

MESA REDONDA

NOVAS DIRETRIZES INTERNACIONAIS 10 COISAS QUE APRENDEMOS A FAZER E NÃO FAZER Diretriz Americana de Valvopatias 2017

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Título da Apresentação: *NOVAS DIRETRIZES INTERNACIONAIS*10 COISAS QUE APRENDEMOS A FAZER E NÃO FAZER
Diretriz Americana de Valvopatias 2017

Não possuo nenhum conflito de interesse relacionado a esta apresentação

CLINICAL PRACTICE GUIDELINE: FOCUSED UPDATE

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

Developed in Collaboration With the American Association for Thoracic Surgery,

American Society of Echocardiography, Society for Cardiovascular Angiography and Interventions,

Society of Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons

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Recommendations for Anticoagulation for Atrial Fibrillation (AF) in Patients With VHD

COR	LOE	RECOMMENDATIONS			
1	B-NR	Anticoagulation with a vitamin K antagonist (VKA) is indicated for patients with rheumatic mitral stenosis		CHA ₂ DS ₂ -VASC Descrição	Pontos
See Onli	ine Data nts 3 and 4.	(MS) and AF (34,35).	С	Insuficiência Cardíaca	1
Supplemen	115 3 and 4.		Ŧ	Hipertensão	1
		Anticoagulation is indicated in patients with AF and a	A ₂	Idade (≥ 75 anos)	2
1	C-LD	CHA ₂ DS ₂ -VASc score of 2 or greater with native aortic	D	Diabetes Mellitus	1
		valve disease, tricuspid valve disease, or MR (36-38).	S2	AIT ou AVC prévio	2
	line Data ents 3 and 4.		٧	Doença Vascular (IAM prévio, <u>Dça</u> arterial periférica ou placa aórtica)	1
			A	Idade (65-74 anos)	1
			Sc	Sexo (se feminino)	1

lla 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 CHA₂DS₂-VASc score of 2 or greater (35–38).

Estenose Aórtica

Escolha do tipo de Intervenção

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.

Estágios da EAo

A – em risco de doença valvar

B – EAo assintomática progressiva

C – EAo assintomática, grave

D – EAo sintomática, grave



Estenose Aórtica

Escolha do tipo de Intervenção





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.



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.



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).

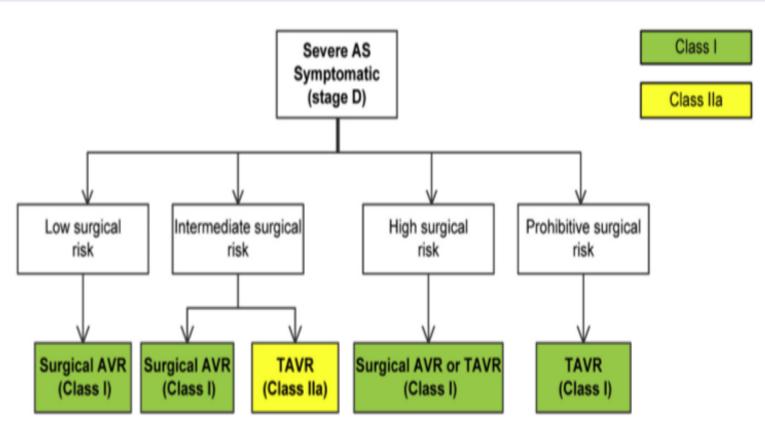
NEW: New RCT showed noninferiority of TAVR to surgical AVR in symptomatic patients with severe AS at intermediate surgical risk.

Obs limited follow-up

Estenose Aórtica



FIGURE 1 Choice of TAVR Versus Surgical AVR in the Patient With Severe Symptomatic AS



AS indicates aortic stenosis; AVR, aortic valve replacement; and TAVR, transcatheter aortic valve replacement.

Insuficiência mitral primária



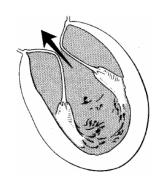
lla C-LD

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.

