

**American College of Radiology
ACR Appropriateness Criteria®
Imaging for Transcatheter Aortic Valve Replacement**

Variant 1: Preintervention planning for transcatheter aortic valve replacement at the aortic valve plane.

Procedure	Appropriateness Category	Relative Radiation Level
CTA chest with IV contrast	Usually Appropriate	☼☼☼
US echocardiography transesophageal	May Be Appropriate	○
MRA chest without IV contrast	May Be Appropriate	○
MRA chest without and with IV contrast	May Be Appropriate	○
CT chest without IV contrast	May Be Appropriate	☼☼☼
CT chest with IV contrast	Usually Not Appropriate	☼☼☼
Aortography thoracic	Usually Not Appropriate	☼☼☼
CT chest without and with IV contrast	Usually Not Appropriate	☼☼☼

Variant 2: Preintervention planning for transcatheter aortic valve replacement in the supravalvular aorta and iliofemoral system.

Procedure	Appropriateness Category	Relative Radiation Level
CTA abdomen and pelvis with IV contrast	Usually Appropriate	☼☼☼☼☼
MRA abdomen and pelvis without and with IV contrast	May Be Appropriate	○
MRA abdomen and pelvis without IV contrast	May Be Appropriate	○
CT abdomen and pelvis without IV contrast	May Be Appropriate	☼☼☼
Aortography abdomen and pelvis	May Be Appropriate	☼☼☼☼
CT abdomen and pelvis without and with IV contrast	Usually Not Appropriate	☼☼☼☼
US intravascular aorta and iliofemoral system	Usually Not Appropriate	○
CT abdomen and pelvis with IV contrast	Usually Not Appropriate	☼☼☼

IMAGING FOR TRANSCATHETER AORTIC VALVE REPLACEMENT

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Summary of Literature Review

Introduction/Background

Aortic stenosis (AS) is the most frequent type of valvular heart disease in Europe and North America. It primarily presents as calcific AS in adults of advanced age (2%-7% of the population, >65 years old) [1]. Although aortic valve replacement (AVR) is a definitive therapy for patients who meet the criteria [2-5] for severe AS, 32% to 48% of those patients do not undergo conventional AVR due to their advanced age, comorbidities, or prohibitive surgical risk [6-8].

Transcatheter aortic valve replacement (TAVR) has dramatically impacted the management of high surgical risk patients [9-18] by enabling a less invasive approach using a transfemoral, transapical, or other vascular access route to position a prosthesis at the aortic annulus that displaces the native aortic valve leaflets toward the aortic wall. Procedure-related complications [11,13,15,16] are linked to inaccurate estimates of annular geometry; unlike surgical AVR, the aortic annulus is not directly inspected by the proceduralist at the time of the procedure, and multiple parameters related to the annulus should be measured. As the annulus has a complex geometry, volumetric data (computed tomography [CT] in particular) have emerged with standardized reformatting along patient-specific anatomic planes for annular assessment and device sizing [9,10,12,17-32].

TAVR planning at or near the aortic annulus is essential because accurate measurements guide optimal choices for device sizing and deployment, with a secondary reduction in TAVR-related complications. Because the transfemoral approach is favored and most commonly used, and because the catheter-based system ranges in size between 14 Fr and 24 Fr, the entire aorta and branches to potential access points (eg, the femoral arteries) must be evaluated for the presence, burden, and distribution of peripheral vascular atherosclerosis.

This document has two limitations in scope. First, the panel did not consider the diagnosis of AS [2-5] or the assessment of coronary artery disease. It is presumed that patients considered in this document are otherwise suitable candidates for TAVR. Second, the panel did not consider planning done at the time of intervention with either catheter angiography, echocardiography done at the time of catheterization, or a combination of both.

Instead, for this document the panel only considered the two clinical tasks required for preprocedure screening: (Variant 1) annular sizing and root evaluation to see if a device is suitable for deployment for patients with no past history of aortic valve surgery or prior TAVR, and then to help guide the choice of the valve prosthesis, considering and minimizing potential complications via multiple measurements; and (Variant 2) imaging the remainder of the aorta and iliofemoral arteries to determine the feasibility of the preferred transfemoral approach, and when this route is high risk, to assess potential alternate access routes.

