



# Intervention for symptomatic severe aortic stenosis

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Aortic valve intervention is indicated for symptomatic aortic stenosis (studies are ongoing into asymptomatic severe disease). The best choice for intervention for aortic stenosis in an individual patient has become increasingly complex because of technological advances - minimal access surgery, rapid-deployment valves, resilient valves, and later-generation transcatheter aortic valve implantation (TAVI) devices - and the extrapolation of clinical trial results beyond carefully defined study cohorts. Cases should be discussed by a Heart Valve Team after detailed clinical assessment to recommend the best approach - full sternotomy or minimal access surgery, or catheter-based intervention - according to the best available clinical evidence and the patient's preference.

**Topic(s):** *Valvular Heart Disease;*

## Intervention for symptomatic severe aortic stenosis

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The diagnostic criteria for severe aortic stenosis are discussed elsewhere. Symptomatic severe aortic stenosis has a poor prognosis after the development of symptoms, and early intervention is recommended for severe high-gradient aortic stenosis (mean transaortic gradient  $\geq 40$  mmHg or peak velocity  $\geq 4$  m/s, Class I recommendation) and severe low-flow, low-gradient aortic stenosis ( $< 40$  mmHg) with reduced ejection fraction and either evidence of contractile reserve (Class I) or with severe aortic stenosis confirmed on computed tomography (CT) calcium scoring (Class IIa).

However, selected patients with significant comorbidities should not have intervention either because expected survival is <1 year or because severe comorbidities and/or advanced age make intervention unlikely to improve overall quality of life (Class III recommendation) [1].

## **Options for intervention in symptomatic severe aortic stenosis**

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The “gold standard” treatment for symptomatic severe aortic stenosis remained surgical aortic valve replacement (AVR) through a median sternotomy until the turn of the century. Since the first proof-of-concept case of transcatheter aortic valve intervention (TAVI) in 2002, the role of TAVI has expanded from the treatment of inoperable/prohibitive-risk cases of aortic stenosis, through high- and intermediate-risk cases, and potentially even to low-risk cases based on the early results of clinical trials; valve-in-valve TAVI allows the less invasive and lower risk treatment of degenerated bioprosthetic aortic valves which may affect the choice of prosthesis for AVR in younger patients.

Within the surgical field, there has been the development of less invasive aortic valve surgery with minimally invasive AVR (miAVR) approaches through a partial upper sternotomy or right anterior thoracotomy. There has also been an expansion in the choice of valve prosthesis for surgical AVR: rapid-deployment or “sutureless” valves enable shorter ischaemic and cardiopulmonary bypass times in higher-risk cases and facilitate miAVR; a new class of “resilient” bioprosthetic valves with novel anti-calcification treatment of leaflet tissue has the potential to offer longer durability in younger (<60 years) patients, and a bileaflet mechanical valve with improved flow dynamics and reduced thrombogenicity allows less intensive anticoagulation than older implants. The options for aortic valve intervention have become broader and there needs to be careful discussion by the Heart Valve Team and between clinician and patient to reach the best recommendation for an individual patient.

## **The role of the Heart Valve Team**

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Patients for aortic valve surgery need careful assessment to help determine the operative risk, because significant comorbidities such as chronic obstructive airways disease, cerebrovascular disease, and renal disease become more common in an ageing population. In some patients, their symptoms and long-term prognosis are affected more by their comorbidities than by valvular disease.

The assessment of operative risk has been facilitated by scoring systems to estimate the risks of cardiac surgery, e.g. the Society for Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) and EuroSCORE II risk scoring systems. However, although these are accurate in identifying higher-risk patients, these scores are based on patients undergoing surgical AVR and overestimate mortality for TAVI. Newer scores have been developed to predict outcomes after TAVI but these have yet to become widely established [2,3].

A recent consensus report has emphasised the importance of a multidisciplinary Aortic Heart Valve Team based within a heart valve centre for the management of patients with aortic valve disease [4]. The decision regarding the indication, timing, and modality of intervention – AVR with a particular surgical approach and prosthesis versus TAVI – merits careful consideration.

Coexisting cardiac or aortic pathology may require concomitant procedures. Significant coronary artery disease usually requires concomitant coronary artery bypass grafting with AVR, and staged or combined percutaneous coronary intervention (PCI) and TAVI may be judged appropriate for patients with predominant angina and severe proximal coronary artery disease with a large volume of myocardium at risk. Historical evidence suggested that functional mitral regurgitation associated with severe aortic stenosis usually improved with aortic intervention alone, although a recent analysis has found poorer long-term survival in patients undergoing AVR with concomitant moderate-severe functional mitral regurgitation [5]. Associated aortic root and ascending aortic pathology may also need replacement according to size criteria and other risk factors [6].

