European and American guidelines for aortic stenosis: diagnosis and treament

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Declaration of interest

Departmental Research grants:
Medtronic, Biotronik, Boston Scientific, Edwards Lifescience

Classes of recommendations

EACTS — European Association for Cardio-Thoracic Surgery

ESC European Society of Cardiology

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.	
Class IIa	*Weight of evidence/opinion is in favour of usefulness/efficacy.*	Should be considered.
Class IIb	*Usefulness/efficacy is less well established by evidence/opinion.*	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.

Level of evidence

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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.

AHA/ACC Guidelines

CLASS (STRENGTH) OF RECOMMENDATION

CLASS I (STRONG) — Benefit >>> Risk

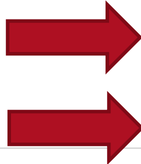
Suggested phrases for writing recommendations:
- Is recommended
- Is indicated/useful/effective/beneficial
- Should be performed/administered/other
- Comparative-Effectiveness Phrases†:
  - Treatment/strategy A is recommended/indicated in preference to treatment B
  - Treatment A should be chosen over treatment B

CLASS IIa (MODERATE) — Benefit >> Risk

Suggested phrases for writing recommendations:
- Is reasonable
- Can be useful/effective/beneficial
- Comparative-Effectiveness Phrases†:
  - Treatment/strategy A is probably recommended/indicated in preference to treatment B
  - It is reasonable to choose treatment A over treatment B

CLASS IIb (WEAK) — Benefit ≥ Risk

Suggested phrases for writing recommendations:
- May/might be reasonable
- May/might be considered
- Usefulness/effectiveness is unknown/unclear/uncertain or not well established



CLASS III: No Benefit (MODERATE) — Benefit = Risk
(Generally, LOE A or B use only)

Suggested phrases for writing recommendations:
- Is not recommended
- Is not indicated/useful/effective/beneficial
- Should not be performed/administered/other

CLASS III: Harm (STRONG) — Risk > Benefit

Suggested phrases for writing recommendations:
- Potentially harmful
- Causes harm
- Associated with excess morbidity/mortality
- Should not be performed/administered/other

LEVEL (QUALITY) OF EVIDENCE‡

LEVEL A — RCT
- High-quality evidence‡ from more than 1 RCT
- Meta-analyses of high-quality RCTs
- One or more RCTs corroborated by high-quality registry studies

LEVEL B-R — (Randomized)
- Moderate-quality evidence‡ from 1 or more RCTs
- Meta-analyses of moderate-quality RCTs

LEVEL B-NR — (Nonrandomized)
- Moderate-quality evidence‡ from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
- Meta-analyses of such studies

LEVEL C-LD — (Limited Data)
- Randomized or nonrandomized observational or registry studies with limitations of design or execution
- Meta-analyses of such studies
- Physiological or mechanistic studies in human subjects

LEVEL C-EO — (Expert Opinion)

Consensus of expert opinion based on clinical experience

COR and LOE are determined independently (any COR may be paired with any LOE).

A recommendation with LOE C does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although RCTs are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

* The outcome or result of the intervention should be specified (an improved clinical outcome or increased diagnostic accuracy or incremental prognostic information).

† For comparative-effectiveness recommendations (COR I and IIa; LOE A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

‡ The method of assessing quality is evolving, including the application of standardized, widely used, and preferably validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee.

COR indicates Class of Recommendation; EO, expert opinion; LD, limited data; LOE, Level of Evidence; NR, nonrandomized; R, randomized; and RCT, randomized controlled trial.

Essential questions in the evaluation of patients for valvular intervention

Questions
• How severe is VHD?
• What is the aetiology of VHD?
• Does the patient have symptoms?
• Are symptoms related to valvular disease?
• Are any signs present in asymptomatic patients that indicate a worse outcome if the intervention is delayed?
• What are the patient's life expectancy and expected quality of life?

www.escardio.org/guidelines

2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease (European Heart Journal 2017 - doi:10.1093/eurheartj/ehx391)

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Essential questions in the evaluation of patients for valvular intervention *(continued)*

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Questions *(continued)*
• Do the expected benefits of intervention (versus spontaneous outcome) outweigh its risks?
• What is the optimal treatment modality? Surgical valve replacement (mechanical or biological), surgical valve repair, or catheter intervention?
• Are local resources (local experience and outcome data for a given intervention) optimal for the planned intervention?
• What are the patient's wishes?

