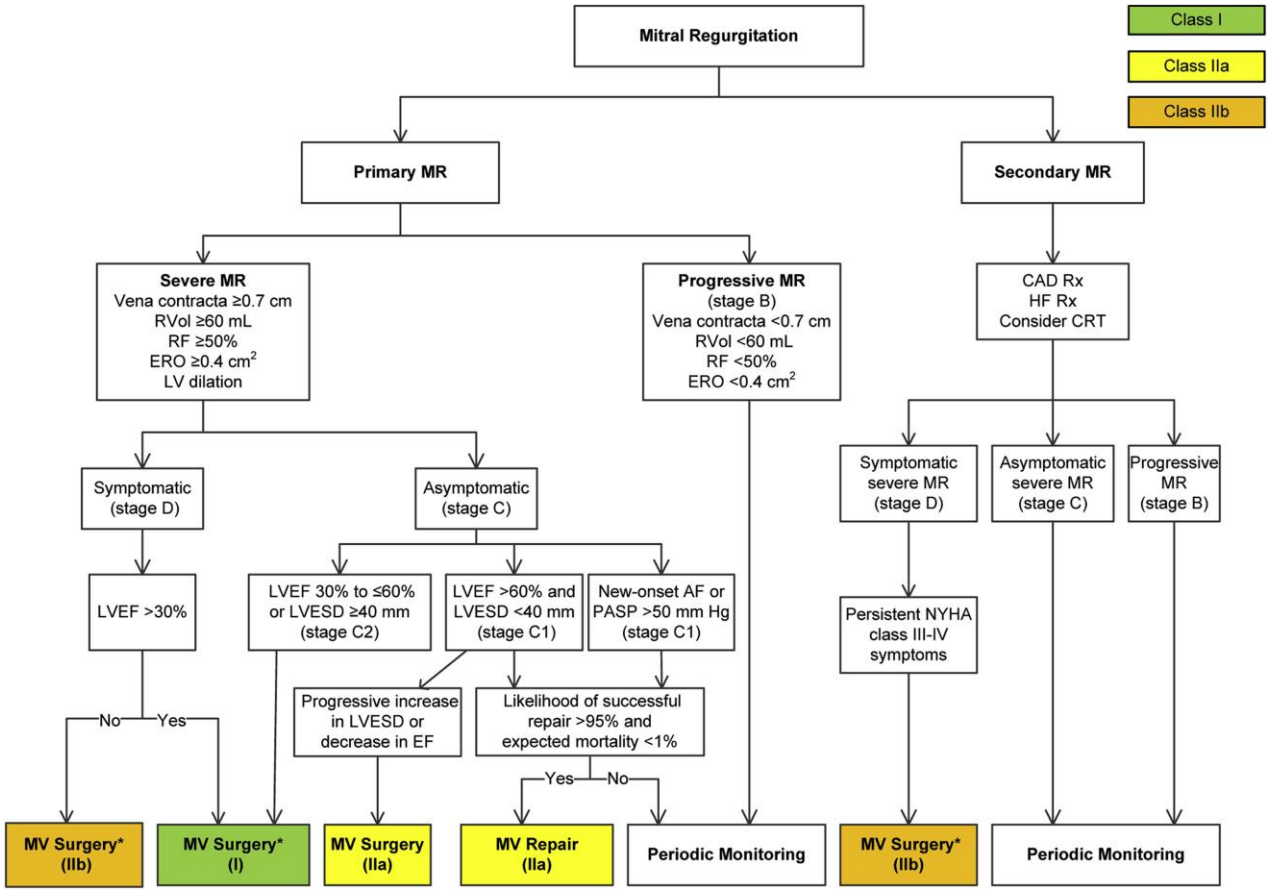
At 2 years, the mean (±SD) LVESVI was 41.2±20.0 ml per square meter of body-surface area in the CABG-alone group and 43.2±20.6 ml per square meter in the combined-procedure group (mean improvement over baseline, −14.1 ml per square meter and −14.6 ml per square meter, respectively). The rate of death was 10.6% in the CABG-alone group and 10.0% in the combined-procedure group (hazard ratio in the combined-procedure group, 0.90; 95% confidence interval, 0.45 to 1.83; P=0.78). There was no significant between-group difference in the rank-based assessment of the LVESVI (including death) at 2 years (z score, 0.38; P=0.71). The 2-year rate of moderate or severe residual mitral regurgitation was higher in the CABG-alone group than in the combined-procedure group (32.3% vs. 11.2%, P<0.001). Overall rates of hospital readmission and serious adverse events were similar in the two groups, but neurologic events and supraventricular arrhythmias remained more frequent in the combined-procedure group.

CONCLUSIONS

In patients with moderate ischemic mitral regurgitation undergoing CABG, the addition of mitral-valve repair did not lead to significant differences in left ventricular reverse remodeling at 2 years. Mitral-valve repair provided a more durable correction of mitral regurgitation but did not significantly improve survival or reduce overall adverse events or readmissions and was associated with an early hazard of increased neurologic events and supraventricular arrhythmias. (Funded by the National Institutes of Health and Canadian Institutes of Health Research; ClinicalTrials.gov number, NCT00806988.)



Indications for Surgery for MR



Prosthetic valves
Type of prosthesis

- Previous versions of the VHD guidelines historically recommend metallic prostheses rather than biological valves in patients younger than 60 years.
- The new version of the guidelines now recommends taking into account the option of the future valve-in-valve procedure in decision making for an individual patient

Recommendations for Intervention of Prosthetic Valves

COR	LOE	Recommendations	Comment/Rationale
I	C-LD	The choice of type of prosthetic heart valve should be a shared decision-making process that accounts for the patient's values and preferences and includes discussion of the indications for and risks of anticoagulant therapy and the potential need for and risk associated with reintervention.[141–146]	**MODIFIED: LOE updated from C to C-LD.** In choosing the type of prosthetic valve, the potential need for and risk of "reoperation" was updated to risk associated with "reintervention." The use of a transcatheter valve-in-valve procedure may be considered for decision making on the type of valve, but long-term follow-up is not yet available, and some bioprosthetic valves, particularly the smaller-sized valves, will not be suitable for a valve-in-valve replacement. Multiple other factors to be considered in the choice of type of valve for an individual patient; these factors are outlined in the text. More emphasis has been placed on shared decision making between the caregiver and patient.
		See Online Data Supplement 20 (Updated From 2014 VHD Guideline)	

ViV procedures are safe and effective

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Transcatheter Aortic and Mitral Valve-in-Valve Implantation for Failed Surgical Bioprosthetic Valves

