The Place of Percutaneous Techniques in the New Guidelines

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2017 AHA/ACC Focused Update of the 2014 Guideline on the Management of Patients With Valvular Heart Disease

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

Rick A. Nishimura, MD, MACC, FAHA, *Co-Chair*
Catherine M. Otto, MD, FACC, FAHA, *Co-Chair*

Heart Team

I	C	**For patients in whom TAVR or surgical AVR is being considered, a heart valve team consisting of an integrated, multidisciplinary group of healthcare professionals with expertise in VHD, cardiac imaging, interventional cardiology, cardiac anesthesia, and cardiac surgery should collaborate to provide optimal patient care.**	2014 recommendation remains current.

JACC 2017;70:252-289

Prohibitive Risk AS Patients

2017 AHA/ACC VHD GL FOCUSED UPDATE

I	A	**TAVR is recommended for symptomatic patients with severe AS (Stage D) and a prohibitive risk for surgical AVR who have a predicted post-TAVR survival greater than 12 months (55-58).**	**MODIFIED: LOE change from B to A.** Longer term follow-up from RCTs and additional observational studies demonstrate the benefit of TAVR in patients with a prohibitive surgical risk.
See Online Data Supplements 5 and 9 (Updated From 2014 Full-Text Guideline)			

TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.[91,94]	I	B

5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial

Samir R Kapadia, Martin B Leon, Raj R Makkar, E Murat Tuzcu, Lars G Svensson, Susheel Kodali, John G Webb, Michael J Mack, Pamela S Douglas, Vinod H Thourani, Vasilis C Babaliaros, Howard C Herrmann, Wilson Y Szeto, Augusto D Pichard, Mathew R Williams, Gregory P Fontana, D Craig Miller, William N Anderson, Jodi J Akin, Michael J Davidson†, Craig R Smith, for the PARTNER trial investigators*

March 2015

High Risk Symptomatic AS

2017 AHA/ACC VHD GL FOCUSED UPDATE

I	A	**Surgical AVR or TAVR is recommended for symptomatic patients with severe AS (Stage D) and high risk for surgical AVR, depending on patient-specific procedural risks, values and preferences (46-48).**	**MODIFIED: COR change from IIa to I, LOE change from B to A.** Longer term follow-up and additional RCTs have demonstrated that TAVR is equivalent to surgical AVR for severe symptomatic AS when surgical risk is high.
See Online Data Supplement 9 (Updated From 2014 Full-Text Guideline)			
TAVR has been studied in RCT's as well as numerous observational studies and multicenter registries			

5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial

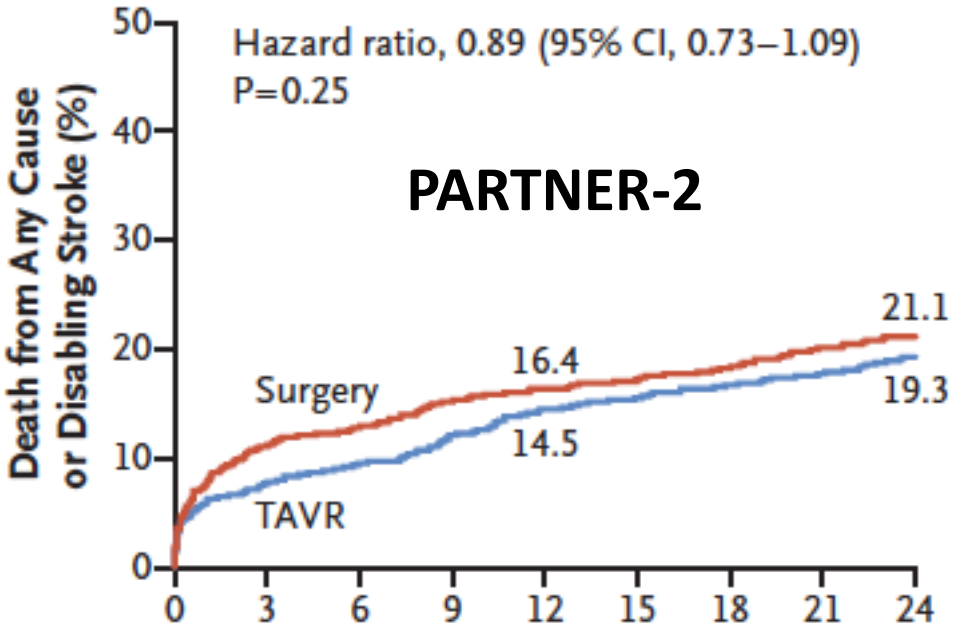
Michael J Mack, Martin B Leon, Craig R Smith, D Craig Miller, Jeffrey W Moses, E Murat Tuzcu, John G Webb, Pamela S Douglas, William N Anderson, Eugene H Blackstone, Susheel K Kodali, Raj R Makkar, Gregory P Fontana, Samir Kapadia, Joseph Bavaria, Rebecca T Hahn, Vinod H Thourani, Vasilis Babaliaros, Augusto Pichard, Howard C Herrmann, David L Brown, Mathew Williams, Jodi Akin, Michael J Davidson†, Lars G Svensson, for the PARTNER 1 trial investigators*