EACTS

Requirements of a heart valve centre

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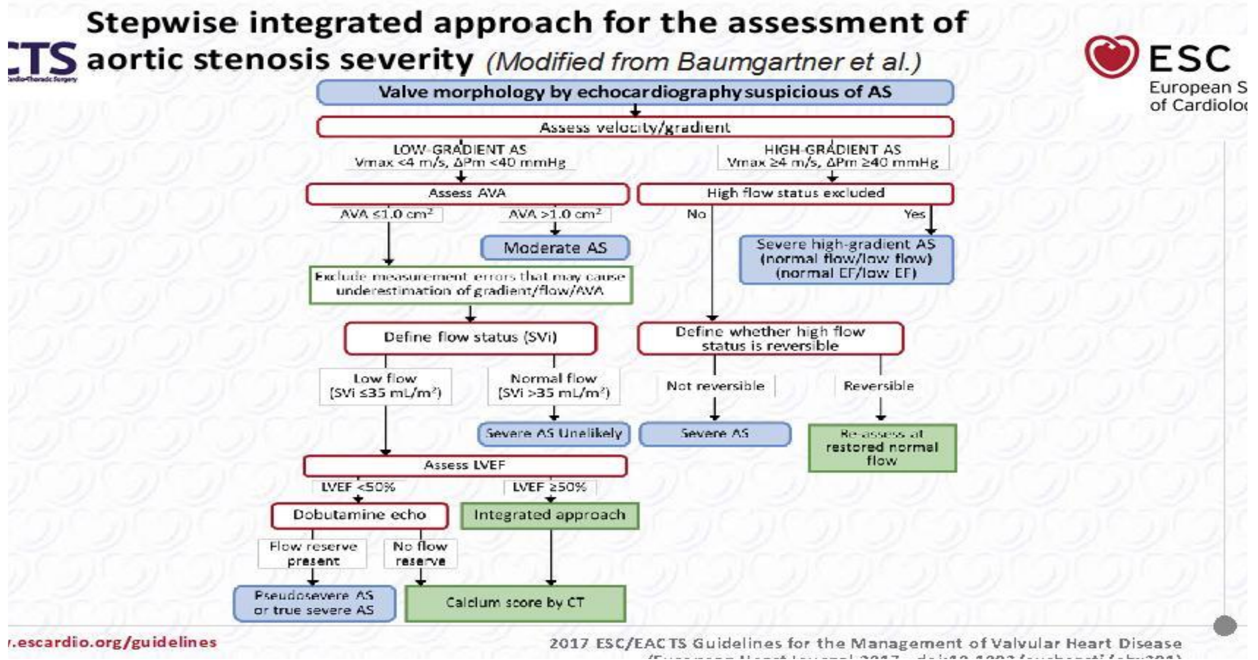
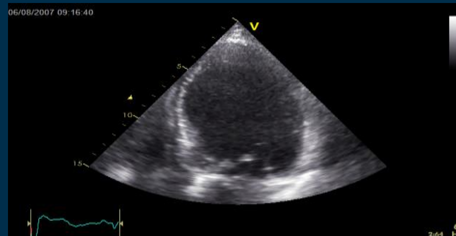
(Modified from Chambers et al.)

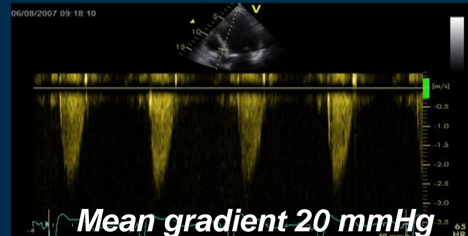
Requirements
Multidisciplinary teams with competencies in valve replacement, aortic root surgery, mitral, tricuspid and aortic valve repair, as well as trans-catheter aortic and mitral valve techniques including reoperations and reinterventions. The Heart Teams must meet on a regular basis and work with standard operating procedures.
Imaging including 3D and stress echocardiographic techniques, peri-operative TOE,cardiac CT, MRI, and positron emission tomography-CT.
Regular consultation with community, other hospitals, and extracardiac departments, and between non-invasive cardiologists and surgeons and interventional cardiologists.