An 8-Year Single-Center Experience

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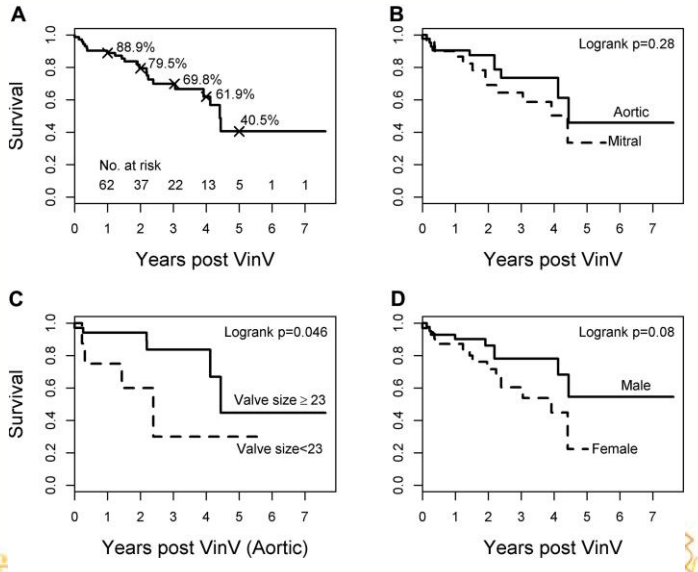
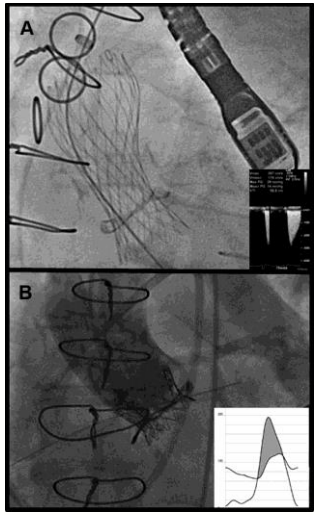


Valvular Heart Disease

Transcatheter Aortic Valve Replacement for Degenerative Bioprosthetic Surgical Valves

Results From the Global Valve-in-Valve Registry

Danny Dvir, MD; John Webb, MD; Stephen Brecker, MD; Sabine Bleiziffer, MD; David Hildick-Smith, MD; Antonio Colombo, MD; Fleur Descoutures, MD; Christian Hengstenberg, MD; Neil E. Moat, FRCS; Raffi Bekeredjian, MD; Massimo Napodano, MD; Luca Testa, MD, PhD; Thierry Lefevre, MD; Victor Guetta, MD; Henrik Nissen, MD, PhD; José-María Hernández, MD; David Roy, MD; Rui C. Teles, MD; Amit Segev, MD; Nicolas Dumonteil, MD; Claudia Fiorina, MD; Michael Gotzmann, MD; Didier Tchetche, MD; Mohamed Abdel-Wahab, MD; Federico De Marco, MD; Andreas Baumbach, MD; Jean-Claude Laborde, MD; Ran Kornowski, MD

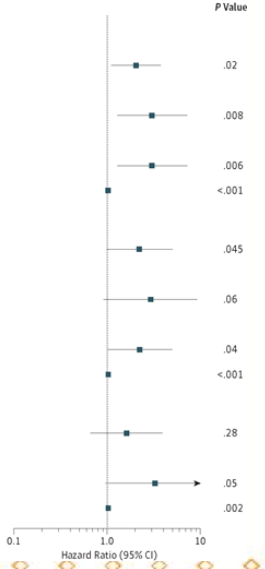


Original Investigation

Transcatheter Aortic Valve Implantation in Failed Bioprosthetic Surgical Valves

Danny Dvir, MD; John G. Webb, MD; Sabine Bleiziffer, MD; Miralem Pasic, MD, PhD; Ron Waksman, MD; Susheel Kodali, MD; Marco Barbanti, MD; Azeem Latib, MD; Ulrich Schaefer, MD; Josep Rodés-Cabau, MD; Hendrik Treede, MD; Nicolo Piazza, MD, PhD; David Hildick-Smith, MD; Dominique Himbert, MD; Thomas Walther, MD; Christian Hengstenberg, MD; Henrik Nissen, MD, PhD; Raffi Bekeredjian, MD; Patrizia Presbitero, MD; Enrico Ferrari, MD; Amit Segev, MD; Arend de Weger, MD; Stephan Windecker, MD; Neil E. Moat, FRCS; Massimo Napodano, MD; Manuel Wilbring, MD; Alfredo G. Cerillo, MD; Stephen Brecker, MD; Didier Tchetche, MD; Thierry Lefèvre, MD; Federico De Marco, MD; Claudia Fiorina, MD; Anna Sonia Petronio, MD; Rui C. Teles, MD; Luca Testa, MD; Jean-Claude Laborde, MD; Martin B. Leon, MD; Ran Kornowski, MD; for the Valve-in-Valve International Data Registry Investigators

	No. of Events	Total	Hazard Ratio (95% CI)	P Value
Overall mortality				
Surgical valve label size				
≤21 mm	28	133	2.04 (1.14-3.67)	.02
>21 mm	34	315		
Type of valve failure				
Stenosis	34	181	3.07 (1.33-7.08)	.008
Regurgitation	12	139		
Transapical access				
Yes	34	171	2.25 (1.26-4.02)	.006
No	30	288		
STS score (per 1% increment)[a]			1.01 (1.00-1.01)	<.001
Early mortality, ≤30 d				
Surgical valve label size				
≤21 mm	15	133	2.25 (1.02-4.98)	.045
>21 mm	17	315		
Type of valve failure				
Stenosis	18	181	2.97 (0.94-9.37)	.06
Regurgitation	6	139		
Transapical access				
Yes	19	171	2.25 (1.03-4.93)	.04
No	15	288		
STS score (per 1% increment)[a]			1.01 (1.00-1.01)	<.001
Late mortality, >30 d				
Surgical valve label size				
≤21 mm	13	133	1.61 (0.68-3.80)	.28
>21 mm	17	315		
Type of valve failure				
Stenosis	16	181	3.33 (1.00-11.31)	.05
Regurgitation	6	139		
STS score (per 1% increment)[a]			1.01 (1.00-1.04)	.002



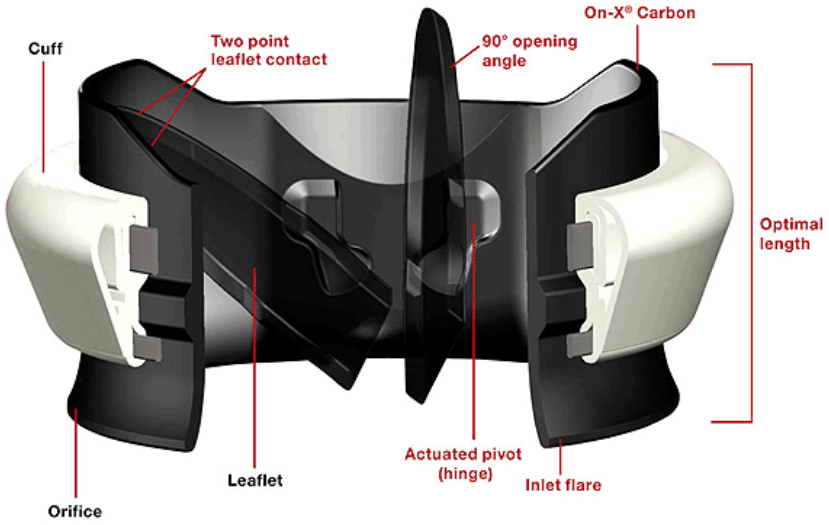
Prosthetic valves
Type of prosthesis

- The age limit for mechanical prosthesis was lowered from 60 to 50 years of age.
- Uncertainity exists about the optimum type of prosthesis (mechanical or bioprosthetic) for patients 50 to 70 years of age.
- Choice of the type of valve should be individualized

Favor Mechanical Prosthesis	Favor Bioprosthesis
Age <50 y▪Increased incidence of structural deterioration with bioprosthesis (15-y risk: 30% for age 40 y, 50% for age 20 y) ▪Lower risk of anticoagulation complications	Age >70 y▪Low incidence of structural deterioration (15-y risk: <10% for age >70 y) ▪Higher risk of anticoagulation complications
Patient preference (avoid risk of reintervention)	Patient preference (avoid risk and inconvenience of anticoagulation and absence of valve sounds)
Low risk of long-term anticoagulation	High risk of long-term anticoagulation
Compliant patient with either home monitoring or close access to INR monitoring	Limited access to medical care or inability to regulate VKA
Other indication for long-term anticoagulation (e.g., AF)	Access to surgical centers with low reoperation mortality rate
High-risk reintervention (e.g., porcelain aorta, prior radiation therapy)	
Small aortic root size for AVR (may preclude valve-in-valve procedure in future).	

