



ESC / EACTS new valvular guidelines- Update

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CME

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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)

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ESC valve guidelines 2007



European Heart Journal doi:10.1093/eurheartj/ehl428 **ESC Guidelines**

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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AHA/ACC valve guidelines 2006/8

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PRACTICE GUIDELINE

2008 Focused Update Incorporated Into the ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 1998 Guidelines for the Management of Patients With Valvular Heart Disease)

Endorsed by the Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons

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מכתבי האיגוד הקרדיולוגי בישראל

מרץ 2007

הערות למסמך ESC בנושא מחלות לב מסתמיות

http://www.escardio.org/knowledge/guidelines/Valvular-Heart-Disease.htm

ד "ר ירון שפירא,

מרפאת מסתמים ויחידת אקו לב ע "ש דן שיינגרטן, המערך הקרדיולוגי, מרכז רפואי רבין, קמפוס בילינסון, בשם האיגוד הקרדיולוגי בישראל

ד״ר יורם אגמון,

המעבדה לאקוקרדיוגרפיה והמרפאה למחלות מסתמיות, המחלקה קרדיולוגית, מרכז רפואי רמביים, חיפה, בשם החוג לאקוקרדיוגרפיה, האיגוד הקרדיולוגי בישראל

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 recommmended/ is indicated.
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.	
Class lla	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 (LOE)

LOE		# (in tables)
A	Data derived from <i>multiple RCTs</i> or <i>meta-analyses</i> .	0
В	Data derived from a <i>single RCT</i> or <i>large non-</i> <i>randomized studies</i> .	9
С	<u>Consensus of opinion</u> of the experts and/ or small studies, retrospective studies, registries.	59

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?

Heart team

 Heart team is encouraged (however unclassified for most entities)

Essential for TAVI and mitraClip

	Class ^a	Level ^b
It is recommended that patients be adequately informed about the potential benefits and short- and long-term risks of a revascularization procedure. Enough time should be spared for informed decision making.	I	с
The appropriate revascularization strategy in patients with MVD should be discussed by the Heart Team.	I.	с

ESC/EACTS revascularization 2010

Patient evaluation Diagnostic modalities

- Echo mainstay modality for the evaluation of VHD
- Indexing for BSA
 - AS (>0.9 cm²/m² mild AS, <0.6 cm²/m² severe AS)
 - AR (LVESD >25 mm/m² favors AVR)
 - MR (LVESD >22 mm/m² favors MV repair)
 - TR (Annulus >22 mm/m² favors TV annuloplasty)
- R/O inconsistencies between various echo parameters, mechanisms of disease, & clinical findings
- Exercise testing is encouraged

Patient evaluation Diagnostic modalities

Exercise echo – mainly for AS, MS, MR
MRI for LV Fx, valve regurgitation
CTA for TAVI

GUIDELINES AND STANDARDS

Echocardiographic Assessment of Valve Stenosis: EAE/ASE Recommendations for Clinical Practice

Helmut Baumgartner, MD,[†] Judy Hung, MD,[‡] Javier Bermejo, MD, PhD,[†] John B. Chambers, MD,[†] Arturo Evangelista, MD,[†] Brian P. Griffin, MD,[‡] Bernard Iung, MD,[†] Catherine M. Otto, MD,[‡] Patricia A. Pellikka, MD,[‡] and Miguel Quiñones, MD[‡]

Eur J Echocardiogr. 2009 Jan;10(1):1-25.



European Journal of Echocardiography (2010) **11**, 223–244 doi:10.1093/ejechocard/jeq030

European Association of Echocardiography recommendations for the assessment of valvular regurgitation. Part 1: aortic and pulmonary regurgitation (native valve disease)

Patrizio Lancellotti (Chair)^{1*}, Christophe Tribouilloy², Andreas Hagendorff³, Luis Moura⁴, Bogdan A. Popescu⁵, Eustachio Agricola⁶, Jean-Luc Monin⁷, Luc A. Pierard¹, Luigi Badano⁸, and Jose L. Zamorano⁹ on behalf of the European Association of Echocardiography



European Journal of Echocardiography (2010) **11**, 307–332 doi:10.1093/ejechocard/jeq031 RECOMMENDATIONS

European Association of Echocardiography recommendations for the assessment of valvular regurgitation. Part 2: mitral and tricuspid regurgitation (native valve disease)

