# American College of Radiology ACR Appropriateness Criteria® Preprocedural Planning for Transcatheter Aortic Valve Replacement

<u>Variant: 1</u> Preintervention planning for transcatheter aortic valve replacement: assessment of aortic root. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
US echocardiography transesophageal	Usually Appropriate	0
MRI heart function and morphology without and with IV contrast	Usually Appropriate	0
MRI heart function and morphology without IV contrast	Usually Appropriate	0
CT heart function and morphology with IV contrast	Usually Appropriate	<b>૽ ૽</b>
MRA chest with IV contrast	May Be Appropriate	0
MRA chest without and with IV contrast	May Be Appropriate	0
CTA chest with IV contrast	May Be Appropriate	<b>♀</b> •
CTA coronary arteries with IV contrast	May Be Appropriate	���
US echocardiography transthoracic resting	Usually Not Appropriate	0
Aortography chest	Usually Not Appropriate	���
MRA coronary arteries without and with IV contrast	Usually Not Appropriate	0
MRA coronary arteries without IV contrast	Usually Not Appropriate	0
CT chest with IV contrast	Usually Not Appropriate	���
CT chest without and with IV contrast	Usually Not Appropriate	���
CT chest without IV contrast	Usually Not Appropriate	���

# <u>Variant: 2</u> Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
CTA chest with IV contrast	Usually Appropriate	<b>૽ ૽</b>
CTA abdomen and pelvis with IV contrast	Usually Appropriate	<b>⊗⊗⊗</b>
CTA chest abdomen pelvis with IV contrast	Usually Appropriate	<b>※※※</b>
US intravascular aorta and iliofemoral system	May Be Appropriate (Disagreement)	0
MRA abdomen and pelvis without and with IV contrast	May Be Appropriate	0
MRA abdomen and pelvis without IV contrast	May Be Appropriate	0
MRA chest abdomen pelvis with IV contrast	May Be Appropriate	0
MRA chest without and with IV contrast	May Be Appropriate	0
US duplex Doppler chest abdomen pelvis	Usually Not Appropriate	0
US echocardiography transesophageal	Usually Not Appropriate	0
US echocardiography transthoracic resting	Usually Not Appropriate	0
Aortography chest abdomen pelvis	Usually Not Appropriate	<b>⊗⊗⊗</b>
CT abdomen and pelvis with IV contrast	Usually Not Appropriate	<b>∵ ∵</b>
CT abdomen and pelvis without IV contrast	Usually Not Appropriate	<b>∵ ∵</b>
CT chest with IV contrast	Usually Not Appropriate	<b>∵ ∵</b>
CT chest without and with IV contrast	Usually Not Appropriate	<b>∵ ∵</b>
CT chest without IV contrast	Usually Not Appropriate	<b>∵ ∵</b>

CT abdomen and pelvis without and with IV contrast	Usually Not Appropriate	<b>⋄⋄</b>
CT chest abdomen pelvis with IV contrast	Usually Not Appropriate	
CT chest abdomen pelvis without and with IV contrast	Usually Not Appropriate	<b>૽ ૽ ૽</b>
CT chest abdomen pelvis without IV contrast	Usually Not Appropriate	<b>૽ ૽ ૽</b>
CT heart function and morphology with IV contrast	Usually Not Appropriate	***

#### **Panel Members**

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### **Summary of Literature Review**

### Introduction/Background

Transcatheter aortic valve replacement (TAVR) has dramatically impacted the management of high-risk surgical patients [1-10], as well as medium- and low-risk patients [11], for the treatment of aortic valve disease. TAVR is a less invasive route (percutaneous endovascular) to position a prosthesis at the aortic annulus that displaces the native aortic valve leaflets toward the aortic wall. Procedure-related complications [3,5,7,8] are linked to inaccurate estimates of annular geometry; unlike surgical aortic valve replacement, 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. Because the annulus has a complex geometry, volumetric data have emerged with standardized reformatting along patient-specific anatomic planes for annular assessment and device sizing [1,2,4,9,10,12-26]. Accurate measurements guide optimal choices for device sizing and deployment, with a secondary reduction in TAVR-related complications. The catheter-based system ranges in size between 14 and 24 Fr with transfemoral, transaxillary, and transaortic as well as direct aortic and left ventricular approaches reported; the entire aorta and branches to potential access points are evaluated for the presence, burden, and distribution of peripheral vascular atherosclerosis.

