

ESC/EACTS Guidelines on Valve Disease Indications for Intervention in Aortic Stenosis

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

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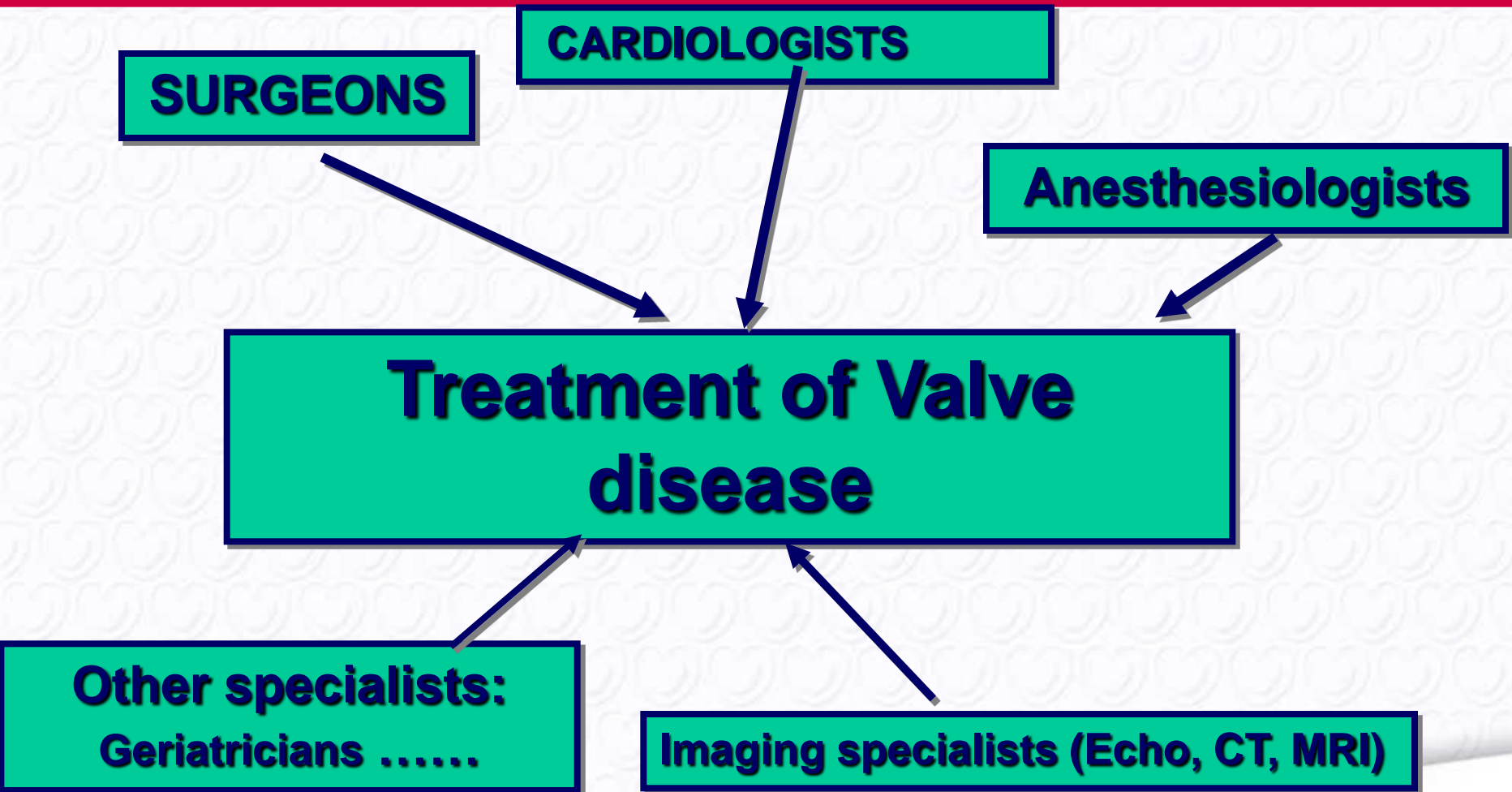
Why do we need new guidelines on the management of valvular disease?

- **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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The « Heart Team »



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?

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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)

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Consistency between indices of AS severity

3483 echocardiographic studies in 2427 pts with AS ($\leq 2 \text{ cm}^2$) with normal LV function (shortening fraction $\geq 30\%$)

Consistent grading

AVA $\geq 1.0 \text{ cm}^2$

$\Delta P \leq 40 \text{ mmHg}$

stroke volume $79 \pm 15 \text{ ml}$

n=983

Inconsistent grading

AVA $< 1.0 \text{ cm}^2$

$\Delta P \leq 40 \text{ mmHg}$

stroke volume $66 \pm 11 \text{ ml}$

n=997 (30%)

Inconsistent grading

AVA $\geq 1.0 \text{ cm}^2$

$\Delta P > 40 \text{ mmHg}$

stroke volume $107 \pm 15 \text{ ml}$

n=29

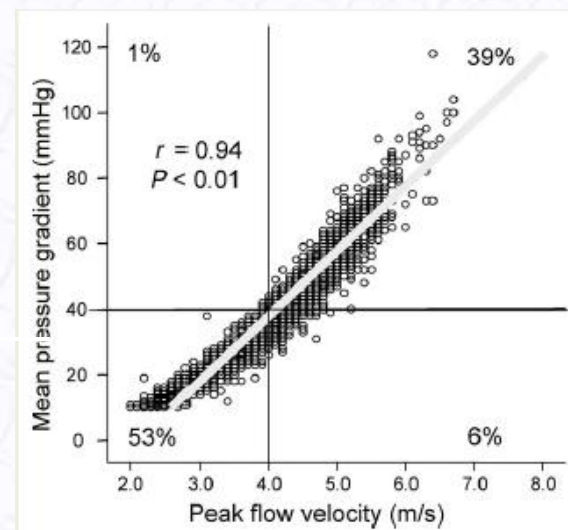
Consistent grading

AVA $< 1.0 \text{ cm}^2$

$\Delta P > 40 \text{ mmHg}$

stroke volume $70 \pm 14 \text{ ml}$

n=1338



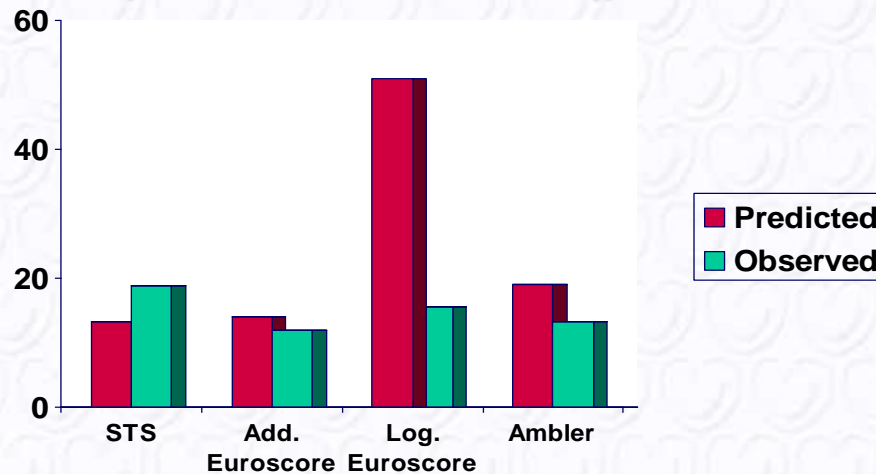
(Minners et al. Eur Heart J 2008;29:1043-8)