Patrizio Lancellotti (Chair)^{1*}, Luis Moura², Luc A. Pierard¹, Eustachio Agricola³, Bogdan A. Popescu⁴, Christophe Tribouilloy⁵, Andreas Hagendorff⁶, Jean-Luc Monin⁷, Luigi Badano⁸, and Jose L. Zamorano⁹ on behalf of the European Association of Echocardiography

Indications for TEE (TOE)

- When TTE is of suboptimal quality
- Susp. valve thrombosis
- Susp prosthetic dysfunction
- Susp endocarditis
- Intraprocedural in surgical valve repair or percutaneous procedures (incl. TAVI, MitraClip, PMC)
- Assessment of aortic diameter for TAVI
- Rarely helpful for AS quantification
- Exclude thrombi before PMC
- Detect SEC

Aortic stenosis

Aortic stenosis Severity

	AHA/ACC 2006/8	ESC 2007	ESC/EACTS 2012
Valve area (cm ²)	<1	<1	<1
Indexed valve area (cm ² /m ² BSA)	<0.6	<0.6	<0.6
Mean gradient (mmHg)	>40	>50	>40
Maximum jet velocity (m/s)	>4		>4
Velocity ratio			<0.25

"...Severe AS is unlikely if CO is normal and there is a mean pressure gradient <50 mmHg" (ESC 2007)

Correlation between AVA, mean gradient & Vmax 3483 exams, 2427 pts, good LV



AVA of 1.0 cm² correlated to a ΔP_m of 21 mmHg and a V_{max} of 3.3 m/s. ΔP_m of 40 mmHg corresponds to an AVA of 0.75 cm² V_{max} of 4.0 m/s to an AVA of 0.82 cm².

Minners et al, EHJ 2008; 29: 1043-8

....Same pattern in invasive hemodynamics



Minners et al, Heart 2010; 96: 1463-8

Paradoxical low-flow AS



Pibarot & Dumesnil, JACC 2012; 60: 1845-1853

Paradoxical low-flow AS



Prognosis of severe AS (AVA<1 cm²) with "good LV" (EF>55%) according to flow & gradient

1ry outcome - Time to occurrence of 1st composite endpoint: CV death or need for AVR motivated by the development of symptoms or LV systolic dysfunction (LVEF <50%).



e adjustment was performed as in the multivariate model reported in Table 4. Pt - patient; other abbreviations as in Figure 1.

Gradient cutoff: 40 mmHg Flow cutoff: 35 cc/m²

Lancellotti et al, JACC 2012; 59: 235-43

Natural History of AS



Severe <u>asymptomatic</u> AS: Short-lived event-free prognosis



Otto et al.





Rosenhek et al





Pellika et al

Early surgery in very severe AS



Kang et al, Circulation. 2010;121:1502-1509



Rosenhek et al, Circulation. 2010;121:151-156

Severe* Vs. Very severe ** AS Actuarial survival



* Severe – V max - 4-5m/s, Mean Gr -40-50 mmHg, AVA - 0.6-1 ** Very severe - V max>5m/s, Mean Gr >50 mmHg, AVA<0.6</p>

Kitai T et al, Heart 2011

Additional predictors of adverse outcome



Natriuretic peptides (Bergler-Klein 2004)

Indications for AVR in severe *symptomatic* AS AHA/ACC Vs ESC/EACTS

		AHA/ACC 2006/8	ESC 2007	ESC/EACTS 2012
Severe symp	otomatic AS	Ι	Ι	Ι
	Good LV	*	-	IIa
Low-flow, low- gradient (<40	LV dysf, myocardial reserve (+)	*	IIa	IIa
mmHg)	LV dysf, myocardial reserve (-)	*	IIb	IIb

Indications for AVR in severe *asymptomatic* AS AHA/ACC Vs ESC/EACTS

	AHA/ACC 2006/8	ESC 2007	ESC/EACTS 2012
LV dysfunction	Ι	Ι	I
Planned CABG / other valvular / aorta	I	Ι	I
Symptoms during ETT	IIb	Ι	I
Predicted rapid progression	IIb	IIa	IIa
Hypotension during ETT	IIb	IIa	IIa
Critical AS, predicted mortality <1%	IIb	-	IIa
High-grade arrhythmia during ETT	-	IIb	-
Severe LVH W/O HTN	-	IIb	IIb
High Natriuretic peptide	-	-	IIb
\uparrow Mean gradient by >20 mmHg during	-	-	IIb