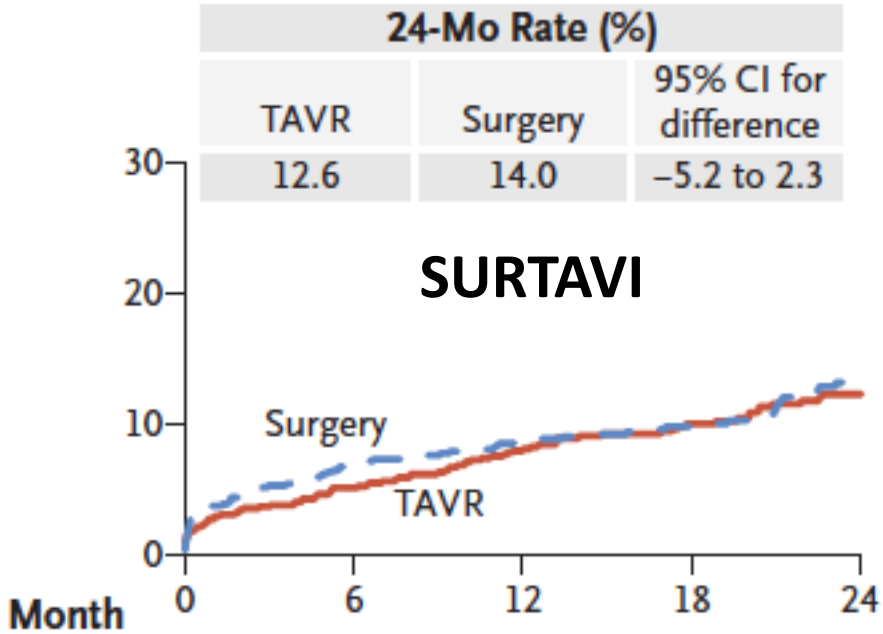
March 2015

Intermediate Risk AS Patients

2017 AHA/ACC VHD GL FOCUSED UPDATE

IIa	**B-R**	**TAVR is a reasonable alternative to surgical AVR for symptomatic patients with severe AS (Stage D) and an intermediate surgical risk, depending on patient-specific procedural risks, values and preferences (59-62).**	**NEW:** New RCTs showed noninferiority of TAVR versus surgical AVR in symptomatic patients with severe AS at intermediate surgical risk.
See Online Data Supplements 5 and 9 (Updated From 2014 Full-Text Guideline)			