Dobutamine stress echocardiography

Baseline

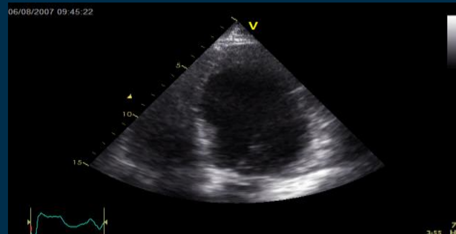


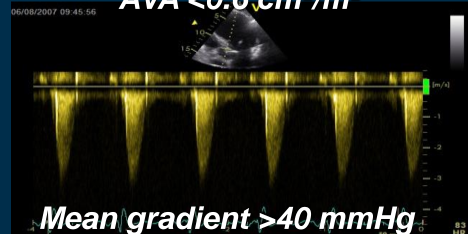


Mean gradient 20 mmHg

AVA <0.6 cm²/m²

Peak DBT 20mcg/kg/min

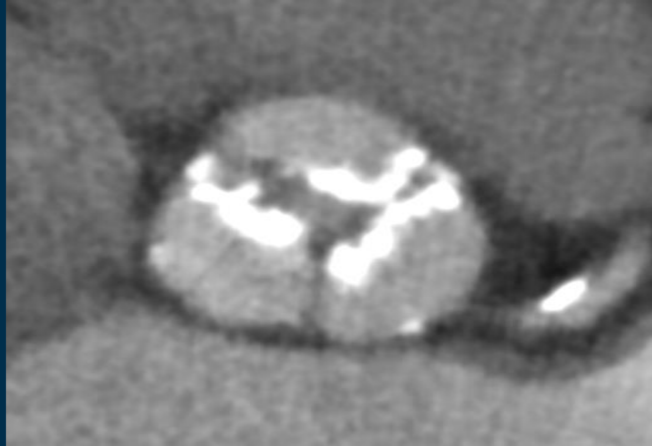




Mean gradient >40 mmHg

AVA <0.6 cm²/m²

Low-flow low-gradient AS vs. MDCT



Cut-off values for aortic valve calcification burden to define severe AS:

Men: >2065 AU
Women: >1275 AU

Cueff et al. Heart 2011
Clavel et al. J Am Coll Cardiol 2013

AHA/ACC Guidelines

Table 3. Stages of Progression of VHD

Stage	Definition	Description
A	At risk	Patients with risk factors for development of VHD
B	Progressive	Patients with progressive VHD (mild-to-moderate severity and asymptomatic)
C	Asymptomatic severe	Asymptomatic patients who have the criteria for severe VHD:
		C1: Asymptomatic patients with severe VHD in whom the left or right ventricle remains compensated
		C2: Asymptomatic patients with severe VHD, with decompensation of the left or right ventricle
D	Symptomatic severe	Patients who have developed symptoms as a result of VHD

VHD indicates valvular heart disease.

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AHA/ACC Guidelines Classification of aortic stenosis