Prosthetic valves/anticoagulation

- The new generation On-X aortic valve prosthesis has been shown in similar embolic complications and lesser bleeding with reduced anticoagulation



IIb | B-R

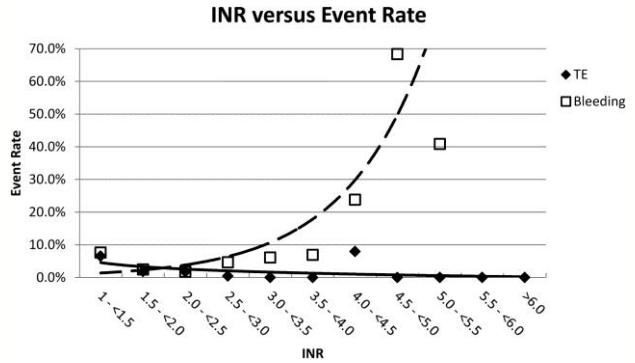
See Online Data Supplement 6.

A lower target INR of 1.5 to 2.0 may be reasonable in patients with mechanical On-X AVR and no thromboembolic risk factors (209).

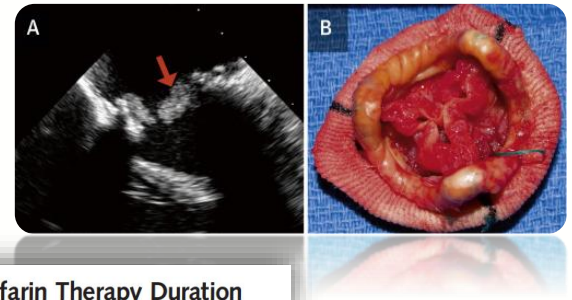
NEW: A lower target INR was added for patients with a mechanical On-X AVR and no thromboembolic risk factors treated with warfarin and low-dose aspirin. A single RCT of lower- versus standard-intensity anticoagulation in patients undergoing On-X AVR showed equivalent outcomes, but the bleeding rate in the control group was unusually high.

Reduced anticoagulation after mechanical aortic valve replacement: Interim results from the Prospective Randomized On-X Valve Anticoagulation Clinical Trial randomized Food and Drug Administration investigational device exemption trial

John Puskas, MD, MSc, FACS, FACC,[a] Marc Gerdisch, MD,[b] Dennis Nichols, MD,[c] Reed Quinn, MD,[d] Charles Anderson, MD,[e] Birger Rhenman, MD,[f] Lilibeth Fermin, MD,[g] Michael McGrath, MD,[h] Bobby Kong, MD,[g] Chad Hughes, MD,[h] Gulshan Sethi, MD,[i] Michael Wait, MD,[j] Tomas Martin, MD,[k] and Allen Graeve, MD,[c] on behalf of all PROACT Investigators

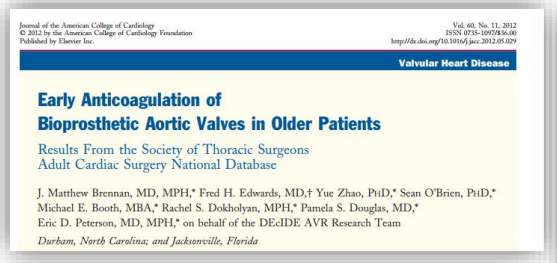


Prosthetic valves/anticoagulation



- Based on recent evidence of a higher risk of thrombosis of biological valves than that recognized previously, a concern was raised on the use of aspirin-only or “no” antithrombotic drug strategies early after bioprosthetic AVR

- The previous relatively complex recommendation sets for anticoagulation regimens early after biological valve replacement surgery have been simplified. Three to as long as 6 months of oral anticoagulation is now recommended as the regimen of choice in patients undergoing either mitral or aortic biological valve replacement



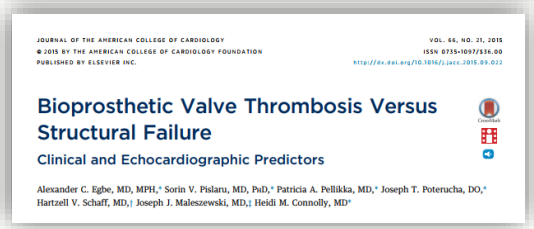
Valvular Heart Disease

Early Anticoagulation of Bioprosthetic Aortic Valves in Older Patients

Results From the Society of Thoracic Surgeons Adult Cardiac Surgery National Database

J. Matthew Brennan, MD, MPH,* Fred H. Edwards, MD,† Yue Zhao, PhD,* Sean O'Brien, PhD,* Michael E. Booth, MBA,* Rachel S. Dokholyan, MPH,* Pamela S. Douglas, MD,* Eric D. Peterson, MD, MPH,* on behalf of the DEcIDE AVR Research Team

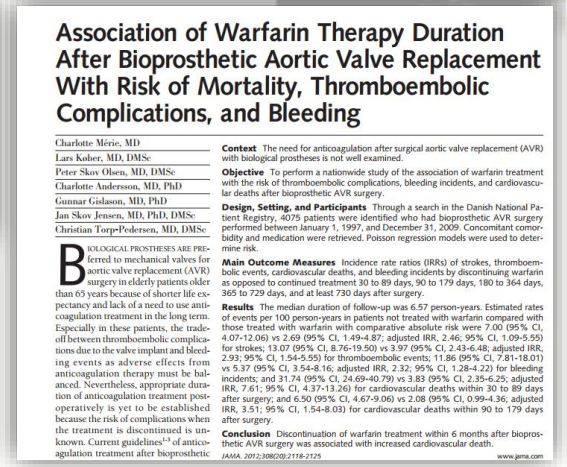
Durham, North Carolina; and Jacksonville, Florida



Bioprosthetic Valve Thrombosis Versus Structural Failure

Clinical and Echocardiographic Predictors

Alexander C. Egbe, MD, MPH,* Sorin V. Pislaru, MD, PhD,* Patricia A. Pellikka, MD,* Joseph T. Poterucha, DO,* Hartzell V. Schaff, MD,† Joseph J. Maleszewski, MD,† Heidi M. Connolly, MD*



Association of Warfarin Therapy Duration After Bioprosthetic Aortic Valve Replacement With Risk of Mortality, Thromboembolic Complications, and Bleeding

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Lars Kober, MD, DMSc
Peter Skov Olsen, MD, DMSc
Charlotte Andersson, MD, PhD
Gunnar Gislason, MD, PhD
Jan Skov Jensen, MD, PhD, DMSc
Christian Torp-Pedersen, MD, DMSc

Context The need for anticoagulation after surgical aortic valve replacement (AVR) with biological prostheses is not well examined.