Balloon Valvuloplasty

2017 AHA/ACC VHD GL FOCUSED UPDATE

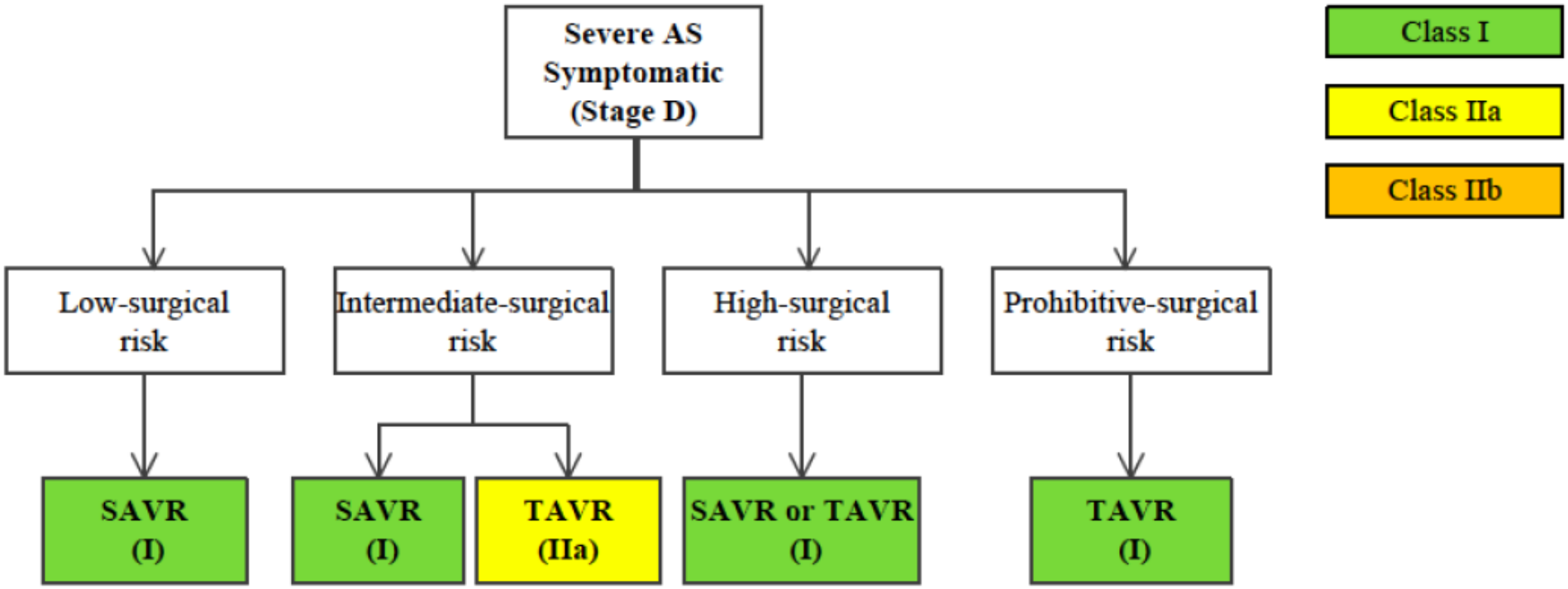
IIb	**C**	**Percutaneous aortic balloon dilation may be considered as a bridge to surgical AVR orTAVR for symptomatic patients with severe AS.**	2014 recommendation remains current.
III: No Benefit	**B**	**TAVR is not recommended in patients in whom existing comorbidities would precludethe expected benefit from correction of AS (58).**	2014 recommendation remains current.

Balloon aortic valvotomy may be considered as a bridge to SAVR or TAVI in haemodynamically unstable patients or in patients with symptomatic severe aortic stenosis who require urgent major non-cardiac surgery.	IIb	C
Balloon aortic valvotomy may be considered as a diagnostic means in patients with severe aortic stenosis or other potential causes for symptoms (i.e. lung disease) and in patients with severe myocardial dysfunction, pre-renal insufficiency or other organ dysfunction that may be reversible with balloon aortic valvotomy when performed in centres that can escalate to TAVI.	IIb	C

JACC 2017;70:252-289

SAVR vs. TAVR for Severe AS

2017 AHA/ACC VHD GL FOCUSED UPDATE



ESC European Society of Cardiology

European Heart Journal (2017) 00, 1–53
doi:10.1093/eurheartj/ehx391

2017 ESC/EACTS Guidelines for the management of valvular heart disease

The Task Force for 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: Helmut Baumgartner* (ESC Chairperson) (Germany), Volkmar Falk*[1] (EACTS Chairperson) (Germany), Jeroen J. Bax (The Netherlands), Michele De Bonis[1] (Italy), Christian Hamm (Germany), Per Johan Holm (Sweden), Bernard Iung (France), Patrizio Lancellotti (Belgium), Emmanuel Lansac[1] (France), Daniel Rodriguez Muñoz (Spain), Raphael Rosenhek (Austria), Johan Sjögren[1] (Sweden), Pilar Tornos Mas (Spain), Alec Vahanian (France), Thomas Walther[1] (Germany), Olaf Wendler[1] (UK), Stephan Windecker (Switzerland), Jose Luis Zamorano (Spain)