Stage	Definition	Valve Anatomy	Valve Hemodynamics	Hemodynamic Consequences	Symptoms
A	At risk of AS	• Bicuspid aortic valve (or other congenital valve anomaly) • Aortic valve sclerosis	• Aortic V_{max} <2 m/s	• None	• None
B	Progressive AS	• Mild-to-moderate leaflet calcification of a bicuspid or trileaflet valve with some reduction in systolic motion or • Rheumatic valve changes with commissural fusion	• Mild AS: Aortic V_{max} 2.0–2.9 m/s or mean ΔP <20 mm Hg • Moderate AS: Aortic V_{max} 3.0–3.9 m/s or mean ΔP 20–39 mm Hg	• Early LV diastolic dysfunction may be present • Normal LVEF	• None
C: Asymptomatic severe AS					
C1	Asymptomatic severe AS	• Severe leaflet calcification or congenital stenosis with severely reduced leaflet opening	• Aortic V_{max} $\geq$4 m/s or mean ΔP $\geq$40 mm Hg • AVA typically is $\leq$1.0 cm^2 (or AVAi $\leq$0.6 cm^2/m^2) • Very severe AS is an aortic V_{max} $\geq$5 m/s or mean ΔP $\geq$60 mm Hg	• LV diastolic dysfunction • Mild LV hypertrophy • Normal LVEF	• None: Exercise testing is reasonable to confirm symptom status
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D2	Symptomatic severe low-flow/low-gradient AS with reduced LVEF	• Severe leaflet calcification with severely reduced leaflet motion	• AVA $\leq$1.0 cm^2 with resting aortic V_{max} <4 m/s or mean ΔP <40 mm Hg • Dobutamine stress echocardiography shows AVA $\leq$1.0 cm^2 with V_{max} $\geq$4 m/s at any flow rate	• LV diastolic dysfunction • LV hypertrophy • LVEF <50%	• HF • Angina • Syncope or presyncope
D3	Symptomatic severe low-gradient AS with normal LVEF or paradoxical low-flow severe AS	• Severe leaflet calcification with severely reduced leaflet motion	• AVA $\leq$1.0 cm^2 with aortic V_{max} <4 m/s or mean ΔP <40 mm Hg • Indexed AVA $\leq$0.6 cm^2/m^2 and • Stroke volume index <35 mL/m^2 • Measured when patient is normotensive (systolic BP <140 mm Hg)	• Increased LV relative wall thickness • Small LV chamber with low stroke volume • Restrictive diastolic filling • LVEF $\geq$50%	• HF • Angina • Syncope or presyncope

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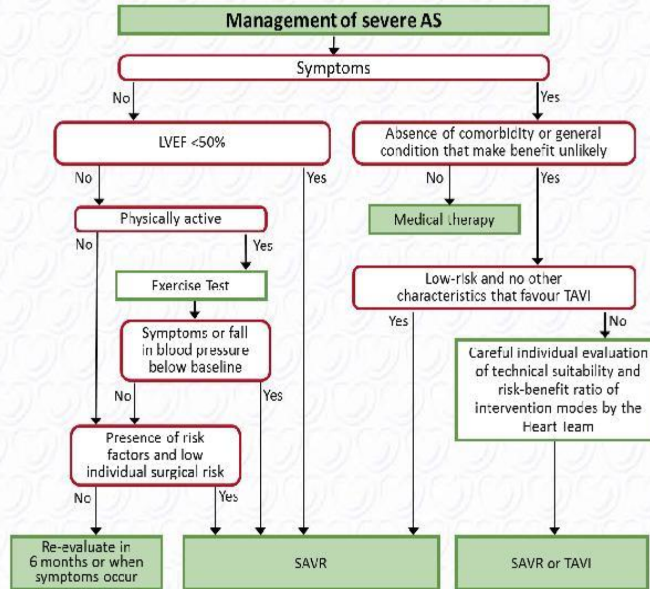

EACTS

Indications for intervention in aortic stenosis and recommendations for the choice of intervention mode

ESC
European Society of Cardiology

Recommendations	Class	Level
a) Symptomatic aortic stenosis		
Intervention is indicated in symptomatic patients with severe, high-gradient aortic stenosis (mean gradient ≥40 mmHg or peak velocity ≥4.0 m/s).	I	B
Intervention is indicated in symptomatic patients with severe low-flow, low-gradient (<40 mmHg) aortic stenosis with reduced ejection fraction, and evidence of flow (contractile) reserve excluding pseudo-severe aortic stenosis.	I	C
Intervention should be considered in symptomatic patients with low flow, low-gradient (<40 mmHg) aortic stenosis with normal ejection fraction after careful confirmation of severe aortic stenosis.	IIa	C

