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2017 ACC Expert Consensus Decision Pathway for Transcatheter Aortic Valve Replacement in the Management of Adults With Aortic Stenosis

A Report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents

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PREFACE

The American College of Cardiology (ACC) develops a number of clinical policy documents to provide members with guidance on clinical topics. Although clinical practice guidelines remain the primary mechanism for offering evidence-based recommendations, such guidelines may contain gaps in how to make clinical decisions, particularly when equipoise is present in a topic. Expert consensus documents are intended to provide guidance for clinicians in areas where evidence may be limited or new and evolving, or where there is a lack of sufficient data to fully inform clinical decision-making.

In an effort to increase the effect of ACC clinical policy on patient care, an ACC Presidential Task Force was formed in 2014 to examine processes of the ACC's clinical documents. The main recommendation of the Task Force was a new focus on concise decision pathways and/or key points of care, instead of the traditional longer documents. The Task Force also established criteria for identifying high-value clinical topics to be addressed, as well as an innovative approach to collecting stakeholder input through a roundtable or think tank meeting. To complement the new focus on brief decision pathways and key points, expert consensus documents were rebranded as Expert Consensus Decision Pathways.

Although decision pathways have a new format, they maintain the same goal of expert consensus documents to develop clinical policy based on expert opinion in areas which important clinical decisions are not adequately addressed by the available existing trials. Expert Consensus Decision Pathways are designed to complement the guidelines and bridge the gaps in

clinical guidance that remain. In some cases, topics covered by Expert Consensus Decision Pathways will be addressed subsequently by ACC/American Heart Association (AHA) guidelines as the evidence base evolves. The writing groups are charged with developing algorithms that are more actionable and can be implemented into tools or applications to accelerate the use of these documents at the point of care. Decision pathways are not intended to provide a single correct answer, but to encourage clinicians to ask certain questions and consider important factors as they come to their own decision on a treatment plan for their patients. There may be multiple pathways that can be taken for treatment decisions, and the goal is to help clinicians make a more informed decision.

James L. Januzzi, Jr, MD, FACC
Chair, ACC Task Force on Clinical Expert Consensus Documents

1. INTRODUCTION

Transcatheter aortic valve replacement (TAVR) is a new and transformational technology for patients with severe aortic valvular stenosis. Although currently approved for use in patients with severe symptomatic aortic stenosis (AS) who are at intermediate to high surgical risk or are inoperable, it is likely that it will be utilized outside of clinical trials in lower-risk surgical candidates in the future. Since the first U.S. Food and Drug Administration approval in 2011, over 50,000 patients have undergone TAVR in the United States alone. Multiple studies have documented favorable outcomes using a wide spectrum of endpoints, including survival, symptom status, quality of life, and need for repeat hospitalizations. The implementation of TAVR into the flow of patient care is complex, involving a Heart Valve Team and consideration of several key factors, such as clinical site selection, operator and team training and experience, patient selection and evaluation, procedural performance and complication management, and postprocedural care. Collaborative stakeholder involvement is required in the successful management of this high-risk patient population with extensive coexistent medical conditions. The intent of this clinical expert consensus pathway is to provide additional details and practical guidance about TAVR with point-of-care checklists and algorithms. These have been separated into 4 sections: 1) preprocedure evaluation of the patient being considered for TAVR; 2) imaging modalities and measurements; 3) key issues in performing the TAVR procedure; and 4) recommendations for patient follow-up after TAVR.

This Clinical Decision Pathway Checklist builds on the recommendations in the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease (1). This pathway starts at the point where a patient with severe AS has an indication for AVR and is being considered for TAVR based on the indication for AVR and choice of valve type (Sections 3.2.3 and 3.2.4 in the guideline [1]). Echocardiographic assessment of AS severity has been performed before making the decision that AVR is needed. Thus, echocardiography is not discussed in detail in this document; readers are referred to recent review papers on this topic for additional information. The current document only addresses TAVR for native valve aortic stenosis; valve-in-valve procedures are not addressed. Many aspects of management of TAVR patients are undergoing rapid change, necessitating general recommendations, for example, in the choice of agent, dose, and duration of antithrombotic therapy after TAVR. Readers are urged to use these checklists as a starting point, revising them as needed to match institutional protocols and updating details as new clinical data become available.

2. METHODS

The 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease provides specific recommendations on timing of aortic valve replacement (AVR) in adults with aortic valve stenosis (Section 3.2.3 in the guideline [1]). That guideline also provides recommendations (Section 3.2.4) on the choice between surgical aortic valve replacement (SAVR) and TAVR based on the published evidence addressing this issue (2014 Valvular Heart Disease Guideline, Data Supplement 9 [1]). In the current document, the data review and commentary start at the point when a patient is considered to meet an indication for an intervention for AS and may be a candidate for the TAVR procedure. The central role of the Heart Valve Team in decision-making at each step along the way is highlighted. To provide an easy-to-follow checklist format, the Writing Committee reviewed currently available checklists from their own and other major institutions as a starting point. After agreeing upon a construct comprising 4 sections (as mentioned in the previous text), available evidence was collated and, where necessary, supplemented by "best practices" recommendations. Guideline documents relating to the management of valvular heart disease (1) and echocardiographic and computed tomography (CT) assessment of the aortic valve (2,3) were preferentially considered for the relevant sections. The 2012 ACCF/AATS/SCAI/STS Expert Consensus Document on Transcatheter Aortic Valve Replacement was also used as a valuable reference for this document (4).

The work of the Writing Committee was supported exclusively by the ACC without commercial support. Writing Committee members volunteered their time to

this effort. Conference calls of the Writing Committee were confidential and were attended only by committee members and ACC staff. A formal peer review process was completed consistent with ACC policy and included expert reviewers nominated by the ACC (see Appendix 2). A public comment period was also held to obtain further feedback. Following reconciliation of all comments, this document was approved for publication by the ACC Clinical Policy Approval Committee.

3. ASSUMPTIONS AND DEFINITIONS

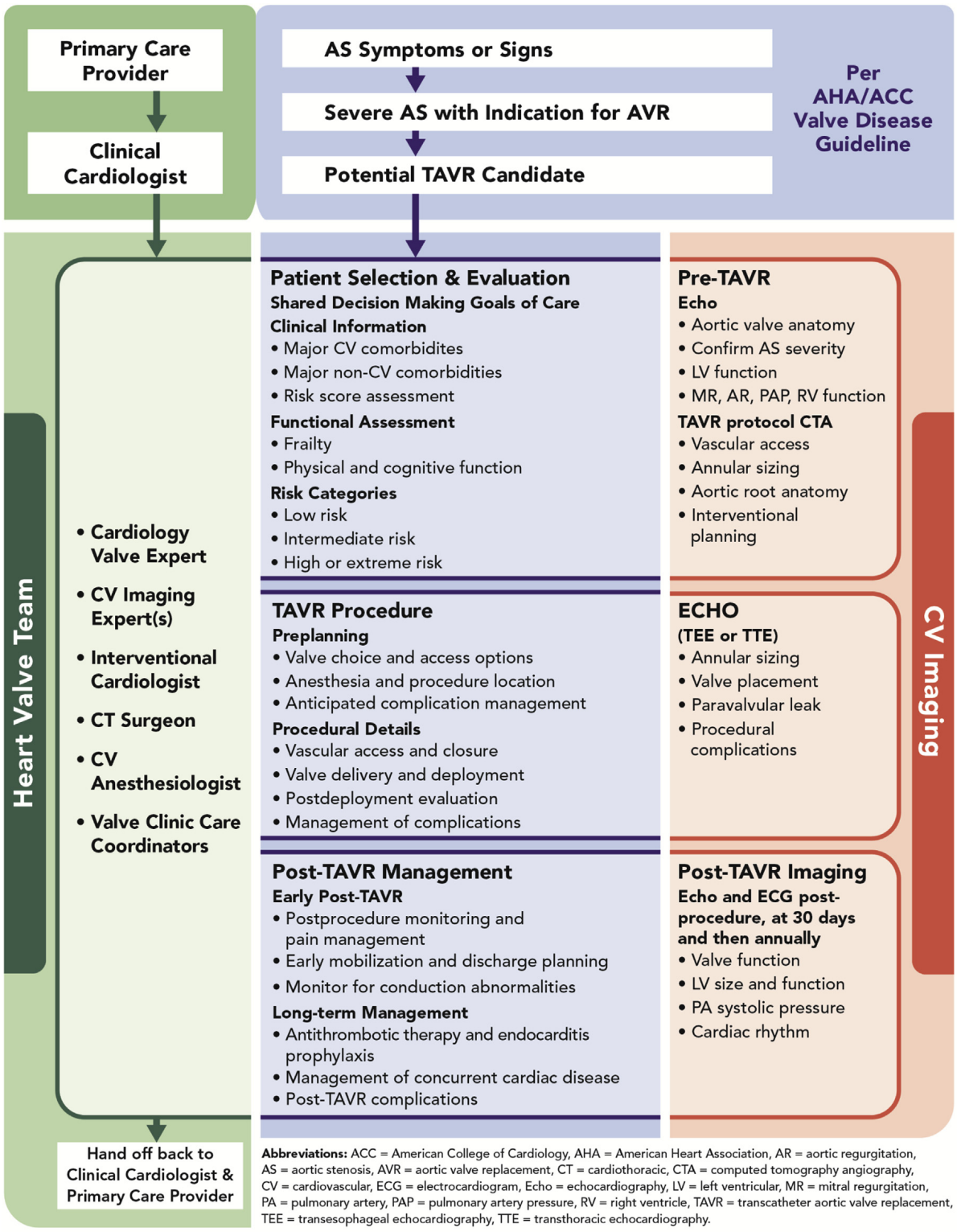
To limit inconsistencies in interpretation, specific assumptions and definitions were considered by the Writing Committee in the development of this document.

1. The most important first step is the accurate diagnosis and staging of AS. All patients being considered for TAVR should have severe symptomatic AS (Stage D). Severe AS is defined as detailed in the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease, Section 3.1 (1), based on integration of data on valve anatomy, valve hemodynamics, hemodynamic consequences, and patient symptoms. Symptomatic severe high-gradient AS (Stage D1) is characterized by valve hemodynamics with an aortic velocity of 4.0 m/s or higher, corresponding to a mean transaortic gradient of 40 mm Hg or higher. Typically, aortic valve area is ≤1.0 cm^2 with an indexed aortic valve area of ≤0.6 cm^2/m^2, but it may be larger, with mixed stenosis and regurgitation. Stage D2 severe symptomatic low-flow low-gradient severe AS with a low left ventricular (LV) ejection fraction (EF) (<50%) is defined by a severely calcified valve with reduced systolic opening and an aortic valve area ≤1.0 cm^2. Aortic velocity is <4.0 m/s at rest but increases to at least 4.0 m/s on low-dose dobutamine stress echocardiography. Stage D3 severe symptomatic low-flow low-gradient severe AS with a normal LVEF is defined as an aortic valve area ≤1.0 cm^2 with an aortic velocity <4.0 m/s and mean gradient <40 mm Hg. Diagnosis of Stage D3 severe AS is challenging, with key features including an indexed aortic valve area of ≤0.6 cm^2/m^2, a stroke volume index <35 ml/m^2, confirmation of hemodynamics when the patient is normotensive, and no other explanation for patient symptoms.
2. These algorithms assume that patients being considered for TAVR are adults with calcific valvular AS. TAVR for congenital AS, rheumatic valve disease, or isolated aortic regurgitation (AR) has not been studied in clinical trials.
3. A central component for TAVR consideration is the underlying risk for SAVR. Our discussions assume risk stratification based on the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease, Section 2.5 (1). This integrated assessment combines the Society of Thoracic Surgeons (STS) Predicted Risk of Mortality score, frailty, main organ system dysfunction, and procedure-specific impediments. The STS Predicted Risk of Mortality risk calculator is the first step in this assessment, with classification into 3 initial categories of risk based on the STS score: <4% (low risk), 4% to 8% (intermediate risk), and >8% (high risk). An assessment of frailty is also central to the decision-making process. Frailty, however, is difficult to define precisely and can be fairly subjective. Recommendations for frailty testing are provided in this document. The importance of considering other major organ system involvement is reviewed and the key procedure-specific impediments are outlined. Risk calculators specific to the TAVR procedure are still in their nascent stages but are expected to become progressively important as this technology and its indications continue to evolve.
4. The document also assumes that the Heart Valve Team will be involved with all aspects of the decision-making and delivery of this complex technology. Although some important aspects for initial assessment of all patients are discussed, a further assumption for the majority of this document is that the patient being considered has already been determined to have an indication for AVR. The checklists and algorithms provided here are intended to provide a starting point for institution-specific checklists, which will necessarily be much more detailed than the broad outlines provided here. Some sections of these checklists, such as monitoring after anesthesia, depend on institution-specific protocols, with only the central elements being listed here. In addition, procedural details will change with newer technology, which will require continuous updating of these protocols along with continuous quality improvement at the institutional level.