2017 ESC/EACTS VHD Guidelines

Requirements for a Heart Center

Multidisciplinary teams with competencies in valve replacement, aortic root surgery, mitral, tricuspid and aortic valve repair, as well as transcatheter 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, perioperative 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.
Back-up services including other cardiologists, cardiac surgeons, intensive care and other medical specialties.
Data review: • Robust internal audit processes including mortality and complications, repair rates, durability of repair, and reoperation rate with a minimum of 1-year follow-up. • Results available for review internally and externally. • Participation in national or European quality databases.

TAVI vs. SAVR

Considerations for Heart Team

ESC 2017

	Favours TAVI	Favours SAVR
Clinical characteristics		
STS/EuroSCORE II <4% (logistic EuroSCORE I <10%)[a]		+
STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%)[a]	+	
Presence of severe comorbidity (not adequately reflected by scores)	+	
Age <75 years		+
Age ≥75 years	+	
Previous cardiac surgery	+	
Frailty[b]	+	
Restricted mobility and conditions that may affect the rehabilitation process after the procedure	+	
Suspicion of endocarditis		+
Cardiac conditions in addition to aortic stenosis that require consideration for concomitant intervention		
Severe CAD requiring revascularization by CABG		+
Severe primary mitral valve disease, which could be treated surgically		+
Severe tricuspid valve disease		+
Aneurysm of the ascending aorta		+
Septal hypertrophy requiring myectomy		+

	Favours TAVI	Favours SAVR
Anatomical and technical aspects		
Favourable access for transfemoral TAVI	+	
Unfavourable access (any) for TAVI		+
Sequelae of chest radiation	+	
Porcelain aorta	+	
Presence of intact coronary bypass grafts at risk when sternotomy is performed	+	
Expected patient–prosthesis mismatch	+	
Severe chest deformation or scoliosis	+	
Short distance between coronary ostia and aortic valve annulus		+
Size of aortic valve annulus out of range for TAVI		+
Aortic root morphology unfavourable for TAVI		+
Valve morphology (bicuspid, degree of calcification, calcification pattern) unfavourable for TAVI		+
Presence of thrombi in aorta or LV		+