Insuficiência Mitral Secundária





lla B-R

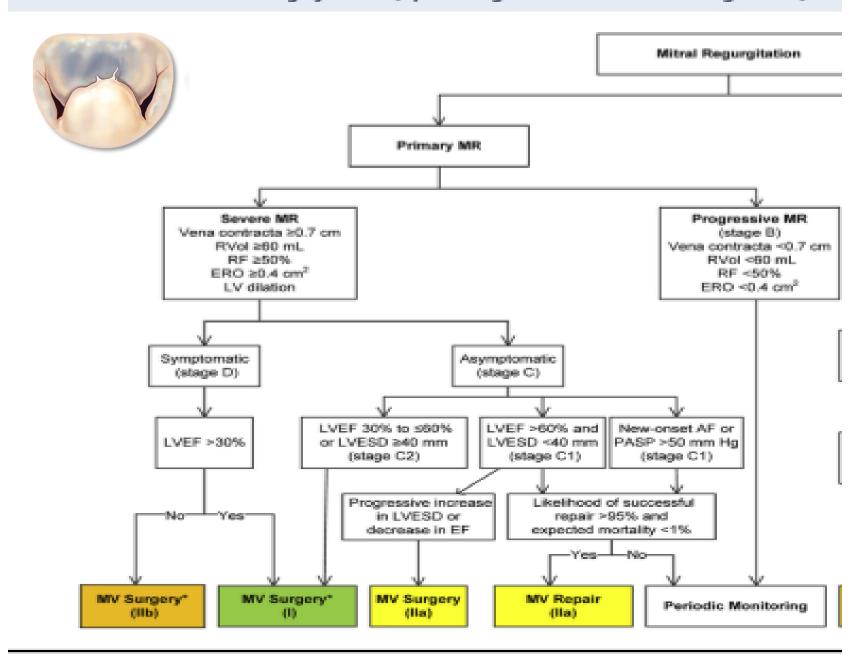
See Online Data Supplement 18 (Updated From 2014 VHD Guideline) It is reasonable to choose chordal-sparing MVR over downsized annuloplasty repair if operation is considered for severely symptomatic patients (NYHA class III to IV) with chronic severe ischemic MR (stage D) and persistent symptoms despite 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.

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).

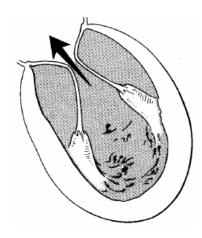
MODIFIED: LOE updated from C to B-R. The 2014 recommendation supported mitral valve repair in this group of patients. An RCT showed no clinical benefit of mitral repair in this population of patients, with increased risk of postoperative complications.

FIGURE 2 Indications for Surgery for MR (Updated Figure 4 From the 2014 VHD guideline)



Mitral Regurgitation







Escolha da Prótese Valvar





Recommendations for Intervention of Prosthetic Valves

COR LOE RECOMMENDATIONS COMMENT/RATIONALE

I C-LD

See Online Data Supplement 20 (Updated From 2014 VHD Guideline) 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.

lia B-NR

See Online Data Supplement 20 (Updated From 2014 VHD Guideline) An aortic or mitral mechanical prosthesis is reasonable for patients less than 50 years of age who do not have a contraindication to anticoagulation (141,149,151,155–157).

MODIFIED: LOE updated from B to B-NR. The age limit for mechanical prosthesis was lowered from 60 to 50 years of age.





Escolha da Prótese Valvar

lla B-NR

See Online Data Supplement 20 (Updated From 2014 VHD Guideline) For patients between 50 and 70 years of age, it is reasonable to individualize the choice of either a mechanical or bioprosthetic valve prosthesis on the basis of individual patient factors and preferences, after full discussion of the trade-offs involved (141–145,157–160).

MODIFIED: Uncertainty exists about the optimum type of prosthesis (mechanical or bioprosthetic) for patients 50 to 70 years of age. There are conflicting data on survival benefit of mechanical versus bioprosthetic valves in this age group, with equivalent stroke and thromboembolic outcomes. Patients receiving a mechanical valve incur greater risk of bleeding, and those undergoing bioprosthetic valve replacement more often require repeat valve surgery.

Escolha da Prótese Valvar





Favor Mechanical Prosthesis	Favor Bioprosthesis	
Age <50 v	Arie >70 v	

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).	

AF indicates atrial fibrillation; AVR, aortic valve replacement; INR, International Normalized Ratio; and VKA, vitamin K antagonist.

TABLE 3 Factors Used for Shared Decision Making About Type of Valve Prosthesis

Survival and Long-term Outcomes Following Bioprosthetic vs Mechanical Aortic Valve Replacement in Patients Aged 50 to 69 Years

eFigure 2. Trend in Mechanical versus Bioprosthetic Valve Usage for Aortic Valve Replacement in Patients Aged 50 to 69 in New York State^a

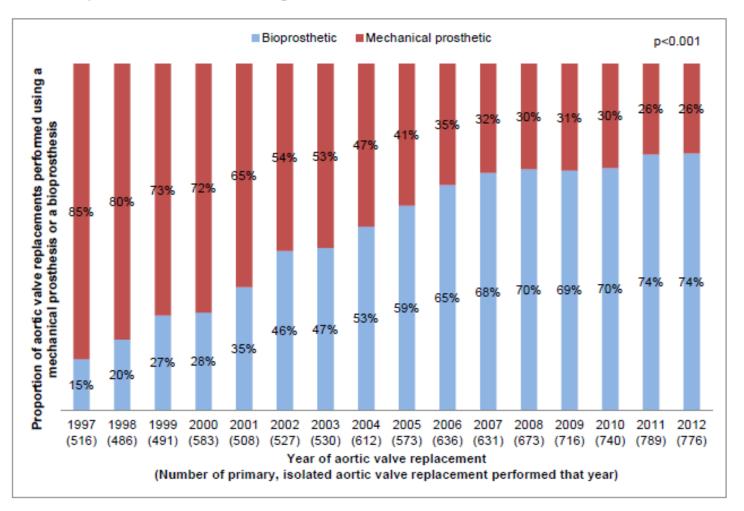
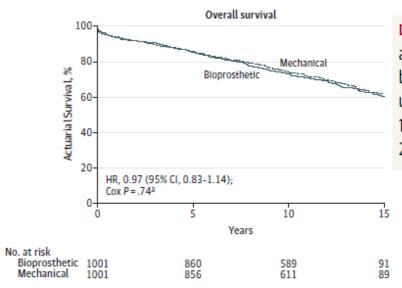