4. PATHWAY SUMMARY GRAPHIC

Figure 1 provides a framework for managing a potential TAVR candidate by outlining key steps in patient selection and evaluation, imaging modalities and measurements, issues in performing the TAVR procedure, and recommendations for post-TAVR management.

FIGURE 1 TAVR Decision Pathway Outline



Abbreviations: ACC = American College of Cardiology, AHA = American Heart Association, AR = aortic regurgitation, AS = aortic stenosis, AVR = aortic valve replacement, CT = cardiothoracic, CTA = computed tomography angiography, CV = cardiovascular, ECG = electrocardiogram, Echo = echocardiography, LV = left ventricular, MR = mitral regurgitation, PA = pulmonary artery, PAP = pulmonary artery pressure, RV = right ventricle, TAVR = transcatheter aortic valve replacement, TEE = transesophageal echocardiography, TTE = transthoracic echocardiography.

5. DESCRIPTION AND RATIONALE

5.1. Pre-TAVR Patient Selection and Evaluation

Table 1 outlines the key steps in pre-TAVR patient selection and evaluation.

TABLE 1 Checklist for Pre-TAVR Patient Selection and Evaluation

Key Steps	Essential Elements	Additional Details
5.1.1 Approach to Care		
Shared decision making	☐ Heart Valve Team	☐ Cardiology: general ☐ Cardiology: interventional ☐ Cardiology/radiology: imaging ☐ CT surgeon ☐ CV anesthesiologist ☐ Valve clinic care coordinators
	☐ Referring physician ☐ Patient input ☐ Family input	
5.1.1 Goals of Care		
Live longer, feel better	☐ Life expectancy ☐ Patient preferences and values ☐ Goals and expectations ☐ End of life construct	☐ Life table estimates ☐ Symptoms and/or survival ☐ What complications to avoid? ☐ Ideas about end of life?
5.1.2 Initial Assessment		
AS symptoms and severity	☐ Symptoms ☐ AS severity	☐ Intensity, acuity ☐ Echocardiography and other imaging (see Imaging Checklist)
Baseline clinical data	☐ Cardiac history ☐ Physical examination and labs ☐ Chest irradiation ☐ Dental evaluation ☐ Allergies ☐ Social support	☐ Prior cardiac interventions ☐ Routine blood tests, PFTs ☐ Access issues, other cardiac effects ☐ Treat dental issues before TAVR ☐ Contrast, latex, medications ☐ Recovery, transportation, postdischarge planning
Major CV comorbidity	☐ Coronary artery disease ☐ LV systolic dysfunction ☐ Concurrent valve disease ☐ Pulmonary hypertension ☐ Aortic disease ☐ Peripheral vascular disease	☐ Coronary angiography ☐ LV ejection fraction ☐ Severe MR or MS ☐ Assess pulmonary pressures ☐ Porcelain aorta (CT scan) ☐ Prohibitive re-entry after previous open heart surgery (CT scan) ☐ Hostile chest ☐ See imaging for PVD
Major non-CV comorbidity	☐ Malignancy ☐ Gastrointestinal and liver disease, bleeding	☐ Remote or active, life expectancy ☐ IBD, cirrhosis, varices, GIB—ability to take antiplatelets/anticoagulation
	☐ Kidney disease	☐ eGFR <30 cc/min/1.73m^2 or dialysis
	☐ Pulmonary disease	☐ Oxygen requirement, FEV1 <50% predicted or DLCO <50% predicted
	☐ Neurological disorders	☐ Movement disorders, dementia
5.1.3 Functional Assessment		
Frailty and disability	☐ Frailty assessment	☐ Gait speed (<0.5 m/s or <0.83 m/s with disability/cognitive impairment) ☐ Frailty (Not frail or frail by assessments)
	☐ Nutritional risk/status	☐ Nutritional risk status (BMI <21 kg/m^2, albumin <3.5 mg/dl, >10-lb weight loss in past year, or ≤11 on MNA)
Physical Function	☐ Physical function and endurance ☐ Independent living	☐ 6-min walk <50 m or unable to walk ☐ Dependent in ≥1 activities
Cognitive Function	☐ Cognitive impairment ☐ Depression ☐ Prior disabling stroke	☐ MMSE <24 or dementia ☐ Depression history or positive screen
Futility	☐ Life expectancy ☐ Lag-time to benefit	☐ <1 year life expectancy ☐ Survival with benefit of <25% at 2 years

Continued on the next page

TABLE 1 Continued

5.1.4 Overall Procedural Risk		
Risk categories	□ Low risk	□ STS-PROM <4% and □ No frailty and □ No comorbidity and □ No procedure specific impediments
	□ Intermediate risk	□ STS-PROM 4%–8% or □ Mild frailty or □ 1 major organ system compromise not to be improved postoperatively or □ A possible procedure-specific impediment
	□ High risk	□ STS-PROM >8% or □ Moderate-severe frailty or □ >2 major organ system compromises not to be improved postoperatively or □ A possible procedure-specific impediment
	□ Prohibitive risk	□ PROMM >50% at 1 year or □ ≥3 major organ system compromises not to be improved postoperatively or □ Severe frailty □ Severe procedure-specific impediments
5.1.5 Integrated Benefit-Risk of TAVR and Shared Decision-Making		
No current indication for AVR	□ AS not severe or □ No AS symptoms or other indication for AVR	□ Periodic monitoring of AS severity and symptoms □ Re-evaluate when AS severe or symptoms occur
AVR indicated but SAVR preferred over TAVR	□ Lower risk for surgical AVR □ Mechanical valve preferred □ Other surgical considerations	□ SAVR recommended in lower-risk patients □ Valve durability considerations in younger patients □ Concurrent surgical procedure needed (e.g., aortic root replacement)
TAVR candidate with expected benefit > risk	□ Symptom relief or improved survival □ Possible complications and expected recovery □ Review of goals and expectations	□ Discussion with patient and family □ Proceed with TAVR imaging evaluation and procedure
Severe symptomatic AS but benefit < risk (futility)	□ Life expectancy <1 year □ Chance of survival with benefit at 2 years <25%	□ Discussion with patient and family □ Palliative care inputs □ Palliative balloon aortic valvuloplasty in selected patients

AS = aortic stenosis; AVR = aortic valve replacement; BMI = body mass index; CT = computed tomography; CV = cardiovascular; DLCO = diffusing capacity of the lung for carbon monoxide; eGFR = estimated glomerular filtration rate; FEV1 = forced expiratory volume in 1 s; GIB = gastrointestinal bleeding; IBD = inflammatory bowel disease; LV = left ventricular; MMSE = mini mental state examination; MNA = mini nutritional assessment; MR = mitral regurgitation; MS = mitral stenosis; PFT = pulmonary function test; PROMM = predicted risk of mortality or major morbidity; PVD = peripheral vascular disease; SAVR = surgical aortic valve replacement; STS-PROM = predicted risk of mortality; TAVR = transcatheter aortic valve replacement.

5.1.1. Shared Decision-Making and the Heart Valve Team

The management of patients with severe AS who are being considered for TAVR is best achieved by a multidisciplinary, collaborative Heart Valve Team that includes cardiologists with expertise in valvular heart disease, structural interventional cardiologists, imaging specialists, cardiovascular surgeons, cardiovascular anesthesiologists, and cardiovascular nursing professionals (1) (**Table 1**). Patient management relies on a shared decision-making approach based on a comprehensive understanding of the risk-benefit ratio of different treatment strategies and integration of patient preferences and values. Shared decision-making involves education of the patient, his or her family, and the referring physician about treatment alternatives. Patient goals and expectations should be established early in this process in the context of a discussion of life expectancy, anticipated improvement in symptoms or survival, and end-of-life constructs, when appropriate. This enables an exchange about the promise of TAVR as well as the realities of advanced age, alternatives to intervention, and palliative care options (**Figure 2**).

The specific tasks for the Heart Valve Team are to: 1) review the patient's medical condition and the severity of the valve abnormality; 2) determine which interventions are indicated, technically feasible, and reasonable; and 3) discuss benefits and risks of these interventions with the patient and family, keeping in mind their values and preferences. The Heart Valve Team should emphasize that the purpose of valvular intervention is to improve symptoms and/or prolong survival, while minimizing adverse outcomes associated with the intervention.

5.1.2. Initial Assessment

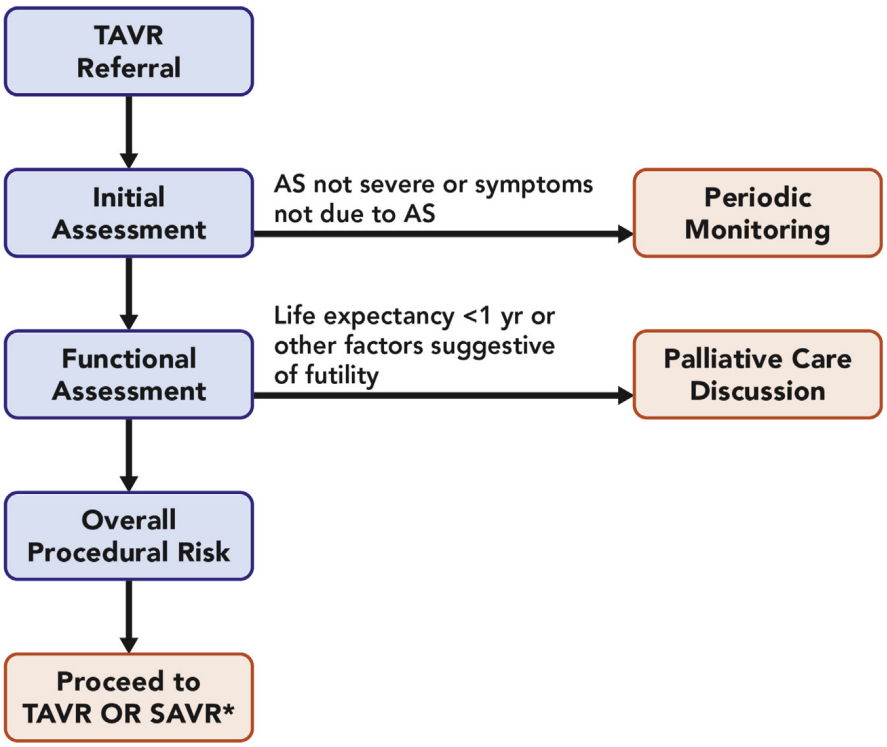
5.1.2.1. Aortic Stenosis Symptoms and Severity

The initial assessment of the patient includes evaluation of AS symptoms, disease severity, and standard clinical data as well as determination of major cardiovascular and noncardiovascular comorbidities. Echocardiographic measures of AS severity should be reviewed, disease severity confirmed, and additional imaging performed as indicated (see Section 5.2).

5.1.2.2. Baseline Clinical Data

Baseline clinical data includes physical examination, standard blood tests, pulmonary function tests, and

FIGURE 2 Pre-TAVR Considerations by the Heart Valve Team



Abbreviations:
AS = aortic stenosis, AVR = aortic valve replacement, TAVR = transcatheter aortic valve replacement

*per current AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease

carotid ultrasound, when indicated. Any previous reactions to contrast agents or latex, as well as medication allergies, should be documented. Dental evaluation is recommended with treatment of any acute issues prior to TAVR to avoid prosthetic valve endocarditis. Evaluation of social support should be considered, particularly with respect to transportation and recovery.

5.1.2.3. Major Cardiovascular Comorbidity

Previous cardiac surgical procedures or transcatheter interventions should be reviewed, as these may be pertinent to the intervention being planned. Diagnostic tests aid in evaluating major cardiovascular comorbidities that might affect treatment decisions. Coronary angiography is indicated in all patients, because coronary artery disease is common in patients undergoing TAVR (40% to 75%) (5). Concurrent coronary revascularization may be needed, particularly if multivessel or left main coronary disease is present, although it is unclear if 30-day mortality is influenced by revascularization status. Until more definitive randomized data are available, the Heart Valve Team should decide whether to revascularize before TAVR on a case-by-case basis using the individual patient's anatomic, clinical, and physiological characteristics. In a *post hoc* analysis of the PARTNER (Placement of Aortic Transcatheter Valves) 2A trial—which enrolled a lower-risk cohort than did the PARTNER 1A trial (high-risk cohort)—revascularization with PCI or coronary artery bypass graft in addition to TAVR did not increase the risk of death or disabling stroke at 2-year follow-up compared with TAVR or SAVR alone, respectively (6).

Other conditions that might increase procedural risk or limit the benefit of the procedure include LV systolic or diastolic dysfunction, severe mitral regurgitation (MR) or mitral stenosis, and severe pulmonary hypertension, all of which can be evaluated by echocardiography. Although low EF has traditionally been identified as a risk marker for poor outcomes after TAVR, recent studies suggest low flow—defined as stroke volume index less than 35 mL/m^2—may also be associated with poor outcomes post-TAVR regardless of EF (7,8). Therefore, both stroke

volume index and EF should be considered for patient selection in TAVR because these patients have poor outcomes regardless of management strategy. The presence of significant mitral valve (MV) disease in patients with severe AS can complicate the decision for TAVR and warrants careful consideration. The prevalence of moderate-to-severe MR in published registries and randomized trials is approximately 20%, with a high prevalence of primary MV disease. Important comorbidities that predict poor outcomes after TAVR in patients with significant MR include primary MV disease, atrial fibrillation (AF), pulmonary hypertension, and reduced EF (1). Secondary MR does tend to improve following TAVR in many patients (9).

