

Recommandations ESC 2017 valvulopathies

A. Darif

Sténose Aortique

Indications for surgery in asymptomatic aortic stenosis

2012	2017
IIb C Markedly elevated BNP levels.	IIa C Markedly elevated BNP levels (>threefold age- and sex-corrected normal range) confirmed by repeated measurements without other explanations.
IIb C Increase of mean pressure gradient with exercise by >20 mmHg.	Taken out
IIb C Excessive LV hypertrophy in the absence of hypertension.	Taken out

2017 New recommendation

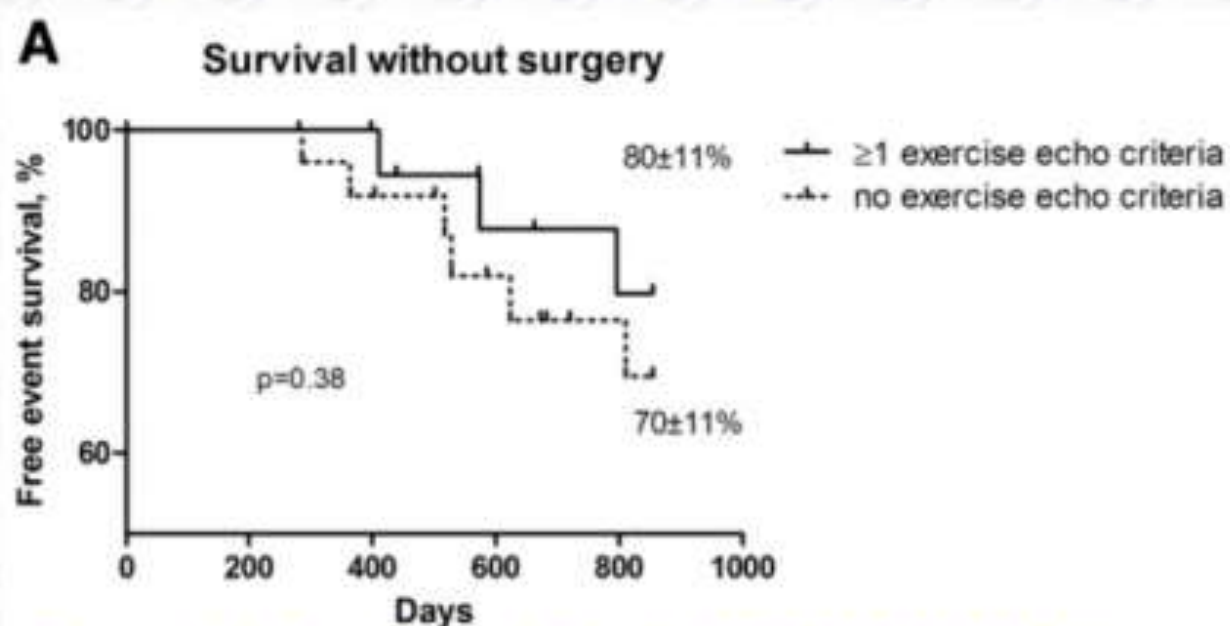
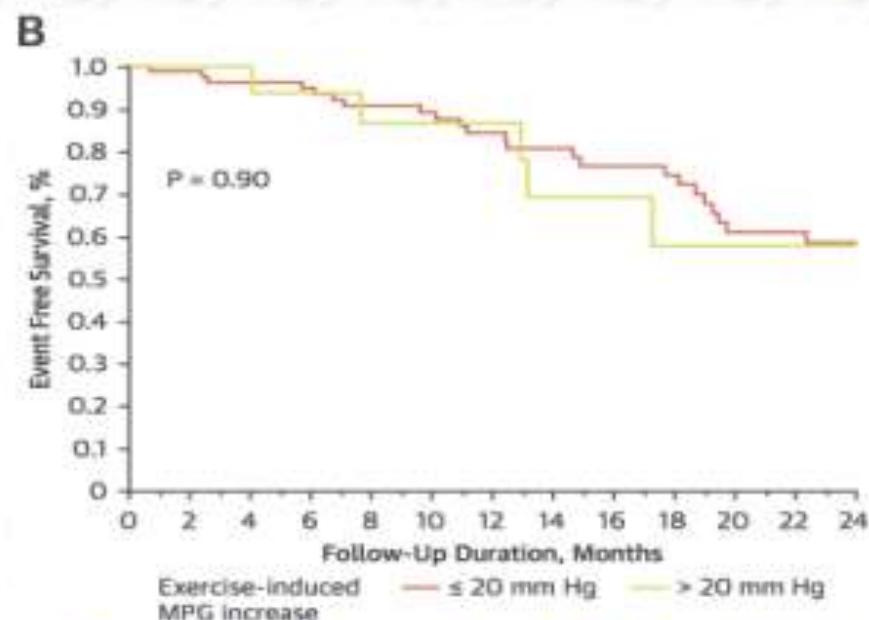
New IIa C recommendation:

Severe pulmonary hypertension (systolic pulmonary artery pressure at rest >60 mmHg confirmed by invasive measurement) without other explanation.

EXERCISE ECHOCARDIOGRAPHY IN ASYMPT. AS

112 pts., mean FU 14 months
 30 events, 25 AVR, no deaths

51 pts., mean FU 21 months
 20 events, all AVR, no deaths



Goublaire C et al JACC-Img 2017;epub Domanski O et al Int J Cardiol 2017;227:908-914

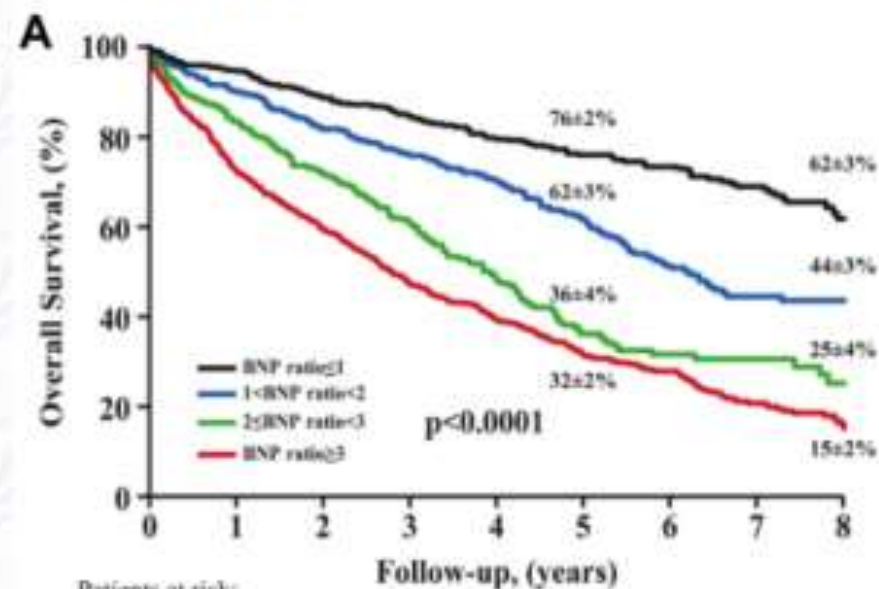
B-TYPE NATRIURETIC PEPTICIDE IN AORTIC STENOSIS

1953 pts. with at least mod. AS

40% asymptomatic

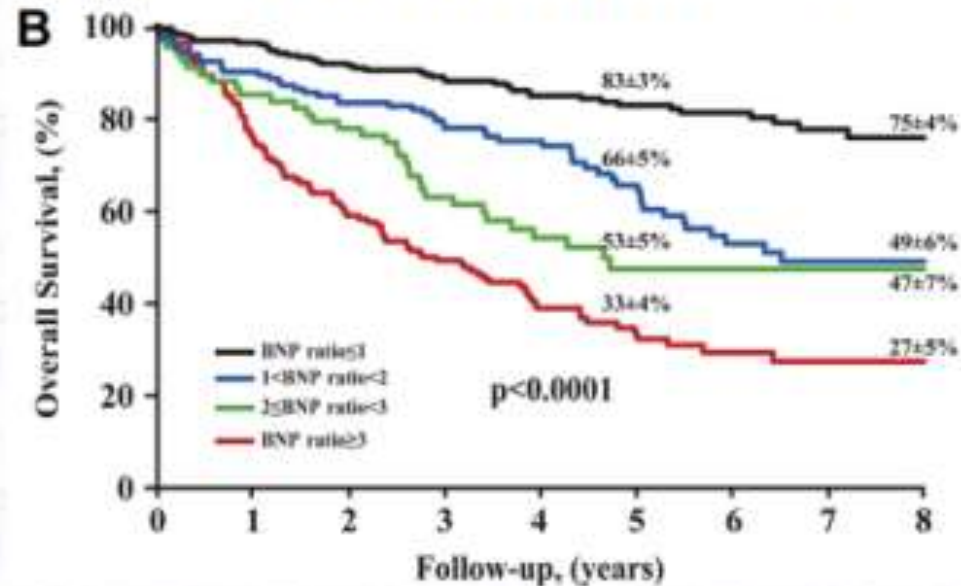
ALL PATIENTS

ASYMPTOMATIC PATIENTS



Patients at risk:

$BNP \text{ ratio} \le 1$	481	427	318	178	48
$1 < BNP \text{ ratio} < 2$	390	322	212	95	32
$2 \le BNP \text{ ratio} < 3$	226	163	88	36	13
$BNP \text{ ratio} \ge 3$	856	511	260	110	23



Clavel A et al *J Am Coll Cardiol* 2014;63:2016-25

PULMONARY HYPERTENSION IN AORTIC STENOSIS

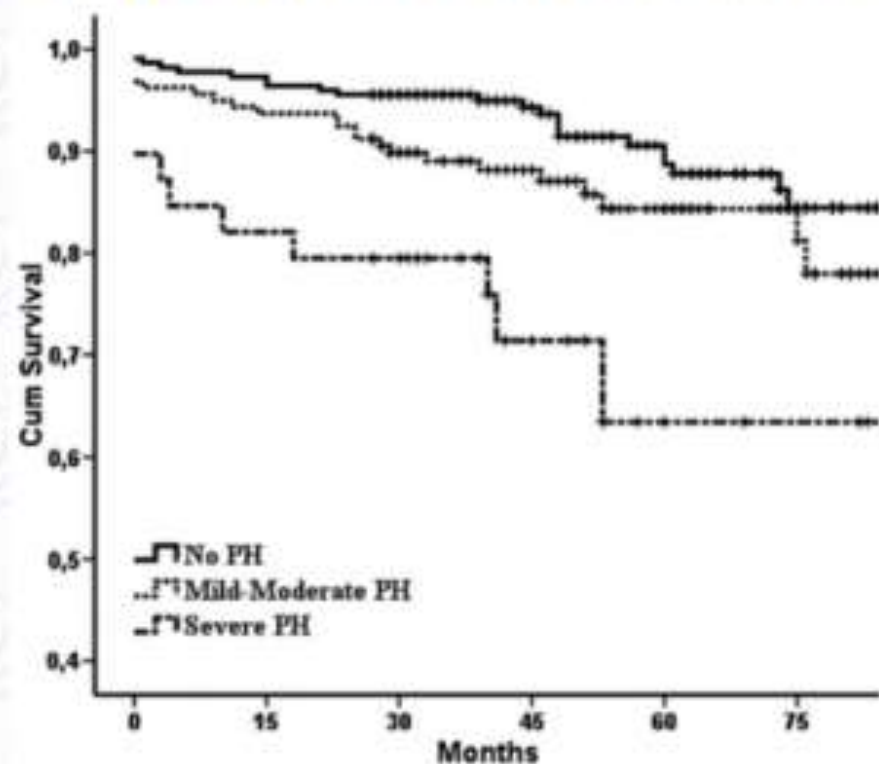


Fig. 1. Kaplan-Meier survival curve according to preoperative PH grade.

Adjusted Survival by Pulmonary Hypertension Group

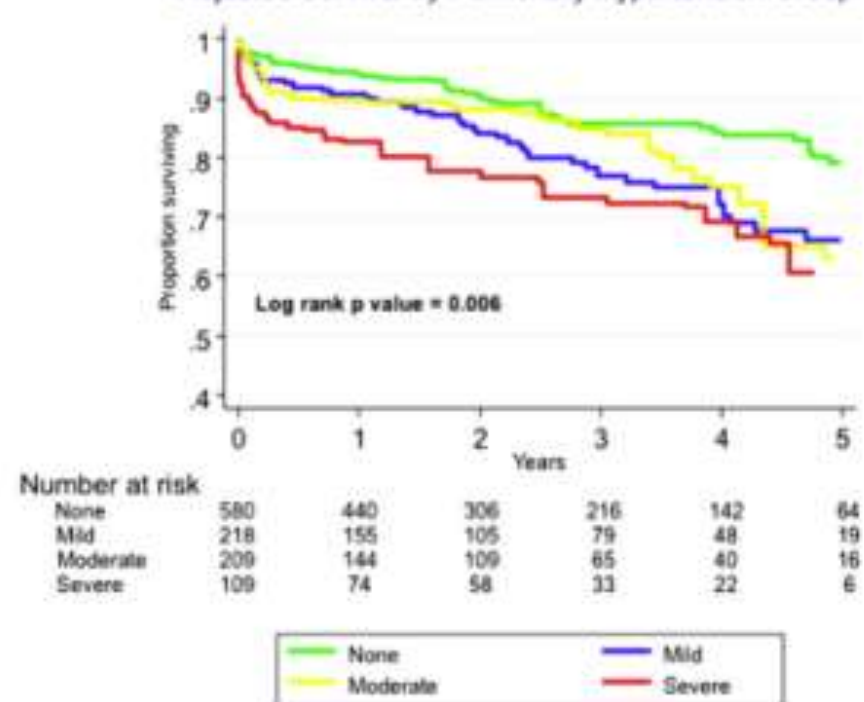


Figure 1. Kaplan-Meier curves for risk-adjusted survival of patients after AVR based on preoperative PH.

Miceli A et al *Int J Cardiol* 2013;168:3556–9

Zlotnick DM et al *Am J Cardiol* 2013;112:1635–

Changes in recommendations	
2012	2017
Indications for intervention in symptomatic aortic stenosis	
IIb C Intervention may be considered in symptomatic patients with low-flow, low-gradient aortic stenosis and reduced ejection fraction without flow (contractile) reserve.	IIa C Intervention should be considered in symptomatic patients with low-flow, low-gradient aortic stenosis and reduced ejection fraction without flow (contractile) reserve, particularly when CT calcium scoring confirms severe aortic stenosis.