Figure 1. Overall Survival Among Propensity-Matched Patients Aged 50 to 69 Years After Bioprosthetic vs Mechanical Aortic Valve Replacement



There were 322 all-cause deaths in the bioprosthesis group vs 318 in the mechanical prosthesis group.

Survival and Long-term Outcomes Following Bioprosthetic vs Mechanical Aortic Valve Replacement in Patients Aged 50 to 69 Years

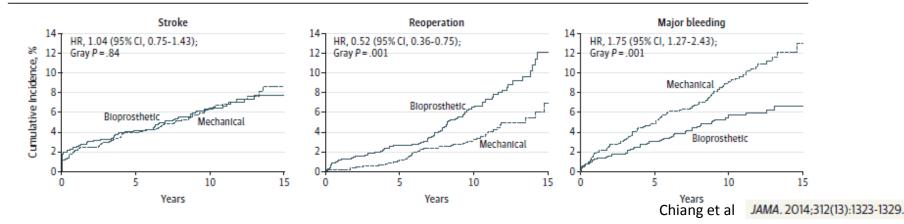
DESIGN, SETTING, AND PARTICIPANTS Retrospective cohort analysis of 4253 patients aged 50 to 69 years who underwent primary isolated aortic valve replacement using bioprosthetic vs mechanical valves in New York State from 1997 through 2004, identified using the Statewide Planning and Research Cooperative System. Median follow-up time was 10.8 years (range, 0 to 16.9 years); the last follow-up date for mortality was November 30, 2013. Propensity matching yielded 1001 patient pairs.

Based on NY Registry

Mortality after complications:

18,7% after stroke9,0% after reoperation13,2% after major bleeding

Figure 2. Cumulative Incidence of Major Morbidity (Stroke, Reoperation, Major Bleeding) Among Propensity-Matched Patients Aged 50 to 69 Years After Bioprosthetic vs Mechanical Aortic Valve Replacement



^a P value calculated using a marginal Cox model with a robust sandwich variance estimator.

Biopróteses Pericárdica e Porcina, 3 modelos

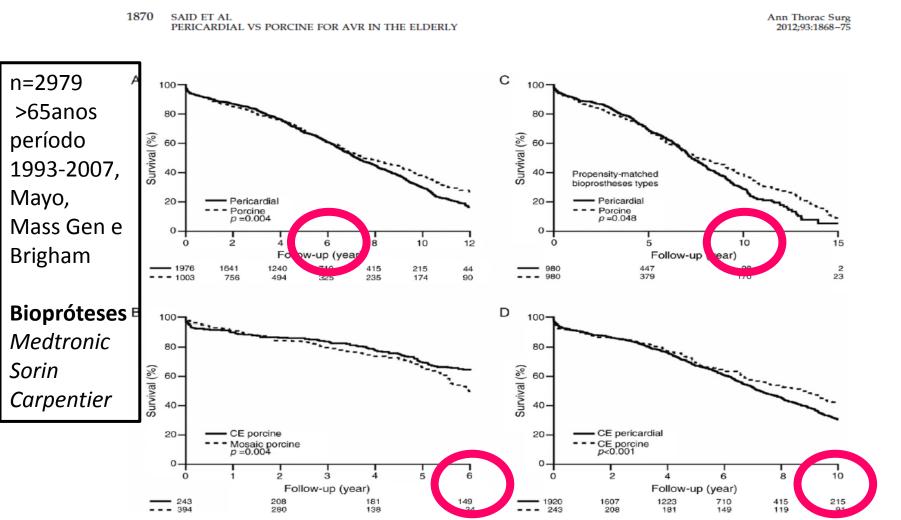


Fig 1. Kaplan-Meier graphs show survival of elderly patients after aortic valve replacement. (A) There was no survival advantage for patients with pericardial (solid line) over porcine (dashed line) bioprostheses (p=0.05). (B), Survival is shown between the two most commonly used porcine brands, the Medtronic Mosaic (dashed line) and the Carpentier-Edwards Perimount (CE, solid line). (C) Survival is compared between propensity-matched pericardial (solid line) and porcine (dashed line) bioprostheses types. (D) There was no survival advantage for the Carpentier-Edwards (CE) Perimount (solid line) over the porcine type (dashed line); in fact, thex porcine brand appeared to have a survival advantage (p<0.001).