Some low-risk candidates for AVR have anatomical factors that increase the risk of surgery. These include prior mediastinal irradiation, chest wall abnormalities, and previous surgical procedures, which result in bypass grafts or vital mediastinal structures being fused to the undersurface of the sternum. In addition to post-treatment scarring from prior irradiation, other effects of radiation on the heart reduce the benefits of aortic valve interventions, including concurrent MV disease, coronary artery disease, myocardial dysfunction, and pericardial involvement. The presence of a "porcelain aorta" is a relative contraindication for SAVR, so TAVR is preferred in patients with this anatomy (10). The anatomy and size of peripheral vessels and the presence of atherosclerosis are important in decision-making about access routes for TAVR and may influence the decision to proceed with SAVR versus TAVR (see Sections 5.2 and 5.3 for further details).

5.1.2.4. Major Noncardiovascular Comorbidity

Patients should be evaluated for major noncardiovascular comorbidities, including active malignancy with limited life expectancy; gastrointestinal disease, such as inflammatory bowel disease, cirrhosis, and varices; active gastrointestinal bleeding with limited ability to take antiplatelet and anticoagulant agents; severe chronic kidney disease (estimated glomerular filtration rate <30 mL/min or dialysis); severe pulmonary disease (oxygen dependence, forced expiratory volume in 1 s <50% predicted, or diffusing capacity of the lungs for carbon monoxide <50% predicted), and neurological disorders such as movement disorders and dementia (e.g., Mini Mental State Examination score <24). A very prevalent and important comorbidity is chronic lung disease, which remains an independent predictor of poor outcomes post-TAVR. Patients with oxygen-dependent chronic obstructive pulmonary disease and very low values of forced expiratory volume in 1 s (<30% predicted) have poor life expectancy, independent of severity of AS. The utility of TAVR in such patients should be carefully considered.

5.1.3. Functional Assessment

5.1.3.1. Frailty and Disability

A comprehensive evaluation includes assessments of frailty, physical function, independence in activities of daily living (e.g., feeding, bathing, dressing, transferring, and toileting), and cognitive function (11). An evaluation should start with screening for independence, cognitive function, and slow walking speed (gait speed—3 timed trials over a 5-m distance). Those with gait speed >0.83 m/s and preserved cognition and independence are likely not frail, but those with gait speed <0.5 m/s or with gait speed <0.83 m/s with disability or cognitive impairment need further evaluation. Additional assessment can be informed by qualitative rating scales like the Canadian Study of Health and Aging Scale, performance-based assessments like the "Up and Go" test and chair stands, deficit accumulation summary measures like the Rockwood Frailty Index, or frailty phenotype scales like the Cardiovascular Health Study Frailty Scale or Edmonton Frail Scale (12–18). Nutritional deficiency (body mass index <21 kg/m^2 or albumin <3.5 g/dL), risk for malnutrition (score ≤11 on Mini Nutritional Assessment), or weight loss (>10 lb decline in 1 year) add information on energy intake and consumption (19). The patient can be classified as not frail, prefrail, or frail with varying severity as an aggregate clinical assessment based on tests performed (20).

5.1.3.2. Physical Functioning

In addition, the 6-min walk test should be utilized to assess the physical functioning and endurance of the patient (21). This test provides predictive information on the likely benefit, long-term mortality, and functional outcomes of patients undergoing TAVR. Independence in basic activities of daily living also informs baseline functional ability and can provide information on post-procedural care needs. These tests are ideally performed in an outpatient setting because results may differ in an inpatient admission setting.

5.1.3.3. Cognitive Function

Cognitive function should be assessed using validated tools to screen for prior disabling stroke, cognitive impairment or dementia, and depression. The Mini Mental State Examination can be used to identify those with dementia, with scores <24 being abnormal (22). Although cognitive function following TAVR is preserved in most (23), assessment can establish baseline cognitive reserve prior to the procedure. Depression is a confounder of cognitive performance; thus, a history followed by a validated tool such as the Center for Epidemiologic Studies Depression Scale is warranted (24).

5.1.3.4. Futility

In addition to frailty and disability, assessment of futility is an important consideration in therapeutic decision-making (4). It is appropriate to avoid intervention in patients who will not benefit in terms of symptoms or improved life span from the procedure. This group of patients in whom SAVR or TAVR for severe AS is considered futile are those with: 1) a life expectancy <1 year, despite a successful procedure; and 2) those who have a chance of "survival with benefit" <25% at 2 years. "Survival with benefit" implies survival with improvement by at least 1 New York Heart Association functional class in heart failure or by at least 1 Canadian Cardiovascular Society class angina symptoms, improvement in quality of life, or improvement in life expectancy (25). If a procedure is considered futile and not recommended, it is important that care plans are put into place to prevent a feeling of abandonment in the patient, family, or caregivers. Input from palliative care specialists is particularly helpful in such situations.

5.1.4. Risk Categories

Estimates of risk in patients referred for TAVR require consideration of the whole patient and several prognostic variables. Individual patient risk assessment combines the STS risk estimate, frailty, major organ system dysfunction, and procedure-specific impediments (see Table 7, Section 2.5 in the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease [1]). The STS risk score is an accepted tool to predict the 30-day risk of SAVR and serves as a starting point for risk assessment in TAVR candidates. Three categories of risk are identified based on the STS score: <4% (low risk), 4% to 8% (intermediate risk), and >8% (high risk). Despite its broad use and its accuracy regarding the risk of SAVR, the STS score has several limitations in risk assessment among elderly patients being considered for TAVR. Specifically, it does not include such indices as frailty; degree of disability; echocardiographic variables such as low-flow AS and pulmonary hypertension; and other comorbidities such as liver disease or hostile chest, among others. A TAVR-specific risk score for predicting patient-level in-hospital mortality has recently been developed and validated from the STS/ACC/Transcatheter Valve Therapy Registry (26). Although this score yields slightly improved discrimination over the STS score and calibration is adequate, it is still limited by a lack of consideration of frailty, disability, and cognitive function. The optimal measure of outcome after TAVR has not been clearly defined, but quality of life following the TAVR procedure as well as mortality should be considered (27).

Currently the AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease recommends a risk assessment scheme based on the STS risk score, frailty, comorbidity, and procedure-specific impediments, and classifies patients with severe AS into 4 global risk categories (see Section 2.5 in the 2014 guidelines [1]):

1. **Low risk:** STS <4% with no frailty, no comorbidity, and no procedure-specific impediments.
2. **Intermediate risk:** STS 4% to 8% with no more than mild frailty or 1 major organ system compromise not to be improved postoperatively, and minimal procedure-specific impediments.
3. **High risk:** STS >8%, or moderate-severe frailty, no more than 2 major organ system compromise not to be improved postoperatively, or a possible procedure-specific impediment.
4. **Prohibitive risk:** Preoperative risk of mortality and morbidity >50% at 1 year, ≥3 major organ system compromise not to be improved postoperatively, severe frailty, or severe procedure-specific impediments.

5.1.5. Integrated Benefit-Risk of TAVR and Shared Decision-Making

Starting from the key elements of pre-TAVR evaluation, the final treatment decision should be individualized using clinical and imaging evaluation, risk category, patient goals and expectations, and futility considerations as recommended in the updated AHA/ACC Guideline for Management of Patients with Valvular Heart Disease (see Section 3.2.4, Aortic Stenosis: Choice of Intervention [1]). If the evaluation indicates that AS is not severe or symptoms are not due to AS, it may be prudent to continue periodic monitoring of AS severity and symptoms, deferring intervention until guideline-based criteria are met. Alternatively, the Heart Valve Team evaluation may conclude that SAVR is the best option for an individual patient if, for example, surgical risk is low, the durability of a mechanical or other tissue valve is preferred in a younger patient, or concurrent surgical procedures such as aortic root replacement or coronary bypass grafting are needed. Even when severe symptomatic AS is present, TAVR is considered futile when the expected benefit from TAVR is less than the expected risk; in these patients, palliative care may be the best option in terms of both quality and length of life. In patients who meet guideline-based criteria for TAVR and for whom pre-TAVR evaluation indicates the benefit of TAVR is greater than risk, discussion with the patient and family should again review the likelihood of symptom relief or improved survival, discuss possible complications and the expected recovery process, and ensure that patient goals and expectations are aligned with the possible procedural outcomes.

5.2. TAVR Imaging Assessment

Table 2 outlines the key measures for TAVR imaging preprocedure, periprocedure, and postprocedure.

TABLE 2 Checklist for TAVR Imaging Assessment

Region of Interest	Recommended Approach and Key Measures	Additional Comments
5.2.2 Preprocedure		
Aortic valve morphology	□ TTE • Trileaflet, bicuspid, or unicuspid • Valve calcification • Leaflet motion • Annular size and shape	□ TEE if can be safely performed, particularly useful for subaortic membranes □ Cardiac MRI if echocardiography is nondiagnostic □ ECG-gated thoracic CTA if MRI is contraindicated
Aortic valve function	□ TTE • Maximum aortic velocity • Mean aortic valve gradient • AVA • Stroke volume index • Presence and severity of AR	□ Additional parameters • Dimensionless index • AVA by planimetry (echocardiography, CT, MRI) • Dobutamine stress echocardiography for LFLG AS-reduced EF • Aortic valve calcium score if LFLG AS diagnosis in question
LV geometry and other cardiac findings	□ TTE • LVEF, regional wall motion • Hypertrophy, diastolic fx • Pulmonary pressure estimate • Mitral valve (MR, MS, MAC) • Aortic sinus anatomy and size	□ CMR: identification of cardiomyopathies □ Myocardial ischemia and scar: CMR, PET, DSE, thallium □ CMR imaging for myocardial fibrosis and scar
Annular sizing	□ TAVR CTA-gated contrast-enhanced CT thorax with multiphasic acquisition. Typically reconstructed in systole 30%-40% of the R-R window.	□ Major/minor annulus dimension □ Major/minor average □ Annular area □ Circumference/perimeter
Aortic root measurements	□ Gated contrast-enhanced CT thorax with multiphasic acquisition. Typically reconstructed in diastole 60%-80%.	□ Coronary ostia heights □ Midsinus of Valsalva (sinus to commissure, sinus to sinus) □ Sinotubular junction □ Ascending aorta (40 cm above valve plane, widest dimension, at level of PA) □ Aortic root and ascending aorta calcification □ For additional measurement, see Table 1
Coronary disease and thoracic anatomy	□ Coronary angiography □ Nongated thoracic CTA	□ Coronary artery disease severity □ Bypass grafts: number/location □ RV to chest wall distance □ Aorta to chest wall relationship
Noncardiac imaging	□ Carotid ultrasound □ Cerebrovascular MRI	□ May be considered depending on clinical history
Vascular Access (Imaging Dependent on Renal Function)	**Recommended Approach**	**Key Parameters**
□ Normal renal function (GFR >60) or ESRD not expected to recover	□ TAVR CTA*	□ Aorta, great vessel, and abdominal aorta □ Dissection, atheroma, stenosis, calcification □ Iliac/subclavian/femoral luminal dimensions, calcification, and tortuosity
□ Borderline renal function	□ Contrast MRA □ Direct femoral angiography (low contrast)	□ Institutional dependent protocols □ Luminal dimensions and tortuosity of peripheral vasculature
□ Acute kidney injury or ESRD with expected recovery	□ Noncontrast CT of chest, abdomen, and pelvis □ Noncontrast MRA □ Can consider TEE if balancing risk/benefits	□ Degree of calcification and tortuosity of peripheral vasculature
5.2.3 Periprocedure		
Imaging Goals	**Recommended Approach**	**Additional Details**
Interventional planning	□ TAVR CTA	□ Predict optimal fluoroscopy angles for valve deployment
Confirmation of annular sizing	□ Preprocedure MDCT	□ Consider contrast aortic root injection if needed □ 3D TEE to confirm annular size†
Valve placement	□ Fluoroscopy under general anesthesia	□ TEE (if using general anesthesia)
Paravalvular leak	□ Direct aortic root angiography	□ TEE (if using general anesthesia)
Procedural complications	□ TTE □ TEE (if using general anesthesia) □ Intracardiac echocardiography (alternative)	□ See Table 5

Continued on the next page

TABLE 2 Continued

5.2.4 Long-Term Postprocedure		
Evaluate valve function	☐ TTE (see post-TAVR checklist for frequency)	☐ Key elements of echocardiography • Maximum aortic velocity • Mean aortic valve gradient • Aortic valve area • Paravalvular and valvular AR
LV geometry and other cardiac findings	☐ TTE • LVEF, regional wall motion • Hypertrophy, diastolic fx • Pulmonary pressure estimate • Mitral valve (MR, MS, MAC)	

*TAVR CTA: Unless otherwise noted, refers to a single arterial phase CTA of the chest, abdomen, and pelvis. Typically, the thorax is acquired using ECG-gated multiphase acquisition. At minimum acquisition and reconstruction should include end systole, usually between 30% and 40% of the R-R window. †TEE: Given use of CT, the role in annular sizing prior to TAVR with TEE is limited. Periprocedural use of TEE is limited to cases performed.

