

ESC/EACTS Guidelines for the Management of Valvular Heart Disease

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Guidelines on the management of valvular heart disease (version 2012)

The Joint Task Force on 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: Alec Vahanian (Chairperson) (France), Ottavio Alfieri (Chairperson) (Italy), Felicità Andreotti (Italy), Manuel J. Antunes (Portugal), Gonzalo Barón-Esquivias (Spain), Helmut Baumgartner (Germany), Michael Andrew Borger (Germany), Thierry P. Carrel (Switzerland), Michele De Bonis (Italy), Arturo Evangelista (Spain), Volkmar Falk (Switzerland), Bernard Jung (France), Patrizio Lancellotti (Belgium), Luc Pierard (Belgium), Susanna Price (UK), Hans-Joachim Schäfers (Germany), Gerhard Schuler (Germany), Janina Stepinska (Poland), Karl Swedberg (Sweden), Johanna Takkenberg (The Netherlands), Ulrich Otto Von Oppell (UK), Stephan Windecker (Switzerland), Jose Luis Zamorano (Spain), Marian Zembala (Poland)

ESC Committee for Practice Guidelines (CPG): Jeroen J. Bax (Chairperson) (The Netherlands), Helmut Baumgartner (Germany), Claudio Ceconi (Italy), Veronica Dean (France), Christi Deaton (UK), Robert Fagard (Belgium), Christian Funck-Brentano (France), David Hasdai (Israel), Arno Hoes (The Netherlands), Paulus Kirchhof (United Kingdom), Juhani Knuuti (Finland), Philippe Kolh (Belgium), Theresa McDonagh (UK), Cyril Moulin (France), Bogdan A. Popescu (Romania), Željko Reiner (Croatia), Udo Sechtem (Germany), Per Anton Simnes (Norway), Michal Tendera (Poland), Adam Torbicki (Poland), Alec Vahanian (France), Stephan Windecker (Switzerland)

Document Reviewers: Bogdan A. Popescu (ESC CPG Review Coordinator) (Romania), Ludwig Von Segesser (EACTS) (Switzerland), Luigi P. Badano (Italy), Matjaž Bunc (Slovenia), Marc J. Claeys (Belgium), Nikša Drinković (Croatia), Gerasimos Filippatos (Greece), Gilbert Habib (France), A. Pieter Kappetein (The Netherlands), Roland Kassab (Lebanon), Gregory Y.H. Lip (UK), Neil Moat (UK), Georg Nickenig (Germany), Catherine M. Otto (USA), John Pepper (UK), Nicolo Piazza (Germany), Petronella G. Pieper (The Netherlands), Raphael Rosenhek (Austria), Naltin Shuka (Albania), Ehud Schwammenthal (Israel), Juerg, Schwitler (Switzerland), Pilar Tornos Mas (Spain), Pedro T. Trindade (Switzerland), Thomas Walther (Germany).

Guidelines on the management of valvular heart disease

The Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology

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ESC Committee for Practice Guidelines (CPG), Silvia G. Priori (Chairperson) (Italy), Jean-Jacques Blanc (France), Andrzej Budaj (Poland), John Camm (UK), Veronica Dean (France), Jaap Deckers (The Netherlands), Kenneth Dickstein (Norway), John Lekakis (Greece), Keith McGregor (France), Marco Metra (Italy), João Morais (Portugal), Ady Osterspey (Germany), Juan Tamargo (Spain), José Luis Zamorano (Spain).

Document Reviewers, José Luis Zamorano (CPG Review Coordinator) (Spain), Annalisa Angelini (Italy), Manuel Antunes (Portugal), Miguel Angel Garcia Fernandez (Spain), Christa Gohlke-Baerwolf (Germany), Gilbert Habib (France), John McMurray (UK), Catherine Otto (USA), Luc Pierard (Belgium), José L. Pomar (Spain), Bernard Prendergast (UK), Raphael Rosenhek (Austria), Miguel Sousa Uva (Portugal), Juan Tamargo (Spain).

Classes of recommendations

Classes of recommendations	Definition	Suggested wording to use
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.	Is recommended/ is indicated.
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.	
<i>Class IIa</i>	<i>Weight of evidence/opinion is in favour of usefulness/efficacy.</i>	<i>Should be considered.</i>
<i>Class IIb</i>	<i>Usefulness/efficacy is less well established by evidence/opinion.</i>	May be considered.
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.	Is not recommended.

Levels of evidence

Level of Evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of Evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.
Level of Evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

Background

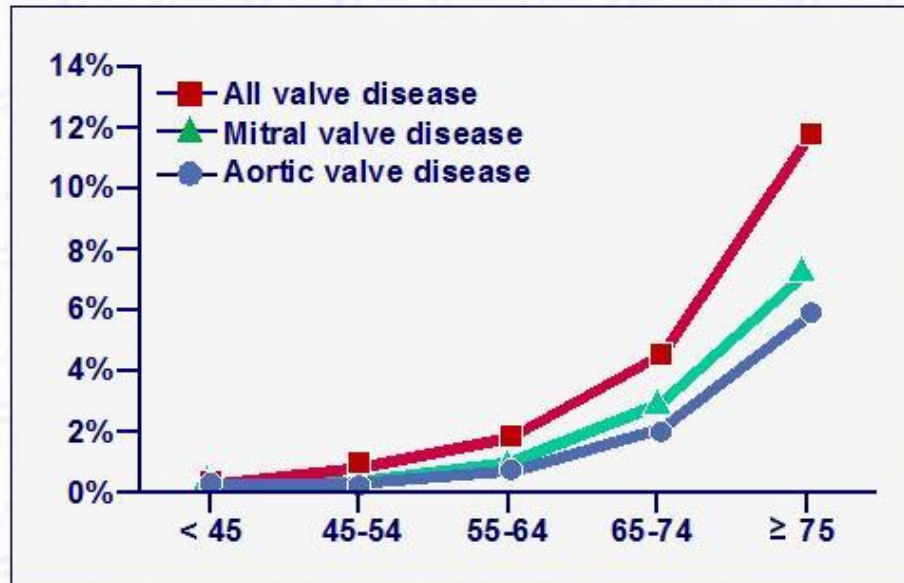
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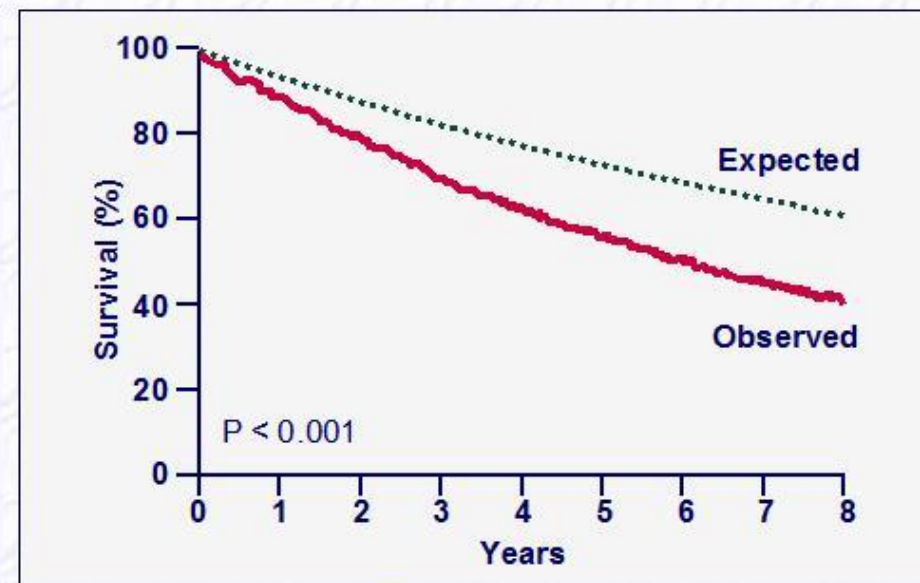