Consistency between indices of AS severity

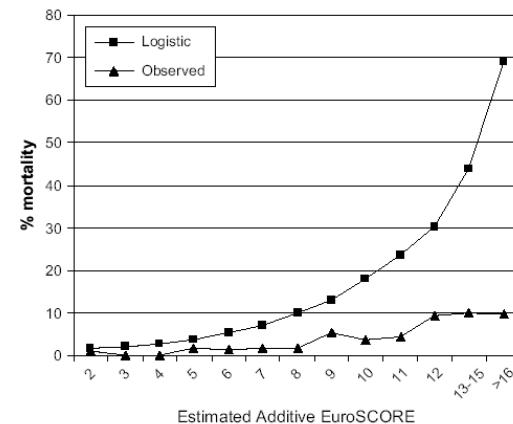
- **Low-flow low-gradient AS with decreased EF**
 - Low-dose dobutamine echocardiography
- **Low-flow low-gradient AS with preserved EF**
 - Paradoxical low-flow low-gradient AS
 - Frequent in the elderly
 - Eliminate first causes of errors of measurements
 - Underestimation of transaortic flow
 - Underestimation of the LVOT diameter
 - Usefulness of quantitative assessment of valve calcification

Risk scores in valve surgery

- Good discrimination (low vs. high risk)
C-index 0.75-0.78
- But poor calibration (predicted vs. observed risk)



(Dewey et al. JTCS 2008;135:180-7)



(Brown et al. JTCS 2008;136:566-71)

- Euroscore II
better calibration but no specific study in high-risk patients
(Nashef et al. Eur J Cardiothorac Surg 2012;41:734-45)

Risk scores in PARTNER

- **Contra indication for surgery (Partner B)**

- 358 patients
- **STS score: 12%**

(Leon et al. N Engl J Med 2010;363:1597-607)

- **High-risk for surgery but operable (Partner A)**

- 699 patients
- **STS score: 12%**

(Smith et al. N Engl J Med 2011;364:2187-98)

“The Model” for the Prediction of the Risk of AVR @ TAVI

- **Simple score based on a limited number of variables**
- **Inclusion of indices of functional and/or cognitive capacities**
- **Specific evaluation in valve patients**
- **Elaborated from a broad spectrum of operative risks**
- **External validation in high- and low-volume centers**
- **Updated on a regular basis**
- **Consider specific model for high-risk patients**

(Rosenhek et al. Eur Heart J 2011, e-pub March 15 2011)

ESC/ EACTS Guidelines for the Management of Valvular Heart Disease

« In the absence of a perfect quantitative score, the risk assessment should mostly rely on the clinical judgement of the heart team in addition to a combination of scores »

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Treatment

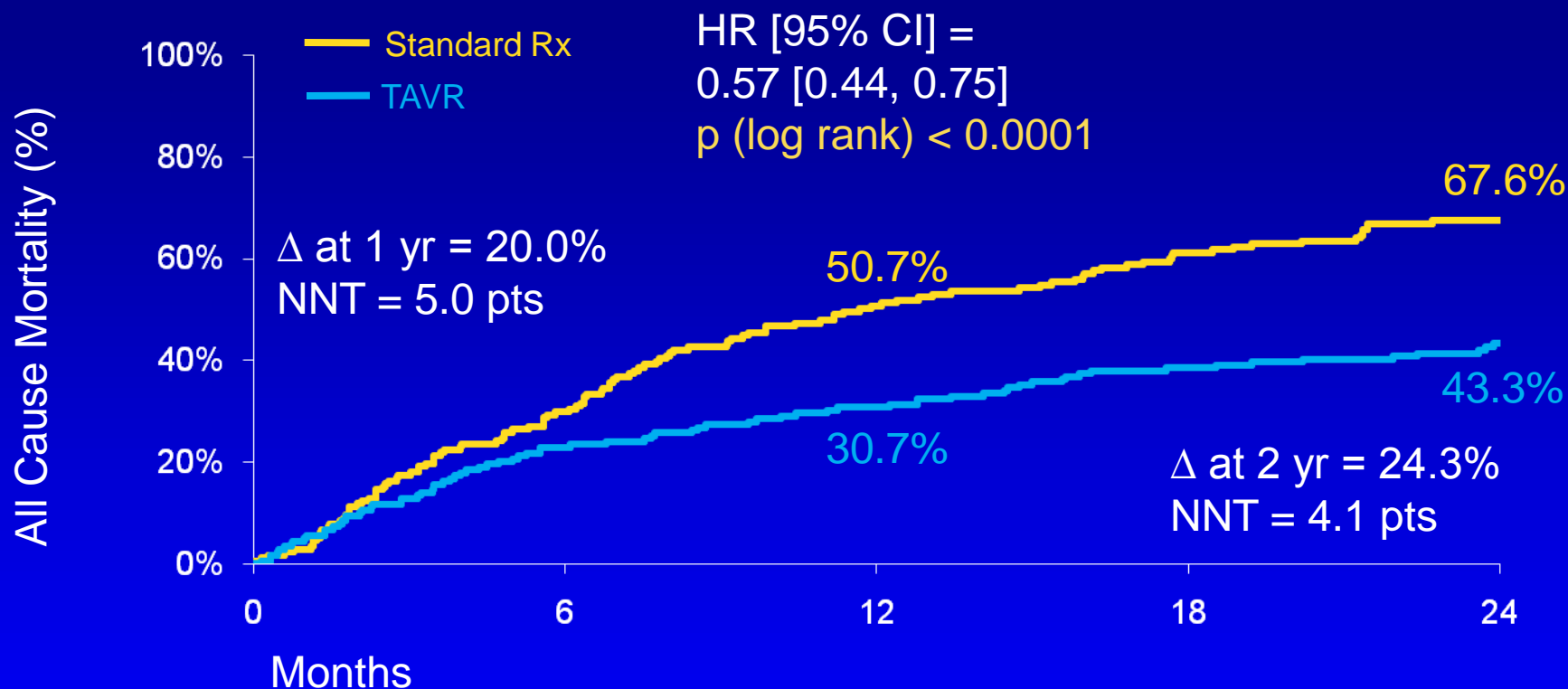
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All Cause Mortality in PARTNER B