Objective To perform a nationwide study of the association of warfarin treatment with the risk of thromboembolic complications, bleeding incidents, and cardiovascular deaths after bioprosthetic AVR surgery.

Design, Setting, and Participants Through a search in the Danish National Patient Registry, 4075 patients were identified who had bioprosthetic AVR surgery performed between January 1, 1997, and December 31, 2009. Concomitant comorbidity and medication were retrieved. Poisson regression models were used to determine risk.

Main Outcome Measures Incidence rate ratios (IRRs) of strokes, thromboembolic events, cardiovascular deaths, and bleeding incidents by discontinuing warfarin as opposed to continued treatment 30 to 89 days, 90 to 179 days, 180 to 364 days, 365 to 729 days, and at least 730 days after surgery.

Results The median duration of follow-up was 6.57 person-years. Estimated rates of events per 100 person-years in patients not treated with warfarin compared with those treated with warfarin with comparative absolute risk were 7.00 (95% CI, 4.07-12.06) vs 2.69 (95% CI, 1.49-4.87; adjusted IRR, 2.46; 95% CI, 1.09-5.55) for strokes; 13.07 (95% CI, 8.76-19.50) vs 3.97 (95% CI, 2.43-6.48; adjusted IRR, 2.93; 95% CI, 1.54-5.55) for thromboembolic events; 11.86 (95% CI, 7.81-18.01) vs 5.37 (95% CI, 3.54-8.16; adjusted IRR, 2.32; 95% CI, 1.28-4.22) for bleeding incidents; and 31.74 (95% CI, 24.69-40.79) vs 3.83 (95% CI, 2.35-6.25; adjusted IRR, 7.61; 95% CI, 4.37-13.26) for cardiovascular deaths within 30 to 89 days after surgery; and 6.50 (95% CI, 4.67-9.06) vs 2.08 (95% CI, 0.99-4.36; adjusted IRR, 3.51; 95% CI, 1.54-8.03) for cardiovascular deaths within 90 to 179 days after surgery.

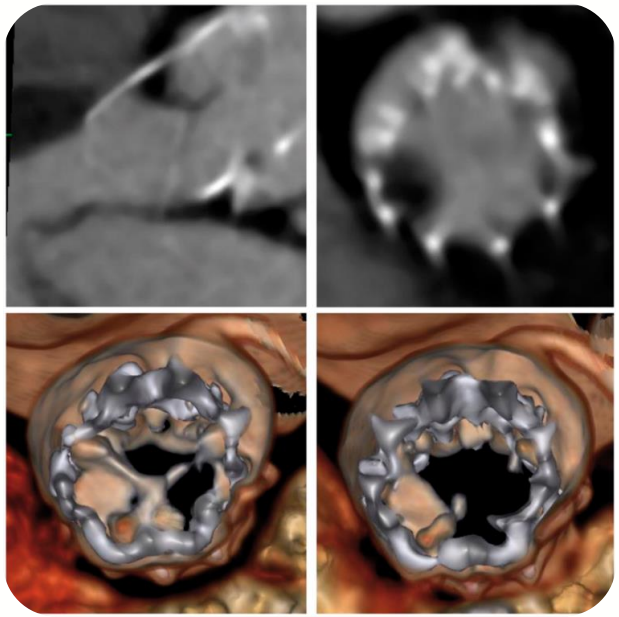
Conclusion Discontinuation of warfarin treatment within 6 months after bioprosthetic AVR surgery was associated with increased cardiovascular death.

JAMA. 2012;308(20):2118-2125

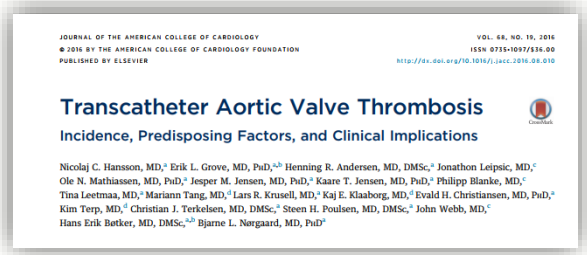
IIa	B-NR		
See Online Data Supplement 6.		Anticoagulation with a VKA to achieve an INR of 2.5 is reasonable for at least 3 months and for as long as 6 months after surgical bioprosthetic MVR or AVR in patients at low risk of bleeding.[195–197]	**MODIFIED: LOE updated from C to B-NR.** Anticoagulation for all surgical tissue prostheses was combined into 1 recommendation, with extension of the duration of anticoagulation up to 6 months. Stroke risk and mortality rate are lower in patients who receive anticoagulation for up to 6 months after implantation of a tissue prosthesis than in those who have do not have anticoagulation. Anticoagulation for a tissue prosthesis is also supported by reports of valve thrombosis for patients undergoing bioprosthetic surgical AVR or MVR, a phenomenon that may be warfarin responsive.

Prosthetic valves/ anticoagulation

- The risk of leaflet thrombosis after TAVI has urged the guidelines to recommend oral anticoagulation for at least 3 months after the procedure with an INR target of 2.5



IIb	B-NR	Anticoagulation with a VKA to achieve an INR of 2.5 may be reasonable for at least 3 months after TAVR in patients at low risk of bleeding.[203,210,211]	**NEW:** Studies have shown that valve thrombosis may develop in patients after TAVR, as assessed by multidetector computerized tomographic scanning. This valve thrombosis occurs in patients who received antiplatelet therapy alone but not in patients who were treated with VKA.
See Online Data Supplement 6.			



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Transcatheter Aortic Valve Thrombosis

Incidence, Predisposing Factors, and Clinical Implications

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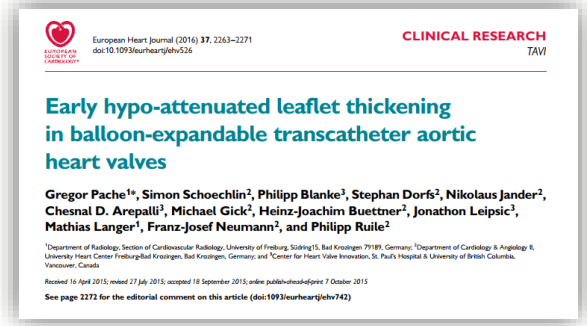

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doi:10.1093/eurheartj/ehv526

CLINICAL RESEARCH
TAVI

Early hypo-attenuated leaflet thickening in balloon-expandable transcatheter aortic heart valves

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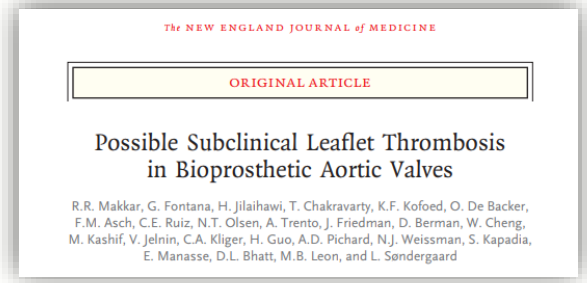
See page 2272 for the editorial comment on this article (doi:1093/eurheartj/ehv742)