This document does not elucidate the diagnosis of aortic valve disease, surgical risk stratification, [27-32] or the assessment of coronary artery disease. It is presumed that patients considered in this document are candidates for TAVR. Also, the panel did not consider planning done at the time of intervention with either catheter angiography, echocardiography, or a combination of both.

For this document, the panel only considered the 2 clinical tasks required for preprocedure screening: (Variant 1) assessment of aortic annulus and aortic root, to help guide the choice of the valve prosthesis, and (Variant 2) assessment of supravalvular aorta and vascular access for potential determination of vascular access site and road mapping the desired device delivery.

#### **Special Imaging Considerations**

For the purposes of distinguishing between CT and CT angiography (CTA), ACR Appropriateness

Criteria topics use the definition in the <u>ACR-NASCI-SIR-SPR Practice Parameter for the Performance and Interpretation of Body Computed Tomography Angiography (CTA)</u> [33]:

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

Imaging should allow characterization and reporting of aortic valve morphology in each patient and degree of calcification [34,35]. Calcified raphe for bicuspid valves and excess leaflet calcification are known to be associated with an increased risk of procedural complications and midterm mortality [36]. The annulus size for bicuspid aortic valve should be measured and reported in the same fashion as for tricuspid aortic valves, even though the basal attachments of the 2 leaflets of bicuspid aortic valve provide only 2 landmarks out of a necessary 3 landmarks to define an annular plane in space [37]. In addition, it is important to evaluate coronary ostial heights, sinus of Valsalva widths, sinotubular junction diameters, and annular/left ventricular outflow tract (LVOT) calcification, all of which are predictive of complication risks with TAVR.

### **Initial Imaging Definition**

Initial imaging is defined as imaging at the beginning of the care episode for the medical condition defined by the variant. More than one procedure can be considered usually appropriate in the initial imaging evaluation when:

• There are procedures that are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient's care)

OR

• There are complementary procedures (ie, more than one procedure is ordered as a set or simultaneously where each procedure provides unique clinical information to effectively manage the patient's care).

### **Discussion of Procedures by Variant**

Variant 1: Preintervention planning for transcatheter aortic valve replacement: assessment of aortic root. Initial imaging.

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### A. Aortography Chest

There is no relevant literature to support the use of aortography chest for annulus sizing and assessment of aortic root.

Variant 1: Preintervention planning for transcatheter aortic valve replacement: assessment

### of aortic root. Initial imaging.

#### **B. CT Chest With IV Contrast**

There is no relevant literature to support the use of chest CT with intravenous (IV) contrast for annulus sizing and assessment of aortic root.

## Variant 1: Preintervention planning for transcatheter aortic valve replacement: assessment of aortic root. Initial imaging.

#### C. CT Chest Without and With IV Contrast

There is no literature in support of chest CT without and with IV contrast for annular sizing and assessment of aortic root.

### Variant 1: Preintervention planning for transcatheter aortic valve replacement: assessment of aortic root. Initial imaging.

#### **D. CT Chest Without IV Contrast**

There is no literature in support of chest CT without IV contrast for annular sizing and assessment of aortic root. Aortic calcification can; however, be assessed on CT chest without IV contrast. Harbaoui et al [38] evaluated ascending aortic calcifications in 189 patients undergoing TAVR and noted ascending aortic calcification (tertile 3 versus tertile 1) appeared predictive of heart failure (hazard ratio [HR]: 2.29; 95% confidence interval [CI], 1.12-4.66; P = .023).

## Variant 1: Preintervention planning for transcatheter aortic valve replacement: assessment of aortic root. Initial imaging.