## **Choice of intervention modality in symptomatic severe aortic stenosis**

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Current guidelines [1] reflect the published literature up to 2017 and include the results of trials comparing TAVI and AVR in intermediate-risk patients, but not the more recent studies in low-risk cohorts. The evidence supporting the current recommendations is limited for TAVI in patients aged <75 years and for low-risk patients, and there remain concerns about the durability of TAVI valves.

Several studies have been published on intermediate-risk patients (STS-PROM 4-8%) since the 2012 ESC/EACTS Valvular Heart Disease guidelines [7-9]. These have shown that TAVI is non-inferior to AVR in intermediate-risk patients with respect to death and disabling stroke, and even superior when transfemoral access is possible [10].

In general, TAVI is associated with higher rates of vascular injury, pacemaker implantation, and paravalvular regurgitation, whereas AVR carries greater risks of major bleeding, acute kidney injury, and new-onset atrial fibrillation. However, these studies on intermediate-risk patients include elderly patients with mean ages around 80 years and a high proportion of cases with high indices of frailty, limiting the applicability of these results to younger intermediate-risk patients. The 5-year outcomes of the PARTNER 2 study also show higher rates of complications in the TAVI group compared with surgery for at least mild paravalvular leak (33.3% vs 6.3%), re-hospitalisation (33.3% vs 25.2%), and aortic valve reintervention (3.2% vs 0.8%) [7].

There have now been four published studies assessing TAVI for aortic stenosis in low-risk patients [11-14] (STS-PROM <4%) and a meta-analysis pooling the results of these studies [15]. In the pooled study-level meta-analysis of four trials including 2,887 patients with mean age 75.4 years and mean STS-PROM 2.3%, compared with surgical AVR, TAVI was associated with lower all-cause death (2.1% vs 3.5%) and cardiovascular death (1.6% vs

2.9%) at one year. Similar to the results of earlier studies, patients treated with TAVI had higher rates of pacemaker implantation and moderate-severe paravalvular leak and lower rates of major bleeding, acute kidney injury, and new-onset atrial fibrillation compared with AVR. The authors conclude that “TAVI may be the preferred option over AVR in low-risk patients with severe aortic stenosis who are candidates for bioprosthetic AVR”. However, the generalisability of these results is limited because these are studies of selected cohorts of predominantly elderly patients with favourable anatomy, e.g. bicuspid aortic valves, more common in younger aortic stenosis patients, were excluded, and there was a short follow-up compared with the >20-year follow-up reported for AVR series, with data lacking on long-term TAVI durability.

Regarding the choice of intervention in symptomatic aortic stenosis, the current guidelines emphasise the role of the Heart Valve Team with structured collaboration between cardiology and cardiac surgery, and careful individual assessment of the suitability and risks of TAVI versus AVR (Class I). In general, AVR should be favoured for patients with an STS-PROM score or EuroSCORE II <4% (logistic EuroSCORE I <10%) and no other risk or technical factors not included in these risk scores such as frailty, porcelain aorta, or the sequelae of chest radiation (Class I).

Surgical AVR should also be favoured in patients with associated cardiac conditions requiring concomitant surgery, e.g. complex severe coronary artery disease, severe primary mitral valve or tricuspid valve disease, ascending aortic aneurysm, and septal hypertrophy requiring myectomy. Anatomical and technical considerations favouring surgery are unsuitable aortic root anatomy (low coronary height above the annulus, extreme annular diameter), valve morphology (bicuspid aortic valve, degree and pattern of calcification), and the presence of aortic or left ventricular thrombus.

TAVI is recommended for patients judged unsuitable for AVR by the Heart Valve Team (Class I), in particular, patients at higher surgical risk (STS-PROM score or EuroSCORE II  $\geq$ 4% [logistic EuroSCORE I  $\geq$ 10%]) or with other risk factors listed above, especially elderly patients with suitable access for transfemoral TAVI. Finally, balloon valvuloplasty may be considered as a bridge to surgery or TAVI in unstable patients (or in patients with symptomatic severe aortic stenosis needing urgent major non-cardiac surgery), or diagnostically in patients with comorbidities to help to define the contribution of aortic stenosis to symptoms or organ dysfunction (Class IIb) [1].