Do Pericardial Bioprostheses Improve Outcome of Elderly Patients Undergoing Aortic Valve Replacement? Said SM et al (Mayo, Mass Gen & Brigham) **Ann Thorac Surg 2012;93:1868 –75**



Diretrizes STS



Existem biopróteses com durabilidade superior ou indicadas para jovens?

sites. To mitigate valve calcification most companies have developed proprietary tissue treatments aimed at removing residual glutaraldehyde or phospholipid moieties to reduce calcium binding and hopefully enhance durability. Among these are treatment with alcohol and various antisurfactants but none has proved superior to others.



Epic™ Stented Tissue Valve with Linx™ AC Technology

We have designed the Epic™ stented tissue valve with Linx™ AC technology for durability and performance; it features a proprietary anticalcification treatment.



Primeira válvula comprovado pro mais de 15 anos exclusiva tecnol proteger contra

					_		_		
İ		Produtos		ards XenoLog MOUNT™/Mag	iX ⁵ ;na™	Edwards Them PER MOUNT™/		Medtronic AOA ⁷ Mosaic™/U tra™	Meditronic T6 ^s Hancock II [™]
		Redução de aldeídos livres	✓			✓		✓	
		2 Extração de Lipídios	√	\checkmark		√			\checkmark
	_	3 Minimiza a absorção de colester	ol 🗸						
	۲	4 Estabiliza o colágeno dos folhet	05						

Não há dados clínicos disponíveis que avaliem o impacto a longo prazo do tratamento de tecidos com anticalcificação em seres humanos.

Carpentier-Edwards PERIMOUNT Magna Ease Aortic Heart Valve

Where MAGNA hemodynamics meets EASE of implantation.



ção.8

ar relio com o comprovado desempenho de bioprótese aórtica PERIMOUNT, com mais de 27 anos de experiência clínica^{9,10}

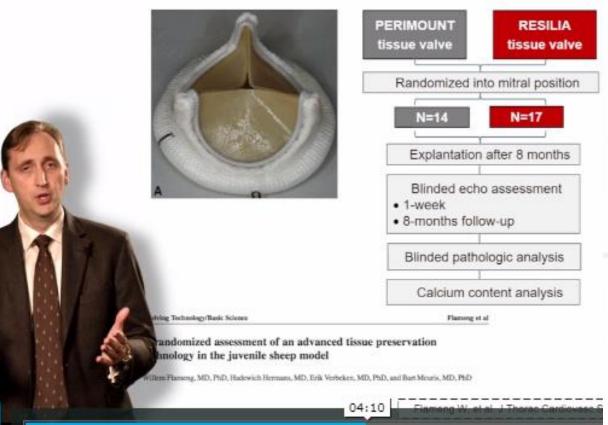
um projeto de estabilidade hemodinâmica comprovada de até 17 anos de

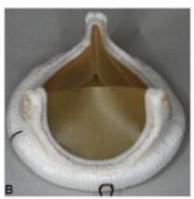
 O Carpentier-Edwards ThermaFix process é a única tecnologia de anti-calcificação projetada para confrontar os locais de maior ligação de cálcio.

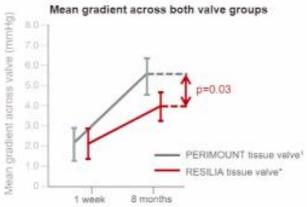
*Nenhum dado clínico está disponível para avaliar o impacto de longo prazo nos pacientes sob tratamento de tecidos Edwards.

RESILIA tissue









Recomendações de Anticoagulação em Próteses

Ila

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).



IIIb

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).



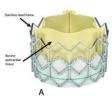


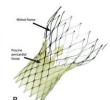
IIIb

B-NR

See Online Data Supplement 6.

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).





Recommendation for Mechanical Prosthetic Valve Thrombosis Diagnosis and Follo

COR	LOE	RECOMMENDATION
1	B-NR	Urgent evaluation with multimodality imaging is indicated in patients with suspected mechanical
See Online Data	a Supplement 7.	prosthetic valve thrombosis to assess valvular function, leaflet motion, and the presence and extent of thrombus (216–222).

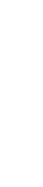


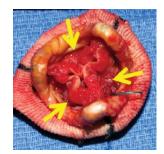


TABLE 4

Fibrinolysis Versus Surgery for Prosthetic Valve Thrombosis

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 cm²)	Small clot (≤0.8 cm²)
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

CAD indicates coronary artery disease; and NYHA, New York Heart Association.





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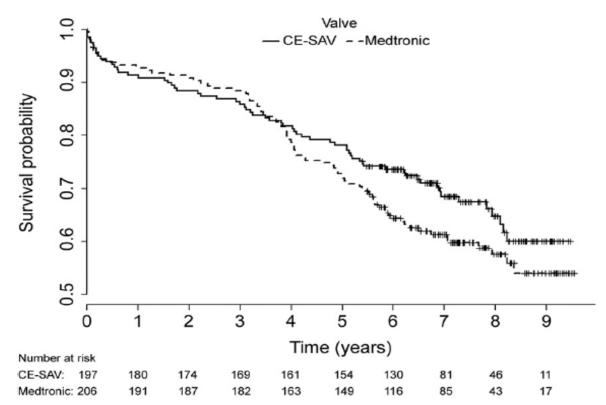


Fig 1. There is no statistically significant difference in the Kaplan-Meier plots of survival between the 2 cohorts of patients (log-rank test p = 0.147). (CE-SAV = Carpentier-Edwards supraannular aortic valve.)

