Transcatheter aortic valve replacement: Indications and periprocedural management

Authors
Stephen JD Brecker, MD, FRCP, FESC, FACC
William H Gaasch, MD
Gabriel S Aldea, MD

Section Editors
Catherine M Otto, MD
Donald Cutlip, MD

Deputy Editor
Susan B Yeon, MD, JD, FACC

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INTRODUCTION — Aortic valve replacement is the mainstay of treatment of symptomatic aortic stenosis (AS). In properly selected patients, this surgical procedure offers substantial improvements in symptoms and life expectancy.

However, aortic valve surgery entails substantial risks for some patients with severe comorbidities, and for some considered at “extreme” risk, surgery is not appropriate. In others, technical limitations, eg, porcelain aorta (extensively calcified ascending aorta and/or aortic arch), may mean that surgery is not feasible. Percutaneous aortic balloon valvotomy was developed as a less invasive means to treat AS but has important limitations. Subsequently developed catheter-based techniques for aortic valve implantation may provide an alternative method for treating AS in patients with unacceptably high estimated surgical risks. A multidisciplinary team approach is recommended in approaching patients with symptomatic AS.

This topic will review transcatheter aortic valve implantation, which has been termed “transcatheter aortic valve replacement.” Indications for aortic valve replacement, surgical aortic valve replacement, estimating the risk of aortic valve surgery, medical therapy of symptomatic AS, and percutaneous aortic valvuloplasty are discussed separately. (See "Indications for valve replacement in aortic stenosis in adults" and "Choice of prosthetic heart valve for surgical replacement" and "Estimating the mortality risk of valvular surgery" and "Medical management of symptomatic aortic stenosis" and "Percutaneous balloon aortic valvotomy".)

RATIONALE — Transcatheter aortic valve replacement (TAVR) has been developed for the treatment of patients with severe symptomatic aortic stenosis who have an unacceptably high estimated surgical risk, or in whom TAVR is preferred due to technical issues with surgery, eg, a porcelain aorta or prior significant mediastinal radiation, prior pericardiectomy with dense adhesions or prior sternal infection with complex reconstruction, or a patent left internal mammary graft lying beneath the sternum (as identified by computed tomography angiography).

TAVR is now also widely used for the treatment of failed surgical bioprosthetic valves in the aortic position (so-called "valve-in-valve" procedure), and indications include bioprosthetic valve stenosis, regurgitation, or a combination of the two [1].

INDICATIONS

Approach to identifying candidates for TAVR — Indications for transcatheter aortic valve replacement

(TAVR) are evolving. Patients may be referred for TAVR for treatment of native aortic valve stenosis, for valve-in-valve treatment of failure of a bioprosthetic aortic valve, or for native aortic valve regurgitation (with the last indication available in Europe but still investigational in North America).

- Among patients with native aortic valve stenosis with an indication for valve replacement, a choice is made between surgical AVR (SAVR) or TAVR (or no intervention) based upon estimated surgical risk and comorbidities. (See "Indications for valve replacement in aortic stenosis in adults".)
- A valve-in-valve TAVR procedure is suggested for symptomatic patients with failure (regurgitation, stenosis, or both) of a surgically implanted bioprosthetic valve with high or greater risk for open surgical valve replacement.
- In Europe, a transapical TAVR system (JenaValve) is an option to treat severe native aortic valve regurgitation in patients with high or greater risk for open surgical valve replacement or repair.

For native aortic valve stenosis — Patients with severe native calcific aortic stenosis (AS) are evaluated for presence of an indication for aortic valve replacement. Among patients with severe AS with an indication for valve replacement, a choice is made between SAVR or TAVR (or no intervention) based upon considerations, including the estimated surgical risk and comorbidities. (See "Indications for valve replacement in aortic stenosis in adults".)