The Burden of Valve Disease

Prevalence



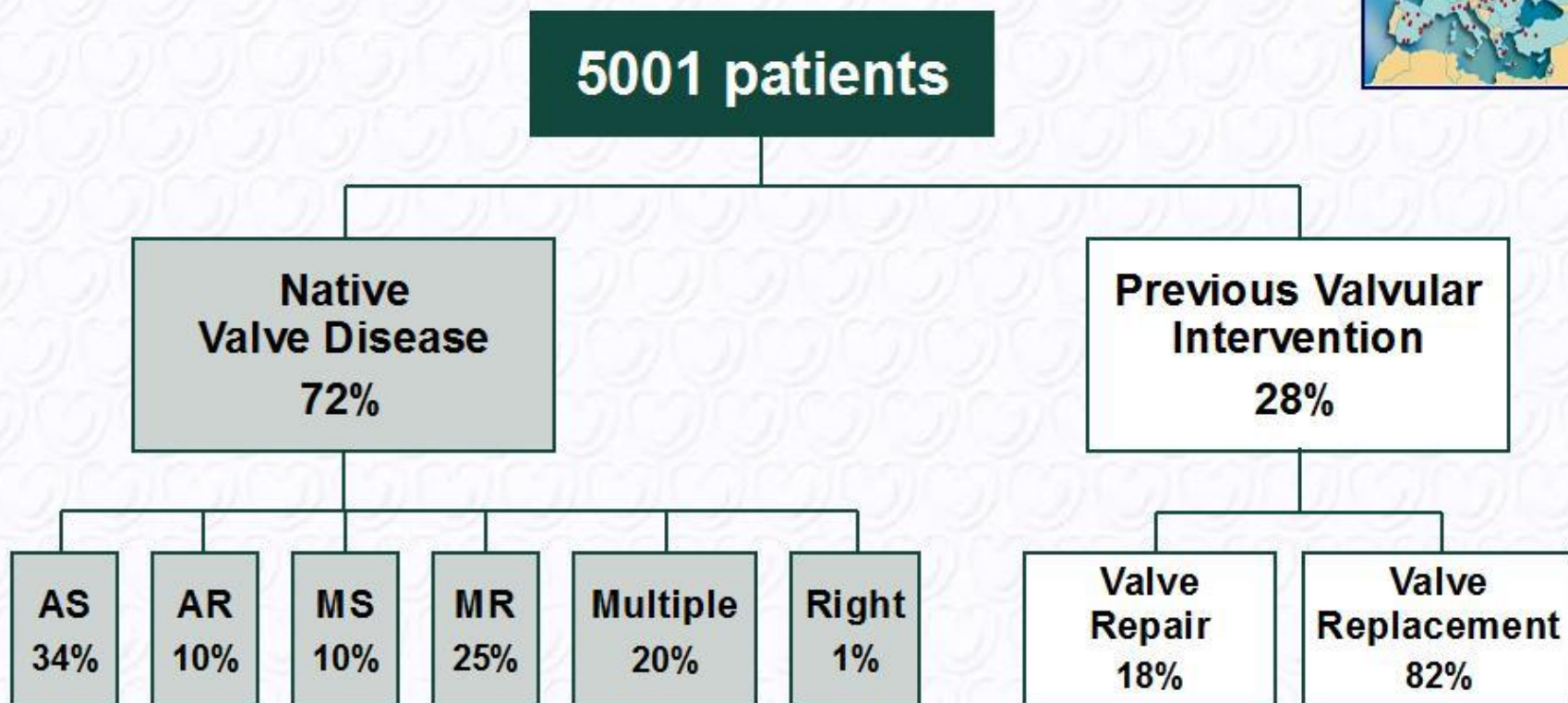
Survival



Nkomo. *Lancet* 2006;368:1005–1011

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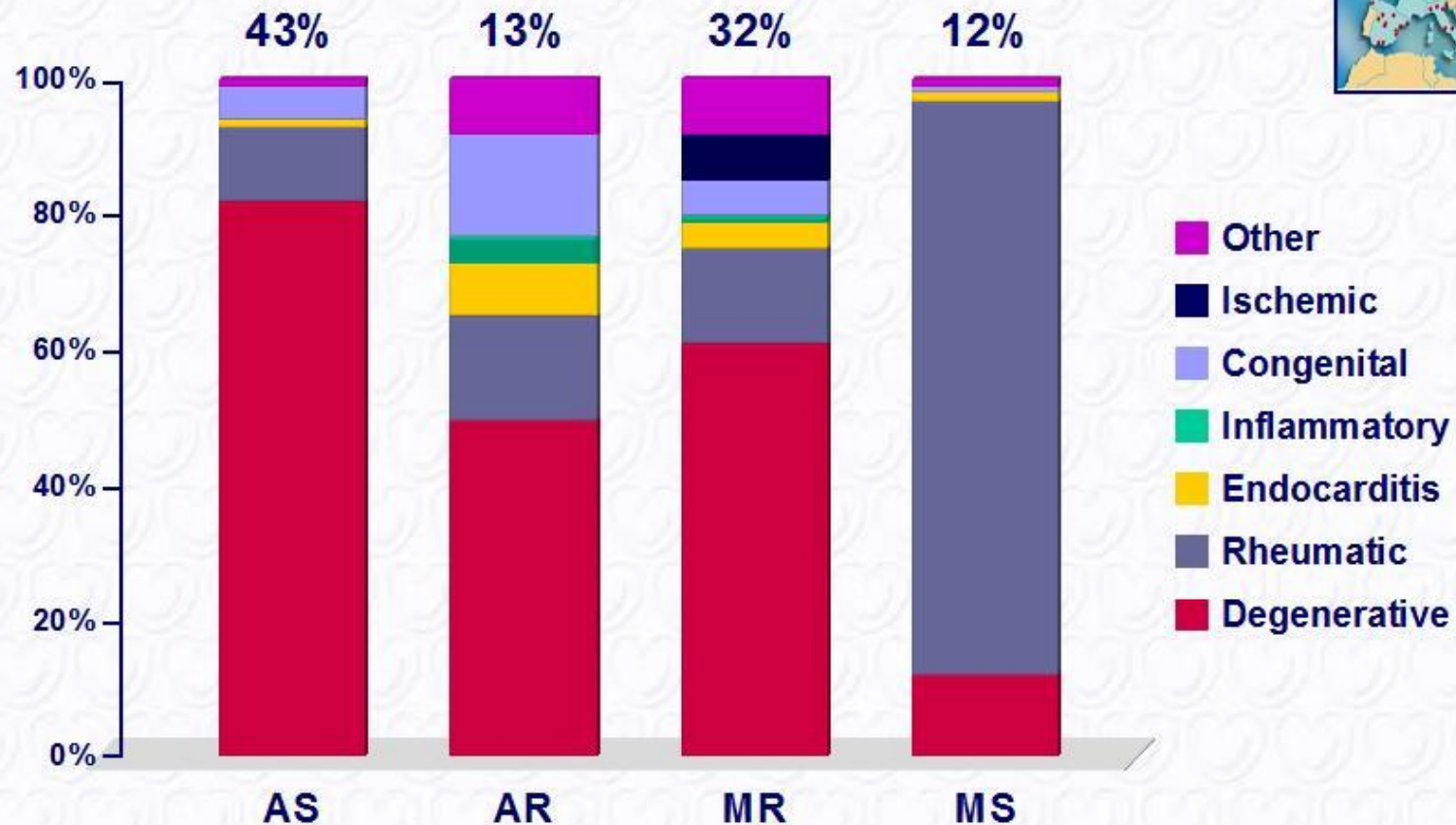
Distribution of Valvular Heart Diseases in the Euro Heart Survey



lung et al. *Eur Heart J* 2003;24:1244-53

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &
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Aetiologies of Single Valvular Heart Diseases in the Euro Heart Survey



lung et al. *Eur Heart J* 2003;24:1244-53

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Patient Characteristics in the Euro Heart Survey



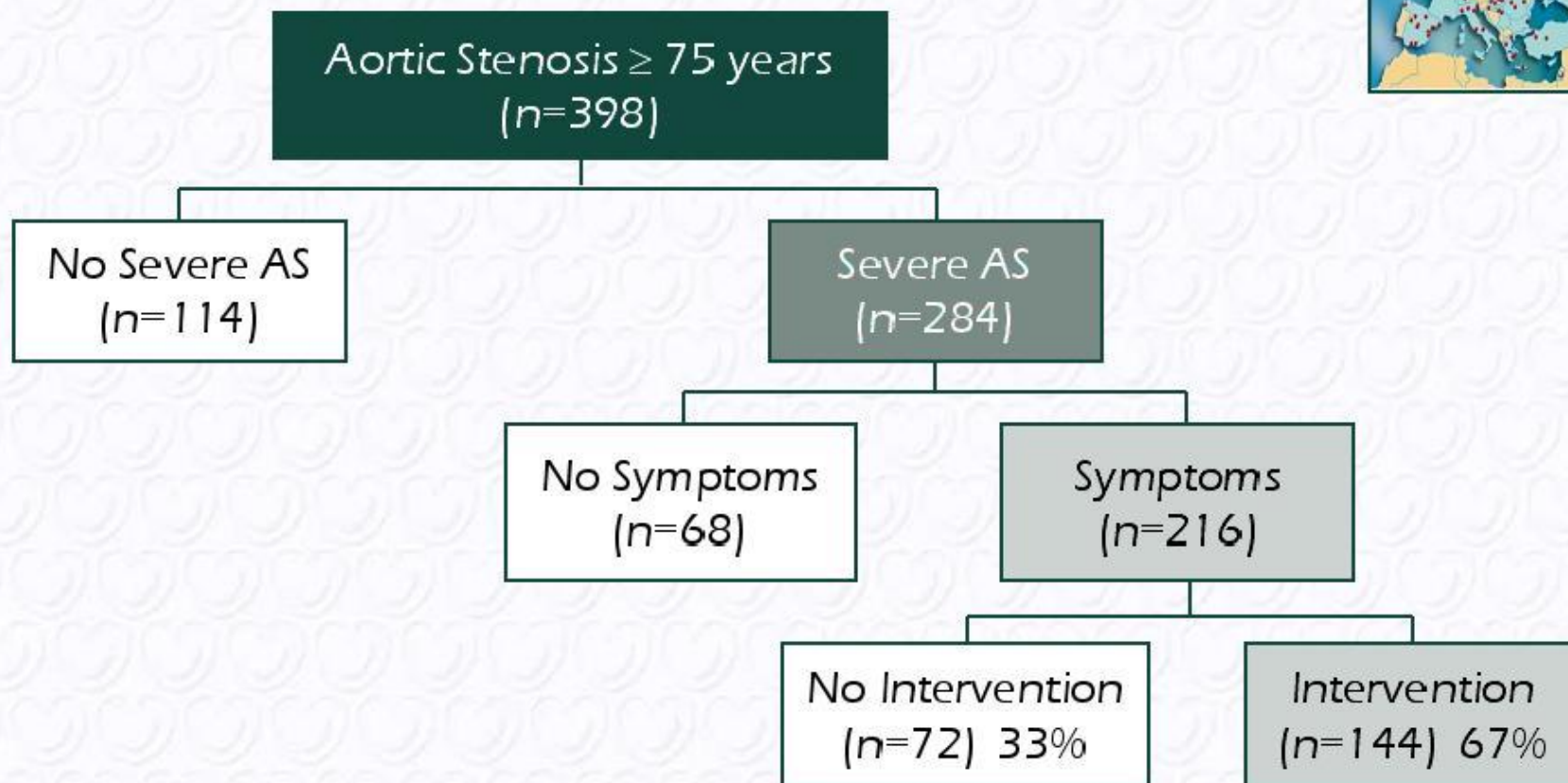
	Age (years)	≥ 70 years (%)	≥ 1 comorbidity (%)
AS	69±12	56	36
AR	58±16	25	26
MS	58±13	18	22
MR	65±14	44	42