CLASSICAL LOW-FLOW

PARADOXICAL LOW-FLOW

www.escardio.org/guidelines

...vular Heart Disease
.../eurheartj/ehx391)

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EACTS European Association for Cardio-Thoracic Surgery

Indications for intervention in aortic stenosis and recommendations for the choice of intervention mode *(continued)*

ESC European Society of Cardiology

Recommendations	Class	Level
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.	IIa	C
Intervention should not be performed in patients with severe comorbidities when the intervention is unlikely to improve quality of life or survival.	III	C
b) Choice of intervention in symptomatic aortic stenosis		
Aortic valve interventions should only be performed in centres with both departments of cardiology and cardiac surgery on-site, and with structured collaboration between the two, including a Heart Team (heart valve centres).	I	C

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2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease (European Heart Journal 2017 - doi:10.1093/eurheartj/ehx391)

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EACTS European Association for Cardio-Thoracic Surgery

Indications for intervention in aortic stenosis and recommendations for the choice of intervention mode *(continued)*

ESC European Society of Cardiology

Recommendations	Class	Level
c) Asymptomatic patients with severe aortic stenosis (refers only to patients eligible for surgical valve replacement)		
SAVR is indicated in asymptomatic patients with severe aortic stenosis and systolic LV dysfunction (LVEF <50%) not due to another cause.	I	C
SAVR is indicated in asymptomatic patients with severe aortic stenosis and abnormal exercise test showing symptoms on exercise clearly related to aortic stenosis.	I	C

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2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease (European Heart Journal 2017 - doi:10.1093/eurheartj/ehx391)

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EACTS

Indications for intervention in aortic stenosis and recommendations for the choice of intervention mode *(continued)*

ESC European Society of Cardiology

Recommendations	Class	Level
SAVR should be considered in asymptomatic patients with severe aortic stenosis and abnormal exercise test showing fall in blood pressure below baseline.	IIa	C
SAVR should be considered in asymptomatic patients with normal ejection fraction and none of the above-mentioned exercise test abnormalities if the surgical risk is low and one of the following findings is present: – very severe aortic stenosis defined by a V_{max} >5.5 m/s, – severe valve calcification and a rate of V_{max} progression ≥0.3m/s/year, – markedly elevated BNP levels (>threefold age- and sex-corrected normalrange) confirmed by repeated measurements without other explanations, – severe pulmonary hypertension (systolic pulmonary artery pressure at rest >60 mmHg confirmed by invasive measurement) without other explanation.	IIa	C

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2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease
(European Heart Journal 2017 - doi:10.1093/eurheartj/ehx391)

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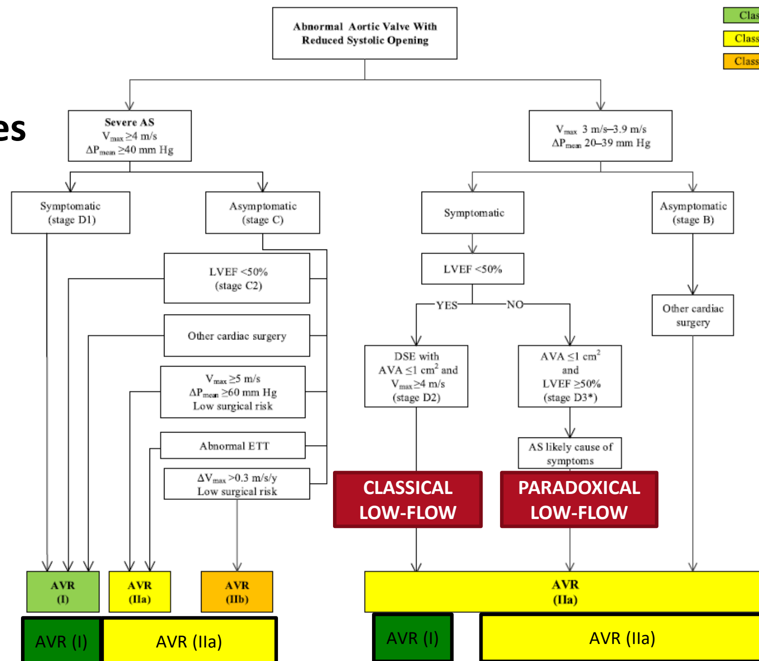
AHA/ACC Guidelines Aortic stenosis