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

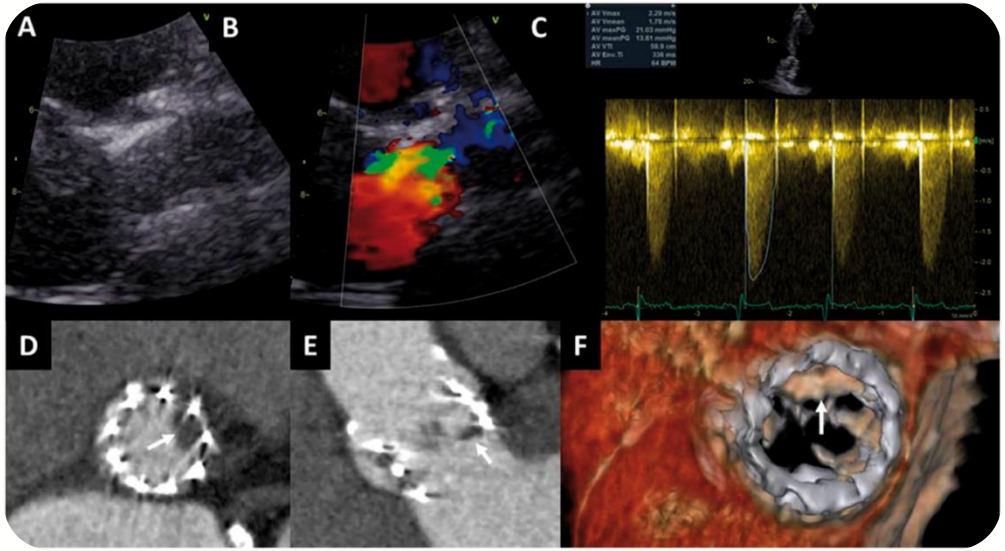
Possible Subclinical Leaflet Thrombosis in Bioprosthetic Aortic Valves

R.R. Makkar, G. Fontana, H. Jilaihawi, T. Chakravarty, K.F. Kofoed, O. De Backer, F.M. Asch, C.E. Ruiz, N.T. Olsen, A. Trento, J. Friedman, D. Berman, W. Cheng, M. Kashif, V. Jelnin, C.A. Kliger, H. Guo, A.D. Pichard, N.J. Weissman, S. Kapadia, E. Manasse, D.L. Bhatt, M.B. Leon, and L. Søndergaard

Prosthetic valves Thrombosis

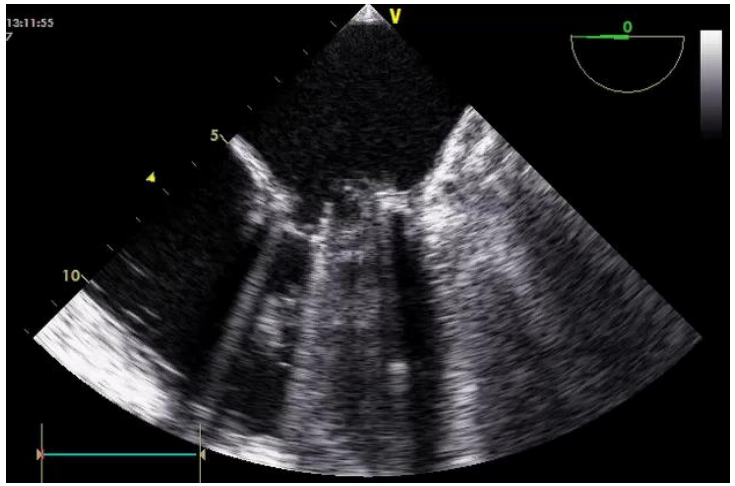
- Based on particular data obtained from studies using three-dimensional transesophageal echocardiography and multislice computed tomography, multimodality imaging in suspected prosthetic valve thrombosis (PVT) is now considered as a class IB indication in the focused update.

Recommendation for Mechanical Prosthetic Valve Thrombosis Diagnosis and Follow-Up			
COR	**LOE**	**Recommendation**	**Comment/Rationale**
I	B-NR	Urgent evaluation with multimodality imaging is indicated in patients with suspected mechanical prosthetic valve thrombosis to assess valvular function, leaflet motion, and the presence and extent of thrombus.[216–222]	**MODIFIED: LOE updated to B-NR.** Multiple recommendations for imaging in patients with suspected mechanical prosthetic valve thrombosis were combined into a single recommendation. Multimodality imaging with transthoracic echocardiography (TTE), transesophageal echocardiography (TEE), fluoroscopy, and/or computed tomography (CT) scanning may be more effective than one imaging modality alone in detecting and characterizing valve thrombosis. Different imaging modalities are necessary because valve function, leaflet motion, and extent of thrombus should all be evaluated.
See Online Data Supplement 7.			



Prosthetic valves/Thrombosis

- Multiple recent nonrandomized studies have shown the efficacy and safety of low-dose and slow-infusion thrombolysis in most patients with left-sided PVT.
- Urgent thrombolysis or surgery for obstructive PVT as the first-line treatment strategy is equally recommended



11.6.3. Intervention: Recommendation

Recommendation for Mechanical Prosthetic Valve Thrombosis Intervention

COR	LOE	Recommendation	Comment/Rationale
I	B-NR	Urgent initial treatment with either slow-infusion low-dose fibrinolytic therapy or emergency surgery is recommended for patients with a thrombosed leftsided mechanical prosthetic heart valve presenting with symptoms of valve obstruction.[224–231]	**MODIFIED: LOE updated to B-NR.** Multiple recommendations based only on NYHA class symptoms were combined into 1 recommendation. Slow-infusion fibrinolytic therapy has higher success rates and lower complication rates than prior high-dose regimens and is effective in patients previously thought to require urgent surgical intervention. The decision for emergency surgery versus fibrinolytic therapy should be based on multiple factors, including the availability of surgical expertise and the clinical experience with both treatments.

See Online Data Supplement 7 and 7A.

Low dose slow infusion of tissue type plasminogen activator

Valvular and Congenital Heart Disease

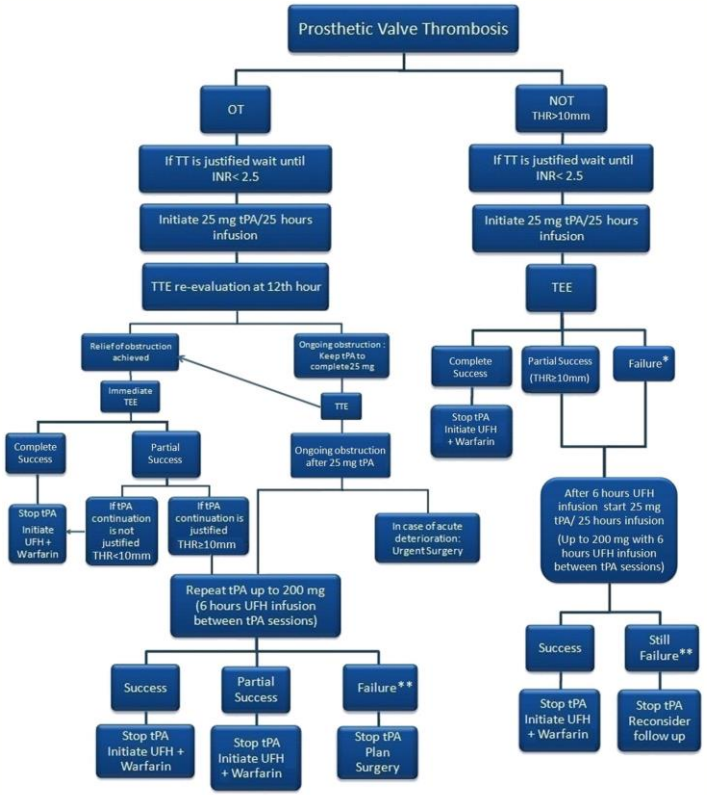
Ultraslow thrombolytic therapy: A novel strategy in the management of PROsthetic MEchanical valve Thrombosis and the prEdictors of outcomE: The Ultra-slow PROMETEE trial