Indications for valve replacement for aortic stenosis — The choice of SAVR versus TAVR in patients with severe AS is made after it is determined that the patient meets an indication for valve intervention for severe AS [2]. AVR is the mainstay of treatment of symptomatic AS, as it improves symptoms and prolongs survival. (See "Indications for valve replacement in aortic stenosis in adults", section on 'Indications for valve replacement'.)

The following are indications for AVR for severe AS that apply to either SAVR or TAVR (table 1 and algorithm 1) [2]:

- AVR is recommended for patients with severe high-gradient AS who have symptoms by history or on exercise testing (stage D1).
- AVR is recommended for asymptomatic patients with severe AS (stage C2) and left ventricular ejection fraction (LVEF) <50 percent.
- AVR is suggested (weak recommendation) in asymptomatic patients (stage C1) with severe AS and decreased exercise tolerance or an exercise fall in blood pressure.
- AVR is suggested in symptomatic patients with low-flow/low-gradient severe AS with reduced LVEF (stage D2) with a low-dose dobutamine stress study that shows an aortic velocity ≥4.0 m/s (or mean pressure gradient ≥40 mmHg) with a valve area ≤1.0 cm^2 at any dobutamine dose.
- AVR is suggested in symptomatic patients who have low-flow/low-gradient severe AS (stage D3) who are normotensive and have an LVEF ≥50 percent if clinical, hemodynamic, and anatomic data support valve obstruction as the most likely cause of symptoms.

Severe AS includes both stage C (asymptomatic) and stage D (symptomatic) disease with anatomic, hemodynamic, and ventricular criteria (table 2).

Choice of surgical or transcatheter AVR — For patients who have an indication for AVR, the choice between SAVR or TAVR is made based upon consideration of the estimated risk and benefit of the procedures, as well as existing comorbidities, including coronary artery disease. For patients being considered for TAVR or high-risk surgical AVR, a multidisciplinary heart valve team (including cardiologists, interventionalists, cardiovascular surgeons, anesthesiologists, and nurses) should collaborate to optimize care [2].

- SAVR is recommended in patients with AS who have an indication for AVR with low or intermediate surgical risk. For patients with intermediate surgical risk, enrollment in a clinical trial comparing SAVR and TAVR is an alternative option.
- TAVR is recommended in patients with AS who have an indication for AVR who have a prohibitive surgical risk and a predicted post-TAVR survival >12 months.
- For patients with severe AS who have an indication for AVR and have a high surgical risk, we recommend SAVR or TAVR with this decision made by a Heart Valve Team with consideration of patient specific factors and patient values and preferences. (See "Transcatheter aortic valve replacement: Outcomes and complications", section on 'In high-risk patients'.)

TAVR is **not** recommended in patients with comorbidities that would preclude an expected benefit from correction of AS.

The above approach is similar to that in the 2014 American Heart Association/American College of Cardiology valve guideline (table 3) [2]. However, the recommendation for TAVR with a self-expanding valve in patients with high surgical risk is based upon the United States CoreValve High Risk study, which was published after the guidelines [3]. (See "Transcatheter aortic valve replacement: Outcomes and complications", section on 'In high-risk patients'.)

Operative risk assessment (including identification of high and prohibitive risk) includes consideration of estimated operative mortality, frailty, major organ system compromised, and comorbidities (table 4). Accurate estimation of the risk of SAVR performed by an experienced cardiothoracic surgeon and multidisciplinary valve team is vital to appropriate evaluation of potential candidates. Risk assessment for valvular surgery is discussed further separately. (See "Estimating the mortality risk of valvular surgery".)

Evidence — Evidence to support the above recommendations on choice of surgical or transcatheter intervention for AS is discussed separately.

Recommendations for SAVR for severe AS are based upon comparisons of the natural history of patients with AS with outcomes after SAVR. Although a randomized trial found that outcomes at one year with TAVR and SAVR were similar, we continue to recommend SAVR in patients with low or intermediate surgical risk at this time because the long-term durability (beyond five years) of transcatheter heart valves is not yet known. (See "Indications for valve replacement in aortic stenosis in adults", section on 'Evidence' and "Transcatheter aortic valve replacement: Outcomes and complications", section on 'In low- and intermediate-risk patients'.)