## **Newer surgical approaches and valves**

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### **Minimally invasive surgical aortic valve replacement**

MiAVR includes AVR through smaller incisions other than median sternotomy but still requiring cardiopulmonary bypass [16]. The most common approaches are a partial “J” upper mini-sternotomy or limited right anterior thoracotomy over the second intercostal space. Cannulation for cardiopulmonary bypass may be central (aorto-atrial) or peripheral (femoro-femoral). Preoperative CT imaging is required to ensure suitable anatomy: sternum to ascending aorta depth  $\leq$ 10 cm (preferable for either approach) and a rightward ascending

aorta (more than half of the aorta lateral to the right sternal border for a right anterior thoracotomy approach). The technique for actual replacement of the aortic valve remains the same as for conventional AVR through a sternotomy (but see below for rapid-deployment prostheses).

Compared with standard AVR, miAVR is associated with longer aortic cross-clamp and cardiopulmonary bypass times, reduced blood and blood product transfusion, and reduced intensive care and hospital stay; mortality and stroke rates are similar for standard AVR and miAVR [17]. However, the studies comparing standard AVR and miAVR have generally been of poor quality, and a recent Cochrane review concluded that further trials assessing clinical outcomes, quality of life, and cost-effectiveness were required [18].

## **Rapid-deployment (“sutureless”) aortic valve replacement**

Rapid-deployment or sutureless aortic valve prostheses are an evolution of standard bioprosthetic valves, often incorporating lessons from TAVI, to facilitate surgery in higher-risk or minimal access cases by reducing aortic cross-clamp and cardiopulmonary bypass times. During AVR with a rapid-deployment valve, the diseased aortic valve is approached and excised following the usual techniques, whether by median sternotomy or by a less invasive approach but, after debridement of the aortic valve, the valve prosthesis is implanted under direct vision without the need for circumferential sutures.

There are two rapid-deployment valves in clinical use, the Perceval (LivaNova, London, UK) and INTUITY (Edwards Lifesciences, Irvine, CA, USA). The Perceval valve is a bovine pericardial valve within a nitinol frame: this is a self-expanding valve although a balloon may be used for post-dilatation to ensure full cuff expansion within the annulus. Three intercommissural sutures are used to guide the valve onto the annulus, but these are removed after valve deployment: this is a true sutureless valve. The INTUITY valve is a bovine pericardial valve mounted within a balloon-expandable stainless-steel frame: the valve is positioned with three guide sutures that are secured after deployment.

A recent meta-analysis has found that rapid-deployment valves allow shorter aortic cross-clamp and cardiopulmonary bypass times compared with standard bioprosthetic valves (mean differences 26.3 and 25.3 minutes, respectively), but, similar to TAVI, there are higher rates of pacemaker implantation and paravalvular leak; there is no difference in early operative mortality [19]. The main obstacle to more widespread use of rapid-deployment valves is their higher cost compared with conventional prostheses.

Currently, rapid-deployment valves may be helpful for specific indications – miAVR to reduce operative times, patients with a small aortic root in whom rapid-deployment valves have been shown to achieve better haemodynamic outcomes [20], and in the small number of cases of a calcified homograft needing redo AVR in which these valves avoid the need for annular decalcification.

## **Resilient valves**

The INSPIRIS RESILIA bioprosthetic valve (Edwards Lifesciences) is the first in a new class of “resilient” valves designed for younger patients aged <60 years needing AVR who would usually undergo mechanical AVR with a requirement for lifelong anticoagulation. The leaflet tissue valve has been treated with a novel anti-calcification treatment with the aim of achieving longer durability in younger, more active patients, avoiding the need for warfarin and allowing another option for women of child-bearing age who might otherwise choose a less durable bioprosthetic valve and require later re-operation. The valve frame has also been engineered to facilitate valve-in-valve TAVI if required. However, although over 30,000 valves had been implanted by the end of 2019, only four-year outcome data have been presented so far, and there are no long-term clinical data confirming long-term freedom from structural valve degeneration [21].

## Lower-intensity coagulation for mechanical valves

The On-X<sup>®</sup> valve (CryoLife, Kennesaw, GA, USA) is a bileaflet mechanical aortic prosthesis designed for lower-intensity anticoagulation. The PROACT (Prospective Randomized On-X Anticoagulation Clinical Trial) tested the safety of dual antiplatelet therapy or reduced anticoagulation therapy for patients with an On-X<sup>®</sup> AVR [22,23]. Patients at low risk of thromboembolism were randomised to dual antiplatelet therapy with aspirin 325 mg and clopidogrel 75 mg daily, but this arm of the study was terminated early for excess thromboembolic events. However, in the high-risk arm, patients randomised to lower-intensity warfarin (INR 1.5-2.0) plus aspirin 81 mg had significantly lower major (1.59% vs 3.94% per patient-year) and minor (1.27% vs 3.49%) bleeding with no differences in thromboembolism (0.42% vs 0.09%) or all-cause mortality. The On-X<sup>®</sup> valve has been licensed for use in the USA with lower-intensity warfarin plus aspirin on the basis of this study. This offers another option of AVR in younger patients.