Mehmet Özkan, MD,[a,b] Sabahattin Gündüz, MD,[b] Ozan Mustafa Gürsoy, MD,[b] Süleyman Karakoyun, MD,[b] Mehmet Ali Astarcıoğlu, MD,[b] Macit Kalçık, MD,[b] Ahmet Çağrı Aykan, MD,[b] Beytullah Çakal, MD,[b] Zübeyde Bayram, MD,[b] Ali Emrah Oğuz, MD,[b] Emre Ertürk, MD,[b] Mahmut Yesin, MD,[b] Tayyar Gökdeniz, MD,[b] Nilüfer Ekşi Duran, MD,[b] Mustafa Yıldız, MD,[b] and Ali Metin Esen, MD[b] *Kars and Istanbul, Turkey*

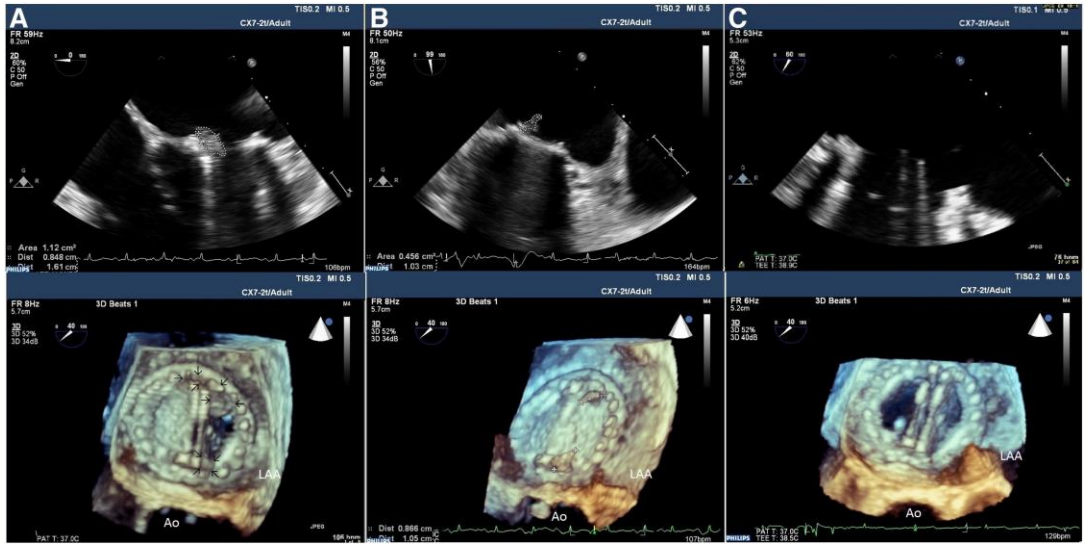
Background Low-dose (25 mg), slow infusion (6 hours) of tissue-type plasminogen activator (t-PA) with repetition as needed has been shown to provide effective and safer thrombolysis in patients with prosthetic valve thrombosis (PVT). Further prolonging the infusion time may be rational with regard to reducing complication rates without reducing success rates. We aimed to investigate the efficacy and safety of ultraslow (25 hours) infusion of low-dose (25 mg) alteplase (t-PA) for PVT.

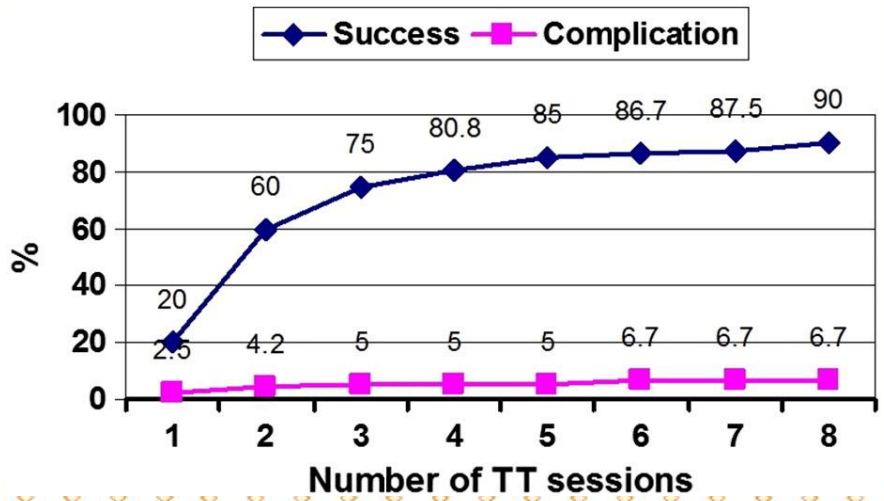
Methods and results Transesophageal echocardiography–guided thrombolytic therapy (TT) was administered to 114 patients with PVT in 120 different episodes between 2009 and 2013 in a single center. Prosthetic valve thrombosis was obstructive in 77 (64.2%) and nonobstructive in 43 (35.8%) episodes. Ultraslow infusion (25 hours) of low-dose (25 mg) t-PA, as the TT regimen, was used in all patients admitted with PVT. The end points were thrombolytic success, mortality, and complication rates. The overall success rate of TT was 90% (95% CI 0.85-0.95). The univariate predictors of an unsuccessful result were higher New York Heart Association (NYHA) class, thrombus cross-sectional area, duration of suboptimal anticoagulation, lower baseline valve area, and presence of atrial fibrillation. The NYHA class was the only independent predictor of TT failure by multiple variable analysis. The overall complication rate was 6.7% (3.3% nonfatal major, 2.5% minor, and 0.8% death). The predictors of complications were presence of atrial fibrillation, higher NYHA class, and thrombus area.

Conclusion Ultraslow (25 hours) infusion of low-dose (25 mg) t-PA without bolus appears to be associated with quite low nonfatal complications and mortality for PVT patients without loss of effectiveness, except for those with NYHA class IV. (Am Heart J 2015;170:409-418.e1.)