The recommendation for TAVR for patients with AS with prohibitive surgical risk is based upon data from a randomized trial and an observational study with historical control. (See "Transcatheter aortic valve replacement: Outcomes and complications", section on 'TAVR versus medical therapy in inoperable patients' and "Transcatheter aortic valve replacement: Outcomes and complications", section on 'Self-expanding TAVR compared to historical control'.)

The recommendation for SAVR or TAVR in patients with high surgical risk is based upon controlled trials. (See "Transcatheter aortic valve replacement: Outcomes and complications", section on 'In high-risk patients'.)

For bioprosthetic aortic valve failure — A valve-in-valve procedure is an option for patients with failure (stenosis, regurgitation, or both) of a surgically implanted bioprosthetic aortic valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (ie, Society of Thoracic Surgeons operative risk score ≥8 percent or at a ≥15 percent risk of mortality at 30 days) [4]. (See "Transcatheter aortic valve replacement: Outcomes and complications", section on 'For prosthetic valve dysfunction treated with valve-in-valve'.)

For native aortic valve regurgitation — SAVR remains the treatment of choice for patients with severe native valve aortic regurgitation. When surgery is absolutely contraindicated, TAVR is a potential option. In Europe, a transapical TAVR system (JenaValve) is approved to treat severe native aortic valve regurgitation in patients with high or greater risk for open surgical therapy. Off-label CoreValve use in this setting has been tried but is limited by risk of insufficient anchoring and risk of paravalvular aortic regurgitation. (See "Transcatheter aortic valve replacement: Outcomes and complications", section on 'For native aortic valve regurgitation'.)

EXCLUSIONS — Patients with a number of conditions are generally excluded from transcatheter aortic valve replacement (TAVR), as recommended in the 2012 American College of Cardiology Foundation/American Association for Thoracic Surgery/Society for Cardiovascular Angiography and Interventions/Society of Thoracic Surgeons expert consensus document on TAVR and the 2012 European Society of Cardiology valve guidelines (table 5) [5,6].

The following exclusion criteria for TAVR are related to the aortic valve:

- Bicuspid or unicuspid or noncalcified aortic valve. While a congenitally bicuspid aortic valve is generally considered an exclusion criterion for TAVR, TAVR has been successfully performed in some patients with this disorder, as discussed separately. Once severe calcific stenosis is present, reliable identification of the number of valve leaflets is problematic, so it is likely that TAVR has been performed in many patients with a congenital bicuspid valve. (See "Management of adults with bicuspid aortic valve disease", section on 'Transcatheter aortic valve replacement'.)

- Native aortic annulus size as measured by computed tomography is <18 mm (for a native valve), <17mm (for a surgical valve), **or** >the largest annulus size for which a TAVR device is available (eg, 29 mm). This criterion is subject to change as the range of available device sizes changes.

  Note that valve size numbers do not correspond to actual annular measurements. Deciding which size valve to select for a given manufacturer is complex and is made using computed tomography annulus imaging area and perimeter measurements (with balloon expandable valves defined by area but self-expanding valve defined by perimeter).

- Severe native aortic regurgitation (>3+) is generally an exclusion criterion when TAVR is performed to treat native aortic valve disease; however, the JenaValve has CE Mark approval for use in Europe to treat native aortic valve stenosis and native aortic valve regurgitation.

  The presence of severe aortic regurgitation is **not** an exclusion criterion when TAVR is performed as a valve-in-valve procedure to treat failed bioprosthetic valve.

- As noted above, TAVR is **not** recommended for patients with comorbidities that would preclude an expected benefit from correction of AS.