The PROACT Xa study (ClinicalTrials.gov identifier NCT04142658) is due to start recruitment soon. This study is a prospective randomised controlled trial comparing apixaban 2.5 or 5 mg daily (according to age, weight, and renal function) with standard warfarin therapy (INR 2.0-3.0) in patients with an On-X<sup>®</sup> AVR; favourable results may improve the acceptability and increase usage of the On-X<sup>®</sup> AVR in the future.

**Table 1. Factors to be considered in the choice of aortic valve intervention and surgical valve prosthesis.**

Interventional approach	Transcatheter aortic valve implantation
<b>Patient characteristics in favour</b>	<ul style="list-style-type: none"> <li>• STS/EuroSCORE II risk score <math>\geq 4\%</math> (logistic EuroSCORE <math>\geq 10\%</math>)</li> <li>• Severe comorbidity (not reflected in risk score) or significant frailty</li> <li>• Age <math>\geq 75</math> years</li> <li>• Previous cardiac surgery</li> </ul>

<b>Anatomical/technical factors</b>	<ul style="list-style-type: none"> <li>• Favourable access for transfemoral TAVI</li> <li>• Previous chest irradiation</li> <li>• Porcelain aorta</li> <li>• Patent coronary bypass grafts</li> <li>• Small aortic annulus at risk of patient-prosthesis mismatch</li> </ul>
<b>Interventional approach</b>	Surgical aortic valve replacement
<b>Patient characteristics in favour</b>	<ul style="list-style-type: none"> <li>• STS/EuroSCORE II risk score &lt;4% (logistic EuroSCORE &lt;10%)</li> <li>• Age &lt;75 years</li> <li>• Suspected endocarditis</li> <li>• Significant cardiac disease requiring concomitant intervention, e.g., coronary artery disease, mitral or tricuspid valvular disease, ascending aortic aneurysm, septal hypertrophy</li> </ul>
<b>Anatomical/technical factors</b>	<ul style="list-style-type: none"> <li>• Unfavourable access for TAVI</li> <li>• Unfavourable aortic valve morphology (bicuspid aortic valve, degree and pattern of calcification)</li> <li>• Unsuitable aortic root anatomy (low coronary ostial height, aortic annular dimensions out of range for TAVI)</li> </ul>
<b>Interventional approach</b>	Surgical valve prosthesis
<b>Patient characteristics in favour</b>	Patient characteristics in favour
<b>Anatomical/technical factors</b>	Anatomical/technical factors in favour
<b>Interventional approach</b>	Rapid-deployment valve
<b>Patient characteristics in favour</b>	<ul style="list-style-type: none"> <li>• Previous cardiac surgery (to facilitate miAVR)</li> <li>• Degenerated calcified homograft aortic root</li> </ul>

<b>Anatomical/technical factors</b>	<ul style="list-style-type: none"> <li>• Small aortic annulus at risk of patient-prosthesis mismatch</li> </ul>
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<b>Interventional approach</b>	Resilient valve
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<b>Patient characteristics in favour</b>	<ul style="list-style-type: none"> <li>• Age &lt;60 years with clinical contraindication to (or strong patient preference to avoid) anticoagulation for a mechanical valve prosthesis</li> </ul>
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<b>Anatomical/technical factors</b>	
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<b>Interventional approach</b>	Lower-intensity mechanical valve
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<b>Patient characteristics in favour</b>	<ul style="list-style-type: none"> <li>• Age &lt;60 years and patient preference to avoid standard anticoagulation for a mechanical prosthesis</li> </ul>
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<b>Anatomical/technical factors</b>	
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<b>Interventional approach</b>	<b>Patient characteristics in favour</b>	<b>Anatomical/technical factors</b>
Transcatheter aortic valve implantation	<ul style="list-style-type: none"> <li>• STS/EuroSCORE II risk score <math>\geq 4\%</math> (logistic EuroSCORE <math>\geq 10\%</math>)</li> <li>• Severe comorbidity (not reflected in risk score) or significant frailty</li> <li>• Age <math>\geq 75</math> years</li> <li>• Previous cardiac surgery</li> </ul>	<ul style="list-style-type: none"> <li>• Favourable access for transfemoral TAVI</li> <li>• Previous chest irradiation</li> <li>• Porcelain aorta</li> <li>• Patent coronary bypass grafts</li> <li>• Small aortic annulus at risk of patient-prosthesis mismatch</li> </ul>