Randomized Trial of Carpentier-Edwards Supraannular Prosthesis Versus Mosaic Aortic Prosthesis: 6 Year Results

Table 5. Gradients at 5 Years

Valve Size	No. of Patients With CE-SAV	Average Gradient CE-SAV (mm Hg)	No. of Patients With Mosaic Valve	Average Gradient Mosaic (mm Hg)	<i>t</i> Test <i>p</i> Value
19	7	35.3 ± 11.6	7	53.9 ± 23.3	0.082
21	21	33.1 ± 18.3	20	37.70 ± 17.2	0.417
23	23	27.4 ± 11.9	17	38.03 ± 21.2	0.052
25	5	35.9 ± 11.4	9	31.94 ± 10.3	0.512
27	8	23.5 ± 6.4	9	24.9 ± 23.2	0.867
29	5	25.382 ± 10.5	1	24.00	NA

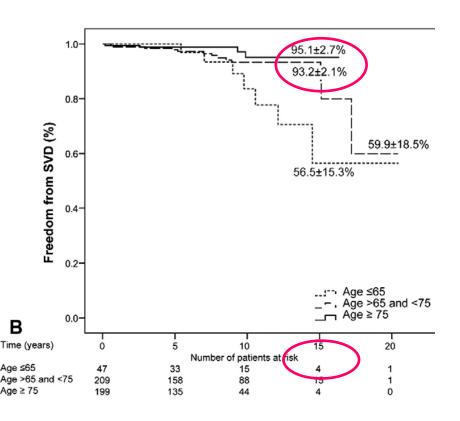
CE-SAV = Carpentier-Edwards supraannular aortic valve;

NA = not available.

Sobrevida livre de degeneração estrutural da bioprótese Ao

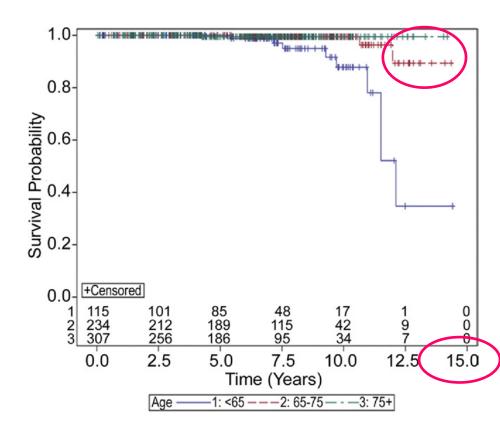
Biocor StJude porcina

Eichinger WB e cols German Heart Center Munich Ann Thorac Surg 2008;86:1204-11



Carpentier-Edwards Pericardial Bioprosthesis

McClureRS e cols, Brigham and Women's Hospital ,Harvard Medical School
Ann Thorac Surg 2010;89:1410-1416



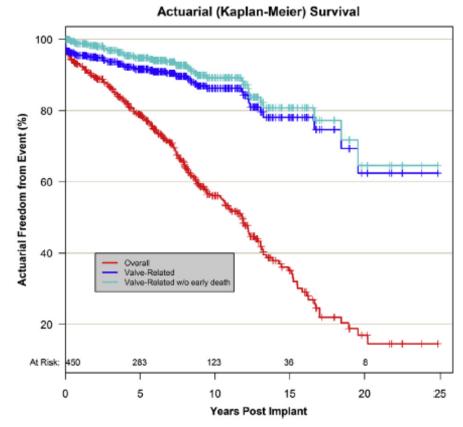


FIGURE 1. Kaplan-Meier estimates of overall and valve-related mortality.

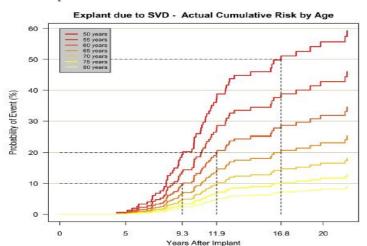


FIGURE 3. Competing risk estimates of explantation because of structural valve deterioration (SVD) stratified by age group.

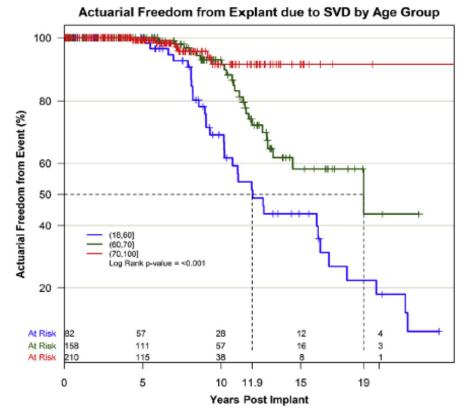


FIGURE 2. Kaplan-Meier estimates of explantation because of structural valve deterioration (SVD) stratified by age group.