lung et al. *Eur Heart J* 2003;24:1244-53

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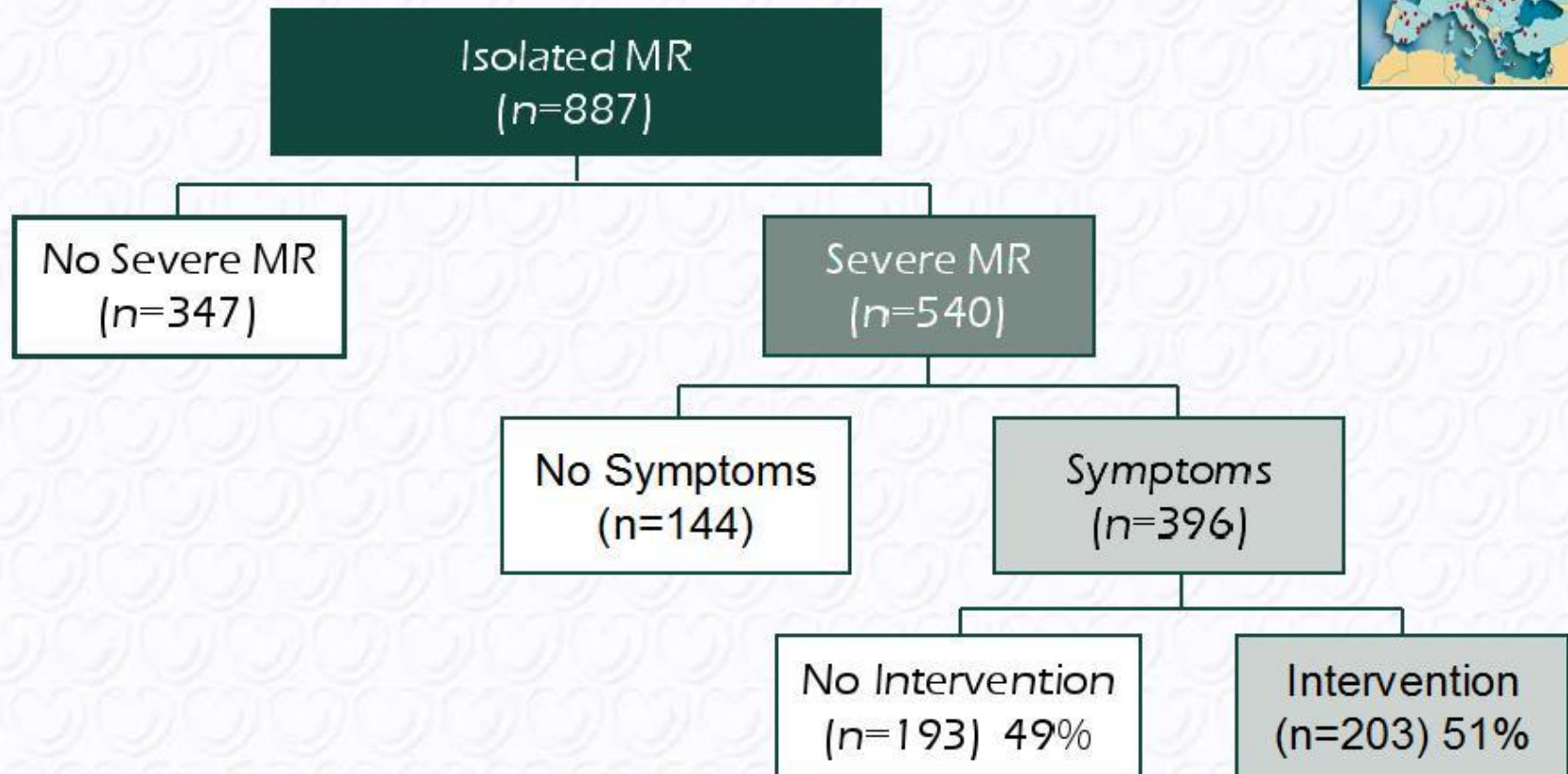
Current Management of Severe Symptomatic AS in the Elderly



lung et al. *Eur Heart J* 2005;26:2714-2720

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &
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doi:10.1093/ejcts/ezs455).

Current Management of Severe MR



Mirabel et al. *Eur Heart J* 2007;28:1358-1365

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doi:10.1093/ejcts/ezs455).

Why do we need new guidelines on the management of valvular disease?

- **New evidence has been accumulated on:**
 - risk stratification,
 - diagnostic methods,
 - therapeutic options.
- **The importance of the collaborative approach between cardiologists and cardiac surgeons, working as a « heart team », has emerged.**

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Patient Evaluation

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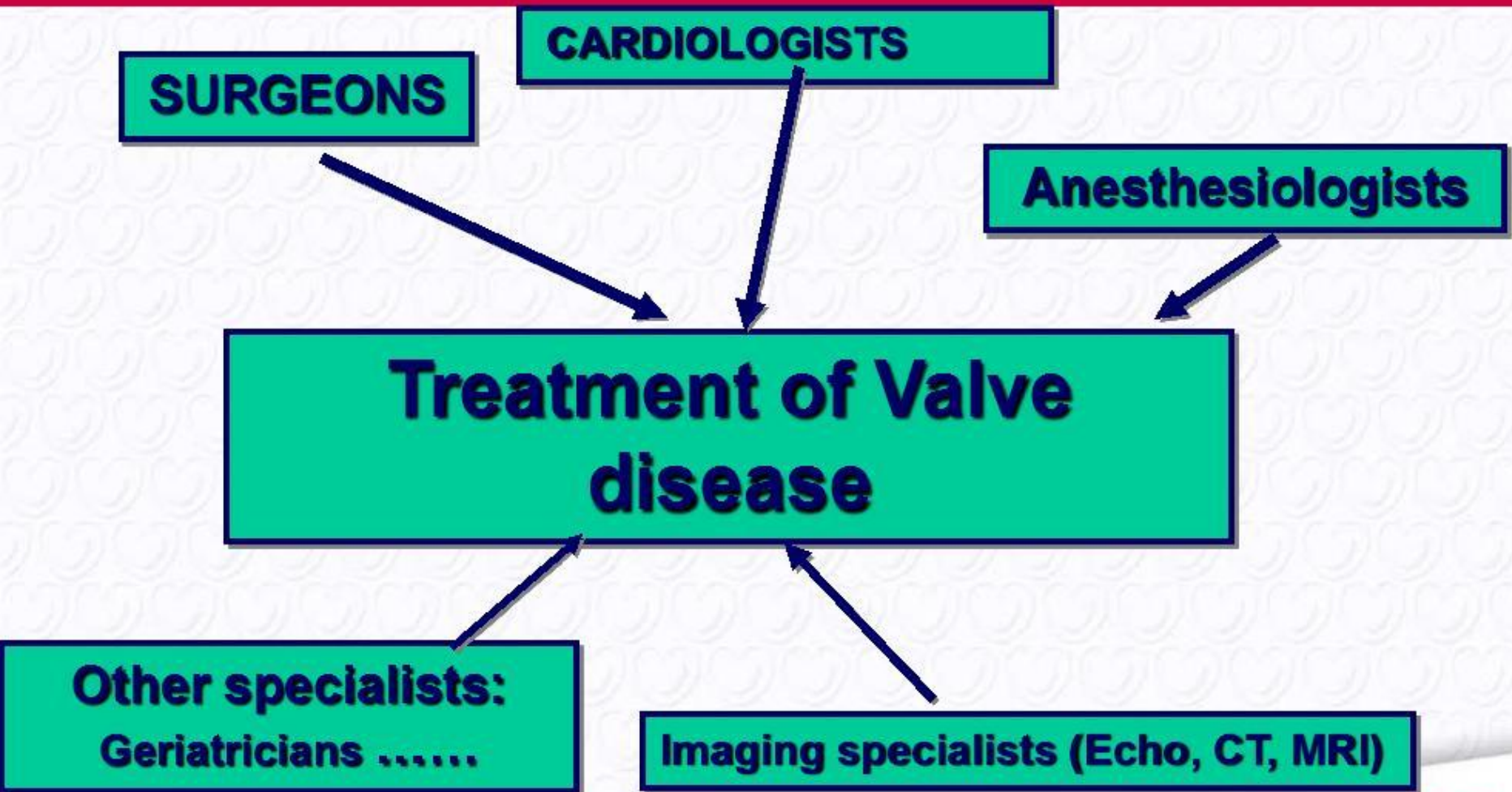


Essential questions in the evaluation of a patient for valvular intervention

- Is valvular heart disease severe?
- Does the patient have symptoms?
- Are symptoms related to valvular disease?
- What are patient life expectancy and expected quality of life?
- Do the expected benefits of intervention (versus spontaneous outcome) outweigh its risks?
- What are the patient's wishes?
- Are local resources optimal for planned intervention?



The « Heart Team »



Patient Evaluation

- **Clinical assessment**
 - Symptoms, comorbidities, patient education.
 - Auscultation.
- **Echocardiography**
 - Key examination to confirm diagnosis and assess severity and prognosis.
 - Need to check consistency between the different echocardiographic findings (severity, mechanism, anatomy of valvular disease) and with clinical assessment.



Echocardiographic criteria for the definition of severe valve stenosis: *an integrative approach*

	Aortic stenosis	Mitral stenosis	Tricuspid stenosis
Valve area (cm ²)	< 1.0	< 1.0	–
Indexed valve area (cm ² /m ² BSA)	< 0.6	–	–
Mean gradient (mmHg)	> 40	> 10	≥ 5
Maximum jet velocity (m/s)	> 4.0	–	–
Velocity ratio	< 0.25	–	–

Adapted from Baumgartner, EAE/ASE recommendations. *Eur J Echocardiogr.* 2010;10:1-25

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &
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doi:10.1093/ejcts/ezs455).

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

	Aortic regurgitation	Mitral regurgitation	Tricuspid regurgitation
Qualitative			
Valve morphology	Abnormal/flail/large coaptation defect	Flail leaflet/ruptured papillary muscle/large coaptation defect	Abnormal/flail/large coaptation defect
Colour flow regurgitant jet	Large in central jets, variable in eccentric jets	Very large central jet or eccentric jet adhering, swirling, and reaching the posterior wall of the left atrium	Very large central jet or eccentric wall impinging jet
CW signal of regurgitant jet	Dense	Dense/triangular	Dense/triangular with early peaking (peak vel < 2 m/s in massive TR)
Other	Holodiastolic flow reversal in descending aorta (EDV > 20 cm/s)	Large flow convergence zone	—

Adapted from Lancellotti, EAE Recommendations. *Eur J Echocardiogr.* 2010;11:223-244 and 307-332

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

	Aortic regurgitation	Mitral regurgitation		Tricuspid regurgitation
Semiquantitative				
Vena contracta width (mm)	> 6	≥ 7 (> 8 for biplane)		≥ 7
Upstream vein flow	-	Systolic pulmonary vein flow reversal		Systolic hepatic vein flow reversal
Inflow	-	E-wave dominant ≥ 1.5 m/s		E-wave dominant ≥ 1 m/s
Other	Pressure half-time < 200 ms	TVI mitral/TVI aortic > 1.4		PISA radius > 9 mm
Quantitative		<i>Primary</i>	<i>Secondary</i>	
EROA (mm ²)	≥ 30	≥ 40	≥ 20	≥ 40
R Vol (ml/beat)	≥ 60	≥ 60	≥ 30	≥ 45
+ enlargement of cardiac chambers/ vessels	LV	LV, LA		RV, RA, inferior vena cava

Adapted from Lancellotti, EAE recommendations. *Eur J Echocardiogr.* 2010;11:223-244 and 307-332

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Other Techniques

- **Exercise testing**
 - Objective assessment if equivocal or no symptoms.
 - Prognosis in asymptomatic AS.
- **Stress echocardiography**
 - Low dose dobutamine echocardiography in AS with low gradient and LV dysfunction.
 - Exercise echocardiography may provide additional information in AS, MR, MS.
- **Magnetic resonance imaging**
 - To assess regurgitation/LV function if echocardiography is inadequate.
 - As a reference method for evaluation of RV.
- **Multislice CT**
 - For imaging of thoracic aorta.
 - For work-up before TAVI.
- **Cardiac catheterisation (to evaluate valve function)**
 - Only if non-invasive findings inconsistent or discordant with clinical assessment.