AR = aortic regurgitation; AS = aortic stenosis; AVA = aortic valve area; CMR = cardiovascular magnetic resonance imaging; CT = computed tomography; CTA = computed tomography angiography; DSE = dobutamine stress echocardiography; ECG = electrocardiogram; EF = ejection fraction; ESRD = end-stage renal disease; fx = fracture; GFR = glomerular filtration rate; LFLG = low-flow low-gradient; LV = left ventricular; LVEF = left ventricular ejection fraction; MAC = mitral annular calcification; MDCT = multidetector computed tomography; MR = mitral regurgitation; MRA = magnetic resonance angiogram; MRI = magnetic resonance imaging; MS = mitral stenosis; PA = pulmonary artery; PET = positron emission tomography; RV = right ventricular; TAVR = transcatheter aortic valve replacement; TEE = transesophageal echocardiography; TTE = transthoracic echocardiography.

5.2.1. General Principles and Technical Considerations

Initial assessment and staging of AS severity is best performed by guideline-based diagnosis with transthoracic echocardiography (TTE) (3). In addition, multimodality imaging is needed for preprocedural planning and intraoperative decision making given the complex 3-dimensional (3D) anatomy of the aortic valve, sinuses, and annulus (28). Imaging guidance helps prevent suboptimal valve deployment, which is associated with an increased risk of complications such as paravalvular regurgitation, aortic injury, heart block, and embolization of the valve prosthesis (29,30). Poor outcomes have been associated with even mild amounts of paravalvular AR, and vascular complications from the large delivery catheters drive the need for optimal imaging (31–33) (**Table 2**).

Multidetector computed tomography (MDCT) provides a rapid and comprehensive 3D dataset with near-isotropic voxels of the complex shape of the aortic root, atherosclerotic burden, and course of the thoracoabdominal aorta and its iliofemoral branches (**Table 3**). MDCT is a core element of the standard imaging pathway for the preprocedural planning of TAVR, both to improve the accuracy of TAVR prosthesis sizing and to reduce peripheral vascular complications (29,34).

In patients being evaluated for TAVR, MDCT systems with at least 64 detectors and a spatial resolution of 0.5 mm to 0.6 mm are recommended. Processing should be performed on a dedicated workstation with the ability to manipulate double oblique orthogonal planes of a 3D dataset. Although scanning protocols vary by vendor, typical protocols involve 2 main components. The first is an electrocardiogram (ECG)-gated acquisition of the aortic annulus and aortic root. ECG-synchronized imaging reduces motion artifact and allows reconstruction at any acquired phase of the cardiac cycle. These images serve a primary goal of valve sizing but also provide detailed information on the coronary arteries, leaflet morphology, calcification, and identification of other challenging anatomical features. The second step is a full chest, abdomen, and pelvic acquisition of the arterial vasculature, which does not typically require ECG gating (2).

Although quick and robust, MDCT does expose patients to potentially nephrotoxic iodinated contrast agents. Because a standard bolus of 80 ml to 120 ml of low-osmolar iodinated contrast is necessary, the benefits and risks of iodinated contrast need to be carefully weighed, particularly in elderly patients. The threshold for the safe performance of a contrast scan is highly individualized and dependent in part on provider preferences and institutional protocols. In patients in whom iodinated contrast is absolutely contraindicated, alternative imaging includes magnetic resonance imaging for vascular access and transesophageal echocardiogram (TEE) for valve sizing, but highly depends on local expertise and will likely require multimodality integration (**Figure 3**) (35).

5.2.2. Preprocedural Evaluation

5.2.2.1. Aortic Valve Morphology

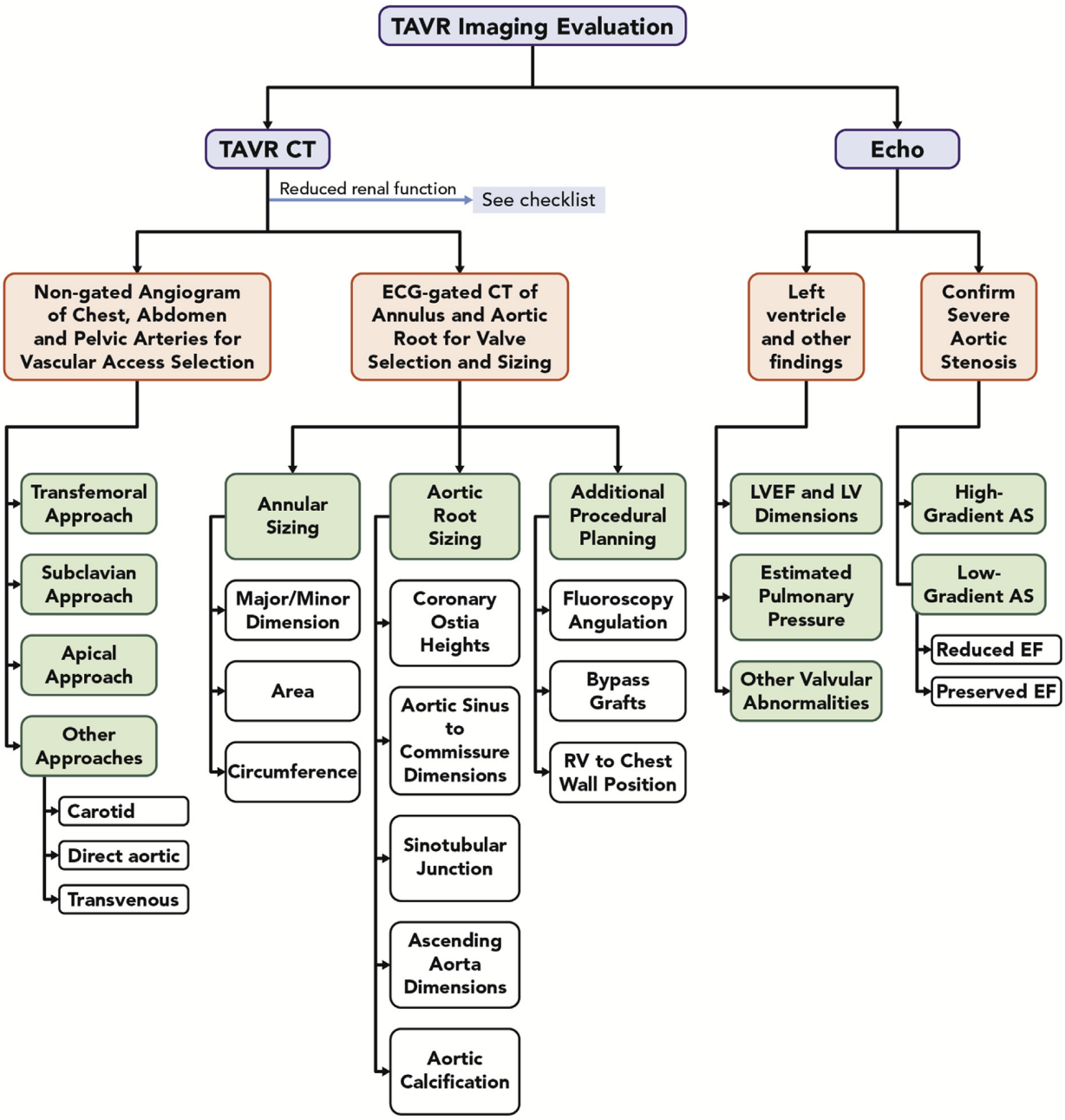
Initial visualization of the aortic valve is performed with TTE, which in most instances allows for clear imaging of the aortic valve to identify the number of leaflets; size, location, and extent of calcification; leaflet motion; and a preliminary view of annular size and shape. At this stage, the role of TEE is limited to patients with a high suspicion of endocarditis or a subaortic membrane. If additional imaging is needed, valve anatomy and function can be evaluated by cardiac magnetic resonance imaging (CMR) or ECG-gated MDCT (35,36). An ECG-gated MDCT of the thoracic aorta can identify the cusp morphology as well as the size, location, and extent of calcium burden present on

TABLE 3 Typical CT-Specific Measurements for TAVR

TAVR CT Measurement Summary			
Valve Size and Type			
Region of Interest	**Specific Measurements**	**Measurement Technique**	**Additional Comments**
Aortic valve morphology and function	Aortic valve	□ If cine images obtained, qualitative evaluation of valve opening □ Planimetry of aortic valve area in rare cases □ Calcium score with Agatston technique or a volumetric technique to quantify calcification of aortic valve	□ Most useful in cases of LFLG AS where diagnosis is otherwise unclear. May be helpful in defining number of valve cusps.
LV geometry and other cardiac findings	LV outflow tract	□ Measured with a double oblique plane at narrowest portion of the LV outflow tract □ Perimeter □ Area □ Qualitative assessment of calcification	□ Quantification of calcification not standardized. Large eccentric calcium may predispose for paravalvular regurgitation and annular rupture during valve deployment.
Annular sizing	Aortic annulus	□ Defined as double oblique plane at insertion point of all 3 coronary cusps □ Major/minor diameter □ Perimeter □ Area	□ Periprocedural TEE and/or balloon sizing can confirm dimensions during case.
Aortic root measurements	Sinus of Valsalva	□ Height from annulus to superior aspect of each coronary cusp □ Diameter of each coronary cusp to the opposite commissure □ Circumference around largest dimension □ Area of the largest dimension	
Coronary and thoracic anatomy	Coronary arteries	□ Height from annulus to inferior margin of left main coronary artery and the inferior margin of the right coronary artery	□ Short coronary artery height increases risk of procedure. □ Evaluation of coronary artery and bypass graft stenosis on select studies. Estimate risk of coronary occlusion during valve deployment.
	Aortic root angulation	□ Angle of root to left ventricle □ Three-cusp angulation to predict best fluoroscopy angle	□ Reduce procedure time and contrast load by reducing number of periprocedural root injections.
Vascular Access Planning			
Vascular access	Aorta	□ Major/minor diameters of the following: • Aorta at sinotubular junction • Ascending aorta in widest dimension • Ascending aorta prior to brachiocephalic artery • Midaortic arch • Descending aorta at isthmus • Descending aorta at level of pulmonary artery • Descending aorta at level of diaphragm • Abdominal aorta at level of renal arteries • Abdominal aorta at the iliac bifurcation	□ Measurements must be perpendicular to aorta in 2 orthogonal planes. □ Identify aortopathies. □ Evaluate burden of atherosclerosis. □ Identify dissection or aneurysms.
	Primary peripheral vasculature	□ Major/minor dimensions, tortuosity, calcification of the following: • Carotid arteries • Subclavian arteries • Brachiocephalic artery • Vertebral arteries • Bilateral subclavian arteries • Great vessels • Iliac arteries • Femoral arteries	□ No well-defined cutoff or definition of tortuosity or calcification has been established.
	Ancillary vasculature	□ Stenosis of the following: • Celiac artery • Superior mesenteric artery • Both renal arteries	
	Relationship of femoral bifurcation and femoral head	□ Distance from inferior margin of femoral head to femoral bifurcation	

AS = aortic stenosis; CT = computed tomography; LFLG = low flow, low gradient; LV = left ventricular; TAVR = transcatheter aortic valve repair; TEE = transesophageal echocardiogram.

FIGURE 3 Imaging for TAVR



Abbreviations:
AS = aortic stenosis, CT = computed tomography, Echo = echocardiography, ECG = electrocardiogram, EF = ejection fraction, LV = left ventricular, LVEF = left ventricular ejection fraction, RV = right ventricular, TAVR = transcatheter aortic valve replacement

Additional evaluation including coronary angiography also is recommended as detailed in the Checklist shown in Table 2. This also includes the approach for patients with reduced renal function.

the aortic valve and aortic annulus. In some cases, a fully retrospective acquisition throughout the cardiac cycle can be obtained to create 4-dimensional cine reconstructions at the expense of a higher radiation exposure.

5.2.2.2. Aortic Valve Function

The high temporal resolution and the ability of Doppler echocardiography to interrogate aortic valve physiology render it superior to all other current imaging modalities. AS severity should be evaluated according to the European Association of Echocardiography/American Society of Echocardiography Recommendations for Evaluation of Valvular Stenosis (3) and staged according to the AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease (1).