### E. CT Heart Function and Morphology With IV Contrast

CT heart function and morphology with IV contrast provides left and right ventricular ejection fractions, ventricular volumes, and wall motion for diagnostic and prognostic purposes. It can be used to derive measurements pertinent to annulus sizing and assessment of aortic root. Although this is feasible, images through the entire cardiac cycle may not significantly affect annulus sizing and choice of TAVR device in comparison with systolic-only images. In a retrospective multicenter study, Murphy et al [39] evaluated 507 patients and noted that the mean annular dimensions were larger during systole than diastole (area:  $474.4 \pm 87.4 \text{ mm}^2 \text{ versus } 438.3 \pm 84.3 \text{ mm}^2 \text{ or } 8.23\%, P < 9.23\%$ .001; perimeter:  $78.5 \pm 7.2$  mm versus  $75.9 \pm 7.2$  mm or 3.36%, P < .001). CTA for annulus sizing is highly reproducible, as demonstrated by Knobloch et al [40] in their analysis of 82 TAVR CTAs, wherein multireader paradigms led to significantly increased precision (lower variability) for scenarios (P = .03). In a retrospective study of 157 patients, Mylotte et al [22] reported that up to 50% of patients received an inappropriate CoreValve size based on transesophageal echocardiography (TEE) alone. CT analysis led to larger annular diameters than TEE (P < .0001). In comparison with TEE, adherence to CT-based oversizing was independently associated with a reduced incidence of paravalvular leak (odds ratio 0.36; 95% CI, 0.14-0.90; P = .029). When CTbased sizing criteria were satisfied, the incidence of paravalvular leak was 21% lower in comparison with echocardiography (14% versus 35%; P = .003). In a prospective study of 266 patients, 133 consecutive patients underwent TAVR with valve prosthesis size recommendation based on a CTA sizing algorithm and were compared with another cohort of 133 consecutive patients who underwent TAVR with valve prosthesis size recommendation based on a combination of echocardiogram measurements and angiographic images. The authors demonstrated a significant reduction in the incidence of paravalvular leak of 5.3% (7/133) in the CT group and 12.8% (17/133) in the control group (P = .032) as a primary endpoint and aortic annulus rupture, and they demonstrated a significant reduction in in-hospital deaths of 3.8% (5/133) in the CTA group and 11.3% (15/133) in the control group (P = .02) as a secondary endpoint [15].

In a multicenter registry study of 6,688 patients, CTA data showed mean left coronary artery ostia height and sinus of Valsalva diameters were lower in 44 patients with coronary obstruction than in control patients (10.6  $\pm$  2.1 mm versus 13.4  $\pm$  2.1 mm, P < .001; 28.1  $\pm$  3.8 mm versus 31.9  $\pm$  4.1 mm, P < .001) [24]. Khalique et al [41], in a comparative study, evaluated the quantity and location of aortic valve complex calcifications as a predictor paravalvular regurgitation in 150 patients and noted the quantity and asymmetry of calcifications for all regions of the aortic valve complex predicted greater than or equal to mild paravalvular regurgitation by receiver operating characteristic analysis (area under the curve = 0.635-0.689). In addition, CTA can provide additional information to determine optimum C-arm angulation. In a retrospective study of 79 patients, the mean absolute difference between CTA and fluoroscopy was 8.8° ± 7.1°. Reproducibility was considered good because the mean difference between 2 independent measures was 5.9° ± 6.1° [42]. Hansson et al [43] evaluated calcium volumes in the upper LVOT in 186 patients undergoing TAVR (median, 29 versus 0 mm<sup>3</sup>; P < .0001) and overall LVOT (median, 74 versus 3 mm<sup>3</sup>; P =.0001) and noted they were higher in 33 patients who experienced aortic root injury compared with the control group of 153 patients. In a large retrospective single center analysis of 1,207 patients who underwent TAVR, Waldschmidt et al [44] noted significant LVOT calcification >10 mm<sup>3</sup> in 451 patients was associated with worse short-term clinical and functional outcomes and 1year mortality rates compared with patients without significant LVOT calcifications.

## Variant 1: Preintervention planning for transcatheter aortic valve replacement: assessment of aortic root. Initial imaging.

#### F. CTA Chest With IV Contrast

There is no literature to support the use of CTA chest with IV contrast for the assessment of the aortic root; however, in absence of motion artifacts, the annulus can be evaluated for size, calcifications, coronary ostial heights, and sinus of Valsalva diameters.

# Variant 1: Preintervention planning for transcatheter aortic valve replacement: assessment of aortic root. Initial imaging.

### **G. CTA Coronary Arteries With IV Contrast**

There is no relevant literature to support the use of CTA coronary arteries with IV contrast as the initial imaging modality for the assessment of aortic root. Although CTA coronary arteries with IV contrast can evaluate coronary anatomy and stenosis, which can be helpful in the management of patients undergoing TAVR, it does not impact selection of device type and/or size. A multiphase coronary CTA can also be used for evaluation and sizing of the annulus and aortic root.