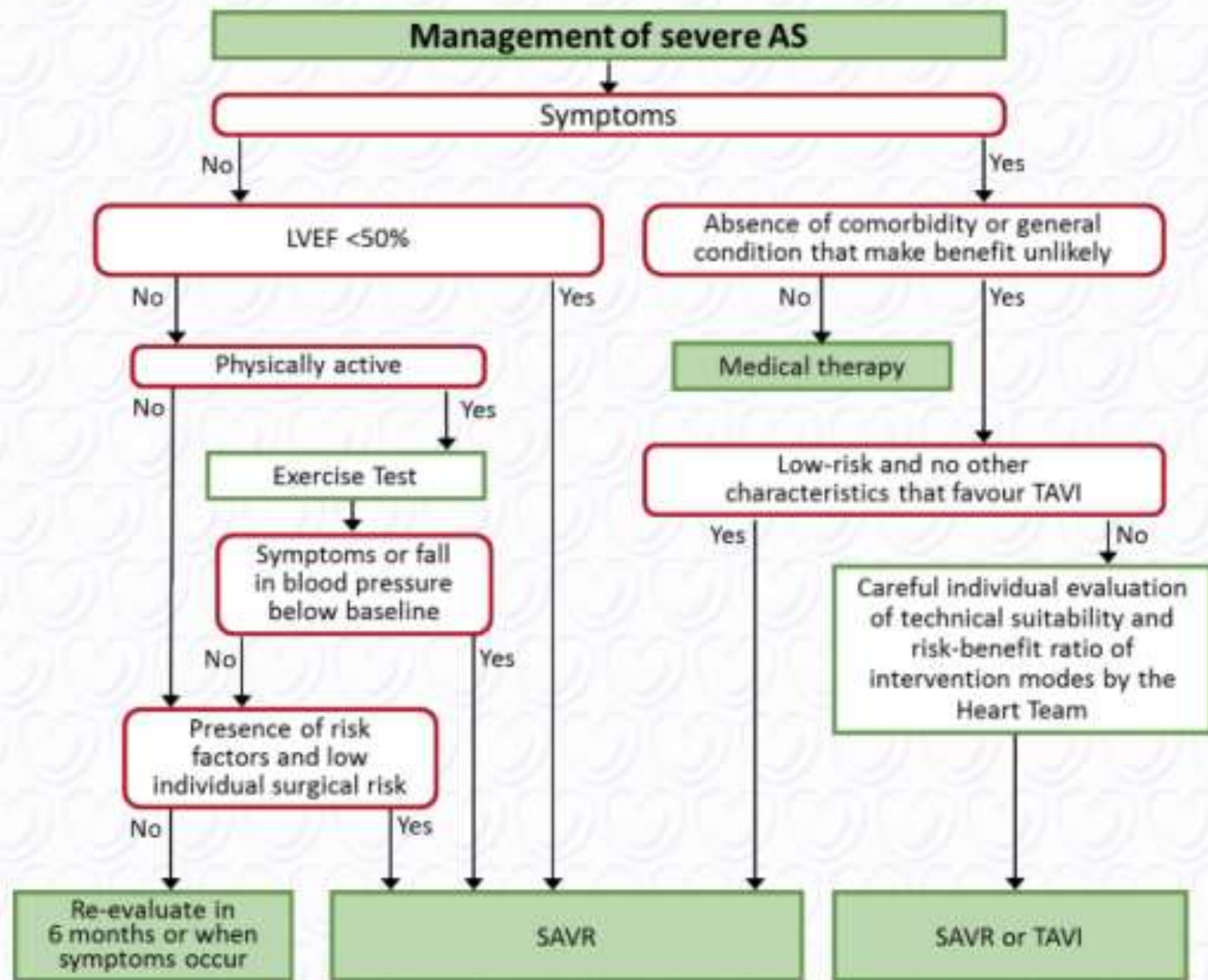
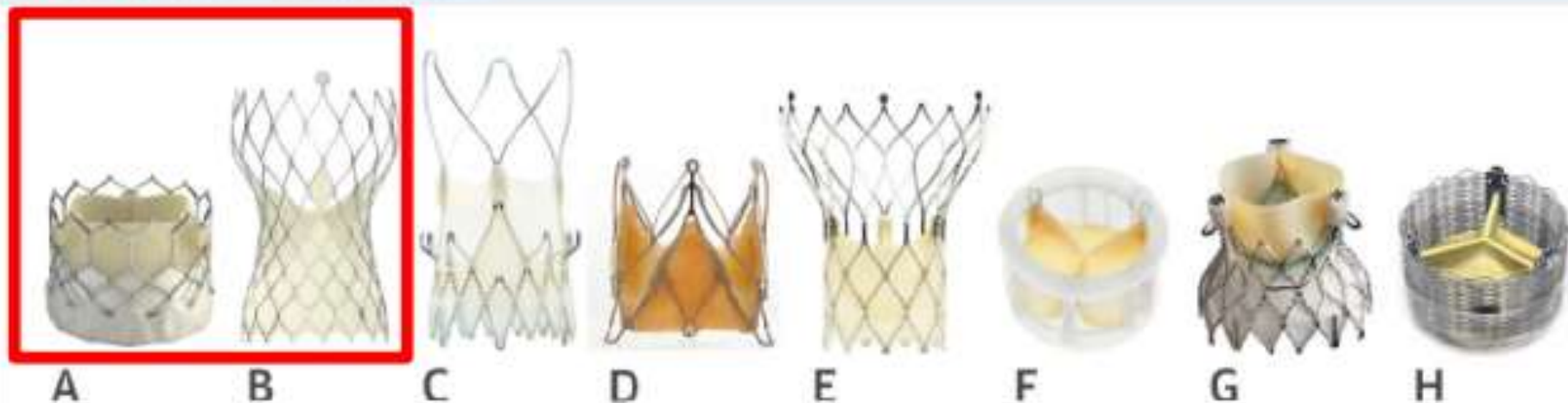


FIGURE 3 Overview of TAVR Systems

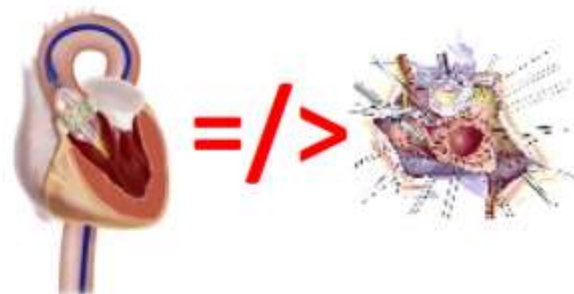
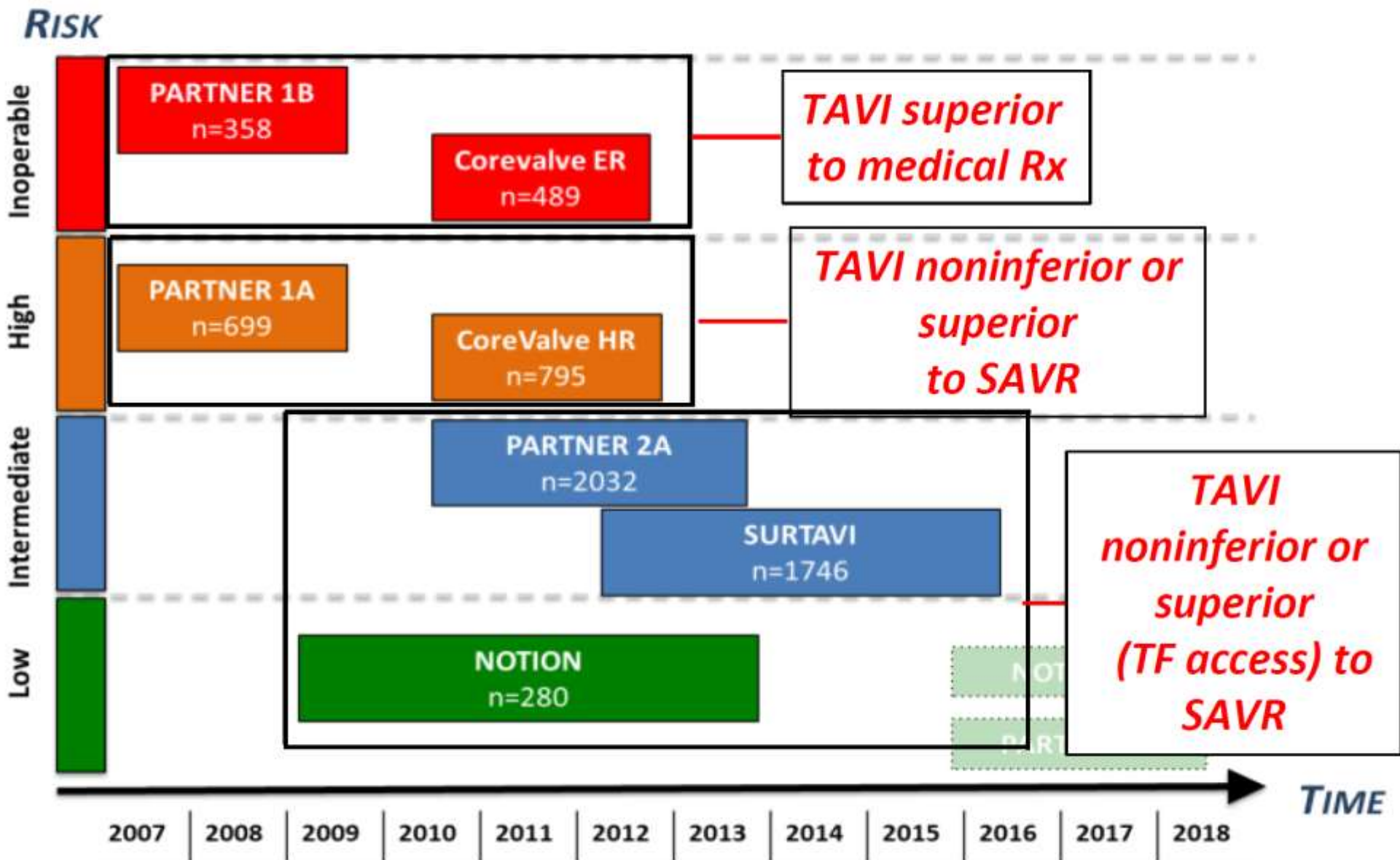