TAVI vs Medical Treatment

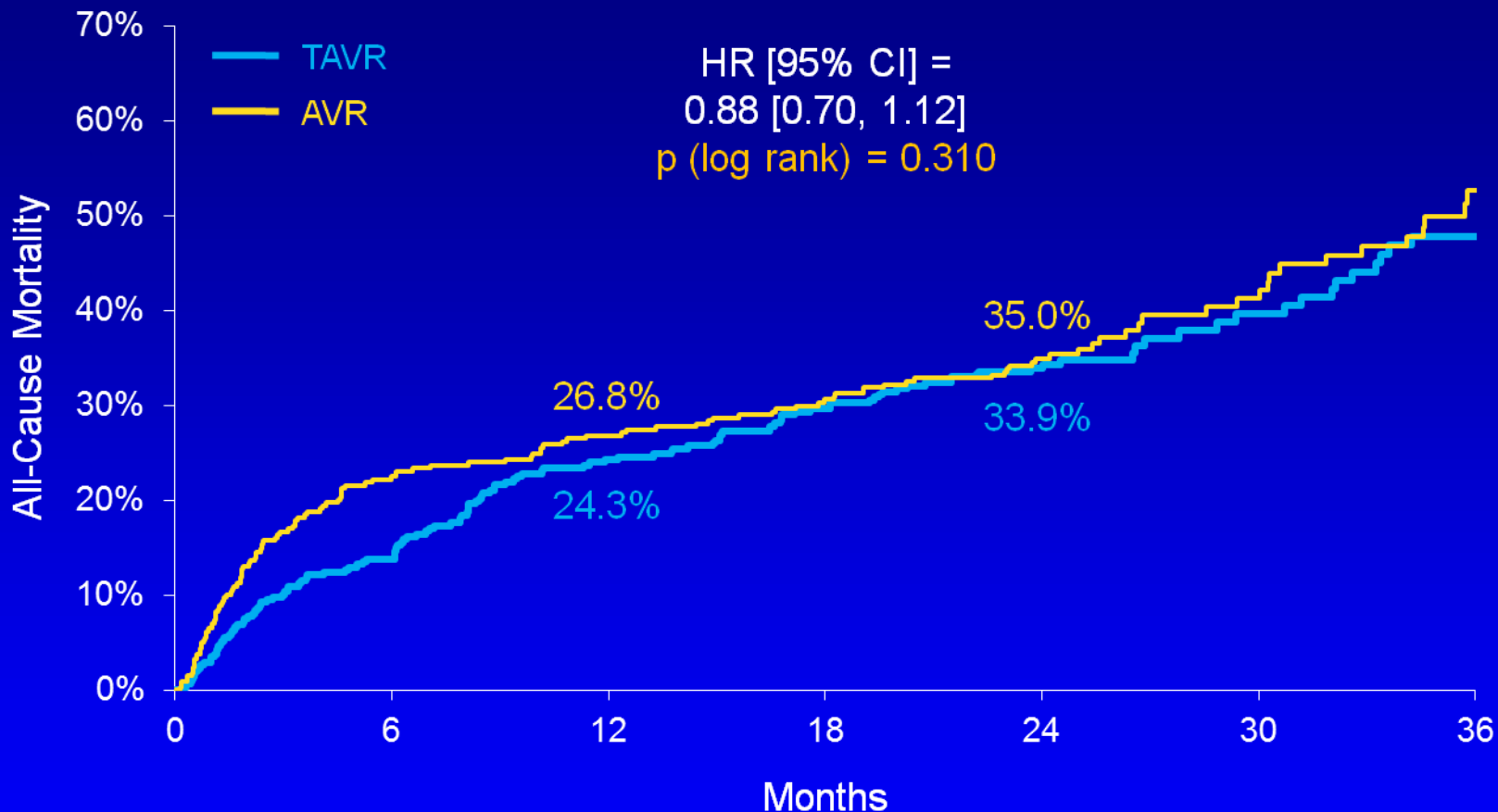


Numbers at Risk

TAVR	179	138	124	110	83
Standard Rx	179	121	85	67	51

All Cause Mortality in PARTNER A

TAVI vs AVR



Numbers at Risk

	0	6	12	18	24	30	36
TAVR	348	298	260	234	172	70	31
AVR	351	252	236	217	165	65	32

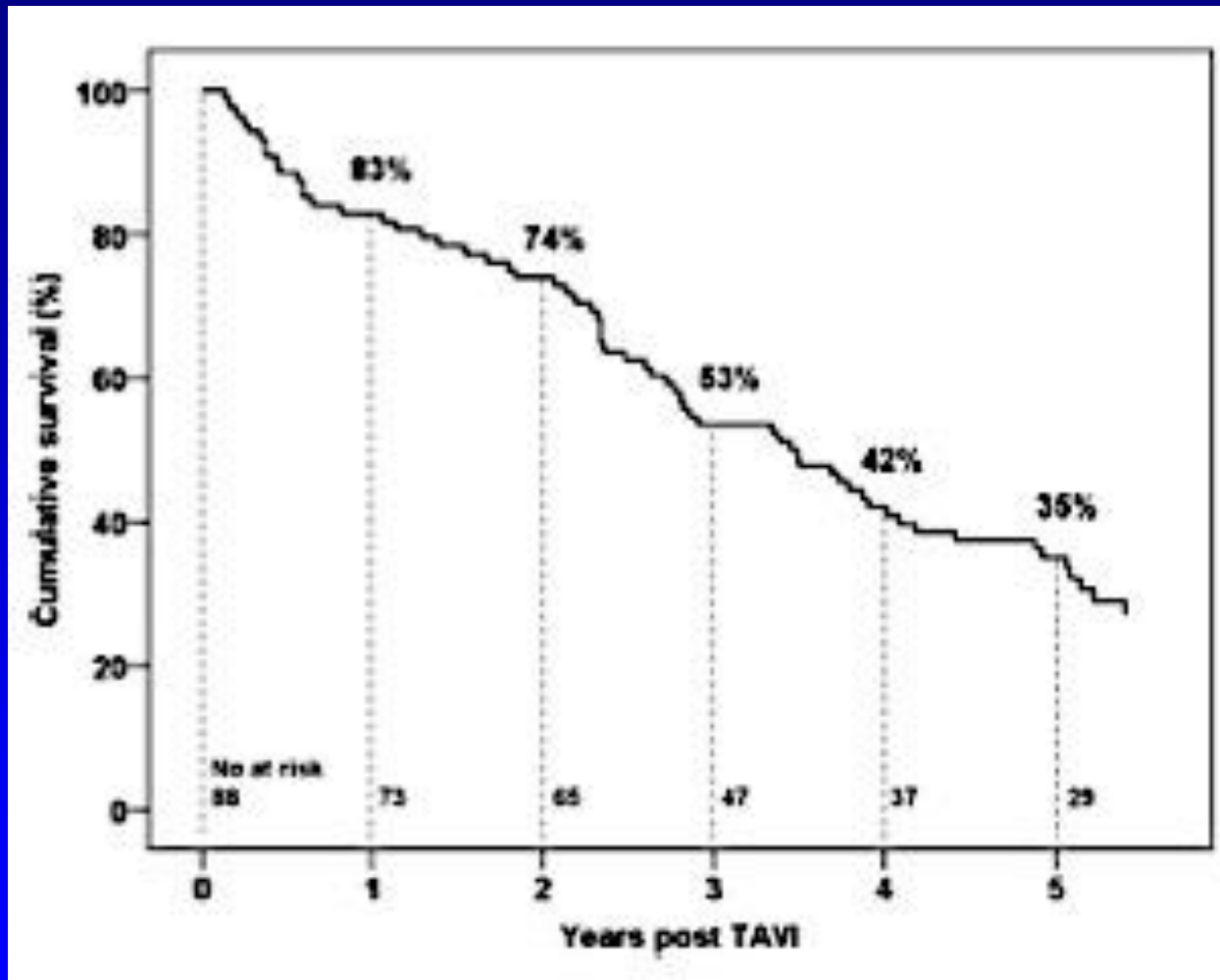
(Kodali, NEJM 2012 ;366:1686-95)

Clinical outcome of TAVI at 30 Days

	ADVANCE Transfemoral N=1015	SOURCE Transfemoral N = 1694	SOURCE Transapical N = 906
All-cause Mortality (%)	4.5	4.3	9.9
Any Stroke (%)	2.9	2.3	2.1
Aortic regurgitation $\geq 2/4$ (%)	-	5.8	3.5
Myocardial Infarction (%)	0.2	0.5	0.7