ESC

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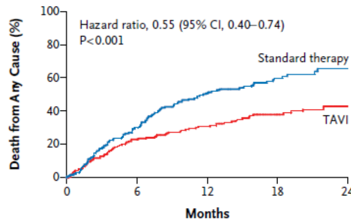
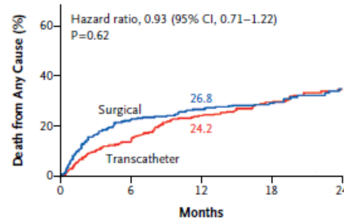
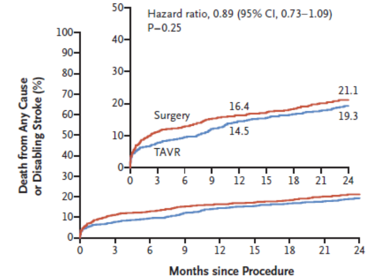
TAVR



No. at Risk					
TAVI	179	138	122	67	26
Standard therapy	179	121	83	41	12



No. at Risk					
Transcatheter	348	298	260	147	67
Surgical	351	252	236	139	65



No. at Risk									
TAVR	1011	918	901	870	842	825	811	801	774
Surgery	1021	838	812	783	770	747	735	717	695

PARTNER-1B
NEJM 2010

PARTNER-1A
NEJM 2011

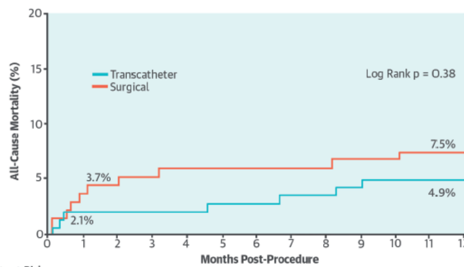
PARTNER-2
NEJM 2016

Prohibitive risk

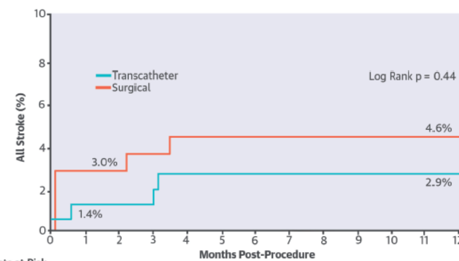
High risk

Intermediate risk

TAVR



Patients at Risk				
Transcatheter	142	139	137	126
Surgical	134	128	125	115



Patients at Risk				
Transcatheter	142	137	134	123
Surgical	134	124	120	110

Thyregod, H.G.H. et al. J Am Coll Cardiol. 2015; 65(20):2184-94.

NOTION
JACC 2015

Indications for intervention in aortic stenosis and recommendations for the choice of intervention mode *(continued)*