Other relative exclusion criteria that may be used include the following:

- Evidence (such as creatine kinase [CK] plus CK-MB elevation and/or troponin elevation) of an acute myocardial infarction within one month before the intended treatment.

- Hemodynamic or respiratory instability requiring inotropic support, mechanical ventilation, or mechanical heart assistance within 30 days of screening evaluation.

- Need for emergency surgery

- Hypertrophic cardiomyopathy with or without obstruction

- Left ventricular ejection fraction <20 percent

- Severe pulmonary hypertension and right ventricular dysfunction
- A known contraindication or hypersensitivity to all anticoagulation regimens or inability to be anticoagulated for the study procedure.
- Renal insufficiency (eg, creatinine >3.0 mg/dL) and/or end-stage renal disease requiring chronic dialysis
- Echocardiographic evidence of intracardiac mass, thrombus, or vegetation
- Magnetic resonance imaging-confirmed stroke or transient ischemic attack within six months (180 days) of the procedure.
- Severe incapacitating dementia
- Estimated life expectancy <12 months due to noncardiac comorbid conditions
- Severe mitral regurgitation
- Significant aortic disease, including the following abnormalities may preclude a transfemoral approach:
    - Thoracic or abdominal aortic aneurysm (luminal diameter ≥5 cm), marked tortuosity (hyperacute bend)
    - Aortic arch atheroma (especially if >5 mm thick, protruding, or ulcerated)
    - Narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta
    - Marked tortuosity (hyperacute bend) of the aorta or severe “unfolding” of the thoracic aorta

SELECTION OF TAVR VALVE TYPE

Patient-specific considerations — For the majority of patients undergoing transcatheter aortic valve replacement (TAVR), either a Sapien, CoreValve, or one of the second generation devices are suitable. For patients treated at a center having sufficient experience with and access to many types of valves, there are certain patient-specific issues that might influence the choice of valve system type:

- Most valves types, but not all, cover the full range of annulus size.
- In a patient deemed to be at high risk of annulus rupture (eg, a patient with a small highly calcified annulus), a self-expanding rather than a balloon-expandable valve may be chosen to reduce the risk of annular rupture (as one of several potential strategies to attempt to reduce the risk of rupture). Annular rupture has been observed almost exclusively after use of a balloon-expandable valve and very rarely after use of a self-explandable valve [7]. (See "Transcatheter aortic valve replacement: Outcomes and complications", section on 'Annular rupture'.)
- If there are concerns about coronary obstruction, then a valve system with recapturable technology may be favored.
- When performing a valve-in-valve procedure to treat a small surgical bioprosthetic valve, a supra-annular TAVR valve might offer greater effective orifice area.

Center-specific considerations — Operators have generally selected the type of TAVR valve to implant based upon local practice, operator training, medical center experience, and availability (based upon the regulatory approval status) rather than specific patient-related factors. Individual center procedure volume is an important factor in establishing and maintaining optimum patient outcomes. As a consequence, the majority of centers have implanted only one type of TAVR valve. While that landscape

is changing, particularly in countries where there are multiple approved devices, maintenance of sufficient experience with each device used continues to be important for optimum patient outcomes. The differences in patient selection and procedural steps among competing device types are greater for various TAVR systems than for most other interventional cardiovascular procedures.

Regulatory status — Regulatory approvals govern the availability of TAVR technologies.

United States Food and Drug Administration approvals include the following:

- The Edwards SAPIEN XT (balloon-expandable) and the Medtronic CoreValve (self-expanding) systems are approved for patients with symptomatic severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (ie, Society of Thoracic Surgeons operative risk score ≥8 percent or are judged by the heart team to be at a ≥15 percent risk of mortality at 30 days).
- The Medtronic CoreValve is also approved for patients with failure (stenosis, regurgitation, or combined) of a surgical bioprosthetic aortic valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (ie, Society of Thoracic Surgeons operative risk score ≥8 percent or at a ≥15 percent risk of mortality at 30 days).