New Pacemaker (%)	26.3	8.0	10.9
Vascular Complication – Major (%)	10.7	7.3	3.6
Renal Failure with Temporary Dialysis) (%)	5.7	1.2	4.0
Major Bleeding (%)	9.7	5.0	11.4

(Bauernschmidt ; Wendler @ EuroPCR 2012)

Long-term results of TAVI



(Toggweiler S et al J Am Coll Cardiol 2013)

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

« At the present stage, TAVI should not be performed in patients at intermediate risk for surgery and trials are required in this population. »

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).

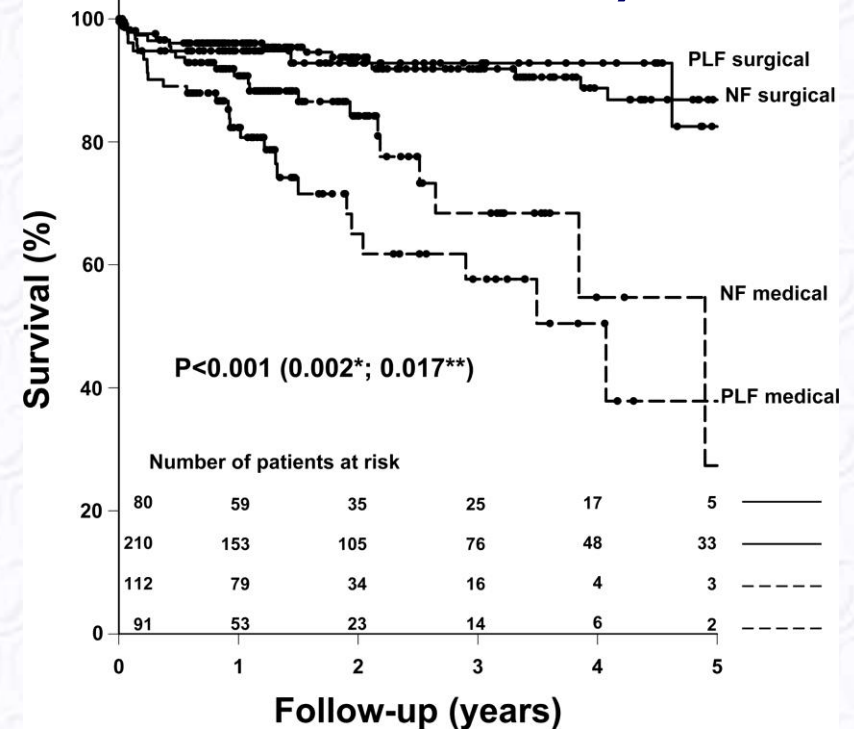
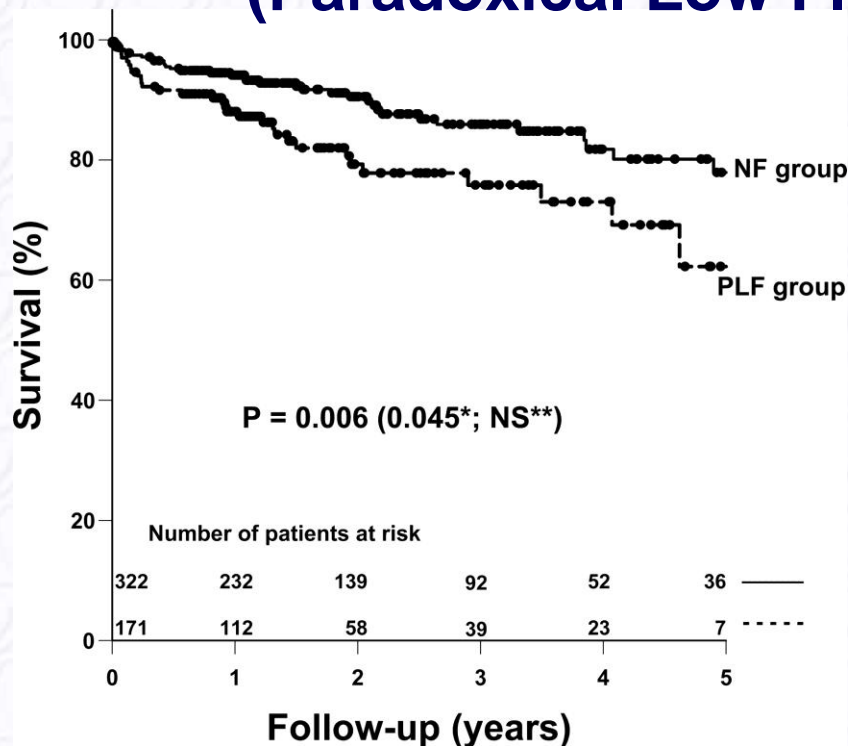
Relative contraindications