Bourguignon et al

Acquired Cardiovascular Disease

Very late outcomes for mitral valve replacement with the Carpentier-Edwards pericardial bioprosthesis: 25-year follow-up of 450 implantations

1 Thorac Cardiovasc Surg 2014

Long-Term Durability of Bioprosthetic Aortic Valves: Implications From 12,569 Implants

Ann Thorac Surg 2015:99:1239-47 JOHNSTON ET AL 1
BIOPROSTHETIC AORTIC VALVE DURABILITY

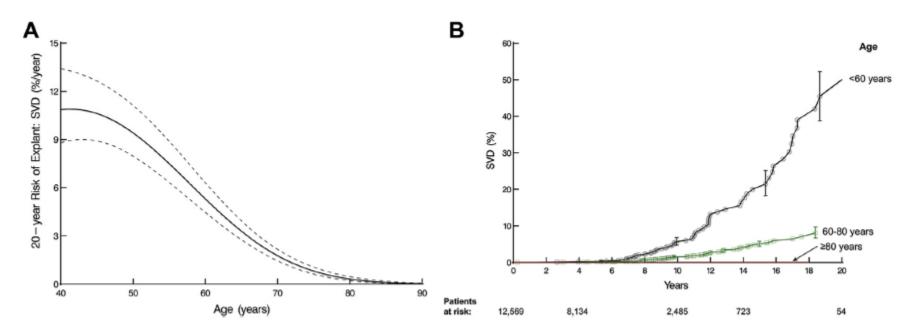


Fig 3. Age and probability of explant owing to structural valve deterioration (SVD). (A) Nomogram of age relationship to SVD from multivariable equation based on preoperative variables alone. (B) Patients are grouped according to age range. Each symbol represents an explant, vertical bars are 68% confidence limits, and numbers along the horizontal axis are patients remaining at risk.

Cleveland Clinic.
Carpentier Perimount Pericardial

1243

Endocardite Infecciosa

III 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. Recommendations about the timing of operative intervention after a stroke in the setting of IE are hindered by the lack of RCTs and reliance on single-center experiences. In early observational data, there was a significantly decreased risk of in-hospital death when surgery was performed >4 weeks after stroke (284). These data were not risk adjusted. In an observational study that did adjust for factors such as age, paravalvular abscess, and HF, the risk of in-hospital death was not significantly higher in the group who underwent surgery within 1 week of a stroke than in patients who underwent surgery ≥8 days after a stroke (285).



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 prohibitively high surgical risk for at least 4 weeks after the hemorrhagic event. One multicenter observational study (286) showed wide variation in patient deaths when those who underwent surgery within 4 weeks of a hemorrhagic stroke were compared with those whose surgery was delayed until after 4 weeks (75% versus 40%, respectively). The percentage of new bleeds postoperatively was 50% in patients whose surgery was performed in the first 2 weeks, 33% in patients whose surgery was performed at least 21 days after the neurological event (286).

Recommendation for IE Prophylaxis

COR

LOE

RECOMMENDATION

COMMENT/RATIONALE

lla

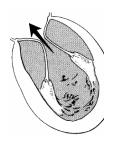
C-LD

See Online Data Supplements 1 and 2.







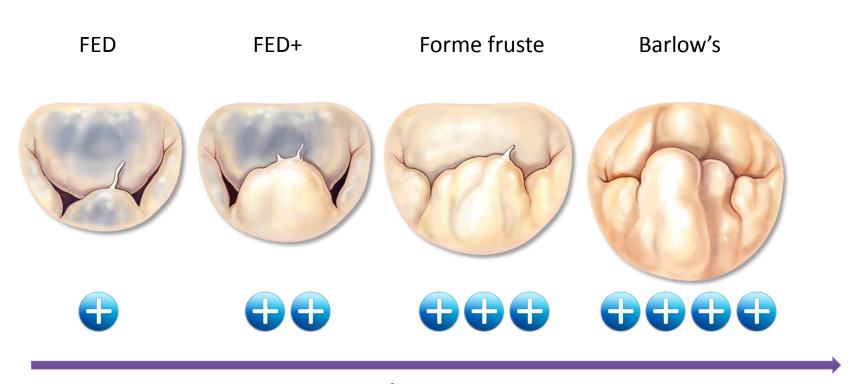


Prophylaxis against IE is reasonable before dental procedures that involve manipulation of gingival tissue, manipulation of the periapical region of teeth, or perforation of the oral mucosa in patients with the following (13,15,23–29):

- Prosthetic cardiac valves, including transcatheterimplanted prostheses and homografts.
- Prosthetic material used for cardiac valve repair, such as annuloplasty rings and chords.
- 3. Previous IE.
- 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.
- 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.