In patients in whom the severity of AS is unclear, repeat TTE by an experienced valve center of excellence can play a role. This may be especially useful in subsets of patients, such as those with low-flow, low-gradient AS with preserved EF (Stage D3). Dobutamine stress echocardiography continues to play an important role in the diagnosis and identification of contractile reserve in patients with low-flow, low-gradient AS with reduced EF (Stage D2). There may also be a role for invasive hemodynamics in select patients. In cases where low-flow, low-gradient AS may be unclear, an aortic valve calcium score has been proposed to be of use (37). It is important to note that velocity-encoded flow imaging by CMR will systematically underestimate peak aortic velocity and should not be used in place of TTE for the identification of the peak aortic velocity and gradients (38).

5.2.2.3. LV Geometry and Other Cardiac Findings

TTE also is recommended for evaluation of LV hypertrophy, chamber size, LV diastolic function, regional wall motion, and EF as well as newer measures of LV function such as global longitudinal strain. In addition, TTE is useful for assessment of aortic dilation, presence of subvalvular outflow tract obstruction, estimation of pulmonary pressures, and identification of other significant valve abnormalities. In patients who have poor acoustic windows, CMR can play a complementary role in assessing the LV geometry by identifying typical late gadolinium-enhanced patterns of amyloidosis, sarcoidosis, hypertrophic cardiomyopathy, or scar burden in ischemic cardiomyopathies. The role of viability testing to guide revascularization at the time of TAVR is also evolving. Evaluation of myocardial ischemia and/or viability may be needed in some patients with single-photon emission CT using a thallium rest redistribution protocol or dobutamine stress echocardiography. However, advancements in CMR and positron emission tomography, combined with CT, are able to image scar with increased fidelity.

5.2.2.4. Annular Sizing

Correct assessment of the aortic annulus can be challenging, as it is an elliptical virtual ring formed by the joining of basal attachments of the aortic valvular leaflets. The 3D dataset of MDCT avoids the systematic underestimation of the major axis of the annulus by TTE (39). With gated MDCT, the annulus can also be measured during systole (typically 30% to 40% of the R-R interval) to avoid undersizing of the prosthesis due to the conformational pulsatile changes that it undergoes during the cardiac cycle. MDCT systolic reconstruction of the annulus orthogonal to the center-axis of the LV outflow tract allows for the assessment of minimal and maximal diameter, circumference, and area measurements. Typically a small degree of prosthesis oversizing is recommended; however, severe oversizing increases the risk of annular rupture (2,28,40).

Measurement of LV outflow tract diameter on TTE has been well-validated for calculation of aortic valve area and continues to be the standard for determination of AS severity. However, TTE annulus or outflow tract measurements are not accurate for selection of prosthetic valve size. TEE, especially with 3D imaging techniques, provides better anatomic delineation of the shape of the aortic annulus, but has the drawback of being somewhat invasive in a complex and high-risk patient population and is not recommended for routine pre-TAVR valve sizing. If TEE is used intraprocedurally, 3D techniques may be used to confirm MDCT annular measurements. CMR can also provide comprehensive assessment of the aortic valve, annulus, and aortic root with good correlation with MDCT (35). Imaging can be performed using a 2-dimensional ECG-gated noncontrast steady-state free precession cine pulse sequence. Typically a stack of images with 6 mm to 8 mm slice thickness without a gap between slices is acquired across the aortic valve and aortic root to provide a detailed assessment of the aortic annulus, valve, root, and coronary ostia similar to that obtained on MDCT. As a 2-dimensional pulse sequence acquisition, precise double oblique orthogonal planes must be correctly lined up at the time of acquisition, which can be time consuming and requires precise image acquisition at the point of care. Alternatively, a free-breathing, noncontrast, navigator-gated, 3D whole-heart acquisition can provide a 3D dataset similar to that provided by an MDCT, although image acquisition is typically limited to a single phase of the cardiac cycles. CMR can be a valuable tool in patients who cannot undergo MDCT.

5.2.2.5. Aortic Root Measurements

In addition to annular sizing, it is important to evaluate the entire aortoannular complex. MDCT allows for the

careful measurement of the size of the sinuses of Valsalva, the coronary ostia distance from the annulus, the size of the aorta at the sinotubular junction and 40 mm above the annulus, and the extent and position of aortic calcifications (2). MDCT allows for measuring of the distance between annulus and coronary ostia, which identifies patients who are at risk for coronary occlusion during TAVR.

With CMR, using the free-breathing, noncontrast, navigator-gated, 3D whole-heart acquisition, images obtained for annular measurement can also be used to evaluate the entire aortoannular complex. Providers with experience and expertise in TAVR planning should be involved in measuring magnetic resonance angiography images.

5.2.2.6. Presurgical Planning

MDCT also may be of use to identify coronary artery and coronary bypass graft location and stenosis, evaluate the RV to chest wall position, and identify the aorta and LV apex to chest wall position in direct aortic approaches. However, complete coronary assessment with MDCT is limited by the high prevalence of advanced calcified disease, precluding precise assessment of luminal stenosis. Therefore, standard invasive coronary angiography is recommended for evaluation of the presence and severity of coronary artery disease (see Section 5.1.2.3).

5.2.2.7. Noncardiac Imaging

Because of the high prevalence of dementia and atherosclerosis in this elderly patient population, a preprocedural work-up including carotid ultrasound and cerebrovascular magnetic resonance imaging might be considered prior to considering or such patients for TAVR. However, further research is necessary prior to making conclusive recommendations.

5.2.2.8. Vascular Access

Because of the relatively large diameter of the delivery sheaths, appropriate vascular access imaging is critical for TAVR. It is important to evaluate the entire thoracoabdominal aorta, major thoracic arterial vasculature, carotids, and iliofemoral vasculature. The extent of atherosclerotic plaque in the ascending aorta and the arch has been shown to be associated with worse outcomes following cardiac surgery and is also likely associated with increased periprocedural complications following TAVR. Small luminal diameter, dense and circumferential and/or horseshoe calcifications, and severe tortuosity are common in the iliofemoral vasculature in these patients and increase the risk of access site complications and cerebral embolization. MDCT is ideal for the evaluation of thoracic and iliofemoral stenosis, tortuosity, and calcifications. It also identifies risk factors such as aortic or vascular dissections, intramural hematomas, aortic ulcerations, and extensive atheroma. In cases with challenging arterial access, imaging with MDCT can guide alternative access approaches such as a surgical sidegraft on the iliac arteries, or transaxillary, transapical, direct aortic, carotid, or even transvenous access approaches.

In patients with reduced renal function, 1 alternate approach involves using a femoral sheath to obtain a pelvic scan after intra-arterial contrast injection into the infrarenal abdominal aorta (left in place after coronary catheterization) using a very low dose (15 ml) of contrast (2). Alternatively a low-volume distal abdominal aortogram can be performed at the time of coronary angiography, augmented with a marker pigtail catheter or peripheral intravascular ultrasound imaging if necessary. If absolutely no contrast administration is tenable, a noncontrast MDCT scan allows for the assessment of overall vessel size, calcification, and tortuosity. This approach requires an alternative method to evaluate for actual luminal stenosis, occlusion, dissection, or other aortic pathology. In patients with reduced but stable renal function, nongated contrast magnetic resonance angiography or intravascular ultrasound could be used to accurately size the remainder of the aorta and peripheral vasculature.

5.2.3. Periprocedural Evaluation

5.2.3.1. Interventional Planning

MDCT can assist with predicting the optimal delivery angle on fluoroscopy prior to valve deployment. Precise coaxial alignment of the stent valve along the centerline of the aortic valve and aortic root is important during positioning to avoid procedural complications. Whereas traditional assessment of root orientation is performed using multiple invasive aortograms in 1 or 2 orthogonal planes, double-oblique multiplanar MDCT reconstruction allows preprocedural prediction of the aortic root angle. This potentially decreases the number of aortograms required during the procedure, thereby shortening both procedure time and contrast usage and potentially increasing the likelihood of coaxial implantation.

5.2.3.2. Confirmation of Annular Sizing

In general, annular sizing preferably is determined with preprocedure MDCT. Additional imaging during the procedure should be confirmatory only. Fluoroscopy typically is the main imaging modality at the time of the procedure. If questions remain about the correct annular sizing, balloon inflation with contrast root injection can be performed (see Section 5.3). The annulus can also be evaluated with 3D TEE at the time of the procedure. These

are not ideal situations, and this approach should be reserved for urgent cases where there is insufficient time for careful preplanning.

5.2.3.3. Valve Placement

Optimal deployment angles are obtained using fluoroscopy and root injections. Deployment is done under fluoroscopy at many institutions, although TEE is an alternative approach.

5.2.3.4. Paravalvular Leak

In patients undergoing general anesthesia, TEE may be helpful for confirming annular cosizing, valve placement, and immediate valvular and paravalvular leak. The use of biplane color Doppler and 3D imaging is helpful for detecting paravalvular leak. Both TEE and TTE approaches may be needed to assess both the anterior and posterior aspects of the valve. Aortic root angiography also may be used to assess for regurgitation after valve implantation. TEE can also assess for immediate gradient changes and the seating of the valve. As the volume of cases performed without general anesthesia increases, there may be an expanding role for periprocedural TTE.

5.2.3.5. Procedural Complications

TEE, TTE, angiography, and direct hemodynamic measurements can all assist with identifying any immediate complications such as annular rupture resulting in pericardial effusion and tamponade (see Section 5.3).

5.2.4. Long-Term Postprocedural Evaluation

5.2.4.1. Evaluate Valve Function

Echocardiography is recommended to evaluate the valve postprocedurally, as detailed in Section 5.4. These studies are important to evaluate for valvular and paravalvular leak, valve migration, complications such as annular or sinus rupture, valve thrombosis, endocarditis, paravalvular abscess, LV size, function and remodeling, and pulmonary pressures. MDCT can be used to evaluate valve anatomy and to evaluate for valve thrombosis (36). CMR can also be used to quantify AR and can be complementary to TTE for the quantification of paravalvular leak.

5.2.4.2. LV Geometry and Other Cardiac Findings

TTE is used to evaluate changes in LV function after TAVR. In patients with a low EF before TAVR, LV systolic function may improve, whereas others may have persistent myocardial dysfunction with implications for medical therapy and frequency of follow-up. Similarly, secondary MR may improve after TAVR, with a reduction in pulmonary pressures due to the unloading effect of relief of AS. In other patients, persistent secondary mitral regurgitation may require further intervention or changes in medical therapy.

5.3. TAVR Procedure

Table 4 outlines the key steps in performing the TAVR procedure.

5.3.1. Preprocedural Planning

Several specific tasks should be considered by the Heart Valve Team before the actual procedure is performed.

5.3.1.1. Valve Choice

The choice of valve depends on 2 key factors: 1) whether a balloon-expandable, self-expanding, or other type of valve is preferred for anatomic reasons or other considerations; and 2) the available valve sizes. Currently, 2 TAVR valves are commercially available in the United States: 1) the balloon-expandable Sapien family of transcatheter heart valves (Edwards Lifesciences, Irvine, California) made of bovine pericardium mounted in a cylindrical, relatively short cobalt-chromium stent; and 2) the self-expanding CoreValve (Medtronic, Minneapolis, Minnesota) family of transcatheter heart valves, which are made of porcine pericardium mounted in a taller, nitinol stent with an adaptive shape and supra-annular design.

Although possibly underpowered, the largest randomized controlled trial comparing a balloon-expandable with a self-expanding valve showed similar 1-year mortality, strokes, and readmissions due to heart failure with either valve (41,42). Several factors must be considered when deciding on the optimal valve platform for a given patient. These include annulus dimensions and geometry, native valve and aortic root/LV outflow tract anatomy, coronary height, and amount and distribution of calcification. In some situations, a self-expanding platform may be preferable to a balloon-expandable one. These include patients with severe calcification of the aortic annulus/LV outflow tract with an attendant risk of rupture, patients with an extremely oval-shaped annulus, or for transfemoral access when femoral artery diameter is between 5.0 mm and 5.5 mm (43–45). Also, the newer generation of self-expanding valves (CoreValve Evolut R, Medtronic) can be recaptured and repositioned prior to full deployment, offering the advantage of reducing complications from malpositioning. This has a potential benefit in patients with low coronary ostia as well. Conversely, a balloon-expandable device may be preferable among patients with a dilated ascending (>43 mm) or severely angulated aorta (aortoventricular angle >70°, particularly for transfemoral access). A balloon-expandable valve is the only option in patients needing a transapical approach (e.g., those with a significant aortic calcification and peripheral vascular disease). In patients who are eligible for either prosthesis, the choice generally comes down to operator and/or institutional preference and experience.