- 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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Low Flow – Low Gradient AS with preserved EF

(Paradoxical Low Flow – Low Gradient AS)

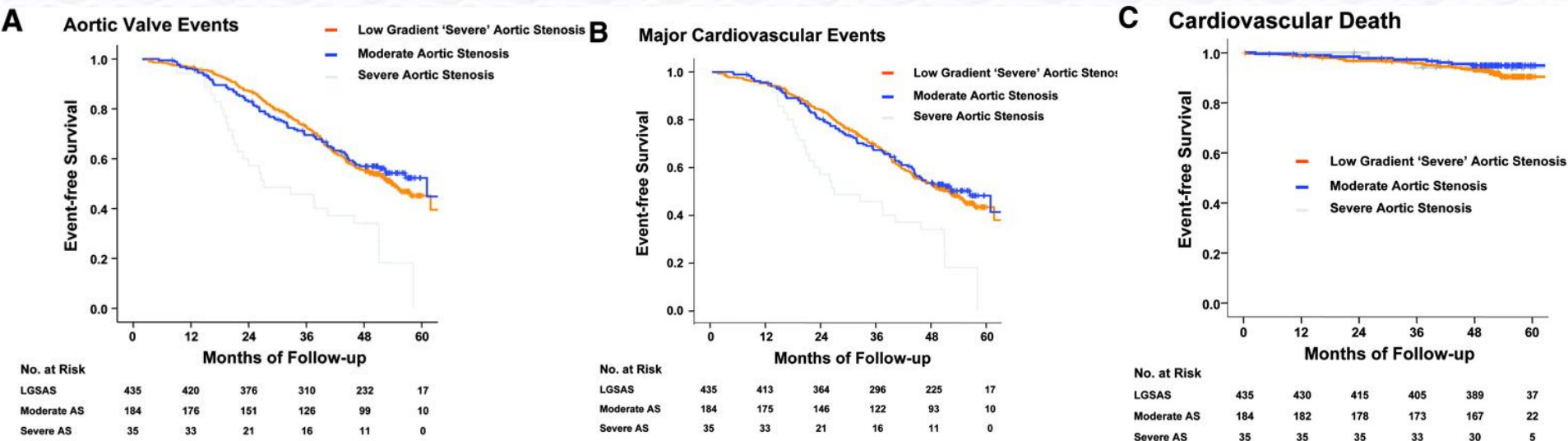


- Retrospective study: 512 patients with severe AS (indexed AVA < 0.6 cm²/m²) and EF > 50 %. 331 NF 181 LF (SVi < 35 ml/m²)

(Hachicha et al. Circulation 2007;115:2856-64)

„Severe“ Low Gradient AS with normal LVEF

- Retrospective analysis of SEAS study data
- 435 patients with mGrad <40mmHg and AVA <1cm² despite EF >55 %
= “severe” low gradient AS (223 with low flow / SVI <35ml/m²).
- 184 patients with moderate AS (AVA 1.0 – 1.5cm²).



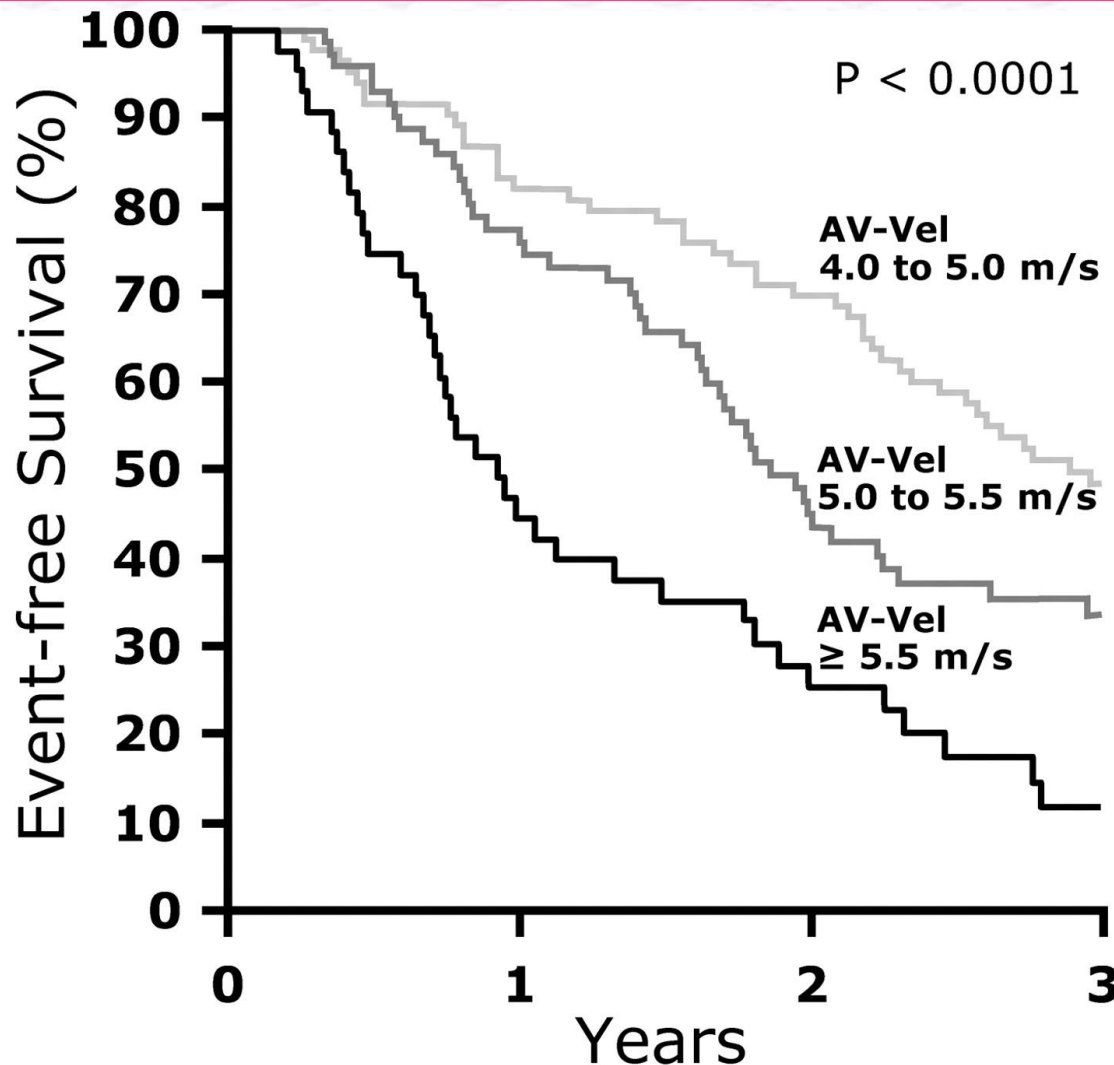
(Jander N et al Circulation 2011;123:887-95)