2017 ESC/EACTS VHD Guidelines

2017Recommendation for the Choice of intervention Mode

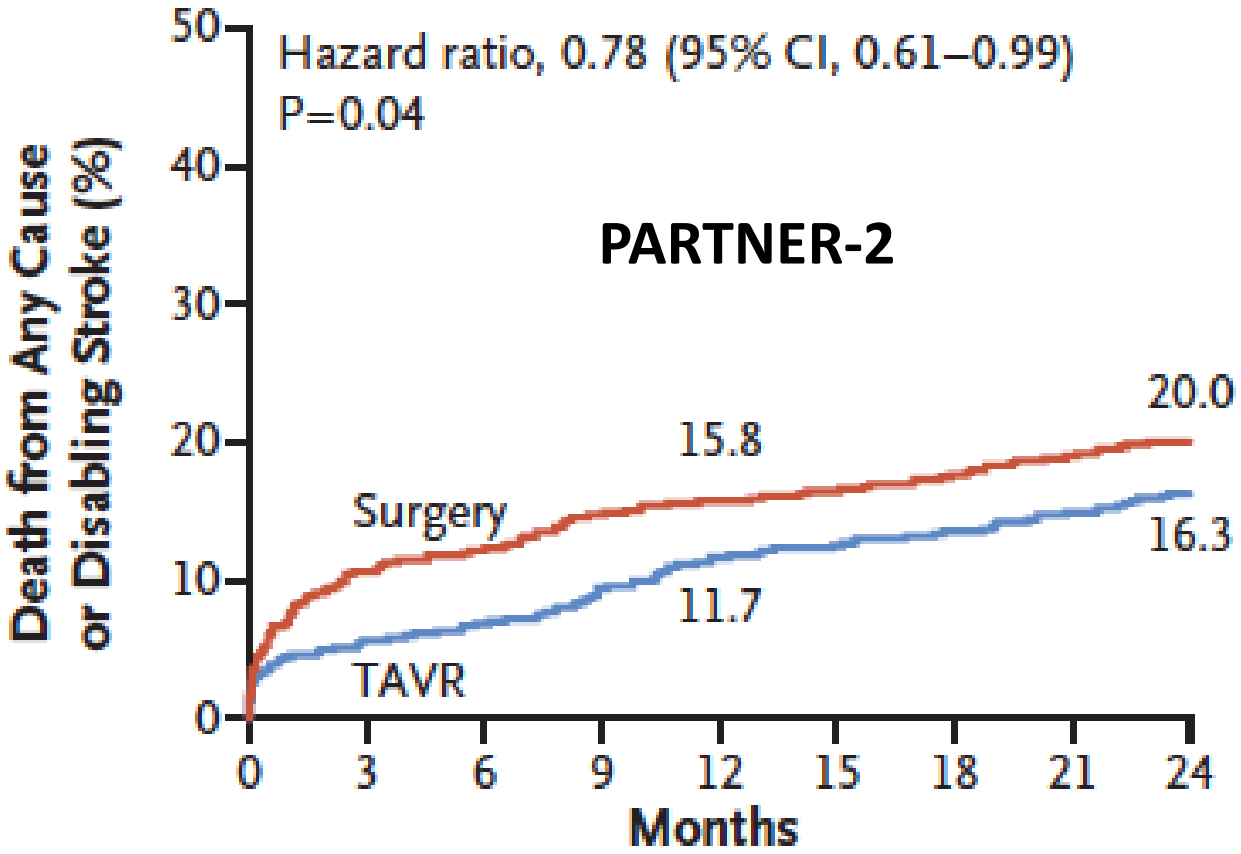
Low vs. increased surgical risk.

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
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 *Table 7*). 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%[d] and no other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation).[93]	I	B
TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.[91,94]	I	B
In patients who are at increased surgical risk (STS or EuroSCORE II ≥ 4% or logistic EuroSCORE I ≥ 10%[d] 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 *Table 7*), with TAVI being favoured in elderly patients suitable for transfemoral access.[91,94–102]	I	B
Balloon aortic valvotomy may be considered as a bridge to SAVR or TAVI in haemodynamically unstable patients or in patients with symptomatic severe aortic stenosis who require urgent major non-cardiac surgery.	IIb	C
Balloon aortic valvotomy may be considered as a diagnostic means in patients with severe aortic stenosis or other potential causes for symptoms (i.e. lung disease) and in patients with severe myocardial dysfunction, pre-renal insufficiency or other organ dysfunction that may be reversible with balloon aortic valvotomy when performed in centres that can escalate to TAVI.	IIb	C