Degenerative mitral valve regurgitation



Leaflet tissue

Recomendação de "bridging"

ommenda	ations for Bridg	ging Therapy for Prosthetic Valves	
COR	LOE	RECOMMENDATIONS	COMMENT/RATIONALE
1	С	Continuation of VKA anticoagulation with a therapeutic INR is recommended in patients with mechanical heart valves undergoing minor procedures (such as dental	2014 recommendation remains current.
		extractions or cataract removal) where bleeding is easily controlled.	
1	С	Temporary interruption of VKA anticoagulation, without bridging agents while the INR is subtherapeutic, is	2014 recommendation remains current.
		recommended in patients with a bileaflet mechanical AVR and no other risk factors for thrombosis who are undergoing invasive or surgical procedures.	
lla	C-LD	Bridging anticoagulation therapy during the time interval when the INR is subtherapeutic preoperatively is reasonable	MODIFIED: COR updated from I to IIa, LOE updated from C to C-LD. RCTs of bridging anticoagulant
	a Supplement 21 014 VHD Guideline)	on an individualized basis, with the risks of bleeding weighed against the benefits of thromboembolism prevention, for patients who are undergoing invasive or	therapy versus no bridging therapy for patients with AF who do not have a mechanical heart valve have shown higher risk of bleeding without a

change in incidence of thromboembolic events. This

may have implications for bridging anticoagulation

therapy for patients with prosthetic valves.

surgical procedures with a 1) mechanical AVR and any

mechanical AVR, or 3) mechanical MVR (199,214,215).

thromboembolic risk factor, 2) older-generation

Trombose em Próteses

Recommendation for Mechanical Prosthetic Valve Thrombosis Diagnosis and Follo

COR	LOE
1	B-NR

See Online Data Supplement 7.

RECOMMENDATION

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).

Recommendation for Mechanical Prosthetic Valve Thrombosis Intervention

RECOMMENDATION

I B-NR

See Online Data
Supplement 7 and 7A.

Urgent initial treatment with either slow-infusion low-dose fibrinolytic therapy or emergency surgery is recommended for patients with a thrombosed left-sided 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.

COMMENT/RATIONALE

Mechanical left-sided prosthetic valve obstruction is a serious complication with high mortality and morbidity and requires urgent therapy with either fibrinolytic therapy or surgical intervention. There has not been an RCT comparing the 2 interventions, and the literature consists of multiple case reports, single-center studies, multicenter studies, registry reports, and meta-analyses—with all the inherent problems of differing definitions of initial diagnosis, fibrinolytic regimens, and surgical expertise (224–235) (Data Supplement 7A). The overall 30-day mortality rate with surgery is 10% to 15%, with a lower mortality rate of <5% in patients with NYHA class I/II symptoms (225,226,232–234). The results of fibrinolytic therapy before 2013 showed an overall 30-day mortality rate of 7% and hemodynamic success rate of 75% but a thromboembolism rate of 13% and major bleeding rate of 6% (intracerebral hemorrhage, 3%) (224–230). However, recent reports using an echocardiogram-guided slow-infusion low-dose fibrinolytic protocol have shown success rates >90%, with embolic event rates <2% and major bleeding rates <2% (231,235). This fibrinolytic therapy regimen can be successful even in patients with advanced NYHA class and larger-sized thrombi. On the basis of these findings, the writing group recommends urgent initial therapy for prosthetic mechanical valve thrombosis resulting in symptomatic obstruction, but the decision for surgery versus fibrinolysis is dependent on individual patient characteristics that would support the recommendation of one treatment over the other, as shown in Table 4, as well as the experience and capabilities of the institution. All factors must be taken into consideration in a decision about therapy, and the decision-making process shared between the caregiver and patient. Final definitive plans chould be based on the initial response to the same.

Recommendations for Prosthetic Valve Stenosis

COR	LOE	RECOMMENDATIONS	COMMENT/RATIONALE
1	С	Repeat valve replacement is indicated for severe symptomatic prosthetic valve stenosis (239–241).	2014 recommendation remains current.
lla	C-LD	In patients with suspected or confirmed bioprosthetic valve thrombosis who are hemodynamically stable and	NEW: Case series of patients presenting with bioprosthetic valve stenosis have suggested
See Online Dat	a Supplement 8.	have no contraindications to anticoagulation, initial treatment with a VKA is reasonable (203,242-246).	improvement in hemodynamics with VKA treatment because of resolution of thrombus on the valve leaflets.

There are no medical therapies known to prevent or treat bioprosthetic valve degeneration. However, bioprosthetic valve thrombosis may present with slowly progressive stenosis months to years after implantation. Small, nonrandomized studies support the use of VKAs to treat patients with bioprosthetic valve thrombosis after both surgical AVR and TAVR (203,242–246). In a retrospective single-center report of 31 patients with bioprosthetic valve thrombosis who were initially treated with either a VKA or surgery/thrombolysis, VKA-treated patients had 87% thrombus resolution and experienced hemodynamic and clinical improvement comparable to surgery/thrombolysis, with no complications (244). Notably, in that case series, the peak incidence of bioprosthetic valve thrombosis occurred 13 to 24 months after implantation, with the longest interval being 6.5 years (244). Surgery or thrombolysis may still be needed for patients who are hemodynamically unstable or have advanced and refractory HF, large mobile thrombus, or high risk of embolism. At present, the DOACs have not been adequately studied, nor has the U.S. Food and Drug Administration approved them for prophylaxis or treatment of prosthetic valve thrombosis.