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
<i>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.</i>	IIa	B
<i>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.</i>	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

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Aortic Jet Velocity Predictor of Outcome in AS



116 pts. AV Vel >5m/s
Median FU 41 mo

96 events:

AVR (90)

Sudden death (1)

Deaths possibly
cardiac related (5):

mean age 83yrs

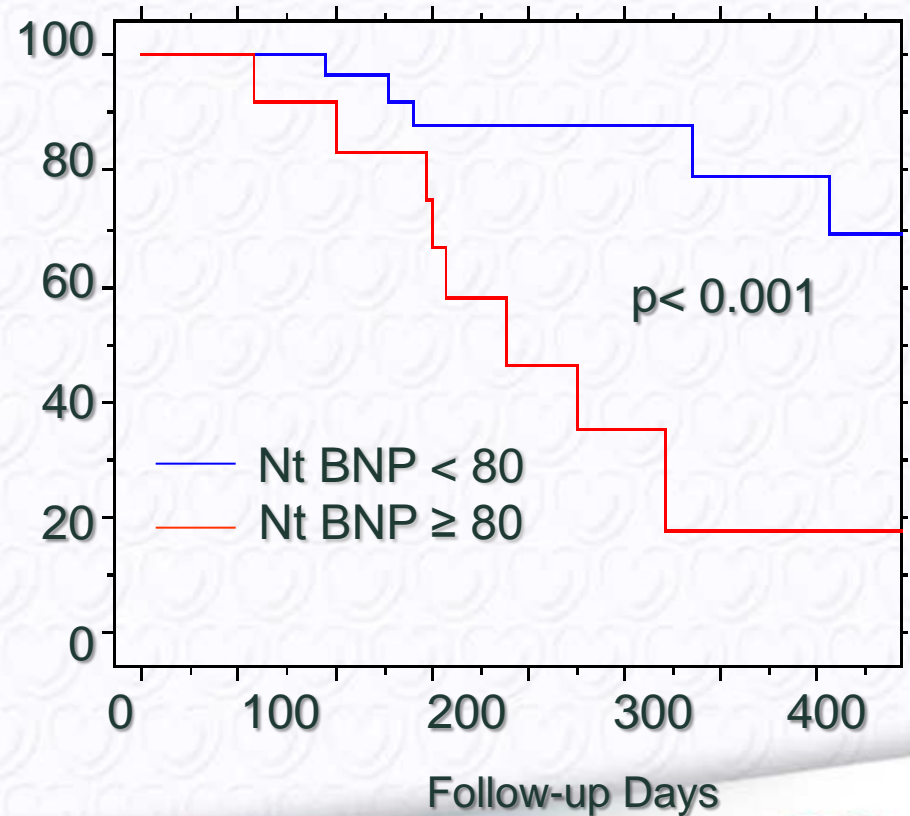
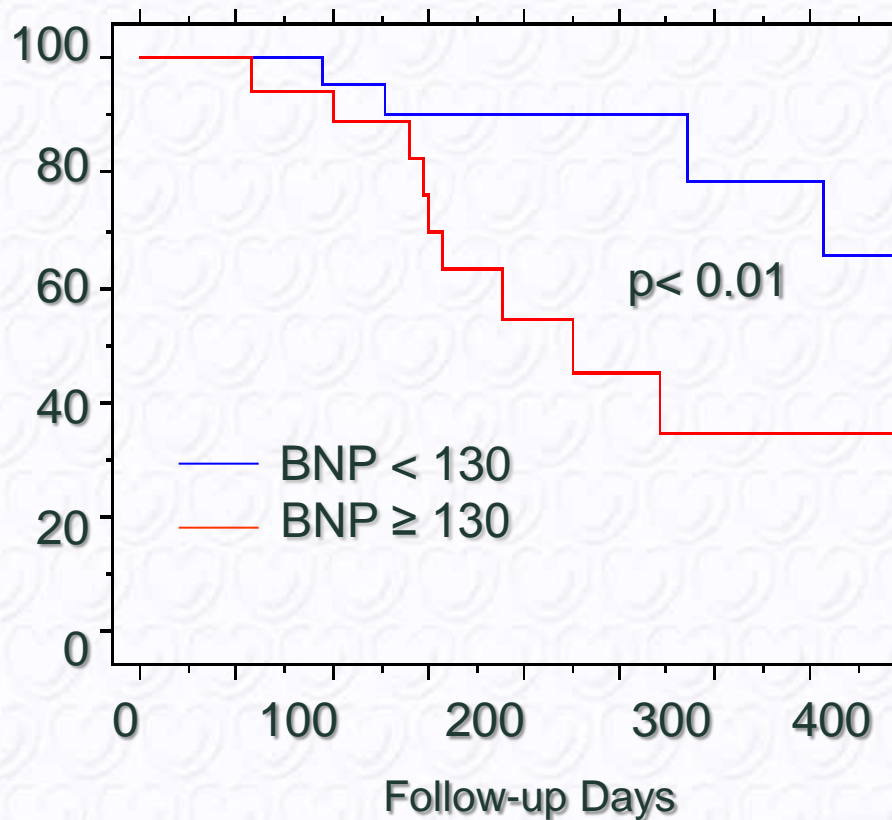
MCI (1)

Sepsis / multiorgan
failure (3)

CHF (1)