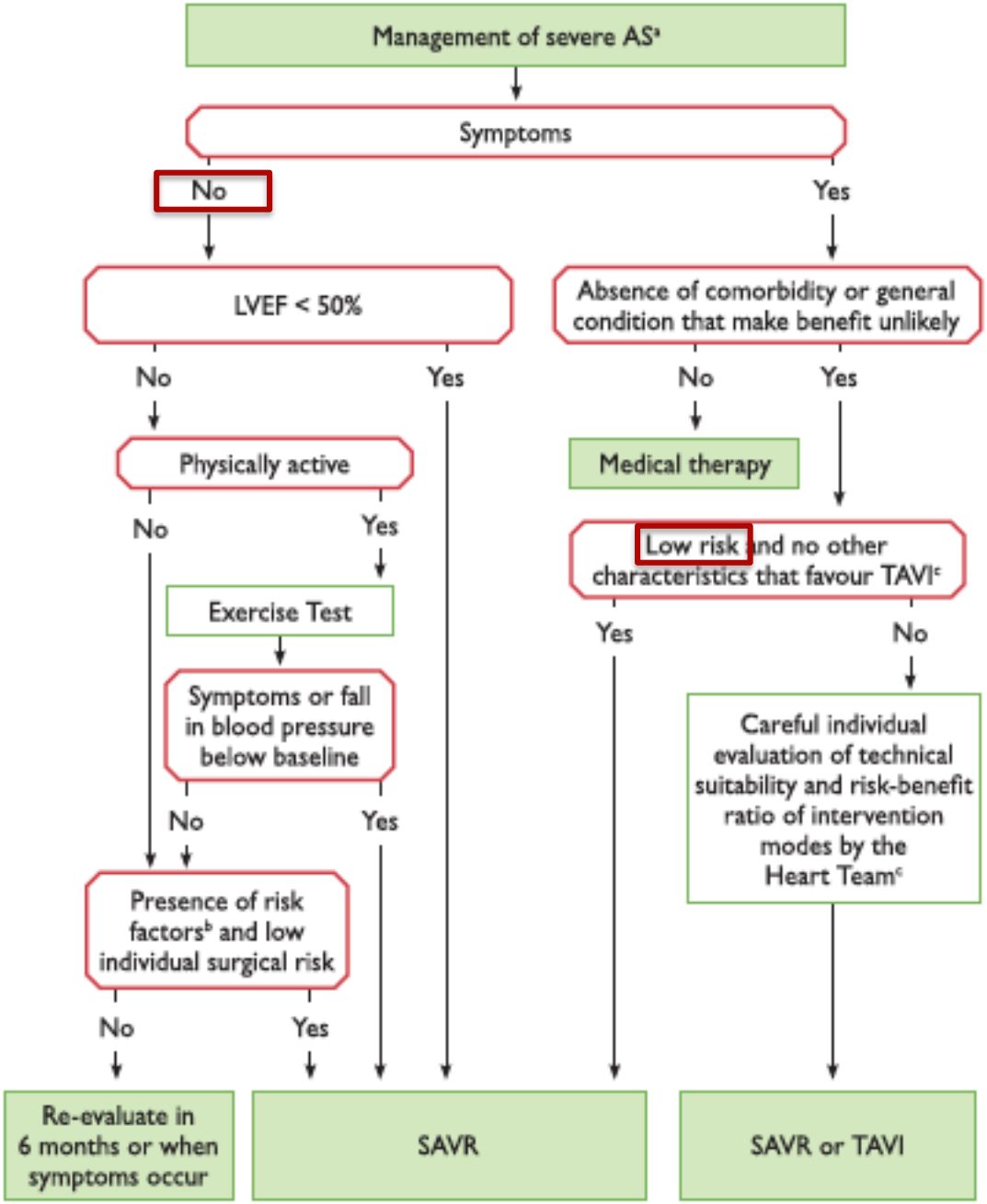
TRANSFEMORAL TAVR

2017 ESC/EACTS VHD Guidelines

In patients who are at increased surgical risk (STS or EuroSCORE II ≥ 4% or logistic EuroSCORE I ≥ 10%[d] 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 *Table 7*), with TAVI being favoured in elderly patients suitable for transfemoral access.[91,94–102]	I	B



ESC/EACTS VHD Guidelines 2017



Baumgartner et al. EHJ 2017

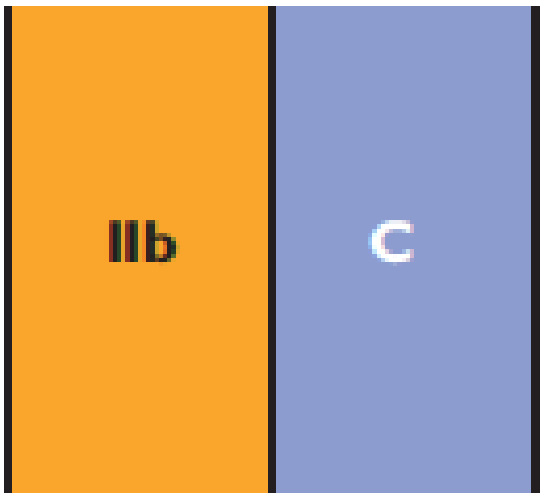
Transcatheter Repair for Primary Mitral Regurgitation

ACC/AHA

Transcatheter mitral valve repair may be considered for severely symptomatic patients (NYHA class III to IV) with chronic severe primary MR (stage D) who have favorable anatomy for the repair procedure and a reasonable life expectancy but who have a prohibitive surgical risk because of severe comorbidities and remain severely symptomatic despite optimal GDMT for heart failure (HF) (124).