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.

11.7.3. Intervention: Recommendation

Re	Recommendations for Prosthetic Valve Stenosis				
_	COR	LOE	RECOMMENDATIONS	COMMENT/RATIONALE	
	1	с	Repeat valve replacement is indicated for severe symptomatic prosthetic valve stenosis (239-241).	2014 recommendation remains current.	
	lla	C-LD	In patients with suspected or confirmed bioprosthetic valve thrombosis who are hemodynamically stable and	NEW: Case series of patients presenting with bioprosthetic valve stenosis have suggested	
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See Online Supplement 9.

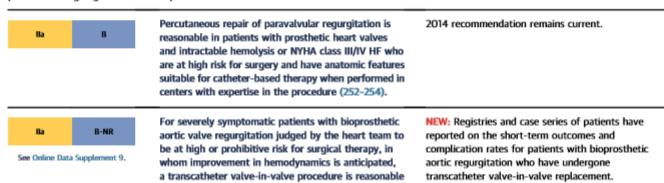
For severely symptomatic patients with bioprosthetic aortic valve stenosis judged by the heart team to be at high or prohibitive risk of reoperation, and in whom improvement in hemodynamics is anticipated, a transcatheter valve-in-valve procedure is reasonable (154,247,248).

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.

11.8. Prosthetic Valve Regurgitation

11.8.3. Intervention: Recommendations

COR	LOE	RECOMMENDATIONS	COMMENT/RATIONALE
1	В	Surgery is recommended for operable patients with mechanical heart valves with intractable hemolysis or HF due to severe prosthetic or paraprosthetic	2014 recommendation remains current.
	_	regurgitation (250,251).	
lla	C-LD	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
(Updated Fr	Supplement 23 om 2014 VHD letine)	is acceptable (241).	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.



(154,247,248).

Insuficiência mitral primária

7.3. Chronic Primary MR

7.3.3. Intervention: Recommendations



Recommendations for Chronic Primary MR Intervention			
COR	LOE	RECOMMENDATIONS	COMMENT/RATIONALE
1	В	Mitral valve surgery is recommended for symptomatic patients with chronic severe primary MR (stage D) and LVEF greater than 30% (73–75).	2014 recommendation remains current.
1	В	Mitral valve surgery is recommended for asymptomatic patients with chronic severe primary MR and LV dysfunction (LVEF 30% to 60% and/or left ventricular end-systolic diameter [LVESD] ≥40 mm, stage C2) (76–82).	2014 recommendation remains current.
1	В	Mitral valve repair is recommended in preference to MVR when surgical treatment is indicated for patients with chronic severe primary MR limited to the posterior leaflet (83–99).	2014 recommendation remains current.
1	В	Mitral valve repair is recommended in preference to MVR when surgical treatment is indicated for patients with chronic severe primary MR involving the anterior leaflet or both leaflets when a successful and durable repair can be accomplished (84,89,95,100-104).	2014 recommendation remains current.
1	В	Concomitant mitral valve repair or MVR is indicated in patients with chronic severe primary MR undergoing cardiac surgery for other indications (105).	2014 recommendation remains current.

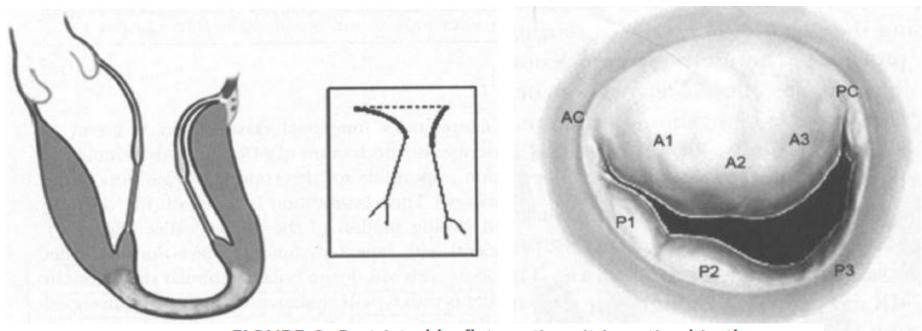


FIGURE 2. Restricted leaflet motion. It is noticed in the cross sectional view of the mitral valve that segments P3/P2 do not coapt due to restricted motion of the leaflet. Type IIIb dysfunction of Carpentier's classification. Reprinted with permission from *Am Heart Hosp J.* 2006;4:261–268.⁶



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CONCLUSÕES

Profilaxia de EI
Anticoagulação em FA
Estenose Aórtica
Insuficiência Mitral Primária
Insuficiência Mitral Secundária
Escolha da Prótese Valvar
Anticoagulação nas Próteses
Trombose de Próteses
Regurgitação em Biopróteses