Management of coronary artery disease in patients with valvular heart disease

	Class	Level
Diagnosis of coronary artery disease		
Coronary angiography is recommended before valve surgery in patients with severe valvular heart disease and any of the following: <ul style="list-style-type: none"> • history of coronary artery disease, • suspected myocardial ischaemia, • left ventricular systolic dysfunction, • men aged over 40 years and postmenopausal women, • ≥ 1 cardiovascular risk factor. 	I	C
Coronary angiography is recommended in the evaluation of secondary mitral regurgitation.	I	C
Indications for myocardial revascularisation		
CABG is recommended in patients with a primary indication for aortic/mitral valve surgery and coronary artery diameter stenosis $\geq 70\%$.	I	C
CABG should be considered in patients with a primary indication for aortic/mitral valve surgery and coronary artery diameter stenosis $\geq 50-70\%$.	IIa	C

Aortic Regurgitation

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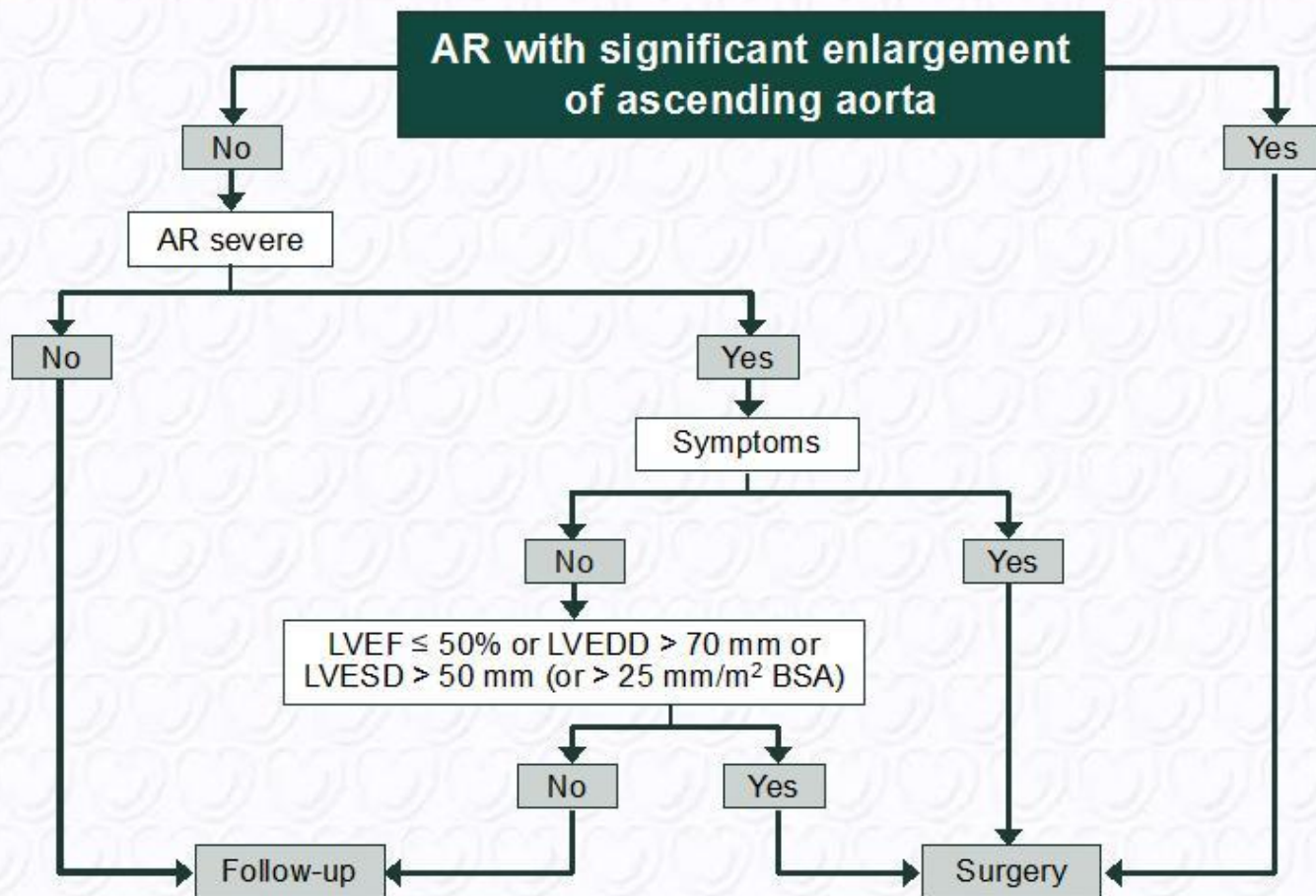
Indications for surgery in severe aortic regurgitation

	Class	Level
Surgery is indicated in symptomatic patients.	I	B
Surgery is indicated in asymptomatic patients with resting LVEF \leq 50%.	I	B
Surgery is indicated in patients undergoing CABG or surgery of ascending aorta, or on another valve.	I	C
Surgery should be considered in asymptomatic patients with resting EF $>$ 50% with severe LV dilatation: LVEDD $>$ 70 mm, or LVESD $>$ 50 mm or LVESD $>$ 25 mm/m ² BSA.	IIa	C

Indications for surgery in aortic root disease (whatever the severity of AR)

	Class	Level
Surgery is indicated in patients who have aortic root disease with maximal ascending aortic diameter ≥ 50 mm for patients with Marfan syndrome	I	C
Surgery should be considered in patients who have aortic root disease with maximal ascending aortic diameter: <ul style="list-style-type: none">• ≥ 45 mm for patients with Marfan syndrome with risk factors,• ≥ 50 mm for patients with bicuspid valve with risk factors,• ≥ 55 mm for other patients.	Ila	C

Management of aortic regurgitation



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Aortic Stenosis

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Indications for aortic valve replacement in symptomatic aortic stenosis

	Class	Level
AVR is indicated in patients with severe AS and any symptoms related to AS.	I	B
AVR is indicated in patients with severe AS undergoing CABG, surgery of the ascending aorta or another valve.	I	C
AVR should be considered in patients with moderate AS undergoing CABG, surgery of the ascending aorta or another valve.	IIa	C
AVR should be considered in high risk patients with severe symptomatic AS who are suitable for TAVI but in whom surgery is favoured by a "heart team" based on the individual risk profile and anatomic suitability.	IIa	B
AVR should be considered in symptomatic patients with low flow, low gradient (< 40 mmHg) AS with normal EF only after careful confirmation of severe AS.	IIa	C
AVR should be considered in symptomatic patients with severe AS, low flow, low gradient with reduced EF, and evidence of flow reserve.	IIa	C
AVR may be considered in symptomatic patients with severe AS low flow, low gradient, and LV dysfunction without flow reserve.	IIb	C

Indications for aortic valve replacement in asymptomatic aortic stenosis

	Class	Level
AVR is indicated in asymptomatic patients with severe AS and systolic LV dysfunction (LVEF < 50%) not due to another cause.	I	C
AVR is indicated in asymptomatic patients with severe AS and abnormal exercise test showing symptoms on exercise clearly related to AS.	I	C
AVR should be considered in asymptomatic patients with severe AS and abnormal exercise test showing fall in blood pressure below baseline.	IIa	C
AVR should be considered in asymptomatic patients, with normal EF and none of the above mentioned exercise test abnormalities, if the surgical risk is low, and one or more of the following findings is present: <ul style="list-style-type: none"> • very severe AS defined by a peak transvalvular velocity > 5.5 m/s, • severe valve calcification and a rate of peak of transvalvular velocity progression ≥ 0.3 m/s per year. 	IIa	C
AVR may be considered in asymptomatic patients with severe AS, normal EF and none of the above mentioned exercise test abnormalities, if surgical risk is low, and one or more of the following findings is present: <ul style="list-style-type: none"> • markedly elevated natriuretic peptide levels confirmed by repeated measurements without other explanations, • increase of mean pressure gradient with exercise by > 20 mmHg, • excessive LV hypertrophy in the absence of hypertension. 	IIb	C

Indications for transcatheter aortic valve implantation

	Class	Level
TAVI should only be undertaken with a multidisciplinary “heart team” including cardiologists and cardiac surgeons and other specialists if necessary.	I	C
TAVI should only be performed in hospitals with cardiac surgery on-site.	I	C
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

Contraindications for transcatheter aortic valve implantation

Absolute contraindications

Absence of a "heart team" and no cardiac surgery on the site.
Appropriateness of TAVI, as an alternative to AVR, not confirmed by a "heart team".

Clinical

- Estimated life expectancy < 1 year.
- Improvement of quality of life by TAVI unlikely because of comorbidities.
- Severe primary associated disease of other valves with major contribution to the patient's symptoms that can be treated only by surgery.