TABLE 4 Checklist for TAVR Procedure

Key Steps	Essential Elements	Additional Details
5.3.1 Preplanning by Heart Team		
Valve choice	□ Balloon-expandable □ Self-expanding □ Other	□ Annulus, native valve and root anatomy/Ca^{++} □ Sheath size □ Avoid rapid pacing when possible
Access choice	□ Transfemoral □ Alternative access	□ Suitability of access – careful reconstructions
Location of procedure	□ Catheterization laboratory □ Operating room □ Hybrid room	□ Imaging needed for procedure □ Possible cardiopulmonary bypass □ Interventional and surgical equipment □ Anesthesia requirements
Anesthesia considerations	□ Conscious sedation □ General anesthesia □ Allergies	□ Need for intraoperative TEE affects anesthesia type
Anticipated complication management	□ Individual team member roles □ Difficult airway management □ Patient-specific concerns (language or communication barriers) □ Valve-related bailout strategies—valve-in-valve, surgical AVR □ Need for leave-in PA catheter, temporary pacer post-implant □ Prophylactic wiring of coronaries for low coronary heights and narrow sinuses/bulky leaflets □ Vascular bailout strategies	□ Feasibility of fem-fem bypass □ Bypass circuit primed or in-room only □ Need for crossover balloon technique □ Duration of temporary pacer per institutional protocol or patient condition □ Conversion to permanent pacing may be needed in certain patients.
5.3.2 Procedure Details		
Anesthesia administration	□ Moderation sedation or general anesthesia □ Temporary pacer lead for rapid pacing □ Defibrillator and pre-placed patches □ Arterial pressure monitoring	□ Avoid hypothermia □ Volume status monitoring and optimization □ Antibiotic prophylaxis
Vascular access and closure	□ Transfemoral □ Transapical □ Transaortic □ Trans-subclavian □ Other: transcarotid, transcaval, antegrade aortic	□ Percutaneous □ Surgical cutdown
Pre-valve implant	□ Optimal fluoroscopic and intraprocedural views for device deployment □ Anticoagulation □ Balloon predilation (and sizing if necessary) □ Valve prepared with delivery system for rapid deployment if needed (if balloon sizing not required)	□ Assess AR immediately post-BAV as well as need for hemodynamic support
Valve delivery and deployment	□ Optimal positioning across the annulus □ Need for rapid pacing	□ Essential for balloon-expandable valve; optional for self-expanding valves
Post-deployment valve assessments	□ Satisfactory device position/location □ Valve embolization □ Assess aortic regurgitation • Central • Paravalvular □ Assess mitral valve	□ Immediate assessment with echocardiography, hemodynamics, aortogram post-implant □ See treatment options in **Table 5**
Other complication assessment and management	□ Shock or hemodynamic collapse □ Coronary occlusion □ Annular rupture □ Ventricular perforation □ Complete heart block □ Stroke □ Bleeding/hemorrhage □ Access site-related complications	□ See treatment options in **Table 5**

AR = aortic regurgitation; AVR = aortic valve replacement; BAV = balloon aortic valvuloplasty; PA = pulmonary artery; TAVR = transcatheter aortic valve replacement; TEE = transesophageal echocardiography.

Femoral delivery sheath requirements for the 2 platforms are similar but may influence valve choice in select patients with peripheral artery disease. Three of the newer-generation balloon-expandable valve sizes (20-mm, 23-mm, and 26-mm Sapien S3) are accommodated through a 14-F expandable sheath, with a minimum vessel diameter requirement of 5.5 mm; the 29-mm Sapien S3 requires a 16-F expandable sheath, with a

minimum vessel diameter requirement of 6 mm. The current self-expanding TAVR platform (23-mm, 26-mm, and 29-mm CoreValve Evolut R) requires a minimum vessel diameter of 5 mm, whereas the larger 31-mm CoreValve Classic requires an 18-F sheath for delivery, with a minimum vessel diameter requirement of 6 mm.

Several other valve designs and platforms are currently under investigation, and future valve teams will need to have a sound understanding of their relative merits and disadvantages for treating specific subsets of patients with AS.

5.3.1.2. Access Choice

Evaluation of the patient's atherosclerotic load and location, arterial size and tortuosity, and presence of mural thrombus are required to assess the best possible delivery site. When possible, transfemoral access is the preferred TAVR delivery route. Since their initial introduction, sheaths have dramatically decreased in size for both delivery platforms, making transfemoral access a possibility in the vast majority of patients who are undergoing TAVR. A variety of nontransfemoral access options are available, including transaortic, trans-subclavian, and transapical (the latter only with the balloon-expandable valve platform). Other approaches are also feasible (transcarotid, transcaval, and antegrade aortic), but are restricted to operators and hospitals with specialized skillsets and experience.

5.3.1.3. Location of the Procedure

The location at which the TAVR procedure is performed varies between institutions and has important physical, personnel, and equipment implications. Optimal equipment requirements include a state-of-the-art, large-field-of-view fluoroscopic imaging system with a fixed overhead or floor-mounted system that has positioning capability rather than a portable C-arm system. Imaging programs that can automatically aid in the selection of orthogonal views for imaging during positioning of the valve (e.g., Fusion Imaging) are also desirable. Integration of echocardiographic images, particularly 3D capabilities, is helpful; the availability of MDCT or CMR is a significant advantage, particularly if image fusion—which will become more widely used in the future—is possible. Full catheterization laboratory hemodynamic capability is also required for all procedural rooms, including hybrid rooms.

Other necessary resources include cardiopulmonary bypass machines and related ancillary supplies, with an inventory of interventional cardiology equipment for balloon aortic valvuloplasty, coronary balloons, stents, and 0.014-inch wires if coronary occlusion occurs as a complication of device deployment. As vascular access is critical, a variety of peripheral arterial balloons and covered stents for treatment of peripheral vascular complications, such as iliac rupture, and a variety of vascular closure devices are also important for completion of the procedure. The procedure location should also be fully capable of providing anesthesia services, including advanced airway management, general anesthesia, full hemodynamic monitoring, and administration of vasoactive agents into the central circulation. As can be seen, these requirements mandate specific room sizes and configurations. Such a hybrid room may be situated in a surgical suite or in a large modified catheterization laboratory (approximately ≥800 square feet) with appropriate air handling and air exchange modifications. In the future, as the types and number of procedures increase for the treatment of a variety of structural heart and endovascular disease procedures, it is anticipated that hybrid rooms will become the standard of care for these team-based therapies.

In addition to the interventional cardiologist, cardiothoracic surgeon, and cardiovascular anesthesiologist, other personnel required during the TAVR procedure include a cardiovascular imaging specialist, cardiac perfusionists, and other personnel who are trained in hemodynamic monitoring and able to rapidly deal with procedural complications.

5.3.1.4. Anesthetic Considerations

Patients who are undergoing TAVR are at a high risk for procedural complications, including hemodynamic collapse. Careful planning and intraoperative anesthetic management can mitigate this risk (46,47). Preventing prolonged hypotension is a key goal. During the preoperative evaluation, special attention is paid to factors that may predict higher risk of intraprocedural instability, particularly the following: depressed EF, elevated pulmonary pressures, significant mitral or tricuspid regurgitation, incomplete revascularization, collateral-dependent coronary and cerebral circulation, chronic lung disease, heart failure, and acute/chronic kidney disease. In the patients who are least likely to tolerate rapid ventricular pacing and hypotension, preventive measures may be instituted and steps taken to allow for rapid institution of cardiopulmonary bypass. Rarely, elective bypass may be utilized. Of critical importance in all patients, but in particular among those at risk for cardiovascular compromise, is a baseline evaluation of the airway. The goal of this examination should focus on the ease or difficulty of emergently securing the airway during cardiovascular compromise or collapse (if not intubated at the outset), with particular attention paid to possible equipment obstruction (such as from the C-arm), which often limits complete access to the airway. A review of allergies, particularly to iodinated contrast, should be performed routinely.

TAVR is evolving from a procedure done routinely under general anesthesia with invasive central monitoring, a pulmonary artery catheter, and transesophageal echocardiography, to one that can safely be performed with conscious sedation and minimal instrumentation. In observational and retrospective studies, conscious sedation, compared with general anesthesia, has been associated with fewer requirements for inotropes/vasopressors, shorter lengths of hospital stay, and shorter procedural/intervention times, with earlier patient mobilization (46–48). An additional advantage of conscious sedation is prompt detection of adverse neurological events. Currently, there are no randomized controlled trials addressing the superiority of conscious sedation or general anesthesia for these procedures (48–50). For now, it is recommended that they should be performed in highly experienced centers, not as an initial starting strategy for a TAVR program, and only using the transfemoral approach. Transthoracic imaging is typically utilized for intraprocedural imaging in these cases. Depending on institutional and anesthesia provider preferences, conscious sedation is best avoided in patients requiring TEE guidance during valve deployment and in those with borderline vascular access, cognitive or language barriers, an inability to stay still or lie flat, chronic pain, morbid obesity, or other issues.

The anesthetic plan for either conscious sedation or general anesthesia should use the fewest medications at the lowest doses needed to control pain and anxiety. Most patients are elderly and frail, with multiple comorbidities. As device sheaths decrease in size, postoperative pain is minimal, especially with a transfemoral approach. For patients receiving general anesthesia, fast-track algorithms should be followed, allowing for immediate extubation in the intervention room when feasible. For patients with important pulmonary issues, a careful plan regarding difficult airway management, extubation parameters, and the need for periextubation supportive respiratory care should be discussed, with inputs solicited from a pulmonary/critical care physician when warranted.

5.3.1.5. Anticipated Complication Management

The roles and responsibilities of each individual person during the TAVR procedure should be clearly defined. The team leader is usually an interventional cardiologist for transfemoral TAVR procedures, whereas a cardiothoracic surgeon usually is team leader for transapical and transaortic procedures or if a subclavian approach is required.

One of the key strategies to minimize complications is to review and anticipate expected complications with initiation of preventative maneuvers and strategies (**Table 5**). For instance, coronary occlusion is a relatively rare complication of TAVR but is more likely in patients with low coronary heights (typically <10 mm), and particularly in those with narrow sinuses and/or bulky aortic leaflets. In these patients, prophylactic wiring of the coronaries should be considered. Another maneuver is to perform balloon valvuloplasty with a balloon size similar to the expected TAVR valve size while simultaneously performing root aortography to assess the movement of the leaflets with respect to the coronary artery ostia. Valve-related bailout strategies should be discussed before starting the procedure. These include valve-in-valve implantation (e.g., valve embolization) and SAVR, recognizing that the latter may not be an option for many patients undergoing this procedure. For patients with major hemodynamic compromise (typically due to cardiac tamponade, coronary occlusion, severe acute AR, aortic rupture, or acute aortic dissection), access options for instituting rapid cardiopulmonary bypass should be reviewed. For patients undergoing transfemoral access, the arterial cannula can be easily placed via the same access or even through the delivery sheath if needed. However, for nontransfemoral cases, accessory cannulation sites in the femoral vessels or with an adjunctive axillary graft and venous cannula should be considered if femoral access sites are not suitable. Central cannulation may also need to be considered in some patients. Another important consideration is whether the bypass circuit will be primed and readily available for all or most cases (contributing to potential resource waste) or in-room only (delay may occur in readying the circuit in the setting of a hemodynamically compromised patient). Vascular bail-out strategies should also be outlined, such as the need for distal aortic occlusion balloons (e.g., in the setting of vascular rupture) or a crossover balloon technique (e.g., to assist with percutaneous closure in morbidly obese patients), in addition to the routine management of vascular complications with covered stents and balloons. Inputs from a vascular surgeon may also be helpful in select situations.

5.3.2. Procedural Details

5.3.2.1. Anesthesia Administration

For general anesthesia cases, including those involving transapical access, insertion of a double-lumen tube or single-lung ventilation is typically not required (50). Typically, a temporary transvenous lead is passed through the femoral or internal jugular veins or, in the case of transapical procedures, can also be sewn directly on the epicardial surface. After placement of the ventricular pacing wire, thresholds are checked at a pacing of rate 10 beats/min to 20 beats/min higher than the patient's intrinsic rates. Arterial pressure monitoring may be done via the radial artery, but in the case of ipsilateral axillary bypass, a plan must be made for additional monitoring from either the contralateral radial or the femoral artery. A monitoring pulmonary artery catheter may be helpful in certain patients (e.g., those with poor

TABLE 5 TAVR Procedural Complications and Management

Complication	Treatment Options
Valve embolization	
• Aortic	• Recapture or deploy in descending aorta if still attached to delivery system (self-expanding) • Valve-in-valve • Endovascular (snare)
• Left ventricle	• Surgical AVR and extraction
Central valvular aortic regurgitation	• Usually self-limited, but may require gentle probing of leaflets with a soft wire or catheter • Delivery of a second TAVR device
Paravalvular aortic regurgitation	• Post-deployment balloon dilation • Delivery of a second TAVR device • Repositioning of valve if low (recapture, snare) • Percutaneous vascular closure devices • Surgical AVR
Shock or hemodynamic collapse	• Assess and treat underlying cause if feasible • Inotropic support • Mechanical circulatory support • CPB
Coronary occlusion	• PCI (easier if coronaries already wired before valve implantation) • CABG
Annular rupture	• Reverse anticoagulation • Surgical repair • Pericardial drainage
Ventricular perforation	• Reverse anticoagulation • Surgical repair • Pericardial drainage
Complete heart block	• Transvenous pacing with conversion to PPM if needed
Stroke • Ischemic • Hemorrhagic	• Catheter-based, mechanical embolic retrieval for large ischemic CVA • Conservative
Bleeding/hemorrhage	• Treat source if feasible • Transfusion • Reversal of anticoagulation
Access site-related complications	• Urgent endovascular or surgical repair

AVR = aortic valve replacement; CABG = coronary artery bypass grafting; CPB = cardiopulmonary bypass; CVA = cerebrovascular accident; PCI = percutaneous coronary intervention; PPM = permanent pacemaker; TAVR = transcatheter aortic valve replacement.