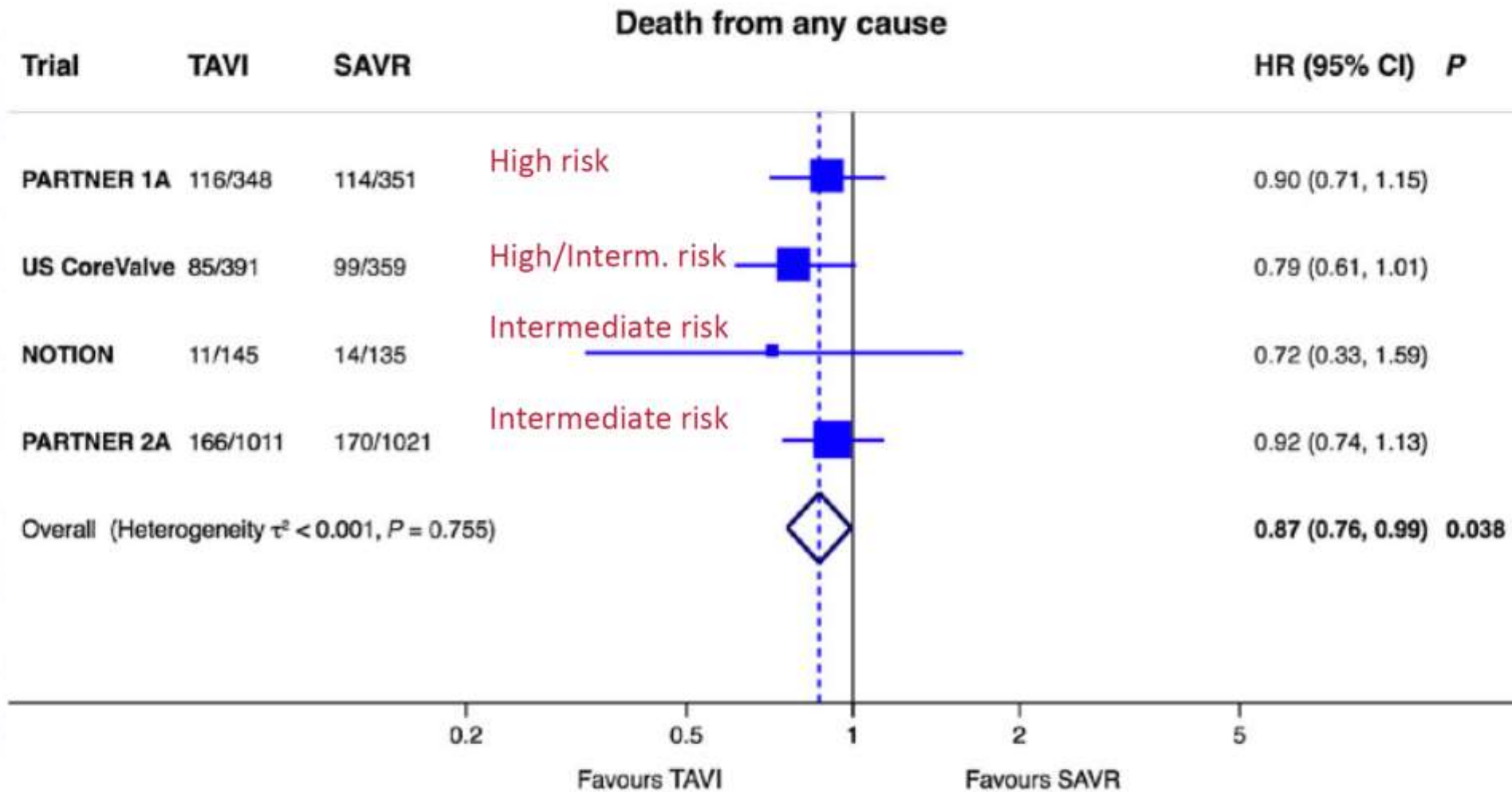
5 randomized trials
1 meta-analysis
Large registries

Systems are commercially available in Europe (A-H), whereas 2 TAVR systems are available in the United States (A, B). (A) Edwards Lifesciences Sapien 3 Valve (Edwards Lifesciences, Irvine, California); (B) Edwards Lifesciences Sapien 3 Valve (Edwards Lifesciences, Irvine, California); (C) Symetis Acurate neo Valve (Symetis, Ecublens, Switzerland); (D) Medtronic CoreValve Pro (Medtronic, Minneapolis, Minnesota); (E) St. Jude Medical Portico Valve (St. Jude Medical, Inc., Santa Rosa, California); (F) Medtronic CoreValve Pro (Medtronic, Minneapolis, Minnesota); (G) Medtronic Engager Valve (Medtronic, Minneapolis, Minnesota); (H) Lotus Valve (Boston Scientific, Marlborough, Massachusetts).

Vahl T et al J Am Coll Cardiol 2016;67:1472-87

PERFORMANCE OF TAVI ACROSS RISK CATEGORIES

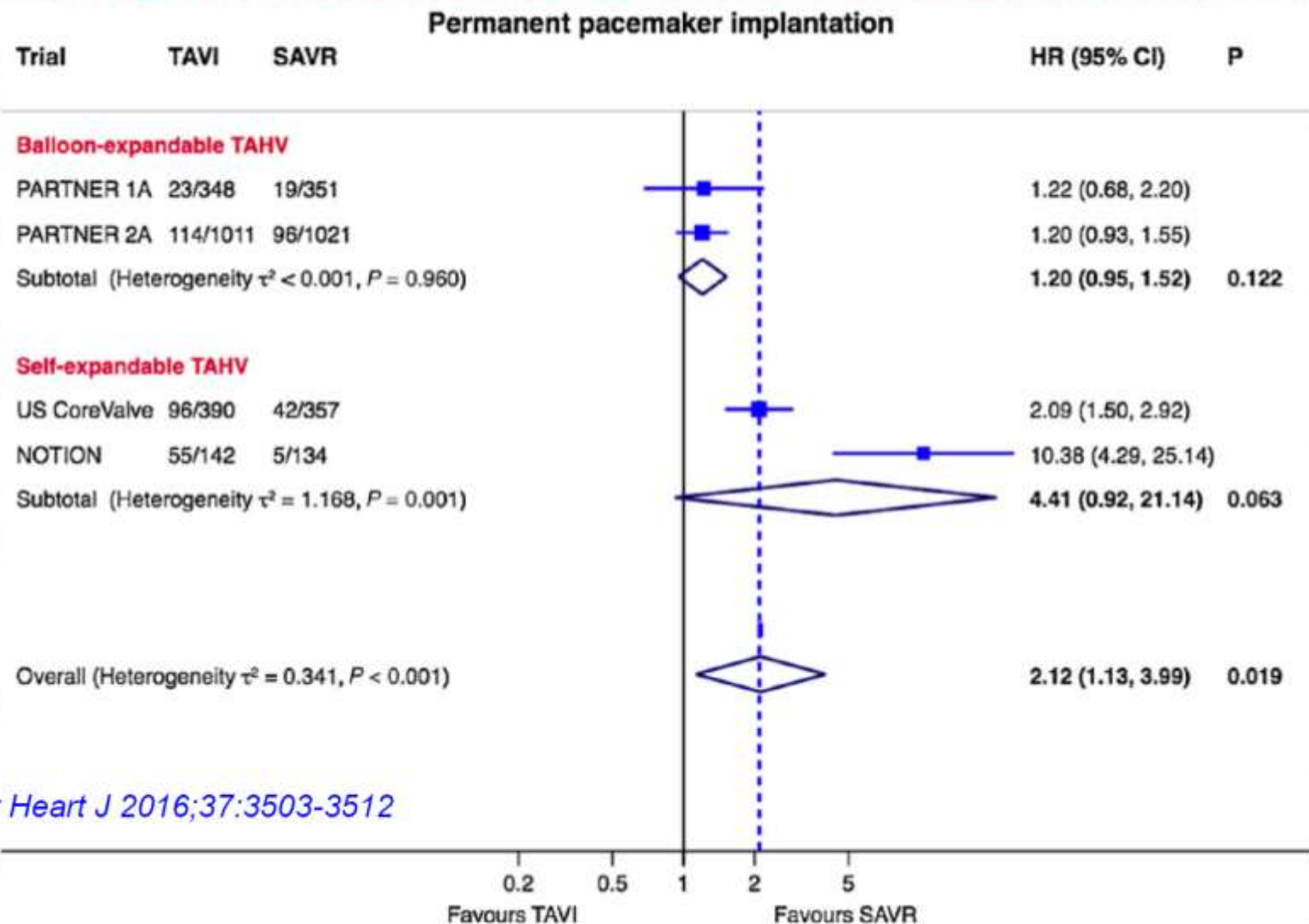




Siontis GCM et al Eur Heart J 2016;37:3503-3512

2017 ESC/EACTS Valvular Heart Disease GL

AORTIC STENOSIS: TAVI vs. SAVR



Siontis GCM et al *Eur Heart J* 2016;37:3503-3512

2012

CHOICE OF INTERVENTION

2017

Recommendations	Class	Level
TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR as assessed by a 'heart team' and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities	I	B
TAVI should be considered in high-risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a 'heart team' based on the individual risk profile and anatomic suitability	Ila	B

Extreme Risk

High Risk

Increased Risk

Low Risk

Recommendations	Class	Level
TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team	I	B
In patients who are at increased surgical risk (STS or EuroSCORE II $\geq 4\%$ or logistic EuroSCORE I $\geq 10\%$, or other risk factors not included in these scores such as frailty, porcelain aorta, sequelae of chest radiation), the decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics <u>with TAVI being favoured in elderly patients suitable for transfemoral access</u>	I	B
SAVR is recommended in patients at low surgical risk (STS or EuroSCORE II $< 4\%$ or logistic EuroSCORE I $< 10\%$ and no other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation)	I	B

Insuffisance Aortique

2017 New recommendations

Indications for surgery in severe aortic regurgitation and aortic root disease

New I C recommendations:

- * Patients with pliable non-calcified tricuspid or bicuspid valves who have a type I (enlargement of the aortic root with normal cusp motion) or type II (cusp prolapse) mechanism of AR.
- Aortic valve repair, using the reimplantation or remodelling with aortic annuloplasty technique, is recommended in young patients with aortic root dilation and tricuspid aortic valves, when performed by experienced surgeons.