Anatomical

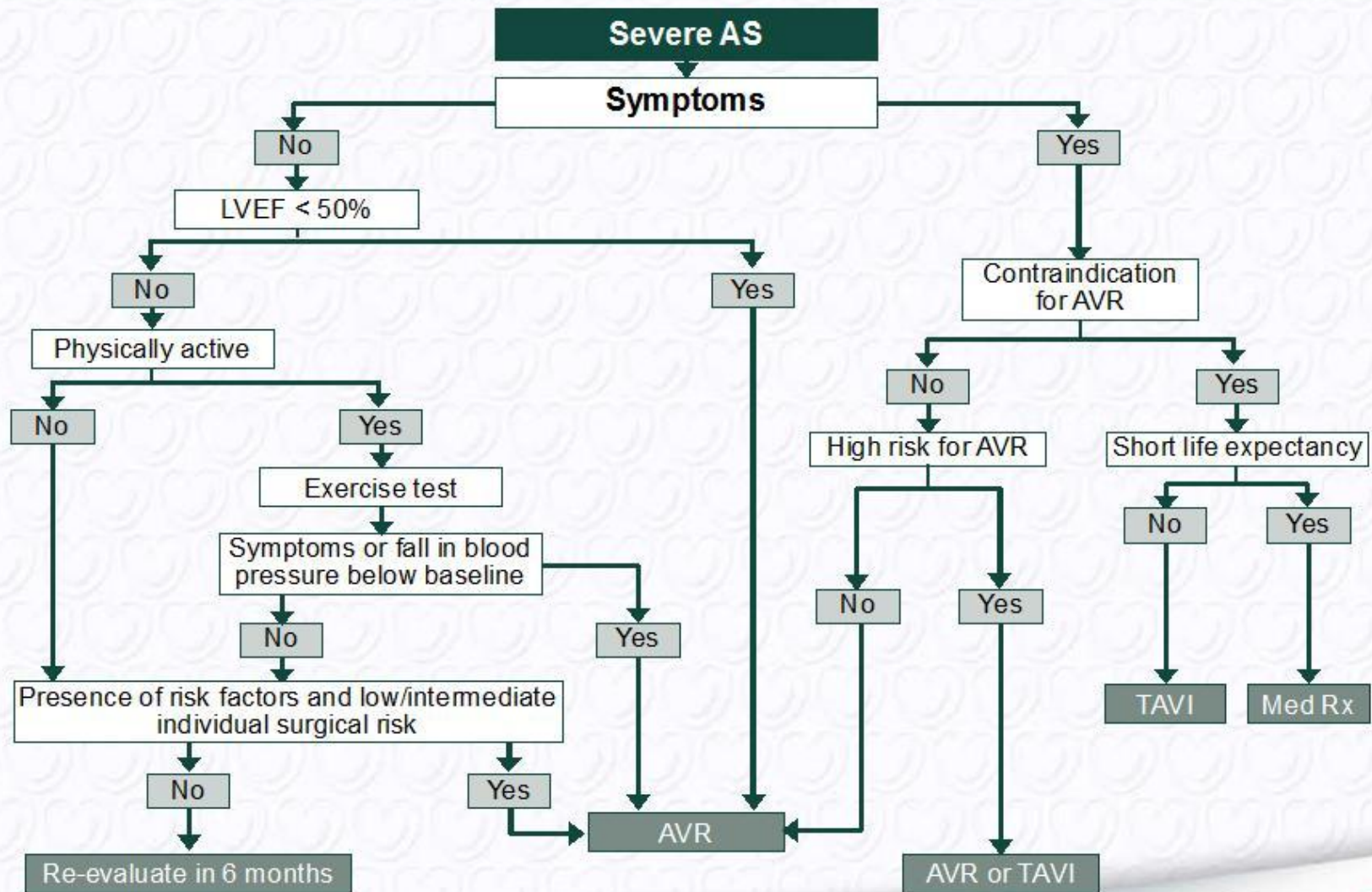
- Inadequate annulus size (< 18 mm, > 29 mm).
- Thrombus in the left ventricle.
- Active endocarditis.
- Elevated risk of coronary ostium obstruction (asymmetric valve calcification, short distance between annulus and coronary ostia, small aortic sinuses).
- Plaques with mobile thrombi in the ascending aorta, or arch.
- For transfemoral/subclavian approach: inadequate vascular access (vessel size, calcification, tortuosity).

Relative contraindications

- Bicuspid or non-calcified valves.
- Untreated coronary artery disease requiring revascularization.
- Haemodynamic instability.
- LVEF < 20%.
- For transapical approach: severe pulmonary disease, LV apex not accessible.

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Management of severe aortic stenosis



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Mitral Regurgitation

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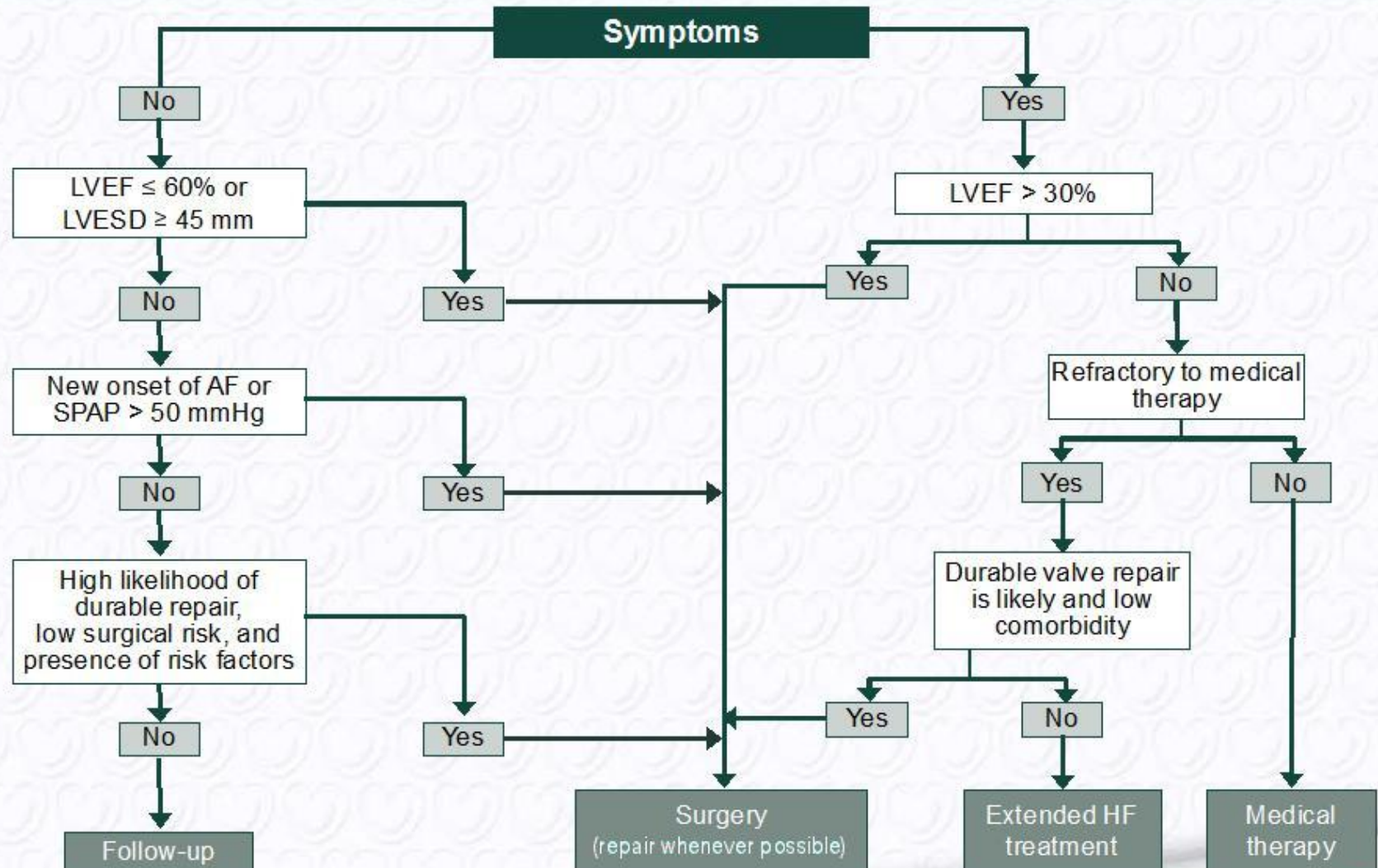
Indications for surgery in symptomatic severe primary MR

	Class	Level
Mitral valve repair should be the preferred technique when it is expected to be durable.	I	C
Surgery is indicated in symptomatic patients with LVEF > 30% and LVESD < 55 mm.	I	B
Surgery should be considered in patients with severe LV dysfunction (LVEF < 30% and/or LVESD > 55 mm) refractory to medical therapy with high likelihood of durable repair and low comorbidity.	IIa	C
Surgery may be considered in patients with severe LV dysfunction (LVEF < 30% and/or LVESD > 55 mm) refractory to medical therapy with low likelihood of durable repair and low comorbidity.	IIb	C

Indications for surgery in asymptomatic severe primary MR

	Class	Level
Surgery is indicated in asymptomatic patients with LV dysfunction (LVESD \geq 45 mm and/or LVEF \leq 60%).	I	C
Surgery should be considered in asymptomatic patients with preserved LV function and new onset of atrial fibrillation or pulmonary hypertension (systolic pulmonary pressure at rest $>$ 50 mmHg).	IIa	C
Surgery should be considered in asymptomatic patients with preserved LV function, high likelihood of durable repair, low surgical risk and flail leaflet and LVESD \geq 40 mm.	IIa	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 \geq 60 ml/m² BSA) and sinus rhythm, or • pulmonary hypertension on exercise (SPAP \geq 60 mmHg at exercise). 	IIb	C

Management of severe chronic primary mitral regurgitation



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Indications for mitral valve surgery in secondary mitral regurgitation

	Class	Level
Surgery is indicated in patients with severe MR undergoing CABG, and LVEF > 30%.	I	C
Surgery should be considered in patients with moderate MR undergoing CABG.	IIa	C
Surgery should be considered in symptomatic patients with severe MR, LVEF < 30%, option for revascularization, and evidence of viability.	IIa	C
Surgery may be considered in patients with severe MR, LVEF > 30%, who remain symptomatic despite optimal medical management (including CRT if indicated) and have low comorbidity, when revascularization is not indicated.	IIb	C

Mitral Stenosis

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Contraindications for percutaneous mitral commissurotomy