LV function or severe pulmonary hypertension). At least 1 large-volume line is obtained peripherally or centrally. Immediate access to a defibrillator device is necessary because ventricular fibrillation can occur with manipulation of catheters within the heart or with rapid ventricular pacing. This may be best accomplished with preapplied defibrillator pads connected to the defibrillator before starting the procedure. Routine steps to prevent significant hypothermia are recommended. These include appropriate ambient room temperature, fluid warmers, and forced air or fluid underbody heating systems.

Unless otherwise indicated, volume status needs to be supplemented, as patients in this age group are usually volume depleted. However, both volume overload and depletion can be problematic, and a combination of pulmonary artery pressures, central venous pressure, and echocardiographic evaluation can guide tailored therapy. Severely underfilled ventricles may pose an additional problem for guidewire/applicator device insertion in these hypertrophied ventricles. Patients with severe concentric LV hypertrophy and intravascular volume depletion may exhibit a rapid and sustained deterioration of hemodynamic status in response to rapid ventricular pacing, intracardiac guidewire or catheter manipulations, or balloon aortic valvuloplasty. Inhaled nitric oxide or inhaled epoprostenol should be readily available for the treatment of severe pulmonary hypertension and right ventricular failure.

Routine surgical antibiotic prophylaxis administered prior to surgical incision or vascular access is warranted to decrease the risk of wound infection and endocarditis.

5.3.2.2. Vascular Access

If needed, preprocedure vascular access imaging can be supplemented with vascular ultrasound to assess vessel wall calcification prior to puncture. Similarly, for transapical and transaortic access, an intraoperative assessment of the optimal surgical entry site may be needed.

For transfemoral access, both percutaneous and cutdown access approaches are used; there are advantages and disadvantages to each. Percutaneous approaches are preferred when access sites are relatively large and free of significant atherosclerotic disease and calcification, and in patients with wound healing concerns. The Heart Valve Team's experience with large-bore access is also an important consideration. Less favorable vessels may require cutdown, often with placement of axillary, iliac, or aortic insertion grafts or conduits to provide access sites. Percutaneous insertions are occasionally converted to open repair or hybrid repairs, utilizing percutaneous closure devices and surgical techniques as needed. For percutaneous access, many operators prefer to "preclose" the access site with commercially available devices. A series of dilators is employed under fluoroscopic vision to reach the size of the deployment sheath. The sheath is passed into the body of the thoracoabdominal aorta.

For transapical cases, access is obtained via a left anterior thoracotomy, which is made after localization of the apex by fluoroscopy, TTE, and/or TEE. Review of the coronary angiogram provides information on the location of the left anterior descending and diagonal coronary arteries. After entering the pleural space, digital inspection can further localize the position of the apex, and a 2-inch to 3-inch segment of rib may need to be resected to facilitate exposure. To reduce postoperative pain, soft tissue retractors are preferred to heavy metal retraction. The proper site of puncture is on the LV apex, which is more anterior and proximal than the anatomic cardiac apex. TEE during digital pressure is of great value in

helping to localize the apex of the LV. Puncture is made, and a 0.035-inch guidewire is passed antegrade through the native valve, taking great care to avoid the mitral subvalvular apparatus. This is then switched out for a stiffer 0.035-inch wire, and the deployment sheath is then passed to a depth of 3 cm to 4 cm.

For transaortic cases, access is either through an upper partial sternotomy or a minithoracotomy at the second or third right intercostal space. Concentric felt pledgeted reinforced purse-string sutures are placed in the ascending aorta at least 5 cm above the valve. A guidewire is then placed retrograde across the valve, and the delivery sheath is introduced as for transapical access described previously.

5.3.2.3. Prevalve Implant

One of the key steps in preimplant is identifying the optimal fluoroscopic and intraprocedural views for device deployment. A pigtail catheter is typically placed in the noncoronary cusp (for self-expanding valves) and right coronary cusp (for balloon-expandable valves), and aortography is performed in a fluoroscopic view perpendicular to the native valve to identify the "coplanar" or coaxial view. Precise positioning can be also be achieved by overlaying preprocedural angiography or MDCT images on the fluoroscopy screen. Newer techniques employing 3D angiographic reconstructions obtained by rotational C-arm fluoroscopic imaging have also been used (51).

Anticoagulation therapy is usually initiated after insertion of the large sheath into the vasculature, and repeated to maintain an activated clotting time of >250 s to 300 s. Following this, the aortic valve is crossed using standard interventional techniques, and a stiff wire exchange is performed, with redundancy in the LV cavity to prevent loss of position.

Prior to passage of the valve, predilation of the annulus may be required. Standard techniques of percutaneous balloon aortic valvuloplasty are employed, with rapid pacing during inflation. Radiographic contrast opacification of the root during maximal inflation may provide useful information when the location of the coronary ostia in relation to the annulus and the leaflet calcification or any other aortic root pathology requires further delineation. This is also helpful in situations where valve sizing falls between valve sizes. For example, use a 22-mm or 23-mm Edwards balloon when deciding between a 23-mm and a 26-mm transcatheter valve. If the 22-mm or 23-mm balloon reaches the hinge points and there is no significant leak around the balloon on angiography, then generally, the 23-mm transcatheter valve would be selected. If the 22-mm balloon does not reach the hinge points and/or there is clear leak into the ventricle around the balloon, then the 26-mm valve would generally be implanted. If balloon aortic valvuloplasty is pursued, unless there is a question about valve sizing, it is advisable to have the transcatheter valve ready for immediate implantation in case there is significant acute AR, with resultant hemodynamic compromise, following the valvuloplasty procedure.

5.3.2.4. Valve Delivery and Deployment

The transcatheter valve is positioned across the annulus in the predetermined coaxial annular plane. The optimal landing zone should be identified and will vary depending on the type of valve. For example, an optimal implantation depth for the CoreValve Evolut R is 3 mm to 5 mm below the annulus. For the Sapien S3, an 80-20 positioning of the valve across the annulus prior to implantation is recommended. Following this, rapid pacing may or may not be required for valve deployment; it is mandatory for balloon-expandable valves and sometimes required for self-expanding valves. For balloon-expandable valves, pacing is performed at a rate of 160 beats/min to 220 beats/min, accompanied by a drop in systolic pressure to <70 mm Hg and a pulse pressure <20 mm Hg. Pacing during positioning of the self-expandable valve is usually undertaken at 100 beats/min to 120 beats/min when needed.

5.3.2.5. Post-deployment Valve Assessments

Immediately following implantation, valve position and location should be checked with echocardiography (TTE or TEE), hemodynamics, and/or aortography. Complications with TAVR are fairly common due to both the complexity of the procedure and the morbidity of the patients being treated, and should be promptly addressed (**Table 2**). A quick assessment for changes in MV or LV function and new pericardial effusion should also be routinely performed.

Post-TAVR AR must be characterized in terms of its location, severity, and cause and should integrate both central and paravalvular origins to allow for an estimate of overall volumetric effect (52). Central regurgitation is generally a result of improper valve deployment or sizing. Heavy guidewires through the valve can cause a substantial leak by holding a leaflet open, and full evaluation of central leak can only be undertaken once these wires are removed. Causes include overhanging leaflet material, a stuck leaflet, and overexpanded transcatheter valve or damage to transcatheter valve leaflets during crimping. Paravalvular regurgitation is generally caused by underdeployment of the prosthesis, very low implants (e.g., below the valve skirt of the self-expanding valve), or calcific deposits, which prevent the valve unit from properly seating and sealing within the annulus. Acute leaks may respond to repeat ballooning of the valve to obtain a better seal and greater expansion of the valve. Predisposing factors include eccentric calcification and heavy irregular calcific deposits within the annular area and incorrectly sized prostheses. Newer TAVR design

modifications, such as the outer skirt on the Sapien S3 valve, are specifically targeted toward reducing paravalvular regurgitation. The newer version of the self-expanding valve (CoreValve Evolut R) has the option of recapture and repositioning prior to full deployment if paravalvular regurgitation appears to be due to poor positioning. In select cases where the valve is felt to be smaller than needed for the annulus, it can be recaptured prior to full deployment and a larger valve inserted. Moderate to severe paravalvular regurgitation typically needs to be addressed with additional measures prior to leaving the procedure room.

Following TAVR deployment, the delivery system and sheath are removed. Anticoagulation is typically reversed, and access site closure is performed. For percutaneous transfemoral access, a completion descending aortogram is recommended after sheath removal and tying of the percutaneous closure sutures to assess for distal aortic or iliofemoral perforations/dissections. Rapid pacing (typically ~120 beats/min) may facilitate tying of aortic and apical sutures for transaortic and transapical approaches. A pleural and/or pericardial drain may need to be placed after completion for transaortic and transapical cases.

5.4. Post-TAVR Clinical Management

Table 6 outlines the key steps for immediate and long-term post-TAVR management of patients.

TABLE 6 Checklist for Post-TAVR Clinical Management

Key Steps	Essential Elements	Additional Details
5.4.1 Immediate Postprocedure Management		
Waking from sedation	☐ Early extubation (general anesthesia) ☐ Monitor mental status	
Post-procedure monitoring	☐ Telemetry and vital signs per hospital protocol for general or moderate sedation ☐ Monitor intake and output ☐ Laboratory results (CBC, M6) ☐ Monitor access (groin or thorax) site for bleeding, hematoma, pseudoaneurysm	☐ Ultrasound of groin site if concern for pseudoaneurysm ☐ Frequent neurological assessment
Pain management	☐ Provide appropriate pain management ☐ Monitor mental status	
Early mobilization	☐ Mobilize as soon as access site allows ☐ Manage comorbidities ☐ PT and OT assessment	☐ Encourage physical activity
Discharge planning	☐ Resume preoperative medications ☐ Plan discharge location ☐ Predischarge echocardiogram and ECG ☐ Schedule postdischarge clinic visits	☐ Family and social support ☐ Ability to perform ADLs ☐ Transportation ☐ Discharge medications ☐ Patient instructions and education
5.4.2 Long-Term Follow-Up		
Timing	☐ TAVR team at 30 days ☐ Primary cardiologist at 6 months and then annually ☐ Primary care MD or geriatrician at 3 months and then as needed	☐ Hand-off from TAVR team to primary cardiologist at 30 days ☐ More frequent follow-up if needed for changes in symptoms, or transient conduction abnormalities. ☐ Coordination of care among TAVR team, primary cardiologist, and primary care MD
Antithrombotic therapy	☐ ASA 75 mg–100 mg daily lifelong ☐ Clopidogrel 75 mg daily for 3–6 months ☐ Consider warfarin (INR 2.0–2.5) if at risk of AF or VTE	☐ Management when warfarin or NOAC needed for other indications
Concurrent cardiac disease	☐ Coronary disease ☐ Hypertension ☐ Heart failure ☐ Arrhythmias (especially AF) ☐ Manage cardiac risk factors (including diet and physical activity)	☐ Monitor laboratory results for blood counts, metabolic panel, renal function ☐ Assess pulmonary, renal, GI, and neurological function by primary care MD annually or as needed
Monitor for post-TAVR complications	☐ Echocardiography at 30 days then annually (if needed) ☐ ECG at 30 days and annually ☐ Consider 24 h ECG if bradycardia	☐ Paravalvular AR ☐ New heart block ☐ LV function ☐ PA systolic pressure
Dental hygiene and antibiotic prophylaxis	☐ Encourage optimal dental care ☐ Antibiotic prophylaxis per AHA/ACC guidelines	

ACC = American College of Cardiology; ADLs = activities of daily living; AF = atrial fibrillation; AHA = American Heart Association; AR = aortic regurgitation; ASA = aspirin; ECG = electrocardiogram; GI = gastrointestinal; LV = left ventricular; MD = medical doctor; NOAC = new oral anticoagulant; OT = occupational therapy; PA = pulmonary artery; PT = physical therapy; TAVR = transcatheter aortic valve replacement; VTE = venous thromboembolism.

The long-term management of patients after TAVR is similar to that of patients after SAVR. The major differences are that patients undergoing TAVR tend to be older and have more comorbid conditions; an access site replaces the surgical incision; and the long-term durability of transcatheter valves is not yet known. Even so, the basic principles for management of patients after valve replacement hold true for surgical and transcatheter valves: 1) periodic monitoring of prosthetic valve function; 2) management of comorbid conditions; 3) monitoring for cardiac conduction defects and heart block; 4) promotion of a healthy life-style with cardiac risk factor reduction; 5) antithrombotic therapy as appropriate; 6) optimal dental hygiene and endocarditis prophylaxis; 7) patient education and coordination of care; and 8) cardiac rehabilitation and promotion of physical activity as appropriate.