Indications for AVR in non-severe AS AHA/ACC Vs ESC/EACTS

	AHA/ACC 2006/8	ESC 2007	ESC/EACTS 2012
Moderate AS, Planned CABG / other valvular / aorta	IIa	IIa	IIa
Mild AS, planned CABG, rapid progression expected	IIb	-	-

ESC/EACTS guidelines for AS - 2012

Management of severe aortic stenosis



IIaC: Vmax >5.5m/s; severe valve calcification + peak velocity progression ≥0.3 m/s/year. IIbC: markedly elevated natriuretic peptide levels; mean gradient increase with exercise >20 mmHg; excessive LVH Avoiding patient-prosthesis mismatch (PPM) in AVR

 "If the valve prosthesis-patient ratio is expected to be ,0.65 cm²/m² BSA,
 enlargement of the annulus to allow
 placement of a larger prosthesis may be
 considered"

Trans-catheter aortic valve implantation (TAVI)



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EXPERT CONSENSUS DOCUMENT

2012 ACCF/AATS/SCAI/STS Expert Consensus Document on Transcatheter Aortic Valve Replacement

Developed in collaboration with the American Heart Association, American Society of Echocardiography, European Association for Cardio-Thoracic Surgery, Heart Failure Society of America, Mended Hearts, Society of Cardiovascular Anesthesiologists, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance

Indications for TAVI ESC/EACTS 2012

	Class	Level
TAVI should only be undertaken with a multidisciplinary "heart team" including cardiologists and cardiac surgeons and other specialists if necessary.	l	С
TAVI should only be performed in hospitals with cardiac surgery on-site.		С
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.	*	в
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.	** lla	В

* PARTNER cohort B ** PARTNER cohort A

Risk assessment for sAVR

Current scores:

- Good discrimination
- Poor calibration in high-risk pts. (overestimation)
- Logistic EuroSCORE >20% (overestimation)
- STS score >10% (more realistic)

Factors not included in current scores:

- Frailty
- Porcelain aorta
- History of chest radiation
- Patent coronary bypass grafts

 Incorporate scores, but <u>always use clinical</u> <u>judgment</u> in addition

CI to TAVI

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^a)

Thrombus in the left ventricle

Active endocarditis

Elevated risk of coronary ostium obstruction (asymmetric valve calcification, short distance between annulus and coronary ostium, small aortic sinuse

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%



Leon M, TCT 2012

DAPT after TAVI

- Low-dose aspirin + a thienopyridine (DAPT) is used early after TAVI and MitraCLip
- Later aspirin or a thienopyridine alone.
- Remarks:
 - Lack of evidence
 - Duration of DAPT ??
- In patients in AF, a combination of VKA and aspirin or thienopyridine is generally used, but should be weighed against increased risk of bleeding.

Aortic regurgitation



Indications for surgery in chronic severe AR AHA/ACC Vs ESC/EACTS

	AHA/ACC	ESC/EACTS 2007/12
Symptomatic (NYHA 2-4)	I	Ι
LVEF <50%	I	Ι
Planned operation - CABG / aorta / other valve	I	I
Marked LV dilatation	IIa LV > 75/55	IIa LV > 70/50 (ESDI>25 mm/m²)
Moderate LV dilatation (70-75/50-55)	IIb	-

Surgery for aortic dilatation Comparison of guidelines

	Aorta (American)	AHA/ACC VHD	ESC	ESC/EACTS
	2010	2006/8	2007	2012
∆ (mm/y)	>5	>5	>5	>2
Marfan	40-50 >40 (desired pregnancy)	>45 >40 (desired pregnancy)	≥45	≥50 ≥45 (RF)*
BAV	40-50	50	≥50	≥55 (≥50+RF)**
Other	55	50	≥55	≥55

* FH of aortic dissection and/or \triangle aortic size >2 mm/year, severe AR or MR, desire of pregnancy. ** FH of dissection \triangle aortic diameter >2 mm/year, coarctation, HTN

- <u>Comparison of values</u>: same technique, same level, side-by-side, confirmed by additional modality
- Lower threshold if AVR is undicated

Mitral stenosis (MS)

Unchanged from 2007 ESC guidelines

Mitral regurgitation

LV dysfunction in 1^{ry} MR

	LVEF	LVESD (mm)
Normal	>60%	<40*/45**
Mild-moderate LV Dx	30-60%	40*/45**-55
Severe LV Dx	<30%	>55