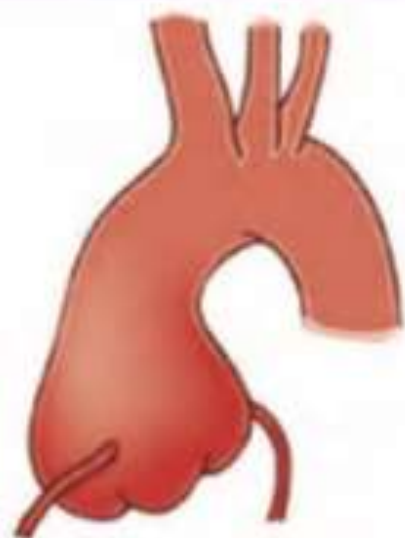
New IIa C recommendation:

Surgery should be considered in patients who have aortic root disease with maximal ascending aortic diameter: ≥ 45 mm in patients with a *TGFBR1* or *TGFBR2* mutation (including Loeys-Dietz syndrome)*.

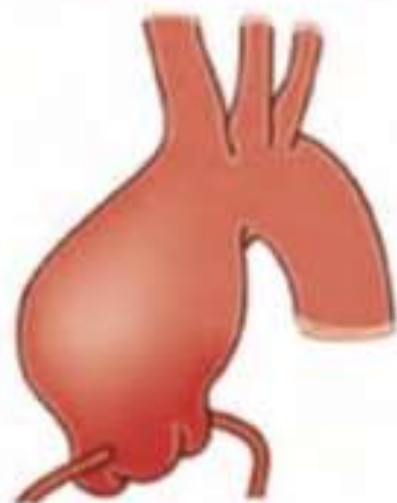
* A lower threshold of 40 mm may be considered in women with low BSA, in patients with a *TGFBR2* mutation, or in patients with severe extra-aortic features.

EVALUATION

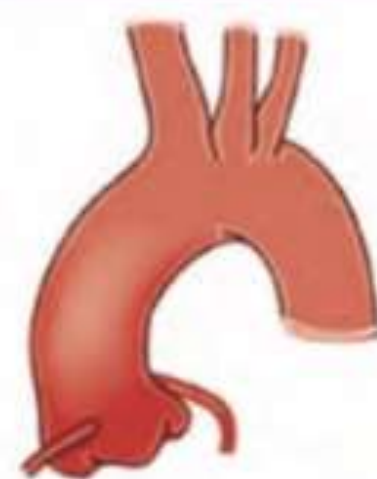
Phenotypes of the aortic root and ascending aorta



Aortic root aneurysm
Sinuses of valsalva ≥ 45 mm



Tubular ascending aorta aneurysm
Sinuses of valsalva ≤ 40 mm

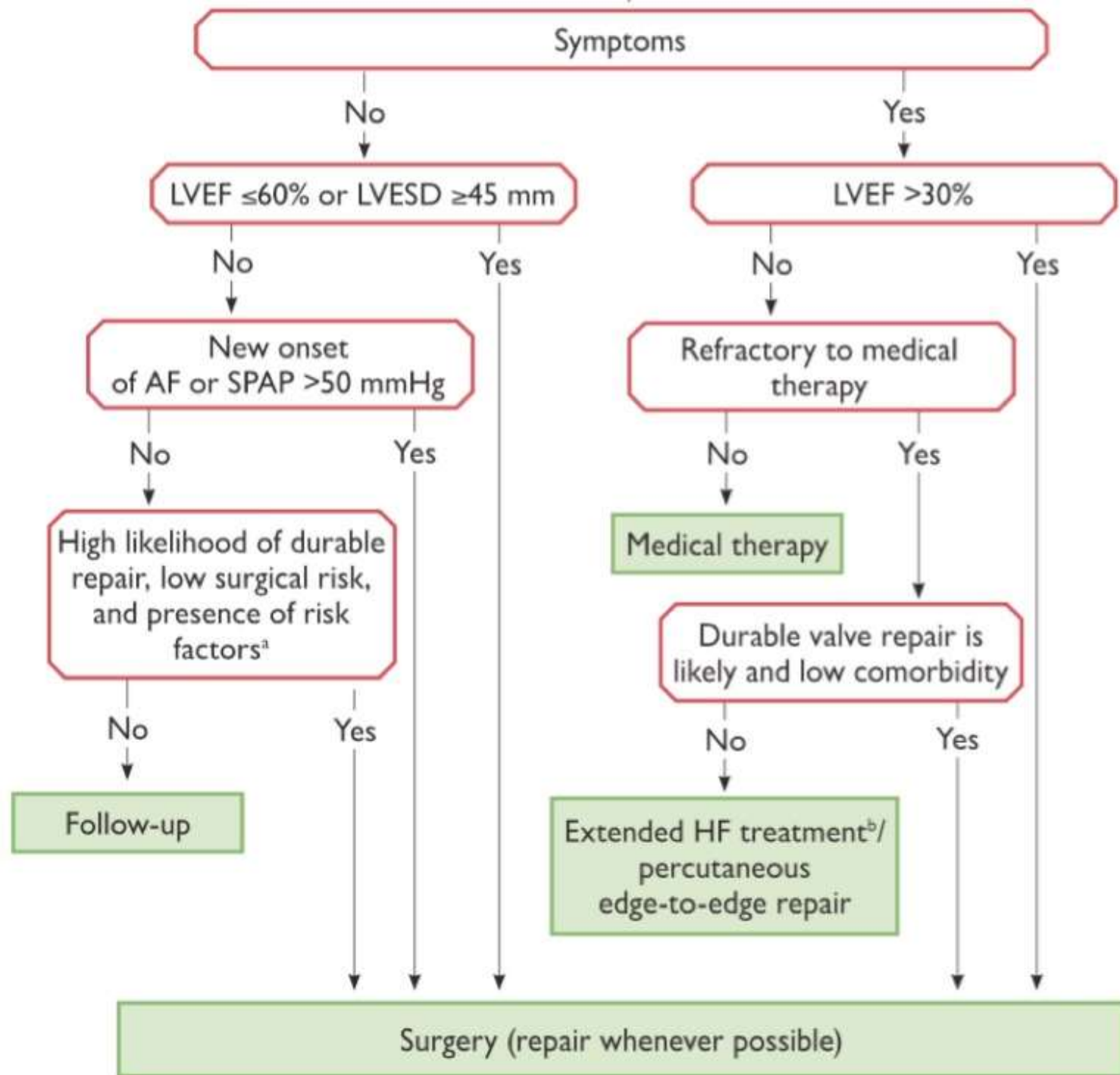


Isolated AR
All diameters < 40 mm

Insuffisance Mitrale

What is new in the 2017 Valvular Heart Disease Guidelines?

Changes in recommendations	
2012	2017
Indications for intervention in asymptomatic severe primary mitral regurgitation	
IIb C Surgery may be considered in asymptomatic patients with preserved LV function, high likelihood of durable repair, low surgical risk, and: <ul style="list-style-type: none"> • Left atrial dilatation (volume index ≥ 60 mL/m² BSA) and sinus rhythm. 	IIa C (modified!) Surgery should be considered in asymptomatic patients with preserved LVEF (>60%) and LVESD 40–44 mm when a durable repair is likely, surgical risk is low, the repair is performed in heart valve centres, and the following finding is present: presence of significant LA dilatation (volume index ≥ 60 mL/m ² BSA) in sinus rhythm.
Pulmonary hypertension on exercise (SPAP ≥ 60 mmHg at exercise).	Taken out



What is new in the 2017 Valvular Heart Disease Guidelines?