ESC/EACTS

Percutaneous edge-to-edge procedure may be considered in patients with symptomatic severe primary mitral regurgitation who fulfil the echocardiographic criteria of eligibility and are judged inoperable or at high surgical risk by the Heart Team, avoiding futility.



Transcatheter Repair for Secondary Mitral Regurgitation

2017 AHA/ACC VHD GL FOCUSED UPDATE

Percutaneous mitral valve repair provides a less invasive alternative to surgery but is not approved for clinical use for this indication in the United States (70,72,125-127). The results of RCTs examining the efficacy of percutaneous mitral valve repair in patients with secondary MR are needed to provide information on this patient group (128,129).

2017 ESC/EACTS VHD Guidelines

Percutaneous Edge-to-edge Repair for Secondary Mitral Regurgitation

When revascularization is not indicated and surgical risk is not low, a percutaneous edge-to-edge procedure 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 who have a suitable valve morphology by echocardiography, avoiding futility.	IIb	C
In patients with severe secondary mitral regurgitation and LVEF <30% who remain symptomatic despite optimal medical management (including CRT if indicated) and who have no option for revascularization, the Heart Team may consider a percutaneous edge-to-edge procedure or valve surgery after careful evaluation for a ventricular assist device or heart transplant according to individual patient characteristics.	IIb	C

Percutaneous Mitral Commisurotomy

Recommendations	Class[a]	Level[b]
PMC is indicated in symptomatic patients without unfavourable characteristics[c] for PMC.[144,146,148]	I	B
PMC is indicated in any symptomatic patients with a contraindication or a high risk for surgery.	I	C
Mitral valve surgery is indicated in symptomatic patients who are not suitable for PMC.	I	C
PMC should be considered as initial treatment in symptomatic patients with suboptimal anatomy but no unfavourable clinical characteristics for PMC.[c]	IIa	C
PMC should be considered in asymptomatic patients without unfavourable clinical and anatomical characteristics[c] for PMC and: • high thromboembolic risk (history of systemic embolism, dense spontaneous contrast in the LA, new-onset 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

Gaps in evidence

- The scores predicting the results and complications of PMC particularly those of severe mitral regurgitation must be refined.
- The potential role of transcatheter mitral valve implantation in high-risk patients is to be determined, particularly in those with sever degenerative mitral stenosis

Transcatheter Repair for Tricuspid Regurgitation

2017 AHA/ACC VHD GL FOCUSED UPDATE

2017 ESC/EACTS VHD Guidelines

Percutaneous repair techniques are in their infancy and must be further evaluated before any recommendations can be made.

BMJ - RAPIDRECS

RAPID RECOMMENDATIONS

Transcatheter or surgical aortic valve replacement for patients with severe, symptomatic, aortic stenosis at low to intermediate surgical risk: a clinical practice guideline

In patients with symptomatic severe aortic stenosis but at lower risk of perioperative death, how do minimally invasive techniques compare with open surgery? Prompted by a recent trial, an expert panel produced these recommendations based on three linked rapid systematic reviews

Per O Vandvik *associate professor*[1 2], Catherine M Otto *professor*[3], Reed A Siemieniuk *methodologist*[4 5], Rodrigo Bagur *assistant clinical professor*[6], Gordon H Guyatt *distinguished professor*[4 7], Lyubov Lytvyn *methodologist*[8], Richard Whitlock *associate professor*[9 10], Trond Vartdal *consultant physician*[11], David Brieger *professor*[12], Bert Aertgeerts *professor*[13], Susanna Price *professor*[14], Farid Foroutan *graduate student*[4 15], Michael Shapiro *community representative and senior health informaticist for RTI International*[16], Ray Mertz *community representative*[17], Frederick A. Spencer *professor*[4 7]

BMJ 2016;354:i5085 doi: 10.1136/bmj.i5085 (Published 29 September 2016)