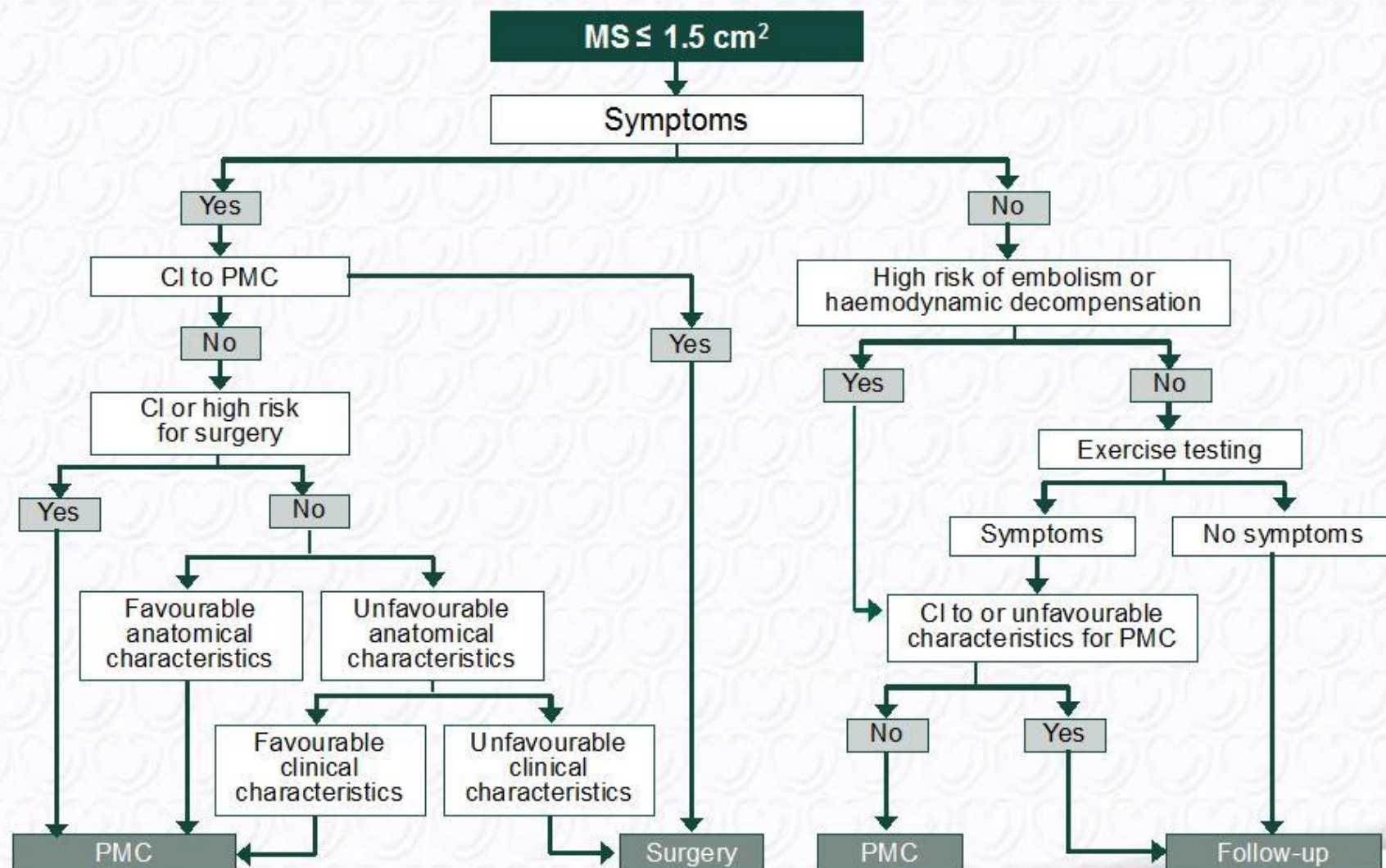
- Mitral valve area $> 1.5 \text{ cm}^2$.
- Left atrial thrombus.
- More than mild mitral regurgitation.
- Severe or bicommissural calcification.
- Absence of commissural fusion.
- Severe concomitant aortic valve disease, or severe combined tricuspid stenosis and regurgitation.
- Concomitant coronary artery disease requiring bypass surgery.



Indications for percutaneous mitral commissurotomy

	Class	Level
PMC is indicated in symptomatic patients with favourable characteristics.	I	B
PMC is indicated in symptomatic patients with contraindication or high risk for surgery.	I	C
PMC should be considered as initial treatment in symptomatic patients with unfavourable anatomy but without unfavourable clinical characteristics.	IIa	C
PMC should be considered in asymptomatic patients without unfavourable characteristics and: <ul style="list-style-type: none"> • high thromboembolic risk (previous history of embolism, dense spontaneous contrast in the left atrium, recent or paroxysmal atrial fibrillation), and/or • high risk of haemodynamic decompensation (systolic pulmonary pressure > 50 mmHg at rest, need for major non-cardiac surgery, desire for pregnancy). 	IIa	C

Management of clinically significant mitral stenosis



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Tricuspid Disease

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Indications for surgery in tricuspid disease

	Class	Level
Surgery is indicated in symptomatic patients with severe TS.	I	C
Surgery is indicated in patients with severe TS undergoing left-sided valve intervention.	I	C
Surgery is indicated in patients with severe primary, or secondary, TR undergoing left-sided valve surgery.	I	C
Surgery is indicated in symptomatic patients with severe isolated primary TR without severe right ventricular dysfunction.	I	C
Surgery should be considered in patients with moderate primary TR undergoing left-sided valve surgery.	IIa	C
Surgery should be considered in patients with mild or moderate secondary TR with dilated annulus (≥ 40 mm or > 21 mm/m ²) undergoing left-sided valve surgery.	IIa	C
Surgery should be considered in asymptomatic or mildly symptomatic patients with severe isolated primary TR and progressive right ventricular dilation or deterioration of right ventricular function.	IIa	C
After left-sided valve surgery, surgery should be considered in patients with severe TR who are symptomatic or have progressive right ventricular dilatation/dysfunction, in the absence of left-sided valve dysfunction, severe right or left ventricular dysfunction, and severe pulmonary vascular disease.	IIa	C

Valve Prosthesis

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Choice of the aortic/mitral prosthesis : in favour of a mechanical prosthesis

	Class	Level
A mechanical prosthesis is recommended according to the desire of the informed patient and if there are no contraindications for long-term anticoagulation.	I	C
A mechanical prosthesis is recommended in patients at risk of accelerated structural valve deterioration.	I	C
A mechanical prosthesis is recommended in patients already on anticoagulation because of a mechanical prosthesis in another valve position.	I	C
A mechanical prosthesis should be considered in patients aged < 60 years for prosthesis in the aortic position and < 65 years for prosthesis in the mitral position.	IIa	C
A mechanical prosthesis should be considered in patients with a reasonable life expectancy, for whom future redo valve surgery would be at high risk.	IIa	C
A mechanical prosthesis may be considered in patients already on long-term anticoagulation due to high risk for thromboembolism.	IIb	C

Choice of the aortic/mitral prosthesis : in favour of a bioprosthesis

	Class	Level
A bioprosthesis is recommended according to the desire of the informed patient.	I	C
A bioprosthesis is recommended when good quality anticoagulation is unlikely (compliance problems, not readily available) or contraindicated because of high bleeding risk (prior major bleed, comorbidities, unwillingness, compliance problems, lifestyle, occupation).	I	C
A bioprosthesis is recommended for reoperation for mechanical valve thrombosis despite good long-term anticoagulant control.	I	C
A bioprosthesis should be considered in patients for whom future redo valve surgery would be at low risk.	IIa	C
A bioprosthesis should be considered in young women contemplating pregnancy.	IIa	C
A bioprosthesis should be considered in patients aged > 65 years for prosthesis in aortic position or > 70 years in mitral position, or those with life expectancy lower than the presumed durability of the bioprosthesis.	IIa	C

Indications for antithrombotic therapy after valvular surgery

	Class	Level
Oral anticoagulation is recommended lifelong for all patients with a mechanical prosthesis.	I	B
Oral anticoagulation is recommended lifelong for patients with bioprostheses who have other indications for anticoagulation.	I	C
The addition of low-dose aspirin should be considered in patients with a mechanical prosthesis and concomitant atherosclerotic disease.	IIa	C
The addition of low-dose aspirin should be considered in patients with a mechanical prosthesis after thromboembolism despite adequate INR.	IIa	C
Oral anticoagulation should be considered for the first 3 months after implantation of a mitral or tricuspid bioprosthesis.	IIa	C
Oral anticoagulation should be considered for the first 3 months after mitral valve repair.	IIa	C
Low-dose aspirin should be considered for the first 3 months after implantation of an aortic bioprosthesis.	IIa	C
Oral anticoagulation may be considered for the first 3 months after implantation of an aortic bioprosthesis.	IIb	C

Risk factors for thromboembolism

- **Prosthesis thrombogenicity**

- Low
 - Carbomedics (aortic position), Medtronic Hall, St.Jude Medical, ON-X.
- Medium
 - Other bileaflet valves.
- High
 - Lillehei-Kaster, Omniscience, Starr-Edwards, Bjork-Shiley, other tilting-disc valves.

- **Patient-related risk factors**

- Mitral, tricuspid, or pulmonary valve replacement.
- Previous thromboembolism.
- Atrial fibrillation.
- Mitral stenosis of any degree.
- Left ventricular ejection fraction < 35%.