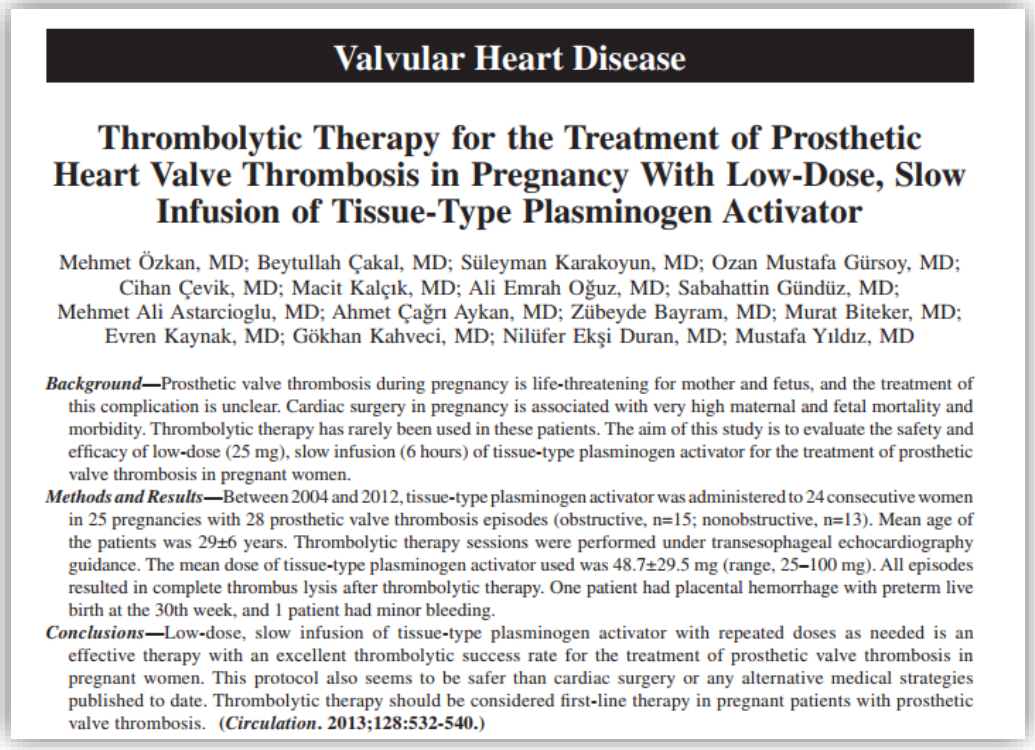


Failure* : Unresponsiveness to TT
Failure: Unresponsiveness to TT or major complication**





Low dose slow infusion of tissue type plasminogen activator



Valvular Heart Disease

Thrombolytic Therapy for the Treatment of Prosthetic Heart Valve Thrombosis in Pregnancy With Low-Dose, Slow Infusion of Tissue-Type Plasminogen Activator

Mehmet Özkan, MD; Beytullah Çakal, MD; Süleyman Karakoyun, MD; Ozan Mustafa Gürsoy, MD; Cihan Çevik, MD; Macit Kalçık, MD; Ali Emrah Oğuz, MD; Sabahattin Gündüz, MD; Mehmet Ali Astarcioglu, MD; Ahmet Çağrı Aykan, MD; Zübeyde Bayram, MD; Murat Biteker, MD; Evren Kaynak, MD; Gökhan Kahveci, MD; Nilüfer Ekşi Duran, MD; Mustafa Yıldız, MD

***Background*—**Prosthetic valve thrombosis during pregnancy is life-threatening for mother and fetus, and the treatment of this complication is unclear. Cardiac surgery in pregnancy is associated with very high maternal and fetal mortality and morbidity. Thrombolytic therapy has rarely been used in these patients. The aim of this study is to evaluate the safety and efficacy of low-dose (25 mg), slow infusion (6 hours) of tissue-type plasminogen activator for the treatment of prosthetic valve thrombosis in pregnant women.

***Methods and Results*—**Between 2004 and 2012, tissue-type plasminogen activator was administered to 24 consecutive women in 25 pregnancies with 28 prosthetic valve thrombosis episodes (obstructive, n=15; nonobstructive, n=13). Mean age of the patients was 29±6 years. Thrombolytic therapy sessions were performed under transesophageal echocardiography guidance. The mean dose of tissue-type plasminogen activator used was 48.7±29.5 mg (range, 25–100 mg). All episodes resulted in complete thrombus lysis after thrombolytic therapy. One patient had placental hemorrhage with preterm live birth at the 30th week, and 1 patient had minor bleeding.

Conclusions*—**Low-dose, slow infusion of tissue-type plasminogen activator with repeated doses as needed is an effective therapy with an excellent thrombolytic success rate for the treatment of prosthetic valve thrombosis in pregnant women. This protocol also seems to be safer than cardiac surgery or any alternative medical strategies published to date. Thrombolytic therapy should be considered first-line therapy in pregnant patients with prosthetic valve thrombosis. (Circulation***. 2013;128:532-540.)**

- Six-hour infusion of 25 mg tPA without a bolus (repeated once after 24 hours, up to 6 times if needed, for a maximum total dose of 150 mg) was used in all pregnant patients with PVT.
- Intravenous heparin during tPA infusions is not used to minimize bleeding risk.
- Heparin 70-IU/ kg bolus and 16 IU/kg per hour (up to 1000 IU/h) infusion with a target activated partial thromboplastin time of 1.5 to 2.0 times the mean of the reference range was started immediately after the tPA infusion.
- If repeat thrombolytic infusion was needed, heparin was held again

Prosthetic valves
Fibrinolysis versus surgery for prosthetic valve thrombosis

- A set of factors to be taken into account when considering one treatment modality over another is provided

Favor Surgery	Favor Fibrinolysis
Readily available surgical expertise	No surgical expertise available
Low surgical risk	High surgical risk
Contraindication to fibrinolysis	No contraindication to fibrinolysis
Recurrent valve thrombosis	First-time episode of valve thrombosis
NYHA class IV	NYHA class I–III
Large clot (>0.8 cm^2)	Small clot (≤0.8 cm^2)
Left atrial thrombus	No left atrial thrombus
Concomitant CAD in need of revascularization	No or mild CAD
Other valve disease	No other valve disease
Possible pannus	Thrombus visualized
Patient choice	Patient choice

Bioprosthetic valve thrombosis

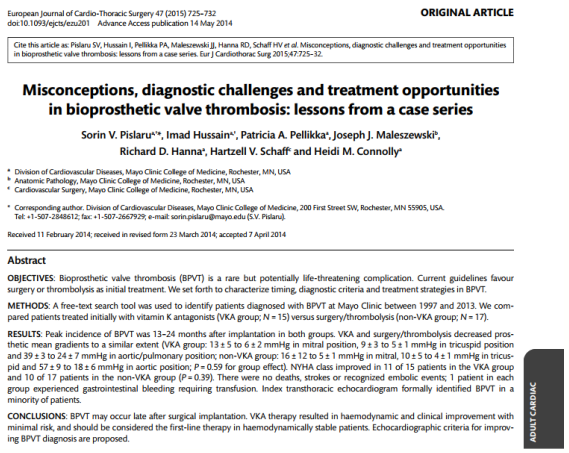
- In pts with stenotic valves, thrombosis may be a major contributing factor to slowly progressing gradients
- In stable patients initial anticoagulation for several months until the resolution of stenosis is recommended

IIa	C-LD

See Online Data Supplement 8.

In patients with suspected or confirmed bioprosthetic valve thrombosis who are hemodynamically stable and have no contraindications to anticoagulation, initial treatment with a VKA is reasonable (203,242-246).

NEW: Case series of patients presenting with bioprosthetic valve stenosis have suggested improvement in hemodynamics with VKA treatment because of resolution of thrombus on the valve leaflets.