BMJ RAPIDRECS

TAVR VS. SAVR

GUIDELINE PANEL

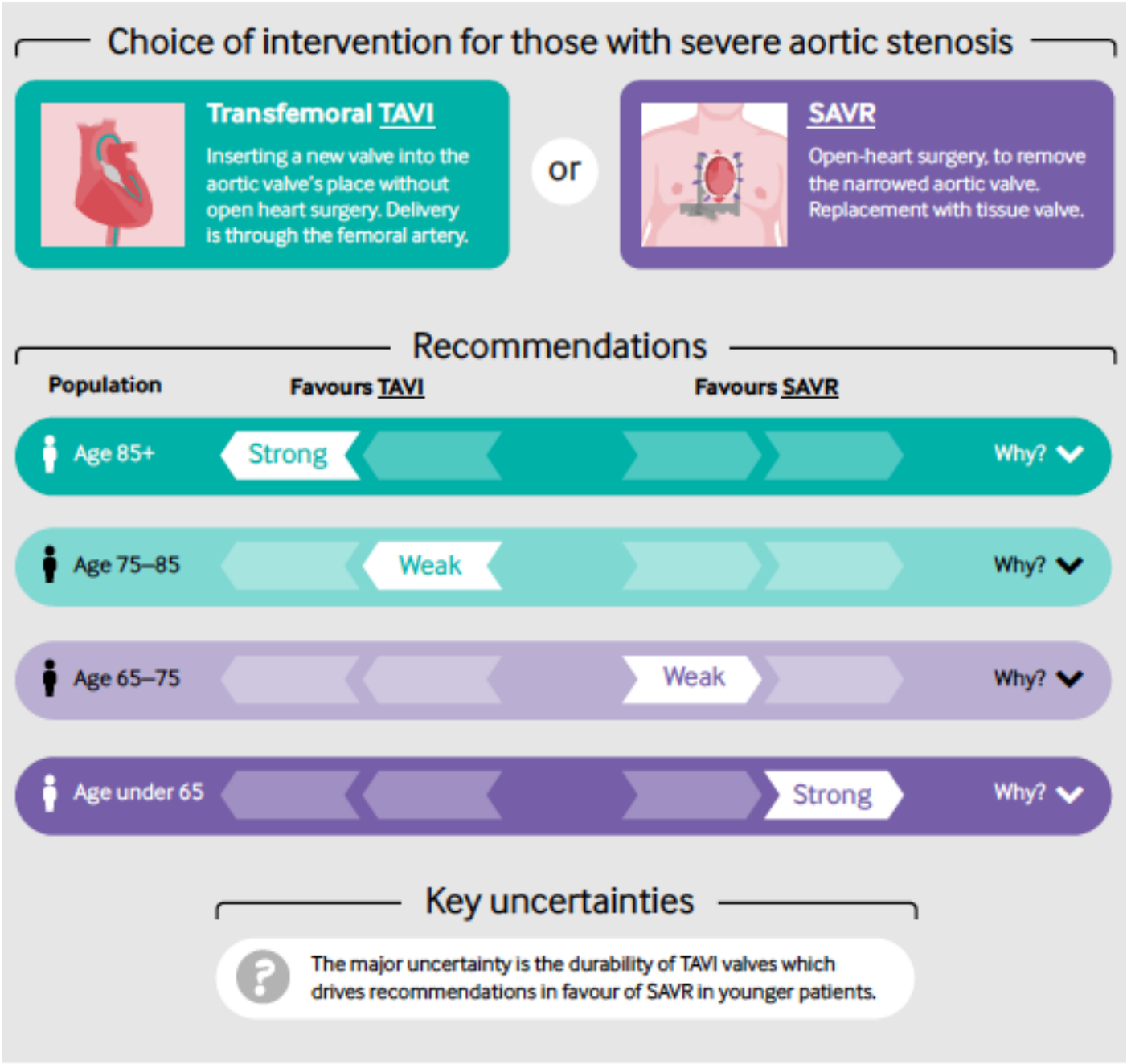
Methodologists
Internists
Cardiologists
CT surgeon
Patient representative

GRADE system

Grading of
Recommendations
Assessment
Development and
Evaluation

MAGIC project

Web based authoring and publication platform



Otto CM, et al Heart 2017;103:3-5

- Science tell us what we can do
- Guidelines tell us what we should do
- Registries tell us what we are actually doing

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