Target international normalized ratio (INR) for mechanical prostheses

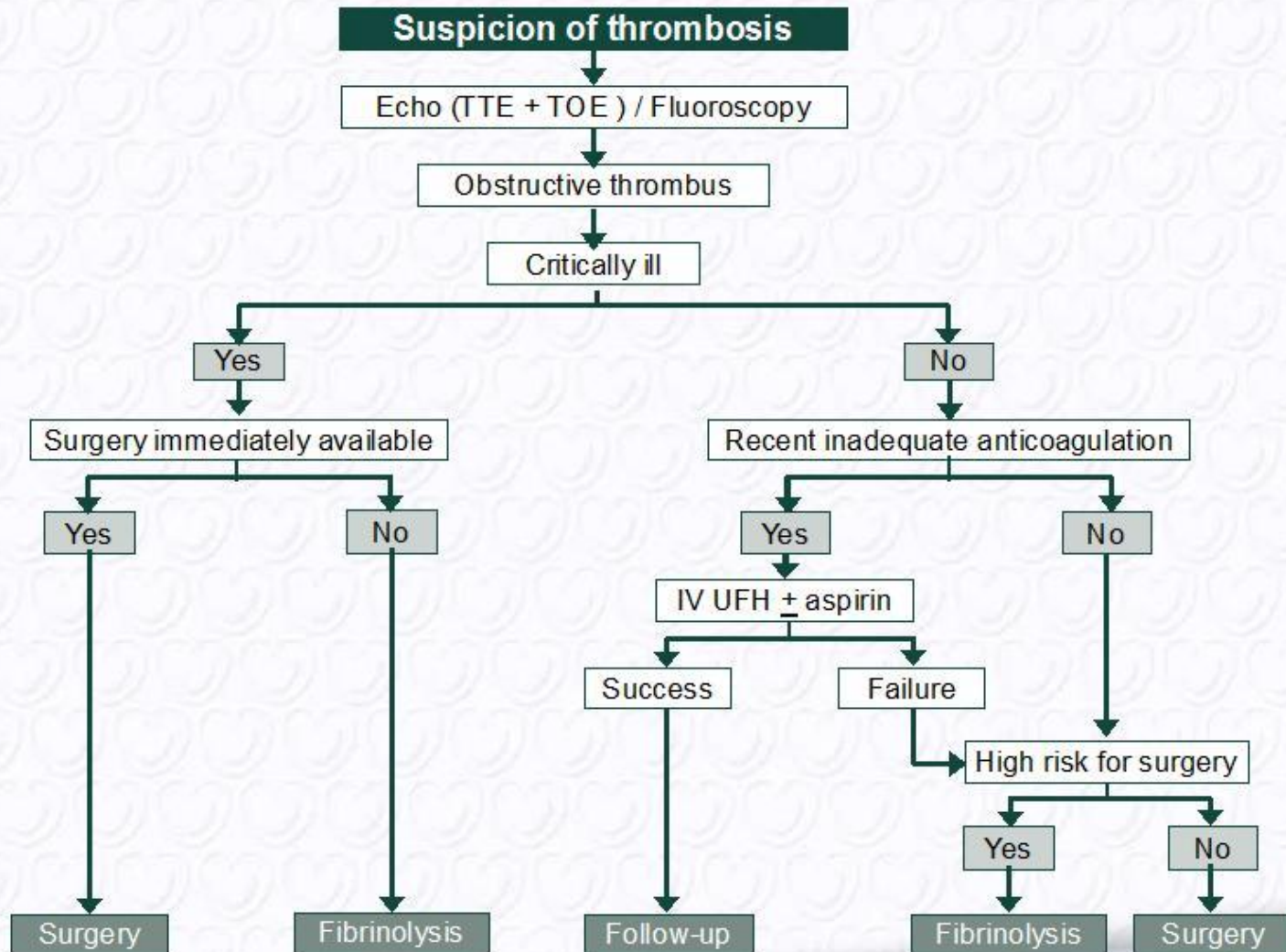
Prosthesis thrombogenicity	Patient-related risk factors	
	No risk factor	≥ 1 risk factor
Low	2.5	3.0
Medium	3.0	3.5
High	3.5	4.0

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &
European Journal of Cardio-Thoracic Surgery 2012 -
doi:10.1093/ejcts/ezs455).

Management after valve replacement

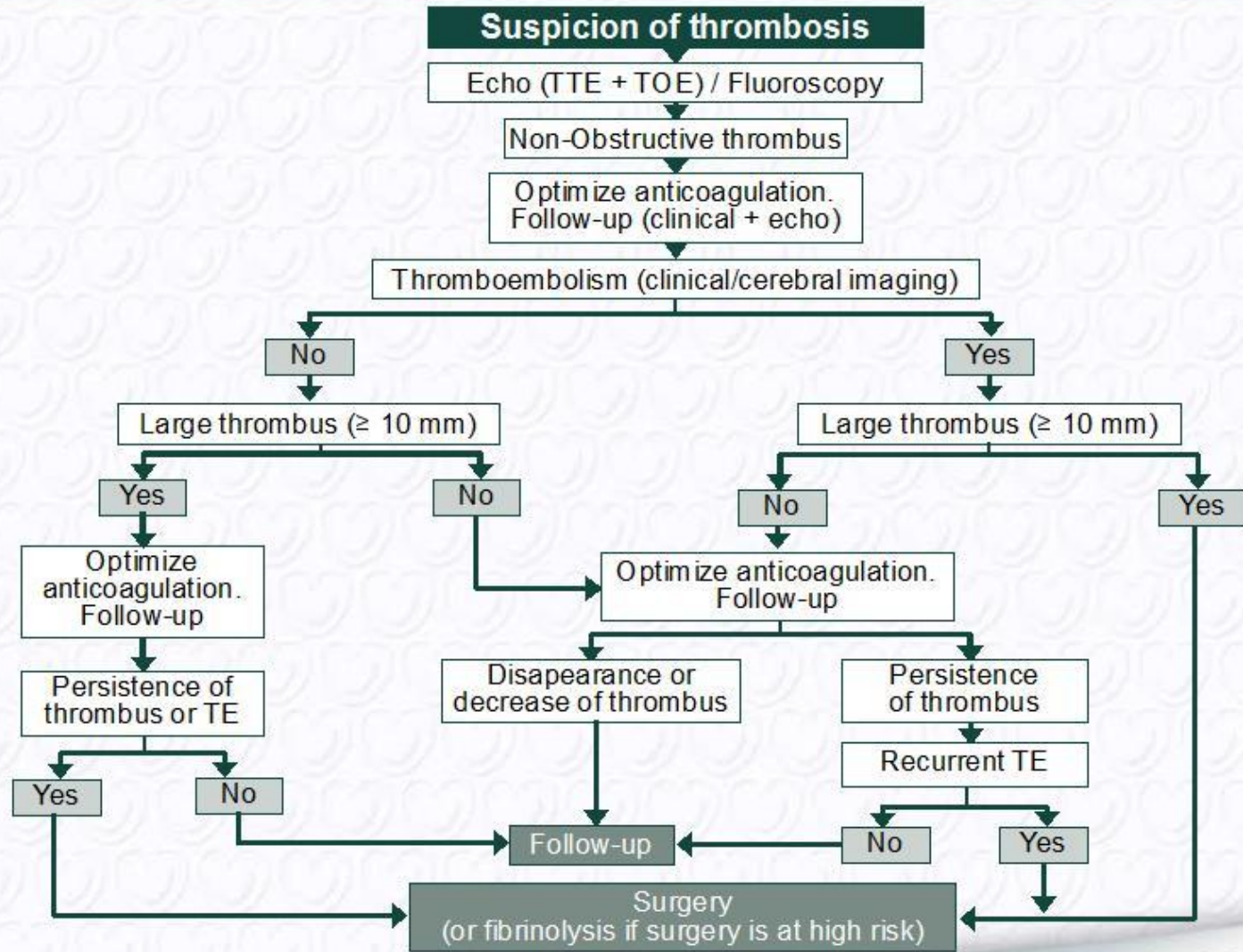
- **Complete baseline assessment**
 - 6 to 12 weeks after surgery.
 - Clinical assessment, chest X-ray, ECG, TTE, blood testing.
- **Antithrombotic therapy**
 - Adapted to prostheses- and patient-related risk factors.
 - Lifelong for all mechanical prostheses.
 - During the first 3 post-operative months for mitral and tricuspid bioprostheses.
- **Detection of complications**
 - Prosthetic thrombosis.
 - Bioprosthetic failure.
 - Haemolysis and paravalvular leak.
 - Heart failure.

Management of left-sided obstructive prosthetic thrombosis



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European Journal of Cardio-Thoracic Surgery 2012 -
doi:10.1093/ejcts/ezs455).

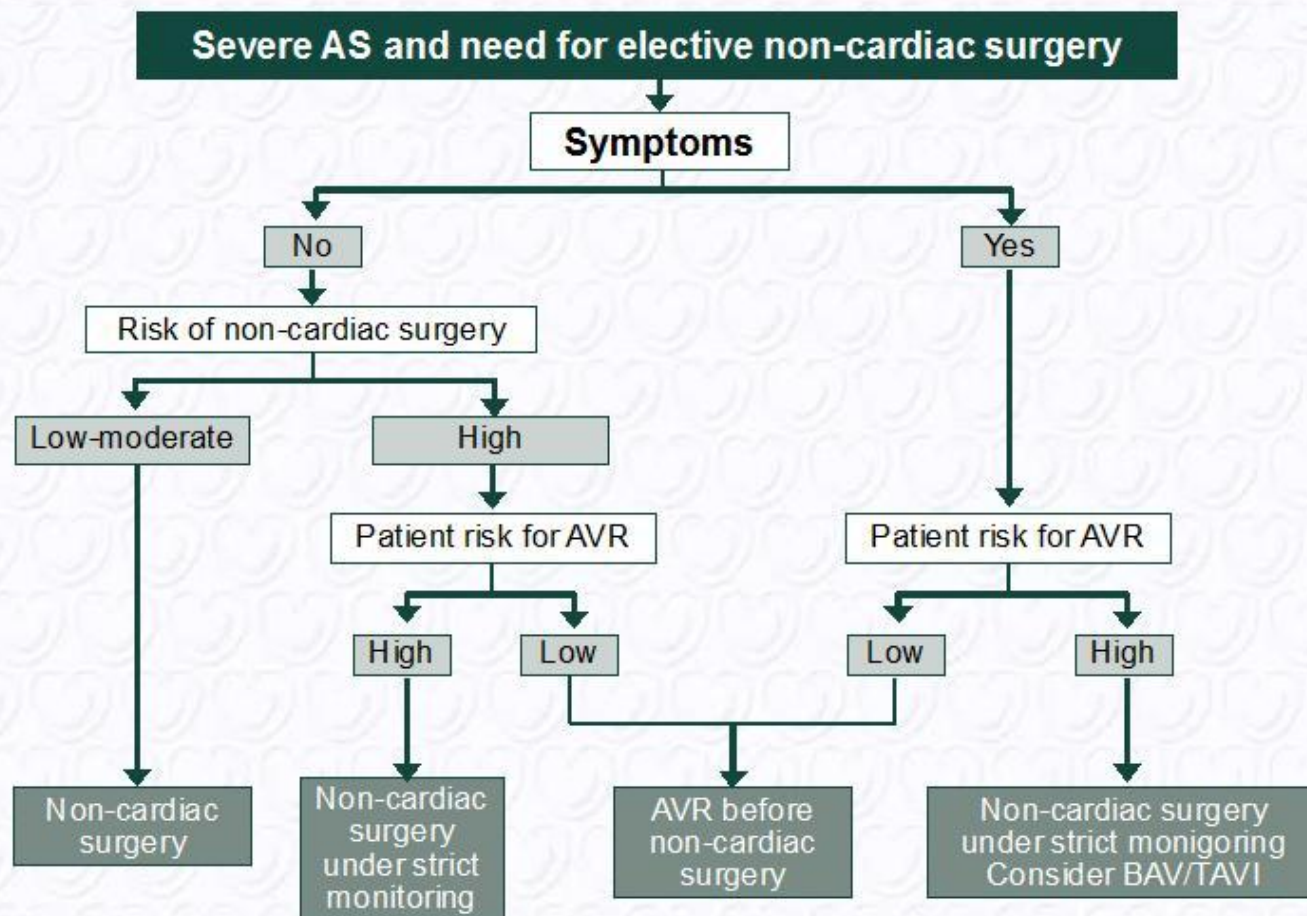
Management of left-sided non-obstructive prosthetic thrombosis



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 European Journal of Cardio-Thoracic Surgery 2012 -
 doi:10.1093/ejcts/ezs455).