A number of TAVR systems have CE mark approval:

- The following devices are approved for use in Europe in patients with severe aortic stenosis at high or greater risk for surgical valve replacement: Medtronic CoreValve, Edwards SAPIEN, Direct Flow Medical (fully repositionable), St. Jude Medical Portico (repositionable prior to deployment), Medtronic Engager (transapical), JenaValve (transapical), Boston Scientific Lotus (repositionable prior to deployment), Medtronic EvolutR (self-expanding and repositionable prior to deployment), and Sapien 3 are approved for patients with severe aortic stenosis with high or greater risk for open surgical valve replacement.
- The CoreValve and the Sapien XT valve are approved for valve-in-valve use in patients with high or greater risk for open surgical valve replacement.
- The JenaValve transapical TAVR system is also approved to treat severe native aortic valve regurgitation in patients who are inoperable or at high risk for open surgical therapy.

PERIPROCEDURAL MANAGEMENT

Preprocedural considerations — Candidates for transcatheter aortic valve replacement (TAVR) should be evaluated for potential risk factors such as depressed left ventricular ejection fraction, coronary artery disease, and kidney disease [5]. For patients at risk of hemodynamic decompensation, preparations should include availability of rapid institution of cardiopulmonary bypass (and rarely elective bypass may be instituted).

Routine antibiotic prophylaxis is recommended for all patients undergoing TAVR prior to surgical incision or vascular access to reduce the risk of wound infection and endocarditis [5].

Monitoring and management — Patients undergoing TAVR generally receive a temporary pacing lead, at least one large bore intravenous line, warming to avoid hypothermia, and monitoring by arterial line, and may have transesophageal echocardiography [5]. A pulmonary artery catheter is seldom used for these cases.

Patients receive either local anesthesia with moderate (conscious) sedation or general anesthesia.

Heparin is administered after placement of standard sheaths and prior to placement of the large sheath.

Management includes early identification and treatment of volume depletion, inotropic agents in patients

with low cardiac output or greater than moderate pulmonary hypertension, mechanical circulatory support as needed in patients with low cardiac output, and treatment of severe pulmonary hypertension and right ventricular failure with inhaled nitric oxide or epoprostenol. (See "Short-term mechanical circulatory assist devices" and "Treatment of pulmonary hypertension in adults".)

Measures to avoid prolonged hypotension include maintenance of mean arterial pressure of >75 mmHg prior to initiation of rapid ventricular pacing (required during valve placement of prostheses other than the CoreValve, and can be performed during the CoreValve procedure as well) with cautious use of intravenous vasopressor (norepinephrine, epinephrine, or phenylephrine) therapy as needed while avoiding hypertension.

Management of complications is discussed separately. (See "Transcatheter aortic valve replacement: Outcomes and complications", section on 'Complications'.)

DELIVERY TECHNIQUES — Three major catheter-based techniques for replacing the aortic valve have been investigated: retrograde percutaneous implantation (via either the transfemoral, subclavian/axillary, or, rarely, carotid artery route), direct transapical puncture, and the use of direct aortic access via either ministernotomy or right anterior thoracotomy. The retrograde femoral arterial approach is the most common method of transcatheter aortic valve replacement delivery.

An antegrade transseptal approach has also been studied but adoption has been abandoned due to procedural complexity and associated risks (eg, development of acute mitral regurgitation) [8,9].

Retrograde approaches

Percutaneous retrograde approach — The retrograde femoral arterial approach via the aortic arch and through the diseased valve is the most common approach. Several types of stent-valve devices with various designs have been successfully implanted using the retrograde femoral approach. The most widely used types are balloon-expandable valves (Edwards SAPIEN, SAPIEN XT, and SAPIEN 3, which have replaced the Cribier-Edwards valve) and self-expanding valves (eg, Medtronic CoreValve) [9]. The Medtronic CoreValve has also been delivered in a retrograde fashion from the subclavian/axillary artery [10], the carotid artery, and via direct aortic access via either ministernotomy or right anterior thoracotomy [11].