Interventional approach	Patient characteristics in favour	Anatomical/technical factors
Surgical aortic valve replacement	<ul style="list-style-type: none"> <li>• STS/EuroSCORE II risk score &lt;4% (logistic EuroSCORE &lt;10%)</li> <li>• Age &lt;75 years</li> <li>• Suspected endocarditis</li> <li>• Significant cardiac disease requiring concomitant intervention, e.g., coronary artery disease, mitral or tricuspid valvular disease, ascending aortic aneurysm, septal hypertrophy</li> </ul>	<ul style="list-style-type: none"> <li>• Unfavourable access for TAVI</li> <li>• Unfavourable aortic valve morphology (bicuspid aortic valve, degree and pattern of calcification)</li> <li>• Unsuitable aortic root anatomy (low coronary ostial height, aortic annular dimensions out of range for TAVI)</li> </ul>
Surgical valve prosthesis	Patient characteristics in favour	Anatomical/technical factors in favour
Rapid-deployment valve	<ul style="list-style-type: none"> <li>• Previous cardiac surgery (to facilitate miAVR)</li> <li>• Degenerated calcified homograft aortic root</li> </ul>	<ul style="list-style-type: none"> <li>• Small aortic annulus at risk of patient-prosthesis mismatch</li> </ul>
Resilient valve	<ul style="list-style-type: none"> <li>• Age &lt;60 years with clinical contraindication to (or strong patient preference to avoid) anticoagulation for a mechanical valve prosthesis</li> </ul>	
Lower-intensity mechanical valve	<ul style="list-style-type: none"> <li>• Age &lt;60 years and patient preference to avoid standard anticoagulation for a mechanical prosthesis</li> </ul>	

## Choice of surgical valve prosthesis

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Biological or bioprosthetic valves for aortic valve replacement are made from glutaraldehyde-fixed porcine aortic leaflet or bovine pericardial tissue with a proprietary anti-calcification treatment mounted in an alloy frame. Modern bileaflet mechanical valves

are made from pyrolytic carbon and offer the advantage of excellent durability, but the disadvantages of long-term anticoagulation to prevent thromboembolism and the associated risk of bleeding, although the On-X<sup>®</sup> valve allows lower-intensity anticoagulation.

The choice of valve prosthesis for an individual patient depends on several factors including, most importantly, patient preference, age and life expectancy, metabolic factors predisposing to calcification and early structural valve deterioration (e.g., chronic kidney disease), any increased bleeding risk or contraindication to anticoagulation, expectation of pregnancy, previous infection, and risk of re-operation.

A mechanical prosthesis is recommended for patients <60 years and a bioprosthesis for patients >65 years or those in whom life expectancy is shorter than expected bioprosthetic valve durability. Freedom from re-operation due to structural valve deterioration for a modern bovine pericardial aortic bioprosthesis has been reported as 70.8% and 38.1% at 15 and 20 years for patients aged <60 years at implantation, compared with 98.1% at 15 years for patients aged >70 years [24]. There are no long-term outcome data for rapid-deployment or resilient valves.

Anticoagulation is required for all currently available mechanical aortic valve prostheses. The intensity of anticoagulation depends on prosthesis valve characteristics, e.g., bileaflet or tilting-disc, and patient factors such as a history of thromboembolism, atrial fibrillation, and left ventricular systolic dysfunction (LVEF <35%): the target INR is 2.5 (range 2.0-3.0) for modern bileaflet mechanical aortic valve prostheses (e.g., Medtronic, St. Jude, LivaNova) and 1.5 (warfarin plus aspirin 81 mg) for the On-X<sup>®</sup> aortic valve in the absence of additional patient risk factors.

## Conclusions

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Aortic valve intervention is indicated for symptomatic severe aortic stenosis. The best modality of intervention depends upon the patient's age, comorbidities, and anatomical and technical factors. Potential cases should be carefully and thoroughly assessed by a Heart Valve Team before discussion of the recommendations. TAVI is non-inferior to surgical AVR in intermediate-risk patients with respect to death and disabling stroke, and even superior when transfemoral access is possible; the latest studies suggest that TAVI may even be superior to surgical AVR for selected intermediate- and low-risk cases, but these studies had important exclusion criteria limiting the wider applicability of these findings, and long-term TAVI durability data are lacking. Minimally invasive AVR and the use of rapid-deployment or resilient valves have the potential to reduce the morbidity of surgical AVR, and mechanical valves needing lower-intensity anticoagulation have reduced some of the long-term risks of mechanical AVR, making this more attractive in individual cases.

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## Notes to editor

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