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The American College of Radiology seeks and encourages collaboration with other organizations on the development of the ACR Appropriateness Criteria through society representation on expert panels. Participation by representatives from collaborating societies on the expert panel does not necessarily imply individual or society endorsement of the final document.

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Discussion of Procedures by Variant

Variant 1: Preintervention planning for TAVR at the aortic valve plane.

CT and CTA

Retrospectively electrocardiogram (ECG)-gated CT angiography (CTA) is the first-line modality for preprocedural annular sizing, as it enables direct planimetry and reference standard measurements for all required annular parameters for TAVR deployment [9,10,12,14,17,18,21,22,26]. Multiple single- and multicenter trials have consistently shown that integration of CTA in preprocedural planning helps reduce the rate of significant paravalvular regurgitation and also allows for the discrimination of risk of annular rupture, coronary occlusion, and vascular injury [21,22,29-33]. Guiding optimum fluoroscopic projections with co-planar angles of the aortic root facilitates appropriate valve deployment [21,24,27]. In addition, CTA provides data regarding the distribution of valve calcification. Whereas vascular access is typically extracardiac (and evaluated in the second variant), when introduction of the TAVR system via the cardiac apex is being considered, CTA is essential for planning.

Noncontrast CT can be used to evaluate valve calcification; however, the incremental role in procedural planning remains uncertain, its primary role is in assisting the diagnosis of AS and not for guiding TAVR. When iodinated contrast is absolutely contraindicated, an alternate method for TAVR planning is generally required. For the large majority of patients who undergo CT for TAVR planning, contrast is administered for first-pass CTA (CTA chest with intravenous [IV] contrast) so that the annular size and related measurements can be performed after image postprocessing. There is essentially no role for imaging the chest after the first pass of contrast or for performing this acquisition after a noncontrast study (CT chest without and with IV contrast).

For the purposes of distinguishing between CT and CTA, the ACR Appropriateness Criteria topics use the definition in the [Practice Parameter for the Performance and Interpretation of Body Computed Tomography Angiography \(CTA\)](#) [34]:

“CTA uses a thin-section CT acquisition that is timed to coincide with peak arterial or venous enhancement. The resultant volumetric dataset is interpreted using primary transverse reconstructions as well as multiplanar reformations and 3-D renderings.”

All procedure elements are essential: (1) timing, (2) recons/reformats, and (3) 3-D renderings. Standard CTs with contrast also include timing issues and recons/reformats. Only in CTA, however, is 3-D rendering a **required** element. This corresponds to the definitions that CMS has applied to the CPT codes.

Echocardiography

Although 2-D transesophageal echocardiography was the initial method of choice for annular sizing [8,11], this method has been replaced with 3-D acquisitions to help with annular sizing. Annular measurements are reproducible and correlate with reference standard CTA [9,14,35,36]. Compared to CT, there is significantly less data for evaluating root features such as coronary ostial height and the presence or absence of sub-annular calcification. It is more commonly used at the time of the procedure, utilization that is not being assessed in this guideline, rather than for planning [35,36]. In the setting of contraindications for CT such as anaphylaxis and severe renal dysfunction, 3-D transesophageal echocardiography is commonly used to assess annular geometry and size. Of note, when echocardiography is used for TAVR planning, transthoracic acquisition (though used in the diagnosis of AS) is not used and was not considered in ratings.

MRA

Although magnetic resonance angiography (MRA) provides highly accurate, low variability annular measurements for patients undergoing surgical AVR [37], there is only modest clinical adoption, and there is a paucity of supporting data for TAVR planning compared to CTA. MRA-based measurements do correlate with CT [37-42]; therefore, MRA could be an alternative to CTA when there is a severe iodine-based contraindication. MRA approaches are limited when there is high-susceptibility artifact, magnetic field-incompatible devices, claustrophobia, and severe arrhythmia [23,37-42]. Finally, the MRA examination is substantially longer than the CT acquisition, which can be problematic for patients with a poor clinical condition.

Aortography

Whereas catheterization images acquired at the time of the procedure are necessary and complementary to planning, increasing data questions the need to perform preprocedural catheterization, based on the fact that all necessary parameters can typically be extracted from the CT images [43]. Specifically, the 2-D projections may

not adequately reflect the complex geometry of the aortic annulus. Instead, catheterization images focus on the assessment of root geometry and coronary height.

Variant 2: Preintervention planning for TAVR in the supravalvular aorta and iliofemoral system.