## Variant 1: Preintervention planning for transcatheter aortic valve replacement: assessment of aortic root. Initial imaging.

#### H. MRA Chest With IV Contrast

Although a majority of the evidence focuses on noncontrast MR angiography (MRA) techniques for root assessment, contrast-enhanced MRA may provide faster acquisition [45].

## Variant 1: Preintervention planning for transcatheter aortic valve replacement: assessment of aortic root. Initial imaging.

#### I. MRA Chest Without and With IV Contrast

In a prospective study of 69 patients, Ruile et al [46] observed good reproducibility of aortic annulus dimensions and calcifications in comparison with cardiac CTA, even in the presence of arrhythmias in the all-comers pre-TAVR population and useful in patients at an increased risk for

contrast-induced nephropathy with an agreement for hypothetical prosthesis sizing in 63 of 67 (94%) patients for systolic CTA and modeled systolic MRA. Also, excellent correlation was reported for the distance to the right or left coronary ostium between diastolic CTA and diastolic MRA.

The role of MRA is; however, limited when there is a high-susceptibility artifact, magnetic field incompatible devices, and severe arrhythmia. Finally, the MRA examination is a technically more complex examination, with longer study time and a higher required degree of patient cooperation, which can be problematic for patients with a poor clinical condition [47].

### Variant 1: Preintervention planning for transcatheter aortic valve replacement: assessment of aortic root. Initial imaging.

### J. MRA Coronary Arteries Without and With IV Contrast

There is no relevant literature to support the use of MRA coronary arteries without and with IV contrast as the initial imaging modality for the assessment of aortic root.

## Variant 1: Preintervention planning for transcatheter aortic valve replacement: assessment of aortic root. Initial imaging.

#### K. MRA Coronary Arteries Without IV Contrast

There is no relevant literature to support the use of MRA coronary arteries without IV contrast as the initial imaging modality for the assessment of aortic root.

## Variant 1: Preintervention planning for transcatheter aortic valve replacement: assessment of aortic root. Initial imaging.

#### L. MRI Heart Function and Morphology Without and With IV Contrast

Mayr et al [48], in a small pilot study of 16 patients, evaluated noncontrast navigator-gated free breathing 3-D "whole heart" MRI measurements of aortic annulus and reported aortic annulus measurements by MRI and CTA showed a very strong correlation (r = 0.956, P < .0001; effective annulus area for MRI 430  $\pm$  74 versus 428  $\pm$  78 mm<sup>2</sup> for CTA, P = .629). However, MRI lacks visualization of valvular wall calcification, and thus, underestimation of the LVOT or valve calcification is possible.

In a comparative study of 26 patients, Pamminger et al [49] tested noncontrast MRA protocols for the aortic annulus area and perimeter along with left and right coronary ostial heights and found aortic root parameters assessed by 3 whole heart MRI strongly correlated (r = 0.679-0.887, all  $P \le .0001$ ) to CTA measurements.

Noncontrast navigator-gated 3-D steady-state free precession MRI with orientation of the viewing plane on the hinge points of the aortic valve to ensure to measure the diameters in the true annular plane was shown to be an alternative with similar accuracy to multidetector CT (MDCT) in aortic annulus sizing for TAVR in a comparative study of 52 patients. MRI yielded a mean perimeter of 76.5  $\pm$  6.7 mm with a good correlation coefficient (r = 0.93, P < .0001). Decision for valve size showed good correlation between both imaging modalities (r = 0.94, P < .0001) [50]. Similarly, a noncontrast protocol for the measurement of aortic annulus area in systole was shown to be feasible and accurate compared with CTA. The 3-D-cardiac MR (CMR) could provide an alternative for annular sizing pre-TAVR assessment in patients who cannot undergo contrast-enhanced CT studies. In this comparative study of 21 patients, the mean systolic annular area was not significantly different between CT and 3-D-CMR (480.0  $\pm$  77.9 mm² versus 479.4  $\pm$  66.2 mm²; P = .98) in systole [51].

Meta-analysis based on 1,040 patients comparing CMR with transthoracic echocardiography (TTE) showed CMR measurements of aortic valve area size were larger compared with TTE but not TEE by an average of 10.7% (absolute difference:  $+0.14 \text{ cm}^2$ , 95% CI, 0.07-0.21, P < .001). Reliability was high for both inter- and intraobserver measurements (0.03 cm<sup>2</sup>  $\pm$  0.04 and 0.02 cm<sup>2</sup>  $\pm$  0.01, respectively) [52].