Smaller delivery devices have resulted in an increasing rate of femoral delivery (eg, from about 50 percent to nearly 90 percent), as well as lower incidence of vascular complications, with an emerging standard of percutaneous vascular closure and a shorter hospital stay.

Transaortic surgical retrograde approach — An alternative retrograde surgical approach can be performed by direct insertion into the ascending aorta (eg, aortotomy) via a small median sternotomy at the second intercostal space.

Transapical antegrade approach — An alternate catheter-based approach consists of direct left ventricular apical puncture and antegrade aortic valve implantation via a small anterolateral thoracotomy without cardiopulmonary bypass or sternotomy. This approach is particularly suited to patients with severe peripheral artery disease and heavily calcified ascending aorta and arch (porcelain aorta) who have an increased risk of stroke and other embolic events using other approaches.

POST-PROCEDURAL CARE

Antithrombotic therapy — Patients receive intravenous heparin during valve implantation and chronic antiplatelet therapy after implantation.

Following implantation of the SAPIEN valve, the following antiplatelet regimen is recommended and consistent with United States Food and Drug Administration labeling since this was the protocol used in randomized trials [12-14]: dual antiplatelet therapy (aspirin 75 or 100 mg daily plus clopidogrel 300 mg

loading dose followed by 75 mg daily) for six months; and after six months, aspirin 75 to 100 mg/day for life.

CoreValve operators will typically recommend three months of dual antiplatelet therapy with aspirin and clopidogrel followed by aspirin alone.

For patients on anticoagulants for atrial fibrillation, practice varies. A commonly used approach is to add clopidogrel to the anticoagulant drug (warfarin or a novel agent) for three months.

SUMMARY AND RECOMMENDATIONS

- The choice of surgical versus transcatheter aortic valve replacement (TAVR) in patients with severe aortic stenosis (AS) is made after it is determined that the patient meets an indication for valve intervention for severe AS. AVR is the mainstay of treatment of symptomatic AS, as it improves symptoms and prolongs survival. (See 'Indications for valve replacement for aortic stenosis' above and "Indications for valve replacement in aortic stenosis in adults", section on 'Indications for valve replacement'.)
- The choice between surgical aortic valve replacement (SAVR) or TAVR is made based upon consideration of the estimated risk and benefit of the procedures, as well as existing comorbidities, including coronary artery disease. (See 'Choice of surgical or transcatheter AVR' above.)
    - We recommend SAVR for patients with AS who have an indication for AVR with low or intermediate surgical risk. For patients with intermediate surgical risk, enrollment in a clinical trial comparing SAVR and TAVR is an alternative option.
    - We recommend TAVR for patients with AS who have an indication for AVR who have a prohibitive surgical risk and a predicted post-TAVR survival >12 months.
    - We recommend either SAVR or TAVR for patients with AS who have an indication for AVR and have a high surgical risk with this decision made by a Heart Valve Team with consideration of patient-specific factors and patient values and preferences.
    - We recommend against TAVR for patients with comorbidities that would preclude an expected benefit from correction of AS.
- For patients being considered for TAVR or high-risk SAVR, a multidisciplinary heart valve team (including cardiologist, cardiovascular surgeon, and interventionalist) should collaborate to optimize care. (See 'Choice of surgical or transcatheter AVR' above.)
- We suggest TAVR for symptomatic patients with failed (stenotic, regurgitant, or both) surgical bioprosthetic aortic valve with high or greater surgical risk. (See 'For bioprosthetic aortic valve failure' above.)
- In Europe, a transapical TAVR system (JenaValve) is an option to treat severe native aortic valve regurgitation in patients with high or greater risk for open surgical valve replacement or repair. (See 'For native aortic valve regurgitation' above.)

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