Changes in recommendations	
2012	2017
Indications for mitral valve intervention in secondary mitral regurgitation	
IIa C Surgery should be considered in patients with moderate secondary mitral regurgitation undergoing CABG	Taken out

What is new in the 2017 Valvular Heart Disease Guidelines?

Changes in recommendations

2012

2017

Indications for mitral valve intervention in secondary mitral regurgitation (*continued*)

Additional statement:

The lower thresholds defining severe MR compared to primary MR are based on their association with prognosis. However, it is unclear if prognosis is independently affected by MR compared to LV dysfunction. For isolated mitral valve treatment in secondary MR, thresholds of severity of MR for intervention still need to be validated in clinical trials. So far, no survival benefit has been confirmed for reduction of secondary MR.

Echocardiographic criteria for the definition of severe valve regurgitation: an integrative approach *(continued)*

(Adapted from Lancellotti et al.)

	Mitral regurgitation	
Quantitative	Primary	Secondary
EROA (mm ²)	≥40	≥20
Regurgitant volume (mL/beat)	≥60	≥30
+ enlargement of cardiac chambers/vessels	LV, LA	

What is new in the 2017 Valvular Heart Disease Guidelines?

Changes in recommendations	
2012	2017
Indications for mitral valve intervention in secondary mitral regurgitation	
IIa C Surgery should be considered in patients with moderate secondary mitral regurgitation undergoing CABG	Taken out
IIb C When revascularization is not indicated, surgery may be considered in patients with severe secondary mitral regurgitation and LVEF >30%, who remain symptomatic despite optimal medical management (including CRT if indicated).	
	IIb C (modified) When revascularization is not indicated, surgery may be considered in patients with severe secondary mitral regurgitation and LVEF >30%, who remain symptomatic despite optimal medical management (including CRT if indicated) and have a <u>low surgical risk</u> .

Changes in recommendations	
2012	2017
Indications for mitral valve intervention in secondary mitral regurgitation (<i>continued</i>)	
	IIb C (modified) (<i>continued</i>) When revascularization is not indicated and <u>surgical risk is not low</u> , a percutaneous edge-to-edge procedure may be considered in patients with severe secondary mitral regurgitation and <u>LVEF >30%</u> , who remain symptomatic despite optimal medical management (including CRT if indicated) and who have a suitable valve morphology by echocardiography, avoiding futility.

The current landscape of TMVR

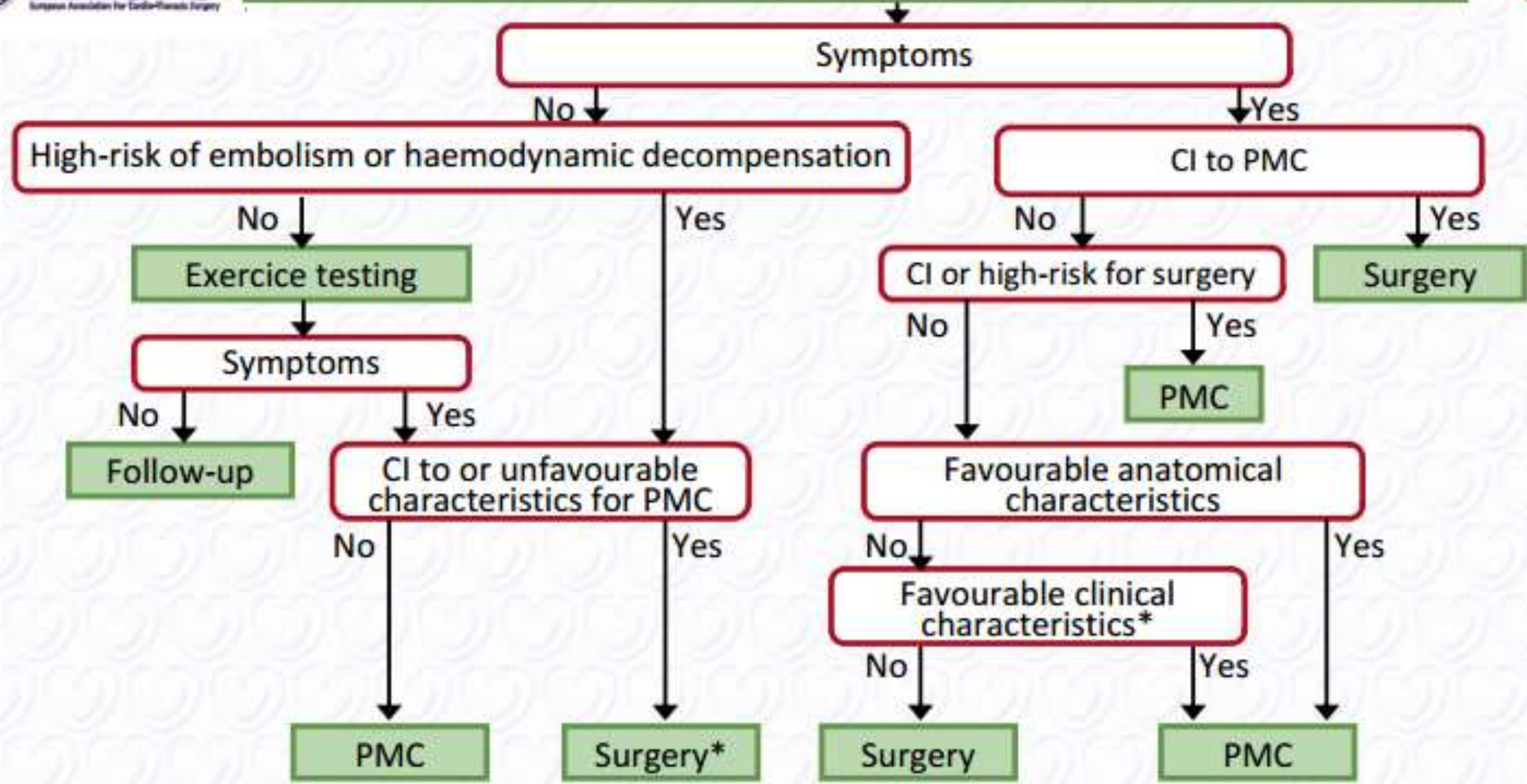
six devices currently actively involved in clinical trials

Company	Neovasc Inc, Richmond, BC	Edwards Lifesciences, Irvine, CA	Tendyne Holding Inc, Roseville, MN	Medtronic, Muncie, MN	HighLife SAS, Paris, France	Caisson Interventional, Maple Grove, MN
Valve Name	Tiara	CardIAQ	Tendyne	Intrepid	HighLife	Caisson
Device Image						
Description	- Self-expanding prosthesis - bovine pericardium	- Self-expanding prosthesis - bovine pericardium	- Self-expanding prosthesis - porcine pericardium	- Self-expanding prosthesis - bovine pericardium	- Self-expanding prosthesis - bovine pericardium	- Self-expanding prosthesis - porcine pericardium
Access	TA	TA/TF	TA	TA	TA (valve) and TF (ring)	TF
Specific characteristics	- D shape inner design - Ridge fixation	- TF - Leaflet and radial force fixation	- tethered	- High-tensile self-cloth	- Tensile component	- Tensile component
Status*	• About 19 patients	• About 13 patients	• About 30 patients	• About 30 patients	• About 30 patients	• About 30 patients

Challenges for TMVR:

- Safe anchorage in mitral annulus
- Avoid LVOT obstruction
- Mostly transapical access

Management of clinically significant mitral stenosis (MVA <1.5 cm²)