## Variant 1: Preintervention planning for transcatheter aortic valve replacement: assessment of aortic root. Initial imaging.

#### M. MRI Heart Function and Morphology Without IV Contrast

Mayr et al [48], in a small pilot study of 16 patients, evaluated noncontrast navigator-gated free breathing 3-D "whole heart" MRI measurements of aortic annulus and reported aortic annulus measurements by MRI and CTA showed a very strong correlation (r = 0.956, P < .0001; effective annulus area for MRI 430  $\pm$  74 versus 428  $\pm$  78 mm<sup>2</sup> for CTA, P = .629). However, MRI lacks visualization of valvular wall calcification, and thus, underestimation of the LVOT or valve calcification is possible.

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Noncontrast navigator-gated 3-D steady-state free precession MRI with orientation of the viewing plane on the hinge points of the aortic valve to ensure measurement of the diameters in the true annular plane was shown to be an alternative with similar accuracy to MDCT in aortic annulus sizing for TAVR in a comparative study of 52 patients. MRI yielded a mean perimeter of  $76.5 \pm 6.7$  mm with a good correlation coefficient (r = 0.93, P < .0001). Decision for valve size showed good correlation between both imaging modalities (r = 0.94, P < .0001) [50]. Similarly, a noncontrast protocol for the measurement of aortic annulus area in systole was shown to be feasible and accurate compared with CTA. The 3-D CMR could provide an alternative for annular sizing pre-TAVR assessment in patients who cannot undergo contrast-enhanced CT studies. In this comparative study of 21 patients, the mean systolic annular area was not significantly different between CT and 3-D-CMR ( $480.0 \pm 77.9 \text{ mm}^2$  versus  $479.4 \pm 66.2 \text{ mm}^2$ ; P = .98) in systole [51].

Meta-analysis based on 1,040 patients comparing CMR with TTE showed CMR measurements of aortic valve area size were larger compared to TTE but not TEE by an average of 10.7% (absolute difference: + 0.14 cm<sup>2</sup>, 95% CI, 0.07-0.21, P < .001). Reliability was high for both inter- and intraobserver measurements (0.03 cm<sup>2</sup>  $\pm$  0.04 and 0.02 cm<sup>2</sup>  $\pm$  0.01, respectively) [52].

## Variant 1: Preintervention planning for transcatheter aortic valve replacement: assessment of aortic root. Initial imaging.

### N. US Echocardiography Transesophageal

In a retrospective analysis of 101 patients who underwent both preoperative MDCT and 3-D TEE for aortic annulus sizing for TAVR planning, the automatic software measurements showed very good agreement with manual values obtained using MDCT and 3-D TEE, with the interactive approach having slightly narrower limits of agreement. The latter also had excellent intra- and interobserver variability. Both fully automatic and interactive analyses showed excellent test-retest reproducibility, with the first having a faster analysis time. Finally, either approach led to good

sizing agreement against the true implanted sizes (>77%) and against MDCT-based sizes (>88%) [53].

A retrospective analysis of 31 patients who underwent transcatheter aortic valve implantation showed an excellent correlation between the aortic annulus measurements obtained by both manual 3-D TEE method and by the automatic software method (intraclass correlation coefficient: 0.731 (0.508-0.862), r: 0.742) for a ortic annulus diameter and (intraclass correlation coefficient: 0.723 (0.662-0.923), r: 0.723) for the aortic annulus area, with no significant differences regardless of the method used. The interobserver variability was superior for the automatic measurements than for the manual ones. In a subgroup of 10 patients, they also found an excellent correlation between the automatic measurements and those obtained by MDCT (intraclass correlation coefficient: 0.941 (0.761-0.985), r. 0.901) for aortic annulus diameter and (intraclass correlation coefficient: 0.853 (0.409-0.964), r: 0.744) for the aortic annulus area. Thus, new automatic 3-D TEE software allows modeling and quantifying the aortic root from 3-D TEE data with high reproducibility and showed good correlation between the automated measurements and other 3-D validated techniques, thus supporting its use in clinical practice as an alternative to MDCT before transcatheter aortic valve implantation for annular sizing (annular area, annular mean diameter and perimeter, sinotubular junction diameter, sinus of Valsalva diameter) [54]. Although TEE can be used intraprocedurally, it has a limited role for preprocedural assessment. Additionally there is a paucity of TEE data for evaluating aortic root features such as coronary ostial height and subannular calcification [55].