Symptomatic 1^{ry} MR

	AHA/ACC	ESC	ESC/EACTS
	2006/8	2007	2012
Good LV	Ι	Ι	I
Mild-moderate LV Dx	Ι	Ι	I
Severe LV Dx, resistant to medical Tx, <u>high</u> likelihood of repair, W/O significant co-morbidity	IIa	IIa	IIa
Severe LV Dx, resistant to medical Tx, <u><i>low</i></u> likelihood of repair, W/O significant co-morbidity		IIb	IIb

Asymptomatic 1^{ry} MR

		AHA/ACC	ESC	ESC/EACTS
		2006/8	2007	2012
Mild-moderate LV Dx		Ι	Ι	Ι
Good LV, AF* or PAP>50		IIa	IIa	IIa
	Any LVESD	IIa	IIb	-
Good LV, high	LVESD>40 mm			IIa **
likelihood of repair, low operative risk	LA volume >60 cc/m ²	-	-	IIb
	PAP>60 mmHg at exercise	IIa	-	IIb

*new onset AF (AHA/ACC, ESC 2012) ** flail leaflet

Asymptomatic 1^{ry} MR LVEF>60%, high likelihood of repair, low predicted mortality

	<40	40-45	>45
AHA/ACC	IIa	I	I
ESC 2007	-	-	I
ESC/EACTS 2012	-	IIa	I

2^{ry} MR (Functional MR – FMR)

Surgery for FMR

MR severity	LVEF	Need for revascularization	Class
Severe	>30%	(CABG)	I
Moderate		(CABG)	IIa
Severe	<30%	(+)	IIa
Severe	>30%	(-)	IIb

Repair whenever possible

Predictors of late failure of MV repair for FMR

- LVEDD >65 mm,
- PML angle >45°
- Distal AML angle >25°
- Systolic tenting area >2.5 cm²,
- Coaptation distance >10 mm
- End-systolic interpapillary muscle distance >20 mm
- Systolic sphericity index >0.7



Surgery for FMR

Unproved survival benefit

No head-to-head comparison between repair & MVR

 Better results if CABG required (look for ischemia & viability)

MitraClip

 IIb indication, LOE – C
 Less effective than surgical MV repair

- Candidates:
 - Severe symptomatic 2^{ry} MR
 - Failure of OMT (incl. CRT)
 - Fulfillment of echo criteria
 - Inoperable / high risk for surgery (<u>Heart Team</u>)



Tricuspid regurgitation

Indications for tricuspid surgery TR

Туре	Severity		AHA/ACC 2006/8	ESC 2007	ESC/EACTS 2012
1ry/2ry	Severe	While undergoing left-sided valve surgery	I	I	I
1ry	Moderate	While undergoing left-sided valve surgery	IIb **	IIa	IIa
2ry	Mild or moderate	Dilated annulus (\geq 40 mm or $>$ 21 mm/m ² *) in pts. undergoing left-sided valve surgery.	IIb	IIa	IIa
1ry	Severe	Symptomatic, isolated TR without severe RV dysfunction	IIa	I***	I
1ry	Severe	Asymptomatic or mildly symptomatic patients with progressive RV dilatation or deterioration of RV function.	-	IIb	IIa
Any	Severe	After left-sided valve surgery, symptomatic patients / progressive RV dilatation/dysfunction, in the absence of left-sided valve dysfunction, severe right or left ventricular dysfunction, and severe pulmonary vascular disease.	_	IIa	IIa

* 21 mm/m² = 36 mm for BSA=1.7 ** If PHT or dilated annulus *** Despite medical Tx

Valve choice

"...according to the desire of the informed patient..." (Class I)

"valve in valve" not yet included in decision algorithms

Age limits for valve choice (IIa recommendation for all)

AVR

	<60	60-65	65-70	>70
AHA/ACC	Mech	Mech	В	iol
ESC 2007	Mech	Mech	Either	Biol
ESC/EACTS 2012	Mech	Either	В	iol

Age limits for valve choice (IIa recommendation for all)

MVR

	<65	65-70	>70
AHA/ACC	Mech	B	iol
ESC 2007	Mech	Either	Biol
ESC/EACTS 2012	Mech	Either	Biol

Arguments in favor of a mechanical valve (beyond age)