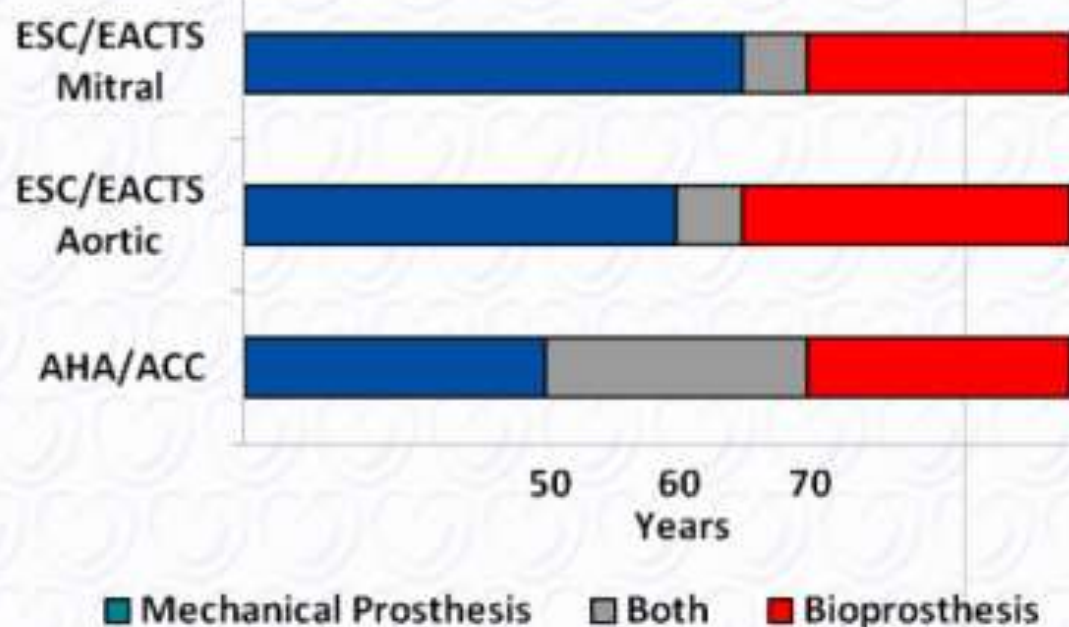


See table of recommendations *If symptoms occur for a low level of exercise and operative risk is low

Choix de prothèse

Age thresholds and choice of the type of prosthesis

IIa	B-NR	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.
See Online Data Supplement 20 (Updated From 2014 VHD Guideline)			
IIa	B-NR	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 2014 recommendation remains current.
See Online Data Supplement 20 (Updated From 2014 VHD Guideline)			
IIa	B	A bioprosthesis is reasonable for patients more than 70 years of age (163-166).	



(Nishimura et al. J Am Coll Cardiol 2017;70:252-89)

Traitement anticoagulant

Indications for antithrombotic therapy for mechanical prostheses

Recommendations	Class	Level
Mechanical prosthesis		
Oral anticoagulation using a VKA is recommended lifelong for all patients.	I	B
Bridging using therapeutic doses of UFH or LMWH is recommended when VKA treatment should be interrupted.	I	C
The addition of low-dose aspirin (75-100 mg/day) to VKA should be considered after thromboembolism despite an adequate INR.	IIa	C
The addition of low-dose aspirin (75-100 mg/day) to VKA may be considered in the case of concomitant atherosclerotic disease.	IIb	C
INR self-management is recommended provided appropriate training and quality control are performed.	I	B

New

New

Indications for antithrombotic therapy for mechanical prostheses *(continued)*

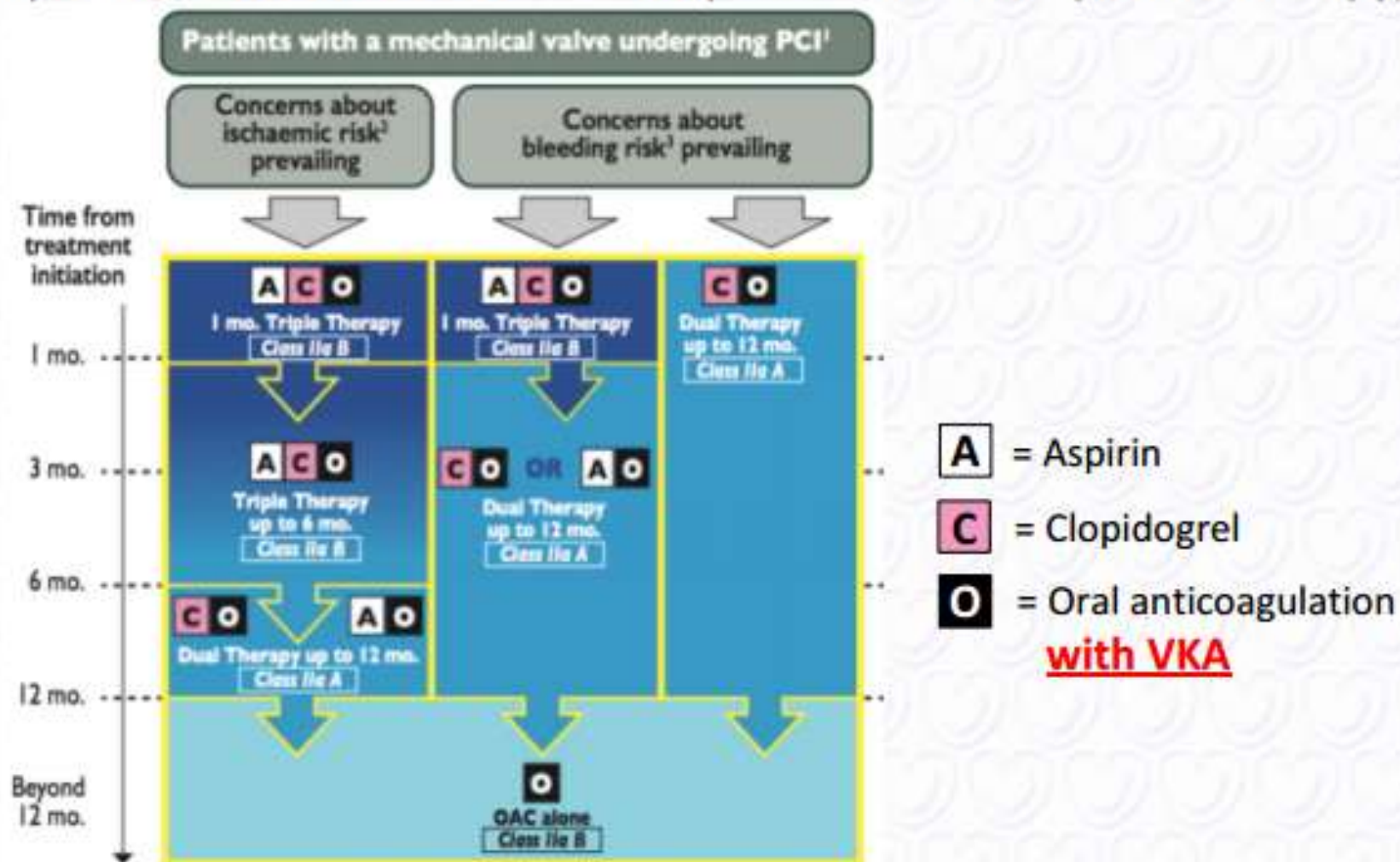
Recommendations	Class	Level	
Mechanical prosthesis			
In patients treated with coronary stent implantation, triple therapy with aspirin (75-100 mg/day), clopidogrel (75 mg/day), and VKA should be considered for 1 month, irrespective of the type of stent used and the clinical presentation (i.e. ACS or stable CAD).	IIa	B	New
Triple therapy comprising aspirin (75-100 mg/day), clopidogrel (75 mg/day), and VKA for longer than 1 month and up to 6 months should be considered in patients with high ischaemic risk due to ACS or other anatomical/procedural characteristics that outweigh the bleeding risk.	IIa	B	New

Indications for antithrombotic therapy for mechanical prostheses *(continued)*

Recommendations	Class	Level	
Mechanical prosthesis <i>(continued)</i>			
Dual therapy comprising VKA and clopidogrel (75 mg/day) should be considered as an alternative to 1-month triple antithrombotic therapy in patients in whom the bleeding risk outweighs the ischaemic risk.	IIa	A	New
In patients who have undergone PCI, discontinuation of antiplatelet treatment should be considered at 12 months.	IIa	B	New
In patients requiring aspirin and/or clopidogrel in addition to VKA, the dose intensity of VKA should be carefully regulated with a target INR in the lower part of the recommended target range and a time in therapeutic range >65-70%.	IIa	B	New
The use of NOACs is contra-indicated.	III	B	New

Antithrombotic therapy in patients with mechanical valve prosthesis undergoing PCI

(Adapted from the 2017 ESC Focused Update on Dual Antiplatelet Therapy)



Indications for antithrombotic therapy for bioprostheses *(continued)*

Recommendations	Class	Level
Bioprostheses <i>(continued)</i>		
Dual antiplatelet therapy should be considered for the first 3-6 months after TAVI, followed by lifelong single antiplatelet therapy in patients who do not need oral anticoagulation for other reasons.	IIa	C
Single antiplatelet therapy may be considered after TAVI in the case of high bleeding risk.	IIb	C
Oral anticoagulation may be considered for the first 3 months after surgical implantation of an aortic bioprosthesis.	IIb	C