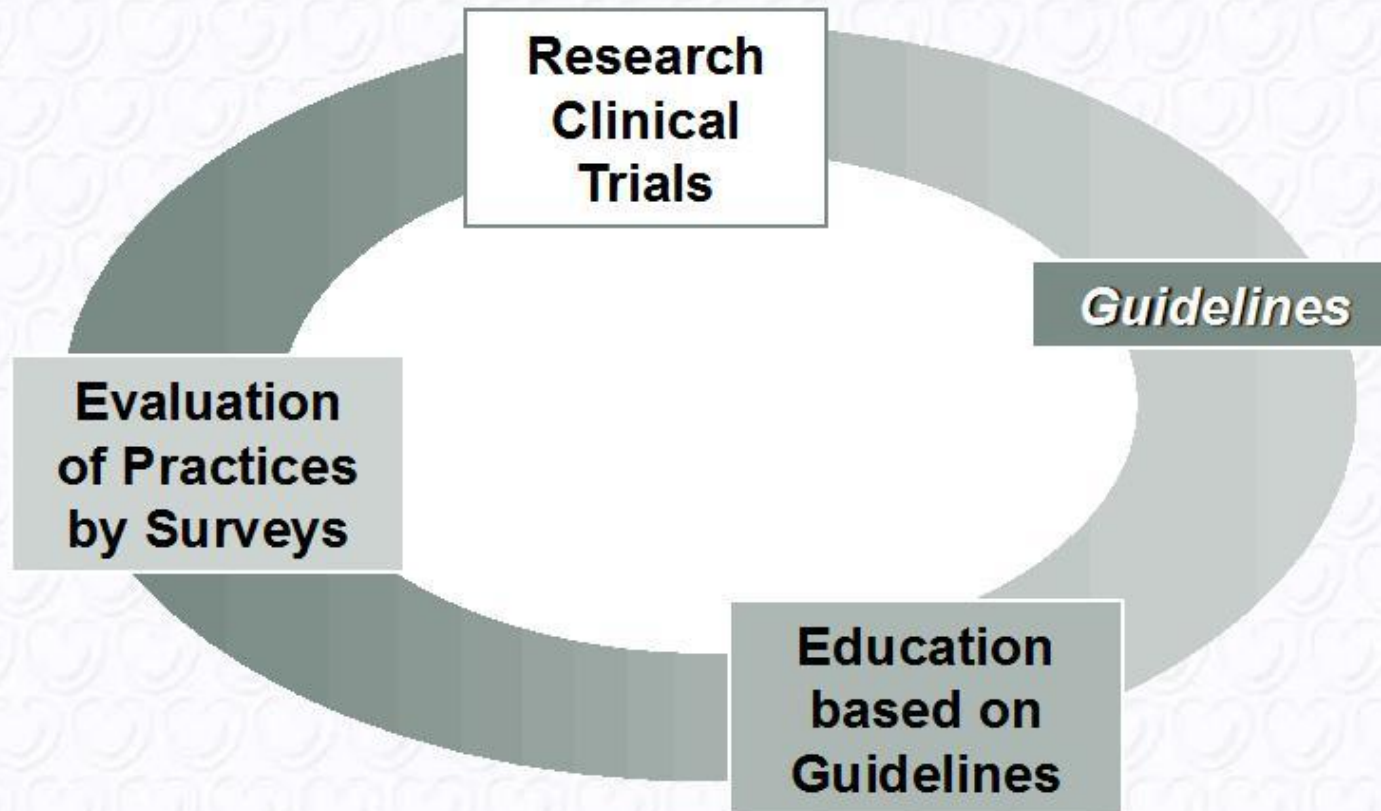


Management of severe aortic stenosis and elective non-cardiac surgery according to patient characteristics and the type of surgery



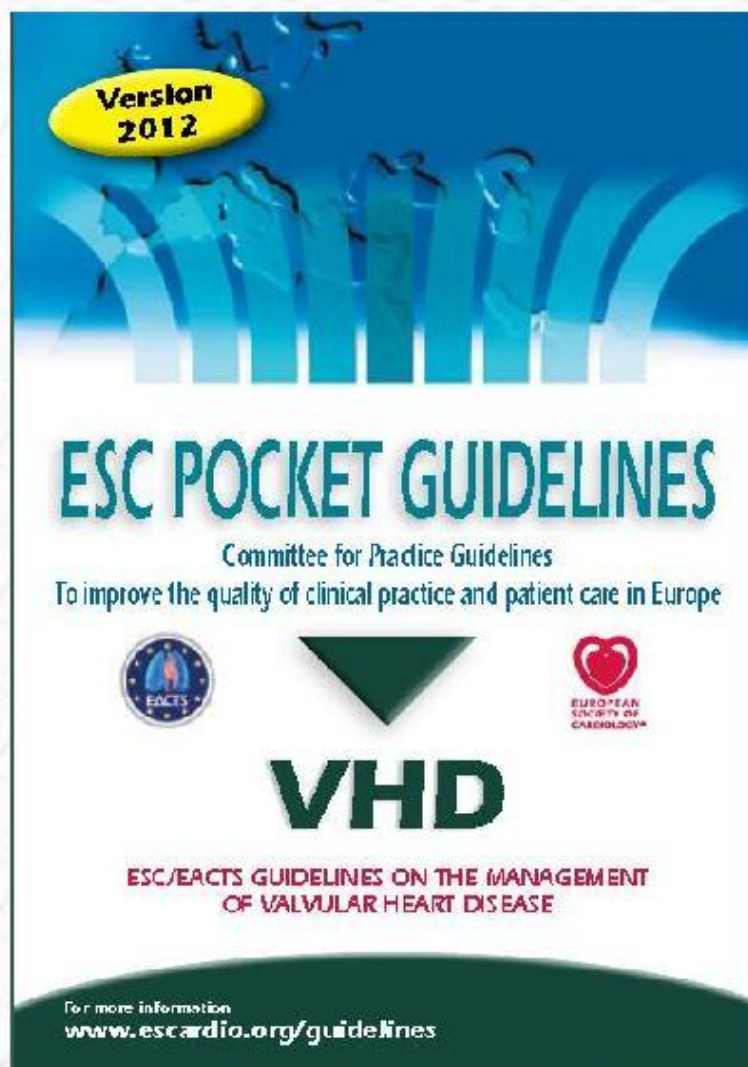
European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &
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"The Loop of Knowledge "



European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &
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Pocket Guidelines



European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &
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doi:10.1093/ejcts/ezs455).

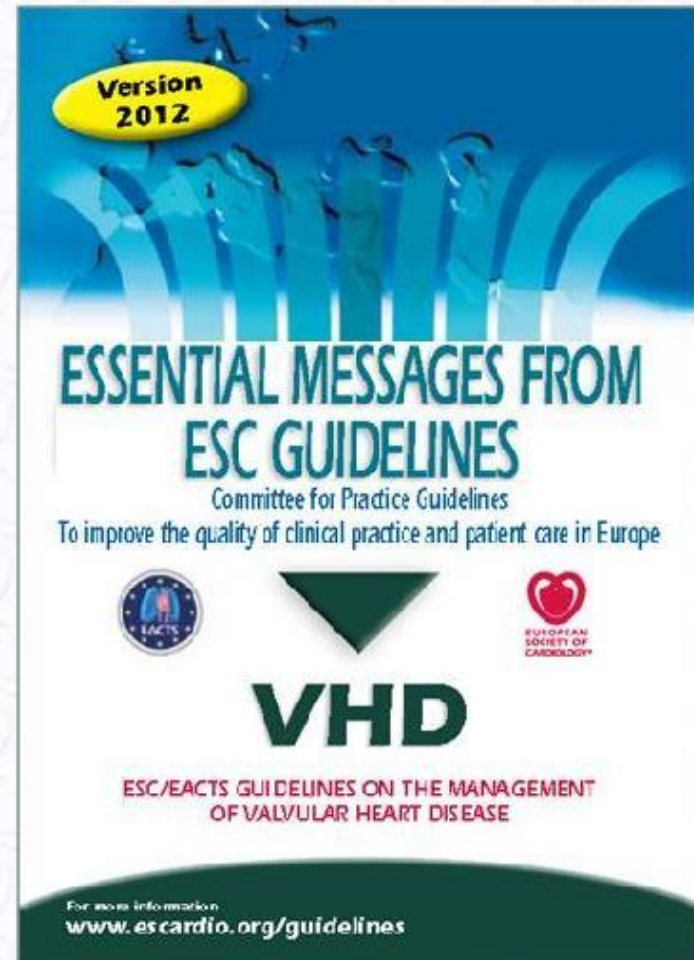
www.escardio.org/guidelines



Essential Messages

<http://www.escardio.org/guidelines-surveys/esc-guidelines/Pages/valvular-heart-disease.aspx>

Read The Take Home Messages & Gaps in Evidence on the ESC Web Site



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