## Variant 1: Preintervention planning for transcatheter aortic valve replacement: assessment of aortic root. Initial imaging.

### O. US Echocardiography Transthoracic Resting

Although ultrasound (US) echocardiography transthoracic resting can diagnose aortic stenosis and can be used during TAVR procedures, there is no relevant literature to support its use for annulus sizing and assessment of aortic root.

Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

## Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

### A. Aortography Chest, Abdomen, and Pelvis

There is no relevant literature to support the use of aortography of the chest, abdomen, and pelvis as the initial imaging modality for the evaluation of vascular access before a TAVR procedure.

## Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

#### **B. CT Abdomen and Pelvis With IV Contrast**

There is no relevant literature to support the use of CT abdomen and pelvis with IV contrast as the initial imaging modality for the valuation of vascular access for a TAVR procedure.

## Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

#### C. CT Abdomen and Pelvis Without and With IV Contrast

There is no relevant literature to support the use of CT abdomen and pelvis without and with IV contrast as the initial imaging modality for evaluation of vascular access for a TAVR procedure.

## Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

#### D. CT Abdomen and Pelvis Without IV Contrast

CT abdomen and pelvis without IV contrast cannot assess lumen size and patency, but mural calcifications can be assessed. In a comparative study of 103 of 588 patients undergoing both noncontrast CT and angiography, with 17 sheath-related complications, Okuyama et al [23] showed there was no difference between noncontrast CT and angiography: area under the curve 0.79 (95% CI, 0.70-0.86) versus area under the curve 0.73 (95% CI, 0.63-0.81) in predicting sheath-related complications.

### Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

#### E. CT Chest, Abdomen, and Pelvis With IV Contrast

There is no relevant literature to support the use of CT chest, abdomen, and pelvis with IV contrast as the initial imaging modality for the evaluation of vascular access before a TAVR procedure.

## Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

### F. CT Chest, Abdomen, and Pelvis Without and With IV Contrast

There is no relevant literature to support the use of CT chest, abdomen, and pelvis without and with IV contrast as the initial imaging modality for the evaluation of vascular access before a TAVR procedure. Aortic calcification can: however, be assessed on CT chest, abdomen, and pelvis without and with IV contrast. Harbaoui et al [38] evaluated 189 patients undergoing TAVR for total aortic calcifications, ascending aortic calcification, descending aorta calcifications, and abdominal aorta calcifications. In their study, total aortic calcification (tertile 3 versus tertile 1) was significantly and strongly associated with cardiac mortality (HR: 16.74; 95% CI, 2.21-127.05; P = .006) and all-cause mortality (HR: 2.39; 95% CI, 1.18-4.84; P = .015). Each aortic calcified segment was associated with cardiac mortality, whereas only ascending aortic calcification (tertile 3 versus tertile 1) appeared predictive of heart failure (HR: 2.29; 95% CI, 1.12-4.66; P = .023).

## Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

#### G. CT Chest, Abdomen, and Pelvis Without IV Contrast

There is no relevant literature to support the use of CT chest, abdomen, and pelvis without IV contrast as the initial imaging modality for the evaluation of vascular access before a TAVR procedure. CT chest, abdomen, and pelvis without IV contrast cannot assess lumen size and patency, but mural calcifications can be assessed.

## Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

#### **H. CT Chest With IV Contrast**

There is no relevant literature to support the use of CT chest with IV contrast as the initial imaging modality for the evaluation of vascular access before a TAVR procedure.

## Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

#### I. CT Chest Without and With IV Contrast

There is no relevant literature to support the use of CT chest without and with IV contrast as the initial imaging modality for the evaluation of vascular access before a TAVR procedure.

### Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

#### J. CT Chest Without IV Contrast

There is no relevant literature to support the use of CT chest without IV contrast as the initial imaging modality for the evaluation of vascular access before a TAVR procedure. CT chest without IV contrast cannot assess lumen size and patency, but mural calcifications can be assessed. Additionally, circumferential aortic calcifications (porcelain aorta) can be detected, which may complicate the device delivery [56].

## Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

### K. CT Heart Function and Morphology With IV Contrast

There is no relevant literature to support the use of CT heart function and morphology with IV contrast as the initial imaging modality for the evaluation of vascular access before a TAVR procedure. Preprocedural CT heart function and morphology with IV contrast can help in identifying left ventricular apex and assess myocardial thickness and left ventricular orientation and in guiding planned mini-thoracotomy.

# Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

#### L. CTA Abdomen and Pelvis With IV Contrast

CTA imaging can assess luminal size, patency, vessel tortuosity, and the extent of mural calcifications. Kinnel et al [57] evaluated aortoiliac and femoral arteries in their comparative study of 175 patients for abdominal aortic tortuosity and noted abdominal aorta tortuosity in 28 patients (16%) with strong association with the occurrence of a complication (adjusted odds ratio 2.7; 95% CI, 1.1-6.6; P = .03).

## Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

#### M. CTA Chest, Abdomen, and Pelvis With IV Contrast

CTA allows the assessment of vessel size, calcifications, and minimal luminal diameters [58]. In a comparative study of 283 of 588 patients undergoing both contrast CT and angiography, with 35 sheath-related complications, Okuyama et al [23] showed a greater predictive value for vascular complications with contrast CT than angiography by area under the curve (P < .001): 0.87 (95% CI, 0.82-0.91) versus 0.72 (95% CI, 0.66-0.77). Recent data from the VICTORY registry of 240 patients also showed a role of CTA in assessing tortuosity. In the study, the authors noted a higher incidence of access and bleeding complications in patients with a higher iliofemoral tortuosity score (56 [36.8%] versus 17 [19.3%]; P = .003). Additionally, in a multivariate logistic regression analysis, only the higher iliofemoral tortuosity score was a significant predictor of the primary endpoint (odds ratio, 2.11; 95% CI, 1.09-4.05; P = .026) [59].

CTA can also be used to evaluate alternate access sites like direct aortic or subclavian/axillary access. Arnett et al [60] retrospectively evaluated 208 patients undergoing CTA and reported on the compared axillary arteries and demonstrated substantially lower rates of significant stenosis (2% versus 12%, P < .01) and significantly lower rates of moderate to severe calcification disease (9% versus 64%, P < .01) than iliofemoral arteries.

## Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

#### N. CTA Chest With IV Contrast

CTA of the chest with IV contrast is helpful for patients undergoing TAVR [49] for the assessment of supravalvular aorta. It has been demonstrated that a subclavian approach leads to morbidity and mortality rates similar to those observed with the transfemoral approach [61]. CTA can also be used to evaluate alternate access sites like direct aortic or subclavian/axillary access. Arnett et al retrospectively evaluated 208 patients undergoing CTA and reported on the compared axillary arteries and demonstrated substantially lower rates of significant stenosis (2% versus 12%, P < .01) and significantly lower rates of moderate to severe calcification disease (9% versus 64%, P < .01) than iliofemoral arteries [60].

### Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

#### O. MRA Abdomen and Pelvis Without and With IV Contrast

There is limited data supporting MRA abdomen and pelvis without and with IV contrast as the initial imaging modality for the evaluation of vascular access before a TAVR procedure.

In a pilot study of 16 patients, Mayr et al [48] observed vessel luminal diameters and angulations of aorto-iliofemoral access as measured by MRA and CTA showed overall very strong correlations (r =0.819-0.996, all P < .001); the agreement of minimal vessel diameter between the 2 modalities revealed a bias of 0.02 mm (upper and lower limit of agreement: 1.02 mm and -0.98 mm).

### Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

#### P. MRA Abdomen and Pelvis Without IV Contrast

In a comparative study of 26 patients, noncontrast MRA- and CTA-based measurements of aortoiliofemoral vessel diameters correlated moderately to very strongly (r = 0.572-0.851, all  $P \le$ .002) with good to excellent interobserver reliability (intraclass correlation coefficient = 0.862-0.999, all P < .0001) regarding quiescent-interval single-shot assessment. The mean diameters of the infrarenal aorta and iliofemoral vessels in this study differed significantly (bias 0.37-0.98 mm, P = .041 to < .0001) between the 2 modalities, and intermethod decision for transfemoral access route was comparable ( $\kappa = 0.866$ , P < .0001) [49]. In a small sample of 5 patients and 10 healthy volunteers, Cannaò et al [62] compared noncontrast MRA with CTA and noted all measurements showed good agreement with CTA in patients (all P > .098). No difference in qualitative ratings between MRA and CTA (all P > .119) was noted, with a good interobserver agreement for MRA ( $\kappa$ = 0.71-0.76) and excellent interobserver agreement for CTA ( $\kappa$  = 0.82-0.84).

### Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

### Q. MRA Chest, Abdomen, and Pelvis With IV Contrast

There is no relevant literature supporting the use of MRA chest, abdomen, and pelvis with IV contrast for the assessment of supra ventricular aorta and vascular access. MRA chest, abdomen, and pelvis with IV contrast can; however, be used as an alternate option in a selected patient population to assess supravalvular aorta and vascular access.

### Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

#### R. MRA Chest With and Without IV Contrast

There is no relevant literature supporting the use of MRA chest with and without IV contrast for the

assessment of supra ventricular aorta and vascular access; however, MRA chest with and without IV contrast can be used as an alternate option in a selected patient population to assess supravalvular aorta and vascular access.

## Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

### S. US Duplex Doppler Chest, Abdomen, and Pelvis

There is no relevant literature to support the use of US duplex doppler chest, abdomen, and pelvis as the initial imaging modality for evaluation of vascular access before a TAVR procedure.

### Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

### T. US Echocardiography Transesophageal

There is no relevant literature to support the use of TEE as the initial imaging modality for the evaluation of vascular access before a TAVR procedure.

## Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

#### **U. US Echocardiography Transthoracic Resting**

There is no relevant literature to support the use of TTE resting as the initial imaging modality for the evaluation of vascular access before a TAVR procedure.

## Variant 2: Preintervention planning for transcatheter aortic valve replacement: assessment of supravalvular aorta and vascular access. Initial imaging.

### V. US Intravascular Aorta and Iliofemoral System

Although US can be used to assist in arterial puncture and serve as a roadmap during the TAVR procedure, there is limited relevant literature to support the use of US intravascular aorta and iliofemoral system as the imaging modality for evaluation of the vascular access before a TAVR procedure. In an observational study, Essa et al [63] evaluated 15 patients and observed strong correlation between intravascular US and CTA for minimum luminal diameter (r = 0.62). Concordance was also strong between CTA and invasive iliofemoral angiography for the assessment of tortuosity (r = 0.75).

#### **Summary of Recommendations**

**Variant 1**: US echocardiography transesophageal, or MRI heart function and morphology without and with IV contrast, or MRI heart function and morphology without IV contrast, or CT heart function and morphology with IV contrast is usually appropriate for the initial imaging assessment of the aortic root in a patient undergoing preintervention planning for TAVR. These procedures are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient's care).

**Variant 2**: CTA chest with IV contrast, or CTA abdomen and pelvis with IV contrast, or CTA chest abdomen pelvis with IV contrast is usually appropriate for the initial imaging assessment of the supravalvular aorta and vascular access in a patient undergoing preintervention planning for TAVR. These procedures are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient's care). The panel did not agree on recommending US intravascular aorta and iliofemoral system in this clinical scenario. There is insufficient medical literature to conclude whether or not these patients would benefit from this

modality in this clinical scenario. Imaging in this patient population is controversial but may be appropriate.

### **Supporting Documents**

The evidence table, literature search, and appendix for this topic are available at <a href="https://acsearch.acr.org/list">https://acsearch.acr.org/list</a>. The appendix includes the strength of evidence assessment and the final rating round tabulations for each recommendation.

For additional information on the Appropriateness Criteria methodology and other supporting documents, please go to the ACR website at <a href="https://www.acr.org/Clinical-Resources/Clinical-Tools-and-Reference/Appropriateness-Criteria">https://www.acr.org/Clinical-Resources/Clinical-Tools-and-Reference/Appropriateness-Criteria</a>.

### **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 riskbenefit 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, because of both 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 with 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

Relative Radiation Level Designations			
Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range	
0	0 mSv	0 mSv	
<b>❸</b>	<0.1 mSv	<0.03 mSv	
<b>⊗ ⊗</b>	0.1-1 mSv	0.03-0.3 mSv	
<b>⊗ ⊗</b>	1-10 mSv	0.3-3 mSv	
	10-30 mSv	3-10 mSv	
$\odot \odot \odot \odot \odot$	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."

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#### **Disclaimer**

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.

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