	AHA/ACC 2006/8	ESC 2007	ESC 2012
Risk of accelerated SVD (age,40, PTH↑)		I	I
Already on OAC D/T an additional mechanical valve	I (AVR)	I	I
When re-do is too risky		IIa	IIa *
Already on OAC D/T high-risk of TE	IIa **	IIa	IIb

* If life expectancy >10y ** MVR + AF

Arguments in favor of a biological valve (beyond age)

	AHA/ACC 2006/8	ESC 2007	ESC 2012
Cannot / will not take OAC	Ι	Ι	I
Re-do for mechanical valve thrombosis despite therapeutic INR	-	-	I
Re-do for mechanical valve thrombosis with proven sub- therapeutic INR	-	I	-
When re-do is at low risk	-	IIa	IIa *
Young women contemplating pregnancy.	-	IIb	IIa

* If life expectancy >10y

OAC / aspirin after valve replacement

Low-dose aspirin (on top of OAC) – selective in ESC guidelines (failure of therapeutic INR, atherosclerosis), mandatory in AHA/ACC guidelines.

No need for *life-long* aspirin in low-risk patients with *bioprosthetic* valves in ESC guidelines (*mandatory* in AHA/ACC guidelines)

OAC / aspirin after valve replacement

	AHA/ACC	ESC/EACTS 2012
Lifelong OAC for all pts. with a mechanical prosthesis.	Ι	Ι
Lifelong OAC for pts. with bioprostheses who have other indications for anticoagulation.	Ι	Ι
Addition of aspirin* in all pts. with a mechanical biological prosthesis regardless of concomitant OAC, valve position and risk profile	I	-
Addition of aspirin [*] in pts. with a mechanical prosthesis and concomitant atherosclerotic disease.		IIa
Addition of aspirin* in pts. with a mechanical prosthesis after thromboembolism despite adequate INR.		IIa
OAC for the first 3 months after implantation of a mitral- or tricuspid bioprosthesis.	Ι	IIa
OAC for the first 3 months after mitral valve repair.		IIa
Aspirin* for the first 3 months after implantation of an aortic bioprosthesis.	Ι	IIa
OAC for the first 3 months after implantation of an aortic bioprosthesis.	IIa	IIb

INR target

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

ESC 2007, ESC/EACTS 2012

Vale position	Low-risk	High-risk		
AVR	2-3	2.5-3.5		
MVR	2.5-3.5	2.5-3.5		
AHA/ACC 2006/8				

Novel oral anticagulants (NOAC) (IIa or Xa inhibitors)

The substitution of <u>vitamin K antagonists</u> by direct oral inhibitors of factor IIa or Xa is <u>not</u>
 <u>recommended</u> in patients with a <u>mechanical</u>
 <u>prosthesis</u>, because specific clinical trials in such patients are not available at this time.

Bridging therapy

	AHA/ACC	Esc 2007	ESC/EACTS 2012
IV UFH	Ι	IIa	Ι
LMWH	IIb	IIb	IIa

Questionable issues

- Prophylactic re-replacement of xenograft >10 Y/O without SVD during open-heart surgery (IIb)
- "...MSCT may be useful in excluding CAD in patients who are at low risk of atherosclerosis" (no classification)

Gaps and challenges

- Elaboration and validation of improved risk scoring systems for predicting outcomes after valve surgery and interventional procedures.
- The prognostic impact and diagnostic value of stress echocardiography should be further evaluated.
- Long term results of aortic valve repair.
- The potential role of TAVI in intermediate risk patients with AS and that of MitraClip in high risk patients with secondary MR.

Gaps and challenges (cont'd)

- The indications for intervention in asymptomatic patients with AS or MR should be further evaluated.
- Controlled clinical trials to better define the modalities of early anticoagulant therapy after valve replacement using a mechanical prosthesis, a bioprosthesis in aortic position or after TAVI.
- The usefulness of direct oral inhibitors of factor IIa or Xa in patients with a mechanical prosthesis.

Valve-in-valve

Key notes

- Collaboration with surgeons (Heart Team).
- Risk stratification.
- TAVI (PARTNER-like pts).
- Paradoxical low-flow AS.
- Asymptomatic critical AS.
- Higher thresholds for replacement of aorta.
- Lower LVESD for MV repair in low-risk 1^{ry} MR
- MitraClip for FMR
- Reduced age limits for biological AVR
- ASA instead of OAC early after biological AVR