EACTS | ESC European Society of Cardiology

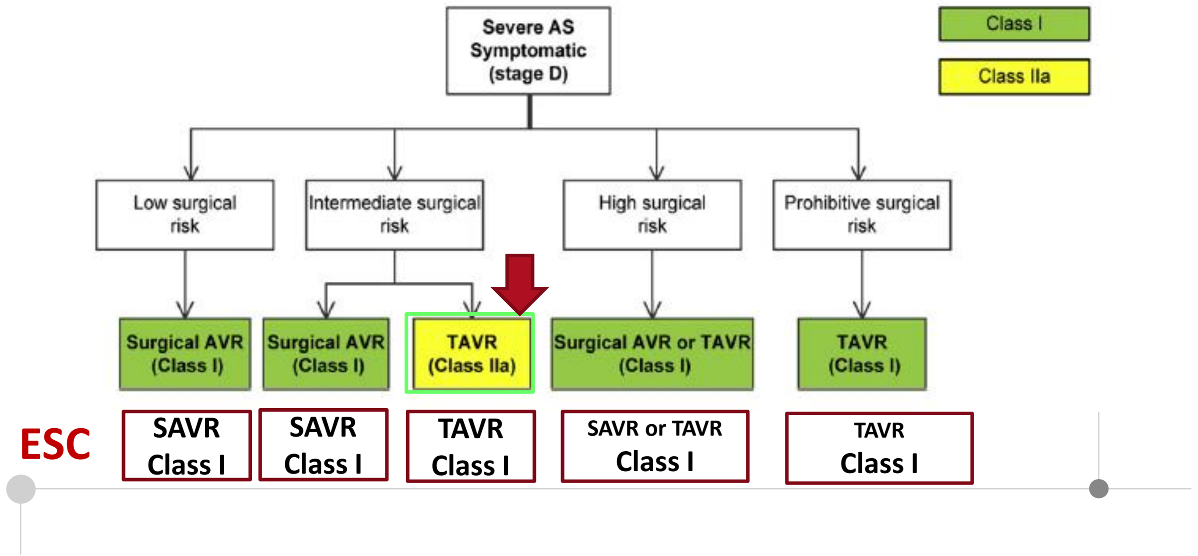
Recommendations	Class	Level
The choice for intervention must be based on careful individual evaluation of technical suitability and weighing of risks and benefits of each modality (aspects to be considered are listed in the according table). In addition, the local expertise and outcomes data for the given intervention must be taken into account.	I	C
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
TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.	I	B

Indications for intervention in aortic stenosis and recommendations for the choice of intervention mode *(continued)*

EACTS | ESC European Society of Cardiology

Recommendations	Class	Level
In patients who are at increased surgical risk (STS or EuroSCORE II ≥4% or logistic EuroSCORE I ≥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 (see according table), with TAVI being favoured in elderly patients suitable for transfemoral access.	I	B

AHA/ACC Guidelines

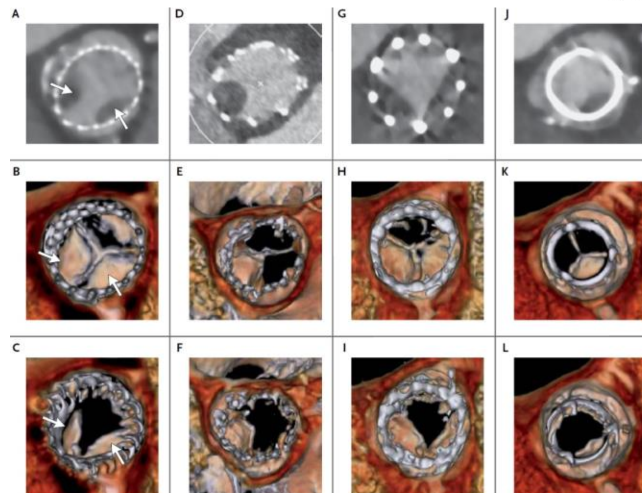


Anticoagulation treatment in bioprostheses

55 patients TAVR
132 patients TAVR or SAVR

4D CT (TEE):
Reduced leaflet motion
(40% and 13% of patients)

No implications for
transvalvular gradients
No increased risk of stroke



Makkar et al. New Engl J Med 2015

EACTS

Indications for antithrombotic therapy for bioprostheses *(continued)*

ESC European Society of Cardiology

Recommendations	Class	Level
Bioprostheses		
Oral anticoagulation is recommended lifelong for patients with surgical or transcatheter implanted bioprostheses who have other indications for anticoagulation.	I	C
Low-dose aspirin (75-100 mg/day) should be considered for the first 3 months after surgical implantation of an aortic bioprosthesis or valve sparing aortic surgery.	IIa	C

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Indications for antithrombotic therapy for bioprostheses *(continued)*

ESC European Society of Cardiology

Recommendations	Class	Level
Bioprostheses *(continued)*		
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

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Aspirin 75 mg to 100 mg per day is reasonable in all patients with a bioprosthetic aortic or mitral valve (178,191–194).

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).

Clopidogrel 75 mg daily may be reasonable for the first 6 months after TAVR in addition to life-long aspirin 75 mg to 100 mg daily.

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).