CT and CTA

CTA acquisition with isotropic voxels enables image postprocessing to accurately depict geometry, lumen size, and the presence of dissections, atherosclerotic disease, and subsequent stenosis from the entire arterial system between the supravalvular aorta and the femoral arteries, the preferred TAVR access point [19,23,29,30,32]. CTA also best identifies concentric or horseshoe calcification that is a relative contraindication for TAVR, especially in those with borderline vessel diameter [19,23,29,30,32]. CTA is also essential for atypical TAVR apparatus access points such as transaortic or transcaval approaches [44].

Whereas CTA is preferred for patients with a strong contraindication to contrast injection, noncontrast imaging can be used to evaluate calcification within the aorta and including the iliofemoral arteries under evaluation for access. If a patient receives IV contrast, CTA images should be acquired, as opposed to later phase imaging (CT abdomen and pelvis with IV contrast). Moreover, there would be no role for performing this acquisition after a noncontrast study (CT abdomen and pelvis without and with IV contrast).

Aortography

Though catheter angiography allows assessment of luminal size, it provides limited evaluation of the arterial wall for plaque burden and calcification [9-18]. Standard catheter angiography is also limited in that it is typically planar and therefore is limited in its capacity to evaluate tortuosity and for the detection of eccentric stenosis. Angiography also plays a limited role in the evaluation of patients for whom alternate access is being considered.

IVUS

Whereas ultrasound (US) is often used to facilitate arterial puncture [45-47], surface-based sonography is insufficient to comprehensively assess arterial size, calcification, and tortuosity of the iliofemoral system and the aorta. There is little or no data regarding the usefulness of intravascular US (IVUS) for TAVR planning. Studies in abdominal aortic aneurysm subjects suggest that IVUS provides reliable information of aortoiliofemoral anatomy, especially luminal dimension, presence of and morphology of atherosclerotic plaque, and calcification [45-47].

MRA

MRA provides an alternative to CT for evaluation of the aorta and iliofemoral arteries. However, it is limited in the assessment of vascular calcification.

Summary of Recommendations

- Preintervention planning for TAVR at the aortic valve plane: 3-D cross sectional imaging of the aortic annular plane is essential with CTA of the chest with IV contrast being the first-line modality.
- Preintervention planning for TAVR in the supravalvular aorta and iliofemoral system: CTA abdomen and pelvis with IV contrast is the preferred and first-line modality for vascular access assessment to identify those patients with potential risk for compromised intra-procedural vascular access.

Summary of Evidence

Of the 48 references cited in the *ACR Appropriateness Criteria® Imaging for Transcatheter Aortic Valve Replacement* document, 15 are categorized as therapeutic references including 4 well-designed studies, and 6 good-quality studies. Additionally, 33 references are categorized as diagnostic references including 2 well-designed studies, 11 good-quality studies, and 7 quality studies that may have design limitations. There are 18 references that may not be useful as primary evidence.

The 48 references cited in the *ACR Appropriateness Criteria® Imaging for Transcatheter Aortic Valve Replacement* document were published from 1997 to 2017.

Although there are references that report on studies with design limitations, 23 well-designed or good-quality studies provide good evidence.

Appropriateness Category Names and Definitions

Appropriateness Category Name	Appropriateness Rating	Appropriateness Category Definition
Usually Appropriate	7, 8, or 9	The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients.
May Be Appropriate	4, 5, or 6	The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal.
May Be Appropriate (Disagreement)	5	The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel's recommendation. "May be appropriate" is the rating category and a rating of 5 is assigned.
Usually Not Appropriate	1, 2, or 3	The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable.

Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults (see Table below). Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® [Radiation Dose Assessment Introduction](#) document [48].

Relative Radiation Level Designations		
Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
○	0 mSv	0 mSv
⊗	<0.1 mSv	<0.03 mSv
⊗⊗	0.1-1 mSv	0.03-0.3 mSv
⊗⊗⊗	1-10 mSv	0.3-3 mSv
⊗⊗⊗⊗	10-30 mSv	3-10 mSv
⊗⊗⊗⊗⊗	30-100 mSv	10-30 mSv

*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (eg, region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies".

Supporting Documents

For additional information on the Appropriateness Criteria methodology and other supporting documents go to www.acr.org/ac.

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The ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.