5.4.1. Immediate Postprocedure Management

After the TAVR procedure, patients should be managed in accordance with institutional protocols for monitoring and recovery after sedation or anesthesia.

5.4.1.1. Waking from Sedation

When general anesthesia is used, early extubation is encouraged, as for any general anesthesia procedure.

5.4.1.2. Postprocedure Monitoring

With both general anesthesia and conscious sedation, hospital protocols are followed for monitoring mental status, telemetry, vital signs, volume status, and postprocedure blood testing. In addition, the access site should be monitored carefully to ensure adequate hemostasis with normal distal blood flow. Monitoring the access site also allows early detection and intervention for bleeding, hematoma, or pseudoaneurysm formation.

5.4.1.3. Pain Management

Appropriate pain management, continued mental status monitoring, and early mobilization are especially important post-TAVR, as patients often are elderly with a high burden of comorbidities. Pre-operative medications should be reviewed, with all that remain appropriate restarted promptly.

5.4.1.4. Early Mobilization

A structured discharge plan should be initiated prior to the procedure and should include physical and occupational therapy assessment to determine the appropriate disposition after hospitalization and scheduling of postdischarge outpatient medical care.

5.4.1.5. Discharge Planning

Early discharge (within 72 h) does not increase the risk of 30-day mortality, bleeding, pacer implantation, or rehospitalization in selected patients undergoing transfemoral TAVR (53).

5.4.2. Long-Term Follow-Up

5.4.2.1. Timing

Integration and coordination of medical care is essential post-TAVR to ensure optimal patient outcomes. Outcomes after TAVR depend strongly on overall patient health and clinical conditions other than the aortic valve disease (54). Readmission rates are over 40% in the first year after the procedure, most often due to noncardiac causes (60% of readmissions); common readmission diagnoses include respiratory problems, infections, and bleeding events. Cardiac readmissions are most often for arrhythmias or heart failure (55,56). Mortality rates after TAVR remain very high, with about 30% of patients dying within 3 years of the procedure (32,57). Noncardiac causes of death predominate after the first 6 months. These data emphasize the need for integrated noncardiac and cardiac care in these patients, including end-of-life planning.

The Heart Valve Team (or interventional/surgical team) is responsible for care for the first 30 days because procedural complications are most likely in this time interval. After 30 days, there should be a formal transfer of care from the Heart Valve Team back to the referring primary cardiologist. In stable patients with no complications and few comorbidities, the primary cardiologist should see the patient at 6 months and then annually, and more frequently as needed for complications or concurrent medical conditions. In addition, the primary care provider or geriatrician should be involved before and after the TAVR procedure and should assume primary responsibility for patient care starting at 30 days, with the first primary care provider appointment scheduled no later than 3 months after the procedure. The primary care provider and cardiologist should communicate frequently to ensure coordination of care, with clear patient instructions on when and how to contact the care team. Education and active involvement of the patient in managing his or her condition is important. Periodic reassessment and discussion of the goal of care (symptoms or survival) and patient preferences are helpful in guiding care and ensuring patient satisfaction.

5.4.2.2. Antithrombotic Therapy

Use of antithrombotic therapy post-TAVR has been based on clinical trial protocols in which patients were treated with clopidogrel 75 mg daily for the first 6 months post-TAVR for balloon-expandable valves and for 3 months with self-expanding valves. All patients also received aspirin 75 mg to 100 mg daily lifelong; however, these patients often needed other antithrombotic therapy for coronary stents or AF as well. Pre-existing AF is present in

about 25% of patients who undergo TAVR; in addition, the incidence of new-onset AF after TAVR ranges from <1% to 8.6%. In the absence of clinical trials evaluating alternate antithrombotic regimens after TAVR, there is no consensus on the optimal agent(s) or duration of therapy.

Although hemodynamically significant valve thrombosis is rare after TAVR, there is concern that subclinical leaflet thrombus formation, detectable by imaging, may be more common after surgical or transcatheter valve replacement than previously appreciated (36). In this small study, patients on vitamin-K antagonist therapy had lower rates of reduced leaflet motion than those on antiplatelet therapy, but there are no randomized studies of different antithrombotic regimens after TAVR. For surgical bioprosthetic AVR, data support a Class IIb indication for 3 months of vitamin K antagonist therapy after valve implantation, but whether these data apply to TAVR is unknown (1).

Thus, the current standard antithrombotic therapy after TAVR is clopidogrel 75 mg orally daily for 3 to 6 months with oral aspirin 75 mg to 100 mg daily lifelong. Patients with chronic AF or other indications for long-term anticoagulation should receive anticoagulation as per guidelines for AF in patients with prosthetic heart valves (58). Vitamin K antagonist therapy may be considered in the first 3 months after TAVR in patients who are at risk of AF or valve thrombosis, depending on the specific risk-benefit ratio in that patient. When vitamin K antagonist therapy is used, continuation of aspirin is reasonable, but it may be prudent to avoid other antiplatelet therapy in some patients given the increased risk of bleeding with multiple simultaneous antithrombotic agents.

5.4.2.3. Concurrent Cardiac Disease

Long-term management focuses on treatment of comorbid cardiac and noncardiac conditions. Cardiac comorbidities often include hypertension, coronary artery disease, AF, LV systolic dysfunction, LV diastolic dysfunction, MV disease, and pulmonary hypertension. Noncardiac comorbidities often include pulmonary disease, renal disease, arthritis, frailty, and cognitive impairment. Many of these noncardiac conditions are best managed by the primary care provider or geriatrician, with the cardiologist providing consultation regarding any changes in cardiac signs or symptoms. Referral back to the Heart Valve Team is appropriate when prosthetic valve dysfunction is a concern or if a second interventional procedure might be needed for another valve or for coronary artery disease. In addition to echocardiography, periodic ECG monitoring is recommended for detection of asymptomatic AF and because heart block or other conduction defects can occur late after TAVR.

5.4.2.4. Monitor for Post-TAVR Complications

Echocardiography before discharge provides a new baseline study of transcatheter valve function and should include the antegrade TAVR velocity, mean transaortic gradient, valve area, and assessment of paravalvular AR. Other key echocardiographic parameters include LV size, regional wall motion and EF, evaluation of MV anatomy and function, estimation of pulmonary pressures, and evaluation of the right ventricle.

Repeat echocardiography is recommended at 30 days and then at least annually to: 1) comply with current requirements for following TAVR patients in a registry; 2) monitor for complications of TAVR; and 3) guide medical therapy of concurrent cardiac conditions, including guideline-recommended medical treatment for LV dysfunction. The long-term durability of transcatheter bioprosthetic valves is not yet known, so annual evaluation for regurgitation, stenosis, and leaflet calcification or thrombosis is appropriate. In addition, many patients undergoing TAVR also have LV systolic and/or diastolic dysfunction, coronary disease, MV disease, and pulmonary hypertension. Periodic echocardiography allows optimization of medical therapy for these conditions and may indicate a need for other structural heart disease interventions.

Routine ECG assessment is also recommended due to a potential need for pacemaker implantation beyond the initial 30-day period, particularly following implantation of the self-expanding TAVR (59).

The TAVR procedure is associated with a high risk of dislodgement of microdebris from arch atheroma or from the valve itself with subsequent embolic stroke. Clinical cerebrovascular event rates are around 3% to 5% at 30 days (31,33), but subclinical microembolism may be more common (60). The long-term effect of these microemboli is unclear, and future research regarding evaluation of the timing and frequency of microemboli, techniques to reduce embolic events, and prognostic implications is of interest.

5.4.2.5. Dental Hygiene and Antibiotic Prophylaxis

TAVR is a risk factor for endocarditis, with reported rates of early prosthetic valve endocarditis ranging from 0.3% to 3.4% per patient-year (61,62). Standard antibiotic prophylaxis after TAVR is the same as for all prosthetic valves per AHA/ACC guidelines (1). In addition, patients should be encouraged to use optimal dental hygiene and see a dentist regularly for routine cleaning and dental care, with antibiotic prophylaxis at each visit.

6. DISCUSSION AND IMPLICATIONS OF PATHWAY

The primary objective of this document is to provide a framework for the several steps involved in managing

patients undergoing TAVR. Optimal care of these complex patients requires close collaboration between several different specialties as part of an integrated Heart Valve Team. The framework provided in this document will need to be expanded and adjusted at each heart valve center to meet the specific needs of that institution and to include additional details.

There continue to be rapid improvements in the types and sizes of prosthetic valves available for TAVR and in methods for valve implantation as TAVR moves into patient populations who are at lower surgical risk. These technological advances will affect the details of the TAVR procedure; however, the general principles outlined in this Decision Pathway will remain relevant to managing these patients in the future. Data on newer delivery platforms, valves, and periprocedural and postprocedural anticoagulation may need to be updated in future iterations of this document as additional clinical trials data are published. Most importantly, the checklists and algorithms provided in this Decision Pathway should be applied only in the context of the most recent update to the AHA/ACC Guideline for Management of Adults with Valvular Heart Disease.

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KEY WORDS ACC Expert Consensus Decision Pathway, aortic stenosis, transcatheter aortic valve replacement

APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2017 ACC EXPERT CONSENSUS DECISION PATHWAY FOR TRANSCATHETER AORTIC VALVE REPLACEMENT IN THE MANAGEMENT OF ADULTS WITH AORTIC STENOSIS

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*Significant relationship.

†No financial benefit.

ACC = American College of Cardiology; DSMB = data and safety monitoring board; FDA = U.S. Food and Drug Administration.

APPENDIX 2. PEER REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (COMPREHENSIVE)—2017 ACC EXPERT CONSENSUS DECISION PATHWAY FOR TRANSCATHETER AORTIC VALVE REPLACEMENT IN THE MANAGEMENT OF ADULTS WITH AORTIC STENOSIS

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Donnette Smith	Organizational Reviewer—Mended Hearts	Mended Hearts—President	None	None	None	None	■ Gilead*	None
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APPENDIX 2. CONTINUED

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
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Richard J. Shemin	Content Reviewer—ACC Surgeons Council	David Geffen School of Medicine at UCLA—Robert and Kelly Day Professor and Chief, Division of Cardiac Surgery; Vice Chairman, Department of Surgery; Co-director, Cardiovascular Center at UCLA	■ AtriCure ■ Edwards Lifesciences ■ Sorin	None	None	None	None	■ Defendant, mitral valve malpractice, 2016
James D. Thomas	Content Reviewer—ACC Imaging Council	Northwestern Memorial Hospital—Director, Center for Heart Valve Disease, Bluhm Cardiovascular Institute	■ Abbott† ■ Edwards Lifesciences† ■ General Electric†	None	None	None	None	■ Defendant, inappropriate referral for surgery, 2015†
Frederick G.P. Welt	Content Reviewer—ACC Interventional Council	University of Utah Health Sciences Center—Director, Interventional Cardiology	■ Medtronic†	None	■ Medtronic ■ Siemens†	■ Athersys ■ Capricor ■ CardioKinetix ■ Medtronic† ■ Renova Therapeutics ■ Siemens† ■ St. Jude ■ TEVA ■ Washington University in St. Louis	None	■ Defendant, negligence, 2015 ■ Defendant, delay in treatment, 2016 ■ Defendant, failure to prescribe, 2016†
Barbara W. Wiggins	Content Reviewer—ACC Task Force on Clinical Expert Consensus Documents	Medical University of South Carolina—Clinical Pharmacy Specialist, Cardiology, Department of Pharmacy Services	None	None	None	None	None	None

This table represents the relationships of reviewers with industry and other entities that were disclosed at the time of peer review and determined to be relevant to this document. It does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$5,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. A relationship is considered to be modest if it is less than significant under the preceding definition. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Names are listed in alphabetical order within each category of review.

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*No financial benefit.

†Significant relationship.

AAPA = American Academy of Physician Assistants; AATS = American Association for Thoracic Surgery; ACC = American College of Cardiology; ACCP = American College of Clinical Pharmacy; AHA = American Heart Association; ASE = American Society of Echocardiography; DSMB = Data Safety Monitoring Board; FDA = U.S. Food and Drug Administration; GDS = Guided Delivery Systems, Inc.; HCRI = Harvard Clinical Research Institute; NIH = National Institutes of Health; PI = principal investigator; SCAI = Society of Cardiovascular Angiography and Interventions; SCMR = Society for Cardiovascular Magnetic Resonance; STS = Society of Thoracic Surgeons.

APPENDIX 3. ABBREVIATIONS

ACC = American College of Cardiology
AF = atrial fibrillation
AHA = American Heart Association
AR = aortic regurgitation
AS = aortic stenosis
AVR = aortic valve replacement
CMR = cardiac magnetic resonance
CT = computed tomography
ECG = electrocardiogram
EF = ejection fraction
LV = left ventricular
MDCT = multidetector computed tomography
MR = mitral regurgitation
MV = mitral valve
SAVR = surgical aortic valve replacement
STS = Society of Thoracic Surgeons
TAVR = transcatheter aortic valve replacement
TEE = transesophageal echocardiography
TTE = transthoracic echocardiography