Severe asymptomatic AS: Predictive value of neurohormones

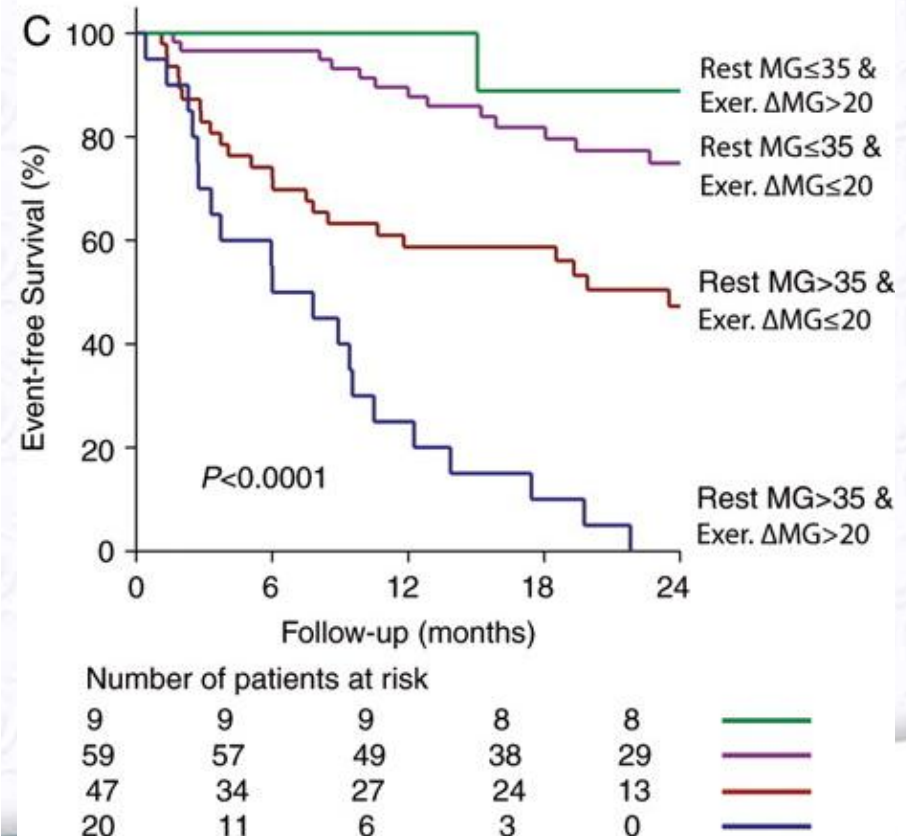
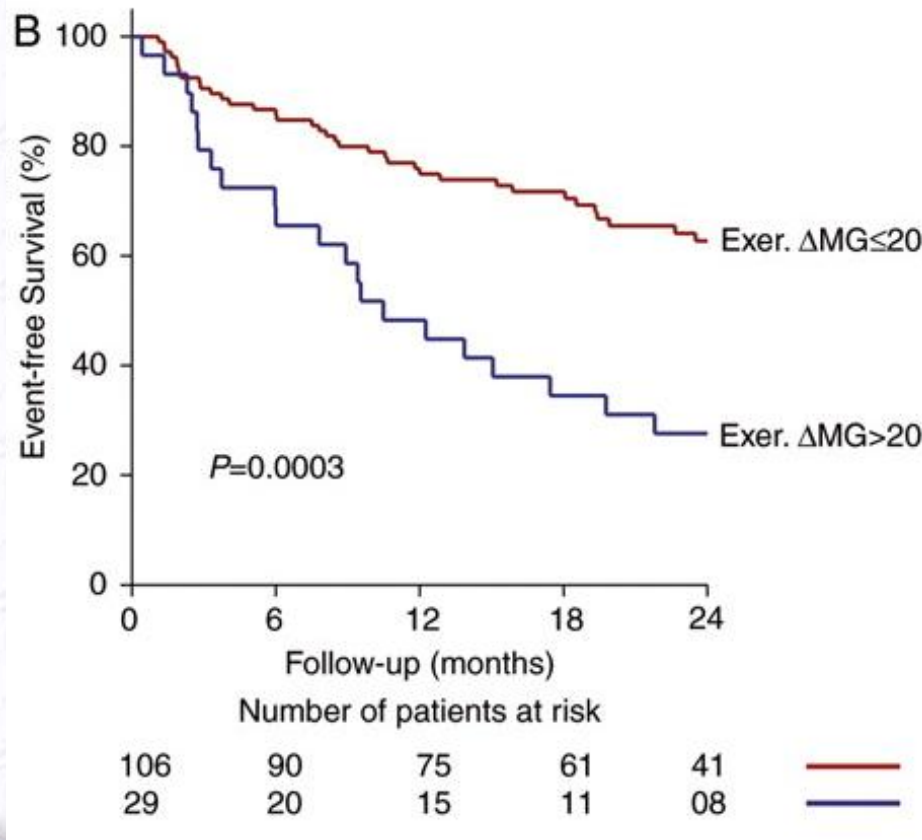
Symptom-Free Survival of Pts. with Severe AS (%)



(Bergler-Klein J. *Circulation* 2004;109:2302-8)

Exercise Echocardiography in Asymptomatic AS

135 asympt. pts. with at least moderate AS and normal standard exercise test

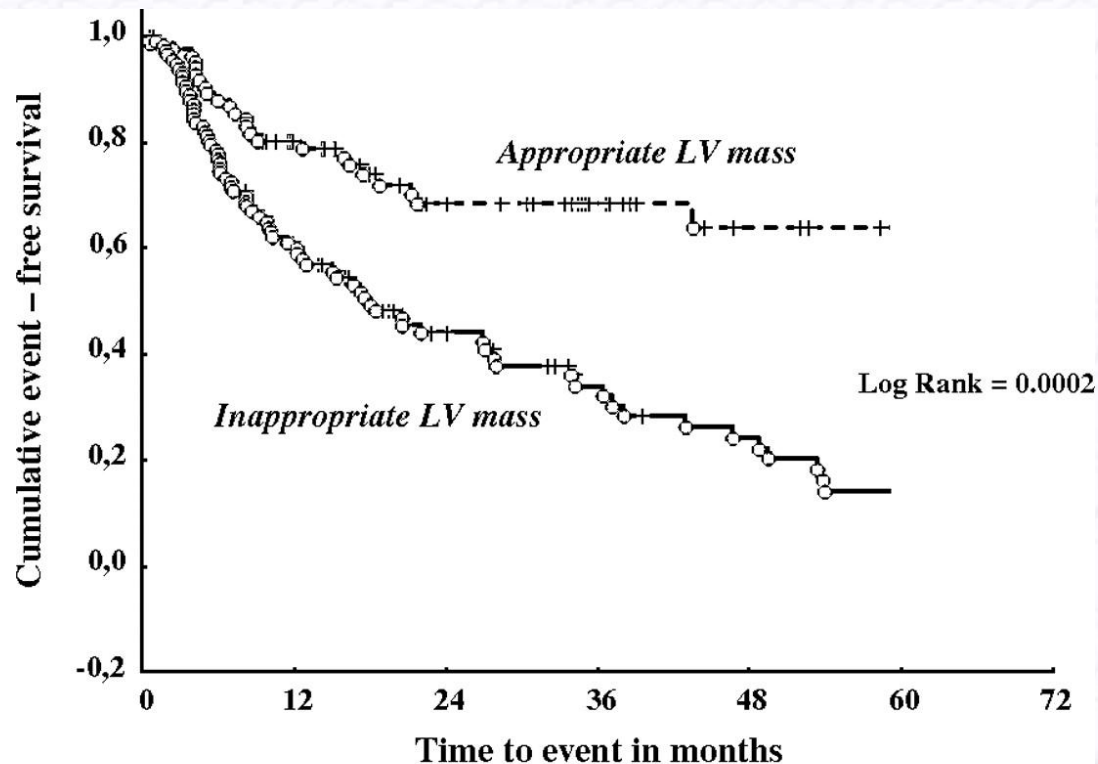


(Maréchaux S et al: Eur Heart J 2010;31:1295-7)