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ORIGINAL ARTICLE

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Misconceptions, diagnostic challenges and treatment opportunities in bioprosthetic valve thrombosis: lessons from a case series

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Abstract

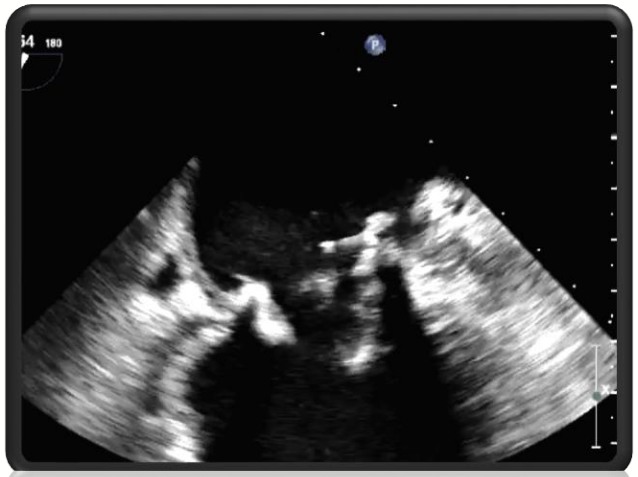
OBJECTIVES: Bioprosthetic valve thrombosis (BPVT) is a rare but potentially life-threatening complication. Current guidelines favour surgery or thrombolysis as initial treatment. We set forth to characterize timing, diagnostic criteria and treatment strategies in BPVT.

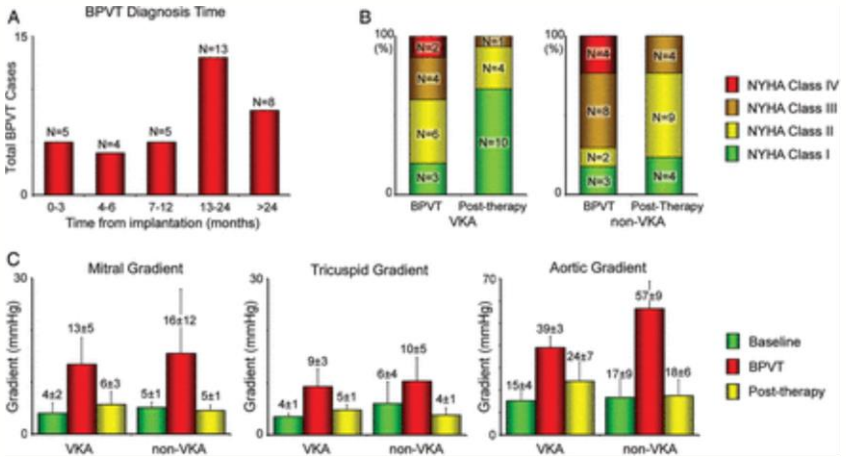
METHODS: A free-text search tool was used to identify patients diagnosed with BPVT at Mayo Clinic between 1997 and 2013. We compared patients treated initially with vitamin K antagonists (VKA group; $N = 15$) versus surgery/thrombolysis (non-VKA group; $N = 17$).

RESULTS: Peak incidence of BPVT was 13–24 months after implantation in both groups. VKA and surgery/thrombolysis decreased prosthetic mean gradients to a similar extent (VKA group: 13 ± 5 to 6 ± 2 mmHg in mitral position, 9 ± 3 to 5 ± 1 mmHg in tricuspid position and 39 ± 3 to 24 ± 7 mmHg in aortic/pulmonary position; non-VKA group: 16 ± 12 to 5 ± 1 mmHg in mitral, 10 ± 5 to 4 ± 1 mmHg in tricuspid and 57 ± 9 to 18 ± 6 mmHg in aortic position; $P = 0.59$ for group effect). NYHA class improved in 11 of 15 patients in the VKA group and 10 of 17 patients in the non-VKA group ($P = 0.39$). There were no deaths, strokes or recognized embolic events; 1 patient in each group experienced gastrointestinal bleeding requiring transfusion. Index transthoracic echocardiogram formally identified BPVT in a minority of patients.

CONCLUSIONS: BPVT may occur late after surgical implantation. VKA therapy resulted in haemodynamic and clinical improvement with minimal risk, and should be considered the first-line therapy in haemodynamically stable patients. Echocardiographic criteria for improving BPVT diagnosis are proposed.

ADULT CARDIAC





ACC Middle East Conference 2017

Bioprosthetic valve

IIa B-NR See Online Supplement 9.	For severely symptomatic patients with bioprosthetic aortic valve stenosis judged by the heart team to be at high or prohibitive risk of reoperation, and in whom improvement in hemodynamics is anticipated, a transcatheter valve-in-valve procedure is reasonable (154,247,248).	NEW: Registries and case series have reported on the short-term outcomes and complication rates in patients with bioprosthetic AS who have undergone transcatheter valve-in-valve therapy.
IIa B-NR See Online Data Supplement 9.	For severely symptomatic patients with bioprosthetic aortic valve regurgitation judged by the heart team to be at high or prohibitive risk for surgical therapy, in whom improvement in hemodynamics is anticipated, a transcatheter valve-in-valve procedure is reasonable (154,247,248).	NEW: Registries and case series of patients have reported on the short-term outcomes and complication rates for patients with bioprosthetic aortic regurgitation who have undergone transcatheter valve-in-valve replacement.
IIa C-LD See Online Data Supplement 23 (Updated From 2014 VHD Guideline)	Surgery is reasonable for asymptomatic patients with severe bioprosthetic regurgitation if operative risk is acceptable (241).	MODIFIED: LOE updated from C to C-LD. A specific indication for surgery is the presence of severe bioprosthetic regurgitation in a patient with acceptable operative risk. With the new recommendation for valve-in-valve therapy, indications for intervention need to account for patients who would benefit from surgery versus those who would benefit from transcatheter therapy, determined by type of valve, symptomatic status, and risk of reoperation.

The transcatheter valve in valve procedure is considered suitable for patients with aortic bioprosthetic regurgitation or stenosis who are severely symptomatic and have a prohibitive surgical risk

Original Investigation

Transcatheter Aortic Valve Implantation in Failed Bioprosthetic Surgical Valves

Danny Dvir, MD; John G. Webb, MD; Sabine Bleiziffer, MD; Miralem Pasic, MD, PhD; Ron Waksman, MD; Susheel Kodali, MD; Marco Barbanti, MD; Azeem Latib, MD; Ulrich Schaefer, MD; Josep Rodés-Cabau, MD; Hendrik Treede, MD; Nicolo Piazza, MD, PhD; David Hildick-Smith, MD; Dominique Himbert, MD; Thomas Walther, MD; Christian Hengstenberg, MD; Henrik Nissen, MD, PhD; Raffi Bekeredjian, MD; Patrizia Presbitero, MD; Enrico Ferrari, MD; Amit Segev, MD; Arend de Weger, MD; Stephan Windecker, MD; Neil E. Moat, FRCS; Massimo Napodano, MD; Manuel Wilbring, MD; Alfredo G. Cerillo, MD; Stephen Brecker, MD; Didier Tchetche, MD; Thierry Lefèvre, MD; Federico De Marco, MD; Claudia Fiorina, MD; Anna Sonia Petronio, MD; Rui C. Teles, MD; Luca Testa, MD; Jean-Claude Laborde, MD; Martin B. Leon, MD; Ran Kornowski, MD; for the Valve-in-Valve International Data Registry Investigators

Thanks for your attention