New
New

INR cibles

Prosthesis thrombogenicity	Patient-related riskfactors ^a	
	None	≥1 risk factor
Low ^b	2.5	3.0
Medium ^c	3.0	3.5
High ^d	3.5	4.0

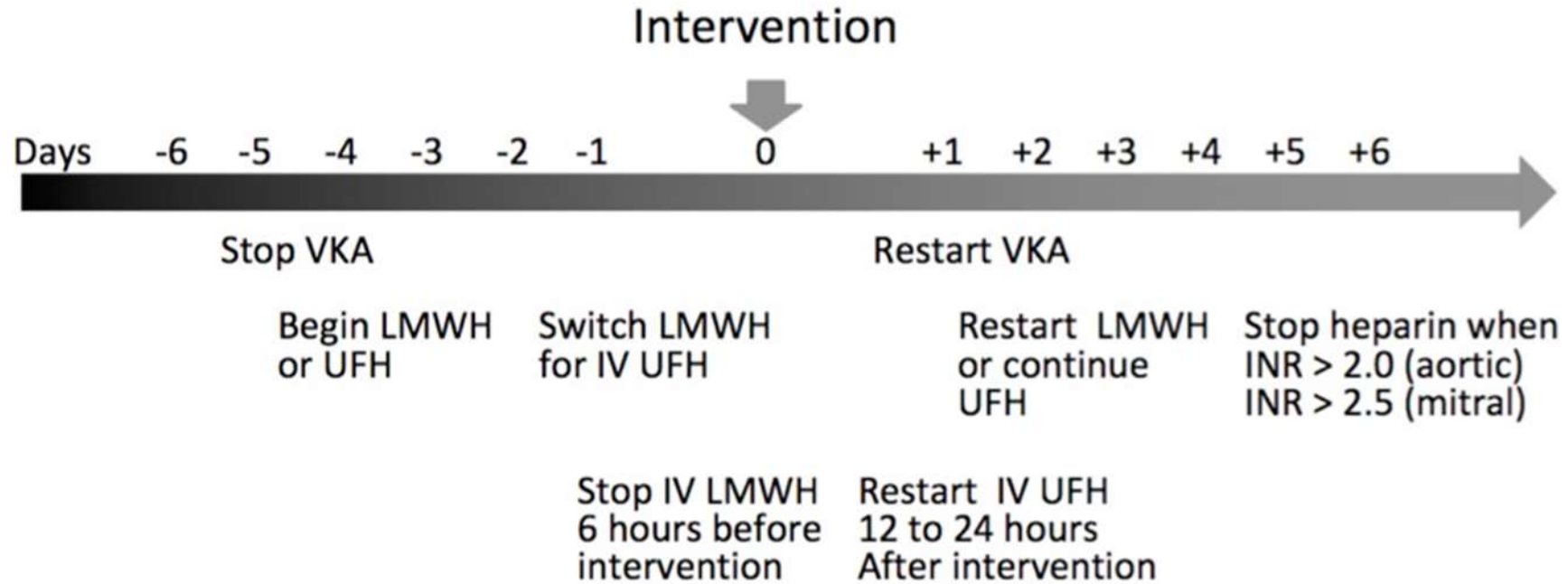
^a Mitral or tricuspid valve replacement, previous thromboembolism, atrial fibrillation, mitral stenosis of any degree, LVEF <35%

^b Carbomedics, Medtronic Hall, ATS, Medtronic Open-Pivot, St. Jude Medical, On-X, Sorin Bicarbon

^c Other bileaflet valves with insufficient data

^d Lillehei-Kaster, Omniscience, Starr-Edwards (ball-cage), Björk-Shiley and other tilting-disc valves

Schéma de bridge



Dysfonction de prothèse

Recommendations	Class	Level
Bioprosthetic thrombosis		
Anticoagulation using a VKA and/or UFH is recommended in bioprosthetic valve thrombosis before considering reintervention.	I	C
Haemolysis and paravalvular leak		
Reoperation is recommended if paravalvular leak is related to endocarditis or causes haemolysis requiring repeated blood transfusions or leading to severe symptoms.	I	C
Transcatheter closure may be considered for paravalvular leaks with clinically significant regurgitation in surgical high-risk patients (Heart Team decision).	IIb	C

New

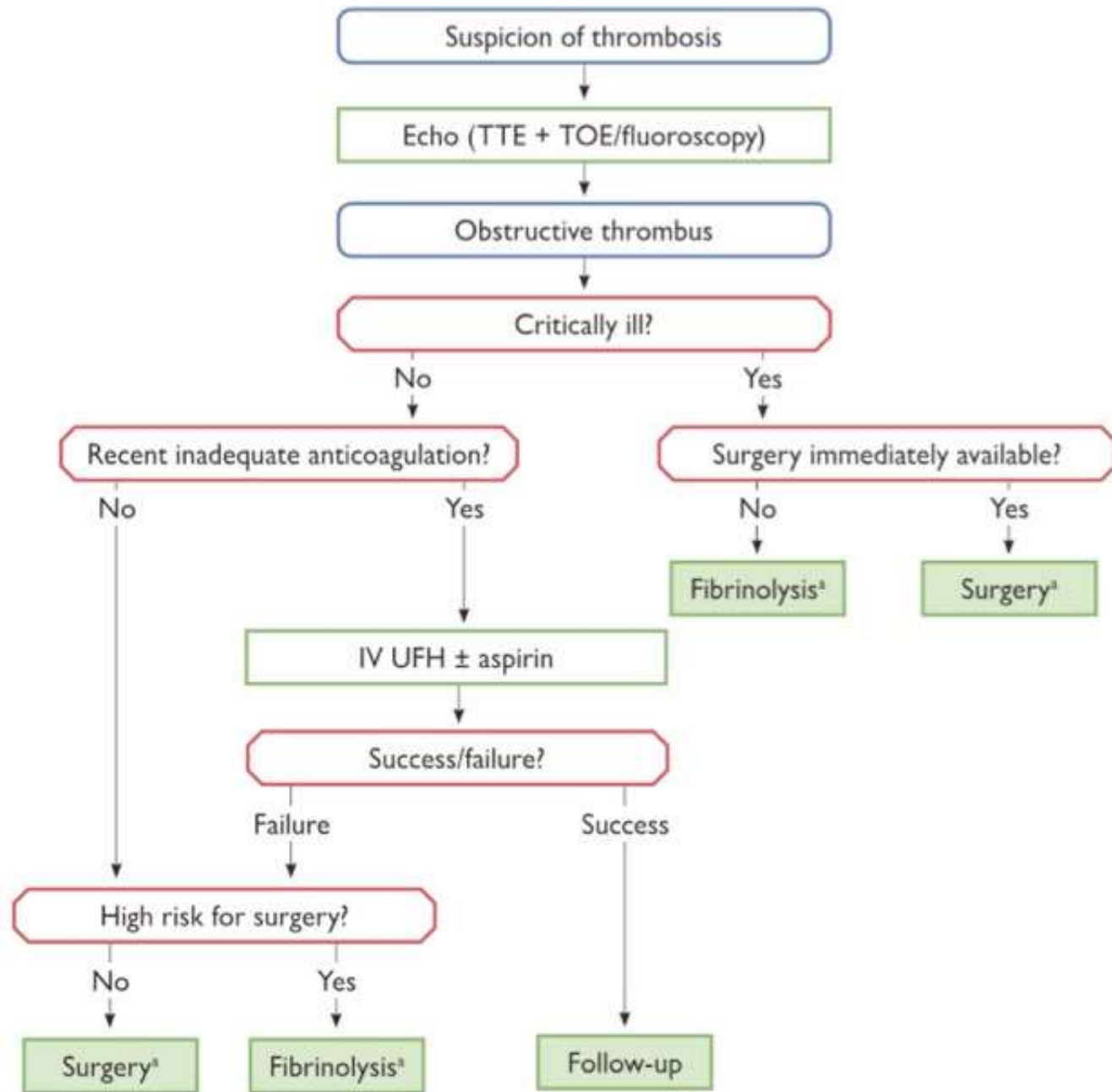
New

Management of prosthetic valve dysfunction *(continued)*

Recommendations	Class	Level
Bioprosthetic failure		
Reoperation is recommended in symptomatic patients with a significant increase in transprosthetic gradient (after exclusion of valve thrombosis) or severe regurgitation.	I	C
Reoperation should be considered in asymptomatic patients with significant prosthetic dysfunction, if reoperation is at low-risk.	IIa	C
Transcatheter valve-in-valve implantation in aortic position should be considered by the Heart Team depending on the risk of reoperation and the type and size of prosthesis.	IIa	C

New

Thrombosis obstructive



Thrombosis non obstructive