Prognostic value of inappropriately high LV mass in asympt. severe AS

209 asympt. pts. with severe AS

Endpoint: death from all causes, AVR, admission for MI or CHF



Number of events:

Inappropriate LV mass (n=121)	48	12	7	7	7
Appropriate LV mass (n=88)	17	7	0	2	0

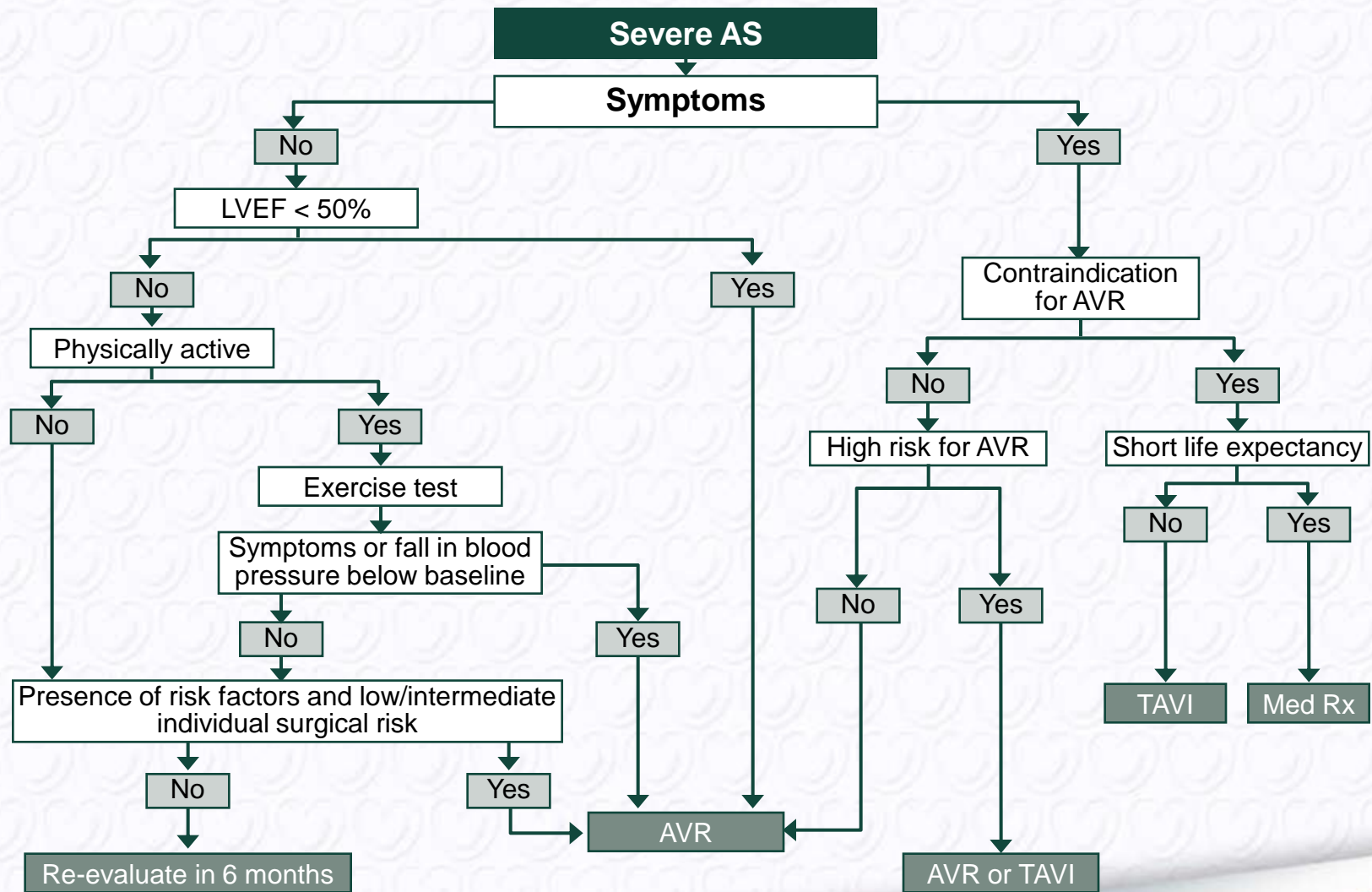
Indications for aortic valve replacement in asymptomatic aortic stenosis

	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
Asymptomatic patients with severe AS and abnormal exercise test showing fall in blood pressure below baseline	IIa	C
<p><i>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:</i></p> <ul style="list-style-type: none"> <i>• very severe AS defined by a peak transvalvular velocity > 5.5 m/s,</i> <i>• severe valve calcification and a rate of peak of transvalvular velocity progression ≥ 0.3 m/s per year.</i> 	IIa	C
<p><i>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:</i></p> <ul style="list-style-type: none"> <i>• markedly elevated natriuretic peptide levels confirmed by repeated measurements without other explanations,</i> <i>• increase of mean pressure gradient with exercise by > 20 mmHg,</i> <i>• excessive LV hypertrophy in the absence of hypertension.</i> 	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.	Ila	C
A bioprosthesis should be considered in young women contemplating pregnancy.	Ila	C
<i>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.</i>	Ila	C

Management of severe aortic stenosis



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Conclusions

- The evaluation of AS should assess both cardiac and extra cardiac condition
- The evaluation of the severity should rely on an integrative approach
- Symptomatic patients are candidates for intervention in the absence of contraindication according to the judgement of the heart team
- Surgery remains the gold standard in patients at low or intermediate risk
- TAVI is indicated in inoperable patients and should be considered in high risk patients
- In the future the respective indications of surgery and TAVI will depend on the improvement in risk stratification, careful evaluation of the results of TAVI, and refinements in technology

